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Implementation Science in Community Pharmacy

Development of frameworks, models and tools for introducing and integrating professional services

Thesis

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CERTIFICATE OF ORIGINAL AUTHORSHIP

I certify that the work in this thesis has not previously been submitted for a degree nor has it been submitted as part of requirements for a degree except as fully acknowledged within the text.

I also certify that the thesis has been written by me. Any help that I have received in my research work and the preparation of the thesis itself has been acknowledged. In addition, I certify that all information sources and literature used are indicated in the thesis.

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Abstract (English)

Background: Internationally, professional pharmacy services are being remunerated and community pharmacies are beginning to implement, however there appears to be a pervasive challenge to achieving widespread support and integration into routine practice. The use of implementation science to conduct implementation studies and evaluate implementation efforts may assist community pharmacy move towards the ultimate goal of sustained service provision and improved health outcomes for the communities they serve.

Objectives: To synthesise, analyse and progress knowledge concerning implementation science, then contextualise and apply this knowledge for the implementation of professional services in community pharmacy internationally. The research aims to conceptualise and define the process, influences and indicators for the implementation of professional services in community pharmacy.

Methodology: Mixed methodologies were employed. Two theoretical works were conducted to develop definitions and models based on reviews of pharmacy practice, health services and implementation science literature (chapters 3 and 6). A systematic review methodology was used to investigate implementation frameworks of innovations in healthcare (chapter 4). A qualitative study involving semi-structured interviews examined the implementation process and influences in community pharmacies across Australia. Thematic framework analysis of the data was performed (chapter 5). In Spain, both qualitative and quantitative approaches were applied to develop and test two tools, for the medication review with follow-up service being implemented in Spain, as measures of the implementation outcome, fidelity (chapter 7).

Results: Professional pharmacy services were defined and placed within a model of the overall service offering of a pharmacy (chapter 3). The core concepts across implementation frameworks (i.e. (i) an innovation, (ii) a multi-level context, (iii) a complex multi-stage process, influenced by a range of (iv) factors, (v) strategies and (vi) evaluations), were collated in a cross-disciplinary, overarching Generic Implementation Framework (GIF) (chapter 4). The concepts were contextualised for community pharmacy as the Framework for the Implementation of Services in Pharmacy (FISpH) (chapter 5). A model for the evaluation of implementation programs and professional pharmacy services was designed to include implementation impact, process and outcome indicators (chapter 6). Two implementation tools were developed and tested: a 39 item adherence index and a 12 item, 2-factor patient responsiveness scale (chapter 7).

Conclusion: Implementation science provides a base for community pharmacy as they move towards the introduction and integration of professional pharmacy service. The incorporated definitions, models and tools of the framework have been applied in practice to develop implementation programs and implementation research protocols, both in Australia and Spain.

Resumen (Español)

Antecedentes: A nivel internacional, los servicios profesionales farmacéuticos están siendo remunerados y las farmacias comunitarias están empezando a implantarlos; sin embargo, lograr su integración generalizada en la práctica rutinaria está resultando un importante desafío. El uso de la ciencia de implantación para desarrollar estudios de implantación y medir indicadores de implantación de servicios puede ayudar a la farmacia comunitaria a avanzar hacia el objetivo final de la prestación sostenible de servicios y la mejora de los resultados de salud para las comunidades que atienden.

Objetivos: Sintetizar, analizar y avanzar el conocimiento relativo a la ciencia de implantación para su posterior contextualización y aplicación en la implantación de servicios profesionales en farmacia comunitaria. Más concretamente, la investigación pretende conceptualizar y definir los procesos, influencias e indicadores para la implantación de dichos servicios profesionales.

Metodología: Se emplearon metodologías mixtas. Se realizaron dos trabajos teóricos basados en la literatura científica del ámbito de la práctica de farmacia, los servicios de salud y la ciencia de implantación para desarrollar definiciones y modelos que contextualizaran el trabajo a realizar (capítulos 3 y 6). Se realizó una revisión sistemática para investigar los marcos teóricos para la implantación de innovaciones en el área de la asistencia sanitaria (capitulo 4). Tambien se llevó a cabo un estudio cualitativo con entrevistas semi-estructuradas que examinó el proceso de implantación y los factores que lo influyen en las farmacias comunitarias en Australia (capitulo 5). En España, se aplicaron metodologías cualitativas y cuantitativas para desarrollar y testar dos herramientas que permitieran medir los resultados de la implantación del servicio de Seguimiento Farmacoterapéutico; concretamente la fidelidad (capitulo 7).

