PHARMACIST PRACTICE IN NEONATAL INTENSIVE CARE UNITS IN AUSTRALIA AND POLAND

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CERTIFICATE OF ORIGINAL AUTHORSHIP

I, Natalia Krzyżaniak declare that this thesis, is submitted in fulfilment of the requirements for the award of Doctor of Philosophy, Discipline of Pharmacy in the Graduate School of Health at the University of Technology Sydney. This thesis is wholly my own work unless otherwise referenced or acknowledged. In addition, I certify that all information sources and literature used are appropriately acknowledged within the thesis.

I certify that the work in this thesis has not been submitted for qualifications at any other academic institution.

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Natalia Krzyżaniak

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You cannot hope to build a better world without improving the individuals. To that end each of us must work for his own improvement, and at the same time share a general responsibility for all humanity, our particular duty being to aid those to whom we think we can be most useful.

Nothing in life is to be feared, it is only to be understood. Now is the time to understand more, so that we may fear less.

Life is not easy for any of us. But what of that? We must have perseverance and above all confidence in ourselves. We must believe that we are gifted for something and that this thing must be attained.

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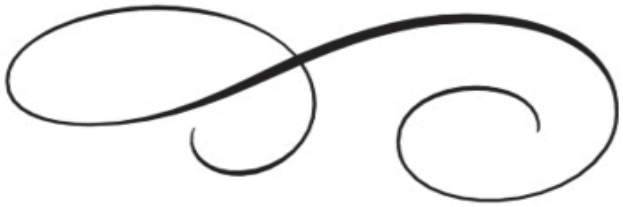

TABLE OF CONTENTS

LIST OF FIGURES

CHAPTER THREE – FOCUS ON SYSTEMS AND PROCESSES

CHAPTER FOUR – FOCUS ON TEAMWORK

CHAPTER FIVE – FOCUS ON MEASUREMENT

CHAPTER SIX – DELPHI PAPERS

LIST OF TABLES

CHAPTER ONE - INTRODUCTION

CHAPTER TWO - FOCUS ON THE PATIENT

LITERATURE REVIEW 1

LITERATURE REVIEW 2

CHAPTER THREE – FOCUS ON SYSTEMS AND PROCESSES

CHAPTER FOUR – FOCUS ON TEAMWORK

CHAPTER SIX – DELPHI STUDIES

AUSTRALIAN DELPHI

POLISH DELPHI

CHAPTER SEVEN – GUIDANCE DOCUMENTS

AUSTRALIAN QUALITY GUIDANCE DOCUMENT

GLOSSARY AND ABBREVIATIONS

ACQSH	Australian Commission on Quality and Safety in Healthcare
ADE	Adverse Drug Event
ANZNN	Australian and New Zealand Neonatal Network
APINCH	Antibiotics, Potassium and other electrolytes, Insulin, Narcotics and other sedatives, Chemotherapy and Heparin and other anticoagulants
ASHP	American Society of Hospital Pharmacists
BAPM	British Association of Perinatal Medicine
CDSS	Clinical Decision Support System
CEC	Clinical Excellence Commission
CPD	Continuing Professional Development
cpKPIs	Clinical Pharmacy Key Performance Indicators
CPOE	Computerised Physician Order Entry
DRP	Drug Related Problems
EAHP	European Association of Hospital Pharmacists
EDQM	European Directorate for the Quality of Medicines and Healthcare
EU	European Union
FIP	International Pharmaceutical Federation
GPP	Good Pharmacy Practice
HDI	High Development Index

HMR	Home Medicine Reviews
ICU	Intensive Care Unit
IM	Intramuscular
IPE	Interprofessional Education
IV	Intravenous
KRUS	Kasa Rolniczego Ubezpieczenia Społecznego - Agricultural Social Insurance Fund
KPI	Key Performance Indicator
MMP	Medication Management Pathway
NANN	National Association of Neonatal Nurses
NFZ	Narodowy Fundusz Zdrowia – National Health Fund
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NICU	Neonatal Intensive Care Unit
NIMC	National Inpatient Medication Chart
PBS	Pharmaceutical Benefits Scheme
PC	Pharmaceutical Care
PCNE	Pharmaceutical Care Network Europe
PICU	Paediatric Intensive Care Unit
PSA	Pharmaceutical Society of Australia
QUM	Quality Use of Medicines

RPWDL	Rejestr Podmiotów Wykonujących Działalność Leczniczą - Register of Facilities delivering Medical Activities
SCN	Special Care Nursery
SHPA	Society of Hospital Pharmacists Australia
SPC	Summary of Product Characteristics
SPSS	Statistical Package for the Social Sciences
TDM	Therapeutic Drug Monitoring
TPN	Total Parenteral Nutrition
UK	United Kingdom
USA	United States of America
VTE	Venous Thromboembolism
WHO	World Health Organisation
ZUS	Zakład Ubezpieczeń Społecznych - Social Insurance Institution

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Invited Presentation

- **Krzyzaniak N, '**Pharmacy in Australia', Lecture Session for the Polish Association of Pharmacy Students (Polskie Towarzystwo Studentów Farmacji – PTSF), 19 January 2017, Gdańsk, Poland

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- **Krzyzaniak N, '**Hospital Pharmacy in Australia', Lecture Session for pharmacy staff at the św. Wojciech Hospital, 22 February 2017, Gdańsk, Poland.

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- **Krzyzaniak N**, Hospital Pharmacy in Australia, II Pomorskie Workshops for Hospital Pharmacy (II Pomorskie Warsztaty Farmacji Szpitalnej), 24 – 26 March 2017, Gdańsk, Poland

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- **Krzyzaniak N, '**Hospital Pharmacy in Australia', Lecture Session for pharmacy staff at the Uniwersyteckie Centrum Kliniczne, 18 May 2017, Gdańsk, Poland.

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- **Krzyzaniak N**, Pharmacy in Australia, Lecture Session for staff of the Department of Biopharmacy and Pharmacodynamics at the Medical University of Gdańsk, 12 June 2017, Gdańsk, Poland

ABSTRACT

BACKGROUND

The quality and safe use of medicines is a global priority, particularly in high-risk patients such as those in the neonatal intensive care unit (NICU). Whilst medication misuse and errors have been widely reported in the published literature across all patient populations, of particular concern are those that occur in neonatal patients.[2-5] Pharmacotherapy is heavily used within the NICU, with a reported average of 8.6 medications prescribed per patient.[6] Furthermore, neonates have a unique set of challenges, including immature and constantly changing body-systems, a lack of suitable formulations for administration, as well as a lack of evidence to inform medicines use in infants, rendering this population particularly vulnerable to experiencing medication errors.[3 7] Medication errors with the potential to cause harm are eight times more likely to occur in the NICU compared with adult wards, and are more likely to cause significant consequences ranging from pressure on clinical resources and increased healthcare costs, to adversely affecting the health outcomes of neonatal patients, i.e., impairing the development of organs and body systems due to neonates' physiological inability to buffer errors.[3 4]

As key facilitators of the quality use of medicines (QUM), clinical pharmacists possess the skills necessary to improve medication management in the NICU.[3 8] Whilst studies have showcased pharmacist interventions and reported significant decreases in medication errors in the NICU, they have failed to describe roles that are provided in actual NICU settings.[9 10] As such, there is a distinct gap in knowledge relating to what roles and services are provided to NICUs in current pharmacy practice, as well as what impact pharmacist-led services have upon clinical outcomes in neonates.

Without relevant practice standards, differences in healthcare systems, legislation, culture, and tertiary education across countries may lead to the variable provision of pharmaceutical care services to this setting. As a result, there is potential for the quality of pharmaceutical care provided to NICU patients to also differ, which may impact on patient outcomes. The World Health Organisation (WHO) reports that health inequalities are a major concern for health systems globally.[11] Currently, there is no literature describing what a quality level of pharmacy practice entails in NICUs, nor are there any standardised means of measuring the quality of pharmaceutical care provided to NICU patients. Quality assurance is an important

concept to confirm whether the level of pharmaceutical care being provided is optimal. Healthcare service quality is most commonly measured via key performance indicators (KPIs) or other quality indicators that assess practice performance, helping to identify service gaps.[12] These indicators are formulated according to evidence-based national or international clinical practice guidelines.[13] However, there is currently (and surprisingly) an apparent lack of medication management policies or KPIs/frameworks needed to guide QUM in the NICU.[14]

Health equity is a shared responsibility of all nations worldwide, and it is a fundamental right of each human being to receive the highest possible standard of healthcare. The RIO Political Declaration on Social Determinants of Health states that all nations should collaborate to identify best practices and adopt coherent policies that promote uniformity across health settings worldwide.[15] Whilst there are significant differences in practice between third and first world countries, it is apparent that there are also variances in pharmacy practice between industrialised countries in Europe, as well as the US, UK, Australia, New Zealand and Canada.[16] It is clear that many nations are challenged in striving for this global uniformity, regardless of their population, location, or wealth. This is also apparent in the context of pharmacy practice where, aside from large studies commissioned by the WHO, European Association of Hospital Pharmacists (EAHP) or the American Society of Hospital Pharmacists (ASHP) comparing general hospital pharmacy services around the world, there is little comparative research focussing on pharmacist practice in NICUs transnationally.[17] Summarily, there is a need to better understand the current state of pharmacy practice in NICUs worldwide, to identify specific issues relating to medication management issues or pharmacy practice, and to create reference points for quality pharmaceutical care and/or benchmarks against which to compare changes in international hospital pharmacy practice.

THESIS OVERVIEW

The purpose of this doctoral research was to explore the current status of pharmacy practice in NICUs in Australian and Polish settings. The overall aim was to develop an initial guidance document to support quality pharmacist practice in NICUs in each country. This document included a list of KPIs aimed at promoting the uniform and QUM in the NICU.

Poland (a country situated in central Europe) was chosen as a comparator as it maintains a healthcare system and pharmacist practice culture that differs from that in Australia, but is at the same time in the process of expanding its implementation of pharmaceutical care (PC) services in both hospital and community settings. Both Australia and Poland are industrialised countries, and both are listed in the very high categories of the human development index (HDI) by the United Nations.[18] The HDI is a composite value of life expectancy, education, and per capita income indicators that measures countries' levels of social and economic development.[19] Hence both of these nations have the resources and the capacity to provide the highest level of care.[18] It is rational to explore and understand the differences in pharmacy practice in NICUs not only within but also between countries, and comparing those with a more advanced level of pharmacy practice to nations that are refining their hospital pharmacy services. This form of comparison will enable the identification of disparities in practice, and highlight the need for the development of a resource to guide the implementation of standardised, quality pharmacy services.

A quality assurance model from the Quality Assurance Project of the Centre for Human Sciences was used to frame each stage of the project.[20] The model comprises four principles: focus on patient, focus on processes and systems, focus on teamwork and focus on measurement. The research has been divided into four parts, which correspond to each principle of the model as follows:

Chapters 1, 2 and 3 provide an introduction to the topic and comprise three background reviews, which canvassed the literature reporting on medication errors in the NICU population, medication use in NICUs worldwide as well as pharmacist roles in NICUs on a global scale. The databases used in each review were selected to identify the maximum possible volume of literature that was readily accessible in the public domain. According to Grewal et.al. at a minimum, the databases Embase and PubMed should be searched for articles as well as Google Scholar.[21] Each of the literature reviews conducted employed the use of these three

main databases: PubMed/Medline, Embase and Google Scholar. Two reviews also employed an additional database, SCOPUS and CINAHL respectively. The reason for the addition of these databases to these reviews was based on the lack of articles obtained in the initial searches, requiring an additional database search to identify more articles. The main findings of the reviews highlighted that medication use in neonates is complex and heavily relied upon, with greater error-related consequences. Furthermore, the reviews found significant gaps in the knowledge-base relating to what current NICU pharmacy practice actually entails.

These findings led to the development of four foundation papers in **Chapters 3 and 4** exploring the perspectives of pharmacists, doctors and nurses on pharmacist practice in each country, and additionally in Poland, the perceptions of medical and pharmacy students. The development of a guidance document required a thorough investigation and understanding of issues localised to each country. These papers identified that, overall, the focus of pharmacy practice in NICUs in Australia versus Poland varied significantly, ranging from clinically-centred, ward-based services to traditional, dispensary-based medication supply duties, respectively. However, the majority of participants from both countries felt that pharmacists should be involved in pharmacotherapy-related decision-making in the NICU.

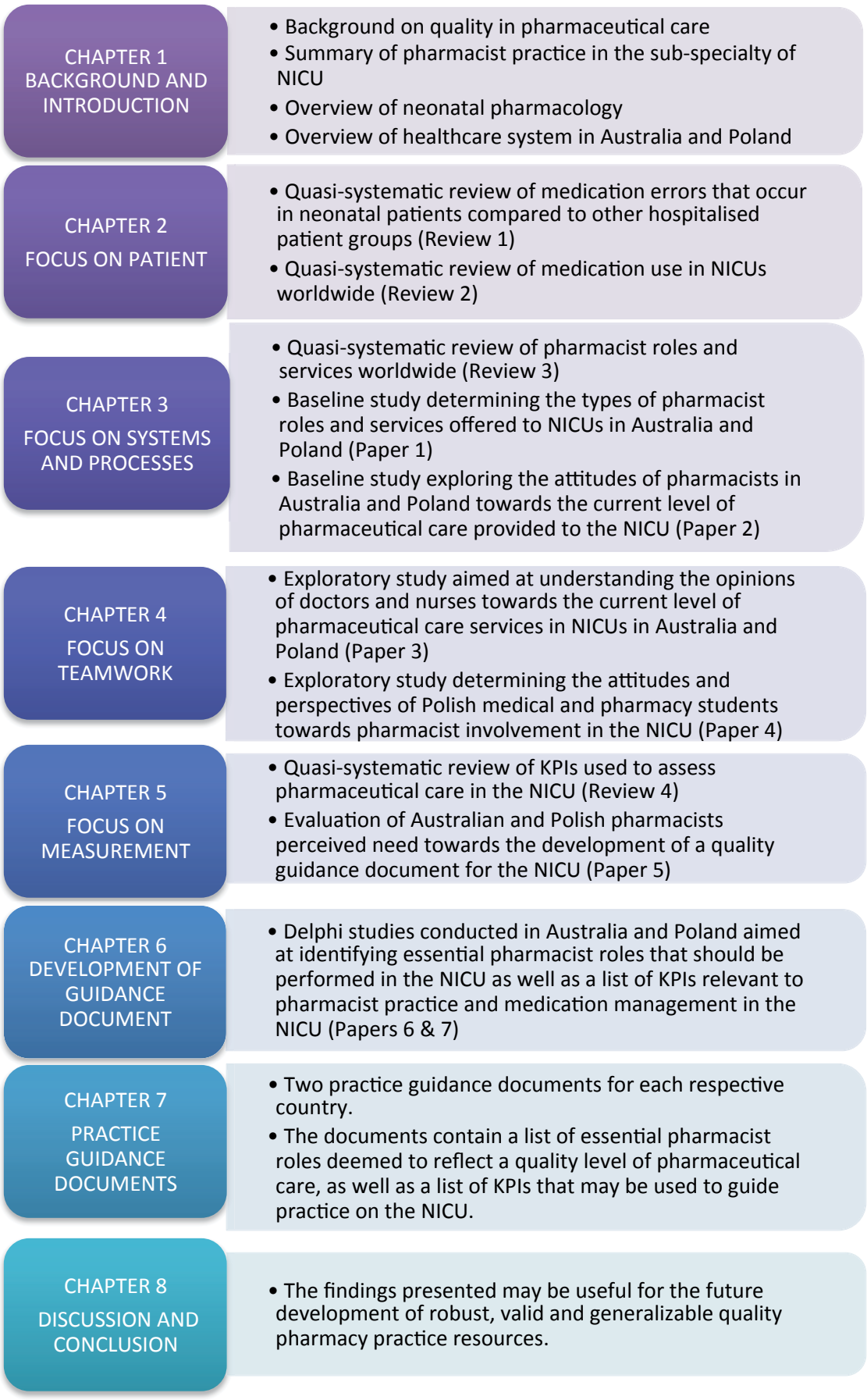
Following on from these foundation papers, the next stage of the research aimed to understand what measures were currently available and being used to evaluate the provision and quality of pharmacist practice in the NICU **(Chapter 5)**. A literature review found that there were no KPIs specifically designed for medication management or pharmacy services in the NICU. This finding then led to the exploration of pharmacist perspectives on the need for, and development of, NICU-specific KPIs for pharmacy service provision. This paper highlighted that although there are significant differences in the types of pharmaceutical care services offered in each country, pharmacists in both Australia and Poland demonstrated significant support for the development of a resource to guide and structure practice in the NICU, and recognised its potential benefits.

The previous chapters helped to inform the research undertaken in **Chapter 6**, to define quality pharmaceutical care. Using the Delphi technique, selected experts derived a list of the pharmacist roles that they perceived to be essential for pharmacy practice in NICUs in their respective countries, as well as the relevant KPIs. These were then used to develop initial guidance documents for Australia and Poland, which are presented in **Chapter 7**. The research presented in this chapter is the first of its kind to present a foundation list of pharmacist roles

and clinical pharmacy KPIs that have been identified by stakeholders as reflecting a high standard of practice in NICUs in Australia and Poland. The findings are a first step in standardising pharmacy practice within each country for this sub-specialty.

Chapter 8 includes a general discussion and conclusion of the research.

Figure 1: Thesis Overview



DETAILED SUMMARY

Chapter 1 provides an understanding of the medication use issues in the NICU and comprises two literature reviews.

The objective of **Review 1** was to describe the medication errors reported in hospitalised patients, comparing medication errors across the age spectrum, including those in neonates. A comprehensive two-tiered search of the literature was performed using the following electronic databases: PubMed, Embase and Google Scholar. In tier 1, a generalised search was performed to find literature relevant to the paediatric, adult and elderly patient populations using the MeSH terms *paediatric*, *children*, *hospitalised patients*, *adult*, *elderly*, *medication safety* and *medication errors*. Subsequent to finding the bulk of the literature, tier 2 of the search was dedicated to finding articles specific to the neonatal population utilising the following MeSH terms: *medication errors*, *medication safety*, *neonate*, *infant* and *NICU*.

A total of 58 articles were reviewed. Medication errors were documented in each patient group at each step of the medication-use process. Overall, prescribing and administration errors were most commonly identified across each population, and mostly related to errors in dosing. Errors due to patient misidentification and overdosing were particularly prevalent in neonates, with 47% of administration errors involving at least tenfold overdoses. While neonatal patients experience the same types of medication errors as other hospitalised patients, the medication-use process within this group is more complex and errors have the potential to impact significantly upon neonatal patient outcomes. Strategies that were suggested within the reviewed research to help overcome medication errors most commonly involved the integration of a clinical pharmacist into the treating team.

Due to the serious nature of medication errors experienced by neonatal patients, **Review 2** focussed on medication use in NICUs worldwide, identifying the most commonly used medicines, mapping these against the A-PINCH high-risk medicines list (i.e., Anti-infectives, Potassium and other electrolytes, Insulin, Narcotics and sedatives, Chemotherapy agents, Heparin and other anticoagulants), and determining whether there are any differences in medicine use between countries. A comprehensive search was performed to find literature relevant to drug utilisation in the NICU using the MeSH terms *neonate, NICU, drug utilisation, prescription patterns* via the following electronic databases: MEDLINE, EMBASE, Scopus and Google Scholar. The search was limited to extract only recent articles published from the year 2000 or later, that is 2000– 2016.

A total of 19 articles from 12 countries were reviewed. Overall, the types of medicines used in NICUs worldwide are similar, consistently reporting on the common use of antibiotics, caffeine and vitamins. An inverse relationship was identified between gestational age and the number of medications that were prescribed. Nine of the 20 most commonly used medicines were listed as A-PINCH medicines, and included antibiotics, fentanyl, morphine and heparin. There are several areas of concern that warrant further investigation to improve the rational use of medicines in the neonatal population, including the high use of antibiotics as well as off-label and unlicensed medicines.

The previous stage highlighted that there is great potential for medication mismanagement in the NICU and it was found that the most commonly identified strategies to effectively improve medication safety were pharmacist-related interventions. However, there is very little current literature available that gives an insight into pharmacist practice on these wards. The purpose of **Review 3** was to describe pharmacist practice and roles performed in the care NICU worldwide and to map these findings along the medicines management pathway (MMP). The literature was retrieved by searching the following electronic databases: Embase, PubMed and Google Scholar. All sources of information including relevant studies, review papers and other publications were canvassed. A two-tiered search strategy was used. In Tier 1, a search was performed utilising the following MeSH headings/keywords: *pharmacist interventions, clinical pharmacist, neonatal intensive care, neonate/infant/newborn, pre-term, protocols, pharmacist role/activities, pharmacist responsibilities*, and *pharmacist impact*. In Tier 2 of the search, relevant grey literature was identified through a Google search using the same MeSH terms. This tier was dedicated to finding service standards, position descriptions as well as descriptive reports.

Thirty sources of information were reviewed. Overall, pharmacist practice in the NICU involves a wide-range of roles, with the most commonly reported involving patient medication chart review, therapeutic drug monitoring and the provision of medication information. Most of the data were collected from the USA (13 of 30), followed by the UK (6 of 30) and other countries. The American, British, South African and Australian articles reported very similar roles, with a pharmacist firmly integrated into the overall structure of the NICU team. However, most of the published literature was approximately 10 years old or older. Therefore, due to the lack of recently published articles it is not possible to accurately report on the roles currently performed in NICUs worldwide, creating a large gap in in understanding what contemporary pharmaceutical services in the NICU comprise.

This review informed the next stage of research, **Paper 1**. The purpose of this study was to compare the pharmaceutical services and clinical pharmacy roles performed in NICUs in Australian and Polish hospitals. Little comparative research has been done exploring pharmacy services performed in NICUs worldwide, particularly between cosmopolitan countries, such as Australia and Eastern European countries, such as Poland. A 20-item survey was distributed electronically to directors of pharmacy as well as neonatal pharmacists in hospitals in Poland and Australia between January and May 2017. Most questions required fixed 'agree/disagree' answers, but were supplemented by open-ended questions. Overall, 30 Australian pharmacists and 22 Polish pharmacists completed the survey. Pharmacist *expectations* of practice in the NICU were the same across both countries, however, the *actual* pharmaceutical care services provided differed vastly. Significant differences were observed for clinical roles, whereby a higher proportion of Australians than Poles provided medication recommendations (Aus = 96.6%, Pol = 9.1%, $p < 0.001$), performed pharmaceutical interventions to resolve drug therapy problems (Aus = 93.1%, Pol = 18.2%, $p < 0.001$) and undertook general patient medication chart reviews (Aus = 96.6%, Pol = 13.6%, $p < 0.001$). All Polish pharmacists did not consider themselves as members of the NICU team and the majority felt that pharmaceutical care on the NICU was practically non-existent.

As an adjunct to this baseline study, pharmacist opinions toward current practices in the NICU were sought out for **Paper 2**. No studies have been performed that investigate or understand pharmacist opinions on performing pharmaceutical care services in NICUs nor their perceived competence to provide tailored clinical services to neonatal patients. A cross-sectional, electronic survey was distributed between January and May 2017 to hospital pharmacists and directors of pharmacy departments based in Australian and Polish hospitals with a NICU. The questions collected information on the participant characteristics, perceptions of the preparedness of pharmacists to provide pharmaceutical care, opinions on the barriers to the provision of pharmaceutical services and changes that are required to improve pharmaceutical care.

A total of 29 participants from Australia and 20 from Poland completed the survey. Overall, both Australian and Polish pharmacists hold positive attitudes towards pharmacist involvement in the NICU. However, it is apparent that Polish pharmacists were more confident in providing traditional pharmacy services to the NICU. In comparison Australian pharmacists feel that they are competent in providing more advanced roles, including clinical and educational services. It was found that Polish pharmacists were unaccustomed to the concept

of the pharmacist as a provider of direct patient care, and identify more with the distribution-focused model of practice. In contrast, Australian pharmacists associate more with the pharmaceutical care model, whereby pharmacists assume responsibility for patient care and are members of the inter-disciplinary treating team. Furthermore, Polish pharmacists perceive the existence of barriers to this form of practice at a higher rate than Australian participants, and were also more inclined to want changes to current pharmacist roles.

The findings from these initial studies highlight the disparities in practice between Australia and Poland. In order to gain a more comprehensive understanding of the pharmaceutical care structure in each country, **Papers 3 & 4** aimed to canvass the 'teamwork' perspective of care in the NICU. Due to the complex nature of the neonatal intensive care unit (NICU), a multidisciplinary and collaborative team network is essential in ensuring positive health outcomes for critically ill newborn patients.[22] Alongside nursing and medical staff, the pharmacist plays an important role in guiding the safe, effective and appropriate use of medicines and in preventing any adverse effects. However, there is no corresponding literature investigating doctor-nurse-pharmacist relationships in the NICU. The primary objective of **Paper 3** was to explore the opinions and perceptions of medical and nursing healthcare professionals towards the role of the pharmacist and the provision of pharmaceutical care in the NICU. An electronic survey was distributed to a cross-section of NICU doctors, nurses and midwives between January and April 2017.

The survey was completed by 77 participants in Australia and 93 in Poland. Similarly to the previous studies, according to the experiences of doctors and nurses, there were significant differences perceived regarding the type of pharmaceutical care services provided in NICUs between Australia and Poland. It is apparent that pharmacists do not commonly participate in ward-based practice in Polish NICUs. Approximately 91.4% of Polish participants identified that pharmacists were not present on the NICU ward at their settings, in comparison with 13% of participants in Australia ($p < 0.001$). As a result, 74% of professionals in Australia agreed that they had a high level of interaction with pharmacists in their daily practice. In contrast, 38% of participants in Poland agreed that they did not collaborate with the pharmacist at all. Significantly more Polish professionals (82.4%) identified that pharmacists were not meeting the pharmacotherapeutic needs of neonatal patients, whereas in Australia 82.9% of medical and nursing staff felt that these services were adequate ($p < 0.001$).

As the previous three studies highlighted that Polish pharmacy services in the NICU were not as clinical or ward-based as those in Australia, **Paper 4** focussed on the education system and explored opinions of future healthcare professionals in Poland. The World Health Organisation (WHO) suggests that the provision of inter-professional education for both under-graduate and post-graduate students is an effective way to improve collaboration and health outcomes for patients.[23] However, the concepts of ward-based pharmaceutical care as well as collaborative practice between pharmacists and other healthcare professionals are still relatively novel in Poland. The purpose of this study was to identify the attitudes, opinions and perceptions of Polish medical and pharmacy university students toward the provision of pharmaceutical care services in the NICU. A cross-sectional, anonymous paper-based survey was distributed to medical and pharmacy university students at a large Polish medical university between January and February 2017.

A total of 147 students completed the survey, comprising 74 pharmacy students and 73 medical students. Overall, there were statistically significant differences between the attitudes of Polish medical and pharmacy students toward the provision of pharmaceutical care services in the NICU. For 10 out of 15 proposed roles (as presented in the survey), a significantly lower proportion of medical students (M) agreed that pharmacists should perform these in the NICU, compared to pharmacy students (P). These roles included: participation in ward rounds ($P = 82.4\%$, $M = 38.4\%$, $p < 0.001$), therapeutic drug monitoring ($P = 98.6\%$, $M = 78.1\%$, $p < 0.001$) and monitoring total parenteral nutrition ($P = 87.8\%$, $M = 37\%$, $p < 0.001$). A significantly higher proportion of pharmacy students agreed that pharmacists should be consulted as part of the treating team when making medication-related decisions for NICU patients compared to medical students ($P = 91.9\%$ vs. $M = 71.2\%$, $p < 0.001$). It is apparent that when it comes to the NICU, medical students felt that pharmacotherapy-related decisions were the responsibility of the medical staff, with pharmacists acting as a support for the administrative processes rather than as an influencing factor in patient care.

Whilst the contrasts seen in each country may be attributed to differences in pharmaceutical legislation, practice culture and pharmacist training, ultimately, each healthcare system should strive for consistency in the delivery of services to ensure equal healthcare provision to patients. These findings have implications for the development of policies to standardise pharmacist practice in the NICU and to bridge the practice gap between countries. Neonatal patients are a unique population that have specific pharmacotherapy needs and requirements that differ from other patient groups. As such, pharmacist practice provided to this ward

should be aimed at a high-quality and homogenous level of care to allow equal opportunity for these high-risk and vulnerable patients to achieve the best possible outcomes.

Due to the differences seen in current NICU pharmacy services provided in Australia and Poland, the next part of the research was dedicated to understanding what KPIs were available to assess the quality of pharmaceutical care being provided to the NICU.

With medication error rates in NICUs reported to be as high as 91 medication errors per 100 patient admissions, QUM in this setting is important. The objectives of **Review 4** were to identify the measures used to evaluate QUM within the NICU and to map these against Donabedian's traditional framework of structure, process and outcome. A quasi-systematic review of the literature was performed and full-text articles were retrieved by searching the following databases: EMBASE, PubMed, CINAHL and Google Scholar. A two-tiered search strategy was used. In Tier 1, a generalised search of the electronic databases was conducted using the following MeSH terms*: quality, quality indicators, neonate/infant/newborn, NICU, medication, medication safety, medication prescribing/transcribing/ dispensing/administration/monitoring, patient safety, pharmacist services/pharmaceutical care*. Tier 2 of the search identified relevant sources of grey literature using a Google search of the same terms. Organisations such as WHO, Council of Europe, Society of Hospital Pharmacists Australia, and Australian state/national government protocols, in particular, were reviewed.

Overall, a total of 47 KPIs were identified and categorised: 17 structure, 19 process and 11 outcome measures. The most common measures related to the availability of medication safety technology in the NICU, written policies on the use of high-risk medications, medication error and adverse drug event reporting systems, and the provision of education for health professionals involved in the medication use process. However, there were no KPIs specifically designed for medication management in the NICU. The review highlighted that there is a need to develop a framework outlining measures that facilitate the appropriate use of medicines in the NICU.

Such measures are needed to effectively gauge the quality of healthcare services being provided and to determine the potential to improve care for patients. As evidenced in the previous review, currently, there is no global consensus on services and roles that should be performed by a clinical pharmacist in the NICU. Furthermore, there are no resources or KPIs available to guide pharmacist practice in this setting. Therefore, the purpose of **Paper 5** was to

explore pharmacist perceptions on the need for, and development of, a NICU-specific guidance resource comprising KPIs for pharmacy service provision. Semi-structured interviews were conducted with directors of pharmacy as well as neonatal pharmacists in Poland and Australia between February and August 2017. The interview guide comprised six key open-ended questions.

Overall, none of the participants were able to identify any readily available NICU-specific guidance resources for pharmacists. Despite the significant differences in the type of pharmacist practice systems functioning in each country, pharmacists in both Australia and Poland demonstrated significant support for the development of resources or tools to guide and structure practice in the NICU, recognising the potential benefits.

Taking these results into consideration, **Papers 6 & 7** were dedicated to the identification of elements of pharmaceutical care that depict a high quality level of service in NICUs in Australia and Poland. The primary objective of this final stage of research was to identify a set of pharmacist roles that were considered essential for practice in the NICU and which were suitable for hospitals in Australia and Poland. Additionally, this research sought to identify a set of KPIs that can be used to benchmark the quality of pharmaceutical care provided to neonatal patients. A modified Delphi technique was used, where an initial set of 65 indicators and 30 proposed roles were presented to an expert panel of doctors, clinical pharmacists, academic pharmacists and nurses. The indicators and roles were compiled from a previously conducted literature review. An online survey was distributed in two consecutive Delphi rounds in August and September 2017, asking experts to rank the indicators and roles against specific criteria.

A total of 15 participants from Australia and 16 from Poland participated as expert panellists. Overall, a consensus threshold of 75% was reached for 31 indicators and for 23 roles by Australian panellists. Experts particularly valued the following roles: pharmacists being a source of medication information (100%), assisting in off-label prescribing (100%), documenting medication errors (100%), medication chart review (100%), and writing medication protocols for the NICU (100%).

In comparison, for Polish participants a consensus of 75% was reached for 25 indicators and for 28 roles. When considering pharmacy services for the NICU, the experts were found to highly value traditional pharmacy roles, such as dispensing and extemporaneous compounding.

However, they were eager for roles in the other domains, such as educational and clinical services, to be listed as essential for NICU practice.

From the results described, two quality guidance documents, one for each country, have been compiled and are presented in **Chapter 7**. These documents contain a list of essential pharmacist roles and KPIs tailored to the NICU setting in each country, as well as definitions and resources that can be used to support pharmaceutical care services on this ward.

CONCLUSION

Clinical pharmacists, as pharmacotherapy experts, are key human resources in improving the safety and quality of medicines used in the NICU. This thesis provides first-hand information and comprehensive insights into current pharmacy services provided to NICUs in Australia and Poland from the perspectives of pharmacists themselves, as well as doctors, nurses and students. The significant differences in practice seen between these two industrialised countries may have varying levels of impact upon patient care and outcomes. There is a need for future research to identify what level of impact these differences in practice do have upon patient outcomes, medication error rates and the quality use of medicines in this setting,

Furthermore, the findings from the research have highlighted that medication use in the NICU is high-risk and is susceptible to medication errors and misuse. Due to the vulnerable nature of neonatal patients, our findings demonstrate that there is a need to determine a minimum standard of practice for NICU pharmacists to encourage the progression and standardisation of hospital pharmacy services. The quality guidance documents developed in this thesis may be useful for the future development of robust, valid and generalisable quality pharmacy practice resources.

CHAPTER ONE

BACKGROUND AND INTRODUCTION

1.1 BACKGROUND

In recent times, the concept of 'quality' has become a priority for healthcare systems worldwide. Defined by the World Health Organisation (WHO) as 'the extent to which healthcare services provided to individuals and patient populations improve desired health outcomes' [24], quality is a critical element in ensuring the delivery of equal healthcare opportunities for patients and is a key component of the right to health. Much research has been dedicated to identifying, measuring and enhancing the quality of healthcare services with a multitude of proposed definitions of quality, quality assurance strategies and quality measurement tools.[25-29] However, despite this, the WHO recognises that there are wide variations in the standards of healthcare delivery within and between healthcare systems leading to potential inequities in care.[30] As differences in service provision may have varying impacts upon patient outcomes, quality healthcare is intrinsically tied to the concepts of health equality and equity. Equality is an important principle within the healthcare industry aimed at ensuring that each population is provided with the same level and number of resources.[31] However it is reported that whilst an *equal* approach ensures that each individual is treated the same, it is not the solution to reducing the health disparities gap.[31 32] An *equitable* approach considers the underlying issues and unique individual needs of each population and thus allows resources to be rationalised effectively to optimise health outcomes.[31 32] Equity is defined by the WHO as "*the absence of avoidable or remediable differences among groups of people, whether those groups are defined socially, economically, demographically, or geographically*."[33] Therefore, in order to achieve health equity, healthcare systems must strive for the provision of the highest possible quality of healthcare. The WHO highlights that in order for quality to be achieved, healthcare must fulfil six criteria, i.e., it must be safe, effective, timely, efficient, equitable and people-centred.[24] These dimensions have been adapted in varying degrees by patient care initiatives from the WHO, Australian Commission on Quality and Safety in Healthcare (ACQSH), Agency for Healthcare Research and Quality and the National Health Service (NHS), in countries such as Australia, US and UK, respectively, to standardise care and improve patient outcomes from a general perspective.[24 34-36]

As healthcare is a composite of services from a range of different healthcare professionals, efforts to improve healthcare quality involve a multi-faceted approach from doctors, nurses and allied health professionals. Pharmacists are central figures in the quality use of medicines. Medications play a vital role in curing disease, maintaining health and preventing illness, and

as a result are recognised as the most commonly used therapeutic interventions in healthcare systems worldwide.[37 38] From a global perspective, efforts to introduce quality into medication management began in 1985 when the WHO developed the Revised Drug Strategy, which endorsed the rational use of medicines by healthcare systems worldwide.[39] This in turn was a concept adopted by the Australian National Medicines Policy in 1999, which included the Quality Use of Medicines (QUM).[40] The Australian Commission on Safety and Quality in Healthcare as well as the Clinical Excellence Commission (CEC) endorse quality initiatives that are directed at the use of medicines such as the A-PINCH High Risk Medicines List, the National Inpatient Medication Chart (NIMC) and the Venous Thromboembolism (VTE) Prevention program among others.[41] However, the adoption of standardised quality initiatives specifically designed for improving pharmaceutical care processes have not been commonly reported in the literature. In particular, pharmacist roles specifically in hospital settings worldwide are not consistent, with varying levels of pharmacist integration into patient care.[42-45]

1.2 PHARMACEUTICAL CARE

Pharmaceutical care (PC) in itself is a quality philosophy, which at its core holds the intent to improve the quality of life for patients, the cost-effectiveness and rationalisation of resources as well as reduce inequalities in healthcare.[37] Defined by Hepler and Strand as "*the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life,*"[46] pharmaceutical care has changed pharmacists focus from a product-oriented to a patient-centred practice. In recent times, the board of the Pharmaceutical Care Network Europe (PCNE) felt the need to re-define this concept to "*unite the current understanding of PC with respect to the evolution of this practice philosophy during the last 35 years*."[47] The updated definition reads: "*pharmaceutical care is the pharmacist's contribution to the care of individuals in order to optimize medicines use and improve health outcomes*" and is intended to be "*representative for various work settings, valid for countries inside and outside of Europe, and adopted to the current time*."[47] As a subset of the overall care of patients, the concept of pharmaceutical care parallels that of quality healthcare, as both focus on the application of health services to achieve specific health outcomes.[48]

The professional identity of the modern pharmacist is increasingly being depicted as a central and authoritative figure in the medication management process. Whilst the profession

represents a discipline steeped in tradition with ancient roots, evidence highlights that the long-established roles of the doctor as prescriber and pharmacist as dispenser are not adequate in ensuring the quality, safety and effectiveness of medicines in current healthcare settings.[49] Medication-related errors occur in all areas of the medication management pathway (i.e. prescribing, dispensing, administration)(Figure 1) and can have significant impact upon patient outcomes as well as healthcare cost (i.e., costs of hospitalisation and remedial therapy). As a result, the scope of pharmacist practice has evolved, particularly in the hospital setting, to encompass roles that contribute to and influence each stage of this pathway. With the increase in pharmacist involvement in patient care, so too has their accountability for the level of pharmaceutical care provided. The FIP acknowledges that pharmacists are to be held responsible for the services provided to patients under their care as well as for the resulting pharmacotherapeutic outcomes.[50] In essence, this recognises the pharmacist as a 'medication expert' and practitioner in their own right. In this way, pharmacists are able to make a unique contribution to the outcome of medication therapy and the patient's quality of life.

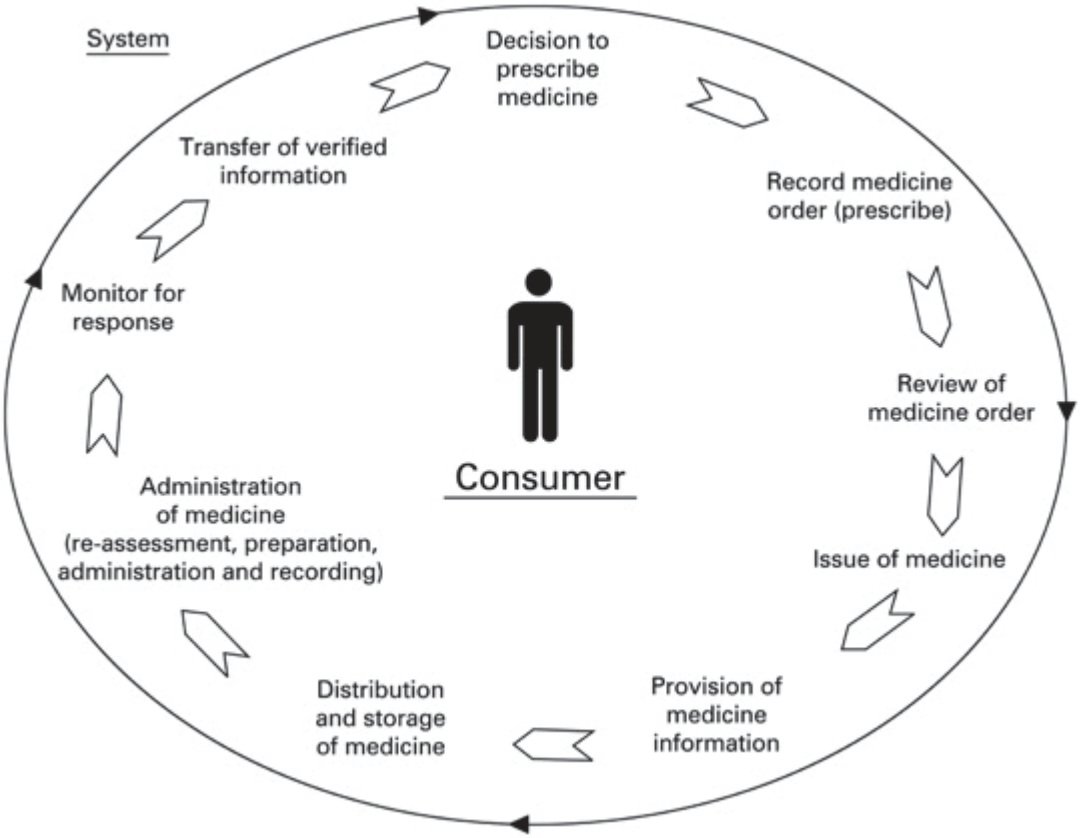


Figure 2: Medication Management Pathway[1]

Figure adapted from: Stowasser DA, Allinson YM, O'Leary KM, 'The Medicines Management Pathway', J Pharm Prac Res 2004; 34: 293-6

To promote consistency in practice, the International Pharmaceutical Federation (FIP) and the WHO have sought to outline the minimum standards for Good Pharmacy Practice (GPP), and include the following roles:

Table 1: Good Pharmacy Practice – Joint FIP/WHO Guidelines on GPP: Standards for quality of pharmacy services[51]	
Role 1: Prepare, obtain, store, secure, distribute, administer, dispense and dispose of medical products	**Function A:** Prepare extemporaneous medicine preparations and medical products
	Function B: Obtain, store and secure medicine preparations and medical products
	Function C: Distribute medicine preparations and medical products
	Function D: Administration of medicines, vaccines and other injectable medications
	Function E: Dispensing of medical products
	Function F: Dispose of medicine preparations and medical products
Role 2: Provide effective medication therapy management	**Function A:** Assess patient health status and needs
	Function B: Manage patient medication therapy
	Function C: Monitor patient progress and outcomes
	Function D: Provide information about medicines and health-related issues
Role 3: Maintain and improve professional performance	**Function A:** Plan and implement continuing professional development strategies to improve current and future performance
Role 4: Contribute to improve effectiveness of the healthcare system and public health	**Function A:** Disseminate evaluated information about medicines and various aspects of self-care
	Function B: Engage in preventive care activities and services
	Function C: Comply with national professional obligations, guidelines and legislations
	Function D: Advocate and support national policies that promote improved health outcomes

Table adapted from: Joint FIP/WHO guidelines on good pharmacy practice: Standards for quality of pharmacy services. Geneva: World Health Organisation, 2011. Report No.: 961.

The roles performed in each country are dependent on, and adapted to, the local contextual factors, such as the operational health system, resourcing, and culture. PC is evident in community-pharmacy practice, via medication counselling, identification of, and interventions for, drug-related problems (DRPs), home medicine reviews (HMRs) and chronic disease management services (i.e. blood pressure and blood glucose testing), which have been implemented in countries such as The Netherlands, Switzerland, Australia, Denmark, USA and the UK.[44 52-54] From a hospital pharmacy perspective, the Basel Statements highlight that pharmacists should be involved in medicines logistics, providing medicine information, monitoring patient outcomes and in providing education to medical and nursing staff.[55] Furthermore, this practice allows pharmacists to make therapeutic recommendations and to monitor patient progress more closely due to more direct access to patient information. The global leaders in providing this form of practice are USA, Australia, New Zealand, Canada and the UK, where clinical roles are well-established and are expected of pharmacists working in hospital settings.[56 57]

The value of PC services and specific pharmacist interventions have been widely demonstrated. Many studies have highlighted positive effects across all areas of practice, including high-risk patients such as paediatric and geriatric groups, chronic diseases such as asthma, and critical health areas, such as patients undergoing organ transplants.[58-60]. These benefits include reductions in medication errors, costs, and duration of hospital stay, as well as improvements in patient outcomes, medication adherence and the rationalisation of resources.[57 61-63] The WHO and FIP recognise that pharmaceutical care is not a practice that should be performed as an isolated service.[50 64] Rather, they state that that it must be provided in collaboration with patients, doctors, nurses and other allied health professions.

1.3 PHARMACEUTICAL CARE IN SPECIALTIES OF PRACTICE

As stated by the FIP; "*as current health systems and patient care continue to evolve in complexity and challenge, there is more demand for pharmacists to provide complex services and to take on roles which are extended specialised and more advanced than current entry level scope of practice*."[65] One such area is the neonatal intensive care unit (NICU), which is home to seriously ill neonates who require additional support and care in their first few days, weeks or months of life. Whilst medication misuse and errors have been widely reported in the

literature across all patient populations, of particular concern are those that occur in neonatal patients.[2-5] Pharmacotherapy is heavily used within the NICU, with a reported average of 8.6 medications prescribed per patient.[6] Furthermore, neonates have a unique set of challenges, including immature and constantly changing body-systems, a lack of suitable formulations for administration, as well as a lack of evidence to inform medicines use in infants, rendering this population particularly vulnerable to experiencing medication errors.[3 7] Medication errors with the potential to cause harm are eight times more likely to occur in the NICU compared with adult wards, and are more likely to cause significant consequences ranging from pressure on clinical resources and increased healthcare costs, to adversely affecting the health outcomes of neonatal patients, i.e., impairing the development of organs and body systems due to neonates' physiological inability to buffer errors.[3 4] It is reported that medication errors comprise 84.2% of all medical errors within the NICU.[4] Therefore, the quality use of medications (QUM) in neonates is integral to achieving medication safety and quality patient outcomes.[7 66 67]

As key facilitators of QUM, clinical pharmacists possess the skills necessary to improve medication management in the NICU.[3 8] Whilst studies have showcased pharmacist interventions and reported significant decreases in medication errors in the NICU, they have failed to describe roles that are provided in actual NICU settings.[9 10] As such, there is a distinct gap in knowledge relating to what roles and services are provided to NICUs in current pharmacy practice, as well as what impact pharmacist-led services have upon clinical outcomes in neonates.

1.3.1 NEONATAL PHARMACOLOGY

Pharmacists play a critical role in the pharmacological management of NICU patients, ensuring the safety and appropriateness of medication use. This is especially vital for NICU patients where the margin for error is much smaller than in adult and paediatric populations. The differences in treating this patient population in comparison to paediatric or adult patient groups are numerous.[68] The neonate is recognised as a 'unique drug recipient' due to rapid developmental changes which impact upon their mass, organ system function and body composition.[69 70] Drug absorption, distribution, metabolism and elimination processes vary with age and have a large impact upon the pharmacologic effects of the drug in the body.

Table 2: Overview of neonatal pharmacokinetics and pharmacodynamics.

Excerpts from NICU Primer for Pharmacists [71]

ABSORPTION	***Gastrointestinal Absorption*** Gastric pH decreases to a pH of 1 to 3 from a neutral pH at birth during the first 48 hours of life. Over the first week of life, gastric pH again neutralises. Gastric pH gradually decreases over the first 2 years of life to adult pH. More neutral gastric pH may contribute to increased bioavailability of acid-labile medications, such as penicillin, and decreased bioavailability of weak bases, such as phenytoin, in preterm and term neonates. Prolonged gastric emptying and decreased intestinal motility reduce the rate of both active and passive medication absorption in neonates. Other factors that may contribute to absorption variances in neonates are variable brush border enzymatic function, decreased intestinal surface area, varying pancreatic enzyme activity and biliary function, and shorter gut transit time. ***Intramuscular (IM) Absorption*** Decreased skeletal muscle blood flow in neonates may reduce absorption of IM administered medications. Less muscle contraction may also reduce absorption. However, neonates typically have capillary dense muscle, which may increase absorption. IM administered medication absorption is considered unpredictable and not routinely recommended. ***Percutaneous Absorption*** Due to skin structure development, medication absorption through the skin may be increased in neonates. Three contributing factors include a larger body surface area to mass ratio, greater hydration of epidermis, and better perfusion of the cutaneous layer in neonates. Caution is recommended when applying localised, topical medication to neonates due to increased risk of systemic exposure.

	Rectal Absorption Medications administered rectally should have increased bioavailability in neonates. The anticipated increase in bioavailability may be attributed to limited first-pass metabolism or decreased hepatic enzyme metabolism in neonates. However, rectal contractions in neonates pulsate resulting in frequent medication evacuation that may limit absorption.
DISTRIBUTION	As a patient ages, body composition as a percentage of total body weight changes. Total body water and total body fat approximate 85% and 1 to 2% in preterm neonates, respectively. Term neonate total body water and total body fat composition approximate 75% and 10 to 15%, respectively. Due to the large percentage of total body water in neonates, both preterm and term, hydrophilic medications have larger volumes of distribution and require larger weight-based dosing strategies. Conversely, lipophilic medications have smaller volumes of distribution in neonates compared to adults. Protein and tissue binding also affect medication distribution. Plasma protein concentrations and protein-binding affinities for medications are often reduced in neonates. Protein-bound medications, such as phenytoin and benzodiazepines, may have increased volumes of distribution in neonates compared to adults due to the decreased number of plasma-binding proteins and the decreased binding affinity of medications compared to bilirubin and free fatty acids. Circulating competitive protein-bound compounds are increased in neonates limiting medication binding to serum albumin, especially foetal albumin. More unbound medication increases effect, toxicity risk, and clearance.
METABOLISM	Metabolism in neonates compared to older populations varies. The variation in enzymatic activity accounts for differences in medication pharmacokinetics and should be taken into account when using medications in neonatal patients. Metabolic enzyme processes mature and change developmentally with patient age. The developmental changes impact medication dosing approaches due to half-life differences in patient populations. Metabolism via cytochrome P450 (CYP) isoenzymes typically

	reaches adult levels at 1 year of age.
EXCRETION	The components of renal elimination mature at different rates. Complete renal function approximates adult function around 1 year of age. In the first weeks of life, glomerular filtration rate may increase little until 34 weeks post-menstrual age when it increases drastically due to increased cardiac output and decreased vascular resistance in the kidneys and approximates adult levels at 6 months of age. Renal tubular function improves steadily over the first year of life. Small tubular size, reduced blood flow, urine pH variances, and limited concentration abilities contribute to the reduced tubular excretion and reabsorption. As a neonate ages, the limitations improve to reach adult renal function. Decreased renal function accounts for initial dosing regimen differences in neonatal populations compared to paediatric and adult patients.

Table adapted from: Holmes AP. NICU Primer for Pharmacists. Bethesda: American Society of Health-System Pharmacists; 2016.

Other neonatal-specific considerations for the use of pharmacotherapy include the following:

- Neonates, and particularly pre-term babies cannot take medications or nutrients orally (by mouth) for a period consisting of days to weeks from their birth.[72] Consequently, the administration of any pharmacotherapies as well as food poses an issue. Parenteral and intravenous formulations are specifically prepared to provide the necessary nutrition and medicinal support that they require.[72]
- NICU patients are at a higher risk for medication errors compared with other patient populations due to three factors: significant exposure to medications during their admission to NICU, a lack of clinical trials on pharmacotherapies in infants and a lack of neonatal-specific formulations for dose administration.[7] Kunac et.al reported that in hospitalised children, the highest number of adverse drug events (ADE) occurred in the NICU.[67] Furthermore, the majority of dosing depends on weight-based calculations, which may need to be refined to the tenth and even hundredth of a milligram. A ten-fold or more dosing error may easily arise because an incorrect decimal placement during prescribing can be easily overlooked.[71]

- NICU patients experience the unique process of 'neonatal transitioning' post-birth, i.e., they undergo rapid physiologic changes to adapt to extra-uterine life.[73] As such, the timing of pharmacotherapy is crucial as their health status can change rapidly.[71]
- The drug formulary used in the NICU is relatively limited compared with that used in other patient populations. There is a constant need to modify drug formulations to suit the needs of neonatal patients.[71]

1.4 PHARMACY PRACTICE ON A GLOBAL SCALE

Globally, there has been limited research conducted into documenting the clinical practices and roles of pharmacists within the NICU. In particular, studies comparing these activities between countries are not common. When considering hospital pharmacy practice from a general perspective, it is apparent that the types of pharmacist services provided are not consistent worldwide. In 2010, the European Association of Hospital Pharmacists (EAHP) found that decentralised clinical services in Europe are not well implemented.[74] In particular, they recognised that in 27 out of 30 countries, less than 20% of hospital pharmacies reported conducting daily pharmacist visits on wards.[74] In comparison, the American Society of Hospital Pharmacists (ASHP) reported that in 34% of hospitals in the US, pharmacists were present on wards for at least 8 hours per day.[75] This apparent diversity in practice may have varying impacts on patient outcomes.

The standardisation of the pharmaceutical care services provided to patients, both on a national and international scale, is important. According to WHO, one of the main priorities for healthcare systems worldwide is the promotion of equity within and between healthcare facilities.[76] Health equity is a shared responsibility of all nations worldwide, and it is a fundamental right of each human being to receive the highest standard of healthcare.[76] As such, the RIO Political Declaration on Social Determinants of Health endorses global collaboration and benchmarking between countries to identify good practices and adopt coherent policies to promote consistent practices.[77] The WHO acknowledges that one of the most effective means of promoting practice uniformity is through the development of standardised practice tools that can be adapted and implemented in all hospital settings both on a national and global scale, such as the WHO High 5's Project.[78] The FIP and WHO have

strived to develop guidelines and training documents including those on developing pharmacy practice, Good Pharmacy Practice (GPP) as well as hospital pharmacy practice, to promote the establishment of a minimum level of practice standards and quality of service.[51 55] However, both of these professional organisations recognise that every country has varying practice conditions with a need to adapt these standards in accordance as appropriate. It is unknown to what degree these guidelines have been implemented in each country. As such, there is a gap in understanding where differences in clinical pharmacy practice lie across settings within and between countries, and the resulting impact upon the quality of care provided to patients.

The literature does give us some understanding of the challenges to providing pharmaceutical care, in both industrialised and developing countries. Doloresco and Vermeulen emphasise that many nations face similar pharmacy practice challenges, regardless of their population, location, or wealth.[16] The most common issues related to financial and resource limitations.[42 79-81] As the implementation of PC increases, there is a greater pressure to increase funding allocated to the pharmacy department, which is often related to increasing the level of pharmacy staff in hospitals. Furthermore, there are discernible practice culture issues. Firstly, pharmacists in some countries struggle with their own professional identities as clinical pharmacists and lack the confidence and skills necessary to practice directly on wards.[80] This may be attributed to ineffective preparation of pharmacists during their university degrees.[42 81] In addition, there is perceived resistance from medical staff, who are the dominant figures in all clinical aspects of patient care.[79] Some studies have reported on how poor the inter-professional relationships are between members of the multi-disciplinary team, which may also hinder pharmacist practice.[56 79 80 82]

These challenges to the integration of the pharmacist in clinical practice underscore the need for reform in healthcare systems worldwide. It is evident that pharmacists play a key role in ensuring the efficacious, safe, rational and quality use of medicines to ensure positive patient outcomes as well as to maintain an affordable and equitable healthcare system. However, to do so, the role of the pharmacist needs to be positioned at the forefront of medication management. The movement toward assessing the quality of pharmaceutical care and clinical pharmacy provided is critical in this process. The use of key performance indicators or standardised measures of quality can provide clinical pharmacists with data, that can then provide evidence, in a qualitative and robust manner, of their contribution to patient care.[83]

1.5 DEFINING QUALITY IN HEALTHCARE

1.5.1 QUALITY PHARMACEUTICAL CARE

Regardless of the level of services available in each practice setting, quality needs to be assured for activities that a pharmacist does fulfil. In recent times, there has been a push for pharmacy services in both community and hospital sectors to undergo quality assessment. These assessments are essential for providing an insight into the performance of pharmacists in both community and hospital settings and to stimulate continuous quality development.[84] In this way, pharmacists are able to measure, assess and improve the implementation of pharmaceutical care and clinical pharmacy services provided to patients. Quality assessment of professional practice predominantly involves the use of key performance indicators throughout the domains of quality as described by Donabedian.

1.5.2 MEASURING QUALITY PHARMACEUTICAL CARE [85]

Donabedian proposed a conceptual framework for assessing the quality of healthcare, comprising three main domains: structure, process and outcome.

A structure of care describes the characteristics of the setting or the organisational framework supporting the process of care (e.g. the number of qualified staff, type of hospital).[86] Donabedian highlighted that these variables do not reflect quality *per se*, but rather the capacity of the facility to provide quality medical care.[85]

Process refers to the method of healthcare service provision and includes the amount and type of activities performed for the patient.[86] Process measures are often considered to be either technical or interpersonal. Technical care in pharmacy represents the procedures, verifications and checks that pharmacists perform. The interpersonal component of process refers to the characteristics of the interaction between patients and the pharmacist. As process measures relate to what actually happens to the patient, they are essential to the subsequent examination of patient outcomes.

Outcomes are classified as the consequences of healthcare and comprise the health status of patients (i.e. morbidity, mortality etc.).[86] It is important to note that outcome measures may

be influenced by other variables, unrelated to the structures or the processes of pharmaceutical care that may affect health status. The care that is provided by other healthcare professionals, i.e. nurses and doctors, may affect pharmacy-related outcomes. Furthermore, patients' individual characteristics (i.e. genetics or race) may also affect outcomes. Therefore, unless strictly controlled under experimental conditions, outcome measures are not valid measures of quality of the specific aspect of care being evaluated.

The FIP states that often the "*quality of pharmacy services can be improved by making changes to the healthcare system or pharmacy system without necessarily increasing resources. Improving the processes of pharmacy practice not only creates better outcomes but also reduces cost through eliminating waste, unnecessary work and repetition of work already done. Thus quality improvement must address both the resources (structures) and activities carried out (processes) to ensure or improve the quality of pharmaceutical care (outcomes).*"[50]

Table 3. Examples of Criteria used to assess the quality of pharmaceutical care as applied to Donabedian's framework[85]

STRUCTURE	**PROCESS**	**OUTCOME**
Licensed pharmacist	**TECHNICAL**	Cure of disease
Presence of appropriate drug information references	Gather prescription information	Reduction or elimination of symptoms
Sufficient inventory	Enter prescription into computer	Slow disease process
Record-keeping capabilities (e.g., computer)	Review patient profiles for drug-therapy problems	Prevent disease and symptoms
Pharmacy computer systems	Obtain appropriate medication from stock	Increased patient knowledge of drug therapy
Usable space of pharmacy counter	Label medication container	Improved medication compliance
Trained and/or certified technicians	Check prescription label, stock bottle, and prescription for consistency	Improved medication therapy
Designated area for compounding	Give prescription to patient	Improved prescribing
Pharmacy business manager	Pharmacist gives the	Improved dispensing

	prescription to patient	
Financial stability	Pharmacist explains drug name, indication, dosing regimen,	Improved medication administration
Private patient counselling area	Possible adverse effects, drug interactions	Improved drug monitoring
	Pharmacist provides written information of indication, dosing frequency, possible adverse effects	Decreased drug interactions (e.g., drug-drug, drug-food, drug-disease)
	Documentation of drug utilization review of patient profile	Decreased adverse drug reactions
	Drug therapy monitoring	Decreased suboptimal therapy
	Telephone call for follow-up	Improved identification of drug allergies
	Blood pressure check	Improved identification of drug intolerances
	Compliance audit documentation	Reduced medication intolerance
	Cholesterol screening	Decreased misuse/abuse
	Inquiry about problems with medication	Patient satisfaction
	Call prescriber with possible prescribing error or recommendation	
	Answer patient queries	
	Answer clinician queries	
	INTERPERSONAL	
	Willing to listen	
	Empathetic	
	Friendly	

	Concerned	
	Considerate	

Table adapted from: Farris KB, Kirking DM. Assessing the quality of pharmaceutical care. II. Application of concepts of quality assessment from medical care. The Annals of pharmacotherapy. 1993;27(2):215-23.

1.5.3 DEVELOPING QUALITY INDICATORS FOR PHARMACIST PRACTICE

Quality indicators or key performance indicators (KPIs) are key tools for quality assessment. Quality indicators in healthcare address measurable aspects of relevant systems, processes and outcomes and are useful in stimulating continuous improvement in patient care.[87] KPIs highlight specific areas of practice and facilitate monitoring of the impact of quality improvement initiatives. Furthermore, they enable facilities to compare their practices against successful industry leaders via the process of benchmarking.[83] Internationally, research has attempted to introduce standard KPIs for hospital pharmacy practice. A study by Ng and Harrison in New Zealand developed a baseline list of indicators which may be adapted for use in hospital settings[83]. A Canadian-based group of hospital pharmacists has also sought to establish a set of clinical pharmacy KPIs.[88] However, no professional organisations have endorsed these as effective measures of quality pharmaceutical care. In Australia, whilst standard KPIs do exist in some states (e.g. South Australia), there is currently no consensus on what KPIs should be used to measure pharmacy service performance.[89] [90] Internationally, particularly in Europe, there is no consensus as to which activities are key indicators of clinical pharmacy performance.

When considering pharmacist practice in sub-specialty settings, such as the NICU, there has been even less effort dedicated to quality assessment, as evidenced by the lack of published literature. Research in this area usually examines a particular pharmacist intervention (e.g., medication chart reviews, staff education programs) and its impact on medication error rates. Therefore, the lack of standardisation of practice as well as absences of KPIs, precludes the ability to benchmark pharmacy services and the adoption of best practice on both a national and international scale.

1.6 CONTEXT OF THE STUDY

It is important to explore and compare practice differences in NICUs not only within but also between countries. Whilst there are significant differences in healthcare between third world and first world nations, there are also differences between industrialised countries.

For the purposes of this thesis, Poland (a country situated in central Europe) was chosen as a comparator to Australia. Both countries have access to resources and the potential to provide the best possible level of quality care. Poland is a member of European Union (EU) and maintains a healthcare system and pharmacist practice culture that differs from that in Australia, but is at the same time in the process of expanding its implementation of pharmaceutical care (PC) services in both hospital and community settings. Pharmacists here are now able to specialise in clinical and hospital pharmacy, and they are implementing initiatives to further increase pharmacist involvement in patient care. Australia is regarded to be a leader in provision of a high-level of pharmaceutical care and any comparative research performed is usually done so with similar countries, such as the UK, USA, Canada or New Zealand. Both countries share similarities in terms of the resources and the capacity to provide the highest level of care, with well-established and financed healthcare systems. Both Australia and Poland are industrialised countries, and both are listed in the very high categories of the human development index (HDI) by the United Nations.[18] The HDI is a composite value of life expectancy, education, and per capita income indicators that measures countries' levels of social and economic development.[19]

It is rational to explore and understand the differences in pharmacy practice in NICUs not only within but also between countries, and comparing those with a more advanced level of pharmacy practice to nations that are refining their hospital pharmacy services. This form of comparison will enable the identification of disparities in practice, and potentially strengthen the argument for the development of a quality resource to guide the implementation of standardised, quality pharmacy services in the NICU.

1.6.1 HEALTHCARE SYSTEM IN AUSTRALIA

According to the New South Wales Government: *"Australia has one of the most affordable, accessible and comprehensive healthcare systems in the world*."[91] This systems ensures that all Australians have ready access to key services including:

- "aged and community care services
- family and children's services
- disability programmes
- public health initiatives
- Medicare and pharmaceutical benefits
- hospital and healthcare funding
- health services for Aboriginal and Torres Strait Islanders
- emergency services for people in crisis."[91]

Pharmaceutical care in Australia is provided at quite a high level, due to the availability of practice standards that emphasise the provision of pharmacy services in both community and hospital settings. O'Leary reported that an average Australian hospital pharmacist spent 47% of their working time providing clinical services, medication information and education; 38% of time compounding and dispensing medicines and 15% of time managing hospital medication policies.[92]

The healthcare system itself is described as a complex web, comprising both public and private-sector funders and providers.[93] It is mainly publicly financed through general taxation and a mandatory tax-based health insurance levy. The national, tax-funded health insurance scheme is known as Medicare, and it offers patients subsidised access to doctors, free public hospital care and subsidised pharmaceuticals (medicines).[94] Healy et.al. state: *"approximately 68% of total health expenditure comes from public sources, with the Australian Government financing 46% and the States 22%; the remaining 32% comes from private sources."*[94] Due to the number of stakeholders in the healthcare system, the ability for one body to regulate practice is limited. However, the Government plays a key role in policy-making and funding healthcare services.[95] *"Public sector health services are provided by all levels of government: local, state, territory and the Australian Government. Private sector health service providers include private hospitals, medical practices and pharmacies. Although public hospitals are*

funded by the state, territory and Australian governments, they are managed by state and territory governments. Private hospitals are owned and operated by the private sector." [93]

A wide range of subsidised medicines is accessible for two groups of Australian patients: general beneficiaries and concessional beneficiaries (patients who hold pension or other entitlement cards). Only very expensive, specialised and/or restricted medications are dispensed through hospital pharmacies, otherwise most prescriptions are filled at privately owned community pharmacies.[91 95]

Under Australian legislation, there is no specific Act that defines the legally required roles to be performed by a pharmacist. This is due to the fact that pharmacist roles are so varied across hospital pharmacy, community pharmacy, and industrial pharmacy. The '*Poisons and Therapeutic Goods Act 1966'*, and the *'Poisons and Therapeutic Goods Regulation 2008'* are principally focussed on how medicines can be supplied, and who can be 'registered' as a practicing pharmacist.[96] The reigning legislation for all health practitioners in Australia is the *'Health Practitioner Regulation National Law Act 2009'*, which defines all the legal requirements of health professionals to be able to practice in Australia.[97] The legal framework is complex, as a number of documents collectively outline the practice standards for a pharmacist. There are specific legal requirements for who can be registered for practice as a pharmacist, i.e., after completing the relevant degree at an accredited university, graduates must further develop their competencies and skills by undertaking one year supervised internship. As a general registered pharmacist, according to the '*National Health Act 1953 – Pharmaceutical Benefits Determination 2007'*, in order to practice lawfully a pharmacist must comply with the Pharmaceutical Society of Australia's Code of Ethics and Professional Practice Standards as well as maintain currency of practice against the Competency Standards for Pharmacists in Australia.[98-100] The criteria for fundamental pharmacy practice identified within these standards include:

- Patient-centred care
- Ethics and professionalism
- Privacy and confidentiality
- Cultural safety and health equity disposal of medicines
- Documentation
- Continuity of care
- Quality use of medicines

- Evidence-based practice
- Communication and collaboration[99]

For pharmacists working in the hospital setting and who engage in clinical practice and/or work within multi-disciplinary teams, the Society of Hospital Pharmacists of Australia (SHPA) provides the Standards of Practice for Clinical Pharmacy Services.[101] This document defines clinical pharmacy as an essential component of healthcare comprising the optimisation of medicines and the minimisation of the risks associated with their use. Although not a legally-binding set of requirements, the majority of hospital pharmacists have adapted their practice around these standards, ensuring that the following roles are performed:

- Medication reconciliation
- Assessing current medication management
- Drug policy and formulary management
- Monitoring of Adverse Drug Events
- Performing Clinical review, Therapeutic Drug Monitoring
- Education of staff
- Responding to information requests
- Participation in ward rounds
- Training and education
- Participating in research
- Quality improvement activities and peer review [101]

Additionally, there are advanced roles that pharmacists can undertake (following additional training and/or accreditation), including:

- becoming a clinical or specialist pharmacist (requires post-graduate study at an approved tertiary institution)
- Home Medicines Reviews/Residential Medicine Management Reviews (requires accreditation through an approved professional organisation) [102]
- Clinical Research

However, it is important to note that there are no professional practice standards available in Australia relating to specialties/sub-specialties of practice. Pharmacists must apply the generic standards outlined above and adapt their practice individually according to the needs of each

field. Whilst these generic advanced clinical pharmacy services, (which may include roles relating to medication safety and optimising medication management), may cover the types of roles delivered to specialty areas, such as the NICU, they fail to recognise the nuances of these areas of practice and the subsequent unique needs of their respective patient populations.

Practice incentive payments are available to community pharmacists via the Sixth Community Pharmacy Agreement (negotiated by the Pharmacy Guild of Australia with the Government) for the following activities [103]:

- Dose administration aids
- Performing and documenting clinical interventions that improve the quality use of medicines
- Staged supply for medications such as analgesics and benzodiazepines
- Primary healthcare – risk assessment for chronic conditions
- Community services support – i.e. needle exchange, opioid substitution dispensing
- Documenting collaboration with a minimum of two non-pharmacist healthcare professionals
- MedsChecks
- Home Medicines Reviews and Residential Medication Management Reviews

1.6.2 HEALTHCARE SYSTEM IN POLAND

As identified in the EAHP survey, several European countries reported low implementation of clinical pharmacy practice in hospital settings.[74] One country included within this list that warrants greater attention is Poland. The literature highlights that Poland is currently undergoing a transition from traditional practice to embracing the concepts of pharmaceutical care and clinical pharmacy.[104] However, despite the introduction of pharmaceutical care into pharmaceutical legislation in 2008, it is still a relatively obscure concept in both community and hospital settings.[74] [105] Furthermore, traditionally, there has not been a strong culture of clinical pharmacy services oriented towards patient-centred care. Pawłowska et.al. (2016) reported that hospital pharmacist practice mainly comprises activities directly associated with drug management including compounding, supply of medicines or participation in Drug and Therapeutic Committees.[45] To gain an understanding of why this is the case, pharmaceutical

care and clinical pharmacy practice is needed to be understood in the greater context of the Polish healthcare system.

Poland is a stable democratic nation that has been a full member of the European Union (EU) since 2004.[106] The Polish Constitution of 1997 guarantees all citizens the right to equal access to health services that are funded by public sources i.e. from health insurance contributions, state government budgets and local authorities.[106] As such, health insurance is mandatory in the Polish healthcare system and employees pay social security contributions of 9% of their personal income to the social security institution.[107] Sagan et.al. state: "*health insurance contributions are collected by two social insurance institutions, the Social Insurance Institution (Zakład Ubezpieczeń Społecznych (ZUS)) and the Agricultural Social Insurance Fund (Kasa Rolniczego Ubezpieczenia Społecznego (KRUS)), and transferred to the central health insurance fund, the National Health Fund (Narodowy Fundusz Zdrowia (NFZ))*."[106] Presently, the Polish healthcare model is funded, supervised and regulated by the Ministry of Health, the NFZ and local governments.[108] There is a clear distinction between healthcare financing and the provision of healthcare services. The NFZ is the body in charge of financing healthcare services and negotiating contracts with public and non-public healthcare providers.[106] It is regulated by the Ministry of Finance (Ministerstwo Finansów). Overall, these bodies are then managed and supervised by the Ministry of Health (Ministerstwo Zdrowia). The Ministry of Health is the key policy maker and regulator of the system, and is responsible for implementing health programmes and research.[106 108] In addition, local governments are responsible for identifying the health needs of their citizens, planning the supply of health services, and promoting health within their regions.[108]

When considering the pharmaceutical sector, all medications are reimbursed by the NFZ for hospital inpatients whereas only prescription medications are reimbursed for patients in the outpatient/community sector. Reimbursement privileges comprising modified or no cost sharing are available for certain population groups (e.g. war veterans, honorary organ donors) and patient groups (e.g. mental disorders, chronic conditions or rare conditions requiring expensive treatment). Throughout a patient's admission to a public hospital, all medications administered during this time are covered by the NFZ.

The relevant legislation governing pharmacist practice includes: the '*Act of 6 September 2001 of the Pharmaceutical Law'* and the *'Act of 19 April 1991 of the Polish Board of Pharmacy'*, which define the range of pharmaceutical services provided and their implementation within

healthcare settings.[109] [110] This legislation dictates that hospital pharmacists who hold the necessary tertiary qualifications in pharmaceutical science fulfil the following roles:

- dispensing of medicines and medical devices;
- extemporaneous compounding of prescription drugs (including parenteral nutrition, enteral nutrition), radiopharmaceuticals;
- preparation of daily doses (including cytostatic drugs);
- production of infusion fluids;
- organising the supply of medicine and medical devices for the hospital;
- providing information and advice on medicines and medical devices;
- preparation of solutions for haemodialysis and intraperitoneal dialysis;
- participation in the monitoring of adverse drug events, clinical trials and the rationalisation of pharmacotherapy
- To provide pharmaceutical care consisting using a documented process in which the pharmacist collaborates with the patient and the doctor, and if necessary with representatives of other medical professions, and supervises over the appropriate course of pharmacotherapy in order to achieve specific effects improving the patient's quality of life;
- Supervising the manufacture, marketing, storage, use and disposal of medicines and medical products[111]

Pharmacists are also able to obtain post-graduate specialist training in twelve specialties, including:

- Pharmaceutical analysis
- Bromatology
- Community Pharmacy
- Clinical Pharmacy
- Industrial Pharmacy
- Hospital Pharmacy
- Pharmacology
- Herbal Medicine
- Microbiology and Pharmaceutical Biotechnology
- Toxicology
- Public Health

- Environmental Health [112]

However, it is important to note that despite these legal provisions and specialist qualifications, pharmaceutical care is still not widely implemented in Poland. Several barriers to practice have been highlighted in the literature, and include: lack of multidisciplinary collaboration and communication, pharmacy staff shortages, pharmacists inability to access patient information records, as well as a lack of funding allocated to the pharmacy department by public funds.[113-115] There is also a perceived general lack of awareness in the healthcare system of the value of pharmaceutical care services. Therefore, as a result of these barriers, there are no practice standards, competencies or policies published by Polish pharmaceutical societies guiding pharmacists in their practice, aside from the legislation. Ward-based clinical pharmacy services in hospital settings have not been thoroughly explored or implemented, and the concept of pharmacist input in specialties of practice is yet to be considered.

1.7 STATEMENT OF THE PROBLEM

Quality measures, whether they take on the form of quality indicators, standards of practice or codes of conduct, are viewed as an important contribution and approach to facilitate quality improvement. The NICU is a complex care environment, and requires unique or modified levels of care, particularly from the perspective of a pharmacist. However, there have not been any advances made to guide or improve upon the quality of pharmacist practice provided to this unit. Work to date has largely focussed on general clinical pharmacist practice in hospital settings. Compounding this are the significant disparities in the levels of practice provided to patients on a global scale. Due to differences in healthcare systems, practice cultures and resource limits, practice is seen to vary significantly which may impact upon patient outcomes. Given the push by the WHO and the FIP to improve pharmaceutical care practices through the standardisation of services, it is prudent to explore the differences in practice, as well as to define a minimum standard of quality care.

1.7.1 THESIS OVERVIEW

This thesis, which explores the concept of quality pharmaceutical care in NICUs in Australia and Poland, comprises 8 chapters.

Chapters 1, 2 and 3 comprise three background reviews, which canvassed the literature reporting on medication errors in the NICU population, medication use in NICUs worldwide as well as pharmacist roles in NICUs on a global scale. The main findings of the reviews highlighted that medication use in neonates is complex and heavily relied upon, with greater error-related consequences. Furthermore, the reviews found significant gaps in the knowledge-base relating to what current NICU pharmacy practice actually entails.

These findings led to the development of four foundation papers in **Chapters 3 and 4** exploring the perspectives of pharmacists, doctors and nurses on pharmacist practice in each country, and additionally in Poland, the perceptions of medical and pharmacy students. The development of a guidance document required a thorough investigation and understanding of issues localised to each country. These papers identified that, overall, the focus of pharmacy practice in NICUs in Australia versus Poland varied significantly, ranging from clinically-centred, ward-based services to traditional, dispensary-based medication supply duties, respectively. However, the majority of participants from both countries felt that pharmacists should be involved in pharmacotherapy-related decision-making in the NICU.

Following on from these foundation papers, the next stage of the research aimed to understand what measures were currently available and being used to evaluate the provision and quality of pharmacist practice in the NICU **(Chapter 5)**. A literature review found that there were no quality measures specifically designed for medication management or pharmacy services in the NICU. This finding then led to the exploration of pharmacist perspectives on the need for, and development of, NICU-specific key performance indicators for pharmacy service provision. This paper highlighted that although there are significant differences in the types of pharmaceutical care services offered in each country, pharmacists in both Australia and Poland demonstrated significant support for the development of a resource to guide and structure practice in the NICU, and recognised its potential benefits.

The previous chapters helped to inform the research undertaken in **Chapter 6**, to define quality pharmaceutical care. Using the Delphi technique, selected experts derived a list of the pharmacist roles that they perceived to be essential for pharmacy practice in NICUs in their

respective countries, as well as the relevant KPIs. These were then used to develop initial guidance documents for Australia and Poland, which are presented in **Chapter 7**. The research presented in this chapter is the first of its kind to present a foundation list of pharmacist roles and clinical pharmacy indicators that have been identified by stakeholders as reflecting a high standard of practice in NICUs in Australia and Poland. The findings are a first step in standardising pharmacy practice within each country for this sub-specialty.

Chapter 8 includes a general discussion and conclusion of the research.

1.7.2 FRAMEWORK USED TO GUIDE STAGES OF RESEARCH

As the purpose of this research was to develop a guidance resource for pharmacists in the NICU, the following quality assurance model has been used as a framework to guide each stage of the project. It has been adapted from the Quality Assurance Project of the Centre for Human Sciences,[20] and describes four core principles that guide quality assurance in healthcare: focus on the patient, focus on systems and processes, focus on teamwork and focus on measurement. In order to develop a quality guidance document for pharmacy practice in Polish and Australian NICUs, each stage of the research sought to address each of the four core principles presented in order to develop a practical and useful resource, tailored to the pharmacy system in each country.

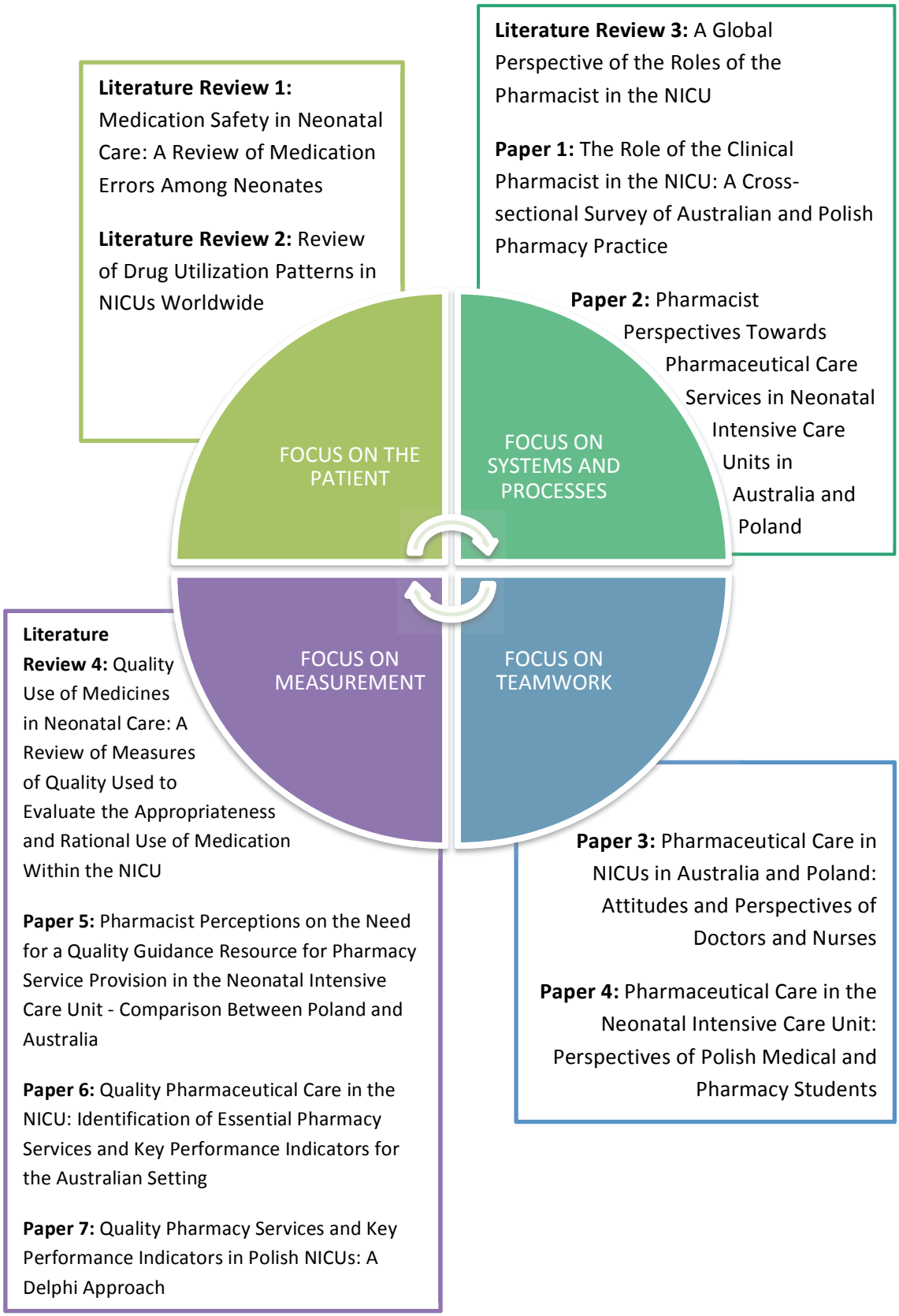


Figure 3: Research Papers Mapped to the Core Principles of the Quality Assurance Project of the Centre for Human Sciences that guide quality assurance in healthcare

Figure adapted from: Quality Assurance Project (QAP) Center for Human Services. QA in Healthcare. Bethesda. 2008. http://www.qaproject.org/methods/resqa.html. Accessed 20/08/2017.

1.8 AIMS OF THE RESEARCH

The aims of this doctoral research were to explore the current status of pharmacy practice in NICUs in Australian and Polish settings. The research was directed at the development of a quality guidance document for each setting comprising a list of quality indicators/key performance indicators (KPIs) aimed at promoting the uniform and quality use of medicines in the NICU.

The specific objectives of each part of the research were:

FOCUS ON PATIENT

LITERATURE REVIEW 1

- To determine a medication error profile that characterises the types of medication errors that are experienced by different hospitalised patient populations across the age spectrum.
- To determine whether there are any medication errors unique to the neonatal population.
- To establish whether there are differences in error type between populations.
- To identify the medicines that are most commonly associated with error in each patient group.

LITERATURE REVIEW 2

- To provide an overview of medicine use in NICUs worldwide.
- To identify the most commonly used medicines, and to compare these with the A-PINCH high-risk medicines list (Anti-infectives, Potassium and other electrolytes, Insulin, Narcotics and sedatives, Chemotherapy agents, Heparin and other anticoagulants).
- To determine whether there are any differences in medicine use between countries
- To highlight any areas that require further attention to improve the rational use of medicines.

FOCUS ON SYSTEMS AND PROCESSES

LITERATURE REVIEW 3

- To provide an overview of pharmacist practice in the NICU and identify, describe and compare pharmacist roles as reported globally in published and grey literature.
- To map the findings along the medicines management pathway (MMP).

PAPER 1

- To compare the pharmaceutical services and clinical pharmacy roles performed in NICUs in Australian and Polish hospitals.
- To identify the roles currently performed by pharmacists in the NICU.
- To describe the pharmacist's perceptions of their integration/role in the NICU team.
- To identify which roles are perceived by pharmacists as essential services to the NICU.

PAPER 2

- To identify the opinions and perceptions of NICU pharmacists and directors of pharmacy in Australia and Poland towards the provision of pharmaceutical care services in NICU.
- To understand pharmacists perceived levels of preparedness to provide clinical services in the NICU.
  To identify what changes are needed to improve pharmaceutical care.
- To identify what barriers currently limit the implementation of pharmaceutical care in the NICU.

FOCUS ON TEAMWORK

PAPER 3

- To explore the attitudes and perceptions of medical and nursing healthcare professionals towards the role of the pharmacist and the provision of pharmaceutical care in the NICU.
- To identify which pharmacists roles are currently provided to NICUs in Australia and Poland.
- To understand which pharmaceutical care services are perceived by doctors and

nurses to be essential in the NICU.

- To identify what changes are needed to improve pharmaceutical care.

PAPER 4

- To identify the opinions and perceptions of Polish medical and pharmacy university students toward the provision of pharmaceutical care services in the NICU.
- To identify which pharmacist roles are perceived as being important for the NICU.
- To identify whether students considered clinical pharmacists to be an important part of the inter-disciplinary therapeutic team.
- identifying student perceptions towards the integration of the pharmacist onto the NICU ward

FOCUS ON MEASUREMENT

LITERATURE REVIEW 4

- To identify quality measures used to evaluate the medication management process within the NICU.
- To identify the range of measures used to evaluate the QUM in the NICU.

PAPER 5

- To canvass pharmacist attitudes from Poland and Australia towards the development of a quality guidance resource to assist in the medication management process in neonatal patients.
- To determine whether pharmacists currently used any practice frameworks or models to guide their practice in the NICU.
- To determine whether pharmacists felt a need for a quality guidance resource to be developed.
- To identify any potential barriers and benefits to the implementation of this resource into practice in each country

PAPERS 6 & 7

- To identify, using an expert panel of stakeholders, the pharmaceutical care services and KPIs that are essential to quality medication management in the Australian and

Polish NICU setting via a two-round Delphi technique.

- To identify the minimum roles and services that NICU pharmacists in Australia and Poland should be consistently performing whilst on the ward to promote medication safety and positive patient outcomes.
- To identify pharmacy-relevant key performance indicators within Donabedian's domains of structure, process and outcome that are suitable for Australian and Polish NICU settings.

1.9 SIGNIFICANCE OF THE STUDY

The purpose of measuring the quality of pharmaceutical care in the NICU setting is to achieve the highest level of patient safety and health outcomes for these seriously ill and vulnerable infants. The development of a quality guidance document will help to improve the clinical practice of pharmacists, further integrate them into the NICU therapeutic team, assist in providing direction in pharmaceutical care practice and educational schemes, as well as support benchmarking and the standardisation of best practices on a national and global scale. This research may also contribute to facilitating pharmacy practice in the NICU as a priority area for future research. The results of this research may be used as a foundation for the development of NICU-specific key performance indicators nationwide in Australia and Poland. It is important to highlight that this is the first research of this kind to explore pharmacy practice and the concept of quality in the sub-specialty of NICU. Furthermore, this research addresses significant practice and knowledge gaps globally, and thus, has the potential to advance pharmacy practice on a worldwide scale.

CHAPTER TWO

FOCUS ON THE PATIENT

2.1 INTRODUCTION

The following chapter comprises two quasi-systematic literature reviews seeking to gain an understanding of the medication use issues in NICUs worldwide. This research provides the background necessary to recognising how medication management in this group of patients differs to that experienced in other hospitalised patient groups, as well as where efforts need to be focussed to promote medication safety in the NICU.

The first review is a copy of the manuscript published in Therapeutic Advances in Drug Safety. There is great potential for medication misuse in the NICU, and this paper highlights the types of medication errors experienced more commonly by neonatal patients and describes the potential impact of errors upon the patient.

The second review is a copy of the manuscript published in the Journal of Clinical Pharmacy and Therapeutics and gives an overview of medicine use in NICUs worldwide. It also gives an indication of pharmacotherapeutic areas where attention is needed to improve the rational use of medicines.

2.2 MEDICATION SAFETY IN NEONATAL CARE: A REVIEW OF MEDICATION ERRORS AMONG NEONATES

Krzyżaniak N, Bajorek B.

THERAPEUTIC ADVANCES IN DRUG SAFETY

2016;7(3):102-19.

Krzyzaniak N, Bajorek B. Medication safety in neonatal care: a review of medication errors among neonates. Therapeutic Advances in Drug Safety. 2016;7(3):102-19. Copyright © [2016]. Reprinted by permission of SAGE Publications.

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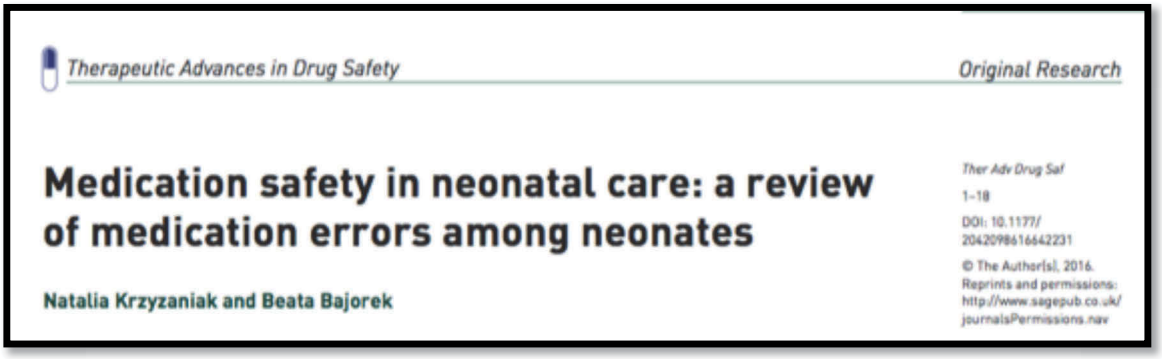

Therapeutic Advances in Drug Safety — Original Research

Medication safety in neonatal care: a review of medication errors among neonates

Natalia Krzyzaniak and Beata Bajorek

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AUTHORS' CONTRIBUTIONS

Natalia Krzyżaniak conducted the search, reviewed the literature and wrote the manuscript. Beata V Bajorek assisted in conceiving the review in terms of structure and scope, as well as critically revising and editing the manuscript prior to submission.

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Signature removed prior to publication.

Natalia Krzyżaniak

Beata V Bajorek

ABSTRACT

Objective: The objective of this study was to describe the medication errors in hospitalized patients, comparing those in neonates with medication errors across the age-spectrum.

Method: In Tier 1 PubMed, Embase and Google Scholar were searched, using selected MeSH terms relating to hospitalized paediatric, adult and elderly populations. Tier 2 involved a search of the same electronic databases for literature relating to hospitalized neonatal patients.

Results: A total of 58 articles were reviewed. Medication errors were well-documented in each patient group. Overall, prescribing and administration errors were most commonly identified across each population, and mostly related to errors in dosing. Errors due to patient misidentification and overdosing were particularly prevalent in neonates, with 47% of administration errors involving at least tenfold overdoses. Unique errors were identified in elderly patients, comprising duplication of therapy and unnecessary prescribing of medicines. Overall, the medicines most commonly identified with error across each patient group included; heparin, antibiotics, insulin, morphine and parenteral nutrition. While neonatal patients experience the same types of medication errors as other hospitalized patients, the medication-use process within this group is more complex and has greater consequences resulting from error. Suggested strategies to overcome medication error most commonly involved the integration of a clinical pharmacist into the treating team.

Conclusion: The review highlights that each step of the medication-use process is prone to error across the age spectrum. Further research is required to develop targeted strategies relevant to specific patient groups that integrate key pharmacy services into wards.

Keywords: Medication error, medication safety, neonates, NICU

INTRODUCTION

Medication errors are common in hospitalized patients and are a high-priority in healthcare systems worldwide.[Fortescue *et al.*, 2003, Wiedenmayer *et al.*, 2006, Roughead *et al.*, 2013] Defined as any mistakes that occur during the medication-use process, medication errors can arise in the course of prescribing, dispensing, transcribing, administering and monitoring medicines.[European Medicines Agency, 2015] Often these errors are preventable, and result in increased patient morbidity and mortality as well as increased healthcare costs and unnecessary hospitalization.[European Medicines Agency, 2015] While the problem of medication errors has been widely reported in published literature, of particular concern are those that occur in neonatal medicine.[Kaushal *et al.*, 2001, Fortescue *et al.*, 2003, Stavroudis *et al.*, 2010] The neonatal population is particularly vulnerable to further risk of harm resulting from medication errors due to their physiological inability to buffer errors.[Kaushal *et al.*, 2001] Medication errors with potential to cause harm are eight times more likely to occur in the neonatal intensive care unit (NICU) compared with adult wards.[Kaushal *et al.*, 2001, Stavroudis *et al.*, 2010] Furthermore, it is reported that medication errors comprise 84.2% of all medical errors within the NICU.[Stavroudis *et al.*, 2010]

There are few studies that compare medication errors across different patient populations, particularly with respect to the neonatal patient group. Each hospitalized patient population has different pharmacotherapeutic needs, and it is important to establish whether there are different medication errors in each group. As such, this lack of information limits the ability of healthcare systems to develop targeted strategies to decrease the incidence of error.

The purpose of this review is to determine a medication error profile that characterizes the types of medication errors that are experienced by different hospitalized patient populations across the age spectrum. The review explores whether there are any medication errors unique to the neonatal population, and establishes whether there are differences in error type between populations. Furthermore, the review identifies the medicines that are most commonly associated with error in each patient group.

METHODS

A comprehensive search of the literature was performed using the following electronic databases: Medline, Embase, Google Scholar. Relevant literature, including reviews, original studies and other articles pertaining to medication safety issues and medication errors, were extracted.

SEARCH STRATEGY

A two-tiered search strategy was used (Figure 1). In tier 1, a generalized search was performed to find literature relevant to the paediatric, adult and elderly patient populations using the MeSH terms *paediatric*, *children*, *hospitalized patients*, *adult*, *elderly*, *medication safety* and *medication errors*. Subsequent to finding the bulk of the literature, tier 2 of the search was dedicated to finding articles specific to the neonatal population utilising the following MeSH terms: *medication errors*, *medication safety*, *neonate*, *infant* and *NICU*. Inclusion criteria for the searches restricted the content to the following: types or nature of medication errors, hospitalized patients, and written in the English language. All full-text articles were retrieved and all evaluations pertaining to the types of medication errors in the NICU were included in the review. Manual bibliographic searches of all relevant articles were also performed in order to identify any articles that were not found in the electronic searches.

STRUCTURE OF REVIEW

The patient populations have been classified into four broad age headings: neonates (0–28 days of age), children or paediatrics (1–18 years), adults and the elderly. Neonatal data were gathered from articles that specifically studied the NICU, or had the NICU as part of their study group. The review included paediatric studies that assessed medication errors on paediatric intensive care units (PICUs), emergency and general paediatric wards. The literature reporting on the adult population comprised studies conducted in intensive care units (ICUs), surgical and medical wards and emergency departments. Articles on the elderly patient group reported on errors in geriatric wards and acute-care wards.

Medication errors have been identified and reported within each phase of the medication-use process, including prescription, transcription, dispensing, administration and monitoring

[Bates *et al*. 1995; Kaushal *et al.* 2001; Pallas *et al.* 2008; Stavroudis *et al.* 2010]. Definitions of the types of medication error associated with each phase are presented in Table 1.

RESULTS

Electronic and manual searches identified a total of 58 full-text articles, from a range of countries. Most of the literature came from USA (20 of 58), with others from Spain, Iran, Finland, Australia, UK, Italy, Turkey, Argentina, Brazil, Denmark, Switzerland, New Zealand, Morocco, India and Canada.

Overall, medication errors were well documented in each patient group, however comparative studies between patient populations were not widely identified.

NEONATAL POPULATION

Among the 20 articles reviewed, the majority used a prospective chart review method to collect data and just over half of the studies were conducted in the USA (10 of 18).[Raju *et al.*, 1989, Vincer *et al.*, 1989, Kaushal *et al.*, 2001, Carroll *et al.*, 2003, Chappell *et al.*, 2004, Cordero *et al.*, 2004, Gray *et al.*, 2004, Simpson *et al.*, 2004, Suresh *et al.*, 2004, Kunac *et al.*, 2005, Van Den Anker, 2005, Gray *et al.*, 2006, Ligi *et al.*, 2008, Pallas *et al.*, 2008, Campino *et al.*, 2009, Jain *et al.*, 2009, Stavroudis *et al.*, 2010, Antonucci *et al.*, 2012, Dabliz *et al.*, 2012, Sorrentino *et al.*, 2012] A summary of the errors reported are presented in Table 2. The prescribing phase was associated with the most medication errors, comprising 14 – 74% of total error reports.[Kaushal *et al.*, 2001, Cordero *et al.*, 2004, Gray *et al.*, 2004, Simpson *et al.*, 2004, Suresh *et al.*, 2004, Pallas *et al.*, 2008, Campino *et al.*, 2009, Jain *et al.*, 2009, Stavroudis *et al.*, 2010, Antonucci *et al.*, 2012, Sorrentino *et al.*, 2012] The most frequently reported error within this phase involved incorrect dosing, with 42% of errors related to overdoses or underdoses.[Jain *et al.*, 2009] Ten articles reported that dosing errors occurred because of miscalculations of doses and incorrect placement of decimal points or units of measurement.[Kaushal *et al.*, 2001, Cordero *et al.*, 2004, Simpson *et al.*, 2004, Van Den Anker, 2005, Pallas *et al.*, 2008, Campino *et al.*, 2009, Jain *et al.*, 2009, Stavroudis *et al.*, 2010, Antonucci *et al.*, 2012, Dabliz *et al.*, 2012] One Indian based study reported that as a result of a dosing error, an infant received a ten-fold increase in the delivery of morphine.[Jain *et al.*, 2009] The consequences of such significant dosing inaccuracies involved long-term injury,

including developmental problems, toxic effects requiring active intervention as well as death.[Folli *et al.*, 1987, Raju *et al.*, 1989, Vincer *et al.*, 1989, Frey *et al.*, 2000, Ross *et al.*, 2000, Kaushal *et al.*, 2001, Frey *et al.*, 2002, Simpson *et al.*, 2004, Suresh *et al.*, 2004] Errors in prescribing were attributed to lack of physician experience, high-intensity physician workloads as well as the lack of neonate-specific drug protocols or policies on the ward.[Gray *et al.*, 2004, Jain *et al.*, 2009] This is an important issue within the NICU, as the majority of literature highlights that due to the lack of evidence-based information, physicians do not have a reliable source of information to refer to, leading to the prescribing of off-label and unlicensed medicines and subsequent erroneous prescribing decisions.[Kaushal *et al.*, 2001, Suresh *et al.*, 2004, Kunac *et al.*, 2005, Van Den Anker, 2005, Campino *et al.*, 2009, Stavroudis *et al.*, 2010, Antonucci *et al.*, 2012, Dabliz *et al.*, 2012, Sorrentino *et al.*, 2012]. Other common prescribing errors reported only within the neonatal population included; incorrect use of units (i.e. grams instead of milligrams) and wrong administration route.[Kaushal *et al.*, 2001, Cordero *et al.*, 2004, Gray *et al.*, 2004, Simpson *et al.*, 2004, Van Den Anker, 2005, Pallas *et al.*, 2008, Campino *et al.*, 2009, Jain *et al.*, 2009, Antonucci *et al.*, 2012, Dabliz *et al.*, 2012]

Transcription-based medication errors ranged between 12 – 18.4% of total errors, and were related to mistakes in the transfer of patient information to patient medication charts.[Kaushal *et al.*, 2001, Carroll *et al.*, 2003, Suresh *et al.*, 2004, Stavroudis *et al.*, 2010, Sorrentino *et al.*, 2012] Two types of transcribing errors were identified: omissions and commissions (recording incorrect patient information), comprising 18.6% and 18.2% of errors respectively.[Carroll *et al.*, 2003] Specifically in NICU, these types of errors included, the use of the incorrect units, omission/incorrect recording of patient characteristics (i.e. weights, allergies), and omission of recording administered dose.[Kaushal *et al.*, 2001, Carroll *et al.*, 2003, Suresh *et al.*, 2004, Stavroudis *et al.*, 2010, Sorrentino *et al.*, 2012] Carroll et.al. identified that these types of documentation errors were more likely to occur in those neonatal patients with higher numbers of medicines, vascular lines and longer hospitalisations.[Carroll *et al.*, 2003]

Dispensing errors comprised 11.9 – 25% of total errors and were most frequently associated with mistakes in labelling and dilution of formulations.[Gray *et al.*, 2004, Suresh *et al.*, 2004, Van Den Anker, 2005, Jain *et al.*, 2009, Stavroudis *et al.*, 2010, Antonucci *et al.*, 2012, Sorrentino *et al.*, 2012] Seven articles identified errors in this phase, which also included: late dispensing, providing the correct drug in the wrong packaging and incorrect calculations/doses.[Gray *et al.*, 2004, Suresh *et al.*, 2004, Van Den Anker, 2005, Stavroudis *et al.*, 2010, Sorrentino *et al.*, 2012] Van den Anker in particular emphasised the importance of

timely dispensing of medicines, and associated a delayed dispensing time of more than two hours with an increased risk of medication errors occurring.[Van Den Anker, 2005]

Seven studies reported on administration errors in neonates and the prevalence ranged from 31 – 63% of total error reports.[Raju *et al.*, 1989, Vincer *et al.*, 1989, Chappell *et al.*, 2004, Suresh *et al.*, 2004, Ligi *et al.*, 2008, Stavroudis *et al.*, 2010, Sorrentino *et al.*, 2012] Almost two-thirds (60.3%) of administration errors were caused by nurses, with the most common errors associated with incorrect administration time.[Raju *et al.*, 1989, Kaushal *et al.*, 2001, Gray *et al.*, 2004, Suresh *et al.*, 2004, Kunac *et al.*, 2005, Ligi *et al.*, 2008, Stavroudis *et al.*, 2010, Antonucci *et al.*, 2012, Sorrentino *et al.*, 2012] One USA based observational study also reported that parents of NICU patients contributed to the incidence of medication errors by administering unauthorised medicines and incorrectly preparing nutrients for feeding.[Suresh *et al.*, 2004] Other neonatal specific administration errors included: incorrect preparation/dilution of medication and administering an extra dose of medication.[Raju *et al.*, 1989, Kaushal *et al.*, 2001, Gray *et al.*, 2004, Suresh *et al.*, 2004, Kunac *et al.*, 2005, Ligi *et al.*, 2008, Stavroudis *et al.*, 2010, Antonucci *et al.*, 2012, Sorrentino *et al.*, 2012] These errors were most commonly associated with the following risk factors: length of stay, low birth-weights and early gestational ages.[Ligi *et al.*, 2008] A significant issue for the NICU related to the level of product manipulation required to improve the compatibility of medicines to the unique characteristics of neonatal patients. This was emphasised by Chappell and Newman who stated that 31% of intravenous medicines were prescribed for neonatal patients at doses less than one tenth of a vial, resulting in a significantly high susceptibility for the incidence of ten-fold or 100-fold dosing errors upon administration.[Chappell *et al.*, 2004, Ligi *et al.*, 2008, Jain *et al.*, 2009] Similarly, Ligi et.al. reported that 47% of administration errors in the NICU were ten-fold dosing errors.[Ligi *et al.*, 2008] Medicines most commonly associated with dosing inaccuracies were identified as intravenous (IV) formulations of: frusemide, benzylpenicillin, diamorphine, gentamicin and insulin.[Chappell *et al.*, 2004] The resulting harm was reported as ranging from minor harm, requiring increased monitoring and specific treatment, to serious harm and death.[Suresh *et al.*, 2004]

Several studies also emphasised the incidence of patient misidentification errors during the administration phase.[Vincer *et al.*, 1989, Gray *et al.*, 2004, Suresh *et al.*, 2004, Van Den Anker, 2005, Stavroudis *et al.*, 2010, Antonucci *et al.*, 2012, Dabliz *et al.*, 2012, Sorrentino *et al.*, 2012] Dabliz et.al. estimated that 25% of medication errors within the NICU were attributed to administering medication to the wrong patient.[Dabliz *et al.*, 2012] The most common causes

of misidentification were similar sounding/identical names and surnames, difficulties in distinguishing multiple birth babies (i.e. twins, triplets) and inability to communicate with patients.[Gray *et al.*, 2006] Furthermore, it was reported that identification bands on wrists and ankles were often removed in order to place IV lines or to take blood samples, and were forgotten to be replaced leading to increased risk for misidentification.[Antonucci *et al.*, 2012, Dabliz *et al.*, 2012]

Errors pertaining to the monitoring phase were uncommon, comprising only 1.4% of all errors.[Suresh *et al.*, 2004] These types of errors often involved the incorrect interpretation of laboratory results, omission of therapeutic drug monitoring and missing the symptoms of adverse events.[Kaushal *et al.*, 2001, Suresh *et al.*, 2004]

PAEDIATRIC

Among the 17 articles reviewed, prescription errors were the most commonly reported type of medication error.[Folli *et al.*, 1987, Aneja *et al.*, 1992, Wilson *et al.*, 1998, Kozer *et al.*, 2002, Fortescue *et al.*, 2003, Taylor *et al.*, 2005, Condren *et al.*, 2009, Al-Jeraisy *et al.*, 2011] Accounting for 10 – 74% of total error reports, these types of errors were most commonly identified via retrospective and prospective reviews of patient charts and medication incident reports.[Folli *et al.*, 1987, Aneja *et al.*, 1992, Wilson *et al.*, 1998, Frey *et al.*, 2000, Ross *et al.*, 2000, Frey *et al.*, 2002, Kozer *et al.*, 2002, Fortescue *et al.*, 2003, Taylor *et al.*, 2005, Otero *et al.*, 2008, Condren *et al.*, 2009, Wong *et al.*, 2009, Ghaleb *et al.*, 2010, Al-Jeraisy *et al.*, 2011, Belela *et al.*, 2011, Ozkan *et al.*, 2011, Manias *et al.*, 2014] Overall, dosing errors were the most common type reported, making up 82.6% of prescribing errors.[Folli *et al.*, 1987, Aneja *et al.*, 1992, Wilson *et al.*, 1998, Kozer *et al.*, 2002, Fortescue *et al.*, 2003, Wong *et al.*, 2009, Al-Jeraisy *et al.*, 2011] Significant overdoses by as much as ten-times over the normal dosage range were identified, with Ross attributing a third of these errors to dose miscalculations by clinicians.[Ross *et al.*, 2000, Fortescue *et al.*, 2003] The consequences of these errors were reported as involving elevated serum levels of medicines, leading to moderate level and life-threatening toxicities.[Wilson *et al.*, 1998, Kozer *et al.*, 2002] These symptoms subsequently led to increased patient monitoring, length of stay, hospital costs and in-hospital deaths.[Kozer *et al.*, 2002] Paediatric prescribing errors were more frequent in seriously ill patients, and were most likely to be caused by trainee doctors.[Kozer *et al.*, 2002, Al-Jeraisy *et al.*, 2011] Condren et.al. identified that prescribing errors, including dosing mistakes and incomplete medication

orders, were present in 9.7% of new prescriptions in a paediatric acute care clinic.[Condren *et al.*, 2009]

Transcription errors were not commonly reported within paediatric studies, with only three articles acknowledging their incidence.[Frey *et al.*, 2000, Frey *et al.*, 2002, Fortescue *et al.*, 2003] These types of errors made up 5.8% of all medication errors, and included: punctuation mistakes (i.e. writing 3 instead of 0.3), omission of medication, wrong unit of measurement (i.e. g instead of mg) and incorrect doses.[Frey *et al.*, 2000, Frey *et al.*, 2002, Fortescue *et al.*, 2003]

Errors within the dispensing phase were not considered to be significant sources of error accounting for only 2.7 – 7% of errors in paediatric patients. Four studies identified that labelling mistakes were the most common sources or error as well as the dispensing of incorrect quantities of medication and supplying incorrect medications.[Wilson *et al.*, 1998, Ross *et al.*, 2000, Frey *et al.*, 2002, Belela *et al.*, 2011]

Medication errors occurred frequently within the administration phase, comprising 12.8 - 73% of total reported errors.[Frey *et al.*, 2002, Ghaleb *et al.*, 2010, Belela *et al.*, 2011, Ozkan *et al.*, 2011] The administration of incorrect doses was the most commonly reported error, and specifically related to ten-fold overdoses.[Wilson *et al.*, 1998, Frey *et al.*, 2000, Ross *et al.*, 2000, Frey *et al.*, 2002, Kozer *et al.*, 2002, Fortescue *et al.*, 2003, Otero *et al.*, 2008, Wong *et al.*, 2009, Ghaleb *et al.*, 2010, Belela *et al.*, 2011, Ozkan *et al.*, 2011] A Canadian retrospective cohort study reported that children were at a greater risk of being administered ten-fold overdoses than adults because the volume of a dose that was ten-times the normal range for paediatric patients would still look like a relatively small volume of stock solution.[Kozer *et al.*, 2002] Wong et.al. stated that an overdose of potent medications in children (e.g. sedatives), may cause respiratory depression and have a critical effect on neurological outcomes.[Wong *et al.*, 2009] Medicines most commonly associated with ten-fold dosing errors included: digoxin, morphine, gentamicin and indomethacin.[Kozer *et al.*, 2002] Two articles also identified errors in incorrectly administering pharmacotherapy to the wrong patient, who had no therapeutic need for the medication.[Wong *et al.*, 2009, Manias *et al.*, 2014] Contributing factors to the incidence of administration errors were identified as including human error, equipment dysfunction and communication failures.[Frey *et al.*, 2000]

None of the studies based in paediatric wards identified monitoring errors as a part of the medication error profile.

ADULT

Among the 11 articles reviewed, the most common study designs were prospective observational studies.[Bates *et al.*, 1995, Calabrese *et al.*, 2001, Barker *et al.*, 2002, Van Den Bemt *et al.*, 2002, Winterstein *et al.*, 2004, Lisby *et al.*, 2005, Kopp *et al.*, 2006, Bohomol *et al.*, 2009, Jennane *et al.*, 2011, Zeraatchi *et al.*, 2013, Saghafi *et al.*, 2014] Bates estimated that 6.5 of 100 adult admissions experienced a medication error and that at least 28% were preventable.[Bates *et al.*, 1995] Most errors occurred within the prescribing phase, making up 56 – 72.5% of total reported medication errors.[Bates *et al.*, 1995, Winterstein *et al.*, 2004] Examples of these errors included: the prescribing of 100 vials of tramadol instead of 100mg and ranitidine erroneously prescribed via nasogastric tube instead of intravenously.[Bohomol *et al.*, 2009] Overall, incorrect dosing was the most commonly reported prescribing error.[Bates *et al.*, 1995, Winterstein *et al.*, 2004, Lisby *et al.*, 2005, Kopp *et al.*, 2006, Bohomol *et al.*, 2009, Jennane *et al.*, 2011, Zeraatchi *et al.*, 2013, Saghafi *et al.*, 2014] Bohomol et.al., Winterstein et.al. and Kopp et.al. emphasised that prescribing errors were mostly caused by physicians lack of detailed pharmacology knowledge and failure to comprehensively consider patient information.[Winterstein *et al.*, 2004, Kopp *et al.*, 2006, Bohomol *et al.*, 2009] Furthermore, a quantitative study that analysed patient prescriptions and incident reports in a Brazilian intensive care unit (ICU) highlighted that patients with polymedication prescriptions admitted to the stressful and fast-paced environment of the ICU were more prone to experiencing prescribing errors.[Bohomol *et al.*, 2009] The consequences of medication error were reported as including uncontrolled pain and infection due to underdosing, renal failure and elevated serum levels, resulting in increased monitoring and additional treatment.[Winterstein *et al.*, 2004, Bohomol *et al.*, 2009]

Transcription errors were well-documented within the adult population, particularly within the Danish and Moroccan studies, and the percentage of reported errors ranged from 6 – 60% of all total medication errors.[Bates *et al.*, 1995, Winterstein *et al.*, 2004, Lisby *et al.*, 2005, Kopp *et al.*, 2006, Bohomol *et al.*, 2009, Jennane *et al.*, 2011, Zeraatchi *et al.*, 2013, Saghafi *et al.*, 2014] The most commonly reported error related to errors in transferring information into patient charts.[Bates *et al.*, 1995, Lisby *et al.*, 2005, Kopp *et al.*, 2006, Jennane *et al.*, 2011, Zeraatchi *et al.*, 2013] Nursing staff were responsible for 40% of transcription errors, due to erroneous interpretations of prescriptions by nurses.[Lisby *et al.*, 2005, Zeraatchi *et al.*, 2013]

Overall, the dispensing phase was not a major source of medication errors, comprising 2.2 – 34% of all errors.[Lisby *et al.*, 2005, Kopp *et al.*, 2006, Saghafi *et al.*, 2014] The most frequently

reported error was associated with mistakes in the preparation of doses for patients.[Bates *et al.*, 1995, Lisby *et al.*, 2005, Kopp *et al.*, 2006]

The administration phase comprised 14.6 – 41% of all medication errors in adult wards.[Calabrese *et al.*, 2001, Barker *et al.*, 2002, Van Den Bemt *et al.*, 2002, Kopp *et al.*, 2006, Zeraatchi *et al.*, 2013, Saghafi *et al.*, 2014] A US based prospective observational study set in adult medical and surgical ICU's identified that one medication error occurred for every five doses of medication administered.[Kopp *et al.*, 2006] The most frequently reported errors involved the administration of medications at the wrong time and omission of administering doses, accounting for 43% and 30% of administration errors respectively.[Calabrese *et al.*, 2001, Barker *et al.*, 2002, Van Den Bemt *et al.*, 2002, Lisby *et al.*, 2005, Kopp *et al.*, 2006, Bohomol *et al.*, 2009] The consequences of late or omitted administration of critical medicines such as anti-infectives and anti-coagulants were reported as leading to sub-optimal management of infection, blood pressure and blood clotting, threatening the success of treatment.[Bohomol *et al.*, 2009] The overdosing of medications was also emphasised as a serious error within adult critical care wards, with Winterstein et.al. documenting nephrotoxic effects as a result of overdosing antibiotics.[Winterstein *et al.*, 2004] Nurses were responsible for generating 40% of administration errors and contributing factors included staff performance deficits, memory lapses and faulty dose checking processes.[Winterstein *et al.*, 2004, Kopp *et al.*, 2006, Zeraatchi *et al.*, 2013]

Errors in the monitoring phase were uncommon, identified in only two studies.[Bohomol *et al.*, 2009, Jennane *et al.*, 2011] These errors were described as the failure to assess patient responses to prescribed medications, including laboratory results and clinical markers within therapeutic drug monitoring practices.[Bohomol *et al.*, 2009, Jennane *et al.*, 2011]

ELDERLY

Among the 10 articles reviewed, medication errors were most commonly identified through prospective observational studies and retrospective review of charts and incident reports.[Briggs, 2006, Picone *et al.*, 2008, Ben-Yehuda *et al.*, 2011, Henri *et al.*, 2012, Maher *et al.*, 2012, Zakharov *et al.*, 2012, Buck *et al.*, 2013, García-Aparicio *et al.*, 2013, Ernawati *et al.*, 2014, Metsälä *et al.*, 2014] The median age of elderly participants ranged from 68 – 84 years of age.[Picone *et al.*, 2008, Ben-Yehuda *et al.*, 2011, Buck *et al.*, 2013, García-Aparicio *et al.*, 2013, Ernawati *et al.*, 2014] Medication errors in the prescribing phase ranged between 1.6 – 46% of

the total reported errors.[Picone *et al.*, 2008, Ben-Yehuda *et al.*, 2011, Ernawati *et al.*, 2014] Incorrect dosing was most commonly reported, comprising 49% of prescribing errors.[Briggs, 2006, Picone *et al.*, 2008, Ben-Yehuda *et al.*, 2011, Maher *et al.*, 2012, Buck *et al.*, 2013, García-Aparicio *et al.*, 2013, Ernawati *et al.*, 2014, Metsälä *et al.*, 2014] A unique error commonly reported in the elderly population involved the prescribing of inappropriate medications.[Briggs, 2006, Picone *et al.*, 2008, Ben-Yehuda *et al.*, 2011, Maher *et al.*, 2012, Buck *et al.*, 2013, García-Aparicio *et al.*, 2013, Ernawati *et al.*, 2014, Metsälä *et al.*, 2014] Described as the ordering of medications that are unnecessary, ineffective or unsafe, these errors most often occur in elderly patients who present with multiple pathologies, requiring multiple medications.[Maher *et al.*, 2012] The consequences of these errors were reported an involving serious adverse drug events and prolonging hospitalisations.[Maher *et al.*, 2012] Furthermore, Ernawati at.al. found that physicians often only partially complete patient medication histories, leading to the prescribing of duplicate therapies because of the inadequate gathering of patient information.[Ernawati *et al.*, 2014]

Transcribing errors were well documented in elderly patients, and were discussed by four articles. The percentage of total errors ranged from 15 – 54%, and the most commonly reported error related to discrepancies in doses between prescriptions and patient charts.[Picone *et al.*, 2008, Ben-Yehuda *et al.*, 2011, Maher *et al.*, 2012, Ernawati *et al.*, 2014] A cohort study set in a 37-bed ward in Israel and involving 137 patients detected that the number of medications being taken was related to a higher risk of transcribing errors.[Ben-Yehuda *et al.*, 2011] Specifically, patients prescribed nine or more medications and whose hospitalisations were 13 days or longer were at a higher risk.[Ben-Yehuda *et al.*, 2011] The medications most commonly associated with this type of error included: simvastatin, valsartan and paracetamol.[Ernawati *et al.*, 2014] Ernawati et.al. commented that there was a need for accuracy during the transcribing process in order to prevent subsequent administration errors.[Ernawati *et al.*, 2014]

Dispensing errors were not considered main sources of error within the elderly population. These errors made-up 2 – 14% of medication errors, with the most common error involving the incorrect labelling and instructions on dispensed medications.[Briggs, 2006, Picone *et al.*, 2008, Maher *et al.*, 2012, Ernawati *et al.*, 2014] Maher et.al. stated that erroneous instructions most often related to labelling medications PRN instead of once a day.[Maher *et al.*, 2012] [Zakharov *et al.*, 2012]

Overall, it was found that administration errors are the most common type in hospitalised elderly patients, comprising 54.2 - 59% of all medication errors.[Briggs, 2006, Picone *et al.*, 2008, Henri *et al.*, 2012, Ernawati *et al.*, 2014, Metsälä *et al.*, 2014] Older patients, suffering from more than one chronic disease and taking five or more medications were identified as being at a greater risk of experiencing these errors.[Picone *et al.*, 2008, Henri *et al.*, 2012] The most frequently reported administration errors were omission of administering prescribed medication and incorrect administration times.[Briggs, 2006, Picone *et al.*, 2008, Henri *et al.*, 2012, Maher *et al.*, 2012, Ernawati *et al.*, 2014, Metsälä *et al.*, 2014] Zakharov et.al. identified that nurses were responsible for 43% of administration errors.[Zakharov *et al.*, 2012] The clinical impact of these errors on patients ranged between minor discomfort to significant morbidity and mortality.[Picone *et al.*, 2008, Henri *et al.*, 2012] Ernawati et.al. conducted a 20-week prospective study in a 13-bed geriatric ward and reported that 10.3% of medication errors had a potentially significant impact, with a further 2.4% being potentially serious.[Ernawati *et al.*, 2014] The drug classes most commonly involved in administration errors included: aminoglycosides, anticoagulants, opioid analgesics and anti-hypertensives.[Ernawati *et al.*, 2014]

Monitoring errors were only identified in one article by Maher et.al. who reported that they were associated with inappropriate clinical monitoring practices.[Maher *et al.*, 2012] Specifically, this error was identified as the failure to identify risk of medication toxicity in patients, which could have been prevented, reversed or reduced by earlier dose adjustments.[Maher *et al.*, 2012]

COMPARISON OF MEDICATION COMMONLY ASSOCIATED WITH ERROR

The review sought to compare the medications most commonly associated with error to the A-PINCH High Risk Medicines List. Compiled by the Australian Clinical Excellence Commission, the list groups together medications that are universally considered to be high-risk and are represented by the acronym A-PINCH.[2015] Each of the medication categories listed on A-PINCH were commonly implicated in errors across each of the reviewed patient populations, including antibiotics (particularly gentamicin), heparin, insulin, potassium chloride, fentanyl, morphine, anti-arrhythmics and parenteral nutrition. (Table 3)

Overall, the neonatal population reported issues with a broader range of agents, as well as medications that were not seen in other populations, including prostaglandins, ketamine,

immunisations, milk and vecuronium. As neonatal patients are administered the majority of medications through the IV or intramuscular (IM) routes, any errors that occur will have a systemic effect. As such, ten-fold errors have been reported more commonly with IV formulations and agents including: insulin, midazolam, frusemide, benzylpenicillin, gentamicin and ranitidine.[Chappell *et al.*, 2004] The literature did not report any errors with antineoplastic medications or with corticosteroids, which were all commonly reported in the other three patient groups. Furthermore, it is reported that NICU patients have a high exposure to medications, and are prescribed an average of 8.6 drugs per infant, increasing the risk for experiencing adverse drug events.[Daniell *et al.*, 1989, Sorrentino *et al.*, 2012]

The elderly and adult populations experience errors within the same groups of medications, particularly cardiovascular and GI medications. Errors are associated with a wider selection of agents in these drug classes in comparison to paediatric and neonatal patients. The elderly population experienced errors with allopurinol and statins, which are medications most often used in older patients.

Paediatric patients experienced the most errors with antibiotics. Due to the large age range of the population (extending from 1 year to 18 years of age), some medications were also the same as those reported in the adult population including adrenaline, anticonvulsants and steroids.

DISCUSSION

The main focus of this article was to highlight the types of medication-related safety issues that occur in hospitalized patients, in particular those within the neonatal population. To our knowledge, this is the only review to compare the types of medication errors that occur within four distinct population groups.

The review demonstrates that each phase of the medication-use process is susceptible to medication error, across the patient age spectrum. (Figure 2) Most literature has identified errors within the prescribing and administration phases. In particular, errors relating to incorrect dosing, incorrect medications and incorrect administration time were the most frequently reported. The ranges of reported error varied greatly, which can be attributed to differences in research methods, although most studies used the chart review method, which is more effective in detecting prescribing errors. In addition, medication error was not

explicitly defined in some studies, particularly within the neonatal and paediatric studies. This may be attributed to the fact that a large proportion of medications used in young patients are prescribed off-label. As such, it is difficult to define prescribing dosing errors if doses have been adapted and extrapolated from adult guidelines.

The findings suggest that there are medication errors seen in certain types of patient population more than in others. In particular, within the neonatal population errors pertaining to patient misidentification, delayed dispensing, parental involvement in administering unauthorized medications, erroneous product dilutions, as well as ten-fold and 100-fold overdoses, were emphasized. Overdoses to this extent were not reported in the adult or elderly populations. The main contributing factors were identified as physician inexperience as well as the lack of neonate-specific dosing protocols and evidence-based information on the efficacy, safety, dosing, pharmacokinetics and clinical use of medication in neonates leading to the common use of off-label or unlicensed medications.[Antonucci *et al.*, 2012] The findings highlight that the prescribing and administration phases were most commonly associated with medication errors. Overall, the use of medication in neonates is more complex than in other patient groups.[Raju *et al.*, 2011, 2014] NICU healthcare professionals are faced with limited amounts of evidence-based information supporting the use of pharmacotherapeutic interventions in neonates, as well as a narrow range of neonatal-specific formulations.[Chedoe *et al.*, 2007] Furthermore, neonates are a non-homogenous group, with differences in maturation of medication-sensitive organs (kidneys, GI tract and liver), weights and gestational ages, requiring individualized weight-based dosing.[Gray *et al.*, 2004, Jain *et al.*, 2009]. (Table 4) The physiological vulnerabilities limit neonates' 'buffering zone' capacity to compensate for error, leaving a narrow margin of safety.[Raju *et al.*, 2011, Antonucci *et al.*, 2012] The resulting impact of these errors is greater than in older children or adult populations. Neonates are at the very start of the developmental age spectrum, and even minor errors can lead to short-term as well as long-term consequences affecting development.[Raju *et al.*, 2011] As the risk of sustaining a medication error has been reported as being eight-times higher within the neonatal group than within any other population, targeted interventions to improve safety and decrease error rates should be prioritized to the neonatal population as the patients of highest risk.[Kaushal *et al.*, 2001, Stavroudis *et al.*, 2010]

Unique errors were also reported within the elderly population. Characteristics of vulnerability including polypharmacy, multi-morbidities and decreased organ function, were reported as important factors that increased risk of experiencing medication errors.[García-Aparicio *et al.*,

2013] Errors pertaining to the prescribing of unnecessary medications and duplication of pharmacotherapies were almost exclusively reported within this group. Most commonly attributed to physicians, these errors were attributed to poor gathering of patient information and the failure to complete full patient medication histories upon admission. The impact of these errors most commonly related to medication toxicities as well as significant adverse effects. However, the consequences of harm are not as great compared to patients at the start of their lifespan.

An important finding of the study is that the medications most commonly associated with error in each of the patient groups were those listed within the A-PINCH. As such, medication safety interventions should focus upon these medications. When considering the neonatal population, the range of medications that are prescribed for use in the NICU are relatively limited in comparison to those used in older paediatric and adult populations.[Gray *et al.*, 2004] However, despite this the findings show that errors occur with a broader range of agents in the neonatal population than other hospitalized patients – indicating that the use of medications in NICU is more complex.

As medication errors can occur at any stage of the medication-use process and can be caused by a range of healthcare professionals, the strategies to improve safety must be multi-factorial. Several studies recommend the use of computerized physician-order entry and the use of a single-medication therapy sheet to improve both prescribing and transcription errors.[Kaushal *et al.*, 2001, Kozer *et al.*, 2002, Fortescue *et al.*, 2003, Gray *et al.*, 2004, Winterstein *et al.*, 2004, Kunac *et al.*, 2005, Lisby *et al.*, 2005, Van Den Anker, 2005, Briggs, 2006, Campino *et al.*, 2009, Condren *et al.*, 2009, Wong *et al.*, 2009, Ghaleb *et al.*, 2010, Antonucci *et al.*, 2012, Dabliz *et al.*, 2012, Maher *et al.*, 2012, Sorrentino *et al.*, 2012, Ernawati *et al.*, 2014] In addition, the formulation of population-specific quality control tools and health indicators has also been regarded as important in improving medication error rates.[Bohomol *et al.*, 2009] However, the most commonly cited strategy identified in half of the literature across all patient groups, is the involvement of a clinical pharmacist on wards.[Folli *et al.*, 1987, Bates *et al.*, 1995, Wilson *et al.*, 1998, Kaushal *et al.*, 2001, Kozer *et al.*, 2002, Van Den Bemt *et al.*, 2002, Fortescue *et al.*, 2003, Gray *et al.*, 2004, Simpson *et al.*, 2004, Kunac *et al.*, 2005, Lisby *et al.*, 2005, Briggs, 2006, Bohomol *et al.*, 2009, Campino *et al.*, 2009, Condren *et al.*, 2009, Wong *et al.*, 2009, Ghaleb *et al.*, 2010, Ben-Yehuda *et al.*, 2011, Jennane *et al.*, 2011, Antonucci *et al.*, 2012, Dabliz *et al.*, 2012, Henri *et al.*, 2012, Maher *et al.*, 2012, Sorrentino *et al.*, 2012, García-Aparicio *et al.*, 2013, Ernawati *et al.*, 2014, Metsälä *et al.*, 2014] Fortescue and colleagues

report that 81% of medication errors in paediatric patients could be avoided with pharmacist monitoring.[Fortescue *et al.*, 2003] High-intensity wards, using high-risk medications, such as ICU's, may benefit the most from a ward-based clinical pharmacist.[Fortescue *et al.*, 2003] In the NICU in particular, the integration of the pharmacist into the treating team leads to medication-use improvement.[Campino *et al.*, 2009] Simpson et.al. reported that following a daily cot-side review of patients, pharmacists significantly reduced monthly medication errors from 24.1 per 1000 neonatal activity days to 5.1 ($p < 0.001$).[Simpson *et al.*, 2004] Clinical pharmacy activities, such as patient medication chart reviews, medication reconciliation as well as participating in medical ward rounds with physicians and nurses are effective in reducing errors.[Fortescue *et al.*, 2003, Simpson *et al.*, 2004, Kunac *et al.*, 2005, Briggs, 2006, Ben-Yehuda *et al.*, 2011, Jennane *et al.*, 2011, Dabliz *et al.*, 2012, Sorrentino *et al.*, 2012, Ernawati *et al.*, 2014] Furthermore, the provision of medication-specific education to the treating team can improve the quality of the healthcare delivered and promotes inter-disciplinary collaboration.[Kunac *et al.*, 2005, Dabliz *et al.*, 2012] In adult wards, Leape and colleagues identified that pharmacist participation on ward rounds reduced the rate of preventable adverse drug events due to prescribing errors by 66%.[Leape *et al.*, 1999] These activities allow for real-time feedback and education, leading to better prescribing decisions, and greater interception of errors before they are realized.[Fortescue *et al.*, 2003, Simpson *et al.*, 2004] Clinical pharmacists possess specialized knowledge that is essential in preventing harm to patients as well as in minimizing hospital-associated costs from extended hospital stays and additional therapy.[Folli *et al.*, 1987]

LIMITATIONS

Differences in study methods, definitions of medication errors, and definitions in error categories makes direct comparison between studies difficult, particularly within the prescribing and administration phases. For example, in some studies errors that were identified prior to the administration of medication were not included in the results and as such only actual administration errors were reported. However, most studies utilized a chart review or medication-order review method of medication error detection, which are ultimately better at detecting prescription-based errors.

Some studies mixed population groups, for example, paediatric studies often included data from a NICU, however did not always disclose the proportions of errors occurring in each ward.

Therefore, results between the two subgroups may be hard to differentiate. There was less data available on elderly patients as most studies concentrated on medication errors that occurred outside of the hospital setting, i.e. in nursing homes.

It is also possible that a large number of studies could have been excluded because they were not available in the English language.

CONCLUSION

Each stage of the medication-use process is prone to medication error, across the age spectrum. The administration and prescribing phases were the most commonly identified phases of error and most often related to incorrect dosing, wrong prescribing or administering of drugs and wrong time of administration. While neonatal patients experience the same types of medication errors as other hospitalized patients, the medication-use process within this group is more complex and has greater consequences in the instance of error. Maintaining safe pharmacotherapeutic practices should be a major priority for all health professionals however clinical pharmacists have the potential to significantly reduce medication errors. Further research is required to develop targeted strategies relevant to specific patient groups that integrate key pharmacy services into wards, as well as quality-control tools and health indicators to prevent medication errors. Additional, investigation is needed to determine the need of pharmacy services on NICU and their impact on patient safety and care.

