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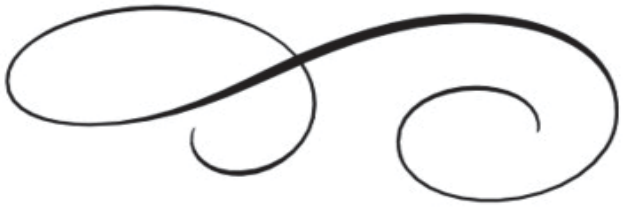
You cannot hope to build a better world without improving the individuals. To that end each of us must work for his own improvement, and at the same time share a general responsibility for all humanity, our particular duty being to aid those to whom we think we can be most useful.

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.

Maria Skłodowska-Curie



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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.

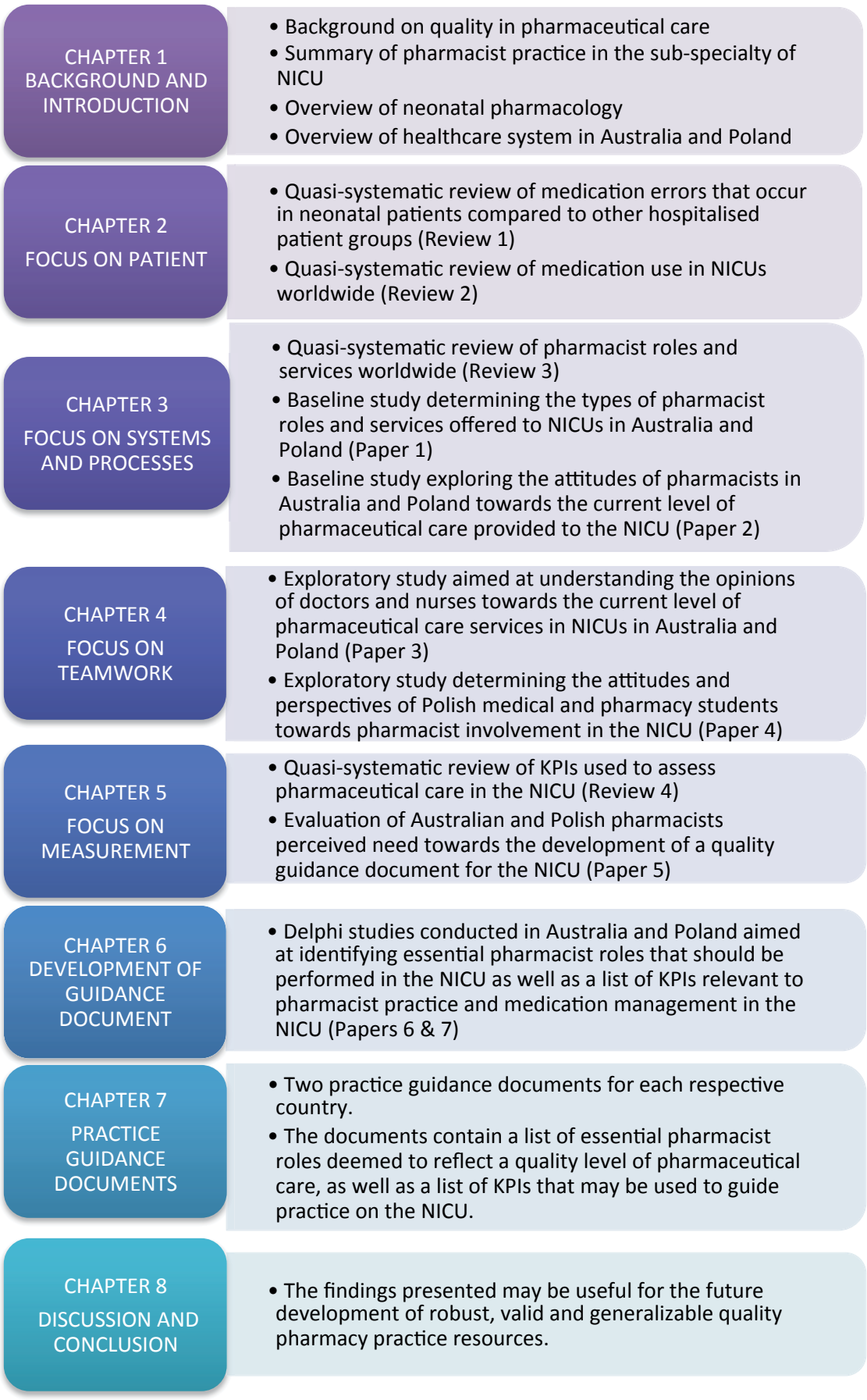
Following on from these foundation papers, the next stage of the research aimed to understand what measures were currently available and being used to evaluate the provision and quality of pharmacist practice in the NICU **(Chapter 5)**. A literature review found that there were no KPIs specifically 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.