Resultados: Los servicios profesionales de la farmacia fueron definidos y contextualizados dentro de la oferta global de servicios que puede realizar una farmacia comunitaria (capitulo 3). Los conceptos fundamentales incluidos en los marcos de implantación (es decir, (i) una innovación, (ii) un contexto multinivel, (iii) un proceso complejo de varias etapas, influido por una serie de (iv) factores, (v) estrategias y (vi) evaluaciones), se recopilaron en un marco interdisciplinario general, el Marco Genérico de la Implantación (capitulo 4). Estos conceptos fueron contextualizados para la farmacia comunitaria en una nueva versión adaptada del mencionado marco (Marco para la Implantación de Servicios en la Farmacia) (capitulo 5). Se desarrolló un modelo para la evaluación de los programas de implantación y los servicios profesionales farmacéuticos, incluyendo indicadores de impacto, proceso y resultados de la implantación (capitulo 6). Finalmente, se desarrollaron y testaron dos herramientas de para medir la implantación de servicios profesionales: un índice de adherencia de 39 ítems y una escala de receptividad del paciente de 12 ítems en 2 factores (capitulo 7).

Conclusiones: La ciencia de la implantación proporciona una base para la introducción e integración de los servicios profesionales en la farmacia comunitaria. Las definiciones, modelos y herramientas incorporadas en el marco genérico de la implantación derivado de esta tesis, se han aplicado en la práctica para el desarrollo de protocolos de investigación y programas de implantación, tanto en Australia y España.

Dissemination of Research

Peer Reviewed Publications

2016 Moullin J.C., Sabater-Hernández D., García-Corpas J.P., Kenny P., Benrimoj S.I., 2016, 'Development and testing of two implementation tools to measure components of professional pharmacy service fidelity', *J Eval Clin* Pract, vol. 22, no. 3, pp. 369-77.

2016 Moullin J.C., Sabater-Hernández D., & Benrimoj S.I., 2016, 'Model for the evaluation of implementation programs and professional pharmacy services', *Res Social Adm Pharm*, vol. 12, no. 3, pp. 515-22.

2015 Moullin, J.C., Sabater-Hernández, D, Fernandez-Llimos, F, Benrimoj S.I., 2015 'A systematic review of implementation frameworks of innovations in healthcare and resulting generic implementation framework', *Health Res Policy Syst*, vol. 13, p. 16.

2013 Moullin J.C., Sabater-Hernández D., Fernandez-Llimos F., & Benrimoj, S.I. 2013, 'Defining professional pharmacy services in community pharmacy', *Res Social Adm Pharm*, vol. 9, no. 6, pp. 989-95.

Published Conference Proceedings, Trade Articles & Letters to Editors

2014 Moullin, J., Sabater-Hernández, D. & Benrimoj, S. 2014, 'Development of a theoretically based implementation protocol', *BMC Health Serv Res*, vol. 14, no. Suppl 2, p. P83

2014 Moullin, J.C., Sabater-Hernández, D. & Benrimoj, S.I. 2014, 'Implementing professional pharmacy services', *Australian Pharmacist,* vol. 33, no. 4, pp. 13-4.

2013 Moullin, J.C., Sabater-Hernández, D. & Benrimoj, S.I. 2013, 'Defining professional pharmacy services - the role of community pharmacy', p. 493 in 'Abstracts 8th working conference of the pharmaceutical care network Europe, 6–8 February 2013, Berlin, Germany' 2013, *Int J Clin Pharm*, vol. 35, no. 3, pp. 488-506.

2013 Moullin, J.C., Sabater-Hernández, D. & Benrimoj, S.I., 'Letter of response to correspondence regarding article "Defining professional pharmacy services in community pharmacy"', *Res Social Adm Pharm*, vol. 9, no. 4, p. 492.

Invited presentations

2015 San Jorge University; 14 December, 2015: Zaragoza, Spain: 'Introduction and implementation of professional pharmacy services in community pharmacy' [Spanish].

2015 University Medical Polyclinic; 8-9th December, 2015; Lausanne, Switzerland: 'Introduction to Implementation Science for healthcare professionals' and 'Implementation science in community pharmacy'.

2015 9th Pharmaceutical Care Network Europe (PCNE) Working Congress; 4-6 February, 2015; Mechelen, Belgium: Workshop leader 'The theory of implementation.'