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Table 1: Definitions and contributing factors for medication error across the medication use process

DEFINITIONS OF THE DIFFERENT TYPES OF MEDICATION ERRORS	
Prescribing	All errors that occur during the decision process and in prescribing/ordering a medication for a patient. Includes: dose errors, wrong drug, wrong regimen, inappropriate drug
Transcription	All errors associated with the transfer of verbal or written information from an order sheet or prescription to patient medication chart or medical records. Includes: discrepancies in drug name, formulation, route, dose, dosing regimen, omission
Dispensing	All errors that occur during the interpretation of medication prescriptions by the pharmacy staff and the subsequent selection, preparation, labelling and distribution of medication
Administration	All errors that occur whilst a medication is being administered to a patient. Includes: omission, wrong drug, wrong dose, wrong time, wrong route
Monitoring	All errors associated with the monitoring of clinical and/or laboratory data that assesses the patient's response to the administered drug therapy i.e. through therapeutic drug monitoring practices. Includes: error in interpreting results, wrong dose suggestions, omission of suggestions, wrong drug suggestions to reverse condition.
CONTRIBUTING FACTORS FOR MEDICATION ERROR IN EACH PATIENT GROUP	
Neonate	Higher number of medications, lack of physician experience, high-intensity physician workloads, length of stay, low birth weights, gestational ages, similar sounding/identical names and surnames, multiple birth babies (i.e. twins), inability to communicate, more vascular lines, long hospitalizations, dispensing medications 2 hours after being ordered
Paediatric	Seriously ill patients, inexperienced physicians, human error, equipment dysfunction, communication failures
Adult	Polymedication prescriptions, physicians lack of pharmacology knowledge, stressful and high-paced work environment, staff

	performance deficits, failure to consider patient information, memory lapses, dose-checking processes
Elderly	Taking five or more medications, prescribed nine or more medications, hospitalizations 13 days or longer, incidence of more than one chronic disease, multiple pathologies

Table 2: Medication errors specific to neonatal patients

	NEONATES
PRESCRIBING	- Wrong route - Wrong use of units i.e. milligrams instead of grams - Lack of neonate specific drug protocols/information
TRANSCRIPTION	- Wrong weight - Wrong dosage regimen - Wrong units
DISPENSING	- Providing the correct drug in the wrong packaging - Incorrect calculations/doses - Late dispensing of medications - Incorrect dilutions in manufacture of drugs
ADMINISTRATION	- Patient misidentification - Additional dose of drug - Wrong dilution - Parents administering unauthorised nutrients
MONITORING	- Nil specific compared to other populations

Table 3: Types of medications most commonly associated with error

PATIENT GROUP	**NEONATES**	**PAEDIATRICS**	**ADULT**	**ELDERLY**
COMMONLY IDENTIFIED MEDICATIONS		Adrenaline [Wong *et al.*, 2009]	Adrenaline [Calabrese *et al.*, 2001]	
A-PINCH LISTED MEDICATION	Antibiotics - Amikacin [Pallas *et al.*, 2008], Benzylpenicillin [Simpson *et al.*, 2004], Gentamicin [Simpson *et al.*, 2004, Pallas *et al.*, 2008, Stavroudis *et al.*, 2010], Vancomycin [Simpson *et al.*, 2004, Pallas *et al.*, 2008]	Antibiotics [Folli *et al.*, 1987, Ross *et al.*, 2000, Kozer *et al.*, 2002]- Benzylpenicillin [Wong *et al.*, 2009], Gentamicin [Wong *et al.*, 2009]	Antibiotics [Winterstein *et al.*, 2004, Jennane *et al.*, 2011, Zeraatchi *et al.*, 2013] Mupirocin [Winterstein *et al.*, 2004]	Antibiotics – Vancomycin, Gentamicin, Cefazolin, Metronidazole [Picone *et al.*, 2008, Ernawati *et al.*, 2014]
A-PINCH LISTED MEDICATION	Anticoagulants [Frey *et al.*, 2002]		Anticoagulants - Warfarin [Calabrese *et al.*, 2001, Winterstein *et al.*, 2004, Jennane *et al.*, 2011, Zeraatchi *et al.*, 2013]	Anticoagulants - Warfarin [Picone *et al.*, 2008, Ernawati *et al.*, 2014]

		Anticonvulsants [Wong *et al.*, 2009]	Anticonvulsants [Winterstein *et al.*, 2004]	
	Sedatives - Midazolam [Frey *et al.*, 2002]	Sedatives [Wong *et al.*, 2009]	Benzodiazepines – Lorazepam, Midazolam [Calabrese *et al.*, 2001, Jennane *et al.*, 2011]	Benzodiazepines – Alprazolam, Lorazepam [Picone *et al.*, 2008, García-Aparicio *et al.*, 2013]
A-PINCH LISTED MEDICATION		Chemotherapy drugs [Folli *et al.*, 1987, Ross *et al.*, 2000]	Antineoplastic agents [Winterstein *et al.*, 2004]	Antineoplastic agents – Azathioprine, Doxorubicin [Picone *et al.*, 2008]
	Anti-arrhythmics [Frey *et al.*, 2002]	Captopril [Wong *et al.*, 2009] Digoxin [Folli *et al.*, 1987, Wong *et al.*, 2009] Propranolol [Folli *et al.*, 1987]	Calcium channel blockers [Winterstein *et al.*, 2004] Digoxin [Calabrese *et al.*, 2001] Sympathomimetic agents - Dobutamine [Calabrese *et al.*, 2001, Winterstein *et al.*, 2004]	Cardiovascular – Digoxin, Metoprolol, Amiodarone [Picone *et al.*, 2008, García-Aparicio *et al.*, 2013, Ernawati *et al.*, 2014] Isosorbide mononitrate [García-Aparicio *et*

				al., 2013]
	Frusemide [Frey *et al.*, 2002, Stavroudis *et al.*, 2010]			Frusemide [Picone *et al.*, 2008, García-Aparicio *et al.*, 2013]
	Ranitidine [Pallas *et al.*, 2008]		Docusate sodium [Winterstein *et al.*, 2004] H_2 antagonists [Winterstein *et al.*, 2004] Metoclopramide [Winterstein *et al.*, 2004]	GI Drugs – Docusate, Omeprazole[Picone *et al.*, 2008, García-Aparicio *et al.*, 2013, Ernawati *et al.*, 2014]
A-PINCH LISTED MEDICATION	Heparin [Frey *et al.*, 2002]	Heparin [Wong *et al.*, 2009]	Thrombolytics - Heparin [Calabrese *et al.*, 2001, Winterstein *et al.*, 2004, Zeraatchi *et al.*, 2013]	Heparin [Picone *et al.*, 2008]
A-PINCH LISTED MEDICATION	Insulin [Simpson *et al.*, 2004]	Insulin [Ross *et al.*, 2000, Wong *et al.*, 2009]	Insulin [Calabrese *et al.*, 2001, Zeraatchi *et al.*, 2013]	Insulin [Picone *et al.*, 2008]
A-PINCH LISTED MEDICATION	Fentanyl [Frey *et al.*, 2002, Pallas *et al.*, 2008,	Morphine [Ross *et al.*, 2000, Wong *et al.*, 2009]	Fentanyl [Calabrese *et al.*, 2001] Morphine	Morphine [Picone *et al.*, 2008, Ernawati *et*

	Stavroudis *et al.*, 2010] Morphine [Simpson *et al.*, 2004, Stavroudis *et al.*, 2010]		[Calabrese *et al.*, 2001, Jennane *et al.*, 2011]	*al.*, 2014]
	NSAIDs - Indomethacin [Frey *et al.*, 2002, Stavroudis *et al.*, 2010]		NSAIDs [Winterstein *et al.*, 2004]	
	Parenteral nutrition – amino acids/fat emulsions [Frey *et al.*, 2002, Stavroudis *et al.*, 2010]	Parenteral nutrition [Folli *et al.*, 1987, Ross *et al.*, 2000]	Electrolyte, caloric and water balance agents [Winterstein *et al.*, 2004]	Nutrients [Picone *et al.*, 2008, Ernawati *et al.*, 2014]
A-PINCH LISTED MEDICATION	Potassium chloride [Stavroudis *et al.*, 2010] Glucose [Frey *et al.*, 2002]	IV fluids [Folli *et al.*, 1987, Ross *et al.*, 2000, Wong *et al.*, 2009]	Potassium chloride [Calabrese *et al.*, 2001]	Electrolyte and water balance – potassium chloride, IV fluids [Picone *et al.*, 2008]
		Steroids [Folli *et al.*, 1987, Ross *et al.*, 2000]	Corticosteroids [Jennane *et al.*,	Hydrocortisone [Picone *et*

			2011]	*al.*, 2008]
INDIVIDUALLY IDENTIFIED MEDICATIONS	Alteplase [Frey *et al.*, 2002] Aminophylline [Simpson *et al.*, 2004] Dopamine [Frey *et al.*, 2002, Pallas *et al.*, 2008] Erythropoietin [Pallas *et al.*, 2008, Stavroudis *et al.*, 2010] Immunisations [Simpson *et al.*, 2004] Ketamine [Frey *et al.*, 2002] Milk [Frey *et al.*, 2002] Pancuronium [Frey *et al.*, 2002] Prostaglandin [Frey *et al.*,	Antihistamines [Kozer *et al.*, 2002] Atropine [Folli *et al.*, 1987] Paracetamol [Kozer *et al.*, 2002, Wong *et al.*, 2009] Phenytoin [Wong *et al.*, 2009] Theophylline [Folli *et al.*, 1987]	Nystatin [Winterstein *et al.*, 2004]	Allopurinol [García-Aparicio *et al.*, 2013] Gabapentin [García-Aparicio *et al.*, 2013] Iron supplements [García-Aparicio *et al.*, 2013] Statins [García-Aparicio *et al.*, 2013]

	2002] Tazocin [Simpson *et al.*, 2004] Vasodilators [Frey *et al.*, 2002] Vecuronium [Stavroudis *et al.*, 2010]			

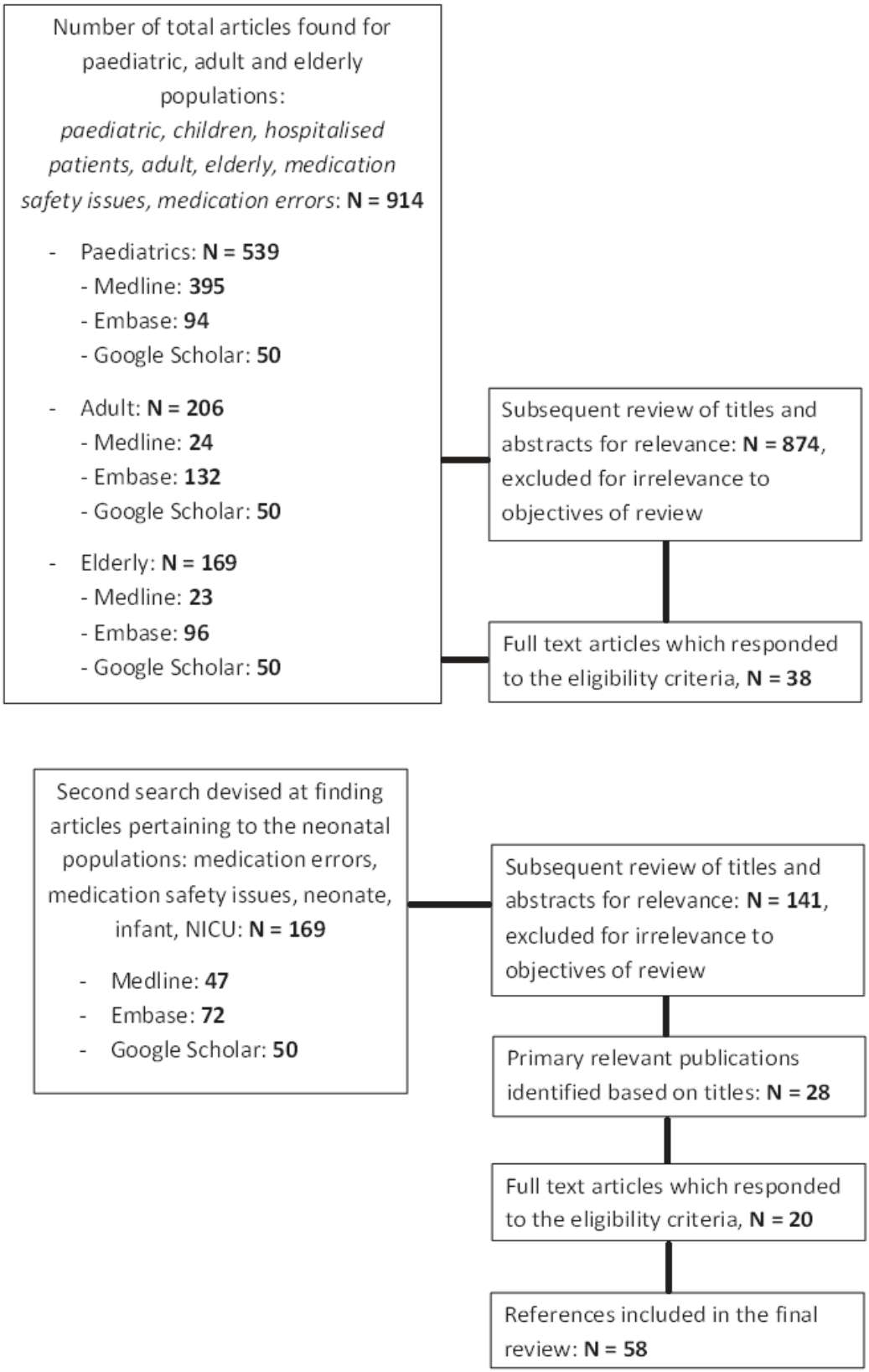
A-PINCH: Compiled by the Australian Clinical Excellence Commission, the list groups together medications that are universally considered to be high-risk and are represented by the acronym A-PINCH. Acronym stands for; A = Anti-infectives, P = Potassium and other electrolytes, I = Insulin, N = Narcotics and other sedatives, C = Chemotherapeutic agents, H = Heparin and other anti-coagulants.[2015]

Table 4: Factors that increase therapeutic risk in neonatal patients

Babies have a higher proportion of body water and less muscle and fat. Water soluble drugs need a higher dose as they are readily distributed into the system Lipid soluble drugs need a smaller dose as they do not distribute and their half-lives increase and accumulate in the body, leading to toxicity.[Berlin Jr, 2013]
Neonates' developmental immaturity influences the function of the kidneys, liver and enzyme systems. Metabolic and clearance mechanisms aren't functioning to their highest capacity. Requires the monitoring of drug serum levels to determine whether doses are therapeutic or whether they are not being cleared properly and need a reduction in dose and frequency to prevent toxic concentrations.[Berlin Jr, 2013]
Lack of neonate specific/appropriate medications available. There are several barriers to clinical trialling in neonatal and paediatric patients, including ethical issues, parental consent, sampling problems, relatively small study population etc. Therefore medication usage is often off-label or unlicensed in nature. Off-label = The use of a medication in a patient group at a dose, frequency or through a specific administration route that is not approved and is considered to be beyond the terms of the product licence.[Conroy, 2011] Unlicensed = The prescribing of medications for indications that are not in the approved product information. Furthermore, there is limited information on the safety, efficacy and clinical use of medication in neonates.[Conroy, 2011]
There are inter-individual differences in weight within the neonatal population, ranging from the smallest babies weighing <500g to the largest at >5000g.[Tayman *et al.*, 2011] The variation in weight ranges requires the calculation of individualised doses that are often very small to ensure therapeutic and safe treatment, which poses an element of risk in regards

to the potential for human error in correctly dosing medications. Calculations need to be frequently repeated as patients are constantly growing and gaining weight, therefore doses needs to be adjusted to account for this.[Chappell *et al.*, 2004, Ahmed, 2008]
Need for significant manipulation of drugs and extemporaneous compounding to ensure medications are compatible for use in neonates. Includes the performance of dilutions and the preparation of liquid formulations as medications are administered by central line, intravenously, orally or enterally.[Ahmed, 2008]
Potential for drug interactions when medications are administered through a single lumen central line. Medications are in close proximity to each other in the tube and can react to each other.[Ahmed, 2008]
The skin of the neonate is very thin. The topical administration of medications through dosage forms such as creams, lotions or ointments can lead to systemic absorption of drug. Similarly, the eyes can absorb and systemically transfer medications from eye drops, potentially leading to adverse effects.[Ahmed, 2008]
Most neonatal patients will require nutritional support; however the administration of a small amount of fluid can have a considerable impact on babies. Extra consideration is required when prescribing enteral nutrition - increasing enteral fluid volumes too quickly can lead to necrotising enterocolitis.[Ahmed, 2008]
Neonates within the NICU have an increased exposure to medications. It is reported that the number of medications administered in the NICU is inversely proportional to the patients gestational age and/or their weight.[Carvalho *et al.*, 2012]
Infants are unable to communicate with health professionals or family members about any concerns with their therapy or advise of any adverse events they are experiencing.[Ahmed, 2008]

Figure 1: Search Strategy



NEONATES	PAEDIATRICS	ADULT	ELDERLY
Prescribing: 14 - 74% - Errors in dosing, including ten-fold overdoses Transcription: 12 - 18.4% - Incorrect medication, incorrect units Dispensing: 11.9 - 25% - Errors in labelling, errors in dilutions during preparation of medication Administration: 31 - 63% - Incorrect administration time, patient misidentification Monitoring: 1.4% - Incorrect interpretation of laboratory results	Prescribing: 10 - 74% - Errors in dosing Transcription: 5.8% - Errors in punctuation, omission of prescribed medication Dispensing: 2.7 - 7% - Errors in labelling Administration: 12.8 - 73% - Incorrect doses, including ten-fold overdoses	Prescribing: 56 - 72.5% - Errors in dosing Transcription: 6 - 60% - Incorrect medication name Dispensing: 2.2 - 34% - Incorrect doses Administration: 14.6 - 41% - Incorrect administration time, omission of administering medication Monitoring - Failure to assess patient response to medication with laboratory tests	Prescribing: 1.6 - 46% - Errors in dosing, prescribing of inappropriate medications, duplication of therapy Transcription: 15 - 54% - Incorrect transfer of doses administered Dispensing: 2 - 14% - Incorrect labelling Administration: 54.2 - 59% - Omitting administration of medication, incorrect administration time Monitoring - Inappropriate clinical monitoring

Figure 2: Most commonly identified medication errors across the age spectrum

2.3 REVIEW OF DRUG UTILIZATION PATTERNS IN NICUS WORLDWIDE

Krzyżaniak N, Pawłowska I, Bajorek B.

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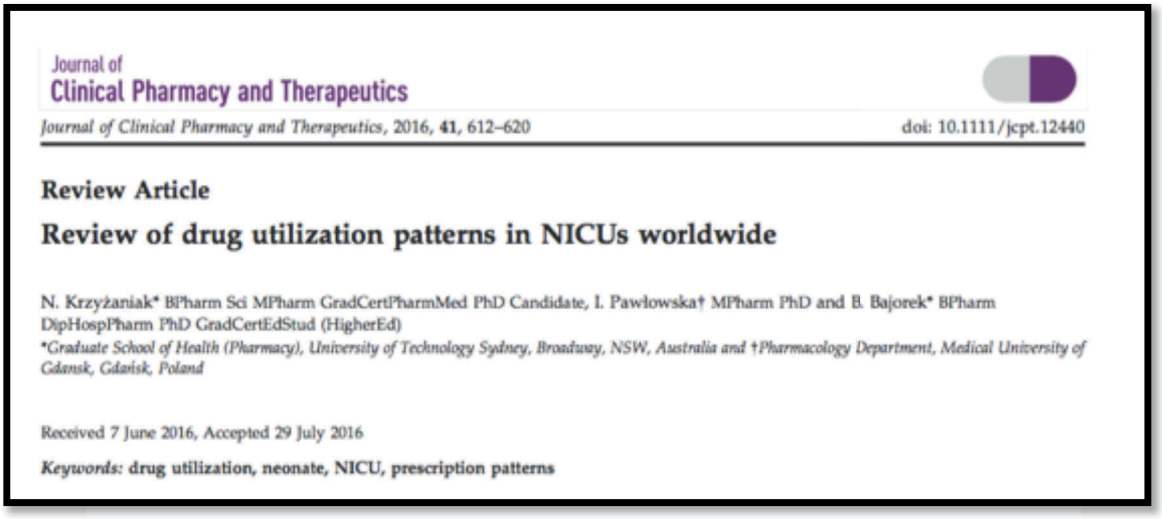

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Review Article

Review of drug utilization patterns in NICUs worldwide

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AUTHORS' CONTRIBUTIONS

Natalia Krzyżaniak conducted the search, reviewed the literature and wrote the manuscript. Iga Pawłowska *and Beata V Bajorek assisted in conceiving the review in terms of structure and scope, as well as critically revising and editing the manuscript prior to submission.*

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ABSTRACT

WHAT IS KNOWN AND OBJECTIVES: When considering acute care settings, such as the neonatal intensive care unit (NICU), the inappropriate use of medicines poses a great risk to vulnerable babies at the start of their lives. However, there is limited published literature that explores the current medication management practices in NICUs and where the main misuse issues lie. Therefore, the purpose of this review is to give an overview of medicine use in NICUs worldwide and identify therapeutic areas requiring more targeted pharmaceutical care. Specific objectives include: identifying the most commonly used medicines, comparing these to the A-PINCH (Anti-infectives, Potassium and other electrolytes, Insulin, Narcotics and sedatives, Chemotherapy agents, Heparin and other anticoagulants), high risk medicines list, and determining whether there are any differences in medicine use between countries.

METHOD: Quasi-systematic literature review

SEARCH STRATEGY: Google Scholar, Medline/PubMed, Scopus and Embase were searched utilising selected MeSH terms.

RESULTS: A total of 19 articles from 12 countries were reviewed. Medication use between countries was very similar with no discernible differences in types of medicines prescribed. The most commonly used medicines included gentamicin, ampicillin, caffeine, furosemide and vitamin K. The median number of medicines prescribed per patient ranged from 3 – 11, and an inverse relationship was identified between gestational age and the number of medications that were prescribed. Nine of the 20 most commonly used medicines were listed as A-PINCH medicines, and included antibiotics, fentanyl, morphine and heparin. Inappropriate prescribing, as well as the high use of off-label/unlicensed medicines, were highlighted as areas of practice that require consideration to improve medication safety and minimise the potential risk for medication errors.

WHAT IS NEW AND CONCLUSION: Overall, the types of medicines used in NICUs worldwide are similar, with consistent reports on the common use of antibiotics, caffeine and vitamins. However, it cannot be definitively stated that the findings of the review accurately depict current practice in NICUs, due to the limited amount of published literature available. There are several areas of concern that warrant further investigation to improve rational use of medicines in the neonatal populations, including high-use of antibiotics and off-label and unlicensed medicines.

1. INTRODUCTION, WHAT IS KNOWN AND OBJECTIVES

The World Health Organization (WHO) estimates that every year, 15 million babies are born prematurely, i.e. before 37 completed weeks of gestation, and 1 million newborns die because of complications of preterm birth. Many more preterm babies die in low-income countries than in their high-income counterparts.(1) To rescue their lives, various procedures in neonatal intensive care units (NICU) are applied in accordance with available guidelines and standards.(2-4) Without doubt, medicines play a pivotal role in the management of preterm babies. The medicines used in NICUs, including their formulations and doses, depends on their availability and accessibility in a particular country, as well as the international/national guidelines and local rules of each setting. Thus, the pattern of prescribing and the drug utilization at different NICUs is not uniform and may vary widely.

WHO has estimated that half of all medicines used worldwide are prescribed or dispensed inappropriately.(5) With consequences including increased patient morbidity, mortality, healthcare expenditures and wastage of resources, the irrational use of medicines is recognised as a major global problem.(5, 6) When considering acute care settings, such as the NICU, the inappropriate use of medicines poses a great risk to vulnerable babies at the start of their lives.(7, 8) The application of pharmacotherapy is complex in hospitalised newborns, with factors of vulnerability including developmental immaturity as well as a lack of licensed formulations and limited evidence based dosing information.(8, 9) NICU patients also have a high drug burden with a reported average of 8.6 medicines prescribed per patient.(10) As such, there is a need to implement a high-quality, safe and rational medicine use process in these patients to ensure optimal outcomes. However, there is limited published literature that explores the current medication management practices in NICUs and where the main misuse issues lie. There are no systematic reviews that comprehensively evaluate drug utilisation in NICUs. What reviews do exist, only give an insight into a subsection of total medicine use, for example, one class of medicines (antibiotics) or off-label/unlicensed use of medicines. (11-14) Ill newborns admitted to the NICU are therapeutic orphans, and where pharmacotherapy does exist, these patients are at high risk of dosing errors and adverse drug effects. Therefore, there is a need for such reviews to be extended to include the full spectrum of medicine use in the NICU and identify targets for the improvement of neonatal patient safety.

The aim of this review is to provide an overview of medicine use in NICUs worldwide. Specific objectives include: identifying the most commonly used medicines, comparing these medications with the A-PINCH high risk medicines list (Anti-infectives, Potassium and other

electrolytes, Insulin, Narcotics and sedatives, Chemotherapy agents, Heparin and other anticoagulants), determining whether there are any differences in medicine use between countries and highlighting any areas that require further attention to improve the rational use of medicines. The review does not focus on drug errors and adverse drug events, rather it seeks to provide better knowledge of the types of medicines prescribed in the NICU and the rates of off-label/unlicensed medicine use.

2. METHOD

A quasi-systematic review (a review that possesses some elements of a systematic review, including pre-defined selection criteria, however does not present a critical evaluation of the quality of studies and thus does not fulfil the criteria of comprehensiveness required from the systematic review method) extracted relevant publications pertaining to drug utilisation and prescription patterns in the NICU.(15-18) The literature was retrieved by searching the following electronic databases: Medline, Embase, Scopus and Google Scholar. The PRISMA guidelines provided a framework for the structure of this review.(19) In general, all active substances and their formulations which may be used in particular NICUs are included in drug formularies that are prepared by Hospital Therapeutic Committees.(20) Moreover, for a special need, other medicines may be used that are not enumerated in these formularies. However, these formularies are not commonly available, therefore only published studies could be a source of information on drug utilization within NICUs.

3. SEARCH STRATEGY

A comprehensive search was performed to find literature relevant to drug utilisation in the NICU using the MeSH terms *neonate, NICU, drug utilisation, prescription patterns*. Inclusion criteria for the searches restricted the content to the following: (i) neonatal patients, (ii) drug utilisation studies, (iii) providing information on drug use patterns, prescriptions patterns or drug consumption and (iv) written in the English language. We applied a date limit so that only recent articles published from the year 2000 or later, i.e. 2000 - 2016 were taken into account. Articles were excluded if they only focussed on evaluating the use of a single class of medications i.e. antibiotics. All full text articles were retrieved. Manual bibliographic searches

were also performed to identify additional articles that were not found in the electronic searches. (Figure 1)

3.1 SCREENING PROCESS FOR INCLUSION

Articles were initially screened for inclusion in the review based on title, then abstract and full text article as necessary.

a. A-PINCH CRITERIA

The review sought to compare the most commonly used medications in the NICU using the A-PINCH high-risk medicines list. Compiled by the Australian Clinical Excellence Commission, the list identifies types of medications that are universally considered to be high-risk and are represented by the acronym A-PINCH.(21) (Table 1) These medications are not necessarily those that have higher error rates or adverse events than other medications, however if misused can have the most severe consequences.(22, 23)

4. RESULTS

General Analysis

Overall, there is limited published literature comprehensively exploring current medication use in NICUs. A total of 19 articles met the inclusion criteria, the majority dated within the last 10 years, 2006 - 2016 (n = 17, 89%).(24-42) The patients enrolled in studies were mostly preterm babies (< 37 weeks) making up 40 – 85% of NICU patient groups, with term babies making up 24.6 – 51% of NICU admissions.(24, 25, 27-30, 33, 35-40) Male newborns comprised 43 – 62.5% of patient samples.(25, 27, 28, 30, 31, 33, 36, 40, 42) The mean gestational ages of patient groups ranged from 31 – 35 weeks, and the median birth weights ranged from 1560 – 2615g.(26, 27, 31-33, 36-39, 42) The mean duration of stay for the studied patients ranged from 15 – 21.1 days.(27, 28, 33, 36, 42)

The most common documented reason for patient admission into the NICU were respiratory distress followed by sepsis/infection, prematurity, neonatal jaundice, congenital malformations, birth asphyxia and seizures.(24, 25, 27, 28, 30, 32, 35, 38, 40)

Geographical distribution

Studies were conducted in 12 countries: USA (n = 4), Italy (n = 3), India (n = 2), Brazil (n = 2), UK, Australia, Estonia, Germany, Israel, Turkey, Ireland and France.

Methodology and Study Design

The majority of studies (n = 13, 68%) used a prospective study design, with the remaining six (32%) utilising a retrospective data extraction. The sample sizes in the studies ranged from 34 to 450,386 patients. This large variation in patient enrolment was attributed mainly to the duration of studies, which ranged from two weeks to nine years. Furthermore, some studies canvassed data from large databases, whilst others focussed their observations on one NICU. For example, two US based studies by Clark et.al. and Hsieh et.al. used retrospective reviews as the method for gathering data for nine year and five year periods of time, respectively.(26, 31) This resulted in large sample sizes and large numbers of prescribed medicines. (Table 2)

The majority of studies (n = 12, 63%) investigated all medicines prescribed and used in the NICU.(24-29, 31, 32, 34, 36, 40, 41) However, the inclusion criteria of seven studies excluded the evaluation of certain products including: standard intravenous (IV) fluids (including electrolytes), oxygen, parenteral nutrition, blood and blood products, vaccinations, vitamin K, prophylactic ophthalmic ointment, phototherapy, expressed breast milk, milk formula, nutritional supplements and drugs used in clinical trials.(30, 33, 35, 37-39, 42)

The criteria for enrolling patients into studies were relatively uniform, and based simply on infant admission into the NICU.

Drug Use Profile

Types of medicines used

Overall, antibiotics (particularly aminoglycosides) including gentamicin as well as ampicillin were identified as the most frequently prescribed medicines in NICUs. This was followed by caffeine, furosemide, multivitamins and vitamin K. Figure 2 presents the 20 most commonly used medications in NICUs and highlights which of these medications are classified in the A-

PINCH list. Nine of the 20 most commonly used medicines were listed as A-PINCH medicines, and included antibiotics, fentanyl, morphine and heparin. (Figure 2) Medications used between countries were very similar with no discernible differences in types of medicines prescribed.

The total number of different types of medications prescribed for the treatment of patients admitted to the NICU ranged from 23 – 409.(26-32, 34-39, 41) This large variation in different pharmacotherapeutic agents can again be attributed to the duration of studies, as some studies collected data over a period of several years which would potentially see the introduction of new active substances, drug formulations and regimens as well as the ceasing of older, less effective medicines.

Number of medicines used

The median number of medicines used per patient ranged from 3 – 11, with one German study by Neubert et.al. observing that two patients received as many as 40 medicines during their admission to the NICU.(27, 29, 32, 34-39) The prospective cohort study evaluating 183 patients by Neubert et.al. also reported that the high average medicine use per patient seen in their study was attributed to the fact that their NICU was a very specialised unit which experienced a higher intake of very premature babies in comparison to other NICUs, leading to increased number of medicines per patient.(36) Overall, the most common route of administration was the IV route, (47 – 92.1% of products used), followed by the oral route (22 – 23.1%), topical (7.5 – 9%), intramuscular (IM) and endotracheal tube.(25, 28, 32, 33)

Patterns of use

In terms of patterns of use, three factors appear to impact on medication use. The first factor as identified in seven studies, is the inverse relationship between gestational age and the number of medications that were prescribed.(25, 27, 28, 33, 36, 38, 42) In an Indian based prospective study Chatterjee et.al. found that the average number of medicines prescribed in the NICU was 8.1 for preterm babies compared to 4.3 for term babies.(25) This is also supported by the Brazilian study, which reported a significant difference ($p < 0.001$) between average medication use in preterm and term neonates.(28) During their 6 month prospective

observational study, de Souza Goncalves et.al. also reported a second relationship between average use of medicines and patient weight. The average number of medicines prescribed to very low birth weight (VLBW) babies (< 1000g) was approximately 3 times greater than the number prescribed to babies with birth weights of 2500g or more.(28) Third, de Souza et.al. found that the mortality rate was inversely proportional to the gestational age of infants in the NICU ($p > 0.05$).(27)

Considerations relating to medication use in the NICU

Off-label/Unlicensed Use

It was widely reported that a significant proportion of medicines have not been approved for use in neonates, and as such there is little to no information available relating to the efficacy and safety of these medicines in infants.(24, 27-39) The lack of information is reported as a major issue by one Brazilian study, identifying that only 20.5% of all medicines used had product information describing use of the medicine in neonates, and only 9.5% of medicines had available information for use in preterm babies.(28) Similarly, the German study by Neubert et.al. highlighted that 62% of all medicines used in their NICU had no information provided about their use in newborns.(36) Chatterjee et.al. reported that information in an Indian NICU was obtained from clinicians' standard neonatology textbooks as well as through online resources.(25)

Despite the lack of information, 22.7 – 63% and 5.7 – 28.8% of all medicines used in NICUs were classified as off-label and unlicensed medicines, respectively.(24, 25, 27, 29, 30, 32, 34, 36, 38, 39) Overall, it was reported that 71 – 100% of infants would receive at least one off-label or unlicensed medicine whilst admitted to a NICU.(24, 27, 32, 34-38) Premature infants were more likely to be administered an off-label or unlicensed therapy in comparison to term babies.(27, 30, 34-36, 38) An Estonian study found that 100% of preterm babies admitted to their NICU received an unlicensed or off-label medicine.(35) This finding is supported by the Irish and German studies who both stated that 100% of preterm infants (<28 weeks gestation) would be administered at least one unlicensed or off-label medicine.(32, 36) Non-approved dosage, frequency of dosing, age, indication, treatment duration and route of administration as well as extemporaneous preparation of novel formulations by hospital pharmacy were identified as the main reasons for the use of medicines in alternative ways to those approved

in the product information, rendering medicines off-label or unlicensed.(24, 27-39) Each of these reasons may have implications on the safety of neonates, with the potential for toxicity, adverse effects and ineffective treatment.(29)

The most commonly administered off-label medicines were reported as benzylpenicillin, furosemide, ranitidine, fentanyl, theophylline and gentamicin.(24, 27-30, 32-38) The most commonly used unlicensed medicines included folic acid, hydrocortisone, caffeine and parenteral nutrition, and were classified as unlicensed because they were specifically compounded by the hospital pharmacy.(24, 27-30, 32-38) (Table 3) An Italian study stated that caffeine is a well-known, effective and safe therapy frequently used for the treatment apnoea in prematurity, however it is not licensed for use in babies.(30) It must be noted that the aforementioned medicines are not classed as off-label/unlicensed in all instances of their use. This classification only applies to their use in certain indications, formulations, countries or as deemed by the definition of off-label/unlicensed in each respective study.

Irrational prescribing

In a study conducted in an Italian NICU, Dell'Aera et.al. drew attention to the prescribing of a number of medicines that were deemed inappropriate for neonatal patients, including: sulfadiazine (contraindicated in premature neonates due to the risk of inducing neonatal jaundice), meropenem (insufficient data on efficacy and tolerance in babies and not recommended in patients < 3 months of age), itraconazole (insufficient data to allow use in paediatric patients), flunisolide (contraindicated in children < 4 years of age), phenobarbital and prednisolone-neomycin (incorrectly administered – IV instead of IM, and intra-nasally instead of intra-ocularly).(29) In an Israeli NICU, Barr et.al. identified that out of a total of 525 prescriptions, 199 were given at a dosage that was unusually high and this included ampicillin, theophylline, amoxycillin, gentamicin, vancomycin and imipenem.(24) A further 25 courses were given in too low dosages and included gentamicin and cisapride.(24) Lass et.al. reported that five products contraindicated for use neonates were prescribed in an Estonian NICU and included: diclofenac, drotaverine, metoclopramide, heparin sodium ointment and ursodeoxycholic acid tablets.(35)

5. DISCUSSION AND WHAT IS NEW

This review provides an insight into medicines use in NICUs worldwide. To our knowledge, this is the only review to explore DUE studies on a global scale. Overall, it appears that the types of medicines used in NICUs worldwide are similar, with high usage of aminoglycosides, penicillins, other antibiotics, caffeine and multivitamins. This is unsurprising as the majority of studies included in the review were from developed countries, and commonly treated the same patient pathologies, including sepsis, complications associated with prematurity and neonatal jaundice. However, there is variability in the average number of medicines used per patient, ranging from 3 – 11. This has been attributed to the specific characteristics of individual NICUs which may experience higher intakes of premature or very low birth weight patients that require longer hospitalisations and more medicines, affecting the overall mean. However, it cannot be definitively stated that the findings of the review accurately depict current practice in NICUs, due to the general lack of literature available. The 19 articles included in the review do not give a thorough account of global usage of medicines in NICUs.

There is a great need, from a pharmacy-based perspective, to promote the rational use of medicines to achieve positive and safe patient outcomes. The data from the drug use evaluation studies has highlighted several areas that should become the focus of neonatologists, pharmacologists and clinical pharmacists to improve efficacy and safety of medicines usage in NICUs:

- **High use of antibiotics:** The review drew attention to the high usage of antibiotics in NICUs. As severe infections are a main cause of neonatal mortality, accounting for more than one million neonatal deaths annually worldwide, the appropriate choice of antibiotic agents is essential to prevent serious consequences.(12) Antimicrobial stewardship programs should be established in NICUs to improve antimicrobial use, promote positive patient results and decrease antimicrobial resistance, adverse effects and excess costs.(43) The Priority Medicines for Europe and the World report by WHO highlighted the need to develop diagnostic tools tailored specifically for neonatal conditions to avoid the inappropriate use of antibiotics in the NICU.(44) Patel et.al. suggested several 'Get Smart' principles to optimise the safe use of antibiotics in the NICU. These included: accurately identifying patients who need antibiotic therapy, using local and regional antibiograms, avoiding prescribing therapies with overlapping activity, giving the right dose and interval of antibiotics, reviewing culture results,

monitoring for toxicity and stopping therapy promptly if indicated by culture results.(45)

- **Irrational Prescribing:** Incorrect choices of medicines, doses, routes of administration and dosing frequencies can be detrimental to neonatal outcomes.(46) Caffeine, for example, is commonly used in the NICU for the treatment of apnoea of prematurity and is well-known for being the safest option available.(47) However, there is still a high incidence of theophylline use, which is associated with higher rates of toxicity.(30, 47) Targeted guidelines are needed to ensure that the most appropriate medicines are being prescribed.
- **Polypharmacy:** Premature infants/very low birth weight babies receive larger numbers of prescribed medicines per patient in comparison to term babies.(25, 28) Consequently, there is an increased risk of duplicate therapies as well as drug interactions and adverse drug reactions.(48) There is a need for regular pharmacist interventions involving medication chart reviews and participation in multi-disciplinary ward rounds which may have an impact on decreasing the incidence duplicated therapies.
- **Use of narrow therapeutic index medicines:** All medicines need to be monitored to ensure that the doses administered are within their therapeutic range.(49) However, for medicines with a narrow therapeutic index, toxic concentrations can be reached quickly leading to adverse effects.(50) The review has highlighted that aminoglycosides and theophylline are commonly used in NICUs. Measures are needed to ensure proper therapeutic drug monitoring and accurate dosing to prevent the misuse of these medicines.
- **High use of A-PINCH medicines:** These medicines are those that have an increased risk of causing harm if they are misused or used in error. Neonates possess characteristics of vulnerability in relation to their pharmacologic capabilities, and given that 9 of the 20 most commonly used medicines found in the results are classified as high-risk medicines, there is a need to be highly vigilant to ensure the safety of neonates. In particular, appropriate guidelines or safety measures should be implemented when these medicines are prescribed to ensure appropriate and safe dosing for patients and the prevention of medication misuse.
- **High use of off-label/unlicensed medicines**: The review shows that the use of these types of medicines is common in NICUs worldwide because of a lack of information and availability of formulations. As such, there is a need to license medicines and for

more clinical trials to be performed to provide reliable information to guide the use of medicines in neonates.(35, 39) However, in the interim, there is a need for a registry or practical guidelines on how to use these therapies based on the best available evidence and experience of health professionals.

- **Origin of dosing recommendations:** When considering the large range in the types of medicines prescribed (23 – 409) in the review, there is concern about the heterogeneity of drug recommendations within, and between, NICUs. A study by Leroux et.al. investigated antibiotic regimens in 45 NICUs in France and found approximately 9 different dosing protocols per drug.(51) This leads to considerable variability in the treatment of neonates, with differences in daily doses and dosing intervals potentially having a significant impact on patient outcomes. As such there is a need for robust evidence base to define pharmacokinetics, pharmacodynamics, safety and efficacy of pharmacotherapy in neonates in order to develop targeted guidelines.(52)
- **Modalities of drug prescription:** Differences in prescribing methods i.e. hand written versus computerised physician order entry (CPOE) and clinical decision support (CDS) systems, may have an impact on rational drug use as well as medication error rates by addressing the accuracy of drug selection and dosing.(53) Kaushal et.al. found that most medication errors in paediatric and neonatal patients occurred at the point of prescribing, and identified that CPOE could have prevented 93% of those events occurring.(54) These decision support tools should be thoroughly considered in NICUs to promote uniform prescribing, decrease medication errors and improve the efficiency of resources.(55)

Whilst the use of medicines in neonates can have positive therapeutic effects on patients, when considering the aforementioned high-risk areas of medication use in the NICU, medication errors have a high risk of occurring in this patient population.(8, 56-58) The most commonly occurring medication errors comprise 10 to 100 fold dosing errors, patient misidentification, drug interactions, incorrect routes of administration and erroneous product dilutions.(56-58) Therefore, the inappropriate use of medicines can have a significant impact upon reducing the potential effectiveness of pharmacotherapy, causing negative effects for patients and producing costly economic outcomes. As such, there is great potential, particularly from the perspective of a clinical pharmacist, to improve medication management in the NICU, and the quality use of medicines should be made a priority to ensure the safety of this high risk population.

LIMITATIONS

Comparisons between countries were difficult due to differences in study methodologies. These included differences in the types and classes of medicines that were included for evaluation as well as differences in the definition of off-label and unlicensed medicines. For example, some studies classified medicines as off-label as those that were used in a manner different to that specified in the summary of product characteristics (SPC's), whereas other studies used a broader description and defined off-label as medicines used in a manner different to that described in books, formularies, package inserts as well as manufacturer information.

6. CONCLUSION

Overall, it is apparent that the types of medicines used in NICUs worldwide are consistent, with the most commonly prescribed medicines including antibiotics, diuretics, caffeine and multivitamins. A-PINCH medicines made up nine of the 20 most commonly used medicines in NICUs and included fentanyl, morphine and heparin. The data available was collected from 12 countries and gave a good representation of drug use in NICUs, however 19 studies is not a substantial amount of data. Therefore, it cannot be definitively stated that the findings of the review accurately depict current practice in NICUs, due to the limited amount of published literature available. There are several areas of concern that warrant further investigation to improve rational use of medicines in the neonatal populations, including high-use of antibiotics and off-label and unlicensed medicines.

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Table 1: A-PINCH Medicines List (21)

HIGH-RISK MEDICINE GROUPS	EXAMPLES OF MEDICINES
A: Anti-infective	Amphotericin Aminoglycosides
P: Potassium and other electrolytes	Injections of potassium, magnesium, calcium, hypertonic sodium chloride
I: Insulin	All insulins
N: Narcotics (opioids) and other sedatives	Hydromorphone, oxycodone, morphine Fentanyl, alfentanil, remifentanil and analgesic patches Benzodiazepines, for example, diazepam, midazolam Thiopentone, propofol and other short term anaesthetics
C: Chemotherapeutic agents	Vincristine Methotrexate Etoposide Azathioprine
H: Heparin and anticoagulants	Warfarin Enoxaparin Rivaroxaban, dabigatran, apixaban

Adapted from the Clinical Excellence Commission website: High Risk Medicines. Clinical Excellence Commission. 2016. http://www.cec.health.nsw.gov.au/programs/high-risk-medicines/high-risk-medicines#eosm. Accessed 04/03/2016.

Table 2: Overview of the studies included in the review

Authors		Year	Country	Study Period	Number of Patients	Study Design
1	Barr J, et.al. (24)	2002	Israel	4 months	105	Prospective study
2	Chatterjee S, et.al. (25)	2007	India	6 months	176	Prospective study
3	Clark RH, et.al. (26)	2006	USA	9 years	253651	Retrospective review
4	De Souza AS, et.al.	2016	Brazil	6 months	192	Retrospective cohort study
5	de Souza Goncalves AC, et.al. (28)	2015	Brazil	6 months	187	Prospective observational study
6	Dell'Aera M, et.al. (29)	2007	Italy	2 months	34	Cross-sectional, prospective study
7	Dessi A, et.al. (30)	2010	Italy	1 month	38	Prospective study
8	Hsieh EM, et.al. (31)	2014	USA	5 years	450,386	Retrospective review
9	Kieran EA, et.al. (32)	2014	Ireland	2 months	110	Prospective observational study
10	Kumar P, et.al. (33)	2007	USA	3 years	2304	Retrospective review
11	Laforgia N, et.al. (34)	2014	Italy	1 month	126	Prospective observational study
12	Lass J, et.al. (35)	2011	Estonia	1 year	490	Prospective cohort study

13	Neubert A, et.al. (36)	2009	Germany	11 months	183	Prospective cohort study
14	Nguyen KA, et.al. (37)	2010	France	4 months	65	Prospective cross-sectional study
15	O'Donnell CP, et.al. (38)	2002	Australia	10 weeks	97	Prospective observational study
16	Oguz SS, et.al. (39)	2012	Turkey	24 hour period	464	Prospective observational study
17	Sharanappa M, et.al. (40)	2014	India	6 months	100	Retrospective review of case records
18	Turner MA, et.al. (41)	2009	UK	2 weeks	49 units	Prospective survey
19	Warrier I, et.al. (42)	2006	USA	7 years	6839	Retrospective data analysis

Table 3: Overview of medication use in each country[1]

Country	Number of Drugs Used Per Patient	Most Commonly Used	How many patients will receive off-label med	Most common off-label/unlicensed meds
Australia	Median: 7	Gentamicin, Morphine, Vancomycin	80% of NICU patients and 93% of babies weighing <1000g received either an off-label or unlicensed medicine or both	Morphine (o), Theophylline (o), Aminophylline (o) sodium chloride (u), Dobutamine (o), paracetamol (o)
Brazil	Mean: 6.4 Median: 11	Fentanyl, Multivitamins, Gentamicin	99.5% of neonates will be exposed to an off-label medicine. Infants with gestational ages < 28 weeks have a higher exposure to unlicensed or off-label prescriptions	Heparin (o), Fentanyl (o), Multi-vitamins (o), injectable Alprostadil (u), Folic acid (u), Hydrocortisone (u)
Estonia	Median: 4	Gentamicin, Heparin, Simeticone	All preterm babies and 97% of term babies will receive at least one off-label or unlicensed medicine.	Furosemide IV (u), Ampicillin (o), Simeticone (O), Salbutamol (o)

[1] O = Off-label Medicine
U = Unlicensed Medicine

France	Median: 4	Vitamin ADEC, Vitamin K, Calcium folinate	71% of babies will receive at least one off-label or unlicensed medicine	Calcium folinate (folic acid) u, Ferrous fumarate (o), Sodium chloride 10%, Benzylpenicillin (o), Amikacin (o),
Germany	Mean: 11.1	Vitamin K, Piperacillin, Tobramycin	70% of patients will receive at least one off-label or unlicensed medicine. 100% of preterm infants received at least one off-label or unlicensed medicine	100% of anaesthetics and analgesics had no info for use in neonates/preterm
India	Mean: 4.8	Ceftriaxone, Amikacin, phenobarbitone, Cefotaxime		
Ireland	Median: 4	Chlorhexidine, IM vitamin K, Gentamicin	91% and 94% of infants <32 weeks received an unlicensed and off-label medicine respectively, 100% of infants <28 weeks will receive an unlicensed and off-label medicine	Caffeine (U), benzyl penicillin (o), gentamicin (o)

Israel	N/A Between 1 - 13	Gentamicin, Ampicillin, Theophylline	93% of babies received at least one off-label or unlicensed medicine	Theophylline (u), cisapride (o)
Italy	Median: 3 – 5.5 Mean: 1.7	Amikacin, Ampicillin-Sulbactam, Parenteral nutrition infusions, Multivitamins, Aminophylline, caffeine, Gentamicin,	Preterm neonates received more unlicensed medicines compared to term newborns (14.5% vs 4.5%)	Parenteral nutrition infusions, amikacin, ranitidine, tobramycin, ofloxacin, caffeine, calcium levofolinate, sodium ferric gluconate complex Caffeine (u), furosemide (o), parenteral nutrition (u), phenobarbital (o), theophylline (o), ranitidine (o) caffeine (u), magnesium sulphate (u), ferrous sulphate (u), gentamicin (o), amoxicillin (o), miconazole (o), salbutamol (o),

Turkey	Median: 3	Ampicillin, Multi-vitamins, Amikacin		
UK	Median: 3.5	Gentamicin, Benzylpenicillin, Folic acid, vitamin K	90% of NICU patients received at least one off-label or unlicensed medicine	Benzylpenicillin (o), folic acid (o), caffeine (u), TPN (u - made in pharmacy), dalivit (o), vitamin k (o), Flucloxacillin (o) Caffeine (U), benzyl penicillin (o), gentamicin (o)
USA	Mean: 3.7 - 4	Ampicillin, Cefotaxime, Survanta, Gentamicin, caffeine citrate, supplemental sodium chloride, potassium chloride, Ferrous sulphate, heparin,		o - fentanyl, erythropoietin, dopamine, midazolam, hydrocortisone, dexamethasone, lorazepam, papaverine, ranitidine, milrinone Only 35% of meds are approved by FDA for use in NICU

Figure 1: Search Strategy

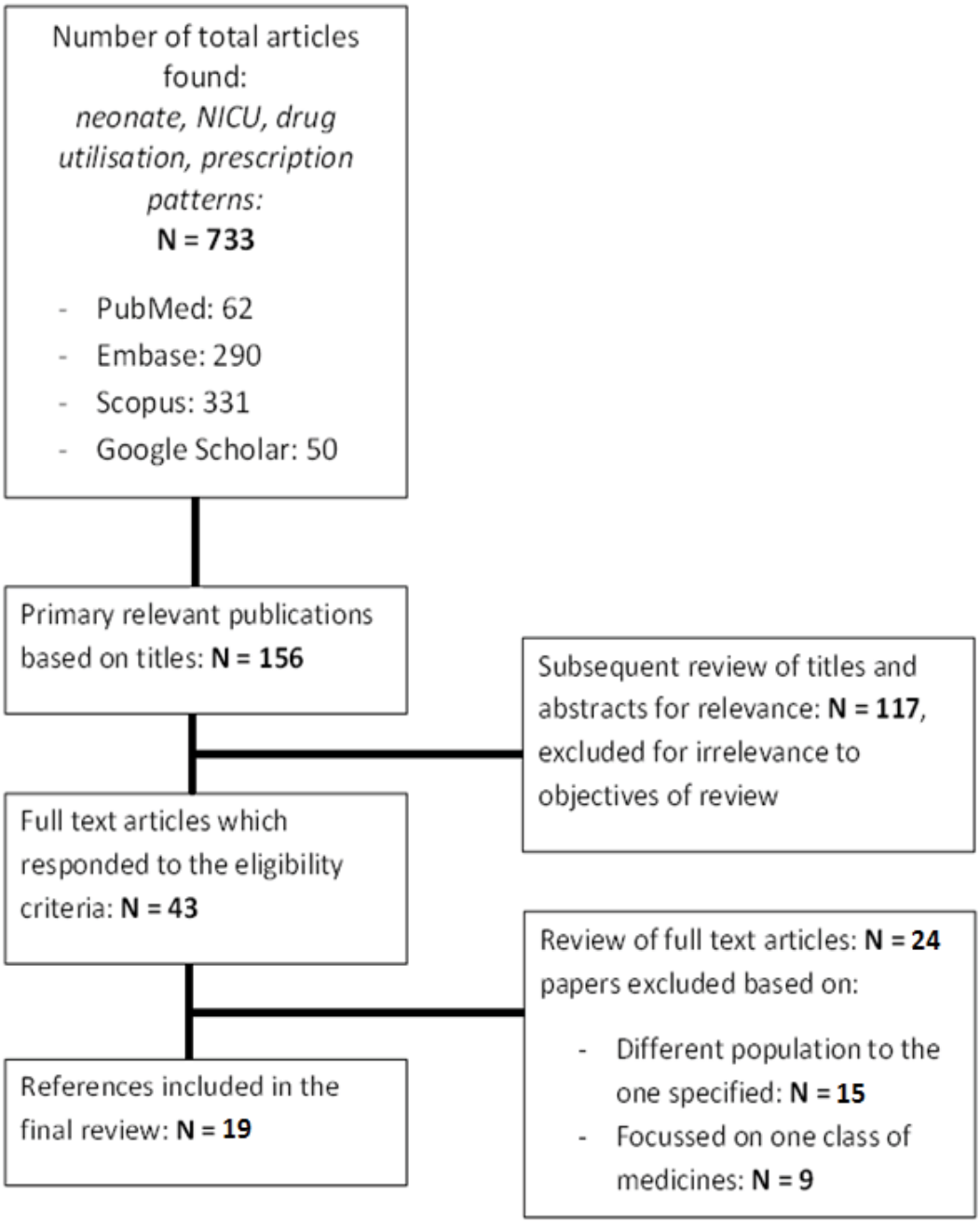
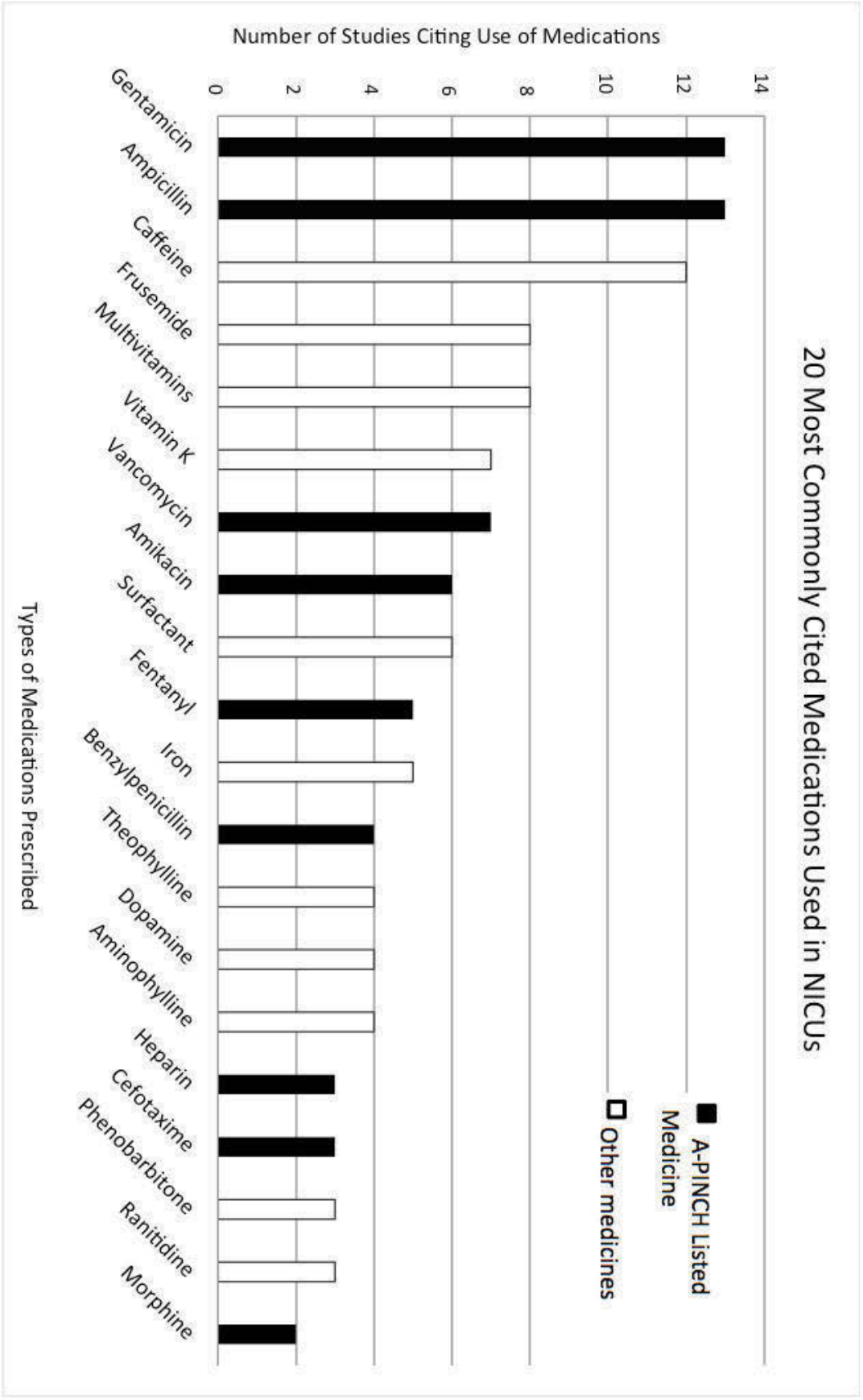


Figure 2: Most commonly cited medicines used in NICUs worldwide



CHAPTER THREE

FOCUS ON SYSTEMS AND PROCESSES

3.1 INTRODUCTION

This chapter presents an overview of pharmacy services delivered to NICU settings in Australia and Poland. First, we present a literature review published in the International Journal of Pharmacy Practice exploring pharmacist roles in the NICU on a global scale. The next two articles are foundation papers that form the baseline part of this thesis. The first paper aims at understanding what pharmacist roles are provided to neonatal patients admitted to NICUs in Australia and Poland. The second article investigates pharmacist attitudes towards the level of service and pharmacist expectations of pharmacy services in this setting.

3.2 A GLOBAL PERSPECTIVE OF THE ROLES OF THE PHARMACIST IN THE NICU

Krzyżaniak N, Bajorek B.

THE INTERNATIONAL JOURNAL OF PHARMACY PRACTICE

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A global perspective of the roles of the pharmacist in the NICU

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AUTHORS' CONTRIBUTIONS

Natalia Krzyżaniak conducted the search, reviewed the literature and wrote the manuscript. Beata V Bajorek assisted in conceiving the review in terms of structure and scope, as well as critically revising and editing the manuscript prior to submission.

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ABSTRACT

Objectives: To describe pharmacist practice and roles performed in the neonatal intensive care unit (NICU) worldwide and to map these findings along the medicines management pathway (MMP).

Method: Quasi-systematic review

Search Strategy: Google Scholar, Medline/PubMed and Embase were searched utilising the selected MeSH terms.

Results: Thirty sources of information were reviewed. Overall, pharmacist practice in the NICU involves a wide-range of roles, with the most commonly reported involving patient medication chart review, therapeutic drug monitoring and the provision of medication information. Studies highlight that pharmacist contribution to total parenteral nutrition (TPN) regimens and patient medication chart review is beneficial for patient outcomes. Roles beyond the regular scope of practice included involvement in immunisation programs and research. Most of the data were collected from the USA (13 of 30), followed by the UK (6 of 30) and reports from other countries. The American, British, South African and Australian articles have reported very similar roles, with a pharmacist firmly integrated into the overall structure of the NICU team.

Conclusion: The literature identifies that there is insufficient evidence to describe what roles are currently performed in NICUs worldwide. This is due to the lack of recently published articles leading to a large gap in knowledge in understanding what contemporary pharmaceutical services in the NICU comprise. Further research is required to address these gaps in knowledge, and identify the impact of the pharmacist's role on neonatal patient outcomes as well as to determine how to better resource NICUs to access pharmacy services.

1. INTRODUCTION

The World Health Organisation (WHO) recognises pharmacists as essential resources for the safe and effective use of medicines.[1] With the outcomes of pharmacist interventions including improved patient quality of life, as well as reduced medication errors and adverse drug events, there are clear benefits to providing clinical pharmacy services to hospitalised patients.[2-6] Current studies describe pharmacist roles within a range of adult settings, including participation in ward rounds, medication reconciliation upon admission and therapeutic drug monitoring (TDM).[4-6, 3] However, there is minimal corresponding literature reporting on pharmacist roles within the neonatal intensive care unit (NICU).

As the NICU population possesses characteristics of vulnerability, which predispose them to a high-risk of medication misadventure, the use of medication in these patients poses significant challenges for the treating team. Current studies showcase pharmacist interventions as having a significant impact on decreasing medication errors in the NICU, however they fail to describe roles beyond those performed as experimental interventions.[7, 8] The roles and practices of pharmacists vary from country to country, and as such it is prudent to explore these differences to determine whether there are any inequalities in medication management in the NICU and where pharmacists focus their practice. Therefore, the purpose of this review is to provide an overview of pharmacist practice in the NICU and identify, describe and compare pharmacist roles as reported globally in published and grey literature. A specific objective of the review is to map the findings along the medicines management pathway (MMP).[9]

2. METHOD

A quasi-systematic review (a review that possesses some elements of a systematic review, including pre-defined selection criteria, however includes grey literature and does not present a critical evaluation of the quality of studies) extracted relevant publications relating to roles, interventions, activities and functions performed by pharmacists in the NICU.[10-12] A robust systematic review could not be performed due to the nature of the literature collected, with the majority consisting of grey literature, review articles and reports and a distinct lack of published studies. The amount and type of literature collected influenced the format of the review, precluding the full application of PRISMA guidelines, and leading to the adoption of a quasi-systematic review.

Literature was retrieved by searching the following electronic databases: Embase, PubMed and Google Scholar. All sources of information including relevant studies, review papers and other publications were canvassed. It is acknowledged that particularly where practice is well established, it is not necessarily based on well-designed clinical trials. Therefore, a broader perspective was obtained by performing a supplemental Google search using the same search terms to identify relevant grey literature.

2.1 SEARCH STRATEGY

A two-tiered search strategy was used. (Figure 1) In Tier 1, a search was performed utilising the following MeSH headings/keywords: *pharmacist interventions*, *clinical pharmacist*, *neonatal intensive care*, *neonate/infant/newborn*, *pre-term*, *protocols*, *pharmacist role/activities*, *pharmacist responsibilities*, and *pharmacist impact*. The Boolean operator 'AND' was employed to combine the search terms. Manual bibliographic searches of all relevant articles were also performed in order to identify any articles that were not identified in the electronic searches. In Tier 2 of the search, relevant grey literature was identified through a Google search using the same MeSH terms. This tier was dedicated to finding service standards, position descriptions as well as descriptive reports.

2.2 STUDY SELECTION

The selection criteria for the searches restricted the content to the following: (i) review articles (including literature reviews and opinion pieces), research articles, or grey literature (ii) with results containing information on pharmacist led activities relating to neonatal patients in the NICU setting and (iii) written in the English language. All full text articles meeting this criteria were retrieved and all evaluations pertaining to the types of pharmacist roles in the NICU were included in the review. Due to the minimal amount of literature available reporting on pharmacist roles in the NICU, no date limits were applied, enabling the collection of data from a broader range of resources.

2.3 THE MEDICINES MANAGEMENT PATHWAY

The pharmacist roles identified in the review were mapped out against the medicines management pathway (MMP). The MMP is a process map that describes the full range of cognitive and physical steps involved in the utilisation of pharmacotherapy in any patient group with the aim of improving the quality use of medicines and identifying any potential safety system improvements.[9] Published by the Society of Hospital Pharmacists Australia (SHPA) the MMP is cyclical in nature and highlights that each element relates to another. (Figure 2)[9]

2.4 DATA EXTRACTION AND ANALYSIS

The data extraction and mapping of the roles against the MMP was performed by Author 1 and verified by Author 2. A standard data extraction form was used to describe the studies and the pharmacist roles performed in NICUs worldwide. The articles retrieved from each tier of searching were pooled for analysis, in-line with the study objectives. The extracted information consisted of a description of the roles performed by pharmacists, the frequency at which they were performed, and the country from which the study originated.

3. RESULTS

A total of thirty sources of information were included in the review.[13-42] This literature was collected from a range of countries, predominantly from the USA (13 of 30) and UK (6 of 30) with reports from Australia, South Africa and Ireland. The types of articles collected consisted of qualitative (5) and quantitative studies (4) (total 9 of 30), review articles (6 of 30) and reports (4 of 30) as well as grey literature including a descriptive article (1 of 30) position descriptions (8 of 30) and neonatal service standards (2 of 30). It was noted that there were no articles that utilised randomised control trials or cohort study designs. Table 1 provides an overview of the articles used in the review.

Overall, there is limited published literature comprehensively exploring the current roles of pharmacists in NICUs. Most of the published literature collected was approximately 10 years old or older, with seven articles published before the year 2000, and three published prior to 2006.[14, 16,

[19-22, 24, 30, 32, 33] As such, grey literature including service standards, guidelines and position statements were used to describe a more contemporary practice where other literature was dated or absent. Due to the lack of available literature, several articles were utilised that were primarily paediatric based, but included a sub-section of neonatal patients within their evaluation.[16, 21, 23, 28, 30] Overall, out of the total proportion of articles included in the review, 24 were specifically related to pharmacists working within NICUs and neonatal care, with the remaining 6 referring to pharmacists working in paediatric settings, including PICUs, children's hospitals and a women's hospital that involved elements that also addressed neonatal patients.

Each of the roles identified were matched to the steps of the MMP; no specific pharmacist roles were identified that could be mapped against the following steps: record of medication order, administration of medication and transfer of verified information.

THE ROLES OF THE NICU PHARMACIST MAPPED AGAINST THE STEPS OF THE MEDICINES MANAGEMENT PATHWAY (MMP)

1.1 DECISION TO TREAT AND PRESCRIBE

The NICU pharmacist has been recognised as an important contributor to the prescribing process. Within relatively older literature, it was reported that pharmacists routinely assisted in the appropriate selection of medications, suggested dose changes, routes of administration, and advised on potential side-effects.[18, 20, 24, 33] Pharmacists most commonly contributed to the prescribing process by participating in medical ward rounds.[18, 20, 24, 33] Ward rounds in the NICU provided an opportunity for pharmacists to engage in bedside pharmacotherapeutic consultations and improve inter-professional communication.[18, 24, 33] These findings are also reflected in the British Association of Perinatal Medicine (BAPM) service standards and in the position descriptions, which detail that NICU pharmacists are required to attend multidisciplinary ward rounds on a daily or weekly basis, as well as provide input at relevant clinical meetings.[34, 37, 38, 40, 42, 13] The Australian position description states that NICU pharmacists are expected to be active members of the multidisciplinary NICU team to optimise patient care, and it has been reported that during ward rounds medical staff rely on the pharmacist to provide accurate medication information and to transmit new research relating to pharmacotherapy in the neonate.[33, 35]

NICU pharmacist involvement was acknowledged in the prescribing of nutritional supplements for neonates.[18, 20, 22, 29, 33, 19, 26] In particular, Ahmed stated that NICU pharmacist input was significant during the prescribing and manufacture of parenteral nutrition for infants.[42] Pharmacists were reported as being commonly involved in the calculation of the daily calorie and protein requirements, preparing total parenteral nutrition (TPN) protocols, prescribing TPN regimens, reviewing TPN orders as well as identifying and resolving errors in nutrition orders.[29, 20, 38] A UK study identified that 47% of NICU pharmacists surveyed were prescribers and mainly ordered parenteral nutrition and supplements (75%).[26] Mulholland added that pharmacist prescribing of TPN promoted patient safety, reduced communication errors and reduced pharmacy costs.[29, 26] An older prospective interventional study performed by Dice et.al. (1981) in a NICU that involved 28 patients, reported that pharmacist monitoring of individualised TPN regimens had significantly increased the mean weight gain and protein intake of infants ($p = < 0.02$), compared to those neonates on standardised TPN formulations with no pharmacist monitoring.[19] Pharmacist monitoring involved calculating the neonate's required fluid and calories, recording changes in weight, documenting laboratory results and recommending changes to TPN solution.[19] Furthermore, pharmacist monitored TPN programs led to greater amounts of nutrients being provided to neonates, fewer medication errors and lower overall pharmacy costs.[19, 29] Prescribing pharmacists in British NICUs felt they were more integrated into the multidisciplinary treating team in the NICU after becoming a non-medical prescriber.[26]

1.2 REVIEW OF ORDER

The majority of the literature reported that NICU pharmacists were involved in the review of patient medication charts.[14, 15, 17, 20, 21, 27, 30, 32-38, 40, 39, 41, 23] As a service uniquely performed by pharmacists, the medication chart review process within the NICU was described in older literature as being a 'standard' practice for the advancement of medication safety.[19, 29] The characteristics of the role involved the evaluation of medication charts for medication appropriateness, correct dosages according to the weight of the neonate, drug-drug/drug-laboratory value/drug-nutrient interactions, allergies, medication duplication, timing of administration (particularly with concurrent IV fluids or supplements), route of administration, adherence to clinical protocols and procedures, as well as the review of relevant patient progress notes, diagnostic tests and laboratory values.[14, 15, 17, 20, 21, 30, 32, 33, 37, 38, 40, 39, 41, 23] In reviewing the patient's medication chart, NICU pharmacists also performed interventions to

rectify medication safety issues which included correcting doses and modifying the route of administration.[16, 19, 21, 24, 28, 31, 40, 41, 37] The benefits of a pharmacist-led chart review were reported in one prospective study conducted in 2004 by Simpson et.al. who found that the implementation of daily pharmacist review in NICU led to a significant reduction in the incidence of medication errors ($p = <0.001$).[32]

Several position descriptions require NICU pharmacists to perform patient medication reviews on at least a daily basis, with the BAPM recommending that pharmacists dedicate at minimum 10 – 20 minutes of time per patient.[36-38, 40, 39, 41, 13] Observational research conducted in a South African NICU, found that 73% of pharmacist time was spent on patient review.[31] In contrast, a study performed by Prot-Labarthe et.al. in four French-speaking countries determined that only 10 – 15% of clinical pharmacist time was spent on clinical activities.[28] This study was conducted in paediatric intensive care units (PICUs), however as it also included neonatal patients (ages ranging from 0 – 6 days) within their study population, it was deemed relevant to this review. It is unknown what proportion of pharmacists' time in providing pharmaceutical services was spent on neonates in comparison to generalised paediatric patients.

1.3 MEDICATION PREPARATION

The extemporaneous compounding service was acknowledged in older articles as being a traditional pharmacist role often undertaken in the care of NICU patients.[14, 20, 33] Pharmacotherapy in neonates often requires the preparation of dosage forms that are not commercially available and the Australian position description requires NICU pharmacists to be able to accurately perform duties in non-sterile and aseptic manufacturing when required.[14, 34] The role was described within two older studies based in the USA (1985) and Australia (1991) respectively, as involving the routine compounding of novel medication formulations as well as specifically adapting adult medications for neonatal patients, including diluting existing products to ensure suitable concentrations for neonates as well as to improve accuracy of dosage measurement.[14, 20] In a study from 1991, Dunkley found that pharmacists at the time most commonly prepared eye drops, topical creams and antiseptics.[20]

1.4 PROVISION OF MEDICATION INFORMATION

A major responsibility of the NICU pharmacist was reported as the provision of a medication information service. The role comprised two components which involved the provision of NICU specialised medication information to other health professionals on the ward. Part of the role required the pharmacist to be readily available at point of care, addressing spontaneous queries from nurses and doctors that arose during care.[13, 16, 23, 24, 27, 31, 32, 34-37, 40, 41] These queries pertain to a wide-range of medication-related issues, including: medication administration, side-effects, correct calculation of dosages and adherence to medication protocols and disease management procedures.[16, 23, 24, 31, 32] Additionally, the Australian position description and BAPM service standards state that one of the main duties of the NICU pharmacists was to provide accurate information on off-label and unlicensed medicines, which are frequently utilised in the NICU.[34, 13] Pharmacists often offered responses to information requests in written as well as verbal form to ensure comprehensibility.[16, 23, 24, 31, 32] Two articles reported that through the provision of accurate and relevant information, pharmacists have the potential to minimise medication errors and adverse medication events.[23, 32] The other part of the medication information role involved pharmacists as primary medication educators to the NICU therapeutic team, providing training and in-services on therapeutic updates in neonatal pharmacotherapy.[42, 14-16, 18, 20, 24, 27, 33-35, 39] An in-service is defined as 'a professional training or staff development effort, where professionals are trained and discuss their work with others in their peer group. It is a key component of continuing medical education for clinicians, pharmacists and other medical professionals.'[43] It is recommended in the older literature, that as a part of their clinical role, NICU pharmacists provide in-services for doctors, nurses, pharmacists, students and other health professionals encompassing: rational medication use, introducing new medications and the latest publications and updates on medications, revising medication administration principles, dose calculations, and classes of medicines most likely to be associated with error in the NICU.[14, 20, 33, 15, 27]

The pharmacist is identified as being the first-line health professional to consult when medication-related issues arise.[16, 23, 24, 31, 32] One South African study conducted a needs analysis of NICU staff on the medication information service provided by a pharmacist and concluded that the surveyed NICU doctors (n = 17) required a pharmacist to be present on the ward to respond to any medication-related questions.[31] Furthermore, the provision of medication information involved 20% of pharmacist time in the South African NICU.[31]

Pharmacists were also actively involved in reviewing, updating and developing NICU-specific medication protocols, guidelines, policies and formularies for the therapeutic team to use to improve drug safety.[14, 15, 20, 33-36, 40, 42, 13] Chedoe et.al. supported these findings by stating that pharmacists should work in multi-disciplinary teams to develop formularies and guidelines that summarise information on medication compatibilities, reconstitution, rates of infusion etc.[15] It is considered in older literature that the provision of detailed medication protocols by pharmacists allows NICU health professionals to become better equipped for prescribing medications and managing pharmacotherapy regimens in neonatal patients.[14, 33]

The pharmacist is responsible for counselling parents and carers on all aspects of medications used for their child.[14] Upon admission, throughout the hospital stay, and at discharge, the pharmacist is required to consult with parents/caregivers on the medications being used for their child, advise on the role of the pharmacist in the care of patients and provide clear and comprehensive information on each aspect of therapy.[14, 20, 33-38, 42, 27] The older literature highlighted that the type of information provided by pharmacists at that time included: indication for therapy, administration intervals, time to pharmacological effect, risks and benefits of therapy, adverse events and possible adverse reactions.[14, 20, 33] It is also reported that pharmacists prepare written instructions on the storage and proper use of the medication for parents upon hospital discharge.[14, 37, 38] Whilst it is apparent that parents and carers of neonates have considerable information needs during the time that their child is admitted to the NICU, there is insufficient evidence to suggest that the NICU pharmacist in contemporary practice fulfils this information provider role.

1.5 DISTRIBUTION AND STORAGE

Two sources discussed that, along with clinical roles, the NICU pharmacist had a specific set of ward 'house-keeping' responsibilities, ensuring the appropriate distribution and storage of medications.[31, 41] This role involved ensuring the timely delivery of required medicines, stock-take, ordering of relevant items required on the ward, checking the medication fridge temperature and ensuring its cleanliness, checking storage conditions for product stability (for vaccines, blood products, and parenteral formulations), and stocking the emergency trolley.[31, 41]

1.6 MONITOR FOR RESPONSE

Overall, NICU pharmacists were highly involved in monitoring drug serum levels in neonatal patients with the most commonly monitored medications identified from older literature as including aminoglycosides, antibiotics, theophylline, chloramphenicol and vancomycin.[14, 20] It must be highlighted that these articles are over 10 years old and as such some of the agents listed may not be as widely used in the NICU in modern practice, i.e. chloramphenicol, however they are still therapeutic agents that if used, require monitoring by pharmacists. The provision of a therapeutic drug monitoring (TDM) service by pharmacists was identified, in eight articles, as an important practice in ensuring optimal neonatal patient outcomes.[14, 15, 20, 31, 28, 16, 24, 13] The role has been described as comprising the provision of correct dosing information from the interpretation of blood levels and recommending appropriate timing intervals for the collecting of blood serum samples.[14-16, 20, 24, 28, 31]

Adverse event surveillance was identified as an important role for NICU pharmacists.[13-15, 20, 21, 37-39, 41] Aside from the standard processes of monitoring, including laboratory tests and observation of physical signs, this also encompassed the development and utilisation of medication error reporting systems, requiring the thorough documentation of any medication errors as well as adverse drug events, followed by pharmacist-led interventions to rectify medication issues including dose adjustments and medication changes.[13-15, 37-39, 41]

EXTENDED ROLES

Extended roles possessed specific objectives that did not correspond to one specific stage of the medication use process, but rather encompassed various steps of the MMP.

Vaccination

There are other potential roles for NICU pharmacists, with two articles identifying pharmacist involvement in implementing immunisation programs for neonatal patients.[22, 25] An American article reported that a pharmacist stationed in the NICU was the primary resource responsible for the identification of eligible infants for routine childhood immunisations.[22] Another US based interventional study by Mills et.al investigated pharmacist involvement in a tetanus toxoid, reduced diphtheria toxoids, and acellular pertussis (Tdap) immunisation program for close contacts of neonates by providing pharmacist-led education of parents and carers of

neonates. This program had clear benefits for neonates, and significantly increased rates of vaccinations for the pertussis vaccine, from 1.3 vaccinations/month pre-study to 85.2 vaccinations/month in the study period ($p < 0.001$).[25] These studies did not specify whether the pharmacists involved within these interventions were NICU pharmacists, or general hospital pharmacists. However, the studies demonstrate the potential value of NICU pharmacist involvement in vaccinations.

Research

NICU pharmacists were also active participants in clinical trials and research.[18, 20, 24, 28, 34, 38, 40, 41, 44] Two sources stated that NICU pharmacists are encouraged to perform drug use evaluation studies, publish innovations in pharmacy and should facilitate investigational drug studies to improve rational and safe use of medicines.[34, 38] An Australian study dated in 1991 highlighted that roles associated with clinical trials at the time specifically involved organising drug supply, maintaining patient records, randomising patients and preparing protocols.[20] A study revealed that in Belgium as much as 50% of pharmacist working time was dedicated to research, however it did not specify roles associated with this practice.[28]

Quality Use of Medicines Strategies

Several position statements required NICU pharmacists to be involved in ensuring medicines used in the NICU were cost-effective and being used rationally.[27, 34, 38, 41] Key duties of the pharmacist included: monitoring the use of expensive medicines, developing cost-saving initiatives for the NICU, involvement in antimicrobial stewardship programs, documenting clinical interventions and cost-avoidance methods as well as performing target drug programs to decrease irrational use of medicines.[38, 41, 34] NICU pharmacists were also tasked with ensuring the quality of pharmaceutical services being provided on the NICU, with increased emphasis on documenting clinical interventions, ensuring all medicine provision services are compliant with legislation and hospital policies and developing safety initiatives.[27, 34, 37-39, 41]

Furthermore, in improving the quality use of medicines, the Irish model of care highlights that pharmacists should have input in implementing and maintaining medication safety technology in NICU practice.[27] These technologies included e-prescribing, barcoding and smart pump technology.[27]

INTERNATIONAL COMPARISON OF PHARMACIST ROLES

Articles from thirteen countries were included in this review, with the largest number from the USA (13 of 30 articles). Table 2 provides an overview of the different roles performed in each country, as identified in the literature. Although a wide-range of pharmacist roles have been identified within the literature, there are discernible differences in practice between certain regions worldwide. Literature gathered from the USA, UK, Australia and South Africa suggest that patient-oriented clinical activities such as patient medication chart review, participation in ward rounds, therapeutic drug monitoring and medication information services make up the majority of the role in NICU. Alternatively, the multi-national study incorporating data from PICUs in Belgium, France, Switzerland and Quebec, did not report on roles in ward rounds and TDM practices. However, pharmacists in these countries were found to be strongly involved in clinical research, provision of medication information and patient medication review. Overall, involvement in immunisations, ward-based housekeeping activities and extemporaneous compounding were not as frequently reported. The apparent lack of current and published literature does not allow for a good understanding of current pharmaceutical services provided worldwide. Furthermore, the literature does not yield any information about practices in South America or Asia. As such, there are inconsistencies and gaps in the literature about the level of practice in each country with respect to NICU pharmacy practice.

4. DISCUSSION

To our knowledge, this is the only review to compare the roles of NICU pharmacists between countries on an international scale. Whilst the amount of international research documenting clinical pharmacist practices in the NICU is limited, there was sufficient literature to map the pharmacist role against the MMP.[9] A total of 16 different pharmacist roles were identified as being reported globally in published and grey literature. However, we are unable to ascertain if these services are currently provided or offered to NICUs worldwide, due to the lack of recently published literature.

Overall, it is difficult to ascertain the true extent of pharmacy practice in each country as relevant literature from Asia, South America and a large proportion of Africa and Europe was not available. The majority of the literature that was sourced was dated more than 10 years ago, and it is difficult to determine whether the data gathered still reflect current practice.

Furthermore, due to the lack of available research, several paediatric studies were included in the review that included a sub-section of neonatal patients in their evaluation. As such, it is unknown what proportion of pharmacy services described in these papers referred to neonatal patients. Relevant studies may have been excluded from the review because they were not available in the English language. Grey literature searches sought to identify service standards and guidelines from different countries, however many were not accessible as they were not publicly available or were published in languages other than English.

The findings of the review demonstrate that the value of pharmacists in USA, UK, South Africa and Australia lies in an interactive type of practice with literature identifying a broad range of roles extending from therapeutic drug monitoring and patient medication chart review through to immunisations, counselling of parents and extemporaneous compounding. The European countries reported roles in TPN prescribing, provision of medication information and patient medication chart review, however, however did not have such an extensive scope of practice. These difference in practice may be attributed to cultural, educational, legislative and funding differences in healthcare systems from country to country, impacting upon the level of pharmacist integration into NICU teams.[45] Diversity in practice may have varying impacts upon patient outcomes. According to WHO, one of the main priorities for healthcare systems worldwide is the promotion of equity within and between healthcare facilities.[46, 47] Health equity is a shared responsibility of all nations worldwide, and it is a fundamental right of each human being to receive the highest standard of healthcare.[46, 48] As such, the RIO Political Declaration on Social Determinants of Health endorses global collaboration and benchmarking between countries to identify good practices and adopt coherent policies to promote consistent practices.[48]

WHO identifies that the most effective pharmaceutical care is provided when clinical pharmacists become integrated into the healthcare team and play an active role in patient care.[1] Pharmacists possess the relevant skills, knowledge and expertise to make valuable contributions to the quality use of medicines and medication safety.[49] The review highlights that NICU pharmacists can provide both a medication support system for other NICU health professionals as well as a patient care role. The majority of the literature reported that the most important features of a NICU pharmacy service involved the physical presence of a pharmacist on the ward, clinically reviewing the parameters of pharmacotherapy and providing medication information. Specifically, the most commonly reported roles are centred on patient medication chart review, therapeutic drug monitoring, provision of education

services and prescribing of TPN therapy. By focussing upon these services, NICU pharmacists improve the rationalisation of therapy, reduce costs associated with therapy, promote collaboration with other healthcare professionals and decrease the incidence of avoidable harm.[19, 23, 26, 32] Furthermore, these roles promote the individualisation of patient pharmacotherapy according to patient needs which is integral to achieving optimal neonatal outcomes.[19] Other roles, relating to participation in ward rounds, adverse drug event monitoring, implementation of quality use of medicines strategies, immunisations, and parent counselling have been less commonly reported however are also important to the management of neonates. The Department of Health in Australia states that one of the current issues within its health system is the promotion of immunisations which are integral to the health of children and the wider community.[50] These roles are potential areas of practice that require improvement and focus.

Clinical pharmacists have long established roles in specialised areas of practice such as in oncology, intensive care and emergency medicine.[51-57] The development of these roles has demonstrated the pharmacist's contribution to the healthcare system, particularly in improving patient safety and rationalising the use of medication.[58, 59, 14] However, whilst the roles of clinical pharmacists have been well described, when looking at the vulnerable neonatal population, who are at the start of the age-spectrum and are at greater risk of medication errors and significant resulting consequences, there is a lack of detail on current pharmacist contributions to the quality use of medicines.[57] Furthermore, there is limited literature that identifies the impact of pharmacist practice on neonatal outcomes. Most of current research focuses upon pharmacist roles in adult populations, with relatively less exploring roles in paediatric practice and even less in neonatal care.[60, 8, 23, 61] Given the challenges and risks of pharmacotherapy in neonates, the role of the pharmacist within the NICU therapeutic team is important. As such due to the limited research undertaken in this area, there is need to conduct investigations to establish what roles are being performed today as well as to develop standards of NICU pharmacy practice that clearly define pharmacist roles that meet the specific needs of the neonatal population. Further research needs to be conducted to identify opportunities to increase pharmacist engagement in each country's healthcare system and improve the level of involvement in the NICU.

5. PRACTICE IMPLICATIONS

The role of the pharmacist in the NICU has the potential to greatly improve patient outcomes as well as decrease incidence of medication error and associated harm. It is important to understand the differences in practice between each country, as it allows for the benchmarking of our own current service delivery system and promotes practice improvement to meet the standards of other settings. As such, this review has identified that the model of NICU pharmacist practice in USA, UK, Australia and South Africa appears to be patient-centred and promotes pharmacist integration into the NICU team. Furthermore, the findings of the review have allowed for the identification of areas of practice (i.e. parent counselling, immunisations) that can be improved upon and have the potential to be further developed into roles that are integral to the quality of medication management in NICU. This review may provide a foundation for future research, including subsequent reviews of the literature, and has the potential to act as a useful comparison of pharmacist practice in NICU to other patient groups, i.e. older paediatric patients and adults, to determine where differences in pharmacist roles lie.

6. CONCLUSION

The literature identifies that there is insufficient evidence to describe what roles are currently performed in NICUs worldwide. This is due to the low quantity of published literature, most of which was out-dated. Given the diversity of practice, it is important to establish clear definitions of pharmacist roles within the NICU and compare roles across different clinical settings and countries. Further research, comprising systematic, rigorous surveys are required if the current international roles of the NICU pharmacist are to be understood.

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Table 1: List of studies that were included in the review

STUDY	TYPE OF LITERATURE	COUNTRY YEAR SETTING	KEY FINDINGS
Ahmed M [42]	Descriptive Article	UK 2008 NICU	The main aspects of a pharmacist's role in the NICU are: educating staff and parents, developing a formulary, providing input into parenteral nutrition, advising on drug choice and attending weekly multidisciplinary ward rounds.
British Association of Perinatal Medicine (BAPM) [13]	Service Standard	UK 2010 Hospitals providing neonatal care	Neonatal pharmacists play a role in the optimisation of pharmacotherapy in neonates. They are required to perform a number of clinical roles including: monitoring of prescriptions, therapeutic drug monitoring as well as provision of advice on off-label and unlicensed medicines.
Bryant BG [14]	Report	USA 1985 NICU	Pharmacists perform daily patient medication reviews for medication appropriateness and any interactions, respond to information requests from medical and nursing staff, prepare dosage formulations suitable for babies and counsel parents.
Cambridge University Hospital [36]	Position Description	UK NICU	The neonatal pharmacist visits the NICU daily and performs the following services: prescription chart review, provides advice to the doctors and nursing team, reviews policies and guidelines and checks TPN orders.

Chedoe I et.al. [15]	Literature review	The Netherlands 2007 NICU	Pharmacist interventions, namely participation in ward rounds and review of medication orders prior to dispensing and distribution, were found to be the most common pharmacist interventions suggested to improve medication safety in the NICU.
Condren M et.al. [16]	Prospective descriptive study	USA 2004 Paediatric ward	The most common services performed by a pharmacist were drug therapy change, pharmacokinetic monitoring, medication information and medication histories. Also identified roles including; patient medication review, adverse drug event monitoring, and provision of medication information.
Conway C et.al. [17]	Literature review	Ireland 2012 NICU	The most important pharmacist roles for maintaining patient safety in NICU included medication chart checking and participation in physician consultations.
De Jager et.al. [18]	Literature review	South Africa 2014 NICU	Clinical pharmacists in NICUs should be involved in the following services; attending daily ward rounds, TDM, parenteral nutrition, patient education and research into safety and efficacy of medications.
Dice JE et.al. [19]	Prospective interventional study	USA 1981 NICU	Pharmacist monitoring of an individualised TPN in neonates had greater mean daily weight gain, introduced a greater amount of nutrients to the infant and was more cost-effective than a standardised program.

Dunkley MK [20]	Prospective study	Australia 1991 NICU	Australian pharmacists provided strong support in extemporaneous manufacturing, parenteral nutrition, provision of medication information, TDM and adverse drug reaction monitoring. Standards of clinical pharmacy service in the NICU need to be developed to promote service equality between hospitals.
Folli H et.al. [21]	Prospective descriptive study	USA 1987 Paediatric hospitals	Pharmacist involvement in reviewing patient medication orders significantly reduced potential harm resulting from erroneous medication orders.
Gold Coast Hospital and Health Service [35]	Position Description	Australia 2015 NICU	The key duties of the neonatal pharmacist include: performing clinical reviews of medication therapies, monitoring patient outcomes and revising treatment strategies accordingly, delivering specialist educational presentations for pharmacists and other health professionals in the hospital and providing information obtained through research to optimise pharmaceutical care provided to complex neonatal patients.
Intermountain Healthcare [41]	Position Description	USA 2015 NICU	The essential duties of the NICU pharmacist include: providing accurate drug information, monitoring physician orders, training and supervising new pharmacy technicians and actively participating in department cost savings initiatives.

Johnson C et.al. [22]	Report	USA 1993 NICU	A pharmaceutical care system was established within NICU. The most important elements of this service included; monitoring of drug dosing, reporting adverse drug reactions, detecting medication interactions, immunisations and counselling of parents.
Kelishadi R et.al. [23]	Literature review	Iran 2012 Paediatrics	Pharmacist-physician-patient collaboration is important in maintaining medication safety in NICU. Pharmacist roles including medication chart checking, participation in multi-disciplinary meetings, parent interviews and clinical interventions were the most effective in medication management in the NICU.
Lobas N et.al. [24]	Descriptive article	USA 1991 NICU	NICU pharmacists participate in ward rounds, TPN therapy, medication information services and pharmacokinetic consultations.
Medical University of South Carolina [37]	Rotation Description	USA 2015 NICU	The pharmacist is expected to participate in daily ward rounds with the inter-professional team, evaluate each patient's drug therapy at least daily, communicate with patient's family or caregiver and provide timely responses to requests for drug information.
Mills B et.al. [25]	Prospective and descriptive study	USA 2014 Pharmacy in women's hospital	Vaccination rates increased after the implementation of a pharmacist-led intervention program for family members of neonates. The pharmacist was recognised as an important source in promoting immunisation for the safety and health of infants. Unknown whether the pharmacists involved were NICU

			pharmacists or general hospital pharmacists.
Mulholland P [26]	Prospective survey	UK 2012 NICU	40% of surveyed pharmacists were prescribers and 70% of these pharmacists were prescribing in the NICU. The main medications being prescribed were parenteral nutrition (75%), supplements (75%), antibiotics and caffeine (50%). Benefits of pharmacist prescribing included reductions in communication errors and timely corrections of wrong prescriptions.
Murphy J et.al. [27]	Model of Care	Ireland 2015 Hospitals providing neonatal care	The role of the neonatal pharmacist involves: ensuring the safe use of medicines in NICUs, prescription monitoring, ordering and monitoring parenteral nutrition, providing information on medicines and educating other health professionals as well as parents.
New South Wales Governme nt [34]	Position Description	Australia 2013 NICU	The NICU pharmacist is responsible for reviewing medicines prescribed and optimising pharmacotherapy in critically ill neonates, ensuring the appropriate ordering and preparation of parenteral nutrition, actively participating in daily ward rounds as well as advising parents on medicine related issues.
Prot-Labarthe S et.al. [28]	Multi-centre, prospective and descriptive study	France, Quebec, Belgium and Switzerland 2013	Pharmacists recorded a break-down of their various activities in PICUs throughout each day, and the roles included student training, clinical research, drug distribution and clinical activities. Over the 6 month study period, the total duration of pharmaceutical care offered by pharmacists was reported as; 550 – France,

		PICU	416 – Quebec, 410 – Switzerland and 124 – Belgium patient days.
Ragab M et.al. [29]	Literature review	Saudi Arabia 2014 NICU	Pharmacists are involved in initiating the neonatal TPN orders and are actively involved in assisting prescribers in the prescribing process, including participating in ward rounds and meetings
Sanghera N et.al. [30]	Systematic literature review	UK 2006 Paediatrics	Reviewing patient charts was deemed to be the most effective pharmacist role in improving medication safety in NICUs
Schellack N et.al. [31]	Prospective study	South Africa 2011 NICU	The majority of pharmacist time was spent on patient care and ward functions. Pharmacists also participated in ward rounds and clinical meetings. Doctors and nurses identified that the role of the pharmacist in NICU is a necessity to improve services provided to neonates.
Simpson JH [32]	Prospective Observational Study	UK 2004 NICU	Close liaison with a ward-based clinical pharmacist is an effective way of reducing medication errors. The role of the pharmacist in staff feedback and education as well as reviewing medication orders was identified as effective in reducing dose calculation and prescribing errors
St David's North Austin Medical Center [39]	Position Description	USA 2016 NICU	NICU pharmacist is responsible for: accurately and effectively providing medication therapy, providing medication counselling, assisting in training and educational programs, providing drug information upon request and reporting medication errors and adverse drug reactions.

University of Kentucky Hospital [38]	Position Description	USA 2009 NICU	The major responsibilities of the NICU pharmacist are: the provision of pharmaceutical care to patients including participation in daily ward rounds, monitoring drug therapy, counselling parents and caregivers and reviewing medication orders for accuracy and appropriateness, as well as facilitating investigational drug studies and providing education to trainees and other health professionals.
Website [40]	Position Description	USA 2015 NICU	The key duties of a NICU pharmacist include: daily multi-disciplinary patient rounds, daily medicine profile review, providing drug information, documenting all interventions performed and training and educating pharmacy students.
Zenk KE [33]	Report	USA 1980 NICU	Every neonatal ward needs a pharmacist who specialises in neonatal pharmacology. Ward-based clinical pharmacists are involved in all aspects of medication in the NICU, and perform specialised compounding and dilutions of medications, and are actively involved in determining TPN formulations, patient medication review, provision of medication information, education of NICU staff, participation in ward rounds, TDM, counselling of parents and preparing drug monographs.

Table 2: Internationally reported roles of pharmacists within the NICU

	COUNTRY	LISTED ACTIVITIES
	United States of America	TPN monitoring/ordering, patient medication review, education sessions with medical staff, participation in ward rounds, involvement in clinical research, parent counselling, TDM, provision of information to medical staff requests, manufacturing capabilities, participation in immunisation programs, establishing/updating policies and protocols, reporting ADE's and medication errors, monitoring the use of expensive medicines, documenting cost saving interventions
	Australia	Review of patient charts, responding to information requests, ordering TPN, TDM, clinical trials/research, contributing to the manufacture of medications, counselling of parents, education for staff, developing drug protocols, reporting ADE's, ensuring adherence to legislation and hospital policies, ward rounds, participating in antimicrobial stewardship
	South Africa	Responding to requests for information, ward activities, educational duties in training relevant medical staff, monitoring medication usage, monitoring pharmacokinetic parameters in TDM
Europe	France	Clinical activities - review of patient charts, student training, participation in clinical research, medication distribution, responding to medication information questions
	Quebec	
	Switzerland	
	Belgium	
	United Kingdom	Reviewing medication orders, staff feedback and education, responding to information requests, prescribing TPN, ADE reporting, attendance at ward rounds and clinical meetings, input into guidelines and policies, developing a formulary, advice on off-label/unlicensed medicines
	Ireland	Prescription monitoring, documenting ADE's, ordering TPN, education of other health professionals, counselling of parents, provision of medication information on existing and new therapies, implementing technology into practice i.e. e-prescribing, barcoding, developing cost-effective and safety initiatives

ADE = Adverse Drug Event, TPN = Total Parenteral Nutrition, TDM = Therapeutic Drug Monitoring

Figure 1: Review of the search strategy employed to find relevant literature

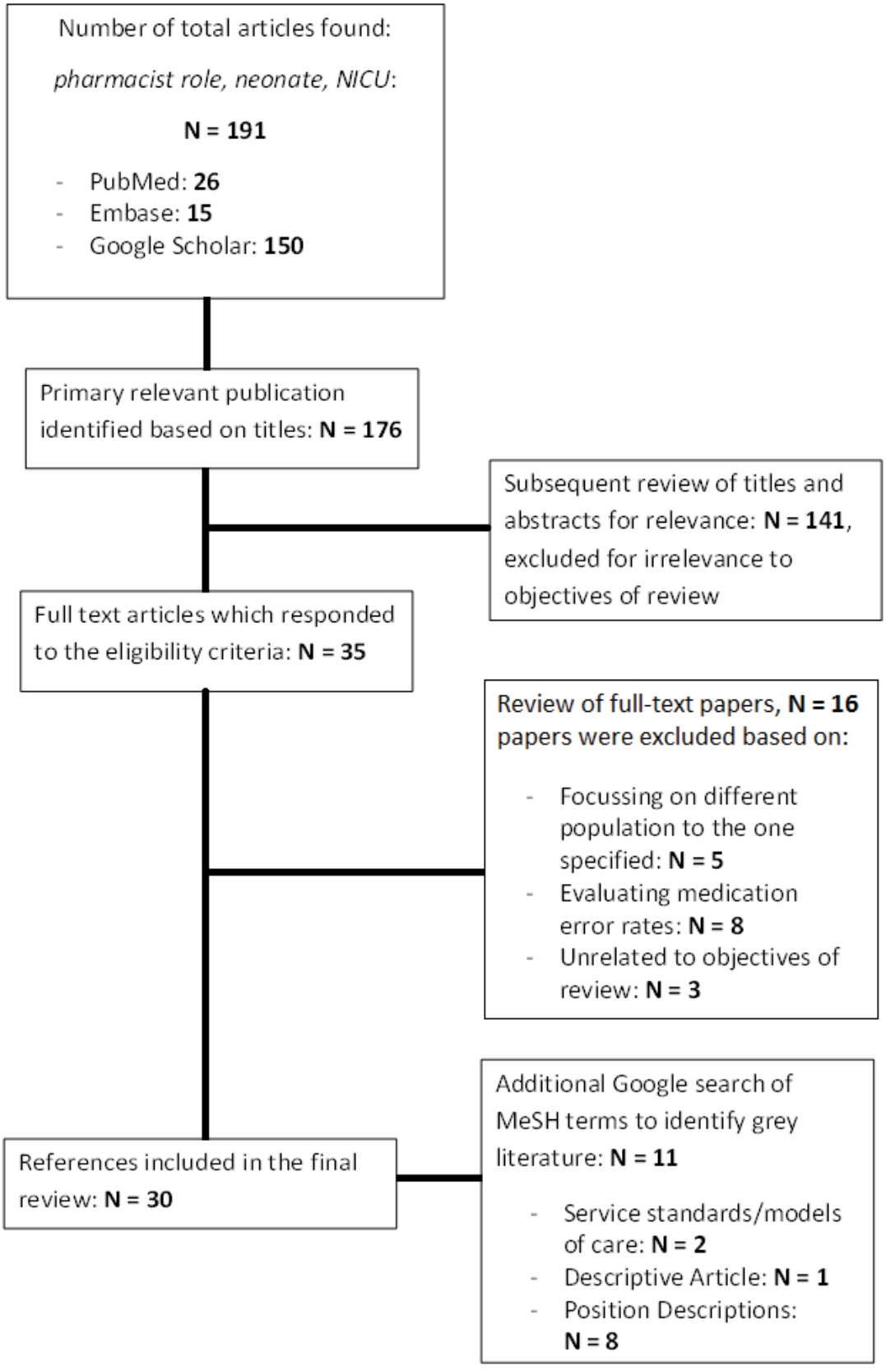
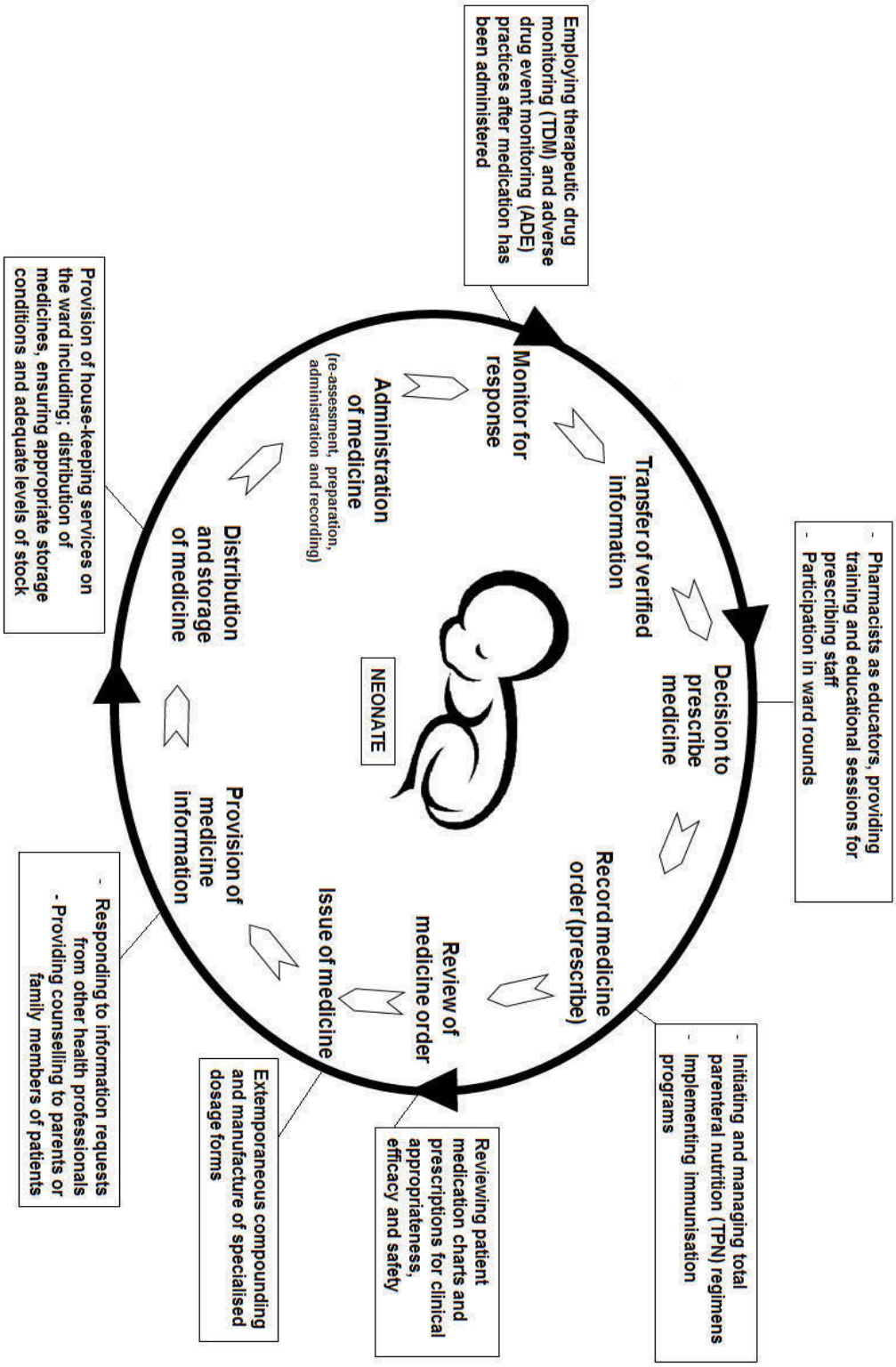


Figure 2: Pharmacist practice in the NICU mapped against the Medicines Management Pathway

Figure adapted from: Stowasser DA, Allinson YM, O'Leary KM, 'The Medicines Management Pathway', J Pharm Prac Res 2004; 34: 293-6 [9]



3.3 THE ROLE OF THE CLINICAL PHARMACIST IN THE NICU: A CROSS-SECTIONAL SURVEY OF AUSTRALIAN AND POLISH PHARMACY PRACTICE

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Original article

The role of the clinical pharmacist in the NICU: a cross-sectional survey of Australian and Polish pharmacy practice

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AUTHORS' CONTRIBUTIONS

Natalia Krzyżaniak was the primary author, collected the data, analysed and interpreted the findings, wrote and organised the manuscript. Beata V. Bajorek and Iga Pawłowska contributed to the idea, drafting of the manuscript, interpretation of findings, and critical review of the manuscript.

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Iga Pawłowska

Beata V Bajorek

ABSTRACT

OBJECTIVES: To describe and compare the pharmaceutical services and clinical pharmacy roles performed in neonatal intensive care units (NICUs) in Australian versus Polish hospitals.

METHOD: A 26-item survey was distributed electronically to directors of pharmacy as well as neonatal pharmacists in hospitals in Poland and Australia. Most questions were fixed 'agree/disagree' answers, supplemented by open-ended questions. The survey was distributed between January and May 2017.

RESULTS: Overall, 30 Australian pharmacists and 22 Polish pharmacists completed the survey. Significant differences were observed in the types of pharmaceutical care services provided to NICUs between Australia and Poland. A higher proportion of Australians than Poles performed clinical roles; e.g. providing medication recommendations (Aus = 96.6%, Pol = 9.1%, $p < 0.001$), pharmaceutical interventions to resolve drug therapy problems (Aus = 93.1%, Pol = 18.2%, $p < 0.001$) general patient medication chart review (Aus = 96.6%, Pol = 13.6%, $p < 0.001$). All (100%) Polish pharmacists did not consider themselves members of the NICU team and the majority (59.1%) felt that pharmaceutical care on the NICU was practically non-existent.

CONCLUSION: Future research should focus on bringing practice in countries such as Poland closer in-line with practice in countries such as Australia.

KEYWORDS: Clinical pharmacy, Neonatology, Quality of Pharmacy Services, International Pharmacy services

WHAT IS ALREADY KNOWN ON THIS SUBJECT? Differences in healthcare systems, legislation, culture, and tertiary education across countries may lead to the variable provision of pharmaceutical care services. Global collaboration is essential in identifying best practices for newborn patient care. However, little has been done to identify what pharmacist roles are actually performed in NICUs worldwide.

WHAT THIS STUDY ADDS: The results from this study provide an insight into the types of clinical pharmacy services currently being delivered to NICUs in Australia and Poland. Pharmacist expectations of practice in the NICU were the same across both countries, however the actual pharmaceutical care services provided differed. Overall, the focus of pharmacy practice in NICUs in Australia and Poland is varied, ranging from clinically-centred services to traditional, dispensary-based medication supply duties respectively.

INTRODUCTION

Approximately 16% of all live born babies in Australia are admitted to special care nurseries (SCN) or neonatal intensive care units (NICUs).[1] The majority of these newborns are pre-term with serious pathologies including infections, respiratory issues, jaundice and congenital malformations.[1 2] To treat and manage these conditions, pharmacotherapy is widely used in conjunction with specialised medical interventions. It is reported that worldwide, NICU patients are prescribed a median range of three to 11 medications, with some babies requiring as many as 40.[3 4] As such, the clinical pharmacist has an important role to play in the quality use of medicines in this patient group, potentially having a large impact on patient outcomes.[5] The high incidence of off-label medicines use, polypharmacy, and frailty in this patient group (characterised by young gestational ages, very small birth weights) increases the risk of medication errors and poses challenges to the safe and effective use of pharmacotherapy.[6] Studies have shown that pharmacist-led interventions can improve medication management in the NICU; daily bedside reviews of medication orders, individualised total parenteral nutrition (TPN) regimens, and education programs, have been shown to reduce medication errors.[7 8]

Differences in healthcare systems, legislation, culture, and tertiary education across countries may lead to the variable provision of pharmaceutical care services. The RIO Political Declaration for Health highlights that international healthcare systems should collaborate to develop coherent policies to promote consistent practice across settings within and between countries.[9] Global collaboration is essential in identifying best practices for newborn patient care, however, little has been done to identify what roles are actually performed in NICUs worldwide, particularly between diverse countries such as Australia and Eastern European countries, such as Poland. When considering the practice of hospital pharmacists in general in Australia and Poland, there are discernible differences. In Poland, general hospital pharmacists are restricted mainly to services in the dispensary, with limited clinical roles performed on wards.[10 11] Pawłowska and Kocić concluded that Polish hospital pharmacists were mainly involved in the distribution of medicines, such that patient-focused services were not common practice.[10] In contrast, hospital pharmacist practice in Australia seems particularly clinically-focused. The Society of Hospital Pharmacists Australia (SHPA) advocates that pharmacists should have direct contact with patients, maintaining key roles in medication reconciliation, participating in ward rounds, providing medication information, and monitoring drug therapy.[12]

Due to the lack of published literature in both countries it is unclear what pharmacy services are specifically performed in NICUs. Therefore, the purpose of this study was to compare the pharmaceutical services and clinical pharmacy roles performed in NICUs in Australian and Polish hospitals. The specific objectives included:

- identifying the roles currently performed by pharmacists in the NICU
- describing the pharmacist's perceptions of their integration/role in the NICU team
- identifying which roles are perceived by pharmacists as essential services to the NICU.

METHODS

A cross-sectional survey was electronically distributed to hospital pharmacists and directors of pharmacy departments employed in Australian and Polish hospitals with a NICU, between January and May 2017. Ethics approval was obtained from the respective human research ethics committees at the University of Technology Sydney, Australia (REF NO. ETH16-1033) and the Medical University of Gdansk, Poland (REF NO. NKBBN/424/2016). Participants were assured of confidentiality and were informed that their responses would be de-identified.

PARTICIPANTS

This study involved the survey of NICU pharmacists as well as directors of pharmacy of hospitals that contained a NICU. Regardless of work status (i.e. full-time/part-time), all Australian pharmacists that fulfilled these criteria were eligible to participate in the study. In Poland however, as clinical pharmacy practice is less developed, all hospital pharmacists and directors of pharmacy at hospitals containing a NICU were invited to complete the survey. Participants were identified through publicly available registers in Poland and Australia i.e. Polish Register of Facilities delivering Medical Activities (Rejestr Podmiotów Wykonujących Działalność Leczniczą – RPWDL), and the Australian and New Zealand Neonatal Network (ANZNN) that lists hospitals with neonatal intensive care units. Furthermore, Australian participants were contacted via the Paedpharm online pharmacists group.

Using a significance level of 5% and a desired power of 80%, a sample size calculation was performed for survey questions. The calculation was based on the precision around the point of estimate of effect, which is acknowledged as the estimated response to specific survey

questions, based on the results of previous research. [10 11 13] A total of 64 participants was found to be the target sample size needed.

SURVEY

The online survey (created in SurveyMonkey) was self-administered by participants. A total of 26 questions were developed following a comprehensive literature review.[14] The majority of questions required fixed 'agree/disagree' answers, and were supplemented by open-ended questions. The questions canvassed the participant characteristics, what roles were performed by pharmacists specifically in, or for, NICUs (within four key categories: administrative, clinical, education, provision), identification of roles that were perceived as being essential to the NICU, and an indication of the level of pharmacist integration in the multidisciplinary NICU team. All questions were pre-coded for data entry. The survey was pre-tested for content, design and readability on a small group of Australian pharmacists. The survey was administered in English and Polish for each respective country. For all surveys that were provided in Polish, the results were translated into English via a tiered process: survey results were translated from Polish to English by one researcher (NK), then these translations were edited and verified by two co-researchers (IP, BB).

A unique survey link was emailed to each pharmacist. Respondents who requested a hard-copy version of the survey were sent one by post. Reminders were emailed to participants one month and one week before the end of the study period.

Surveys that were at least 50% completed by participants were included in the analysis. Incomplete responses were considered as missing values.

DATA ANALYSIS

Descriptive statistics (percentages, frequencies) were used to analyse quantitative data via the Statistical Package for the Social Sciences (SPSS) Version 22. The Chi-square test was applied to test the association between independent categorical variables (e.g., nationality - Australian and Polish) and dependent variables (e.g., proportion of agree/disagree responses to questions relating to: roles that are performed by pharmacists specifically in or for NICUs, roles that are

perceived as being essential to the NICU as well as pharmacist integration in the multidisciplinary NICU team). Statistical significance was accepted as a *p* value of <0.05.

Any qualitative data pertaining to pharmacist responses to open-answer questions were thematically analysed using manual inductive coding. Significant statements were identified from pharmacist responses and patterns were coded into non-overlapping themes and subthemes around the study objectives.[15] Three researchers (NK, IP, BB) independently analysed the data before comparing the themes to attain consensus. The analysis was structured by an essentialist/realist theoretical framework which reflects on the experiences, meanings and the reality of participants.[16] To ensure comprehension, the qualitative responses of participants are represented by the code 'AP' for Australian pharmacists and 'PP' for Polish pharmacists.

RESULTS

Due to the specialised nature of NICU pharmacy practice and the small number of NICUs in each country, the number of possible participants was limited. An accurate response rate is difficult to ascertain as it is unspecified how many Australian pharmacists have access to the Paedpharm online pharmacists group. Furthermore, it is also unknown how many surveys were distributed among colleagues within each hospital. As such, the response rate was calculated with the denominator being the number of surveys sent out electronically by researchers. A total of 55 surveys were sent out to Australian participants, with 30 responses received (response rate = 54.5%), and 40 surveys were distributed to Polish participants, of which 22 returned a completed survey (response rate = 55%) (Table 1).

Of the 30 participants from Australia and the 22 from Poland who completed the survey, 76.7% and 72.7% respectively were female (Table 1). Most participants had between 1-5 years of practice experience (Aus = 43.3%, Pol = 54.5%), and did not possess specialised qualifications related to neonatal or paediatric practice. More than half of the Polish participants (59.1%) worked in the main hospital pharmacy (i.e., dispensary). None of the pharmacists from Poland identified themselves as dedicated NICU pharmacists, in comparison to 44.8% of Australian pharmacists who did.

PHARMACIST INTERACTION WITH THE NICU

Whilst the majority of participants had contact with the NICU on a daily basis (Aus = 72.4%, Pol = 63.6%), the nature of pharmacists interaction with the ward differed between the two countries (Table 2). A significantly higher proportion of Australian pharmacists (93.3%) agreed that they provided pharmaceutical care services directly on the NICU, compared to Polish pharmacists (4.5%, $p < 0.001$). Over a third of Australian pharmacists agreed that they spent an average of 1-3 hours on the NICU ward per day, and 75% agreed that they covered all patient beds during this time.

All (100%) Polish pharmacists reported that they worked in the main hospital pharmacy; half (54.5%) stated that telephone contact was their only form of communication with the ward., as reinforced by their qualitative responses:

> *'Co-operation is based on contact through the telephone between the ward and the compounding laboratory…. Our collaboration is based on the completion of medication orders sent by the ward*.' **PP6**

> *'Collaboration is only associated with the preparation of drugs for the ward, formulations for individual patients such as powders, feeding bags or antibiotics… contact with doctors is very limited. The most common contact is with the NUM*.' **PP18**

PHARMACIST ROLES CURRENTLY PERFORMED IN THE NICU

In Australia, pharmacists reported being frequently involved in direct-patient care and decision-making related to pharmacotherapy in the NICU (Table 3). A significantly higher proportion of Australians than Poles agreed that they provided medication recommendations to medical staff (Aus = 96.6%, Pol = 9.1%, $p < 0.001$), intervened to resolve drug therapy problems (Aus = 93.1%, Pol = 18.2%, $p < 0.001$), and routinely reviewed patient medication charts (Aus = 96.6%, Pol = 13.6%, $p < 0.001$). All (100%) Australian participants reported that they were a source of medication information on the ward, and responded to queries raised by nursing and medical staff. Nine times as many Australians than Poles were involved in checking patient progress on prescribed pharmacotherapy (Aus = 96.6%, Pol = 13.6%, $p < 0.001$), along with therapeutic drug monitoring (TDM) (Aus = 96.6%, Pol = 13.6%, $p < 0.001$) and recommending doses to medical and nursing staff (Aus = 96.6%, Pol = 13.6%, $p < 0.001$).

Australian respondents often expressed that they focused on medication safety to reduce medication errors arising from prescribing (dosing, drug selection) or administration errors, in this high-risk patient population. Furthermore, Australian pharmacists emphasised their role in developing key medication guidelines and protocols for the NICU, which were heavily relied upon by staff:

> *'Prescribing and administration error are unfortunately quite common in NICUs despite best practice drug guidelines available. Routine medication chart review and being present on ward rounds where the majority of prescribing is done can minimise the risk of dose errors occurring... Regularly consulted for guideline development and drug selection*.' **AP1**

> *'Medication safety focus, routine medication chart/pharmaceutical review, guideline review and development*.' **AP16**

> **'***Nursing staff have become reliant on medication guidelines and are hesitant to work outside of these guidelines without pharmacy involvement*.' **AP17**

Polish pharmacists reported being mostly involved in dispensary-based roles, including medication supply and administrative activities. Compared to the Australians, a higher proportion of Polish pharmacists identified that they were involved in dispensing (Pol = 100%, Aus = 82.8%, p = 0.040), extemporaneous compounding (Pol = 95.5%, Aus = 75.9%, p = 0.057), house-keeping duties (i.e. maintenance tasks e.g. stocking the ward with medicines, checking expiry dates; Pol = 100%, Aus = 67.9%, p = 0.003), and purchasing pharmaceutical products for the NICU (Pol = 95.5%, Aus = 72.4%, p = 0.033). None of the Polish pharmacists reported being involved in: training and education of medical staff; neonatal research; counselling parents/carers of patients; clinical meetings; evaluating patient laboratory tests; or ward rounds.

> '*The pharmacist does not participate in ward rounds and has no knowledge of the patient's laboratory test results. They only become aware of problematic situations when the medical staff contact them*.' **PP1**

> '*We do not participate in the processes of prescribing and monitoring pharmacotherapy*.' **PP2**

> *'Role of a pharmacist is limited to the ordering of medicines - unused potential*.' **PP7**

Similar proportions of respondents from both countries reported monitoring of total parenteral nutrition (Aus = 86.2%, Pol = 81.8%), developing NICU drug formularies (Aus = 98.7%, Pol = 95.5%), managing the NICU drug budget (Aus = 57.1%, Pol = 68.2%), and attending non-clinical meetings (Aus = 72.4%, Pol = 77.3%).

PHARMACIST EXPECTATIONS OF ROLES THAT SHOULD BE PERFORMED IN THE NICU

Despite the differences in the types of pharmaceutical care services provided to NICUs between Australia and Poland, the majority of pharmacists in each country highlighted very similar expectations towards pharmacist practice. (Table 4) The majority of respondents (≥ 90%) from both countries agreed that pharmacists should undertake clinical roles, such as TDM (Aus = 100%, Pol = 95%), medication chart review (Aus = 100%, Pol = 90%) and checking patient response to prescribed pharmacotherapy (Aus = 100%, Pol = 90%). All (100%) Polish participants agreed that pharmacists should provide advice to medical staff when selecting medications and prescribing off-label products, as well as performing pharmaceutical interventions and collaborating with nursing and medical staff. Compared to Australian pharmacists, a significantly higher proportion of Polish participants expected that pharmacists should provide medication supply roles including dispensing (Pol = 100%, Aus = 73.9%, $p = 0.014$), extemporaneous compounding (Pol = 100%, Aus = 60.9%, $p = 0.002$) and house-keeping activities (Pol = 100%, Aus = 60.9%, $p = 0.002$). Furthermore, a significantly higher proportion of Poles than Australians agreed that administrative roles, such as management of the drug budget ($p < 0.001$) and purchasing medications for the ward ($p = 0.027$), should be performed by pharmacists.

Australian pharmacists, however, focused more on clinical roles, with ≥ 80% of respondents agreeing that 13 out of 15 roles listed in the 'clinical' category of the survey were expected to be performed. In their qualitative responses, overall, Australian participants felt there was a great need for pharmacist involvement in the care of this patient population. They described pharmacotherapy-related issues that were more prominent in neonatal patients, for example, interindividual variability in pharmacokinetics and dosing errors.

> *'In Australia, NICUs are considered as areas that require essential clinical pharmacy services… Neonatal clinical pharmacist is essential for the medication/patient safety in this very high risk population to ensure the delivery of effective pharmacotherapy*.' **AP6**

'*Having a pharmacist permanently on NICU allows for consistency in patient care. I find on days that a pharmacist is unable to work in NICU that weaning of sedation/analgesia always gets missed, antibiotic doses aren't adjusted for age etc.*.' **AP24**

PHARMACIST INTEGRATION INTO THE NICU ENVIRONMENT

All (100%) Australians and 95.4% of Poles agreed that pharmacists should have visiting or permanent positions on the ward (Table 5). However, differences were identified about the current level of pharmacist integration, with a significantly higher proportion of Polish pharmacists compared to Australian participants expressing that they were not considered to be members of the NICU team (Aus = 13.3%, Pol = 100%, $p < 0.001$). In comparison, the majority of Australian pharmacists (86.7%) reported being integral members of the NICU team. In their qualitative responses, they commonly described a respectful and collaborative relationship with the doctors and nurses, supported by effective communication. They stated that they were regularly approached on the ward to answer questions, being seen as a source of medication information.

'Neonatal clinical pharmacist is a valuable NICU team member.' **AP6**

'Great multidisciplinary team-work. The NICU pharmacist is an integral part of the team. Effective rapport and communication between medical staff, nursing staff and pharmacist. Regular consultation for pharmacist input during medical rounds, and throughout the day.' **AP21***'Stable member of the team. Well experienced NICU pharmacist plays a very important liaison role between rotating medical staff, nurses and patients and families*.' **AP12**

Polish participants noted that doctors would sometimes reach out to the pharmacy for assistance with pharmacotherapy-related problems encountered on the NICU, however, input into medication management was generally limited to the preparation and delivery of medications to the ward. Given the indirect nature of the contact, pharmacists emphasised they communicated more often with nurses, and that contact with doctors was 'rare'.

'The level of contact is very formal, lack of awareness and confidence in pharmacists and their abilities.' **PP12**

'Doctors very rarely get in touch with the pharmacists, nurses do from time to time.'

PP16

A significantly higher proportion of Australian pharmacists (Aus = 70%, Pol = 19%, $p < 0.001$) identified that the current pharmacy services being delivered to NICUs in their local settings were meeting patient needs. In comparison, 81% of Polish pharmacists indicated that the pharmacotherapy requirements of neonatal patients were not being fulfilled by their pharmaceutical care system. Additionally, 59.1% of Polish participants deemed that pharmaceutical care in the NICU was currently non-existent.

DISCUSSION

The results from this study provide an insight into the types of clinical pharmacy services currently being delivered to NICUs in Australia and Poland. To date, there has been limited literature detailing pharmacist practice in the NICU in these countries. In order to promote the standardisation of practice, both nationally and worldwide, exploratory research needs to identify where gaps in practice lie.

According to the World Health Organisation (WHO), pharmacists should incorporate seven roles into their practice regardless of the setting they work in: care-giver, decision maker, communicator, manager, life-long learner, teacher and researcher.[17] However, the roles that are actually implemented and provided to patients may vary. Our results highlight that pharmaceutical care delivered to NICUs in Australia and Poland does differ significantly. These variances mainly lie within the apparent value placed on pharmacist services in this unit, with the Polish system seemingly steered towards traditional roles, such as dispensing. In contrast, Australian pharmacists are seen to provide a progressive level of practice, comprising both clinical and dispensary based services. These findings are mirrored by those found in other limited studies based in Poland and Australia respectively.[10 11 18 19]

Whilst the contrasts seen in each country may be attributed to differences in pharmaceutical legislation, practice culture and pharmacist training, ultimately, each healthcare system should strive for consistency in the delivery of services to ensure equal healthcare opportunities for patients. The WHO identifies health equity as a priority for healthcare systems worldwide, in promoting uniform healthcare services between and within hospital settings.[20] Standardised

care is particularly important in critically ill patients, such as those in the NICU, whose outcomes depend on the provision of high-quality care that consistently meets their needs. However, the WHO recognises that one of the biggest challenges in improving patient safety, is the uniform implementation of best practices across hospital settings nationally or internationally.[21] Leotsakos et.al. report that fluctuating patterns of healthcare services may result in varying patient outcomes and highlight that the standardisation of care practices can reduce costs, inefficiencies, and risk.[21] The WHO acknowledges that one of the most effective means of promoting practice uniformity is through the development of standardised practice tools that can be adapted and implemented in all hospital settings, both on a national and global scale, such as the WHO High 5's Project.[21] A reported benefit to standardisation, is the ability to benchmark services between settings, which allows policy-makers as well as healthcare professionals to compare patient outcomes and to interpret the significance and value of an intervention.[21] Ryan states that benchmarking of pharmacist services is best achieved using a three-tiered approach, comparing against best practice standards, against peers and against yourself, and over time.[22] Given our findings that pharmacist practice varies significantly in Polish and Australian NICU settings, it is imperative that future research focuses on identifying how standards can be widely operationalised, to bring practice in countries such as Poland closer in-line with practice in countries such as Australia.

LIMITATIONS

This survey was completed by only a proportion of hospital pharmacists in Australia and Poland, and may not be representative of all pharmacists in each country.

CONCLUSION

Pharmacist expectations of practice in the NICU were the same across both countries, however the actual pharmaceutical care services provided differed. Overall, the focus of pharmacy practice in NICUs in Australia and Poland is varied, ranging from clinically-centred services to traditional, dispensary-based medication supply duties respectively. However, the majority of participants from both countries highlighted that pharmacists should be involved in pharmacotherapy-related decision-making in the NICU. Disparities in practice may have

varying influences on the health outcomes of a sensitive patient population. Future research should focus on promoting the standardisation of pharmaceutical care services to this ward through the development of practice guidelines and policies.

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Table 1: Participant Characteristics

	AUSTRALIA (%)	POLAND (%)
NUMBER OF RESPONDENTS	30	22
GENDER OF RESPONDENTS		
Female	23 (76.7)	16 (72.7)
QUALIFICATIONS		
Bachelors Degree	8 (26.7)	0
Masters Degree	12 (40)	20 (90.9)
PhD Degree	1 (3.3)	0
Qualifications held by participants other than those specified in the survey	9 (30)	2 (9.1)
- Post-Graduate Certificate/Diploma	9 (30)	0
- Clinical Pharmacy Specialisation	0	2 (9.1)
SPECIALISED QUALIFICATIONS		
Yes	1 (3.3)	0
Postgraduate Certificate – (Neonatal And Paediatric Specific)	1 (3.3)	
No	29 (96.7)	22 (100)
POSITION IN THE HOSPITAL	N = 29	
Neonatal Pharmacist	13 (44.8)	0
Director Of Pharmacy	5 (17.2)	8 (36.4)
Pharmacist Working In Main Hospital Pharmacy	3 (10.3)	13 (59.1)

Other	8 (27.6)	1 (4.5)
Deputy Director	1 (3.4)	1 (4.5)
Senior Clinical Pharmacist	2 (6.9)	
Medicines Information Pharmacist	2 (6.9)	
Specialist Women, Youth And Children Pharmacist	2 (6.9)	
Aseptic CIVAS Pharmacist	1 (3.4)	
EXPERIENCE		
< 1 Year	6 (20)	2 (9.1)
Between 1-5 Years	13 (43.3)	12 (54.5)
Between 6-10 Years	4 (13.3)	1 (4.5)
> 10 Years	7 (23.3)	7 (31.8)
NUMBER OF BEDS IN NICU (RANGE)	8 - 110	4 – 28

DEFINITION OF A NEONATAL INTENSIVE CARE UNIT

"Neonatal unit that must be capable of assessing, diagnosing and managing all newborn infants requiring neonatal intensive care including infants:

- requiring continuing assisted ventilation via an endotracheal tube, and for the 24 hours following endotracheal tube removal

- requiring oxygen therapy (more than 60%) for more than four hours

- with tracheostomies requiring intermittent positive pressure ventilation (IPPV) or continuous positive airway pressure (CPAP)

- requiring a nasopharyngeal tube (without CPAP) to maintain airway patency

- requiring an arterial line for continuing blood gas and/or blood pressure monitoring

- having frequent seizures - undergoing major surgery, on the day of the procedure and

for 48 hours postoperatively, including:

- any procedure where a body cavity is opened
- repair of neural tube defect
- placement of a ventriculoperitoneal shunt or temporary ventricular drainage device

- requiring 1:1 nursing care"[23]

Table 2: Pharmaceutical care provided on the NICU in Australia and Poland

	AUSTRALIA (%)	**POLAND (%)**	**P-value (Comparison of proportions between Australian and Polish participants)**
IS THERE A PHARMACIST CURRENTLY PROVIDING SERVICES DIRECTLY ON THE NICU?	N = 30	N = 22	<0.001
Yes	28 (93.3)	1 (4.5)	
No	2 (6.7)	21 (95.5)	
IF NOT WORKING DIRECTLY ON THE NICU, WHERE ARE PHARMACISTS LOCATED?	N = 2	N = 22	<0.001
Dispensary	0	22 (100)	
Pharmacy Administration/Office	2 (100)	0	
IF NOT WORKING DIRECTLY IN THE NICU, DOES THE PHARMACIST HAVE ANY FORM OF CONTACT WITH THE NICU?	N = 2	N = 22	
Yes – Via Phone	0	12 (54.5)	
Yes – Yes, Both Phone And Email	1 (50)	9 (40.9)	
No	1 (50)	1 (4.5)	
IF NOT WORKING DIRECTLY IN THE NICU, HOW FREQUENTLY DOES THE PHARMACIST CONTACT THE NICU?	N = 1	N = 22	
Daily	1 (100)	14 (63.6)	
2 – 3 Times Per Week	0	4 (18.2)	
Upon Request	0	4 (18.2)	
HOW FREQUENTLY DOES A PHARMACIST DIRECTLY PROVIDE	N = 29	N = 1	

SERVICES IN THE NICU?			
Daily	21 (72.4)	1 (100)	
2 – 3 Times Per Week	3 (10.3)		
Monthly	1 (3.4)		
Upon Request	1 (3.4)		
Other	3 (10.3)		
AVERAGE DURATION OF PHARMACIST VISIT ON THE NICU	N = 29	N = 1	
Less Than 1 Hour	2 (6.9)	1 (100)	
Between 1 And 3 Hours	12 (41.4)		
Between 4 And 6 Hours	4 (13.8)		
All Day (7+ Hours)	11 (37.9)		
HOW MANY BEDS DOES THE PHARMACIST COVER PER VISIT?	N = 28	N = 1	
All	21 (75)		
More Than Half	6 (21.4)		
Less Than Half	1 (3.6)	1 (100)	

Table 3: Roles that are performed by pharmacists in the NICU[2]

ADMINISTRATIVE ROLES			
	AUSTRALIA (%)	**POLAND (%)**	**P-value (Comparison of proportions between Australian and Polish participants)**
Development/implementation of a drug formulary service	26 (89.7%) 29	21 (95.5%) 22	0.445
Attendance at non-clinical meetings i.e. Drug and Therapeutics Committee	21 (72.4%) 29	17 (77.3%) 22	0.693
Conducting quality assurance measures i.e. drug usage evaluations, workload documentation, auditing	25 (86.2%) 29	7 (31.8%) 22	<0.001
Management of the drug budget	16 (57.1%) 28	15 (68.2%) 22	0.425
Evaluation, selection and purchasing of pharmaceuticals for the unit	21 (72.4%) 29	21 (95.5%) 22	0.033
Development of drug policies/protocols/guidelines for the NICU	28 (96.6%) 29	5 (22.7%) 22	<0.001

[2] Proportions were calculated as the number of participants who responded to each question as the denominator

CLINICAL ROLES			
	AUSTRALIA (%)	**POLAND (%)**	**P-value (Comparison of proportions between Australian and Polish participants)**
Patient medication chart review	28 (96.6%) 29	3 (13.6%) 22	<0.001
Participation in medical ward rounds	25 (86.2%) 29	0 (0%) 22	<0.001
Monitoring the efficacy of pharmacotherapy in patients	28 (96.6%) 29	3 (13.6%) 22	<0.001
Documenting/monitoring Adverse Drug Events/Reactions	26 (89.7%) 29	15 (68.2%) 22	0.056
Documenting Medication Errors	28 (96.6%) 29	4 (18.2%) 22	<0.001
Evaluating patient's clinical laboratory tests	28 (96.6%) 29	0 (0%) 22	<0.001
Therapeutic Drug Monitoring (TDM)	28 (96.6%) 29	3 (13.6%) 22	<0.001
Immunisations	19 (67.9%) 28	1 (4.5%) 22	<0.001
Monitoring Total Parenteral Nutrition (TPN)	25 (86.2%) 29	18 (81.8%)	0.670

		22	
Participation in clinical meetings	23 (79.3%) 29	0 (0%) 22	<0.001
Calculating and recommending doses and dosing schedules for specific patients	28 (96.6%) 29	3 (13.6%) 22	<0.001
Assisting doctors in prescribing off-label/unlicensed medicines	28 (96.6%) 29	6 (27.3%) 22	<0.001
Identifying and performing interventions for individual patients to prevent or resolve drug therapy problems i.e. interactions, incompatibilities, allergies etc.	27 (93.1%) 29	4 (18.2%) 22	<0.001
Recommending drugs and contributing to the pharmacotherapy decision making process for specific patients	28 (96.6%) 29	2 (9.1%) 22	<0.001
Collaborating and discussing specific patients with doctors and nurses	27 (96.4%) 28	4 (18.2%) 22	<0.001

EDUCATION/COMMUNICATION/RESEARCH			
	AUSTRALIA (%)	**POLAND (%)**	**P-value (Comparison of proportions between Australian and Polish participants)**
Providing training/in-services for other health professionals on NICU related topics and drug related problems	27 (93.1%) 29	0 (0%) 22	<0.001

Contributing to and/or attending NICU related conferences	22 (75.9%) 29	7 (31.8%) 22	0.002
Involved in clinical trials	19 (67.9%) 28	13 (59.1%) 22	0.522
Involved in research related to neonatal pharmacotherapy	18 (64.3%) 28	0 (0%) 22	<0.001
Source of drug information - responding to information requests from health professionals on the ward	29 (100%) 29	19 (86.4%) 22	0.040
Counselling parents/carers of neonatal patients	25 (86.2%) 29	0 (0%) 22	<0.001

PROVISION OF MEDICINES			
	AUSTRALIA (%)	**POLAND (%)**	**P-value (Comparison of proportions between Australian and Polish participants)**
Dispensing prescriptions	24 (82.8%) 29	22 (100%) 22	0.040
Extemporaneous compounding of formulations for the NICU	22 (75.9%) 29	21 (95.5%) 22	0.057

Stocking the ward with essential medicines/house-keeping activities i.e. checking expiry dates, fridge temperatures etc.	19 (67.9%) 28	22 (100%) 22	0.003

Table 4: Pharmacist expectations towards roles that should be performed by pharmacists in the NICU[3]

ADMINISTRATIVE ROLES			
	AUSTRALIA (%)	**POLAND (%)**	**P-value (Comparison of proportions between Australian and Polish participants)**
Development/implementation of a drug formulary service	19 (86.4%) 22	21 (100%) 21	0.079
Attendance at non-clinical meetings i.e. Drug and Therapeutics Committee	13 (59.1%) 22	21 (100%) 21	0.001
Conducting quality assurance measures i.e. drug usage evaluations, workload documentation, auditing	21 (95.5%) 22	20 (95.2%) 21	0.973
Management of the drug budget	9 (40.9%) 22	18 (94.7%) 19	<0.001
Evaluation, selection and purchasing of pharmaceuticals for the unit	15 (68.2%) 22	19 (95%) 20	0.027
Development of drug policies/protocols/guidelines for the NICU	22 (100%) 22	17 (81%) 21	0.032

[3] Proportions were calculated as the number of participants who responded to each question as the denominator

CLINICAL ROLES			
	AUSTRALIA (%)	**POLAND (%)**	**P-value (Comparison of proportions between Australian and Polish participants)**
Patient medication chart review	23 (100%) 23	18 (90%) 20	0.120
Participation in medical ward rounds	20 (83.3%) 24	15 (75%) 20	0.495
Monitoring the efficacy of pharmacotherapy in patients	24 (100%) 24	18 (90%) 20	0.113
Documenting/monitoring Adverse Drug Events/Reactions	23 (100%) 23	19 (95%) 20	0.278
Documenting Medication Errors	22 (95.7%) 23	18 (90%) 20	0.468
Evaluating patient's clinical laboratory tests	20 (87%) 23	8 (40%) 20	0.001
Therapeutic Drug Monitoring (TDM)	23 (100%) 23	19 (95%) 20	0.278
Immunisations	13 (54.2%) 24	5 (25%) 20	0.050
Monitoring Total Parenteral Nutrition (TPN)	18 (78.3%) 23	19 (95%) 20	0.114

Participation in clinical meetings	19 (82.6%) 23	17 (85%) 20	0.832
Calculating and recommending doses and dosing schedules for specific patients	21 (95.5%) 22	17 (85%) 20	0.249
Assisting doctors in prescribing off-label/unlicensed medicines	23 (95.8%) 24	20 (100%) 20	0.356
Identifying and performing interventions for individual patients to prevent or resolve drug therapy problems i.e. interactions, incompatibilities, allergies etc.	23 (100%) 23	20 (100%) 20	Constant
Recommending drugs and contributing to the pharmacotherapy decision making process for specific patients	21 (91.3%) 23	20 (100%) 20	0.177
Collaborating and discussing specific patients with doctors and nurses	21 (91.3%) 23	19 (100%) 19	0.188

EDUCATION/COMMUNICATION/RESEARCH			
	AUSTRALIA (%)	**POLAND (%)**	**P-value (Comparison of proportions between Australian and Polish participants)**
Providing training/in-services for other health professionals on NICU related topics and drug related problems	20 (87%) 23	19 (95%) 20	0.365
Contributing to and/or attending NICU related conferences	16 (66.7%)	17	0.079

	24	(89.5%) 19	
Involved in clinical trials	14 (60.9%) 23	19 (95%) 20	0.008
Involved in research related to neonatal pharmacotherapy	16 (64%) 25	17 (85%) 20	0.113
Source of drug information - responding to information requests from health professionals on the ward	21 (91.3%) 23	20 (100%) 20	0.177
Counselling parents/carers of neonatal patients	23 (95.8%) 24	16 (84.2%) 19	0.193

PROVISION OF MEDICINES			
	AUSTRALIA (%)	**POLAND (%)**	**P-value (Comparison of proportions between Australian and Polish participants)**
Dispensing prescriptions	17 (73.9%) 23	20 (100%) 20	0.014
Extemporaneous compounding of formulations for the NICU	14 (60.9%) 23	20 (100%) 20	0.002
Stocking the ward with essential medicines/house-keeping activities i.e. checking expiry dates, fridge temperatures.	14 (60.9%) 23	20 (100%) 20	0.002

Table 5: Perceptions towards pharmacist integration into the NICU team[4]

	AUSTRALIA	POLAND	P-value (Comparison of proportions between Australian and Polish participants)
SHOULD PHARMACISTS BE ON THE NICU?	N = 30	N = 22	
Yes – Routinely Visiting	15 (50)	18 (81.8)	
Yes – Permanently Stationed	15 (50)	3 (13.6)	
No	0	1 (4.5)	
IS THE PHARMACIST CURRENTLY CONSIDERED PART OF MULTI-DISCIPLINARY NICU TEAM?	N = 30	N = 22	
Yes	26 (86.7)	0 (0)	<0.001
No	4 (13.3)	22 (100)	
SHOULD THE PHARMACIST BE CONSULTED AS PART OF THE TEAM WHEN MAKING PHARMACOTHERAPY RELATED DECISIONS?	N = 30	N = 22	
Yes	29 (96.7)	21 (95.5)	0.822
No	1 (3.3)	1 (4.5)	
RATE THE CURRENT INTER-PROFESSIONAL RELATIONSHIP BETWEEN PHARMACISTS AND THE MEDICAL AND NURSING STAFF	N = 30	N = 22	
Good	25 (83.3)	7 (31.8)	
Average	3 (10)	7 (31.8)	
Poor	1 (3.3)	7 (31.8)	
Non-Existent	1 (3.3)	1 (4.5)	
RATE CURRENT PHARMACEUTICAL CARE	N = 30	N = 22	

[4] Proportions were calculated as the number of participants who responded to each question as the denominator

PRACTICE IN THE NICU			
Good	18 (60)	2 (9.1)	
Average	10 (33.3)	3 (13.6)	
Poor	0	4 (18.2)	
Non-Existent	2 (6.7)	13 (59.1)	
ARE CURRENT PHARMACY SERVICES MEETING MEDICATION MANAGEMENT NEEDS IN THE NICU?	N = 30	N = 21	
Yes	21 (70)	4 (19)	<0.001
No	9 (30)	17 (81)	

3.4 PHARMACIST PERSPECTIVES TOWARDS PHARMACEUTICAL CARE SERVICES IN NEONATAL INTENSIVE CARE UNITS IN AUSTRALIA AND POLAND

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AUTHORS' CONTRIBUTIONS

Natalia Krzyżaniak was the primary author, collected the data, analysed and interpreted the findings, wrote and organised the manuscript. Beata V. Bajorek and Iga Pawłowska contributed to the idea, drafting of the manuscript, interpretation of findings, and critical review of the manuscript.

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ABSTRACT

OBJECTIVES: The purpose of this study was to, first, investigate the perceptions of neonatal intensive care unit (NICU) pharmacists and directors of pharmacy in Australia and Poland regarding their level of preparation to perform pharmaceutical care services in the NICU, and second, identify practice barriers and ways to improve services.

METHOD: A cross-sectional, electronic-based survey was distributed among NICU pharmacists and directors of pharmacy working in hospitals with a NICU in Australia and Poland. The survey comprised 12 items, and the majority of questions were fixed binary 'agree/disagree' answers, supplemented by open-ended questions.

RESULTS: A total of 29 participants from Australia and 20 from Poland completed the survey. Overall, it is apparent that Australian pharmacists felt more competent in clinical and educational roles than Polish participants. For 14 of the 15 clinical roles listed, more than 70% of Australian participants felt that pharmacists had a 'good' level of preparation to provide services to the NICU, including performing medication chart reviews (93.1%), performing pharmaceutical interventions (96.6%), and collaborating with medical and nursing staff (93.1%). A significantly higher proportion of Polish than Australian pharmacists agreed that changes were needed to improve pharmacist practice in the NICU (Aus = 53.6%, Pol = 90%, $p = 0.007$).

CONCLUSION: Future efforts should focus on developing guidelines and practice standards for sub-specialties of pharmacist practice, such as neonatology, to promote the standardization of practice.

Keywords: Neonatology, Clinical pharmacy, Quality of pharmacy services, International pharmacy services, Hospital pharmacy competencies, Australia, Poland

KEY POINTS:

- This study provides a preliminary insight into the reality of pharmacist practice in NICUs in Poland and Australia. Polish pharmacists perceived practice barriers at a higher rate than Australian participants, and were also more inclined to want changes to pharmacist roles to be made.
- These findings have implications for the development of standardized pharmacist practice policies for the NICU on a national and international scale to bridge the practice gap between countries.

- It is apparent that Polish pharmacists are unaccustomed to the concept of the pharmacist as a provider of direct patient care, and identify more with the distributive model of practice. Alternatively, Australian pharmacists associate more with the pharmaceutical care practice model, whereby pharmacists assume responsibility for patient care and are members of the inter-disciplinary treating team.

1. INTRODUCTION

The neonatal intensive care unit (NICU) is arguably a high priority ward in the hospital setting. With a vulnerable patient group made up of mostly premature infants experiencing serious comorbidities, who are also at high risk of experiencing long-term developmental consequences resulting from errors or unsuccessful treatment, the NICU is a high-pressure environment.[1] Furthermore, it is a large consumer of pharmacotherapy resources, with neonatal patients reportedly being prescribed an average of 8.6 medicines per patient.[2] A significant proportion of these medicines are deemed high risk in terms of the potential to do harm in the case of medication misadventure, and the higher reliance on pharmacotherapy in these patients adds another layer of complexity to the challenging medication use process.[3] As such the sub-specialty of the NICU warrants not only specialized medical care, but also specialized pharmaceutical care services.

The modern role of the pharmacist is built upon the concept of pharmaceutical care. Defined as: “the extent to which pharmacy services deliver effective, efficient, patient-centered, equitable and safe pharmacotherapy”, pharmaceutical care is a widely adopted practice worldwide.[4] However, the lack of minimum practice standards, protocols or key performance indicators, specifically tailored to the NICU means the quality and type of pharmacy services provided may vary within and between countries.[1] The World Health Organization emphasizes that global collaboration is essential in identifying best practices and in promoting the implementation of uniform services across settings.[5] While there are significant differences in practice between third- and first-world countries, it is apparent that pharmacy practice also varies between industrialized countries in Eastern Europe, as well as the USA, UK, Australia, New Zealand and Canada.[6] In Eastern European countries, such as Poland, the implementation of ward-based pharmaceutical services in hospitals is not extensively developed, with most efforts concentrated on dispensary-based functions.[7, 8] Alternatively, in Australia a 1991 study by Dunkley highlighted that pharmacists in NICUs performed services ranging from participation in multi-disciplinary ward rounds to reviews of patient medication charts.[9] The disparities in practice may be attributed to differing levels of emphasis placed on clinical pharmacy services during tertiary training. It is apparent that pharmacy programs in Poland are strongly focused on the traditional scope of pharmacist services i.e. dispensary-based compounding activities, with little to no focus on clinical pharmacy practice.[10] Alternatively, Australian universities seek to prepare pharmacy students for more integrated roles in ward environments, including simulation-based sessions

relating to patient care, as well as interdisciplinary teamwork.[11-13] These variances may influence the capability of the pharmacists to perform in clinical roles.

A recent study by Krzyzaniak et.al. demonstrated that the focus of NICU pharmaceutical care services in Australia and Poland varied significantly.[14] Australian pharmacists were seen to be mostly dedicated to clinical, ward-based services, whereas Polish pharmacists were accustomed to a compounding and distributive model of practice.[14] These differences may lead to varying levels of impact upon neonatal patient outcomes and medication error rates. Pharmacists are key members of the NICU treating team with significant potential to improve pharmacotherapy-related outcomes and reduce costs associated with the use of resources.[15] Therefore, we need to better understand the current state of pharmacy services in NICUs in each country, to identify specific pharmacy practice issues that lead to these significant differences. No studies have investigated pharmacist opinions on performing these services in NICUs or their perceived competencies in providing tailored clinical services to neonatal patients.

2. AIM OF THE STUDY

The purpose of this study was to identify the opinions and perceptions of NICU pharmacists and directors of pharmacy in Australia and Poland about the provision of pharmaceutical care services in the NICU. This research follows on from a previously published study that identified pharmaceutical care services provided in NICUs in these countries.[14] This research intended to provide greater context and understanding to the pharmacy practice system functioning in NICUs in Australia and Poland. Specific objectives included:

- Understanding pharmacists' perceived levels of preparedness to provide clinical services in the NICU
- Identifying what changes are needed to improve pharmaceutical care, and
- Identifying what barriers currently limit the implementation of pharmaceutical care in the NICU.

3. ETHICS APPROVAL

Ethics approval was obtained from the respective ethics committees at the University of Technology Sydney (UTS), Australia (REF NO. ETH16-1033) and the Medical University of Gdansk, Poland (REF NO. NKBBN/424/2016).

Participants were advised that their responses would be de-identified.

4. METHOD

A cross-sectional, online survey was distributed between January and May 2017 to hospital pharmacists and directors of pharmacy departments based in Australian and Polish hospitals with a NICU. The survey was created using SurveyMonkey and comprised 12 questions developed from the findings of a literature review and was adapted previous study by Katoue et.al. that assessed pharmacist perspectives on pharmaceutical care in hospitals in Kuwait.[16, 1] The majority of questions were fixed binary 'agree/disagree' answers accompanied by open-ended questions. It is important to highlight that this research is exploratory in nature, and as such, a mixed-methods approach involving both quantitative and qualitative data collection was adopted to ensure a fuller understanding of practice. The questions collected information on the participant characteristics, perceptions of the preparedness of pharmacists to provide pharmaceutical care, opinions on the barriers to the provision of pharmaceutical services and changes that are required to improve pharmaceutical care. All questions were pre-coded for data entry. The survey was pre-tested on a small group of Australian pharmacists for question clarity, and was refined accordingly. Participants were provided with surveys in their respective languages i.e., English or Polish. For all surveys that were administered in Polish, the results were translated into English via a tiered process: survey results were translated from Polish to English by one researcher (NK), then these translations were edited and verified by two co-researchers (IP, BB).

Emails containing a unique online survey link and a brief description of the survey were emailed to pharmacists. Respondents who requested a hard-copy version of the survey were sent one by post. Reminders were emailed to participants one month and one week before the end of the study period.

Responses from participants who completed at least 50% of the survey were included in the analysis. Incomplete responses were considered as missing values.

4.1 COMPARING AUSTRALIA AND POLAND

This research follows on from our previous studies investigating pharmacist practice in these two countries.[17, 18] Poland and Australia were selected as comparators as there is minimal collaboration between countries that practice under a more traditional scope of practice, such as those in Eastern Europe, and those with a more progressive and modern form of practice, such as the USA and Australia. A global perspective is important in order to facilitate the adoption of coherent policies and establishing best practices.[19] We thought a comparison between Australia and Poland would provide a new and unique perspective on pharmacist practice in NICUs.[18] It is important to note that, because of the highly specialized nature of the NICU, this study was intended to provide a preliminary understanding of the pharmacy practice background in each country.

4.2 PARTICIPANTS

According to published literature and the structure of the healthcare system in Poland, it is apparent that clinical pharmacy practice is less developed and as such all hospital pharmacists and directors of pharmacy at hospitals containing a NICU were invited to complete the survey.[14] All Australian pharmacists working in NICUs, as well as directors of pharmacy of hospitals that contained a NICU, were eligible to participate in the study, regardless of work status (i.e. full-time/part-time). Participants were contacted through the Paedpharm online pharmacists group and through publicly available registers in Poland and Australia i.e. Polish Register of Facilities delivering Medical Activities (Rejestr Podmiotów Wykonujących Działalność Leczniczą – RPWDL), and the Australian and New Zealand Neonatal Network (ANZNN) that list hospitals with neonatal intensive care units. Pharmacists were also asked to forward the survey among any interested colleagues and to any relevant networks to expand the sample.

A sample size calculation was performed for survey questions using a significance level of 5% and a desired power of 80%. The calculation was based on the precision around the point of estimate of effect. The point estimate of effect was the anticipated response to specific survey questions, based on the results of previous research. [8, 7, 20] The target sample size needed was found to be 64 participants total.

4.3 DATA ANALYSIS

Quantitative data were analyzed via descriptive statistics (percentages, frequencies) using the Statistical Package for the Social Sciences (SPSS) Version 22. The Chi-square test was used to test the association between independent categorical variables (e.g., nationality - Australian and Polish) and dependent variables (e.g., proportion of agree/disagree responses to questions relating to: perceptions of the preparedness of pharmacists to provide pharmaceutical care, opinions on the barriers to the provision of pharmaceutical services and changes that are required to improve pharmaceutical care). Statistical significance was accepted at a *p* value of <0.05.

Qualitative data (i.e., pharmacist responses to open-answer questions) were thematically analyzed. Manual inductive coding was used, i.e. significant statements in participants responses were identified and subsequently categorized into key themes around the study objectives.[21] To ensure correct interpretation and coding of data into emerging themes, three researchers (NK, IP, BB) independently analyzed the data before comparing the themes to attain consensus. The analysis was guided by Braun and Clarke's approach i.e., an essentialist/realist theoretical framework was adopted to reflect on the experiences, meanings and the reality of participants.[22] To ensure comprehension, the responses recorded were read several times and patterns were coded into non-overlapping themes and subthemes.

The qualitative responses of participants are represented by the code 'AP' for Australian pharmacists and 'PP' for Polish pharmacists.

5. RESULTS

As this is a very narrow area of clinical pharmacy practice, the numbers of possible participants in each country were limited. We do not know how many pharmacists subscribe to the Paedpharm online pharmacists register, or how many surveys were distributed among colleagues within each hospital. As such, the response rate was calculated with the denominator being the number of surveys sent out electronically by researchers. A total of 55 surveys were sent out to Australian participants, of which 29 responded (response rate = 52.7%) and 40 surveys were sent out to Polish participants, of which 20 responded (response rate = 50%) completed the survey (Table 1).

The majority of participants in each country were female (75.9% in Australia and 85% in Poland). Most Polish pharmacists (65%) were employed as general hospital pharmacists, and 48.3% of Australian participants identified themselves as NICU pharmacists.

5.1 PERCEIVED LEVELS OF COMPETENCY TO PERFORM PHARMACEUTICAL CARE SERVICES

Participants were asked to provide their opinions on their perceived preparedness in providing pharmaceutical care services to the NICU. (Table 2) Overall, it is apparent that Australian pharmacists felt more competent in the provision of clinical and educational roles than did Polish participants. In 14/15 clinical roles listed, more than 70% of Australian participants felt that pharmacists had a 'good' level of preparation to provide services to the NICU, including performing medication chart reviews (93.1%), performing pharmaceutical interventions (96.6%), and collaborating with medical and nursing staff (93.1%). In comparison, most Polish pharmacists identified a 'poor' level of preparedness to deliver 10 of the 15 clinical services including participation in ward rounds (85%, $p < 0.001$), evaluating patients' laboratory test results (90%, $p < 0.001$), and recommending medications and contributing to the pharmacotherapy decision-making process (65%, $p < 0.001$). Interestingly, Polish pharmacists felt well prepared to provide one clinical role: monitoring total parenteral nutrition (90%). Overall, Polish pharmacists felt most confident in their roles relating to the provision of medicines. All (100%) of Polish participants agreed that they had a 'good' level of preparation in the dispensing and extemporaneous compounding of medicines for this ward.

When considering administrative roles, a significantly higher proportion of Australian than Polish pharmacists agreed that they were competent in the provision of two administrative services: conducting quality assurance measures (Aus = 72.4%, Pol = 30%, $p = 0.001$) and creating medication policies and guidelines for the NICU (Aus = 86.2%, Pol = 30%, $p < 0.001$). Furthermore, a significantly higher proportion of Australian than Polish pharmacists also felt adequately prepared to counsel parents of patients (Aus = 89.7%, Pol = 5%, $p < 0.001$) to be a source of medication information for NICU medical and nursing staff (Aus = 89.7%, Pol = 45%, $p = 0.001$), and to provide training on topics related to neonatal pharmacotherapy (Aus = 79.3%, Pol = 5%, $p < 0.001$).

5.2 CURRENT BARRIERS

Significant differences were identified when considering pharmacist perceptions of barriers to pharmacist practice in the NICU (Table 3). More than 80% of Polish participants agreed to 10 of the 16 barrier items. In comparison, Australian participants had a low perception of barriers, with most responses remaining lower than 45%. The barriers most commonly referred to by Polish pharmacists related to a lack of legislation regulating pharmacist practice on the NICU (Aus = 34.5%, Pol = 90%, $p < 0.001$), lack of an apparent need for a pharmacist to be present on this ward (Aus = 17.2%, Pol = 85%, $p < 0.001$) and medical and nursing staff ignorance of pharmacist competencies and skills (Aus = 34.5%, Pol = 85%, $p < 0.001$). Participants' qualitative responses also referred to a lack of guidelines or policies at both local and national levels to guide their practice. They emphasized the absence of legislation specifying what pharmaceutical care services should be provided directly on the ward.

> '*Lack of procedures*.' **PP11**

> '*It is not legally regulated, it does not exist in hospital practice*.' **PP15**

Furthermore, they noted reluctance on the part of doctors to accept pharmacists as partners in the medication management process.

> *'…in our country, however, the division of roles between staff is roles is traditional/classic*.' **PP2**

> '*Pharmacists are not treated as equal co-workers*.' **PP12**

> '*Doctors do not know and do not understand the potential of a pharmacist, and as such they are not willing to co-operate… there is a lack of consent from the doctors. In Poland, clinical pharmacists are rare*.' **PP15**

Conversely, Australian pharmacists highlighted that the greatest barriers apparent in their healthcare system included a shortage of pharmacy staff (Aus = 72.4%, Pol = 100%, $p = 0.010$), lack of pharmacist time to deliver the necessary services to the NICU (Aus = 65.5%, Pol = 80%, $p = 0.270$) and a lack of pharmacists with the skills and knowledge necessary to be able to practice in the NICU (Aus = 62.1%, Pol = 90%, $p = 0.030$).

> '*On the days there is pharmacy cover in NICU there is good pharmaceutical practice but there is often a staff deficit not allowing full coverage of the ward*.' **AP24**

Not enough time to dedicate to unit as role is shared with other ward responsibilities, outpatient clinics and dispensary duties.' **AP15**

'*Bed to pharmacist ratio could be better to allow more detailed input into each patient's care*.' **AP18**

Interestingly, Polish participants also strongly identified with these barriers, particularly pharmacist shortages in the hospital. Due to limited funding and subsequent staffing deficiencies were identified as key reasons for the lack of clinical pharmacy practice in the NICU. As a result, pharmacists are overloaded with dispensary-based duties and are unable to provide clinical activities on the ward.

'*At the hospital, there are only a few pharmacists employed, about a dozen or so, to cover about 1200 beds, it is physically unfeasible*.' **PP18**

Participants also felt that their formal training (pharmacy degree) did not adequately prepare them for clinical practice, and they, therefore, lacked confidence in making recommendations to the NICU team.

'lack of pharmacist experience in this area….' **PP15**

'… neither the university studies nor the post-graduate specialization courses prepare pharmacists for such a role. We do not have enough knowledge to be able to advise doctors.' **PP18**

5.3 CHANGES NEEDED TO IMPROVE SERVICES

A significantly higher proportion of Polish pharmacists agreed that changes were needed to improve pharmacist practice in the NICU (Aus = 53.6%, Pol = 90%, p = 0.007) (Table 4). Indeed, all (100%) Polish participants agreed to all 11 of the proposed changes listed. The qualitative responses from Polish pharmacists highlighted that changes were necessary to improve patient safety and the quality of care. Furthermore, they acknowledged that the current healthcare system did not use pharmacists and their skills to their maximum potential.

'*Changes to the role of the pharmacist in the NICU would increase the safety of pharmacotherapy, which would have a positive influence on pharmacoeconomy and improve a patients level of comfort*.' **PP1**

'*The knowledge of pharmacists is not fully utilized and therefore underestimated*.' **PP12**

'The pharmacist would introduce an alternative point of view and bring knowledge that would increase the safety of treatment (e.g. with interactions, too high doses), and improve economics, leading to better medicines management.' **PP16**

In comparison, Australian pharmacists most commonly felt that changes needed to be directed at increasing the staffing of the pharmacy department to allow more pharmacists to be introduced to the NICU (91.3%), providing education and training opportunities for pharmacists in the fields of neonatology, and clinical pharmacy (86.4%), and increasing pharmacists' own motivation towards practice on this ward (86.4%).

'*I would like to see greater involvement of pharmacists in activities that directly improve clinical outcomes for patients. This includes a variety of clinical and non-clinical activities, including research*.' **AP4**

'*All NICUs should have their own dedicated NICU clinical pharmacists*.' **AP5**

6. DISCUSSION

The findings of this study highlight significant differences in the perceptions of Polish and Australian pharmacists towards practice in the NICU. To our knowledge, this is the first study to compare pharmacist opinions about pharmaceutical care services provided to NICUs in two countries. It is important to note that this research is exploratory in nature and was intended to provide context and understanding of the differences in practice seen in NICUs in Australia and Poland. Future research is aimed at further qualitative studies exploring not only pharmacist perceptions of practice, but also other healthcare professionals in this setting i.e., doctors and nurses, to ensure a fuller insight into practice.

One concept arising from the data that warrants discussion is the finding that pharmacists in Poland and Australia held significantly different perceptions of their own competencies in delivering pharmaceutical care to the NICU. Polish pharmacists felt most confident about delivering traditional pharmacist activities, including dispensing and extemporaneous compounding. This is not unexpected, as the published literature indicates that pharmacist practice in Poland is often limited to dispensary-based activities.[7] However, their perceived competence in providing clinical and educational-based roles was lower. In comparison, Australian participants were particularly confident about the clinical and educational areas of

practice, signifying more experience and familiarity with these services. This is also reflected in the literature, highlighting the integrated role of the Australian pharmacist in pharmacotherapy-related decision-making in hospital wards.[23, 24] It is apparent that Polish pharmacists are unaccustomed to the concept of the pharmacist as a provider of direct patient care, and identify more with the distributive model of practice. Conversely, Australian pharmacists associate more with the pharmaceutical care practice model, wherein pharmacists assume responsibility for patient care and are members of the inter-disciplinary treating team.[25]

Furthermore, Polish pharmacists perceived practice barriers at a higher rate than Australian participants, and were also more inclined to want changes to pharmacist roles. In particular, Polish participants commonly highlighted throughout the survey, the apparent lack of support from doctors and nurses for the pharmacist's role in the NICU. The absence of interdisciplinary collaboration with the hospital pharmacist was previously discussed by Piecuch et.al. who highlighted that the hierarchical structure of the healthcare system in Poland does not encourage collaborative practice.[26] Rather, the doctor is seen to dominate treatment, and pharmacists are not involved in the pharmacotherapy process, aside from dispensing and preparing medicines. In comparison, Australian participants felt valued by the medical and nursing staff, and instead voiced concerns with the staffing of the NICU and with ensuring a full-range of services are provided. As such, the focus of pharmacist concerns are different for each country. This also further highlights the need for insights from other stakeholders/members of the NICU team.

While these differences in perceptions may be attributed to contrasting healthcare systems, legislation, practice culture and educational systems, these findings are important to consider as they provide an insight into the reality of pharmacist practice in NICUs in Poland and Australia. The barriers identified and the perceptions of pharmacist competence highlight the gap in practice observed between Poland and Australia. These differences in perceptions raise the question – what impact are these different levels of service having on the outcomes of such a vulnerable patient group? The World Health Organization (WHO) and International Pharmaceutical Federation (FIP) both call for practice equality and the standardization of practice on a global scale.[27, 28] Efforts by the FIP have brought about the Basel Statements, which have sought to standardize hospital pharmacy practice on an international scale from a general perspective.[29] However, there is a need for the development of such standards for sub-specialties in pharmacy, where patients, such as those in the NICU, require unique considerations from a pharmacotherapy perspective. The Society of Hospital Pharmacists

Australia (SHPA) has recognized this need and introduced specialty support groups, ranging from cardiology, infectious diseases and emergency medicine to rural and remote practice, to encourage the exchange of information and the ability for pharmacists to develop their specialty practice.[30] These practice groups have the potential to then define criteria outlining essential pharmacist roles for their respective sub-specialties.

These findings have implications for the development of standardized pharmacist practice policies for the NICU and bridging the practice gap between countries. Neonatal patients are a unique population that have specific pharmacotherapy needs and requirements that differ from other patient groups. As such, pharmacist practice provided to this ward should be aimed at a consistent, high-quality and homogenous level of care to allow equal opportunity for these high-risk and vulnerable patients to achieve the best possible outcomes. Future research should be directed at investigating the barriers contributing to practice differences, and identifying facilitators that would assist in bridging the gap in NICU pharmacist practice within and between countries.

6.1 LIMITATIONS

While this study is the first to report on pharmacist perceptions of their preparation for practice in Australian and Polish NICUs, the findings are subject to some limitations. A major limitation is that the assessment of practice preparedness and competence is highly prone to self-report bias. The traditional pharmacy practice structure in Poland means the number of pharmacists who considered their role to be that of a NICU pharmacist differed from that in Australia. Pharmacists subjectively self-assessed their capabilities in performing roles in the four listed domains. Therefore, the findings may be overestimated because of the potential for social desirability bias. Furthermore, individual participants may have interpreted differently the good/average/ poor categories and the pharmacist practice roles, i.e., total parenteral nutrition monitoring. Therefore, results should be interpreted with caution.

The low response rate and the small number of participants mean the survey data may not be representative of all pharmacists in Poland and Australia or generalizable across settings in each country.

The sample size was not reached, but this can be attributed to the narrow scope and highly specialized nature of practice and the subsequent limited possible number of participants who

could be included in this study. As such, further research is needed to verify these findings.

7. CONCLUSION

Overall, it is apparent that Polish pharmacists are more confident in providing traditional pharmacy services to the NICU than other services. In comparison, Australian pharmacists felt competent in providing more advanced roles, including clinical and educational services. Statistically significant differences were also perceived when considering the barriers currently limiting practice in the NICU, with Polish pharmacists facing reluctance from doctors and nurses. Future efforts should focus on developing pharmacist practice guidelines and practice standards for the sub-specialty of neonatology to promote the standardization of practice.

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Table 1: Participant Characteristics

	AUSTRALIA (%)	POLAND (%)
NUMBER OF RESPONDENTS	29	20
GENDER OF RESPONDENTS		
Female	22 (75.9)	17 (85)
QUALIFICATIONS		
Bachelors Degree	8 (27.6)	0
Masters Degree	12 (41.4)	19 (95)
PhD Degree	1 (3.4)	0
Other	8 (27.6)	1 (5)
Post-Graduate Certificate/Diploma	8	0
Clinical Pharmacy Specialisation	0	1
SPECIALISED QUALIFICATIONS		
Yes	2 (6.9)	0
Postgraduate Certificate – (Neonatal And Paediatric Specific)		
No	27 (93.1)	20 (100)
POSITION IN THE HOSPITAL		
Neonatal Pharmacist	14 (48.3)	0
Director Of Pharmacy	5 (17.2)	5 (25)
Pharmacist Working In Main Hospital Pharmacy	3 (10.3)	13 (65)
Other	7 (24.1)	2 (10)

Hospital Pharmacy Co-ordinator		1 (50)
Deputy Director	1 (14.3)	
Clinical Pharmacist	2 (28.6)	1 (50)
Medicines Information Pharmacist	2 (28.6)	
Specialist Women, Youth And Children Pharmacist	1 (14.3)	
Aseptic CIVAS Pharmacist	1 (14.3)	
EXPERIENCE		
< 1 Year	6 (20.7)	2 (10)
Between 1-5 Years	13 (44.8)	11 (55)
Between 6-10 Years	3 (10.3)	1 (5)
> 10 Years	7 (24.1)	6 (30)
NUMBER OF BEDS IN NICU (RANGE)	8 - 110	5 – 28

Table 2: Pharmacist Perceived Competencies towards Pharmacist Roles in the NICU

ADMINISTRATIVE ROLES							
	AUSTRALIA (%) N = 29			**POLAND (%) N = 20**			**P-value ***
	GOOD	AVERAGE	POOR	GOOD	AVERAGE	POOR	
Development/implementation of a drug formulary service	22 (75.9)	7 (24.1)	0	15 (75)	5 (25)	0	0.945
Attendance at non-clinical meetings i.e. Drug and Therapeutics Committee	21 (72.4)	6 (20.7)	2 (6.9)	10 (50)	8 (40)	2 (10)	0.269
Conducting quality assurance measures i.e. drug usage evaluations, workload documentation, auditing	21 (72.4)	7 (24.1)	1 (3.4)	6 (30)	5 (25)	9 (45)	0.001
Management of the drug budget	14 (48.3)	9 (31)	6 (20.7)	9 (45)	8 (40)	3 (15)	0.775
Evaluation, selection and purchasing of pharmaceuticals for the unit	19 (65.5)	8 (27.6)	2 (6.9)	17 (85)	1 (5)	2 (10)	0.133
Development of drug policies/protocols/ guidelines for the NICU	25 (86.2)	4 (13.8)	0	6 (30)	4 (20)	10 (50)	<0.001

CLINICAL ROLES							
	AUSTRALIA (%) N = 29			**POLAND (%) N = 20**			**P-value ***
	GOOD	AVERAGE	POOR	GOOD	AVERAGE	POOR	
Patient medication chart review	27 (93.1)	1 (3.4)	1 (3.4)	7 (35)	2 (10)	11 (55)	<0.001
Participation in medical ward rounds	21 (72.4)	5 (17.2)	3 (10.3)	2 (10)	1 (5)	17 (85)	<0.001
Monitoring the efficacy of pharmacotherapy in patients	26 (89.7)	2 (6.9)	1 (3.4)	1 (5)	5 (25)	14 (70)	<0.001
Documenting/monitoring Adverse Drug Events/Reactions	24 (82.8)	4 (13.8)	1 (3.4)	5 (25)	12 (60)	3 (15)	<0.001
Documenting Medication Errors	25 (86.2)	3 (10.3)	1 (3.4)	4 (20)	6 (30)	10 (50)	<0.001
Evaluating patients clinical laboratory tests	22 (75.9)	6 (20.7)	1 (3.4)	1 (5)	1 (5)	18 (90)	<0.001
Therapeutic Drug Monitoring (TDM)	24 (82.8)	4 (13.8)	1 (3.4)	3 (15)	5 (25)	12 (60)	<0.001
Immunisations	17 (58.6)	6 (20.7)	6 (20.7)	0	3 (15)	17 (85)	<0.001
Monitoring Total Parenteral Nutrition (TPN)	21 (72.4)	7 (24.1)	1 (3.4)	18 (90)	2 (10)	0	0.296
Participation in clinical meetings	23 (79.3)	5 (17.2)	1 (3.4)	1 (5)	7 (35)	12 (60)	<0.001

Calculating and recommending doses and dosing schedules for specific patients	26 (89.7)	2 (6.9)	1 (3.4)	5 (25)	8 (40)	7 (35)	<0.001
Assisting doctors in prescribing off-label/unlicensed medicines	27 (93.1)	2 (6.9)	0	5 (25)	6 (30)	9 (45)	<0.001
Identifying and performing interventions for individual patients to prevent or resolve drug therapy problems i.e. interactions, incompatibilities, allergies etc.	28 (96.6)	0	1 (3.4)	4 (20)	8 (40)	8 (40)	<0.001
Recommending drugs and contributing to the pharmacotherapy decision making process for specific patients	24 (82.8)	4 (13.8)	1 (3.4)	1 (5)	6 (30)	13 (65)	<0.001
Collaborating and discussing specific patients with doctors and nurses	27 (93.1)	1 (3.4)	1 (3.4)	2 (10)	8 (40)	10 (50)	<0.001

EDUCATION/COMMUNICATION/RESEARCH							
	AUSTRALIA (%) N = 29			POLAND (%) N = 20			P-value *
	GOOD	AVERAGE	POOR	GOOD	AVERAGE	POOR	
Providing training/in-services for other health professionals on NICU related topics and drug related problems	23 (79.3)	6 (20.7)	0	1 (5)	4 (20)	15 (75)	<0.001
Contributing to and/or attending NICU related conferences	17 (58.6)	9 (31)	3 (10.3)	6 (30)	6 (30)	8 (40)	0.035
Involved in clinical trials	18 (62.1)	7 (24.1)	4 (13.8)	13 (65)	2 (10)	5 (25)	0.348
Involved in research related to neonatal pharmacotherapy	14 (48.3)	8 (27.6)	7 (24.1)	5 (25)	3 (15)	12 (60)	0.040
Source of drug information - responding to information requests from health professionals on the ward	26 (89.7)	3 (10.3)	0	9 (45)	5 (25)	6 (30)	0.001
Counselling parents/carers of neonatal patients	26 (89.7)	1 (3.4)	2 (6.9)	1 (5)	3 (15)	16 (80)	<0.001

PROVISION OF MEDICINES							
	AUSTRALIA (%) N = 29			**POLAND (%) N = 20**			**P-value ***
	GOOD	AVERAGE	POOR	GOOD	AVERAGE	POOR	
Dispensing prescriptions	25 (86.2)	4 (13.8)	0	20 (100)	0	0	0.083
Extemporaneous compounding of formulations for the NICU	23 (79.3)	4 (13.8)	2 (6.9)	20 (100)	0	0	0.095
Stocking the ward with essential medicines/house-keeping activities i.e. checking expiry dates, fridge temperatures etc.	21 (72.4)	6 (20.7)	2 (6.9)	18 (90)	2 (10)	0	0.263

* **(Comparison of proportions between Australian and Polish participants)**

Table 3: Barriers to Pharmacist Practice in the NICU

Barriers	AUSTRALIA N = 29 (%)	POLAND N = 20 (%)	P-value (Comparison of proportions between Australian and Polish participants)
Lack of policy/legislation for pharmacists to be regulated to perform services in the NICU	10 (34.5%)	18 (90%)	<0.001
Lack of pharmacist time to perform duties	19 (65.5%)	16 (80%)	0.270
Lack of pharmacy staff i.e. not enough pharmacy technicians to cover dispensing	21 (72.4%)	20 (100%)	0.010
There is no need for pharmacist to be on NICU	5 (17.2%)	17 (85%)	<0.001
Doctors/nurses are unaware of what services pharmacists can provide in the NICU	10 (34.5%)	17 (85%)	<0.001
Doctor/nurse reluctance or resistance to pharmacist role in the NICU	6 (20.7%)	15 (75%)	0.001
Lack of financial compensation/remuneration for pharmacists to perform activities on the NICU	10 (34.5%)	17 (85%)	<0.001
Pharmacist is physically removed from the NICU	6 (20.7%)	6 (30%)	0.456

A lack of clinical pharmacy training/knowledge opportunities related to neonatal practice	14 (48.3%)	16 (80%)	0.025
Pharmacists are not interested in performing clinical pharmacy services in the NICU	2 (6.9%)	4 (21.1%) N = 19	0.147
Unwilling to change current practice	9 (31%)	4 (20%)	0.390
Lack of communication with pharmacists	5 (17.2%)	10 (52.6%) N = 19	0.010
Lack of support from administration/hospital	13 (44.8%)	18 (90%)	0.001
Lack of confidence in own ability	9 (31)	11 (55)	0.093
Lack of pharmacists with the necessary skills and training	18 (62.1%)	18 (90%)	0.030
Lack of recognition of the contribution of the pharmacist to NICU care	12 (41.4%)	4 (20%)	0.117

Table 4: Changes needed to current practice

Is there a need to change pharmacist roles in the NICU?	**AUSTRALIA N = 28**	**POLAND N = 20**	**P-value (Comparison of proportions between Australian and Polish participants)**
YES	15 (53.6)	18 (90)	0.007
TYPES OF CHANGES NEEDED	**AUSTRALIA N = 22 (%)**	**POLAND N = 20 (%)**	**P-value (Comparison of proportions between Australian and Polish participants)**
Increased support from the hospital administration i.e. from hospital directors in creating and funding clinical pharmacist positions.	17 (77.3%)	20 (100%)	0.023
Increased levels of staffing in the pharmacy	21 (91.3%) N = 23	20 (100%)	0.177
Increased levels of communication with pharmacists	14 (63.6%)	20 (100%)	0.003
Increasing the level of support from doctors and nurses for the role of the pharmacist in the NICU	14 (63.6%)	20 (100%)	0.003
Increasing educational opportunities for pharmacists related specifically to	19 (86.4%)	20 (100%)	0.087

neonatal/paediatric pharmacotherapy			
Providing more training for pharmacists on clinical pharmacy services	19 (86.4%)	20 (100%)	0.087
Increasing nurse/doctor awareness of the roles and services that pharmacists can provide in the NICU	15 (68.2%)	20 (100%)	0.006
Increasing pharmacist salaries	9 (40.9%)	20 (100%)	<0.001
Creating specific NICU clinical pharmacist positions in the hospital i.e. organisational changes	17 (77.3%)	20 (100%)	0.023
Legislative changes regulating clinical pharmacy practice in the NICU	9 (40.9%)	20 (100%)	<0.001
Pharmacists own motivation and interest towards improving upon the current level of practice	19 (86.4%)	20 (100%)	0.087

CHAPTER FOUR

FOCUS ON TEAMWORK

4.1 INTRODUCTION

Having identified pharmacists' perspectives on practice, our research also sought to explore the attitudes of medical and nursing staff, as well as medical and pharmacy students towards pharmacy services in the NICU. The opinions of these groups of professionals give a greater understanding of the practice culture evident within each country and the form of pharmacist interaction with the multi-disciplinary team on the NICU. The perspectives of Polish students give an insight into how the tertiary system is structured and how they will approach this form of inter-disciplinary collaboration as future health professionals. Due to the less-established nature of pharmacy practice in hospitals in Poland, only Polish medical and pharmacy students were surveyed during this part of the research to give greater understanding around the level of interdisciplinary education provided to pharmacy and medical students.

4.2 PHARMACEUTICAL CARE IN NICUS IN AUSTRALIA AND POLAND: ATTITUDES AND PERSPECTIVES OF DOCTORS AND NURSES

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AUTHORS' CONTRIBUTIONS

Natalia Krzyżaniak was the primary author, collected the data, analysed and interpreted the findings, wrote and organised the manuscript. Beata V. Bajorek and Iga Pawłowska contributed to the idea, drafting of the manuscript, interpretation of findings, and critical review of the manuscript.

Production Note:
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ABSTRACT

BACKGROUND: A multidisciplinary and collaborative team network is essential in ensuring positive health outcomes for critically ill neonatal patients.

OBJECTIVE: To investigate the perceptions of neonatal intensive care unit (NICU) doctors and nurses in Australia and Poland towards pharmaceutical care services in the NICU.

METHOD: A cross-sectional, anonymous electronic-based survey was distributed between January and April 2017 among a sample of NICU doctors, nurses and midwives.

RESULTS: A total of 77 participants from Australia and 93 from Poland completed the survey. Overall, from the perspectives of medical and nursing staff, it is apparent that clinical pharmacy practice on the NICU is more established in Australia than in Poland. Only 8.6% of Polish participants reported that a pharmacist worked directly on the NICU, in comparison with 87% of Australian participants ($p < 0.001$). The main roles performed by pharmacists in Polish NICUs related to the provision of medicines, whereas Australian pharmacists were highly involved in all aspects of pharmacotherapy, particularly in the clinical and education domains.

CONCLUSION: Future efforts should focus on how practice is structured in each country, and what support can be implemented from educational, cultural and legislative levels to enable better pharmacist integration into the NICU therapeutic team.

KEY WORDS: Inter-disciplinary collaboration, NICU/neonates, clinical pharmacist, pharmaceutical care

PRECIS: Statistically significant differences were observed among the opinions and perspectives of medical and nursing staff across Australia and Poland towards pharmaceutical care in the NICU.

INTRODUCTION

Due to the complex nature of the neonatal intensive care unit (NICU), a multidisciplinary and collaborative team network is essential in ensuring positive health outcomes for critically ill newborn patients.[1] Alongside nursing and medical staff, the pharmacist plays an important role in guiding the safe, effective and appropriate use of medicines and in preventing any adverse effects. Several studies have documented the positive effects of collaborative relationships in healthcare, with the pharmacist included within the team facilitating better patient care and clinical results.[2-4] Makowsky et.al. highlighted that pharmacist integration into the therapeutic team enhanced patient outcomes by improving team pharmacotherapy decision-making, continuity of care and patient safety.[5]

A recent literature review highlighted that pharmacist roles performed in NICUs internationally varied significantly. Pharmacy practice in the USA, UK, South Africa and Australia was found to be more interactive with patients and the ward environment with a broad range of roles identified, in comparison to the European countries which did not have an extensive scope of practice.[6] This diversity in practice may have varying impacts upon neonatal patient outcomes. The World Health Organization (WHO) is a strong advocate for health equity and encourages healthcare systems on a global scale to provide universal and standardised safe, high-quality and effectives services.[7] They further highlight that international collaboration in health research is a valuable mechanism for advancing knowledge, promoting the standardisation of healthcare services and strengthening research capacity.[8] When considering Australia and an industrialised Eastern European country, such as Poland, there is not a strong collaborative research background identified within published literature – particularly within the domain of pharmaceutical care services. The subsequent differences in health care systems and practice cultures between the two countries may influence medication management on this ward. Indeed, a recent study by Krzyzaniak et.al. reported that the focus of pharmaceutical care services differed between the two countries, ranging from clinically-centered services in Australia to traditional, dispensary-based medication supply duties in Poland.[9] Considering the disparities in practice, there has been little investigation conducted into exploring the practice context affecting the services being provided in either country. In particular, there is no corresponding literature investigating doctor-nurse-pharmacist relationships in the NICU. Due to the multidisciplinary nature of the NICU, there is a need to explore these relationships and identify how other health professionals view and understand the role of the pharmacist in the NICU. The perspectives of doctors and nurses are helpful in better understanding the current situation of pharmaceutical care in the NICU as well as the

pharmacy practice culture in each country. Furthermore, they have potential in identifying areas where attention is needed and what improvements are required to advance practice.[10]

AIM OF THE STUDY

The aim of this study was to explore the attitudes and perceptions of medical and nursing health care professionals towards the role of the pharmacist and the provision of pharmaceutical care in the NICU. Specific objectives include:

- Identifying which pharmacists roles are currently provided to NICUs in Australia and Poland
- Understanding which pharmaceutical care services are perceived by doctors and nurses to be essential in the NICU
- Identifying what changes are needed to improve pharmaceutical care

ETHICS APPROVAL

A cross-sectional survey was distributed among doctors and nurses working in NICUs across Australia and Poland between January 2017 and April 2017. Ethics approval was sought and obtained from the respective ethics committees at the University of Technology Sydney (UTS), Australia (UTS HREC REF NO. ETH16-1033) and the Medical University of Gdansk (GUMed), Poland (GUMed HREC REF NO. NKBBN/424/2016).

Participants were assured of confidentiality and were informed that their responses would be de-identified.

METHOD

PARTICIPANTS

The study population was made up of doctors, nurses and midwives who were currently working within level 3 NICUs in Australia and Poland. Participants were identified through publicly available registers in Poland and Australia (Register of Facilities delivering Medical Activities - Rejestr Podmiotów Wykonujących Działalność Leczniczą – RPWDL, and the

Australian New Zealand Neonatal Network - ANZNN), which list hospitals with neonatal intensive care units.

To determine an appropriate sample frame, a sample size calculation was performed for each question using a significance level of 5% and a desired power of 80%. The calculation was based on the precision around the point of estimate of effect, i.e., the anticipated response to specific survey questions, guided by the results of previous research. [11-13] The target sample size needed was found to be 64 participants total.

SURVEY

The electronically-based questionnaires were self-administered and were distributed to participants via email by one researcher (NK). Participants who preferred a hard-copy version of the survey were forwarded a version by post. The surveys were made available to participants in the languages of their respective countries i.e. English and Polish. For all surveys that were administered in Polish, the results were translated into English via a tiered process; survey results were translated from Polish to English by one researcher (NK); these translations were edited and verified by two researchers (IP, BB) to determine whether the language was correct.

The survey comprised 20 questions and the majority of questions were fixed binary 'agree/disagree answers, supplemented by open-ended questions. This research was exploratory in nature and a mixed methods approach was adopted (involving both qualitative and quantitative data collection) to ensure a more comprehensive insight into current practice. The questionnaire included items relating to demographic characteristics, pharmacy services currently provided in the NICU, essential pharmaceutical care services in the NICU, and changes that are required to improve pharmaceutical care. The questions in the survey were adapted from a validated survey instrument used in a previous study by Katoue et.al. that assessed pharmacist perspectives on pharmaceutical care in hospitals in Kuwait.[14] Modifications were made to the survey questions to make them more applicable to the NICU setting and as such, the survey does not have reliability or validity values to report. All questions were pre-coded for data entry. The survey was pre-tested for content, design and readability on a small group of Australian pharmacists, and was adjusted accordingly.

The survey was conducted between January 2017 and April 2017. As an incentive for an early response, a textbook prize was offered. Reminders were sent by email to participants one

month and one week before the end of the study period. Incomplete responses were considered as missing values.

DATA ANALYSIS

Quantitative data were analysed using descriptive statistics (percentages, frequencies) using the Statistical Package for the Social Sciences (SPSS) Version 22. The Chi-square test was used to test the association between independent categorical variables (e.g., Nationality - Australian and Polish) and dependent variables (e.g., proportion of agree/disagree responses to questions relating to: current pharmacy services, essential pharmacist roles that should be performed in the NICU, and changes needed to improve pharmacy services). Statistical significance was accepted at a p value of <0.05.

Qualitative data (i.e., responses to open-answer questions) were thematically analysed. Manual inductive coding was used, which involved the identification of significant statements in participants responses and subsequent categorisation into key themes around the study objectives.[15] To ensure correct interpretation and coding of data into emerging themes, three researchers (NK, IP, BB) independently analysed the data before comparing the themes to attain consensus. The analysis was guided by Braun and Clarke's approach i.e. an essentialist/realist theoretical framework was adopted to reflect on the experiences, meanings and the reality of participants.[16] To ensure comprehension, the responses recorded were read several times and patterns were coded into non-overlapping themes and subthemes. The qualitative responses of participants are represented by the code 'PN' for Polish nurses and 'PD' for Polish doctors, and 'AN' for Australian nurses and 'AD' for Australian doctors.

RESULTS

The survey was completed by 77 participants in Australia and 93 in Poland. As depicted in Table 1, more than half of participants from each country were female (Aus = 68.8%, Pol = 86%). Nursing staff made up 45.5% and 60.2% of participants from Australia and Poland respectively. More than half of all professionals had more than 5 years' experience, and most participants possessed specialised training related to neonatal practice, ranging from post-graduate neonatal nursing degrees to medical specialties.

In Australia, the majority of participants worked in level 3 NICU settings, however some were found to work in level 4 and level 6 units – which included surgical as well as medical patients. Poland also has a three-tiered neonatal care specification system, and all participants were found to work in a level 3 or higher. The number of NICU beds available at settings in each country ranged from 4 - 79 in Australia, and 4 – 70 in Poland.

PHARMACIST INVOLVEMENT IN THE NICU

According to the experiences of doctors and nurses, there are significant differences perceived between Australia and Poland regarding the type of pharmaceutical care services provided in NICUs. It is apparent that pharmacists do not commonly participate in ward-based practice in Polish NICUs. Approximately 91.4% of Polish participants identified that pharmacists are not present on the NICU ward at their settings, in comparison with 13% of participants in Australia ($p < 0.001$). As a result, 74% of professionals in Australia agreed that they had a high level of interaction with pharmacists in their daily practice. Alternatively, in Poland, 38% of participants agreed that they did not collaborate with the pharmacist at all. When asked whether pharmacists were meeting the medication management needs of NICU patients, similar variances were noted. Significantly more Polish professionals (82.4%) identified that pharmacists were not meeting the pharmacotherapy needs of neonatal patients, whereas in Australia 82.9% of medical and nursing staff felt that these services were adequate ($p < 0.001$).

A high proportion of Australian NICU professionals had more positive responses when considering their perceptions towards inter-professional relationships with the pharmacy team. Again, the majority of Australian participants perceived having a good relationship with the NICU pharmacist (81.6%), compared with 31.2% of Polish participants who considered pharmacy liaisons to be poor. However, similar responses between the two countries were identified when considering direct pharmacist positions on the NICU. Rates of agreement were higher than 90% when considering whether pharmacists should be included and consulted during pharmacotherapy-related decision making on the NICU. Furthermore, 67.1% of Australian and 76.1% of Polish professionals agreed that pharmacists should have a visiting position on the NICU ward. (Table 2)

ROLES THAT ARE CURRENTLY PERFORMED IN THE NICU

Participants were asked to identify which pharmacist roles were performed within the NICU settings they worked in. The perceived types of NICU pharmaceutical care services offered varied widely, and statistically significant values were identified for the majority of roles in each of the domains, aside from the provision of medicines. (Figure 1) According to nurses and doctors in Poland, the main roles performed by pharmacists in the NICU are related to traditional, dispensary-based practice i.e. dispensing, compounding and stocking the ward with the necessary medications, as well as monitoring the TPN of neonatal patients. Significantly more Australian participants agreed that pharmacists delivered clinical roles, such as participation in medication chart review (91.8% vs. 40.4%, $p < 0.001$), ward rounds (79.1% vs. 10.1%, $p < 0.001$) and therapeutic drug monitoring (82.6% vs. 33.3%, $p < 0.001$) in NICUs compared to Polish participants. Furthermore, it is evident that direct input into pharmacotherapy-related decision-making is not a common practice for pharmacists in Poland. Less than 30% of Polish medical and nursing staff agreed that pharmacists were involved in recommending doses ($p < 0.001$), off-label and unlicensed prescribing ($p < 0.001$), drug selection ($p < 0.001$) and performing pharmacotherapeutic interventions ($p < 0.001$).

Alternatively, a significantly high proportion of Australian doctors and nurses agreed that pharmacists were highly involved in all aspects of pharmacotherapy, particularly in the clinical and education domains. Professionals most commonly identified Australian pharmacist involvement in: collaborating with doctors and nurses on specific neonatal patients (93.1%, $p < 0.001$), performing interventions (94.4%, $p < 0.001$), providing medication-related information (95.8%, $p < 0.001$) and dispensing (93%, $p = 0.045$). Quality assurance measures were performed by four times as many Australians (83.1%) as Polish pharmacists (19.1%, $p < 0.001$), along with counselling of parents (76.1% vs. 18.9%, $p < 0.001$) and the provision of training/education for NICU health professionals (85.9% vs. 24.4%, $p < 0.001$).

Involvement in immunisations was not a normal duty in either country, with less than 50% involvement. The only role perceived by medical and nursing staff as being performed more commonly by Polish pharmacists than Australian pharmacists was the monitoring of TPN regimens (76.9% vs. 67.6%).

MEDICAL AND NURSING STAFF EXPECTATIONS OF PHARMACIST ROLES IN THE NICU

Medical and nursing professionals in Australia and Poland both share high expectations relating to roles to be performed by pharmacists. All participants had higher than 80% agreement rates for pharmacists to perform the majority of clinical roles (12/15), in particular medication chart review, therapeutic drug monitoring, documenting medication errors and therapeutic drug monitoring. (Table 3) Statistically significant differences between countries were observed when considering participation in ward rounds (Aus = 86.3%, Pol = 67.5%, $p < 0.016$,) and TPN (Aus = 70.8%, Pol = 93.8%, $p < 0.001$,). Interestingly, a higher proportion of Polish participants agreed to expecting pharmacists to perform; counselling of parents (78.9% vs. 85.9%), documenting adverse drug reactions (93.9% vs. 96.3%), and monitoring the efficacy of pharmacotherapy in patients (88.2% vs. 93.7%). This is of particular interest as these roles were previously identified by participants as those that were not highly performed by Polish pharmacists in NICUs. These findings indicate, that despite pharmacists not having a high level of direct input into neonatal pharmacotherapy, these services are perceived as essential by medical and nursing staff.

CHANGES NEEDED TO IMPROVE PHARMACIST PRACTICE IN THE NICU

The majority of Polish medical and nursing staff (80.6%) stated that it was necessary for changes to be made to pharmacist practice in the NICU. (Table 2) However, 52% of Australian participants were satisfied with current service provision and did not want to see any changes to pharmacist roles. Nevertheless, all proposed changes listed achieved high acceptance rates from both Australia and Poland. The most commonly identified changes needed to improve pharmaceutical care in the NICU across both countries included increased levels of staffing (Aus = 92.5%, Pol = 95.2%), provision of neonatal specific training opportunities for pharmacists (Aus = 86.8%, Pol = 95.2%) and the creation of NICU pharmacist positions on the ward (Aus = 90.6%, Pol = 91.7%). The changes that were commonly chosen by Polish participants related to increasing doctor and nurse awareness of pharmacist roles, greater administrative support from the hospital and increased channels of communication with pharmacists.

THEMES

The themes that emerged from Polish participants are as follows:

THEME P1: Pharmacists Are Needed On The NICU To Improve Pharmacotherapy

Polish medical and nursing staff commonly highlighted that they perceived a need for the clinical pharmacist to be present on the NICU and to be available to perform pharmaceutical care services.

Sub-theme P1.1: Needed to Assist Medical and Nursing Staff

The activities perceived to be the most important by these health care professionals related to the preparation of medicines for neonatal patients, which in some settings are prepared by nursing staff on the ward, as well as involvement in planning pharmacotherapy regimens. Interestingly, quite a few participants wanted the pharmacist to absorb some of their current roles to 'free up' their time for more meaningful activities. This indicates that some medical and nursing staff do not see the pharmacist as being able to contribute as an independent expert, but rather as an assistant.

> *'I would like the pharmacists to do all the medicines, and prepare them according to procedures and not like how it is at the moment. The nurses prepare medications in the patients room.'* **PN18**

Polish doctors (especially those with overseas experience) were supportive of having the pharmacist as part of the team – and were less focused on prescribing and preventing errors, and more focused on optimising treatment and providing tailored advice. Doctors appeared to have insight into the specialist knowledge of pharmacist – referring to pharmacokinetics, pharmacodynamics, drug effectiveness, off-label drug use, improving the quality of treatment, better patient care, and referred to better inter-disciplinary collaboration. Interestingly, nurses were slightly greater advocates for changing the existing system to allow pharmacists on the ward.

> *'Constant contact and collaboration whilst treating patients is needed, especially in the NICU between doctors and pharmacists.'* **PD14**

Sub-theme P1.2: Benefits of Pharmacist Contributions

Some practitioners also identified several benefits to pharmacist involvement, including more individualised medication regimens, increased medication safety and improved quality of care.

> *'A pharmacist on the NICU would result in better-matched medicines for children. Ability to prepare medicines according to the individual needs of the child.'* **PN23**

> *'Pharmacists should be employed in the NICU to improve and facilitate care provided to patients.'* **PN46**

THEME P2: Minimal To No Pharmacy Support On The NICU

Polish practitioners highlighted that pharmacists are not normally present on NICU wards, and as such there was no pharmacy support delivered to the NICU. A team-approach was reported to not exist at all, some practitioners noted that access to pharmacists was limited to telephone calls to the main hospital pharmacy as needed. As such, this restricted level of communication was attributed to leading to poor inter-professional relationships with the pharmacist. Furthermore, the level of services provided was identified as minimal; usually comprising preparation of TPN and the ordering of necessary medicines.

> *'An inter-professional relationship does not exist because there is no direct collaboration between midwives/nurses and the pharmacist.'* **PN6**

> *'Contact with the pharmacist is limited to ordering medicines and receiving TPN and PPN.'* **PD2**

THEME P3: Lack Of Structure/Support System For Clinical Pharmacists To Be Able To Practice On The NICU

Most participants felt that the hospital was unable to support pharmacists being on wards due to limited funding. Other barriers to the performance of clinical pharmacy services on the NICU were attributed to the lack of support and structure from the hospital administration, in failing to create paediatric or neonatal specific clinical pharmacist positions. Furthermore, a lack of hospital pharmacy staff was also attributed to the absence of pharmacist involvement in the ward.

'The number of pharmacists working in the hospital pharmacy is too small.' **PD5**

Other participants identified that pharmacists were not adequately trained in neonatal pharmacotherapy and did not possess the relevant knowledge necessary to make appropriate decisions in the NICU. Interestingly, one doctor also identified that education was needed for medical staff themselves to improve their understanding of the pharmacists role and what services they are able to provide to the NICU to assist practitioners in medication management.

'I think the main barriers are finances. Education is also needed – we doctors do not know we need pharmacists.' **PD3**

'At the present time, there is no group of pharmacists available that is adequately prepared for clinical practice.' **PD6**

Furthermore, differences in practice culture were identified among Polish participants. Approximately one third of participants didn't feel that there was a need to change current practice and/or engage the pharmacist more than currently. Some felt that dispensing was all the pharmacist needed to do, whereas others felt that doctors or nurses were capable of fulfilling the tasks of a pharmacist.

'They fulfil their role working in the dispensary.' **PD10**

'There is no need for changes regarding the role of the pharmacist, as these are performed by a nurse and midwife.' **PN19**

The two themes identified in the Australian responses are as follows:

THEME A1: The Pharmacist Is An Effective Member Of The Multi-Disciplinary NICU Team

Pharmacists were acknowledged in Australian settings as being valuable members of the NICU therapeutic team and both doctors and nurses described positive experiences of having a pharmacist on the ward. The majority of medical and nursing staff who identified that they had a full-time pharmacist on the ward, were able to describe specific roles that they performed for example, reviewing patient medication charts, supplying medications, minimising medication errors etc. They highlighted that pharmacists were actively involved in ward-based roles and were an invaluable source of advice. Participants commonly expressed that they often collaborated with the pharmacist, and found interactions to be of great assistance to

medication management in the NICU. In particular, it was frequently emphasised that pharmacists are respected and included as a part of the team. Pharmacists were commonly referred to as professional, dedicated, collaborative, approachable, involved and approachable.

> *'Personally in our unit the pharmacist is an integral part of our service that is relied upon, trusted and utilised to its full potential… They are experienced and part of the team. We rely on them for their expertise in the field.'* **AN8**

> *'We have a permanent full time pharmacist for the NICU and Special Care Nursery who contribute greatly to the multi-disciplinary team, service decisions and research and quality and safety. Invaluable service.'* **AD11**

Whilst both medical and nursing staff had positive responses relating to pharmacist involvement, nurses were more likely to describe the issues relating to a lack of pharmacist services. This may be attributed to the fact that nurses may liaise more frequently with pharmacists than doctors on the ward.

THEME A2: Need For A Dedicated Pharmacist Position With Regular/Routine NICU Hours

Some participants in Australia reported that there were no pharmacists specifically allocated to their NICU, or that pharmacists were restricted with the amount of time they were able to dedicate to the ward. This was most commonly attributed to financing issues and was seen as a significant barrier to the provision of the necessary level of pharmaceutical care. Other reasons for having no pharmacist on the ward related to pharmacy department rosters, where in some instances, no pharmacists were scheduled to cover the ward when the main NICU pharmacist was away or new pharmacists were scheduled on a rotational basis, disrupting the continuity of care. As such practitioners called for the employment of more hospital pharmacists as well as the creation of NICU specific pharmacist positions that allowed pharmacists to spend the necessary amount of time needed to provide clinical services. It was identified that the therapeutic team values having a pharmacist more often on the ward, and that contributions were more favourably accepted from a pharmacist familiar with the medical and nursing staff.

> *'Pharmacist should be in NICU every weekday, attending rounds, reviewing charts, providing education, discussing discharge meds with parents.'* **AN15**

'Need consistency in the staff number, not changing every few weeks as is the current practice….By being permanently appointed they are able to develop relationships with the staff which ultimately leads to best patient care and outcomes.' **AN25**

'There is no-one allocated to the role of pharmacist for NICU. There needs to be a dedicated pharmacist with NICU knowledge, even if part time.' **AD24**

COMPARISON BETWEEN COUNTRIES

Overall, the participants responses highlight significant differences in the type of pharmacy practice that undertaken in each country. (Table 3) According to Polish medical and nursing staff, the concept of clinical pharmacy is not yet well established, highlighted by the lack of clinical and educational services provided by pharmacists directly on the ward. Polish pharmacists are based in the dispensary, not on the ward, where their services are focused on the supply of medicines. Although this was the understood and currently accepted form of pharmacy practice, nearly all Polish participants felt that their pharmacists could do more to meet the specific medication management needs of the vulnerable NICU patient population.

In contrast, Australian participants strongly emphasised that clinical pharmacy practice was well established in the NICU, highlighting their reliance on the pharmacist during routine decision-making around pharmacotherapy. Australian doctors and nurses felt that their NICU pharmacists provided a highly-integrated service across each phase of the medication use process. Participants expressed that they had a good interdisciplinary relationship with their ward-based NICU pharmacists.

Despite apparent differences, there were some key similarities between the two countries. The first relates to expectations towards pharmacist practice in the NICU; the majority of participants strongly perceived that there was a need for pharmacists to be directly involved in clinical practice on the ward. The second similarity was that both Polish and Australian participants felt that there was a need to further improve the provision of services in their respective settings. However, the barriers that needed to be addressed differed in each setting. Polish participants focused on the foundational elements required to enable the provision of clinical pharmacy services, for example, support from the hospital administration in creating and funding hospital pharmacist positions. In contrast, Australian participants identified areas of current practice that require further improvement, i.e. staffing issues and increasing amounts of time allocated to the NICU.

DISCUSSION

This study explored the opinions, attitudes and perceptions of Australian and Polish medical and nursing staff towards the provision of pharmaceutical care services on the NICU. This research was exploratory in nature and to our knowledge, this is the first study to compare the perspectives of doctors and nurses towards pharmacist services provided in NICUs across two countries. This research clearly demonstrates how widely practice can differ in healthcare settings around the world, with key differences in pharmacist roles between Australia and Poland. Polish participants commonly referred to a traditional, dispensary-based type of practice in comparison with Australian participants who described a well-established clinical pharmacy practice. These findings are similar to those reported in other studies in both Poland and Australia describing hospital pharmacy practice on other hospital wards.[11,12,17-20]

The differences found between countries can be attributed to a number of reasons. Firstly, Australia has a longer history of pharmacy involvement not only in the NICU, but also in clinical pharmacy positions in the hospital setting. Dunkley performed a foundational nation-wide study in 1991 that found that Australian pharmacists were involved in providing ward-based services in NICUs, including medication chart reviews, therapeutic drug monitoring and adverse drug reaction monitoring.[21] Clinical pharmacy has progressed significantly in the 26 years since, and as a result, practice is more established and more readily accepted into the ward environment. Alternatively, clinical pharmacy is not well developed in Poland, and pharmacists may face many cultural, educational and legislative barriers to practice. As highlighted by Polish participants in this study, pharmacists are perceived as being inadequately prepared for practice on the NICU and do not receive the necessary support from hospital administration to be able to fulfil practice as a clinical pharmacist on the NICU. The differences perceived between the two countries highlight that these findings may also be applicable outside of Poland and Australia, to countries that have similar pharmacy practice structures and practice cultures. The perceptions held by Polish participants may be similar to those held by nursing and medical staff in Eastern European countries with comparable healthcare systems. These findings may serve to improve awareness of the status of clinical pharmacy worldwide and the opportunity to increase the presence of clinical pharmacist in the NICU. Likewise, in Western countries such as New Zealand, UK and USA, with more advanced clinical pharmacy practice frameworks, these findings may help to reinforce the need for the pharmacist in the NICU.

The results also found that the majority of Polish medical and nursing staff expressed that they were unaware of what pharmaceutical care services a pharmacist could provide to the NICU. As the concept of pharmaceutical care is developing within this country, it is important for the pharmacist to be recognised as a valuable contributor to patient care. McDonough and Doucette highlight that the initial step towards initiating a collaborative, ward-based practice is to establish professional awareness among staff.[22] Education should be provided to doctors and nurses to improve understanding of pharmacist competencies. Sjölander et.al highlight that in addition to training medical and nursing staff, pharmacists also require appropriate training as well as clinical experience in patient care to be able to make high-quality clinical recommendations.[23] This is turn helps to foster trust needed between healthcare professionals to be able to collaborate and willingness to share responsibilities.[23]

Another interesting finding of the study is that pharmacists were viewed by participants in both countries as essential members of the NICU therapeutic team. Furthermore, Polish participants identified that they felt a need for changes to be made to pharmacist practice to better integrate them into the NICU. These attitudes are encouraging, particularly when considering the complex environment of the NICU, and highlights that medical and nursing staff are aware of the value of pharmacist involvement. The pharmacist has a great opportunity to become involved in pharmacotherapeutic-care processes on this ward, due to the need for specialised dosing, dilutions/calculations and formulations that are dependent on patient gestational ages, weights and surface areas. The roles of the pharmacist, doctor and nurses, in this capacity, are complementary. Therefore, the findings from the manuscript highlight the need for the development of multi-disciplinary teams in the NICU that include clinical pharmacists. “The practice of pharmaceutical care does not exist and should not exist in isolation from other health care services. It must be provided in collaboration with patients, doctors, nurses, and other health care providers.”[10] The establishment of a respectful and collaborative relationship between these professionals is important for the delivery of individualised and effective pharmaceutical care.[24]

From the perspectives of the participating nurses and doctors, the integration of pharmacists into the NICU team was felt to be a positive concept, and was thought to support the provision of quality patient care, medication management and patient safety. The findings of this study inform neonatal nursing practice as they increase the awareness of the potential roles and contributions of clinical pharmacists on the NICU, and highlight that pharmacists, nurses and doctors could play a part in and benefit from working together as a team. This study has provided a baseline level comparison of pharmacy practice as well as medical and nursing staff

attitudes between two countries, a practice encouraged by the International Pharmaceutical Federation (FIP). The FIP states: 'pharmacy needs a global vision that encompasses the sharing of experiences, gathering of evidence and collaborative guidance to facilitate country-level initiatives.'[25] Future efforts should focus on how practice is structured in each country, and what support can be implemented from educational, cultural and legislative levels to enable better pharmacist integration into the NICU therapeutic team. The barriers to the implementation of pharmaceutical care in the NICU, as identified by the participants, are only able to be overcome through a collaborative effort from government policy makers, hospital administrators, directors of pharmacy, NICU medical and nursing staff, and, importantly, clinical pharmacists.

Further research is needed, particularly in Poland, which focuses on redefining the role of the clinical pharmacist within the NICU multi-disciplinary team as well as identifying strategies that promote successful team-based care.

LIMITATIONS

Participants were recruited from a select sample of Polish and Australian hospitals that contained a NICU and as such, results may not be representative of the population of medical and nursing professionals of Australia and Poland, and should be interpreted with caution. Some questions in the survey may have been misunderstood and were not able to be clarified by the researchers. Furthermore, it is acknowledged that participant responses were self-reported, and may be subject to bias. The survey was adapted from a validated survey instrument from a previous study and modified to suit the NICU setting, and as such does not have validity or reliability values to report. Therefore, results should be interpreted with caution.

CONCLUSION

Statistically significant differences were observed among the opinions and perspectives of medical and nursing staff across Australia and Poland. Australian settings were found to implement ward-based clinical pharmacy services more commonly than Polish units. Most Polish participants identified that the extent of medication management was not meeting neonatal patient needs and that they had no contact with pharmacists on the ward. Future

efforts should focus on how practice is structured in each country, and what support can be implemented from educational, cultural and legislative levels to enable better pharmacist integration into the NICU therapeutic team.

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Table 1: Demographic information

		AUSTRALIA (%)	POLAND (%)
	NUMBER OF PARTICIPANTS	77	93
	GENDER OF PARTICIPANTS		
	Female	53 (68.8)	80 (86.0)
	QUALIFICATIONS		
	Bachelors Degree	33 (42.9)	36 (38.7)
	Masters Degree	26 (33.8)	28 (30.1)
	PhD Degree	11 (14.3)	15 (16.1)
	Other	7 (9.1)	14 (15.1)
	SPECIALISED QUALIFICATIONS		
	Yes	60 (77.9)	44 (47.3)
	No	17 (22.1)	49 (52.7)
	Specialisation in neonatology/paediatrics – FRACP, MRCPCH	38 (63.3)	17 (38.6)
TRAINING COURSES	**Post-graduate course in Neonatal/Perinatal Nursing**	25 (41.7)	18 (40.9)
	Ultrasound and aviation	1 (1.7)	
	American Board of Neonatal/Perinatal Medicine	1 (1.7)	
	Neonatal Immunisation training		4 (9.1)
	Lactation training		1 (2.3)
	Other medical specialisations i.e. neurology, cardiology		2 (4.5)
	Ultrasound training		1 (2.3)
	POSITION IN THE HOSPITAL		
	NICU Nurse	21 (27.3)	23 (24.7)
	Midwife	2 (2.6)	30 (32.3)
	Nurse/Midwife Unit Manager	4 (5.2)	3 (3.2)

Other Specialist Nursing Positions – Educator/Consultant/Clinical Support/Practitioner	8 (10.4)	
Neonatologist	31 (40.3)	23 (24.7)
NICU Doctor	10 (13.0)	13 (14)
Consultant Paediatrician/Neonatologist	1 (1.3)	1 (1.1)
EXPERIENCE		
< 1 Year	3 (3.9)	3 (3.2)
Between 1-5 Years	21 (27.3)	11 (11.8)
Between 6-10 Years	18 (23.4)	16 (17.2)
> 10 Years	35 (45.5)	63 (67.7)
NUMBER OF BEDS IN NICU (RANGE)	4 - 79	4 – 70

Table 2: Perceptions of pharmaceutical care provided on the NICU

	AUSTRALIA (%)	**POLAND (%)**	**P-value (Comparison of proportions between Australian and Polish participants)**
IS THERE A PHARMACIST CURRENTLY WORKING ON THE NICU THAT YOU ARE EMPLOYED IN?	N = 77 (%)	N = 93 (%)	**<0.001**
Yes	67 (87.0%)	8 (8.6%)	
No	10 (13.0%)	85 (91.4%)	
WHAT IS YOUR CURRENT LEVEL OF INTERACTION WITH THE PHARMACIST?	N = 77 (%)	N = 92 (%)	
High	57 (74.0%)	28 (30.4%)	
Average	10 (13.0%)	7 (7.6%)	
Rare	6 (7.8%)	16 (17.4%)	
None	2 (2.6%)	35 (38.0%)	
Other	2 (2.6%)	6 (6.5%)	
DO YOU BELIEVE THAT THE PHARMACIST IS CURRENTLY MEETING ALL MEDICATION MANAGEMENT NEEDS IN THE NICU?	N = 76 (%)	N = 91 (%)	**<0.001**
Yes	63 (82.9)	16 (17.6)	
No	13 (17.1)	75 (82.4)	
LEVEL OF CURRENT PHARMACEUTICAL CARE PRACTICE IN THE NICU	N = 76 (%)	N = 93 (%)	

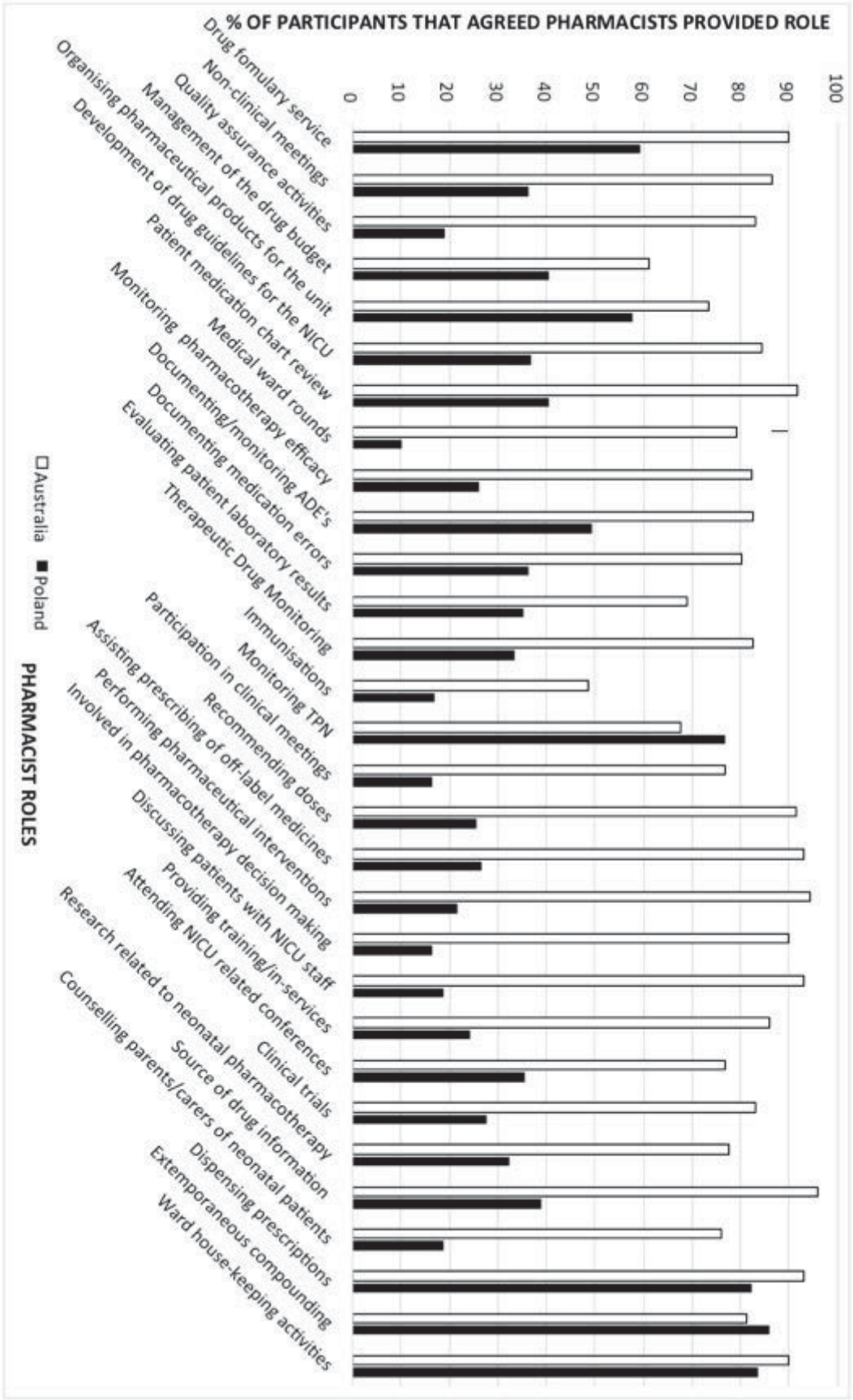
Good	60 (78.9)	21 (22.6)	
Average	7 (9.2)	24 (25.8)	
Poor	5 (6.6)	13 (14.0)	
Non-Existent	4 (5.3)	35 (37.6)	
IS THERE A NEED TO CHANGE PHARMACIST ROLES?	N = 75	N = 93	**<0.001**
Yes	36 (48.0)	78 (83.9)	
No	39 (52.0)	15 (16.1)	
SHOULD THE PHARMACIST BE CONSULTED AS PART OF THE TREATING TEAM FOR MEDICATION-RELATED DECISION-MAKING IN THE NICU?	N = 76	N = 93	**0.467**
Yes	71 (93.4)	84 (90.3)	
No	5 (6.6)	9 (9.7)	
SHOULD PHARMACISTS HAVE A VISITING OR PERMANENT POSITION ON THE NICU?	N = 76	N = 92	
Yes – Visiting	51 (67.1)	70 (76.1)	
Yes – Permanent	25 (32.9)	6 (6.5)	
No	0	16 (17.4)	
LEVEL OF CURRENT INTER-PROFESSIONAL RELATIONSHIP BETWEEN PHARMACISTS AND THE MEDICAL AND NURSING STAFF	N = 76	N = 93	
Good	62 (81.6)	22 (23.7)	
Average	6 (7.9)	23 (24.7)	
Poor	3 (3.9)	29 (31.2)	
Non-Existent	5 (6.6)	19 (20.4)	

Table 3: Comparison of pharmacist practice in NICUs between Australia and Poland

	AUSTRALIA	POLAND
TOP 3 COMMONLY PERFORMED ROLES IN THE NICU	1. Source of drug information - responding to information requests from health professionals on the ward 2. Identifying and performing interventions for individual patients to prevent or resolve drug therapy problems i.e. interactions, incompatibilities, allergies etc. 3. Collaborating and discussing specific patients with doctors and nurses	1. Extemporaneous compounding of formulations for the NICU 2. Stocking the ward with essential medicines/house-keeping activities i.e. checking expiry dates, fridge temperatures etc. 3. Dispensing prescriptions
TOP 3 COMMONLY EXPECTED ROLES TO BE PERFORMED IN THE NICU	1. Medication chart review 2. Calculating and recommending doses and dosing schedules for specific patients 3. Providing training/in-services for other health professionals on NICU related topics and drug related problems	1. Providing training/in-services for other health professionals on NICU related topics and drug related problems 2. Extemporaneous compounding of formulations for the NICU 3. Documenting Medication Errors
TOP 3 COMMONLY IDENTIFIED	1. Increased levels of staffing in the pharmacy	1. Increasing nurse/doctor awareness

CHANGES NEEDED TO IMPROVE PRACTICE	2. Creating specific NICU clinical pharmacist positions in the hospital i.e. organisational changes 3. Increasing educational opportunities for the up-skilling of pharmacists in topics related specifically to neonatal/paediatric pharmacotherapy	of the roles and services that pharmacists can provide in the NICU 2. Increased communication with pharmacists 3. Administrative support from the hospital i.e. from directors

Figure 1: Pharmacist roles performed on NICUs in Australia and Poland as perceived by medical and nursing staff



4.3 PHARMACEUTICAL CARE IN THE NEONATAL INTENSIVE CARE UNIT: PERSPECTIVES OF POLISH MEDICAL AND PHARMACY STUDENTS

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CURRENTS IN PHARMACY TEACHING AND LEARNING – UNDER PEER REVIEW

Krzyżaniak N, Pawłowska I, Pawłowski L, Kocić I, Bajorek B. Pharmaceutical Care in the Neonatal Intensive Care Unit: Perspectives of Polish Medical and Pharmacy Students, Currents in Pharmacy Teaching and Learning – Under Peer Review

AUTHORS' CONTRIBUTIONS

Natalia Krzyżaniak was the primary author, collected the data, analysed and interpreted the findings, wrote and organised the manuscript. Beata V. Bajorek and Iga Pawłowska contributed to the idea, drafting of the manuscript, interpretation of findings, and critical review of the manuscript.

Production Note:
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ABSTRACT

INTRODUCTION: The concepts of ward-based pharmaceutical care as well as collaborative practice are still relatively novel in Poland, particularly in specialty areas of practice such as the neonatal intensive care unit (NICU). No studies have explored whether student expectations of their future practice align with the current healthcare system seen in Poland, or whether they are more in line with the advanced form of collaborative pharmaceutical care practiced in other nations.

OBJECTIVES: The purpose of this study was to identify the opinions and perceptions of Polish medical and pharmacy university students toward the provision of pharmaceutical care services in the NICU as well as pharmacist integration into the ward-based multidisciplinary NICU treating team.

METHOD: A cross-sectional, mixed-method survey was distributed among medical and pharmacy university students at a large Polish medical university. The majority of questions comprised fixed 'agree/disagree' answers, supplemented by open-ended questions.

RESULTS: A total of 147 students completed the survey, comprising 73 medical students and 74 pharmacy students. Overall, there are statistically significant differences between the perspectives of medical and pharmacy students towards the provision of pharmaceutical care services in the NICU. For 10 out of 15 proposed clinical roles listed, a significantly lower proportion of medical students (M) agreed that pharmacists should perform these in the NICU, compared to pharmacy students (P). These roles included: participation in ward rounds (M = 38.4%, P = 82.4%, $p < 0.001$), therapeutic drug monitoring (M = 78.1%, P = 98.6%, $p < 0.001$) and monitoring total parenteral nutrition (M = 37%, P = 87.8%, $p = < 0.001$). Furthermore, a significantly higher proportion of pharmacy students agreed that pharmacists should be consulted as part of the treating team when making medication-related decisions for NICU patients compared to medical students (M = 71.2% vs. P = 91.9%, $p < 0.001$).

CONCLUSION: Further investigation is needed to develop educational strategies directed at clinical, patient-centered roles, particularly for specialty areas of practice such as the NICU, that have the potential to facilitate the provision of a more advanced and comprehensive level of pharmaceutical care.

Keywords: Student perspectives, interprofessional education, NICU/neonates

SPECIFIC CONTRIBUTION TO THE LITERATURE:

- Overall, the results draw attention to three major issues – the absence of multidisciplinary collaboration, poor understanding of the pharmacist's role and their potential in the NICU and a lack of structural support and preparation for pharmacists in undertaking clinical practice.

- These findings indicate a significant need for the development of educational strategies that address these gaps in knowledge to better prepare graduates for their future careers in healthcare teams.

INTRODUCTION

Hepler and Strand defined pharmaceutical care as the "responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life"[1]. Since its introduction, this concept has been widely adopted worldwide and is now regarded as the foundation of modern pharmacy practice. Pharmaceutical care is promoted by organizations such as the World Health Organization (WHO) and the International Pharmaceutical Federation, which encourage pharmacists to be highly and purposefully involved in the medication management process[2,3]. The WHO, in particular, highlights that pharmacists should be able to access patient medical records, perform interventions to address drug-related problems, collaborate with medical and nursing staff, and monitor therapeutic outcomes in patients[3]. The uptake of patient-centered pharmaceutical care has been particularly strong in countries such as Australia, Canada, UK and USA[4-8]. However, within Europe, in particular Eastern European countries such as Poland, the implementation of pharmaceutical care is not yet fully realized[9].

Pharmaceutical care was introduced into Polish pharmaceutical legislation as a type of service in 2008, 19 years after the concept was originally published by Hepler and Strand in 1989[1,9,10]. It is defined within the legislation as a documented process whereby pharmacists collaborate with the patient, doctor, and, wherever necessary, with other medical professionals to optimize pharmacotherapy for the purposes of achieving specific outcomes that improve a patient's quality of life[10]. However, since its introduction very little has changed in terms of service provision[9]. Currently, pharmacy-based services in Poland are primarily limited to the dispensary. Pawłowska and Kocić reported that pharmacists mainly spent their time on dispensing medications and compounding medicinal products, as well as related administrative tasks[11]. Pharmacists have little to no direct contact with patients nor do they have a significant role in pharmacotherapeutic decision-making[11]. This is due to a multitude of reasons, but predominantly attributed to a lack of legislation outlining the roles and responsibilities of pharmacists, the lack of pharmacist-physician collaboration, as well as the inability for pharmacists to access confidential patient information within medical records[9,12,13]. Furthermore, there are no specific educational programs or professional bodies to co-ordinate and support the provision of pharmaceutical care in either the community or hospital setting[12].

Ward-based, clinically driven pharmaceutical care services are relatively abstract concepts within hospital settings in Poland and are not widely implemented.[14] A national study in 2016 found that only 15.2% of hospital pharmacists performed pharmaceutical care services on hospital wards[14]. Rather, the role of the pharmacist is limited to the dispensing of medicines within a traditional distribution-based system, with no legal or professional obligations to implement any form of clinical practice[15]. Additionally, there is minimal collaboration and pharmacist interaction with the multidisciplinary team. The pharmacist is often excluded from pharmacotherapy-related decision-making and consultations are restricted to medication procurement issues or advice relating to drug interactions or adverse events[14]. With pharmaceutical care advancing in other countries around the world, there is debate in Poland surrounding the capacity of pharmacists to undertake a more clinically-oriented, collaborative role in hospital therapy[13]. These two concepts are of particular importance when considering specialties of care, such as the neonatal intensive care unit (NICU).

Pharmacotherapy is a highly relied upon intervention in the care of neonatal patients, and current literature emphasizes the importance of the pharmacist serving as a core member of the multi-disciplinary treating team[16]. Interventions by clinical pharmacists have been shown to help rationalize the use of medicines and decrease medication error rates in the NICU setting[16-19]. Thus, pharmacists are well-placed within the NICU multi-disciplinary team alongside doctors, nurses, dieticians and physiotherapists, in achieving quality neonatal patient outcomes[20]. However, a study exploring pharmacy services provided to NICUs in Australia and Poland highlighted significant practice gaps between countries with highly developed clinical pharmacy practices and those in which practice is less progressive[21]. Only 18.2% of Polish pharmacists surveyed reported that they collaborated with medical and nursing staff on the NICU, in comparison with 96.4% of Australian pharmacists[21]. Indeed, all of the Polish pharmacists surveyed did not consider themselves members of the NICU team[21]. Furthermore, a higher proportion of Australian pharmacists was found to perform clinical services than their Polish counterparts[21]. Current efforts by professional bodies such as the International Pharmaceutical Federation (FIP) and the European Association of Hospital Pharmacists (EAHP), are directed at the development of standardized guidelines promoting the adoption of consistent and coherent pharmaceutical care services between settings both nationally and internationally[2,22]. As such, the significant practice gaps evidenced between these two industrialized countries are a concern. Thus, there is a need from the Polish perspective to identify and implement strategies to help narrow the practice gap.

The implementation of changes into tertiary schooling programs has been credited as one of the most effective methods of instigating change in healthcare systems[3,23]. Education of medical and pharmacy students has been highlighted as having a crucial role in preparing future practitioners to appropriately respond to and facilitate the implementation of pharmaceutical care[24]. Furthermore, the World Health Organization (WHO) highlights the necessity of inter-professional education for both under-graduate and post-graduate students in enabling more effective multi-disciplinary teamwork and collaboration as future health practitioners[25,26]. However, the current Polish tertiary healthcare schooling system is seen to focus on a uni-professional, rather than an inter-professional form of education and does not prepare health graduates for collaborative practice[27-29]. Cerbin-Koczorowska et.al. found disparities between student groups when exploring their attitudes toward establishing co-operative relationships[26]. Medical students at a Polish medical university did not consider collaboration with pharmacists as necessary during therapeutic decision-making, whereas pharmacy students were open to pharmacist-physician co-operation[26]. Furthermore, it is reported that pharmacy students' attitudes towards engagement in clinical services were similar to those seen in other international studies; that is, they were interested in developing the pharmacist's role in patient care, beyond traditional services such as dispensing and stock control[26,30-33]. However, no studies have explored student perceptions towards pharmaceutical care practices specifically in high-risk wards, or in specialties of practice such as the NICU.

Given the significant pharmacy practice gaps evidenced in the NICU between Poland and western countries, such as Australia, there is a need to canvass the perspectives of medical and pharmacy students to gain an understanding of the direction of future pharmacy practice in specialties of care. It is important to investigate two concepts – attitudes towards pharmacist involvement in clinical roles in the NICU, as well as towards the integration of the pharmacist into the NICU multi-disciplinary team. Given that pharmacists in Poland have the ability to obtain 12 post-graduate specializations in pharmacy practice, including clinical pharmacy, it is important to explore whether the student expectations of their future practice align with the current healthcare system seen in Poland, or whether they are more in line with the advanced form of collaborative, ward-based pharmaceutical care practiced in other nations.

AIM OF STUDY

The purpose of this study was to identify the opinions and perspectives of Polish medical and pharmacy university students toward the provision of pharmaceutical care services in the NICU. The specific objectives included:

- identifying student opinions, as future health professionals, towards which pharmaceutical care roles are perceived as being important for the NICU
- whether students considered clinical pharmacists to be an important part of the inter-disciplinary therapeutic team
- identifying student perceptions towards the integration of the pharmacist onto the NICU ward
-

METHODS

A cross-sectional, paper-based survey was distributed among university students undertaking medical and pharmacy degrees at a Polish medical university between January and February 2017.

ETHICAL CONSIDERATIONS

Ethics approval was sought and obtained from the respective human research ethics committees at the University of Technology (UTS), Australia (HREC REF NO. ETH16-1033) and the Medical University of Gdansk (GUMed), Poland (HREC REF NO. NKBBN/424/2016). Ethics approval was obtained from GUMed in Poland, where the research was carried out in a local medical university. Although data was not collected in Australia, ethics approval was also obtained from UTS, as two of the researchers were based in Australia.

Participants were assured of confidentiality and were informed that their responses would be de-identified.

PARTICIPANTS

The study population was made up of university students undertaking medical and pharmacy degrees in their final three years of study at a Polish medical university. Medical degrees at this university take 6 years of undergraduate study, and pharmacy degrees 5.5 years. This study

sought to identify pharmacy and medical students perceptions towards pharmacy services in the NICU, based on their theoretical knowledge of this patient population as well as of current hospital pharmacy practice in Poland. Medical students are introduced to pediatric pharmacology in the third year of their studies, whilst pharmacy students are introduced to pediatric physiology and pharmacology in their fourth year of study[34,35]. Whilst students in this study did not have practical experience with the NICU, they held an overall theoretical knowledge relating to pharmacology and pharmacotherapies used in the pediatric population, and are also familiar with the general pharmaceutical care system functioning in hospitals in Poland.

To determine an appropriate sample frame, a sample size calculation was performed for each question using a significance level of 5% and a desired power of 80%. The calculation was based on the precision around the point of estimate of effect, i.e., the anticipated response to specific survey questions, guided by the results of previous research[14,36,37]. The target sample size needed was found to be 38 participants total.

SURVEY

A self-administered, anonymous, paper-based questionnaire was distributed by one researcher (NK) to students during two lecture sessions as well as during an academic presentation session. Due to the exploratory nature of this research, the research instrument adopted a mixed-methods approach, whereby both quantitative and qualitative data was collected. This method was utilized in order to enable a greater understanding of student perspectives on current and future practice. The questionnaire was made up of 12 questions and the majority of questions were fixed 'agree/disagree' answers, supplemented by 2 open-ended questions:

- Describe whether the current pharmaceutical care system in Poland is fulfilling the pharmacotherapeutic needs of NICU patients
- Describe the benefits or disadvantages to having a pharmacist practicing on the NICU

The close-ended questions in the survey were split into four distinct sections that gathered data relating to: participant characteristics (e.g. degree, year of study), attitudes towards pharmaceutical care in the NICU, opinions on the integration of the pharmacist into the therapeutic team and onto the NICU as well as students' preferences regarding which roles should be performed by pharmacists in the NICU (within four key categories: administrative, clinical, education, provision). The survey questions were adapted from a previously validated

survey instrument used in a study by El Hajj et.al. where pharmacy student attitudes towards pharmaceutical care in Qatar were explored[33]. The survey item used was based on the validated Pharmaceutical Care Attitudes Survey (PCAS) tool. Slight modifications were made to these survey questions to ensure relevance to the NICU setting. Our researcher-modified survey was not further tested for reliability or validity.

The surveys were administered in Polish, and the results translated into English via a-three-tiered process. All survey results were initially translated to English by one researcher (NK). These translations were then revised and confirmed by two researchers independently (BB, IP) to determine whether the language was correct.

All questions were pre-coded for data entry. The survey was pre-tested for content, design and readability on a small group of Polish pharmacists and was modified where deemed necessary. Within this study, no further validation of the questionnaire was undertaken beyond checking of face validity and pilot testing among the researchers.

All surveys whose close-ended questions were 100% completed by participants were included for analysis.

DATA ANALYSIS

Quantitative data were analyzed using descriptive statistics in the Statistical Package for the Social Sciences (SPSS) Version 22. The Chi-square test was applied to examine the association between independent variables (e.g., degree type - pharmacy and medicine) and dependent variables (e.g., proportion of agree/disagree responses to questions relating to: expectations of pharmacist roles that should be performed in the NICU, and inter-professional integration into the therapeutic NICU team). Statistical significance was accepted at a p value of <0.05.

Qualitative data (i.e., the students responses to 2 open-answer questions in the survey) were thematically analyzed via manual inductive coding[38,39]. For reliability, three researchers (NK, IP, BB), independently analyzed the transcripts. A pragmatic approach was used in the analysis of data, in line with that used in other survey studies[40-42] and involved: 1) carefully re-reading responses to identify important statements and any patterns; 2) categorizing responses into key themes structured around the research objectives; and 3) iterative comparison and review to elicit non-overlapping themes and sub-themes. Codes were used to identify significant statements in the text[43]. Similar codes were organized into categories, from which themes

were derived. A total of 25 codes were initially derived from the data to generate 6 broad categories, which were then combined to 3 themes[40]. Any points of disagreement were discussed and resolved by consensus among the researchers (theme verification)[40,41,44-46].

Three researchers (NK, IP, BB) independently evaluated the data to ensure the appropriate interpretation of data into descriptive themes in line with the existing questions and study objectives.

The qualitative responses of participants are represented by the code 'M' for medical students and 'P' for pharmacy students.

RESULTS

Overall, 100 surveys were sent out to each group of medical students and pharmacy students. A total of 147 students completed the survey comprising 73 medical students (response rate = 73%) and 74 pharmacy students (response rate = 74%). All of the returned surveys were included in the analysis as they were all fully completed by participants. The majority of students were in their final two years of study, i.e. 5th or 6th year for medical students, 4th or 5th year for pharmacy students (Table 1).

OPINIONS ON THE ESSENTIAL ROLES OF A NICU PHARMACIST

Overall, a high proportion of both medical (M) and pharmacy (P) student groups agreed to wanting pharmacist involvement in the NICU. When presented with pharmacist roles that should be performed in the NICU, respondents recorded similar responses to responsibilities listed within the administrative, educational and medication provision categories (Table 2). All medical students (100%) and 98.6% of pharmacy students agreed that extemporaneous compounding was expected to be performed by pharmacists in the NICU. Significantly more medical than pharmacy students (95.9% vs. 85.1%) agreed that pharmacists should provide pharmacotherapy-related training and education to health professionals on the NICU ($p=0.027$). However, a higher proportion of pharmacy students compared to medical students agreed that counseling of families/carers of patients should be performed by pharmacists (M = 69.9% vs. P = 90.5%, $p < 0.002$).

Statistically significant differences were identified across the majority of clinical roles (11/15) when comparing medical and pharmacy student responses, with all pharmacy students expressing high rates of agreement (10/15 clinical roles >80%) (Figure 1). Clinical roles included: participation in ward rounds (M = 38.4%, P = 82.4%, $p < 0.001$), total parenteral nutrition (TPN) monitoring (M = 37.0%, P = 87.8%, $p < 0.001$), therapeutic drug monitoring (TDM) (M = 78.1%, P = 98.6%, $p < 0.001$), calculating and recommending doses (M = 76.7%, P = 100%, $p < 0.001$), and monitoring the efficacy of pharmacotherapy in patients (M = 69.9%, P = 100%, $p < 0.001$). When considering pharmacist involvement in the evaluation of laboratory results, only a small proportion of medical or pharmacy students agreed that this was expected to be performed, at 16.4% and 37.8% respectively.

INTEGRATION INTO THE INTER-DISCIPLINARY THERAPEUTIC NICU TEAM

Although the majority of all students agreed overall, significantly more pharmacy students than their medical student counterparts agreed that pharmacists should be consulted as part of the therapeutic NICU team when making medication-related decisions for NICU patients (M = 71.2% vs. P = 91.9%, $p < 0.001$). Participants were also questioned whether pharmacists should be directly employed on the NICU; all (100%) pharmacy students agreed that pharmacists should either have a routine or permanent position on the ward, whereas 16.4% of medical students agreed that pharmacists should not have any ward-based positions on the NICU (Table 3). Furthermore, all (100%) pharmacy students agreed that pharmacists should hold direct (face-to-face) consultations with medical staff, whilst 19.7% of medical students agreed that doctor-pharmacist contact should be through telephone or email.

THEMES

Of the 147 students who completed the close-ended questions of the survey, a total of 92 students comprising 39 medical students (response rate = 53.4%) and 53 pharmacy students (response rate = 71.6%) filled in the open-ended questions.

Three key themes were identified within the responses of medical and pharmacy students:

1. Pharmacist's support of the prescribing process
2. Clinical pharmacy practice is not well-developed in Poland

The third theme comprised 4 sub-themes:

3. Issues around adding a clinical pharmacist to the therapeutic team
   3.1 Cost implications
   3.2 Pharmacists preparation for clinical practice in the NICU
   3.3 Acknowledgement of the pharmacist as part of the multi-disciplinary team
   3.4 Lack of inter-disciplinary support for the clinical pharmacist

THEME 1: PHARMACIST'S SUPPORT OF THE PRESCRIBING PROCESS

The majority of both pharmacy and medical students were supportive of the role of the pharmacist in providing assistance during pharmacotherapy-related decision-making on the NICU. In particular, both groups valued the 'consultant' role of the pharmacist, and identified the pharmacist as a medication expert, contributing to a more efficient and safe prescribing process.

> *'Up-to-date knowledge of medicines is passed onto doctors to keep them informed and advice is provided about drug interactions and pharmacotherapy for patients.'* **M42**
>
> *'A pharmacist is a valuable source of information/advice on equivalent medications, possible undesirable effects, poly-therapy and interactions with other medications in specific NICU patient cases.'* **M66**
>
> *'The pharmacist has a thorough knowledge on the subject of medicines, thereby improving the quality of patient care. Their presence on the ward allows for quick consultations.'* **P45**
>
> *'The pharmacist has knowledge of medicines, pharmacology and drug technology. This knowledge is necessary to improve the quality of pharmacotherapy, and this knowledge should be more utilized in the NICU.'* **P43**

However, differences were observed when considering student opinions on the advantages associated with the pharmacist's role on the NICU. Medical students were found to view pharmacists more as a support system, or a safety net, for the medical team during the

pharmacotherapy-decision making process. They valued the direct role on the ward mostly for the purposes of having access to drug information with emphasis on assisting doctors with prescribing, and cited that in this way, pharmacists contributed to a reduction in medication errors, drug interactions and side-effects. As such, medical students more often associated pharmacist involvement with the process of managing pharmacotherapy i.e. in selecting medications, preventing drug interactions and monitoring side-effects.

> *'A pharmacist permanently present in the intensive care unit can assist the doctor in the treatment of newborns. This can reduce the risk of error in drug selection and allow the doctor to focus on his/her practice.'* **M2**
>
> *'A pharmacist working directly in intensive care could provide doctors with pharmacotherapy related consultations for a rare, uncommon illness where it is not known which drugs to use. With routine treatment, the doctor follows the guidelines and the pharmacist's consultation seems to be unnecessary.'* **M5**
>
> *'Most procedures have pharmacotherapy guidelines so a pharmacist's daily work on the ward does not make much sense. On the other hand, the ability to use their knowledge in the treatment of cases not responding to recommendations using routine treatment would certainly help and would assist the work of doctors in charge of the patients concerned.'* **M15**

In contrast, pharmacy students considered the role of the pharmacist more holistically, and were focused on the continuum of care and the pharmacist's involvement in monitoring a patient's therapy throughout their admission, reflecting a more patient-centered approach. In particular, pharmacy students referred to pharmaceutical care services as an opportunity to better utilize the knowledge and expertise of the pharmacists to resolve patient care problems, to optimize pharmacotherapy, provide better quality of care and to benefit the team. Pharmacy students emphasized that the pharmacist's role would improve the appropriateness of therapy, efficacy of treatment and promote the individualization of therapy. Furthermore, they highlighted that due to the high-risk nature of the vulnerable neonatal population, these roles would also contribute to increasing medication safety.

'Safe use of drugs, which is especially important in neonatal therapy.' **P42**

'The advantage of a pharmacist working directly in the NICU is the ability to control a patient's course of pharmacotherapy in a continuous manner. Greater safety of pharmacotherapy for patients.' **P72**

'Control of the pharmacotherapy regimen reduces the risk of adverse drug reactions caused by inappropriate drug administration and its storage, interactions or incompatibilities.' **P73**

'A pharmacist working in a team with a doctor, increases the individualization of pharmacotherapy, focusing on the patient.' **P25**

THEME 2: CLINICAL PHARMACY PRACTICE IS NOT WELL-DEVELOPED IN POLAND

The majority of students (both medical and pharmacy) felt that there was no real pharmaceutical care provided in the Polish health system. They also identified a lack of overall support from the hospital and broader health system to support the clinical pharmacist's role on the ward. Medical students more often referred to the ward-based, clinical model of practice as being 'abstract' or foreign to the Polish healthcare system. These participants viewed this as a reality of working in the system, and did not take issue with it, as they also more often suggested that a full-time pharmacist presence was likely not needed in the NICU.

'*The vision of a pharmacist being available on the NICU ward and also on all others seems to be a bit abstract for the Polish situation but it would of course be very valuable for the patient and the medical staff*.' **M5**

'*I believe that consultations with a pharmacist would be very helpful, but I do not think it is necessary for a pharmacist to be permanently located on the ward because doubts about pharmacotherapy occur sporadically.'* **M50**

On the other hand, pharmacy students highlighted that the lack of pharmaceutical care was problematic, inferring that it reflected suboptimal practice.

'I think the current model of pharmaceutical care practice conducted within the NICU does not meet the medication management needs of neonatal patients. Pharmacists do not play a role in pharmaceutical care provided on hospital wards. The pharmacist should have a permanent position on the NICU ward.' **P72**

'At present, pharmacists in Poland do not actively participate in pharmacotherapy, they do not have direct contact with the patient.' **P21**

'*The current pharmaceutical care model within the NICU does not meet the needs of patients due to the small input of pharmacists in the life of the unit, limited to drug delivery and preparation of prescription drugs*.' **P26**

'*The current model does not meet the needs, because the level of care and monitoring is not adequate. Pharmacists are missing in hospitals.'* ***P47***

THEME 3: ISSUES AROUND ADDING A CLINICAL PHARMACIST TO THE THERAPEUTIC TEAM

Both groups of participants believed that introducing a NICU-based pharmacist to the therapeutic team would be met with several barriers:

Sub-theme 3.1: Cost Implications

Financial issues were commonly identified by both medical and pharmacy students, and mostly related to the pressures of cost containment, with participants commonly reporting that the creation of a pharmacist's position on the ward would have a significant impact upon allocated ward budgets. Pharmacy students tended to refer to the economic considerations in terms of net cost-savings and net benefits, whereas medical students used negative terms such as 'burden' on hospital funds.

'The pharmacist is an additional burden on the ward budget.' **M50**

'Employment of a pharmacist on the NICU ward = generation of costs (even though the pharmacist contributes to a decrease in pharmacotherapeutic costs).' **P33**

'There is a lack of parties willing to finance the position.' **P48**

'The regulations of the current care system do not involve or pay for pharmaceutical care within the NICU.' **P33**

Sub-theme 3.2: Pharmacist's Preparation For Clinical Practice In The NICU

Pharmacists were perceived by both medical and pharmacy students to be underprepared for clinical practice in the NICU. This was most commonly associated with a perceived insufficient level of clinical knowledge relating to the types of pharmacotherapy used in neonates, as well as a lack of practical, ward-based experience. However, differences between the perspectives of pharmacy and medical students were identified. Medical students perceived that pharmacists were unable to apply their knowledge to patient care in the NICU, and therefore felt that the pharmacist would not be able to support higher functions in decision-making.

'The theoretical knowledge of the pharmacist may not agree with the practical experience of the physician.' **M10**

'The pharmacist does not fully understand the patient's clinical problem and should not be involved in therapy.' **M29**

'The level of education and competencies of a pharmacist are not sufficient to enable them to make decisions about the treatment of patients, in accordance with their current training system.' **M49**

On the other hand, pharmacy students, referred to the fact that the current education system did not adequately train pharmacists for specialized clinical practice in the NICU. However, given enough educational opportunities, these participants felt that pharmacists would be able to contribute significantly to medication management in the neonatal population.

'The current level of education does not consider neonatal pharmacotherapy – the pharmacist does not have up-to-date knowledge on this topic.' **P11**

'Pharmacists could be trained in this particular category and have a lot of knowledge about these particular therapies and this patient population.' **P51**

Sub-theme 3.3: Acknowledgement Of Pharmacist As Part Of The Multi-Disciplinary Therapeutic Team

Only pharmacy students acknowledged that involving the pharmacist in clinical roles on the NICU would give recognition to their expertise and increase their job satisfaction. They also emphasized a need for pharmacists to be acknowledged as a member of the therapeutic team in the NICU. Pharmacy students reported that through the creation of a direct, ward-based clinical pharmacy position on the NICU, pharmacists would be able to contribute to medication safety, patient care and to the medical team itself.

'A pharmacist is a specialist in pharmacotherapy, and in collaboration with a doctor who appropriately diagnoses a disease, can optimize treatment and exclude certain side-effects and interactions.' **P32**

'All staff would have the opportunity to benefit from the knowledge/advice of the pharmacist.' **P67**

'The doctor is responsible for the diagnosis and the pharmacist for the selection of drugs, doses and identifying interactions.' **P71**

However, in addition, pharmacists also emphasized that the greater engagement of the pharmacist into the NICU environment would be associated with increased responsibility, workload and stress.

'**Increased responsibility and level of stress.**' **P37**

'*Only advantages, but they come with great responsibility*.' **P52**

'*Stress, complicated medical cases*.' P63

Sub-theme 3.4: Lack Of Inter-Disciplinary Support For The Clinical Pharmacist

Pharmacy students identified that the main barrier to pharmacist practice on the NICU would be resistance from the medical team to collaborate, particularly senior doctors. Respondents also perceived that the provision of clinical pharmacy services directly on the ward would be met with distrust:

> *'There is a lack of desire from doctors to collaborate with pharmacists.'* **P42**
>
> *'Polish doctors will not change their approach to pharmaceutical care.'* **P44**
>
> *'The pharmacist has very limited powers and is often not seen as a partner by doctors.'* **P45**
>
> *'It is believed that the place of the pharmacist is only in the dispensary. There is no possibility of active participation in pharmacotherapy.'* **P51**
>
> *'For a pharmacist in this position, they could be faced with too little trust from the doctors as well as too much responsibility.'* **P65**

DISCUSSION

The purpose of this study was to explore the opinions and attitudes of Polish medical and pharmacy students towards the provision of pharmaceutical care services to the NICU. To our knowledge, this is the first study of its kind to investigate student perceptions towards a specialty area of pharmaceutical care.

Our research demonstrates that both Polish medical and pharmacy students recognize that the hospital pharmacists traditional supply function is becoming outdated, particularly in high-intensity and high-risk wards such as the NICU, which demand a multi-disciplinary group of healthcare providers. This finding is encouraging given the structure of the current health system in Poland. Both medical and pharmacy students acknowledged that no form of pharmaceutical care was currently being provided to the NICU, or within the hospital setting in the Polish healthcare system. However, the results highlight that the majority of both groups of students did envision pharmacists holding positions directly on NICU wards to some degree,

and were also receptive towards collaborative professional relationships between doctors and pharmacists.

However, distinct differences were also identified between the attitudes of the two groups of students towards the provision of pharmaceutical care services in the NICU. Medical students expressed less positive responses towards direct pharmacist involvement in ward-based activities, including clinical roles, and highlighted that medical and nursing staff could perform these services. These findings are similar to those obtained in a Croatian study by Seselja-Perisin et.al. investigating medical and pharmacy student attitudes towards pharmacist-physician collaboration[47]. In their study, Seselja-Perisin et.al. highlighted distinct differences in perceptions between 'shared authority' and 'interprofessional education', with pharmacy students expressing the most positive attitudes in comparison to medical students who showed the lowest attitudes towards collaboration[47]. Seselja-Perisin et.al. cite that these findings may impact upon interprofessional collaboration in students future careers as health care professionals[47]. It is apparent that when it comes to the NICU, medical students feel that pharmacotherapy-related decisions are the responsibility of the medical staff, with pharmacists acting as a support for the administrative processes rather than as an influencing factor in patient care. These results are similar to those obtained from the study conducted in Poland by Swieczkowski et.al., who assessed medical and student perceptions towards pharmaceutical care in the community setting [48]. Swieczkowski et.al. highlighted that the majority of medical students felt that doctors are solely responsible for selection of pharmacotherapy, TDM and patient education, whereas teamwork with pharmacists was expected in the reporting of adverse drug reactions and drug interactions[48]. Medical students viewed pharmacists more as an adjunct to the medical team, and perceived their value to lie in their capacity as a source of medication information. This indicates that medical students do not understand the fundamental concept of pharmaceutical care (PC) and also have a limited understanding of the potential scope of pharmacist practice in a ward-based environment. PC is defined as "*a philosophy of practice in which the patient is the primary beneficiary of the pharmacist's actions. PC focuses the attitudes, behaviors, commitments, concerns, ethics, functions, knowledge, responsibilities and skills of the pharmacist on the provision of drug therapy with the goal of achieving definite therapeutic outcomes toward patient health and quality of life*"[1,3]. These results mirror those obtained by Swieczkowski et.al. who reported that the majority of Polish medical students in their study could not identify a correct definition of pharmaceutical care[48].

In contrast, pharmacy students expressed favorable attitudes towards integrating the pharmacist into the therapeutic team. The majority indicated that pharmacists should be consulted on pharmacotherapy-related decisions on the NICU and should also have a direct role on the ward in a clinical capacity. These findings are consistent with those collected by Pawłowska et.al. in their study relating to pharmacist practice in hospitals in Poland, whereby 33% of hospital pharmacists indicated that they would like to be included as a member of the therapeutic team[14]. When comparing practicing pharmacists opinions to those of pharmacy students, our study found that 91.9% of pharmacy students felt that as future pharmacists they should be involved in pharmacotherapy-related decisions. Similar sentiments were found among Kuwaiti pharmacy students, who expressed positive attitudes towards the provision of pharmaceutical care[31]. This indicates that pharmacy students are more comfortable with the concept of pharmacists having an active role in prescribing and monitoring pharmacotherapy on the NICU and being a contributor to the multidisciplinary treating team than medical students. Pharmacy students consistently reported the positive impact of pharmacist involvement in the NICU, and recognized the importance of pharmaceutical care being extended throughout a patient's admission to the NICU. However, it was observed that despite their interest to perform more clinical roles, pharmacy students felt unprepared to carry out ward-based services in their future practice.

The differences in opinions seen between pharmacy and medical students may be attributed to several reasons. First, there are socio-cultural elements that need to be considered, relating to the perceived hierarchy of healthcare providers in the hospital. Traditionally, doctors in Poland have been regarded as authoritative figures in the hospital, responsible for all aspects of decision-making relating to the patient[49]. In comparison, nurses and pharmacists are considered to work in a supportive capacity, assisting in the delivery of services[49]. Currently, pharmacists do not provide ward-based services in hospitals, and fulfill their function from within the dispensary. As such, these ingrained perceptions may influence the current opinions of students. This traditional form of pharmacy practice and multi-disciplinary collaboration has also influenced the way the pharmacy and medical studies are delivered at universities in Poland. The current tertiary education system focuses on uni-professional education of students rather than an inter-professional form of education. At present, each health-related discipline i.e. medicine, nursing, pharmacy and physiotherapy is taught separately from the others as a distinct, individual course, with minimal to no multi-disciplinary collaboration. In addition to this, pharmacy curricula in Poland are strongly focused on the traditional scope of pharmacist services i.e. dispensary based compounding activities, with little to no focus on

clinical pharmacy practice. There are no subjects that prepare students for more integrated roles on ward environments, and there is no learning involving simulations relating to patient care, or teamwork. This is also observed within the medical curriculum, where there is no emphasis placed on teaching medical students about the roles and potential contributions of the pharmacist as a member of the multi-disciplinary treating team. As such, the current schooling system does not fully expose students to pharmaceutical care and students are not fully prepared for a collaborative form of practice. The findings of this study reinforce this point given that small proportion of students from both disciplines felt the evaluation of laboratory results was a role for pharmacists, but a large proportion thought pharmacists should be involved with TDM and TPN monitoring which both primarily involve laboratory interpretation. As such, this reinforces that the students' replies are primarily based on theoretical knowledge and they may not actually understand the potential roles on which they are being asked to comment.

Overall, the results draw attention to three major issues – the absence of multidisciplinary collaboration, poor understanding of the pharmacist's role and their potential in the NICU and a lack of structural support and preparation for pharmacists in undertaking clinical practice. As such, these findings indicate a significant need for the development of educational strategies that address these gaps in knowledge to better prepare graduates for their future careers in healthcare teams. Interprofessional education (IPE) has been cited as an effective tool in improving collaboration and increasing the understanding of each profession's capabilities and their responsibilities on the ward[50]. The WHO acknowledges that, "*health professionals who are taught together in a interprofessional educational setting and learn to collaborate as a team during their student years, are more likely to work effectively together in their professional lives in a clinical setting*"[51]. This approach is particularly important to the NICU, as the quality of neonatal care and the safety of patients is dependent on team-based care[50]. Barbosa highlights that "*a collaborative, multidisciplinary team approach that emphasizes shared responsibility, practices effective communication, and respects and recognizes that no one functions independently in the NICU is recommended to promote the best possible outcome for infants and families*"[52]. NICU-specific IPE strategies have been reported as including simulated case studies, for example involving respiratory distress syndrome or sepsis, requiring nursing, medical, pharmacy and respiratory therapy students to role play working through the case as they would in practice i.e., reviewing the plan of care, determine priorities, and discuss any needed changes[50]. Other interactive activities has been described as practice simulations, or immersive experiences, involving videotaped procedures, which encourage

collaboration and communication among students[50]. The subsequent reported benefits for students of NICU-specific IPE include: improved general interactions and communication between future health professionals, improved understanding of overlapping professional functions, an understanding of each professions roles in healthcare delivery and the value of these roles in relation to patient management as well as a better understanding of illnesses and therapeutic interventions in this area of practice[53,54].

As such, the implementation of IPE into Polish medical and pharmacy programs could assist in introducing clinical aspects of the role to pharmacy students as well as help to challenge the traditional stereotypes of a pharmacist, as perceived by medical students. A study by Swieczkowski et.al. which canvassed the opinions of a group of Polish pharmacy and medical students, highlighted that 89.9% of students agreed that during medical training there should be more emphasis on developing a collaborative relationship between doctors and pharmacists[48]. Both the WHO and FIP have agreed that: "*IPE leads to a collaborative practice-ready workforce, and collaborative practice leads to a strengthened healthcare system, resulting in improved patient health outcomes*"[55]. Therefore, future research is needed to develop educational strategies that further integrate both interprofessional education as well as more clinically-driven courses into the pharmacy and medical curriculum, specifically for specialty areas of practice.

LIMITATIONS

This survey was distributed among students at only one medical university, and as such, the sampling frame and sample size are limited. Furthermore, the study used convenience sampling and the manual distribution of surveys during lectures may have also limited the number of participants. Overall, the small sample size and limited survey data may not be representative of all pharmacy and medical health professionals or students in Poland and might not be generalizable across university settings nationally. Furthermore, the responses obtained from students are based on their theoretical knowledge of pharmaceutical care given that they have had limited contact with this type of practice to date. In regard to the study design, surveys are unable to elicit in-depth qualitative data in the way that interviews or focus groups can, and therefore the researchers were unable to fully explore participants' underlying reasons for these responses. Therefore, the results should be interpreted with caution.

However, this study can inform future qualitative research to capture a more comprehensive story of student perceptions towards advancing pharmacy services in hospitals.

CONCLUSION

Overall, Polish pharmacy and medical students have positive attitudes towards the concept of pharmaceutical care in the NICU. However, significant differences were identified regarding expectations around clinical roles, and pharmacist integration into multi-disciplinary medication consultations. Future efforts should be aimed at developing and integrating inter-professional education into medical and pharmacy programs to encourage effective inter-disciplinary collaboration in future practice. Furthermore, there is a perceived need from pharmacy students to be better supported in their future roles as clinical pharmacists. As such, further investigation is also needed to develop educational strategies directed at clinical, patient-centered roles, particularly for specialty areas of practice such as the NICU, that have the potential to facilitate the provision of a more advanced and comprehensive level of pharmaceutical care. Whilst this study is the first to report on pharmacy and medical students perceptions towards pharmacist practice in Polish NICUs, the findings are subject to some limitations, which are primarily related to the study being conducted at a single Polish university, limiting the sample size and generalizability of the results.

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Table 1: Demographic information for participating medical and pharmacy students

	PHARMACY (n = 74) (%)	**MEDICINE (n = 73) (%)**
GENDER		
Female	61 (82.4)	52 (71.2)
Male	13 (17.6)	21 (28.8)
YEAR OF STUDY		
3	4 (5.4)	0
4	27 (36.5)	0
5	43 (58.1)	66 (90.4)
6	N/A	7 (9.6)

Table 2: Proportion of students agreeing that specific roles should be performed by pharmacists in the NICU

ADMINISTRATIVE ROLES			
	Pharmacy Students (%) N = 74	**Medical Students (%) N = 73**	**P-value (Comparison of proportions between pharmacy and medical students)**
Development/implementation of a drug formulary service	69 (93.2)	63 (86.3)	0.164
Attendance at non-clinical meetings i.e. Drug and Therapeutics Committee	70 (94.6)	67 (91.8)	0.498
Conducting quality assurance measures i.e. drug usage evaluations, workload documentation, auditing	73 (98.6)	71 (97.3)	0.552
Management of the drug budget	52 (70.3)	41 (56.2)	0.076
Evaluation, selection and purchasing of pharmaceuticals for the unit	58 (78.4)	56 (76.7)	0.809
Development of drug policies/protocols/guidelines for the NICU	72 (97.3)	71 (97.3)	0.989

EDUCATION/COMMUNICATION/RESEARCH			
	Pharmacy Students (%) N = 74	**Medical Students (%) N = 73**	**P-value (Comparison of proportions**

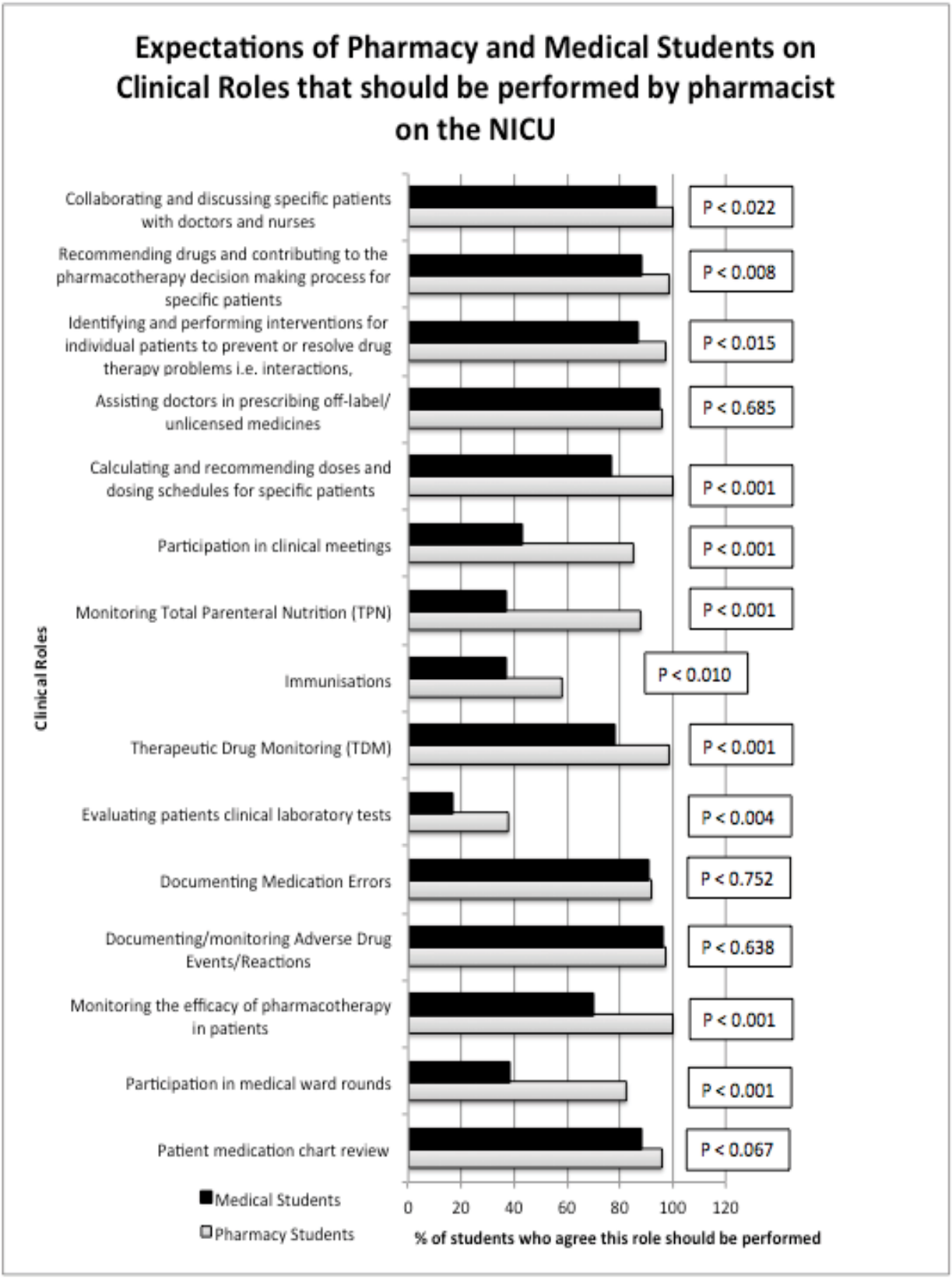
			between pharmacy and medical students)
Providing training/in-services for other health professionals on NICU related topics and drug related problems	63 (85.1)	70 (95.9)	0.026
Contributing to and/or attending NICU related conferences	72 (97.3)	64 (87.7)	0.027
Involved in clinical trials	73 (98.6)	72 (98.6)	0.992
Involved in research related to neonatal pharmacotherapy	72 (97.3)	71 (97.3)	0.989
Source of drug information - responding to information requests from health professionals on the ward	69 (93.2)	72 (98.6)	0.099
Counselling parents/carers of neonatal patients	67 (90.5)	51 (69.9)	0.002

PROVISION OF MEDICINES			
	Pharmacy Students (%) N = 74	**Medical Students (%) N = 73**	**P-value (Comparison of proportions between pharmacy and medical students)**
Dispensing prescriptions	64 (86.5)	58 (79.5)	0.256
Extemporaneous compounding of formulations for the NICU	73 (98.6)	73 (100)	0.319
Stocking the ward with essential medicines/house-keeping activities i.e. checking expiry dates, fridge temperatures etc.	66 (89.2)	66 (90.4)	0.807

Table 3: Proportion of student opinions agreeing on pharmacist involvement in the NICU

OPINIONS	PHARMACY N = 74	MEDICINE N = 73	P-value (Comparison of proportions between pharmacy and medical students)
Should the pharmacist be consulted as part of the treating team when making medication-related decisions for NICU patients?	68 (91.9%)	52 (71.2%)	0.001
Is there a need for a pharmacist to be stationed permanently or routinely visiting the NICU?			
Yes routinely (PART TIME, VISITING POSITION ON THE WARD)	27 (36.5%)	43 (58.9%)	-
Yes permanently (FULL TIME POSITION ON THE WARD)	47 (63.5%)	18 (24.7%)	-
No	0	12 (16.4%)	-
In your future practice, would you like to see collaboration between the doctor and the pharmacist?	72 (97.3%)	70 (95.9%)	0.638
In what way?			
Direct consultation with visiting pharmacist	24 (33.3%) N = 72	36 (50.7%) N = 71	-
Direct consultation with permanent pharmacist	48 (66.7%)	21 (29.6%)	-
Email/telephone contact	0	14 (19.7%)	-

Figure 1: Student opinions on clinical roles that should be performed by pharmacists on the NICU



CHAPTER FIVE

FOCUS ON MEASUREMENT

5.1 INTRODUCTION

This chapter comprises two manuscripts aimed at understanding what quality measures are currently available to assess pharmacist practice in the NICU. The first paper is a copy of a literature review published in Drugs and Therapy Perspectives, which aimed to identify the key performance indicators or quality measures used to guide pharmacist practice in NICUs worldwide. The second paper is a qualitative study, involving semi-structured interviews with NICU pharmacists in Poland and Australia. This research aimed at identifying what quality measures pharmacists used to evaluate their current practice in the NICU, and to identify whether there is a need to develop a guidance document depicting a quality level of pharmacy service in the NICU.

5.2 QUALITY USE OF MEDICINES IN NEONATAL CARE: A REVIEW OF MEASURES OF QUALITY USED TO EVALUATE THE APPROPRIATENESS AND RATIONAL USE OF MEDICATION WITHIN THE NICU

Krzyżaniak N, Bajorek B.

DRUGS & THERAPY PERSPECTIVES

2016;32(9):392-402.

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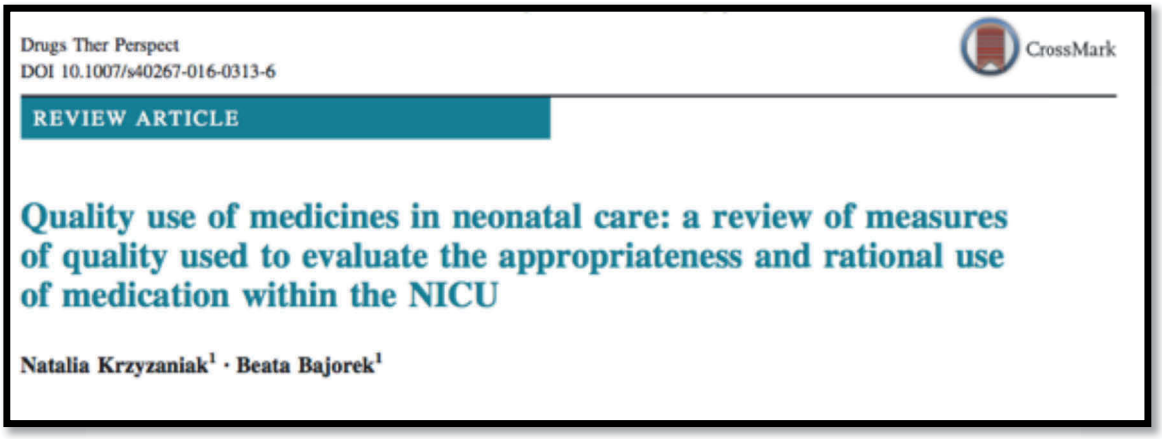
Drugs Ther Perspect
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REVIEW ARTICLE

Quality use of medicines in neonatal care: a review of measures of quality used to evaluate the appropriateness and rational use of medication within the NICU

Natalia Krzyzaniak[1] · Beata Bajorek[1]

AUTHORS' CONTRIBUTIONS

Natalia Krzyżaniak conducted the literature search and wrote the manuscript. Beata V Bajorek assisted in critically revising the manuscript prior to submission.

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Signature removed prior to publication.

Natalia Krzyżaniak

Beata V Bajorek

ABSTRACT

With medication error rates in neonatal intensive care units (NICUs) reported to be as high as 91 medication errors per 100 patient admissions, the quality use of medicines (QUM) in this setting is important. Comprising the safe, rational, appropriate and effective use of pharmacotherapy, QUM is integral to achieving medication safety and optimal patient outcomes. To improve QUM in the NICU, the medication use process needs to undergo a quality assessment, using quality measures or indicators. As such, the objectives of this quasi-systematic literature review were to identify the measures used to evaluate QUM within the NICU and to map these against Donabedian's traditional framework of structure, process and outcome. We searched Embase, PubMed, CINAHL, Google Scholar as well as Google for relevant published and grey literature. Overall, a total of 47 quality measures were identified and categorised: 17 structure, 19 process and 11 outcome measures. The most common measures related to: the availability of medication safety technology on the NICU, written policies on the use of high risk medications, medication error and adverse drug event reporting systems, and the provision of education for health professionals involved in the medication use process. However, there were no quality measures specifically designed for medication management in the NICU. The literature does not provide a comprehensive evaluation of the quality of care provided along the medication use process in the NICU. There is a need to develop a quality framework outlining measures that facilitate the appropriate use of medicines in the NICU.

1. INTRODUCTION

Medication safety is of utmost priority in the neonatal intensive care unit (NICU).[1] Medications are heavily utilised within the NICU, with a reported average of 8.6 medications being prescribed per patient.[2] The high-risk characteristics of neonatal patients, including physiological vulnerabilities, varying pharmacokinetics as well as the limited amount of evidence-based information available on the use of pharmacotherapy in infants, increase the complexity of the medication use process.[3-5] In combination with the fast-paced, challenging NICU environment, neonates are at a high risk of medication misadventure with potentially significant consequences that may have long-term impacts upon a child's development.[3] With medication error rates reported in NICUs as high as 91 medication errors per 100 patient admissions, the quality use of medicines (QUM) in this setting is important.[5] Comprising the safe, rational, appropriate and effective use of pharmacotherapy, QUM is integral to achieving medication safety and optimal patient outcomes.[6-8]

In order to improve QUM in the NICU, the medication management process needs to undergo a quality assessment, using quality measures or indicators.[9] Quality indicators are measurable elements that refer to the structure, process and outcomes of pharmacotherapy in the NICU.[9, 10] The medication management process is complex and comprises several phases: prescribing, transcribing, dispensing, administering and monitoring.[11] As such, in order to provide an all-inclusive quality assessment, indicators must consider each aspect of the medication management process. Previous studies describe various measures related to the appropriate use of medications in adult patients, including the Assessing Care of Vulnerable Elders (ACOVE) quality framework, however, there is relatively minimal corresponding literature in other patient groups, particularly neonates.[12] Therefore, the aim of this review was to identify quality measures used to evaluate the medication management process within the NICU. A specific objective was to identify the range of measures used to evaluate the quality use of medicines in the NICU.

2. METHOD

A quasi-systematic review (a review that possesses some elements of a systematic review, including pre-defined selection criteria, however includes grey literature and does not present a critical evaluation of the quality of studies) of the literature was performed and the findings

were mapped against Donabedian's framework of structure, process and outcomes.[10, 13-16] A structure of care describes the characteristics of the setting or the organisational framework supporting the process of care, for example, the number of qualified staff, type of hospital, level of NICU. [17, 18] Process refers to the method of healthcare service provision and includes the amount and type of activities performed for the patient. This relates to what is done to the patient, including types of interventions, evidence based treatment regimens, etc.[9, 17-20] Outcomes are classified as the consequences of healthcare and comprise the health status of patients i.e. morbidity, mortality etc.[9]

For the purpose of this review a definition of quality was adapted from the World Health Organisation's (WHO) description of quality in healthcare.[21] This definition was modified to characterise quality relating to the medication use process in the NICU, including the quality of the structure and process systems as well as the outcomes they produce.[21] As such, quality is described across six dimensions, as follows:

- Effective: Using medicines that are evidence-based and which result in improved health outcomes for individuals based on need.
- Efficient: Using medicines in a manner that maximises resource use and minimises waste.
- Accessible: Using medicines in a manner that is timely and provided in a setting where skills and resources are appropriate to therapeutic need.
- Patient-centred: Using medicines in a manner that takes into account the preferences of individual patients.
- Equitable: Using medicines that do not vary in quality because of personal characteristics.
- Safe: Using medicines in a manner that minimise risk and harm to patients. [21]

The review sought to identify quality measures relating to the medication use process in accordance with this definition. Quality measures included guidelines, consensus statements, position statements and quality assessment tools. (Table 1) Furthermore, due to a lack of available literature, the review also included studies that suggested interventions or resources to improve any of the aforementioned dimensions of quality and had the potential to be applied in the future as quality indicators.

Full-text articles were retrieved by searching the following databases: Embase, PubMed, CINAHL and Google Scholar, in the period from March 2015 – March 2016. Citations and

reference lists were also hand-searched to find articles that were not identified in the original search. This was supplemented by a Google search to identify relevant grey literature. Articles were selected for the review if they included quality measures/indicators relating to the use of medicines, if the quality indicators were applicable to the NICU and if they stated recommendations for the improvement of medication management. The articles were mapped against Donabedian's domains of healthcare quality, in three steps. If articles used Donabedian's terms within their findings, they were reviewed to determine their design i.e. study, guideline etc. Secondly, measures were identified as belonging to structure, process or outcome per the definition used in Donabedian's framework or via author verification. Third, these measures were categorised into their corresponding domains on the discretion of Author 1 and were verified by Author 2.

3. SEARCH STRATEGY

A two-tiered search strategy was used. (Figure 1) In Tier 1, a generalised search of the electronic databases was conducted using the MeSH terms: *quality, quality indicators, neonate/infant/newborn*, *NICU*, *medication, medication safety, medication prescribing/transcribing/dispensing/administration/monitoring, patient safety, pharmacist services/pharmaceutical care*. The search terms combined keywords and medical subject headings for neonate, medication safety and quality indicators. The search parameters limited the inclusion of articles relating to the use of medication in NICU, neonatal patients and written in the English language. We applied a date limit so that only recent articles published from the year 2000 or later, i.e. 2000 - 2016 were taken into account. Tier 2 of the search identified relevant sources of grey literature using a Google search of the same terms. Organisations such as WHO, Council of Europe, Society of Hospital Pharmacists Australia, and Australian state/national government protocols in particular were reviewed. The articles retrieved from each tier of searching were pooled for analysis, in-line with the study objectives.

4. RESULTS

A total of 20 sources of information were identified, comprising seven reports [22-28], four studies (including cohort and observational studies)[1, 29-31], one literature review [32], three position statements [33-35], four hospital service standards/guidelines [36-39] and one quality assessment tool developed by the WHO [40]. (Table 2) The literature collected came from the USA (12 of 20 articles) [22-31, 33, 35] and UK (3 of 20 articles) [37-39], with singular reports from the Netherlands [32], Australia [36], New Zealand [1] and Qatar [34]. No randomised control trials were identified in the search.

Overall, the search identified limited published literature comprehensively exploring the quality measures associated with QUM in NICUs. Among the included literature, a total of 47 quality measures were identified and categorised: 17 structure measures, 19 process measures and 11 outcome measures. (Table 3)

4.1 MEASURES OF QUALITY RELATING TO STRUCTURE

Overall, structure measures most commonly related to the staffing and support systems available on the NICU. Three structure measures referred to the presence of a qualified and experienced NICU pharmacist on the ward. A ward-based pharmacist was reported as a key facilitator for the QUM on the NICU, compared to just having access to an externally provided service based in the main hospital pharmacy.[28, 36-39] 'Qualified' was defined in the Scottish and British NICU guidelines as a pharmacist who held postgraduate qualifications in paediatric practice or possessed the equivalent level of skills and knowledge.[37, 38] The National Institute for Health and Care Excellence (NICE) standard also reaffirmed that all NICU pharmacists were required to be sufficiently skilled and compliant with NICU-based competency standards according to each setting's regulations (i.e. British Department of Health Toolkit).[39] Required competencies included possessing comprehensive knowledge of neonatal development, metabolic pathways, as well as pharmacokinetics and pharmacodynamics in neonates.[38] Two resources also reported on the requirement for NICU pharmacists to continue to update their knowledge through continuing education to ensure currency of practice.[33, 38] Additionally, two resources stipulated that there was a need for adequate levels of qualified nursing and medical staff on the NICU, with appropriate workloads and sufficient rest breaks to prevent fatigue errors from occurring.[35, 38] The British

Association of Perinatal Medicine (BAPM) guideline recommended that due to the complex needs of infants in the NICU, the ratio of neonatal nurses should be 1 nurse : 1 baby, and medical staff should consist of a minimum of 8 staff comprising specialists, consultants and residents.[38]

The amount of time required and the capacity for pharmacists to provide pharmaceutical care in NICU was also emphasised as a relevant structure measure. The BAPM guideline recommended that NICU pharmacists should allocate at least 10-20 minutes of time (care) per patient-cot as well as attend medical ward rounds and meetings.[38] The Australian standard proposed an alternative method of pharmacist involvement, by allocating pharmacist time to NICU according to the complexity of care within a specific unit (Level 1 – caring for infants with minor conditions with gestations > 37 weeks, Level 2 – caring for newborns with gestations >34 weeks and requiring incubation, oxygen and intravenous therapy, Level 3 – caring for newborns with serious conditions requiring 1:1 nursing care) (Table 1). It was recommended that Level 1 and 2 NICUs required routine pharmacist access, however Level 3 NICUs required a 24-hour pharmacy support service to be available.[36]

In addition to staffing, four structure measures reported that specific facilities were important requirements for QUM in NICUs. A well-lit work environment, with sufficient work-space, minimal distractions and easily accessible to reference materials was described as optimal for medication safety.[35] Additional important elements also included: space within the unit for medication preparation; and aseptic preparation sites.[36, 38] This was further verified by the WHO quality assessment tool, which specifically recommended that essential medicines (such as caffeine and surfactants) are readily accessible for the timely application of pharmacotherapy.[40]

Structure measures were also associated with the availability of medication management systems. In maintaining medication safety, two guidelines and one quality assessment tool identified the need for evidence-based clinical practice guidelines and protocols for high-risk medications within the NICU to assist with medication selection and administration as well as standard references to assist the general prescribing of medications for neonates.[34, 35, 38, 40] Additionally, it was acknowledged that it was important to have clear, specific policies that were accessible to all healthcare professionals on how medications in the NICU were prescribed, processed, dispensed, administered and monitored.[35] TPN was highlighted as an area requiring additional attention, and it was reported by Grissinger as requiring standardised prescribing methods including pre-printed forms or standard order sets that prompted correct

dosing, established three-fold verification of TPN dispensing and administration processes as well as automated dose limit warnings built into pharmacy computer systems.[23] Other measures suggested for the improvement of medication safety included the availability of emergency medication sheets, listing doses by weight, as well as an established neonatal formulary with standardised concentrations of medications to be used in the NICU.[25, 28, 35]

Several resources referred to the utilisation of technology to promote the safe and rational use of medicines. These resources included: barcode verification systems, smart-pumps, computerised physician order entry (CPOE), clinical decision support systems (CDSS), computerised calculation of doses, automated drug dispensing robots and electronic health records.[24-26, 28, 29, 32, 35] Morriss et.al. attributed a barcode verified administration system with reducing the risk of targeted, preventable ADE's in neonatal patients by 47%.[29] Furthermore, in the event of an adverse reaction or medication error, three resources identified that it was essential for the NICU to have a reliable electronic reporting system to document the implicated medications.[33-35, 38] These systems allow for the collection of data regarding the types and causes of error, and allow for the identification of trends in error.[22] McCartney states that electronic database can identify more errors than a paper based reporting method and can facilitate a retrospective analysis of errors.[26] Furthermore, these types of systems enable drug usage data to be tracked. Ellsbury and Ursprung reported that medication misuse could be attributed to failures in collection, reporting and review of drug utilisation data by NICU treating teams.[22] Drug utilisation data provides an insight into patterns of use and allows for benchmarking against other databases.[22]

4.2 MEASURES OF QUALITY RELATING TO PROCESS

Process measures were deemed by de Boer et.al. to be the best method of evaluating quality use of medicines in NICU as they identify factors directly associated with patient care.[41] Process measures relating to NICU medication practice were well-documented within the literature and can be divided into three categories: clinical pharmacist interventions, education/training, and documentation and monitoring of medication-related problems. Clinical pharmacist interventions related to the number and type of interventions performed, including therapeutic drug monitoring, review of patient medication charts, participation in ward rounds, verifying prescriptions, participating in clinical research, and optimising intravenous and TPN therapy.[28, 32-35, 38] The British NICE and BAPM guidelines identified

that clinical pharmacist activities improved the quality of medication management in NICU, as these roles improved the rationalisation of resources, reduced costs and reduced medication errors.[38, 39] Four measures related to medication information services and involved pharmacist's providing a medication counselling service to parents, providing general medication information to other NICU professionals, and educating NICU staff on medication protocols. In particular, it was noted that involving parents in the care process was important in achieving quality pharmaceutical care, and required regular communication and consultation with parents in making decisions about pharmacotherapy for their child.[39] Furthermore, only one standard identified the need for pharmacists to advise physicians regarding the use of off-label and unlicensed medicines, including the choice of medication and the type of formulation required.[38] Potentially more attention may be required in this area, as a significant proportion of medications are prescribed off-label or on an unlicensed basis in NICU.

Education was viewed as an important element to the QUM on the NICU in ensuring uniformity and currency of medication management practice.[1, 32-35, 38] Specifically, the National Association of Neonatal Nurses (NANN) position statement highlighted the importance of providing education to NICU staff involved in the medication use process on medication safety principles, the appropriate use of medication delivery devices, calculating doses as well as appropriate prescribing, preparing, and administering of medications.[35] Kunac et.al. highlighted that higher rates of medication errors occurred when new or intern doctors join the neonatal team, however noted training on safe prescribing practices was rarely provided to these staff.[1]

Furthermore, two position statements and one guideline emphasised the importance of the pharmacist in monitoring and reporting and adverse drug events in neonatal patients.[33, 34, 38] It is acknowledged that adverse drug reactions are avoidable when documentation is complete and readily accessible, leading to increased patient safety.[38] In response to any errors that occur, two resources identified that critical incident or root cause analyses should be thoroughly conducted to identify how these errors occurred and to develop strategies and action plans for preventing their recurrence and addressing flaws in the medication use process.[28, 35]

Pain management is highlighted as a high-risk area of practice in the neonatal population, with reports of over-prescribing of opioids as well as adverse effects from opioids. Sharek et.al. suggested process measures to improve pain assessment and management of neonates

experiencing pain in the NICU, including the use of pain scales for assessment of patients to determine appropriate pain management as well as the use of pain protocols for patient groups and specific procedures.[30] Additionally, Sullivan et.al. found that the use of a prescribing error feedback programme, which reported back to prescribers on trends in opioid prescribing errors in their NICU as well as on their own prescribing errors over the previous fortnight, had a relative reduction of opioid prescription errors by 83%.[31]

4.3 MEASURES OF QUALITY RELATING TO OUTCOME

It was reported that, due to multiple treatment modalities and multidisciplinary staff, outcome measures were the most difficult to attribute to the quality use of medicines.[41, 42] However, Kunac et.al. highlighted several outcome measures that were related to QUM in the NICU including: monthly audit of medication charts (with a target of at least 80% of correct time of administration), monthly audit of the labelling of all parenteral fluid/medication lines (to be labelled with access type and fluid/medication being administered, with a target of at least 90% correct labels) and monthly audit of prescribing against prescribing guidelines (target 90%).[1]

Furthermore, important areas of practice identified as being high-risk in neonatal patients included antimicrobial therapy and pain assessment. Outcome measures related to antimicrobial therapy were dedicated to monitoring antibiotics that were used most frequently in the NICU, and which also incurred the most costs, had the greatest risk of toxicity or the greatest risk of inducing antibiotic resistance.[27] Pain management measures related to the number of appropriate pain management interventions prescribed.[30]

Five resources also identified more general outcome measures relevant to the healthcare of the neonatal population.[17, 40, 42-44] The most commonly identified measures referred to the mortality rate of infants in NICU as well as the incidence of patient morbidity, neonatal sepsis and nosocomial infection, the duration of TPN therapy and daily weight gain.[17, 40, 42-44] However, it is unknown to what extent these measures are influenced by medication use or whether they directly reflect quality use of medicines in the NICU.

We also sought to identify outcome measures that were relevant to QUM, but which were not specific to a particular patient population, but which might be relevant to the NICU.[45] These

included the number of medication errors, adverse drug events, pharmacist interventions performed, and the costs of drug therapy.[45] Furthermore, another study was identified with outcome measures that may be applicable to the neonatal population.[46] These included: quarterly dispensing errors (target < 5%), drug related problems (target < 10%), pharmacist participation in research projects (target > 1 – publications conferences).[46]

5. DISCUSSION

To our knowledge, this is the only review that identifies the range of quality measures relevant to medication use within the neonatal population. A total of 47 measures within the 20 sources of literature were identified relating to quality use of medicines in the NICU. (Table 3) The majority of these measures referred to the structure and process domains and most commonly described the availability of medication safety technology on the NICU, written policies on the use of high risk medications, medication error and adverse drug event reporting systems, and the provision of education for health professionals involved in the medication use process. The literature collected did not comprehensively address medication management in each phase of the medication use process. Most of the quality measures identified referred to the prescribing of medications, with less attention paid to medication dispensing and administration. As such, the findings of the review inform the need for a framework of quality measures to be developed that represents quality use of medicines in the NICU. Such a framework would allow for the benchmarking of medication usage in the ward, tracking the performance of medication related processes and identification of areas requiring improvement.

Current studies that identify quality measures in NICU are predominantly based in other fields of healthcare, i.e. nursing, and do not relate to quality use of medicines.[17] One study related to nursing and physician care by Profit et.al., designed the baby-MONITOR quality framework which involved the use of clinical indicators including timely retinopathy of prematurity examinations, oxygen at 36 weeks and rates of first hour hypothermia.[47] Other nursing literature has used general NICU based health indicators to establish the level of quality healthcare being delivered and has measured the number of incubators available, nursing staff levels, incidence of intraventricular haemorrhage and rates of necrotizing enterocolitis.[19, 48, 49]

Studies that do identify medication-based quality measures are not studied within NICU settings. Within the elderly population, several studies emphasise the use of the ACOVE set of quality indicators that measure the processes of pharmaceutical care in both hospitalised and community based settings, including the rates of prescribing appropriate medications, therapeutic drug monitoring, correct transcribing of medication orders and comprehensive discharge summaries.[12, 50] It is unknown whether quality measures assessing medication management in adult patient groups are relevant to medication processes in the NICU. However, it is recognised that specific quality indicators need to be adapted to particular patient groups, for example, in the instance of surgical patients the measurement of the rates of patients receiving suitable peri-operative antibiotic prophylaxis.[41]

Upon birth neonates are already at a high risk of mortality, with a reported two thirds of neonatal deaths occurring within the first week of life.[51] In addition, once admitted to the NICU, patients are also subjected to complex pharmacotherapy regimens, increasing the potential for medication error which may further compromise the health of these patients.[5] Quality indicators are necessary to improve medication safety in the NICU, as they facilitate transparency of medication-use processes and help to benchmark NICU performance.[9, 52] As of yet, there are no reliable and valid quality indicators available in the literature that clearly define and evaluate the quality use of medicines in the NICU. More attention should be paid to the development of measures that assess each phase of the medication use process and address pharmacist as well as nursing and clinician input.

LIMITATIONS

Due to the lack of good-quality literature exploring this area, it is difficult to determine whether the key measures identified are applicable to current practice. Relevant literature from Asia, Africa, South America was not available, precluding a truly global perspective. It is also possible that a large number of studies were excluded due to not being available in the English language.

6. CONCLUSION

Quality measures within the NICU were most frequently identified within the structure and process domains, with limited outcome measures specific to quality use of medicines in the NICU. The most common measures related to: the availability of medication safety technology on the NICU, written policies on the use of high risk medications, medication error and adverse drug event reporting systems, and the provision of education for health professionals involved in the medication use process. However, there were no validated quality indicators specifically evaluating medication use in the NICU. Further research is required to address these gaps in knowledge and develop a quality framework that identifies key quality measures that facilitate appropriate and quality use of medicines in the NICU.