2014 San Jorge University; 14 May, 2014: Zaragoza, Spain: 'Implementation of professional pharmacy services'.

2014 74th International Pharmaceutical Federation (FIP) World Congress of Pharmacy and Pharmaceutical Sciences; 31 August - 4 September, 2014; Bangkok, Thailand: 'Implementation science: frameworks for implementation - theory and practice'.

2013 73rd International Pharmaceutical Federation (FIP) World Congress of Pharmacy and Pharmaceutical Sciences; 31 August to 5 September, 2013; Dublin, Ireland: 'Development of a professional pharmacy service implementation framework'.

2013 World Healthcare Students' Symposium (WHSS); 8-13 September, 2013; Lausanne, Switzerland: 'Innovation: which strategy to implement a new service?'

2013 8th Pharmaceutical Care Network Europe (PCNE) Working Congress; 6-8 February, 2013; Berlin, Germany: 'Implementation Science'.

Oral communications to scientific meetings without proceedings

2015 Global Implementation Conference (GIC) 2015; 26-28 May, 2015, Dublin, Ireland: 'Measuring implementation: the construction and validation of tools'.

Poster communications to scientific meetings without proceedings

2015 75th International Pharmaceutical Federation (FIP) World Congress of Pharmacy and Pharmaceutical Sciences; 29 September - 3 October, 2015; Düsseldorf, Germany: 'The development and testing of two tools to measure components of fidelity of pharmacy service provision'.

2015 IX National Congress of Pharmaceutical Care; 15-17 October, 2015; Toledo, Spain: 'Model to evaluate the implementation of professional services in the community pharmacy' [Spanish].

2014 2nd Biennial Australian Implementation conference (AIC); 17-18 September 2014; Sydney, Australia: 'Operationalising the Generic Implementation Framework'.

2014 74th International Pharmaceutical Federation (FIP) World Congress of Pharmacy and Pharmaceutical Sciences; 31 August - 4 September, 2014; Bangkok, Thailand: 'Preliminary evaluation the Framework for the Implementation of Services in Pharmacy'.

2013 73rd International Pharmaceutical Federation (FIP) World Congress of Pharmacy and Pharmaceutical Sciences; 31 August to 5 September, 2013; Dublin, Ireland: 'Implementation Science: its application to the implementation of professional pharmacy services'.

2012 72nd International Pharmaceutical Federation (FIP) World Congress of Pharmacy and Pharmaceutical Sciences; 3-8 October 2012; Amsterdam, Netherlands: 'Professional Service Implementation Index'.

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Preface

This thesis is presented in fulfilment of the joint doctoral degree (Doctor of Philosophy) requirements, under the candidate program agreement between the University of Technology Sydney, Australia and the University of Granada, Spain.

The thesis is structured as a PhD by publication. Chapter 1 provides background and reasoning for the topic and the theoretical and conceptual backbone. This includes the stimulus for the central theories chosen and developed by the dissertation. Chapter 2 presents the research overview and disposition of the dissertation. An outline of the overall rationale, objectives, and organisation of the thesis is followed by an introduction to the sub-studies, how they interrelate and methodological choices. Chapters 3-8 comprise the sequential suite of results, four of which have been accepted as publications and are displayed as copies. These are proceeded by Chapter 9, which discusses the results, including critiquing the data collection, analysis and interpretations, as well summarising the collective contribution of the work. Finally a synthesis of the main findings and recommendations for future research is offered.

Where participants were involved ethics approval and informed consent of participants were obtained. The ethics approvals and associated documentation are supplied as appendices following the corresponding research studies (chapter 5 and chapter 7). All responses remain confidential.

Joanna C Moullin is the primary author of each publication. In addition the publications have co-authors including thesis supervisors and collaborators who contributed to the concept, design, data collection, data analysis, data interpretation, or revision of the manuscripts.

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Abbreviations

AF-FC Forum	Community Pharmacy Pharmaceutical Care Forum (Foro de Atención Farmacéutica en Farmacia Comunitaria)
AHI	Administrative, Handling and Infrastructure
AIC	Australian Implementation Conference
APA	Australian Postgraduate Award
ARC	Availability, Responsiveness and Continuity model
BCT	Behavioural Change Techniques Taxonomy
BCW	Behavioural Change Wheel
CFIR	Consolidated Framework for Implementation Research
CPD	Continued Professional Development
CMI	Consumer Medicines Information
CMM	Comprehensive Medicines Management
COM-B	Capability, Opportunity, Motivation – Behaviour
CONSORT	Consolidated Standards of Reporting Trials
CPA	Community Pharmacy Agreement
DIISRTE	Department of Industry, Innovation, Science, Research and Tertiary Education
DRP	Drug Related Problems
EBP	Evidence Based Practice
EFA	Exploratory Factor Analysis
EPOC	Effective Practice and Organisation of Care (Cochrane group)
ERIC	Expert Recommendations for Implementing Change
FIP	International Pharmaceutical Federation
FISpH	Framework for the Implementation of Services in Pharmacy
GIC	Global Implementation Conference
GIF	Generic Implementation Framework
GTO	Getting to Outcomes
HMR	Home Medicines Reviews
IHI	Institute for Healthcare Improvement
ISF	Interactive Systems Framework for Dissemination and Implementation
KTA	Knowledge to Action
MRC	Medical Research Council
MTA	Medicines Therapy Assessment
MTM	Medication Therapy Management

MUR	Medicine Use Review
NHS	National Health System
NIRN	National Implementation Research Network
NOM	Negative Outcomes associated with Medication
NPT	Normalisation Process Theory
PARIHS	Promoting Action on Research Implementation in Health Services
PBS	Pharmaceutical Benefits Scheme
PCA	Principle Component Analysis
PCNE	Pharmaceutical Care Network Europe
PDP	Pharmacy Development Program
PPI	Pharmacy Practice Incentive
PRECIS	Pragmatic-Explanatory Continuum Indicator Summary
QCPP	Quality Care Pharmacy Program
RE-AIM	Reach, Efficacy/Effectiveness, Adoption, Implementation Maintenance
REP	Replicating Effective Programs
RES	Research Excellence Scholarship
RMMR	Residential Medication Management Reviews
RPBS	Repatriation Pharmaceutical Benefits Scheme
SFT	Seguimiento Farmacoterapéutico (Medication review with follow-up)
SIC	Stages of Implementation Completion
SQUIRE	Standards for Quality Improvement Reporting Excellence
TDF	Theoretical Domains Framework
TIDC	Integrated checklist of determinants of practice
UGR	University of Granada
UTS	University of Technology Sydney
WHO	World Health Organisation
WHSS	World Healthcare Students' Symposium
WIDER	Workgroup for Intervention Development and Evaluation Research

Chapter 1

Background

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Evidence Pathway

The road to evidence-based practice is long and complex. In medical disciplines the traditional research pipeline usually begins with biomedical inquiry and preclinical or animal studies. Translational research follows, involving phase one and two clinical trials and case studies, moving discoveries to human trials, from "bench to bedside". Next a second translational stage, involving phase three and four human clinical trials and controlled observational studies are conducted, moving the evidence to clinical practice (Colditz 2012). It has been proposed that this second translational stage is sufficiently complex to warrant further division: translation to patients (synthesising the evidence including guideline development and systematic reviews), translation to practice (diffusion, dissemination, implementation and sustainability) and translation to population (scale-up and spread) (Colditz 2012; Westfall, Mold & Fagnan 2007). Each one of these translations is a research field in its own right and requires theoretical bases, study designs and indicators. Studies are required to understand and improve the evidence of each phase of the pathway.

A similar evidence pathway is promulgated for human services, including health services [Figure 1]. Research begins with developing a service and testing its efficacy and effectiveness in improving patient outcomes (health and quality of life) and economic outcomes (cost-effectiveness) from the perspective of the [pharmacy] organisation and healthcare system. Next, diffusion and dissemination (communication) studies are required, to further the evidence of how to spread the research findings in order to increase knowledge, awareness and interest. Finally, the service is expected to be adopted, implemented and sustained into routine practice. As with the traditional medical research pipeline, this "implementation process" has been posited as being sufficiently long and complex to consist of multiple phases rather than being a single event. Furthermore, each portion or sub-phase of the service evidence pathway is its own research field that requires theoretical bases, study designs and indicators for evaluation.