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Table 1: Definitions of terms used in review

TERM	DEFINITION
CLINICAL INDICATOR	"Measures of elements of clinical care which may, when assessed over time, provide a method of assessing the quality and safety of care at a system level. Can be measures of process, structure and/or outcomes of patient care"[53, 54]
CONSENSUS STATEMENT	"A comprehensive summary of the opinions of a panel of experts about a particular scientific, medical, nursing or administrative issue. Its purpose is to provide guidance to healthcare professionals, particularly on poorly understood or controversial aspects of care"[55]
GUIDELINE	"Systematically developed statements to assist practitioner and patient decisions prospectively for specific clinical circumstances"[54, 56]
KEY PERFORMANCE INDICATOR (KPI)	"Measures of performance that are used by organisations to measure how well they are performing against targets or expectations. KPIs measure performance by showing trends to demonstrate that improvements are being made over time"[57, 58]
POSITION STATEMENT	"A written statement that articulates a position, viewpoint, or policy of a healthcare system or hospital organisation regarding best practices, standard care, or inconclusive evidence-based research".[59]
QUALITY ASSESSMENT TOOL	"A document that provides a semi-quantitative assessment of the quality of care in a variety of key areas, and can be used to assess and monitor the baseline situation and subsequent improvements, thus providing key information before and after interventions to improve quality of care, as well as for incentives and accreditation schemes"[40]

QUALITY IMPROVEMENT	*"*An organised process that assesses and evaluates health services to improve practice or quality of care*"[60]*
QUALITY MEASURE	"Quality measures are tools that help measure or quantify healthcare processes, outcomes, patient perceptions, and organizational structure and/or systems that are associated with the ability to provide high-quality healthcare and/or that relate to one or more quality goals for healthcare. These goals include: effective, safe, efficient, patient-centered, equitable, and timely care." [61]
QUALITY PHARMACEUTICAL CARE	"The extent to which pharmacy services deliver effective, efficient, patient-centred, equitable and safe pharmacotherapy"[21]
QUALITY STANDARD	"The level of compliance with a criterion or indicator. A standard is set prospectively and stipulates the level of care that a provider must strive to meet"[54, 56]
QUALITY USE OF MEDICINES	"Selecting management options wisely, choosing suitable medicines if a medicine is considered necessary so that the best available option is selected and using medicines safely and effectively to get the best possible results"[6-8]
LEVEL 1 NEONATAL INTENSIVE CARE UNIT (NICU): BASIC	"A nursery that must be capable of assessing, diagnosing and managing uncomplicated pregnancies and: - newborn infants without complications • gestation 37 weeks or greater • birth weight 2,500 grams or greater - newborn infants with minor conditions not requiring additional nursing or specialist medical treatment - newborn infants requiring phototherapy (in consultation with a specialist paediatrician)"[36]
LEVEL 2 NICU	"A neonatal unit that must be capable of assessing, diagnosing and managing:

	- newborn infants without complications • gestation 34 weeks or greater • birth weight 2,000 grams or greater, including growing preterm and convalescing infants - newborn infants requiring incubator care for: • short-term transition problems • mild complications: - oxygen requirement (not exceeding 40%) - apnoea monitoring - blood glucose monitoring - short term intravenous therapy - phototherapy - gavage feeding"[36]
LEVEL 3 NICU	"Neonatal unit that must be capable of assessing, diagnosing and managing all newborn infants requiring neonatal intensive care including infants: - requiring continuing assisted ventilation via an endotracheal tube, and for the 24 hours following endotracheal tube removal - requiring oxygen therapy (more than 60%) for more than four hours - with tracheostomies requiring intermittent positive pressure ventilation (IPPV) or continuous positive airway pressure (CPAP) - requiring a nasopharyngeal tube (without CPAP) to maintain airway patency - requiring an arterial line for continuing blood gas and/or blood

	pressure monitoring - having frequent seizures - undergoing major surgery, on the day of the procedure and for 48 hours postoperatively, including: • any procedure where a body cavity is opened • repair of neural tube defect • placement of a ventriculoperitoneal shunt or temporary ventricular drainage device - requiring 1:1 nursing care”[36]

Table 2: Summary of findings documenting quality measures related to quality use of medicines within the NICU[5]

INTERNATIONAL GUIDELINES / HOSPITAL SERVICE STANDARDS		
COUNTRY	**PUBLISHING ASSOCIATION**	**GUIDELINE**
Scotland	Neonatal Expert Advisory Group	*Neonatal Care in Scotland: A Quality Framework* [37]
UK	British Association of Perinatal Medicine	*Service Standards for Hospitals Providing Neonatal Care* [38]
UK	National Institute for Health and Care Excellence	*Specialist Neonatal Care Quality Standard* [39]
Australia	Victorian Government	*Neonatal Service Guidelines – Defining Levels of Care in Victorian Hospitals* [36]
POSITION STATEMENTS ON PHARMACIST ROLES WITHIN NICU		
COUNTRY	**SERVICE PROVIDER**	**ROLE**
USA	University of Kentucky Hospital – Pharmacy Services	*NICU Clinical Pharmacist Specialist* [33]
USA	National Association of Neonatal Nurses	*Medication Safety in the Neonatal Intensive Care Unit – Position Statement #3060* [35]
Qatar	Sidra Medical and Research Center	*Clinical Pharmacist Intensive Care (PCICU, PICU, ED and NICU*) [34]
QUALITY ASSESSMENT TOOL		
REGION	**PUBLISHING ASSOCIATION**	**TOOL**
Europe	WHO	*Making Pregnancy Safer – Assessment tool for the Quality of Hospital Care for Mothers and Newborn Babies* [40]

[5] PCICU = Paediatric Cardiac Intensive Care Unit
[2] PICU = Paediatric Intensive Care Unit
[3] ED = Emergency Department
[4] NICU = Neonatal Intensive Care Unit

REPORTS/REVIEWS		
COUNTRY	**AUTHOR / YEAR**	**TITLE**
The Netherlands	Chedoe, I., et al. (2007)	*Incidence and Nature of Medication Errors in Neonatal Intensive Care with Strategies to Improve Safety* *A Review of the Current Literature* [32]
USA	Ellsbury, D. L. and R. Ursprung (2012)	*A quality improvement approach to optimizing medication use in the neonatal intensive care unit* [22]
USA	Grissinger, M. (2011)	*A fatal zinc overdose in a neonate: confusion of micrograms with milligrams* [23]
USA	Lemoine, J. B. and H. M. Hurst (2012)	*Using smart pumps to reduce medication errors in the NICU* [24]
USA	Lucas, A. J. (2004)	*Improving medication safety in a neonatal intensive care unit* [25]
USA	McCartney, P. R. (2006)	*Using technology to promote perinatal patient safety* [26]
USA	Patel, S. J. and L. Saiman (2012)	*Principles and strategies of antimicrobial stewardship in the neonatal intensive care unit* [27]
USA	Simons, S. L. (2007)	*Designing medication safety in the NICU* [28]
STUDIES		
COUNTRY	**AUTHOR**	**TITLE**
New Zealand	Kunac, D. L. and D. M. Reith (2005)	*Identification of priorities for medication safety in neonatal intensive care* [1]
USA	Morriss, F. H., et al. (2009)	*Effectiveness of a barcode*

		medication administration system in reducing preventable adverse drug events in a neonatal intensive care unit: a prospective cohort study [29]
USA	Sharek, P. J., et al. (2006)	*Evaluation and development of potentially better practices to improve pain management of neonates* [30]
USA	Sullivan, K. M., et al. (2013)	*Personalised performance feedback reduces narcotic prescription errors in a NICU* [31]

Table 3: Summary of Quality Measures associated with the rational and appropriate use of medications in the NICU[6]

QUALITY INDICATORS OF PHARMACEUTICAL SERVICES IN NEONATAL CARE		SOURCE OF INFORMATION
STRUCTURE	• Staffing – full-time/part-time pharmacist [36] • Staffing – nurses and medical staff [35, 38] • Qualifications of pharmacist [37-39] • Experience of pharmacist in NICU [38] • Continuing education of pharmacy practitioners [33, 38] • Well-lit environment, with sufficient workspace, minimal distractions [35] • Availability of aseptic compounding facilities for the formulation of IV and non-standard medications [38] • Availability of facility and instruments for medication preparation [36] • Availability of essential medicines for specific use within NICU [40] • Written policies/protocols/guidelines for high-risk medications i.e. antibiotics, pain-relief, parenteral nutrition [34, 35, 38, 40] • Clear policies on how to prescribe, dispense, administer and monitor medications in the NICU [35] • Neonatal formulary with standard	[36] Australia [34] Qatar [32] The Netherlands [37-39] UK [22, 24-26, 28, 29, 33, 35] USA [40] WHO

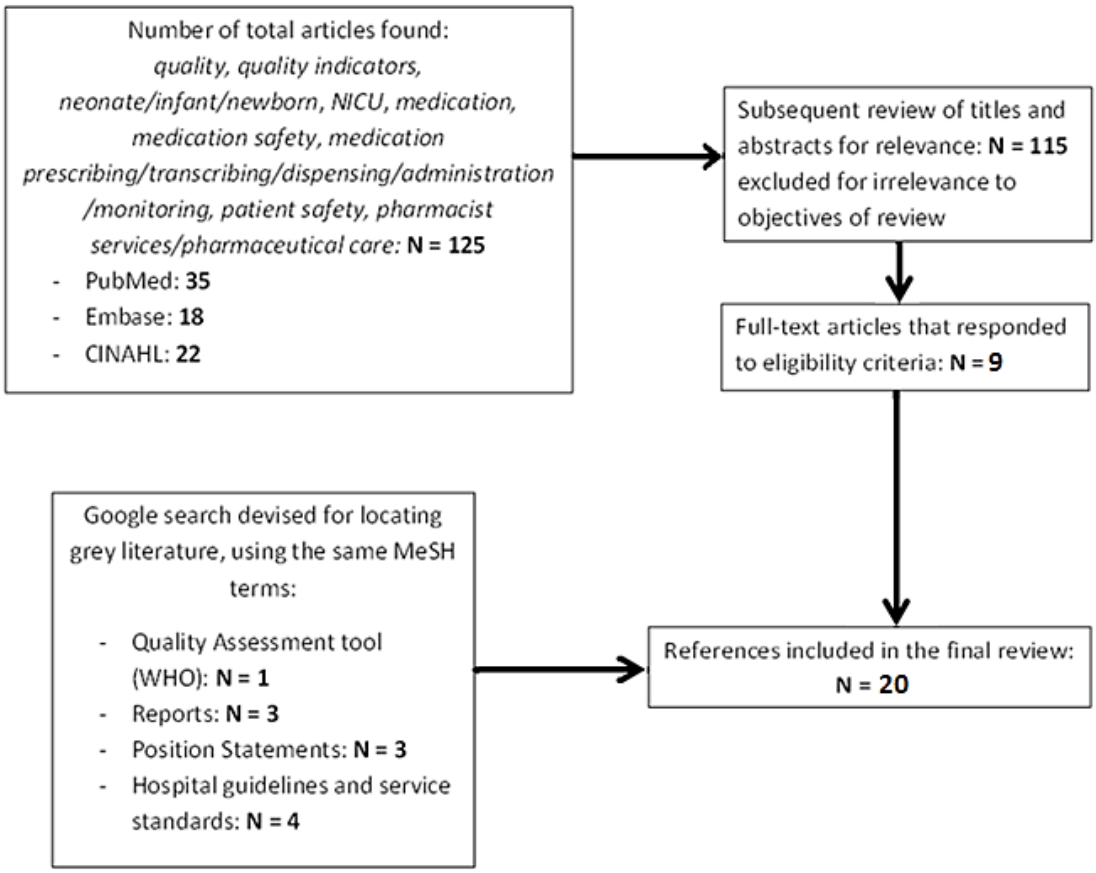
[1] CPOE = Computerised Physician Order Entry
[2] CDSS = Clinical Decision Support Systems
[3] ETT = Endotracheal Tube
[4] EDQM = European Directorate for the Quality of Medicines
[5] IV = Intravenous
[6] MRSA = Methicillin Resistant Staphylococcus Aureus
[7] NICU = Neonatal Intensive Care Unit
[8] PIV = Peripheral Intravenous
[9] PRN = 'Pro Re Nata' – as needed
[10] STAT = 'Statum' – immediately
[11] TPN = Total Parenteral Nutrition

	concentrations [25, 28, 35] • Emergency medicines sheets, with listed doses per weight [25, 28] • Standard references for use in the selection, use and evaluation of medications [35] • Medication error and adverse drug event reporting (systems) [33-35, 38] • Collection of drug use data [22] • Availability of safety technology including: CPOE, CDSS, barcode verification, smart pumps, computerised calculation of orders, automated drug dispensing units, electronic health records [24-26, 28, 29, 32, 35]	
PROCESS	• Therapeutic Drug Monitoring [34, 38] • Counselling of parents [33, 34] • Advice on off-label/unlicensed medications [38] • Adverse Drug Event Monitoring and documentation – Identification, Monitoring, Rectifying, Prevention [33, 34, 38] • Medication preparation by pharmacy department [35] • Monitoring of medication orders [33, 34, 38] • Medication errors – Identification, rectifying, prevention [38] • Review, verification and clarification of medication charts [33] • Education/training of health professionals [1, 32-35, 38] • Provision of drug information [34, 38] • Participation in multi-disciplinary ward rounds and meetings [33, 34] • Optimisation of TPN [38, 40]	[1] New Zealand [34] Qatar [32] The Netherlands [38] UK [28, 30, 31, 33, 35] USA [40] WHO

	• Optimisation of IV formulations [38] • Use of pain scales [30] • Use of pain protocols for patient groups and specific procedures [30] • Participation in clinical research [33, 34] • Verification process, medicines and calculations checked by another licensed healthcare professionals before administration [35] • Critical incident /root case analysis [28, 35] • Prescribing error feedback programme [31]	
OUTCOME	• Monthly audit of medication charts with a target of at least 80% correct time of administration (wrong time was defined as more than 1 hour of prescribing for stat/PRN meds, and for regular meds dose not given prior to the next scheduled dose) [1] • Monthly audit of the labelling of all lines – to be labelled with access type and fluid/medication being administered with a target of at least 90% correct labels [1] • Monthly audit of prescribing against prescribing guidelines – target 90% [1] • Episodes of ineffective empiric antibiotic therapy (organism/antibiotic mismatch) [27] • Mean time to target vancomycin trough concentration for infants with known MRSA infection [27] • Proportion of infants receiving appropriate dosing and timing of perioperative prophylaxis [27] • Episodes of antibiotic-associated adverse events [27]	[45] EDQM [42] India [1] New Zealand [43] UK [17, 27, 30, 44] USA [40] WHO

	• Duration of treatment for culture-negative presumed late onset sepsis [27] • Rates of infections with multi-drug resistant gram-negative infections [27] • Percentage of patients who received at least 1 pain management intervention during heel sticks, PIV insertions, venipunctures, umbilical arterial catheterizations, nasogastric tube placements and ETT suctioning [30] • Percentage of all defined procedures that were treated with a pain treatment intervention [30] **General healthcare outcome measures related to neonatal patients:** • Incidence of nosocomial infection [17, 40, 42] • Incidence of neonatal sepsis [17, 42] • Length of stay [17] • Days on TPN [17, 40] • Growth velocity (daily weight gain) [17, 40] • Mortality rates [17, 42-44] **Pharmacotherapy specific outcome measures as proposed by the EDQM: [45]** • Medication Error rates/reports • Adverse Drug Event rates/reports • Number of pharmaceutical care interventions performed • Dispensing errors rates/reports • Number of parents counselled • Costs of drug therapy • Costs saved	

Figure 1: Search Strategy



5.3 PHARMACIST PERCEPTIONS ON THE NEED FOR A QUALITY GUIDANCE RESOURCE FOR PHARMACY SERVICE PROVISION IN THE NEONATAL INTENSIVE CARE UNIT – COMPARISON BETWEEN POLAND AND AUSTRALIA

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ROYAL PHARMACEUTICAL SOCIETY

Research Paper

Pharmacist perceptions on the need for a quality guidance resource for pharmacy service provision in the neonatal intensive care unit: comparison between Poland and Australia

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AUTHORS' CONTRIBUTIONS

Natalia Krzyżaniak was the primary author, collected the data, analysed and interpreted the findings, wrote and organised the manuscript. Beata V. Bajorek and Iga Pawłowska contributed to the idea, drafting of the manuscript, interpretation of findings, and critical review of the manuscript.

Production Note:
Signature removed prior to publication.

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ABSTRACT

OBJECTIVES: There is no global consensus on services and roles that should be performed by a clinical pharmacist in the neonatal intensive care unit (NICU). Furthermore, there are no quality guidance resources or key performance indicators (KPIs) available to guide pharmacist practice in this setting. The purpose of this research was to explore pharmacist perceptions on the need for, and development of, a NICU-specific quality guidance resource containing KPIs for pharmacy service provision.

METHODS: Semi-structured interviews were conducted with directors of pharmacy as well as neonatal pharmacists in Poland and Australia. The interviews were conducted between February and August 2017.

KEY FINDINGS: Overall, three key themes were categorised around the study objectives: 1) Lack of guidance in the provision of NICU pharmaceutical care services, 2) Embracing a pharmacist-specific, quality guidance resource for the NICU and 3) Constraints limiting the use of quality guidance resource. None of the participants from either country were able to identify any readily available NICU-specific quality guidance resources for pharmacists. However, the majority of participants from both countries were open towards the development of a quality guidance resource and felt that this would be useful. Differences between countries were noted when considering the type of pharmacy practice models functioning in each country and the perceived barriers to implementing the proposed quality guidance resource into practice.

CONCLUSION: Although there are significant differences in the type of pharmacist practice systems functioning in each country, pharmacists in both Australia and Poland demonstrated significant support for the development of a quality measurement tool to guide and structure practice in the NICU and recognised benefits to its implementation. Future efforts should focus on the development of quality measures that can be adapted to different NICU settings, both on a national and international scale.

KEYWORDS: Clinical pharmacy; neonatal intensive care unit/neonate; quality measurement/key performance indicators

INTRODUCTION

The management of pharmacotherapy within the neonatal intensive care unit (NICU) is complex and requires the guidance of a pharmacotherapeutics expert.[1] Due to their unique characteristics, comprising considerable inter-individual differences in pharmacokinetics, birth weights and gestational ages, neonates are particularly vulnerable to sustaining medication errors.[2] Furthermore, this patient population is prone to experiencing significant consequences as a result of medication misadventure.[2] As such, the role of the pharmacist within the specialist area of neonatology is continually advancing towards more direct involvement in patient care.[3] Indeed, the benefits of pharmacist interventions include reduced incidence of medication errors, optimisation of total parenteral nutrition (TPN) regimens and better rationalisation of pharmacotherapy.[4-7]

It is evident that pharmacist practice varies in NICU settings both on a national and international scale.[8] A recent study by Krzyzaniak et.al. highlighted that pharmacy services delivered to NICU settings in Poland and Australia differed significantly, with the focus of practice in each country centred on dispensary-based and clinical, ward-based services respectively.[9] Further research by Pawłowska et.al. investigating general hospital pharmacy practice in Poland, supports these findings and demonstrates that the concept of clinical pharmacy is not yet widely adopted in Polish hospital settings, and pharmacists are often stationed predominantly in the dispensary and limited to medication supply roles.[10] In contrast, Australian studies suggest that pharmacists are integrated into the interdisciplinary team and have a large input into ward-based pharmacotherapy-related decision-making as well as other clinical roles including medication chart review and therapeutic drug monitoring (TDM).[11,12] This variability in practice may impact upon the outcomes achieved by vulnerable neonates.

There have been efforts made from the International Pharmaceutical Federation (FIP) and the World Health Organisation (WHO) to improve the standardisation of pharmaceutical care services through the publication of standards, such as the Good Pharmacy Practice (GPP) guidelines.[13] However, it is apparent that there are no guidelines available to direct pharmacists in their clinical practice in specialty areas of pharmaceutical care, such as the NICU.[13] A literature review reported that there are currently no established key performance indicators (KPIs) to serve as a point of reference for neonatal pharmacists.[14] Whilst existing standards for pharmacy practice in critical care settings might have applicability, as well as non-pharmacist guidelines from neonatal societies, pharmacist-specific NICU-based guidelines

are particularly important in the care of critically ill infants for the provision of a consistent and quality pharmacy service.[15,16] KPIs are an effective means of gauging the quality of healthcare services being provided and in determining the potential to improve this level of care for patients.[17] They also have the potential to standardise care provided in comparable hospital settings, through the process of benchmarking.[18]

Due to the apparent variability in pharmacist practice in NICU settings within and between countries, there is a need for KPIs or quality practice guidance resources to be made available to promote the standardisation of pharmacist practice in this high-risk and fragile patient group.[8] As there is currently a lack of NICU-specific quality frameworks targeted at pharmaceutical care services, it is important to gain an understanding of whether pharmacists working in these settings require or even want a resource of this nature to be developed. However, there is no research available that explores the opinions and perspectives of clinical pharmacists on the implementation of NICU-specific quality measures. It is prudent to understand pharmacist perceptions not only within but also between countries, and comparing those with a more advanced level of pharmacy practice to nations that are refining their hospital pharmacy services. This form of comparison will enable the identification of overlapping perceptions, and potentially strengthen the argument for the development of a global resource. Therefore, this study aims to canvass pharmacist attitudes from two industrialised countries with differing pharmacy service structures - Poland and Australia - towards the development of a quality guidance resource to assist in the medication management process in neonatal patients.

Specific objectives included:

1. Determining whether pharmacists currently used any practice frameworks or models to guide their practice in the NICU
2. Determining whether pharmacists felt a need for a quality guidance resource to be developed
3. Identifying potential barriers and benefits to the implementation of this resource into practice in each country

METHOD

Study design

A qualitative study, comprising semi-structured individual interviews with Australian and Polish NICU pharmacists, hospital pharmacists and directors of pharmacy was undertaken between February and August 2017. A qualitative approach was used as it was deemed the most suitable method for this exploratory research, enabling a fuller understanding of the context behind pharmacist opinions and attitudes, as well as the perceived needs of pharmacists in improving existing practices and beliefs. Ethics approval was sought and obtained from the respective human research ethics committees at the University of Technology Sydney (UTS), Australia (UTS HREC REF NO. ETH16-1033) and the Medical University of Gdansk (GUMed), Poland (GUMed HREC REF NO. NKBBN/424/2016).

Participants were assured of confidentiality and were informed that their responses would be de-identified.

Australia and Poland as comparators

Poland and Australia were specifically chosen as comparators in this study for several reasons. First, traditionally, there is minimal collaboration between Eastern European countries and western countries that have a more advanced level of pharmaceutical care, such as the US, Canada, Australia and New Zealand. A literature review highlighted that the majority of published data investigating pharmacist practice in the NICU originates in the USA, with little to no equivalent or comparative research performed with European countries.[8] The WHO highlights that transnational collaborative research is important in stimulating the adoption of coherent policies and establishing best practices.[19] Therefore, there is a need to expand research horizons to encompass a more global perspective, to encourage the formation research alliances between nations that are not often highly publicised. This research follows on from previous studies that the authors have performed investigating pharmacist practice in these two countries. A comparison between Australia and Poland was thought to be useful in providing a new and unique perspective on pharmacist practice in NICUs. Due to the variability in NICU pharmacist practice between these two countries, this comparison also enabled a

fuller understanding of the range of potential barriers limiting the implementation of standardised practice guidelines and KPIs for pharmacists in this area of practice.

Setting and participants

Purposive, homogenous sampling was used to recruit participants.[20] This method was thought to be the most appropriate form of recruitment as it '*focuses on one particular subgroup in which all the sample members are similar, such as a particular occupation or level in an organization's hierarchy*.'[21] The objectives of the research were specific to the characteristics of the particular group of interest (NICU pharmacists), which was then subsequently examined in detail.[22] Participants were recruited based on the following inclusion criteria:

1. Registered pharmacists, with at least 1 year of hospital pharmacy experience.
2. Practicing within hospitals containing a NICU, providing either direct or indirect pharmaceutical care to the NICU as pharmacist or director of hospital pharmacy.

In this case, indirect pharmacy services refer to dispensary-based roles that include but are not limited to extemporaneous compounding, administrative activities and dispensing. Direct pharmacy services refer to ward-based, patient-direct services including medication chart reviews, therapeutic drug monitoring, counselling of parents etc.

In Poland, clinical pharmacy is not yet well-established in hospital settings, and as such pharmacists do not commonly practice on wards. Therefore, participants in this country were included in the study if they identified as hospital pharmacists who provided some form of pharmaceutical care services (i.e., direct or indirect, as described previously) for the NICU.

Participants were contacted via email through the Paedpharm online pharmacists group and through publicly available registers in Poland and Australia (Register of Facilities delivering Medical Activities (Rejestr Podmiotów Wykonujących Działalność Leczniczą – RPWDL and the Australian and New Zealand Neonatal Network - ANZNN) that identified hospitals with neonatal intensive care units. Paedpharm is an online paediatric pharmacy network that provides pharmacists in Australia and New Zealand a forum to exchange information related to paediatric therapeutics.[23] Furthermore, participants were identified from a previously performed study, involving an online-questionnaire relating to pharmacy services provided in NICUs in Australia and Poland.[9] At the end of the questionnaire, participants were asked whether they would be interested in participating in further research, involving semi-

structured interviews related to the development of a quality guidance resource for pharmacy practice the NICU. Individuals who voluntarily expressed their interest to participate, were then provided the full study details.

To ensure as minimal as possible disruption for participants, interviews were organised to be conducted at times and locations that were convenient for the participant (i.e. in their workplace), and the researcher (NK) travelled to the participant. In the instance that the distance between the researcher and participant was too great, interviews were conducted over the phone.

Each participant was made aware of the personal goals of the lead researcher in publishing this research as a part of her PhD thesis. The sample size was based on the number of participants targeted to achieve data saturation, and was set at a minimum of 10 participants in each country (10 Australia, 10 Poland).[24] Guest et.al. state that for interview studies which *"aim to understand common perceptions and experiences among a group of relatively homogeneous individuals, twelve interviews should suffice to attain data saturation and enable the development of meaningful themes and useful interpretations* [24]."

Data collection

For consistency, each interview was facilitated by one researcher (NK) using a purpose-designed interview guide. The interview guide was adapted from a previous study by Minard et.al. who used focus groups to identify pharmacist perceptions on the implementation of clinical pharmacy KPIs in hospitals in Canada.[25] The interview guide comprised six key open-ended questions, which canvassed the opinions of pharmacists towards the development of a quality measurement tool:

1. What are the guidelines or practice models that you refer to that identify what pharmacist roles or pharmacy services should be performed in the NICU?
2. Which documents contain key performance indicators (KPIs) or quality indicators that are tailored to pharmacist practice and medication management specifically in the NICU?
3. Would you like to see an integrated document comprising a quality guidance resource, which includes a list of clinical pharmacy KPIs specifically tailored for the NICU? Why?
4. What kind of items would you like this resource to contain?

5. What would encourage the use or the implementation of this type of document into the NICU?
6. What are the barriers that you can think of that could oppose its implementation?

The interview guide was pilot-tested for question clarity prior to use. The average interview time was approximately 20 minutes. Field notes were taken during the interviews and each interview was digitally (audio)-recorded and later transcribed verbatim by one researcher (NK). No repeat interviews were carried out as all the relevant information was obtained during each individual interview. Each interview was conducted with participants in their native language i.e. English and Polish. For all interviews that were performed in Polish, the transcripts were translated into English via a tiered process; transcripts were translated from Polish to English by one researcher (NK); these translations were edited and verified by two researchers (IP, BB) to determine whether the language was correct. All transcripts were returned to participants in both Poland and Australia for review and editing. To ensure ease of readability, the qualitative responses of participants are represented by the code 'AP' for Australian pharmacists and 'PP' for Polish pharmacists.

Data Analysis

The interview transcripts were thematically analysed. Manual inductive coding was used, whereby after transcription, each interview was repeatedly read and the transcript annotated with significant statements from participants responses. Subsequent analysis of these statements led to their categorisation into key themes around the study objectives.[26] The information obtained was triangulated through the participation of a team of investigators. Three researchers (NK, BB, IP) independently evaluated the data to ensure the appropriate interpretation of data into emerging themes. These initial themes were compared, checked and verified to attain consensus. A pragmatic approach was used to frame the analysis; which allows data to be analysed without the limitations of any specific philosophy.[27]

RESULTS

Out of the 18 pharmacists in Australia, and 20 pharmacists in Poland invited by the research team, 15 from each country agreed to participate, with a total of 30 interviews taking place. Out of the total group, five participants from Australia, and seven from Poland were participants from a previous study relating to pharmacist practice in the NICU. Thematic saturation appeared to have been achieved with this number of participants in each country, with no new information emerging from interviews, therefore no further sampling was conducted. Participant characteristics are presented in Table 1. The majority of Australian participants identified themselves as NICU pharmacists, and had 1 – 5 years working experience. In comparison, most Polish pharmacists reported that they were general hospital pharmacists based in the dispensary, and 73.3% had over 10 years work experience.

Three key themes were identified from the interviews held with Polish participants:

1) Lack of guidance in the provision of NICU pharmaceutical care services

2) Embracing a pharmacist-specific, quality guidance resource for the NICU

3) Constraints limiting the use of quality guidance resource

1) LACK OF GUIDANCE IN THE PROVISION OF NICU PHARMACEUTICAL CARE SERVICES

None of the participants were able to identify any NICU specific quality guidance resources for pharmacists (Table 2). In Australia, pharmacists referred to in-hospital practice standards and training workbooks, however stated that these were all developed by hospitals individually and not shared between sites. Two pharmacists highlighted resources from the pharmacy board as well as state-wide policies, however these were general resources for all hospital pharmacists and were not specific to the NICU.

> '*I'm not aware of any particular guidelines or practice models for a NICU framework*.' **AP3**

> '*We don't have specific NICU KPIs at this point in time*.' **AP4**

In comparison, Polish participants highlighted that the only resource available that dictated what roles a pharmacist was to perform was the pharmaceutical legislation, and similarly to

Australian responses, comprised a general list of services for all hospital pharmacists and did not define services for the NICU.

> '*According to the pharmaceutical law, the pharmacist should prepare TPN, cytotoxic medicines (if they are being prescribed) and to participate in clinical research. That is all the law states. It is generalised, not specific to this ward*.' **PP14**

> '*No - everything is generic. There are no indicators that I am aware of, the only ones are those related to oncology wards with chemotherapy… When considering neonatology, I haven't heard of anything like* this.' **PP8**

2) EMBRACING A PHARMACIST-SPECIFIC, QUALITY GUIDANCE RESOURCE FOR THE NICU

All Australian participants and 93.3% of Polish participants were open towards the development of a quality guidance resource and felt that this would be useful. The remaining Polish pharmacist, whilst seeing the benefit of such a resource, highlighted that its implementation into the Polish healthcare system would be unsuccessful and unachievable due to the underdeveloped nature of pharmaceutical care in hospitals and did not feel it was relevant for current day practice.

The criteria of this resource varied slightly between countries. Polish pharmacists viewed this resource as more of an introductory framework outlining what clinical services should look like in the NICU, rather than as a quality assessment tool. Respondents highlighted that they were unsure what clinical services to provide to the NICU, as they mostly functioned at a distributive level of practice, and they wanted to have a point of reference clearly outlining what was expected of them. This was viewed as being valuable for pharmacists in order to advance their level of practice and strengthen their clinical roles in ward-based medication management. This type of document was also perceived as an effective means of communicating and asserting to the NICU medical and nursing staff, as well as to hospital management that the pharmacist is a valuable contributor to the therapeutic team. Interestingly, several pharmacists commented that there needed to be a clear distinction between the role of the doctor and the pharmacist in the NICU, with a definition of what each profession was responsible for so as to not intrude on each other's competencies. Other elements that were

proposed included: pharmacist to bed ratios, information on the types of medications used in NICUs as well as examples of commonly encountered medical conditions and their treatment.

> '*I would be more inclined to view is as a way to strengthen the position of the pharmacist and the role of pharmacist in the treatment process. It also increases knowledge of the role of the pharmacist and what they can do to help improve the general care of the patient comprehensively, from the beginning to the end, taking into account each aspect. I see this document providing highly positive contributions*.' **PP2**

> '*Definitely a list of services, definitely how many pharmacists would be needed to service a specific ward. An indication of our legal rights, so what we are able to do and what we are responsible for, and what not to become involved in and what should be left for the doctors and nurses*.' **PP14**

Alternatively, as clinical pharmacy is readily practised in Australia, the proposed resource was viewed as having potential as a standard of practice that outlined the niche roles of the pharmacist in the NICU and distinguished pharmacists in this subspecialty from general clinical practice. As such, participants commented that it would be used as a means of maintaining a standardised, quality level of care and also as an accreditation document, proving that these standards were being met. Participants also referred to the inclusion of key performance indicators (KPIs) in this resource, which were perceived as elements that would allow pharmacists to better prioritise their time on roles deemed to be important to the quality use of medicines as well as allow the monitoring of pharmacist performance. Furthermore, the proposed quality guidance resource was identified as being a good training kit for new pharmacists coming into this field, needing the inclusion of educational information comprising an overview of the physiology of the neonate, medications used in the NICU and useful resources to refer to.

> '*I think it would be a good educational tool, not only for pharmacists who have perhaps been doing that role for a long time, but also for newer pharmacists, more junior pharmacists in their career who may need to cover that area or be on call for that area. I think it would be a good tool to document practice and advocate for that subspecialty.*' **AP3**

> '*The SHPA (Society of Hospital Pharmacists Australia) have recommended hours and bed numbers for NICU and special care nurseries… it would be useful to have some*

recommended tasks and what the key performance indicators should be. Maybe minimum medication safety components as well… it would be good to have recommended texts, minimum texts, minimum standards or minimum guidelines and staffing as well that would be good.' **AP2**

Both Australian and Polish participants highlighted that that they would like this resource to contain a list of pharmaceutical services that should be provided to the NICU to uphold a minimum standard of quality care (Table 3).

'*I think a list of pharmaceutical services – this should be outlined, what clinical pharmacists are responsible for*.' **PP15**

'I think a breakdown of the role a pharmacist actually has to play in the NICU would be good. Like expectations, I guess of what a pharmacist could contribute to the role.' **AP6**

'*Its an important component of practice for people to understand what their roles are, but also to give them an insight into aspects of their clinical roles that they might not have necessarily thought about, and aspects of their clinical role that they might not have thought about being able to evaluate*.' **AP13**

3) CONSTRAINTS LIMITING THE IMPLEMENTATION OF QUALITY GUIDANCE RESOURCE

Common barriers to the implementation of the proposed resource across both countries included financial constraints and pharmacists possessing the necessary level of neonatal training (Table 4).

FINANCES

Funding was identified as a major barrier in both Australia and Poland to implementing any resource promoting an advanced form of clinical practice on the NICU. Polish participants reported that currently, funding opportunities for the pharmacy department were scarce, resulting in the employment of only a few pharmacists per hospital. The majority of Polish

pharmacists recognised that the implementation of the proposed resource would require the engagement of more pharmacists, which the system would simply not be able to afford. Therefore, as a result the limited number of pharmacy staff available at each hospital would also impact upon the uptake of this resource, simply because there are not enough people to do the work required.

> '*I think first and foremost, there are financial barriers in hiring pharmacists for this position. If pharmacists were to work on the wards, then they would have to hire 4 or 5 times more pharmacists than we already have. Unfortunately, when considering funding, then it is not good*.' **PP13**

Similarly, Australian participants referred to financial constraints relating to sourcing funding opportunities specifically for the employment of pharmacists in the NICU to provide the required level of services outlined in the proposed resource. One pharmacist commented that this correlated with the level of value that pharmacy management associated with this service and allocating the relevant funding against other competing resources.

> '*The ultimate barrier is around management and management's perception around the role and value of pharmacy services in that area. If you tried to summarise that, it is on the one hand funding and the availability of funds to employ pharmacists to provide the level of service.'* **AP13**

EDUCATION AND EXPERIENCE

Pharmacists in both countries also voiced concerns regarding the level of neonatal-based training available to up-skill pharmacists. Some Australian pharmacists commented that neonatal pharmacology was not often offered during pharmacy training programs, and as such there was a perceived lack of awareness and understanding of the medication management processes in this patient population. Pharmacists indicated that this had the potential to limit the implementation of the proposed resource in two ways: pharmacists reluctance in engaging in this field because of the patient group and pharmacists being insufficiently skilled to be able to practice on this ward.

> '*It's an area where you don't learn at university, how to be a neonatal pharmacist. I would like to see a lot more paediatric and neonatal pharmacology or just awareness in*

the undergraduate degree, because people are very frightened of getting involved if the patients are so small.' **AP2**

Polish pharmacists voiced concerns relating to foundational-level issues, highlighting their own lack of experience with models of clinical pharmacy. Whilst they expressed a high-level of interest in providing clinical roles, they reported that they did not hold the necessary level of preparation or knowledge in offering such services and were hesitant about the feasibility and possibility of initiating this type of practice.

'…the lack of pharmacist preparation. This is absolutely not spoken about here. There are absolutely no clinical placements, we do not leave the pharmacy and we do not enter the wards. So at the moment, I do not feel at all prepared to fulfil this kind of role.' **PP11**

Furthermore, they credited the current education system as being inadequate in preparing pharmacists for clinical practice. "Clinical pharmacy" was identified as being a certified specialisation within Poland, however participants reported that the Polish pharmacy schools offered this course in a limited capacity, with no practical experience on hospital wards, and the entirety of the course being theory-based. Some pharmacists highlighted that they needed to go externally (overseas) to acquire such training. However, one participant identified that even if this training was sufficient, there is nowhere for pharmacists to practically apply that knowledge in the current system.

'*The barriers start at the university level. We are not adequately prepared for this type of practice. Even a specialisation in clinical pharmacy does not prepare us. We have some of the necessary knowledge after we finish this type of specialisation, but we do not know how to implement it. Not only should our universities prepare us for the work of a clinical pharmacist, but hospitals should also create clinical pharmacist positions. It should be made mandatory that there is a clinical pharmacist employed on all of the hospital wards. This type of practice model would certainly work to satisfy us*.' **PP15**

CURRENT HEALTHCARE SYSTEM

Polish participants identified that the current healthcare practice model functioning in Polish hospitals was a significant barrier to the implementation of a clinical pharmacy-focussed

resource in the NICU. One pharmacist commented that they did not see clinical pharmacy practice being present in Poland for another 50 years.

> '*For us it is fascinating to think that maybe, I do not know, in 50 years we will also have a similar system. For the moment, the momentum is not here at all*.' **PP5**

The healthcare system was described by participants as being a long-established, traditional, hierarchical structure, whereby doctors and nurses practice on wards, whilst pharmacists are dedicated to the dispensary, managing the supply and preparation of medications. Many participants referred to the practice-culture and mentality of healthcare professionals towards changing pharmacist practice in the NICU. In particular, they expressed to the lack of awareness of doctors and the hospital management around the value and need for the pharmacist to provide ward-based services for neonatal patients.

> '*For me at this point, if I have to be honest and this is my personal opinion, there is no awareness within the hospital management that the pharmacist may actually contribute to the safety of medications*.' **PP1**

> '*It has to do with the ingrained practice culture. It also depends on how the doctors perceive this model*.' **PP7**

> '*I think above all, the mentality and the long-established procedures, as well as the inter-professional relationship between the doctor and the pharmacist, which in Poland simply does not function. This is the main barrier*.' **PP11**

It is apparent that there is no incentive within the Polish healthcare system to modify the current pharmacy practice model as it is perceived that the level of care being provided to neonates is satisfactory, and the professional roles allocated to doctors, nurses and pharmacists are being fulfilled. Furthermore, participants reported that hospital pharmacists are not well reimbursed for their services, and therefore there is reluctance to perform additional roles for minimal reward.

> '*… I must say that our level of care is good because we have good results when it comes to treating these children. The care is not bad, but I think it would be even better if there was a pharmacist involved*.' **PP3**

LEGISLATION

Only Polish participants drew attention to the fact that there is no appropriate pharmaceutical legislation authorising pharmacist involvement on the ward. This was identified as a significant issue, as the this 'permission' was perceived as essential in giving pharmacists the power to make pharmacotherapy-related decisions and become involved in patient care in the NICU. Furthermore, pharmacists highlighted that there was no regulation in the law that specified pharmacist to bed ratios. This was also deemed to be important, due to the current staff shortages in hospitals, which are seen to impact upon the ability of the pharmacy department to provide services.

> '*I will begin by saying that our pharmaceutical law does not state that the pharmacist is allowed to enter any ward. Of course a hospital director or someone who manages a hospital may authorise this, but if it is not written in the law we are unsure what the pharmacist should be there for what they are responsible for and what role they play*.' **PP3**

Interestingly, only one pharmacist recognised that the laws did not say that a pharmacist could not be in a ward.

> '*I am not sure if the legislation prevents us from accessing it. In my opinion it is not properly regulated. It is simply not specified that we are able to have access. No-one took this under consideration, that is why the pharmacist is not present on the ward*.' **PP4**

SUPPORT FROM PROFESSIONAL PHARMACY BODIES

Interestingly, only pharmacists from Australia identified that in order for the proposed resource to be considered by NICU practice settings, it would need the acceptance and support of a national pharmacy body or neonatal organisation. Without this, participants felt that the hospital management would not support greater pharmacist involvement in this ward. Furthermore, participants highlighted that where practice is established, both pharmacists and doctors may be reluctant to change and adapt to a new system. From a personal perspective, pharmacists recognised increased workload as a barrier to the implementation process, mainly due to the time needed to dedicate to fulfilling the standards outlined in the tool.

'*You'd have to have appropriate stakeholder engagement. So you would have to either have the document prepared, and then a professional organisation support it. So I would think you would need to get it endorsed either by the SHPA and the other option that I think would be quite appropriate is if the SHPA acted as a advocate through the ANZNN (Australian and New Zealand Neonatal Network), so you would want that to be a jointly endorsed from both of those professional bodies for it to be effective I would think*.' **AP10**

'*People not being willing to change practice or measure practice. Time constraints as well. A lot of times, the NICU is co-allocated with another role so obviously you have only a certain amount of time that you can spend on it, so you may not be able to adhere to the guidelines*.' **AP4**

DISCUSSION

To our knowledge, this is the first qualitative study to explore pharmacist opinions towards the development of a quality measurement tool specifically for clinical pharmacy practice in the NICU. This qualitative research is valuable as it provides an initial insight into understanding the needs of NICU pharmacists and assessing whether there is a demand for quality guidance resources to be made available for sub-specialties of pharmacy practice.

One concept arising from the study that warrants discussion is that pharmacists in both Australia and Poland identified a lack of NICU clinical pharmacy guidelines and a subsequent lack of professional guidance to practicing within this setting. Similarly, a literature review published by Krzyzaniak et.al. emphasised that there were no quality guidance resources, comprising relevant KPIs, currently available that were tailored specifically for pharmacists in the NICU.[14] As such, the findings of both the review as well as from this study draw attention to a significant gap in practice. The provision of pharmaceutical care services in NICUs in both Australia and Poland are based on each hospital settings' individual and varied interpretations of the concept of 'good pharmacy practice', without the guidance of a minimum standard of practice. As a result, there is potential for differences in the level of pharmacy services delivered to NICU settings between these two countries. This is evidenced in another study by Krzyzaniak et.al. who highlighted that pharmacist roles in NICUs in Australia and Poland are significantly varied, each focussed on a ward-based and dispensary-based service respectively.[9]

It is not known what impact these variances have upon patient outcomes or the rational use of resources. However, despite these differences in practice, both Australian and Polish participants in this research perceived a need for the development of a quality or guidance tool to standardise pharmacy practice in the NICU at least on a local and national level. This finding is reinforced by the International Pharmaceutical Federation (FIP), who highlight that national standards, depicting good pharmacy practice and comprising a quality management framework, should be set by pharmacy organisations.[13] The FIP recognise that pharmacy practice may vary in settings between and within countries, however state that a 'baseline' should be established that outlines the minimum level of quality practice.[13] However, to date there have not been any guidance documents or performance measures established for neonatal pharmacists. Furthermore, there are no standardised measures facilitating the benchmarking of pharmacy services between settings nationally and internationally. Krzyzaniak et.al. highlighted that when considering the complex nature of the medication management process in the NICU, there was a significant need for the development of quality measures that addressed pharmacist involvement.[14] Ng et.al. report that in a resource-scare environment, clinical governance demands that clinical pharmacy, in accordance with other clinical health services, must demonstrate the value of its contribution to patient care.[18] They highlight that without the availability of key performance indicators or quality measures, pharmacists are unable to justify in a quantitative and robust manner their contributions to patient care.[18] This is of particular significance to the Polish setting, when considering the current issues within the healthcare system that limit the implementation of clinical pharmacy practice.

When considering the barriers identified by participants towards the implementation of a quality guidance resource, some of our findings were consistent with other research dedicated to identifying challenges affecting the engagement of clinical pharmacy key performance indicators (cpKPIs) in the hospital setting.[25] Minard et.al. reported barriers comprised of environmental constraints, relating to inconsistent staffing levels, funding or resources, as well as work burden issues.[25] Another study by Mekonnen et.al. investigating the implementation of new medication safety programs in Ethiopian hospitals mandated by updated minimum practice guidelines, highlighted a significant barrier as a lack of pharmacist knowledge and skills necessary for the performance of clinical services required by the guidelines.[28] This barrier in particular is similar to that expressed by Polish participants, and their unfamiliarity with the direct provision of ward-based, clinical services potentially outlined in the quality resource. The barriers identified in this research out-numbered the perceived benefits to the

quality guidance resource, and varied between Australia and Poland. The differences observed in the participant responses between the two countries may be attributed to the numerous variations in healthcare systems, including legislation, funding and education. However, it is apparent that practice culture is a significant influencing factor. Overall, Polish participants were more conservative and expressed concerns relating to the current hospital hierarchy i.e. maintaining the status quo. Polish interviewees often focused on the lack of legislation in specifying that a pharmacist was able to participate in ward-based medication management. These findings are similar to those presented by Pawłowska et.al. who highlighted that the majority of Polish hospital pharmacists surveyed felt that significant changes to legislation were necessary to improve hospital pharmacy practice.[29] However, only one pharmacist acknowledged that it may be more of a case that the law does not specifically state that pharmacists are not permitted to practice on the ward. As such, this raises the question as to whether Polish pharmacists are actually receptive to practice changes. In comparison, Australian pharmacists seemed to be more engaged and proactive in their practice, and were willing to further advance service provision to this ward to permit the standardisation of practice. As such, these diverse attitudes may have varying impact on pharmacists willingness and motivation to adapt to a different model of practice.

It is important to note that pharmacists from both countries readily highlighted the potential benefits to the implementation of a quality resource, including allowing pharmacists a full understanding of the roles needed to be undertaken in this setting, improving the standardisation of care, as well as and strengthening pharmacist positions on the NICU, particularly in reference to their standing among other members of the multidisciplinary treating team. These findings are similar to those obtained by Minard et.al., who explored the perceived barriers and facilitators towards the use of cpKPIs in general hospital settings in Canada.[25] They highlight that pharmacists perceived the implementation of cpKPIs would improve consistency in pharmacy practice, help align the expectations of other healthcare professionals and allow pharmacists a clear focus of roles and services that need to be performed.[25]

The findings of this study emphasise that there is a lack of pharmacist support and guidance in both Australia and Poland relating to practice in the NICU. There is an opportunity for future research to address this gap in knowledge, and potentially develop quality measures tailored specifically to this patient population that could be adapted to each practice setting. As this is a specialised area of practice, with only limited numbers of neonatal beds in each country, a

standardised quality tool may in fact help the benchmarking of clinical pharmacy services on an national scale and promote a more co-ordinated approach to advancing pharmaceutical care providing to this high-risk patient population. By assessing pharmacist perspectives towards the implementation of a quality resource, as well as the perceived barriers limiting its use, these findings are an important step in the knowledge-to-action process and may be useful in future research in the selection and development of interventions for both Australia and Poland.

LIMITATIONS

The sample size used in this study was small, and as such the opinions expressed may not be representative of all pharmacists in Australia and Poland. In addition, due to the voluntary nature of participation in interviews, there is a possibility that pharmacists who participated may have different views to those who chose not to volunteer. Sampling bias may be associated with participants who were recruited from the previous study. The sample of participants from each country were non-equivalent in terms of their personal characteristics (i.e., practice experience, educational background, position in hospital). Therefore, the results may, to some extent, reflect those differences in addition to country-specific differences.

There is potential for researcher bias in interpreting the responses from participants. This has sought to be minimised by ensuring three individual analyses of the data by three separate researchers. The themes that achieved consensus were then combined to form the final results.

Furthermore, the interviews were transcribed and translated by one researcher, and any errors that were made may not have been picked up in the analyses performed by the other researchers.

CONCLUSION

Although there are significant differences in the type of pharmacist practice systems functioning in each country, pharmacists in both Australia and Poland demonstrated significant support for the development of a quality measurement tool to guide and structure practice in

the NICU, and recognised benefits to its implementation. Future efforts should be directed at standardising pharmacy practice in NICUs through the development of quality measures, including practice standards and key performance indicators that can be adapted to different practice settings, both on a national and international scale.

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Table 1: Demographics

	AUSTRALIA (%)	POLAND (%)
NUMBER OF RESPONDENTS	15	15
GENDER OF RESPONDENTS		
FEMALE	11 (73.3)	14 (93.3)
QUALIFICATIONS		
BACHELORS DEGREE	4 (26.7)	0
MASTERS DEGREE	7 (46.7)	14 (93.3)
PHD DEGREE	1 (6.7)	1 (6.7)
POST-GRADUATE CERTIFICATE/DIPLOMA	3 (20)	0
SPECIALISED QUALIFICATIONS/TRAINING		
YES	1 (6.7)	2 (13.3)
CIVAS/TPN PHARMACIST	1 (6.7)	0
CLINICAL PHARMACY	0	2 (13.3)
NO	14 (93.3)	13 (86.7)
POSITION IN THE HOSPITAL		
NICU PHARMACIST	10 (66.7)	0
DIRECTOR OF PHARMACY	3 (20)	4 (26.7)
PHARMACIST WORKING IN MAIN HOSPITAL PHARMACY		11 (73.3)
OTHER	2 (13.3)	
DEPUTY DIRECTOR	1 (6.7)	0
SPECIALIST WOMEN, YOUTH AND CHILDREN PHARMACIST	1 (6.7)	0

EXPERIENCE		
< 1 YEAR	2 (13.3)	0
BETWEEN 1-5 YEARS	9 (60)	0
BETWEEN 6-10 YEARS	2 (13.3)	4 (26.7)
> 10 YEARS	2 (13.3)	11 (73.3)

Table 2: Pharmacist perceptions

	AUSTRALIA **N = 15 (%)**	**POLAND** **N = 15 (%)**
ARE THERE ANY GUIDELINES/PRACTICE MODELS/KEY PERFORMANCE INDICATORS (KPIS)/QUALITY INDICATORS THAT YOU ARE AWARE OF THAT PHARMACISTS CAN USE TO GUIDE THEIR MEDICATION MANAGEMENT SPECIFICALLY IN THE NICU?		
YES	0	0
NO	14 (93.3)	12 (80)
UNSURE	1 (6.7)	3 (20)
WOULD YOU LIKE TO SEE AN INTEGRATED DOCUMENT COMPRISING AN IDEAL PRACTICE MODEL, WHICH INCLUDES A LIST OF CLINICAL PHARMACY KPIS SPECIFICALLY TAILORED FOR THE NICU?		
YES	15 (100)	14 (93.3)
NOT ACHIEVABLE WITH CURRENT SYSTEM	0	1 (6.7)
DO YOU BELIEVE THAT THE CURRENT MODEL OF PHARMACEUTICAL CARE PRACTICE IN YOUR COUNTRY WORKS AND MEETS THE NEEDS OF NICU PATIENTS?		
YES	13 (86.7)	3 (20)
NO	1 (6.7)	11 (73.3)
UNSURE	1 (6.7)	1 (6.7)

Table 3: What should a quality guidance resource contain?

POLAND	AUSTRALIA
'*…what it means to be a pharmacist working on this ward, with a list of activities that a pharmacist would have to fulfil. A scope of practice. Also the relevant legislation and responsibilities – I believe that this should be defined in detail*.' **PP1**	'*Some specific recommendations around therapeutic drug monitoring in the NICU… what should be specific around these guidelines is the differences between the services in a neonatal unit and a more general intensive care unit or a general or paediatric unit. And so its highlighting what sort of differences pharmacist who are providing services in the NICU need to be aware of and cognisant of for the babies*.' **AP1**
'*For sure, something would have to be written that highlights the scope of our responsibilities, what we can do, and what they will ask us. In the sense that examples should be provided of dosing for certain indications. The scope of our responsibilities, whether we are only able to advise or are we responsible for this service, and who signs off on this service. Well, it would be good if there was some sort of guideline prepared by pharmacists relating to the administration of medicines, because on the ward they have their own standards (where to administer, how much and how*).' **PP5**	'*I think it should be written by NICU pharmacists who know the business, who have been working there for a while, and should include perhaps things like, recommended reading for people new to the area. It should include information on the conditions the patients have, information on current and up-to-date treatments, medications… It should include those KPIs that should give guidance to help those experienced NICU pharmacists, junior NICU pharmacists and also the people who manage them to know what they do. If they are supposed to go in there 40 hours a week, what are they supposed to be doing, how do we know if they are doing the right thing? I think it demonstrates to management, to*
'I definitely think a list of pharmaceutical services, because a pharmacist who would have to practice on this ward would have to know what they are responsible for. You would have to define the role of the pharmacist and the role of the doctor so that there is no confusion. There would also have	

to be a ratio of how many pharmacists per beds, because without this I think the hospital management is likely to take short-cuts, and having a single pharmacist on the ward might exhaust them.' **PP6**	*the executive at the hospital, to medical staff and to nursing staff that this is why we are doing what we are doing*.' **AP3**
'*I would want some information on what medications are used on this ward, and then it would possibly be easier for us to identify relevant literature that would be useful…. Some standards of conduct for the neonatal ward, or what to do in difficult situations which are not covered by the existing standards*.' **PP11**	'*Minimum required services for certain levels of care. Like a competency assessment model that contains what the requirements are, what are the competencies that should be met for those standards. That would be useful. KPIs that are within that as well that should be monitored*.' **AP10**
'It would be great if it included the roles of the pharmacist and I think it would be easier for us and for the nurses and doctors to understand what we do. Because they would see that these are our duties, this is what we do and I think there would finally be some sort of organisation. There would be greater control over what happens on the ward.' **PP12**	'*I think it would be really good to have basics regarding the infant in the neonate. So looking at their care, what problems that you would see, just basic – these are the air-pressures that you would see in a neonate, this is what you are likely to see in terms of their lines and what's going on with their lung functions and those things. And then where the medication fits in there. And then what is expected for you to look around that*.' **AP11**
	'*I suppose if you use something like the SHPA standards of practice as a model document, I think that does include aspects around the core components. The*

	only other aspect is around training and education resources. There is a lot of interest around up-skilling staff, so its one thing to tell people this is what you should be doing but they need to have the skills to be able to interpret what they are looking at. This is extremely important in the neonatal setting, some of the drugs they might not have seen before, that type of thing.' **AP13**

Table 4: Barriers to implementing quality guidance document

POLAND	AUSTRALIA
FINANCES	
'*Everything is dependent on the employment of people and the number of employees. Considering the model that we currently use to provide pharmaceutical services, we would not have enough people to be able to cope with it all. This is strictly related to healthcare financing, whereby the national health fund reimburses specific services*.' **PP2** '*The fundamental barrier is a small number of staff. This is a fundamental barrier, without additional personnel we will not be able to overcome it - 700 beds, 6 people - that is one person per 100 beds. How? And this is not just monitoring the ward, but also the administrative duties, tenders, and other such things that take up a lot of time because some things are only able to be done and signed off by the pharmacist. There is not enough of us to even check the work of the technicians*.' **PP5** *'Financial barriers. When anyone wants to introduce new changes, this is the first barrier that they face, maybe not the first, but one of the first questions is 'how much will this cost?'. Obviously, for this to work you need people, pharmacists, and for that you need money. So I think that the financial barrier is present, because when you look at a personnel barrier, sooner or later people*	'*I guess the obvious one is resourcing. There are different levels of resources in different hospitals across Australia and its sometimes a bit of a struggle to get through the workload, but I think guidance documents such as these should help. Both in informing current practice and in future planning*.' **AP1** '*Financial, if you've got competing resources. Financial is going to be one of them.'* **AP3** *'I think both financial resources and additional staff are drivers for any kind of service. And like I said before, I think that provided that it was evidence-based and up-to-date then I think that would probably be the other driver*.' **AP6**

will be convinced that it works when they see its positive effects. On the other hand, this financial barrier is apparent, and I think it is big.' **PP6**	
EDUCATION AND EXPERIENCE	
'*One barrier is definitely our education system. The system of educating pharmacists and doctors would have to change. This issue is not independent of doctors. I think this is an important barrier*.' **PP7** '*Our model of education in Poland does not prepare us for practice in a clinical capacity, or on the ward. Above all, education. Our level of education is directed at a different type of practice, something other than actual ward-based practice with the patient*.' **PP9** *'…the lack of pharmacist preparation. This is absolutely not spoken about here. There are absolutely no clinical placements, we do not leave the pharmacy and we do not enter the wards. So at the moment, I do not feel at all prepared to fulfil this kind of role*.' **PP11**	*'…what we learn in the NICU is obviously what we have been trained for by the pharmacists. But it is not something that is focused on in terms of in your pre-registration year when you are an intern, no-one really looks at NICU. I know that it is quite specific and there isn't that many NICU beds, but it is not something that is ever touched on. You don't learn it in your degree and you don't learn it when you are an intern, unless you are actually exposed to it. Even in our hospital, we have the pharmacists that cover the nursery but we don't really have the interns covering them because fear that there is too much of a high risk. So you don't really get that exposure until you actually need to do it, and by then it might be a little bit too late*.' **AP11**
CURRENT HEALTHCARE SYSTEM	**SUPPORT FROM PROFESSIONAL PHARMACY BODY AND OTHER PROFESSIONAL STAFF**
'*We have a problem, and I will continue to point out that the pharmacist is not valued. This kind of research that you are undertaking demonstrates that it is necessary to realise that the pharmacist can perform certain tasks and support the doctor*	'*It would have to be accepted and supported by some large national body, for a hospital service to make sure that its introduced. So if you had SHPA support, or children's health Australasia support, something like along those lines, or even the Australian Commission on Safety and*

on the ward.' **PP1** '*Under these conditions, I think it would be difficult. That is why, from what I see, there is no such option for the pharmacist to become closer to the ward. I think it would be an issue for the doctors. Not for the pharmacist, I think they would adapt quickly. Because they would understand what their duties are, but it would be more difficult to communicate to the medical community that there is someone else present who has insight into similar things and who can make decisions on similar matters. So, I believe there would be resistance and a lack of trust for the pharmacist*.' **PP4** '*The barriers that we have here are that people are not very willing to change*.' **PP4**	*Quality in Healthcare, someone like that to ratify it, then you'd be more likely to get the hospital to accept it*.' **AP2** *'… support from the NICU executives as well as support from pharmacy management. If you were reporting KPIs, some sort of support from a national or state body like we would do with other med safety indicators.'* **AP7** '*Unless it had some official status or standing or a body that came out to say this is our expectation or standard of practice for pharmacy within neonatology it would be unlikely to gather enough weight… I guess resources and support. Whoever your neonatal director is, in terms of your NICU, they need to support having a pharmacist in there. If you don't have that support within the clinical unit, whether its doctors and nursing, but particularly the lead clinicians, then it will never move. You also need support from the head of the pharmacy department to say this is a good use of resources. And then you need to get the executives on board to say here's some money to make this happen*.' **AP9**
LEGISLATION	
'*First of all, the legal regulations do not specify what is an appropriate number of pharmacists to be employed. There are pharmaceutical laws that define the role that a pharmacist should fulfil and within that it is*	

specified that they should provide medication information, and that's it… The law does not support us, does not have a standard that states how many pharmacists per bed. It is only starting to be fought for now. Previously, there used to be one pharmacist per 100 beds. That was a couple of years ago. Now there is no norm… Also, the truth is that professional duties are often done by technicians and not qualified pharmacists, who should be doing it, and no-one has time to even just look into the ward or talk to the doctor. There is no support system that would allow this.' **PP5**	

CHAPTER SIX

DEVELOPMENT OF GUIDANCE RESOURCE

6.1 INTRODUCTION

Having identified that there is a need in both Poland and Australia to develop a quality guidance document for practice in NICUs, and also having identified potential indicators in the literature, further assessment of their applicability and use in Australian and Polish contexts was required. One method used to assess the relevance of indicators is the consensus approach, using the Delphi method. The following papers describe the results of a modified Delphi technique involving Australian and Polish experts.

The two papers in this chapter are copies of manuscripts that have been submitted to the Journal of Pharmacy Practice and Research and the International Journal of Clinical Pharmacy respectively and are currently under peer review. The manuscripts present a baseline list of pharmacist roles and clinical pharmacy indicators that have been identified by stakeholders as reflecting a quality standard of practice in NICUs in Australia and Poland.

THE DELPHI TECHNIQUE

Due to the geographical separation of participants in both Australia and Poland, the costs associated with having face-to-face discussions with participants precluded this method of research. Therefore instead a modified Delphi technique was chosen for this phase of the study to achieve consensus on a list of essential pharmacist roles as well as key performance indicators assessing the quality of pharmaceutical care in the NICU. The purpose of the Delphi technique is to gain data or consensus from group of people, within their domain of expertise, on a topic where there is not necessarily a definitive answer or clarity.[116] The method itself employs a series of questionnaires, delivered in sequential rounds to collect data from panellists. These rounds are continued until consensus is achieved.[117-119] It has been used successfully in the identification of quality indicators and has been used in healthcare to develop indicators for emergency medicine, paediatric nursing, prescribing as well as clinical pharmacy.[83 88 120-122] This method is characterised by participant anonymity, and allows for the contribution of a large number of individuals who are geographically separated.[123 124] There is no standard or universally accepted requirement for using this method and as a result there is ambiguity surrounding several parameters of the Delphi technique, including definition of expert as well as size of expert panels, number of rounds and defining group consensus. The variances are discussed below:

- **PANELLIST SELECTION**

  The common term to describe panellists is 'experts', however there is ambiguity surrounding the definition of an expert and what qualifications they need to hold. In general, experts are considered to be "*highly trained and competent individuals within the specialised area of knowledge related to the target issue*."[123] It is argued that a heterogeneous panel of experts may lead to a better result than a homogenous group.[125] A panel comprised of a full range of stakeholders who have an interest in the study will ensure a wider range of opinions, which may enrich the results of the research.[117 123] Furthermore, it is reported that in order to maintain a high response rate, it is important that panellists are provided the opportunity to agree to participate in the research, allowing them to become more involved in the process.[126]

- **NUMBER OF PANELLISTS**

  The number of experts or panellists within studies using the Delphi technique vary considerably, from as little as 3 to as many as 418.[117] There is no consensus in the literature outlining was constitutes an optimal number of participants, with decisions made based on the topic itself, inclusion and exclusion criteria.[116] However, this is an important consideration as if the sample size is too small, the panel may be considered as not representative of the possible pool of opinions regarding the target issue.[123] Alternatively, if the sample is too large, there is the potential for low response rates.[123]

- **NUMBER OF ROUNDS**

  Another key point of difference between Delphi studies is the number of questionnaire rounds used. There is limited scientific evidence outlining evidence on the optimal number of rounds to use, however typically this ranges from two to four.[117]

- **DEFINING CONSENSUS**

  Boulkedid highlights that the definition of consensus is the most sensitive methodological issue surrounding the use of the Delphi technique.[117] Again there is no standard level of consensus as this is dependent on the aims of the research. Some studies have argued that 51% consensus is acceptable, whilst others chose 85%.[127 128] In generals, levels of 70% or greater are considered strong cut off points.[128-130]

6.2 QUALITY PHARMACEUTICAL CARE IN THE NICU: IDENTIFICATION OF ESSENTIAL PHARMACY SERVICES AND KEY PERFORMANCE INDICATORS FOR THE AUSTRALIAN SETTING

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AUTHORS' CONTRIBUTIONS

Natalia Krzyżaniak was the primary author, collected the data, analysed and interpreted the findings, wrote and organised the manuscript. Beata V. Bajorek and Iga Pawłowska contributed to the idea, drafting of the manuscript, interpretation of findings, and critical review of the manuscript.

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ABSTRACT

BACKGROUND: When considering sub-specialties of clinical pharmacy practice, such as the neonatal intensive care unit (NICU), no key performance indicators (KPIs) or practice standards have been published by national or international pharmacy organisations.

AIM: To identify a list of essential pharmacist roles that should be performed in the NICU. Also, to identify a set of clinical pharmacy KPIs that can be used to benchmark the quality of pharmaceutical care provided to patients in Australian NICU settings.

METHOD: A modified Delphi technique was used to send 65 indicators and 30 proposed roles to an expert panel of doctors, pharmacists and nurses. The indicators and roles were compiled from a previously conducted literature review. An online survey sent in two consecutive Delphi rounds in August and September 2017 asked experts to rank the indicators and roles against specific criteria.

RESULTS: A total of 15 healthcare professionals from Australia participated as expert panellists. Overall, consensus of 75% was reached for 31 indicators and for 23 roles by Australian panellists. Experts particularly valued the following roles: pharmacists being a source of medication information (100%, Median = 1.00), assisting in off-label prescribing (100%, Median = 1.00), documenting medication errors (100%, Median = 1.00), medication chart review (100%, Median = 1.00), and writing medication protocols for the NICU (100%, Median = 1.00).

CONCLUSION: Future investigation is needed to formalise a set of NICU specific, clinical pharmacy KPIs and a practice model to form the foundations of national and international standardised practice guidelines for this sub-specialty.

KEY WORDS: Delphi technique, KPIs, Quality Measurement, NICU/neonates, clinical pharmacist, pharmaceutical care

INTRODUCTION

The quality and safe use of medicines is a global priority, particularly in high-risk patients such as those in the neonatal intensive care unit (NICU). Medication errors occur commonly in this ward, and are often avoidable.(1) Krzyzaniak and Bajorek highlighted that medication errors in NICU including patient misidentification, delayed dispensing, parental involvement in administering unauthorized medications, erroneous product dilutions, as well as tenfold and 100-fold overdoses, are more prevalent than in other patient populations.(2) The consequences of error can be significant, ranging from impact upon the use of resources resulting in cost increases, to significantly affecting the health outcomes of neonatal patients, i.e. impairing development of organs and body systems.(1, 3-5) As such, the clinical pharmacist has a critical role in preventing errors from occurring and ensuring the safety of pharmacotherapy. The role of the clinical pharmacist has evolved to comprise cognitive roles in patient care, medication management and in hospital quality improvement.(6) When considering the Australian context, overall clinical pharmacy has been shown to be well-established in wards such as the NICU, paediatric care, and palliative care, and pharmacists are found to be highly involved in the pharmacotherapy decision-making process.(7-9) As such, the pharmacist's influence over care can have significant impact upon the quality of patient outcomes. Therefore, it is important to assess the need for a minimum standard of care to be practiced by pharmacists in this setting to achieve the best possible use of pharmacotherapy. Furthermore, in doing so, there must also be a means of measuring the quality of care provided by these health care professionals.

One means of standardizing practice both within and between countries is through the development of practice policies and validated quality measurement tools, such as key performance indicators (KPIs).(10) KPIs are viewed as key resources in improving performance, and can be used to benchmark health services to determine whether they are meeting the minimum level of quality.(6) However, when considering clinical pharmacy, no KPIs have been published or adopted by national or international pharmacy organisations. Furthermore, when considering sub-specialties of clinical pharmacy practice, such as the NICU, there is even less literature available to guide pharmacists in their roles. Ng and Harrison sought to develop a set of KPIs that were measureable and relevant to clinical pharmacy, however, these are focused on hospital pharmacy practice overall, and are not specific to practice in any particular ward, especially the NICU.(6) As such, due to the lack of established KPIs, there is an inability to collect and use data to benchmark the quality of pharmaceutical care being provided for neonatal patients.

AIM OF THE STUDY

The purpose of this study was to identify, using an expert panel of stakeholders, the pharmaceutical care services and KPI's that are essential to quality medication management in the Australian NICU setting via a two-round Delphi technique.

Specific Objectives

- To identify the minimum roles and services that NICU pharmacists in Australia should be consistently performing whilst on the ward to promote medication safety and positive patient outcomes.
- To identify pharmacy-relevant key performance indicators within Donabedian's domains of structure, process and outcome that are suitable for Australian NICU settings

METHOD

An online, self-administered survey was distributed to panellists in the form of a two round Delphi technique between August and September 2017.(6) Ethics approval was sought and obtained from the respective ethics committees at the University of Technology Sydney (UTS), Australia (UTS HREC REF NO. ETH17-1584). Panellists were assured of confidentiality and were informed that their responses would be de-identified.

PANELLISTS

The study population was made up of key stakeholders/experts involved in NICU care including: pharmacists, nurses and medical doctors as identified from neonatal organisations as well as data papers and articles. Panellists were specifically sought and recruited from within Australia. Publicly available registers in Australia included the Australian New Zealand Neonatal Network (ANZNN) that identified hospitals with neonatal intensive care units.

Experts were defined as: 1) Frontline medical doctors, nurses, hospital pharmacists, members of national hospital pharmacy organisations or pharmacists based in academia, 2) who had

experience with hospital based clinical pharmacy services, and where possible 3) experience in caring for neonatal patients.

INITIAL CONSTRUCTION OF INDICATORS

To collate a list of potential pharmacist roles and key performance indicators, a review of the literature was undertaken relating to quality and pharmacist-specific key performance indicators used in neonatal and paediatric care settings.(11) Based on the findings of this review, 30 potential pharmacist roles and 66 potential indicators that were deemed sensitive to clinical pharmacy practice were included in round 1 for Australian panellists. This list of roles and indicators was collated by the research team (NK, IP, BB), each of whom hold post-graduate qualifications in pharmacy.

All indicators were categorized according to structure, process and outcome.

SURVEY

The structures of the surveys used in the Delphi rounds were adapted from two previous studies by Wilson et.al. who sought to develop a set of nursing indicators for paediatric hospitals in Australia and Fernandes et.al. who developed a set of clinical pharmacy key performance indicators for hospital pharmacists.(12, 13)

A survey consisting of three distinct sections, including panellist demographics (Section A), essential pharmacist roles in NICU (Section B) and a preliminary set of indicators (Section C), was distributed to panellists in round 1. In section B, relating to pharmacist roles, the panellists were asked to determine whether each proposed pharmacy role/service fit three criteria:

1) the role should be provided to NICU
2) that the role is realistically able to be performed for the NICU
3) the role reflects an ideal level of pharmacy practice in the NICU

In section C, the panellists were asked to determine how well the proposed key performance indicators fit the selection criteria. This selection criteria was adapted from the study performed by Fernandes et.al. and includes the following points - that the item:

1) reflects a desired level of quality practice;
2) links to direct patient care in the NICU;

3) is pharmacy or pharmacist sensitive;
4) is feasible to measure;
5) is generalizable to all hospital pharmacy types and;
6) is important for optimal medication management in this setting.(13)

The panellists were asked to rate each item on a 5 point Likert scale ranging from strongly agree (1) to strongly disagree (5). Panellists were invited to comment at the end of the survey and suggest additional indicators/roles. Any comments provided were used to rephrase questions and suggested indicators/roles were included in the next round of questionnaires. In round 2, the modified set of KPI's/roles were rated again using the same selection criteria.
The surveys were delivered via 2 rounds, over 2 months. The online software program Survey Monkey™ was used for each round. The surveys took approximately 15 minutes to complete and each round was open for 2 weeks. Reminders were emailed at the beginning and at the end of week 2. round 1 was piloted by a small number of pharmacists.

DATA ANALYSIS

Quantitative data were analysed using descriptive statistics (percentages, frequencies) using the Statistical Package for the Social Sciences (SPSS) Version 22™. After each round of Delphi ratings, consensus was deemed to have been attained when 75% or more of panellists rated 'agreed' for an indicator. All scores listed as 1 and 2 were combined as agree, and all scores listed as 4 and 5 were combined as disagree. Scores of 3 (unsure) were excluded. All items with ≥ 75% agreement were included in the final set. If an indicator did not reach this consensus, it was not included in the subsequent round.

RESULTS

Overall, 15 healthcare professionals from a possible 27 in Australia, became expert panellists and participated in at least one Delphi round. The remaining individuals did not respond. Ten experts completed both Delphi rounds. Approximately half of panellists in each round were pharmacists or directors of pharmacy, and the remaining experts consisted of neonatologists, nurses, and midwives (Table 1).

ROUND 1

A total of 14 panellists completed round 1.

PHARMACIST ROLES

A list of 30 pharmacist roles was presented to panellists. Overall, respondents from both countries had strongly agreed to the proposed services. Australian panellists achieved consensus for 26 roles, and the remaining four including: immunisations (71.4%), monitoring of TPN (71.4%), extemporaneous compounding (57.1%), and house-keeping activities (64.3%), were removed from inclusion in the following round (Table 2). Median scores ranged from 1.00 (IQR = 0) for patient medication chart review to 2.00 (IQR = 2.00) for house-keeping activities. No new roles were proposed by panellists for the subsequent round.

PROPOSED INDICATORS FOR ASSESSING THE QUALITY OF PHARMACY SERVICES IN THE NICU

Overall, 13 structure (Table 3), 24 process (Table 4) and 28 outcome indicators (Table 5) were presented to Australian panellists (total = 65). Of these, only 28 reached consensus, the remaining 37 were excluded from analysis in round 2. Median scores ranged from 1.00 (IQR = 0) to 3.00 (IQR = 1). Panellists recommended 16 indicators to be included into the next round.

ROUND 2

A total of 10 panellists completed round 2.

PHARMACIST ROLES

Consensus was reached for 23 roles by Australian panellists (Table 2). Australian panellists particularly valued the following roles: pharmacists being a source of medication information (100%, Median = 1.00), assisting in off-label prescribing (100%, Median = 1.00), documenting medication errors (100%, Median = 1.00), medication chart review (100%, Median = 1.00), and writing medication protocols for the NICU (100%, Median = 1.00). Experts excluded another three roles comprising: dispensing (60%), evaluating patient laboratory test results (60%), and managing the drug budget (70%). Median scores achieved by Australian experts ranged from 1.00 (IQR = 0) – 2.00 (IQR = 2). Overall, panellists responded strongly to the proposed pharmacist roles, with the majority responding ‘strongly agree’.

PROPOSED INDICATORS FOR ASSESSING THE QUALITY OF PHARMACY SERVICES IN THE NICU

A total of 44 indicators were presented to Australian experts, comprising: 12 structure, 13 process and 19 outcome indicators. Consensus of > 75% was achieved for 31 items. Panellists responded strongly to structure indicators, with the majority reaching a consensus of 90% and higher. The median scores ranged from 1.00 (IQR = 0) to 2.50 (2).

DISCUSSION

This is the first study to investigate the development of practice standards and a standardised national set of KPIs for pharmacy practice in Australian NICUs.

The findings highlight that pharmacists, nurses and doctors alike value the integrated roles of the pharmacist in the NICU therapeutic team. Australian panellists excluded all provision of medicines roles, which indicates that where practice is established, having pharmacists moving further into a patient-care capacity is being encouraged. The experts also indicated their agreement with pharmacists undertaking clinical roles. These perceptions may be a reflection of familiarity with current practice as hospital pharmacists in Australia are often an ingrained part of the multidisciplinary treating team.

When considering the indicators selected by panellists, the responses obtained are also encouraging. First, Australian experts were selective with the indicators that they chose, excluding a total of 50. However, they 'strongly agreed' to the remaining indicators. Interestingly, many indicators in the outcomes domain did not reach consensus by Australian experts. This may be attributed to the fact that patient outcomes in the NICU are the result of a collaborative effort from a team of experts from the medical, nursing and other allied health fields. As such, it is difficult to attribute outcomes specifically to pharmacist input.

Clinical pharmacists, as pharmacotherapy experts, are key resources in improving the safety and quality of medicines used. Literature demonstrates the positive contributions of pharmacist involvement in pharmacotherapy-related decision making and in reducing medication errors in the NICU, and there is a need to further embed pharmacists into this specialty field of practice.(5, 14, 15) The World Health Organisation (WHO) recently launched the Global Patient Safety Challenge on Medication Safety, which aims to reduce medication errors on a global scale by 50% in 5 years.(16) One of the proposed strategies by WHO to reduce these errors is to develop global norms and standards to address deficiencies in

healthcare systems that lead to medication errors and any resulting patient harm.(16) Ng and Harrison argue that there is a need for a 'centralised governance model' in clinical pharmacy to allow the profession to advance.(6) A standardised system for measuring the quality of pharmaceutical care being provided is a valuable means of promoting the value of pharmacists in this ward, and allowing pharmacists to prioritise patient care activities.(10) As such, there is a need to further build upon the findings presented, to develop a robust, valid and generalizable set of practice standards on a national as well as global scale to promote the standardisation of quality pharmacy practice.

LIMITATIONS

There are several limitations to consider. Firstly, the expert panels were comprised of only a very small number of panellists. This may be attributed to the very specific nature of this research, which may have put-off potential respondents from contributing their expertise. Furthermore, agreement/disagreement with a structure/process/outcome indicator may be associated with the local or national expectations of professional pharmacist practice or experience of each panellist. Therefore, the results may be influenced by the professional roles of the participants, years of working experience, as well as the range in working experience between panellists (noting that within the category of '1 to 5 years of experience', there could be much variability in actual experience and exposure to the NICU). This may affect the generalisability of the results and they should be interpreted with caution.

Despite the small size of the panel groups, the experts who responded to the surveys worked in a variety of different roles and contributed a diverse range of neonatal and pharmacy experiences and expertise.

Some of the indicators presented have been proposed by panellists, and as such they have not been tested for validity, reliability or measurability.

The study was undertaken in the context of the Australian healthcare system. As such, the results may not be generalizable or applicable to countries with different healthcare systems.

In addition, due to the nature of the survey and the way that the question was delivered to participants, we are unable to differentiate which participants were NICU pharmacists and those who were Directors of Pharmacy. In hindsight, this would have been a useful differentiation for the study.

CONCLUSION

The findings of this study present a baseline list of pharmacist roles and clinical pharmacy indicators that have been identified by stakeholders as reflecting a quality standard of practice in NICUs in Australia. The findings are a first step in standardising practice within this country. Future investigation is needed to formalise a set of NICU specific, clinical pharmacy KPIs and a practice model to form the foundations of national and international standardised practice guidelines for this sub-specialty.

CONFLICT OF INTEREST: The authors declare no conflict of interest.

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Table 1: Characteristics of expert panel

	ROUND 1	ROUND 2
	AUSTRALIA (%)	**AUSTRALIA (%)**
NUMBER OF PANELLISTS	14	10
GENDER OF PANELLISTS		
Female	9 (64.3)	6 (60)
SPECIALISED QUALIFICATIONS RELATING TO NEONATES		
Yes	5 (35.7)	1 (10)
No	9 (64.3)	9 (90)
Specialisation in neonatology/paediatrics – Fellow of the Royal Australasian College of Physicians (FRACP), Membership of the Royal College of Paediatrics and Child Health (MRCPCH)	1	
PhD	1	1
Postgraduate certificate in neonatal nursing	2	
Diploma in Child Health	1	
POSITION IN THE HOSPITAL		
NICU pharmacist/Director of pharmacy	7 (50)	5 (50)
Pharmacist in academia	0	0
Neonatologist/NICU Doctor	4 (28.6)	3 (30)
NICU Nurse/Midwife	3 (21.4)	2 (20)
YEARS WORKING IN CURRENT POSITION		
Between 1-5 Years	8 (57.1)	5 (50)
Between 6-10 Years	3 (21.4)	3 (30)
> 10 Years	3 (21.4)	2 (20)

Table 2: Roles that pharmacists should perform in the NICU according to the Australian expert panel

	ROUND 1		ROUND 2	
	MEDIAN (IQR) ⁎	**CONSENSUS %**	**MEDIAN (IQR) ⁎**	**CONSENSUS %**
ADMINISTRATIVE ROLES				
Development/implementation of a drug formulary service	1.00 (1)	92.9	1.00 (0)	100
Attendance at non-clinical meetings i.e. Drug and Therapeutics Committee	2.00 (1)	85.7	1.50 (1)	90
Conducting quality assurance measures i.e. drug usage evaluations, workload documentation, auditing	1.00 (1)	100	1.00 (1)	100
Management of the drug budget	2.00 (0)	85.7	2.00 (1)	70
Evaluation, selection and purchasing of pharmaceuticals for the unit	1.50 (1)	85.7	2.00 (1)	90
Development of drug policies/protocols/guidelines for the NICU	1.00 (0)	100	1.00 (0)	100
CLINICAL ROLES				
Patient medication chart review	1.00 (0)	100	1.00 (0)	100
Participation in medical ward rounds	1.50 (1)	85.7	1.00 (1)	100
Monitoring the efficacy of pharmacotherapy in patients	1.00 (1)	100	1.00 (1)	100
Documenting/monitoring side-effects and Adverse Drug Events/Reactions	1.00 (1)	85.7	1.00 (1)	100
Documenting Medication Errors	1.00 (0)	85.7	1.00 (0)	100

Evaluating patients clinical laboratory tests	2.00 (0)	78.6	2.00 (2)	60
Therapeutic Drug Monitoring (TDM)	1.00 (1)	100	1.00 (1)	100
Immunisations	2.00 (2)	71.4	-	-
Monitoring Total Parenteral Nutrition (TPN)	2.00 (2)	71.4	-	-
Participation in clinical meetings	1.00 (1)	100	1.50 (1)	100
Calculating and recommending doses and dosing schedules for specific patients	1.50 (1)	92.9	1.00 (0)	90
Assisting doctors in prescribing off-label/unlicensed medicines	1.50 (1)	100	1.00 (0)	100
Identifying and performing interventions for individual patients to prevent or resolve drug therapy problems i.e. interactions, incompatibilities, allergies etc.	1.00 (1)	100	1.00 (0)	100
Recommending drugs and contributing to the pharmacotherapy decision making process for specific patients	2.00 (1)	92.9	1.00 (1)	100
Collaborating and discussing specific patients with doctors and nurses	1.50 (1)	100	1.00 (1)	100
EDUCATIONAL ROLES				
Providing training/in-services for other health professionals on NICU related topics and drug related problems	1.00 (0)	100	1.00 (1)	100
Contributing to and/or attending NICU related conferences	2.00 (1)	92.9	2.00 (1)	100
Involved in clinical trials	2.00 (1)	78.6	1.50 (1)	90
Involved in research related to neonatal pharmacotherapy	2.00 (1)	85.7	1.00 (1)	90
Source of drug information -	1.00 (1)	100	1.00 (0)	100

responding to information requests from health professionals on the ward				
Counselling parents/carers of neonatal patients on medication	2.00 (1)	85.7	1.50 (1)	80
PROVISION OF MEDICINES ROLES				
Dispensing prescriptions	2.00 (1)	78.6	1.50 (2)	60
Extemporaneous compounding of formulations for the NICU	2.00 (2)	57.1	-	-
Stocking the ward with essential medicines/house-keeping activities i.e. checking expiry dates, fridge temperatures etc.	2.00 (2)	64.3	-	-
⁎ 1 – 5 Likert rating scale used - Role that did not achieve consensus in initial round				

Table 3: Structure indicators

	ROUND 1		ROUND 2	
	MEDIAN (IQR) ⁎	**CONSENSUS %**	**MEDIAN (IQR) ⁎**	**CONSENSUS %**
PERSONNEL				
Availability of a funded NICU clinical pharmacist position (full-time/part-time) in the hospital (17)	1.00 (0)	100	1.00 (0)	100
NICU pharmacist holds qualifications in clinical pharmacy or NICU/paediatric pharmacy (18-20)	1.00 (1)	100	1.00 (2)	70
FACILITIES/ENVIRONMENT/RESOURCES				
Dedicated area/station on the ward for the pharmacist that is a well-lit, with sufficient workspace, minimal distractions (21)	2.00 (2)	64.3	-	-
Availability of suitable fridges for vaccines and TPN on the ward (22)	1.00 (0)	100	1.00 (0)	90
Dedicated area on the ward for medication preparation that contains the relevant instruments needed (17, 22)	1.50 (2)	71.4	-	-
Direct availability on the ward of essential medicines for specific use within the NICU (23)	1.00 (0)	100	1.00 (0)	90
Availability of written policies/protocols/guidelines for high-risk medications i.e. antibiotics, pain-relief, parenteral nutrition (19, 21, 23, 24)	1.00 (0)	100	1.00 (0)	100
Availability of clear policies on how to prescribe, dispense, administer and monitor medications in the NICU	1.00 (0)	100	1.00 (0)	100

(21)				
Easily accessible neonatal formulary with standard concentrations (4, 21, 25)	1.00 (0)	100	1.00 (0)	100
Availability of emergency medicines sheets, with listed doses per weight (4, 25)	1.00 (1)	85.7	1.50 (1)	100
Availability of standard neonatal/paediatric references for use in the selection, use and evaluation of medications i.e. textbooks (BNF P, Neofax), online resources (21)	2.00 (1)	92.9	1.50 (1)	90
Availability of electronic medication error and adverse drug event reporting (systems) (19, 21, 24, 26)	1.00 (1)	85.7	1.00 (1)	90
Availability of safety technology including: CPOE, CDSS, barcode verification, smart pumps, computerised calculation of orders, automated drug dispensing units, electronic health records (4, 21, 25, 27-30)	1.00 (1)	92.9	1.00 (0)	90
Availability of clear guidelines and documents developed by pharmacists for Morphine – relating to dosing, pain scores, weaning, and adequately treating withdrawal in infants ∆	-	-	1.00 (0)	100

⁎ 1 – 5 Likert rating scale used

- Indicator that did not achieve consensus in initial round

∆ Indicator proposed by panellists

Table 4: Process Indicators

	ROUND 1		ROUND 2	
	MEDIAN (IQR) ⁎	**CONSENSUS %**	**MEDIAN (IQR) ⁎**	**CONSENSUS %**
Proportion of medicine charts reviewed by clinical pharmacists within 24 hours of admission (6, 31)	1.00 (1)	100	1.00 (1)	100
Proportion of patients who receive formal documented admission medication reconciliation by a pharmacist (includes medication history from the mother of patient) (6, 13)	2.00 (2)	71.4	-	-
Number of potential or actual drug related problems identified by a pharmacist per patient per bed day (6, 13)	2.00 (1)	71.4	-	-
Monthly audit of the number of total drug therapy problems resolved by pharmacists in the NICU (13)	2.00 (1)	78.6	1.50 (1)	90
Number of drug therapy problems resolved for 'high-alert' medications by pharmacists (13)	2.00 (1)	78.6	2.00 (1)	90
Proportion of patients for whom pharmacists have completed a medication action plan (13)	3.00 (1)	42.9	-	-
Proportion of patients prescribed narrow therapeutic index medications (i.e. aminoglycosides, digoxin) who are monitored by a pharmacist (Therapeutic Drug Monitoring) (19, 24)	1.50 (1)	78.6	1.50 (1)	100
Proportion of NICU inpatients	2.00 (2)	71.4	-	-

parents/carers that received verbal counselling and/or written information about their medicines prior to discharge (6, 24, 26, 31)				
Proportion of unlicensed/off-label prescriptions that involved the consultation of a pharmacist (19)	2.00 (1)	78.6	2.00 (2)	70
Proportion of Adverse Drug Events that were identified, monitored, rectified, prevented, and reported per number of admissions (6, 19, 24, 26)	2.00 (1)	78.6	2.00 (0.876)	70
Proportion of dispensing errors identified and rectified by pharmacist per number of admissions (21)	2.00 (2)	57.1	-	-
Number of education/training sessions provided by pharmacists relating to pharmacotherapy in the NICU for other health professionals (19, 21, 24, 26, 27, 32)	2.00 (1)	85.7	2.00 (1)	80
Number of pharmacotherapy related consultations provided to medical personnel by pharmacists (19, 24)	2.00 (1)	78.6	2.00 (1)	80
Participation in multi-disciplinary ward rounds and meetings (24, 26) – proportion of pharmacists who actively participate in interprofessional patient care rounds to improve medication management	2.00 (2)	64.3	-	-
Proportion of TPN regimens that have been monitored/optimised by a pharmacist (19, 23)	2.00 (2)	71.4	-	-
Proportion of IV medications that have been monitored by a pharmacist (19)	2.00 (1)	78.6	2.00 (1)	80

Number of pharmacists involved in conducting drug use evaluations in the NICU (33)	2.00 (1)	71.4	-	-
Use of pain protocols for patient groups and specific procedures (33)	2.00 (1)	71.4	-	-
Proportion of pharmacists involved in NICU related clinical research (24, 26)	2.00 (1)	85.7	2.00 (1)	90
Proportion of dose calculations checked by pharmacist before administration (21)	2.00 (2)	71.4	-	-
The percentage of discharge prescriptions reviewed and reconciled by a pharmacist prior to dispensing (31)	2.00 (2)	71.4	-	-
Proportion of pharmacists involved in a prescribing error feedback programme (34)	2.00 (1)	78.6	2.00 (1)	80
Proportion of multiple birth babies that have were correctly identified and had the correct medicines prescribed and administered (35)	2.00 (1)	57.1	-	-
Proportion of IV medications whose doses were checked prior to administration (19)	2.00 (2)	64.3	-	-
Number of pharmacist reviews provided verifying the appropriateness of medications prescribed for infants ∆	-	-	2.00 (1)	100
Proportion of neonatal patients monitored with pain scores ∆	-	-	2.50 (2)	60

⁎ 1 – 5 Likert rating scale used

- Indicator that did not achieve consensus in initial round

∆ Indicator proposed by panellists

Table 5: Outcome indicators

	ROUND 1		ROUND 2	
	MEDIAN (IQR) ⁎	**CONSENSUS %**	**MEDIAN (IQR) ⁎**	**CONSENSUS %**
Monthly audit of medication charts with a target of at least 80% correct time of administration (wrong time defined as more than 1 hour of prescribing for stat/PRN medications and regular medications doses not given prior to the next scheduled dose) (32)	2.00 (2)	64.3	-	-
Prescribing errors: Identification and resolution of unintentional departure from recommended prescribing practices per patient per bed day (6)	2.00 (1)	78.6	2.00 (1)	90
Monthly audit of the labelling of all lines – to be labelled with access type and fluid/medication being administered with a target of at least 90% correct labels (32)	2.00 (3)	64.3	-	-
Monthly audit of prescribing against prescribing guidelines – target 90% (32)	1.50 (2)	78.6	1.00 (1)	90
Monthly audit of prescribing pain relief against pain protocols for specific procedures (33)	2.50 (2)	50	-	-
Monthly audit of episodes of	1.50 (2)	64.3	-	-

ineffective empiric antibiotic therapy (organism/antibiotic mismatch) (36)				
Mean time to target vancomycin trough concentration for infants with known MRSA infection (36)	2.00 (2)	57.1	-	-
Proportion of infants receiving appropriate dosing and timing of perioperative prophylaxis (6, 36)	3.00 (2)	42.9	-	-
Monthly audit of episodes of antibiotic-associated adverse events (36)	2.00 (2)	57.1	-	-
Duration of treatment for culture-negative presumed late onset sepsis (36)	2.00 (2)	64.3	-	-
Monthly audit of rates of infections with multi-drug resistant gram-negative infections (36)	2.00 (2)	50	-	-
Proportion of patients with toxic or sub-therapeutic aminoglycoside concentration whose dosage has been adjusted prior to next dose (6)	2.00 (1)	85.7	1.50 (1)	90
Proportion of prescriptions for restricted antibiotics that are concordant with hospital approved criteria (6)	2.00 (2)	71.4	-	-
Proportion of patients prescribed hospital initiated warfarin whose loading doses are consistent with a hospital	3.00 (2)	35.7	-	-

approved protocol (6, 37)				
Percentage of patients who received at least 1 pain management intervention during heel sticks, PIV insertions, venipunctures, umbilical arterial catheterizations, nasogastric tube placements and EET suctioning (33)	3.00 (2)	50	-	-
Percentage of all defined procedures that were treated with a pain treatment intervention (33)	3.00 (2)	50	-	-
Administration errors: identification and resolution of unintended departure from recommended administration practices per patient per bed day (6)	2.00 (2)	71.4	-	-
Proportion of patients families that have had a face-to-face discussion about medicines related information (6)	2.00 (2)	64.3	-	-
Incidence of nosocomial infection (23, 38, 39)	2.50 (2)	50	-	-
Percentage of medication orders that include the correct dose per kilogram (or body surface area) AND an effective and safe total dose (6)	2.00 (2)	71.4	-	-
Incidence of neonatal sepsis (38, 39)	2.00 (1)	64.3	-	-
Mean length of stay (38)	2.50 (1)	50	-	-

Days on TPN (23, 38)	2.00 (1)	78.6	2.00 (3)	70
Growth velocity (daily weight gain) (23, 38)	3.00 (1)	42.9	-	-
Mortality rates (38-41)	3.00 (1)	42.9	-	-
Medication Error rates/reports per 6 months (42)	2.00 (1)	92.9	1.50 (1)	90
Adverse Drug Event rates/reports per 6 months (42)	2.00 (1)	78.6	1.00 (1)	90
Number of pharmacotherapy related critical incident /root case analyses performed per 6 months (21, 25)	2.00 (2)	71.4	-	-
Percentage of medication guidelines that have been updated within the previous 1-2 years Δ	-	-	1.00 (0)	100
Percentage of medications used in the NICU for which a medication guidelines is available Δ	-	-	1.50 (1)	100
Percentage of infants with therapeutic hypothermia who have appropriate doses and levels of Gentamicin Δ	-	-	1.50 (2)	60
Percentage of infants who receive appropriate pain management Δ	-	-	2.00 (1)	70
Proportion of infants that had antibiotics ceased at the earliest opportunity Δ	-	-	1.50 (2)	70
Proportion of infants that were monitored with pain scores Δ	-	-	2.00 (2)	70
Proportion of infants that received doses of surfactant	-	-	2.00 (2)	70

when indicated and/or did not receive surfactant when not indicated ∆				
Proportion of infants that had their coagulation profiles checked by a pharmacist ∆	-	-	2.50 (1)	50
Proportion of infants that had their electrolytes measured within 5 days of starting Frusemide ∆	-	-	2.00 (1)	80
Proportion of patients that had Ranitidine ceased immediately when the indication was no longer present ∆	-	-	2.50 (2)	50
Duration of treatment ∆	-	-	1.50 (2)	60
Proportion of infants who received a targeted treatment (for a confirmed indication) vs. empirical treatment ∆	-	-	1.50 (1)	90
Proportion of infants who experienced a medication related adverse effect and the time required until review of medication and/or treatment reversal of adverse effect ∆	-	-	1.50 (1)	90
⁎ 1 – 5 Likert rating scale used - Indicator that did not achieve consensus in initial round ∆ Indicator proposed by panellists				

6.3 QUALITY PHARMACY SERVICES AND KEY PERFORMANCE INDICATORS IN POLISH NEONATAL INTENSIVE CARE UNITS: A DELPHI APPROACH

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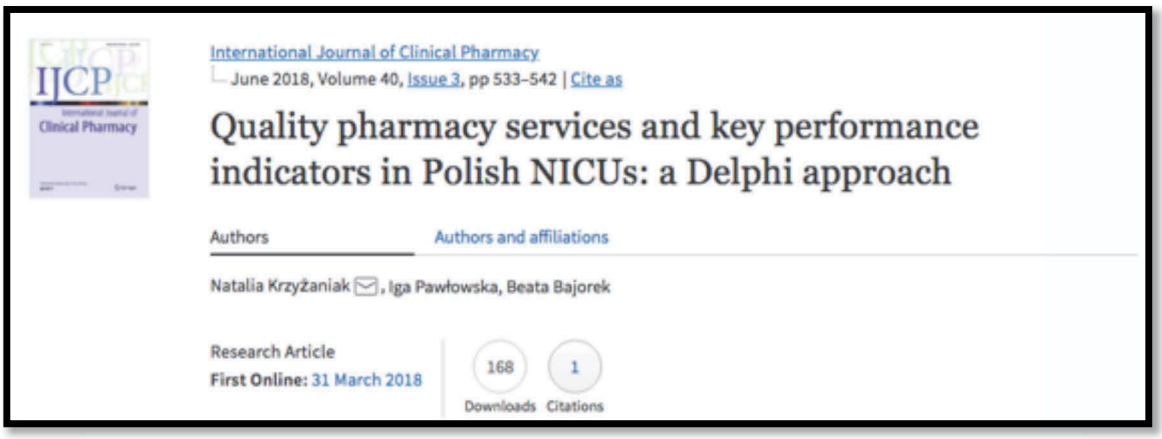

AUTHORS' CONTRIBUTIONS

Natalia Krzyżaniak was the primary author, collected the data, analysed and interpreted the findings, wrote and organised the manuscript. Beata V. Bajorek and Iga Pawłowska contributed to the idea, drafting of the manuscript, interpretation of findings, and critical review of the manuscript.

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ABSTRACT

BACKGROUND: Currently, there is no literature describing what a quality level of practice entails in Polish neonatal intensive care units (NICUs), nor are there any means of currently measuring the quality of pharmaceutical care provided to NICU patients.

OBJECTIVE: To identify a set of essential pharmacist roles and pharmacy-relevant key performance indicators (KPIs) suitable for Polish NICUs.

SETTING: A selection of Polish hospital pharmacies and NICUs.

METHOD: Using a modified Delphi technique, potential KPIs structured along Donabedian's domains as well as pharmacy services were presented to an expert panel of stakeholders. Two online, consecutive Delphi rounds, were completed by panellists between August and September 2017.

MAIN OUTCOME MEASURE: To identify which pharmacist roles are perceived as essential for pharmacy practice and what KPIs would reflect a high quality of pharmaceutical care in a Polish NICU.

RESULTS: A total of 16 panellists contributed to the expert panel. Overall, consensus of 75% was reached for 25 indicators and for 28 roles. When considering pharmacy services for the NICU, the experts were found to highly value traditional pharmacy roles, such as dispensing and extemporaneous compounding, however, they were still eager for roles in the other domains, such as educational and clinical services, to be listed as essential for NICU practice. Panellists were found to positively value the list of indicators presented, and excluded only 9 out of the total list.

CONCLUSION: There is a need for future research to establish a minimum standard of practice for Polish pharmacists to encourage the progression and standardisation of hospital pharmacy services to meet the level of practice seen in NICUs worldwide.

KEY WORDS: Delphi technique, KPI's, Quality Measurement, NICU/neonates, clinical pharmacist, pharmaceutical care

Impact of findings on practice statements

- The findings demonstrate that there is a need to determine a minimum standard of practice for Polish pharmacists to encourage the progression and standardisation of hospital pharmacy services to meet the level of practice seen worldwide.

INTRODUCTION

Despite its widespread adoption and implementation in the US, UK, Australia and Canada, clinical pharmacy practice within hospital settings in Poland is still in its infancy [1-6]. Indeed, hospital pharmacy practice as a whole is predominantly limited to dispensary-based activities focussed on the safety and effectiveness of medicines rather than patient-centred care. Pawłowska et.al. highlighted that only 7% of hospital pharmacists surveyed had contact with patients, and that their roles in the hospital were mainly associated with the provision of medicines [7]. Piecuch further indicated that pharmacists are not involved in the provision of direct, individualised care to patients and as such often have little to no input in the pharmacotherapy decision-making process [8]. Whilst pharmacists have the ability to acquire post-graduate specialisations in clinical and hospital pharmacy, their skills in these fields are unable to manifest on hospital wards due to several barriers. These include: lack of appropriate legislation specifically outlining the authority of the pharmacist in this setting, insufficient staffing of hospital pharmacies, lack of financing for additional pharmaceutical care services as well as a limited awareness of other members of the healthcare team towards the possible benefits of pharmacist involvement in the hospital structure [9].

Studies worldwide indicate that pharmacists are an integral component of patient care, and demonstrate their impact upon optimising patient outcomes, improving the rational use of resources and decreasing medication error rates [10, 2, 11, 12]. This is of particular importance to high-risk hospitalised patient groups, especially infants admitted to the neonatal intensive care unit (NICU). These children have a high level of exposure to medications throughout their admission, and due to their unique pharmacokinetic and physical characteristics, are prone to medication misadventure which may have significant impact upon their development [13]. Studies show that pharmacists in the NICU: have prevented significant errors from occurring, including 10 – 100 fold overdoses; can optimise pharmacotherapy, such as total parenteral nutrition regimens (TPN); and are highly valued by doctors and nurses on the ward [14-16, 13, 17, 18].

However, clinical pharmacy services are relatively absent in the Polish hospital setting, in comparison to other countries. This raises questions relating to the quality pharmaceutical care being provided to NICU patients, and whether the services being provided are achieving the best possible patient outcomes. Healthcare service quality is most commonly measured via key performance indicators (KPIs) or other quality indicators that assess practice performance, helping to identify where improvements are needed to minimise service gaps[19]. These

indicators are formulated using nationally or internationally agreed clinical practice guidelines based on meaningful, reliable evidence [20]. Currently, there is no literature describing what a quality level of practice entails in Polish NICUs, nor are there any means of currently measuring the quality of pharmaceutical care provided to NICU patients.

The European Directorate for the Quality of Medicines and Healthcare (EDQM) has co-ordinated the development of generally applicable indicators for the implementation of pharmaceutical care in Europe [21]. However, these indicators have been designed for use both in community and hospital settings, and are not specific to sub-speciality patient groups, such as neonates. As such, apart from the pharmaceutical law regulating which activities should be provided by hospital pharmacies to all inpatients, there are no guidance documents to support hospitals pharmacists in meeting the needs of the neonatal patient population and they are unable to measure their performance to benchmark against other settings nationally. Scobie et.al. state that the measurement of safety and quality is fundamental to health delivery [22].

AIM OF THE STUDY

The purpose of this Delphi study was to identify essential pharmacist roles and KPIs that reflect quality pharmaceutical care in a Polish NICU setting. Specific objectives were to:

- identify a set of pharmacy-based key performance indicators in Donabedian's domains of process, structure and outcome that can be used to benchmark the quality of pharmaceutical care provided to patients in Polish NICU settings.
- identify the minimum level of pharmacy services that should be consistently provided to NICU patients.

ETHICS APPROVAL

Ethics approval was sought and obtained from the respective ethics committees at the University of Technology Sydney (UTS), Australia (UTS HREC REF NO. ETH17-1584) and the Medical University of Gdansk (GUMed), Poland (GUMed HREC REF NO. NKBBN/424-184/2017). Panellists were assured of confidentiality and were informed that their responses would be de-identified.

METHOD

PANEL SELECTION

Experts were recruited using a combined purposive and criterion sampling approach [23]. Potential panellists were identified from neonatal organisations as well as data papers and articles publicly available registers in Poland including the Polish Register of Facilities delivering Medical Activities (Rejestr Podmiotów Wykonujących Działalność Leczniczą – RPWDL) to identify hospitals with neonatal intensive care units.

The expert panel was made up of key stakeholders involved in NICU care, and were defined as: 1) hospital pharmacists, or pharmacists based in academia, as well as leading medical doctors and nurses, 2) people who had experience with hospital based clinical pharmacy services, and where possible, 3) people with experience in the NICU.

COLLATING PHARMACY-SENSTIVE INDICATORS

To find quality and pharmacist-specific key performance indicators used in neonatal and paediatric care settings, a review of the literature was undertaken [24]. Due to the nature of hospital pharmacy practice in Poland (i.e., less well established level of pharmaceutical care and clinical practice; focused mainly on dispensary-based activities), the proposed indicators were carefully considered for relevance to the Polish system. Two of the researchers (NK, IP) consulted a small group of Polish health professionals to assess the applicability of indicators to current Polish pharmacy practice and canvas whether the indicators would be understood by panellists in this country. Only those indicators that pharmacists would reasonably be expected to understand in the context of current Polish pharmacy practice were included. This was based on a recent study conducted by Krzyzaniak et.al. who highlighted that pharmaceutical care services delivered to NICUs in Poland were mostly dispensary based, i.e., compounding, with little to no involvement in clinical, ward-based roles. Therefore, many concepts and terms such as medication reconciliation, medication action plans are foreign to Polish pharmacists. In order to minimise the incidence of misunderstanding as well as any social desirability bias, indicators that contained concepts and terms that were abstract to the Polish pharmacy practice setting were excluded. Overall, a modified list of 32 indicators, categorised according to Donabedian's domains of structure, process and outcome, was provided to Polish panellists.

DATA COLLECTION

The surveys used in the Delphi rounds were structured on the basis of two previous studies by Fernandes et.al. and Wilson et.al. who published a set of pharmacy and nursing indicators respectively for hospital practice [23, 26].

The study comprised two Delphi rounds, structured as two consecutive surveys delivered between August and September 2017 via the online software program Survey Monkey™. Mullen highlights that when a sample size is small, often no more than one round is needed to obtain consensus. However, in order to allow feedback and 'revision of responses', a minimum of two rounds are recommended. As the target group of individuals for this study practice within a sub-specialty of care, there are a subsequent limited number of possible participants. Therefore, a two-round Delphi survey was considered upfront as the most appropriate to ensure maximum response rate as well as to minimise the possibility of participant fatigue. Each Delphi round comprised three parts. These included: panellist demographics (Part A), essential pharmacist roles in the NICU (Part B) and a baseline set of key performance indicators (Part C). Panellists were asked to rate each item on a 5 point Likert scale ranging from strongly agree (1) to strongly disagree (5) against pre-set criteria (Figure 1).

At the end of Round 1, panellists were invited to suggest additional indicators/roles and to provide any comments. These suggestions were used to rephrase questions and refine the list of indicators/roles for inclusion in the next round of surveys. In Round 2, the modified set of KPIs/roles were rated again using the same selection criteria.

Each Delphi round was open for 2 weeks, and reminders were emailed at the beginning and at the end of each 2-week period. Each survey took approximately 15 minutes to complete. The non-completion of the previous round did not rule out panellists from contributing to the following round. Round 1 was piloted by a small number of pharmacists.

DATA ANALYSIS

Descriptive statistics (percentages, frequencies) were used to analyse the quantitative data, via the Statistical Package for the Social Sciences (SPSS) Version 22™. All Likert scale scores listed as 1 and 2 were combined as agree, and all scores listed as 4 and 5 were combined as disagree. Scores of 3 (unsure) were excluded. Consensus was considered to have been reached when 75% or more of panellists rated 'agreed' for an indicator. If an indicator did not reach this

consensus, it was not included in the subsequent round. All items with ≥ 75% agreement were included in the final set. According to Keeney et.al. a consensus level of 75% is considered to be the minimum in ensuring accuracy and confidence in the consensus achieved by participants [30].

RESULTS

Overall, of the 29 panellists who agreed to participate in this research, only 16 became expert panellists and participated in at least one Delphi round (response rate = 55.2%). The remaining individuals did not respond. Seven experts completed both Delphi rounds. Approximately half of panellists in each round were pharmacists or directors of pharmacy, and the remaining panellists comprised neonatologists, nurses, midwives and academic pharmacists (Table 1).

ROUND 1

A total of 13 panellists completed round 1.

PHARMACIST ROLES

A list of 30 pharmacist roles was presented to panellists. Overall, respondents strongly agreed to the majority of the proposed roles. Polish experts achieved consensus for 28 roles; two services pertaining to evaluating laboratory tests (69.2%) and immunisations (46.2%) were excluded (Table 2). Using the 5-point Likert scale, the range of median scores was from 1.00 (IQR = 0) for extemporaneous compounding to 3.00 (IQR = 2) for involvement in immunisations. A new role was proposed for inclusion in the next round, that being the preparation of individual, unit dose parenteral and oral dose forms for neonatal patients.

PHARMACY-BASED KEY PERFORMANCE INDICATORS FOR QUALITY PHARMACEUTICAL CARE IN THE NICU

Polish experts were presented with 10 structure, 11 process and 11 outcome indicators (total = 32). A consensus of > 75% was achieved for 25 items (Table 3). Therefore, 7 items were excluded from subsequent analysis. These items included: dedicated area/station on the ward for the pharmacist (69.2%), number of education/training sessions provided by pharmacists relating to pharmacotherapy in the NICU for other health professionals (69.2%), proportion of

pharmacists involved in NICU related clinical research (61.5%), monthly audit of episodes of ineffective empiric antibiotic therapy (organism/antibiotic mismatch) (69.2%), proportion of infants receiving appropriate dosing and timing of perioperative prophylaxis (69.2%), proportion of patients families that have had a face-to-face discussion about medicines related information (53.8%) and incidence of neonatal sepsis (61.5%).

Panellists did not recommend any new indicators for inclusion in round 2. Median scores for panellists ranged from 1.00 (IQR = 0) to 2.00 (IQR = 2).

ROUND 2

A total of 12 panellists completed round 2.

PHARMACIST ROLES

Consensus was reached for 28 roles (Table 2). Overall, panellists responded strongly to the proposed pharmacist roles, with the majority responding 'strongly agree'. Polish experts most strongly responded to pharmacist roles in the provision domain, including: extemporaneous compounding (100%, Median = 1.00), stocking the ward with medication (100%, Median = 1.00) and the newly added role, preparing unit doses for parenteral and oral medicines (100%, Median = 1.00). Counselling of the families of NICU patients did not reach consensus by Polish panellists (58.3%); median scores achieved by Polish experts ranged from 1.00 (IQR = 0) – 2.00 (IQR = 2).

PHARMACY-BASED KEY PERFORMANCE INDICATORS FOR QUALITY PHARMACEUTICAL CARE IN THE NICU

A total of 27 indicators were rated by panellists, and were split evenly across Donabedian's domains, with 9 structure, 9 process and 9 outcome indicators. Consensus was reached for 25 indicators. Median scores were similar to the previous round for most indicators and ranged from 1.00 (IQR = 0) to 2.00 (IQR = 2). Polish panellists responded strongly throughout each of the structure, process and outcome domains, with consensus higher than 90% for the majority of indicators. Two indicators in the outcomes domain did not achieve consensus: percentage of patients who received at least 1 pain management intervention during heel sticks, PIV insertions, venipunctures, umbilical arterial catheterizations, nasogastric tube placements and

EET suctioning (66.7%) and proportion of prescriptions for restricted antibiotics that are concordant with hospital approved criteria (66.7%).

DISCUSSION

This is the first study in Poland to identify a set of pharmacist roles and KPIs that may be useful in structuring and guiding future practice in the NICU. Furthermore, this research is the first of its kind to combine the concept of clinical pharmacy practice and a sub-specialty of pharmacy, such as the NICU setting, in Poland.

In considering pharmacy services, experts highly valued traditional pharmacy roles, such as dispensing and extemporaneous compounding, but were still highly supportive of roles in the other domains, such as educational and clinical services, to be included as essential for NICU practice. These traditional perceptions may stem from ingrained practice cultures in Poland, whereby pharmacists are predominantly perceived to be based in the dispensary [7]. However, it is extremely encouraging that, despite these attitudes, medical and pharmacy staff alike are open to the pharmacists providing ward-based services to the NICU and being involved in the pharmacotherapy decision-making process. Similarly, experts expressed strong levels of support for the key performance indicators. This is of particular significance, as currently Poland does not have any national initiatives for quality assurance for hospital pharmacy practice. As such, it is encouraging that despite having little to no experience with clinical pharmacy KPIs, the experts were extremely enthusiastic towards selecting indicators, with high levels of agreement for those remaining in the final list.

These findings demonstrate that there is a need to determine a minimum standard of practice for Polish pharmacists to encourage the progression and standardisation of hospital pharmacy services to meet the level of practice seen worldwide. According to the World Health Organisation (WHO), the concept of health equity is a priority for healthcare systems worldwide, and it is a fundamental right of each human being to receive the highest standard of healthcare [31, 32]. The literature highlights that Polish pharmacists are aware of the differences in practice evident between Poland and other industrialised countries, such as Australia and the UK [8, 9, 33]. However, Urbanczyk highlights that the clinical pharmacist is simply not viewed by policy-makers or other healthcare professionals as a medicines expert, and does not hold the relevant position or authority to be able to directly influence

pharmacotherapy [9]. This is a point of concern, as the studies demonstrate the positive contributions of pharmacist involvement in pharmacotherapy-related decision making and in reducing medication errors in the NICU [14, 17, 34]. Neonatal patients are a priority for each healthcare profession, and the key to stepping forward in the Polish setting is to accept the pharmacist as an essential member of the interdisciplinary therapeutic team and then develop strategies to embed pharmacists into this setting. The International Pharmaceutical Federation (FIP) endorses the development of standardised national pharmacy guidelines and services to identify good practices and adopt coherent policies to promote practice consistency [35]. The findings presented here may be useful for the future development of quality pharmacy practice resources in Poland. These resources are important for quality improvement activities, such as benchmarking to demonstrate differences between settings on a national scale, pharmacy practice accreditation, as well as enhancing transparency about hospital pharmacy service quality, which are important for the progression of hospital pharmacy practice in Poland [36]. The findings of this research may be transposable to practice in other countries, particularly those in Eastern Europe, as the healthcare system issues faced in Poland are similar to those experienced in these countries. This may be attributed to the impact of historical events upon the political, economic and societal climate.

LIMITATIONS

There are several limitations to consider. First, the expert panels comprised only a small number of panellists. This may be attributed to the very specific nature of this research, which may have deterred potential respondents from contributing their expertise. Therefore, this may affect the generalisability of the results and they should be interpreted with caution.

Despite the small size of the panel, care was taken to ensure that the experts who responded to the surveys reflected a range of expertise and contributed a diverse range of neonatal and pharmacy experiences. However, this panel cannot be said to be representative of each profession in Poland.

The study was undertaken in the context of the Polish healthcare system. As such, the results may not be generalisable or applicable to countries with different healthcare systems.

Furthermore, the key performance indicators are not a comprehensive set of indicators for the assessment of hospital pharmacy practice in a Polish context. They simply represent consensus amongst experts in defining a preliminary quality level of pharmacy practice in the NICU.

CONCLUSION

The baseline quality indicators and pharmacy services identified, give insight in to what experts deem to be essential aspects of quality pharmaceutical care in Polish NICU settings. These findings are the first to consider the integration of the clinical pharmacist into NICU settings in Poland. The practical considerations of applying these indicators will need careful consideration before they can be seen as valid performance measurement tools. There are several barriers in the current healthcare system limiting pharmacy services on the NICU, which require attention. Further research is needed to established the validity, acceptability and feasibility of the proposed indicators to practice on a national level, as well as to develop strategies to further integrate the pharmacist into the NICU therapeutic team.

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Table 1: Characteristics of expert panel

	ROUND 1	ROUND 2
	POLAND (%)	**POLAND (%)**
NUMBER OF PANELLISTS	13	12
GENDER OF PANELLISTS		
Female	12 (92.3)	11 (91.7)
SPECIALISED QUALIFICATIONS RELATING TO NEONATES		
Yes	5 (38.5)	4 (33.3)
No	8 (61.5)	8 (66.7)
Specialisation in neonatology/paediatrics	1	3
Hospital/Clinical Pharmacy specialisation	3	1
Postgraduate certificate in neonatal nursing	1	
POSITION IN THE HOSPITAL		
NICU pharmacist/Director of pharmacy	9 (69.2)	6 (50)
Pharmacist in academia	2 (15.4)	2 (16.7)
Neonatologist/NICU Doctor	1 (7.7)	4 (33.3)
NICU Nurse/Midwife	1 (7.7)	0
EXPERIENCE		
Between 1-5 Years	3 (23.1)	2 (16.7)
Between 6-10 Years	1 (7.7)	1 (8.3)
> 10 Years	9 (69.2)	9 (75)

Table 2: Roles that pharmacists should perform in the NICU according to the Polish expert panel

Pharmacist Services/Roles	ROUND 1		ROUND 2	
	MEDIAN (IQR) ⁎	CONSENSUS %	MEDIAN (IQR) ⁎	CONSENSUS %
ADMINISTRATIVE ROLES				
Development/implementation of a drug formulary service	1.00 (0)	100	1.00 (0)	100
Attendance at non-clinical meetings i.e. Drug and Therapeutics Committee	1.00 (1)	100	1.00 (1)	100
Conducting quality assurance measures i.e. drug usage evaluations, workload documentation, auditing	1.00 (1)	92.3	1.00 (1)	100
Management of the drug budget	2.00 (1)	100	1.00 (1)	91.7
Evaluation, selection and purchasing of pharmaceuticals for the unit	1.00 (0)	100	1.00 (0)	100
Development of drug policies/protocols/guidelines for the NICU	1.00 (1)	100	1.00 (1)	100
CLINICAL ROLES				
Patient medication chart review	1.00 (0)	100	1.00 (1)	100
Participation in medical ward rounds	1.00 (1)	84.6	1.50 (1)	83.3
Monitoring the efficacy of pharmacotherapy in patients	1.00 (1)	84.6	2.00 (1)	91.7
Documenting/monitoring side-effects and Adverse Drug Events/Reactions	1.00 (0)	100	1.00 (0)	100
Documenting Medication Errors	1.00 (1)	100	1.00 (1)	100

Evaluating patients clinical laboratory tests	2.00 (2)	69.2	-	-
Therapeutic Drug Monitoring (TDM)	1.00 (1)	92.3	2.00 (1)	91.7
Immunisations	3.00 (2)	46.2	-	-
Monitoring Total Parenteral Nutrition (TPN)	1.00 (0)	100	1.00 (0)	100
Participation in clinical meetings	2.00 (1)	84.6	2.00 (1)	83.3
Calculating and recommending doses and dosing schedules for specific patients	1.00 (1)	84.6	1.00 (1)	91.7
Assisting doctors in prescribing off-label/unlicensed medicines	1.00 (1)	92.3	1.00 (1)	100
Identifying and performing interventions for individual patients to prevent or resolve drug therapy problems i.e. interactions, incompatibilities, allergies etc.	1.00 (0)	100	1.00 (1)	100
Recommending drugs and contributing to the pharmacotherapy decision making process for specific patients	1.00 (1)	100	1.00 (1)	100
Collaborating and discussing specific patients with doctors and nurses	1.00 (1)	92.3	1.00 (1)	100
EDUCATIONAL ROLES				
Providing training/in-services for other health professionals on NICU related topics and drug related problems	1.00 (1)	84.6	1.00 (1)	91.7
Contributing to and/or attending NICU related conferences	1.00 (0)	100	1.00 (1)	100

Involved in clinical trials	1.00 (1)	100	1.00 (1)	91.7
Involved in research related to neonatal pharmacotherapy	1.00 (1)	100	1.00 (1)	91.7
Source of drug information - responding to information requests from health professionals on the ward	1.00 (1)	100	1.00 (0)	100
Counselling parents/carers of neonatal patients on medication	2.00 (2)	76.9	2.00 (2)	58.3
PROVISION OF MEDICINES ROLES				
Dispensing prescriptions	1.00 (0)	100	1.00 (0)	100
Extemporaneous compounding of formulations for the NICU	1.00 (0)	100	1.00 (0)	100
Stocking the ward with essential medicines/house-keeping activities i.e. checking expiry dates, fridge temperatures etc.	1.00 (0)	100	1.00 (0)	100
Preparing unit doses for parenteral and oral medicines †	-	-	1.00 (0)	100
⁎ 1 – 5 Likert rating scale used † Role proposed by panellists				

Table 3: Structure indicators

	ROUND 1		ROUND 2	
	MEDIAN (IQR) ⁕	**CONSENSUS %**	**MEDIAN (IQR) ⁕**	**CONSENSUS %**
PERSONNEL				
Availability of a funded NICU clinical pharmacist position (full-time/part-time) in the hospital [37]	1.00 (2)	76.9	2.00 (2)	75
NICU pharmacist holds qualifications in clinical pharmacy or NICU/paediatric pharmacy [38-40]	2.00 (2)	76.9	1.50 (1)	91.7
FACILITIES/ENVIRONMENT/RESOURCES				
Dedicated area/station on the ward for the pharmacist that is a well-lit, with sufficient workspace, minimal distractions [41]	2.00 (2)	69.2	-	-
Availability of suitable fridges for vaccines and TPN on the ward [42]	1.00 (1)	92.3	1.00 (1)	91.7
Direct availability on the ward of essential medicines for specific use within the NICU [43]	1.00 (1)	100	1.00 (1)	91.7
Availability of written policies/protocols/guidelines for high-risk medications i.e. antibiotics, pain-relief, parenteral nutrition [39, 41, 43, 44]	1.00 (0)	100	1.00 (0)	100
Availability of clear policies on how to prescribe, dispense, administer and monitor	1.00 (0)	100	1.00 (1)	91.7

medications in the NICU [41]				
Availability of emergency medicines sheets, with listed doses per weight [45, 46]	1.00 (0)	100	1.00 (0)	100
Availability of standard neonatal/paediatric references for use in the selection, use and evaluation of medications i.e. textbooks (BNF P, Neofax), online resources [41]	1.00 (0)	100	1.00 (0)	100
Availability of electronic medication error and adverse drug event reporting (systems) [39, 41, 44, 47]	1.00 (0)	100	1.00 (0)	100
⁎ 1 – 5 Likert rating scale used				

Table 4: Process indicators

	ROUND 1		ROUND 2	
	MEDIAN (IQR) ⁕	**CONSENSUS %**	**MEDIAN (IQR) ⁕**	**CONSENSUS %**
Proportion of unlicensed/off-label prescriptions that involved the consultation of a pharmacist [39]	2.00 (1)	92.3	2.00 (1)	100
Proportion of Adverse Drug Events that were identified, monitored, rectified, prevented, and reported per number of admissions [39, 44, 47]	1.00 (1)	100	1.00 (1)	91.7
Proportion of dispensing errors identified and rectified by pharmacist per number of admissions [48]	2.00 (2)	76.9	1.00 (1)	91.7
Number of education/training sessions provided by pharmacists relating to pharmacotherapy in the NICU for other health professionals [39, 41, 44, 47, 49, 50]	2.00 (2)	69.2	-	-
Number of pharmacotherapy related consultations provided to medical personnel by pharmacists [39, 41, 44, 47, 49, 50]	1.00 (1)	92.3	1.00 (1)	100
Proportion of TPN regimens that have been monitored/optimised by a pharmacist [39, 43]	1.00 (0)	92.3	1.00 (0)	100
Proportion of IV medications that have been monitored by a pharmacist [39]	1.00 (1)	92.3	1.00 (1)	100

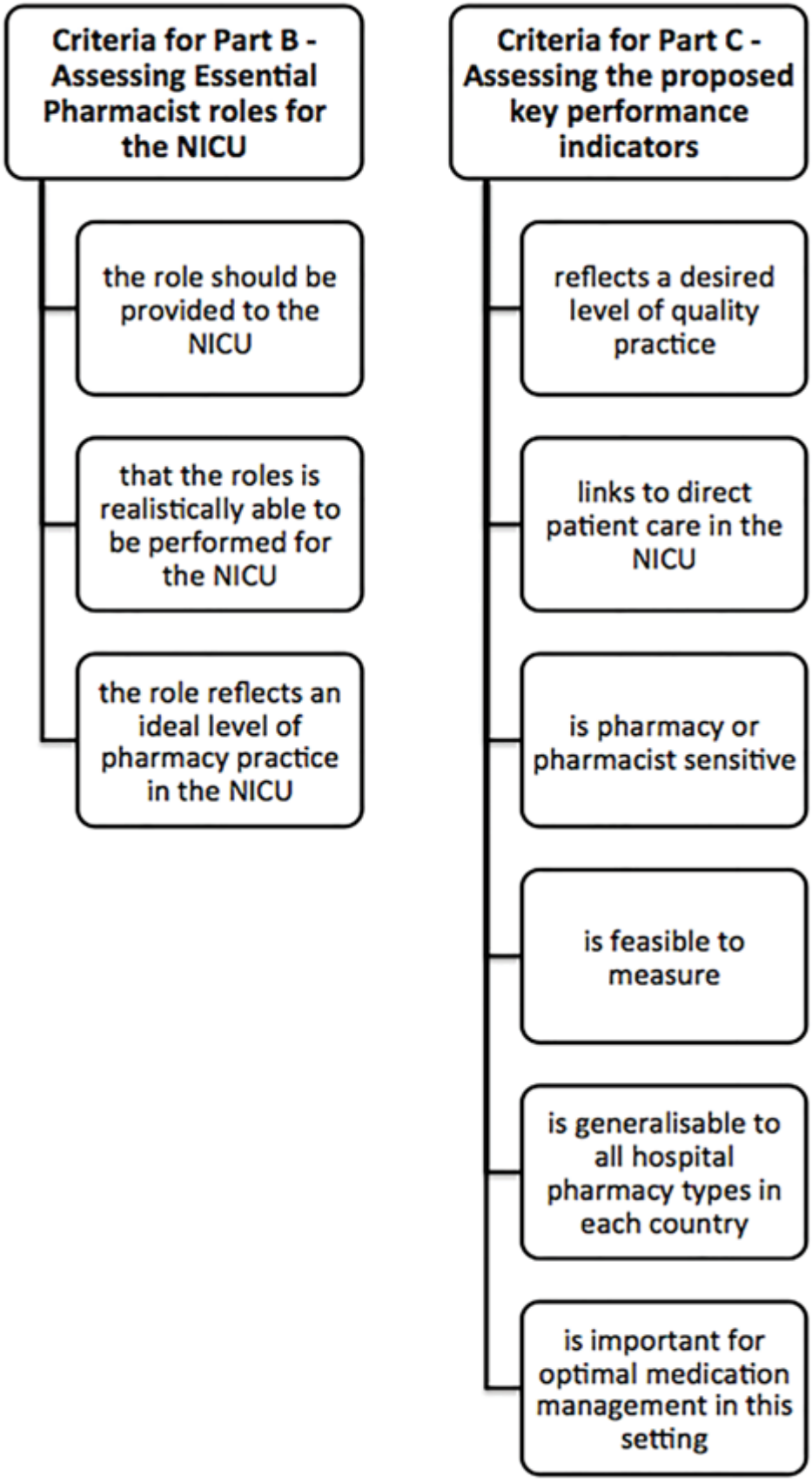
Proportion of pharmacists involved in NICU related clinical research [44, 47]	2.00 (2)	61.5	-	-
Proportion of dose calculations checked by pharmacist before administration [41]	2.00 (2)	76.9	1.00 (1)	100
Proportion of patients whose therapy is being monitored by a pharmacist [51]	2.00 (2)	76.9	2.00 (1)	100
Proportion of extemporaneous medications that have been prepared and monitored by a pharmacist for the NICU [41]	1.00 (0)	100	1.00 (0)	100
⁎ 1 – 5 Likert rating scale used				

Table 5: Outcome indicators

	ROUND 1		ROUND 2	
	MEDIAN (IQR) ⁕	**CONSENSUS %**	**MEDIAN (IQR) ⁕**	**CONSENSUS %**
Monthly audit of episodes of ineffective empiric antibiotic therapy (organism/antibiotic mismatch) [52]	1.00 (2)	69.2	-	-
Proportion of infants receiving appropriate dosing and timing of perioperative prophylaxis [52]	2.00 (2)	69.2	-	-
Monthly audit of episodes of antibiotic-associated adverse events [52]	1.00 (2)	76.9	1.00 (1)	83.3
Proportion of prescriptions for restricted antibiotics that are concordant with hospital approved criteria [51]	1.00 (1)	84.6	1.00 (2)	66.7
Percentage of patients who received at least 1 pain management intervention during heel sticks, PIV insertions, venepunctures, umbilical arterial catheterizations, nasogastric tube placements and EET suctioning [53]	2.00 (2)	76.9	2.00 (2)	66.7
Proportion of patients families that have had a face-to-face discussion about medicines related information [51]	2.00 (2)	53.8	-	-
Percentage of medication orders that include the correct dose per kilogram (or body surface area)	1.00 (1)	92.3	1.00 (1)	91.7

AND an effective and safe total dose [51]				
Incidence of neonatal sepsis [54, 55]	2.00 (2)	61.5	-	-
Medication Error rates/reports per 6 months [48]	1.00 (1)	92.3	1.00 (1)	83.3
Adverse Drug Event rates/reports per 6 months [48]	1.00 (1)	84.6	1.00 (1)	91.7
Costs of Therapy [85]	2.00 (1)	92.3	1.00 (2)	75
⁎ 1 – 5 Likert rating scale used				

Figure 1: Criteria used by the expert Delphi panel to assess essential pharmacy services and key performance indicators for NICU practice



CHAPTER SEVEN

PROPOSED GUIDANCE DOCUMENTS

7.1 INTRODUCTION

From the results described in Chapter 6, two practice guidance documents outlining elements of quality pharmaceutical care in the NICU were developed for the Australian and Polish setting. These documents are presented in this chapter. This research is the first of its kind to define what quality from a pharmacist's perspective actually represents in the NICU, in terms of the services that should be provided. Furthermore, these documents also present a list of pharmacist-sensitive key performance indicators specifically tailored to the NICU that can be used as a self-assessment or as a tool to benchmark services nationally.

The research presented in this chapter may form the foundations of future research in standardising pharmaceutical care in the NICU and also in defining what the term 'quality' refers to in this sub-specialty of care.

7.2 AUSTRALIAN QUALITY GUIDANCE DOCUMENT

QUALITY PHARMACEUTICAL CARE IN THE NICU: DEVELOPMENT OF A GUIDANCE DOCUMENT AND KEY PERFORMANCE INDICATORS FOR AUSTRALIAN NICUS

- GUIDANCE DOCUMENT TO SUPPORT PHARMACY PRACTICE IN THE NICU -

RESEARCHERS:

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CONFIDENTIAL

MEMBERS OF THE TEAM

This guidance document has been created by a team of researchers comprising Natalia Krzyżaniak and A/Prof Beata Bajorek from the University of Technology Sydney and Dr Iga Pawłowska from the Medical University of Gdansk, Poland, and aims to help standardise pharmaceutical care provided to vulnerable neonatal patients admitted to Australian neonatal intensive care units (NICUs). This document forms part of a PhD thesis and research led by NK. Each element within the document has been derived from previously performed literature reviews and research, focussed on defining quality pharmaceutical care and services for the NICU.



TABLE OF CONTENTS

DEFINTION OF PHARMACEUTICAL CARE

"Pharmaceutical care is a philosophy of practice in which the patient is the primary beneficiary of the pharmacist's actions. Pharmaceutical care focuses the attitudes, behaviours, commitments, concerns, ethics, functions, knowledge, responsibilities and skills of the pharmacist on the provision of drug therapy with the goal of achieving definite therapeutic outcomes toward patient health and quality of life" [1, 2].

LEGAL REGULATIONS

Under Australian legislation, there is no specific Act that specifies the legally required services and roles of a pharmacist. The legal framework is complex, and there are a number of documents that outline the practice standards for a pharmacist.

The *National Health Act 1953* stipulates that under the *National Health (Pharmaceutical Benefits) Determination 2007* as a standard of practice, pharmacists must comply with the Pharmaceutical Society of Australia's (PSA) code of professional conduct and professional practice standards [3]. Within these two codes, the roles of pharmacists can be broken down into 3 domains; basic roles, clinical services and advanced practice, which illustrate a continuum of care in the Australian pharmaceutical care system. Furthermore, the process of medication use within Australia is depicted in the Medication Management Pathway (MMP), which describes the cognitive and physical steps undertaken by health professionals to ensure quality use of medicines. In an Australian context, pharmacists have an established role within all areas of the medication use process; however these roles vary across settings. Refer to Figure 1 for a depiction of the scope of practice for community and hospital pharmacists in Australia in the MMP.

At the foundational level, all pharmacists in Australia are required to adopt a patient-centred approach in their provision of professional services [4]. According to the PSA Professional Practice Standards, as part of their responsibilities, pharmacists are required to work in an ethical and legal manner and adhere to all principles of patient autonomy, privacy and confidentiality for the sole purpose of achieving quality patient health outcomes and wellbeing [5]. In addition to these principles, pharmacists are required to perform the following fundamental roles associated with their occupation as medication experts:

- Dispensing
- Compounding
- Counselling
- Medication Management
- Disposal
- Stock
- Storage
- Continuing Professional Development (CPD)

DEFINING LEVELS OF NEONATAL CARE IN AUSTRALIA

CARE LEVEL	DEFINTION [6]
LEVEL 1	• provides care for healthy infants greater than or equal to 37 weeks gestational age. • emphasis is on parenting, bonding, and support for feeding and lactation. • care predominantly provided by registered nurses and/or midwives in community settings or home -based care. • has capability to provide basic life support for infants and can stabilise infants requiring transfer to higher level of service. • documented processes for referral to/from higher-level services within relevant neonatal service network.
LEVEL 2	• primarily provides planned care for healthy infants greater than or equal to 37 weeks gestational age. • has capability to retain and/or accept infants of less than 37 weeks gestational age who are physiologically stable and feeding well. • care of infants of less than 35 weeks gestational age must always occur in consultation with higher level of service. • may be limited birthing services available
LEVEL 3	• provides planned care for healthy infants greater than or equal to 37 weeks gestational age. • has capability to retain and/or accept infants of 35 to 37 weeks gestational age who are physiologically stable. • care of infants less than 35 weeks gestational age must always occur in consultation with higher level of service.
LEVEL 4	• where continuous positive airway pressure (CPAP) device accessible on -site and adequately trained staff in sufficient numbers to care for baby on CPAP, capability to plan and deliver care to infants greater than or equal to 32 weeks gestational age, or who have estimated birth weight

CARE LEVEL	DEFINTION [6]
	of greater than or equal to 1500g, with no additional risk factors (if born at that hospital). • where CPAP not on -site, has capability to plan and deliver care for infants greater than or equal to 34 weeks gestational age. • may accept back - transfer of infants of any weight or gestational age from a Level 5 or 6 service once infants considered suitably stable for such transfer by higher level unit. • where unplanned births of infants of less than 32 weeks gestational age and/or infants with birth weight less than 1500 grams occur, care must be provided in consultation with Level 5 or 6 neonatal service. • admissions reported according to registration criteria of Australian and New Zealand Neonatal Network (ANZNN). • documented plans with public or licensed private health facilities to support patient referral and transfer to/from higher and lower level services.
LEVEL 5	• capability to plan and deliver care for infants born at hospital or back - transferred from higher level service who are greater than or equal to 29 weeks gestational age with estimated birth weight of more than 1000 grams. • where unplanned births of infants at less than 29 weeks gestational age and/or with birth weight less than 1000 grams occur, care must be provided in consultation with Level 6 neonatal service. • no neonatal surgery provided at this level.
LEVEL 6	• provides highest level of care to infants. • Has personnel and equipment to provide continuous life support and comprehensive multidisciplinary care for extremely high -risk newborns and those with complex and critical illnesses. • may perform neonatal surgery. • multidisciplinary follow -up programs provided for very premature infants and, where required, access to multidisciplinary early

CARE LEVEL	DEFINTION [6]
	developmental programs provided. • provides education links to lower level services, as required, and has documented processes, within relevant neonatal service network, with lower levels of neonatal services to support patient transfer and care. • also provides educational support to less comprehensive neonatal services. • plays strategic role in planning of clinical statewide services related to perinatal care, and participates in perinatal morbidity and mortality meetings within service network.

SPECIFIC CLASSIFICATIONS OF NEONATAL CARE SERVICES IN EACH STATE:

- Queensland – https://www.health.qld.gov.au/__data/assets/pdf_file/0023/444272/cscf-neonatal.pdf
- New South Wales - http://www1.health.nsw.gov.au/pds/ActivePDSDocuments/GL2016_018.pdf
- Victoria – https://www2.health.vic.gov.au/hospitals-and-health-services/patient-care/perinatal-reproductive/maternity-newborn-services/newborn-care-in-victoria
- South Australia - http://www.sahealth.sa.gov.au/wps/wcm/connect/ed65e3804e49ec039092d8c09343dd7f/15137.2-16+Maternity+%26+Neonatal-WebSec.pdf?MOD=AJPERES&CACHEID=ed65e3804e49ec039092d8c09343dd7f
- Western Australia - http://www.healthnetworks.health.wa.gov.au/modelsofcare/docs/Framework_for_the_Care_of_Neonates_in_WA.pdf

GOALS FOR PHARMACY SERVICES IN THE NICU:

- To have a comprehensive pharmacy service on-site, plus on-call arrangements 24 hours/day, 7 days/week delivering the recommended services to neonatal patients [6-9].
- Recommended number of pharmacists needed per bed: For neonates, 15 beds to 1 full-time equivalent (FTE) pharmacist on-site for clinical services at least 5 days per week [10].
- Recommended time allocation – 10 – 20 minutes per patient plus time required to attend ward rounds and relevant clinical meetings [7].
- Recommended that all pharmacists on this ward are suitably trained in the area of neonatology, namely: pharmacokinetics and pharmacodynamics of the neonate, development of the metabolic pathways in the neonate and the subsequent impact on the use of medication in this population [7]. Furthermore, it is recommended that pharmacists are aware of the most common neonatal problems that present in the NICU and their treatment i.e. necrotising enterocolitis, respiratory distress syndrome, patient ductus arteriosus, apnoea [11].
- Understanding routine neonatal screening tests and assessments i.e. APGAR scoring [11].
- Understanding prophylactic treatment i.e. for haemorrhagic disease of the newborn, also neonatal immunisations [11].
- It is recommended that all pharmacists working on this ward undertake continuing education to maintain their level of knowledge and skills needed on this ward [7].

RECOMMENDED LEVELS OF PHARMACY ACCESS ACCORDING TO THE NATIONAL MATERNITY SERVICES CAPABILITY FRAMEWORK

[6]	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**	**Level 6**
Access on-site or referral to pharmacist and drugs – private or hospital imprest	✓	✓	✓	✓	✓	✓
Access on-site or referral to pharmacist and drugs supplied through hospital imprest		✓	✓	✓	✓	✓
Access on-site but not on-call 24 hours to a pharmacy service			✓	✓	✓	✓
Access on-site and 24 hours to a pharmacy service				✓	✓	✓

ROLES THAT SHOULD BE CONSISTENTLY PROVIDED TO NICUs

Roles that should be performed by a pharmacist in the NICU, as identified through research via 'Quality Pharmaceutical Care In The NICU: Identification of Essential Pharmacy Services And Key Performance Indicators for the Australian setting' [12]. These roles were deemed to be essential for the quality use of medicines in this patient population.

ADMINISTRATION/MANAGEMENT
Developing/implementing a drug formulary service
Attending non-clinical meetings i.e. Drug and Therapeutics Committee
Conducting quality assurance measures i.e. drug usage evaluations, workload documentation, auditing
Evaluating and selecting pharmaceuticals for the unit
Developing drug policies/protocols/guidelines for the NICU
CLINICAL ROLES
Patient medication chart review
Participating in medical ward rounds
Monitoring the efficacy of pharmacotherapy in patients
Documenting/monitoring side-effects and Adverse Drug Events/Reactions
Documenting Medication Errors
Therapeutic Drug Monitoring (TDM)
Participating in clinical meetings
Calculating and recommending doses and dosing schedules for specific patients
Assisting doctors in prescribing off-label/unlicensed medicines
Identifying and performing interventions for individual patients to prevent or resolve drug therapy problems i.e. interactions, incompatibilities, allergies etc.
Recommending medicines and contributing to the pharmacotherapy decision making process for specific patients
Consulting and collaboration with doctors and nurses about specific patients

EDUCATION/COMMUNICATION/RESEARCH
Providing training/in-services for other health professionals on NICU related topics and drug related problems
Contributing to and/or attending NICU related conferences
Participating in clinical trials
Participating in research related to neonatal pharmacotherapy
Responding to information requests from health professionals on the ward - source of drug information
Counselling parents/carers of neonatal patients on medication

KEY PERFORMANCE INDICATORS (KPIs)

Research derived KPIs for pharmacist practice in the NICU.

(Quality Pharmaceutical Care In The NICU: Identification of Essential Pharmacy Services And Key Performance Indicators for the Australian setting'[12]

STRUCTURE
☐ Availability of a funded NICU clinical pharmacist position (full-time/part-time) in the hospital
☐ Availability of suitable fridges for vaccines and total parenteral nutrition (TPN) on the ward
☐ Direct availability on the ward of essential medicines for specific use within the NICU
☐ Availability of written policies/protocols/guidelines for high-risk medications i.e. antibiotics, pain-relief, parenteral nutrition
☐ Availability of clear policies on how to prescribe, dispense, administer and monitor medications in the NICU
☐ Easily accessible neonatal formulary with standard concentrations
☐ Availability of emergency medicines sheets, with listed doses per weight
☐ Availability of standard neonatal/paediatric references for use in the selection, use and evaluation of medications i.e. textbooks (BNF Paediatrics, Neofax), online resources
☐ Availability of electronic medication error and adverse drug event reporting (systems)
☐ Availability of safety technology including: computerised physician order entry

(CPOE), clinical decision support system (CDSS), barcode verification, smart pumps, computerised calculation of orders, automated drug dispensing units, electronic health records
☐ Availability of clear guidelines and documents developed by pharmacists for Morphine - relating to dosing, pain scores, weaning, and adequately treating withdrawal in infants

PROCESS
☐ Proportion of medicine charts reviewed by clinical pharmacists within 24 hours of admission
☐ Monthly audit of the number of total drug therapy problems resolved by pharmacists in the NICU
☐ Number of drug therapy problems resolved for 'high-alert' medications by pharmacists
☐ Proportion of patients prescribed narrow therapeutic index medications (i.e. aminoglycosides, digoxin) who are monitored by a pharmacist (Therapeutic Drug Monitoring)
☐ Number of education/training sessions provided by pharmacists relating to pharmacotherapy in the NICU for other health professionals
☐ Number of pharmacotherapy related consultations provided to medical personnel by pharmacists
☐ Proportion of intravenous (IV) medications that have been monitored by a pharmacist
☐ Proportion of pharmacists involved in NICU related clinical research
☐ Proportion of pharmacists involved in a prescribing error feedback programme

☐ Number of pharmacist reviews provided verifying the appropriateness of medications prescribed for infants

OUTCOME
☐ Prescribing errors: Identification and resolution of unintentional departure from recommended prescribing practices per patient per bed day
☐ Monthly audit of prescribing against prescribing guidelines – target 90%
☐ Proportion of patients with toxic or sub-therapeutic aminoglycoside concentration whose dosage has been adjusted prior to next dose
☐ Medication Error rates/reports per 6 months
☐ Adverse Drug Event rates/reports per 6 months
☐ Percentage of medication guidelines that have been updated within the previous 1- 2 years
☐ Percentage of medications used in the NICU for which a medication guideline is available
☐ Proportion of infants that had their electrolytes measured within 5 days of starting Frusemide
☐ Proportion of infants who received a targeted treatment (for a confirmed indication) vs. empirical treatment
☐ Proportion of infants who experienced a medication related adverse effect and the time required until review of medication and/or treatment/reversal of adverse effect

TERMINOLOGY AND DEFINITIONS

Apgar scores	Apgar is a quick test performed on a baby at 1 and 5 minutes after birth. The 1-minute score determines how well the baby tolerated the birthing process. The 5-minute score tells the healthcare provider how well the baby is doing outside the mother's womb. The Apgar test is done by a doctor, midwife, or nurse. The provider examines the baby's: • Breathing effort • Heart rate • Muscle tone • Reflexes • Skin colour Each category is scored with 0, 1, or 2, depending on the observed condition [13].
Biliblanket	A portable phototherapy device for the treatment of neonatal jaundice (hyperbilirubinaemia).
Chorioamnionitis	Chorioamnionitis is a bacterial infection that occurs before or during labour. The name refers to the chorion (outer membrane) and the amnion (fluid-filled sac). These membranes surround the foetus. Chorioamnionitis occurs when bacteria infect the chorion, amnion, and the fluid around the foetus (amniotic fluid). The condition can lead to a preterm birth or serious infection in the mother and the baby. Chorioamnionitis is most commonly seen in preterm births. It occurs in approximately 2 to 4 percent of full-term deliveries. Chorioamnionitis usually develops due to an infection. The infection can occur when bacteria that are normally present in the vagina ascend into the uterus, where the foetus is located. The amniotic fluid and placenta — as well as the baby — can become infected. *E. coli*, group B *streptococci*, and anaerobic bacteria are the most common causes of chorioamnionitis [14].
CNLD	Chronic Neonatal Lung Disease

CPAP	Continuous Positive Airway Pressure
CTG	Cardiotocograph
EBM	Expressed Breast Milk
ELBW	Extremely Low Birth Weight
Gravida	The total number of confirmed pregnancies that a woman has had, regardless of the outcome.
GDM	Gestational Diabetes Mellitus
HIE	Hypoxic-Ischaemic Encephalopathy
IUGR	Intrauterine Growth Restriction
Meconium	The dark green substance forming the first faeces of a newborn infant.
NEC	Necrotising Enterocolitis
NST	Newborn Screening Test
Parity	The number of births that a woman has had after 20 weeks gestation.
PDA	Patent Ductus Arteriosus
PICC	Peripherally inserted central catheters
Placenta praevia	The placenta has implanted at the bottom of the uterus, over the cervix or close by), and the baby can't be born vaginally. 'Partial placenta praevia' means the cervix is partly blocked, while 'complete placenta praevia' means the entire cervix is obstructed [15].
PN	Parenteral Nutrition
PPHN	Persistent Pulmonary Hypertension of the Newborn
PROM	Premature Rupture of Membranes
RDS	Respiratory Distress Syndrome
SBr	Serum Bilirubin
SVD	Single Ventricle Defects
TFI	Total Fluid Intake
UAC	Umbilical artery catheter
UVC	Umbilical Venous Catheter

RECOMMENDED RESOURCES FOR PHARMACISTS

ONLINE RESOURCES

- **KEMH Medical Library: NeoHub**
  A range of helpful resources in one place including, Medication Protocols, Clinical Guidelines, Clinical Trials registers, IV compatibility resources and research groups and networks.
  https://kemh.libguides.com/friendly.php?s=library/elibrary/nccu_neonatal_hub
- **NICU Primer for Pharmacists,** Amy P. Holmes
  Online textbook, available from the American Society of Hospital Pharmacists:
  https://store.ashp.org/Default.aspx?TabID=251&productId=324860061
- Queensland Statewide Maternity and Neonatal Guidelines via QHEPS
  http://www.health.qld.gov.au/qcg/html/publications.aspp
- Auckland Hospital, Newborn Services, Teaching Resources
  http://www.adhb.govt.nz/newborn/TeachingResources.htm
- Neonatology on the Web
  http://www.neonatology.org/neo.clinical.html
- NETS (Victoria) Neonatal Handbook
- http://www.health.vic.gov.au/neonatalhandbook/
- eNeonatal Review
  http://www.hopkinscme.edu/ofp/eNeonatalReview/index.html
- Lactmed
  https://toxnet.nlm.nih.gov/newtoxnet/lactmed.htm
- Neofax – Online database

TEXTBOOK RESOURCES

- British National Formulary (BNF) for Children
- Drug Doses - Frank Shann
- Medication and Mothers Milk - Thomas W. Hale

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7.3 POLISH QUALITY GUIDANCE DOCUMENT

JAKOŚĆ OPIEKI FARMACEUTYCZNEJ W ITN: OPRACOWANIE MODELU PRAKTYKI FARMACEUTYCZNEJ I KLUCZOWYCH WSKAŹNIKÓW EFEKTYWNOŚCI

- PORADNIK WSPIERAJĄCY OPIEKE FARMACEUTYCZNĄ NA ODDZIALE ITN -

BADACZE:

Natalia Krzyżaniak

Dr Iga Pawłowska

A/Prof Beata Bajorek

PRYWATNE

CZŁONKOWIE ZESPOŁU BADAWCZEGO

Niniejszy poradnik został opracowany przez zespół badaczy, w skład którego wchodzą Natalia Krzyżaniak i A / Prof Beata Bajorek z University of Technology Sydney, Australia oraz Dr Iga Pawłowska z Gdańskiego Uniwersytetu Medycznego, i ma na celu poprawę standaryzacji opieki farmaceutycznej noworodkom w oddziałach intensywnej terapii noworodkowej (ITN). Dokument ten stanowi część pracy doktorskiej i badań prowadzonych przez NK. Każdy element w dokumencie został wprowadzony z wcześniej wykonanych przeglądów literatury i badań, które miały na celu zdefiniowanie jakości opieki farmaceutycznej i usług farmaceutycznych dla ITN.

SPIS TREŚCI

DEFINICJA: OPIEKA FARMACEUTYCZNA

“Usługa farmaceutyczna polegająca na dokumentowanym procesie, w którym farmaceuta, współpracując z pacjentem i lekarzem, a w razie potrzeby z przedstawicielami innych zawodów medycznych, czuwa nad prawidłowym przebiegiem farmakoterapii w celu uzyskania określonych jej efektów poprawiających jakość życia pacjenta.”[1, 2]

PRAWO FARMACEUTYCZNE

Apteki szpitalne, zgodnie z ustawą z dnia 6 września 2001 r. Prawo farmaceutyczne, to apteki zaopatrujące szpitale lub inne przedsiębiorstwa podmiotów leczniczych wykonujących stacjonarne i całodobowe świadczenia zdrowotne (art. 87 ust. 1 pkt 2 ustawy).**[3]**

Apteki szpitalne świadczą usługi farmaceutyczne określone w art. 86 ust. 2 ustawy, a ponadto świadczą usługi farmaceutyczne (art.86 ust. 3), obejmujące:

- sporządzanie leków do żywienia pozajelitowego,
- sporządzanie leków do żywienia dojelitowego,
- przygotowywanie leków w dawkach dziennych, w tym leków cytostatycznych,
- wytwarzanie płynów infuzyjnych,
- organizowanie zaopatrzenia szpitala w produkty lecznicze i wyroby medyczne,
- przygotowywanie roztworów do hemodializy i dializy dootrzewnowej,
- udział w monitorowaniu działań niepożądanych leków,
- udział w badaniach klinicznych prowadzonych na terenie szpitala,
- udział w racjonalizacji farmakoterapii,
- współuczestniczenie w prowadzeniu gospodarki produktami leczniczymi i wyrobami medycznymi w szpitalu.

W aptekach szpitalnych, poza udzielaniem usług farmaceutycznych, prowadzona jest ewidencja próbek do badań klinicznych oraz uzyskiwanych darów produktów leczniczych i

wyrobów medycznych oraz ustalane są procedury wydawania produktów leczniczych lub wyrobów medycznych przez aptekę szpitalną na oddziały oraz dla pacjenta (art.86, ust.4 ustawy).

Apteka szpitalna, zgodnie z art. 106 ust. 1 ustawy, może być uruchomiona po uzyskaniu zgody właściwego wojewódzkiego inspektora farmaceutycznego pod warunkiem spełnienia wymogów określonych w art. 98 i zatrudnienia kierownika apteki spełniającego wymogi określone w art. 88 ust. 2.

Istniejące w dniu wejścia w życie Prawa farmaceutycznego apteki szpitalne niespełniające wymogów, o których mowa w art. 98 ust. 5 Prawa farmaceutycznego, muszą dostosować się do tych wymogów w terminie 3 lat, a niespełniające wymogów, o których mowa w art. 98 ust. 1 i ust. 4 Prawa farmaceutycznego - w terminie 5 lat.

Podstawa prawna:

Ustawa z dnia 6 września 2001 r. Prawo farmaceutyczne (Dz. U. 2008 nr 45 poz. 271 z późn. zm.)

SZPITALE - STOPNIE REFERENCYJNOŚCI W POLSCE

STOPIEN	DEFINICJE [4]
I STOPIEN	**W szpitalach o I stopniu referencyjności** rodzą kobiety w ciąży niepowikłanej, bez większej patologii i rodzące w terminie. Zazwyczaj są to szpitale miejskie i rejonowe. W takich szpitalach sprawuje się opiekę nad: • zdrowymi, donoszonymi noworodkami • noworodkami niedonoszonymi, urodzonymi w 35-37 tygodniu ciąży, ale u których nie stwierdza się objawów choroby, oprócz niedojrzałości • noworodkami z ciąż i porodów o przebiegu patologicznym, które wymagały resuscytacji bezpośrednio po urodzeniu, a następnie wnikliwej obserwacji w pierwszych dobach życia • noworodkami z niezbyt nasilonymi objawami chorobowymi, które mogą pozostać w szpitalu.
II STOPIEN	**Szpitale o II stopniu referencyjności** to przeważnie szpitale wojewódzkie, gdzie rodzą kobiety będące w ciąży zagrożonej. W takich jednostkach znajduje się pododdział intensywnej opieki wcześniaków. W szpitalach o II stopniu referencyjności sprawuje się opiekę nad: • noworodkami urodzonymi w ciężkiej zamartwicy, które uzyskały od 0-3 pkt. Apgar w 1 min życia, 5 pkt w 5 min życia, • noworodkami urodzonymi przed 35 tygodniem ciąży, • noworodkami z masą urodzeniową ciała < 2600g, • noworodkami u których konieczne jest monitorowanie czynności serca, czynności oddechowej i temperatury, • noworodkami z zaburzeniami oddychania, • noworodkami u których sinica nie ustępuje po zastosowaniu 30% tlenu w powietrzu wdychanym, • noworodkami, które ze względu na swój stan otrzymują wlewy dożylne z glukozą, elektrolitami, u których konieczna jest długoterminowa tlenoterapia, • noworodkami żywionymi przez zgłębnik,

	• noworodkami podejrzanymi o chorobę hemolityczną w zakresie układu ABO i Rh.
III STOPIEN	**Szpitale o III stopniu referencyjności** to szpitale kliniczne państwowych uczelni medycznych lub państwowych uczelni prowadzących działalność dydaktyczną i badawczą w dziedzinie nauk medycznych. Placówki o III stopniu referencyjności są przeznaczone dla kobiet o wysokim zagrożeniu ciąży, jej patologicznym przebiegu, gdzie jest bardzo wysokie ryzyko urodzenie wcześniaka przed 31 tygodniem ciąży, czy dziecka z wielowodziem itp. W szpitalach o III stopniu referencyjności sprawuje się opiekę nad: • noworodkami wymagającymi długotrwałej, sztucznej wentylacji i całkowitego żywienia pozajelitowego, • noworodkami z ciężkimi zaburzeniami oddechowymi, • noworodkami z nasilonymi zaburzeniami metabolicznymi, • noworodkami z ciężkimi zakażeniami, • wcześniakami urodzonymi przed 30 tygodniem ciąży, • noworodkami z masą urodzeniową < 1500g, • noworodkami z wadami wrodzonymi serca, • noworodkami z wadami rozwojowymi wymagającymi diagnostyki i leczenia operacyjnego, • noworodkami z utrzymującymi się objawami neurologicznymi, drgawkami.

CELE DLA OPIEKI FARMACEUTYCZNEJ W ODDZIAŁACH ITN

- ☐ Odpowiednie przygotowanie farmaceutów do wykonywania usług farmaceutycznych na oddziałach ITN np. sprawdzanie kart pacjenta, współpraca w farmakoterapii z lekarzami i pielęgniarkami. [5-8]
- ☐ Zwiększenie liczba farmaceutów zatrudnionych w szpitalach, które by pozwoliło farmaceutom skupić się na klinicznych usługach.[5]
- ☐ Wdrożenie farmaceutów na oddziały ITN, i posiadanie przez nich pozycje które by pozwoliły na jakikolwiek bezpośredni kontakt z pacjentami i z wykonywaniem usług farmaceutycznych np. obchody lekarskie, przygotowanie i preparacja dawek dla noworodków. [5-8]
- ☐ Rekomendacja dla wszystkich farmaceutów pracujących na oddziale noworodkowym o posiadaniu odpowiedniego przeszkolenia w kierunku neonatologii, [5] na przykład:
- ☐ Rozwój dróg metabolicznych i ich efekty na używanie leków w tej grupie
- ☐ Podstaw podawania leków przy karmieniu piersią i bezpieczeństwo ich używania w ciąży. [9]
- ☐ Dawek opartych na wadze oraz ich kalkulacji. [10]
- ☐ Odpowiedne dawkowanie i wybieranie preparaty leków. [10]
- ☐ Odpowiedniego dopasowywanie elektrolitów i ich kalkulacja. [10]
- ☐ Powszechne patogeny znalezione u niemowląt i ich leczenie. [10]
- ☐ Odpowiedne drogi podawania leków. [10]
- ☐ Żywienie pozajelitowe. [10]
- ☐ Urządzenia medyczne i techniki podawania leków dożylnie. [10]
- ☐ Rekomendacje dla farmaceutów do posiadania wiedzy o najczęściej występujących w ITN chorobach, problemów i wadach wrodzonych i ich leczenie np. martwicze zapalenie jelit, zespół zaburzeń oddechowych, przewód tętniczy, bezdech.[9]
- ☐ Rekomendacje dla farmaceutów pracujących na oddziale ITN, do kontynuowania dalszej nauki w ww. kierunku, i podtrzymywania poziomu wiedzy i umiejętności niezbędnych do praktyki na tym oddziale.[5]

USŁUGI FARMACEUTYCZNE KTÓRE SĄ NIEZBĘDNE DLA PRAWIDŁOWEGO I BEZPIECZNEGO STOSOWANIA LEKÓW W ITN

Poniższa tabela przedstawia usługi farmaceutyczne oraz inne zadania prowadzone przez farmaceutów, które zostały zweryfikowane przez zespół ekspertów przy użyciu techniki Delphi jako niezbędne do prawidłowego i bezpiecznego stosowania leków dla ITN.

USŁUGI ADMINISTRACYJNE
Opracowanie/wdrożenie receptariusza
Uczęszczanie w nieklinicznych spotkaniach np. posiedzeniach komitetu terapeutycznego szpitala
Prowadzenie badań jakości farmakoterapii np. ocena stosowanych leków
Zarządzanie budżetem do zakupu leków
Zamawianie leków dla ITN
Opracowanie protokołów dla leków ITN
USŁUGI KLINICZNE
Przeprowadzanie przeglądu leków dla pacjentów
Udział farmaceuty w obchodzie w ITN
Monitorowanie skuteczności leków u pacjenta
Dokumentowanie/monitorowanie oraz zgłaszanie działań niepożądanych leków
Dokumentowanie błędów lekowych (Medication Errors)
Monitorowanie farmakoterapii (Therapeutic Drug Monitoring)
Współudział w żywieniu pozajelitowym
Udział w klinicznych spotkaniach z lekarzem, pielęgniarką, rodzina pacjenta itd.
Obliczanie i zalecanie dawek i schematów dawkowania dla wybranych pacjentów
Wspieranie lekarzy w stosowaniu leków poza wskazaniami medycznymi (off label/unlicensed use)
Identyfikacja problemów lekowych oraz prowadzenie interwencji dla poszczególnych pacjentów w celu zapobiegania lub rozwiązywania tych problemów (np. interakcje, niezgodności , alergie)
Współudział w wyborze właściwej farmakoterapii dla pacjentów

Doradztwo prowadzone dla lekarzy, położnych i pielęgniarek w zakresie farmakoterapii pacjentów
EDUKACJA/KOMUNIKACJA/BADANIA
Prowadzenie szkoleń dla lekarzy/położnych/pielęgniarek dotyczących farmakoterapii noworodków
Uczestnictwo w konferencja naukowych dotyczących ITN
Współuczestniczenie w badaniach klinicznych leków
Współuczestniczenie w badaniach naukowych dotyczących farmakoterapii u noworodków
Udzielanie informacji personelowi medycznemu
ZAOPATRYWANIE W LEKI
Wydawanie leków i materiałów medycznych na oddział ITN
Wykonywanie leków recepturowych dla pacjentów w ITN
Kontrola właściwego przechowywania leków na oddziale/dat ważności leków/leków wstrzymanych i wycofanych z obrotu
Wykonywanie dawek indywidualnych leków podawanych pozajelitowo i doustnie

KLUCZOWE WSKAŹNIKI JAKOŚCIOWE

Poniżej zostały przedstawione determinanty jakości usług farmaceutycznych zweryfikowane przez zespół ekspertów przy użyciu techniki Delphi, które mogą stanowić kryterium oceny jakości usług farmaceutycznych w ITN.

STRUKTURA
☐ Zatrudnienie farmaceuty na oddziale neonatologicznym (każdy wymiar czasu pracy)
☐ Posiadanie przez farmaceutę specjalizacji z zakresu farmacji klinicznej
☐ Dostępność lodówek na oddziałach do przechowywania szczepionek, TPN
☐ Bezpośredni dostęp do leków często stosowanych na oddziale
☐ Dostępność protokołów/wytycznych dotyczących leków wysokiego ryzyka, np. Antybiotyki, przeciwbólowe, żywienie pozajelitowe [11-14]
☐ Dostępność protokołów dotyczących zlecania, wydawania, zarządzania i monitorowania leków na oddziale ITN
☐ Dostępność protokołów dotyczących leków stosowane w sytuacjach zagrożenia życia, z dawkami na kilogramy [15, 16]
☐ Szeroka dostępność źródeł informacji dotyczących stosowania leków (np. wytycznych, indeksów) [14]
☐ Dostępność elektronicznych systemów do monitorowania działań niepożądanych)

PROCES
☐ Procent pacjentów u których stosuje się leki poza wskazaniami (off-label) po konsultacji z farmaceutą
☐ Zgłaszanie przez farmaceutę działań niepożądanych leków
☐ Proporcja błędów przy wydawaniu leków zidentyfikowanych i poprawionych przez farmaceutę na liczbę przyjęć
☐ Liczba konsultacji udzielona personelowi medycznemu przez farmaceutę
☐ Zaangażowanie farmaceuty w optymalizację żywienia pozajelitowego
☐ Optymalizacja postaci leków do podawania dożylnego
☐ Proporcja obliczeń dawek sprawdzana przez farmaceutę przed podaniem
☐ Procent pacjentów których terapia jest monitorowana przez farmaceutę
☐ Procent leków recepturowych przygotowywane dla oddziałów neonatologicznych przez farmaceutę

WYNIKI
☐ Miesięczny wykaz epizodów działań niepożądanych związanych z antybiotykami
☐ Odsetek zamówień na leki, które zawierają prawidłową dawkę na kilogram (lub powierzchnię ciała) oraz skuteczne i bezpieczne ich działanie
☐ Wykrywalność błędów lekowych/6 miesięcy
☐ Skala zgłaszania działań niepożądanych/6 miesięcy
☐ Koszty terapii

TERMINOLOGIE I DEFINICJE

Bezdech	Występuje wtedy, gdy dziecko przestaje oddychać przez okres 10–20 sekund lub dłużej [17].
BiPAP	Dostarcza tlen i powietrze pod dodatnim ciśnieniem do płuc, aby wspomagać proces oddychania. Ciśnienie jest nieco wyższe przy wdechu i ustawiona jest określona szybkość oddechu [17].
CFM - Monitorowanie funkcji mózgu	Prezentuje całkowitą aktywność elektryczną kory mózgowej [17].
CLD - Przewlekła choroba płuc	Schorzenie płuc występujące u niektórych wcześniaków, które były mechanicznie wentylowane, wymagały korzystania z urządzenia CPAP lub podawano im tlen w leczeniu RDS [17].
CNGF - Karmienie za pomocą zgłębnika nosowo- żołądkowego	Sposób podawania małym niemowlętom niewielkich ilości mleka powoli przez sondę nosowo-żołądkową [17].
CPAP - Stałe dodatnie ciśnienie w drogach oddechowych	Dostarcza tlen i powietrze pod dodatnim ciśnieniem do płuc, aby wspomagać proces oddychania [17].
EBM - Expressed Breast Milk	Skrót od angielskich słów „expressed breast milk”, oznaczające kobiece mleko ściągnięte z piersi [17].
Hipotermia	Procedura obniżania temperatury dziecka do 33,5°C [17].
Inkubator	Tworzy stabilne ciepłe środowisko i pozwala na ścisłą obserwację każdego dziecka [17].
IVH - Krwawienia dokomorowe	Krwawienie do komór i okolic mózgu [17].
MAS - Zespół aspiracji smółki (MAS)	Choroba płuc spowodowana zassaniem smółki do płuc przed urodzeniem się dziecka [17].
Metoda kangura	Kangurowanie to trzymanie dziecka w taki sposób, aby nastąpił kontakt skóra do skóry; dziecko układane jest na piersi mamy lub taty, dotykając jego nagiej skóry. Ma to wiele korzyści fizycznych i emocjonalnych dla obu stron. Pomaga uspokoić

	dziecko, reguluje jego tętno i oddech oraz zachęca do głębszego snu, który szybko poprawia tempo przyrostu masy ciała. Kangurowanie pomaga w tworzeniu trwałej więzi między rodzicem a dzieckiem poprzez dotyk i zapach. Rodzic czuje się z nim bliżej związany i zyskuje większą pewność siebie podczas pielęgnacji. Inną korzyścią jest rozpoczęcie produkcji mleka przez organizm kobiety i późniejsza możliwość podjęcia karmienia piersią [17].
Mieszanka wzbogacająca pokarm naturalny	To mleko w proszku, które dostarcza dodatkowych kalorii i składników odżywczych i jest dodawane do pokarmu kobiecego [17].
NE - Encefalopatia noworodkowa	Uszkodzenie mózgu, które występuje w wyniku zmniejszonego podawania tlenu do mózgu z łożyska [17].
NEC - Martwicze zapalenie jelit	Stan zapalny jelit, który dotyka niektóre noworodki i wcześniaki [17].
Odma opłucnowa (zapadnięte płuco)	Występuje wtedy, gdy powietrze przedostaje się z płuc do przestrzeni otaczającej płuca [17].
OG - Zgłębnik żołądkowy	Rurka przechodząca przez usta do żołądka. Może służyć do karmienia lub podawania leków. Dzieci używające aparatu CPAP mają założony zgłębnik żołądkowy [17].
OITN	Oddział Intensywnej Terapii Noworodka
PDA - Przetrwały przewód tętniczy	Występuje wtedy, gdy otwarta pozostaje mała szczelina pomiędzy naczyniami krwionośnymi zaopatrującymi płuca a naczyniami krwionośnymi zaopatrującymi resztę ciała [17].
PICC - Wkłucie centralne do żył obwodowych	Cewnik dożylny założony na żyle głębokiej, może być stosowany przez wiele tygodni [17].
PPHN - Utrzymujące się nadciśnienie płucne noworodków	Występuje wtedy, gdy układ krążenia noworodka nie dostosowuje się do oddychania poza łonem matki [17].
RDS - Zespół zaburzeń oddychania	Choroba płuc, częsta występująca u wcześniaków z powodu niedojrzałości płuc i braku surfaktantu [17].

ROP - Retinopatia wcześniaków	Choroba oczu, która może rozwinąć się u wcześniaków [17].
Sinica	Niebieskawy kolor warg dziecka i skóry spowodowany zbyt małą ilością tlenu [17].
Skala Apgar	Skala używana w medycynie w celu określenia stanu noworodka zaraz po porodzie w 1, 5 i 15. minucie życia. Skala ocenia pięć ważne parametry: • Oddychanie • Puls/na min • Napięcie mięśni • Reakcja na bodźce • Kolor skory Dziecko minimalnie może dostać 0, a maksymalnie 10 punktów [18].
TTN	Przemijający szybki oddech noworodka [17].
UAC - Pępowinowy cewnik dotętniczy	Przewód wstawiony do tętnicy pępowinowej dziecka przez „pępek". Służy do pobierania próbek krwi i monitorowania ciśnienia krwi [17].
UVC - Pępowinowy cewnik dożylny	Rurka umieszczona w żyle pępowinowej dziecka przez „pępek". Służy do podawania kroplówek i leków [17].
Pobieranie krwi z pięty	Metoda uzyskiwania małej próbki krwi do badań [17].
Wcześniak	Oznacza niemowlę urodzone przed ukończeniem 37. tygodnia ciąży.[17].
Wiek ciążowy	Dojrzałość dziecka, która odpowiada liczbie tygodni ciąży [17].
Żółtaczka	Żółtawe zabarwienie skóry i oczu spowodowane przez nadmiar bilirubiny [17].
Żywienie pozajelitowe (PN)	Dożylne podawanie płynu, który zawiera węglowodany, białka, tłuszcze i składniki odżywcze niezbędne dla wzrostu i rozwoju [17].

ZALECONE ZASOBY DLA FARMACEUTÓW

MIĘDZYNARODOWE ZASOBY INTERNETOWE:

- **KEMH Medical Library: NeoHub -** Australijskie protokoły lekowe i standardy leczenia: http://kemh.health.libguides.com/library/elibrary/nccu_neonatal_hub
- **NICU Primer for Pharmacists,** Amy P. Holmes - Podręcznik elektroniczny: https://store.ashp.org/Default.aspx?TabID=251&productId=324860061
- Queensland State-wide Maternity and Neonatal Guidelines via QHEPS http://www.health.qld.gov.au/qcg/html/publications.asp
- Auckland Hospital, Newborn Services, Teaching Resources http://www.adhb.govt.nz/newborn/TeachingResources.htm
- Neonatology on the Web
- http://www.neonatology.org/neo.clinical.html
- NETS (Victoria) Neonatal Handbook: http://www.health.vic.gov.au/neonatalhandbook/
- Lactmed https://toxnet.nlm.nih.gov/newtoxnet/lactmed.htm
- Neofax

MIĘDZYNARODOWE PODRĘCZNIKI

- British National Formulary (BNF) for Children
- Drug Doses - Frank Shann
- Medication and Mothers Milk - Thomas W. Hale

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CHAPTER EIGHT

DISCUSSION AND CONCLUSION

8.1 INTRODUCTION

The FIP states: "*pharmacy needs a global vision that encompasses the sharing of experiences, gathering of evidence and collaborative guidance to facilitate country-level and international initiatives*."[65] What this thesis has identified, is that at this stage, this 'global vision' does not apply to pharmacy practice in subspecialties of care. There is a lack of clearly defined minimum standards of practice and a lack of standardised quality measures guiding specialist pharmacists in their practice, particularly within the NICU setting. This indicates that NICUs both nationally and internationally are delivering services based on their individual interpretations of general hospital pharmacy guidelines and individual hospital policies. This is evident in the significantly different forms of practice delivered by pharmacists in Australia and Poland. Pharmaceutical care services in these two countries appear to focus on opposing ends of the of the practice spectrum. Whilst some degree of variability between settings is natural, due to different service delivery models, practice cultures, resource availabilities, legislation and education, there should be an agreed set of minimum requirements for the provision of quality pharmaceutical care. Without these, practice will differ according to the variables influencing each setting leading to diversity in the type of care provided to patients, with subsequent potential for varying impact upon patient outcomes, medication error rates and the quality use of medicines.

According to Leotsakos et.al., "*in healthcare, evidence shows that divergent patterns of care result in worse clinical outcomes and that removal of variance can reduce risk, inefficiencies and costs*."[78] This was the first investigation of its kind to establish a need for changes to be made to policy and practice. Namely, for NICU pharmacy practice to be better supported through standardised practice guidelines, promoting consistency in the provision of best practices. As a result, the research within this thesis is novel as it presents the first studies to develop a quality guidance document, outlining the minimum pharmacy services that should be provided to NICUs as well as national standardised KPIs for NICU pharmacy practice in Australia and Poland. Each baby admitted to the NICU, regardless of their geographic location, has a right to a defined minimum standard of care. Neonates are a unique patient group, who experience unique medication errors that subsequently require a unique or modified form of pharmaceutical care. Likewise, our findings highlighted that clinical pharmacy subspecialty areas, such as the NICU, require different or supplemental resources to help advance clinical pharmacy practice and the quality of patient care.[51 55 65 90 98 101 105 131] It is believed that these proposed quality guidance resources can be used to facilitate the standardisation of services in

each country. Perceived benefits of these documents include enhancing professional transparency and accountability and allowing the advancement of services toward desired quality practices.[88] The resources can be used in future research to assist in defining minimum standards of pharmacy practice in each country. Furthermore, the addition of KPIs allows for comparisons of clinical pharmacy services within and between settings on a national scale and the facilitation of NICU pharmacist performance management.[88]

This research also sought to identify barriers and facilitators to the initiation of practice and policy changes in each country. By doing so, our findings serve as an important step in the knowledge-to-action process. This information may be used in future research to ease the implementation process locally, and nationally.

It is hoped that the quality guidance resources developed in this thesis will be used as the foundation for global pharmacy organisations to initiate the development of national and/or international standards of practice.

8.2 WHAT DOES THIS RESEARCH ADD?

8.2.1 CLEARLY HIGHLIGHTS A PERCEIVED NEED FOR CHANGE TO POLICY AND PRACTICE

Overall, this research provided a clear understanding of the need to change current policy and practice to optimise patient care in the NICU from three different perspectives. The first perspective related to the need for the development of pharmacy guidelines and standards that reflect the nuances of practice in the NICU. The studies within this thesis drew attention to the unique nature of medication management in this population. This distinctiveness was based on a combination of factors including: patient characteristics, a high-reliance on high-risk pharmacotherapy, lack of evidence supporting the use of many medications, incidence of unique types of medication errors, and a potential for significant consequences for the patient as a result of error. Therefore, it was acknowledged that to adequately meet patient needs, pharmacists working in this capacity were required to tailor their practice to ensure positive patient outcomes and an optimal level of pharmaceutical care. Whilst general pharmacy practice standards are available, such as those from the PSA, SHPA, FIP, WHO, EDQM, ACSQHC, their perceived applicability to this setting was limited. [51 55 65 90 98 101 105 131] Therefore, there is a need for the realisation of appropriate guidance resources to recognise the specialist nature of

this practice, and to outline the elements that distinguish NICU pharmacy practice from general hospital pharmacy. This was deemed important in order to adequately care for this patient group, and to support pharmacists in their service provision.

The second perspective referred to the perceived need to place medication management in specialties of care, such as the NICU, at the forefront of policymaking and standardisation initiatives – not only to support the uniform delivery of services, but also to support pharmacists wishing to advance or specialise their practice.[65] Other literature does report upon the significance of nurses and other allied health professionals such as occupational therapists, dieticians and physiotherapists and clearly outlines their roles in neonatal care.[132-135] However, pharmacists are often only referred to within a sub-section of practice standards i.e. the NICE guidelines, and do not have a stand-alone resource. Furthermore, standardised guidelines, containing measures of quality were perceived as necessary for pharmaceutical care in the NICU in order to stimulate practice progression, and to provide pharmacists the opportunity to specialise in neonatal care and to provide a more advanced level of practice.[83] These findings hold relevance to the current global trend identified by FIP relating to advanced pharmacist practice and specialisation. According to a report published by FIP, 28 countries currently have advanced practitioner frameworks available, and 10 of these indicated that their country frameworks had been adapted from those published by other nations.[65] In Australia, there has been recognition of advanced practitioners in some areas of the pharmacy workforce and research has been undertaken to formally credential advance practice pharmacists.[136] In Poland, pharmacists are able to acquire practice specialisations in 12 specialties – however at this stage, neither of these countries considers pharmacist specialisation in neonatal care.

The third perspective related to the need to implement practice changes within the Polish hospital pharmacy system. From the perspective of the Polish participants, there is some obvious room for improvement in the way care is delivered in the NICU. Participants recognised that the scope of practice was not as expansive or collaborative as it could be and felt a strong need for the development of a minimum standard of practice that clearly defined roles depicting a quality level of pharmaceutical care. This was viewed as essential in promoting the bridging of the practice gap between Poland and other countries, and as a tool to benchmark services nationwide. Pharmacists here were particularly receptive to the advancement of their roles to match the level of service provision seen worldwide. Furthermore, due to practice culture issues, there was a perceived need for these resources to justify the position and the value of pharmacists in this sub-specialty to other healthcare

professions, as well as to hospital management and even further to policymakers within the health ministry.

8.2.2 ADDRESSES GAP IN KNOWLEDGE

The quality guidance resources developed for Australia and Poland in this research are the first of their kind to outline or define elements that depict a quality level of pharmaceutical care in the NICU. Due to the significant differences in pharmacist practice between the two countries, it was difficult to design a universal set of indicators that were suitable and appropriate for practice in both settings. In order to avoid a 'one size fits all' approach, it was decided that the pharmacist roles and indicators in question (derived from earlier stages of research) would be tailored to the Australian and Polish setting individually. Overall, both the pharmacist roles and key performance indicators selected by panellists in each country still require further standardised definitions and pilot studies to assess their validity, reliability, feasibility and suitability for use in both the Australian and Polish context. However, there now exists a foundational list of essential pharmacist roles depicting a quality level of care, as well as pharmacist-sensitive NICU indicators that measure each quality domain. There is potential for future research to build upon this baseline, to determine an international minimum standard of practice as well as quality measures applicable to pharmacy practice in this sub-specialty. There is a need for further research to support the implementation of these country-specific designs and further validation needs to occur before using pharmacist-sensitive indicators in the NICU population.

8.3 CHALLENGES TOWARDS THE IMPLEMENTATION OF PRACTICE CHANGES

Our studies clearly demonstrate how widely practice can differ in healthcare settings around the world with key differences identified in pharmacist roles between Australia and Poland. It is important to note that the research in this thesis has not set out to criticise the practices of any country, but rather to identify the perceptions around practice and opportunities that support optimal pharmaceutical care and barriers that limit its implementation. In doing so, this research has identified that the process of change both on a national and international scale can be hampered or delayed by not only resources (monetary or human), but also by the

traditions and cultures underpinning expectations of health professionals across disciplines. These may also be influenced by history, which may shape the approaches to national economics and also governance – both of which affect the delivery of healthcare. The five major challenges towards changing policy and practice within NICUs in Australia and Poland that were consistently identified throughout the research included the following:

8.3.1 HISTORY OF CLINICAL PHARMACY

In comparison to other European countries, the Polish healthcare system has been strongly impacted by the consequences of historical and political experiences of the country.[108] The scope of healthcare in this country suffered significant setbacks following the Second World War, and disadvantaged the development of the structural, legislative, financial, organisational, and quantitative aspects of care.[108] As a result, ward-based hospital pharmacy services in Poland are a relatively new concept and are not yet implemented into routine practice. Hospital pharmacy practice is still firmly embedded in traditional roles, namely compounding.

Alternatively, among the Western countries, Australia has a very effective healthcare system, but it is also a conservative one. As such, advances in pharmacy practice have also been somewhat delayed relative to that in countries such as the USA, UK, or Canada.

8.3.2 LEGISLATION

This research highlights the presence of key systemic barriers that prevent the implementation of clinical pharmacy services in Polish NICUs. Chief among these was the lack of clarity around a pharmacist's legal authority to undertake ward-based services. Due to the absence of clear regulations stipulating pharmacist responsibilities in this setting, many participants perceived that the provision of NICU-based clinical services would be encroaching upon the competencies of both doctors and nursing staff. Without the availability of supporting legislation validating their positions on the ward, pharmacists perceived that this would result in interprofessional issues and would limit the implementation of any changes.

8.3.3 PRACTICE CULTURE

Barbosa recommends that "*a collaborative, multidisciplinary team approach that emphasises shared responsibility, practices effective communication, and respects and recognises that no one functions independently in the NICU is recommended to promote the best possible outcome for infants and families*."[137] However, the Polish healthcare system currently functions at a more conservative, traditional level. The professional identities of doctors and nurses are strongly associated with being the primary decision-makers of pharmacotherapy, whilst pharmacists are dedicated to the dispensary, managing the supply and preparation of medications. Therefore, changes to these traditional practice structures by introducing pharmacists into the NICU and involving them in clinical roles may be met with resistance from all healthcare professions. It is acknowledged that changing any form of established behaviour is difficult due to the complex "*factors influencing an individual's resistance which are associated with a combination of psychological, contextual and sociological barriers*".[138]

8.3.4 LACK OF EDUCATION

A common theme within the research was that Polish pharmacists felt that they were unprepared for any form of ward-based practice. Whilst, current pharmacy qualifications allow pharmacists to specialise in 12 areas of practice, the majority of this knowledge is theory-based with very minimal practical experience.[112] Furthermore, the tertiary system is focussed on a uni-professional teaching structure, which the limits opportunity for health professionals to interact and learn from one another. Alternatively, whilst Australian pharmacists seemed confident in their level of preparation to perform clinical services, there was a perceived need for more training on neonatal-specific aspects of pharmacy practice due to the lack of qualifications in sub-specialties of pharmacy. Pharmacists here are unable to specialise in any form of pharmacy practice, therefore any knowledge (both theory and practical based) must be obtained on the job. The lack of appropriate education in both countries may contribute to a limited understanding of the meaning and scope of changes needed to improve care. Furthermore, pharmacists are potentially ill equipped to competently carry out changes related to more integrative components of care in the NICU. Pharmacists require appropriate training to ensure they have the skills to deliver best practice.

8.3.5 LACK OF RESOURCES

Practical barriers, relating to a lack of funding, resources and personnel were also considered limiting factors to change. In Poland in particular, the lack of pharmacists employed within the hospital was considered a significant barrier to adapting any practice changes related to ward-based care. In Australia, whilst pharmacists are present on wards, funding allocated to financing NICU pharmacist positions is not necessarily readily available across settings, limiting the potential number of pharmacists working in this area. The configuration of services and the infrastructure of the organisation need to be altered to ensure better funding of pharmacist positions in order to allow change to occur.

8.4 FACILITATING CHANGES IN PRACTICE IN AUSTRALIA AND POLAND

The changes to policy and practice proposed in this research have the potential to restructure the way pharmaceutical care is approached and delivered to specialties of practice. Overall, the research highlights that from both the Australian as well as the Polish perspective, there is an indication of readiness to change and an interest to advance pharmacy practice in the NICU. The FIP has acknowledged that Australia has a strong commitment to evolving pharmacy practice.[139] Professional bodies such as the SHPA lead the drive to change the pharmacy workforce and the adoption of best practices. Whilst Polish pharmacy practice has remained consistent for many years, there is growing support within the literature for the advancement of clinical pharmacy, which is being supported by a transitioning economy.[108] Whilst the KPIs developed within this research help define what practice should look like, there needs to be a process of change to get practice to that level. However, the implementation of any changes to policy and practice in each country is acknowledged as challenging due to the pluralistic nature of the healthcare systems as a whole. Chreim et.al. state that: "*the pluralistic domain is one characterised by the presence of divergent objectives (such as individual care, population health and cost containment) and multiple actors (such as administrators, various professional practitioners, government bodies) linked through fluid power arrangements*."[140] Given the complexity of behaviour change and getting multiple actors in a healthcare setting to agree on the content of change, the process of bringing it about requires a comprehensive approach with a variety of enabling factors. This will take time, resources as well as the support and commitment of stakeholders in the healthcare system. Despite the differences in practice

between countries, the literature consistently recommends three factors as effective facilitators of change. These mainly address issues related to the initiation of changes.

When launching transformative changes, such as those proposed for the Polish healthcare system, communication, education and training are regarded as key elements to overcoming any form of resistance and are a first step in culture change efforts.[141] As an example, in response to increased reports of medical error, Holland et.al. introduced an educational initiative to change the perceptions of US medical residents towards healthcare quality and patient safety.[142] Residents undertook a one-month web-based curriculum, which focused on quality improvement. The results highlighted that participants demonstrated significantly enhanced levels of knowledge and attitudes about patient safety and quality improvement.[142] Furthermore, residents introduced 20 quality improvement project proposals with a 50% rate of hospital-wide implementation which were attributed to leading to meaningful changes to the processes and procedures that affect patient care.[142] These educational initiatives have significant potential for the Polish system in promoting the concept of clinical pharmacy as well as a multidisciplinary, collaborative form of care. Cultural influences are important to consider, as they drive behaviours in both individuals and groups (i.e., organisations), and changing those behaviours is challenging. As described by Al-Abri: "*effective change has been characterised as unfreezing old behaviours, introducing new ones, and re-freezing*."[143] When introducing changes into an organisation, particularly those that are hierarchical in nature, literature highlights that there is a need to first establish a clear vision of the direction of the change process.[141 143] Communicating the "*strategic reasons for the change, what will happen, how individuals will be involved and what is expected from them and their team, as well as why it is important to the practice and the patients*", are regarded as essential elements in assuring successful change.[141]

Gesme highlights that in addition to a shared vision to change, there is a need for effective and strong leadership.[141] Leaders must be able to communicate the goals of the change and articulate a vision of future practice to individuals at all levels of the organisation to generate a need for the initiative.[141] Furthermore, these individuals are needed to motivate and energise stakeholders, whose support is essential for the engagement of the necessary resources to facilitate the change. Literature highlights the use of 'change champions' for moving new innovations through the phases of initiation, development, and implementation.[144] Shaw et.al. found that having two types of 'change champions' – organisational and project, was effective in implementing and sustaining diabetes improvements in a primary care setting.[144] In this

study, the project champion's role was focused on and derived-from a specific project-based innovation whereas the organisational change champion's role assumed a wider scope that involved managing individual changes in the context of a larger mission of practice transformation.[144] This finding has relevance to both the Australian and Polish setting, as there is a need for pharmacists themselves to initiate and sustain changes to their practice.

In shifting from a culture that is satisfied with the status quo to one that is ready to change, there is a need to provide evidence or data that proves there is a need for change.[141] McGrath et.al state that any proposed initiatives need to be evidence-based.[145] Data that highlights the inadequacies of the current system are highlighted as the most effective propellers of instigating change.[141] In this instance, those that refer to practice quality, patient safety or economic improvements may enhance the uptake of the project. This type of data increases the engagement of policymakers, professional pharmacy bodies as well as pharmacists, and other health professionals and may improve their perceptions towards a need for change. The NICE guidelines recommend that to engage individuals in quality improvement in healthcare, "*the use of clinical audit and feedback involving retrospective reporting of information to individuals or organisations about their practice*" is important to drive quality improvement initiatives.[146] They recommended data collection from actual practice to provide insight into particular aspects of care, through either internal or external audits.[146] Feedback referred to outcomes of care, costs, elements of clinical performance, and also had the potential to include comparison between settings on a local and national scale.[146] This is of particular importance to both the Australian and Polish systems to engage the support of policymakers and to other healthcare professionals to highlight the need for pharmacy practice changes in the NICU.

The changes proposed in this thesis have the possibility of being applicable to practice globally, therefore it also important to consider any additional factors that may influence the perceived need for change on a larger scale. When considering the up-scaling of changes and innovations across countries, Ziemann et.al. cited several 'external context' factors as significant influencers of the implementation of healthcare innovations, which included: the socio-political climate between nations, inter-organisational norms and incentives and mandates.[147] The NICE guidelines report that: "*the financial and political environment can impact on healthcare professionals' desire, motivation and ability to make changes. At an organisational level, financial systems may not facilitate payments for new interventions and resources may*

be constrained. Incentive mechanisms and regulatory processes may not be aligned with what's needed to implement the changes."[146]

8.5 OPPORTUNITIES TO OPTIMISE CARE FOR NEONATAL PATIENTS – AREAS FOR FUTURE RESEARCH

Several implications can be derived from the results of this thesis.

8.5.1 GLOBALLY

This research informs the need for further investigations on a larger scale that detail the impact of pharmacy practice disparities between settings both nationally and internationally on medication errors and patient outcomes in the NICU. This evidence can then be used to strengthen the argument for the development of an international framework of quality measures and as well as a minimum standard of accepted practice representing a quality level of pharmaceutical care in the NICU.

Overall, there is also a need for greater focus on promoting quality pharmaceutical care in high-risk and specialty areas of practice, such as the NICU. The SHPA states: "*patient groups most at risk of medicines-related problems should be prioritised to receive clinical pharmacy services*."[101] The pharmacy profession is evolving to practising at advanced levels of care however, specialties of practice are not as commonly addressed in guidance documents, leaving pharmacists unsupported in their practice. There is a need for professional pharmacy organisations, both nationally and internationally, to likewise provide policies and model approaches for the quality and safe use of medicines in the NICU setting. The WHO, EDQM and FIP have previously launched worldwide initiatives for general hospital pharmacy to promote consistency in the use of medicines to improve the delivery of high quality care, health outcomes, and achieve better use of resources within health systems.[51 55 105] Likewise, future research is needed to determine the priorities of pharmaceutical care in specialist areas of practice to define, structure and support the provision of quality pharmaceutical care in these areas. Furthermore, they must encompass a means for data collection to support benchmarking and the sharing of best practices. Quality indicators are a valuable tool for achieving safe, high-quality care, cost-effective therapy and rational use of medicines.[148] The quality guidance document developed in this thesis, provides a platform from which future

research can build upon to create indicators that are robust, reliable, valid and feasible to measure, through relevant field-testing and compliance with agreed, standardised methods.[105]

The research findings indicate that the development of pharmacist-sensitive quality measures for NICU across Australia and Poland was challenging due to the differences between their respective healthcare systems. Further international collaboration initiatives are needed to assist in the development of consistent pharmaceutical care practices and to develop strategies that will help to bridge the gap between countries, thereby eliminating health inequities. The EDQM states: "*A common process of decision-making for policymakers has relevance for the vast majority of countries, regardless of their particular circumstances. The principles of quality management are largely identical across all countries, as they build on optimal use of scarce resources, client orientation, and sound planning, as well as evidence for improved quality of services".*[105] There is a need for professional pharmacy organisations to form collaborative international research relationships, and synergistically work together to avoid duplication of efforts and meet the objective of achieving quality, patient-centred pharmaceutical care.[105]

8.5.2 FOR POLAND

The research has demonstrated that from the perspectives of Polish pharmacists clinical pharmacy services in Polish NICUs are not as wide-ranging as those practiced in Australia, and do not extend far past the dispensary. In order to be able to apply the proposed quality guidance resource developed in the research into daily practice, there is a need for the healthcare system in Poland to implement specific support structures to encourage the implementation of pharmaceutical care.

The concept of pharmaceutical care should be considered a priority in improving the effective and safe use of medicines. Future research needs to be directed at the performance of pharmacist intervention studies in NICUs and their subsequent impact upon medication error rates, the use of resources as well as patient outcomes. Due to the long-standing traditional practice culture as well as the hierarchical structure within the Polish hospital setting, there is a need for these studies to provide 'evidence' to policymakers, and other stakeholders that the pharmacist is an integral contributor to patient safety, and the rational use of medicines. Whilst these types of studies have been published in other countries, there is a need for

research to be acknowledged from within a Polish context and highlight that pharmaceutical care "*could enhance responsible use of medicines, improve medication safety, better meet the health needs of patients, and achieve cost-effectiveness*."[105]

Subsequent to this research, there is a need for this 'evidence' to be acknowledged by policymakers in a political context, to establish a legal basis for the implementation of pharmaceutical care. The findings of the research highlight that legislation is needed to permit pharmacists the opportunity of practicing on wards and able to take responsibility for patient care as well as access to patient medication charts. Subsequently, this will allow the development of a practice framework supporting the implementation of the pharmaceutical care philosophy in NICUs nationally, as well as the creation of incentives for healthcare professionals to invest time and resources in pharmaceutical care activities.[105]

Future research also needs to be directed at identifying strategies to improve post-graduate and continuing education of pharmacists in Poland to better support them in the provision of patient-centred care. The EDQM suggests educational improvements related to clinical pharmacy, pharmacotherapy management services, inter-professional collaboration and communication skills are needed to aid the introduction of pharmaceutical care into the Polish healthcare system.[105]

Effective pharmaceutical care is dependent on successful co-operation with a multi-disciplinary team of healthcare professionals in designing, implementing and monitoring a pharmacotherapeutic plan that will ensure specific therapeutic outcomes for NICU patients. Due to the apparent hierarchy in the hospital systems in Poland, future research also is needed to develop strategies to overcome these barriers as well as to investigate the implementation of interprofessional education in medical, nursing and pharmacy programs.

8.5.3 FOR AUSTRALIA

The findings of this research highlighted that Australian pharmaceutical care services delivered to NICUs are well-established and practice itself is progressing towards advanced practice roles and specialisations. As such, to optimise care there is a need to further support pharmacists in these areas. Whilst KPIs in general healthcare settings are being more frequently published, there is potential for pharmacists to assert and further justify their presence on these wards

through the development of standardised quality measures for NICU settings nationally. There is potential for the quality guidance document developed in this thesis to be used in future research conducted in conjunction with the SHPA special practice groups relating to women's and newborn health or paediatrics and neonatology, to design and implement a robust and valid quality guidance resource for use in Australian NICUs. Currently, NICU pharmacists are seen to operate according to each individual hospitals practice policy, with little to no collaboration between units. Therefore, there is a need to establish validated measures that have the potential to enhance the clinical practice of pharmacists, provide direction for pharmacy education, support benchmarking and sharing of best practices and promote the standardisation of practice.

To support the sharing of information, a database or repository for quality measures and key performance indicators should be established so that researchers, pharmacists and policymakers alike access to valid measures for the assessment, monitoring, and evaluation of the quality of pharmaceutical care in NICUs at national and regional levels.[105]

There is a need for more educational support of pharmacists entering into specialised areas of practice, such as the NICU. The findings of the research highlighted that new pharmacists coming into the NICU feel unprepared for practice in this ward. Therefore, future research should be aimed at improving post-graduate training programs that allow pharmacists to specialise in different areas of practice, such as neonatal care, geriatrics, palliative medicine etc.

8.6 STRENGTHS

The studies within this thesis are the first form of collaborative and comparative research between Polish and Australian pharmacy practice. Furthermore, this is the first kind of research to explore the concept of quality pharmaceutical care as applied to the sub-specialty of NICU in either country. Using research instruments that encompassed both qualitative and quantitative methods, the studies were able to provide a comprehensive insight and background into pharmaceutical care services in Polish and Australian NICUs and demonstrated how widely practice can vary in industrialised countries. This research also effectively drew attention to the absence of quality measures as well as standards of practice for pharmaceutical care services in the NICU.

In response to these gaps in knowledge as well as the perceived needs of pharmacists in NICU settings, this research has enabled the development of a preliminary quality guidance document, tailored to the needs of each country. The Delphi technique used to seek consensus provided a sound basis for the selection and verification of quality measures included in this document evaluating the quality of NICU pharmaceutical care. The indicators chosen by the participants represented each domain proposed by Donabedian, as well as the conceptual framework used to frame this research. By representing each domain of quality assurance, quality is being considered comprehensively.

8.7 LIMITATIONS

Several limitations need to be considered when reviewing the results of this thesis. As the research was undertaken in Poland and Australia, the panel of experts that contributed to the Delphi phase reflect the Polish and Australian context respectively. Therefore, the generalisation of the results to other countries with different healthcare systems and pharmaceutical care services must be applied with caution. It is also important to note that an experts agreement/disagreement with a structure/process/outcome indicator may be associated with the local or national expectations of professional pharmacist practice or experience of each panellist. Thus the results may be influenced by the professional roles of the participants, as well as the range in working experience between panellists, resulting in the potential for much variability in actual experience and exposure to the NICU in Australian and Polish settings. This may affect the generalisability of the results and they should be interpreted with caution.

Pharmacy services in the NICU are a very narrow area of practice, resulting in a more restricted number of possible participants. As a result, the small sample sizes evident in the research mean that the research may not be representative of all pharmacists in Australia and Poland. However, due to the restricted nature of this topic, they may be considered representative of NICU settings in each country. Furthermore, the experts who responded to the Delphi questionnaires worked in a variety of different roles and contributed a diverse range of neonatal and pharmacy experiences and expertise.

Due to the voluntary nature of participation in the research, there is a possibility that pharmacists who participated may have different views to those who chose not to volunteer.

Furthermore, pharmacists assessment of practice preparedness and competence is highly prone to self-report bias.

The pharmaceutical care system, in particular clinical pharmacy, is not well developed in Poland. Therefore there is a possibility for participants from this country to experience social desirability bias in over and under-reporting on their practices in the NICU. Furthermore, whilst all efforts were made to ensure clarity in the survey instruments used, there is a possibility for misunderstanding of terms which were unable to be clarified by researchers.

The key performance indicators identified in the research are not a comprehensive set of indicators for the assessment of hospital pharmacy practice in each country. The KPIs simply represent consensus amongst experts in defining a preliminary quality level of pharmacy practice in the NICU and require further research to establish their validity, reliability, feasibility and suitability to practice.

8.8 CONCLUSION

Overall this research has sought to initiate a global discussion around the development of minimum pharmacy practice standards for specialties of care, in this instance within the NICU. Clinical pharmacists, as pharmacotherapy experts, are key resources in improving the safety and quality of medicines used in the NICU. Thus, there is a strong perceived need for change relating to policy and practice to reflect the value of the pharmacist in this setting this and to better support pharmacists in their provision of care.

This thesis provides first-hand information and comprehensive insight into current pharmacy services provided to NICUs in Australia and Poland from the perspectives of pharmacists themselves, as well as doctors, nurses and students. According to participants, Polish pharmacy services are primarily dispensary-based, with little to no input into ward-based pharmacotherapy-related decision-making. On the other hand, Australian practice in general functions at an advanced level, with pharmacists present on NICUs, performing clinical roles and being involved in medication management. These differences in practice were commonly attributed to practice culture, pharmacy legislation, and tertiary education. However, despite these apparent differences, the majority of participants in both countries, and from each health profession held positive expectations towards pharmacist roles in the NICU. Pharmacists were expected to hold positions that allowed them access to the ward and permitted them to have a greater role in patient care. However, the significant differences in

practice seen between these two industrialised countries may have varying levels of impact upon patient care and outcomes. These findings reinforce the need for future research to identify what level of impact these differences in practice do have upon patient outcomes, medication error rates and the quality use of medicines in this setting.

Medication use in the NICU is high-risk and patients are susceptible to medication errors and misuse. Due to the vulnerable characteristics of neonatal patients and the distinct gaps in practice between Australia and Poland, these findings reinforce the need to determine a minimum standard of practice for NICU pharmacists to encourage the progression and standardisation of hospital pharmacy services. When asked about quality guidance documents or of key performance indicators specifically for pharmacist practice in the NICU setting, none of the participants in either country were able to identify any available resources. From these results, two quality guidance documents, one for each country, were compiled. These documents contain a list of essential pharmacist roles and KPIs tailored to the NICU setting in each country, as well as definitions and resources that can be used to support pharmaceutical care services on this ward. The quality guidance documents developed in this thesis may be used as a platform for the future development of robust, valid and generalisable quality pharmacy practice resources. These resources are important for quality improvement activities, such as benchmarking to demonstrate differences between settings on a national scale, to improve the performance of pharmacy services, as well as to enhance transparency about hospital pharmacy service quality, which are important for the progression of the NICU pharmacy practice. Further research is needed to evaluate usefulness and appropriateness of these documents to practice in Australia and Poland.

From an international perspective, future research should be directed at investigating the barriers contributing to practice differences, and identifying facilitators that would assist in bridging the gap in NICU pharmacist practice within and between countries.

For Polish pharmacists, it is essential for future efforts to focus on how practice is structured and what support can be implemented from educational, cultural and legislative levels to enable better pharmacist integration into the NICU therapeutic team and for services to meet the level of practice seen worldwide

For the Australian setting, future work is needed to encourage the standardisation of services across NICUs nationwide, through the establishment of national policies and practice standards, advanced practice frameworks and opportunities for practice specialisation.

APPENDICES

APPENDIX A – HUMAN RESEARCH AND ETHICS APPROVAL FOR THE CONDUCT OF PART A, B AND C

A.1 HREC APPROVAL FROM THE UNIVERSITY OF TECHNOLOGY SYDNEY

A.2 HREC APPROVAL FROM THE MEDICAL UNIVERSITY OF GDANSK, POLAND

A.1 HREC APPROVAL FROM THE UNIVERSITY OF TECHNOLOGY SYDNEY

Friday, 16 December 2016

Dear Applicant

Thank you for your response to the Committee's comments for your project titled, "Evaluation of pharmacist practice in neonatal intensive care units in Australia and Poland: Developing a best practice model and quality indicator list - Stages 1 - 3". Your response satisfactorily addresses the concerns and questions raised by the Committee who agreed that the application now meets the requirements of the NHMRC National Statement on Ethical Conduct in Human Research (2007). I am pleased to inform you that ethics approval is now granted.

Your approval number is **UTS HREC REF NO. ETH16-1033**.

Approval will be for a period of five (5) years from the date of this correspondence subject to the provision of annual reports. Your approval number must be included in all participant material and advertisements. Any advertisements on the UTS Staff Connect without an approval number will be removed. Please note that the ethical conduct of research is an on-going process. The National Statement on Ethical Conduct in Research Involving Humans requires us to obtain a report about the progress of the research, and in particular about any changes to the research which may have ethical implications. This report form must be completed at least annually from the date of approval, and at the end of the project (if it takes more than a year). The Ethics Secretariat will contact you when it is time to complete your first report.

I also refer you to the AVCC guidelines relating to the storage of data, which require that data be kept for a minimum of 5 years after publication of research. However, in NSW, longer retention requirements are required for research on human subjects with potential long-term effects, research with long-term environmental effects, or research considered of national or international significance, importance, or controversy. If the data from this research project falls into one of these categories, contact University Records for advice on long-term retention.

You should consider this your official letter of approval. If you require a hardcopy please contact Research.Ethics@uts.edu.au.

To access this application, please follow the URLs below:

* if accessing within the UTS network: https://rm.uts.edu.au

* if accessing outside of UTS network: https://vpn.uts.edu.au , and click on " RM6 – Production " after logging in.

We value your feedback on the online ethics process. If you would like to provide feedback please go to: http://surveys.uts.edu.au/surveys/onlineethics/index.cfm

If you have any queries about your ethics approval, or require any amendments to your research in the future, please do not hesitate to contact Research.Ethics@uts.edu.au.

Yours sincerely,

Professor Marion Haas

Chairperson

UTS Human Research Ethics Committee

C/- Research & Innovation Office

University of Technology, Sydney

E: Research.Ethics@uts.edu.au

A.2 HREC APPROVAL FROM THE MEDICAL UNIVERSITY OF GDANSK, POLAND

NIEZALEŻNA KOMISJA BIOETYCZNA DO SPRAW BADAŃ NAUKOWYCH
PRZY GDAŃSKIM UNIWERSYTECIE MEDYCZNYM
80-210 Gdańsk, ul. M. Skłodowskiej-Curie 3a
Sekretariat: tel. 58/349-10-11, fax 58/349-11-70, Przewodniczący tel. 58/349-12-60

NKBBN/**424**/2016

Gdańsk, 2016-10-25

Pan
Prof. dr hab. med. Ivan Kocić
Kierownik Katedry i Zakładu Farmakologii
Gdański Uniwersytet Medyczny

W odpowiedzi na zgłoszenie badań z dnia 27.09.2016r. na temat: **„Rola i zadania farmaceuty w oddziałach intensywnej terapii noworodkowej – opracowanie najlepszego modelu praktyki oraz czynniki jakości usług farmaceutycznych"** *(praca doktorska mgr Natalii Krzyżaniak planowana do przeprowadzenia pod kierunkiem promotora prof. Beaty Bajorek z University of Technology Sydney, Australia, i opiekuna dr n. farm. Igi Pawłowskiej z Katedry i Zakładu Farmakologii GUMed)* - Niezależna Komisja Bioetyczna do Spraw Badań Naukowych przy Gdańskim Uniwersytecie Medycznym na posiedzeniu w dniu 19 października 2016 roku zapoznała się z powyższym projektem pracy i wyraża zgodę na jej prowadzenie w zakresie przedstawionym we wniosku, gdyż są to badania poznawcze, nie budzące zastrzeżeń natury etycznej.

Niniejsza zgoda jest ważna do 31 października 2019 roku, zgodnie z planowanym przez badacza okresem przeprowadzenia ww. badań.

NIEZALEŻNA KOMISJA BIOETYCZNA
DO SPRAW BADAŃ NAUKOWYCH
PRZY GDAŃSKIM UNIWERSYTECIE MEDYCZNYM
80-210 Gdańsk, ul. M. Skłodowskiej-Curie 3a
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PRZEWODNICZĄCY
Niezależnej Komisji Bioetycznej
do Spraw Badań Naukowych
prof. dr hab. med. Stefan Ruszkiewicz

POLISH ETHICS APPROVAL – TRANSLATION

INDEPENDENT COMMITTEE FOR SCIENTIFIC RESEARCH AT THE

MEDICAL UNIVERSITY OF GDAŃSK

80 – 210 GDAŃSK, ul. SKŁODOWSKIEJ-CURIE 3a

Secretariat: tel. 58/349-10-11, fax 58/349-11-70, Chairman tel. 58/349-12-60

NKBBN/**424**/2016 Gdańsk, 2016-10-25

Prof. dr hab. med. Ivan Kocić

Head of the Department of Pharmacology

Medical University of Gdańsk

In response to the notification of research dated 27.09.2016 titled: **"Roles and responsibilities of pharmacists in the neonatal intensive care unit: development of a best practice model and quality indicators for clinical pharmacist services"** *(doctoral thesis of Natalia Krzyżaniak planned to be carried out under the guidance of supervisor A.Prof Beata Bajorek from the University of Technology Sydney, Australia and supervisor Iga Pawłowska from the Department of Pharmacology at the Medical University of Gdańsk)* – the Independent Committee on Bioethical Matters relating to Scientific Research at the Medical University of Gdańsk at its meeting on the 19th of October 2016 became acquainted with the aforementioned project and agreed to its implementation according to the information outlined in the application, as this is a baseline study which does not violate the ethical nature of research.

This consent is valid until 31st of October 2019, in accordance with the investigators plans to carry out the aforementioned research.

STAMPS

Independent Committee on Bioethical Matters relating to Scientific Research at the Medical University of Gdańsk

80-210 Gdańsk, ul. M. Skłodowskiej-Curie 3a

tel. 58 349 10 11, fax. 58 349 11 70

Chairman of the Independent Committee on Bioethical Matters relating to Scientific Research at the Medical University of Gdańsk

Prof. dr hab. Med. Stefan Raszeja

APPENDIX B - PROJECT RECRUITMENT AND INFORMATION SHEETS FOR PAPER 1, CHAPTER 2

PROJECT TITLE: THE ROLE OF THE CLINICAL PHARMACIST IN NICU - AN EVALUATION OF AUSTRALIAN AND POLISH PHARMACY PRACTICE

B.1 INVITATION LETTER TO PARTICIPANTS (ENGLISH)

B.2 INVITATION LETTER TO PARTICIPANTS (POLISH)

B.3 INFORMATION SHEET (ENGLISH)

B.4 INFORMATION SHEET (POLISH)

B.5 PARTICIPANT CONSENT FORM (ENGLISH)

B.6 PARTICIPANT CONSENT FORM (POLISH)

B.1 INVITATION LETTER TO PARTICIPANTS (ENGLISH)

PARTICIPANT INFORMATION FORM – STAGE 1 SURVEY

Dear Participant,

My name is Natalia Krzyzaniak and I am a PhD student at the University of Technology, Sydney.

I am currently undertaking research that is aimed at developing a definitive practice model and set of quality indicators that will guide clinical pharmacists in the provision of pharmacy services and pharmaceutical care to neonatal intensive care units (NICUs) in Australian and Polish hospitals. The initial phase of my project intends to gain an insight into current pharmacist practice in NICUs in Poland and Australia and involves the collection of information relating to the types of pharmacist roles performed in your NICU through a questionnaire. Pharmacists are important contributors to patient safety as well as the quality and rational use of resources in the NICU. However there is limited literature available that documents currently performed pharmacist services within the NICU. No previous studies have compared Australian pharmacist practice to Polish pharmacist practice.

The data from this study will provide an overview of NICU pharmacist practice within the two countries, determine where any differences lie between Poland and Australia and evaluate the role of the pharmacist in the multi-disciplinary NICU therapeutic team. Furthermore, this survey aims to identify which pharmacist services are deemed to be important to the quality and rational use of medicines in the NICU.

The study will require the completion of a survey, which should take no more than 15 minutes of your time. If you are interested in participating, please read both pages of the 'Participant Information – Stage 1 Survey' and sign the 'Participant Consent – Stage 1 Survey'. For any further clarification or queries, please do not hesitate to contact me on [redacted] or on my email: Natalia.krzyzaniak@student.uts.edu.au.

You are under no obligation to participate in this research. This research has received no funding.

Thank-you very much for your time,

Yours sincerely,

Natalia Krzyzaniak

Address: Graduate School of Health-Pharmacy, Building 7 level 4

University of Technology Sydney NSW 2007

Phone: +

Email: Natalia.krzyzaniak@student.uts.edu.au

B.2 INVITATION LETTER TO PARTICIPANTS (POLISH)

INFORMACJE DLA UCZESTNIKOW - ETAP 1

Szanowni Państwo,

Nazywam się Natalia Krzyżaniak i jestem doktorantem na University of Technology w Sydney, Australia.

Obecnie prowadzę badania, które mają na celu opracowanie modelu praktyki i zestawu kluczowych wskaźników jakościowych, które będą ułatwiały farmaceutom prowadzenie klinicznych usług farmaceutycznych i opiekę farmaceutyczną dla noworodków na oddziałach intensywnej terapii (ITN) w polskich szpitalach. Pierwszy etap mojego projektu, składający się z badania kwestionariuszowego, będzie prowadził do poznania obecnej pracy farmaceuty w oddziałach ITN w Polsce i obejmuje zbieranie informacji dotyczących roli farmaceuty ww. ITN. Praca farmaceuty jest ważnym czynnikiem przyczyniającym się do bezpieczeństwa pacjentów, jak również jakości i racjonalnego wykorzystania leków w oddziałach ITN. Obecnie brakuje badań które przedstawiają wykonywane usługi farmaceutyczne w oddziałach ITN. Wyniki poniższego badania wskażą aktualny obraz praktyki farmaceutycznej w ITN w Polsce oraz ocenią rolę farmaceuty w multidyscyplinarnym zespole terapeutycznym. Ponadto, badanie to ma na celu określenie, które usługi farmaceutyczne są uważane za niezbędne dla jakości i racjonalnego stosowania leków u noworodków.

Badanie będzie wymagało wypełnienia kwestionariusza i nie powinno trwać dłużej niż 15 minut.

Jeśli są Państwo zainteresowani uczestnictwem, prosimy o zapoznanie się z "Informacją dla uczestnika - etap 1 kwestionariusz" i podpisać "uczestnik Zgoda - Etap 1 kwestionariusz ". W celu uzyskania dalszych wyjaśnień lub pytań, proszę się ze mną , lub na mój e-mail: Natalia.krzyzaniak@student.uts.edu.au.

Udział w badaniu jest dobrowolny. Badania te nie otrzymały pomocy finansowej.

Dziękuję Państwu za poświęcony czas,

Natalia Krzyżaniak

Adres: Graduate School of Health-Pharmacy, Building 7 level 4

University of Technology Sydney NSW 2007

Phone: +

Email: Natalia.krzyzaniak@student.uts.edu.au

B.3 INFORMATION SHEET (ENGLISH)

PARTICIPANT INFORMATION – STAGE 1 SURVEY

WHO IS DOING THE RESEARCH?

My name is Natalia Krzyzaniak and I am a PhD student at The University of Technology, Sydney. (My supervisor is Associate Professor Beata Bajorek, and my associate supervisor is Dr Iga Pawłowska)

WHAT IS THIS SURVEY ABOUT?

This survey will be investigating the roles of pharmacists on the neonatal intensive care unit (NICU) and the various pharmacy services performed. The data from this study will present a current picture of NICU pharmacist practice within the two countries, determine where any differences lie between Poland and Australia and evaluate the role of the pharmacist in the multi-disciplinary NICU therapeutic team. Furthermore, this survey aims to identify which pharmacist services are deemed to be important to the quality and rational use of medicines in the NICU.

IF I SAY YES, WHAT WILL IT INVOLVE?

I will ask you to complete a survey

ARE THERE ANY RISKS?

There is not considered to be any likelihood of physical harm associated with participating in this research, but there may be some inconvenience in terms of the time required to respond to questions and completing the survey, burden of commitment and restriction of ability to comment on practice structure/culture that is apparent in your hospital. If the questionnaire addresses issues that you feel uncomfortable commenting about or causes any of the aforementioned issues, the survey is entirely voluntary and you may elect not to further contribute to the research.

WHY HAVE I BEEN ASKED?

You are a valuable member of the hospital team; please confirm the following by ticking the boxes, which apply to you (you may tick more than one)

☐ I am a Director of Pharmacy OR;

☐ I am a pharmacist involved in patient care in the NICU

If you do not meet either criterion above, thank you for your time, however you are not suitable for this research.

DO I HAVE TO SAY YES?

You do not have to agree to participate in this survey. The decision to become involved in this research is entirely up to your own discretion.

WHAT WILL HAPPEN IF I SAY NO?

I will thank you for your time and will not contact you about this research again.

IF I SAY YES, CAN I CHANGE MY MIND LATER?

You can change your mind at any time and you do not have to offer any explanation. I will thank you for your time and will not contact you about this research again.

WHAT IF I HAVE CONCERNS OR A COMPLAINT?

If you have concerns about the research that you think I can help you with, please feel free to contact me on [redacted] or Natalia.krzyzaniak@student.uts.edu.au, or my supervisors A/Prof Beata Bajorek, Beata.Bajorek@uts.edu.au and Dr Iga Pawłowska, iga112@gumed.edu.pl.

If you would like to talk to someone who is not connected with the research, you may contact the Research Ethics Officer on 02 9514 9772 or research.ethics@uts.edu.au, and quote this number **(UTS HREC REF NO. ETH16-1033, GUMed HREC NO. NKBBN/424/2016).**

B.4 INFORMATION SHEET (POLISH)

ROLA FARMACEUTY W ODDZIALACH INTENSYWNEJ TERAPII NOWORODKA
(UTS HREC REF NO. ETH16-1033, GUMed HREC NO. NKBBN/424/2016)

INFORMACJE DLA UCZESTNIKOW – ETAP 1

KTO PROWADZI BADANIE?

Nazywam się Natalia Krzyżaniak i jestem doktorantem na University of Technology Sydney. (Moim promotorem jest A/Prof Dr Beata Bajorek, a natomiast promotorem pomocniczym jest Dr Iga Pawłowska)

O CZYM JEST TO BADANIE?

Badanie ma określić rolę farmaceuty i jakie usługi farmaceutyczne są wykonywane na oddziałach intensywnej terapii noworodkowej (ITN). Dane z tych badań wskażą aktualny obraz praktyki farmaceutycznej w oddziałach ITN w Polsce i określą rolę farmaceuty w multidyscyplinarnym zespole terapeutycznym. Ponadto, badanie to ma wskazać, które usługi farmaceutyczne są uważane za ważne dla jakości i racjonalnego stosowania leków u noworodków.

JEŚLI SIE ZGODZĘ NA UCZESTNICTWO W BADANIU, JAKIE BĘDĘ MIEĆ OBOWIĄZKI?

Poproszę uczestników o wypełnienie ankiety.

CZY ISTNIEJE JAKIEŚ RYZYKO?

Uczestnicząc w tym badaniu nie ponosicie żadnego ryzyka, ale mogą wystąpić niedogodności spowodowane z czasem wymaganego na wypełnienie ankiety. Jeśli podczas wypełniania ankiety, napotkają Państwo na jakieś problemy, lub niektóre pytania będą niekomfortowe, zawsze można zrezygnować z badania.

DLACZEGO ZOSTALEM/AM SPYTANA O UDZIAL W TYM BADANIU?

Pan/Pani jest cennym członkiem zespołu szpitalnego. Proszę potwierdzić, (poprzez zaznaczenie pola), które odnoszą się do Państwa (można zaznaczyć więcej niż jedną odpowiedź)

☐ Kierownik apteki szpitalnej

☐ Farmaceuta zaangażowany w opiekę nad pacjentem w intensywnej terapii noworodkowej

Jeśli nie spełniają Państwo wymagań kryterium, nie mogą Państwo wziąć udziału w badaniu. Bardzo dziękuję Państwu za poświęcony czas.

CZY MUSZĘ ZGODZIĆ SIĘ NA UCZESTNICTWO W TYM BADANIU?

Udział w badaniu jest dobrowolny.

CO SIE STANIE JEŚLI ODMÓWIĘ?

Podziękuję Państwu za poświęcony czas i nie będę ponownie kontaktowała się z Państwem.

JEŚLI TERAZ SIĘ ZGODZĘ, MOGE PÓŹNIEJ ZMIENIĆ ZDANIE?

Mogą Państwo zmienić zdanie w każdej chwili, nie podając żadnych wyjaśnień. Podziękuję za poświęcony czas i nie będę ponownie kontaktowała się z Państwem.

CO ZROBIC JESLI MAM PYTANIA?

Jeśli Państwo mają wątpliwości co do badań, proszę o kontakt ze mną pod nr telefonu: [redacted] lub Natalia.krzyzaniak@student.uts.edu.au, lub z którymś z moich promotorów A/Prof Beata Bajorek, beata.bajorek@uts.edu.au i Dr Iga Pawłowska, iga112@gumed.edu.pl.

Jeśli Państwo chcą porozmawiać z osobą, która nie jest związana z badaniami, można skontaktować się z przedstawicielem Komisji Bioetycznej 02 9514 9772 lub mailowo, research.ethics@uts.edu.au **(UTS HREC REF NO. ETH16-1033, GUMed HREC NO. NKBBN/424/2016).**

B.5 PARTICIPANT CONSENT FORM (ENGLISH)

PARTICIPANT CONSENT FORM – STAGE 1 SURVEY

You are a valuable member of the hospital team; please confirm the following by ticking the box that applies to you (you may tick more than one)

☐ I am a Director of Pharmacy OR;

☐ I am a pharmacist involved in patient care in the NICU

If you do not meet either criterion above, thank you for your time, however you do not appear be suitable for this research.

I_____ agree to participate in the research project *'the role of the clinical pharmacist in the NICU – an evaluation of Australian and Polish pharmacy practice' (UTS HREC REF NO. ETH16-1033, GUMed HREC NO. NKBBN/424/2016)* being conducted by Natalia Krzyzaniak, Building 7 level 4, University of Technology Sydney NSW 2007, +61 2 9514 1448 of the University of Technology, Sydney as part of her Doctor of Philosophy. This research has not been funded.

I understand that the purpose of this study is to gain an insight into the pharmacist roles and pharmacy services performed in neonatal intensive care units in Polish and Australian hospitals.

I understand that my participation in this research will involve completing a survey. The survey should only take, at most, 15 minutes to complete.

I am aware that I can contact Natalia Krzyzaniak or her supervisor A/Professor Beata Bajorek or co-supervisor Dr Iga Pawłowska if I have any concerns about the research. I also understand that I am free to withdraw my participation from this research project at any time I wish, without consequences, and without giving a reason.

I agree that the research data gathered from this project may be published in a form that does not identify me in any way.

_____ ____/____/____

Signature (participant)

_____ ____/____/____

Signature (researcher or delegate)

NOTE:

This study has been approved by the University of Technology, Sydney Human Research Ethics Committee. If you have any complaints or reservations about any aspect of your participation in this research which you cannot resolve with the researcher, you may contact the Ethics Committee through the Research Ethics Officer (ph: +61 2 9514 9772 Research.Ethics@uts.edu.au) and quote the UTS HREC reference number. Any complaint you make will be treated in confidence and investigated fully and you will be informed of the outcome.

B.6 PARTICIPANT CONSENT FORM (POLISH)

FORMULARZ ZGODY DLA UCZESTNIKOW – ETAP 1 ANKIETA

Pan/Pani jest cennym członkiem zespołu szpitalnego. Proszę potwierdzić, (poprzez zaznaczenie pola), które odnoszą się do Państwa (można zaznaczyć więcej niż jedną):

☐ Kierownik apteki szpitalnej
☐ Farmaceuta zaangażowany w opiekę nad pacjentem w intensywnej terapii noworodkowej

Jeśli nie spełniają Państwo wymagań kryterium, nie mogą Państwo wziąć udziału w badaniu. Bardzo dziękuję Państwu za poświęcony czas.

POTWIERDZENIE

Ja_____ zgadzam się na udział w projekcie badawczym "*Rola farmaceuty w oddziałach intensywnej terapii noworodkowa*" **(UTS HREC REF NO. ETH16-1033, GUMed HREC NO. NKBBN/424/2016)** prowadzony przez Natalię Krzyżaniak, University of Technology Sydney w ramach swojego doktoratu.

Badania te nie otrzymały pomocy finansowej.

Rozumiem, że celem tego badania jest określeniem roli farmaceuty i usługi farmaceutyczne wykonywane w oddziałach intensywnej terapii noworodkowej w polskich szpitalach.

Rozumiem, że mój udział w tym badaniu będzie wymagało wypełnienie kwestionariusza i nie powinno trwać dłużej niż 15 minut.

Rozumiem, że mogę się skontaktować z Natalia Krzyżaniak lub jej promotorka A/Profesor Dr Beata Bajorek lub promotorem pomocniczym Dr Iga Pawłowska, jeśli mam jakiekolwiek wątpliwości do badań.

Rozumiem ze udział w badaniu jest dobrowolny. Rozumiem ze mam prawo do wyrażenia sprzeciwu wobec udziału w badaniu lub wycofania się z uczestnictwa na każdym jego etapie.

Zgadzam się, że dane badawcze zgromadzone w ramach tego projektu mogą być opublikowane w formie, która nie identyfikuje mnie w żaden sposób.

_____ ____/____/____

Podpis (uczestnik)

_____ ____/____/____

Podpis (badacz)

APPENDIX C – DATA COLLECTION FORM FOR PAPER 1, CHAPTER 3

PROJECT TITLE: THE ROLE OF THE CLINICAL PHARMACIST IN NICU - AN EVALUATION OF AUSTRALIAN AND POLISH PHARMACY PRACTICE

C.1 QUESTIONNAIRE (ENGLISH)

C.2 QUESTIONNAIRE (POLISH)

C.1 QUESTIONNAIRE (ENGLISH)

Participant Code: _ _ / _ _ / _ _

THE ROLE OF THE PHARMACIST IN THE NICU: COMPARISON BETWEEN POLAND AND AUSTRALIA

- PHARMACIST SURVEY -

RESEARCHERS:

Natalia Krzyzaniak

A/Prof Beata Bajorek

Dr Iga Pawłowska

CONFIDENTIAL

Dear Participant,

Thank you for taking the time to complete this survey. To gather information on pharmacist practice in the NICU, you are asked to complete the following questionnaire. Please answer all questions to the best of your knowledge; there is a section at the end of the survey to add any additional comments.

Please insert a (x) in the corresponding box that most appropriately reflects your response.

DEMOGRAPHIC INFORMATION - Please tell us about your practice background and setting:	
1. Gender	☐$_1$ Female ☐$_2$ Male
2. Country of practice	☐$_1$ Australia ☐$_2$ Poland
3. What is the highest pharmacy qualification that you currently hold?	☐$_1$ Diploma ☐$_2$ Bachelor's Degree ☐$_3$ Master's Degree ☐$_4$ PhD ☐$_5$ Other – please specify ……
4. Do you hold any specialised qualifications related to NICU/paediatric pharmacy?	☐$_1$ Yes, please specify: …… ☐$_2$ No
5. What is your current occupation/position within the hospital?	☐$_1$ NICU pharmacist ☐$_2$ Director of Pharmacy ☐$_3$ Pharmacist working in the main hospital pharmacy ☐$_4$ Other – please specify: ……
6. How many years have you been working in this position?	☐$_1$ Less than 1 year ☐$_2$ Between 1 and 5 years ☐$_3$ Between 6 and 10 years ☐$_4$ Over 10 years

HOSPITAL AND NICU CHARACTERISTICS **We would like to know some information about the NICU at the hospital you work in. Can you please provide us with answers to the following:**	
7. What is the number of beds available in your NICU?	…….
8. What is the type of neonatal unit that you work in/is available at your hospital?	☐$_1$ **Level 1** – Normal low-risk pregnancies and births and management of babies ≥37+0 weeks gestation with minimal complications ☐$_2$ **Level 2A** – Low to moderate risk pregnancies and births and management of babies ≥34+0 weeks gestation with minimal neonatal complications ☐$_3$ **Level 2B** – Moderate to high-risk pregnancies and births and management of babies ≥32+0 weeks gestation with minimal complications ☐$_4$ **Level 3 (NICU)** – High-risk, high dependency pregnancies and births. Management of babies < 32+0 weeks gestation ☐$_5$ **Other** – please specify ……[149]

CURRENTLY PERFORMED PHARMACY SERVICES AND ROLES IN NICUS **We would like to gain some information on the roles and services performed by you or the NICU pharmacist/s in your hospital. Please indicate which of the following characteristics applies:**	
9. Is there a pharmacist that is currently providing direct clinical pharmacy services to the NICU?	☐$_1$ Yes (Proceed to Q. 13) ☐$_2$ No (Proceed to Q. 10)
10. If not working directly within the NICU, where are you/your pharmacists located? (Proceed to Q 11)	☐$_1$ Dispensary (hospital pharmacy) ☐$_2$ Other wards ☐$_3$ Pharmacy administration/office ☐$_4$ Other – please specify: ……
11. If not working directly within the NICU, do you or other pharmacists have any form of contact with the NICU? i.e. answering queries or checking to see if the ward needs any pharmacy assistance (Proceed to Q 12)	☐$_1$ Yes – telephonic (Proceed to Q. 12) ☐$_2$ Yes – email (Proceed to Q. 12) ☐$_3$ Yes – both phone and email (Proceed to Q. 12) ☐$_4$ No (Proceed to Q. 16)
12. If not working directly within the NICU, how frequently do you/a pharmacist contact the NICU? (Proceed to Q. 16)	☐$_1$ Daily ☐$_2$ 2 – 3 times per week ☐$_3$ Once a week ☐$_4$ Monthly ☐$_5$ Upon request ☐$_6$ Other – please specify ……

13. How frequently do you/a pharmacist provide clinical pharmacy services in the NICU:	☐$_1$ Daily ☐$_2$ 2 – 3 times per week ☐$_3$ Once a week ☐$_4$ Monthly ☐$_5$ Upon request/when needed/applicable ☐$_6$ Other – please specify ……
14. What is the average duration of your/a pharmacists visits?	☐$_1$ Less than 1 hour ☐$_2$ Between 1 and 3 hours ☐$_3$ Between 4 and 6 hours ☐$_4$ All day (7 + hours)
15. If working on the NICU, how many beds would you/the pharmacist cover per visit?	☐$_1$ All ☐$_2$ More than half ☐$_3$ Half ☐$_4$ Less than half

17. **What pharmacist services/roles are currently performed within the NICU at your hospital?**
18. **Which of the following pharmacist services do you perceive as being essential elements of pharmaceutical care that should be consistently provided in the NICU?**

Pharmacist Services/Roles	**Yes Performed** 1	**Not Performed** 2	**Essential role** 1	**Not essential** 2
ADMINISTRATION/MANAGEMENT				
Development/implementation of a drug formulary service	☐	☐	☐	☐
Attendance at non-clinical meetings i.e. Drug and Therapeutics Committee	☐	☐	☐	☐
Conducting quality assurance measures i.e. drug usage evaluations, workload documentation, auditing	☐	☐	☐	☐
Management of the drug budget	☐	☐	☐	☐
Evaluation, selection and purchasing of pharmaceuticals for the unit	☐	☐	☐	☐
Development of drug policies/protocols/guidelines for the NICU	☐	☐	☐	☐
CLINICAL ROLES				
Patient medication chart review	☐	☐	☐	☐
Participation in medical ward rounds	☐	☐	☐	☐
Monitoring side-effects and the efficacy of pharmacotherapy in patients	☐	☐	☐	☐
Documenting/monitoring Adverse Drug Events/Reactions	☐	☐	☐	☐
Documenting Medication Errors	☐	☐	☐	☐
Evaluating patients clinical laboratory tests	☐	☐	☐	☐
Therapeutic Drug Monitoring (TDM)	☐	☐	☐	☐
Immunisations	☐	☐	☐	☐
Prescribing/monitoring Total Parenteral Nutrition (TPN)	☐	☐	☐	☐
Participation in clinical meetings	☐	☐	☐	☐
Calculating and recommending doses and dosing	☐	☐	☐	☐

schedules for specific patients				
Assisting doctors in prescribing off-label/unlicensed medicines	☐	☐	☐	☐
Identifying and performing interventions for individual patients to prevent or resolve drug therapy problems i.e. interactions, incompatibilities, allergies etc.	☐	☐	☐	☐
Recommending drugs and contributing to the pharmacotherapy decision making process for specific patients	☐	☐	☐	☐
Collaborating and discussing specific patients with doctors and nurses	☐	☐	☐	☐
EDUCATION/COMMUNICATION/RESEARCH				
Providing training/in-services for other health professionals on NICU related topics and drug related problems	☐	☐	☐	☐
Contributing to and/or attending NICU related conferences	☐	☐	☐	☐
Involved in clinical trials	☐	☐	☐	☐
Involved in research related to neonatal pharmacotherapy	☐	☐	☐	☐
Source of drug information - responding to information requests from health professionals on the ward	☐	☐	☐	☐
Counselling parents/carers of neonatal patients	☐	☐	☐	☐
PROVISION OF MEDICINES				
Dispensing prescriptions	☐	☐	☐	☐
Extemporaneous compounding of formulations for the NICU	☐	☐	☐	☐
Stocking the ward with essential medicines/house-keeping activities i.e. checking expiry dates, fridge temperatures etc.	☐	☐	☐	☐

PHARMACIST INTEGRATION INTO MULTI-DISCIPLINARY TEAM	
1. Do you believe that there should be a pharmacist stationed permanently on the NICU or routinely visiting the ward?	☐$_1$ Yes – routinely visiting ☐$_2$ Yes – permanently stationed ☐$_3$ No
2. Why do you think that? i.e. what benefits/disadvantages would a pharmacist bring to the NICU?	……..…… ……..…… ……..…… ……..……
3. Is the pharmacist currently considered to be a part of the multidisciplinary treating team in the NICU?	☐$_1$ Yes ☐$_2$ No
4. Do you think that the pharmacist should be consulted as part of the multidisciplinary treating team when making medication-related decisions for NICU patients?	☐$_1$ Yes ☐$_2$ No
5. How would you rate the current inter-professional relationship/collaboration between doctors, nurses and the pharmacist in the NICU?	☐$_1$ Good ☐$_2$ Average ☐$_3$ Poor
6. Why do you think that the inter-professional relationship between doctors, nurses and the pharmacist is good/average/poor?	……..…… ……..…… ……..…… ……..……
7. How would you rate current pharmaceutical care practice in the NICU?	☐$_1$ Good ☐$_2$ Average ☐$_3$ Poor ☐$_4$ Non-existent

8. Why did you give this score?	……..…… ……..…… ……..…… ……..……
9. Do you believe that current pharmacy services are meeting the medication management needs of the NICU?	☐$_1$ Yes ☐$_2$ No

Additional Comments:

……

……

……

……

……

C.2 QUESTIONNAIRE (POLISH)

Kod Uczestnika: _ _ / _ _ / _ _

Szanowni Państwo,

Zwracamy się z prośbą o wypełnienie kwestionariusza dotyczącego roli farmaceuty na oddziałach intensywnej terapii noworodka, które jest częścią projektu badawczego prowadzonego także w Australii. Badanie ma charakter anonimowy i jest prowadzone w celach naukowych przez zespół z University of Technology Sydney oraz Katedry i Zakładu Farmakologii GUMed (kontakt: Natalia Krzyżaniak, ul. Dębowa 23, 80-204 Gdańsk, tel. 583491812, e-mail: Natalia.krzyzaniak@student.uts.edu.au). Mają Państwo prawo do wyrażenia sprzeciwu wobec udziału w badaniu lub wycofania się z uczestnictwa na każdym jego etapie. Wypełnienie kwestionariusza zajmie Państwu około 15 minut czasu.

Dziękujemy Państwu za udział w badaniu!

ROLA FARMACEUTY NA ODDZIAŁACH INTENSYWNEJ TERAPII NOWORODKA

- PRYWATNE -

- ANKIETA DLA FARMACEUTÓW -

INFORMACJE DOTYCZĄCE RESPONDENTÓW	
1. Płeć:	☐$_1$ Kobieta ☐$_2$ Mężczyzna
2. Obywatelstwo	☐$_1$ Inne ☐$_2$ Polskie
3. Wykształcenie	☐$_1$ Magister ☐$_2$ Doktor ☐$_3$ Profesor
4. Dodatkowe kwalifikacje dotyczące sprawowania opieki farmaceutycznej nad noworodkami/ dziećmi	☐$_1$ Tak, jakie?..... ☐$_2$ Nie
5. Miejsce pracy/stanowisko	☐$_1$ Farmaceuta pracujący w oddziale intensywnej terapii noworodka (ITN) ☐$_2$ Kierownik apteki szpitalnej ☐$_3$ Farmaceuta pracujący w aptece szpitalnej ☐$_4$ Inne – proszę podać: …… ……
6. Doświadczenie na tym stanowisku	☐$_1$ < 1 ☐$_2$ 1 - 5 lat ☐$_3$ 6 - 10 lat ☐$_4$ > 10 lat

INFORMACJE O SZPITALU I ODDZIALE INTENSYWNEJ TERAPII NOWORODKA (ITN)	
7. Liczba łóżek w ITN:	……..
8. Rodzaj ITN:	☐$_1$ **Poziom 1** – Normalne ciąże niskiego ryzyka i porody i zarządzanie dzieci ≥37 + 0 tygodnia ciąży z minimalnymi powikłaniami ☐$_2$ **Poziom 2A** – Opieka specjalna: Niski do umiarkowanego ryzyka dla ciąży i narodzin i zarządzanie dzieci ≥34 + 0 tygodnia ciąży z minimalnymi powikłaniami noworodków ☐$_3$ **Poziom 2B** – Umiarkowane do ciąż wysokiego ryzyka i urodzeń oraz zarządzanie dzieci ≥32 + 0 tygodnia ciąży z minimalnymi powikłaniami ☐$_4$ **Poziom 3** – wysokiego ryzyka ciąż wysokiego uzależnienia i porody. Zarządzanie dzieci <32 + 0 tygodnia ciąży ☐$_5$ **Inny** – proszę określić : ……[149]
USLUGI FARMACEUTYCZNE OBECNIE PROWADZONE W ODDZIALE ITN	
9. Czy farmaceuci pracują lub prowadzą usługi farmaceutyczne w oddziale ITN?	☐$_1$ Tak (Przejdź do P. 13) ☐$_2$ Nie (Przejdź do P. 10)
10. Jeśli farmaceuci nie pracują bezpośrednio w ITN, to gdzie pracują? **(Przejdź do P. 11)**	☐$_1$ Apteka szpitalna ☐$_2$ Inne oddziały ☐$_3$ Administracja w aptece ☐$_4$ Inne – proszę podać: ……

11. Jeśli farmaceuci nie pracują bezpośrednio na oddziale, czy mają jakikolwiek kontakt z oddziałem ITN?	☐$_1$ Tak – telefoniczny (Przejdź do P. 12) ☐$_2$ Tak – mailowy (Przejdź do P. 12) ☐$_3$ Tak – zarówno telefonicznie i mailowo (Przejdź do P. 12) ☐$_4$ Nie (Przejdź do P. 16)
12. Jeśli farmaceuci nie pracują bezpośrednio na oddziale ITN, jak często maja kontakt z oddziałem ITN? (Przejdź do P. 16)	☐$_1$ Codziennie ☐$_2$ 2 – 3 razy w tygodniu ☐$_3$ Raz w tygodniu ☐$_4$ Raz w miesiącu ☐$_5$ Na życzenie lekarza/położnej/pielęgniarki ☐$_6$ Inne – proszę podać: ……
13. Jak często farmaceuci wykonują usługi farmaceutyczne na oddziale ITN?	☐$_1$ Codziennie ☐$_2$ 2 – 3 razy w tygodniu ☐$_3$ Raz w tygodniu ☐$_4$ Raz w miesiącu ☐$_5$ Na życzenie lekarza/położnej/pielęgniarki ☐$_6$ Inne – proszę podać: ……
14. Jaki jest średni czas wizyty w ITN?	☐$_1$ < 1 godzinę ☐$_2$ Pomiędzy 1 i 3 godzin ☐$_3$ Pomiędzy 4 i 6 godzin ☐$_4$ Cały dzień (7 + godzin)
15. Iloma pacjentami zajmuje się farmaceuta podczas każdej wizyty?	☐$_1$ Wszystkimi ☐$_2$ Więcej niż połową ☐$_3$ Połową ☐$_4$ Mniej niż połową

16. **W powyższej tabeli proszę zaznaczyć czy wymienione czynności farmaceuty/usługi farmaceutyczne są wykonywane lub nie**

oraz

17. **Czy są one potrzebne lub nie.**

Role/Usługi Farmaceutyczne	**Wykonywane**[1]	**Niewykonywane**[2]	**Niezbędne (potrzebne dla oddziału)** [1]	**Niepotrzebne**[2]
USŁUGI ADMINISTRACYJNE				
Opracowanie / wdrożenie receptariusza	☐	☐	☐	☐
Uczęszczanie w nieklinicznych spotkaniach np. posiedzeniach komitetu terapeutycznego szpitala	☐	☐	☐	☐
Prowadzenie badań jakości farmakoterapii np. ocena stosowanych leków	☐	☐	☐	☐
Zarządzanie budżetem do zakupu leków	☐	☐	☐	☐
Zamawianie leków dla ITN	☐	☐	☐	☐
Opracowanie protokołów dla leków ITN	☐	☐	☐	☐
USŁUGI KLINICZNE				
Przeprowadzanie przeglądu leków dla pacjentów	☐	☐	☐	☐
Udział farmaceuty w obchodzie w ITN	☐	☐	☐	☐
Monitorowanie skuteczności leków u pacjenta	☐	☐	☐	☐
Dokumentowanie/monitorowanie oraz zgłaszanie działań niepożądanych leków	☐	☐	☐	☐
Dokumentowanie błędów lekowych (Medication Errors)	☐	☐	☐	☐
Analiza wyników badan pacjenta np. badania krwi, badanie mykologiczne	☐	☐	☐	☐
Monitorowanie farmakoterapii	☐	☐	☐	☐
Współudział w szczepieniach	☐	☐	☐	☐
Współudział w żywieniu pozajelitowym	☐	☐	☐	☐
Udział w klinicznych spotkaniach z lekarzem, pielęgniarka, rodzina pacjenta itd.	☐	☐	☐	☐
Obliczanie i zalecanie dawek i schematów dawkowania dla wybranych pacjentów	☐	☐	☐	☐
Wspieranie lekarzy w stosowaniu leków poza wskazaniami medycznymi (off label use)	☐	☐	☐	☐
Identyfikacja problemów lekowych oraz prowadzenie interwencji dla poszczególnych pacjentów w celu zapobiegania lub	☐	☐	☐	☐

rozwiązywania tych problemów (np. interakcje, niezgodności , alergie)				
Współudział w wyborze właściwej farmakoterapii dla pacjentów	☐	☐	☐	☐
Doradztwo prowadzone dla lekarzy, położnych i pielęgniarek w zakresie farmakoterapii pacjentów	☐	☐	☐	☐
EDUKACJA/KOMUNIKACJA/BADANIA				
Prowadzenie szkoleń dla lekarzy/położnych/pielęgniarek dotyczących farmakoterapii noworodków	☐	☐	☐	☐
Uczestnictwo w konferencja naukowych dotyczących INT	☐	☐	☐	☐
Współuczestniczenie w badaniach klinicznych leków	☐	☐	☐	☐
Współuczestniczenie w badaniach naukowych dotyczących farmakoterapii u noworodków	☐	☐	☐	☐
Udzielanie informacji personelowi medycznemu	☐	☐	☐	☐
Edukacja rodzin oraz opiekunów noworodków	☐	☐	☐	☐
ZAOPATRYWANIE W LEKI				
Wydawanie leków i materiałów medycznych na oddział INT	☐	☐	☐	☐
Wykonywanie leków recepturowych dla pacjentów w ITN	☐	☐	☐	☐
Kontrola właściwego przechowywania leków na oddziale/dat ważności leków/leków wstrzymanych i wycofanych z obrotu	☐	☐	☐	☐

UDZIAŁ FARMACEUTY INTERDYSCYPLINARNYM ZESPOLE TERAPEUTYCZNYM ITN	
18. Czy uważasz, że farmaceuta powinien stale przebywać na oddziale ITN lub przebywać tam nieregularnie w zależności od potrzeb?	☐$_1$ Tak – obecny stale ☐$_2$ Tak – przebywać nieregularnie ☐$_3$ Nie
19. Jeśli tak, to dlaczego? Jakie korzyści mogą wynikać z wykonywanych usług farmaceutycznych dla oddziałów ITN?	…… …… …… ……
20. Jeśli nie, dlaczego?	…… …… …… ……
21. Czy farmaceuta obecnie jest częścią zespołu leczącego w ITN?	☐$_1$ Tak ☐$_2$ Nie
22. Czy uważasz, że farmaceuta powinien udzielać konsultacji zespołowi terapeutycznemu dotyczących farmakoterapii noworodków?	☐$_1$ Tak ☐$_2$ Nie
23. Jak oceniasz obecny związek między lekarzami/ położnymi/pielęgniarkami a farmaceutami w ITN?	☐$_1$ Dobry ☐$_2$ Średni ☐$_3$ Słaby
24. Dlaczego tak uważasz?	…… ……

DODATKOWE KOMENTARZE:

25. Jak oceniasz obecną praktykę opieki farmaceutycznej w ITN?	☐$_1$ Dobra ☐$_2$ Średnia ☐$_3$ Słaba ☐$_4$ Nieistniejąca
26. Dlaczego?	……..…… ……..…… ……..…… ……..…… ……
27. Czy uważasz, że obecne usługi farmaceutyczne zaspokajają potrzeby lekowe na ITN?	☐$_1$ Tak ☐$_2$ Nie

……

……

APPENDIX D - PROJECT RECRUITMENT AND INFORMATION SHEETS FOR PAPER 2, PAPER 3 AND PAPER 4, CHAPTERS 3 AND 4

PROJECT TITLE: PHARMACEUTICAL CARE IN AUSTRALIA AND POLAND: PERSPECTIVES OF PHARMACISTS, DOCTORS, NURSES AND MEDICAL/PHARMACY STUDENTS

D.1 INVITATION LETTER TO PARTICIPANTS (ENGLISH)

D.2 INVITATION LETTER TO PARTICIPANTS (POLISH)

D.3 INFORMATION SHEET (ENGLISH)

D.4 INFORMATION SHEET (POLISH)

D.5 PARTICIPANT CONSENT FORM (ENGLISH)

D.6 PARTICIPANT CONSENT FORM (POLISH)

D.1 INVITATION LETTER TO PARTICIPANTS (ENGLISH)

PARTICIPANT INFORMATION FORM – STAGE 2

Dear Participant,

My name is Natalia Krzyzaniak and I am a PhD student at the University of Technology, Sydney.

I am currently undertaking research that is aimed at developing a definitive practice model and set of quality indicators that will guide clinical pharmacists in the provision of pharmacy services and pharmaceutical care to neonatal intensive care units (NICUs) in Australian and Polish hospitals. The second phase of my project intends to investigate the perceptions and expectations of pharmacists as well as other health professionals about pharmacists' role in NICUs in hospitals in Australia and Poland. Furthermore the study also aims to identify the perceived barriers towards the implementation of pharmaceutical care in the NICU. This stage leads on from will provide background data that will clarify why pharmacist practice in Poland and Australia is the way it is. It is important to understand these perspectives and opinions to better understand the situation of pharmaceutical care in each country so that measures can be developed to improve, change and enhance the role of the pharmacist to better meet the medication needs of NICU patients.

The study will be conducted in three sections, with the same/similar questionnaire being sent out to three different groups of healthcare professionals. The first survey will be sent out to pharmacists working in NICUs or in the dispensary in hospitals. The second questionnaire will be sent out to clinicians and nurses who work in NICUs. Finally, the third survey will be distributed among a class of medicine students at the Medical University of Gdansk to gauge their opinion on an ideal level of pharmaceutical care in the NICU.

The study will require the completion of a survey, which should take no more than 15 minutes of your time. If you are interested in participating, please read both pages of the 'Participant Information – Stage 2 Survey' and sign the 'Participant Consent – Stage 2 Survey'. For any further clarification or queries, please do not hesitate to contact me on 04342 279 272, or on my email: Natalia.krzyzaniak@student.uts.edu.au.

You are under no obligation to participate in this research. This research has received no funding.

Thank-you very much for your time,

Yours sincerely,

Lead Investigator

Natalia Krzyzaniak

Address: Graduate School of Health-Pharmacy, Building 7 level 4

University of Technology Sydney NSW 2007

Phone: +

Email: Natalia.krzyzaniak@student.uts.edu.au

D.2 INVITATION LETTER TO PARTICIPANTS (POLISH)

INFORMACJE DLA UCZESTNIKOW – ETAP 2

Szanowni Państwo,

Nazywam się Natalia Krzyżaniak i jestem doktorantem na University of Technology Sydney Australia.

Obecnie prowadzę badania, które mają na celu opracowanie modelu praktyki i zestawu kluczowych wskaźników jakościowych, które będą ułatwiały farmaceutom prowadzenie klinicznych usług farmaceutycznych i opiekę farmaceutyczną dla noworodków na oddziałach intensywnej terapii (ITN) w polskich szpitalach. Drugi etap mojego projektu, będzie prowadził do określenia postawy, poglądów i oczekiwań farmaceutów, jak również innych pracowników służby zdrowia oraz studentów medycyny i farmacji wobec roli farmaceuty w ww. ITN w szpitalach w Polsce. Ponadto badanie ma na celu zidentyfikowanie postrzeganych barier w kierunku realizacji opieki farmaceutycznej w ITN. Wyniki tego badania wskażą aktualny obraz praktyki farmaceutycznej w ITN w Polsce oraz ocenią rolę farmaceuty w multidyscyplinarnym zespole terapeutycznym.

Badanie będzie prowadzone w trzech częściach. Pierwsza ankieta zostanie wysłana do kierowników aptek szpitalnych i farmaceutów pracujących na ITN oraz w aptece szpitalnej. Druga ankieta zostanie wysłana do lekarzy i pielęgniarek, pracujących na oddziałach ITN. Trzecia ankieta zostanie przekazana studentom farmacji i medycyny z Uniwersytetu Medycznego w Gdańsku, aby ocenili poziom opieki farmaceutycznej w oddziałach ITN.

Badanie będzie wymagało wypełnienie kwestionariusza i nie powinno trwać dłużej niż 15 minut.

Jeśli są Państwo zainteresowani uczestnictwem, prosimy o zapoznanie się z "Informacją dla uczestników - Etap 2 kwestionariusz " i podpisać "uczestnik Zgoda - Etap 2 kwestionariusz ". W celu uzyskania dalszych wyjaśnień lub pytań, proszę się ze mną skontaktować na [redacted] lub na mój e-mail: Natalia.krzyzaniak@student.uts.edu.au.

Udział w badaniu jest dobrowolny. Badania te nie otrzymały pomocy finansowej.

Dziękuję Państwu za poświęcony czas,

Z poważaniem,

Natalia Krzyzaniak

Adres: Graduate School of Health-Pharmacy, Building 7 level 4

University of Technology Sydney NSW 2007, Phone: +6415 721 78

D.3 INFORMATION SHEET (ENGLISH)

PHARMACEUTICAL CARE IN AUSTRALIA AND POLAND: PERSPECTIVES OF PHARMACISTS, DOCTORS, NURSES AND MEDICAL STUDENTS

(UTS HREC REF NO. ETH16-1033, GUMed HREC NO. NKBBN/424/2016)

PARTICIPANT INFORMATION FORM – STAGE 2

WHO IS DOING THE RESEARCH?

My name is Natalia Krzyzaniak and I am a PhD student at The University of Technology, Sydney. (My supervisor is Associate Professor Beata Bajorek, and my associate supervisor is Dr Iga Pawłowska)

WHAT IS THIS SURVEY ABOUT?

This survey will be investigating the attitudes, perceptions and expectations of pharmacists, nurses, doctors and medical students towards the provision of pharmaceutical care and the pharmacy services in NICUs in hospitals in Australia and Poland. Furthermore the study also aims to identify the perceived barriers towards the implementation of pharmaceutical care in the NICU. It is important to understand these perspectives and opinions to better understand the situation of pharmaceutical care in each country so that measures can be developed to improve, change and enhance the role of the pharmacist to better meet the medication needs of NICU patients.

IF I SAY YES, WHAT WILL IT INVOLVE?

I will ask you to complete a survey

ARE THERE ANY RISKS?

There is not considered to be any likelihood of physical harm associated with participating in this research, but there may be some inconvenience in terms of the time required to respond to questions and completing the survey, burden of commitment and restriction of ability to comment on practice structure/culture that is apparent in your hospital. If the questionnaire addresses issues that you feel uncomfortable commenting about or causes any of the

aforementioned issues, the survey is entirely voluntary and you may elect not to further contribute to the research.

WHY HAVE I BEEN ASKED?

You are a valuable member of the hospital team; please confirm the following by ticking the boxes which apply to you (you may tick more than one)

☐ I am a Director of Pharmacy/pharmacist involved in patient care in the NICU; OR

☐ I am a nurse/midwife;

☐ I am a neonatologist/doctor OR;

☐ I am a medical student

If you do not meet either criterion above, thank you for your time, however you are not suitable for this research.

DO I HAVE TO SAY YES?

You do not have to agree to participate in this survey. The decision to become involved in this research is entirely up to your own discretion.

WHAT WILL HAPPEN IF I SAY NO?

I will thank you for your time and will not contact you about this research again.

IF I SAY YES, CAN I CHANGE MY MIND LATER?

You can change your mind at any time and you do not have to offer any explanation. I will thank you for your time and will not contact you about this research again.

WHAT IF I HAVE CONCERNS OR A COMPLAINT?

If you have concerns about the research that you think I can help you with, please feel free to contact me on [redacted] or Natalia.krzyzaniak@student.uts.edu.au, or my supervisors A/Prof Beata Bajorek, Beata.Bajorek@uts.edu.au and Dr Iga Pawłowska, iga112@gumed.edu.pl.

If you would like to talk to someone who is not connected with the research, you may contact the Research Ethics Office on 02 9514 9772, or research.ethics@uts.edu.au and quote this number **(UTS HREC REF NO. ETH16-1033, GUMed HREC NO. NKBBN/424/2016).**

D.4 INFORMATION SHEET (POLISH)

OPIEKA FARMACEUTYCZNA W ITN W POLSCE: z PERSPEKTYWY FARMACEUTOW, LEKARZY, PIELEGNIAREK I STUDENTOW MEDYCYNY I FARMACJI

(UTS HREC REF NO. ETH16-1033, GUMed HREC NO. NKBBN/424/2016)

INFORMACJA DLA UCZESTNIKOW – ETAP 2

KTO PROWADZI BADANIE?

Nazywam się Natalia Krzyżaniak i jestem doktorantem na University of Technology Sydney. (Moim promotorem jest A/Prof Dr Beata Bajorek, a natomiast promotorem pomocniczym jest Dr Iga Pawłowska)

O CZYM JEST TO BADANIE?

Badanie ma określić postawy, poglądy i oczekiwania farmaceutów, pielęgniarek, lekarzy i studentów medycyny lub farmacji wobec obecnie prowadzone usługi i opiekę farmaceutyczną w oddziałach ITN w szpitalach w Polsce. Ponadto badanie ma również na celu zidentyfikowanie postrzeganych barier w kierunku realizacji opieki farmaceutycznej na oddziałach ITN. Ważne jest, aby lepiej zrozumieć sytuację opieki farmaceutycznej w każdym kraju, tak aby rozwijać działania zmierzające do poprawy, zmiany i wzmocnienia roli farmaceuty w celu lepszego zaspokojenia farmaceutycznych potrzeb pacjentów ITN.

JEŚLI SIE ZGODZĘ NA UCZESTNICTWO W BADANIU, JAKIE BĘDĘ MIEĆ OBOWIĄZKI?

Poproszę uczestników o wypełnienie ankiety.

CZY ISTNIEJE JAKIEŚ RYZYKO?

Uczestnicząc w tym badaniu nie ponosicie żadnego ryzyka, ale mogą wystąpić niedogodności spowodowane z czasem wymaganego na wypełnienie ankiety. Jeśli podczas wypełniania ankiety, napotkają Państwo na jakieś problemy, lub niektóre pytania będą niekomfortowe, zawsze można zrezygnować z badania.

DLACZEGO ZOSTALEM/AM SPYTANA O UDZIAL W TYM BADANIU?

Pan/Pani jest cennym członkiem zespołu szpitalnego. Proszę potwierdzić, (poprzez zaznaczenie pola), które odnoszą się do Państwa (można zaznaczyć więcej niż jedną odpowiedź)

☐ Farmaceuta pracujący w aptece szpitalnej / Kierownik apteki szpitalnej

☐ Neonatolog / Lekarz pracujący na ITN

☐ Pielęgniarka neonatologiczna / Położna

☐ Student medycyny/farmacji

Jeśli nie spełniają Państwo wymagań kryterium, nie mogą Państwo wziąć udziału w badaniu. Bardzo dziękuję Państwu za poświęcony czas.

CZY MUSZĘ ZGODZIĆ SIĘ NA UCZESTNICTWO W TYM BADANIU?

Udział w badaniu jest dobrowolny.

CO SIE STANIE JEŚLI ODMÓWIĘ?

Podziękuję Państwu za poświęcony czas i nie będę ponownie kontaktowała się z Państwem.

JEŚLI TERAZ SIĘ ZGODZĘ, MOGE PÓŹNIEJ ZMIENIĆ ZDANIE?

Mogą Państwo zmienić zdanie w każdej chwili, nie podając żadnych wyjaśnień. Podziękuję za poświęcony czas i nie będę ponownie kontaktowała się z Państwem.

CO ZROBIC JESLI MAM PYTANIA?

Jeśli Państwo mają wątpliwości co do badań, proszę o kontakt ze mną pod nr telefonu: [redacted] lub Natalia.krzyzaniak@student.uts.edu.au, lub z którymś z moich promotorów A/Prof Beata Bajorek, beata.bajorek@uts.edu.au i Dr Iga Pawłowska, iga112@gumed.edu.pl.

Jeśli Państwo chcą porozmawiać z osobą, która nie jest związana z badaniami, można skontaktować się z przedstawicielem Komisji Bioetycznej 02 9514 9772 lub mailowo, research.ethics@uts.edu.au **(UTS HREC REF NO. ETH16-1033, GUMed HREC NO. NKBBN/424/2016).**

D.5 PARTICIPANT CONSENT FORM (ENGLISH)

PARTICIPANT CONSENT FORM – STAGE 2 SURVEY

Please confirm the following by ticking the box that applies to you (you may tick more than one)

☐ I am a Director of Pharmacy/pharmacist involved in patient care in the NICU; OR

☐ I am a nurse/midwife;

☐ I am a neonatologist/doctor OR;

☐ I am a medical student

If you do not meet either criterion above, thank you for your time, however you do not appear be suitable for this research.

I _____agree to participate in the research project *'Pharmaceutical care in Australia and Poland: perspectives of pharmacists, doctors, nurses and medical students' (UTS HREC REF NO. ETH16 1033, GUMed HREC NO. NKBBN/424/2016)* being conducted by Natalia Krzyzaniak, Building 7 level 4, University of Technology Sydney NSW 2007, +61 2 9514 1448 of the University of Technology, Sydney as part of her Doctor of Philosophy. This research has not been funded.

I understand that the purpose of this study is to gain an insight into the perspectives, attitudes and barriers towards the provision of pharmaceutical care and pharmacy services in the neonatal intensive care unit in Poland and Australia.

I understand that my participation in this research will involve completing a survey. The survey should only take, at most, 15 minutes to complete.

I am aware that I can contact Natalia Krzyzaniak or her supervisor A/Professor Beata Bajorek or co-supervisor Dr Iga Pawłowska if I have any concerns about the research. I also understand that I am free to withdraw my participation from this research project at any time I wish, without consequences, and without giving a reason.

I agree that the research data gathered from this project may be published in a form that does not identify me in any way.

_____ ____/____/____

Signature (participant)

_____ ____/____/____

Signature (researcher or delegate)

NOTE:

This study has been approved by the University of Technology, Sydney Human Research Ethics Committee. If you have any complaints or reservations about any aspect of your participation in this research which you cannot resolve with the researcher, you may contact the Ethics Committee through the Research Ethics Officer (ph: +61 2 9514 9772 Research.Ethics@uts.edu.au) and quote the UTS HREC reference number. Any complaint you make will be treated in confidence and investigated fully and you will be informed of the outcome.

D.6 PARTICIPANT CONSENT FORM (POLISH)

FORMULARZ ZGODY – ETAP 2 ANKIETA

Pan/Pani jest cennym członkiem zespołu szpitalnego. Proszę potwierdzić, (poprzez zaznaczenie pola), które odnoszą się do Państwa (można zaznaczyć więcej niż jedną):

☐ Farmaceuta pracujący w aptece szpitalnej / Kierownik apteki szpitalnej

☐ Neonatolog / Lekarz pracujący na ITN

☐ Pielęgniarka neonatologiczna / Położna

☐ Studentem medycyny/farmacji

Jeśli nie spełniają Państwo wymagań kryterium, nie mogą Państwo wziąć udziału w badaniu. Bardzo dziękuję Państwu za poświęcony czas.

POTWIERDZENIE

Ja _____ zgadzam się na udział w projekcie badawczym "*Opieka farmaceutyczna w ITN w Polsce: perspektywy farmaceutów, lekarzy, pielęgniarek i studentów medycyny/farmacji*" *(UTS HREC REF NO. ETH16-1033, GUMed HREC NO. NKBBN/424/2016)* prowadzony przez Natalię Krzyżaniak, University of Technology Sydney w ramach swojego doktoratu.

Badania te nie otrzymały pomocy finansowej.

Rozumiem, że celem tego badania jest określenie postawy, poglądów i oczekiwań farmaceutów, jak również innych pracowników służby zdrowia oraz studentów medycyny i farmacji wobec roli farmaceuty w ww. ITN w szpitalach w Polsce.

Rozumiem, że mój udział w tym badaniu będzie wymagało wypełnienie kwestionariusza i nie powinno trwać dłużej niż 15 minut.

Rozumiem, że mogę się skontaktować z Natalia Krzyżaniak lub jej promotorka A/Profesor Dr Beata Bajorek lub promotorem pomocniczym Dr Iga Pawłowska, jeśli mam jakiekolwiek wątpliwości do badań.

Rozumiem ze udział w badaniu jest dobrowolny. Rozumiem ze mam prawo do wyrażenia sprzeciwu wobec udziału w badaniu lub wycofania się z uczestnictwa na każdym jego etapie.

Zgadzam się, że dane badawcze zgromadzone w ramach tego projektu mogą być opublikowane w formie, która nie identyfikuje mnie w żaden sposób.

_____ ____/____/____

Podpis (uczestnik)

_____ ____/____/____

Podpis (badacz)

APPENDIX E – DATA COLLECTION FORMS FOR PAPER 2, PAPER 3, AND PAPER 4, CHAPTERS 3 AND 4

PROJECT TITLE: PHARMACEUTICAL CARE IN AUSTRALIA AND POLAND: PERSPECTIVES OF PHARMACISTS, DOCTORS, NURSES AND MEDICAL STUDENTS

E.1 QUESTIONNAIRE PAPER 2 (ENGLISH)

E.2 QUESTIONNAIRE PAPER 2 (POLISH)

E.3 QUESTIONNAIRE PAPER 3 (ENGLISH)

E.4 QUESTIONNAIRE PAPER 3 (POLISH)

E.5 QUESTIONNAIRE PAPER 4 (ENGLISH)

E.6 QUESTIONNAIRE PAPER 4 (POLISH)

E.1 QUESTIONNAIRE PAPER 2 (ENGLISH)

Participant Code: _ _ / _ _ / _ _

PHARMACEUTICAL CARE IN NICUS IN AUSTRALIA AND POLAND:

HOSPITAL PHARMACISTS PERSPECTIVES

- PHARMACIST SURVEY -

RESEARCHERS:

Natalia Krzyzaniak

A/Prof Beata Bajorek

Dr Iga Pawłowska

CONFIDENTIAL

Dear Participant,

Thank you for taking the time to complete this survey. To gather information on pharmacist practice in the NICU, you are asked to complete the following questionnaire. Please answer all questions to the best of your knowledge; there is a section at the end of the survey to add any additional comments.

Please insert a (x) in the corresponding box that most appropriately reflects your response.

DEMOGRAPHIC INFORMATION - Please tell us about your practice background and setting:	
1. Gender	☐$_1$ Female ☐$_2$ Male
2. Country of practice	☐$_1$ Australia ☐$_2$ Poland
3. What is the highest pharmacy qualification that you currently hold?	☐$_1$ Diploma ☐$_2$ Bachelor's Degree ☐$_3$ Master's Degree ☐$_4$ PhD ☐$_5$ Other – please specify ……
4. Do you hold any specialised qualifications related to NICU/paediatric pharmacy?	☐$_1$ Yes , please specify:…….. ☐$_2$ No
5. What is your current occupation/position within the hospital?	☐$_1$ NICU pharmacist ☐$_2$ Director of Pharmacy ☐$_3$ Pharmacist working in the main hospital pharmacy ☐$_4$ Other – please specify: ……
6. How many years have you been working in this position?	☐$_1$ Less than 1 year ☐$_2$ Between 1 and 5 years ☐$_3$ Between 6 and 10 years ☐$_4$ Over 10 years

HOSPITAL AND NICU CHARACTERISTICS **We would like to know some information about the NICU at the hospital you work in. Can you please provide us with answers to the following:**	
7. What is the number of beds available in your NICU?	……..
8. What is the type of NICU that you work in/is available at your hospital?	☐$_1$ **Level 1** – Normal low-risk pregnancies and births and management of babies ≥37+0 weeks gestation with minimal complications ☐$_2$ **Level 2A** – Low to moderate risk pregnancies and births and management of babies ≥34+0 weeks gestation with minimal neonatal complications ☐$_3$ **Level 2B** – Moderate to high-risk pregnancies and births and management of babies ≥32+0 weeks gestation with minimal complications ☐$_4$ **Level 3 (NICU)** – High-risk, high dependency pregnancies and births. Management of babies < 32+0 weeks gestation ☐$_5$ **Other** – please specify ……[149]

9. ATTITUDES TOWARDS THE PROVISION OF PHARMACEUTICAL SERVICES IN THE NICU

Please indicate your agreement/disagreement with the following statements about pharmaceutical care services in the NICU:

Items	AGREE$_1$	DISAGREE$_2$
Pharmacists should perform pharmaceutical care services directly on the NICU	☐	☐
Pharmaceutical care services are beneficial for NICU patient outcomes	☐	☐
The performance of pharmaceutical care services is important for integration into the NICU therapeutic team	☐	☐
Pharmaceutical care services are essential for the quality use of medicines in the NICU	☐	☐
The primary responsibility of pharmacists working in the NICU should be to practice pharmaceutical care	☐	☐
Pharmaceutical care services improve medication safety in the NICU	☐	☐
Pharmacists are essential members of the therapeutic team in the NICU	☐	☐
The pharmacist is responsible for pharmacotherapy outcomes in the NICU	☐	☐
Pharmaceutical care services are unnecessary in the NICU	☐	☐
Pharmaceutical care services can be performed by doctors and nurses in the NICU	☐	☐
The pharmacist's role should be exclusive to dispensing and supplying medicines	☐	☐
Doctors and nurses do not support the pharmacists pharmaceutical care role in the NICU	☐	☐

Pharmaceutical care services have no effect on patient outcomes or on medication management in the NICU	☐	☐
Pharmaceutical care in the NICU is not worth the additional workload it places on the pharmacist and takes too much time and effort	☐	☐
Pharmacotherapy based outcomes are ultimately achieved by the doctor as they prescribe drug therapy	☐	☐

Definitions:

[7]**Pharmaceutical care/services:**

"Pharmaceutical care is a philosophy of practice in which the patient is the primary beneficiary of the pharmacist's actions. Pharmaceutical care focuses the attitudes, behaviours, commitments, concerns, ethics, functions, knowledge, responsibilities and skills of the pharmacist on the provision of drug therapy with the goal of achieving definite therapeutic outcomes toward patient health and quality of life."[1, 2]

Quality use of medicines:

''Selecting management options wisely, choosing suitable medicines if a medicine is considered necessary so that the best available option is selected and using medicines safely and effectively to get the best possible results.''[3, 4, 5]

[7] [1] Hepler, CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. Am J. Hosp Pharm, 1990; 47: 533-543.
[2] Commission to Implement Change in Pharmaceutical Education. A position paper Entry-level Education in Pharmacy: A Commitment to Change. American Association of Colleges of Pharmacy News. Special Report. Alexandria VA 1991
[3] The National Strategy for Quality Use of Medicines. Australian Government Department of Health; 2004.
[4] Quality Use of Medicines & the medicines industry. Medicines Australia. http://medicinesaustralia.com.au/files/2012/05/MA_QUM_External_Reduced.pdf. Accessed 22 Sept 2015.
[5] Quality Use of Medicines (QUM). Department of Health, Australian Government. http://www.health.gov.au/internet/main/publishing.nsf/content/nmp-quality.htm. Accessed 05 Oct 2015.

10. PERCEPTIONS OF THE COMPETENCE/PREPAREDNESS OF PHARMACISTS TO PROVIDE PHARMACEUTICAL CARE IN THE NICU

Please identify your/pharmacists level of preparedness to perform each of the following pharmaceutical care services/roles in the NICU in your hospital:

Pharmacist Services/Roles	**GOOD$_1$**	**AVERAGE$_2$**	**POOR$_3$**
ADMINISTRATION/MANAGEMENT			
Development/implementation of a drug formulary service	☐	☐	☐
Attendance at non-clinical meetings i.e. Drug and Therapeutics Committee	☐	☐	☐
Conducting quality assurance measures i.e. drug usage evaluations, workload documentation, auditing	☐	☐	☐
Management of the drug budget	☐	☐	☐
Evaluation, selection and purchasing of pharmaceuticals for the unit	☐	☐	☐
Development of drug policies/protocols/guidelines for the NICU	☐	☐	☐
CLINICAL ROLES			
Patient medication chart review	☐	☐	☐
Participation in medical ward rounds	☐	☐	☐
Monitoring side-effects and the efficacy of pharmacotherapy in patients	☐	☐	☐
Documenting/monitoring Adverse Drug Events/Reactions	☐	☐	☐
Documenting Medication Errors	☐	☐	☐
Evaluating patients clinical laboratory tests	☐	☐	☐
Therapeutic Drug Monitoring (TDM)	☐	☐	☐
Immunisations	☐	☐	☐
Prescribing/monitoring Total Parenteral Nutrition (TPN)	☐	☐	☐
Participation in clinical meetings	☐	☐	☐
Calculating and recommending doses and dosing schedules for specific patients	☐	☐	☐

Assisting doctors in prescribing off-label/unlicensed medicines	☐	☐	☐
Identifying and performing interventions for individual patients to prevent or resolve drug therapy problems i.e. interactions, incompatibilities, allergies etc.	☐	☐	☐
Recommending drugs and contributing to the pharmacotherapy decision making process for specific patients	☐	☐	☐
Collaborating and discussing specific patients with doctors and nurses	☐	☐	☐
EDUCATION/COMMUNICATION/RESEARCH			
Providing training/in-services for other health professionals on NICU related topics and drug related problems	☐	☐	☐
Contributing to and/or attending NICU related conferences	☐	☐	☐
Involved in clinical trials	☐	☐	☐
Involved in research related to neonatal pharmacotherapy	☐	☐	☐
Source of drug information - responding to information requests from health professionals on the ward	☐	☐	☐
Counselling parents/carers of neonatal patients	☐	☐	☐
PROVISION OF MEDICINES			
Dispensing prescriptions	☐	☐	☐
Extemporaneous compounding of formulations for the NICU	☐	☐	☐
Stocking the ward with essential medicines/house-keeping activities i.e. checking expiry dates, fridge temperatures etc.	☐	☐	☐

11. OPINIONS ABOUT THE BARRIERS TO THE PROVISION OF A PHARMACEUTICAL CARE SERVICE IN THE NICU

Please indicate whether you agree or disagree about the perceived barriers to the implementation of pharmaceutical care in NICUs in your country

Barriers	AGREE$_1$	DISAGREE$_2$
Lack of policy/legislation for pharmacists to be regulated to perform services in the NICU	☐	☐
Lack of pharmacist time to perform duties	☐	☐
Lack of pharmacy staff i.e. not enough pharmacy technicians to cover dispensing	☐	☐
Lack of demand/necessity for pharmacist to be on NICU	☐	☐
Doctor/nurse resistance to pharmacist role in the NICU	☐	☐
Lack of financial compensation/remuneration for pharmacists to perform activities on the NICU	☐	☐
Pharmacist is physically removed from the NICU	☐	☐
Lack of clinical pharmacy training/knowledge related to neonatal practice	☐	☐
Not interested in performing clinical pharmacy services in the NICU	☐	☐
Unwilling to change current practice	☐	☐
Lack of communication between doctors/nurses and pharmacists	☐	☐
Lack of support from administration/hospital	☐	☐
Lack of confidence in own ability	☐	☐
Lack of pharmacists with the necessary	☐	☐

skills and training		
Lack of recognition of the contribution of the pharmacist to NICU care	☐	☐

Other: …….

…….

…….

…….

…….

12. OPINIONS RELATING TO THE NEED FOR CHANGE TO PHARMACEUTICAL CARE SERVICES IN THE NICU

Please indicate your perceived opinion on the need for change relating to pharmacist practice in the NICU

	YES$_1$	**NO$_2$**
Is there a need to change pharmacist roles within NICU?	☐	☐
Please comment why you think so, and if yes, what types of changes you would like to see i.e. more pharmacist participation in wards rounds etc.	……..…… ……..…… ……..…… ……..…… ……..…… ……..……	

13. If yes, what types of changes would improve current pharmaceutical care services in the NICU?

CHANGES	YES$_1$	NO$_2$
Administrative support from the hospital i.e. from directors	☐	☐
Increased levels of staffing in the pharmacy	☐	☐
More support from other health professionals i.e. doctors/nurses	☐	☐
Increasing educational opportunities related specifically to neonatal/paediatric pharmacotherapy	☐	☐
Providing more training for clinical pharmacy services	☐	☐
Increasing pharmacist salaries	☐	☐
Creating specific NICU clinical pharmacist positions in the hospital i.e. organisational changes	☐	☐
Legislative changes regulating clinical pharmacy practice in the NICU	☐	☐
Pharmacists own motivation and interest towards improving upon the current level of practice	☐	☐

Additional Comments:

……

……

……

……

……

E.2 QUESTIONNAIRE PAPER 2 (POLISH)

- ANKIETA DLA FARMACEUTOW -

INFORMACJE DOTYCZĄCE RESPONDENTÓW	
1. Płeć:	☐$_1$ Kobieta ☐$_2$ Mężczyzna
2. Obywatelstwo	☐$_1$ Inne ☐$_2$ Polskie
3. Wykształcenie	☐$_1$ Magister ☐$_2$ Doktor ☐$_3$ Profesor
4. Dodatkowe kwalifikacje dotyczące sprawowania opieki farmaceutycznej nad noworodkami/ dziećmi	☐$_1$ Tak, jakie?..... ☐$_2$ Nie
5. Miejsce pracy/stanowisko	☐$_1$ Farmaceuta pracujący w oddziale intensywnej terapii noworodka (ITN) ☐$_2$ Kierownik apteki szpitalnej ☐$_3$ Farmaceuta pracujący w aptece szpitalnej ☐$_4$ Inne – proszę podać: …… ……
6. Doświadczenie na tym stanowisku	☐$_1$ < 1 ☐$_2$ 1 - 5 lat ☐$_3$ 6 - 10 lat ☐$_4$ > 10 lat

INFORMACJE O SZPITALU I ODDZIALE INTENSYWNEJ TERAPII NOWORODKA (ITN)	
7. Liczba łóżek w ITN:	……
8. Rodzaj ITN:	☐$_1$ **Poziom 1** – Normalne ciąże niskiego ryzyka i porody i zarządzanie dzieci ≥37 + 0 tygodnia ciąży z minimalnymi powikłaniami ☐$_2$ **Poziom 2A** – Opieka specjalna: Niski do umiarkowanego ryzyka dla ciąży i narodzin i zarządzanie dzieci ≥34 + 0 tygodnia ciąży z minimalnymi powikłaniami noworodków ☐$_3$ **Poziom 2B** – Umiarkowane do ciąż wysokiego ryzyka i urodzeń oraz zarządzanie dzieci ≥32 + 0 tygodnia ciąży z minimalnymi powikłaniami ☐$_4$ **Poziom 3** – wysokiego ryzyka ciąż wysokiego uzależnienia i porody. Zarządzanie dzieci <32 + 0 tygodnia ciąży ☐$_5$ **Inna** – proszę określić [149]

9. OPINIA DOTYCZĄCA WYKONYWANIA USŁUG FARMACEUTYCZNYCH DLA ODDZIAŁÓW INTENSYWNEJ TERAPII NOWORODKA

Proszę zaznaczyć właściwą odpowiedź

	TAK$_1$	**NIE**$_2$
Farmaceuci powinni wykonywać usługi farmaceutyczne bezpośrednio na oddziale ITN	☐	☐
Opieka farmaceutyczna lub usługi farmaceutyczne mają korzystny wpływ na efekty leczenia pacjenta	☐	☐
Wykonywanie usług farmaceutycznych na oddziale ITN jest istotne dla zespołu terapeutycznego	☐	☐
Usługi farmaceutyce są niezbędne dla prawidłowego stosowania leków w ITN	☐	☐
Podstawowym obowiązkiem farmaceutów pracujących w ITN powinno być wykonywanie usług farmaceutycznych	☐	☐
Usługi farmaceutyczne zwiększają bezpieczeństwo stosowania leków na oddziałach ITN	☐	☐
Farmaceuci są członkami zespołu terapeutycznego w intensywnej terapii	☐	☐
Farmaceuci są odpowiedzialni za efekty farmakoterapii u noworodków	☐	☐
Usługi farmaceutyczne są niepotrzebne w ITN	☐	☐
Opieka farmaceutyczna lub jej elementy mogą być wykonywane przez lekarzy, położne i pielęgniarki w ITN	☐	☐
Zadania farmaceuty powinny obejmować wyłączenie zaopatrywanie w leki i inne materiały medyczne	☐	☐
Lekarze, położne i pielęgniarki nie popierają opieki farmaceutycznej w ITN	☐	☐

Opieka farmaceutyczna nie ma wpływu na wyniki leczenia pacjentów lub gospodarka lekową w ITN	☐	☐
Wykonywanie opieki farmaceutycznej w ITN wiąże się z dodatkowym obciążeniem farmaceuty i zajmuje zbyt dużo czasu i wysiłku	☐	☐
Tylko lekarz jest odpowiedzialny za wynik farmakoterapeutyczny pacjenta, ponieważ to on zleca odpowiednią farmakoterapię	☐	☐

Definicja:

Usługi/Opieka Farmaceutyczna:

Usługa farmaceutyczna polegająca na dokumentowanym procesie, w którym farmaceuta, współpracując z pacjentem i lekarzem, a w razie potrzeby z przedstawicielami innych zawodów medycznych, czuwa nad prawidłowym przebiegiem farmakoterapii w celu uzyskania określonych jej efektów poprawiających jakość życia pacjenta.

10. GOTOWOŚĆ i PRZYGOTOWANIE FARMACEUTÓW DO ŚWIADCZENIA USŁUG NA ODDZIAŁACH ITN - Proszę zaznaczyć właściwą odpowiedź w tabeli

Role/Usługi Farmaceutyczne	**DOBRY**$_1$	**SREDNI**$_2$	**SLABY**$_3$
USŁUGI ADMINISTRACYJNE			
Opracowanie / wdrożenie receptariusza	☐	☐	☐
Uczęszczanie w nieklinicznych spotkaniach np. posiedzeniach komitetu terapeutycznego szpitala	☐	☐	☐
Prowadzenie badań jakości farmakoterapii np. ocena stosowanych leków	☐	☐	☐
Zarządzanie budżetem do zakupu leków	☐	☐	☐
Zamawianie leków dla ITN	☐	☐	☐
Opracowanie protokołów dla leków ITN	☐	☐	☐
USŁUGI KLINICZNE			
Przeprowadzanie przeglądu leków dla pacjentów	☐	☐	☐
Udział farmaceuty w obchodzie w ITN	☐	☐	☐
Monitorowanie skuteczności leków u pacjenta	☐	☐	☐
Dokumentowanie/monitorowanie oraz zgłaszanie działań niepożądanych leków	☐	☐	☐
Dokumentowanie błędów lekowych (Medication Errors)	☐	☐	☐
Analiza wyników badan pacjenta np. badania krwi, badanie mykologiczne	☐	☐	☐
Monitorowanie farmakoterapii	☐	☐	☐
Współudział w szczepieniach	☐	☐	☐
Współudział w żywieniu pozajelitowym	☐	☐	☐
Udział w klinicznych spotkaniach z lekarzem, pielęgniarką, rodzina pacjenta	☐	☐	☐
Obliczanie i zalecanie dawek i schematów dawkowania dla wybranych pacjentów	☐	☐	☐
Wspieranie lekarzy w stosowaniu leków poza wskazaniami medycznymi (off label use)	☐	☐	☐
Identyfikacja problemów lekowych oraz prowadzenie interwencji dla poszczególnych pacjentów w celu zapobiegania lub rozwiązywania tych problemów	☐	☐	☐

(np. interakcje, niezgodności, alergie)			
Współudział w wyborze właściwej farmakoterapii dla pacjentów	☐	☐	☐
Doradztwo prowadzone dla lekarzy, położnych i pielęgniarek w zakresie farmakoterapii pacjentów	☐	☐	☐
EDUKACJA/KOMUNIKACJA/BADANIA			
Prowadzenie szkoleń dla lekarzy/położnych/pielęgniarek dotyczących farmakoterapii noworodków	☐	☐	☐
Uczestnictwo w konferencja naukowych dotyczących INT	☐	☐	☐
Współuczestniczenie w badaniach klinicznych leków	☐	☐	☐
Współuczestniczenie w badaniach naukowych dotyczących farmakoterapii u noworodków	☐	☐	☐
Udzielanie informacji personelowi medycznemu	☐	☐	☐
Edukacja rodzin oraz opiekunów noworodków	☐	☐	☐
ZAOPATRYWANIE W LEKI			
Wydawanie leków i materiałów medycznych na oddział INT	☐	☐	☐
Wykonywanie leków recepturowych dla pacjentów w ITN	☐	☐	☐
Kontrola właściwego przechowywania leków na oddziale/dat ważności leków/leków wstrzymanych i wycofanych z obrotu	☐	☐	☐

11. OPINIE NA TEMAT BARRIER W WYKONYWANIU OPIEKI FARMACEUTYCZNEJ NA ODDZIAŁACH ITN

Proszę zaznaczyć swoją opinię dotyczącą barier w sprawowaniu opieki farmaceutycznej na oddziałach ITN

BARIERY	**ZGADZAM SIE$_1$**	**NIE ZGADZAM SIE$_2$**
Brak legislacji prawnych dotyczących wykonywania usług w ITN	☐	☐
Brak czasu ze strony farmaceuty	☐	☐
Niewystarczająca liczba zatrudnionych farmaceutów w szpitalu	☐	☐
Brak uzasadnienia dla zaangażowania farmaceuty w ITN	☐	☐
Niechęć za strony lekarzy/pielęgniarek do zaangażowania farmaceuty w ITN	☐	☐
Brak wynagrodzenia dla farmaceutów za wykonywanie usług w ITN	☐	☐
Apteka szpitalna, w której pracuje farmaceuta znajduje się w dalekiej odległości od oddziału ITN	☐	☐
Niewystarczające przygotowanie farmaceutów do pracy na oddziale ITN	☐	☐
Brak zainteresowanie ze strony farmaceuty pracą w ITN	☐	☐
Brak chęci do zmian ze strony farmaceuty	☐	☐
Brak komunikacji między lekarzami/położnymi pielęgniarkami i farmaceutami	☐	☐
Brak wsparcia ze strony administracji / szpitala	☐	☐
Brak zaufania do własnych umiejętności	☐	☐
Brak farmaceutów z wymaganymi kwalifikacjami	☐	☐
Brak dowodów na pozytywny wpływ farmaceutów na poprawę jakości opieki farmakoterapeutycznej na oddziałach ITN	☐	☐

Inne: ……

……

12. OPINIE DOTYCZĄCE ZMIAN, KTÓRE NALEŻOŁOBY WPROWADZIĆ W ITN

	TAK$_1$	**NIE**$_2$
Czy istnieje potrzeba zmian dotyczących roli farmaceuty w ITN?	☐	☐
Proszę o komentarz, dlaczego tak myślisz	……..…… ……..…… ……..…… ……..…… ……..…… ……..…… ……..…… ……..…… ……..……	

13. Jeśli tak, jakie zmiany mogą poprawić sprawowanie usług farmaceutycznych (w tym opieki farmaceutycznej) na oddziałach ITN

ZMIANY	TAK[1]	NIE[2]
Wsparcie administracyjne ze strony dyrektora szpitala	☐	☐
Zwiększone zatrudnienie personelu fachowego w aptece	☐	☐
Większe wsparcie od innych pracowników służby zdrowia (lekarzy, położnych, pielęgniarek)	☐	☐
Zwiększanie dostępności kształcenia dla farmaceutów dotyczącego farmakoterapia u noworodków lub stosowania leków u dzieci	☐	☐
Zapewnienie większej liczby szkoleń dotyczących klinicznych usług farmaceutycznych	☐	☐
Zwiększenie wynagrodzenia dla farmaceuty	☐	☐
Stworzenie konkretnych miejsc pracy do wykonywania usług farmaceutycznych dla farmaceutów klinicznych na oddziałach ITN	☐	☐
Zmiany legislacyjne regulujące wykonywanie usług farmaceutycznych w ITN	☐	☐
Zwiększenie zainteresowania farmaceutów i motywacji do pracy na oddziałach ITN	☐	☐

DODATKOWE KOMENTARZE:

……

……

……

……

E.3 QUESTIONNAIRE PAPER 3 (ENGLISH)

Participant Code: _ _ / _ _ / _ _

PHARMACEUTICAL CARE IN AUSTRALIA AND POLAND: PERSPECTIVES OF PHARMACISTS, DOCTORS, NURSES AND MEDICAL STUDENTS

- NURSES AND DOCTORS SURVEY -

RESEARCHERS:

Natalia Krzyzaniak

A/Prof Beata Bajorek

Dr Iga Pawłowska

CONFIDENTIAL

Dear Participant,

Thank you for taking the time to complete this survey. To gather information on pharmacist practice in the NICU, you are asked to complete the following questionnaire. Please answer all questions to the best of your knowledge; there is a section at the end of the survey to add any additional comments.