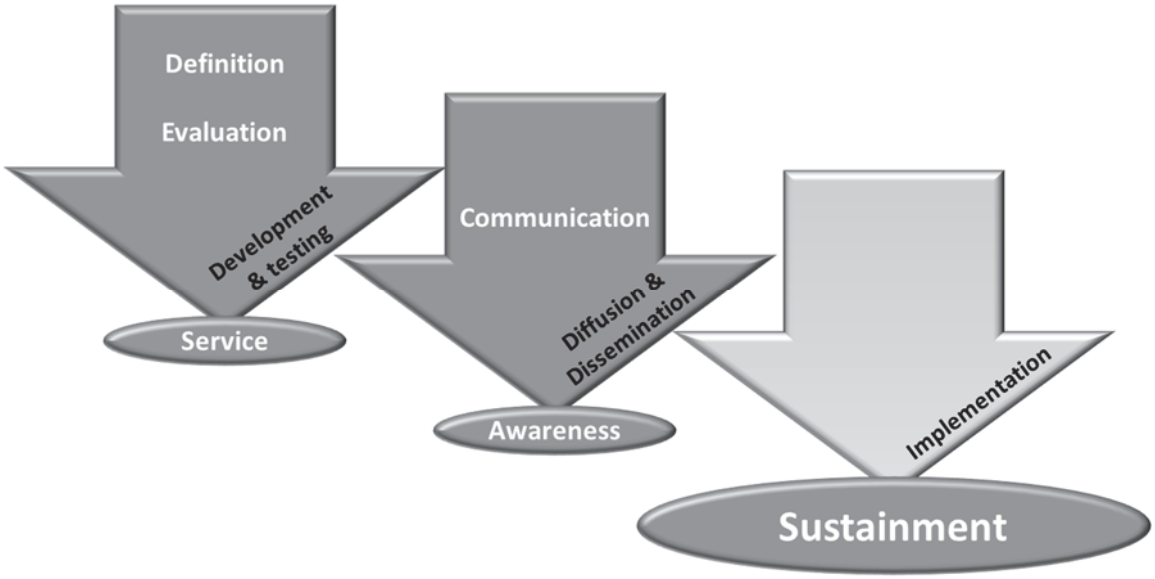

Figure 1 – Evidence pathway for health service research

Until recently, research and crucially funding, have largely been allocated to the development and testing portion of the evidence pathway (Colditz 2012; Rycroft-Malone & Bucknall 2010). Little thought or resources have been assigned to either dissemination or implementation. As a consequence, knowledge and countless innovations have sat idle in academia (Kothari & Wathen 2013). Failure to apply research, including poor utilisation of evidence in decision making by patients, practitioners or policy makers, is an intellectual and financial waste as it does not permit achievement of the outcomes in which the research served to improve (Grimshaw et al. 2012; Proctor et al. 2009). It appears governments are recognising this, indicated by grant proposals requiring the inclusion of both strategies for the translation of results and the expected real-World impact (Research Excellence Framework 2014). These proposals, termed end of grant knowledge-translation, however, are often limited to dissemination rather than implementation strategies, such as publication and conference presentations (Canadian Institutes of Health Research 2015). Consequently a push for implementation strategies and moreover for integrated implementation, that is where implementation principles are applied to the whole research process, has arisen (Kitson et al. 2013; Kothari & Wathen 2013).

Service developers and researchers should consider the final goal, of integration and sustained delivery, and the factors influencing the achievement of this goal, throughout the evidence pathway. As an example, when an innovation or service is developed, consideration should be given to, "how will the service be received?" and, "how difficult will the service be for practitioners to apply in practice?" Such questions are crucial to achieving sustainment and scale-up. In addition the move for integrated implementation involves collaboration or co-production, and different research approaches such as realist evaluation (Dalkin et al. 2015; Pawson et al. 2005; Rycroft-Malone et al. 2012; Salter & Kothari 2014) and participatory action-research (Leykum et al. 2009; Lindamer et al. 2009). For many years services were created by researchers, with the primary objective of attaining evidence of efficacy (Glasgow, Lichtenstein & Marcus 2003). As such, study designs such as randomised controlled trials were used, but which may not have been reflective of the real-World, nor considered future wide-spread implementation. It has been be said the 'state of the science (what researchers collectively know) and the state of the art (what practitioners collectively do) co-existed more or less autonomously, each realm of activity having little effect on the other' (Dearing & Kee 2012, p. 55). The idea of integrated implementation is that innovation use is more likely if both end-users and stakeholders are involved in the research, from development right through to sustainability (Bartholomew et al. 2011; Craig et al. 2013; Kaae et al. 2009; Proctor et al. 2012). In addition, integrated implementation acknowledges the overlap in the research phases and the iterative nature of the pathway.