Please insert a (x) in the corresponding box that most appropriately reflects your response.

DEMOGRAPHIC INFORMATION: Please tell us about your practice background and setting:	
1. Gender	☐$_1$ Female ☐$_2$ Male
2. Country of practice	☐$_1$ Australia ☐$_2$ Poland
3. What is the highest pharmacy qualification that you currently hold?	☐$_1$ Diploma ☐$_2$ Bachelor's Degree ☐$_3$ Master's Degree ☐$_4$ PhD ☐$_5$ Other – please specify ……
4. Do you hold any specialised qualifications related to NICU/paediatric practice?	☐$_1$ Yes ☐$_2$ No
5. What is your current occupation/position within the hospital?	☐$_1$ NICU Nurse/Midwife (including nursing students) ☐$_2$ NICU Nurse Unit Manager ☐$_3$ Neonatologist ☐$_4$ Doctor working on the NICU ☐$_5$ Other – please specify:……..
6. How many years have you been working in this position?	☐$_1$ Less than 1 year ☐$_2$ Between 1 and 5 years ☐$_3$ Between 6 and 10 years ☐$_4$ Over 10 years

HOSPITAL AND NICU CHARACTERISTICS **We would like to know some information about the NICU at the hospital you work in. Can you please provide us with answers to the following:**	
7. What is the number of beds available in your NICU?	…….. ..
8. What is the type of NICU that you work in/is available at your hospital?	☐$_1$ **Level 1** – Normal low-risk pregnancies and births and management of babies ≥37+0 weeks gestation with minimal complications ☐$_2$ **Level 2A** – Low to moderate risk pregnancies and births and management of babies ≥34+0 weeks gestation with minimal neonatal complications ☐$_3$ **Level 2B** – Moderate to high-risk pregnancies and births and management of babies ≥32+0 weeks gestation with minimal complications ☐$_4$ **Level 3 (NICU)** – High-risk, high dependency pregnancies and births. Management of babies < 32+0 weeks gestation ☐$_5$ **Other** – please specify ..... [149]

9. ATTITUDES TOWARDS THE PROVISION OF PHARMACEUTICAL SERVICES IN THE NICU

Please indicate your agreement/disagreement with the following statements about the pharmacists role and pharmaceutical care services in the NICU:

Items	AGREE$_1$	DISAGREE$_2$
Pharmacists should perform pharmaceutical care services directly on the NICU	☐	☐
Pharmaceutical care services are beneficial for NICU patient outcomes	☐	☐
The performance of pharmaceutical care services is important for integration into the NICU therapeutic team	☐	☐
Pharmaceutical care services are essential for the quality use of medicines in the NICU	☐	☐
The primary responsibility of pharmacists working in the NICU should be to practice pharmaceutical care	☐	☐
Pharmaceutical care services improve medication safety in the NICU	☐	☐
Pharmacists are essential members of the therapeutic team	☐	☐
Pharmacists are responsible for pharmacotherapy outcomes for neonatal patients	☐	☐
The performance of pharmaceutical care services by a pharmacist on the NICU is unnecessary	☐	☐
Pharmaceutical care services can be performed by doctors and nurses in the NICU	☐	☐
The pharmacists role should be exclusively related to ordering, dispensing and supplying medicines	☐	☐
Pharmacists are not needed in therapeutic decision-making related to patients in the NICU	☐	☐

Pharmaceutical care services do not have any impact on patient outcomes or medication management in the NICU	☐	☐
Pharmaceutical care in the NICU is not worth the additional workload it places on the pharmacist and takes too much time and effort	☐	☐
Pharmacotherapy based outcomes are ultimately achieved by the doctor as they prescribe drug therapy	☐	☐

Definitions:

[8]**Pharmaceutical care/services:**

"Pharmaceutical care is a philosophy of practice in which the patient is the primary beneficiary of the pharmacist's actions. Pharmaceutical care focuses the attitudes, behaviours, commitments, concerns, ethics, functions, knowledge, responsibilities and skills of the pharmacist on the provision of drug therapy with the goal of achieving definite therapeutic outcomes toward patient health and quality of life."[1, 2]

Quality use of medicines:

''Selecting management options wisely, choosing suitable medicines if a medicine is considered necessary so that the best available option is selected and using medicines safely and effectively to get the best possible results.''[3, 4,5]

[8] [1] Hepler, CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. Am J. Hosp Pharm, 1990; 47: 533-543.
[2] Commission to Implement Change in Pharmaceutical Education. A position paper Entry-level Education in Pharmacy: A Commitment to Change. American Association of Colleges of Pharmacy News. Special Report. Alexandria VA 1991
[3] The National Strategy for Quality Use of Medicines. Australian Government Department of Health; 2004.
[4] Quality Use of Medicines & the medicines industry. Medicines Australia. http://medicinesaustralia.com.au/files/2012/05/MA_QUM_External_Reduced.pdf. Accessed 22 Sept 2015.
[5] Quality Use of Medicines (QUM). Department of Health, Australian Government. http://www.health.gov.au/internet/main/publishing.nsf/content/nmp-quality.htm. Accessed 05 Oct 2015.

ROLES CURRENTLY PERFORMED BY PHARMACISTS

10. Is there a pharmacist currently practising on the NICU you are working in?	☐$_1$ Yes ☐$_2$ No
11. What is the current level of interaction that you have with a pharmacist on the NICU?	☐$_1$ Regular ☐$_2$ Occasional ☐$_3$ Rare ☐$_4$ None ☐$_5$ Other – please specify: ……
12. If there is no pharmacist on the ward, what resources do you consult to make any medication related decisions?	☐$_1$ Books ☐$_2$ Medication Protocols ☐$_3$ Online resources ☐$_4$ Other staff members ☐$_5$ Main hospital pharmacy ☐$_6$ Use my own knowledge/experience
13. Do you believe that the pharmacist is meeting the current medication management needs of the NICU?	☐$_1$ Yes ☐$_2$ No
14. How would you rate current pharmaceutical care practice in the NICU?	☐$_1$ Good ☐$_2$ Average ☐$_3$ Poor

15. **BASED ON YOUR EXPERIENCE, WHAT ROLES ARE CURRENTLY PERFORMED BY PHARMACISTS IN THE NICU?**
16. **WHAT ROLES DO YOU PERCEIVE AS BEING ESSENTIAL AND YOU EXPECT TO BE PERFORMED BY PHARMACISTS IN THE NICU (Tick all that apply)?**

Pharmacist Services/Roles	**Yes – Performed** $_1$	**Not Performed**$_2$	**I expect to be performed**$_1$	**Not expected to be performed**$_2$
ADMINISTRATION/MANAGEMENT				
Development/implementation of a drug formulary service	☐	☐	☐	☐
Attendance at non-clinical meetings i.e. Drug and Therapeutics Committee	☐	☐	☐	☐
Conducting quality assurance measures i.e. drug usage evaluations, workload documentation, auditing	☐	☐	☐	☐
Management of the drug budget	☐	☐	☐	☐
Evaluation, selection and purchasing of pharmaceuticals for the unit	☐	☐	☐	☐
Development of drug policies/protocols/guidelines for the NICU	☐	☐	☐	☐
CLINICAL ROLES				
Patient medication chart review	☐	☐	☐	☐
Participation in medical ward rounds	☐	☐	☐	☐
Monitoring side-effects and the efficacy of pharmacotherapy in patients	☐	☐	☐	☐
Documenting/monitoring Adverse Drug Events/Reactions	☐	☐	☐	☐
Documenting Medication Errors	☐	☐	☐	☐

Evaluating patients clinical laboratory tests	☐	☐	☐	☐
Therapeutic Drug Monitoring (TDM)	☐	☐	☐	☐
Immunisations	☐	☐	☐	☐
Prescribing/monitoring Total Parenteral Nutrition (TPN)	☐	☐	☐	☐
Participation in clinical meetings	☐	☐	☐	☐
Calculating and recommending doses and dosing schedules for specific patients	☐	☐	☐	☐
Assisting doctors in prescribing off-label/unlicensed medicines	☐	☐	☐	☐
Identifying and performing interventions for individual patients to prevent or resolve drug therapy problems i.e. interactions, incompatibilities, allergies etc.	☐	☐	☐	☐
Recommending drugs and contributing to the pharmacotherapy decision making process for specific patients	☐	☐	☐	☐
Collaborating and discussing specific patients with doctors and nurses	☐	☐	☐	☐
EDUCATION/COMMUNICATION/RESEARCH				
Providing training/in-services for other health professionals on NICU related topics and drug related problems	☐	☐	☐	☐
Contributing to and/or attending NICU related conferences	☐	☐	☐	☐
Involved in clinical trials	☐	☐	☐	☐
Involved in research related to neonatal pharmacotherapy	☐	☐	☐	☐

Source of drug information - responding to information requests from health professionals on the ward	☐	☐	☐	☐
Counselling parents/carers of neonatal patients	☐	☐	☐	☐
PROVISION OF MEDICINES				
Dispensing prescriptions	☐	☐	☐	☐
Extemporaneous compounding of formulations for the NICU	☐	☐	☐	☐
Stocking the ward with essential medicines/house-keeping activities i.e. checking expiry dates, fridge temperatures etc.	☐	☐	☐	☐

INTERPROFESSIONAL RELATIONSHIP WITH THE PHARMACIST

17. Do you think that the pharmacist should be consulted as part of the multidisciplinary treating team when making medication-related decisions for NICU patients?	☐$_1$ Yes ☐$_2$ No
18. In your opinion is there a need for a pharmacist to be stationed permanently or routinely visiting the NICU?	☐$_1$ Yes – routinely visiting ☐$_2$ Yes – permanently stationed ☐$_3$ No
19. How would you rate current inter-professional relationship/collaboration with the pharmacist?	☐$_1$ Good ☐$_2$ Average ☐$_3$ Poor ☐$_4$ Non-existent

20. Why do you think that the current inter-professional relationship with the pharmacist in the NICU is excellent/good/average/non-existent?

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21. OPINIONS ABOUT THE BARRIERS TO THE PROVISION OF A PHARMACEUTICAL CARE SERVICE IN THE NICU

Please indicate whether you agree or disagree about the perceived barriers that are apparent in the provision of pharmaceutical care in the NICU in your country

Barriers	**AGREE$_1$**	**DISAGREE$_2$**
Lack of policy/legislation for pharmacists to be regulated to perform services in the NICU	☐	☐
Lack of pharmacist time to perform duties	☐	☐
Lack of pharmacy staff i.e. not enough pharmacy technicians to cover dispensing	☐	☐
There is no need for pharmacist to be on NICU	☐	☐
I am unsure what services a pharmacists can provide in the NICU	☐	☐
Lack of financial compensation/remuneration for pharmacists to perform activities on the NICU	☐	☐
Pharmacist is physically removed from the NICU	☐	☐
Lack of clinical pharmacy training/knowledge related to neonatal practice	☐	☐
Pharmacists are not interested in performing	☐	☐

clinical pharmacy services in the NICU		
Unwilling to change current practice	☐	☐
Lack of communication with pharmacists	☐	☐
Lack of support from administration/hospital	☐	☐
Pharmacists do not have the skills necessary to practice on the NICU	☐	☐
Lack of pharmacists with the necessary skills and training	☐	☐

Other: ……

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22. OPINIONS RELATING TO THE NEED FOR CHANGE TO PHARMACEUTICAL CARE SERVICES IN THE NICU

Please indicate your perceived opinion on the need for change relating to pharmacist practice in the NICU

	YES$_1$	**NO$_2$**
Is there a need to change pharmacist roles within NICU?	☐	☐
Please comment why you think so, and if yes, what types of changes you would like to see i.e. more pharmacist participation in wards rounds etc.	……..…… ……..…… ……..…… ……..…… ……..…… ……..……	

23. If yes, what types of changes would improve current pharmaceutical care services in the NICU?

CHANGES	**YES$_1$**	**NO$_2$**
Administrative support from the hospital i.e. from directors	☐	☐
Increased levels of staffing in the pharmacy	☐	☐
Increased levels of communication with pharmacists	☐	☐
Increasing pharmacist training related specifically to neonatal/paediatric pharmacotherapy	☐	☐
Increasing nurse/doctor awareness of the roles and services pharmacists can provide in the NICU	☐	☐
Increasing pharmacist salaries	☐	☐

Creating specific NICU clinical pharmacist positions in the hospital i.e. organisational changes		
Legislative changes regulating clinical pharmacy practice in the NICU	☐	☐
Pharmacists own motivation and interest towards improving upon the current level of practice	☐	☐

Additional Comments:

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E.4 QUESTIONNAIRE PAPER 3 (POLISH)

OPIEKA FARMACEUTYCZNA W ITN W POLSCE: Z PERSPEKTYWY FARMACEUTÓW, LEKARZY, PIELEGNIAREK I STUDENTÓW MEDYCYNY

Kod Uczestnika: _ _ / _ _ / _ _

Szanowni Państwo,

Zwracamy się z prośbą o wypełnienie kwestionariusza dotyczącego roli farmaceuty na oddziałach intensywnej terapii noworodka, które jest częścią projektu badawczego prowadzonego także w Australii. Badanie ma charakter anonimowy i jest prowadzone w celach naukowych przez zespół z University of Technology Sydney oraz Katedry i Zakładu Farmakologii GUMed (kontakt: Natalia Krzyżaniak, ul. Dębowa 23, 80-204 Gdańsk, tel. 583491812, e-mail: Natalia.krzyzaniak@student.uts.edu.au). Mają Państwo prawo do wyrażenia sprzeciwu wobec udziału w badaniu lub wycofania się z uczestnictwa na każdym jego etapie. Wypełnienie kwestionariusza zajmie Państwu około 15 minut czasu.

Dziękujemy Państwu za udział w badaniu!

- ANKIETA DLA LEKARZY I PIELEGNIAREK -

INFORMACJE DOTYCZĄCE RESPONDENTÓW	
1. Płeć:	☐$_1$ Kobieta ☐$_2$ Mężczyzna
2. Obywatelstwo	☐$_1$ Inne: ……. ☐$_2$ Polskie
3. Wykształcenie	☐$_1$ Licencjat ☐$_2$ Lekarz ☐$_3$ Magister ☐$_4$ Doktor ☐$_5$ Profesor
4. Dodatkowe kwalifikacje/specjalizacje dotyczące pracy na ITN	☐$_1$ Tak, jakie?..... …… ……
5. Wykonywany zawód	☐$_1$ Pielęgniarka /położna ☐$_2$ Położna ☐$_3$ Pielęgniarka oddziałowa na ITN ☐$_4$ Położna oddziałowa na ITN ☐$_5$ Neonatolog ☐$_6$ Lekarz pracujący na ITN ☐$_7$ Inne ……..
6. Doświadczenie na tym stanowisku	☐$_1$ < 1 rok ☐$_2$ 1 - 5 lat ☐$_3$ 6 - 10 lat ☐$_4$ > 10 lat

INFORMACJE O SZPITALU I ODDZIALE INTENSYWNEJ TERAPII NOWORODKA (ITN)	
7. Liczba łóżek w ITN:	……
8. Rodzaj ITN:	☐$_1$ **Poziom 1** – Normalne ciąże niskiego ryzyka i porody i zarządzanie dzieci ≥37 + 0 tygodnia ciąży z minimalnymi powikłaniami ☐$_2$ **Poziom 2A** – Opieka specjalna: Niski do umiarkowanego ryzyka dla ciąży i narodzin i zarządzanie dzieci ≥34 + 0 tygodnia ciąży z minimalnymi powikłaniami noworodków ☐$_3$ **Poziom 2B** – Umiarkowane do ciąż wysokiego ryzyka i urodzeń oraz zarządzanie dzieci ≥32 + 0 tygodnia ciąży z minimalnymi powikłaniami ☐$_4$ **Poziom 3** – wysokiego ryzyka ciąż wysokiego uzależnienia i porody. Zarządzanie dzieci <32 + 0 tygodnia ciąży ☐$_5$ **Inna** – proszę określić : ……[149]

9. Opinie dotyczące usług farmaceutycznych na oddziałach ITN

Proszę uzupełnić tabelę zgodnie z Pani/Pana opinią

TWIERDZENIE	ZGADZAM SIE$_1$	NIE ZGADZAM SIE$_2$
Farmaceuci powinni wykonywać usługi farmaceutyczne bezpośrednio na oddziale ITN	☐	☐
Opieka farmaceutyczna lub usługi farmaceutyczne mają korzystny wpływ na efekty leczenia pacjenta	☐	☐
Wykonywanie usług farmaceutycznych na oddziale ITN jest istotne dla zespołu terapeutycznego	☐	☐
Usługi farmaceutyce są niezbędne dla prawidłowego stosowania leków w ITN	☐	☐
Podstawowym obowiązkiem farmaceutów pracujących w ITN powinno być wykonywanie usług farmaceutycznych	☐	☐
Usługi farmaceutyczne zwiększają bezpieczeństwo stosowania leków na oddziałach ITN	☐	☐
Farmaceuci są członkami zespołu terapeutycznego w intensywnej terapii	☐	☐
Farmaceuci są odpowiedzialni za efekty farmakoterapii u noworodków	☐	☐
Usługi farmaceutyczne są niepotrzebne w ITN	☐	☐
Opieka farmaceutyczna lub jej elementy mogą być wykonywane przez lekarzy, położne i pielęgniarki w ITN	☐	☐
Zadania farmaceuty powinny obejmować wyłączenie zaopatrywanie w leki i inne materiały medyczne	☐	☐

Lekarze, położne i pielęgniarki nie popierają opieki farmaceutycznej w ITN	☐	☐
Opieka farmaceutyczna nie ma wpływu na wyniki leczenia pacjentów lub gospodarka lekową w ITN	☐	☐
Wykonywanie opieki farmaceutycznej w ITN wiąże się z dodatkowym obciążeniem farmaceuty i zajmuje zbyt dużo czasu i wysiłku	☐	☐
Tylko lekarz jest odpowiedzialny za wynik farmakoterapeutyczny pacjenta, ponieważ to on zleca odpowiednią farmakoterapię	☐	☐

Definicja:

Usługi/Opieka Farmaceutyczna:

Usługa farmaceutyczna polegająca na dokumentowanym procesie, w którym farmaceuta, współpracując z pacjentem i lekarzem, a w razie potrzeby z przedstawicielami innych zawodów medycznych, czuwa nad prawidłowym przebiegiem farmakoterapii w celu uzyskania określonych jej efektów poprawiających jakość życia pacjenta.

OBECNY UDZIAŁ FARMACEUTY NA ODDZIAŁACH ITN

10. Czy farmaceuta obecnie praktykuje w oddziale ITN na którym pracujesz?	☐$_1$ Tak ☐$_2$ Nie
11. Jakie jest obecna współpraca/kontakt z farmaceutą na ITN?	☐$_1$ Regularny ☐$_2$ Częsty ☐$_3$ Rzadki ☐$_4$ Okazjonalny ☐$_5$ Żaden ☐$_6$ Inny – proszę określić: ……
12. Jeśli nie ma bezpośredniej współpracy z farmaceuty na oddziale ITN, z jakich innych środków korzystasz przy podejmowaniu decyzji farmakoterapeutycznych?	☐$_1$ Podręczniki ☐$_2$ Charakterystyka produktu leczniczego ulotka dołączona do leku ☐$_3$ Zasoby internetowe ☐$_4$ Inni pracownicy ☐$_5$ Apteka szpitalna (telefon) ☐$_6$ Używam własną wiedzę/doświadczenie
13. Czy uważasz, że farmaceuta spełnia aktualne potrzeby związane z zarzadzaniem leków na ITN?	☐$_1$ Tak ☐$_2$ Nie
14. Jak oceniasz obecną opiekę farmaceutyczna w ITN?	☐$_1$ Dobra ☐$_2$ Średnia ☐$_3$ Słaba ☐$_4$ Nie istnieje

15. KTÓRE USŁUGI FARMACEUTYCZNE LUB INNE CZYNNOŚCI FARMACEUTYSĄ OBECNIE WYKONYWANE NA ODDZIALE ITN?

16. KTÓRE USŁUGI FARMACEUTYCZNE LUB INNE CZYNNOŚCI FARMACEUTY POWINNY BYĆ WYKONYWANE NA ODDZILE ITN

(odpowiadając na te dwa pytania proszę uzupełnić tabelę)

Role/Usługi Farmaceutyczne	**Wykonywane** [1]	**Niewykonywane**[2]	**Niezbędne (potrzebne dla oddziału)** [1]	**Niepotrzebne**[2]
USŁUGI ADMINISTRACYJNE				
Opracowanie / wdrożenie receptariusza	☐	☐	☐	☐
Uczęszczanie w nieklinicznych spotkaniach np. posiedzeniach komitetu terapeutycznego szpitala	☐	☐	☐	☐
Prowadzenie badań jakości farmakoterapii np. ocena stosowanych leków	☐	☐	☐	☐
Zarządzanie budżetem do zakupu leków	☐	☐	☐	☐
Zamawianie leków dla ITN	☐	☐	☐	☐
Opracowanie protokołów dla leków ITN	☐	☐	☐	☐
USŁUGI KLINICZNE				
Przeprowadzanie przeglądu leków dla pacjentów	☐	☐	☐	☐
Udział farmaceuty w obchodzie w ITN	☐	☐	☐	☐
Monitorowanie skuteczności leków u pacjenta	☐	☐	☐	☐
Dokumentowanie/monitorowanie oraz zgłaszanie działań niepożądanych leków	☐	☐	☐	☐
Dokumentowanie błędów lekowych (Medication Errors)	☐	☐	☐	☐
Analiza wyników badan pacjenta np. badania krwi, badanie mykologiczne	☐	☐	☐	☐
Monitorowanie farmakoterapii	☐	☐	☐	☐
Współudział w szczepieniach	☐	☐	☐	☐

Współudział w żywieniu pozajelitowym	☐	☐	☐	☐
Udział w klinicznych spotkaniach z lekarzem, pielęgniarką, rodzina pacjenta itd.	☐	☐	☐	☐
Obliczanie i zalecanie dawek i schematów dawkowania dla wybranych pacjentów	☐	☐	☐	☐
Wspieranie lekarzy w stosowaniu leków poza wskazaniami medycznymi (off label use)	☐	☐	☐	☐
Identyfikacja problemów lekowych oraz prowadzenie interwencji dla poszczególnych pacjentów w celu zapobiegania lub rozwiązywania tych problemów (np. interakcje, niezgodności , alergie)	☐	☐	☐	☐
Współudział w wyborze właściwej farmakoterapii dla pacjentów	☐	☐	☐	☐
Doradztwo prowadzone dla lekarzy, położnych i pielęgniarek w zakresie farmakoterapii pacjentów	☐	☐	☐	☐
EDUKACJA/KOMUNIKACJA/BADANIA				
Prowadzenie szkoleń dla lekarzy/położnych/pielęgniarek dotyczących farmakoterapii noworodków	☐	☐	☐	☐
Uczestnictwo w konferencja naukowych dotyczących INT	☐	☐	☐	☐
Współuczestniczenie w badaniach klinicznych leków	☐	☐	☐	☐
Współuczestniczenie w badaniach naukowych dotyczących farmakoterapii u noworodków	☐	☐	☐	☐
Udzielanie informacji personelowi medycznemu	☐	☐	☐	☐
Edukacja rodzin oraz opiekunów noworodków	☐	☐	☐	☐

ZAOPATRYWANIE W LEKI				
Wydawanie leków i materiałów medycznych na oddział INT	☐	☐	☐	☐
Wykonywanie leków recepturowych dla pacjentów w ITN	☐	☐	☐	☐
Kontrola właściwego przechowywania leków na oddziale/dat ważności leków/leków wstrzymanych i wycofanych z obrotu	☐	☐	☐	☐

JAK OCENIASZ OBECNĄ WSPÓŁPRACĘ Z FARMACEUTĄ?

17. Czy uważasz, że farmaceuta mógłby udzielać konsultacji dla członków zespołu leczącego przy podejmowaniu decyzji związanych z leczeniem farmakologicznym chorych noworodków?	☐$_1$ Tak ☐$_2$ Nie
18. Czy uważasz, że farmaceuta powinien stale przebywać na oddziale ITN lub przebywać tam nieregularnie w zależności od potrzeb?	☐$_1$ Tak – obecny stale ☐$_2$ Tak – przebywać nieregularnie ☐$_3$ Nie
19. Jak oceniasz obecny współpracę między lekarzami/położnymi/pielęgniarkami i farmaceutami w ITN?	☐$_1$ Dobra ☐$_2$ Średnia ☐$_3$ Słaba ☐$_4$ Nie istnieje

20. Dlaczego tak uważasz? (odpowiedź na pytanie 19)

……

……

……

……

21. OPINIE NA TEMAT BARRIER W WYKONYWANIU OPIEKI FARMACEUTYCZNEJ NA ODDZIALACH ITN

Proszę zaznaczyć swoją opinię dotyczącą barier w sprawowaniu opieki farmaceutycznej na oddziałach ITN

BARIERY	**ZGADZAM SIE$_1$**	**NIE ZGADZAM SIE$_2$**
Brak legislacji prawnych dotyczących wykonywania usług w ITN	☐	☐
Brak czasu ze strony farmaceuty	☐	☐
Niewystarczająca liczba zatrudnionych farmaceutów w szpitalu	☐	☐
Brak uzasadnienia dla zaangażowania farmaceuty w INT	☐	☐
Niechęć za strony lekarzy/pielęgniarek do zaangażowania farmaceuty w ITN	☐	☐
Brak wynagrodzenia dla farmaceutów za wykonywanie usług w ITN	☐	☐
Apteka szpitalna, w której pracuje farmaceuta znajduje się w dalekiej odległości od oddziału ITN	☐	☐
Niewystarczające przygotowanie farmaceutów do pracy na oddziale ITN	☐	☐
Brak zainteresowanie ze strony farmaceuty pracą w ITN	☐	☐
Brak chęci do zmian ze strony farmaceuty	☐	☐
Brak komunikacji między lekarzami/położnymi pielęgniarkami i farmaceutami	☐	☐
Brak wsparcia ze strony administracji / szpitala	☐	☐
Brak zaufania do własnych umiejętności	☐	☐
Brak farmaceutów z wymaganymi kwalifikacjami	☐	☐

Brak dowodów na pozytywny wpływ farmaceutów na poprawę jakości opieki farmakoterapeutycznej na oddziałach ITN	☐	☐

Inne: ……

……

……

……

22. OPINIE DOTYCZĄCA ZMIAN, KTÓRE NALEŻOŁOBY WPROWADZIĆ W ITN W ODNIESIENIU DO PRACY FARMACEUTY

	TAK$_1$	**NIE$_2$**
Czy istnieje potrzeba zmian dotyczących roli farmaceuty w ITN	☐	☐
Proszę o komentarz, dlaczego tak myślisz	……...…… ……...…… ……...……	

24. JEŚLI TAK, JAKIE ZMIANY MOGĄ POPRAWIĆ SPRAWOWANIE USŁUG FARMACEUTYCZNYCH (W TYM OPIEKI FARMACEUTYCZNEJ) NA ODDZIAŁACH ITN

ZMIANY	TAK$_1$	NIE$_2$
Wsparcie administracyjne ze strony dyrektora szpitala	☐	☐
Zwiększone zatrudnienie personelu fachowego w aptece	☐	☐
Większe wsparcie od innych pracowników służby zdrowia (lekarzy, położnych, pielęgniarek)	☐	☐
Zwiększanie dostępności kształcenia dla farmaceutów dotyczącego farmakoterapia u noworodków lun stosowania leków u dzieci	☐	☐
Zapewnienie większej liczby szkoleń dotyczących klinicznych usług farmaceutycznych	☐	☐
Zwiększenie wynagrodzenia dla farmaceuty	☐	☐
Stworzenie konkretnych miejsc pracy do wykonywania usług farmaceutycznych dla farmaceutów klinicznych na oddziałach ITN	☐	☐
Zmiany legislacyjne regulujące wykonywanie usług farmaceutycznych w ITN	☐	☐
Zwiększenie zainteresowania farmaceutów i motywacji do pracy na oddziałach ITN	☐	☐

DODATKOWE KOMENTARZE

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E.5 QUESTIONNAIRE PAPER 4 (ENGLISH)

Participant Code: _ _ / _ _ / _ _

PHARMACEUTICAL CARE PROVIDED IN NICUS IN POLAND AND AUSTRALIA: PERSPECTIVES OF MEDICAL STUDENTS

- MEDICAL AND PHARMACY STUDENT SURVEY -

RESEARCHERS:

Natalia Krzyzaniak

A/Prof Beata Bajorek

Dr Iga Pawłowska

CONFIDENTIAL

Dear Participant,

Thank you for taking the time to complete this survey. To gather information on pharmacist practice in the NICU, you are asked to complete the following questionnaire. Please answer all questions to the best of your knowledge; there is a section at the end of the survey to add any additional comments.

Please insert a (x) in the corresponding box that most appropriately reflects your response.

DEMOGRAPHIC INFORMATION **Can you please indicate which of these following characteristics apply to you:**	
1. Gender:	☐$_1$ Female ☐$_2$ Male
2. What degree are you currently enrolled in?	☐$_1$ Medical Student ☐$_2$ Pharmacy Student
3. What year of this degree are you currently enrolled in?	☐$_1$ 1 ☐$_2$ 2 ☐$_3$ 3 ☐$_4$ 4 ☐$_5$ 5 ☐$_6$ 6

4. ATTITUDES TOWARDS THE PROVISION OF PHARMACEUTICAL SERVICES IN THE NICU

Please indicate your agreement/disagreement with the following statements about pharmaceutical care services in the NICU:

Items	AGREE$_1$	DISAGREE$_2$
Pharmacists should perform pharmaceutical care services directly on the NICU	☐	☐
Pharmaceutical care services are beneficial for NICU patient outcomes	☐	☐
The performance of pharmaceutical care services is important for integration into the NICU therapeutic team	☐	☐
Pharmaceutical care services are essential for the quality use of medicines in the NICU	☐	☐
The primary responsibility of pharmacists working in the NICU should be to practice pharmaceutical care	☐	☐
Pharmaceutical care services improve medication safety in the NICU	☐	☐
Pharmacists are essential members of the therapeutic team in the NICU	☐	☐
The pharmacist is responsible for pharmacotherapy outcomes in the NICU	☐	☐
The performance of pharmaceutical care services by a pharmacist on the NICU is unnecessary	☐	☐
Pharmaceutical care services can be performed by doctors and nurses in the NICU	☐	☐
The pharmacists role should be exclusive to dispensing and supplying medicines	☐	☐
Pharmaceutical care services have no effect on patient outcomes or on medication management in the NICU	☐	☐
Pharmaceutical care in the NICU is not worth the additional workload it places on the	☐	☐

pharmacist and takes too much time and effort		
Pharmacotherapy based outcomes are ultimately achieved by the doctor as they prescribe drug therapy	☐	☐

Definitions:

[9]Pharmaceutical care/services:

"Pharmaceutical care is a philosophy of practice in which the patient is the primary beneficiary of the pharmacist's actions. Pharmaceutical care focuses the attitudes, behaviours, commitments, concerns, ethics, functions, knowledge, responsibilities and skills of the pharmacist on the provision of drug therapy with the goal of achieving definite therapeutic outcomes toward patient health and quality of life."[1, 2]

Quality use of medicines:

''Selecting management options wisely, choosing suitable medicines if a medicine is considered necessary so that the best available option is selected and using medicines safely and effectively to get the best possible results.''[3, 4, 5]

[9] Hepler, CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. Am J. Hosp Pharm, 1990; 47: 533-543.
[2] Commission to Implement Change in Pharmaceutical Education. A position paper Entry-level Education in Pharmacy: A Commitment to Change. American Association of Colleges of Pharmacy News. Special Report. Alexandria VA 1991
[3] The National Strategy for Quality Use of Medicines. Australian Government Department of Health; 2004.
[4] Quality Use of Medicines & the medicines industry. Medicines Australia. http://medicinesaustralia.com.au/files/2012/05/MA_QUM_External_Reduced.pdf. Accessed 22 Sept 2015.
[5] Quality Use of Medicines (QUM). Department of Health, Australian Government. http://www.health.gov.au/internet/main/publishing.nsf/content/nmp-quality.htm. Accessed 05 Oct 2015.

5. IN YOUR OPINION WHAT ROLES SHOULD BE PERFORMED BY PHARMACISTS IN THE NICU?

Pharmacist Services/Roles	**AGREE$_1$**	**DISAGREE$_2$**
ADMINISTRATION/MANAGEMENT		
Development/implementation of a drug formulary service	☐	☐
Attendance at non-clinical meetings i.e. Drug and Therapeutics Committee	☐	☐
Conducting quality assurance measures i.e. drug usage evaluations, workload documentation, auditing	☐	☐
Management of the drug budget	☐	☐
Evaluation, selection and purchasing of pharmaceuticals for the unit	☐	☐
Development of drug policies/protocols/guidelines for the NICU	☐	☐
CLINICAL ROLES		
Patient medication chart review	☐	☐
Participation in medical ward rounds	☐	☐
Monitoring side-effects and the efficacy of pharmacotherapy in patients	☐	☐
Documenting/monitoring Adverse Drug Events/Reactions	☐	☐
Documenting Medication Errors	☐	☐
Evaluating patients clinical laboratory tests	☐	☐
Therapeutic Drug Monitoring (TDM)	☐	☐
Immunisations	☐	☐
Prescribing/monitoring Total Parenteral Nutrition (TPN)	☐	☐
Participation in clinical meetings	☐	☐
Calculating and recommending doses and dosing schedules for specific patients	☐	☐
Assisting doctors in prescribing off-label/unlicensed medicines	☐	☐
Identifying and performing interventions for individual patients to prevent or resolve drug therapy problems	☐	☐

i.e. interactions, incompatibilities, allergies etc.		
Recommending drugs and contributing to the pharmacotherapy decision making process for specific patients	☐	☐
Collaborating and discussing specific patients with doctors and nurses	☐	☐
EDUCATION/COMMUNICATION/RESEARCH		
Providing training/in-services for other health professionals on NICU related topics and drug related problems	☐	☐
Contributing to and/or attending NICU related conferences	☐	☐
Involved in clinical trials	☐	☐
Involved in research related to neonatal pharmacotherapy	☐	☐
Source of drug information - responding to information requests from health professionals on the ward	☐	☐
Counselling parents/carers of neonatal patients	☐	☐
PROVISION OF MEDICINES		
Dispensing prescriptions	☐	☐
Extemporaneous compounding of formulations for the NICU	☐	☐
Stocking the ward with essential medicines/house-keeping activities i.e. checking expiry dates, fridge temperatures etc.	☐	☐

6. In your opinion, do you believe that the current pharmaceutical care practice model provided to NICUs are meeting the medication management needs of neonatal patients? Why/Why not?

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……

7. Do you think that the pharmacist should be consulted as part of the treating team when making medication-related decisions for NICU patients?	☐$_1$ Yes ☐$_2$ No
8. In your opinion is there a need for a pharmacist to be stationed permanently or routinely visiting the NICU?	☐$_1$ Yes – routinely visiting ☐$_2$ Yes – permanently stationed ☐$_3$ No

9. In your opinion, what are the benefits/disadvantages of a pharmacist working directly on the NICU?

……

……

…….

10. In your future practice, would you like to see collaboration between the doctor and the pharmacist?	☐ Yes **(1)** ☐ No **(2)**
11. In what way?	☐ Direct consultations with visiting pharmacists **(1)** ☐ Direct consultations with pharmacists working on the ward **(2)** ☐Contact through email or telephone contact **(3)**

Additional Comments:

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E.6 QUESTIONNAIRE PAPER 4 (POLISH)

OPIEKA FARMACEUTYCZNA W ITN W POLSCE: z PERSPEKTYWY FARMACEUTOW, LEKARZY, PIELEGNIAREK I STUDENTOW MEDYCYNY

Kod Uczestnika: _ _ / _ _ / _ _

Szanowni Państwo,

Zwracamy się z prośbą o wypełnienie kwestionariusza dotyczącego Państwa opinii na temat roli farmaceuty na oddziałach intensywnej terapii noworodka, które jest częścią projektu badawczego prowadzonego także w Australii. Badanie ma charakter anonimowy i jest prowadzone w celach naukowych przez zespół z University of Technology Sydney oraz Katedry i Zakładu Farmakologii GUMed (kontakt: Natalia Krzyżaniak, ul. Dębowa 23, 80-204 Gdańsk, tel. 583491812, e-mail: Natalia.krzyzaniak@student.uts.edu.au). Wypełnienie i zwrot kwestionariusza jest równoznaczny z wyrażeniem zgody na udział w badaniu. Mają Państwo prawo do wyrażenia sprzeciwu wobec udziału w badaniu lub wycofania się z uczestnictwa na każdym jego etapie. Wypełnienie kwestionariusza zajmie Państwu około 15 minut czasu.

Dziękujemy Państwu za udział w badaniu!

OPIEKA FARMACEUTYCZNA W ITN W POLSCE: z PERSPEKTYWY FARMACEUTOW, LEKARZY, PIELEGNIAREK I STUDENTOW MEDYCYNY

- PRYWATNE -

- ANKIETA DLA STUDENTÓW -

INFORMACJE DOTYCZĄCE RESPONDENTÓW	
1. Płeć:	☐$_1$ Kobieta ☐$_2$ Mężczyzna
2. Kierunek studiów	☐$_1$ Student medycyny ☐$_2$ Student farmacji
3. Rok studiów	☐$_1$ 1 ☐$_2$ 2 ☐$_3$ 3 ☐$_4$ 4 ☐$_5$ 5 ☐$_6$ 6

4. OPINIA DOTYCZĄCA WYKONYWANIA USŁUG FARMACEUTYCZNYCH DLA ODDZIAŁÓW INTENSYWNEJ TERAPII NOWORODKA (ITN)

Proszę zaznaczyć właściwą odpowiedź z którą się zgadzasz:

	TAK$_1$	**NIE**$_2$
Farmaceuci powinni wykonywać usługi farmaceutyczne bezpośrednio na oddziale ITN	☐	☐
Opieka farmaceutyczna lub usługi farmaceutyczne mają korzystny wpływ na efekty leczenia pacjenta	☐	☐
Wykonywanie usług farmaceutycznych na oddziale ITN jest istotne dla zespołu terapeutycznego	☐	☐
Usługi farmaceutyce są niezbędne dla prawidłowego stosowania leków w ITN	☐	☐
Podstawowym obowiązkiem farmaceutów pracujących w ITN powinno być wykonywanie usług farmaceutycznych	☐	☐
Usługi farmaceutyczne zwiększają bezpieczeństwo stosowania leków na oddziałach ITN	☐	☐
Farmaceuci są odpowiedzialni za efekty farmakoterapii u noworodków	☐	☐
Usługi farmaceutyczne są niepotrzebne w ITN	☐	☐
Opieka farmaceutyczna lub jej elementy mogą być wykonywane przez lekarzy, położne i pielęgniarki w ITN	☐	☐
Zadania farmaceuty powinny obejmować wyłączenie zaopatrywanie w leki i inne materiały medyczne	☐	☐
Farmaceuci są członkami zespołu terapeutycznego oddziału ITN	☐	☐

Opieka farmaceutyczna nie ma wpływu na wyniki leczenia pacjentów lub gospodarka lekową w ITN	☐	☐
Wykonywanie opieki farmaceutycznej w ITN wiąże się z dodatkowym obciążeniem farmaceuty i zajmuje zbyt dużo czasu i wysiłku	☐	☐
Tylko lekarz jest odpowiedzialny za wynik farmakoterapeutyczny pacjenta, ponieważ to on zleca odpowiednią farmakoterapię	☐	☐

Definicja: Usługi/Opieka Farmaceutyczna:

Usługa farmaceutyczna polegająca na dokumentowanym procesie, w którym farmaceuta, współpracując z pacjentem i lekarzem, a w razie potrzeby z przedstawicielami innych zawodów medycznych, czuwa nad prawidłowym przebiegiem farmakoterapii w celu uzyskania określonych jej efektów poprawiających jakość życia pacjenta.

5. TWOIM ZDANIEM JAKIE ROLE POWINNY BYĆ WYKONYWANE PRZEZ FARMACEUTÓW W ITN?

Role/Usługi Farmaceutyczne	**Zgadzam Sie$_1$**	**Nie Zgadzam Sie$_2$**
USŁUGI ADMINISTRACYJNE		
Opracowanie / wdrożenie receptariusza	☐	☐
Uczęszczanie w nieklinicznych spotkaniach np. posiedzeniach komitetu terapeutycznego szpitala	☐	☐
Prowadzenie badań jakości farmakoterapii np. ocena stosowanych leków	☐	☐
Zarządzanie budżetem do zakupu leków	☐	☐
Zamawianie leków dla ITN	☐	☐
Opracowanie szczegółowej informacji dla leków stosowanych w ITN	☐	☐
USŁUGI KLINICZNE		
Przeprowadzanie przeglądu leków dla pacjentów	☐	☐
Udział farmaceuty w obchodzie w ITN	☐	☐
Monitorowanie skuteczności leków u pacjenta	☐	☐
Dokumentowanie/monitorowanie oraz zgłaszanie działań niepożądanych leków	☐	☐
Dokumentowanie błędów lekowych	☐	☐
Analiza wyników badan pacjenta np. badania krwi, badanie mykologiczne	☐	☐
Monitorowanie farmakoterapii	☐	☐
Współudział w szczepieniach	☐	☐
Współudział w żywieniu pozajelitowym	☐	☐
Udział w klinicznych spotkaniach z lekarzem, pielęgniarką, rodzina pacjenta itd.	☐	☐
Obliczanie i zalecanie dawek i schematów dawkowania dla wybranych pacjentów	☐	☐
Wspieranie lekarzy w stosowaniu leków poza wskazaniami medycznymi (off label use)	☐	☐
Identyfikacja problemów lekowych oraz prowadzenie interwencji	☐	☐

dla poszczególnych pacjentów w celu zapobiegania lub rozwiązywania tych problemów (np. interakcje, niezgodności , alergie)		
Współudział w wyborze właściwej farmakoterapii dla pacjentów	☐	☐
Doradztwo prowadzone dla lekarzy, położnych i pielęgniarek w zakresie farmakoterapii pacjentów	☐	☐
EDUKACJA/KOMUNIKACJA/BADANIA		
Prowadzenie szkoleń dla lekarzy/położnych/pielęgniarek dotyczących farmakoterapii noworodków	☐	☐
Uczestnictwo w konferencja naukowych dotyczących ITN	☐	☐
Współuczestniczenie w badaniach klinicznych leków	☐	☐
Współuczestniczenie w badaniach naukowych dotyczących farmakoterapii u noworodków	☐	☐
Udzielanie informacji personelowi medycznemu	☐	☐
Edukacja rodzin oraz opiekunów noworodków	☐	☐
ZAOPATRYWANIE W LEKI		
Wydawanie leków i materiałów medycznych na oddział ITN	☐	☐
Wykonywanie leków recepturowych dla pacjentów w ITN	☐	☐
Kontrola właściwego przechowywania leków na oddziale/dat ważności leków/leków wstrzymanych i wycofanych z obrotu	☐	☐

6. Twoim zdaniem, czy wierzysz, że obecny model opieki farmaceutycznej praktyki przeprowadzony w ITN spełniają potrzeby zarządzania leki chorych noworodków? Dlaczego? Dlaczego nie?

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7. Czy uważasz, że farmaceuta powinien udzielać konsultacji w ramach zespołu leczącego przy podejmowaniu decyzji związanych z leczeniem farmakologicznym u pacjentów ITN?	☐$_1$ Tak ☐$_2$ Nie
8. Czy Twoim zdaniem istnieje potrzeba aby farmaceuta miał stałą pozycje lub rutynowo odwiedzał ITN?	☐$_1$ Tak – rutynowo odwiedzał ☐$_2$ Tak – stała pozycja ☐$_3$ Nie

9. W swojej opinii, jakie są zalety / wady farmaceuty pracującego bezpośrednio na intensywnej terapii?

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10. Czy w przyszłości chciałbyś współpracować z farmaceutą?	☐$_1$ Tak ☐$_2$ Nie
11. W jakiej formie?	☐$_1$ Bezpośrednia konsultacja z farmaceutą przychodzącym na oddział ☐$_2$ Bezpośrednia konsultacja z farmaceutą pracującym na oddziale ☐$_3$ Poprzez kontakt e-mailowy, telefoniczny

Dodatkowe komentarze:

……

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……

APPENDIX F - PROJECT RECRUITMENT AND INFORMATION SHEETS FOR PAPER 5, CHAPTER 5

PROJECT TITLE: PHARMACIST PERCEPTIONS ON THE NEED FOR CLINICAL PHARMACY KEY PERFORMANCE/QUALITY INDICATORS IN THE NICU – COMPARISON BETWEEN POLAND AND AUSTRALIA

F.1 INVITATION LETTER TO PARTICIPANTS (ENGLISH)

F.2 INVITATION LETTER TO PARTICIPANTS (POLISH)

F.3 INFORMATION SHEET (ENGLISH)

F.4 INFORMATION SHEET (POLISH)

F.5 PARTICIPANT CONSENT FORM (ENGLISH)

F.6 PARTICIPANT CONSENT FORM (POLISH)

F.1 INVITATION LETTER TO PARTICIPANTS (ENGLISH)

PARTICIPANT INFORMATION FORM – STAGE 3

Dear Participant,

My name is Natalia Krzyzaniak and I am a PhD student at the University of Technology, Sydney.

I am currently undertaking research that is aimed at developing a definitive practice model and set of quality indicators that will guide clinical pharmacists in the provision of pharmacy services and pharmaceutical care to neonatal intensive care units (NICUs) in Australian and Polish hospitals. The third phase of my project intends to investigate the perceptions and opinions of pharmacists on the development and implementation of a set of clinical pharmacy key performance indicators/quality indicators in the NICU. Currently, there is no global consensus on services and roles that should be performed by a clinical pharmacist in the NICU. Furthermore, there are no quality indicators or key performance indicators (KPIs) available to guide pharmacist practice in this setting. It is important to understand these perspectives and opinions to better understand the situation of pharmaceutical care in each country so that measures can be developed to improve, change and enhance the role of the pharmacist to better meet the medication needs of NICU patients. The pharmacist attitudes and perceptions will help inform the next stages in developing these indicators.

The study will require participation in a semi-structured interview, which should take no more than 1 hour of your time. The interviews will be held either in person, or over the phone – whatever you prefer. If you are interested in participating, please read both pages of the 'Participant Information – Stage 3 Interview' and sign the 'Participant Consent – Stage 3 Interview'. For any further clarification or queries, please do not hesitate to contact me on [redacted], or on my email: Natalia.krzyzaniak@student.uts.edu.au.

You are under no obligation to participate in this research. This research has received no funding.

Thank-you very much for your time,

Yours sincerely,

Lead Investigator

Natalia Krzyzaniak

Address: Graduate School of Health-Pharmacy, Building 7 level 4

University of Technology Sydney NSW 2007

Phone: +6415 721 785

Email: Natalia.krzyzaniak@student.uts.edu.au

F.2 INVITATION LETTER TO PARTICIPANTS (POLISH)

INFORMACJE DLA UCZESTNIKOW – ETAP 3

Szanowni Państwo,

Nazywam się Natalia Krzyżaniak i jestem doktorantem na University of Technology.

Obecnie prowadzę badania, które mają na celu opracowanie modelu praktyki i zestawu kluczowych wskaźników jakościowych, które będą ułatwiały farmaceutom prowadzenie klinicznych usług farmaceutycznych i opiekę farmaceutyczną dla noworodków na oddziałach intensywnej terapii (ITN) w polskich szpitalach. Trzeci etap mojego projektu prowadzi do określenia poglądów i opinii farmaceutów dotyczących wdrożenia kluczowych wskaźników jakościowych w ITN. Obecnie nie ma wytycznych o tym jaką funkcje mają spełnić farmaceuci w oddziałach ITN. Nie ma również wskaźników jakościowych potrzebnych do kierowania praktykami farmaceutów na tych oddziałach. Ważne jest, aby zrozumieć perspektywy i opinie opieki farmaceutycznej w każdym kraju, żeby rozwijać działania zmierzające do poprawy, zmiany i wzmocnienia roli farmaceuty w celu lepszego zaspokojenia farmakoterapeutycznych potrzeb pacjentów w ITN.

Badanie będzie wymagało uczestnictwa w wywiadzie i nie powinno trwać dłużej niż ½ godziny. Rozmowy odbędą się osobiście lub przez telefon.

Jeśli są Państwo zainteresowani uczestnictwem, prosimy o zapoznanie się z "Informacją dla uczestnika - etap 3 Wywiad" i podpisać "uczestnik Zgoda - etap 3 Wywiad". W celu uzyskania dalszych wyjaśnień lub pytań, proszę się ze mną skontaktować na [redacted], lub na mój e-mail: Natalia.krzyzaniak@student.uts.edu.au.

Udział w badaniu jest dobrowolny. Badania te nie otrzymały pomocy finansowej.

Dziękuję Państwu za poświęcony czas,

Z poważaniem,

Natalia Krzyzaniak

Adres: Graduate School of Health-Pharmacy, Building 7 level 4

University of Technology Sydney NSW 2007

Phone: +6415 721 785

Email: Natalia.krzyzaniak@student.uts.edu.au

F.3 INFORMATION SHEET (ENGLISH)

PARTICIPANT INFORMATION FORM – STAGE 3

WHO IS DOING THE RESEARCH?

My name is Natalia Krzyzaniak and I am a PhD student at The University of Technology, Sydney. (My supervisor is Associate Professor Beata Bajorek, and my associate supervisor is Dr Iga Pawłowska)

WHAT IS THIS SURVEY ABOUT?

This interview will be investigating the opinions and perceptions of pharmacists, towards the development and implementation of a set of clinical pharmacy key performance indicators/quality indicators in the NICU. Furthermore the study also aims to identify the perceived barriers towards the implementation of these indicators in the NICU. It is important to understand these perspectives and opinions to better understand the situation of pharmaceutical care in each country so that measures can be developed to improve, change and enhance the role of the pharmacist to better meet the medication needs of NICU patients.

IF I SAY YES, WHAT WILL IT INVOLVE?

I will ask you to participate in a semi-structured interview (either in person or over the phone)

ARE THERE ANY RISKS?

There is not considered to be any likelihood of physical harm associated with participating in this research, but there may be some inconvenience in terms of the time required to respond to questions. If the interview addresses issues that you feel uncomfortable commenting about or causes any of the aforementioned issues, the interview is entirely voluntary and you may elect not to further contribute to the research.

WHY HAVE I BEEN ASKED?

You are a valuable member of the hospital team; please confirm the following by ticking the boxes, which apply to you (you may tick more than one)

☐ I am a Director of Pharmacy/; OR

☐ pharmacist involved in patient care in the NICU

If you do not meet either criterion above, thank you for your time, however you are not suitable for this research.

DO I HAVE TO SAY YES?

You do not have to agree to participate in this interview. The decision to become involved in this research is entirely up to your own discretion.

WHAT WILL HAPPEN IF I SAY NO?

I will thank you for your time and will not contact you about this research again.

IF I SAY YES, CAN I CHANGE MY MIND LATER?

You can change your mind at any time and you do not have to offer any explanation. I will thank you for your time and will not contact you about this research again.

WHAT IF I HAVE CONCERNS OR A COMPLAINT?

If you have concerns about the research that you think I can help you with, please feel free to contact me on [redacted] or Natalia.krzyzaniak@student.uts.edu.au, or my supervisors A/Prof Beata Bajorek, beata.bajorek@uts.edu.au and Dr Iga Pawłowska, iga112@gumed.edu.pl.

If you would like to talk to someone who is not connected with the research, you may contact the Research Ethics Officer on 02 9514 9772, or Research.Ethics@uts.edu.au and quote this number *(UTS HREC REF NO. ETH16-1033, GUMed HREC NO. NKBBN/424/2016)*

F.4 INFORMATION SHEET (POLISH)

OPINIE FARMACEUTOW DOTYCZĄCE OPRACOWANIA I WDROŻENIA ZESTAWU KLUCZOWYCH WSKAŹNIKÓW JAKOŚCIOWYCH W ODDZIAŁACH ITN

(UTS HREC REF NO. ETH16-1033, GUMed HREC NO. NKBBN/424/2016)

INFORMACJE DLA UCZESTNIKOW – ETAP 3

KTO PROWADZI BADANIE?

Nazywam się Natalia Krzyżaniak i jestem doktorantem na University of Technology Sydney. (Moim promotorem jest A/Prof Dr Beata Bajorek, a natomiast promotorem pomocniczym jest Dr Iga Pawłowska)

O CZYM JEST TO BADANIE?

Wywiad bada opinie i poglądy farmaceutów dotyczące opracowania i wdrożenia zestawu kluczowych wskaźników jakościowych w oddziałach ITN. Ponadto badanie to ma na celu postrzeganie barier dotyczących realizacji wskaźników w oddziałach ITN. Ważne jest, aby zrozumieć perspektywy i opinie opieki farmaceutycznej w każdym kraju, żeby rozwijać działania zmierzające do poprawy, zmiany i wzmocnienia roli farmaceuty w celu lepszego zaspokojenia farmakoterapeutycznych potrzeb pacjentów w ITN.

JEŚLI SIE ZGODZE, CO TO BADANIE BĘDZIE WYMAGAC?

Badanie będzie wymagało uczestnictwa w wywiadzie i nie powinno trwać dłużej niż ½ godziny. Rozmowy odbędą się osobiście lub przez telefon.

CZY ISTNIEJE JAKIEŚ RYZYKO?

Uczestnicząc w tym wywiadzie nie ponosicie żadnego ryzyka, ale mogą wystąpić niedogodności spowodowane z czasem (może się wydłużyć). Jeśli podczas wywiadu, napotkają Państwo na jakieś problemy, lub niektóre pytania będą niekomfortowe, zawsze można zrezygnować z badania.

DLACZEGO ZOSTALEM/AM SPYTANA O UDZIAL W TYM BADANIU?

Pan/Pani jest cennym członkiem zespołu szpitalnego.

Proszę potwierdzić, (poprzez zaznaczenie pola), które odnoszą się do Państwa (można zaznaczyć więcej niż jedną)

☐ farmaceuta zaangażowany w opiekę nad pacjentem w ITN; lub

☐ kierownik apteki szpitalnej

Jeśli nie spełniają Państwo wymagań kryterium, nie mogą Państwo wziąć udziału w badaniu. Bardzo dziękuję Państwu za poświęcony czas.

CZY MUSZĘ ZGODZIĆ SIĘ NA UCZESTNICTWO W TYM BADANIU?

Udział w badaniu jest dobrowolny.

CO SIE STANIE JEŚLI ODMÓWIĘ?

Podziękuję Państwu za poświęcony czas i nie będę ponownie kontaktowała się z Państwem.

JEŚLI TERAZ SIĘ ZGODZĘ, MOGE PÓŹNIEJ ZMIENIĆ ZDANIE?

Mogą Państwo zmienić zdanie w każdej chwili, nie podając żadnych wyjaśnień. Podziękuję za poświęcony czas i nie będę ponownie kontaktowała się z Państwem.

CO ZROBIC JESLI MAM PYTANIA?

Jeśli Państwo mają wątpliwości co do badań, proszę o kontakt ze mną pod nr telefonu: [redacted] lub Natalia.krzyzaniak@student.uts.edu.au, lub z którymś z moich promotorów A/Prof Beata Bajorek, beata.bajorek@uts.edu.au i Dr Iga Pawłowska, iga112@gumed.edu.pl.

Jeśli Państwo chcą porozmawiać z osobą, która nie jest związana z badaniami, można skontaktować się z przedstawicielem Komisji Bioetycznej 02 9514 9772 lub mailowo, research.ethics@uts.edu.au **(UTS HREC REF NO. ETH16-1033, GUMed HREC NO. NKBBN/424/2016).**

F.5 PARTICIPANT CONSENT FORM (ENGLISH)

PARTICIPANT CONSENT FORM – STAGE 3 INTERVIEW

Please confirm the following by ticking the box that applies to you (you may tick more than one)

☐ I am a Director of Pharmacy; OR

☐ pharmacist involved in patient care in the NICU

If you do not meet either criterion above, thank you for your time, however you do not appear be suitable for this research.

I_____agree to participate in the research project *'Pharmacist perceptions on the need for clinical pharmacy key performance/quality indicators in the NICU – comparison between Poland and Australia' (UTS HREC REF NO. ETH16-1033, GUMed HREC NO. NKBBN/424/2016)* being conducted by Natalia Krzyzaniak, Building 7 level 4, University of Technology Sydney NSW 2007, +61 2 9514 1448 of the University of Technology, Sydney as part of her Doctor of Philosophy. This research has not been funded.

I understand that the purpose of this study is to gain an insight into the perspectives and opinions towards the development and implementation of a set of clinical pharmacy key performance indicators/quality indicators in the NICU.

I understand that my participation in this research will involve participating in an interview. The interview should only take, at most, 1 hour to complete.

I am aware that I can contact Natalia Krzyzaniak or her supervisor A/Professor Beata Bajorek or co-supervisor Dr Iga Pawłowska if I have any concerns about the research. I also understand that I am free to withdraw my participation from this research project at any time I wish, without consequences, and without giving a reason.

I agree that the research data gathered from this project may be published in a form that does not identify me in any way.

_____ ____/____/____

Signature (participant)

_____ ____/____/____

Signature (researcher or delegate)

NOTE:

This study has been approved by the University of Technology, Sydney Human Research Ethics Committee. If you have any complaints or reservations about any aspect of your participation in this research which you cannot resolve with the researcher, you may contact the Ethics Committee through the Research Ethics Officer (ph: +61 2 9514 9772 Research.Ethics@uts.edu.au) and quote the UTS HREC reference number. Any complaint you make will be treated in confidence and investigated fully and you will be informed of the outcome.

F.6 PARTICIPANT CONSENT FORM (POLISH)

FORMULARZ ZGODY – ETAP 3 WYWIAD

Jesteś cennym członkiem zespołu szpitalnego; Proszę potwierdzić, co następuje poprzez zaznaczenie pola, które odnoszą się do ciebie (można zaznaczyć więcej niż jedną)

□ Jestem kierownikiem apteki szpitalnej; lub

□ farmaceuta zaangażowany/a w opiekę nad pacjentem w ITN

Jeśli nie spełniają Państwo wymagań kryterium, nie mogą Państwo wziąć udziału w badaniu. Bardzo dziękuję Państwu za poświęcony czas.

POTWIERDZENIE

Ja _____ zgadzam się na udział w projekcie badawczym "*Opinie farmaceutów dotyczące opracowania i wdrożenia zestawu kluczowych wskaźników jakościowych w oddziałach ITN" (UTS HREC REF NO. ETH16-1033, GUMed HREC NO. NKBBN/424/2016)* prowadzone przez Natalię Krzyżaniak z University of Technology Sydney w ramach swojego doktoratu.

Badania te nie otrzymały pomocy finansowej.

Rozumiem, że celem tego jest zbadanie poglądów i opinii dotyczących wdrożenia kluczowych wskaźników jakościowych w ITN.

Rozumiem, że mój udział w tym badaniu będzie obejmować uczestnictwo w wywiadzie i nie powinno trwać dłużej niż ½ godziny. Rozmowy odbędą się osobiście lub przez telefon.

Rozumiem, że mogę się skontaktować z Natalią Krzyżaniak lub jej promotorką A/Profesor Dr Beata Bajorek lub promotorem pomocniczym Dr Iga Pawłowska, jeśli mam jakiekolwiek wątpliwości do badań.

Rozumiem ze udział w badaniu jest dobrowolny. Rozumiem ze mam prawo do wyrażenia sprzeciwu wobec udziału w badaniu lub wycofania się z uczestnictwa na każdym jego etapie.

Zgadzam się, że dane badawcze zgromadzone w ramach tego projektu mogą być opublikowane w formie, która nie identyfikuje mnie w żaden sposób.

_____ ____/____/____

Podpis (uczestnik)

_____ ____/____/____

Podpis (badacz)

APPENDIX G – DATA COLLECTION FORM FOR PAPER 5, CHAPTER 5

PROJECT TITLE: PHARMACIST PERCEPTIONS ON THE NEED FOR CLINICAL PHARMACY KEY PERFORMANCE/QUALITY INDICATORS IN THE NICU – COMPARISON BETWEEN POLAND AND AUSTRALIA

G.1 INTERVIEW GUIDE PAPER 2 (ENGLISH)

G.2 INTERVIEW GUIDE PAPER 2 (POLISH)

G.1 INTERVIEW GUIDE PAPER 2 (ENGLISH)

Participant Code: _ _ / _ _ / _ _

PHARMACIST PERCEPTIONS ON THE NEED FOR CLINICAL PHARMACY KEY PERFORMANCE/QUALITY INDICATORS IN THE NICU – COMPARISON BETWEEN POLAND AND AUSTRALIA

- PHARMACIST INTERVIEW -

RESEARCHERS:

Natalia Krzyzaniak

A/Prof Beata Bajorek

Dr Iga Pawłowska

CONFIDENTIAL

INTERVIEW QUESTIONS

DEMOGRAPHIC/UNIT QUESTIONS

Gender	Male Female
Highest qualifications in pharmacy	BPharm MPharm PhD
Are you specially trained in the NICU/paediatrics?	Yes No
Specialised qualifications	Diploma MClinPharm
How long have you been a pharmacist?	
Nationality/Country of practice	Australian Polish

QUESTIONS RELATING TO THE ROLE OF THE PHARMACIST IN NICU

- Would you please be able to describe the current type of practice model that currently functions in the NICU at the hospital that you work in?
- Do you believe that this model works and meets the needs of these patients?
- Why?
- Do you believe that a pharmacist is needed on the NICU?
- What kind of benefits does a pharmacist bring to the NICU?
- Are there any guidelines or practice models that you are aware of that identify what pharmacist roles or pharmacy services should be performed in the NICU?
- Are there any key performance indicators or quality indicators that you are aware of that pharmacists use to guide their medication management specifically in the NICU?
- Would you like to see an integrated document comprising an ideal practice model, that includes a list of clinical pharmacy key performance indicators specifically tailored for the NICU?

- What kind of things would you like it to contain?
- If this kind of document was made available, do you believe that it would be implemented or used in your hospital?
- Would you use it to evaluate your own level of practice?
- What would encourage the use or the implementation of this type of document into the NICU?
- What are the barriers that you can think of that could oppose its implementation?
- What kind of benefits do you think that this type of document could bring?
- Using this type of document, with the clinical pharmacy KPIs, it will be possible to compare practice between units or settings in Australia. In your opinion, would it be useful to benchmark or compare pharmacy services provided in your unit to other units in Australia?
- Are you interested in how other units practice – not only in Australia but also internationally?
- Would you use this comparative information to improve or modify your own model of practice?
- How do you think current pharmacy services in your NICU compare to practice in other countries?

Thank-you very much for your time. If you would like to read the results of this stage of the project, please provide an email address for us to send the article to.

G.2 INTERVIEW GUIDE PAPER 2 (POLISH)

OPINIE FARMACEUTÓW DOTYCZĄCE OPRACOWANIA I WDROŻENIA ZESTAWU KLUCZOWYCH WSKAŹNIKÓW JAKOŚCIOWYCH W ODDZIAŁACH ITN

Kod Uczestnika: _ _ / _ _ / _ _

Przykładowe pytania na wywiady

Demograficzne pytania

- Płeć: Mężczyzna Kobieta
- Podstawowe kwalifikacje farmaceutyczne: BPharm, MPharm, PhD
- Specjalistyczne kwalifikacje: dyplom, MClinPharm
- Jak długo jesteś farmaceuta?
- Specjalizacja w ITN/ pediatrii?
- Obywatelstwo - polskie / inne

Pytania odnoszące się do roli farmaceuty w ITN

- Czy możecie opisać aktualny model farmaceutyczny, który obecnie funkcjonuje w ITN w swoim szpitalu – np. obecny na oddziale, Ile farmaceutów w aptece szpitalnej, farmaceuta na pełnym etacie – godziny pracy etc.
- Czy myślicie, że ten model działa lub zaspokaja potrzeby pacjentów w tym oddziale?
  • Dlaczego? Dlaczego nie?
- Czy uważacie, że farmaceuta jest potrzebny w ITN?
  - Dlaczego? Dlaczego nie?
- Czy w Polsce istnieją wytyczne / modele, które identyfikują usługi lub role farmaceutyczne które powinny być wykonywane w ITN?
  - Jeżeli tak – jakie?
- Czy w Polsce istnieje dokument z key performance indicators (mierzalne wskaźniki jakościowe), które pomagają w zarzadzaniu leków w ITN? E.g. neonatal formulary, safety technology etc.

- Czy chcielibyście żeby taki dokument był dostępny? Dlaczego?
- Co chcielibyście żeby ten dokument zawierał? np. Lista usług farmaceutycznych które powinny być prowadzone, ile farmaceutów trzeba zatrudnić, ile czasu poświęcać na usługi kliniczne, jakie są bariery w wykonywaniu takich usług, obecny stan farmaceuty w prawie
  - Jeżeli tak, to jakie?
- Gdybym przedstawiła dokument zawierający zarówno idealny model praktyki jak i listę wskaźników specjalnie sformułowane dla ITN.
- Czy myślicie ze taki dokument byłby używany w ITN w swoim szpitalu?
  - Dlaczego? Dlaczego nie?
- Czy korzystalibyście z tej listy aby ocenić własny poziom praktyki?
- Co by Was zachęciło do korzystania lub wdrożenie tego modelu w swojej aptece i na tym oddziale? Finansowe, dodatkowe środki
- Jakie bariery istnieją w obecnym systemie ograniczające wdrożenie tego modelu do Waszej apteki lub oddziału?
- Jakie korzyści mogą wyniknąć z wdrożenia tego modelu? i.e. zwiększenie bezpieczeństwa, wpływ na wyniki pacjentów w ITN, zarzadzaniem jakości leków w ITN
- Używając tych wskaźników, można porównać ogólny stan opieki farmaceutycznej prowadzonej w innych szpitalach. Czy uważacie ze takie porównywanie byłoby użyteczne?
  - Dlaczego? Dlaczego nie?
- Czy jesteście zainteresowani jak wygląda praktyka farmaceutów w innych szpitalach – w Polsce i zagranica?
- Czy używalibyście tej informacji porównawczej żeby poprawić lub zmienić własną praktykę farmaceutyczną i ogólną praktykę w tym szpitalu?
- Jak teraz porównacie aktualny poziom opieki farmaceutycznej w Waszym szpitalu z innymi szpitalami w innych krajach, czy myślicie ze istnieją jakieś różnice? Myślicie, że jest lepiej/gorzej?

Dziękuję za poświęcony czas. Jeżeli chcecie się zapoznać się z wynikami tego etapu projektu, proszę podać adres mailowy, abym mogła wysłać informacje.

APPENDIX H – HUMAN RESEARCH AND ETHICS APPROVAL FOR THE CONDUCT OF PAPERS 6 AND 7, CHAPTER 6

H.1 HREC APPROVAL FROM THE UNIVERSITY OF TECHNOLOGY SYDNEY

H.2 HREC APPROVAL FROM THE MEDICAL UNIVERSITY OF GDANSK, POLAND

H.1 HREC APPROVAL FROM THE UNIVERSITY OF TECHNOLOGY SYDNEY

Dear Applicant

Thank you for your response to the Committee's comments for your project titled, "Evaluation of Pharmacist Practice in Neonatal Intensive Care Units in Australia and Poland: Developing A Pharmacy Practice Model and Quality Indicator List.". Your response satisfactorily addresses the concerns and questions raised by the Committee who agreed that the application now meets the requirements of the NHMRC National Statement on Ethical Conduct in Human Research (2007). I am pleased to inform you that ethics approval is now granted.

Your approval number is UTS HREC REF NO. ETH17-1584.

Approval will be for a period of five (5) years from the date of this correspondence subject to the provision of annual reports.

Your approval number must be included in all participant material and advertisements. Any advertisements on the UTS Staff Connect without an approval number will be removed.

Please note that the ethical conduct of research is an on-going process. The National Statement on Ethical Conduct in Research Involving Humans requires us to obtain a report about the progress of the research, and in particular about any changes to the research which may have ethical implications. This report form must be completed at least annually from the date of approval, and at the end of the project (if it takes more than a year). The Ethics Secretariat will contact you when it is time to complete your first report.

I also refer you to the AVCC guidelines relating to the storage of data, which require that data be kept for a minimum of 5 years after publication of research. However, in NSW, longer retention requirements are required for research on human subjects with potential long-term effects, research with long-term environmental effects, or research considered of national or international significance, importance, or controversy. If the data from this research project falls into one of these categories, contact University Records for advice on long-term retention.

You should consider this your official letter of approval. If you require a hardcopy please contact Research.Ethics@uts.edu.au.

To access this application, please follow the URLs below:
* if accessing within the UTS network: https://rm.uts.edu.au

* if accessing outside of UTS network: https://vpn.uts.edu.au , and click on " RM6 – Production " after logging in.

We value your feedback on the online ethics process. If you would like to provide feedback please go to: http://surveys.uts.edu.au/surveys/onlineethics/index.cfm

If you have any queries about your ethics approval, or require any amendments to your research in the future, please do not hesitate to contact Research.Ethics@uts.edu.au.

Yours sincerely,

Associate Professor Beata Bajorek
Chairperson
UTS Human Research Ethics Committee
C/- Research & Innovation Office
University of Technology, Sydney
E: Research.Ethics@uts.edu.au

H.2 HREC APPROVAL FROM THE MEDICAL UNIVERSITY OF GDANSK, POLAND

NIEZALEŻNA KOMISJA BIOETYCZNA DO SPRAW BADAŃ NAUKOWYCH
PRZY GDAŃSKIM UNIWERSYTECIE MEDYCZNYM
80-210 Gdańsk, ul. M. Skłodowskiej-Curie 3a
Sekretariat: tel. 58/349-10-11, fax 58/349-11-70, Przewodniczący tel. 58/349-12-60

*NKBBN/**424-184**/2017* Gdańsk, 2017-05-22

Pan
Prof. dr hab. med. Ivan Kocić
Kierownik Katedry i Zakładu Farmakologii
Gdański Uniwersytet Medyczny

W odpowiedzi na zgłoszenie badań z dnia 26.04.2017r. na temat: **„Rola i zadania farmaceuty w oddziałach intensywnej terapii noworodkowej – opracowanie najlepszego modelu praktyki oraz czynniki jakości usług farmaceutycznych – Część 2"** *(praca doktorska mgr Natalii Krzyżaniak pod kierunkiem promotora prof. Beaty Bajorek z University of Technology, Sydney, Australia, i opiekuna dr n. farm. Igi Pawłowskiej z Katedry i Zakładu Farmakologii GUMed – kontynuacja badania, na które została wydana zgoda komisji bioetycznej NKBBN/424/2016 z dnia 25.10.2016r.)* - Niezależna Komisja Bioetyczna do Spraw Badań Naukowych przy Gdańskim Uniwersytecie Medycznym na posiedzeniu w dniu 18 maja 2017 roku zapoznała się powyższym projektem pracy i wyraża zgodę na jej prowadzenie w zakresie przedstawionym we wniosku, gdyż są to badania poznawcze, nie budzące zastrzeżeń natury etycznej.

Niniejsza zgoda jest ważna do 31 maja 2020 roku, zgodnie z planowanym przez badacza okresem przeprowadzenia ww. badań.

NIEZALEŻNA KOMISJA BIOETYCZNA
DO SPRAW BADAŃ NAUKOWYCH
PRZY GDAŃSKIM UNIWERSYTECIE MEDYCZNYM
80-210 Gdańsk, ul. M. Skłodowskiej-Curie 3a
tel. 58 349 10 11, fax 58 349 11 70

PRZEWODNICZĄCY
Niezależnej Komisji Bioetycznej
do Spraw Badań Naukowych
prof. dr hab. med. Stefan Ruszkiewicz

POLISH ETHICS APPROVAL – TRANSLATION

INDEPENDENT COMMITTEE FOR SCIENTIFIC RESEARCH AT THE MEDICAL UNIVERSITY OF GDAŃSK

80 – 210 GDAŃSK, ul. SKŁODOWSKIEJ-CURIE 3a

Secretariat: tel. 58/349-10-11, fax 58/349-11-70, Chairman tel. 58/349-12-60

NKBBN/**424-184**/2017 Gdańsk, 2017-05-22

Prof. dr hab. med. Ivan Kocić

Head of the Department of Pharmacology

Medical University of Gdańsk

In response to the notification of research dated 26.04.2017 titled: **"Roles and responsibilities of pharmacists in the neonatal intensive care unit: development of a best practice model and quality indicators for clinical pharmacist services – Part 2"** *(doctoral thesis of Natalia Krzyżaniak planned to be carried out under the guidance of supervisor A.Prof Beata Bajorek from the University of Technology Sydney, Australia and supervisor Dr Iga Pawłowska from the Department of Pharmacology at the Medical University of Gdańsk – a continuation of research which obtained ethics approval from the committee: NKKBN/424/2016 on the 25.10.2016)* – the Independent Bioethics Commission for Research at the Medical University of Gdańsk at its meeting on the 18th of May 2017 became acquainted with

the aforementioned project and agreed to its implementation according to the information outlined in the application, as this is a baseline study which does not violate the ethical nature of research.

This consent is valid until 31st of May 2020, in accordance with the investigators plans to carry out the aforementioned research.

STAMPS

Independent Bioethics Commission for Research at the Medical University of Gdańsk

80-210 Gdańsk, ul. M. Skłodowskiej-Curie 3a tel.
58 349 10 11, fax. 58 349 11 70

Chairman of the Independent Bioethics Commission for Research at the Medical University of Gdańsk

Prof. dr hab. Med. Stefan Raszeja

APPENDIX I - PROJECT RECRUITMENT AND INFORMATION SHEETS FOR PAPERS 6 AND 7, CHAPTER 6

PROJECT TITLE: EVALUATION OF PHARMACIST PRACTICE IN NEONATAL INTENSIVE CARE UNITS IN AUSTRALIA AND POLAND: DEVELOPING A PHARMACY PRACTICE MODEL AND QUALITY INDICATOR LIST

I.1 INVITATION LETTER TO PARTICIPANTS (ENGLISH)

I.2 INVITATION LETTER TO PARTICIPANTS (POLISH)

I.3 INFORMATION SHEET (ENGLISH)

I.4 INFORMATION SHEET (POLISH)

I.5 PARTICIPANT CONSENT FORM (ENGLISH)

I.6 PARTICIPANT CONSENT FORM (POLISH)

I.1 INVITATION LETTER TO PARTICIPANTS (ENGLISH)

PARTICIPANT INFORMATION

Dear Participant,

My name is Natalia Krzyzaniak and I am a PhD student at the University of Technology, Sydney.

I am currently undertaking research that is aimed at developing a definitive practice model and set of quality indicators that will guide clinical pharmacists in the provision of pharmacy services and pharmaceutical care to neonatal intensive care units (NICUs) in Australian and Polish hospitals. This phase of my research has two major objectives: to identify pharmacy services/roles that are considered essential to the quality use of medicines in the NICU, and to identify indicators of quality pharmaceutical care by identifying structures, processes and outcomes perceived as appropriate for Australian and Polish NICUs by experts in the field.

The study will use a three round Delphi technique, which will involve 3 sequential surveys, which should each take no more than 15 minutes of your time per survey. If you are interested in participating, please contact me for further information on [redacted], or on my email: Natalia.krzyzaniak@student.uts.edu.au.

You are under no obligation to participate in this research. This research has received no funding.

Thank-you very much for your time,

Yours sincerely,

Natalia Krzyzaniak

Address: Graduate School of Health-Pharmacy, Building 7 level 4

University of Technology Sydney NSW 2007

Phone: +6415 721 785

Email: Natalia.krzyzaniak@student.uts.edu.au

I.2 INVITATION LETTER TO PARTICIPANTS (POLISH)

INFORMACJE DLA UCZESTNIKOW

Szanowni Państwo,

Nazywam się Natalia Krzyżaniak i jestem doktorantem na University of Technology w Sydney Australia.

Obecnie prowadzę badania, które mają na celu opracowanie modelu praktyki i zestawu kluczowych wskaźników jakościowych, które będą ułatwiały farmaceutom prowadzenie klinicznych usług farmaceutycznych i opiekę farmaceutyczną dla noworodków na oddziałach intensywnej terapii (ITN) w polskich szpitalach. Ostatni etap moich badań ma dwa główne cele: 1) zidentyfikowanie usługi i role farmaceuty niezbędnie do zarzadzania lekami w ITN, oraz 2) określenie wskaźników jakościowych kierujących opieką farmaceutyczna na ITN.

Farmaceuci są ważnymi osobami przyczyniającymi się do bezpieczeństwa pacjentów, i racjonalnego wykorzystania leków w oddziałach ITN. Obecnie, brakuje literatury która dokumentuje aktualnie wykonywane usługi farmaceuty w oddziałach ITN. Dane z tego badania przedstawia aktualny obraz praktyki farmaceutycznej w ITN w Polsce, i ocenia role farmaceuty w multidyscyplinarnym zespole terapeutycznym. Ponadto, badanie to ma na celu określenie, które usługi farmaceutyczne są uważane za niezbędne dla właściwego stosowania leków na ITN.

Badanie będzie wymagało wypełnienia trzech ankiet: wypełnienie ankiety nie powinno zając więcej czasu niż 15 minut.

Jeśli są Państwo zainteresowani uczestnictwem, prosimy o zapoznanie się z "Informacją dla uczestnika - etap 4 Delphi" i podpisać "uczestnik Zgoda - etap 4 Delphi". W celu uzyskania dalszych wyjaśnień lub pytań, proszę się ze mną skontaktować na [redacted], lub na mój e-mail: Natalia.krzyzaniak@student.uts.edu.au.

Udział w badaniu jest dobrowolny. Badania te nie otrzymały pomocy finansowej.

Dziękuję Państwu za poświęcony czas,

Z poważaniem,

Natalia Krzyżaniak

Adres: Graduate School of Health-Pharmacy, Building 7 level 4

University of Technology Sydney NSW 2007

Phone: +6415 721 785

Email: Natalia.krzyzaniak@student.uts.edu.au

I.3 INFORMATION SHEET (ENGLISH)

PARTICIPANT INFORMATION

WHO IS DOING THE RESEARCH?

My name is Natalia Krzyzaniak and I am a PhD student at the University of Technology, Sydney. My supervisor is Associate Professor Beata Bajorek, from UTS and my associate supervisor is Dr Iga Pawłowska from the Medical University of Gdansk, Poland.

WHAT IS THIS SURVEY ABOUT?

These surveys will ask for your opinion, as an expert in neonatal care or clinical pharmacy practice, on which elements of pharmaceutical care are deemed essential for the quality and rational use of medicines in the neonatal intensive care unit (NICU). Specifically, these surveys will ask you to rank key performance indicators that can be used by pharmacists to assess the quality of medication management in the NICU and to improve clinical pharmacy practice. The data from this study will be used to develop a 'pharmacy practice model' tailored to the NICU setting.

IF I SAY YES, WHAT WILL IT INVOLVE?

I will ask you to complete three surveys, delivered to you sequentially using a three round Delphi technique. These surveys will each take approximately 15 minutes of time to complete (total 45 minutes).

ARE THERE ANY RISKS?

There is no likelihood of physical harm in participating in this study, but there may be some inconvenience in terms of the time required to respond to questions and completing the survey, burden of commitment. If the survey addresses issues that you feel uncomfortable commenting on or causes any of the aforementioned issues, you may elect not to further contribute to the research as the survey is entirely voluntary.

WHY HAVE I BEEN ASKED?

You are an expert and a valuable member of the hospital team; please confirm the following by ticking the boxes, which apply to you (you may tick more than one)

☐ I have experience with hospital based clinical pharmacy services AND;

☐ I am an academic interested in quality pharmaceutical care OR;

☐ I am a pharmacist involved in patient care in the NICU OR;

☐ I am a doctor involved in patient care in the NICU OR;

☐ I am a nurse/midwife involved in patient care in the NICU

If you do not meet any of the above criteria, thank you for your time, however you are not suitable for this research.

DO I HAVE TO SAY YES?

You do not have to agree to participate in this survey. The decision to become involved in this research is entirely up to your own discretion.

WHAT WILL HAPPEN IF I SAY NO?

I will thank you for your time and will not contact you about this research again. Your participation or withdrawal will not affect your relationship with the researchers, hospital or universities.

IF I SAY YES, CAN I CHANGE MY MIND LATER?

You can change your mind at any time and you do not have to offer any explanation. I will thank you for your time and will not contact you about this research again.

WHAT IF I HAVE CONCERNS OR A COMPLAINT?

If you have concerns about the research that you think I can help you with, please feel free to contact me on [redacted] or Natalia.krzyzaniak@student.uts.edu.au, or my supervisors A/Prof Beata Bajorek, Beata.Bajorek@uts.edu.au and Dr Iga Pawłowska, iga112@gumed.edu.pl.

If you would like to talk to someone who is not connected with the research, you may contact the Research Ethics Office on 02 9514 9772, or research.ethics@uts.edu.au and quote this number: UTS HREC REF NO. ETH17-1584, GUMed HREC REF NO. NKBBN/424-184/2017.

I.4 INFORMATION SHEET (POLISH)

INFORMACJE DLA UCZESTNIKOW

KTO PROWADZI BADANIE?

Nazywam się Natalia Krzyżaniak i jestem doktorantem na University of Technology Sydney. (Moim promotorem jest A/Prof Dr Beata Bajorek, a natomiast promotorem pomocniczym jest Dr Iga Pawłowska)

O CZYM JEST TO BADANIE?

Badanie ma na celu przedstawienie roli farmaceuty i rodzaj usług farmaceutycznych wykonywanych na oddziałach intensywnej terapii noworodkowych (ITN). Ponadto, badanie to ma na celu określenie, które wskaźniki jakościowe oraz usługi farmaceutyczne są uważane za ważne dla racjonalnego stosowania leków u noworodków.

JEŚLI SIE ZGODZE, CO TO BADANIE BĘDZIE WYMAGAC?

Badanie będzie wymagało wypełnienia trzech ankiet

CZY ISTNIEJE JAKIEŚ RYZYKO?

Uczestnicząc w tym badaniu nie ponosicie żadnego ryzyka, ale mogą wystąpić niedogodności spowodowane z czasem wymaganego na wypełnienie ankiety. Jeśli podczas wypełniania ankiety, napotkają Państwo na jakieś problemy, lub niektóre pytania będą niekomfortowe, zawsze można zrezygnować z badania.

DLACZEGO ZOSTALEM/AM SPYTANA O UDZIAL W TYM BADANIU?

Pan/Pani jest cennym członkiem zespołu szpitalnego.

Proszę potwierdzić, (poprzez zaznaczenie pola), które odnoszą się do Państwa (można zaznaczyć więcej niż jedną)

- ☐ Farmaceuta pracujący w aptece szpitalnej / Kierownik apteki szpitalnej
- ☐ Farmaceuta pracujący na stanowisku naukowym
- ☐ Neonatolog / Lekarz pracujący na ITN
- ☐ Pielęgniarka neonatologiczna / Położna

Jeśli nie spełniają Państwo wymagań kryterium, nie mogą Państwo wziąć udziału w badaniu. Bardzo dziękuję Państwu za poświęcony czas.

CZY MUSZĘ ZGODZIĆ SIĘ NA UCZESTNICTWO W TYM BADANIU?

Udział w badaniu jest dobrowolny.

CO SIE STANIE JEŚLI ODMÓWIĘ?

Podziękuję Państwu za poświęcony czas i nie będę ponownie kontaktowała się z Państwem.

JEŚLI TERAZ SIĘ ZGODZĘ, MOGE PÓŹNIEJ ZMIENIĆ ZDANIE?

Mogą Państwo zmienić zdanie w każdej chwili, nie podając żadnych wyjaśnień. Podziękuję za poświęcony czas i nie będę ponownie kontaktowała się z Państwem.

CO ZROBIC JESLI MAM PYTANIA?

Jeśli Państwo mają wątpliwości co do badań, proszę o kontakt ze mną pod nr telefonu: [redacted] lub Natalia.krzyzaniak@student.uts.edu.au, lub z którymś z moich promotorów A/Prof Beata Bajorek, beata.bajorek@uts.edu.au i Dr Iga Pawłowska, iga112@gumed.edu.pl.

Jeśli Państwo chcą porozmawiać z osobą, która nie jest związana z badaniami, można skontaktować się z przedstawicielem Komisji Bioetycznej 02 9514 9772 lub mailowo, research.ethics@uts.edu.au **(UTS HREC REF NO. ETH17-1584, GUMed HREC REF NO. NKBBN/424-184/2017).**

I.5 PARTICIPANT CONSENT FORM (ENGLISH)

APPENDIX – CONSENT FORM FOR PAPER 6 ENGLISH

I_____agree to participate in the research project *'Stage 4 (Delphi Panel): Evaluation Of Pharmacist Practice In Neonatal Intensive Care Units In Australia And Poland: Developing A Pharmacy Practice Model And Quality Indicator List* **(***UTS HREC REF NO. ETH17-1584, GUMed HREC REF NO. NKBBN/424-184/2017)* being conducted by Natalia Krzyzaniak, Building 7 level 4, University of Technology Sydney NSW 2007, +61 2 9514 1448 of the University of Technology, Sydney as part of her Doctor of Philosophy. This research has not been funded.

I understand that the purpose of this study is to identify pharmacist roles and clinical pharmacy key performance indicators that can be used in a pharmacy practice model to guide pharmaceutical care services in the neonatal intensive care unit (NICU). I understand that my participation in this research will involve completing three sequential surveys using a three round Delphi technique. Each survey should only take, at most, 15 minutes to complete.

I am aware that I can contact Natalia Krzyzaniak or her supervisor A/Professor Beata Bajorek or co-supervisor Dr Iga Pawłowska if I have any concerns about the research. I also understand that I am free to withdraw my participation from this research project at any time I wish, without consequences, and without giving a reason.

I agree that the research data gathered from this project may be published in a form that does not identify me in any way.

I have been invited to participate because; please confirm the following by ticking the box that applies to you (you may tick more than one)

☐ I have experience with hospital based clinical pharmacy services AND;

☐ I am an academic interested in quality pharmaceutical care OR;

☐ I am a pharmacist involved in patient care in the NICU OR;

☐ I am a doctor involved in patient care in the NICU OR;

☐ I am a nurse/midwife involved in patient care in the NICU

If you do not meet any of the above criteria, thank you for your time, however you are not suitable for this research.

_____ ____/____/____

Signature (participant)

_____ ____/____/____

Signature (researcher or delegate)

NOTE: This study has been approved by the University of Technology, Sydney Human Research Ethics Committee. If you have any complaints or reservations about any aspect of your participation in this research which you cannot resolve with the researcher, you may contact the Ethics Committee through the Research Ethics Officer (ph: +61 2 9514 9772 Research.Ethics@uts.edu.au) and quote the UTS HREC reference number. Any complaint you make will be treated in confidence and investigated fully and you will be informed of the outcome.

I.6 PARTICIPANT CONSENT FORM (POLISH)

FORMULARZ ZGODY DLA UCZESTNIKOW – ETAP 4

Pan/Pani jest cennym członkiem zespołu szpitalnego. Proszę potwierdzić, (poprzez zaznaczenie pola), które odnoszą się do Państwa (można zaznaczyć więcej niż jedną):

☐ Farmaceuta pracujący w aptece szpitalnej / Kierownik apteki szpitalnej

☐ Farmaceuta pracujący na stanowisku naukowym

☐ Neonatolog / Lekarz pracujący na ITN

☐ Pielęgniarka neonatologiczna / Położna

Jeśli nie spełniają Państwo wymagań kryterium, nie mogą Państwo wziąć udziału w badaniu. Bardzo dziękuję Państwu za poświęcony czas.

POTWIERDZENIE

Ja _____ zgadzam się na udział w projekcie badawczym "*Jakość opieki farmaceutycznej w ITN: opracowanie modelu praktyki farmaceutycznej i kluczowych wskaźników efektywności*" (*UTS HREC REF NO. ETH17-1584, GUMed HREC REF NO. NKBBN/424-184/2017)* prowadzony przez Natalię Krzyżaniak, z University of Technology Sydney w ramach swojego doktoratu.

Badania te nie otrzymały pomocy finansowej.

Rozumiem, że celem tego badania jest określenie, które wskaźniki jakościowe oraz usługi farmaceutyczne są uważane za ważne dla racjonalnego stosowania leków u noworodków.

Rozumiem, że mój udział w tym badaniu będzie wymagało wypełnienie trzech kwestionariuszy i nie powinno trwać dłużej niż 15 minut.

Rozumiem, że mogę się skontaktować z Natalią Krzyżaniak lub jej promotorką A/Profesor Dr Beata Bajorek lub promotorem pomocniczym Dr Iga Pawłowska, jeśli mam jakiekolwiek wątpliwości do badań.

Rozumiem ze udział w badaniu jest dobrowolny. Rozumiem ze mam prawo do wyrażenia sprzeciwu wobec udziału w badaniu lub wycofania się z uczestnictwa na każdym jego etapie.

Zgadzam się, że dane badawcze zgromadzone w ramach tego projektu mogą być opublikowane w formie, która nie identyfikuje mnie w żaden sposób.

_____ ____/____/____

Podpis (uczestnik)

_____ ____/____/____

Podpis (badacz)

APPENDIX J – DATA COLLECTION FORM FOR PAPERS 6 AND 7, CHAPTER 6

PROJECT TITLE: EVALUATION OF PHARMACIST PRACTICE IN NEONATAL INTENSIVE CARE UNITS IN AUSTRALIA AND POLAND: DEVELOPING A PHARMACY PRACTICE MODEL AND QUALITY INDICATOR LIST

J.1 ROUND 1 DELPHI PAPER 6 (ENGLISH)

J.2 ROUND 1 DELPHI PAPER 7 (POLISH)

J.1 ROUND 1 DELPHI PAPER 6 (ENGLISH)

DELPHI ROUND 1

Dear Participant,

Thank you for taking the time to complete this survey. This survey forms Round 1 of the Delphi research method used in this project and you will be asked to rate each element to the best of your knowledge. There is a section at the end of the survey to add any additional comments.

Please confirm which of the following apply to you:

• I am an academic interested in quality pharmaceutical care OR; • I am a pharmacist involved in patient care in the NICU OR; • I am a doctor involved in patient care in the NICU OR; • I am a nurse/midwife involved in patient care in the NICU	☐ ☐ ☐ ☐
Experience with hospital based clinical pharmacy services	☐

If you do not meet any of the above criteria, thank you for your time, however you are not suitable for this research.

Please insert a (x) in the corresponding box that most appropriately reflects your response.

PART A: DEMOGRAPHIC INFORMATION **Please tell us about your practice background:**	
Gender:	☐$_1$ Female ☐$_2$ Male
Nationality	☐$_1$ Australian ☐$_2$ Polish
Any specialised qualifications related to NICU/paediatric pharmacy?	☐$_1$ Yes Please specify: ……. ☐$_2$ No
Which position best describes your current role?	☐$_1$ NICU pharmacist/Director of Pharmacy ☐$_2$ Pharmacist working in academia ☐$_3$ Neonatologist/doctor working on the NICU ☐$_4$ Neonatal nurse/midwife ☐$_5$ Other – please specify: ……
Years of experience in this role:	☐$_1$ Less than 1 year ☐$_2$ Between 1 and 5 years ☐$_3$ Between 6 and 10 years ☐$_4$ Over 10 years

PART B – PHARMACIST ROLES WHICH ARE ESSENTIAL FOR THE QUALITY USE OF MEDICINES IN THE NICU

The table below identifies clinical pharmacist roles and services. Please identify which of the following roles, in your opinion, fulfil each of the three following criteria:

- Should be performed for the NICU;
- Is realistically able to be performed for the NICU, in accordance with the current pharmacy practice system functioning Australia/Poland; and
- Reflects an ideal level of pharmacy practice in the NICU

  Please identify your level of agreement:

Pharmacist Services/Roles	**Strongly Disagree** 1	**Disagree** 2	**Neutral** 3	**Agree** 4	**Strongly Agree** 5
ADMINISTRATION/MANAGEMENT					
Development/implementation of a drug formulary service	☐	☐	☐	☐	☐
Attendance at non-clinical meetings i.e. Drug and Therapeutics Committee	☐	☐	☐	☐	☐
Conducting quality assurance measures i.e. drug usage evaluations, workload documentation, auditing	☐	☐	☐	☐	☐
Management of the drug budget	☐	☐	☐	☐	☐
Evaluation, selection and purchasing of pharmaceuticals for the unit	☐	☐	☐	☐	☐
Development of drug policies/protocols/guidelines for the NICU	☐	☐	☐	☐	☐
CLINICAL ROLES					
Patient medication chart review	☐	☐	☐	☐	☐
Participation in medical ward rounds	☐	☐	☐	☐	☐
Monitoring the efficacy of	☐	☐	☐	☐	☐

pharmacotherapy in patients					
Documenting/monitoring side-effects and Adverse Drug Events/Reactions	☐	☐	☐	☐	☐
Documenting Medication Errors	☐	☐	☐	☐	☐
Evaluating patients clinical laboratory tests	☐	☐	☐	☐	☐
Therapeutic Drug Monitoring (TDM)	☐	☐	☐	☐	☐
Immunisations	☐	☐	☐	☐	☐
Monitoring Total Parenteral Nutrition (TPN)	☐	☐	☐	☐	☐
Participation in clinical meetings	☐	☐	☐	☐	☐
Calculating and recommending doses and dosing schedules for specific patients	☐	☐	☐	☐	☐
Assisting doctors in prescribing off-label/unlicensed medicines	☐	☐	☐	☐	☐
Identifying and performing interventions for individual patients to prevent or resolve drug therapy problems i.e. interactions, incompatibilities, allergies etc.	☐	☐	☐	☐	☐
Recommending drugs and contributing to the pharmacotherapy decision making process for specific patients	☐	☐	☐	☐	☐
Collaborating and discussing specific patients with doctors and nurses	☐	☐	☐	☐	☐
EDUCATION/COMMUNICATION/RESEARCH					
Providing training/in-services for other health professionals on NICU related topics and drug related problems	☐	☐	☐	☐	☐
Contributing to and/or attending NICU related conferences	☐	☐	☐	☐	☐
Involved in clinical trials	☐	☐	☐	☐	☐
Involved in research related to neonatal pharmacotherapy	☐	☐	☐	☐	☐

Source of drug information - responding to information requests from health professionals on the ward	☐	☐	☐	☐	☐
Counselling parents/carers of neonatal patients on medication	☐	☐	☐	☐	☐
PROVISION OF MEDICINES					
Dispensing prescriptions	☐	☐	☐	☐	☐
Extemporaneous compounding of formulations for the NICU	☐	☐	☐	☐	☐
Stocking the ward with essential medicines/house-keeping activities i.e. checking expiry dates, fridge temperatures etc.	☐	☐	☐	☐	☐

PART C: SELECTING KEY PERFORMANCE INDICATORS RELATED TO PHARMACIST PRACTICE IN THE NICU

Please assess whether each proposed key performance conforms to the selection criteria outlined below:

That the item

- reflects a desired level of quality practice
- links to direct patient care in the NICU
- is pharmacy or pharmacist sensitive
- is feasible to measure
- is generalizable to all hospital pharmacy types in your country of practice (Australia/Poland)
- is important for optimal medication management in this setting

The first set of indicators refer to the STRUCTURE of pharmaceutical services:

INDICATORS	**STRONGLY DISAGREE$_1$**	**DISAGREE$_2$**	**NEUTRAL$_3$**	**AGREE$_4$**	**STRONGLY AGREE$_5$**
STRUCTURE					
PERSONNEL					
Availability of a funded NICU clinical pharmacist position (full-time/part-time) in the hospital [150]	☐	☐	☐	☐	☐
NICU pharmacist holds qualifications in clinical pharmacy or NICU/paediatric pharmacy [151-153]	☐	☐	☐	☐	☐
FACILITIES/ENVIRONMENT/RESOURCES					
Dedicated area/station on the ward for the pharmacist that is a well-lit, with sufficient workspace, minimal distractions [82]	☐	☐	☐	☐	☐

Availability of suitable fridges for vaccines and TPN on the ward [154]	☐	☐	☐	☐	☐
Dedicated area on the ward for medication preparation that contains the relevant instruments needed [150] [154]	☐	☐	☐	☐	☐
Direct availability on the ward of essential medicines for specific use within the NICU [155]	☐	☐	☐	☐	☐
Availability of written policies/protocols/guidelines for high-risk medications i.e. antibiotics, pain-relief, parenteral nutrition [82] [152] [155] [156]	☐	☐	☐	☐	☐
Availability of clear policies on how to prescribe, dispense, administer and monitor medications in the NICU [82]	☐	☐	☐	☐	☐
Easily accessible neonatal formulary with standard concentrations [82] [157] [158]	☐	☐	☐	☐	☐
Availability of emergency medicines sheets, with listed doses per weight [157] [158]	☐	☐	☐	☐	☐
Availability of standard neonatal/paediatric references for use in the selection, use and evaluation of medications i.e. textbooks (BNF P, Neofax), online	☐	☐	☐	☐	☐

resources [82]					
Availability of electronic medication error and adverse drug event reporting (systems) [82 152 156 159]	☐	☐	☐	☐	☐
Availability of safety technology including: CPOE, CDSS, barcode verification, smart pumps, computerised calculation of orders, automated drug dispensing units, electronic health records [7 82 157 158 160-162]	☐	☐	☐	☐	☐
Comments:					

The second set of indicators refer to the PROCESS of pharmaceutical services i.e. what is done to the patient:

PROCESS					
INDICATORS	**STRONGLY DISAGREE$_1$**	**DISAGREE$_2$**	**NEUTRAL$_3$**	**AGREE$_4$**	**STRONGLY AGREE$_5$**
Proportion of medicine charts reviewed by clinical pharmacists within 24 hours of admission	☐	☐	☐	☐	☐
Proportion of patients who receive formal documented admission medication reconciliation by a pharmacist (includes medication history from the mother of patient)	☐	☐	☐	☐	☐
Number of potential or actual drug related problems identified by a pharmacist per patient per bed day	☐	☐	☐	☐	☐
Number of total drug therapy problems resolved by pharmacists in the NICU	☐	☐	☐	☐	☐
Number of drug therapy problems resolved for 'high-alert' medications by pharmacists	☐	☐	☐	☐	☐
Proportion of patients for whom pharmacists have completed a medication action plan	☐	☐	☐	☐	☐
Proportion of patients prescribed narrow therapeutic index	☐	☐	☐	☐	☐

medications who are monitored by a pharmacist (Therapeutic Drug Monitoring) [152] [156]					
Proportion of parents of NICU patients that received medication counselling at discharge [156] [159]	☐	☐	☐	☐	☐
Proportion of unlicensed/off-label prescriptions that involved the consultation of a pharmacist [152]	☐	☐	☐	☐	☐
Proportion of Adverse Drug Events that were identified, monitored, rectified, prevented, and reported per number of admissions [152] [156] [159]	☐	☐	☐	☐	☐
Proportion of dispensing errors identified and rectified by pharmacist per number of admissions [82]	☐	☐	☐	☐	☐
Number of education/training sessions provided by pharmacists relating to pharmacotherapy in the NICU for other health professionals [7] [82] [152] [156] [159] [163]	☐	☐	☐	☐	☐
Number of pharmacotherapy related consultations provided to medical personnel by pharmacists [152] [156]	☐	☐	☐	☐	☐

Participation in multi-disciplinary ward rounds and meetings [156] [159] – proportion of pharmacists who actively participate in interprofessional patient care rounds to improve medication management	☐	☐	☐	☐	☐
Proportion of TPN regimens that have been monitored/optimised by a pharmacist [152] [155]	☐	☐	☐	☐	☐
Proportion of IV medications that have been monitored by a pharmacist [152]	☐	☐	☐	☐	☐
Number of pharmacists involved in conducting drug use evaluations in the NICU [164]	☐	☐	☐	☐	☐
Use of pain protocols for patient groups and specific procedures [164]	☐	☐	☐	☐	☐
Proportion of pharmacists involved in NICU related clinical research [156] [159]	☐	☐	☐	☐	☐
Proportion of dose calculations checked by pharmacist before administration [82]	☐	☐	☐	☐	☐
The percentage of discharge prescriptions reviewed and reconciled by a pharmacist prior to dispensing.	☐	☐	☐	☐	☐

Proportion of pharmacists involved in a prescribing error feedback programme [165]	☐	☐	☐	☐	☐
Proportion of multiple birth babies that have were correctly identified and had the correct medicines prescribed and administered	☐	☐	☐	☐	☐
Proportion of IV medications whose doses were checked prior to administration	☐	☐	☐	☐	☐
TPN THERAPY, MINERALS, VITAMINS	Unable to find any specific KPIs for these particular drug categories, however these are commonly identified in the literature as being the most frequently used in NICUs worldwide and also experience the most medication errors. Any suggestions for KPIs?				
ANTIBIOTIC THERAPY					
PAIN THERAPY – FENTANYL, MORPHINE, NSAIDs					
SURFACTANTS					
ANTICOAGULANTS AND HEPARIN					
CARDIAC MEDICINES					
FRUSEMIDE, RANITIDINE, CAFFEINE, INSULIN					
Comments:					

The third set of indicators refer to the OUTCOME of pharmaceutical services:

OUTCOME					
INDICATORS	**STRONGLY DISAGREE$_1$**	**DISAGREE$_2$**	**NEUTRAL$_3$**	**AGREE$_4$**	**STRONGLY AGREE$_5$**
Monthly audit of medication charts with a target of at least 80% correct time of administration (wrong time defined as more than 1 hour of prescribing for stat/PRN medications, and for regular medications dose not given prior to the next scheduled dose) [163]	☐	☐	☐	☐	☐
Prescribing errors: Identification and resolution of unintentional departure from recommended prescribing practices per patient per bed day					
Monthly audit of the labelling of all lines – to be labelled with access type and fluid/medication being administered with a target of at least 90% correct labels [163]	☐	☐	☐	☐	☐
Monthly audit of prescribing against prescribing guidelines – target 90% [163]	☐	☐	☐	☐	☐
Monthly audit of prescribing pain relief against pain protocols for specific procedures	☐	☐	☐	☐	☐
Episodes of ineffective	☐	☐	☐	☐	☐

empiric antibiotic therapy (organism/antibiotic mismatch) [166]					
Mean time to target vancomycin trough concentration for infants with known MRSA infection [166]	☐	☐	☐	☐	☐
Proportion of infants receiving appropriate dosing and timing of perioperative prophylaxis [166]	☐	☐	☐	☐	☐
Episodes of antibiotic-associated adverse events [166]	☐	☐	☐	☐	☐
Duration of treatment for culture-negative presumed late onset sepsis [166]	☐	☐	☐	☐	☐
Rates of infections with multi-drug resistant gram-negative infections [166]	☐	☐	☐	☐	☐
Proportion of patients with toxic or sub-therapeutic aminoglycoside concentration whose dosage has been adjusted prior to next dose	☐	☐	☐	☐	☐
Proportion of prescriptions for restricted antibiotics that are concordant with hospital approved criteria	☐	☐	☐	☐	☐
Proportion of patients prescribed hospital initiated warfarin whose loading doses are consistent with a	☐	☐	☐	☐	☐

hospital approved protocol					
Percentage of patients who received at least 1 pain management intervention during heel sticks, PIV insertions, venipunctures, umbilical arterial catheterizations, nasogastric tube placements and EET suctioning [164]	☐	☐	☐	☐	☐
Percentage of all defined procedures that were treated with a pain treatment intervention [164]	☐	☐	☐	☐	☐
Administration errors: identification and resolution of unintended departure from recommended administration practices per patient per bed day	☐	☐	☐	☐	☐
Proportion of patients families that have had a face-to-face discussion about medicines related information	☐	☐	☐	☐	☐
Incidence of nosocomial infection [155 167 168]	☐	☐	☐	☐	☐
Percentage of medication orders that include the correct dose per kilogram (or body surface area) AND an effective and safe total dose	☐	☐	☐	☐	☐
Incidence of neonatal sepsis [167 168]	☐	☐	☐	☐	☐

Length of stay [167]	☐	☐	☐	☐	☐
Days on TPN [155 167]	☐	☐	☐	☐	☐
Growth velocity (daily weight gain) [155 167]	☐	☐	☐	☐	☐
Mortality rates [167-170]	☐	☐	☐	☐	☐
Medication Error rates/reports	☐	☐	☐	☐	☐
Adverse Drug Event rates/reports	☐	☐	☐	☐	☐
Number of pharmacotherapy related critical incident /root case analyses performed per 6 months [82 158]	☐	☐	☐	☐	☐
Comments					

If you can think of any other elements that can be used as key performance indicators of the quality of pharmaceutical care provided to NICU patients, please write them below. If possible, please include the reasons for considering each item suggested. They will be included in the next round of the Delphi study.

……

……

J.2 ROUND 1 DELPHI PAPER 7 (POLISH)

JAKOŚĆ OPIEKI FARMACEUTYCZNEJ W NICU: OPRACOWANIE MODELU PRAKTYKI FARMACEUTYCZNEJ I KLUCZOWYCH WSKAŹNIKÓW EFEKTYWNOŚCI

Kod Uczestnika: _ _ / _ _ / _ _

Szanowni Państwo,

Zwracamy się z prośbą o wypełnienie kwestionariusza dotyczącego roli farmaceuty na oddziałach intensywnej terapii noworodka, które jest częścią projektu badawczego prowadzonego także w Australii. Badanie ma charakter anonimowy i jest prowadzone w celach naukowych przez zespół z University of Technology Sydney oraz Katedry i Zakładu Farmakologii GUMed (kontakt: Natalia Krzyżaniak, ul. Dębowa 23, 80-204 Gdańsk, tel. 583491812, e-mail: Natalia.krzyzaniak@student.uts.edu.au). Mają Państwo prawo do wyrażenia sprzeciwu wobec udziału w badaniu lub wycofania się z uczestnictwa na każdym jego etapie. Wypełnienie kwestionariusza zajmie Państwu około 15 minut czasu.

Dziękujemy Państwu za udział w badaniu!

JAKOŚĆ OPIEKI FARMACEUTYCZNEJ W NICU: OPRACOWANIE MODELU PRAKTYKI FARMACEUTYCZNEJ I KLUCZOWYCH WSKAŹNIKÓW EFEKTYWNOŚCI

- PRYWATNE -

- DELPHI ANKIETA – RUNDA 1 -

INFORMACJE DOTYCZĄCE RESPONDENTÓW	
1. Płeć**:**	☐$_1$ Kobieta ☐$_2$ Mężczyzna
2. Obywatelstwo	☐$_2$ Polskie ☐$_1$ Inne: …….
3. Dodatkowe kwalifikacje/specjalizacje dotyczące pracy na ITN	☐$_1$ Tak, jakie?…… ☐$_2$ Nie
4. Wykonywany zawód	☐$_1$ Farmaceuta pracujący w aptece szpitalnej / Kierownik apteki szpitalnej ☐$_2$ Farmaceuta pracujący na stanowisku naukowym ☐$_3$ Neonatolog / Lekarz pracujący na ITN ☐$_4$ Pielęgniarka / Położna ☐$_5$ Inne, proszę podać: …… ……
5. Doświadczenie na tym stanowisku	☐$_1$ < 1 rok ☐$_2$ 1 - 5 lat ☐$_3$ 6 - 10 lat ☐$_4$ > 10 lat

USŁUGI FARMACEUTYCZNE KTORE SĄ NIEZBĘDNE DLA PRAWIDŁOWEGO I BEZPIECZNEGO STOSOWANIA LEKOW W ITN

Poniższa tabela przedstawia usługi farmaceutyczne oraz inne zadania prowadzone przez farmaceutów. Które z tych usług według Państwa są niezbędne do prawidłowego i bezpiecznego stosowania leków dla ITN? Proszę zaznaczyć pole w tabeli.

Role/Usługi Farmaceutyczne	**Zdecydowanie Się Zgadzam** 1	**Raczej Się Zgadzam** 2	**Nie Mam Zdania** 3	**Raczej Się Nie Zgadzam** 4	**Zdecydowanie Nie Zgadzam Się** 5
USŁUGI ADMINISTRACYJNE					
Opracowanie/wdrożenie receptariusza	☐	☐	☐	☐	☐
Uczęszczanie w nieklinicznych spotkaniach np. posiedzeniach komitetu terapeutycznego szpitala	☐	☐	☐	☐	☐
Prowadzenie badań jakości farmakoterapii np. ocena stosowanych leków	☐	☐	☐	☐	☐
Zarządzanie budżetem do zakupu leków	☐	☐	☐	☐	☐
Zamawianie leków dla ITN	☐	☐	☐	☐	☐
Opracowanie protokołów dla leków ITN	☐	☐	☐	☐	☐
USŁUGI KLINICZNE					
Przeprowadzanie przeglądu leków dla pacjentów	☐	☐	☐	☐	☐

Udział farmaceuty w obchodzie w ITN	☐	☐	☐	☐	☐
Monitorowanie skuteczności leków u pacjenta	☐	☐	☐	☐	☐
Dokumentowanie/monitorowanie oraz zgłaszanie działań niepożądanych leków	☐	☐	☐	☐	☐
Dokumentowanie błędów lekowych (Medication Errors)	☐	☐	☐	☐	☐
Analiza wyników badan pacjenta np. badania krwi, badanie mykologiczne	☐	☐	☐	☐	☐
Monitorowanie farmakoterapii	☐	☐	☐	☐	☐
Współudział w szczepieniach	☐	☐	☐	☐	☐
Współudział w żywieniu pozajelitowym	☐	☐	☐	☐	☐
Udział w klinicznych spotkaniach z lekarzem, pielęgniarką, rodzina pacjenta itd.	☐	☐	☐	☐	☐
Obliczanie i zalecanie dawek i schematów dawkowania dla wybranych pacjentów	☐	☐	☐	☐	☐
Wspieranie lekarzy w stosowaniu leków poza wskazaniami medycznymi (off label/unlicensed use)	☐	☐	☐	☐	☐
Identyfikacja problemów lekowych oraz prowadzenie interwencji dla poszczególnych pacjentów w celu zapobiegania lub	☐	☐	☐	☐	☐

rozwiązywania tych problemów (np. interakcje, niezgodności, alergie)					
Współudział w wyborze właściwej farmakoterapii dla pacjentów	☐	☐	☐	☐	☐
Doradztwo prowadzone dla lekarzy, położnych i pielęgniarek w zakresie farmakoterapii pacjentów	☐	☐	☐	☐	☐
EDUKACJA/KOMUNIKACJA/BADANIA					
Prowadzenie szkoleń dla lekarzy/położnych/pielęgniarek dotyczących farmakoterapii noworodków	☐	☐	☐	☐	☐
Uczestnictwo w konferencja naukowych dotyczących ITN	☐	☐	☐	☐	☐
Współuczestniczenie w badaniach klinicznych leków	☐	☐	☐	☐	☐
Współuczestniczenie w badaniach naukowych dotyczących farmakoterapii u noworodków	☐	☐	☐	☐	☐
Udzielanie informacji personelowi medycznemu	☐	☐	☐	☐	☐
Edukacja rodzin oraz opiekunów noworodków	☐	☐	☐	☐	☐

ZAOPATRYWANIE W LEKI					
Wydawanie leków i materiałów medycznych na oddział ITN	☐	☐	☐	☐	☐
Wykonywanie leków recepturowych dla pacjentów w ITN	☐	☐	☐	☐	☐
Kontrola właściwego przechowywania leków na oddziale/dat ważności leków/leków wstrzymanych i wycofanych z obrotu	☐	☐	☐	☐	☐

OKREŚLENIE WSKAŹNIKOW (DETERMINANTÓW) JAKOŚCI USŁUG FARMACEUTYCZNYCH W ITN

Poniżej zostały przedstawione determinanty jakości usług farmaceutycznych opracowane na podstawie danych literaturowych, które mogą stanowić kryterium oceny jakości usług farmaceutycznych w ITN. Czy Państwa zdaniem wymienione w tabeli determinanty mogą być stosowane do oceny jakości usług farmaceutycznych w praktyce polskich oddziałów neonatologicznych? Podczas dokonywania oceny mogą Państwo rozważyć w szczególności, czy dany czynnik wskazuje na optymalny poziom jakości usług farmaceutycznych, dotyczy bezpośredniej opieki nad pacjentem w ITN, dotyczy apteki szpitalnej lub farmaceuty szpitalnego, jest możliwy do zmierzenia, może być dostosowany do każdej apteki szpitalnej w Polsce lub jest niezbędnym elementem dla prawidłowego stosowania leków w ITN.

STRUKTURA					
DETERMINANTY	**Zdecydowanie Się Zgadzam 1**	**Raczej Się Zgadzam 2**	**Nie Mam Zdania 3**	**Raczej Się Nie Zgadzam 4**	**Zdecydowanie Nie Zgadzam Się 5**
Czy zgadzają się Państwo, z twierdzeniem, że niżej wymienione determinanty mogą być kryterium oceny jakości usług farmaceutycznych?					
Zatrudnienie farmaceuty na oddziale neonatologicznym (każdy wymiar czasu pracy) [150]	☐	☐	☐	☐	☐
Posiadanie przez farmaceutę specjalizacji z zakresu farmacji klinicznej [151-153]	☐	☐	☐	☐	☐
Wydzielone miejsce na oddziale dla farmaceuty [82]	☐	☐	☐	☐	☐
Dostępność lodówek na oddziałach do przechowywania szczepionek [154]	☐	☐	☐	☐	☐

Bezpośredni dostęp do leków często stosowanych na oddziale[155]	☐	☐	☐	☐	☐
Dostępność zasad dotyczących zlecania, wydawania, zarządzania i monitorowania leków na oddziale ITN [82]	☐	☐	☐	☐	☐
Szeroka dostępność źródeł informacji dotyczących stosowania leków (np. wytycznych, indeksów) [82]	☐	☐	☐	☐	☐
Dostępność elektronicznych systemów do monitorowania działań niepożądanych) [82 152 156 159]	☐	☐	☐	☐	☐
Komentarze:					

PROCES					
DETERMINANTY	**Zdecydowanie Się Zgadzam** 1	**Raczej Się Zgadzam** 2	**Nie Mam Zdania** 3	**Raczej Się Nie Zgadzam** 4	**Zdecydowanie Nie Zgadzam Się** 5
Czy zgadzają się Państwo, z twierdzeniem, że niżej wymienione determinanty mogą być kryterium oceny jakości usług farmaceutycznych?					
Procent pacjentów których terapia jest monitorowana przez farmaceutę [152 156]	☐	☐	☐	☐	☐
Procent pacjentów u których stosuje się leki poza wskazaniami po konsultacji z farmaceutą [152]	☐	☐	☐	☐	☐
Zgłaszanie przez farmaceutę działań niepożądanych leków [152 156 159]	☐	☐	☐	☐	☐
Przygotowywanie leków recepturowych dla oddziałów neonatologicznych [82]	☐	☐	☐	☐	☐
Liczba konsultacji udzielona personelowi medycznemu przez farmaceutę [152 156]	☐	☐	☐	☐	☐
Zaangażowanie farmaceuty w optymalizację żywienia pozajelitowego [152 155]	☐	☐	☐	☐	☐
Procent farmaceutów zaangażowanych w badania naukowe prowadzone na oddziałach neonatologicznych [156 159]	☐	☐	☐	☐	☐
Optymalizacja postaci leków do podawania dożylnego [152]	☐	☐	☐	☐	☐
Komentarz					

WYNIKI					
DETERMINANTY	**Zdecydowanie Się Zgadzam** 1	**Raczej Się Zgadzam** 2	**Nie Mam Zdania** 3	**Raczej Się Nie Zgadzam** 4	**Zdecydowanie Nie Zgadzam Się** 5
Czy zgadzają się Państwo, z twierdzeniem, że niżej wymienione determinanty mogą być kryterium oceny jakości usług farmaceutycznych?					
Wykrywalność błędów lekowych	☐	☐	☐	☐	☐
Skala zgłaszania działań niepożądanych	☐	☐	☐	☐	☐
Skala wykrywania błędów lekowych	☐	☐	☐	☐	☐
Koszty terapii	☐	☐	☐	☐	☐
Komentarze					

Proszę podać inne Państwa zdaniem determinanty które mogą być wykorzystane jako wskaźniki oceny jakości usług farmaceutycznych. Zostaną włączeni w następnej rundy badania Delphi

……

……

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APPENDIX L – PDF VERSIONS OF PUBLISHED ARTICLES

L.1 MEDICATION SAFETY IN NEONATAL CARE: A REVIEW OF MEDICATION ERRORS AMONG NEONATES

Therapeutic Advances in Drug Safety *Original Research*

Medication safety in neonatal care: a review of medication errors among neonates

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Abstract

Objective: The objective of this study was to describe the medication errors in hospitalized patients, comparing those in neonates with medication errors across the age spectrum.

Method: In tier 1, PubMed, Embase and Google Scholar were searched, using selected MeSH terms relating to hospitalized paediatric, adult and elderly populations. Tier 2 involved a search of the same electronic databases for literature relating to hospitalized neonatal patients.

Results: A total of 58 articles were reviewed. Medication errors were well documented in each patient group. Overall, prescribing and administration errors were most commonly identified across each population, and mostly related to errors in dosing. Errors due to patient misidentification and overdosing were particularly prevalent in neonates, with 47% of administration errors involving at least tenfold overdoses. Unique errors were identified in elderly patients, comprising duplication of therapy and unnecessary prescribing of medicines. Overall, the medicines most frequently identified with error across each patient group included: heparin, antibiotics, insulin, morphine and parenteral nutrition. While neonatal patients experience the same types of medication errors as other hospitalized patients, the medication-use process within this group is more complex and has greater consequences resulting from error. Suggested strategies to help overcome medication error most commonly involved the integration of a clinical pharmacist into the treating team.

Conclusion: This review highlights that each step of the medication-use process is prone to error across the age spectrum. Further research is required to develop targeted strategies relevant to specific patient groups that integrate key pharmacy services into wards.

Keywords: medication error, medication safety, neonates, NICU

Introduction

Medication errors are common in hospitalized patients and are a high priority in healthcare systems worldwide [Fortescue *et al.* 2003; Wiedenmayer *et al.* 2006; Roughead *et al.* 2013]. Defined as any mistakes that occur during the medication-use process, medication errors can arise in the course of prescribing, dispensing, transcribing, administering and monitoring medicines [European Medicines Agency, 2015]. Often, these errors are preventable and result in increased patient morbidity and mortality as well as increased healthcare costs and unnecessary hospitalization [European Medicines Agency, 2015]. While the problem of medication errors has been widely reported in published literature, of particular concern are those that occur in neonatal medicine [Kaushal *et al.* 2001; Fortescue *et al.* 2003; Stavroudis *et al.* 2010]. The neonatal population is particularly vulnerable to further risk of harm resulting from medication errors due to their physiological inability to buffer errors [Kaushal *et al.* 2001]. Medication errors with potential to cause harm are eight times more likely to occur in the neonatal intensive care unit (NICU) compared with adult wards [Kaushal *et al.* 2001; Stavroudis *et al.* 2010]. Furthermore, it is reported that medication errors comprise 84.2% of all medical errors within the NICU [Stavroudis *et al.* 2010].

There are few studies that compare medication errors across different patient populations, particularly with respect to the neonatal patient group. Each hospitalized patient population has different pharmacotherapeutic needs, and it is

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important to establish whether there are different medication errors in each group. As such, this lack of information limits the ability of healthcare systems to develop targeted strategies to decrease the incidence of error.

The purpose of this review is to determine a medication error profile that characterizes the types of medication errors that are experienced by different hospitalized patient populations across the age spectrum. The review explores whether there are any medication errors unique to the neonatal population, and establishes whether there are differences in error type between populations. Furthermore, the review identifies the medicines that are most commonly associated with error in each patient group.

Methods

A comprehensive search of the literature was performed using the following electronic databases: Medline, Embase, Google Scholar. Relevant literature, including reviews, original studies and other articles pertaining to medication safety issues and medication errors, were extracted.

Search strategy

A two-tiered search strategy was used (Figure 1). In tier 1, a generalized search was performed to find literature relevant to the paediatric, adult and elderly patient populations using the MeSH terms *paediatric*, *children*, *hospitalized patients*, *adult*, *elderly*, *medication safety* and *medication errors*. Subsequent to finding the bulk of the literature, tier 2 of the search was dedicated to finding articles specific to the neonatal population utilising the following MeSH terms: *medication errors*, *medication safety*, *neonate*, *infant* and *NICU*. Inclusion criteria for the searches restricted the content to the following: types or nature of medication errors, hospitalized patients, and written in the English language. All full-text articles were retrieved and all evaluations pertaining to the types of medication errors in the NICU were included in the review. Manual bibliographic searches of all relevant articles were also performed in order to identify any articles that were not found in the electronic searches.

Structure of review

The patient populations have been classified into four broad age headings: neonates (0–28 days of age), children or paediatrics (1–18 years), adults and the elderly. Neonatal data were gathered from articles that specifically studied the NICU, or had the NICU as part of their study group. The review included paediatric studies that assessed medication errors on paediatric intensive care units (PICUs), emergency and general paediatric wards. The literature reporting on the adult population comprised studies conducted in intensive care units (ICUs), surgical and medical wards and emergency departments. Articles on the elderly patient group reported on errors in geriatric wards and acute-care wards.

Medication errors have been identified and reported within each phase of the medication-use process, including prescription, transcription, dispensing, administration and monitoring [Bates *et al.* 1995; Kaushal *et al.* 2001; Pallas *et al.* 2008; Stavroudis *et al.* 2010]. Definitions of the types of medication error associated with each phase are presented in Table 1.

Results

Electronic and manual searches identified a total of 58 full-text articles, from a range of countries. Most of the literature came from the USA (20 of 58), with others from Spain, Iran, Finland, Australia, UK, Italy, Turkey, Argentina, Brazil, Denmark, Switzerland, New Zealand, Morocco, India and Canada.

Overall, medication errors were well documented in each patient group, however, comparative studies between patient populations were not widely identified.

Neonatal population

Among the 20 articles reviewed, the majority used a prospective chart review method to collect data and just over half of the studies were conducted in the USA (10 of 18) [Raju *et al.* 1989; Vincer *et al.* 1989; Kaushal *et al.* 2001; Carroll *et al.* 2003; Chappell and Newman, 2004; Cordero *et al.* 2004; Gray and Goldmann, 2004; Gray *et al.* 2006; Simpson *et al.* 2004; Suresh *et al.* 2004; Kunac and Reith, 2005; Van Den Anker, 2005; Ligi *et al.* 2008; Pallas *et al.* 2008; Campino *et al.* 2009; Jain *et al.* 2009; Stavroudis *et al.* 2010; Antonucci and Porcella, 2012; Dabliz and Levine, 2012; Sorrentino and Alegiani, 2012]. A summary of the errors reported are presented in Table 2. The prescribing phase was

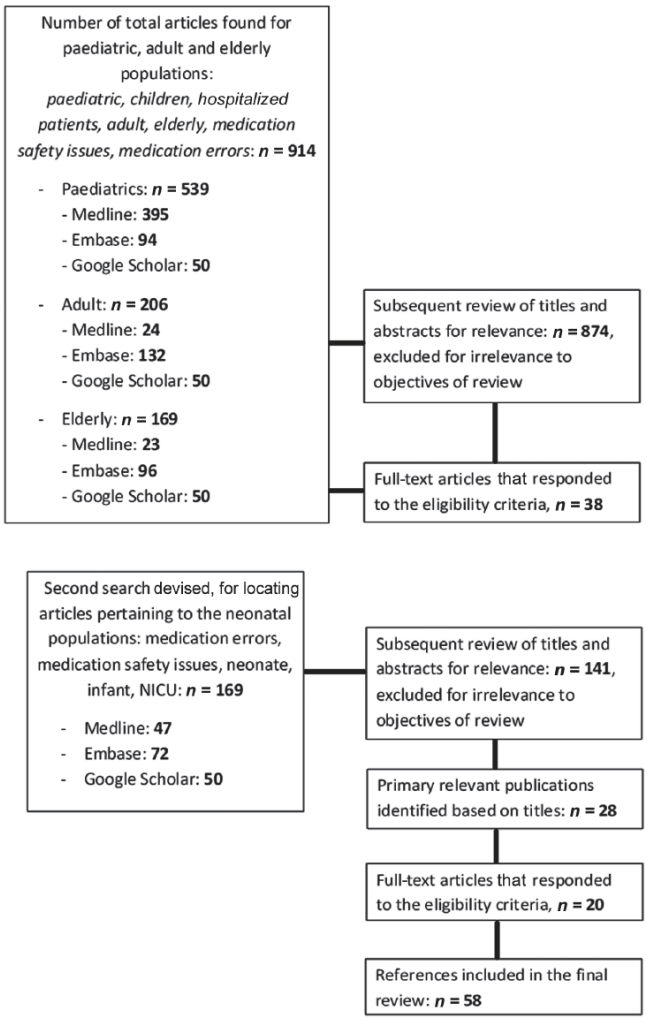

Figure 1. Search Strategy.

associated with the highest incidence of medication errors, comprising 14–74% of total error reports [Kaushal *et al.* 2001; Cordero *et al.* 2004; Gray and Goldmann, 2004; Simpson *et al.* 2004; Suresh *et al.* 2004; Pallas *et al.* 2008; Campino *et al.* 2009; Jain *et al.* 2009; Stavroudis *et al.* 2010; Antonucci and Porcella, 2012; Sorrentino and Alegiani, 2012]. The most frequently reported error within this phase involved incorrect dosing, with 42% of errors relating to overdoses or underdoses [Jain *et al.* 2009]. Ten articles reported that dosing errors occurred because of miscalculation of doses and incorrect placement of decimal points or units of measurement [Kaushal *et al.* 2001; Cordero *et al.* 2004; Simpson *et al.* 2004; Van Den Anker, 2005; Pallas *et al.* 2008; Campino *et al.* 2009; Jain *et al.* 2009; Stavroudis *et al.* 2010; Antonucci and Porcella, 2012; Dabliz and Levine, 2012]. One Indian-based study reported that as a result of a dosing error, an infant received a tenfold increase in the delivery of morphine [Jain *et al.* 2009].

Table 1. Definitions and contributing factors for medication error across the medication-use process.

Definitions of the different types of medication errors	
Prescribing	All errors that occur during the decision process and in prescribing/ordering a medication for a patient. Includes: dose errors, wrong drug, wrong regimen and inappropriate drug.
Transcription	All errors associated with the transfer of verbal or written information from an order sheet or prescription to patient, medication chart or medical records. Includes: discrepancies in drug name, formulation, route, dose, dosing regimen and omission.
Dispensing	All errors that occur during the interpretation of medication prescriptions by the pharmacy staff and the subsequent selection, preparation, labelling and distribution of medication.
Administration	All errors that occur whilst a medication is being administered to a patient. Includes: omission, wrong drug, wrong dose, wrong time and wrong route.
Monitoring	All errors associated with the monitoring of clinical and/or laboratory data that assess the patient's response to the administered drug therapy i.e. through therapeutic drug-monitoring practices. Includes: error in interpreting results, wrong dose suggestions, omission of suggestions and wrong drug suggestions to reverse condition.
Contributing factors for medication error in each patient group	
Neonate	Higher number of medications, lack of physician experience, high-intensity physician workloads, length of stay, low birth weights, gestational ages, similar-sounding or identical names and surnames, multiple-birth babies (i.e. twins), inability to communicate, more vascular lines, long hospitalizations and dispensing medications 2 hours after being ordered.
Paediatric	Seriously ill patients, inexperienced physicians, human error, equipment dysfunction and communication failures.
Adult	Polymedication prescriptions, physicians' lack of pharmacology knowledge, stressful and high-paced work environment, staff performance deficits, failure to consider patient information, memory lapses and dose-checking processes.
Elderly	Taking five or more medications, prescribed nine or more medications, hospitalizations 13 days or longer, incidence of more than one chronic disease and multiple pathologies.

Table 2. Medication errors specific to neonatal patients.

	Neonates
Prescribing	Wrong route Wrong use of units i.e. milligrams instead of grams Lack of neonate-specific drug protocols or information
Transcription	Wrong weight Wrong dosage regimen Wrong units
Dispensing	Providing the correct drug in the wrong packaging Incorrect calculations or doses Late dispensing of medications Incorrect dilutions in manufacture of drugs
Administration	Patient misidentification Additional dose of drug Wrong dilution Parents administering unauthorized nutrients
Monitoring	Nil specific compared with other populations

The consequences of such significant dosing inaccuracies involved long-term injury, including developmental problems, toxic effects requiring active intervention, as well as death [Folli *et al.* 1987; Raju *et al.* 1989; Vincer *et al.* 1989; Frey *et al.* 2000, 2002; Ross *et al.* 2000; Kaushal *et al.*

2001; Simpson *et al.* 2004; Suresh *et al.* 2004]. Errors in prescribing were attributed to lack of physician experience, high-intensity physician workloads as well as the lack of neonate-specific drug protocols or policies on the ward [Gray and Goldmann, 2004; Jain *et al.* 2009]. This is an important issue within the NICU, as the majority of literature highlights that due to the lack of evidence-based information, physicians do not have a reliable source of information to refer to, leading to the prescribing of off-label and unlicensed medicines and subsequent erroneous prescribing decisions [Kaushal *et al.* 2001; Suresh *et al.* 2004; Kunac and Reith, 2005; Van Den Anker, 2005; Campino *et al.* 2009; Stavroudis *et al.* 2010; Antonucci and Porcella, 2012; Dabliz and Levine, 2012; Sorrentino and Alegiani, 2012]. Other common prescribing errors reported only within the neonatal population included: incorrect use of units (i.e. grams instead of milligrams) and wrong administration route [Kaushal *et al.* 2001; Cordero *et al.* 2004; Gray and Goldmann, 2004; Simpson *et al.* 2004; Van Den Anker, 2005; Pallas *et al.* 2008; Campino *et al.* 2009; Jain *et al.* 2009; Antonucci and Porcella, 2012; Dabliz and Levine, 2012].

Transcription-based medication errors (range 12–18.4% of total errors) were related to mistakes in the transfer of patient information to patient medication charts [Kaushal *et al.* 2001; Carroll *et al.* 2003; Suresh *et al.* 2004; Stavroudis *et al.* 2010; Sorrentino and Alegiani, 2012]. Two types of transcribing errors were identified: omissions and commissions (recording incorrect patient information), comprising 18.6% and 18.2% of errors, respectively [Carroll *et al.* 2003]. Specifically in the NICU, these types of errors included: the use of the incorrect units, omission or incorrect recording of patient characteristics (i.e. weights, allergies), and omission of recording administered dose [Kaushal *et al.* 2001; Carroll *et al.* 2003; Suresh *et al.* 2004; Stavroudis *et al.* 2010; Sorrentino and Alegiani, 2012. Carroll and colleagues identified that these types of documentation errors were more likely to occur in those neonatal patients with higher numbers of medicines, vascular lines and longer hospitalizations [Carroll *et al.* 2003].

Dispensing errors comprised 11.9–25% of total errors and were most frequently associated with mistakes in labelling and dilution of formulations [Gray and Goldmann, 2004; Suresh *et al.* 2004; Van Den Anker, 2005; Jain *et al.* 2009; Stavroudis *et al.* 2010; Antonucci and Porcella, 2012; Sorrentino and Alegiani, 2012]. Seven articles identified errors in this phase, which also included: late dispensing, providing the correct drug in the wrong packaging and incorrect calculations or doses [Gray and Goldmann, 2004; Suresh *et al.* 2004; Van Den Anker, 2005; Stavroudis *et al.* 2010; Sorrentino and Alegiani, 2012]. Van den Anker, in particular, emphasized the importance of timely dispensing of medicines, and associated a delayed dispensing time of more than two hours with an increased risk of medication errors occurring [Van Den Anker, 2005].

Seven studies reported on administration errors in neonates and the prevalence had a range of 31–63% of total error reports [Raju *et al.* 1989; Vincer *et al.* 1989; Chappell and Newman, 2004; Suresh *et al.* 2004; Ligi *et al.* 2008; Stavroudis *et al.* 2010; Sorrentino and Alegiani, 2012]. Almost two thirds (60.3%) of administration errors were caused by nurses, with the most common errors associated with incorrect administration time [Raju *et al.* 1989; Kaushal *et al.* 2001; Gray and Goldmann, 2004; Suresh *et al.* 2004; Kunac and Reith, 2005; Ligi *et al.* 2008; Stavroudis *et al.* 2010; Antonucci and Porcella, 2012; Sorrentino and Alegiani, 2012]. One USA-based observational study also reported that parents of NICU patients contributed to the incidence of medication errors by administering unauthorized medicines and incorrectly preparing nutrients for feeding [Suresh *et al.* 2004]. Other neonatal-specific administration errors included: incorrect preparation or dilution of medication and administering an extra dose of medication [Raju *et al.* 1989; Kaushal *et al.* 2001; Gray and Goldmann, 2004; Suresh *et al.* 2004; Kunac and Reith, 2005; Ligi *et al.* 2008; Stavroudis *et al.* 2010; Antonucci and Porcella, 2012; Sorrentino and Alegiani, 2012]. These errors were most commonly associated with the following risk factors: length of stay, low birthweights and early gestational ages [Ligi *et al.* 2008]. A significant issue for the NICU related to the level of product manipulation required to improve the compatibility of medicines to the unique characteristics of neonatal patients. This was emphasized by Chappell and Newman who stated that 31% of intravenous medicines were prescribed for neonatal patients at doses less than one tenth of a vial, resulting in a significantly high susceptibility for the incidence of tenfold or 100-fold dosing errors upon administration [Chappell and Newman, 2004; Ligi *et al.* 2008; Jain *et al.* 2009]. Similarly, Ligi and colleagues reported that 47% of administration errors in the NICU

were tenfold dosing errors [Ligi *et al.* 2008]. Medicines most commonly associated with dosing inaccuracies were identified as intravenous (IV) formulations of: frusemide, benzylpenicillin, diamorphine, gentamicin and insulin [Chappell and Newman, 2004]. The resulting harm was reported as ranging from minor harm, requiring increased monitoring and specific treatment, to serious harm and death [Suresh *et al.* 2004].

Several studies also emphasized the incidence of patient misidentification errors during the administration phase [Vincer *et al.* 1989; Gray and Goldmann, 2004; Suresh *et al.* 2004; Van Den Anker, 2005; Stavroudis *et al.* 2010; Antonucci and Porcella, 2012; Dabliz and Levine, 2012; Sorrentino and Alegiani, 2012]. Dabliz and Levine estimated that 25% of medication errors within the NICU were attributed to administering medication to the wrong patient [Dabliz and Levine, 2012]. The most common causes of misidentification were similar-sounding or identical names and surnames, difficulties in distinguishing multiple-birth babies (i.e. twins and triplets) and inability to communicate with patients [Gray *et al.* 2006]. Furthermore, it was reported that identification bands on wrists and ankles were often removed in order to place IV lines or to take blood samples, and were forgotten to be replaced leading to increased risk for misidentification [Antonucci and Porcella, 2012; Dabliz and Levine, 2012].

Errors pertaining to the monitoring phase were uncommon, comprising only 1.4% of all errors [Suresh *et al.* 2004]. These types of errors often involved the incorrect interpretation of laboratory results, omission of therapeutic drug monitoring and missing the symptoms of adverse events [Kaushal *et al.* 2001; Suresh *et al.* 2004].

Paediatric

Among the 17 articles reviewed, prescription errors were the most commonly reported type of medication error [Folli *et al.* 1987; Aneja *et al.* 1992; Wilson *et al.* 1998; Kozer *et al.* 2002; Fortescue *et al.* 2003; Taylor *et al.* 2005; Condren *et al.* 2010; Al-Jeraisy *et al.* 2011]. Accounting for 10–74% of total error reports, these types of errors were most commonly identified via retrospective and prospective reviews of patient charts and medication incident reports [Folli *et al.* 1987; Aneja *et al.* 1992; Wilson *et al.* 1998; Frey *et al.* 2000, 2002; Ross *et al.* 2000; Kozer *et al.* 2002; Fortescue *et al.* 2003; Taylor *et al.* 2005; Otero *et al.* 2008; Condren *et al.* 2010; Wong *et al.* 2009; Ghaleb *et al.* 2010; Al-Jeraisy *et al.* 2011; Belela *et al.* 2011; Ozkan *et al.* 2011; Manias *et al.* 2014]. Overall, dosing errors were the most common type reported, making up 82.6% of prescribing errors [Folli *et al.* 1987; Aneja *et al.* 1992; Wilson *et al.* 1998; Kozer *et al.* 2002; Fortescue *et al.* 2003; Wong *et al.* 2009; Al-Jeraisy *et al.* 2011]. Significant overdoses by as much as ten-times over the normal dosage range were identified, with Ross and colleagues attributing a third of these errors to dose miscalculations by clinicians [Ross *et al.* 2000; Fortescue *et al.* 2003]. The consequences of these errors were reported as involving elevated serum levels of medicines, leading to moderate-level and life-threatening toxicities [Wilson *et al.* 1998; Kozer *et al.* 2002]. These symptoms subsequently led to increased patient monitoring, length of stay, hospital costs and in-hospital deaths [Kozer *et al.* 2002]. Paediatric prescribing errors were more frequent in seriously ill patients, and were most likely to be caused by trainee doctors [Kozer *et al.* 2002; Al-Jeraisy *et al.* 2011]. Condren and colleagues identified that prescribing errors, including dosing mistakes and incomplete medication orders, were present in 9.7% of new prescriptions in a paediatric acute-care clinic [Condren *et al.* 2010].