Paradoxically, to integrated implementation, the evidence pathway appears as at least three distinct phases, where development and testing, diffusion and dissemination, and implementation each deserve direct study (Proctor et al. 2012). Evidence of the implementation process, its influences and indicators, may be subsequently applied to guide the other research phases. Furthermore, as noted, there are developed and tested innovations and services, ready for introduction and integration into practice. As such, research specific for implementing these developed innovations and services is expedient. Implementation as a research field is

gaining increasing momentum and funding (Eccles & Mittman 2006) and divisions of universities, courses and grants dedicated to implementation science and knowledge translation are booming (Padek et al. 2015; Society for Implementation Reseach Collaboration).

Pharmacy practice research

The evidence pathway and research focus of other human service disciplines, are analogous to pharmacy practice research. Internationally, community pharmacy is attempting to introduce and integrate professional services into practice (Houle et al. 2014; Hughes et al. 2010; Wiedenmayer 2006). Professional Pharmacy Services have been developed for decades (Carr & Benrimoj 1996), and remuneration structures studied (Bernsten et al. 2010; Chan et al. 2008), yet many have failed to be successfully implemented (Patwardhan, Amin & Chewning 2014). Current research and funding remains disproportionately allocated to the initial phase of service definition and clinical and cost effectiveness evaluation (Patwardhan, Amin & Chewning 2014). Funding and research attention must be extended to try to understand and improve the introduction and integration of services, as these developed and tested services, even if remunerated and ready for uptake, often struggle at one or more of the stages of the dissemination or implementation process (Bacci et al. 2014; Makowsky et al. 2013; Niquille, Lattmann & Bugnon 2010). Both a lack of integrated implementation in the development stages and a lack of implementation research may be implicated.

Numerous professional pharmacy services have been conceptualised and their clinical effectiveness (Rotta et al. 2015) and cost-effectiveness (Jódar-Sánchez et al. 2015) tested. Although, the true effectiveness and implementability of some services are now being questioned (Rotta et al. 2015). On the one hand, there is scope for improvement in the development and testing of services. Service developers would benefit from using implementation science and conducting research that integrates implementation principles across the entire evidence pathway, such as expanding the contexts and stakeholders involved in the studies, to develop new services. On the other hand, there are developed services ready to move onto practice, and researchers should consider conducting implementation research to investigate their diffusion, dissemination and implementation and subsequently develop theoretically based implementation programs.

Internal and external to pharmacy, implementation research, employing implementation science to develop and evaluate implementation, is scarce (Davies, Walker & Grimshaw 2010; Kaae & Christensen 2012; Magid et al. 2005; Mott et al. 2014; Murphy et al. 2014; Patwardhan, Amin & Chewning 2014; Westbury, Peterson & Bindoff 2014). Dissemination and implementation research in pharmacy has begun but remains predominantly focused on service characteristics, the introduction/adoption (Westrick & Mount 2009), barriers and facilitators across different pharmacy contexts and services (Chui, Mott & Maxwell 2012; Culler et al. 2009; Roberts et al. 2008; Wells et al. 2014), pharmacy culture (Clark & Mount 2006; Scahill et al. 2009) and perceptions of pharmacy and pharmacy services by various stakeholders (Almarsdóttir, Kaae & Traulsen 2014; Montgomery et al. 2010; Saramunee et al. 2014). Minimal research appears on dissemination and implementation strategies and

evaluation (Patwardhan, Amin & Chewning 2014; Scott et al. 2012). The effectiveness of implementation/knowledge translation strategies used in health disciplines, including pharmacy were analysed as part of one systematic review (Scott et al. 2012). Implementation strategies employed in pharmacy studies included educational meetings, materials, outreach visits, audit and feedback, financial incentives and mass media (Scott et al. 2012). Implementation research, where an implementation program or implementation strategy is the intervention being investigated (rather than a clinical intervention or professional service), is in its infancy (Patwardhan, Amin & Chewning 2014).