Transcription errors were not commonly reported within paediatric studies, with only three articles acknowledging their incidence [Frey *et al.* 2000, 2002; Fortescue *et al.* 2003]. These types of errors made up 5.8% of all medication errors, and included: punctuation mistakes (i.e. writing '3' instead of '0.3'), omission of medication, wrong unit of measurement (i.e. g instead of mg) and incorrect doses [Frey *et al.* 2000, 2002; Fortescue *et al.* 2003].

Errors within the dispensing phase were not considered to be significant sources of error, accounting for only 2.7–7.0% of errors in paediatric patients. Four studies identified that labelling mistakes were the most common sources or error as well as the dispensing of incorrect quantities of medication and supplying incorrect medications [Wilson *et al.* 1998; Ross *et al.* 2000; Frey *et al.* 2002; Belela *et al.* 2011].

Medication errors occurred frequently within the administration phase, comprising 12.8–73% of total reported errors [Frey *et al.* 2002; Ghaleb *et al.* 2010; Belela *et al.* 2011; Ozkan *et al.* 2011].

The administration of incorrect doses was the most commonly reported error, and specifically related to tenfold overdoses [Wilson *et al.* 1998; Frey *et al.* 2000, 2002; Ross *et al.* 2000; Kozer *et al.* 2002; Fortescue *et al.* 2003; Otero *et al.* 2008; Wong *et al.* 2009; Ghaleb *et al.* 2010; Belela *et al.* 2011; Ozkan *et al.* 2011]. A Canadian retrospective cohort study reported that children were at a greater risk of being administered tenfold overdoses than adults because the volume of a dose that was ten-times the normal range for paediatric patients would still look like a relatively small volume of stock solution [Kozer *et al.* 2002]. Wong and colleagues stated that an overdose of potent medications in children (e.g. sedatives), may cause respiratory depression and have a critical effect on neurological outcomes [Wong *et al.* 2009]. Medicines most commonly associated with tenfold dosing errors included: digoxin, morphine, gentamicin and indomethacin [Kozer *et al.* 2002]. Two articles also identified errors in incorrectly administering pharmacotherapy to the wrong patient, who had no therapeutic need for the medication [Wong *et al.* 2009; Manias *et al.* 2014]. Contributing factors to the incidence of administration errors were identified as including human error, equipment dysfunction and communication failures [Frey *et al.* 2000].

None of the studies based in paediatric wards identified monitoring errors as a part of the medication error profile.

Adult

Among the 11 articles reviewed, the most common study designs were prospective observational studies [Bates *et al.* 1995; Calabrese *et al.* 2001; Barker *et al.* 2002; Van Den Bemt *et al.* 2002; Winterstein *et al.* 2004; Lisby *et al.* 2005; Kopp *et al.* 2006; Bohomol *et al.* 2009; Jennane *et al.* 2011; Zeraatchi *et al.* 2013; Saghafi and Zargarzadeh, 2014]. Bates and colleagues estimated that 6.5 of 100 adult admissions experienced a medication error and that at least 28% were preventable [Bates *et al.* 1995]. Most errors occurred within the prescribing phase, making up 56–72.5% of total reported medication errors [Bates *et al.* 1995; Winterstein *et al.* 2004]. Examples of these errors included: the prescribing of 100 vials of tramadol instead of 100mg and ranitidine erroneously prescribed via nasogastric tube instead of intravenously [Bohomol *et al.* 2009]. Overall, incorrect dosing was the most commonly reported prescribing error [Bates *et al.* 1995; Winterstein *et al.* 2004; Lisby *et al.* 2005; Kopp *et al.* 2006; Bohomol *et al.* 2009; Jennane *et al.* 2011; Zeraatchi *et al.* 2013; Saghafi and Zargarzadeh, 2014]. Bohomol and colleagues, Winterstein and colleagues and Kopp and colleagues emphasized that prescribing errors were mostly caused by physicians' lack of detailed pharmacology knowledge and failure to comprehensively consider patient information [Winterstein *et al.* 2004; Kopp *et al.* 2006; Bohomol *et al.* 2009]. Furthermore, a quantitative study that analysed patient prescriptions and incident reports in a Brazilian ICU highlighted that patients with polymedication prescriptions admitted to the stressful and fast-paced environment of the ICU were more prone to experiencing prescribing errors [Bohomol *et al.* 2009]. The consequences of medication error were reported as including uncontrolled pain and infection due to underdosing, renal failure and elevated serum levels, resulting in increased monitoring and additional treatment [Winterstein *et al.* 2004; Bohomol *et al.* 2009].

Transcription errors were well documented within the adult population, particularly within the Danish and Moroccan studies, and the percentage of reported errors had a range of 6–60% of all total medication errors [Bates *et al.* 1995; Winterstein *et al.* 2004; Lisby *et al.* 2005; Kopp *et al.* 2006; Bohomol *et al.* 2009; Jennane *et al.* 2011; Zeraatchi *et al.* 2013; Saghafi and Zargarzadeh, 2014]. The most commonly reported error related to errors in transferring information into patient charts [Bates *et al.* 1995; Lisby *et al.* 2005; Kopp *et al.* 2006; Jennane *et al.* 2011; Zeraatchi *et al.* 2013]. Nursing staff were responsible for 40% of transcription errors, due to erroneous interpretations of prescriptions by nurses [Lisby *et al.* 2005; Zeraatchi *et al.* 2013].

Overall, the dispensing phase was not a major source of medication errors, comprising 2.2–34% of all errors [Lisby *et al.* 2005; Kopp *et al.* 2006; Saghafi and Zargarzadeh, 2014]. The most frequently reported error was associated with mistakes in the preparation of doses for patients [Bates *et al.* 1995; Lisby *et al.* 2005; Kopp *et al.* 2006].

The administration phase comprised 14.6–41% of all medication errors in adult wards [Calabrese *et al.* 2001; Barker *et al.* 2002; Van Den Bemt *et al.* 2002; Kopp *et al.* 2006; Zeraatchi *et al.* 2013; Saghafi and Zargarzadeh, 2014]. A US-based, prospective, observational study set in

adult medical and surgical ICUs identified that one medication error occurred for every five doses of medication administered [Kopp *et al.* 2006]. The most frequently reported errors involved the administration of medications at the wrong time and omission of administering doses, accounting for 43% and 30% of administration errors, respectively [Calabrese *et al.* 2001; Barker *et al.* 2002; Van Den Bemt *et al.* 2002; Lisby *et al.* 2005; Kopp *et al.* 2006; Bohomol *et al.* 2009]. The consequences of late or omitted administration of critical medicines such as anti-infectives and anticoagulants were reported as leading to suboptimal management of infection, blood pressure and blood clotting, threatening the success of treatment [Bohomol *et al.* 2009]. The overdosing of medications was also emphasized as a serious error within adult critical care wards, with Winterstein and colleagues documenting nephrotoxic effects as a result of overdosing antibiotics [Winterstein *et al.* 2004]. Nurses were responsible for generating 40% of administration errors and contributing factors included staff performance deficits, memory lapses and faulty dose-checking processes [Winterstein *et al.* 2004; Kopp *et al.* 2006; Zeraatchi *et al.* 2013].

Errors in the monitoring phase were uncommon, identified in only two studies [Bohomol *et al.* 2009; Jennane *et al.* 2011]. These errors were described as the failure to assess patient responses to prescribed medications, including laboratory results and clinical markers within therapeutic drug-monitoring practices [Bohomol *et al.* 2009; Jennane *et al.* 2011].

Elderly

Among the 10 articles reviewed, medication errors were most commonly identified through prospective observational studies, and retrospective review of charts and incident reports [Briggs, 2006; Picone *et al.* 2008; Ben-Yehuda *et al.* 2011; Henri *et al.* 2012; Maher and Hajjar, 2012; Zakharov *et al.* 2012; Buck *et al.* 2013; García-Aparicio and Herrero-Herrero, 2013; Ernawati *et al.* 2014; Metsälä and Vaherkoski, 2014]. The median age of elderly participants ranged from 68 to 84 years of age [Picone *et al.* 2008; Ben-Yehuda *et al.* 2011; Buck *et al.* 2013; García-Aparicio and Herrero-Herrero, 2013; Ernawati *et al.* 2014]. Medication errors in the prescribing phase had a range of 1.6–46% of the total reported errors [Picone *et al.* 2008; Ben-Yehuda *et al.* 2011; Ernawati *et al.* 2014]. Incorrect dosing was most commonly reported, comprising 49% of prescribing errors [Briggs, 2006; Picone *et al.* 2008; Ben-Yehuda *et al.* 2011; Maher and Hajjar, 2012; Buck *et al.* 2013; García-Aparicio and Herrero-Herrero, 2013; Ernawati *et al.* 2014; Metsälä and Vaherkoski, 2014]. A unique error commonly reported in the elderly population involved the prescribing of inappropriate medications [Briggs, 2006; Picone *et al.* 2008; Ben-Yehuda *et al.* 2011; Maher and Hajjar, 2012; Buck *et al.* 2013; García-Aparicio and Herrero-Herrero, 2013; Ernawati *et al.* 2014; Metsälä and Vaherkoski, 2014]. Described as the ordering of medications that are unnecessary, ineffective or unsafe, these errors most often occur in elderly patients who present with multiple pathologies, requiring multiple medications [Maher and Hajjar, 2012]. The consequences of these errors were reported as involving serious adverse drug events and prolonging hospitalizations [Maher and Hajjar, 2012]. Furthermore, Ernawati and colleagues found that physicians often only partially complete patient medication histories, leading to the prescribing of duplicate therapies because of the inadequate gathering of patient information [Ernawati *et al.* 2014].

Transcribing errors were well documented in elderly patients, and were discussed by four articles. The percentage range of total errors was 15–54%, and the most commonly reported error related to discrepancies in doses between prescriptions and patient charts [Picone *et al.* 2008; Ben-Yehuda *et al.* 2011; Maher and Hajjar, 2012; Ernawati *et al.* 2014]. A cohort study set in a 37-bed ward in Israel and involving 137 patients detected that the number of medications being taken was related to a higher risk of transcribing errors [Ben-Yehuda *et al.* 2011]. Specifically, patients prescribed nine or more medications and whose hospitalizations were 13 days or longer were at a higher risk [Ben-Yehuda *et al.* 2011]. The medications most commonly associated with this type of error included: simvastatin, valsartan and paracetamol [Ernawati *et al.* 2014]. Ernawati and colleagues commented that there was a need for accuracy during the transcribing process in order to prevent subsequent administration errors [Ernawati *et al.* 2014].

Dispensing errors were not considered main sources of error within the elderly population. These errors made up 2–14% of medication errors, with the most common error involving the incorrect labelling and instructions on dispensed medications [Briggs, 2006; Picone *et al.* 2008;

Maher and Hajjar, 2012. Maher and Hajjar stated that erroneous instructions most often related to labelling medications 'PRN' (as required) instead of 'once a day' [Maher and Hajjar, 2012; Zakharov *et al.* 2012].

Overall, it was found that administration errors are the most common type in hospitalized elderly patients, comprising 54.2–59% of all medication errors [Briggs, 2006; Picone *et al.* 2008; Henri *et al.* 2012; Ernawati *et al.* 2014; Metsälä and Vaherkoski, 2014]. Older patients, suffering from more than one chronic disease and taking five or more medications were identified as being at a greater risk of experiencing these errors [Picone *et al.* 2008; Henri *et al.* 2012]. The most frequently reported administration errors were omission of administering prescribed medication and incorrect administration times [Briggs, 2006; Picone *et al.* 2008; Henri *et al.* 2012; Maher and Hajjar, 2012; Ernawati *et al.* 2014; Metsälä and Vaherkoski, 2014]. Zakharov and colleagues identified that nurses were responsible for 43% of administration errors [Zakharov *et al.* 2012]. The clinical impact of these errors on patients ranged from minor discomfort to significant morbidity and mortality [Picone *et al.* 2008; Henri *et al.* 2012]. Ernawati and colleagues conducted a 20-week prospective study in a 13-bed geriatric ward and reported that 10.3% of medication errors had a potentially significant impact, with a further 2.4% being potentially serious [Ernawati *et al.* 2014]. The drug classes most commonly involved in administration errors included: aminoglycosides, anticoagulants, opioid analgesics and antihypertensives [Ernawati *et al.* 2014].

Monitoring errors were only identified in one article by Maher and Hajjar, who reported that they were associated with inappropriate clinical monitoring practices [Maher and Hajjar, 2012]. Specifically, this error was identified as the failure to identify risk of medication toxicity in patients, which could have been prevented, reversed or reduced by earlier dose adjustments [Maher and Hajjar, 2012].

Comparison of medication commonly associated with error

This review sought to compare the medications most commonly associated with error to the A-PINCH High Risk Medicines List. Compiled by the Australian Clinical Excellence Commission, the list groups together medications that are universally considered to be high risk and are represented by the acronym A-PINCH [Clinical Excellence Commission, 2015]. Each of the medication categories listed on A-PINCH were commonly implicated in errors across each of the reviewed patient populations, including antibiotics (particularly gentamicin), heparin, insulin, potassium chloride, fentanyl, morphine, antiarrhythmics and parenteral nutrition (Table 3).

Overall, the neonatal population reported issues with a broader range of agents, as well as medications that were not seen in other populations, including prostaglandins, ketamine, immunizations, milk and vecuronium. As neonatal patients are administered the majority of medications through the IV or intramuscular (IM) routes, any errors that occur will have a systemic effect. As such, tenfold errors have been reported more commonly with IV formulations and agents including: insulin, midazolam, frusemide, benzylpenicillin, gentamicin and ranitidine [Chappell and Newman, 2004]. The literature did not report any errors with antineoplastic medications or with corticosteroids, which were all commonly reported in the other three patient groups. Furthermore, it is reported that NICU patients have a high exposure to medications, and are prescribed an average of 8.6 drugs per infant, increasing the risk for experiencing adverse drug events [Daniell and Darlow, 1989; Sorrentino and Alegiani, 2012].

The elderly and adult populations experience errors within the same groups of medications, particularly cardiovascular and GI medications. Errors are associated with a wider selection of agents in these drug classes in comparison with paediatric and neonatal patients. The elderly population experienced errors with allopurinol and statins that are medications most often used in older patients.

Paediatric patients experienced the most errors with antibiotics. Due to the large age range of the population (extending from 1 to 18 years of age), some medications were also the same as those reported in the adult population including adrenaline, anticonvulsants and steroids.

Discussion

The main focus of this article was to highlight the types of medication-related safety issues that occur in hospitalized patients, in particular those

Table 3. Types of medications most commonly associated with error.

Patient group	Neonates	Paediatrics	Adult	Elderly
Commonly identified medications		Adrenaline [Wong *et al.* 2009]	Adrenaline [Calabrese *et al.* 2001];	
A-PINCH-listed medication	Antibiotics: Amikacin [Pallas *et al.* 2008], Benzylpenicillin [Simpson *et al.* 2004]; Gentamicin [Simpson *et al.* 2004; Pallas *et al.* 2008; Stavroudis *et al.* 2010]; Vancomycin [Simpson *et al.* 2004; Pallas *et al.* 2008];	Antibiotics [Folli *et al.* 1987; Ross *et al.* 2000; Kozer *et al.* 2002]; Benzylpenicillin [Wong *et al.* 2009]; Gentamicin [Wong *et al.* 2009]	Antibiotics [Winterstein *et al.* 2004; Jennane *et al.* 2011; Zeraatchi *et al.* 2013]; Mupirocin [Winterstein *et al.* 2004]	Antibiotics: Vancomycin, Gentamicin, Cefazolin, Metronidazole [Picone *et al.* 2008; Ernawati *et al.* 2014]
A-PINCH-listed medication	Anticoagulants [Frey *et al.* 2002]		Anticoagulants: Warfarin [Calabrese *et al.* 2001; Winterstein *et al.* 2004; Jennane *et al.* 2011; Zeraatchi *et al.* 2013]	Anticoagulants: Warfarin [Picone *et al.* 2008; Ernawati *et al.* 2014]
		Anticonvulsants [Wong *et al.* 2009]	Anticonvulsants [Winterstein *et al.* 2004]	
	Sedatives: Midazolam [Frey *et al.* 2002]	Sedatives [Wong *et al.* 2009]	Benzodiazepines: Lorazepam, Midazolam [Calabrese *et al.* 2001; Jennane *et al.* 2011]	Benzodiazepines: Alprazolam, Lorazepam [Picone *et al.* 2008; García-Aparicio and Herrero-Herrero, 2013]
A-PINCH-listed medication		Chemotherapy drugs [Folli *et al.* 1987; Ross *et al.* 2000]	Antineoplastic agents [Winterstein *et al.* 2004]	Antineoplastic agents: Azathioprine, Doxorubicin [Picone *et al.* 2008]
	Anti-arrhythmics [Frey *et al.* 2002]	Captopril [Wong *et al.* 2009]; Digoxin [Folli *et al.* 1987; Wong *et al.* 2009]; Propranolol [Folli *et al.* 1987]	Calcium-channel blockers [Winterstein *et al.* 2004]; Digoxin [Calabrese *et al.* 2001]; Sympathomimetic agents: Dobutamine [Calabrese *et al.* 2001; Winterstein *et al.* 2004]	Cardiovascular: Digoxin, Metoprolol, Amiodarone [Picone *et al.* 2008; García-Aparicio and Herrero-Herrero, 2013; Ernawati *et al.* 2014]; Isosorbide mononitrate [García-Aparicio and Herrero-Herrero, 2013]
	Frusemide [Frey *et al.* 2002; Stavroudis *et al.* 2010]			Frusemide [Picone *et al.* 2008; García-Aparicio and Herrero-Herrero, 2013]
	Ranitidine [Pallas *et al.* 2008]		Docusate sodium [Winterstein *et al.* 2004]; H_2 antagonists [Winterstein *et al.* 2004]; Metoclopramide [Winterstein *et al.* 2004];	GI Drugs: Docusate, Omeprazole[Picone *et al.* 2008; García-Aparicio and Herrero-Herrero, 2013; Ernawati *et al.* 2014]
A-PINCH-listed medication	Heparin [Frey *et al.* 2002]	Heparin [Wong *et al.* 2009]	Thrombolytics: Heparin [Calabrese *et al.* 2001; Winterstein *et al.* 2004; Zeraatchi *et al.* 2013]	Heparin [Picone *et al.* 2008]
A-PINCH-listed medication	Insulin [Simpson *et al.* 2004]	Insulin [Ross *et al.* 2000; Wong *et al.* 2009]	Insulin [Calabrese *et al.* 2001; Zeraatchi *et al.* 2013]	Insulin [Picone *et al.* 2008]

Table 3. (Continued)

Patient group	Neonates	Paediatrics	Adult	Elderly
A-PINCH-listed medication	Fentanyl [Frey *et al.* 2002; Pallas *et al.* 2008; Stavroudis *et al.* 2010] Morphine [Simpson *et al.* 2004; Stavroudis *et al.* 2010]	Morphine [Ross *et al.* 2000; Wong *et al.* 2009]	Fentanyl [Calabrese *et al.* 2001] Morphine [Calabrese *et al.* 2001; Jennane *et al.* 2011]	Morphine [Picone *et al.* 2008; Ernawati *et al.* 2014]
	NSAIDs: Indomethacin [Frey *et al.* 2002; Stavroudis *et al.* 2010]		NSAIDs [Winterstein *et al.* 2004]	
	Parenteral nutrition: amino acids/fat emulsions [Frey *et al.* 2002; Stavroudis *et al.* 2010]	Parenteral nutrition [Folli *et al.* 1987; Ross *et al.* 2000]	Electrolyte, caloric and water balance agents [Winterstein *et al.* 2004]	Nutrients [Picone *et al.* 2008; Ernawati *et al.* 2014]
A-PINCH listed medication	Potassium chloride [Stavroudis *et al.* 2010] Glucose [Frey *et al.* 2002]	IV fluids [Folli *et al.* 1987; Ross *et al.* 2000; Wong *et al.* 2009]	Potassium chloride [Calabrese *et al.* 2001]	Electrolyte and water balance –potassium chloride, IV fluids [Picone *et al.* 2008]
		Steroids [Folli *et al.* 1987; Ross *et al.* 2000]	Corticosteroids [Jennane *et al.* 2011]	Hydrocortisone [Picone *et al.* 2008]
Individually identified medications	Alteplase [Frey *et al.* 2002] Aminophylline [Simpson *et al.* 2004] Dopamine [Frey *et al.* 2002; Pallas *et al.* 2008] Erythropoietin [Pallas *et al.* 2008; Stavroudis *et al.* 2010] Immunizations [Simpson *et al.* 2004] Ketamine [Frey *et al.* 2002] Milk [Frey *et al.* 2002] Pancuronium [Frey *et al.* 2002] Prostaglandin [Frey *et al.* 2002] Tazocin [Simpson *et al.* 2004] Vasodilators [Frey *et al.* 2002] Vecuronium [Stavroudis *et al.* 2010]	Antihistamines [Kozer *et al.* 2002] Atropine [Folli *et al.* 1987] Paracetamol [Kozer *et al.* 2002; Wong *et al.* 2009] Phenytoin [Wong *et al.* 2009] Theophylline [Folli *et al.* 1987]	Nystatin [Winterstein *et al.* 2004]	Allopurinol [García-Aparicio and Herrero-Herrero, 2013] Gabapentin [García-Aparicio and Herrero-Herrero, 2013] Iron supplements [García-Aparicio and Herrero-Herrero, 2013] Statins [García-Aparicio and Herrero-Herrero, 2013]

A-PINCH, compiled by the Australian Clinical Excellence Commission, the list groups together medications that are universally considered to be high-risk and are represented by the acronym A-PINCH: A, anti-infectives; P, potassium and other electrolytes; I, insulin; N, narcotics and other sedatives; C, chemotherapeutic agents; H, heparin and other anticoagulants [Clinical Excellence Commission, 2015].
GI, gastrointestinal; IV, intravenous; NSAIDs, nonsteroidal anti-inflammatory drugs.

within the neonatal population. To our knowledge, this is the only review to compare the types of medication errors that occur within four distinct population groups.

This review demonstrates that each phase of the medication-use process is susceptible to medication error, across the patient age spectrum (Figure 2). Most literature has identified errors within the

Prescribing: 14–74% Errors in dosing, including tenfold overdoses Transcription: 12–18.4% Incorrect medication, incorrect units Dispensing: 11.9–25% Errors in labelling, errors in dilutions during preparation of medication Administration: 31–63% Incorrect administration time, patient misidentification Monitoring: 1.4% Incorrect interpretation of laboratory results	Prescribing: 10–74% Errors in dosing Transcription: 5.8% Errors in punctuation, omission of prescribed medication Dispensing: 2.7–7% Errors in labelling Administration: 12.8–73% Incorrect doses, including tenfold overdoses	Prescribing: 56–72.5% Errors in dosing Transcription: 6–60% Incorrect medication name Dispensing: 2.2–34% Incorrect doses Administration: 14.6–41% Incorrect administration time, omission of administering medication Monitoring Failure to assess patient response to medication with laboratory tests	Prescribing: 1.6–46% Errors in dosing, prescribing of inappropriate medications, duplication of therapy Transcription: 15–54% Incorrect transfer of doses administered Dispensing: 2–14% Incorrect labelling Administration: 54.2–59% Omitting administration of medication, incorrect administration time Monitoring Inappropriate clinical monitoring

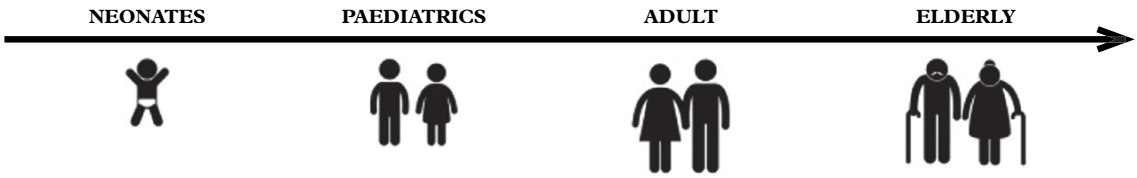

Figure 2. Most commonly identified medication errors across the age spectrum.

prescribing and administration phases. In particular, errors relating to incorrect dosing, incorrect medications and incorrect administration time were the most frequently reported. The ranges of reported error varied greatly, which can be attributed to differences in research methods, although most studies used the chart-review method, which is more effective in detecting prescribing errors. In addition, medication error was not explicitly defined in some studies, particularly within the neonatal and paediatric studies. This may be attributed to the fact that a large proportion of medications used in young patients are prescribed off-label. As such, it is difficult to define prescribing dosing errors if doses have been adapted and extrapolated from adult guidelines.

The findings suggest that there are medication errors seen in certain types of patient population more than in others. In particular, within the neonatal population errors pertaining to patient misidentification, delayed dispensing, parental involvement in administering unauthorized medications, erroneous product dilutions, as well as tenfold and 100-fold overdoses, were emphasized. Overdoses to this extent were not reported in the adult or elderly populations. The main contributing factors were identified as physician inexperience, as well as the lack of neonate-specific dosing protocols and evidence-based information on the efficacy, safety, dosing, pharmacokinetics and clinical use of medication in neonates, leading to the common use of off-label or unlicensed medications [Antonucci and Porcella, 2012]. The findings highlight that the prescribing and administration phases were most commonly associated with medication errors. Overall, the use of medication in neonates is more complex than in other patient groups [Raju *et al.* 2011; National Association of Neonatal Nurses, 2014]. NICU healthcare professionals are faced with limited amounts of evidence-based information supporting the use of pharmacotherapeutic interventions in neonates, as well as a narrow range of neonatal-specific formulations [Chedoe *et al.* 2007]. Furthermore, neonates are a nonhomogenous group, with differences in maturation of medication-sensitive organs (kidneys, GI tract and liver), weights and gestational ages, requiring individualized weight-based dosing [Gray and Goldmann, 2004; Jain *et al.* 2009]. (Table 4). The physiological vulnerabilities limit

Table 4. Factors that increase therapeutic risk in neonatal patients.

1. Babies have a higher proportion of body water and less muscle and fat. 2. Water-soluble drugs need a higher dose as they are readily distributed into the system. 3. Lipid-soluble drugs need a smaller dose as they do not distribute and their half-lives increase and accumulate in the body, leading to toxicity [Berlin, 2013].
1. Neonates' developmental immaturity influences the function of the kidneys, liver and enzyme systems. 2. Metabolic and clearance mechanisms aren't functioning to their highest capacity. 3. Requires the monitoring of drug serum levels to determine whether doses are therapeutic or whether they are not being cleared properly and need a reduction in dose and frequency to prevent toxic concentrations [Berlin, 2013].
1. Lack of neonate-specific or appropriate medications available. 2. There are several barriers to clinical trialling in neonatal and paediatric patients, including ethical issues, parental consent, sampling problems, relatively small study population, etc. Therefore medication usage is often off-label or unlicensed in nature. 3. Off-label: the use of a medication in a patient group at a dose, frequency or through a specific administration route that is not approved and is considered to be beyond the terms of the product licence [Conroy, 2011]. 4. Unlicensed: the prescribing of medications for indications that are not in the approved product information. 5. Furthermore, there is limited information on the safety, efficacy and clinical use of medication in neonates [Conroy, 2011].
1. There are interindividual differences in weight within the neonatal population, ranging from the smallest babies weighing <500 g to the largest at >5000 g [Tayman *et al.* 2011]. 2. The variation in weight ranges requires the calculation of individualized doses that are often very small to ensure therapeutic and safe treatment that poses an element of risk with regard to the potential for human error in correctly dosing medications. 3. Calculations need to be frequently repeated as patients are constantly growing and gaining weight, therefore doses need adjusting to account for this [Chappell and Newman, 2004; Ahmed, 2008].
1. Need for significant manipulation of drugs and extemporaneous compounding to ensure medications are compatible for use in neonates. 2. Includes the performance of dilutions and the preparation of liquid formulations as medications are administered by central line, intravenously, orally or enterally [Ahmed, 2008].
1. Potential for drug interactions when medications are administered through a single-lumen central line. 2. Medications are in close proximity to each other in the tube and can react to each other [Ahmed, 2008].
1. The skin of the neonate is very thin. 2. The topical administration of medications through dosage forms such as creams, lotions or ointments can lead to systemic absorption of a drug. 3. Similarly, the eyes can absorb and systemically transfer medications from eye drops, potentially leading to adverse effects [Ahmed, 2008].
1. Most neonatal patients will require nutritional support; however, the administration of a small amount of fluid can have a considerable impact on babies. 2. Extra consideration is required when prescribing enteral nutrition; increasing enteral fluid volumes too quickly can lead to necrotising enterocolitis [Ahmed, 2008].
1. Neonates within the NICU have an increased exposure to medications. 2. It is reported that the number of medications administered in the NICU is inversely proportional to the patients gestational age or their weight [Carvalho *et al.* 2012].
1. Infants are unable to communicate with health professionals or family members about any concerns with their therapy or advise of any adverse events they are experiencing [Ahmed, 2008].

neonates' 'buffering zone' capacity to compensate for error, leaving a narrow margin of safety [Raju *et al.* 2011; Antonucci and Porcella, 2012]. The resulting impact of these errors is greater than in older children or adult populations. Neonates are at the very start of the developmental age spectrum, and even minor errors can lead to short-term as well as long-term consequences affecting development [Raju *et al.* 2011]. As the risk of sustaining a medication error has been

reported as being eight-times higher within the neonatal group than within any other population, targeted interventions to improve safety and decrease error rates should be prioritized to the neonatal population as the patients of highest risk [Kaushal *et al.* 2001; Stavroudis *et al.* 2010].

Unique errors were also reported within the elderly population. Characteristics of vulnerability including polypharmacy, multimorbidities and decreased organ function were reported as important factors that increased risk of experiencing medication errors [García-Aparicio and Herrero-Herrero, 2013]. Errors pertaining to the prescribing of unnecessary medications and duplication of pharmacotherapies were almost exclusively reported within this group. Most commonly attributed to physicians, these errors were attributed to poor gathering of patient information and the failure to complete full patient medication histories upon admission. The impact of these errors most commonly related to medication toxicities as well as significant adverse effects. However, the consequences of harm are not as great compared with patients at the start of their lifespan.

An important finding of this study is that the medications most commonly associated with error in each of the patient groups were those listed within the A-PINCH. As such, medication safety interventions should focus upon these medications. When considering the neonatal population, the range of medications that are prescribed for use in the NICU are relatively limited in comparison with those used in older paediatric and adult populations [Gray and Goldmann, 2004]. However, despite this, the findings show that errors occur with a broader range of agents in the neonatal population than other hospitalized patients, indicating that the use of medications in the NICU is greater.

As medication errors can occur at any stage of the medication-use process and can be caused by a range of healthcare professionals, the strategies to improve safety must be multifactorial. Several studies recommend the use of computerized physician-order entry and the use of a single-medication therapy sheet to improve both prescribing and transcription errors [Kaushal *et al.* 2001; Kozer *et al.* 2002; Fortescue *et al.* 2003; Gray and Goldmann, 2004; Winterstein *et al.* 2004; Kunac and Reith, 2005; Lisby *et al.* 2005; Van Den Anker, 2005; Briggs, 2006; Campino *et al.* 2009; Condren *et al.* 2010; Wong *et al.* 2009; Ghaleb *et al.* 2010; Antonucci and Porcella, 2012; Dabliz and Levine, 2012; Maher and Hajjar, 2012; Sorrentino and Alegiani, 2012; Ernawati *et al.* 2014]. In addition, the formulation of population-specific quality control tools and health indicators has also been regarded as important in improving medication error rates [Bohomol *et al.* 2009]. However, the most commonly cited strategy identified in half of the literature across all patient groups, is the involvement of a clinical pharmacist on wards [Folli *et al.* 1987; Bates *et al.* 1995; Wilson *et al.* 1998; Kaushal *et al.* 2001; Kozer *et al.* 2002; Van Den Bemt *et al.* 2002; Fortescue *et al.* 2003; Gray and Goldmann, 2004; Simpson *et al.* 2004; Kunac and Reith, 2005; Lisby *et al.* 2005; Briggs, 2006; Bohomol *et al.* 2009; Campino *et al.* 2009; Condren *et al.* 2010; Wong *et al.* 2009; Ghaleb *et al.* 2010; Ben-Yehuda *et al.* 2011; Jennane *et al.* 2011; Antonucci and Porcella, 2012; Dabliz and Levine, 2012; Henri *et al.* 2012; Maher and Hajjar, 2012; Sorrentino and Alegiani, 2012; García-Aparicio and Herrero-Herrero, 2013; Ernawati *et al.* 2014; Metsälä and Vaherkoski, 2014]. Fortescue and colleagues report that 81% of medication errors in paediatric patients could be avoided with pharmacist monitoring [Fortescue *et al.* 2003]. High-intensity wards using high-risk medications, such as ICUs, may benefit the most from a ward-based clinical pharmacist [Fortescue *et al.* 2003]. In the NICU in particular, the integration of the pharmacist into the treating team leads to medication-use improvement [Campino *et al.* 2009]. Simpson and colleagues reported that following a daily cot-side review of patients, pharmacists significantly reduced monthly medication errors from 24.1 per 1000 neonatal activity days to 5.1 ($p < 0.001$) [Simpson *et al.* 2004]. Clinical pharmacy activities, such as patient medication chart reviews, medication reconciliation, as well as participating in medical ward rounds with physicians and nurses are effective in reducing errors [Fortescue *et al.* 2003; Simpson *et al.* 2004; Kunac and Reith, 2005; Briggs, 2006; Ben-Yehuda *et al.* 2011; Jennane *et al.* 2011; Dabliz and Levine, 2012; Sorrentino and Alegiani, 2012; Ernawati *et al.* 2014]. Furthermore, the provision of medication-specific education to the treating team can improve the quality of the healthcare delivered and promotes interdisciplinary collaboration [Kunac and Reith, 2005; Dabliz and Levine, 2012]. In adult wards, Leape and colleagues identified that pharmacist participation on ward rounds reduced the rate of preventable adverse drug events due to

prescribing errors by 66% [Leape *et al.* 1999]. These activities allow for real-time feedback and education, leading to better prescribing decisions and greater interception of errors before they are realized [Fortescue *et al.* 2003; Simpson *et al.* 2004]. Clinical pharmacists possess specialized knowledge that is essential in preventing harm to patients as well as in minimizing hospital-associated costs from extended hospital stays and additional therapy [Folli *et al.* 1987].

Limitations

Differences in study methods, definitions of medication errors and definitions in error categories make direct comparison between studies difficult, particularly within the prescribing and administration phases. For example, in some studies, errors that were identified prior to the administration of medication were not included in the results and as such only actual administration errors were reported. However, most studies utilized a chart review or medication-order review method of medication-error detection, which are ultimately better at detecting prescription-based errors.

Some studies mixed population groups, for example, paediatric studies often included data from a NICU, however, did not always disclose the proportions of errors occurring in each ward. Therefore, results between the two subgroups may be hard to differentiate. There were less data available on elderly patients as most studies concentrated on medication errors that occurred outside of the hospital setting, that is, in nursing homes.

It is also possible that a large number of studies could have been excluded because they were not available in the English language.

Conclusion

Each stage of the medication-use process is prone to medication error across the age spectrum. The administration and prescribing phases were the most commonly identified phases of error and most often related to incorrect dosing, wrong prescribing or administering of drugs and wrong time of administration. While neonatal patients experience the same types of medication errors as other hospitalized patients, the medication-use process within this group is more complex and has greater consequences in the instance of error. Maintaining safe pharmacotherapeutic practices should be a major priority for all health professionals however clinical pharmacists have the potential to significantly reduce medication errors. Further research is required to develop targeted strategies relevant to specific patient groups that integrate key pharmacy services into wards, as well as quality-control tools and health indicators to prevent medication errors. Additional investigation is needed to determine the need of pharmacy services on the NICU and their impact on patient safety and care.

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Conflict of interest statement

The authors declare that there is no conflict of interest.

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L.2 REVIEW OF DRUG UTILIZATION PATTERNS IN NICUS WORLDWIDE

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Review Article

Review of drug utilization patterns in NICUs worldwide

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Keywords: **drug utilization, neonate, NICU, prescription patterns**

SUMMARY

What is known and objectives: **When considering acute care settings, such as the neonatal intensive care unit (NICU), the inappropriate use of medicines poses a great risk to vulnerable babies at the start of their lives. However, there is limited published literature that explores the current medication management practices in NICUs and where the main misuse issues lie. Therefore, the purpose of this review was to give an overview of medicine use in NICUs worldwide and identify therapeutic areas requiring more targeted pharmaceutical care. Specific objectives include the following: identifying the most commonly used medicines, comparing these to the A-PINCH (Anti-infectives, Potassium and other electrolytes, Insulin, Narcotics and sedatives, Chemotherapy agents, Heparin and other anticoagulants), high-risk medicines list, and determining whether there are any differences in medicine use between countries.**

Method: **Quasi-systematic literature review.**

Search strategy: **Google Scholar, MEDLINE/PubMed, Scopus and EMBASE were searched utilizing selected MeSH terms.**

Results: **A total of 19 articles from 12 countries were reviewed. Medication use between countries was very similar with no discernible differences in types of medicines prescribed. The most commonly used medicines included gentamicin, ampicillin, caffeine, furosemide and vitamin K. The median number of medicines prescribed per patient ranged from 3 to 11, and an inverse relationship was identified between gestational age and the number of medications that were prescribed. Nine of the 20 most commonly used medicines were listed as A-PINCH medicines, and included antibiotics, fentanyl, morphine and heparin. Inappropriate prescribing, as well as the high use of off-label/unlicensed medicines, was highlighted as areas of practice that require consideration to improve medication safety and minimize the potential risk for medication errors.**

What is new and conclusion: **Overall, the types of medicines used in NICUs worldwide are similar, with consistent reports on the common use of antibiotics, caffeine and vitamins. However, it cannot be definitively stated that the findings of the review accurately depict current practice in NICUs, due to the limited amount of published literature available. There are several areas of concern that warrant further investigation to improve rational use of medicines in the neonatal populations, including high use of antibiotics and off-label and unlicensed medicines.**

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WHAT IS KNOWN AND OBJECTIVES

The World Health Organization (WHO) estimates that every year, 15 million babies are born prematurely, that is before 37 completed weeks of gestation, and 1 million newborns die because of complications of preterm birth. Many more preterm babies die in low-income countries than in their high-income counterparts.[1] To rescue their lives, various procedures in neonatal intensive care units (NICU) are applied in accordance with available guidelines and standards.[2–4] Without doubt, medicines play a pivotal role in the management of preterm babies. The medicines used in NICUs, including their formulations and doses, depend on their availability and accessibility in a particular country, as well as the international/national guidelines and local rules of each setting. Thus, the pattern of prescribing and the drug utilization at different NICUs is not uniform and may vary widely.

The World Health Organization has estimated that half of all medicines used worldwide are prescribed or dispensed inappropriately.[5] With consequences including increased patient morbidity, mortality, healthcare expenditures and wastage of resources, the irrational use of medicines is recognized as a major global problem.[5,6] When considering acute care settings, such as the NICU, the inappropriate use of medicines poses a great risk to vulnerable babies at the start of their lives.[7,8] The application of pharmacotherapy is complex in hospitalized newborns, with factors of vulnerability including developmental immaturity as well as a lack of licensed formulations and limited evidence-based dosing information.[8,9] NICU patients also have a high drug burden with a reported average of 8·6 medicines prescribed per patient.[10] As such, there is a need to implement a high-quality, safe and rational medicine use process in these patients to ensure optimal outcomes. However, there is limited published literature that explores the current medication management practices in NICUs and where the main misuse issues lie. There are no systematic reviews that comprehensively evaluate drug utilization in NICUs. What reviews do exist, only give an insight into a subsection of total medicine use, for example one class of medicines (antibiotics) or off-label/unlicensed use of medicines.[11–14] Ill newborns admitted to the NICU are therapeutic orphans, and where pharmacotherapy does exist, these patients are at high risk of dosing errors and adverse drug effects. Therefore, there is a need for such reviews to be extended to

include the full spectrum of medicine use in the NICU and identify targets for the improvement of neonatal patient safety.

The aim of this review was to provide an overview of medicine use in NICUs worldwide. Specific objectives include the following: identifying the most commonly used medicines, comparing these medications with the A-PINCH high-risk medicines list (Anti-infectives, Potassium and other electrolytes, Insulin, Narcotics and sedatives, Chemotherapy agents, Heparin and other anticoagulants), determining whether there are any differences in medicine use between countries and highlighting any areas that require further attention to improve the rational use of medicines. The review does not focus on drug errors and adverse drug events, rather it seeks to provide better knowledge of the types of medicines prescribed in the NICU and the rates of off-label/unlicensed medicine use.

METHOD

A quasi-systematic review (a review that possesses some elements of a systematic review, including predefined selection criteria, however does not present a critical evaluation of the quality of studies and thus does not fulfil the criteria of comprehensiveness required from the systematic review method) extracted relevant publications pertaining to drug utilization and prescription patterns in the NICU.[15–18] The literature was retrieved by searching the following electronic databases: MEDLINE, EMBASE, Scopus and Google Scholar. The PRISMA guidelines provided a framework for the structure of this review.[19] In general, all active substances and their formulations which may be used in particular NICUs are included in drug formularies that are prepared by Hospital Therapeutic Committees.[20] Moreover, for a special need, other medicines may be used that are not enumerated in these formularies. However, these formularies are not commonly available, and therefore, only published studies could be a source of information on drug utilization within NICUs.

SEARCH STRATEGY

A comprehensive search was performed to find literature relevant to drug utilization in the NICU using the MeSH terms *neonate, NICU, drug utilisation, prescription patterns*. Inclusion criteria for the searches restricted the content to the following: (i) neonatal patients, (ii) drug utilization studies, (iii) providing information on drug-use patterns, prescriptions patterns or drug consumption and (iv) written in the English language. We applied a date limit so that only recent articles published from the year 2000 or later, that is 2000–2016, were taken into account. Articles were excluded if they only focussed on evaluating the use of a single class of medications, that is antibiotics. All full-text articles were retrieved. Manual bibliographic searches were also performed to identify additional articles that were not found in the electronic searches (Fig. 1).

Screening process for inclusion

Articles were initially screened for inclusion in the review based on title, then abstract and full-text article as necessary.

A-PINCH criteria

The review sought to compare the most commonly used medications in the NICU using the A-PINCH high-risk medicines list. Compiled by the Australian Clinical Excellence Commission, the list identifies types of medications that are universally considered to be high risk and are represented by the acronym A-PINCH.[21] (Table 1) These medications are not necessarily those that have higher error rates or adverse events than other medications, however if misused can have the most severe consequences.[22,23]

RESULTS

General analysis

Overall, there is limited published literature comprehensively exploring current medication use in NICUs. A total of 19 articles met the inclusion criteria, the majority dated within the last 10 years, 2006–2016 (n = 17, 89%).[24–42] The patients enrolled in studies were mostly preterm babies (<37 weeks) making up 40%–85% of NICU patient groups, with term babies making up 24·6%–51% of NICU admissions.[24,25,27–30,33,35–40] Male newborns comprised 43%–62·5% of patient samples.[26,27,31–33,36–39,42] The mean gestational ages of patient groups ranged from 31 to 35 weeks, and the median birthweights ranged from 1560 to 2615 g.[26,27,31–33,36–39,42] The mean duration of stay for the studied patients ranged from 15 to 21·1 days.[27,28,33,36,42]

The most common documented reason for patient admission into the NICU was respiratory distress followed by sepsis/infection, prematurity, neonatal jaundice, congenital malformations, birth asphyxia and seizures.[24,25,27,28,30,32,35,38,40]

Geographical distribution

Studies were conducted in 12 countries: USA (n = 4), Italy (n = 3), India (n = 2), Brazil (n = 2), UK, Australia, Estonia, Germany, Israel, Turkey, Ireland and France.

Methodology and study design

The majority of studies (n = 13, 68%) used a prospective study design, with the remaining six (32%) utilizing a retrospective data extraction. The sample sizes in the studies ranged from 34 to 450,386 patients. This large variation in patient enrolment was attributed mainly to the duration of studies, which ranged from 2 weeks to 9 years. Furthermore, some studies canvassed data from large databases, whereas others focussed their observations on one NICU. For example, two US-based studies by Clark *et al.*[26] and Hsieh *et al.*[31] used retrospective reviews as the method for gathering data for 9-year and 5-year periods of time, respectively. This resulted in large sample sizes and large numbers of prescribed medicines (Table 2).

The majority of studies (n = 12, 63%) investigated all medicines prescribed and used in the NICU.[24–29,31,32,34,36,40,41] However, the inclusion criteria of seven studies excluded the evaluation of certain products, including standard intravenous (IV) fluids (including electrolytes), oxygen, parenteral nutrition, blood and blood products, vaccinations, vitamin K, prophylactic ophthalmic ointment, phototherapy, expressed breast milk, milk formula, nutritional supplements and drugs used in clinical trials.[30,33,35,37–39,42]

The criteria for enrolling patients into studies were relatively uniform, and based simply on infant admission into the NICU.

Drug-use profile

Types of medicines used. Overall, antibiotics (particularly aminoglycosides) including gentamicin as well as ampicillin were

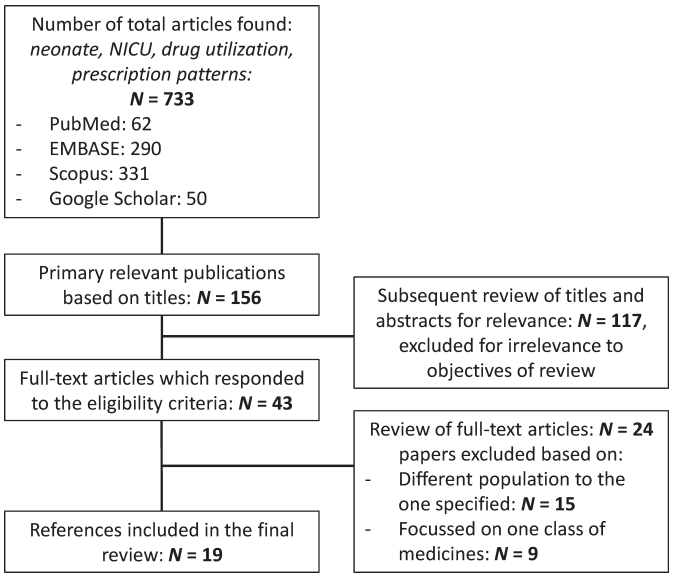

Fig. 1. Search strategy.

identified as the most frequently prescribed medicines in NICUs. This was followed by caffeine, furosemide, multivitamins and vitamin K. Figure 2 presents the 20 most commonly used medications in NICUs and highlights which of these medications are classified in the A-PINCH list. Nine of the 20 most commonly used medicines were listed as A-PINCH medicines, and included antibiotics, fentanyl, morphine and heparin (Fig. 2). Medications used between countries were very similar with no discernible differences in types of medicines prescribed.

The total number of different types of medications prescribed for the treatment of patients admitted to the NICU ranged from 23 to 409.[26–32,34–39,41] This large variation in different pharmacotherapeutic agents can again be attributed to the duration of studies, as some studies collected data over a period of several years which would potentially see the introduction of new active substances, drug formulations and regimens as well as the ceasing of older, less effective medicines.

Number of medicines used. The median number of medicines used per patient ranged from 3 to 11, with one German study by Neubert et.al. observing that two patients received as many as 40 medicines during their admission to the NICU.[27,29,32,34–39] The prospective cohort study evaluating 183 patients by Neubert *et al.*[36] also reported that the high average medicine use per patient seen in their study was attributed to the fact that their NICU was a very specialized unit which experienced a higher intake of very premature babies in comparison with other NICUs, leading to increased number of medicines per patient. Overall, the most common route of administration was the IV route (47%–92·1% of products used), followed by the oral route (22%–23·1%), topical (7·5%–9%), intramuscular (IM) and endotracheal tube.[25,28,32,33]

Patterns of use. In terms of patterns of use, three factors appear to impact on medication use. The first factor, as identified in seven studies, is the inverse relationship between gestational age and the number of medications that were prescribed.[25,27,28,33,36,38,42] In an Indian-based prospective study, Chatterjee *et al.*[25] found that the average number of medicines prescribed in the NICU was 8·1 for preterm babies compared to 4·3 for term babies. This is also supported by the Brazilian study, which reported a significant difference ($P < 0{\cdot}001$) between average medication use in preterm and term neonates.[28] During their 6-month prospective observational study, de Souza Goncalves *et al.* also reported a second relationship between average use of medicines and patient weight. The average number of medicines prescribed to very low-birthweight (VLBW) babies (<1000 g) was approximately three times greater than the number prescribed to babies with birthweights of 2500 g or more.[28] Third, de Souza et.al. found that the mortality rate was inversely proportional to the gestational age of infants in the NICU ($P > 0{\cdot}05$).[27]

Considerations relating to medication use in the NICU

Off-label/unlicensed use. It was widely reported that a significant proportion of medicines have not been approved for use in neonates, and as such there is little to no information available relating to the efficacy and safety of these medicines in infants.[24,27–39] The lack of information is reported as a major issue by one Brazilian study, identifying that only 20·5% of all medicines used had product information describing use of the medicine in neonates, and only 9·5% of medicines had available information for use in preterm babies.[28] Similarly, the German study by

Table 1. A-PINCH medicines list[21]

High-risk medicine groups	Examples of medicines
A: Anti-infective	Amphotericin
	Aminoglycosides
P: Potassium and other electrolytes	Injections of potassium, magnesium, calcium, hypertonic sodium chloride
I: Insulin	All insulins
N: Narcotics (opioids) and other sedatives	Hydromorphone, oxycodone, morphine
	Fentanyl, alfentanil, remifentanil and analgesic patches
	Benzodiazepines, for example, diazepam, midazolam
	Thiopentone, propofol and other short-term anaesthetics
C: Chemotherapeutic agents	Vincristine
	Methotrexate
	Etoposide
	Azathioprine
H: Heparin and anticoagulants	Warfarin
	Enoxaparin
	Rivaroxaban, dabigatran, apixaban

Adapted from the New South Wales Clinical Excellence Commission, Australia website: High Risk Medicines. Clinical Excellence Commission. 2016. http://www.cec.health.nsw.gov.au/programs/high-risk-medicines/high-risk-medicines#eosm. Accessed on 04/03/2016.

Neubert *et al.* highlighted that 62% of all medicines used in their NICU had no information provided about their use in newborns.[36] Chatterjee *et al.*[25] reported that information in an Indian NICU was obtained from clinicians' standard neonatology textbooks as well as through online resources.

Despite the lack of information, 22·7%–63% and 5·7%–28·8% of all medicines used in NICUs were classified as off-label and unlicensed medicines, respectively.[24,25,27,29,30,32,34,36,38,39] Overall, it was reported that 71%–100% of infants would receive at least one off-label or unlicensed medicine whilst admitted to a NICU.[24,27,32,34–38] Premature infants were more likely to be administered an off-label or unlicensed therapy in comparison with term babies.[27,30,34–36,38] An Estonian study found that 100% of preterm babies admitted to their NICU received an unlicensed or off-label medicine.[35] This finding is supported by the Irish and German studies who both stated that 100% of preterm infants (<28 weeks gestation) would be administered at least one unlicensed or off-label medicine.[32,36] Non-approved dosage, frequency of dosing, age, indication, treatment duration and route of administration as well as extemporaneous preparation of novel formulations by hospital pharmacy were identified as the main reasons for the use of medicines in alternative ways to those approved in the product information, rendering medicines off-label or unlicensed.[24,27–39] Each of these reasons may have implications on the safety of neonates, with the potential for toxicity, adverse effects and ineffective treatment.[29]

The most commonly administered off-label medicines were reported as benzylpenicillin, furosemide, ranitidine, fentanyl, theophylline and gentamicin.[24,27–30,32–38] The most commonly used unlicensed medicines included folic acid, hydrocortisone, caffeine and parenteral nutrition, and were classified as unlicensed because they were specifically compounded by the hospital pharmacy.[24,27–30,32–38] (Table 3) An Italian study stated that caffeine is a well-known, effective and safe therapy frequently used for the treatment apnoea in prematurity; however, it is not licensed for use in babies.[30] It must be noted that the aforementioned medicines are not classed as off-label/unlicensed in all instances of their use. This classification only applies to their use in certain indications, formulations, countries or as deemed by the definition of off-label/unlicensed in each respective study.

Irrational prescribing. In a study conducted in an Italian NICU, Dell'Aera *et al.* drew attention to the prescribing of a number of medicines that were deemed inappropriate for neonatal patients,

Table 2. Overview of the studies included in the review

	Authors	Year	Country	Study period	Number of patients	Study design
1	Barr *et al.*[24]	2002	Israel	4 months	105	Prospective study
2	Chatterjee *et al.*[25]	2007	India	6 months	176	Prospective study
3	Clark *et al.*[26]	2006	USA	9 years	253 651	Retrospective review
4	de Souza *et al.* [27]	2016	Brazil	6 months	192	Retrospective cohort study
5	de Souza Goncalves *et al.*[28]	2015	Brazil	6 months	187	Prospective observational study
6	Dell'Aera *et al.*[29]	2007	Italy	2 months	34	Cross-sectional, prospective study
7	Dessi *et al.*[30]	2010	Italy	1 month	38	Prospective study
8	Hsieh *et al.*[31]	2014	USA	5 years	450 386	Retrospective review
9	Kieran *et al.*[32]	2014	Ireland	2 months	110	Prospective observational study
10	Kumar *et al.*[33]	2007	USA	3 years	2304	Retrospective review
11	Laforgia *et al.*[34]	2014	Italy	1 month	126	Prospective observational study
12	Lass *et al.*[35]	2011	Estonia	1 year	490	Prospective cohort study
13	Neubert *et al.*[36]	2009	Germany	11 months	183	Prospective cohort study
14	Nguyen *et al.*[37]	2010	France	4 months	65	Prospective cross-sectional study
15	O'Donnell *et al.*[38]	2002	Australia	10 weeks	97	Prospective observational study
16	Oguz *et al.*[39]	2012	Turkey	24 h period	464	Prospective observational study
17	Sharanappa *et al.*[40]	2014	India	6 months	100	Retrospective review of case records
18	Turner *et al.*[41]	2009	UK	2 weeks	49 units	Prospective survey
19	Warrier *et al.*[42]	2006	USA	7 years	6839	Retrospective data analysis

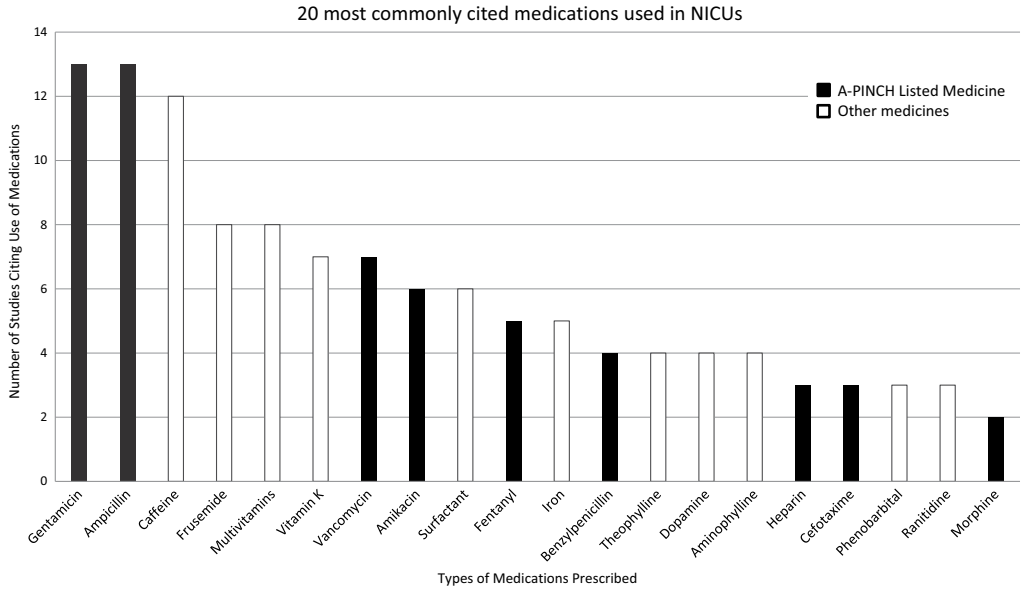

Fig. 2. Most commonly cited medicines used in nicus worldwide.

including sulfadiazine (contraindicated in premature neonates due to the risk of inducing neonatal jaundice), meropenem (insufficient data on efficacy and tolerance in babies and not recommended in patients <3 months of age), itraconazole (insufficient data to allow use in paediatric patients), flunisolide (contraindicated in children <4 years of age), phenobarbital and prednisolone–neomycin (incorrectly administered – IV instead of IM, and intranasally instead of intraocularly).[29] In an Israeli NICU, Barr *et al.*[24] identified that out of a total of 525 prescriptions, 199 were given at a dosage that was unusually high and this included ampicillin, theophylline, amoxicillin, gentamicin, vancomycin and imipenem. A further 25 courses were given in too low dosages and included gentamicin and cisapride.[24] Lass *et al.*[35] reported that five products contraindicated for use neonates were prescribed in an Estonian NICU and included the following diclofenac, drotaverine, metoclopramide, heparin sodium ointment and ursodeoxycholic acid tablets.

DISCUSSION AND WHAT IS NEW

This review provides an insight into medicines use in NICUs worldwide. To our knowledge, this is the only review to explore DUE studies on a global scale. Overall, it appears that the types of medicines used in NICUs worldwide are similar, with high usage of aminoglycosides, penicillins, other antibiotics, caffeine and multivitamins. This is unsurprising as the majority of studies included in the review were from developed countries, and commonly treated the same patient pathologies, including sepsis, complications associated with prematurity and neonatal jaundice. However, there is variability in the average number of medicines used per patient, ranging from 3 to 11. This has been attributed to the specific characteristics of individual NICUs which may experience higher intakes of premature or VLBW patients that require longer hospitalizations and more medicines, affecting the overall mean. However, it cannot be definitively stated that the findings of the review accurately depict current practice in NICUs, due to the general lack of literature available. The 19 articles included in the review do not give a thorough account of global usage of medicines in NICUs.

There is a great need, from a pharmacy-based perspective, to promote the rational use of medicines to achieve positive and safe patient outcomes. The data from the drug-use evaluation studies have highlighted several areas that should become the focus of neonatologists, pharmacologists and clinical pharmacists to improve efficacy and safety of medicines usage in NICUs:

- *High use of antibiotics*: The review drew attention to the high usage of antibiotics in NICUs. As severe infections are a main cause of neonatal mortality, accounting for more than one million neonatal deaths annually worldwide, the appropriate choice of antibiotic agents is essential to prevent serious consequences.[12] Antimicrobial stewardship programmes should be established in NICUs to improve antimicrobial use, promote positive patient results and decrease antimicrobial resistance, adverse effects and excess costs.[43] The Priority Medicines for Europe and the World report by WHO highlighted the need to develop diagnostic tools tailored specifically for neonatal conditions to avoid the inappropriate use of antibiotics in the NICU.[44] Patel *et al.* suggested several 'Get Smart' principles to optimize the safe use of antibiotics in the NICU. These included

Table 3. Overview of medication use in each country[a]

Country	Number of drugs used per patient	Most commonly used	How many patients will receive off-label medicine	Most common off-label/unlicensed medicines
Australia	Median: 7	Gentamicin, morphine, vancomycin	80% of NICU patients and 93% of babies weighing <1000 g received either an off-label or unlicensed medicine or both	Morphine (O), Theophylline (O), Aminophylline (O) sodium chloride (U), Dobutamine (O), paracetamol (O)
Brazil	Mean: 6·4 Median: 11	Fentanyl, multivitamins, gentamicin	99·5% of neonates will be exposed to an off-label medicine. Infants with gestational ages <28 weeks have a higher exposure to unlicensed or off-label prescriptions	Heparin (O), Fentanyl (O), Multivitamins (O), injectable Alprostadil (U), Folic acid (U), Hydrocortisone (U)
Estonia	Median: 4	Gentamicin, heparin, simethicone	All preterm babies and 97% of term babies will receive at least one off-label or unlicensed medicine.	Furosemide IV (U), Ampicillin (O), Simethicone (O), Salbutamol (O)
France	Median: 4	Vitamin ADEC, vitamin K, calcium folinate	71% of babies will receive at least one off-label or unlicensed medicine	Calcium folinate (folic acid) u, Ferrous fumarate (O), Sodium chloride 10%, Benzylpenicillin (O), Amikacin (O),
Germany	Mean: 11·1	Vitamin K, piperacillin, tobramycin	70% of patients will receive at least one off-label or unlicensed medicine. 100% of preterm infants received at least one off-label or unlicensed medicine	100% of anaesthetics and analgesics had no info for use in neonates/preterm
India	Mean: 4·8	Ceftriaxone, amikacin, phenobarbital, cefotaxime		
Ireland	Median: 4	Chlorhexidine, IM vitamin K, gentamicin	91% and 94% of infants <32 weeks received an unlicensed and off-label medicine, respectively. 100% of infants <28 weeks will receive an unlicensed and off-label medicine	Caffeine (U), benzyl penicillin (O), gentamicin (O)
Israel	N/A Between 1 and 13	Gentamicin, ampicillin, theophylline	93% of babies received at least one off-label or unlicensed medicine	Theophylline (U), cisapride (O)
Italy	Median: 3–5·5 Mean: 1·7	Amikacin, ampicillin-sulbactam, parenteral nutrition infusions, multivitamins, aminophylline, caffeine, gentamicin	Preterm neonates received more unlicensed medicines compared to term newborns (14·5% vs. 4·5%)	Parenteral nutrition infusions, amikacin, ranitidine, tobramycin, ofloxacin, caffeine, calcium levofolinate, sodium ferric gluconate complex Caffeine (U), furosemide (O), parenteral nutrition (U), phenobarbital (O), theophylline (O), ranitidine (O) caffeine (U), magnesium sulphate (U), ferrous sulphate (U), gentamicin (O), amoxicillin (O), miconazole (O), salbutamol (O),
Turkey	Median: 3	Ampicillin, multivitamins, amikacin		
UK	Median: 3·5	Gentamicin, benzylpenicillin, folic acid, vitamin K	90% of NICU patients received at least one off-label or unlicensed medicine	Benzylpenicillin (O), folic acid (O), caffeine (U), TPN (u–made in pharmacy), dalivit (O), vitamin k (O), Flucloxacillin (O) Caffeine (U), benzyl penicillin (O), gentamicin (O)
USA	Mean: 3·7–4	Ampicillin, cefotaxime, survanta, gentamicin, caffeine citrate, supplemental sodium chloride, potassium chloride, ferrous sulphate, heparin,		o-fentanyl, erythropoietin, dopamine, midazolam, hydrocortisone, dexamethasone, lorazepam, papaverine, ranitidine, milrinone Only 35% of meds are approved by FDA for use in NICU

[a]O, off-label medicine; U, unlicensed medicine

the following: accurately identifying patients who need antibiotic therapy, using local and regional antibiograms, avoiding prescribing therapies with overlapping activity, giving the right dose and interval of antibiotics, reviewing culture results, monitoring for toxicity and stopping therapy promptly if indicated by culture results.[45]

- *Irrational prescribing*: Incorrect choices of medicines, doses, routes of administration and dosing frequencies can be detrimental to neonatal outcomes.[46] Caffeine, for example, is commonly used in the NICU for the treatment of apnoea of prematurity and is well known for being the safest option available.[47] However, there is still a high incidence of theophylline use, which is associated with higher rates of toxicity.[30,47] Targeted guidelines are needed to ensure that the most appropriate medicines are being prescribed.
- *Polypharmacy*: Premature infants/VLBW babies receive larger numbers of prescribed medicines per patient in comparison with term babies.[25,28] Consequently, there is an increased risk of duplicate therapies as well as drug interactions and adverse drug reactions.[48] There is a need for regular pharmacist interventions involving medication chart reviews and participation in multidisciplinary ward rounds which may have an impact on decreasing the incidence duplicated therapies.
- *Use of narrow therapeutic index medicines*: All medicines need to be monitored to ensure that the doses administered are within their therapeutic range.[49] However, for medicines with a narrow therapeutic index, toxic concentrations can be reached quickly leading to adverse effects.[50] The review has highlighted that aminoglycosides and theophylline are commonly used in NICUs. Measures are needed to ensure proper therapeutic drug monitoring and accurate dosing to prevent the misuse of these medicines.
- *High use of A-PINCH medicines*: These medicines are those that have an increased risk of causing harm if they are misused or used in error. Neonates possess characteristics of vulnerability in relation to their pharmacologic capabilities, and given that 9 of the 20 most commonly used medicines found in the results are classified as high-risk medicines, there is a need to be highly vigilant to ensure the safety of neonates. In particular, appropriate guidelines or safety measures should be implemented when these medicines are prescribed to ensure appropriate and safe dosing for patients and the prevention of medication misuse.
- *High use of off-label/unlicensed medicines*: The review shows that the use of these types of medicines is common in NICUs worldwide because of a lack of information and availability of formulations. As such, there is a need to license medicines and for more clinical trials to be performed to provide reliable information to guide the use of medicines in neonates.[35,39] However, in the interim, there is a need for a registry or practical guidelines on how to use these therapies based on the best available evidence and experience of health professionals.
- *Origin of dosing recommendations*: When considering the large range in the types of medicines prescribed (23–409) in the review, there is concern about the heterogeneity of drug recommendations within, and between, NICUs. A study by Leroux et.al. investigated antibiotic regimens in 45 NICUs in France and found approximately nine different dosing protocols per drug.[51] This leads to considerable variability in the treatment of neonates, with differences in daily doses and dosing intervals potentially having a significant impact on patient outcomes. As such, there is a need for robust evidence base to define pharmacokinetics, pharmacodynamics, safety and efficacy of pharmacotherapy in neonates in order to develop targeted guidelines.[52]
- *Modalities of drug prescription*: Differences in prescribing methods, that is hand written vs. computer physician order entry (CPOE) and clinical decision support systems, may have an impact on rational drug use as well as medication error rates by addressing the accuracy of drug selection and dosing.[53] Kaushal *et al.*[54] found that most medication errors in paediatric and neonatal patients occurred at the point of prescribing, and identified that CPOE could have prevented 93% of those events occurring. These decision support tools should be thoroughly considered in NICUs to promote uniform prescribing, decrease medication errors and improve the efficiency of resources.[55]

Whilst the use of medicines in neonates can have positive therapeutic effects on patients, when considering the aforementioned high-risk areas of medication use in the NICU, medication errors have a high risk of occurring in this patient population.[8,56–58] The most commonly occurring medication errors comprise 10- to 100-fold dosing errors, patient misidentification, drug interactions, incorrect routes of administration and erroneous product dilutions.[56–58] Therefore, the inappropriate use of medicines can have a significant impact upon reducing the potential effectiveness of pharmacotherapy, causing negative effects for patients and producing costly economic outcomes. As such, there is great potential, particularly from the perspective of a clinical pharmacist, to improve medication management in the NICU, and the quality use of medicines should be made a priority to ensure the safety of this high-risk population.

LIMITATIONS

Comparisons between countries were difficult due to differences in study methodologies. These included differences in the types and classes of medicines that were included for evaluation as well as differences in the definition of off-label and unlicensed medicines. For example, some studies classified medicines as off-label as those that were used in a manner different to that specified in the summary of product characteristics, whereas other studies used a broader description and defined off-label as medicines used in a manner different to that described in books, formularies, package inserts as well as manufacturer information.

CONCLUSION

Overall, it is apparent that the types of medicines used in NICUs worldwide are consistent, with the most commonly prescribed medicines including antibiotics, diuretics, caffeine and multivitamins. A-PINCH medicines made up nine of the 20 most commonly used medicines in NICUs and included fentanyl, morphine and heparin. The data available were collected from 12 countries and gave a good representation of drug use in NICUs; however, 19 studies is not a substantial amount of data. Therefore, it cannot be definitively stated that the findings of the review accurately depict current practice in NICUs, due to the limited amount of published literature available. There are several areas of concern that warrant further investigation to improve rational use of medicines in the neonatal populations, including high use of antibiotics and off-label and unlicensed medicines.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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Review Article

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A global perspective of the roles of the pharmacist in the NICU

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Keywords
Neonatal care; neonatal intensive care unit; pharmacist roles; pharmacy services

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Abstract

Objectives To describe pharmacist practice and roles performed in the neonatal intensive care unit (NICU) worldwide and to map these findings along the medicines management pathway (MMP).
Method Quasi-systematic review.
Search Strategy Google Scholar, Medline/PubMed and Embase were searched utilising the selected MeSH terms.
Results Thirty sources of information were reviewed. Overall, pharmacist practice in the NICU involves a wide-range of roles, with the most commonly reported involving patient medication chart review, therapeutic drug monitoring and the provision of medication information. Studies highlight that pharmacist contribution to total parenteral nutrition (TPN) regimens and patient medication chart review is beneficial to patient outcomes. Roles beyond the regular scope of practice included involvement in immunisation programmes and research. Most of the data were collected from the USA (13 of 30), followed by the UK (6 of 30) and reports from other countries. The American, British, South African and Australian articles have reported very similar roles, with a pharmacist firmly integrated into the overall structure of the NICU team.
Conclusion The literature identifies that there is insufficient evidence to describe what roles are currently performed in NICUs worldwide. This is due to the lack of recently published articles leading to a large gap in knowledge in understanding what contemporary pharmaceutical services in the NICU comprise. Further research is required to address these gaps in knowledge, and identify the impact of the pharmacist's role on neonatal patient outcomes as well as to determine how to better resource NICUs to access pharmacy services.

Introduction

The World Health Organisation (WHO) recognises pharmacists as essential resources for the safe and effective use of medicines.[1] With the outcomes of pharmacist interventions including improved patient quality of life, as well as reduced medication errors and adverse drug events, there are clear benefits to providing clinical pharmacy services to hospitalised patients.[2–6] Current studies describe pharmacist roles within a range of adult settings, including participation in ward rounds, medication reconciliation upon admission and therapeutic drug monitoring (TDM).[3–6] However, there is minimal corresponding literature reporting on pharmacist roles within the neonatal intensive care unit (NICU).

As the NICU population possesses characteristics of vulnerability, which predispose them to a high-risk of medication misadventure, the use of medication in these patients poses significant challenges for the treating team. Current studies showcase pharmacist interventions as having a significant impact on decreasing medication errors in the NICU, however they fail to describe roles beyond those performed as experimental interventions.[7,8] The roles and practices of pharmacists vary from country to

country, and as such it is prudent to explore these differences to determine whether there are any inequalities in medication management in the NICU and where pharmacists focus their practice. Therefore, the purpose of this review is to provide an overview of pharmacist practice in the NICU and identify, describe and compare pharmacist roles as reported globally in published and grey literature. A specific objective of the review is to map the findings along the medicines management pathway (MMP).[9]

Method

A quasi-systematic review (a review that possesses some elements of a systematic review, including pre-defined selection criteria, however includes grey literature and does not present a critical evaluation of the quality of studies) extracted relevant publications relating to roles, interventions, activities and functions performed by pharmacists in the NICU.[10–12] A robust systematic review could not be performed due to the nature of the literature collected, with the majority consisting of grey literature, review articles and reports and a distinct lack of published studies. The amount and type of literature collected influenced the format of the review, precluding the full application of PRISMA guidelines, and leading to the adoption of a quasi-systematic review.

Literature was retrieved by searching the following electronic databases: Embase, PubMed and Google Scholar. All sources of information including relevant studies, review papers and other publications were canvassed. It is acknowledged that particularly where practice is well established, it is not necessarily based on well-designed clinical trials. Therefore, a broader perspective was obtained by performing a supplemental Google search using the same search terms to identify relevant grey literature.

Search strategy

A two-tiered search strategy was used. (Figure 1) In Tier 1, a search was performed utilising the following MeSH headings/keywords: *pharmacist interventions*, *clinical pharmacist*, *neonatal intensive care*, *neonate/infant/newborn*, *pre-term*, *protocols*, *pharmacist role/activities*, *pharmacist responsibilities*, and *pharmacist impact*. The Boolean operator 'AND' was employed to combine the search terms. Manual bibliographic searches of all relevant articles were also performed in order to identify any articles that were not identified in the electronic searches. In Tier 2 of the search, relevant grey literature was identified through a Google search using the same MeSH terms. This tier was dedicated to finding service standards, position descriptions as well as descriptive reports.

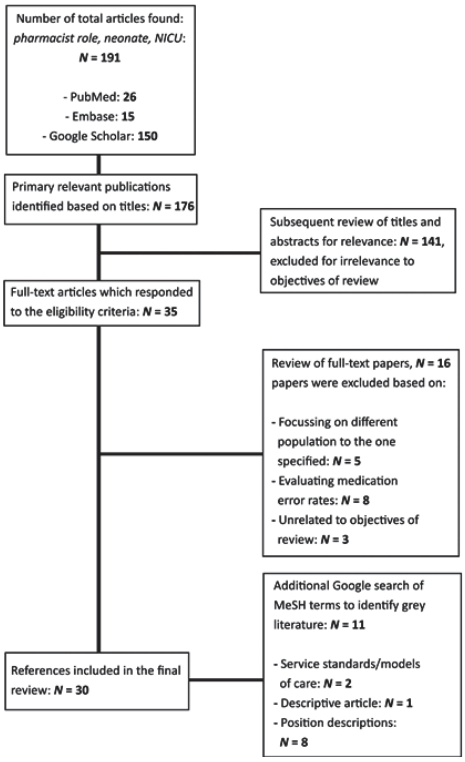

Figure 1 Review of the search strategy employed to find relevant literature.

Study selection

The selection criteria for the searches restricted the content to the following: (1) review articles (including literature reviews and opinion pieces), research articles, or grey literature; (2) with results containing information on pharmacist-led activities relating to neonatal patients in the NICU setting; and (3) written in the English language. All full text articles meeting these criteria were retrieved and all evaluations pertaining to the types of pharmacist roles in the NICU were included in the review. Due to the minimal amount of literature available reporting on pharmacist roles in the NICU, no date limits were applied, enabling the collection of data from a broader range of resources.

The medicines management pathway

The pharmacist roles identified in the review were mapped out against the MMP. The MMP is a process

map that describes the full range of cognitive and physical steps involved in the utilisation of pharmacotherapy in any patient group with the aim of improving the quality use of medicines and identifying any potential safety system improvements.[9] Published by the Society of Hospital Pharmacists Australia (SHPA) the MMP is cyclical in nature and highlights that each element relates to another (Figure 2).[9]

Data extraction and analysis

The data extraction and mapping of the roles against the MMP were performed by Author 1 and verified by Author 2. A standard data extraction form was used to describe the studies and the pharmacist roles performed in NICU's worldwide. The articles retrieved from each tier of searching were pooled for analysis, in-line with the study objectives. The extracted information consisted of a description of the roles performed by pharmacists, the frequency at which they were performed, and the country from which the study originated.

Results

A total of thirty sources of information were included in the review.[13–42] This literature was collected from a range of countries, predominantly from the USA (13 of 30) and UK (6 of 30) with reports from Australia, South Africa and Ireland. The types of articles collected consisted of qualitative (5) and quantitative studies (4) (total 9 of 30), review articles (6 of 30) and reports (4 of 30) as well as grey literature, including a descriptive article (1 of 30) position descriptions (8 of 30) and neonatal service standards (2 of 30). It was noted that there were no articles that utilised randomised control trials or cohort study designs. Table 1 provides an overview of the articles used in the review.

Overall, there is limited published literature comprehensively exploring the current roles of pharmacists in NICUs. Most of the published literature collected was approximately 10 years old or older, with seven articles published before the year 2000, and three published prior to 2006.[14,16,19–22,24,30,32,33] As such, grey literature including

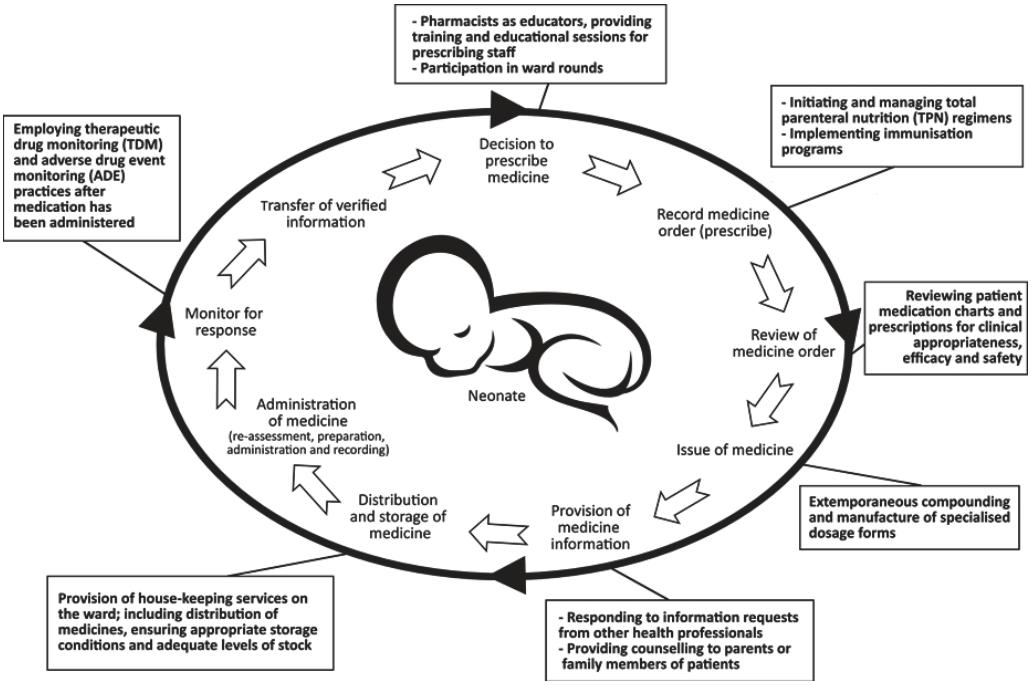

Figure 2 Pharmacist practice in the neonatal intensive care unit mapped against the Medicines Management Pathway. Figure adapted from: Stowasser[9]

Table 1 List of studies that were included in the review

Study	Type of literature	Country year setting	Key findings
Ahmed M[42]	Descriptive article	UK 2008 NICU	The main aspects of a pharmacist's role in the NICU are: educating staff and parents, developing a formulary, providing input into parenteral nutrition, advising on drug choice and attending weekly multidisciplinary ward rounds.
British Association of Perinatal Medicine (BAPM)[13]	Service standard	UK 2010 Hospitals providing neonatal care	Neonatal pharmacists play a role in the optimisation of pharmacotherapy in neonates. They are required to perform a number of clinical roles including: monitoring of prescriptions, therapeutic drug monitoring (TDM) as well as provision of advice on off-label and unlicensed medicines.
Bryant BG[14]	Report	USA 1985 NICU	Pharmacists perform daily patient medication reviews for medication appropriateness and any interactions, respond to information requests from medical and nursing staff, prepare dosage formulations suitable for babies and counsel parents.
Cambridge University Hospital[36]	Position description	UK NICU	The neonatal pharmacist visits the NICU daily and performs the following services: prescription chart review, provides advice to the doctors and nursing team, reviews policies and guidelines and checks TPN orders.
Chedoe I *et al.*[15]	Literature review	the Netherlands 2007 NICU	Pharmacist interventions, namely participation in ward rounds and review of medication orders prior to dispensing and distribution, were found to be the most common pharmacist interventions suggested to improve medication safety in the NICU.
Condren M *et al.*[16]	Prospective descriptive study	USA 2004 Paediatric ward	The most common services performed by a pharmacist were drug therapy change, pharmacokinetic monitoring, medication information and medication histories. Also identified roles including; patient medication review, adverse drug event monitoring, and provision of medication information.
Conway C *et al.*[17]	Literature review	Ireland 2012 NICU	The most important pharmacist roles for maintaining patient safety in NICU included medication chart checking and participation in physician consultations.
De Jager *et al.*[18]	Literature review	South Africa 2014 NICU	Clinical pharmacists in NICUs should be involved in the following services; attending daily ward rounds, TDM, parenteral nutrition, patient education and research into safety and efficacy of medications.
Dice JE *et al.*[19]	Prospective interventional study	USA 1981 NICU	Pharmacist monitoring of an individualised TPN in neonates had greater mean daily weight gain, introduced a greater amount of nutrients to the infant and was more cost-effective than a standardised programme.
Dunkley MK[20]	Prospective study	Australia 1991 NICU	Australian pharmacists provided strong support in extemporaneous manufacturing, parenteral nutrition, provision of medication information, TDM and adverse drug reaction monitoring. Standards of clinical pharmacy service in the NICU need to be developed to promote service equality between hospitals.

Table 1 Continued

Study	Type of literature	Country year setting	Key findings
Folli H *et al.*[21]	Prospective descriptive study	USA 1987 Paediatric hospitals	Pharmacist involvement in reviewing patient medication orders significantly reduced potential harm resulting from erroneous medication orders.
Gold Coast Hospital and Health Service[35]	Position description	Australia 2015 NICU	The key duties of the neonatal pharmacist include: performing clinical reviews of medication therapies, monitoring patient outcomes and revising treatment strategies accordingly, delivering specialist educational presentations for pharmacists and other health professionals in the hospital and providing information obtained through research to optimise pharmaceutical care provided to complex neonatal patients.
Intermountain Healthcare[41]	Position description	USA 2015 NICU	The essential duties of the NICU pharmacist include: providing accurate drug information, monitoring physician orders, training and supervising new pharmacy technicians and actively participating in department cost savings initiatives.
Johnson C *et al.*[22]	Report	USA 1993 NICU	A pharmaceutical care system was established within NICU. The most important elements of this service included; monitoring of drug dosing, reporting adverse drug reactions, detecting medication interactions, immunisations and counselling of parents.
Kelishadi R *et al.*[23]	Literature review	Iran 2012 Paediatrics	Pharmacist-physician-patient collaboration is important in maintaining medication safety in NICU. Pharmacist roles including medication chart checking, participation in multi-disciplinary meetings, parent interviews and clinical interventions were the most effective in medication management in the NICU.
Lobas N *et al.*[24]	Descriptive article	USA 1991 NICU	NICU pharmacists participate in ward rounds, TPN therapy, medication information services and pharmacokinetic consultations.
Medical University of South Carolina[37]	Rotation description	USA 2015 NICU	The pharmacist is expected to participate in daily ward rounds with the inter-professional team, evaluate each patient's drug therapy at least daily, communicate with patient's family or caregiver and provide timely responses to requests for drug information.
Mills B *et al.*[25]	Prospective and descriptive study	USA 2014 Pharmacy in women's hospital	Vaccination rates increased after the implementation of a pharmacist-led intervention programme for family members of neonates. The pharmacist was recognised as an important source in promoting immunisation for the safety and health of infants. Unknown whether the pharmacists involved were NICU pharmacists or general hospital pharmacists.
Mulholland P[26]	Prospective survey	UK 2012 NICU	40% of surveyed pharmacists were prescribers and 70% of these pharmacists were prescribing in the NICU. The main medications being prescribed were parenteral nutrition (75%), supplements (75%), antibiotics and caffeine (50%). Benefits of pharmacist prescribing included reductions in communication errors and timely corrections of wrong prescriptions.

Table 1 Continued

Study	Type of literature	Country year setting	Key findings
Murphy J *et al.*[27]	Model of care	Ireland 2015 Hospitals providing neonatal care	The role of the neonatal pharmacist involves: ensuring the safe use of medicines in NICUs, prescription monitoring, ordering and monitoring parenteral nutrition, providing information on medicines and educating other health professionals as well as parents.
New South Wales Government[34]	Position description	Australia 2013 NICU	The NICU pharmacist is responsible for reviewing medicines prescribed and optimising pharmacotherapy in critically ill neonates, ensuring the appropriate ordering and preparation of parenteral nutrition, actively participating in daily ward rounds as well as advising parents on medicine related issues.
Prot-Labarthe S *et al.*[28]	Multi-centre, prospective and descriptive study	France, Quebec, Belgium and Switzerland 2013 PICU	Pharmacists recorded a break-down of their various activities in PICUs throughout each day, and the roles included student training, clinical research, drug distribution and clinical activities. Over the 6 month study period, the total duration of pharmaceutical care offered by pharmacists was reported as; 550–France, 416–Quebec, 410–Switzerland and 124–Belgium patient days.
Ragab M *et al.*[29]	Literature review	Saudi Arabia 2014 NICU	Pharmacists are involved in initiating the neonatal TPN orders and are actively involved in assisting prescribers in the prescribing process, including participating in ward rounds and meetings
Sanghera N *et al.*[30]	Systematic literature review	UK 2006 Paediatrics	Reviewing patient charts was deemed to be the most effective pharmacist role in improving medication safety in NICUs
Schellack N *et al.*[31]	Prospective study	South Africa 2011 NICU	The majority of pharmacist time was spent on patient care and ward functions. Pharmacists also participated in ward rounds and clinical meetings. Doctors and nurses identified that the role of the pharmacist in NICU is a necessity to improve services provided to neonates.
Simpson JH[32]	Prospective Observational study	UK 2004 NICU	Close liaison with a ward-based clinical pharmacist is an effective way of reducing medication errors. The role of the pharmacist in staff feedback and education as well as reviewing medication orders was identified as effective in reducing dose calculation and prescribing errors
St David's North Austin Medical Center[39]	Position description	USA 2016 NICU	NICU pharmacist is responsible for: accurately and effectively providing medication therapy, providing medication counselling, assisting in training and educational programmes, providing drug information upon request and reporting medication errors and adverse drug reactions.
University of Kentucky Hospital[38]	Position description	USA 2009 NICU	The major responsibilities of the NICU pharmacist are: the provision of pharmaceutical care to patients including participation in daily ward rounds, monitoring drug therapy, counselling parents and caregivers and reviewing medication orders for accuracy and appropriateness, as well as facilitating investigational drug studies and providing education to trainees and other health professionals.

Table 1 Continued

Study	Type of literature	Country year setting	Key findings
Website[40]	Position description	USA 2015 NICU	The key duties of a NICU pharmacist include: daily multi-disciplinary patient rounds, daily medicine profile review, providing drug information, documenting all interventions performed and training and educating pharmacy students.
Zenk KE[33]	Report	USA 1980 NICU	Every neonatal ward needs a pharmacist who specialises in neonatal pharmacology. Ward-based clinical pharmacists are involved in all aspects of medication in the NICU, and perform specialised compounding and dilutions of medications, and are actively involved in determining TPN formulations, patient medication review, provision of medication information, education of NICU staff, participation in ward rounds, TDM, counselling of parents and preparing drug monographs.

NICU, neonatal intensive care unit; PICU, paediatric intensive care unit; TPN, total parenteral nutrition.

service standards, guidelines and position statements were used to describe a more contemporary practice where other literature was dated or absent. Due to the lack of available literature, several articles were utilised that were primarily paediatric based, but included a sub-section of neonatal patients within their evaluation.[16,21,23,28,30] Overall, out of the total proportion of articles included in the review, 24 were specifically related to pharmacists working within NICUs and neonatal care, with the remaining 6 referring to pharmacists working in paediatric settings, including paediatric intensive care units (PICUs), children's hospitals and a women's hospital that involved elements that also addressed neonatal patients.

Each of the roles identified were matched to the steps of the MMP; no specific pharmacist roles were identified that could be mapped against the following steps: record of medication order, administration of medication and transfer of verified information.

The roles of the NICU pharmacist mapped against the steps of the MMP

Decision to treat and prescribe

The NICU pharmacist has been recognised as an important contributor to the prescribing process. Within relatively older literature, it was reported that pharmacists routinely assisted in the appropriate selection of medications, suggested dose changes, routes of administration, and advised on potential side-effects.[18,20,24,33] Pharmacists most commonly contributed to the prescribing process by participating in medical ward rounds.[18,20,24,33] Ward rounds in the NICU provided an opportunity for pharmacists to engage in bedside pharmacotherapeutic consultations and improve inter-professional communication.[18,24,33] These findings are also reflected in the British Association of Perinatal Medicine (BAPM) service standards and in the position descriptions, which detail that NICU pharmacists are required to attend multidisciplinary ward rounds on a daily or weekly basis, as well as provide input at relevant clinical meetings.[13,34,37,38,40,42] The Australian position description states that NICU pharmacists are expected to be active members of the multidisciplinary NICU team to optimise patient care, and it has been reported that during ward rounds medical staff rely on the pharmacist to provide accurate medication information and to transmit new research relating to pharmacotherapy in the neonate.[33,35]

NICU pharmacist involvement was acknowledged in the prescribing of nutritional supplements for neonates.[18–20,22,26,29,33] In particular, Ahmed stated that NICU pharmacist input was significant during the prescribing and manufacture of parenteral nutrition for infants.[42] Pharmacists were reported as being commonly involved in the calculation of the daily calorie and protein requirements, preparing total parenteral nutrition (TPN) protocols, prescribing TPN regimens, reviewing TPN orders as well as identifying and resolving errors in nutrition orders.[20,29,38] A UK study identified that 47% of NICU pharmacists surveyed were prescribers and mainly ordered parenteral nutrition and supplements (75%).[26] Mulholland added that pharmacist prescribing of TPN promoted patient safety, reduced communication errors and reduced pharmacy costs.[26,29] An older prospective interventional study performed by Dice *et al.* (1981) in an NICU that involved 28 patients, reported that pharmacist monitoring of individualised TPN regimens had significantly increased the mean weight gain and protein intake of infants

($P < 0.02$), compared to those neonates on standardised TPN formulations with no pharmacist monitoring.[19] Pharmacist monitoring involved calculating the neonate's required fluid and calories, recording changes in weight, documenting laboratory results and recommending changes to TPN solution.[19] Furthermore, pharmacist monitored TPN programmes led to greater amounts of nutrients being provided to neonates, fewer medication errors and lower overall pharmacy costs.[19,29] Prescribing pharmacists in British NICUs felt they were more integrated into the multidisciplinary treating team in the NICU after becoming a non-medical prescriber.[26]

Review of order

The majority of the literature reported that NICU pharmacists were involved in the review of patient medication charts.[14,15,17,20,21,23,27,30,32–41] As a service uniquely performed by pharmacists, the medication chart review process within the NICU was described in older literature as being a 'standard' practice for the advancement of medication safety.[19,29] The characteristics of the role involved the evaluation of medication charts for medication appropriateness, correct dosages according to the weight of the neonate, drug–drug/drug–laboratory value/drug–nutrient interactions, allergies, medication duplication, timing of administration (particularly with concurrent IV fluids or supplements), route of administration, adherence to clinical protocols and procedures, as well as the review of relevant patient progress notes, diagnostic tests and laboratory values.[14,15,17,20,21,23,30,32,33,37–41] In reviewing the patient's medication chart, NICU pharmacists also performed interventions to rectify medication safety issues which included correcting doses and modifying the route of administration.[16,19,21,24,28,31,37,40,41] The benefits of a pharmacist-led chart review were reported in one prospective study conducted in 2004 by Simpson *et al.* who found that the implementation of daily pharmacist review in NICU led to a significant reduction in the incidence of medication errors ($P < 0.001$).[32]

Several position descriptions require NICU pharmacists to perform patient medication reviews on at least a daily basis, with the BAPM recommending that pharmacists dedicate at minimum 10–20 min of time per patient.[13,36–41] Observational research conducted in a South African NICU, found that 73% of pharmacist time was spent on patient review.[31] In contrast, a study performed by Prot-Labarthe *et al.* in four French-speaking countries determined that only 10 – 15% of clinical pharmacist time was spent on clinical activities.[28] This study was conducted in PICUs, however as it also included neonatal patients (ages ranging from 0 to 6 days) within their study population, it was deemed relevant to this review. It is unknown what proportion of pharmacists' time in providing pharmaceutical services was spent on neonates in comparison to generalised paediatric patients.

Medication preparation

The extemporaneous compounding service was acknowledged in older articles as being a traditional pharmacist role often undertaken in the care of NICU patients.[14,20,33] Pharmacotherapy in neonates often requires the preparation of dosage forms that are not commercially available and the Australian position description requires NICU pharmacists to be able to accurately perform duties in non-sterile and aseptic manufacturing when required.[14,34] The role was described within two older studies based in the USA (1985) and Australia (1991) respectively, as involving the routine compounding of novel medication formulations as well as specifically adapting adult medications for neonatal patients, including diluting existing products to ensure suitable concentrations for neonates as well as to improve accuracy of dosage measurement.[14,20] In a study from 1991, Dunkley found that pharmacists at the time most commonly prepared eye drops, topical creams and antiseptics.[20]

Provision of medication information

A major responsibility of the NICU pharmacist was reported as the provision of a medication information service. The role comprised two components which involved the provision of NICU specialised medication information to other health professionals on the ward. Part of the role required the pharmacist to be readily available at point of care, addressing spontaneous queries from nurses and doctors that arose during care.[13,16,23,24,27,31,32,34–37,40,41] These queries pertain to a wide-range of medication-related issues, including: medication administration, side-effects, correct calculation of dosages and adherence to medication protocols and disease management procedures.[16,23,24,31,32] Additionally, the Australian position description and BAPM service standards state that one of the main duties of the NICU pharmacists was to provide accurate information on off-label and unlicensed medicines, which are frequently utilised in the NICU.[13,34] Pharmacists often offered responses to information requests in written as well as verbal form to ensure comprehensibility.[16,23,24,31,32] Two articles reported that through the provision of accurate and relevant information, pharmacists have the potential to minimise medication errors and adverse medication events.[23,32] The other part of the medication information role involved pharmacists as primary medication educators to the NICU therapeutic team, providing training and in-services on therapeutic updates in neonatal pharmacotherapy.[14–16,18,20,24,27,33–35,39,42] An

in-service is defined as 'a professional training or staff development effort, where professionals are trained and discuss their work with others in their peer group. It is a key component of continuing medical education for clinicians, pharmacists and other medical professionals.'[43] It is recommended in the older literature, that as a part of their clinical role, NICU pharmacists provide in-services for doctors, nurses, pharmacists, students and other health professionals encompassing: rational medication use, introducing new medications and the latest publications and updates on medications, revising medication administration principles, dose calculations, and classes of medicines most likely to be associated with error in the NICU.[14,15,20,27,33]

The pharmacist is identified as being the first-line health professional to consult when medication-related issues arise.[16,23,24,31,32] One South African study conducted a needs analysis of NICU staff on the medication information service provided by a pharmacist and concluded that the surveyed NICU doctors (n = 17) required a pharmacist to be present on the ward to respond to any medication-related questions.[31] Furthermore, the provision of medication information involved 20% of pharmacist time in the South African NICU.[31]

Pharmacists were also actively involved in reviewing, updating and developing NICU-specific medication protocols, guidelines, policies and formularies for the therapeutic team to use to improve drug safety.[13–15,20,33–36,40,42] Chedoe *et al.* supported these findings by stating that pharmacists should work in multi-disciplinary teams to develop formularies and guidelines that summarise information on medication compatibilities, reconstitution, rates of infusion etc.[15] It is considered in older literature that the provision of detailed medication protocols by pharmacists allows NICU health professionals to become better equipped for prescribing medications and managing pharmacotherapy regimens in neonatal patients.[14,33]

The pharmacist is responsible for counselling parents and carers on all aspects of medications used for their child.[14] Upon admission, throughout the hospital stay, and at discharge, the pharmacist is required to consult with parents/caregivers on the medications being used for their child, advise on the role of the pharmacist in the care of patients and provide clear and comprehensive information on each aspect of therapy.[14,20,27,33–38,42] The older literature highlighted that the type of information provided by pharmacists at that time included: indication for therapy, administration intervals, time to pharmacological effect, risks and benefits of therapy, adverse events and possible adverse reactions.[14,20,33] It is also reported that pharmacists prepare written instructions on the storage and proper use of the medication for parents upon hospital discharge.[14,37,38] Whilst it is apparent that parents and carers of neonates have considerable information needs during the time that their child is admitted to the NICU, there is insufficient evidence to suggest that the NICU pharmacist in contemporary practice fulfils this information provider role.

Distribution and storage

Two sources discussed that, along with clinical roles, the NICU pharmacist had a specific set of ward 'house-keeping' responsibilities, ensuring the appropriate distribution and storage of medications.[31,41] This role involved ensuring the timely delivery of required medicines, stock-take, ordering of relevant items required on the ward, checking the medication fridge temperature and ensuring its cleanliness, checking storage conditions for product stability (for vaccines, blood products, and parenteral formulations) and stocking the emergency trolley.[31,41]

Monitor for response

Overall, NICU pharmacists were highly involved in monitoring drug serum levels in neonatal patients with the most commonly monitored medications identified from older literature as including aminoglycosides, antibiotics, theophylline, chloramphenicol and vancomycin.[14,20] It must be highlighted that these articles are over 10 years old and as such some of the agents listed may not be as widely used in the NICU in modern practice, i.e. chloramphenicol, however they are still therapeutic agents that if used, require monitoring by pharmacists. The provision of a TDM service by pharmacists was identified, in eight articles, as an important practice in ensuring optimal neonatal patient outcomes.[13–16,20,24,28,31] The role has been described as comprising the provision of correct dosing information from the interpretation of blood levels and recommending appropriate timing intervals for the collecting of blood serum samples.[14–16,20,24,28,31]

Adverse event surveillance was identified as an important role for NICU pharmacists.[13–15,20,21,37–39,41] Apart from the standard processes of monitoring, including laboratory tests and observation of physical signs, this also encompassed the development and utilisation of medication error reporting systems, requiring the thorough documentation of any medication errors as well as adverse drug events, followed by pharmacist-led interventions to rectify medication issues including dose adjustments and medication changes.[13–15,37–39,41]

Extended roles

Extended roles possessed specific objectives that did not correspond to one specific stage of the medication use process, but rather encompassed various steps of the MMP.

Vaccination

There are other potential roles for NICU pharmacists, with two articles identifying pharmacist involvement in implementing immunisation programmes for neonatal patients.[22,25] An American article reported that a pharmacist stationed in the NICU was the primary resource responsible for the identification of eligible infants for routine childhood immunisations.[22] Another US-based interventional study by Mills *et al.* investigated pharmacist involvement in a tetanus toxoid, reduced diphtheria toxoids, and acellular pertussis (Tdap) immunisation programme for close contacts of neonates by providing pharmacist-led education of parents and carers of neonates. This programme had clear benefits for neonates, and significantly increased rates of vaccinations for the pertussis vaccine, from 1.3 vaccinations/month pre-study to 85.2 vaccinations/month in the study period ($P < 0.001$).[25] These studies did not specify whether the pharmacists involved within these interventions were NICU pharmacists, or general hospital pharmacists. However, the studies demonstrate the potential value of NICU pharmacist involvement in vaccinations.

Research

NICU pharmacists were also active participants in clinical trials and research.[18,20,24,28,34,38,40,41,44] Two sources stated that NICU pharmacists are encouraged to perform drug use evaluation studies, publish innovations in pharmacy and should facilitate investigational drug studies to improve rational and safe use of medicines.[34,38] An Australian study dated in 1991 highlighted that roles associated with clinical trials at the time specifically involved organising drug supply, maintaining patient records, randomising patients and preparing protocols.[20] A study revealed that in Belgium as much as 50% of pharmacist working time was dedicated to research, however it did not specify roles associated with this practice.[28]

Quality use of medicines strategies

Several position statements required NICU pharmacists to be involved in ensuring medicines used in the NICU were cost-effective and being used rationally.[27,34,38,41] Key duties of the pharmacist included: monitoring the use of expensive medicines, developing cost-saving initiatives for the NICU, involvement in antimicrobial stewardship programmes, documenting clinical interventions and cost-avoidance methods as well as performing target drug programmes to decrease irrational use of medicines.[34,38,41] NICU pharmacists were also tasked with ensuring the quality of pharmaceutical services being provided on the NICU, with increased emphasis on documenting clinical interventions, ensuring all medicine provision services are compliant with legislation and hospital policies and developing safety initiatives.[27,34,37–39,41]

Furthermore, in improving the quality use of medicines, the Irish model of care highlights that pharmacists should have input in implementing and maintaining medication safety technology in NICU practice.[27] These technologies included e-prescribing, barcoding and smart pump technology.[27]

International comparison of pharmacist roles

Articles from thirteen countries were included in this review, with the largest number from the USA (13 of 30 articles). Table 2 provides an overview of the different roles performed in each country, as identified in the literature. Although a wide-range of pharmacist roles have been identified within the literature, there are discernible differences in practice between certain regions worldwide. Literature gathered from the USA, UK, Australia and South Africa suggest that patient-oriented clinical activities such as patient medication chart review, participation in ward rounds, TDM and medication information services make up the majority of the role in NICU. Alternatively, the multi-national study incorporating data from PICUs in Belgium, France, Switzerland and Quebec, did not report on roles in ward rounds and TDM practices. However, pharmacists in these countries were found to be strongly involved in clinical research, provision of medication information and patient medication review. Overall, involvement in immunisations, ward-based housekeeping activities and extemporaneous compounding were not as frequently reported. The apparent lack of current and published literature does not allow for a good understanding of current pharmaceutical services provided worldwide. Furthermore, the literature does not yield any information about practices in South America or Asia. As such, there are inconsistencies and gaps in the literature about the level of practice in each country with respect to NICU pharmacy practice.

Discussion

To our knowledge, this is the only review to compare the roles of NICU pharmacists between countries on an international scale. Whilst the amount of international research documenting clinical pharmacist practices in the NICU is limited, there was sufficient literature to map the pharmacist role against the MMP.[9] A total of 16 different pharmacist roles were identified as being reported globally in published and grey literature. However, we are unable to ascertain if these services are currently provided or offered to NICUs worldwide, due to the lack of recently published literature.

Table 2 Internationally reported roles of pharmacists within the neonatal intensive care unit

Country	Listed activities
United States of America	TPN monitoring/ordering, patient medication review, education sessions with medical staff, participation in ward rounds, involvement in clinical research, parent counselling, TDM, provision of information to medical staff requests, manufacturing capabilities, participation in immunisation programmes, establishing/updating policies and protocols, reporting ADE's and medication errors, monitoring the use of expensive medicines, documenting cost saving interventions
Australia	Review of patient charts, responding to information requests, ordering TPN, TDM, clinical trials/research, contributing to the manufacture of medications, counselling of parents, education for staff, developing drug protocols, reporting ADE's, ensuring adherence to legislation and hospital policies, ward rounds, participating in antimicrobial stewardship
South Africa	Responding to requests for information, ward activities, educational duties in training relevant medical staff, monitoring medication usage, monitoring pharmacokinetic parameters in TDM
Europe	
France Quebec Switzerland Belgium	Clinical activities – review of patient charts, student training, participation in clinical research, medication distribution, responding to medication information questions
United Kingdom	Reviewing medication orders, staff feedback and education, responding to information requests, prescribing TPN, ADE reporting, attendance at ward rounds and clinical meetings, input into guidelines and policies, developing a formulary, advice on off-label/unlicensed medicines
Ireland	Prescription monitoring, documenting ADE's, ordering TPN, education of other health professionals, counselling of parents, provision of medication information on existing and new therapies, implementing technology into practice i.e. e-prescribing, barcoding, developing cost-effective and safety initiatives

ADE, adverse drug event; TPN, total parenteral nutrition; TDM, therapeutic drug monitoring.

Overall, it is difficult to ascertain the true extent of pharmacy practice in each country as relevant literature from Asia, South America and a large proportion of Africa and Europe was not available. The majority of the literature that was sourced was dated more than 10 years ago, and it is difficult to determine whether the data gathered still reflect current practice. Furthermore, due to the lack of available research, several paediatric studies were included in the review that included a sub-section of neonatal patients in their evaluation. As such, it is unknown what proportion of pharmacy services described in these papers referred to neonatal patients. Relevant studies may have been excluded from the review because they were not available in the English language. Grey literature searches sought to identify service standards and guidelines from different countries, however many were not accessible as they were not publicly available or were published in languages other than English.

The findings of the review demonstrate that the value of pharmacists in USA, UK, South Africa and Australia lies in an interactive type of practice with literature identifying a broad range of roles extending from TDM and patient medication chart review through to immunisations, counselling of parents and extemporaneous compounding. The European countries reported roles in TPN prescribing, provision of medication information and patient medication chart review however did not have such an extensive scope of practice. These difference in practice may be attributed to cultural, educational, legislative and funding differences in health care systems from country to country, impacting upon the level of pharmacist integration into NICU teams.[45] Diversity in practice may have varying impacts upon patient outcomes. According to WHO, one of the main priorities for health care systems worldwide is the promotion of equity within and between health care facilities.[46,47] Health equity is a shared responsibility of all nations worldwide, and it is a fundamental right of each human being to receive the highest standard of health care.[46,48] As such, the RIO Political Declaration on Social Determinants of Health endorses global collaboration and benchmarking between countries to identify good practices and adopt coherent policies to promote consistent practices.[48]

WHO identifies that the most effective pharmaceutical care is provided when clinical pharmacists become integrated into the health care team and play an active role in patient care.[1] Pharmacists possess the relevant skills, knowledge and expertise to make valuable contributions to the quality use of medicines and medication safety.[49] The review highlights that NICU pharmacists can provide both a medication support system for other NICU health professionals as well as a patient care role. The majority of the literature reported that the most important features of an NICU pharmacy service involved the physical presence of a pharmacist on the ward, clinically reviewing the parameters of pharmacotherapy and providing medication information. Specifically, the most commonly reported roles are centred on patient medication chart review, TDM,

provision of education services and prescribing of TPN therapy. By focussing upon these services, NICU pharmacists improve the rationalisation of therapy, reduce costs associated with therapy, promote collaboration with other health care professionals and decrease the incidence of avoidable harm.[19,23,26,32] Furthermore, these roles promote the individualisation of patient pharmacotherapy according to patient needs which is integral to achieving optimal neonatal outcomes.[19] Other roles, relating to participation in ward rounds, adverse drug event monitoring, implementation of quality use of medicines strategies, immunisations and parent counselling have been less commonly reported, however, these are also important to the management of neonates. The Department of Health in Australia states that one of the current issues within its health system is the promotion of immunisations which are integral to the health of children and the wider community.[50] These roles are potential areas of practice that require improvement and focus.

Clinical pharmacists have long established roles in specialised areas of practice such as in oncology, intensive care and emergency medicine.[51–57] The development of these roles has demonstrated the pharmacist's contribution to the health care system, particularly in improving patient safety and rationalising the use of medication.[14,58,59] However, whilst the roles of clinical pharmacists have been well described, when looking at the vulnerable neonatal population, who are at the start of the age spectrum and are at greater risk of medication errors and significant resulting consequences, there is a lack of detail on current pharmacist contributions to the quality use of medicines.[57] Furthermore, there is limited literature that identifies the impact of pharmacist practice on neonatal outcomes. Most of current research focuses upon pharmacist roles in adult populations, with relatively less exploring roles in paediatric practice and even less in neonatal care.[8,23,60,61] Given the challenges and risks of pharmacotherapy in neonates, the role of the pharmacist within the NICU therapeutic team is important. As such due to the limited research undertaken in this area, there is need to conduct investigations to establish what roles are being performed today as well as to develop standards of NICU pharmacy practice that clearly define pharmacist roles that meet the specific needs of the neonatal population. Further research needs to be conducted to identify opportunities to increase pharmacist engagement in each country's health care system and improve the level of involvement in the NICU.

Practice implications

The role of the pharmacist in the NICU has the potential to greatly improve patient outcomes as well as decrease incidence of medication error and associated harm. It is important to understand the differences in practice between each country, as it allows for the benchmarking of our own current service delivery system and promotes practice improvement to meet the standards of other settings. As such, this review has identified that the model of NICU pharmacist practice in USA, UK, Australia and South Africa appears to be patient-centred and promotes pharmacist integration into the NICU team. Furthermore, the findings of the review have allowed for the identification of areas of practice (i.e. parent counselling, immunisations) that can be improved upon and have the potential to be further developed into roles that are integral to the quality of medication management in NICU. This review may provide a foundation for future research, including subsequent reviews of the literature, and has the potential to act as a useful comparison of pharmacist practice in NICU to other patient groups, i.e. older paediatric patients and adults, to determine where differences in pharmacist roles lie.

Conclusion

The literature identifies that there is insufficient evidence to describe what roles are currently performed in NICUs worldwide. This is due to the low quantity of published literature, most of which was out-dated. Given the diversity of practice, it is important to establish clear definitions of pharmacist roles within the NICU and compare roles across different clinical settings and countries. Further research, comprising systematic, rigorous surveys are required if the current international roles of the NICU pharmacist are to be understood.

Declarations

Conflicts of interest

The Author(s) declare(s) that they have no conflicts of interest to disclose.

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Author's contribution

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Original article

The role of the clinical pharmacist in the NICU: a cross-sectional survey of Australian and Polish pharmacy practice

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ABSTRACT

Objectives To describe and compare the pharmaceutical services and clinical pharmacy roles performed in neonatal intensive care units (NICUs) in Australian versus Polish hospitals.

Methods A 26-item survey was distributed electronically to directors of pharmacy as well as neonatal pharmacists in hospitals in Poland and Australia. Most questions were fixed 'agree/disagree' answers, supplemented by open-ended questions. The survey was distributed between January and May 2017.

Results Overall, 30 Australian pharmacists and 22 Polish pharmacists completed the survey. Significant differences were observed in the types of pharmaceutical care services provided to NICUs between Australia and Poland. A higher proportion of Australians than Poles performed clinical roles: for example, providing medication recommendations (Aus=96.6%, Pol=9.1%, P<0.001); pharmaceutical interventions to resolve drug therapy problems (Aus=93.1%, Pol=18.2%, P<0.001); and general patient medication chart review (Aus=96.6%, Pol=13.6%, P<0.001). All (100%) Polish pharmacists did not consider themselves members of the NICU team and the majority (59.1%) felt that pharmaceutical care on the NICU was practically non-existent.

Conclusion Future research should focus on bringing practice in countries such as Poland closer in line with practice in countries such as Australia.

INTRODUCTION

Approximately 16% of all live-born babies in Australia are admitted to special care nurseries (SCN) or neonatal intensive care units (NICUs).[1] The majority of these newborns are pre-term with serious pathologies including infections, respiratory issues, jaundice and congenital malformations.[1 2] To treat and manage these conditions, pharmacotherapy is widely used in conjunction with specialised medical interventions. It is reported that worldwide, NICU patients are prescribed a median range of three to 11 medications, with some babies requiring as many as 40.[3 4] As such, the clinical pharmacist has an important role to play in the quality use of medicines in this patient group, potentially having a large impact on patient outcomes.[5] The high incidence of off-label medicines use, polypharmacy and frailty in this patient group (characterised by young gestational ages, very small birthweights) increases the risk of medication errors and poses challenges to the safe and effective use of pharmacotherapy.[6] Studies have shown that pharmacist-led interventions can improve medication management in the NICU: daily bedside reviews of medication orders, individualised total parenteral nutrition (TPN) regimens and education programmes, have been shown to reduce medication errors.[7 8]

Differences in healthcare systems, legislation, culture and tertiary education across countries may lead to the variable provision of pharmaceutical care services. The RIO Political Declaration for Health highlights that international healthcare systems should collaborate to develop coherent policies to promote consistent practice across settings within and between countries.[9] Global collaboration is essential in identifying best practices for newborn patient care, however, little has been done to identify what roles are actually performed in NICUs worldwide, particularly between diverse countries such as Australia and eastern European countries, such as Poland. When considering the practice of hospital pharmacists in general in Australia and Poland, there are discernible differences. In Poland, general hospital pharmacists are restricted mainly to services in the dispensary, with limited clinical roles performed on wards.[10 11] Pawłowska and Kocić[10] concluded that Polish hospital pharmacists were mainly involved in the distribution of medicines, such that patient-focused services were not common practice. In contrast, hospital pharmacist practice in Australia seems particularly clinically-focused. The Society of Hospital Pharmacists Australia (SHPA) advocates that pharmacists should have direct contact with patients, maintaining key roles in medication reconciliation, participating in ward rounds, providing medication information and monitoring drug therapy.[12]

Due to the lack of published literature in both countries it is unclear which pharmacy services are specifically performed in NICUs. Therefore, the purpose of this study was to compare the pharmaceutical services and clinical pharmacy roles performed in NICUs in Australian and Polish hospitals. The specific objectives included:

- identifying the roles currently performed by pharmacists in the NICU
- describing the pharmacist's perceptions of their integration/role in the NICU team
- identifying which roles are perceived by pharmacists as essential services to the NICU.

METHODS

A cross-sectional survey was electronically distributed to hospital pharmacists and directors of pharmacy departments employed in Australian and

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Polish hospitals with a NICU, between January and May 2017. Participants were assured of confidentiality and were informed that their responses would be de-identified.

Participants

This study involved the survey of NICU pharmacists as well as directors of pharmacy of hospitals that contained a NICU. Regardless of work status (ie, full-time/part-time), all Australian pharmacists that fulfilled these criteria were eligible to participate in the study. In Poland however, as clinical pharmacy practice is less developed, all hospital pharmacists and directors of pharmacy at hospitals containing a NICU were invited to complete the survey. Participants were identified through publicly available registers in Poland and Australia, that is, the Polish Register of Facilities delivering Medical Activities (Rejestr Podmiotów Wykonujących Działalność Leczniczą – RPWDL) and the Australian New Zealand Neonatal Network (ANZNN) that list hospitals with neonatal intensive care units. Furthermore, Australian participants were contacted via the Paedpharm online pharmacists group.

Using a significance level of 5% and a desired power of 80%, a sample size calculation was performed for survey questions. The calculation was based on the precision around the point of estimate of effect, which is acknowledged as the estimated response to specific survey questions, based on the results of previous research.[10 11 13] A total of 64 participants was found to be the target sample size required.

Survey

The online survey (created in SurveyMonkey) was self-administered by participants. A total of 26 questions were developed following a comprehensive literature review.[14] The majority of questions required fixed 'agree/disagree' answers, and were supplemented by open-ended questions. The questions canvassed the participant characteristics, which roles were performed by pharmacists specifically in, or for, NICUs (within four key categories: administrative, clinical, education, provision), identification of roles that were perceived as being essential to the NICU and an indication of the level of pharmacist integration in the multidisciplinary NICU team. All questions were pre-coded for data entry. The survey was pre-tested for content, design and readability in a small group of Australian pharmacists. The survey was administered in English and Polish for each respective country. For all surveys that were provided in Polish, the results were translated into English via a tiered process: survey results were translated from Polish to English by one researcher (NK), then these translations were edited and verified by two co-researchers (IP, BB).

A unique survey link was emailed to each pharmacist. Respondents who requested a hard-copy version of the survey were sent one by post. Reminders were emailed to participants 1 month and 1 week before the end of the study period.

Surveys that were at least 50% completed by participants were included in the analysis. Incomplete responses were considered as missing values.

Data analysis

Descriptive statistics (percentages, frequencies) were used to analyse quantitative data via the Statistical Package for the Social Sciences (SPSS) Version 22. The Chi-square test was applied to test the association between independent categorical variables (eg, nationality – Australian and Polish) and dependent variables (eg, proportion of agree/disagree responses to questions relating to: roles that are performed by pharmacists specifically in or for NICUs and roles that are perceived as being essential to the NICU as well as pharmacist integration in the multidisciplinary NICU team). Statistical significance was accepted at a P value of <0.05.

Any qualitative data pertaining to pharmacist responses to open-answer questions were thematically analysed using manual inductive coding. Significant statements were identified from pharmacist responses and patterns were coded into non-overlapping themes and subthemes around the study objectives.[15] Three researchers (NK, IP, BB) independently analysed the data before comparing the themes to attain consensus. The analysis was structured by an essentialist/realist theoretical framework which reflects on the experiences, meanings and the reality of participants.[16] To ensure comprehension, the qualitative responses of participants are represented by the code 'AP' for Australian pharmacists and 'PP' for Polish pharmacists.

RESULTS

Due to the specialised nature of NICU pharmacy practice and the small number of NICUs in each country, the number of possible participants was limited. An accurate response rate is difficult to ascertain as it is unspecified how many Australian pharmacists have access to the Paedpharm online pharmacists group. Furthermore, it is also unknown how many surveys were distributed among colleagues within each hospital. As such, the response rate was calculated with the denominator being the number of surveys sent out electronically by researchers. A total of 55 surveys were sent out to Australian participants, with 30 responses received (response rate=54.5%), and 40 surveys were distributed to Polish participants, of which 22 returned a completed survey (response rate=55%) (table 1).

Of the 30 participants from Australia and the 22 from Poland who completed the survey, 76.7% and 72.7% respectively were female (table 1). Most participants had between 1 to 5 years of practice experience (Aus=43.3%, Pol=54.5%), and did not possess specialised qualifications related to neonatal or paediatric practice. More than half of the Polish participants (59.1%) worked in the main hospital pharmacy (ie, dispensary). None of the pharmacists from Poland identified themselves as dedicated NICU pharmacists, in comparison to 44.8% of Australian pharmacists who did.

Pharmacist interaction with the NICU

While the majority of participants had contact with the NICU on a daily basis (Aus=72.4%, Pol=63.6%), the nature of pharmacists' interaction with the ward differed between the two countries (table 2). A significantly higher proportion of Australian pharmacists (93.3%) agreed that they provided pharmaceutical care services directly on the NICU, compared with Polish pharmacists (4.5%, $P<0.001$). Over a third of Australian pharmacists agreed that they spent an average of 1– to 3 hours on the NICU ward per day, and 75% agreed that they covered all patient beds during this time.

All (100%) Polish pharmacists reported that they worked in the main hospital pharmacy: half (54.5%) stated that telephone contact was their only form of communication with the ward, as reinforced by their qualitative responses:

> Co-operation is based on contact through the telephone between the ward and the compounding laboratory… Our collaboration is based on the completion of medication orders sent by the ward. **PP6**

Table 1 Participant characteristics

	Australia (%)	Poland (%)
Number of respondents	30	22
Gender of respondents		
Female	23 (76.7)	16 (72.7)
Qualifications		
Bachelors Degree	8 (26.7)	0
Masters Degree	12 (40)	20 (90.9)
PhD Degree	1 (3.3)	0
Qualifications held by participants other than those specified in the survey	9 (30)	2 (9.1)
Post-graduate Certificate/Diploma	9 (30)	0
Clinical pharmacy specialisation	0	2 (9.1)
Specialised qualifications		
Yes	1 (3.3)	0
Postgraduate Certificate – (neonatal and paediatric-specific)	1 (3.3)	
No	29 (96.7)	22 (100)
Position in the hospital	n = 29	
Neonatal pharmacist	13 (44.8)	0
Director of pharmacy	5 (17.2)	8 (36.4)
Pharmacist working in main hospital pharmacy	3 (10.3)	13 (59.1)
Other	8 (27.6)	1 (4.5)
Deputy Director	1 (3.4)	1 (4.5)
Senior clinical pharmacist	2 (6.9)	
Medicines information pharmacist	2 (6.9)	
Specialist women, youth and children pharmacist	2 (6.9)	
Aseptic CIVAS pharmacist	1 (3.4)	
Experience		
<1 year	6 (20)	2 (9.1)
Between 1–5 years	13 (43.3)	12 (54.5)
Between 6–10 years	4 (13.3)	1 (4.5)
>10 years	7 (23.3)	7 (31.8)
Number of beds in NICU (range)	8–110	4–28
Definition of a Neonatal Intensive Care Unit 'Neonatal unit that must be capable of assessing, diagnosing and managing all newborn infants requiring neonatal intensive care including infants: ► requiring continuing assisted ventilation via an endotracheal tube, and for the 24 hours following endotracheal tube removal ► requiring oxygen therapy (more than 60%) for more than 4 hours ► with tracheostomies requiring intermittent positive pressure ventilation (IPPV) or continuous positive airway pressure (CPAP) ► requiring a nasopharyngeal tube (without CPAP) to maintain airway patency ► requiring an arterial line for continuing blood gas and/or blood pressure monitoring ► having frequent seizures – undergoing major surgery, on the day of the procedure and for 48 hours postoperatively, including: – any procedure where a body cavity is opened – repair of neural tube defect – placement of a ventriculoperitoneal shunt or temporary ventricular drainage device ► requiring 1:1 nursing care[23]		

> Collaboration is only associated with the preparation of drugs for the ward, formulations for individual patients such as powders, feeding bags or antibiotics… contact with doctors is very limited. The most common contact is with the NUM. **PP18**

Pharmacist roles currently performed in the NICU

In Australia, pharmacists reported being frequently involved in direct-patient care and decision-making related to pharmacotherapy in the NICU (table 3). A significantly higher proportion of Australians than Poles agreed that they provided medication recommendations to medical staff (Aus=96.6%, Pol=9.1%, P<0.001), intervened to resolve drug therapy problems (Aus=93.1%, Pol=18.2%, P<0.001) and routinely reviewed patient medication charts (Aus=96.6%, Pol=13.6%, P<0.001). All (100%) Australian participants reported that they were a source of medication information on the ward, and responded to queries raised by nursing and medical staff. Nine times as many Australians than Poles were involved in checking patient progress on prescribed pharmacotherapy (Aus=96.6%, Pol=13.6%, P<0.001), along with therapeutic drug monitoring (TDM) (Aus=96.6%, Pol=13.6%, P<0.001) and recommending doses to medical and nursing staff (Aus=96.6%, Pol=13.6%, P<0.001). Australian respondents often expressed that they focused on medication safety to reduce medication errors arising from prescribing (dosing, drug selection) or administration errors, in this high-risk patient population. Furthermore, Australian pharmacists emphasised their role in developing key medication guidelines and protocols for the NICU, which were heavily relied on by staff.

> Prescribing and administration errors are unfortunately quite common in NICUs despite best practice drug guidelines available. Routine medication chart review and being present on ward rounds

Table 2 Pharmaceutical care provided on the NICU in Australia and Poland

	Australia (%)	Poland (%)	P value (Comparison of proportions between Australian and Polish participants)
Is there a pharmacist currently providing services directly on the NICU?	n=30	n=22	<0.001
Yes	28 (93.3)	1 (4.5)	
No	2 (6.7)	21 (95.5)	
If not working directly on the NICU, where are pharmacists located?	n=2	n=22	<0.001
Dispensary	0	22 (100)	
Pharmacy administration/office	2 (100)	0	
If not working directly in the NICU, does the pharmacist have any form of contact with the NICU?	n=2	n=22	
Yes – via phone	0	12 (54.5)	
Yes – both phone and email	1 (50)	9 (40.9)	
No	1 (50)	1 (4.5)	
If not working directly in the NICU, how frequently does the pharmacist contact the NICU?	n=1	n=22	
Daily	1 (100)	14 (63.6)	
2–3 times per week	0	4 (18.2)	
On request	0	4 (18.2)	
How frequently does a pharmacist directly provide services in the NICU?	n=29	n=1	
Daily	21 (72.4)	1 (100)	
2–3 times per week	3 (10.3)		
Monthly	1 (3.4)		
On request	1 (3.4)		
Other	3 (10.3)		
Average duration of pharmacist visit on the NICU	n=29	n=1	
<1 hour	2 (6.9)	1 (100)	
Between 1 and 3 hours	12 (41.4)		
Between 4 and 6 hours	4 (13.8)		
All day (7+Hours)	11 (37.9)		
How many beds does the pharmacist cover per visit?	n=28	n=1	
All	21 (75)		
More than half	6 (21.4)		
Less than half	1 (3.6)	1 (100)	

where the majority of prescribing is done can minimise the risk of dose errors occurring… Regularly consulted for guideline development and drug selection. **AP1**

Medication safety focus, routine medication chart/pharmaceutical review, guideline review and development. **AP16**

Nursing staff have become reliant on medication guidelines and are hesitant to work outside of these guidelines without pharmacy involvement. **AP17**

Polish pharmacists reported being mostly involved in dispensary-based roles, including medication supply and administrative activities. Compared with the Australians, a higher proportion of Polish pharmacists identified that they were involved in dispensing (Pol=100%, Aus=82.8%, P=0.040), extemporaneous compounding (Pol=95.5%, Aus=75.9%, P=0.057), house-keeping duties (ie, maintenance tasks e.g. stocking the ward with medicines, checking expiry dates; Pol=100%, Aus=67.9%, P=0.003) and purchasing pharmaceutical products for the NICU (Pol=95.5%, Aus=72.4%, P=0.033). None of the Polish pharmacists reported being involved in: training and education of medical staff; neonatal research; counselling parents/carers of patients; clinical meetings; evaluating patient laboratory tests; or ward rounds.

The pharmacist does not participate in ward rounds and has no knowledge of the patient's laboratory test results. They only become aware of problematic situations when the medical staff contact them. **PP1**

We do not participate in the processes of prescribing and monitoring pharmacotherapy. **PP2**

Role of a pharmacist is limited to the ordering of medicines – unused potential. **PP7**

Similar proportions of respondents from both countries reported monitoring of total parenteral nutrition (Aus=86.2%, Pol=81.8%), developing NICU drug formularies (Aus=98.7%, Pol=95.5%), managing the NICU drug budget (Aus=57.1%, Pol=68.2%) and attending non-clinical meetings (Aus=72.4%, Pol=77.3%).

Pharmacist expectations of roles that should be performed in the NICU

Despite the differences in the types of pharmaceutical care services provided to NICUs between Australia and Poland, the majority of pharmacists in each country highlighted very similar expectations towards pharmacist practice. (table 4) The majority of respondents (≥90%) from both countries agreed that pharmacists should undertake clinical roles, such as TDM (Aus=100%, Pol=95%), medication chart review (Aus=100%, Pol=90%) and checking patient response to prescribed pharmacotherapy

Table 3 Roles that are performed by pharmacists in the NICU*

Administrative roles			
	Australia (%)	Poland (%)	P value (Comparison of proportions between Australian and Polish participants)
Development/implementation of a drug formulary service	26 (89.7) 29	21 (95.5) 22	0.445
Attendance at non-clinical meetings that is, Drug and Therapeutics Committee	21 (72.4) 29	17 (77.3) 22	0.693
Conducting quality assurance measures that is, drug usage evaluations, workload documentation, auditing	25 (86.2) 29	7 (31.8) 22	<0.001
Management of the drug budget	16 (57.1) 28	15 (68.2) 22	0.425
Evaluation, selection and purchasing of pharmaceuticals for the unit	21 (72.4) 29	21 (95.5) 22	0.033
Development of drug policies/protocols/guidelines for the NICU	28 (96.6) 29	5 (22.7) 22	<0.001
Clinical roles			
	Australia (%)	Poland (%)	P value (Comparison of proportions between Australian and Polish participants)
Patient medication chart review	28 (96.6) 29	3 (13.6) 22	<0.001
Participation in medical ward rounds	25 (86.2) 29	0 (0) 22	<0.001
Monitoring the efficacy of pharmacotherapy in patients	28 (96.6) 29	3 (13.6) 22	<0.001
Documenting/monitoring adverse drug events/reactions	26 (89.7) 29	15 (68.2) 22	0.056
Documenting medication errors	28 (96.6) 29	4 (18.2) 22	<0.001
Evaluating patients' clinical laboratory tests	28 (96.6) 29	0 (0) 22	<0.001
Therapeutic Drug Monitoring (TDM)	28 (96.6) 29	3 (13.6) 22	<0.001
Immunisations	19 (67.9) 28	1 (4.5) 22	<0.001
Monitoring Total Parenteral Nutrition (TPN)	25 (86.2) 29	18 (81.8) 22	0.670
Participation in clinical meetings	23 (79.3) 29	0 (0) 22	<0.001
Calculating and recommending doses and dosing schedules for specific patients	28 (96.6) 29	3 (13.6) 22	<0.001
Assisting doctors in prescribing off-label/unlicensed medicines	28 (96.6) 29	6 (27.3) 22	<0.001
Identifying and performing interventions for individual patients to prevent or resolve drug therapy problems that is, interactions, incompatibilities, allergies etc.	27 (93.1) 29	4 (18.2) 22	<0.001
Recommending drugs and contributing to the pharmacotherapy decision making process for specific patients	28 (96.6) 29	2 (9.1) 22	<0.001
Collaborating and discussing specific patients with doctors and nurses	27 (96.4) 28	4 (18.2) 22	<0.001
Education/communication/research			
	Australia (%)	Poland (%)	P value (Comparison of proportions between Australian and Polish participants)
Providing training/in-services for other health professionals on NICU-related topics and drug-related problems	27 (93.1) 29	0 (0) 22	<0.001
Contributing to and/or attending NICU-related conferences	22 (75.9) 29	7 (31.8) 22	0.002
Involved in clinical trials	19 (67.9) 28	13 (59.1) 22	0.522

Continued

Table 3 Continued

Education/communication/research			
	Australia (%)	Poland (%)	P value (Comparison of proportions between Australian and Polish participants)
Involved in research related to neonatal pharmacotherapy	18 (64.3) 28	0 (0) 22	<0.001
Source of drug information – responding to information requests from health professionals on the ward	29 (100) 29	19 (86.4) 22	0.040
Counselling parents/carers of neonatal patients	25 (86.2) 29	0 (0) 22	<0.001
Provision of medicines			
	Australia (%)	Poland (%)	P value (Comparison of proportions between Australian and Polish participants)
Dispensing prescriptions	24 (82.8) 29	22 (100) 22	0.040
Extemporaneous compounding of formulations for the NICU	22 (75.9) 29	21 (95.5) 22	0.057
Stocking the ward with essential medicines/house-keeping activities, that is, checking expiry dates, fridge temperatures etc.	19 (67.9) 28	22 (100) 22	0.003

*Proportions were calculated as the number of participants who responded to each question as the denominator.

(Aus=100%, Pol=90%). All (100%) Polish participants agreed that pharmacists should provide advice to medical staff when selecting medications and prescribing off-label products, as well as performing pharmaceutical interventions and collaborating with nursing and medical staff. Compared with Australian pharmacists, a significantly higher proportion of Polish participants expected that pharmacists should provide medication supply roles including dispensing (Pol=100%, Aus=73.9%, P=0.014), extemporaneous compounding (Pol=100%, Aus=60.9%, P=0.002) and house-keeping activities (Pol=100%, Aus=60.9%, P=0.002). Furthermore, a significantly higher proportion of Poles than Australians agreed that administrative roles, such as management of the drug budget (P<0.001) and purchasing medications for the ward (P=0.027), should be performed by pharmacists.

Australian pharmacists, however, focused more on clinical roles, with ≥80% of respondents agreeing that 13 out of 15 roles listed in the 'clinical' category of the survey were expected to be performed. In their qualitative responses, overall, Australian participants felt there was a great need for pharmacist involvement in the care of this patient population. They described pharmacotherapy-related issues that were more prominent in neonatal patients, for example, interindividual variability in pharmacokinetics and dosing errors.

> In Australia, NICUs are considered as areas that require essential clinical pharmacy services… Neonatal clinical pharmacist is essential for the medication/patient safety in this very high risk population to ensure the delivery of effective pharmacotherapy. **AP6**

> Having a pharmacist permanently on NICU allows for consistency in patient care. I find on days that a pharmacist is unable to work in NICU that weaning of sedation/analgesia always gets missed, antibiotic doses aren't adjusted for age etc… **AP24**

Pharmacist integration into the NICU environment

All (100%) Australians and 95.4% of Poles agreed that pharmacists should have visiting or permanent positions on the ward (table 5). However, differences were identified about the current level of pharmacist integration, with a significantly higher proportion of Polish pharmacists compared with Australian participants expressing that they were not considered to be members of the NICU team (Aus=13.3%, Pol=100%, P<0.001). In comparison, the majority of Australian pharmacists (86.7%) reported being integral members of the NICU team. In their qualitative responses, they commonly described a respectful and collaborative relationship with the doctors and nurses, supported by effective communication. They stated that they were regularly approached on the ward to answer questions, being seen as a source of medication information.

> Neonatal clinical pharmacist is a valuable NICU team member. **AP6**

> Great multidisciplinary team-work. The NICU pharmacist is an integral part of the team. Effective rapport and communication between medical staff, nursing staff and pharmacist. Regular consultation for pharmacist input during medical rounds, and throughout the day. **AP21**

> Stable member of the team. Well experienced NICU pharmacist plays a very important liaison role between rotating medical staff, nurses and patients and families. **AP12**

Polish participants noted that doctors would sometimes reach out to the pharmacy for assistance with pharmacotherapy-related problems encountered on the NICU, however, input into medication management was generally limited to the preparation and delivery of medications to the ward. Given the indirect nature of the contact, pharmacists emphasised they communicated more often with nurses, and that contact with doctors was 'rare'.

> The level of contact is very formal, lack of awareness and confidence in pharmacists and their abilities. **PP12**

> Doctors very rarely get in touch with the pharmacists, nurses do from time to time. **PP16**

A significantly higher proportion of Australian pharmacists (Aus=70%, Pol=19%, P<0.001) identified that the current pharmacy services being delivered to NICUs in their local settings were meeting patient needs. In comparison, 81% of Polish pharmacists indicated that the pharmacotherapy requirements of neonatal patients were not being fulfilled by their pharmaceutical care system. Additionally, 59.1% of Polish participants deemed that pharmaceutical care in the NICU was currently non-existent.

Table 4 Pharmacist expectations towards roles that should be performed by pharmacists in NICU*

Administrative roles			
	Australia (%)	Poland (%)	P value (Comparison of proportions between Australian and Polish participants)
Development/implementation of a drug formulary service	19 (86.4) 22	21 (100) 21	0.079
Attendance at non-clinical meetings, that is, Drug and Therapeutics Committee	13 (59.1) 22	21 (100) 21	0.001
Conducting quality assurance measures, that is, drug usage evaluations, workload documentation, auditing	21 (95.5) 22	20 (95.2) 21	0.973
Management of the drug budget	9 (40.9) 22	18 (94.7) 19	<0.001
Evaluation, selection and purchasing of pharmaceuticals for the unit	15 (68.2) 22	19 (95) 20	0.027
Development of drug policies/protocols/guidelines for the NICU	22 (100) 22	17 (81) 21	0.032
Clinical roles			
	Australia (%)	Poland (%)	P value (Comparison of proportions between Australian and Polish participants)
Patient medication chart review	23 (100) 23	18 (90) 20	0.120
Participation in medical ward rounds	20 (83.3) 24	15 (75) 20	0.495
Monitoring the efficacy of pharmacotherapy in patients	24 (100) 24	18 (90) 20	0.113
Documenting/monitoring adverse drug events/reactions	23 (100) 23	19 (95) 20	0.278
Documenting medication errors	22 (95.7) 23	18 (90) 20	0.468
Evaluating patient's clinical laboratory tests	20 (87) 23	8 (40) 20	0.001
Therapeutic Drug Monitoring (TDM)	23 (100) 23	19 (95) 20	0.278
Immunisations	13 (54.2) 24	5 (25) 20	0.050
Monitoring Total Parenteral Nutrition (TPN)	18 (78.3) 23	19 (95) 20	0.114
Participation in clinical meetings	19 (82.6) 23	17 (85) 20	0.832
Calculating and recommending doses and dosing schedules for specific patients	21 (95.5) 22	17 (85) 20	0.249
Assisting doctors in prescribing off-label/unlicensed medicines	23 (95.8) 24	20 (100) 20	0.356
Identifying and performing interventions for individual patients to prevent or resolve drug therapy problems, that is, interactions, incompatibilities, allergies etc	23 (100) 23	20 (100) 20	Constant
Recommending drugs and contributing to the pharmacotherapy decision making process for specific patients	21 (91.3) 23	20 (100) 20	0.177
Collaborating and discussing specific patients with doctors and nurses	21 (91.3) 23	19 (100) 19	0.188
Education/communication/research			
	Australia (%)	Poland (%)	P value (Comparison of proportions between Australian and Polish participants)
Providing training/in-services for other health professionals on NICU-related topics and drug-related problems	20 (87) 23	19 (95) 20	0.365
Contributing to and/or attending NICU-related conferences	16 (66.7) 24	17 (89.5) 19	0.079
Involved in clinical trials	14 (60.9) 23	19 (95) 20	0.008

Continued

Table 4 Continued

Education/communication/research			
	Australia (%)	Poland (%)	P value (Comparison of proportions between Australian and Polish participants)
Involved in research related to neonatal pharmacotherapy	16 (64) 25	17 (85) 20	0.113
Source of drug information – responding to information requests from health professionals on the ward	21 (91.3) 23	20 (100) 20	0.177
Counselling parents/carers of neonatal patients	23 (95.8) 24	16 (84.2) 19	0.193
Provision of medicines			
	Australia (%)	Poland (%)	P value (Comparison of proportions between Australian and Polish participants)
Dispensing prescriptions	17 (73.9) 23	20 (100) 20	0.014
Extemporaneous compounding of formulations for the NICU	14 (60.9) 23	20 (100) 20	0.002
Stocking the ward with essential medicines/house-keeping activities, that is, checking expiry dates, fridge temperatures etc	14 (60.9) 23	20 (100) 20	0.002

*Proportions were calculated as the number of participants who responded to each question as the denominator.

DISCUSSION

The results from this study provide an insight into the types of clinical pharmacy services currently being delivered to NICUs in Australia and Poland. To date, there has been limited literature detailing pharmacist practice in the NICU in these countries. In order to promote the standardisation of practice, both nationally and worldwide, exploratory research needs to identify where gaps in practice lie.

According to the WHO, pharmacists should incorporate seven roles into their practice regardless of the setting they

Table 5 Perceptions towards pharmacist integration into the NICU team*

	Australia	Poland	P value (Comparison of proportions between Australian and Polish participants)
Should pharmacists be on the NICU?	n=30	n=22	
Yes – routinely visiting	15 (50)	18 (81.8)	
Yes – permanently stationed	15 (50)	3 (13.6)	
No	0	1 (4.5)	
Is the pharmacist currently considered part of multi-disciplinary NICU team?	n=30	n=22	<0.001
Yes	26 (86.7)	0 (0)	
No	4 (13.3)	22 (100)	
Should the pharmacist be consulted as part of the team when making pharmacotherapy-related decisions?	n=30	n=22	0.822
Yes	29 (96.7)	21 (95.5)	
No	1 (3.3)	1 (4.5)	
Rate the current inter-professional relationship between pharmacists and the medical and nursing staff	n=30	n=22	
Good	25 (83.3)	7 (31.8)	
Average	3 (10)	7 (31.8)	
Poor	1 (3.3)	7 (31.8)	
Non-existent	1 (3.3)	1 (4.5)	
Rate current pharmaceutical care practice in the NICU	n=30	n=22	
Good	18 (60)	2 (9.1)	
Average	10 (33.3)	3 (13.6)	
Poor	0	4 (18.2)	
Non-existent	2 (6.7)	13 (59.1)	
Are current pharmacy services meeting medication management needs in the NICU?	n=30	n=21	<0.001
Yes	21 (70)	4 (19)	
No	9 (30)	17 (81)	

*Proportions were calculated as the number of participants who responded to each question as the denominator.

work in: care-giver, decision maker, communicator, manager, life-long learner, teacher and researcher.[17] However, the roles that are actually implemented and provided to patients may vary. Our results highlight that pharmaceutical care delivered to NICUs in Australia and Poland does differ significantly. These variances mainly lie within the apparent value placed on pharmacist services in this unit, with the Polish system seemingly steered towards traditional roles, such as dispensing. In contrast, Australian pharmacists are seen to provide a progressive level of practice, comprising both clinical- and dispensary-based services. These findings are mirrored by those found in other limited studies based in Poland and Australia respectively.[10 11 18 19]

While the contrasts seen in each country may be attributed to differences in pharmaceutical legislation, practice culture and pharmacist training, ultimately, each healthcare system should strive for consistency in the delivery of services to ensure equal healthcare opportunities for patients. The WHO identifies health equity as a priority for healthcare systems worldwide, in promoting uniform healthcare services between and within hospital settings.[20] Standardised care is particularly important in critically ill patients, such as those in the NICU, whose outcomes depend on the provision of high-quality care that consistently meets their needs. However, the WHO recognises that one of the biggest challenges in improving patient safety, is the uniform implementation of best practices across hospital settings nationally or internationally.[21] Leotsakos et.al. report that fluctuating patterns of healthcare services may result in varying patient outcomes and highlight that the standardisation of care practices can reduce costs, inefficiencies and risk.[21] The WHO acknowledges that one of the most effective means of promoting practice uniformity is through the development of standardised practice tools that can be adapted and implemented in all hospital settings, both on a national and global scale, such as the WHO High 5's Project.[21] A reported benefit to standardisation, is the ability to benchmark services between settings, which allows policy-makers as well as healthcare professionals to compare patient outcomes and to interpret the significance and value of an intervention.[21] Ryan states that benchmarking of pharmacist services is best achieved using a three-tiered approach, comparing against best practice standards, against peers and against yourself, and over time.[22] Given our findings that pharmacist practice varies significantly in Polish and Australian NICU settings, it is imperative that future research focuses on identifying how standards can be widely operationalised, to bring practice in countries such as Poland closer in line with practice in countries such as Australia.