Conceptual frameworks, models or theories have been applied in pharmacy practice research, across community, hospital and university sectors including: organisational theories such as the lean principles (Benfield et al. 2015), six-sigma (Kumar & Kwong 2011), Leavitt's organisational model (Mandt et al. 2010; Penm et al. 2014), change management (Feletto et al. 2013; Roberts et al. 2006), organisational flexibility for capacity building (Feletto et al. 2010), continuous quality improvement (Boyle et al. 2014); work system approach (Chui, Mott & Maxwell 2012); intervention mapping (Sabater-Hernández et al. 2015; Wheeler, Fowler & Hattingh 2013); community engagement (Mott et al. 2014); RE-AIM (Magid et al. 2005; Mott et al. 2014); social network analysis (Brazinha & Fernandez-Llimos 2014); Normalisation Process Theory (NPT) (Lowrie et al. 2014); theory of planned behaviour (Demik et al. 2013; Salgado et al. 2012); diffusion of innovations (Dualde 2009; Kaae & Christensen 2012; Makowsky et al. 2013; Teeter et al. 2014; Westrick 2010; Westrick & Mount 2009); Consolidated Framework for Implementation Research (CFIR) (Murphy et al. 2014); and Theoretical Domains Framework (TDF) and Behavioural Change Wheel (BCW) (Murphy et al. 2014; Westbury, Peterson & Bindoff 2014). Despite, the use of or reference to, theories of change, a large number of studies fostered efficacy and effectiveness evidence, with patient and service outcomes rather than indicators of implementation, being used. It appears there are a number of gaps in pharmacy practice research including a need to progress implementation evidence.

Community Pharmacy

Community pharmacy and community pharmacists have experienced numerous role changes over history; though by nature have always provided a degree of service. Formerly pharmacies were apothecaries compounding medicinal products, adapting over time to dispensing industry manufactured goods and providing counselling, education and product advice. In recent years the profession has begun to approach a further role change as it attempts to incorporate professional services into pharmacists' practice and the business model of community pharmacy (Almarsdóttir, Kaae & Traulsen 2014).

Pharmacists are well placed to play an active role in healthcare services, as exemplified by a recent description of pharmacists being:

> **"***health specialist trained to exercise independent judgement when dispensing medicines and reviewing the use of medicines, in order to ensure that the medicines are safe and appropriate for the patient and that they conform to prescribers' (generally doctors') requirements. A pharmacist may advise prescribers and patients on the proper use of medicines, and provide primary health care services by educating consumers regarding health promotion and disease prevention."*
>
> (Australian National Audit Office 2015, p. 37)

In addition, community pharmacy is a suitable healthcare setting for the provision of such healthcare services. Community pharmacy is often considered one of the most accessible in terms of location, operating hours and time to be seen (Menzies Centre for Health Policy & Nous Group 2012; Wiedenmayer 2006). Pharmacies are staffed by highly trained, respected and trusted healthcare professionals (Department of Health 2008; Lam 2014; Malewski, Ream & Gaither 2015; Roy Morgan Research 2014). Ownership legislation differs between countries, although generally they are regulated by state or national governments (Chan et al. 2008). Each country has a unique remuneration system, varying between product-based, dispensing-based, service-based or mixed (Sandulli 2014). The financial model of independent community pharmacies has been largely dependent on product: the dispensing and provision of medications, over-the-counter items, and other retail goods. Advice, counselling and healthcare services are part of pharmacy practice, but generally provided, up until recently, without direct remuneration (Farris, Fernandez-Llimos & Benrimoj 2005; Houle et al. 2014).

Internationally, independent pharmacies are under intense financial pressure, largely as a result of economic downturn and governments' need to reduce healthcare budgets (Australia Government Department of Health 2015; Sandulli 2014). In addition there is an increasing awareness of the underutilisation of pharmacists' skills and knowledge and the unique healthcare setting in which they work (Department of Health 2008; Habeeb Ibrahim, Jose & Jegan 2012). As a result, in Australia, Spain and across the World there is a move towards the development, dissemination, implementation, sustainment and profession-wide scale-up of professional pharmacy services.

Australian situation

Australia has 5 457 community pharmacies (Department of Human Services 2014) and 28 950 pharmacists, 26 025 of which are registered and practicing (Pharmacy Board of Australia 2015). Approximately 63% of registered pharmacists work in community pharmacy, the majority as employees (Health Workforce Australia 2014). On average each community pharmacy serves 4 366 people (Australian Bureau of Statistics 2015). Community pharmacies are the primary health destination for medication distribution.