Limitations

This survey was completed by only a proportion of hospital pharmacists in Australia and Poland, and may not be representative of all pharmacists in each country.

CONCLUSION

Pharmacist expectations of practice in the NICU were the same across both countries, however the actual pharmaceutical care services provided differed. Overall, the focus of pharmacy practice in NICUs in Australia and Poland is varied, ranging from clinically-centred services to traditional, dispensary-based medication supply duties respectively. However, the majority of participants from both countries highlighted that pharmacists should be involved in pharmacotherapy-related decision-making in the NICU. Disparities in practice may have varying influences on the health outcomes of a sensitive patient population. Future research should focus on promoting the standardisation of pharmaceutical care services to this ward through the development of practice guidelines and policies.

What this paper adds

What is already known on this subject

Differences in healthcare systems, legislation, culture and tertiary education across countries may lead to the variable provision of pharmaceutical care services. Global collaboration is essential in identifying best practices for newborn patient care. However, little has been done to identify which pharmacist roles are actually performed in NICUs worldwide.

What this study adds

The results from this study provide an insight into the types of clinical pharmacy services currently being delivered to NICUs in Australia and Poland. Pharmacist expectations of practice in the NICU were the same across both countries, however the actual pharmaceutical care services provided differed. Overall, the focus of pharmacy practice in NICUs in Australia and Poland is varied, ranging from clinically-centred services to traditional, dispensary-based medication supply duties respectively.

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Competing interests None declared.

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L.5 PHARMACIST PERSPECTIVES TOWARDS PHARMACEUTICAL CARE SERVICES IN NEONATAL INTENSIVE CARE UNITS IN AUSTRALIA AND POLAND

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ORIGINAL RESEARCH ARTICLE

Pharmacist perspectives towards pharmaceutical care services in neonatal intensive care units in Australia and Poland

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Abstract

Objectives The purpose of this study was to, first, investigate the perceptions of neonatal intensive care unit (NICU) pharmacists and directors of pharmacy in Australia and Poland regarding their level of preparation to perform pharmaceutical care services in the NICU, and second, identify practice barriers and ways to improve services.

Method A cross-sectional, electronic-based survey was distributed among NICU pharmacists and directors of pharmacy working in hospitals with a NICU in Australia and Poland. The survey comprised 12 items, and the majority of questions were fixed binary 'agree/disagree' answers, supplemented by open-ended questions.

Results A total of 29 participants from Australia and 20 from Poland completed the survey. Overall, it is apparent that Australian pharmacists felt more competent in clinical and educational roles than Polish participants. For 14 of the 15 clinical roles listed, more than 70% of Australian participants felt that pharmacists had a 'good' level of preparation to provide services to the NICU, including performing medication chart reviews (93.1%) and pharmaceutical interventions (96.6%), and collaborating with medical and nursing staff (93.1%). A significantly higher proportion of Polish than Australian pharmacists agreed that changes were needed to improve pharmacist practice in the NICU (90 vs. 53.6%; $p = 0.007$).

Conclusion Future efforts should focus on developing guidelines and practice standards for sub-specialties of pharmacist practice, such as neonatology, to promote the standardization of practice.

Introduction

The neonatal intensive care unit (NICU) is arguably a high-priority ward in the hospital setting. With a vulnerable patient group made up of mostly premature infants experiencing serious comorbidities, who are also at high risk of experiencing long-term developmental consequences from errors or unsuccessful treatment, the NICU is a high-pressure environment [1]. Furthermore, it is a large consumer of pharmacotherapy resources, with neonatal patients reportedly being prescribed an average of 8.6 medicines per patient [2]. A significant proportion of these medicines are deemed high risk in terms of the potential to do harm in the case of medication misadventure, and the high reliance on pharmacotherapy in these patients adds another layer of complexity to the challenging medication use process [3]. As such, the sub-specialty of the NICU warrants not only specialized medical care, but also specialized pharmaceutical care services.

The modern role of the pharmacist is built upon the concept of pharmaceutical care. Defined as "the extent to which pharmacy services deliver effective, efficient, patient-centered, equitable and safe pharmacotherapy", pharmaceutical care is a widely adopted practice worldwide [4]. However, the lack of minimum practice standards, protocols, or key performance indicators specifically tailored to the NICU means the quality and type of pharmacy services provided may vary within and between countries [1]. The World Health Organization (WHO) emphasizes that global collaboration is essential in identifying best practices and in promoting the implementation of uniform services across settings [5]. While there are significant differences in

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practice between third- and first-world countries, it is apparent that pharmacy practice also varies between industrialized countries in Eastern Europe, as well as the USA, UK, Australia, New Zealand, and Canada [6]. In Eastern European countries such as Poland, the implementation of ward-based pharmaceutical services in hospitals is not extensively developed, with most efforts concentrated on dispensary-based functions [7, 8]. Alternatively, in Australia, a 1991 study by Dunkley [9] highlighted that pharmacists in NICUs performed services ranging from participation in multidisciplinary ward rounds to reviews of patient medication charts. The disparities in practice may be attributed to differing levels of emphasis placed on clinical pharmacy services during tertiary training. It is apparent that pharmacy programs in Poland are strongly focused on the traditional scope of pharmacist services, i.e., dispensary-based compounding activities, with little to no focus on clinical pharmacy practice [10]. Alternatively, Australian universities seek to prepare pharmacy students for more integrated roles in ward environments, including simulation-based sessions relating to patient care, as well as interdisciplinary teamwork [11–13]. These variances may influence the capability of the pharmacists to perform in clinical roles.

A recent study by Krzyzaniak et al. [14] demonstrated that the focus of NICU pharmaceutical care services in Australia and Poland varied significantly. Australian pharmacists were seen to be mostly dedicated to clinical, ward-based services, whereas Polish pharmacists were accustomed to a compounding and distributive model of practice [14]. These differences may lead to varying levels of impact upon neonatal patient outcomes and medication error rates. Pharmacists are key members of the NICU treating team with significant potential to improve pharmacotherapy-related outcomes and reduce costs associated with the use of resources [15]. Therefore, we need to better understand the current state of pharmacy services in NICUs in each country to identify specific pharmacy practice issues that lead to these significant differences. No studies have investigated pharmacist opinions on performing these services in NICUs or their perceived competencies in providing tailored clinical services to neonatal patients.

Aim of the study

The purpose of this study was to identify the opinions and perceptions of NICU pharmacists and directors of pharmacy in Australia and Poland about the provision of pharmaceutical care services in the NICU. This research follows on from a previously published study that identified pharmaceutical care services provided in NICUs in these countries [14]. This research intended to provide greater context and understanding to the pharmacy practice system functioning in NICUs in Australia and Poland. Specific objectives included

- understanding pharmacists' perceived levels of preparedness to provide clinical services in the NICU,
- identifying what changes are needed to improve pharmaceutical care, and
- identifying what barriers currently limit the implementation of pharmaceutical care in the NICU.

Ethics approval

Ethics approval was obtained from the respective ethics committees at the University of Technology Sydney, Australia (ref. no. ETH16-1033) and the Medical University of Gdansk, Poland (ref. no. NKBBN/424/2016). Participants were advised that their responses would be de-identified.

Methods

A cross-sectional, online survey was distributed between January and May 2017 to hospital pharmacists and directors of pharmacy departments based in Australian and Polish hospitals with a NICU. The survey was created using SurveyMonkey and comprised 12 questions developed from the findings of a literature review and was adapted from a previous study by Katoue et al. [16] that assessed pharmacist perspectives on pharmaceutical care in hospitals in Kuwait [1]. The majority of questions were fixed binary 'agree/disagree' answers accompanied by open-ended questions. It is important to highlight that this research is exploratory in nature and, as such, a mixed-methods approach involving both quantitative and qualitative data collection was adopted to ensure a fuller understanding of practice. The questions collected information on participant characteristics, perceptions of the preparedness of pharmacists to provide pharmaceutical care, opinions on the barriers to the provision of pharmaceutical services, and changes required to improve pharmaceutical care. All questions were pre-coded for data entry. The survey was pretested on a small group of Australian pharmacists for question clarity and refined accordingly. Participants were provided with surveys in their respective languages, i.e., English or Polish. Results from surveys administered in Polish were translated into English via a tiered process: survey results were translated from Polish to English by one researcher (NK), then these translations were edited and verified by two co-researchers (IP, BB).

Emails containing a unique link to the online survey and a brief description of the survey were emailed to pharmacists. Respondents who requested a hard-copy version of

the survey were sent one by post. Reminders were emailed to participants 1 month and 1 week before the end of the study period.

Responses from participants who completed at least 50% of the survey were included in the analysis. Incomplete responses were considered as missing values.

Comparing pharmacy practice in Australia and Poland

This research follows on from our previous studies investigating pharmacist practice in these two countries [17, 18]. Poland and Australia were selected as comparators as there is minimal collaboration between countries that practice under a more traditional scope of practice, such as those in Eastern Europe, and those with a more progressive and modern form of practice, such as the USA and Australia. A global perspective is important to facilitate the adoption of coherent policies and establish best practices [19]. We thought a comparison between Australia and Poland would provide a new and unique perspective on pharmacist practice in NICUs [18]. It is important to note that, because of the highly specialized nature of the NICU, this study was intended to provide a preliminary understanding of the pharmacy practice background in each country.

Participants

According to published literature and the structure of the healthcare system in Poland, it is apparent that clinical pharmacy practice is less developed and, as such, all hospital pharmacists and directors of pharmacy at hospitals containing a NICU were invited to complete the survey [14]. All Australian pharmacists working in NICUs and directors of pharmacy in hospitals containing a NICU were eligible to participate in the study, regardless of work status (i.e., full or part time). Participants were contacted through the Paedpharm online pharmacists group and through publicly available registers in Poland and Australia, i.e., Polish Register of Facilities delivering Medical Activities (Rejestr Podmiotów Wykonujących Działalność Leczniczą [RPWDL]), and the Australian and New Zealand Neonatal Network (ANZNN), which lists hospitals with NICUs. Pharmacists were also asked to forward the survey to any interested colleagues and any relevant networks to expand the sample.

A sample size calculation was performed for survey questions using a significance level of 5% and a desired power of 80%. The calculation was based on the precision around the point of estimate of effect. The point estimate of effect was the anticipated response to specific survey questions, based on the results of previous research [7, 8, 20]. The target sample size needed was found to be 64 participants in total.

Data analysis

Quantitative data were analyzed via descriptive statistics (percentages, frequencies) using the Statistical Package for the Social Sciences (SPSS) version 22. The Chi-squared test was used to test the association between independent categorical variables (e.g., nationality—Australian and Polish) and dependent variables (e.g., proportion of agree/disagree responses to questions relating to perceptions of the preparedness of pharmacists to provide pharmaceutical care, opinions on the barriers to the provision of pharmaceutical services, and changes that are required to improve pharmaceutical care). Statistical significance was accepted at a p value of < 0.05.

Qualitative data (i.e., pharmacist responses to open-answer questions) were thematically analyzed, and manual inductive coding was used, i.e., significant statements in participants' responses were identified and subsequently categorized into key themes around the study objectives [21]. To ensure correct interpretation and coding of data into emerging themes, three researchers (NK, IP, BB) independently analyzed the data before comparing the themes to attain consensus. The analysis was guided by Braun and Clarke's [22] approach, i.e., an essentialist/realist theoretical framework was adopted to reflect on the experiences, meanings, and reality of participants. To ensure comprehension, the recorded responses were read several times, and patterns were coded into nonoverlapping themes and subthemes.

The qualitative responses of participants are represented by the code 'AP' for Australian pharmacists and 'PP' for Polish pharmacists.

Results

As this is a very narrow area of clinical pharmacy practice, the numbers of possible participants in each country were limited. We do not know how many pharmacists subscribe to the Paedpharm online pharmacists register, or how many surveys were distributed among colleagues within each hospital. As such, the response rate was calculated with the denominator being the number of surveys sent out electronically by researchers. A total of 55 surveys were sent to Australian participants, of which 29 responded (response rate 52.7%), and 40 surveys were sent to Polish participants, of which 20 responded (response rate 50%) [Table 1].

The majority of participants in each country were female (75.9% in Australia and 85% in Poland). Most Polish pharmacists (65%) were employed as general hospital pharmacists, and 48.3% of Australian participants identified themselves as NICU pharmacists.

Table 1 Responder characteristics

Characteristic	No. of participants (%)	
	Australia ($n=29$)	Poland ($n=20$)
Sex		
Female	22 (75.9)	17 (85)
Qualification		
Bachelor's degree	12 (41.4)	19 (95)
Master's degree	1 (3.4)	0
PhD degree	8 (27.6)	1 (5)
Qualifications held by participants other than those specified in the survey		
Post-graduate certificate/diploma	8	0
Clinical pharmacy specialization	0	1
Specialised qualification (neonatal and paediatric-specific postgraduate certificate)		
Yes	2 (6.9)	0
No	27 (93.1)	20 (100)
Position in the hospital		
Neonatal pharmacist	14 (48.3)	0
Director of pharmacy	5 (17.2)	5 (25)
Pharmacist working in main hospital pharmacy	3 (10.3)	13 (65)
Other	7 (24.1)[a]	2 (10)[b]
Experience		
< 1 year	6 (20.7)	2 (10)
1–5 years	13 (44.8)	11 (55)
6–10 years	3 (10.3)	1 (5)
> 10 years	7 (24.1)	6 (30)
Number of beds in NICU (range)	8–110	5–28

CIVAS centralized intravenous additive services, *NICU* neonatal intensive care unit

[a]Included one deputy director, two clinical pharmacists, two medicines information pharmacists, one specialist women, youth and children pharmacist, and one ascetic CIVAS pharmacist

[b]Included one hospital pharmacy co-ordinator and one clinical pharmacist

Perceived levels of competency to perform pharmaceutical care services

Participants were asked to provide their opinions on their perceived preparedness to provide pharmaceutical care services to the NICU (Table 2). Overall, it was apparent that Australian pharmacists felt more competent in the provision of clinical and educational roles than did Polish participants. In 14 of the 15 clinical roles listed, more than 70% of Australian participants felt that pharmacists had a 'good' level of preparation to provide services to the NICU, including performing medication chart reviews (93.1%) and pharmaceutical interventions, (96.6%) and collaborating with medical and nursing staff (93.1%). In comparison, most Polish pharmacists identified a 'poor' level of preparedness to deliver 10 of the 15 clinical services, including participation in ward rounds (85%, $p<0.001$), evaluating patients' laboratory test results (90%, $p<0.001$), and recommending medications and contributing to the pharmacotherapy decision-making process (65%, $p<0.001$). Interestingly, Polish pharmacists felt well prepared to provide one clinical role: monitoring total parenteral nutrition (90%). Overall, Polish pharmacists felt most confident in their roles relating to the provision of medicines. All (100%) of Polish participants agreed that they had a 'good' level of preparation in the dispensing and extemporaneous compounding of medicines for this ward.

When considering administrative roles, a significantly higher proportion of Australian than Polish pharmacists agreed that they were competent in the provision of two administrative services: conducting quality assurance measures (AP 72.4%, PP 30%; $p=0.001$), and creating medication policies and guidelines for the NICU (AP 86.2%, PP 30%; $p<0.001$). Furthermore, a significantly higher proportion of Australian than Polish pharmacists also felt adequately prepared to counsel parents of patients (AP 89.7%, PP 5%; $p<0.001$), to be a source of medication information for NICU medical and nursing staff (AP 89.7%, PP 45%; $p=0.001$), and to provide training on topics related to neonatal pharmacotherapy (AP 79.3%, PP 5%; $p<0.001$).

Table 2 Pharmacist-perceived competencies towards pharmacist roles in the NICU

Competency	No. of responders (%)						*p* value (Australia vs. Poland)
	Australia ($n=29$)			Poland ($n=20$)			
	Good	Average	Poor	Good	Average	Poor	
Administrative roles							
Development/implementation of a drug formulary service	22 (75.9)	7 (24.1)	0	15 (75)	5 (25)	0	0.945
Attendance at non-clinical meetings (i.e., Drug and Therapeutics Committee)	21 (72.4)	6 (20.7)	2 (6.9)	10 (50)	8 (40)	2 (10)	0.269
Conducting quality assurance measures (i.e., drug usage evaluations, workload documentation, auditing)	21 (72.4)	7 (24.1)	1 (3.4)	6 (30)	5 (25)	9 (45)	0.001
Management of the drug budget	14 (48.3)	9 (31)	6 (20.7)	9 (45)	8 (40)	3 (15)	0.775
Evaluation, selection and purchasing of pharmaceuticals for the unit	19 (65.5)	8 (27.6)	2 (6.9)	17 (85)	1 (5)	2 (10)	0.133
Development of drug policies/protocols/guidelines for the NICU	25 (86.2)	4 (13.8)	0	6 (30)	4 (20)	10 (50)	<0.001
Clinical roles							
Patient medication chart review	27 (93.1)	1 (3.4)	1 (3.4)	7 (35)	2 (10)	11 (55)	<0.001
Participation in medical ward rounds	21 (72.4)	5 (17.2)	3 (10.3)	2 (10)	1 (5)	17 (85)	<0.001
Monitoring the efficacy of pharmacotherapy in patients	26 (89.7)	2 (6.9)	1 (3.4)	1 (5)	5 (25)	14 (70)	<0.001
Documenting/monitoring adverse drug events/reactions	24 (82.8)	4 (13.8)	1 (3.4)	5 (25)	12 (60)	3 (15)	<0.001
Documenting medication errors	25 (86.2)	3 (10.3)	1 (3.4)	4 (20)	6 (30)	10 (50)	<0.001
Evaluating patients' clinical laboratory tests	22 (75.9)	6 (20.7)	1 (3.4)	1 (5)	1 (5)	18 (90)	<0.001
Therapeutic drug monitoring	24 (82.8)	4 (13.8)	1 (3.4)	3 (15)	5 (25)	12 (60)	<0.001
Immunizations	17 (58.6)	6 (20.7)	6 (20.7)	0	3 (15)	17 (85)	<0.001
Monitoring total parenteral nutrition	21 (72.4)	7 (24.1)	1 (3.4)	18 (90)	2 (10)	0	0.296
Participation in clinical meetings	23 (79.3)	5 (17.2)	1 (3.4)	1 (5)	7 (35)	12 (60)	<0.001
Calculating and recommending doses and dosing schedules for specific patients	26 (89.7)	2 (6.9)	1 (3.4)	5 (25)	8 (40)	7 (35)	<0.001
Assisting doctors in prescribing off-label/unlicensed medicines	27 (93.1)	2 (6.9)	0	5 (25)	6 (30)	9 (45)	<0.001
Identifying and performing interventions for individual patients to prevent or resolve drug therapy problems (i.e., interactions, incompatibilities, allergies, etc.)	28 (96.6)	0	1 (3.4)	4 (20)	8 (40)	8 (40)	<0.001
Recommending drugs and contributing to the pharmacotherapy decision-making process for specific patients	24 (82.8)	4 (13.8)	1 (3.4)	1 (5)	6 (30)	13 (65)	<0.001
Collaborating and discussing specific patients with doctors and nurses	27 (93.1)	1 (3.4)	1 (3.4)	2 (10)	8 (40)	10 (50)	<0.001
Education/communication/research							
Providing training/in-services for other health professionals on NICU-related topics and drug-related problems	23 (79.3)	6 (20.7)	0	1 (5)	4 (20)	15 (75)	<0.001
Contributing to and/or attending NICU-related conferences	17 (58.6)	9 (31)	3 (10.3)	6 (30)	6 (30)	8 (40)	0.035
Involved in clinical trials	18 (62.1)	7 (24.1)	4 (13.8)	13 (65)	2 (10)	5 (25)	0.348
Involved in research related to neonatal pharmacotherapy	14 (48.3)	8 (27.6)	7 (24.1)	5 (25)	3 (15)	12 (60)	0.040
Source of drug information: responding to information requests from health professionals on the ward	26 (89.7)	3 (10.3)	0	9 (45)	5 (25)	6 (30)	0.001
Counselling parents/carers of neonatal patients	26 (89.7)	1 (3.4)	2 (6.9)	1 (5)	3 (15)	16 (80)	<0.001
Provision of medicines							
Dispensing prescriptions	25 (86.2)	4 (13.8)	0	20 (100)	0	0	0.083
Extemporaneous compounding of formulations for the NICU	23 (79.3)	4 (13.8)	2 (6.9)	20 (100)	0	0	0.095
Stocking the ward with essential medicines/house-keeping activities (checking expiry dates, fridge temperature, etc.)	21 (72.4)	6 (20.7)	2 (6.9)	18 (90)	2 (10)	0	0.263

NICU neonatal intensive care unit

Current barriers

Significant differences were identified when considering pharmacist perceptions of barriers to pharmacist practice in the NICU (Table 3). More than 80% of Polish participants agreed with 10 of the 16 barrier items. In comparison, Australian participants had a low perception of barriers, with most responses remaining lower than 45%. The barriers most commonly referred to by Polish pharmacists related to a lack of legislation regulating pharmacist practice on the NICU (AP 34.5%, PP 90%; $p < 0.001$), lack of an apparent need for a pharmacist to be present on this ward (AP 17.2%, PP 85%; $p < 0.001$), and medical and nursing staff ignorance of pharmacist competencies and skills (AP 34.5%, PP 85%; $p < 0.001$). Participants' qualitative responses also referred to a lack of guidelines or policies at both local and national levels to guide their practice. They emphasized the absence of legislation specifying what pharmaceutical care services should be provided directly on the ward.

"Lack of procedures." **PP11**

"It is not legally regulated, it does not exist in hospital practice." **PP15**

Furthermore, they noted reluctance on the part of doctors to accept pharmacists as partners in the medication-management process.

"… in our country, however, the division of roles between staff is roles is traditional/classic." **PP2**

"Pharmacists are not treated as equal co-workers." **PP12**

"Doctors do not know and do not understand the potential of a pharmacist and, as suc,h they are not willing to co-operate … there is a lack of consent from the doctors. In Poland, clinical pharmacists are rare." **PP15**

Conversely, Australian pharmacists highlighted that the greatest barriers apparent in their healthcare system included a shortage of pharmacy staff (AP 72.4%, PP 100%; $p = 0.010$), lack of pharmacist time to deliver the necessary services to the NICU (AP 65.5%, PP 80%; $p = 0.270$), and a lack of pharmacists with the skills and knowledge necessary to be able to practice in the NICU (AP 62.1%, PP 90%; $p = 0.030$).

Table 3 Barriers to pharmacist practice in the NICU

Barrier	No. of responders (%)		
	Australia ($n = 29$)	Poland ($n = 20$)[a]	p value (Australia vs. Poland)
Lack of policy/legislation for pharmacists to be regulated to perform services in the NICU	10 (34.5)	18 (90)	< 0.001
Lack of pharmacist time to perform duties	19 (65.5)	16 (80)	0.270
Lack of pharmacy staff (i.e., not enough pharmacy technicians to cover dispensing)	21 (72.4)	20 (100)	0.010
There is no need for pharmacist to be on NICU	5 (17.2)	17 (85)	< 0.001
Doctors/nurses are unaware of what services pharmacists can provide in the NICU	10 (34.5)	17 (85)	< 0.001
Doctor/nurse reluctance or resistance to pharmacist role in the NICU	6 (20.7)	15 (75)	0.001
Lack of financial compensation/remuneration for pharmacists to perform activities on the NICU	10 (34.5)	17 (85)	< 0.001
Pharmacist is physically removed from the NICU	6 (20.7)	6 (30)	0.456
A lack of clinical pharmacy training/knowledge opportunities related to neonatal practice	14 (48.3)	16 (80)	0.025
Pharmacists are not interested in performing clinical pharmacy services in the NICU	2 (6.9)	4 (21.1)[b]	0.147
Unwilling to change current practice	9 (31)	4 (20)	0.390
Lack of communication with pharmacists	5 (17.2)	10 (52.6)[b]	0.010
Lack of support from administration/hospital	13 (44.8)	18 (90)	0.001
Lack of confidence in own ability	9 (31)	11 (55)	0.093
Lack of pharmacists with the necessary skills and training	18 (62.1)	18 (90)	0.030
Lack of recognition of the contribution of the pharmacist to NICU care	12 (41.4)	4 (20)	0.117

NICU neonatal intensive care unit

[a]Unless otherwise noted

[b]No. of respondents = 19

"On the days there is pharmacy cover in NICU, there is good pharmaceutical practice but there is often a staff deficit not allowing full coverage of the ward." **AP24**

"Not enough time to dedicate to unit as role is shared with other ward responsibilities, outpatient clinics, and dispensary duties." **AP15**

"Bed-to-pharmacist ratio could be better to allow more detailed input into each patient's care." **AP18**

Interestingly, Polish participants also strongly identified with these barriers, particularly pharmacist shortages in the hospital. Limited funding and subsequent staffing deficiencies were identified as key reasons for the lack of clinical pharmacy practice in the NICU. As a result, pharmacists are overloaded with dispensary-based duties and unable to provide clinical activities on the ward.

"At the hospital, there are only a few pharmacists employed, about a dozen or so, to cover about 1200 beds, it is physically unfeasible." **PP18**

Participants also felt that their formal training (pharmacy degree) did not adequately prepare them for clinical practice, and they, therefore, lacked confidence in making recommendations to the NICU team.

"Lack of pharmacist experience in this area …" **PP15**

"… neither the university studies nor the post-graduate specialization courses prepare pharmacists for such a role. We do not have enough knowledge to be able to advise doctors." **PP18**

Changes needed to improve services

A significantly higher proportion of Polish pharmacists agreed that changes were needed to improve pharmacist practice in the NICU (AP 53.6%, PP 90%; $p = 0.007$) [Table 4]. Indeed, all (100%) Polish participants agreed to all 11 of the proposed changes listed. The qualitative responses from Polish pharmacists highlighted that changes were necessary to improve patient safety and the quality of care. Furthermore, they acknowledged that the current healthcare system did not use pharmacists and their skills to their maximum potential.

"Changes to the role of the pharmacist in the NICU would increase the safety of pharmacotherapy, which would have a positive influence on pharmacoeconomy and improve a patient's level of comfort." **PP1**

Table 4 Changes needed to current practice

Changes needed	No. of responders (%)		*p* value (Australia vs. Poland)
	Australia ($n = 22$)[a]	Poland ($n = 20$)	
Answered 'yes' to the question: is there a need to change pharmacist roles in the NICU?	15 (53.6)[b]	18 (90)	0.007
Types of changes needed			
Increased support from the hospital administration (i.e., from hospital directors in creating and funding clinical pharmacist positions)	17 (77.3)	20 (100)	0.023
Increased levels of staffing in the pharmacy	21 (91.3)[c]	20 (100)	0.177
Increased levels of communication with pharmacists	14 (63.6)	20 (100)	0.003
Increasing the level of support from doctors and nurses for the role of the pharmacist in the NICU	14 (63.6)	20 (100)	0.003
Increasing educational opportunities for pharmacists related specifically to neonatal/pediatric pharmacotherapy	19 (86.4)	20 (100)	0.087
Providing more training for pharmacists on clinical pharmacy services	19 (86.4)	20 (100)	0.087
Increasing nurse/doctor awareness of the roles and services that pharmacists can provide in the NICU	15 (68.2)	20 (100)	0.006
Increasing pharmacist salaries	9 (40.9)	20 (100)	< 0.001
Creating specific NICU clinical pharmacist positions in the hospital (i.e., organizational changes)	17 (77.3)	20 (100)	0.023
Legislative changes regulating clinical pharmacy practice in the NICU	9 (40.9)	20 (100)	< 0.001
Pharmacists' own motivation and interest towards improving upon the current level of practice	19 (86.4)	20 (100)	0.087

NICU neonatal intensive care unit

[a]Unless otherwise noted

[b]No. of respondents = 28

[c]No. of respondents = 23

"The knowledge of pharmacists is not fully utilized and, therefore, underestimated." **PP12**

"The pharmacist would introduce an alternative point of view and bring knowledge that would increase the safety of treatment (e.g., with interactions, too high doses), and improve economics, leading to better medicines management." **PP16**

In comparison, Australian pharmacists most commonly felt that changes needed to be directed at increasing the staffing of the pharmacy department to allow more pharmacists to be introduced to the NICU (91.3%), providing education and training opportunities for pharmacists in the fields of neonatology and clinical pharmacy (86.4%), and increasing pharmacists' own motivation towards practice on this ward (86.4%).

"I would like to see greater involvement of pharmacists in activities that directly improve clinical outcomes for patients. This includes a variety of clinical and non-clinical activities, including research." **AP4**

"All NICUs should have their own dedicated NICU clinical pharmacists." **AP5**

Discussion

The findings of this study highlight significant differences in the perceptions of Polish and Australian pharmacists towards practice in the NICU. To our knowledge, this is the first study to compare pharmacist opinions about pharmaceutical care services provided to NICUs in two countries. It is important to note that this research is exploratory in nature and was intended to provide context for and understanding of the differences in practice seen in NICUs in Australia and Poland. Future research is aimed at further qualitative studies exploring not only pharmacist perceptions of practice, but also that of other healthcare professionals in this setting, i.e., doctors and nurses, to provide a fuller insight into practice.

One concept arising from the data that warrants discussion is the finding that pharmacists in Poland and Australia held significantly different perceptions of their own competencies in delivering pharmaceutical care to the NICU. Polish pharmacists felt most confident about delivering traditional pharmacist activities, including dispensing and extemporaneous compounding. This is not unexpected, as the published literature indicates that pharmacist practice in Poland is often limited to dispensary-based activities [7]. However, their perceived competence in providing clinical and educational-based roles was lower. In comparison, Australian participants were particularly confident about the clinical and educational areas of practice, signifying more experience and familiarity with these services. This is also reflected in the literature, highlighting the integrated role of the Australian pharmacist in pharmacotherapy-related decision making in hospital wards [23, 24]. It is apparent that Polish pharmacists are unaccustomed to the concept of the pharmacist as a provider of direct patient care, and identify more with the distributive model of practice. Conversely, Australian pharmacists associate more with the pharmaceutical care practice model, wherein pharmacists assume responsibility for patient care and are members of the interdisciplinary treating team [25].

Furthermore, Polish pharmacists perceived practice barriers at a higher rate than Australian participants, and were also more inclined to want changes to pharmacist roles. In particular, Polish participants commonly highlighted, throughout the survey, the apparent lack of support from doctors and nurses for the pharmacist's role in the NICU. The absence of interdisciplinary collaboration with the hospital pharmacist was previously discussed by Piecuch et al. [26], who highlighted that the hierarchical structure of the healthcare system in Poland does not encourage collaborative practice. Rather, the doctor is seen to dominate treatment, and pharmacists are not involved in the pharmacotherapy process, aside from dispensing and preparing medicines. In comparison, Australian participants felt valued by the medical and nursing staff, and instead voiced concerns with the staffing of the NICU and with ensuring a full range of services are provided. As such, the focus of pharmacist concerns are different for each country. This also further highlights the need for insights from other stakeholders/members of the NICU team.

While these differences in perceptions may be attributed to contrasting healthcare systems, legislation, practice culture, and educational systems, these findings are important to consider as they provide an insight into the reality of pharmacist practice in NICUs in Poland and Australia. The barriers identified and the perceptions of pharmacist competence highlight the gap in practice observed between Poland and Australia. These differences in perceptions raise the question—what impact are these different levels of service having on the outcomes of such a vulnerable patient group? The WHO and the International Pharmaceutical Federation (FIP) both call for practice equality and the standardization of practice on a global scale [27, 28]. Efforts by the FIP have brought about the Basel Statements, which have sought to standardize hospital pharmacy practice on an international scale from a general perspective [29]. However, there is a need for the development of such standards for sub-specialties in pharmacy, where patients, such as those in the NICU, require unique considerations from a pharmacotherapy perspective. The Society of Hospital Pharmacists Australia has recognized this need and introduced

specialty support groups, ranging from cardiology, infectious diseases, and emergency medicine to rural and remote practice, to encourage the exchange of information and the ability for pharmacists to develop their specialty practice [30]. These practice groups have the potential to then define criteria outlining essential pharmacist roles for their respective sub-specialties.

These findings have implications for the development of standardized pharmacist practice policies for the NICU and bridging the practice gap between countries. Neonatal patients are a unique population with specific pharmacotherapy needs and requirements that differ from those of other patient groups. As such, pharmacist practice provided to this ward should be aimed at a consistent, high-quality, and homogenous level of care to allow equal opportunity for these high-risk and vulnerable patients to achieve the best possible outcomes. Future research should be directed at investigating the barriers contributing to practice differences and identifying facilitators that would assist in bridging the gap in NICU pharmacist practice within and between countries.

Limitations

While this study is the first to report on pharmacist perceptions of their preparation for practice in Australian and Polish NICUs, the findings are subject to some limitations. A major limitation is that the assessment of practice preparedness and competence is highly prone to self-report bias. The traditional pharmacy practice structure in Poland means the number of pharmacists who considered their role to be that of a NICU pharmacist differed from that in Australia. Pharmacists subjectively self-assessed their capabilities in performing roles in the four listed domains. Therefore, the findings may be overestimated because of the potential for social desirability bias. Furthermore, individual participants may have interpreted differently the good/average/poor categories and the pharmacist practice roles, i.e., total parenteral nutrition monitoring. Therefore, results should be interpreted with caution.

The low response rate and the small number of participants mean the survey data may not be representative of all pharmacists in Poland and Australia or generalizable across settings in each country.

The sample size was not reached, but this can be attributed to the narrow scope and highly specialized nature of practice and the subsequent limited possible number of participants who could be included in this study. As such, further research is needed to verify these findings.

Conclusions

Overall, it is apparent that Polish pharmacists are more confident in providing traditional pharmacy services to the NICU than other services. In comparison, Australian pharmacists felt competent in providing more advanced roles, including clinical and educational services. Statistically significant differences were also perceived when considering the barriers currently limiting practice in the NICU, with Polish pharmacists facing reluctance from doctors and nurses. Future efforts should focus on developing pharmacist practice guidelines and practice standards for the subspecialty of neonatology to promote the standardization of practice.

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Compliance with ethical standards

Ethical approval Ethics approval was obtained from the ethics committees at the University of Technology Sydney, Australia (ref no. ETH16-1033) and the Medical University of Gdansk, Poland (ref no. NKBBN/424/2016).

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L.6 QUALITY USE OF MEDICINES IN NEONATAL CARE: A REVIEW OF MEASURES OF QUALITY USED TO EVALUATE THE APPROPRIATENESS AND RATIONAL USE OF MEDICATION WITHIN THE NICU

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REVIEW ARTICLE

Quality use of medicines in neonatal care: a review of measures of quality used to evaluate the appropriateness and rational use of medication within the NICU

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Abstract With medication error rates in neonatal intensive care units (NICUs) reported to be as high as 91 medication errors per 100 patient admissions, the quality use of medicines (QUM) in this setting is important. Comprising the safe, rational, appropriate and effective use of pharmacotherapy, QUM is integral to achieving medication safety and optimal patient outcomes. To improve QUM in the NICU, the medication use process needs to undergo a quality assessment, using quality measures or indicators. As such, the objectives of this quasi-systematic literature review were to identify the measures used to evaluate QUM within the NICU and to map these against Donabedian's traditional framework of structure, process and outcome. We searched EMBASE, PubMed, CINAHL, Google Scholar and Google for relevant published and grey literature. Overall, a total of 47 quality measures were identified and categorised: 17 structure, 19 process and 11 outcome measures. The most common measures related to the availability of medication safety technology in the NICU, written policies on the use of high-risk medications, medication error and adverse drug event reporting systems, and the provision of education for health professionals involved in the medication use process. However, there were no quality measures specifically designed for medication management in the NICU. The literature does not provide a comprehensive evaluation of the quality of care provided along the medication use process in the NICU. There is a need to develop a quality framework outlining measures that facilitate the appropriate use of medicines in the NICU.

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Introduction

Medication safety is of utmost priority in the neonatal intensive care unit (NICU) [1]. Medications are heavily utilised within the NICU, with a reported average of 8.6 medications being prescribed per patient [2]. The high-risk characteristics of neonatal patients, including physiological vulnerabilities and varying pharmacokinetics, as well as the limited amount of evidence-based information available on the use of pharmacotherapy in infants, increase the complexity of the medication use process [3–5]. In combination with the fast-paced, challenging NICU environment, neonates are at a high risk of medication misadventure with potentially significant consequences that may have a long-term impact upon a child's development [3]. With medication error rates reported in NICUs as high as 91 medication errors per 100 patient admissions, the quality use of medicines (QUM) in this setting is important [5]. Comprising the safe, rational, appropriate and effective use of pharmacotherapy, the QUM is integral to achieving medication safety and optimal patient outcomes [6–8].

In order to improve the QUM in the NICU, the medication management process needs to undergo a quality assessment, using quality measures or indicators [9]. Quality indicators are measurable elements that refer to the structure, process and outcomes of pharmacotherapy in the NICU [9, 10]. The medication management process is complex and comprises several phases: prescribing,

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transcribing, dispensing, administering and monitoring [11]. As such, in order to provide an all-inclusive quality assessment, indicators must consider each aspect of the medication management process. Previous studies describe various measures related to the appropriate use of medications in adult patients, including the Assessing Care of Vulnerable Elders (ACOVE) quality framework; however, there is relatively minimal corresponding literature in other patient groups, particularly neonates [12]. Therefore, the aim of this review was to identify quality measures used to evaluate the medication management process within the NICU. A specific objective was to identify the range of measures used to evaluate the QUM in the NICU.

Methodology

A quasi-systematic review (a review that possesses some elements of a systematic review, including pre-defined selection criteria, but includes grey literature and does not present a critical evaluation of the quality of studies) of the literature was performed and the findings were mapped against Donabedian's framework of structure, process and outcome [10, 13–16]. A structure of care describes the characteristics of the setting or the organisational framework supporting the process of care (e.g. the number of qualified staff, type of hospital and level of NICU) [17, 18]. Process refers to the method of healthcare service provision and includes the amount and type of activities performed for the patient. This relates to what is done to the patient, including types of interventions, evidence-based treatment regimens, etc. [9, 17–20]. Outcomes are classified as the consequences of healthcare and comprise the health status of patients (i.e. morbidity, mortality etc.) [9].

For the purpose of this review, a definition of quality was adapted from the World Health Organisation's (WHO) description of quality in healthcare [21]. This definition was modified to characterise quality relating to the medication use process in the NICU, including the quality of the structure and process systems, as well as the outcomes they produce [21]. As such, quality is described across six dimensions, as follows:

- *Effective* Using medicines that are evidence-based and which result in improved health outcomes for individuals based on need.
- *Efficient* Using medicines in a manner that maximises resource use and minimises waste.
- *Accessible* Using medicines in a manner that is timely and provided in a setting where skills and resources are appropriate to therapeutic need.
- *Patient-centred* Using medicines in a manner that takes into account the preferences of individual patients.
- *Equitable* Using medicines that do not vary in quality because of personal characteristics.
- *Safe* Using medicines in a manner that minimises risk and harm to patients [21].

The review sought to identify quality measures relating to the medication use process in accordance with this definition. Quality measures included guidelines, consensus statements, position statements and quality assessment tools (Table 1). Furthermore, due to a lack of available literature, the review also included studies that suggested interventions or resources to improve any of the aforementioned dimensions of quality and had the potential to be applied in the future as quality indicators.

Full-text articles were retrieved by searching the following databases: EMBASE, PubMed, CINAHL and Google Scholar, during the period of March 2015–March 2016. Citations and reference lists were also hand-searched to find articles that were not identified in the original search. This was supplemented by a Google search to identify relevant grey literature. Articles were selected for the review if they included quality measures/indicators relating to the use of medicines, if the quality indicators were applicable to the NICU and if they stated recommendations for the improvement of medication management. The articles were mapped against Donabedian's domains of healthcare quality in three steps. If articles used Donabedian's terms within their findings, they were reviewed to determine their design (i.e. study, guideline etc.). Secondly, measures were identified as belonging to structure, process or outcome per the definition used in Donabedian's framework or via author verification. Third, these measures were categorised into their corresponding domains on the discretion of Author 1 and were verified by Author 2.

Search strategy

A two-tiered search strategy was used (Fig. 1). In Tier 1, a generalised search of the electronic databases was conducted using the following MeSH terms: *quality, quality indicators, neonate/infant/newborn*, *NICU*, *medication, medication safety, medication prescribing/transcribing/dispensing/administration/monitoring, patient safety, pharmacist services/pharmaceutical care*. The search terms combined keywords and medical subject headings for neonate, medication safety and quality indicators. The search parameters limited the inclusion of articles to those relating to the use of medication in NICU, neonatal patients and written in the English language. We applied a date limit so that only recent articles published from the year 2000 or later (i.e. 2000–2016) were taken into account. Tier 2 of the search identified relevant sources of grey literature using a Google search of the same terms. Organisations such as WHO, Council of Europe, Society of

Table 1 Definitions of terms used in review

Definitions of general terms	
Clinical indicator	"Measures of elements of clinical care which may, when assessed over time, provide a method of assessing the quality and safety of care at a system level. Can be measures of process, structure and/or outcomes of patient care" [53, 54]
Consensus statement	"A comprehensive summary of the opinions of a panel of experts about a particular scientific, medical, nursing or administrative issue. Its purpose is to provide guidance to healthcare professionals, particularly on poorly understood or controversial aspects of care" [55]
Guideline	"Systematically developed statements to assist practitioner and patient decisions prospectively for specific clinical circumstances" [54, 56]
KPI	"Measures of performance that are used by organisations to measure how well they are performing against targets or expectations. KPIs measure performance by showing trends to demonstrate that improvements are being made over time" [57, 58]
Position statement	"A written statement that articulates a position, viewpoint, or policy of a healthcare system or hospital organisation regarding best practices, standard care, or inconclusive evidence-based research" [59]
Quality assessment tool	"A document that provides a semi-quantitative assessment of the quality of care in a variety of key areas, and can be used to assess and monitor the baseline situation and subsequent improvements, thus providing key information before and after interventions to improve quality of care, as well as for incentives and accreditation schemes" [40]
Quality improvement	"An organised process that assesses and evaluated health services to improve practice of quality of care" [60]
Quality measure	"Quality measures are tools that help measure or quantify healthcare processes, outcomes, patient perceptions, and organizational structure and/or systems that are associated with the ability to provide high-quality health care and/or that relate to one or more quality goals for health care. These goals include: effective, safe, efficient, patient-centered, equitable, and timely care" [61]
Quality pharmaceutical care	"The extent to which pharmacy services deliver effective, efficient, patient-centred, equitable and safe pharmacotherapy" [21]
Quality standard	"The level of compliance with a criterion or indicator. A standard is set prospectively and stipulates the level of care that a provider must strive to meet" [54, 56]
Quality use of medicines	"Selecting management options wisely, choosing suitable medicines if a medicine is considered necessary so that the best available option is selected and using medicines safely and effectively to get the best possible results" [6–8]
Definitions of neonatal intensive care unit levels [36]	
Level 1 (basic)	"A nursery that must be capable of assessing, diagnosing and managing uncomplicated pregnancies and: – newborn infants without complications with • gestation 37 weeks or greater • birth weight 2500 grams or greater – newborn infants with minor conditions not requiring additional nursing or specialist medical treatment – newborn infants requiring phototherapy (in consultation with a specialist paediatrician)"
Level 2	"A neonatal unit that must be capable of assessing, diagnosing and managing: – newborn infants without complications with • gestation 34 weeks or greater • birth weight 2000 grams or greater, including growing preterm and convalescing infants – newborn infants requiring incubator care for: • short-term transition problems • mild complications: – oxygen requirement (not exceeding 40 %) – apnoea monitoring – blood glucose monitoring – short-term intravenous therapy – phototherapy – gavage feeding"

Table 1 continued

Level 3	"Neonatal unit that must be capable of assessing, diagnosing and managing all newborn infants requiring neonatal intensive care including infants: – requiring continuing assisted ventilation via an endotracheal tube, and for the 24 h following endotracheal tube removal – requiring oxygen therapy (more than 60 %) for more than 4 h with tracheostomies requiring IPPV or CPAP – requiring a nasopharyngeal tube (without CPAP) to maintain airway patency – requiring an arterial line for continuing blood gas and/or blood pressure monitoring – having frequent seizures – undergoing major surgery, on the day of the procedure and for 48 h postoperatively, including: • any procedure where a body cavity is opened • repair of neural tube defect • placement of a ventriculoperitoneal shunt or temporary ventricular drainage device – requiring 1:1 nursing care"

CPAP continuous positive airway pressure, *IPPV* intermittent positive pressure ventilation, *KPI* key performance indicator

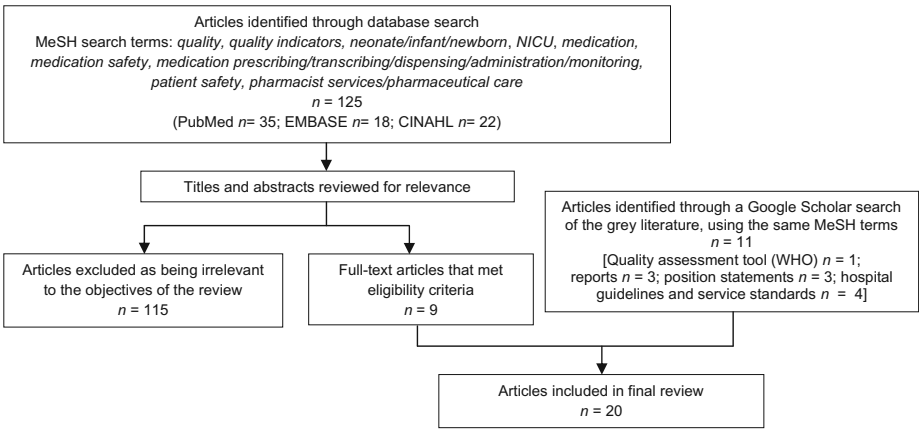

Fig. 1 Search strategy. *NICU* neonatal intensive care unit, *WHO* World Health Organization

Hospital Pharmacists Australia, and Australian state/national government protocols, in particular, were reviewed. The articles retrieved from each tier of searching were pooled for analysis, in line with the study objectives.

Results

A total of 20 sources of information were identified, comprising seven reports [22–28], four studies (including cohort and observational studies) [1, 29–31], one literature review [32], three position statements [33–35], four hospital service standards/guidelines [36–39] and one quality assessment tool [40] (Table 2). The literature collected came from the USA (12 articles) [22–31, 33, 35] and the UK (3 articles) [37–39], with singular reports from the Netherlands [32], Australia [36], New Zealand [1], Qatar [34] and the WHO [40]. No randomised control trials were identified in the search.

Overall, the search identified limited published literature comprehensively exploring the quality measures associated with the QUM in NICUs. Among the included literature, a total of 47 quality measures were identified and categorised: 17 structure measures, 19 process measures and 11 outcome measures (Table 3).

Measures of quality relating to structure

Overall, structure measures were most commonly related to the staffing and support systems available in the NICU. Three structure measures referred to the presence of a qualified and experienced NICU pharmacist on the ward. A

Table 2 Summary of findings documenting quality measures related to quality use of medicines within the NICU

Country/region	Publishing association/author (year)	Guideline/tool/title
International guidelines/hospital service standards		
Scotland	Neonatal Expert Advisory Group	Neonatal care in Scotland: a quality framework [37]
UK	British Association of Perinatal Medicine	Service standards for hospitals providing neonatal care [38]
UK	National Institute for Health and Care Excellence	Specialist neonatal care quality standard [39]
Australia	Victorian Government	Neonatal service guidelines: defining levels of care in Victorian hospitals [36]
Position statements on pharmacist roles within the NICU		
USA	University of Kentucky Hospital: Pharmacy Services	NICU clinical pharmacist specialist [33]
USA	National Association of Neonatal Nurses	Medication safety in the neonatal intensive care unit: position statement #3060 [35]
Qatar	Sidra Medical and Research Center	Clinical pharmacist intensive care (PCICU, PICU, ED and NICU) [34]
Quality assessment tool		
Europe	WHO	Making pregnancy safer: assessment tool for the quality of hospital care for mothers and newborn babies [40]
Reports/reviews		
The Netherlands	Chedoe et al. (2007)	Incidence and nature of medication errors in neonatal intensive care with strategies to improve safety: a review of the current literature [32]
USA	Ellsbury and Ursprung (2012)	A quality improvement approach to optimizing medication use in the neonatal intensive care unit [22]
USA	Grissinger (2011)	A fatal zinc overdose in a neonate: confusion of micrograms with milligrams [23]
USA	Lemoine and Hurst (2012)	Using smart pumps to reduce medication errors in the NICU [24]
USA	Lucas (2004)	Improving medication safety in a neonatal intensive care unit [25]
USA	McCartney (2006)	Using technology to promote perinatal patient safety [26]
USA	Patel and Saiman (2012)	Principles and strategies of antimicrobial stewardship in the neonatal intensive care unit [27]
USA	Simons (2007)	Designing medication safety in the NICU [28]
Studies		
New Zealand	Kunac and Reith (2005)	Identification of priorities for medication safety in neonatal intensive care [1]
USA	Morriss et al. (2009)	Effectiveness of a barcode medication administration system in reducing preventable adverse drug events in a neonatal intensive care unit: a prospective cohort study [29]
USA	Sharek et al. (2006)	Evaluation and development of potentially better practices to improve pain management of neonates [30]
USA	Sullivan et al. (2013)	Personalised performance feedback reduces narcotic prescription errors in a NICU [31]

ED emergency department, *ICU* intensive care unit, *NICU* neonatal ICU, *PCICU* paediatric cardiac ICU, *PICU* paediatric ICU

ward-based pharmacist was reported as a key facilitator for the QUM in the NICU, compared with just having access to an externally provided service based in the main hospital pharmacy [28, 36–39]. 'Qualified' was defined in the Scottish and British NICU guidelines as a pharmacist who held postgraduate qualifications in paediatric practice or possessed the equivalent level of skills and knowledge [37, 38]. The National Institute for Health and Care Excellence (NICE) standard also reaffirmed that all NICU pharmacists were required to be sufficiently skilled and compliant with NICU-based competency standards according to each setting's regulations (i.e. British Department of Health Toolkit) [39]. Required competencies included possessing comprehensive knowledge of neonatal development, metabolic pathways, as well as pharmacokinetics and pharmacodynamics in neonates [38]. Two resources also reported on the requirement for NICU pharmacists to continue to update their knowledge through continuing education to ensure currency of practice [33, 38]. Additionally, two resources stipulated that there was a need for adequate levels of qualified nursing and medical staff in the NICU, with appropriate workloads and

Table 3 Summary of quality measures associated with the rational and appropriate use of medications in the NICU

Structure	Source of information: [36] Australia, [34] Qatar, [32] The Netherlands, [37–39] UK, [22, 24–26, 28, 29, 33, 35] USA, [40] WHO
Staffing: full-time/part-time pharmacist [36]	
Staffing: nurses and medical staff [35, 38]	
Qualifications of pharmacist [37–39]	
Experience of pharmacist in NICU [38]	
Continuing education of pharmacy practitioners [33, 38]	
Well-lit environment, with sufficient workspace, minimal distractions [35]	
Availability of aseptic compounding facilities for the formulation of IV and non-standard medications [38]	
Availability of facility and instruments for medication preparation [36]	
Availability of essential medicines for specific use within NICU [40]	
Written policies/protocols/guidelines for high-risk medications, i.e. antibiotics, pain-relief, parenteral nutrition [34, 35, 38, 40]	
Clear policies on how to prescribe, dispense, administer and monitor medications in the NICU [35]	
Neonatal formulary with standard concentrations [25, 28, 35]	
Emergency medicines sheets, with listed doses per weight [25, 28]	
Standard references for use in the selection, use and evaluation of medications [35]	
Medication error and adverse drug event reporting (systems) [33–35, 38]	
Collection of drug use data [22]	
Availability of safety technology including CPOE, CDSS, barcode verification, smart pumps, computerised calculation of orders, automated drug dispensing units, electronic health records [24–26, 28, 29, 32, 35]	
Process	Source of information: [1] New Zealand, [34] Qatar, [32] The Netherlands, [38] UK, [28, 30, 31, 33, 35] USA, [40] WHO
Therapeutic drug monitoring [34, 38]	
Counselling of parents [33, 34]	
Advice on off-label/unlicensed medications [38]	
Adverse drug event monitoring and documentation: identification, monitoring, rectifying, prevention [33, 34, 38]	
Medication preparation by pharmacy department [35]	
Monitoring of medication orders [33, 34, 38]	
Medication errors: identification, rectifying, prevention [38]	
Review, verification and clarification of medication charts [33]	
Education/training of health professionals [1, 32–35, 38]	
Provision of drug information [34, 38]	
Participation in multi-disciplinary ward rounds and meetings [33, 34]	
Optimisation of TPN [38, 40]	
Optimisation of IV formulations [38]	
Use of pain scales [30]	
Use of pain protocols for patient groups and specific procedures [30]	
Participation in clinical research [33, 34]	
Verification process, medicines and calculations checked by another licensed healthcare professional before administration [35]	
Critical incident/root case analysis [28, 35]	
Prescribing error feedback programme [31]	

Table 3 continued

Outcome	Source of information: [45] EDQM, [42] India, [1] New Zealand, [43] UK, [17, 27, 30, 44] USA, [40] WHO
Monthly audit of medication charts with a target of at least 80 % correct time of administration (wrong time was defined as more than 1 h of prescribing for STAT/PRN meds, and for regular meds dose not given prior to the next scheduled dose) [1]	
Monthly audit of the labelling of all lines—to be labelled with access type and fluid/medication being administered with a target of at least 90 % correct labels [1]	
Monthly audit of prescribing against prescribing guidelines—target 90 % [1]	
Episodes of ineffective empiric antibiotic therapy (organism/antibiotic mismatch) [27]	
Mean time to target vancomycin trough concentration for infants with known MRSA infection [27]	
Proportion of infants receiving appropriate dosing and timing of perioperative prophylaxis [27]	
Episodes of antibiotic-associated adverse events [27]	
Duration of treatment for culture-negative presumed late-onset sepsis [27]	
Rates of infections with multidrug-resistant gram-negative infections [27]	
Percentage of patients who received at least one pain management intervention during heel sticks, PIV insertions, venipunctures, umbilical arterial catheterisations, nasogastric tube placements and ETT suctioning [30]	
Percentage of all defined procedures that were treated with a pain treatment intervention [30]	
General healthcare outcome measures related to neonatal patients:	
Incidence of nosocomial infection [17, 40, 42]	
Incidence of neonatal sepsis [17, 42]	
Length of stay [17]	
Days on TPN [17, 40]	
Growth velocity (daily weight gain) [17, 40]	
Mortality rates [17, 42–44]	
Pharmacotherapy-specific outcome measures as proposed by the EDQM [45]:	
Medication error rates/reports	
Adverse drug event rates/reports	
Number of pharmaceutical care interventions performed	
Dispensing errors rates/reports	
Number of parents counselled	
Costs of drug therapy	
Costs saved	

CDSS clinical decision support systems, *CPOE* computerised physician order entry, *EDQM* European Directorate for the Quality of Medicines, *ETT* endotracheal tube, *IV* intravenous, *MRSA* methicillin-resistant *Staphylococcus aureus*, *NICU* neonatal intensive care unit, *PIV* peripheral IV, *PRN* as needed, *STAT* immediately, *TPN* total parenteral nutrition

sufficient rest breaks to prevent fatigue errors from occurring [35, 38]. The British Association of Perinatal Medicine (BAPM) guideline recommended that, due to the complex needs of infants in the NICU, the ratio of neonatal nurses should be one nurse: one baby, and medical staff should consist of a minimum of eight staff comprising specialists, consultants and residents [38].

The amount of time required and the capacity for pharmacists to provide pharmaceutical care in the NICU was also emphasised as a relevant structure measure. The BAPM guideline recommended that NICU pharmacists should allocate at least 10–20 min of time (care) per patient-cot, as well as attend medical ward rounds and meetings [38]. The Australian standard proposed an alternative method of pharmacist involvement, by allocating pharmacist time to the NICU according to the complexity of care within a specific unit (Level 1: caring for infants with minor conditions with gestations >37 weeks; Level 2: caring for newborns with gestations >34 weeks and requiring incubation, oxygen and intravenous therapy; Level 3: caring for newborns with serious conditions requiring 1:1 nursing care) [Table 1]. It was recommended that Level 1 and 2 NICUs required routine pharmacist access; however, Level 3 NICUs required a 24-h pharmacy support service to be available [36].

In addition to staffing, four structure measures reported that specific facilities were important requirements for the QUM in NICUs. A well-lit work environment, with sufficient work-space, minimal distractions and easy access to reference materials was described as optimal for medication safety [35]. Additional important elements also included space within the unit for medication preparation

and aseptic preparation sites [36, 38]. This was further verified by the WHO quality assessment tool, which specifically recommended that essential medicines (such as caffeine and surfactants) are readily accessible for the timely application of pharmacotherapy [40].

Structure measures were also associated with the availability of medication management systems. In maintaining medication safety, two guidelines and one quality assessment tool identified the need for evidence-based clinical practice guidelines and protocols for high-risk medications within the NICU to assist with medication selection and administration, as well as standard references to assist the general prescribing of medications for neonates [34, 35, 38, 40]. Additionally, it was acknowledged that it was important to have clear, specific policies that were accessible to all healthcare professionals on how medications in the NICU were prescribed, processed, dispensed, administered and monitored [35]. Total parenteral nutrition (TPN) was highlighted as an area requiring additional attention, and it was reported by Grissinger as requiring standardised prescribing methods, including preprinted forms or standard order sets that prompted correct dosing, established threefold verification of TPN dispensing and administration processes, as well as automated dose limit warnings built into pharmacy computer systems [23]. Other measures suggested for the improvement of medication safety included the availability of emergency medication sheets, listing doses by weight, as well as an established neonatal formulary with standardised concentrations of medications to be used in the NICU [25, 28, 35].

Several resources referred to the utilisation of technology to promote the safe and rational use of medicines. These resources included barcode verification systems, smart-pumps, computerised physician order entry (CPOE), clinical decision support systems (CDSS), computerised calculation of doses, automated drug dispensing robots and electronic health records [24–26, 28, 29, 32, 35]. Morriss et al. attributed a barcode-verified administration system with reducing the risk of targeted, preventable adverse drug events in neonatal patients by 47 % [29]. Furthermore, in the event of an adverse reaction or medication error, three resources identified that it was essential for the NICU to have a reliable electronic reporting system to document the implicated medications [33–35, 38]. These systems allow for the collection of data regarding the types and causes of error, and allow for the identification of trends in error [22]. McCartney states that an electronic database can identify more errors than a paper-based reporting method and can facilitate a retrospective analysis of errors [26]. Furthermore, these types of systems enable drug usage data to be tracked. Ellsbury and Ursprung reported that medication misuse could be attributed to failures in collection, reporting and review of drug utilisation data by NICU treating teams [22]. Drug utilisation data provide an insight into patterns of use and allows for benchmarking against other databases [22].

Measures of quality relating to process

Process measures were deemed by de Boer et al. to be the best method of evaluating the QUM in NICUs, as they identify factors directly associated with patient care [41]. Process measures relating to NICU medication practice were well documented within the literature, and can be divided into three categories: clinical pharmacist interventions, education/training, and documentation and monitoring of medication-related problems. Clinical pharmacist interventions were related to the number and type of interventions performed, including therapeutic drug monitoring, review of patient medication charts, participation in ward rounds, verifying prescriptions, participating in clinical research, and optimising intravenous and TPN therapy [28, 32–35, 38]. The British NICE and BAPM guidelines identified that clinical pharmacist activities improved the quality of medication management in NICUs, as these roles improved the rationalisation of resources and reduced costs and medication errors [38, 39]. Four measures were related to medication information services, and involved pharmacists providing a medication counselling service to parents, providing general medication information to other NICU professionals, and educating NICU staff on medication protocols. In particular, it was noted that involving parents in the care process was important in achieving quality pharmaceutical care, and required regular communication and consultation with parents in making decisions about pharmacotherapy for their child [39]. Furthermore, only one standard identified the need for pharmacists to advise physicians regarding the use of off-label and unlicensed medicines, including the choice of medication and the type of formulation required [38]. Potentially more attention may be required in this area, as a significant proportion of medications are prescribed off-label or on an unlicensed basis in NICUs.

Education was viewed as an important element to the QUM in the NICU in ensuring uniformity and currency of medication management practice [1, 32–35, 38]. Specifically, the National Association of Neonatal Nurses position statement highlighted the importance of providing education to NICU staff involved in the medication use process on medication safety principles, the appropriate use of medication delivery devices, calculating doses, as well as appropriate prescribing, preparing, and administering of medications [35]. Kunac and Reith highlighted that higher rates of medication errors occurred when new or intern doctors join the neonatal team, but noted training on safe prescribing practices was rarely provided to these staff [1].

Furthermore, two position statements and one guideline emphasised the importance of the pharmacist in monitoring

and reporting and adverse drug events in neonatal patients [33, 34, 38]. It is acknowledged that adverse drug reactions are avoidable when documentation is complete and readily accessible, leading to increased patient safety [38]. In response to any errors that occur, two resources identified that critical incident or root cause analyses should be thoroughly conducted to identify how these errors occurred and to develop strategies and action plans for preventing their recurrence and addressing flaws in the medication use process [28, 35].

Pain management is highlighted as a high-risk area of practice in the neonatal population, with reports of over-prescribing of opioids, as well as adverse effects from opioids. Sharek et al. suggested process measures to improve pain assessment and management of neonates experiencing pain in the NICU, including the use of pain scales for assessment of patients to determine appropriate pain management, as well as the use of pain protocols for patient groups and specific procedures [30]. Additionally, Sullivan et al. found that the use of a prescribing error feedback programme, which reported back to prescribers on trends in opioid prescribing errors in their NICU, as well as on their own prescribing errors over the previous fortnight, was associated with a relative reduction in opioid prescription errors of 83 % [31].

Measures of quality relating to outcome

It was reported that, due to multiple treatment modalities and multidisciplinary staff, outcome measures were the most difficult to attribute to the QUM [41, 42]. However, Kunac and Reith highlighted several outcome measures that were related to the QUM in the NICU, including monthly audit of medication charts (with a target of at least 80 % of correct time of administration), monthly audit of the labelling of all parenteral fluid/medication lines (to be labelled with access type and fluid/medication being administered, with a target of at least 90 % correct labels) and monthly audit of prescribing against prescribing guidelines (target 90 %) [1].

Furthermore, important areas of practice identified as being high risk in neonatal patients included antimicrobial therapy and pain assessment. Outcome measures related to antimicrobial therapy were dedicated to monitoring antibiotics that were used most frequently in the NICU, and which also incurred the most costs, had the greatest risk of toxicity or the greatest risk of inducing antibiotic resistance [27]. Pain management measures were related to the number of appropriate pain management interventions prescribed [30].

Five resources also identified more general outcome measures relevant to the health care of the neonatal population [17, 40, 42–44]. The most commonly identified measures referred to the mortality rate of infants in the NICU, as well as the incidence of patient morbidity, neonatal sepsis and nosocomial infection, the duration of TPN therapy and daily weight gain [17, 40, 42–44]. However, it is unknown to what extent these measures are influenced by medication use or whether they directly reflect the QUM in the NICU.

We also sought to identify outcome measures that were relevant to the QUM, but were not specific to a particular patient population, but might be relevant to the NICU [45]. These included the number of medication errors, adverse drug events, pharmacist interventions performed and the costs of drug therapy [45]. Furthermore, another study was identified with outcome measures that may be applicable to the neonatal population [46]. These included quarterly dispensing errors (target <5 %), drug-related problems (target <10 %) and pharmacist participation in research projects (target >1 publication/conference) [46].

Discussion

To our knowledge, this is the only review that identifies the range of quality measures relevant to medication use within the neonatal population. A total of 47 measures within the 20 sources of literature were identified relating to the QUM in the NICU (Table 3). The majority of these measures referred to the structure and process domains and most commonly described the availability of medication safety technology in the NICU, written policies on the use of high-risk medications, medication error and adverse drug event reporting systems, and the provision of education for health professionals involved in the medication use process. The literature collected did not comprehensively address medication management in each phase of the medication use process. Most of the quality measures identified referred to the prescribing of medications, with less attention paid to medication dispensing and administration. As such, the findings of the review inform the need for a framework of quality measures to be developed that represents the QUM in the NICU. Such a framework would allow for the benchmarking of medication usage in the ward, tracking the performance of medication-related processes and identification of areas requiring improvement.

Current studies that identify quality measures in the NICU are predominantly based in other fields of healthcare (i.e. nursing) and do not relate to the QUM [17]. One study related to nursing and physician care by Profit et al. designed the baby-MONITOR quality framework, which involved the use of clinical indicators including timely retinopathy of prematurity examinations, oxygen at 36 weeks and rates of first-hour hypothermia [47]. Other nursing literature has used general NICU-based health indicators to establish the level of quality healthcare being delivered and has measured the number of incubators available, nursing staff levels, incidence of intraventricular haemorrhage and rates of necrotising enterocolitis [19, 48, 49].

Studies that do identify medication-based quality measures are not studied within NICU settings. Within the elderly population, several studies emphasise the use of the ACOVE set of quality indicators that measure the processes of pharmaceutical care in both hospitalised and community-based settings, including the rates of prescribing appropriate medications, therapeutic drug monitoring, correct transcribing of medication orders and comprehensive discharge summaries [12, 50]. It is unknown whether quality measures assessing medication management in adult patient groups are relevant to medication processes in the NICU. However, it is recognised that specific quality indicators need to be adapted to particular patient groups; for example, in the instance of surgical patients, the measurement of the rates of patients receiving suitable perioperative antibiotic prophylaxis [41].

Upon birth, neonates are already at a high risk of mortality, with a reported two-thirds of neonatal deaths occurring within the first week of life [51]. In addition, once admitted to the NICU, patients are also subjected to complex pharmacotherapy regimens, increasing the potential for medication error, which may further compromise the health of these patients [5]. Quality indicators are necessary to improve medication safety in the NICU, as they facilitate transparency of medication-use processes and help to benchmark NICU performance [9, 52]. As of yet, there are no reliable and valid quality indicators available in the literature that clearly define and evaluate the QUM in the NICU. More attention should be paid to the development of measures that assess each phase of the medication use process and address pharmacist, as well as nursing and clinician input.

Limitations

Due to the lack of good-quality literature exploring this area, it is difficult to determine whether the key measures identified are applicable to current practice. Relevant literature from Asia, Africa and South America was not available, precluding a truly global perspective. It is also possible that a large number of studies were excluded due to not being available in the English language.

Conclusion

Quality measures within the NICU were most frequently identified within the structure and process domains, with limited outcome measures specific to the QUM in the NICU. The most common measures were related to the availability of medication safety technology in the NICU, written policies on the use of high-risk medications, medication error and adverse drug event reporting systems, and the provision of education for health professionals involved in the medication use process. However, there were no validated quality indicators specifically evaluating medication use in the NICU. Further research is required to address these gaps in knowledge and develop a quality framework that identifies key quality measures that facilitate appropriate and quality use of medicines in the NICU.

Compliance with ethical standards

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L.7 PHARMACIST PERCEPTIONS ON THE NEED FOR A QUALITY GUIDANCE RESOURCE FOR PHARMACY SERVICE PROVISION IN THE NEONATAL INTENSIVE CARE UNIT: COMPARISON BETWEEN POLAND AND AUSTRALIA

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Pharmacist perceptions on the need for a quality guidance resource for pharmacy service provision in the neonatal intensive care unit: comparison between Poland and Australia

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Abstract

Objectives There is no global consensus on services and roles that should be performed by a clinical pharmacist in the neonatal intensive care unit (NICU). Furthermore, there are no quality guidance resources or key performance indicators (KPIs) available to guide pharmacist practice in this setting. The purpose of this research was to explore pharmacist perceptions on the need for, and development of, a NICU-specific quality guidance resource containing KPIs for pharmacy service provision.

Methods Semi-structured interviews were conducted with directors of pharmacy as well as neonatal pharmacists in Poland and Australia. The interviews were conducted between February and August 2017.

Key findings Overall, three key themes were categorised around the study objectives: (1) Lack of guidance in the provision of NICU pharmaceutical care services, (2) Embracing a pharmacist-specific, quality guidance resource for the NICU and (3) Constraints limiting the use of quality guidance resource. None of the participants from either country were able to identify any readily available NICU-specific quality guidance resources for pharmacists. However, the majority of participants from both countries were open towards the development of a quality guidance resource and felt that this would be useful. Differences between countries were noted when considering the type of pharmacy practice models functioning in each country and the perceived barriers to implementing the proposed quality guidance resource into practice.

Conclusion Although there are significant differences in the type of pharmacist practice systems functioning in each country, pharmacists in both Australia and Poland demonstrated significant support for the development of a quality measurement tool to guide and structure practice in the NICU and recognised benefits to its implementation. Future efforts should focus on the development of quality measures that can be adapted to different NICU settings, both on a national scale and international scale.

Keywords clinical pharmacy; neonatal intensive care unit/neonate; quality measurement/key performance indicators

Introduction

The management of pharmacotherapy within the neonatal intensive care unit (NICU) is complex and requires the guidance of a pharmacotherapeutics expert.[1] Due to their unique characteristics, comprising considerable interindividual differences in pharmacokinetics, birthweights and gestational ages, neonates are particularly vulnerable to sustaining medication errors.[2] Furthermore, this patient population is prone to experiencing significant consequences as a result of medication misadventure.[2] As such, the role of the pharmacist within the specialist area of neonatology is continually advancing towards more direct involvement in patient care.[3] Indeed, the benefits of pharmacist interventions include reduced incidence of medication errors, optimisation of total parenteral nutrition (TPN) regimens and better rationalisation of pharmacotherapy.[4–7]

It is evident that pharmacist practice varies in NICU settings both on a national scale and international scale.[8] A recent study by Krzyżaniak *et al.*[9] highlighted that pharmacy services delivered to NICU settings in Poland and Australia differed significantly,

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with the focus of practice in each country centred on dispensary-based and clinical, ward-based services respectively. Further research by Pawłowska *et al.*[10] investigating general hospital pharmacy practice in Poland supports these findings and demonstrates that the concept of clinical pharmacy is not yet widely adopted in Polish hospital settings, and pharmacists are often stationed predominantly in the dispensary and limited to medication supply roles. In contrast, Australian studies suggest that pharmacists are integrated into the interdisciplinary team and have a large input into ward-based pharmacotherapy-related decision-making as well as other clinical roles including medication chart review and therapeutic drug monitoring (TDM).[11,12] This variability in practice may impact upon the outcomes achieved by vulnerable neonates.

There have been efforts made from the International Pharmaceutical Federation (FIP) and the World Health Organisation (WHO) to improve the standardisation of pharmaceutical care services through the publication of standards, such as the Good Pharmacy Practice (GPP) guidelines.[13] However, it is apparent that there are no guidelines available to direct pharmacists in their clinical practice in specialty areas of pharmaceutical care, such as the NICU.[13] A literature review reported that there are currently no established key performance indicators (KPIs) to serve as a point of reference for neonatal pharmacists.[14] Whilst existing standards for pharmacy practice in critical care settings might have applicability, as well as non-pharmacist guidelines from neonatal societies, pharmacist-specific NICU-based guidelines are particularly important in the care of critically ill infants for the provision of a consistent and quality pharmacy service.[15,16] KPIs are an effective means of gauging the quality of healthcare services being provided and in determining the potential to improve this level of care for patients.[17] They also have the potential to standardise care provided in comparable hospital settings, through the process of benchmarking.[18]

Due to the apparent variability in pharmacist practice in NICU settings within and between countries, there is a need for KPIs or quality practice guidance resources to be made available to promote the standardisation of pharmacist practice in this high-risk and fragile patient group.[8] As there is currently a lack of NICU-specific quality frameworks targeted at pharmaceutical care services, it is important to gain an understanding of whether pharmacists working in these settings require or even want a resource of this nature to be developed. It is prudent to understand pharmacist perceptions not only within but also between countries, and comparing those with a more advanced level of pharmacy practice to nations that are refining their hospital pharmacy services. This form of comparison will enable the identification of overlapping perceptions and potentially strengthen the argument for the development of a global resource. Therefore, this study aimed to canvass pharmacist attitudes from two industrialised countries with differing pharmacy service structures – Poland and Australia – towards the development of a quality guidance resource to assist in the medication management process in neonatal patients.

Specific objectives included:

1 Determining whether pharmacists currently used any practice frameworks or models to guide their practice in the NICU.
2 Determining whether pharmacists felt a need for a quality guidance resource to be developed.
3 Identifying potential barriers and benefits to the implementation of this resource into practice in each country.

Method

Study design

A qualitative study, comprising semi-structured individual interviews with Australian and Polish NICU pharmacists, hospital pharmacists and directors of pharmacy, was undertaken between February and August 2017. A qualitative approach was used as it was deemed the most suitable method for this exploratory research, enabling a fuller understanding of the context behind pharmacist opinions and attitudes, as well as the perceived needs of pharmacists in improving existing practices and beliefs. Ethics approval was sought and obtained from the respective human research ethics committees at the University of Technology Sydney (UTS), Australia (UTS HREC REF NO. ETH16-1033) and the Medical University of Gdansk (GUMed), Poland (GUMed HREC REF NO. NKBBN/424/2016).

Participants were assured of confidentiality and were informed that their responses would be de-identified.

Australia and Poland as comparators

Poland and Australia were specifically chosen as comparators in this study for several reasons. First, traditionally, there is minimal collaboration between Eastern European countries and Western countries that have a more advanced level of pharmaceutical care, such as the USA, Canada, Australia and New Zealand. A literature review highlighted that the majority of published data investigating pharmacist practice in the NICU originates in the USA, with little to no equivalent or comparative research performed with European countries.[8] The WHO highlights that transnational collaborative research is important in stimulating the adoption of coherent policies and establishing best practices.[19] Therefore, there is a need to expand research horizons to encompass a more global perspective, to encourage the formation research alliances between nations that are not often highly publicised. This research follows on from previous studies that the authors have performed investigating pharmacist practice in these two countries. A comparison between Australia and Poland was thought to be useful in providing a new and unique perspective on pharmacist practice in NICUs. Due to the variability in NICU pharmacist practice between these two countries, this comparison also enabled a fuller understanding of the range of potential barriers limiting the implementation of standardised practice guidelines and KPIs for pharmacists in this area of practice.

Setting and participants

Purposive, homogenous sampling was used to recruit participants.[20] This method was thought to be the most appropriate form of recruitment as it 'focuses on one particular subgroup in which all the sample members are similar, such as a particular occupation or level in an organisation's hierarchy.'[21] The objectives of the research were specific to the characteristics of the particular group of interest (NICU pharmacists), which was then subsequently examined in detail.[22] Participants were recruited based on the following inclusion criteria:

1 Registered pharmacists, with at least 1 year of hospital pharmacy experience.
2 Practicing within hospitals containing a NICU, providing either direct or indirect pharmaceutical care to the NICU as pharmacist or director of hospital pharmacy.

In this case, indirect pharmacy services refer to dispensary-based roles that include but are not limited to extemporaneous compounding, administrative activities and dispensing. Direct pharmacy services refer to ward-based, patient-direct services including medication chart reviews, TDM and counselling of parents.

In Poland, clinical pharmacy is not yet well-established in hospital settings, and as such pharmacists do not commonly practice on wards. Therefore, participants in this country were included in the study if they identified as hospital pharmacists who provided some form of pharmaceutical care services (i.e. direct or indirect, as described previously) for the NICU.

Participants were contacted via email through the Paedpharm online pharmacists group and through publicly available registers in Poland, (Register of Facilities delivering Medical Activities [Rejestr Podmiotów Wykonujących Działalność Leczniczą] – RPWDL), and Australia, (Australian and New Zealand Neonatal Network – ANZNN) that identified hospitals with NICUs. Paedpharm is an online paediatric pharmacy network that provides pharmacists in Australia and New Zealand a forum to exchange information related to paediatric therapeutics.[23] Furthermore, participants were identified from a previously performed study, involving an online questionnaire relating to pharmacy services provided in NICUs in Australia and Poland.[9] At the end of the questionnaire, participants were asked whether they would be interested in participating in further research, involving semi-structured interviews related to the development of a quality guidance resource for pharmacy practice the NICU. Individuals, who voluntarily expressed their interest to participate, were then provided the full study details.

To ensure as minimal as possible disruption for participants, interviews were organised to be conducted at times and locations that were convenient for the participant (i.e. in their workplace), and the researcher (NK) travelled to the participant. In the instance that the distance between the researcher and participant was too great, interviews were conducted over the phone. The researcher (NK) travelled to participants in both countries. Decisions to conduct interviews over the phone were based on the location of the researcher at the time, that is either in Gdansk, Poland or Sydney, Australia and depended on whether the participant was easily reachable by car or public transport.

Each participant was made aware of the personal goals of the lead researcher in publishing this research as a part of her PhD thesis. The sample size was based on the number of participants targeted to achieve data saturation and was set at a minimum of 10 participants in each country (10 Australia, 10 Poland).[24] Guest *et al.*[24] state that for interview studies which 'aim to understand common perceptions and experiences among a group of relatively homogeneous individuals, twelve interviews should suffice to attain data saturation and enable the development of meaningful themes and useful interpretations'.

Data collection

For consistency, each interview was facilitated by one researcher (NK) using a purpose-designed interview guide. The interview guide was adapted from a previous study by Minard *et al.*[25] who used focus groups to identify pharmacist perceptions on the implementation of clinical pharmacy KPIs in hospitals in Canada. The interview guide comprised six key open-ended questions, which canvassed the opinions of pharmacists towards the development of a quality measurement tool:

1 What are the guidelines or practice models that you refer to that identify what pharmacist roles or pharmacy services should be performed in the NICU?
2 Which documents contain KPIs or quality indicators that are tailored to pharmacist practice and medication management specifically in the NICU?
3 Would you like to see an integrated document comprising a quality guidance resource, which includes a list of clinical pharmacy KPIs specifically tailored for the NICU? Why?
4 What kind of items would you like this resource to contain?
5 What would encourage the use or the implementation of this type of document into the NICU?
6 What are the barriers that you can think of that could oppose its implementation?

The interview guide was pilot-tested for question clarity prior to use. The average interview time was approximately 20 min. Field notes were taken during the interviews, and each interview was digitally (audio)-recorded and later transcribed verbatim by one researcher (NK). No repeat interviews were carried out as all the relevant information was obtained during each individual interview. Each interview was conducted with participants in their native language, that is English and Polish. For all interviews that were performed in Polish, the transcripts were translated into English via a tiered process; transcripts were translated from Polish to English by one researcher (NK); these translations were edited and verified by two researchers (IP, BB) to determine whether the language was correct. All transcripts were returned to participants in both Poland and Australia for review and editing. To ensure ease of readability, the qualitative responses of participants are represented by the code 'AP' for Australian pharmacists and 'PP' for Polish pharmacists.

Data analysis

The interview transcripts were thematically analysed. Manual inductive coding was used, whereby after transcription, each interview was repeatedly read and the transcript annotated with significant statements from participants responses. Subsequent analysis of these statements led to their categorisation into key themes around the study objectives.[26] The information obtained was triangulated through the participation of a team of investigators. Three researchers (NK, BB and IP) independently evaluated the data to ensure the appropriate interpretation of data into descriptive themes in line with the existing questions and study objectives. These initial themes were compared, checked and verified to attain consensus. A pragmatic approach was used to frame the analysis, which allows data to be analysed without the limitations of any specific philosophy.[27]

Results

Of the 18 pharmacists in Australia, and 20 pharmacists in Poland invited by the research team, 15 from each country agreed to participate, with a total of 30 interviews taking place. Of the total group, five participants from Australia, and seven from Poland were participants from a previous study relating to pharmacist practice in the NICU. Thematic saturation appeared to have been achieved with this number of participants in each country, with no new information emerging from interviews; therefore, no further sampling was conducted. Participant characteristics are presented in Table 1. The majority of Australian participants identified themselves as NICU pharmacists and had 1–5 years working experience. In comparison, most Polish pharmacists reported that they were general hospital pharmacists based in the dispensary, and 73.3% had over 10-year work experience.

Three key themes were explored during the interviews held with Australian and Polish participants:

1 Lack of guidance in the provision of NICU pharmaceutical care services.
2 Embracing a pharmacist-specific, quality guidance resource for the NICU.
3 Constraints limiting the use of quality guidance resource.

Lack of guidance in the provision of NICU pharmaceutical care services

None of the participants were able to identify any NICU-specific quality guidance resources for pharmacists (Table 2). In Australia, pharmacists referred to in-hospital practice standards and training workbooks, however, stated that these were all developed by hospitals individually and not shared between sites. Two pharmacists highlighted resources from the pharmacy board as well as state-wide policies; however, these were general resources for all hospital pharmacists and were not specific to the NICU.

> I'm not aware of any particular guidelines or practice models for a NICU framework. AP3

Table 1 Demographics

	Australia (%)	Poland (%)
Number of respondents	15	15
Gender of respondents		
Female	11 (73.3)	14 (93.3)
Qualifications		
Bachelors degree	4 (26.7)	0
Masters degree	7 (46.7)	14 (93.3)
PhD degree	1 (6.7)	1 (6.7)
Postgraduate certificate/diploma	3 (20)	0
Specialised qualifications/training		
Yes	1 (6.7)	2 (13.3)
Centralized intravenous additive services (CIVAS)/Total parenteral nutrition pharmacist	1 (6.7)	0
Clinical pharmacy	0	2 (13.3)
No	14 (93.3)	13 (86.7)
Position in the hospital		
Neonatal intensive care unit pharmacist	10 (66.7)	0
Director of pharmacy	3 (20)	4 (26.7)
Pharmacist working in main hospital pharmacy		11 (73.3)
Other		
Deputy director	1 (6.7)	0
Specialist women, youth and children pharmacist	1 (6.7)	0
Experience		
<1 year	2 (13.3)	0
Between 1 and 5 years	9 (60)	0
Between 6 and 10 years	2 (13.3)	4 (26.7)
>10 years	2 (13.3)	11 (73.3)

Table 2 Pharmacist perceptions

	Australia $N = 15$ (%)	Poland $N = 15$ (%)
Are there any guidelines/Practice models/Key performance indicators (KPI'S)/Quality indicators that you are aware of that pharmacists can use to guide their medication management specifically in the neonatal intensive care unit (NICU)?		
Yes	0	0
No	14 (93.3)	12 (80)
Unsure	1 (6.7)	3 (20)
Would you like to see an integrated document comprising an ideal practice model, which includes a list of clinical pharmacy KPI's specifically tailored for thE NICU?		
Yes	15 (100)	14 (93.3)
Not achievable with current system	0	1 (6.7)
Do you believe that the current model of pharmaceutical care practice in your country works and meets the needs of NICU patients?		
Yes	13 (86.7)	3 (20)
No	1 (6.7)	11 (73.3)
Unsure	1 (6.7)	1 (6.7)

> We don't have specific NICU KPIs at this point in time. AP4

In comparison, Polish participants highlighted that the only resource available that dictated what roles a pharmacist

was to perform was the pharmaceutical legislation, and similarly to Australian responses, comprised a general list of services for all hospital pharmacists and did not define services for the NICU.

> According to the pharmaceutical law, the pharmacist should prepare TPN, cytotoxic medicines (if they are being prescribed) and to participate in clinical research. That is all the law states. It is generalised, not specific to this ward. PP14

> No – everything is generic. There are no indicators that I am aware of, the only ones are those related to oncology wards with chemotherapy... When considering neonatology, I haven't heard of anything like this. PP8

Embracing a pharmacist-specific, quality guidance resource for the NICU

All Australian participants and 93.3% of Polish participants were open towards the development of a quality guidance resource and felt that this would be useful. The remaining Polish pharmacist, whilst seeing the benefit of such a resource, highlighted that its implementation into the Polish healthcare system would be unsuccessful and unachievable due to the underdeveloped nature of pharmaceutical care in hospitals and did not feel it was relevant for current day practice.

The criteria of this resource varied slightly between countries. Polish pharmacists viewed this resource as more of an introductory framework outlining what clinical services should look like in the NICU, rather than as a quality assessment tool. Respondents highlighted that they were unsure what clinical services to provide to the NICU, as they mostly functioned at a distributive level of practice, and they wanted to have a point of reference clearly outlining what was expected of them. This was viewed as being valuable for pharmacists to advance their level of practice and strengthen their clinical roles in ward-based medication management. This type of document was also perceived as an effective means of communicating and asserting to the NICU medical and nursing staff, as well as to hospital management that the pharmacist is a valuable contributor to the therapeutic team. Interestingly, several pharmacists commented that there needed to be a clear distinction between the role of the doctor and the pharmacist in the NICU, with a definition of what each profession was responsible for so as to not intrude on each other's competencies. Other elements that were proposed included: pharmacist to bed ratios, information on the types of medications used in NICUs as well as examples of commonly encountered medical conditions and their treatment.

> I would be more inclined to view it as a way to strengthen the position of the pharmacist and the role of the pharmacist in the treatment process. It also increases knowledge of the role of the pharmacist and what they can do to help improve the general care of the patient comprehensively, from the beginning to the end, taking into account each aspect. I see this document providing highly positive contributions. PP2

> Definitely a list of services, definitely how many pharmacists would be needed to service a specific ward. An indication of our legal rights, so what we are able to do and what we are responsible for, and what not to become involved in and what should be left for the doctors and nurses. PP14

Alternatively, as clinical pharmacy is readily practised in Australia, the proposed resource was viewed as having potential as a standard of practice that outlined the niche roles of the pharmacist in the NICU and distinguished pharmacists in this subspecialty from general clinical practice. As such, participants commented that it would be used as a means of maintaining a standardised, quality level of care and also as an accreditation document, proving that these standards were being met. Participants also referred to the inclusion of KPIs in this resource, which was perceived as elements that would allow pharmacists to better prioritise their time on roles deemed to be important to the quality use of medicines as well as allow the monitoring of pharmacist performance. Furthermore, the proposed quality guidance resource was identified as being a good training kit for new pharmacists coming into this field, needing the inclusion of educational information comprising an overview of the physiology of the neonate, medications used in the NICU and useful resources to refer to.

> I think it would be a good educational tool, not only for pharmacists who have perhaps been doing that role for a long time, but also for newer pharmacists, more junior pharmacists in their career who may need to cover that area or be on call for that area. I think it would be a good tool to document practice and advocate for that subspecialty. AP3

> The SHPA (Society of Hospital Pharmacists Australia) have recommended hours and bed numbers for NICU and special care nurseries... it would be useful to have some recommended tasks and what the key performance indicators should be. Maybe minimum medication safety components as well... it would be good to have recommended texts, minimum texts, minimum standards or minimum guidelines and staffing as well that would be good. AP2

Both Australian and Polish participants highlighted that that they would like this resource to contain a list of pharmaceutical services that should be provided to the NICU to uphold a minimum standard of quality care (Table 3).

> I think a list of pharmaceutical services – this should be outlined, what clinical pharmacists are responsible for. PP15

> I think a breakdown of the role a pharmacist actually has to play in the NICU would be good. Like expectations, I guess of what a pharmacist could contribute to the role. AP6

Table 3 What should a quality guidance resource contain?

Poland	Australia
. . .what it means to be a pharmacist working on this ward, with a list of activities that a pharmacist would have to fulfil. A scope of practice. Also the relevant legislation and responsibilities – I believe that this should be defined in detail. PP1	Some specific recommendations around therapeutic drug monitoring in the NICU. . . what should be specific around these guidelines is the differences between the services in a neonatal unit and a more general intensive care unit or a general or paediatric unit. And so its highlighting what sort of differences pharmacist's who are providing services in the NICU need to be aware of and cognisant of for the babies. AP1
For sure, something would have to be written that highlights the scope of our responsibilities, what we can do, and what they will ask us. In the sense that examples should be provided of dosing for certain indications. The scope of our responsibilities, whether we are only able to advise or are we responsible for this service, and who signs off on this service. Well, it would be good if there was some sort of guideline prepared by pharmacists relating to the administration of medicines, because on the ward they have their own standards (where to administer, how much and how). PP5	I think it should be written by NICU pharmacists who know the business, who have been working there for a while, and should include perhaps things like, recommended reading for people new to the area. It should include information on the conditions the patients have, information on current and up-to-date treatments, medications. . . It should include those KPI's that should give guidance to help those experienced NICU pharmacists, junior NICU pharmacists and also the people who manage them to know what they do. If they are supposed to go in there 40 hours a week, what are they supposed to be doing, how do we know if they are doing the right thing? I think it demonstrates to management, to the executives at the hospital, to medical staff and to nursing staff that this is why we are doing what we are doing. AP3
I definitely think a list of pharmaceutical services, because a pharmacist who would have to practice on this ward would have to know what they are responsible for. You would have to define the role of the pharmacist and the role of the doctor so that there is no confusion. There would also have to be a ratio of how many pharmacists per beds, because without this I think the hospital management is likely to take short-cuts, and having a single pharmacist on the ward might exhaust them. PP6	Minimum required services for certain levels of care. Like a competency assessment model that contains what the requirements are, what are the competencies that should be met for those standards. That would be useful. KPIs that are within that as well that should be monitored. AP10
I would want some information on what medications are used on this ward, and then it would possibly be easier for us to identify relevant literature that would be useful. . .. Some standards of conduct for the neonatal ward, or what to do in difficult situations which are not covered by the existing standards. PP11	I think it would be really good to have basics regarding the infant and the neonate. So looking at their care, what problems that you would see, just basic – these are the air-pressures that you would see in a neonate, this is what you are likely to see in terms of their lines and what's going on with their lung functions and those things. And then where the medication fits in there. And then what is expected for you to look around that. AP11
It would be great if it included the roles of the pharmacist and I think it would be easier for us and for the nurses and doctors to understand what we do. Because they would see that these are our duties, this is what we do and I think there would finally be some sort of organisation. There would be greater control over what happens on the ward. PP12	I suppose if you use something like the SHPA (Society of Hospital Pharmacists Australia) standards of practice as a model document, I think that does include aspects around the core components. The only other aspect is around training and education resources. There is a lot of interest around up-skilling staff, so its one thing to tell people this is what you should be doing but they need to have the skills to be able to interpret what they are looking at. This is extremely important in the neonatal setting, some of the drugs they might not have seen before, that type of thing. AP13

> Its an important component of practice for people to understand what their roles are, but also to give them an insight into aspects of their clinical roles that they might not have necessarily thought about, and aspects of their clinical role that they might not have thought about being able to evaluate. AP13

Constraints limiting the implementation of quality guidance resource

Common barriers to the implementation of the proposed resource across both countries included financial constraints, legislative issues, problems associated with the healthcare system and pharmacists possessing the necessary level of neonatal education or training and experience (Table 4).

Finances

Funding was identified as a major barrier in both Australia and Poland to implementing any resource promoting an advanced form of clinical practice on the NICU. Polish participants reported that currently, funding opportunities for the pharmacy department were scarce, resulting in the employment of only a few pharmacists per hospital. The majority of Polish pharmacists recognised that the implementation of the proposed resource would require the engagement of more pharmacists, which the system would simply not be able to afford. Therefore, as a result the limited number of pharmacy staff available at each hospital would also impact upon the uptake of this resource, simply because there are not enough people to do the work required.

> I think first and foremost, there are financial barriers in hiring pharmacists for this position. If pharmacists were to work on the wards, then they would have to hire 4 or 5 times more pharmacists than we already have. Unfortunately, when considering funding, then it is not good. PP13

Similarly, Australian participants referred to financial constraints relating to sourcing funding opportunities specifically for the employment of pharmacists in the NICU to provide the required level of services outlined in the proposed resource. One pharmacist commented that this correlated with the level of value that pharmacy management associated with this service and allocating the relevant funding against other competing resources.

> The ultimate barrier is around management and management's perception around the role and value of pharmacy services in that area. If you tried to summarise that, it is on the one hand funding and the availability of funds to employ pharmacists to provide the level of service. AP13

Education and experience

Pharmacists in both countries also voiced concerns regarding the level of neonatal-based training available to up-skill pharmacists. Some Australian pharmacists commented that neonatal pharmacology was not often offered during pharmacy training programmes, and as such there was a perceived lack of awareness and understanding of the medication management processes in this patient population. Pharmacists indicated that this had the potential to limit the implementation of the proposed resource in two ways: pharmacists reluctance in engaging in this field because of the patient group and pharmacists being insufficiently skilled to be able to practice on this ward.

> It's an area where you don't learn at university, how to be a neonatal pharmacist. I would like to see a lot more paediatric and neonatal pharmacology or just awareness in the undergraduate degree, because people are very frightened of getting involved if the patients are so small. AP2

Polish pharmacists voiced concerns relating to foundational-level issues, highlighting their own lack of experience with models of clinical pharmacy. Whilst they expressed a high-level of interest in providing clinical roles, they reported that they did not hold the necessary level of preparation or knowledge in offering such services and were hesitant about the feasibility and possibility of initiating this type of practice.

> . . .the lack of pharmacist preparation. This is absolutely not spoken about here. There are absolutely no clinical placements, we do not leave the pharmacy and we do not enter the wards. So at the moment, I do not feel at all prepared to fulfil this kind of role. PP11

Furthermore, they credited the current education system as being inadequate in preparing pharmacists for clinical practice. 'Clinical pharmacy' was identified as being a certified specialisation within Poland; however, participants reported that the Polish pharmacy schools offered this course in a limited capacity, with no practical experience on hospital wards, and the entirety of the course being theory-based. Some pharmacists highlighted that they needed to go externally (overseas) to acquire such training. However, one participant identified that even if this training was sufficient, there is nowhere for pharmacists to practically apply that knowledge in the current system.

> The barriers start at the university level. We are not adequately prepared for this type of practice. Even a specialisation in clinical pharmacy does not prepare us. We have some of the necessary knowledge after we finish this type of specialisation, but we do not know how to implement it. Not only should our universities prepare us for the work of a clinical pharmacist, but hospitals should also create clinical pharmacist positions. It should be made mandatory that there is a clinical pharmacist employed on all of the hospital wards. This type of practice model would certainly work to satisfy us. PP15

Current healthcare system

Polish participants identified that the current healthcare practice model functioning in Polish hospitals was a

Table 4 Barriers to implementing quality guidance document

Poland	Australia
Finances	
Everything is dependent on the employment of people and the number of employees. Considering the model that we currently use to provide pharmaceutical services, we would not have enough people to be able to cope with it all. This is strictly related to health care financing, whereby the national health fund reimburses specific services. PP2	I guess the obvious one is resourcing. There are different levels of resources in different hospitals across Australia and its sometimes a bit of a struggle to get through the workload, but I think guidance documents such as these should help. Both in informing current practice and in future planning. AP1
The fundamental barrier is a small number of staff. This is a fundamental barrier, without additional personnel we will not be able to overcome it – 700 beds, 6 people – that is one person per 100 beds. How? And this is not just monitoring the ward, but also the administrative duties, tenders, and other such things that take up a lot of time because some things are only able to be done and signed off by the pharmacist. There is not enough of us to even check the work of the technicians. PP5	Financial, if you've got competing resources. Financial is going to be one of them. AP3
Financial barriers. When anyone wants to introduce new changes, this is the first barrier that they face, maybe not the first, but one of the first questions is "how much will this cost?" Obviously, for this to work you need people, pharmacists, and for that you need money. So I think that the financial barrier is present, because when you look at a personnel barrier, sooner or later people will be convinced that it works when they see its positive effects. On the other hand, this financial barrier is apparent, and I think it is big. PP6	I think both financial resources and additional staff are drivers for any kind of service. And like I said before, I think that provided that it was evidence-based and up-to-date then I think that would probably be the other driver. AP6
Education and experience	
One barrier is definitely our education system. The system of educating pharmacists and doctors would have to change. This issue is not independent of doctors. I think this is an important barrier. PP7	. . .what we learn in the NICU is obviously what we have been trained for by the pharmacists. But it is not something that is focused on in terms of in your pre-registration year when you are an intern, no-one really looks at NICU. I know that it is quite specific and there isn't that many NICU beds, but it is not something that is ever touched on. You don't learn it in your degree and you don't learn it when you are an intern, unless you are actually exposed to it. Even in our hospital, we have the pharmacists that cover the nursery but we don't really have the interns covering them because of fear that there is too much of a high risk. So you don't really get that exposure until you actually need to do it, and by then it might be a little bit too late. AP11
Our model of education in Poland does not prepare us for practice in a clinical capacity, or on the ward. Above all, education. Our level of education is directed at a different type of practice, something other than actual ward-based practice with the patient. PP9	

Table 4 (continued)

Poland	Australia
Current health care system	**Support from professional pharmacy body and other professional staff**
We have a problem, and I will continue to point out that the pharmacist is not valued. This kind of research that you are undertaking demonstrates that it is necessary to realise that the pharmacist can perform certain tasks and support the doctor on the ward. PP1	It would have to be accepted and supported by some large national body, for a hospital service to make sure that its introduced. So if you had SHPA support, or children's health Australasia support, something like along those lines, or even the Australian Commission on Safety and Quality in Healthcare, someone like that to ratify it, then you'd be more likely to get the hospital to accept it. AP2
Under these conditions, I think it would be difficult. That is why, from what I see, there is no such option for the pharmacist to become closer to the ward. I think it would be an issue for the doctors. Not for the pharmacist, I think they would adapt quickly. Because they would understand what their duties are, but it would be more difficult to communicate to the medical community that there is someone else present who has insight into similar things and who can make decisions on similar matters. So, I believe there would be resistance and a lack of trust for the pharmacist. PP4	. . . support from the NICU executives as well as support from pharmacy management. If you were reporting KPIs, some sort of support from a national or state body like we would do with other med safety indicators. AP7
The barriers that we have here are that people are not very willing to change. PP4	Unless it had some official status or standing or a body that came out to say this is our expectation or standard of practice for pharmacy within neonatology it would be unlikely to gather enough weight. . . I guess resources and support. Whoever your neonatal director is, in terms of your NICU, they need to support having a pharmacist in there. If you don't have that support within the clinical unit, whether its doctors and nursing, but particularly the lead clinicians, then it will never move. You also need support from the head of the pharmacy department to say this is a good use of resources. And then you need to get the executives on board to say here's some money to make this happen. AP9
Legislation	
First of all, the legal regulations do not specify what is an appropriate number of pharmacists to be employed. There are pharmaceutical laws that define the role that a pharmacist should fulfil and within that it is specified that they should provide medication information, and that's it. . . The law does not support us, does not have a standard that states how many pharmacists per bed. It is only starting to be fought for now. Previously, there used to be one pharmacist per 100 beds. That was a couple of years ago. Now there is no norm. . . Also, the truth is that professional duties are often done by technicians and not qualified pharmacists, who should be doing it, and no-one has time to even just look into the ward or talk to the doctor. There is no support system that would allow this. PP5	

significant barrier to the implementation of a clinical pharmacy-focussed resource in the NICU. One pharmacist commented that they did not see clinical pharmacy practice being present in Poland for another 50 years.

> For us it is fascinating to think that maybe, I do not know, in 50 years we will also have a similar system. For the moment, the momentum is not here at all. PP5

The healthcare system was described by participants as being a long-established, traditional, hierarchical structure, whereby doctors and nurses practice on wards, whilst pharmacists are dedicated to the dispensary, managing the supply and preparation of medications. Many participants referred to the practice–culture and mentality of healthcare professionals towards changing pharmacist practice in the NICU. In particular, they expressed to the lack of awareness of doctors and the hospital management around the value and need for the pharmacist to provide ward-based services for neonatal patients.

> For me at this point, if I have to be honest and this is my personal opinion, there is no awareness within the hospital management that the pharmacist may actually contribute to the safety of medications. PP1

> It has to do with the ingrained practice culture. It also depends on how the doctors perceive this model. PP7

> I think above all, the mentality and the long-established procedures, as well as the inter-professional relationship between the doctor and the pharmacist, which in Poland simply does not function. This is the main barrier. PP11

It is apparent that there is no incentive within the Polish healthcare system to modify the current pharmacy practice model as it is perceived that the level of care being provided to neonates is satisfactory, and the professional roles allocated to doctors, nurses and pharmacists are being fulfilled. Furthermore, participants reported that hospital pharmacists are not well reimbursed for their services, and therefore, there is reluctance to perform additional roles for minimal reward.

> . . . I must say that our level of care is good because we have good results when it comes to treating these children. The care is not bad, but I think it would be even better if there was a pharmacist involved. PP3

Legislation

Only Polish participants drew attention to the fact that there is no appropriate pharmaceutical legislation authorising pharmacist involvement on the ward. This was identified as a significant issue, as this 'permission' was perceived as essential in giving pharmacists the power to make pharmacotherapy-related decisions and become involved in patient care in the NICU. Furthermore, pharmacists highlighted that there was no regulation in the law that specified pharmacist to bed ratios. This was also deemed to be important, due to the current staff shortages in hospitals, which are seen to impact upon the ability of the pharmacy department to provide services.

> I will begin by saying that our pharmaceutical law does not state that the pharmacist is allowed to enter any ward. Of course a hospital director or someone who manages a hospital may authorise this, but if it is not written in the law we are unsure what the pharmacist should be there for what they are responsible for and what role they play. PP3

Interestingly, only one pharmacist recognised that the laws did not say that a pharmacist could not access the ward.

> I am not sure if the legislation prevents us from accessing it. In my opinion it is not properly regulated. It is simply not specified that we are able to have access. No-one took this under consideration, that is why the pharmacist is not present on the ward. PP4

Support from professional pharmacy bodies

Interestingly, only pharmacists from Australia identified that in order for the proposed resource to be considered by NICU practice settings, it would need the acceptance and support of a national pharmacy body or neonatal organisation. Without this, participants felt that the hospital management would not support greater pharmacist involvement in this ward. Furthermore, participants highlighted that where practice is established, both pharmacists and doctors may be reluctant to change and adapt to a new system. From a personal perspective, pharmacists recognised increased workload as a barrier to the implementation process, mainly due to the time needed to dedicate to fulfilling the standards outlined in the tool.

> You'd have to have appropriate stakeholder engagement. So you would have to either have the document prepared, and then a professional organisation support it. So I would think you would need to get it endorsed either by the SHPA and the other option that I think would be quite appropriate is if the SHPA acted as a advocate through the ANZNN (Australian and New Zealand Neonatal Network), so you would want that to be a jointly endorsed from both of those professional bodies for it to be effective I would think. AP10

> People not being willing to change practice or measure practice. Time constraints as well. A lot of times, the NICU is co-allocated with another role so obviously you have only a certain amount of time that you can spend on it, so you may not be able to adhere to the guidelines. AP4

Discussion

To our knowledge, this is the first qualitative study to explore pharmacist opinions towards the development of a quality measurement tool specifically for clinical pharmacy practice in the NICU. This qualitative research is valuable

as it provides an initial insight into understanding the needs of NICU pharmacists and assessing whether there is a demand for quality guidance resources to be made available for subspecialties of pharmacy practice.

One concept arising from the study that warrants discussion is that pharmacists in both Australia and Poland identified a lack of NICU clinical pharmacy guidelines and a subsequent lack of professional guidance to practicing within this setting. As such, the findings from this study draw attention to a significant gap in practice. The provision of pharmaceutical care services in NICUs in both Australia and Poland is based on each hospital settings' individual and varied interpretations of the concept of 'GPP', without the guidance of a minimum standard of practice. As a result, there is potential for differences in the level of pharmacy services delivered to NICU settings between these two countries. It is not known what impact these variances have upon patient outcomes or the rational use of resources. However, despite these differences in practice, both Australian and Polish participants in this research perceived a need for the development of a quality or guidance tool to standardise pharmacy practice in the NICU at least on a local level and national level. This finding is reinforced by the FIP, who highlights that national standards, depicting GPP and comprising a quality management framework, should be set by pharmacy organisations.[13] The FIP recognise that pharmacy practice may vary in settings between and within countries, however, state that a 'baseline' should be established that outlines the minimum level of quality practice.[13] However, to date, there have not been any guidance documents or performance measures established for neonatal pharmacists. Furthermore, there are no standardised measures facilitating the benchmarking of pharmacy services between settings nationally and internationally. Ng *et al.*[18] report that in a resource-scare environment, clinical governance demands that clinical pharmacy, in accordance with other clinical health services, must demonstrate the value of its contribution to patient care. They highlight that without the availability of KPIs or quality measures, pharmacists are unable to justify in a quantitative and robust manner their contributions to patient care.[18] This is of particular significance to the Polish setting, when considering the current issues within the healthcare system that limit the implementation of clinical pharmacy practice.

When considering the barriers identified by participants towards the implementation of a quality guidance resource, some of our findings were consistent with other research dedicated to identifying challenges affecting the engagement of clinical pharmacy KPIs (cpKPIs) in the hospital setting.[25] Minard *et al.*[25] reported barriers comprised of environmental constraints, relating to inconsistent staffing levels, funding or resources, as well as work burden issues. Another study by Mekonnen *et al.*[28] investigating the implementation of new medication safety programmes in Ethiopian hospitals mandated by updated minimum practice guidelines highlighted a significant barrier as a lack of pharmacist knowledge and skills necessary for the performance of clinical services required by the guidelines. This barrier in particular is similar to that expressed by Polish participants, and their unfamiliarity with the direct provision of ward-based, clinical services potentially outlined in the quality resource. The barriers identified in this research outnumbered the perceived benefits to the quality guidance resource and varied between Australia and Poland. The differences observed in the participant responses between the two countries may be attributed to the numerous variations in healthcare systems, including legislation, funding and education. However, it is apparent that practice culture is a significant influencing factor. Overall, Polish participants were more conservative and expressed concerns relating to the current hospital hierarchy, that is maintaining the status quo. Polish interviewees often focused on the lack of legislation in specifying that a pharmacist was able to participate in ward-based medication management. These findings are similar to those presented by Pawłowska *et al.*[29] who highlighted that the majority of Polish hospital pharmacists surveyed felt that significant changes to legislation were necessary to improve hospital pharmacy practice. However, only one pharmacist acknowledged that it may be more of a case that the law does not specifically state that pharmacists are not permitted to practice on the ward. As such, this raises the question as to whether Polish pharmacists are actually receptive to practice changes. In comparison, Australian pharmacists seemed to be more engaged and proactive in their practice and were willing to further advance service provision to this ward to permit the standardisation of practice. As such, these diverse attitudes may have varying impact on pharmacists willingness and motivation to adapt to a different model of practice.

It is important to note that pharmacists from both countries readily highlighted the potential benefits to the implementation of a quality resource, including allowing pharmacists a full understanding of the roles needed to be undertaken in this setting, improving the standardisation of care, as well as strengthening pharmacist positions on the NICU, particularly in reference to their standing among other members of the multidisciplinary treating team. These findings are similar to those obtained by Minard *et al.*,[25] who explored the perceived barriers and facilitators towards the use of cpKPIs in general hospital settings in Canada. They highlight that pharmacists perceived the implementation of cpKPIs would improve consistency in pharmacy practice, help align the expectations of other healthcare professionals and allow pharmacists a clear focus of roles and services that need to be performed.[25]

The findings of this study emphasise that there is a lack of pharmacist support and guidance in both Australia and Poland relating to practice in the NICU. There is an opportunity for future research to address this gap in knowledge and potentially develop quality measures tailored specifically to this patient population that could be adapted to each practice setting. As this is a specialised area of practice, with only limited numbers of neonatal beds in each country, a standardised quality tool may in fact help the benchmarking of clinical pharmacy services on a national scale and promote a more co-ordinated approach to advancing pharmaceutical care provided to this high-risk patient population. By assessing pharmacist perspectives towards the implementation of a quality resource, as well as the perceived barriers limiting its use, these findings are an

important step in the knowledge-to-action process and may be useful in future research in the selection and development of interventions for both Australia and Poland.

Limitations

The sample size used in this study was small, and as such the opinions expressed may not be representative of all pharmacists in Australia and Poland. In addition, due to the voluntary nature of participation in interviews, there is a possibility that pharmacists who participated may have different views to those who chose not to volunteer. Sampling bias may be associated with participants who were recruited from the previous study. The sample of participants from each country was nonequivalent in terms of their personal characteristics (i.e., practice experience, educational background, position in hospital). Therefore, the results may, to some extent, reflect those differences in addition to country-specific differences.

There is potential for researcher bias in interpreting the responses from participants. This has sought to be minimised by ensuring three individual analyses of the data by three separate researchers. The themes that achieved consensus were then combined to form the final results.

Furthermore, the interviews were transcribed and translated by one researcher, and any errors that were made may not have been picked up in the analyses performed by the other researchers.

Conclusion

Although there are significant differences in the type of pharmacist practice systems functioning in each country, pharmacists in both Australia and Poland demonstrated significant support for the development of a quality measurement tool to guide and structure practice in the NICU and recognised benefits to its implementation. Future efforts should be directed at standardising pharmacy practice in NICUs through the development of quality measures, including practice standards and KPIs that can be adapted to different practice settings, both on a national scale and international scale.

Declarations

Conflict of interests

All authors declare that she has no conflict of interest.

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Authors' contributions

All Authors state that they had complete access to the study data that support the publication.

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L.8 QUALITY PHARMACY SERVICES AND KEY PERFORMANCE INDICATORS IN POLISH NICUS: A DELPHI APPROACH

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RESEARCH ARTICLE

Quality pharmacy services and key performance indicators in Polish NICUs: a Delphi approach

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Abstract
Background Currently, there is no literature describing what a quality level of practice entails in Polish neonatal intensive care units (NICUs), nor are there any means of currently measuring the quality of pharmaceutical care provided to NICU patients. *Objective* To identify a set of essential pharmacist roles and pharmacy-relevant key performance indicators (KPI's) suitable for Polish neonatal intensive units (NICUs). *Setting* Polish hospital pharmacies and NICUs. *Method* Using a modified Delphi technique, potential KPI's structured along Donabedian's domains as well as pharmacy services were presented to an expert panel of stakeholders. Two online, consecutive Delphi rounds, were completed by panellists between August and September 2017. *Main outcome measure* To identify the minimum level of pharmacy services that should be consistently provided to NICU patients. *Results* A total of 16 panellists contributed to the expert panel. Overall, consensus of 75% was reached for 23 indicators and for 28 roles. When considering pharmacy services for the NICU, the experts were found to highly value traditional pharmacy roles, such as dispensing and extemporaneous compounding, however, they were still eager for roles in the other domains, such as educational and clinical services, to be listed as essential for NICU practice. Panellists were found to positively value the list of indicators presented, and excluded only 9 out of the total list. *Conclusion* There is a need for future research to establish a minimum standard of practice for Polish pharmacists to encourage the progression and standardisation of hospital pharmacy services to meet the level of practice seen in NICUs worldwide.

Keywords Delphi technique · Key performance indicators · Neonatal Intensive Care Unit · Pharmaceutical care · Poland · Quality measurement

Impacts on practice

- The integration of the clinical pharmacist into NICU settings in Poland must be considered.
- Quality pharmacy practice resources in Poland should be further developed for hospital pharmacy practice. These resources are important for quality improvement activities, as well as enhancing transparency about hospital pharmacy service quality, which are important for the progression of hospital pharmacy practice.

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Introduction

Despite its widespread adoption and implementation in the US, UK, Australia and Canada, clinical pharmacy practice within hospital settings in Poland is still in its infancy [1–6]. Indeed, hospital pharmacy practice as a whole is predominantly limited to dispensary-based activities focussed on the safety and effectiveness of medicines rather than patient-centred care. Pawlowska et al. [7] highlighted that only 7% of hospital pharmacists surveyed had contact with patients, and that their roles in the hospital were mainly associated with the provision of medicines. Piecuch [8] further indicated that pharmacists are not involved in the provision of direct, individualised care to patients and as such often have little to no input in the pharmacotherapy decision-making process. Whilst pharmacists have the ability to acquire post-graduate specialisations in clinical and hospital pharmacy, their skills in these fields are unable to manifest on hospital wards due to several barriers. These include: lack of

appropriate legislation specifically outlining the authority of the pharmacist in this setting, insufficient staffing of hospital pharmacies, lack of financing for additional pharmaceutical care services as well as a limited awareness of other members of the healthcare team towards the possible benefits of pharmacist involvement in the hospital structure [9].

Studies worldwide indicate that pharmacists are an integral component of patient care, and demonstrate their impact upon optimising patient outcomes, improving the rational use of resources and decreasing medication error rates [2, 10–12]. This is of particular importance to high-risk hospitalised patient groups, especially infants admitted to the neonatal intensive care unit (NICU). These children have a high level of exposure to medications throughout their admission, and due to their unique pharmacokinetic and physical characteristics, are prone to medication misadventure which may have significant impact upon their development [13]. Studies show that pharmacists in the NICU: have prevented significant errors from occurring, including 10–100 fold overdoses; can optimise pharmacotherapy, such as total parenteral nutrition regimens (TPN); and are highly valued by doctors and nurses on the ward [13–18].

However, clinical pharmacy services are relatively absent in the Polish hospital setting, in comparison to other countries. This raises questions relating to the quality pharmaceutical care being provided to NICU patients, and whether the services being provided are achieving the best possible patient outcomes. Healthcare service quality is most commonly measured via key performance indicators (KPIs) or other quality indicators that assess practice performance, helping to identify where improvements are needed to minimise service gaps [19]. These indicators are formulated using nationally or internationally agreed clinical practice guidelines based on meaningful, reliable evidence [20]. Currently, there is no literature describing what a quality level of practice entails in Polish NICUs, nor are there any means of currently measuring the quality of pharmaceutical care provided to NICU patients.

The European Directorate for the Quality of Medicines and Healthcare (EDQM) has co-ordinated the development of generally applicable indicators for the implementation of pharmaceutical care in Europe [21]. However, these indicators have been designed for use both in community and hospital settings, and are not specific to sub-speciality patient groups, such as neonates. As such, apart from the pharmaceutical law regulating which activities should be provided by hospital pharmacies to all inpatients, there are no guidance documents to support hospitals pharmacists in meeting the needs of the neonatal patient population and they are unable to measure their performance to benchmark against other settings nationally. Scobie et al. [22] state that the measurement of safety and quality is fundamental to health delivery.

Aim of the study

The aim of this Delphi study was to identify essential pharmacist roles and KPIs that reflect quality pharmaceutical care in a Polish NICU setting. Specific objectives were to:

- Identify a set of pharmacy-based key performance indicators in Donabedian's domains of process, structure and outcome that can be used to benchmark the quality of pharmaceutical care provided to patients in Polish NICU settings.
- Identify the minimum level of pharmacy services that should be consistently provided to NICU patients.

Ethics approval

Ethics approval was obtained from the respective ethics committees at the University of Technology Sydney (UTS), Australia (UTS HREC REF NO. ETH17-1584) and the Medical University of Gdansk (GUMed), Poland (GUMed HREC REF NO. NKBBN/424-184/2017). Panellists were assured of confidentiality and were informed that their responses would be de-identified.

Method

Panel selection

Experts were recruited using a combined purposive and criterion sampling approach [23]. Potential panellists were identified from neonatal organisations as well as data papers and articles publicly available registers in Poland including the Polish Register of Facilities delivering Medical Activities (Rejestr Podmiotow Wykonujacych Dzialalnosc Lecznicza—RPWDL) to identify hospitals with neonatal intensive care units.

The expert panel was made up of key stakeholders involved in NICU care, and were defined as: (1) hospital pharmacists, or pharmacists based in academia, as well as leading medical doctors and nurses, (2) people who had experience with hospital based clinical pharmacy services, and where possible, (3) people with experience in the NICU.

Collating pharmacy-sensitive indicators

To find quality and pharmacist-specific key performance indicators used in neonatal and paediatric care settings, a review of the literature was undertaken [24]. Due to the nature of hospital pharmacy practice in Poland (i.e., less well established level of pharmaceutical care and clinical

practice; focused mainly on dispensary-based activities), the proposed indicators were carefully considered for relevance to the Polish system. Two of the researchers (NK, IP) consulted a small group of Polish health professionals to assess the applicability of indicators to current Polish pharmacy practice and canvas whether the indicators would be understood by panellists in this country. Only those indicators that pharmacists would reasonably be expected to understand in the context of current Polish pharmacy practice were included. This was based on a recent study conducted by Krzyzaniak et al. who highlighted that pharmaceutical care services delivered to NICUs in Poland were mostly dispensary based, i.e., compounding, with little to no involvement in clinical, ward-based roles [25]. Therefore, many concepts and terms such as medication reconciliation, medication action plans are foreign to Polish pharmacists. In order to minimise the incidence of misunderstanding as well as any social desirability bias, indicators that contained concepts and terms that were abstract to the Polish pharmacy practice setting were excluded. Overall, a modified list of 32 indicators, categorized according to Donabedian's domains of structure, process and outcome, was provided to Polish panellists.

Data collection

The surveys used in the Delphi rounds were structured on the basis of two previous studies by Fernandes et al. and Wilson et al. who published a set of pharmacy and nursing indicators respectively for hospital practice [23, 26].

The study comprised two Delphi rounds, structured as two consecutive surveys delivered between August and September 2017 via the online software program Survey Monkey™. Mullen highlights that when a sample size is small, often no more than one round is needed to obtain consensus [27]. However, in order to allow feedback and 'revision of responses', a minimum of two rounds are recommended [27]. As the target group of individuals for this study practice within a sub-specialty of care, there are a subsequent limited number of possible participants. Therefore, a two-round Delphi survey was considered upfront as the most appropriate to ensure maximum response rate as well as to minimise the possibility of participant fatigue [28, 29]. Each Delphi round comprised three parts. These included: panellist demographics (Part A), essential pharmacist roles in the NICU (Part B) and a baseline set of key performance indicators (Part C). Panellists were asked to rate each item on a 5 point Likert scale ranging from strongly agree (1) to strongly disagree (5) against pre-set criteria (Fig. 1).

At the end of Round 1, panellists were invited to suggest additional indicators/roles and to provide any comments. These suggestions were used to rephrase questions and refine the list of indicators/roles for inclusion in the next round of surveys. In Round 2, the modified set of KPIs/roles were rated again using the same selection criteria.

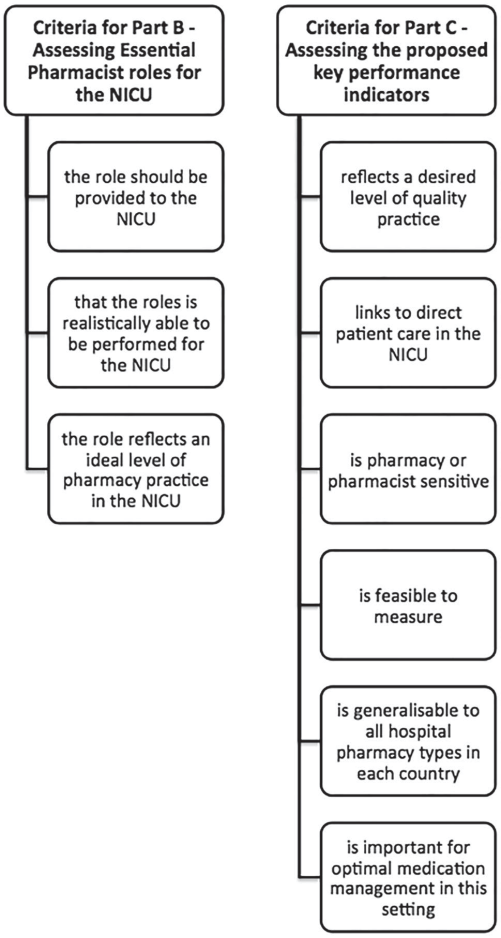

Fig. 1 Criteria used by the expert Delphi panel to assess essential pharmacy services and key performance indicators for NICU practice

Each Delphi round was open for 2 weeks, and reminders were emailed at the beginning and at the end of each 2-week period. Each survey took approximately 15 min to complete. The non-completion of the previous round did not rule out panellists from contributing to the following round. Round 1 was piloted by a small number of pharmacists.

Data analysis

Descriptive statistics (percentages, frequencies) were used to analyse the quantitative data, via the Statistical Package for the Social Sciences (SPSS) Version 22™. All Likert scale scores listed as 1 and 2 were combined as agree, and all scores listed as 4 and 5 were combined as disagree. Scores of 3 (unsure) were excluded. Consensus was considered to have been reached when 75% or more of panellists rated 'agreed' for an indicator. If an indicator did not reach this consensus, it was not included in the subsequent round. All items with ≥ 75% agreement were included in the final set. According to Keeney et al. a consensus level of 75% is considered to be the minimum in ensuring accuracy and confidence in the consensus achieved by participants [30].

Results

Overall, of the 29 panellists who agreed to participate in this research, only 16 became expert panellists and participated in at least one Delphi round (response rate = 55.2%). The remaining individuals did not respond. Seven experts completed both Delphi rounds. Approximately half of panellists in each round were pharmacists or directors of pharmacy, and the remaining panellists comprised neonatologists, nurses, midwives and academic pharmacists (Table 1).

Table 1 Characteristics of expert panel

	Round 1 Poland (%)	Round 2 Poland (%)
Number of panellists	13	12
Gender of panellists		
Female	12 (92.3)	11 (91.7)
Specialised qualifications relating to neonates		
Yes	5 (38.5)	4 (33.3)
No	8 (61.5)	8 (66.7)
Specialisation in neonatology/paediatrics	1	3
Hospital/clinical pharmacy specialisation	3	1
Postgraduate certificate in neonatal nursing	1	
Position in the hospital		
NICU pharmacist/director of pharmacy	9 (69.2)	6 (50)
Pharmacist in academia	2 (15.4)	2 (16.7)
Neonatologist/NICU doctor	1 (7.7)	4 (33.3)
NICU nurse/midwife	1 (7.7)	0
Participants who completed both delphi rounds		
NICU pharmacist/director of pharmacy	6	
Pharmacist in academia	2	
Neonatologist/NICU doctor	1	
Experience		
Between 1 and 5 years	3 (23.1)	2 (16.7)
Between 6 and 10 years	1 (7.7)	1 (8.3)
> 10 years	9 (69.2)	9 (75)

Round 1

A total of 13 panellists completed round 1.

Pharmacist roles

A list of 30 pharmacist roles was presented to panellists. Overall, respondents strongly agreed to the majority of the proposed roles. Polish experts achieved consensus for 28 roles; two services pertaining to evaluating laboratory tests (69.2%) and immunisations (46.2%) were excluded (Table 2). Using the 5-point Likert scale, the range of median scores was from 1.00 (IQR = 0) for extemporaneous compounding to 3.00 (IQR = 2) for involvement in immunisations. A new role was proposed for inclusion in the next round, that being the preparation of individual, unit dose parenteral and oral dose forms for neonatal patients.

Pharmacy-based key performance indicators for quality pharmaceutical care in the NICU

Polish experts were presented with 10 structure, 11 process and 11 outcome indicators (total = 32). A consensus of > 75% was achieved for 25 items (Table 3). Therefore, 7 items were excluded from subsequent analysis. These items included: dedicated area/station on the ward for the pharmacist (69.2%), number of education/training sessions provided by pharmacists relating to pharmacotherapy in the NICU for other health professionals (69.2%), proportion of pharmacists involved in NICU related clinical research (61.5%), monthly audit of episodes of ineffective empiric antibiotic therapy (organism/antibiotic mismatch) (69.2%), proportion of infants receiving appropriate dosing and timing of perioperative prophylaxis (69.2%), proportion of patients families that have had a face-to-face discussion about medicines related information (53.8%) and incidence of neonatal sepsis (61.5%).

Panellists did not recommend any new indicators for inclusion in round 2. Median scores for panellists ranged from 1.00 (IQR = 0) to 2.00 (IQR = 2).

Round 2

A total of 12 panellists completed round 2.

Table 2 Roles that pharmacists should perform in the NICU according to the Polish expert panel

Pharmacist services/roles	Round 1		Round 2	
	Median (IQR)*	Consensus %	Median (IQR)*	Consensus %
Administrative roles				
Development/implementation of a drug formulary service	1.00 (0)	100	1.00 (0)	100
Attendance at non-clinical meetings i.e. drug and therapeutics committee	1.00 (1)	100	1.00 (1)	100
Conducting quality assurance measures i.e. drug usage evaluations, workload documentation, auditing	1.00 (1)	92.3	1.00 (1)	100
Management of the drug budget	2.00 (1)	100	1.00 (1)	91.7
Evaluation, selection and purchasing of pharmaceuticals for the unit	1.00 (0)	100	1.00 (0)	100
Development of drug policies/protocols/guidelines for the NICU	1.00 (1)	100	1.00 (1)	100
Clinical roles				
Patient medication chart review	1.00 (0)	100	1.00 (1)	100
Participation in medical ward rounds	1.00 (1)	84.6	1.50 (1)	83.3
Monitoring the efficacy of pharmacotherapy in patients	1.00 (1)	84.6	2.00 (1)	91.7
Documenting/monitoring side-effects and adverse drug events/reactions	1.00 (0)	100	1.00 (0)	100
Documenting medication errors	1.00 (1)	100	1.00 (1)	100
Evaluating patients clinical laboratory tests	2.00 (2)	69.2	–	–
Therapeutic drug monitoring (TDM)	1.00 (1)	92.3	2.00 (1)	91.7
Immunisations	3.00 (2)	46.2	–	–
Monitoring total parenteral nutrition (TPN)	1.00 (0)	100	1.00 (0)	100
Participation in clinical meetings	2.00 (1)	84.6	2.00 (1)	83.3
Calculating and recommending doses and dosing schedules for specific patients	1.00 (1)	84.6	1.00 (1)	91.7
Assisting doctors in prescribing off-label/unlicensed medicines	1.00 (1)	92.3	1.00 (1)	100
Identifying and performing interventions for individual patients to prevent or resolve drug therapy problems i.e. interactions, incompatibilities, allergies etc.	1.00 (0)	100	1.00 (1)	100
Recommending drugs and contributing to the pharmacotherapy decision making process for specific patients	1.00 (1)	100	1.00 (1)	100
Collaborating and discussing specific patients with doctors and nurses	1.00 (1)	92.3	1.00 (1)	100
Educational roles				
Providing training/in-services for other health professionals on NICU related topics and drug related problems	1.00 (1)	84.6	1.00 (1)	91.7
Contributing to and/or attending NICU related conferences	1.00 (0)	100	1.00 (1)	100
Involved in clinical trials	1.00 (1)	100	1.00 (1)	91.7
Involved in research related to neonatal pharmacotherapy	1.00 (1)	100	1.00 (1)	91.7
Source of drug information—responding to information requests from health professionals on the ward	1.00 (1)	100	1.00 (0)	100
Counselling parents/carers of neonatal patients on medication	2.00 (2)	76.9	2.00 (2)	58.3
Provision of medicines roles				
Dispensing prescriptions	1.00 (0)	100	1.00 (0)	100
Extemporaneous compounding of formulations for the NICU	1.00 (0)	100	1.00 (0)	100
Stocking the ward with essential medicines/house-keeping activities i.e. checking expiry dates, fridge temperatures etc.	1.00 (0)	100	1.00 (0)	100
Preparing unit doses for parenteral and oral medicines†	–	–	1.00 (0)	100

*1–5 Likert rating scale used

†Role proposed by panellists

Pharmacist roles

Consensus was reached for 28 roles (Table 2). Overall, panellists responded strongly to the proposed pharmacist roles, with the majority responding 'strongly agree'. Polish experts most strongly responded to pharmacist roles in the provision domain, including: extemporaneous compounding (100%, Median = 1.00), stocking the ward with

Table 3 Structure indicators

	Round 1		Round 2	
	Median (IQR)*	Consensus %	Median (IQR)*	Consensus %
Personnel				
Availability of a funded NICU clinical pharmacist position (full-time/part-time) in the hospital [37]	1.00 (2)	76.9	2.00 (2)	75
NICU pharmacist holds qualifications in clinical pharmacy or NICU/paediatric pharmacy [38–40]	2.00 (2)	76.9	1.50 (1)	91.7
Facilities/environment/resources				
Dedicated area/station on the ward for the pharmacist that is a well-lit, with sufficient workspace, minimal distractions [41]	2.00 (2)	69.2	–	–
Availability of suitable fridges for vaccines and TPN on the ward [42]	1.00 (1)	92.3	1.00 (1)	91.7
Direct availability on the ward of essential medicines for specific use within the NICU [43]	1.00 (1)	100	1.00 (1)	91.7
Availability of written policies/protocols/guidelines for high-risk medications i.e. antibiotics, pain-relief, parenteral nutrition [39, 41, 43, 44]	1.00 (0)	100	1.00 (0)	100
Availability of clear policies on how to prescribe, dispense, administer and monitor medications in the NICU [41]	1.00 (0)	100	1.00 (1)	91.7
Availability of emergency medicines sheets, with listed doses per weight [45, 46]	1.00 (0)	100	1.00 (0)	100
Availability of standard neonatal/paediatric references for use in the selection, use and evaluation of medications i.e. textbooks (BNF P, Neofax), online resources [41]	1.00 (0)	100	1.00 (0)	100
Availability of electronic medication error and adverse drug event reporting (systems) [39, 41, 44, 47]	1.00 (0)	100	1.00 (0)	100

*1–5 Likert rating scale used

medication (100%, Median = 1.00) and the newly added role, preparing unit doses for parenteral and oral medicines (100%, Median = 1.00). Counselling of the families of NICU patients did not reach consensus by Polish panellists (58.3%); median scores achieved by Polish experts ranged from 1.00 (IQR = 0) − 2.00 (IQR = 2) (Tables 4 and 5).

Pharmacy-based key performance indicators for quality pharmaceutical care in the NICU

A total of 25 indicators were rated by panellists, and were split across Donabedian's domains, with 9 structure, 9 process and 7 outcome indicators. Consensus was reached for 23 indicators. Median scores were similar to the previous round for most indicators and ranged from 1.00 (IQR = 0) to 2.00 (IQR = 2). Polish panellists responded strongly throughout each of the structure, process and outcome domains, with consensus higher than 90% for the majority of indicators. Two indicators in the outcomes domain did not achieve consensus: percentage of patients who received at least 1 pain management intervention during heel sticks, PIV insertions, venipunctures, umbilical arterial catheterizations, nasogastric tube placements and EET suctioning (66.7%) and proportion of prescriptions for restricted antibiotics that are concordant with hospital approved criteria (66.7%).

Discussion

This is the first study in Poland to identify a set of pharmacist roles and KPIs that may be useful in structuring and guiding future practice in the NICU. Furthermore, this research is the first of its kind to combine the concept of clinical pharmacy practice and a sub-specialty of pharmacy, such as the NICU setting, in Poland.

In considering pharmacy services, experts highly valued traditional pharmacy roles, such as dispensing and extemporaneous compounding, but were still highly supportive of roles in the other domains, such as educational and clinical services, to be included as essential for NICU practice. These traditional perceptions may stem from ingrained practice cultures in Poland, whereby pharmacists are predominantly perceived to be based in the dispensary [7]. However, it is extremely encouraging that, despite these attitudes, medical and pharmacy staff alike are open to the pharmacists providing ward-based services to the NICU and being involved in

Table 4 Process indicators

	Round 1		Round 2	
	Median (IQR)*	Consensus %	Median (IQR)*	Consensus %
Proportion of unlicensed/off-label prescriptions that involved the consultation of a pharmacist [39]	2.00 (1)	92.3	2.00 (1)	100
Proportion of adverse drug events that were identified, monitored, rectified, prevented, and reported per number of admissions [39, 44, 47]	1.00 (1)	100	1.00 (1)	91.7
Proportion of dispensing errors identified and rectified by pharmacist per number of admissions [48]	2.00 (2)	76.9	1.00 (1)	91.7
Number of education/training sessions provided by pharmacists relating to pharmacotherapy in the NICU for other health professionals [39, 41, 44, 47, 49, 50]	2.00 (2)	69.2	–	–
Number of pharmacotherapy related consultations provided to medical personnel by pharmacists [39, 41, 44, 47, 49, 50]	1.00 (1)	92.3	1.00 (1)	100
Proportion of TPN regimens that have been monitored/optimised by a pharmacist [39, 43]	1.00 (0)	92.3	1.00 (0)	100
Proportion of IV medications that have been monitored by a pharmacist [39]	1.00 (1)	92.3	1.00 (1)	100
Proportion of pharmacists involved in NICU related clinical research [44, 47]	2.00 (2)	61.5	–	–
Proportion of dose calculations checked by pharmacist before administration [41]	2.00 (2)	76.9	1.00 (1)	100
Proportion of patients whose therapy is being monitored by a pharmacist [51]	2.00 (2)	76.9	2.00 (1)	100
Proportion of extemporaneous medications that have been prepared and monitored by a pharmacist for the NICU [41]	1.00 (0)	100	1.00 (0)	100

*1–5 Likert rating scale used

Table 5 Outcome indicators

	Round 1		Round 2	
	Median (IQR)*	Consensus %	Median (IQR)*	Consensus %
Monthly audit of episodes of ineffective empiric antibiotic therapy (organism/antibiotic mismatch) [52]	1.00 (2)	69.2	–	–
Proportion of infants receiving appropriate dosing and timing of perioperative prophylaxis [52]	2.00 (2)	69.2	–	–
Monthly audit of episodes of antibiotic-associated adverse events [52]	1.00 (2)	76.9	1.00 (1)	83.3
Proportion of prescriptions for restricted antibiotics that are concordant with hospital approved criteria [51]	1.00 (1)	84.6	1.00 (2)	66.7
Percentage of patients who received at least 1 pain management intervention during heel sticks, PIV insertions, venepunctures, umbilical arterial catheterizations, nasogastric tube placements and EET suctioning [53]	2.00 (2)	76.9	2.00 (2)	66.7
Proportion of patients families that have had a face-to-face discussion about medicines related information [51]	2.00 (2)	53.8	–	–
Percentage of medication orders that include the correct dose per kilogram (or body surface area) AND an effective and safe total dose [51]	1.00 (1)	92.3	1.00 (1)	91.7
Incidence of neonatal sepsis [54, 55]	2.00 (2)	61.5	–	–
Medication error rates/reports per 6 months [48]	1.00 (1)	92.3	1.00 (1)	83.3
Adverse drug event rates/reports per 6 months [48]	1.00 (1)	84.6	1.00 (1)	91.7
Costs of therapy [48]	2.00 (1)	92.3	1.00 (2)	75

*1–5 Likert rating scale used

the pharmacotherapy decision-making process. Similarly, experts expressed strong levels of support for the key performance indicators. This is of particular significance, as currently Poland does not have any national initiatives for quality assurance for hospital pharmacy practice. As such, it is encouraging that despite having little to no experience

with clinical pharmacy KPIs, the experts were extremely enthusiastic towards selecting indicators, with high levels of agreement for those remaining in the final list.

These findings demonstrate that there is a need to determine a minimum standard of practice for Polish pharmacists to encourage the progression and standardisation of hospital pharmacy services to meet the level of practice seen worldwide. According to the World Health Organisation (WHO), the concept of health equity is a priority for healthcare systems worldwide, and it is a fundamental right of each human being to receive the highest standard of health care [31, 32]. The literature highlights that Polish pharmacists are aware of the differences in practice evident between Poland and other industrialised countries, such as Australia and the UK [8, 9, 33]. However, Urbanczyk highlights that the clinical pharmacist is simply not viewed by policy-makers or other healthcare professionals as a medicines expert, and does not hold the relevant position or authority to be able to directly influence pharmacotherapy [9]. This is a point of concern, as the studies demonstrate the positive contributions of pharmacist involvement in pharmacotherapy-related decision making and in reducing medication errors in the NICU [14, 17, 34]. Neonatal patients are a priority for each healthcare profession, and the key to stepping forward in the Polish setting is to accept the pharmacist as an essential member of the interdisciplinary therapeutic team and then develop strategies to embed pharmacists into this setting. The International Pharmaceutical Federation (FIP) endorses the development of standardised national pharmacy guidelines and services to identify good practices and adopt coherent policies to promote practice consistency [35]. The findings presented here may be useful for the future development of quality pharmacy practice resources in Poland. These resources are important for quality improvement activities, such as benchmarking to demonstrate differences between settings on a national scale, pharmacy practice accreditation, as well as enhancing transparency about hospital pharmacy service quality, which are important for the progression of hospital pharmacy practice in Poland [36]. The findings of this research may be transposable to practice in other countries, particularly those in Eastern Europe, as the healthcare system issues faced in Poland are similar to those experienced in these countries. This may be attributed to the impact of historical events upon the political, economic and societal climate.

Limitations

There are several limitations to consider. First, the expert panels comprised only a small number of panellists. This may be attributed to the very specific nature of this research, which may have deterred potential respondents from contributing their expertise. Therefore, this may affect the generalisability of the results and they should be interpreted with caution.

Despite the small size of the panel, care was taken to ensure that the experts who responded to the surveys reflected a range of expertise and contributed a diverse range of neonatal and pharmacy experiences. However, this panel cannot be said to be representative of each profession in Poland.

The study was undertaken in the context of the Polish healthcare system. As such, the results may not be generalizable or applicable to countries with different healthcare systems.

Furthermore, the key performance indicators are not a comprehensive set of indicators for the assessment of hospital pharmacy practice in a Polish context. They simply represent consensus amongst experts in defining a preliminary quality level of pharmacy practice in the NICU.

Conclusion

The baseline quality indicators and pharmacy services identified, give insight into what experts deem to be essential aspects of quality pharmaceutical care in Polish NICU settings. These findings are the first to consider the integration of the clinical pharmacist into NICU settings in Poland. The practical considerations of applying these indicators will need careful consideration before they can be seen as valid performance measurement tools. There are several barriers in the current healthcare system limiting pharmacy services on the NICU, which require attention. Further research is needed to established the validity, acceptability and feasibility of the proposed indicators to practice on a national level, as well as to develop strategies to further integrate the pharmacist into the NICU therapeutic team.

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