Australian community pharmacies are remunerated by the government to provide subsidised medicines, pharmaceutical benefits, to citizens and eligible overseas visitors through the Pharmaceutical Benefits Scheme (PBS) and the Repatriation Pharmaceutical Benefits Scheme (RPBS). In 1990 the Pharmacy Guild of Australia signed the first of six, successive five year Community Pharmacy Agreements (CPAs). The overarching principle of the agreements is to ensure all Australians (including Aboriginal and Torres Strait Islander people and those in rural and remote areas), have access to safe and efficacious medications and quality, evidence-based, patient-centred professional pharmacy services, to improve healthcare outcomes, maintain a viable community pharmacy network and maximise value to the healthcare system, taxpayer and government (Australia Government Department of Health 2015; The Commonwealth Department of Health and Ageing 2000, 2005, 2010). For the first five agreements the remuneration structure for pharmacy remained largely the same, based on a prescription dispensing fee, a mark-up on the cost of goods and the cost of goods, however, there has been increasing level of remuneration for professional programs and services [Table 1].

> *"While the main purpose of the agreements has been to set out remuneration arrangements for the owners of retail pharmacies that dispense PBS prescriptions, the scope of agreements has progressively broadened to establish a range of government funded professional programs (such as medication reviews), and a funding pool for pharmaceutical wholesalers"*
>
> (Australian National Audit Office 2015, p. 35)

In the first Community Pharmacy Agreement remuneration was only provided for dispensing of prescriptions (The Department of Community Services and Health 1990). The second agreement supplemented prescription remuneration with $4 million for research and development, which included funds for medication management reviews conducted in residential care facilities (The Department of Human Services and Health 1995). The third agreement introduced a Pharmacy Development Program (PDP) to promote community pharmacy moving into service delivery (The Commonwealth Department of Health and Ageing 2000). This was primarily used for a Quality Care Pharmacy Program (QCPP) and Consumer Medicines Information (CMI) handouts, including information technology enhancements to facilitate CMI implementation. In addition, medication management was expanded from residential facilities to incorporate home medication reviews, and an allowance to support aboriginal health services was added under rural initiatives. The dispensing fee was reduced to source funds for the professional services.

Table 1 – Breakdown of professional programs and service remuneration of the Australian Community Pharmacy Agreements

	1CPA	2CPA	3CPA	4CPA	5CPA	6CPA
Medication Management Services			$114 million	$150 million	$164 million	$613 million
General service initiatives			Professional Development Program $165.5 million	Better Community Health $ 178 million	Pharmacy Practice Incentives $75 million	
Services administration			$7.5 million		$277 million	
Rural initiatives			$ 74 million	$ 138 million	$136 million	
Research and Development		$4 million	$15 million	$14 million	$11 million	$50 million
New initiatives				$20 million eHealth	$1 million medication continuance	$600 million TBA
TOTAL FUNDING FOR PROFESSIONAL PROGRAMS		**$ 4 million**	**$376 million**	**$500 million**	**$663 million (c)**	**$1 263 million (d)**
TOTAL CPA VALUE (a)	**$3 286 million**	**$5 497 million**	**$8 804 million**	**$12 158 million (b)**	**$15 385 million**	**$18 886 million (e)**

(Australia Government Department of Health 2015; The Commonwealth Department of Health and Ageing 2000, 2005, 2010; The Department of Community Services and Health 1990; The Department of Human Services and Health 1995)

(a) Community pharmacy agreements also included:
   i. Prescription remuneration: Includes wholesale mark-up, pharmacy mark-up, dispensing fees, dangerous drug fee, extemporaneous preparation fee, premium free dispensing initiative and electronic prescription fee. NOTE: In the 6 CPA an Administration, Handling and Infrastructure (AHI) fee, replaces the previous pharmacy mark-up; Dispensing remuneration to be indexed to the Consumer Price Index
   ii. Community Service Obligation (CSO): Funding pool for pharmaceutical wholesalers that meet the requirements of the CSO, which generally requires participating wholesalers to be able to supply PBS items to any retail pharmacy in Australia within 24 hours

(b) Not included in this figure is the additional $69 million added to the Community Services Obligation pool during the course of the agreement.

(c) Programs and service ($386 million) and administrative arrangements for the programs, including additional programs to support patient services ($277 million).

(d) The total sum is expected to be divided as $613 million for continued investment and remuneration of programs, $50 million for funding a pharmacy trials relating to community pharmacy programs and $600 million to support new and expanded programs with across these figures 3.5% for administration.

(e) Estimated patient contribution of $3.4 billion, across dispensing remuneration and programs, as well as remuneration for wholesalers excluding the Community Services Obligation are not included.

The fourth Community Pharmacy Agreement established a Professional Programs and Services Advisory Committee to 'ensure transparent, contestable, merit based allocation of funds within an accountability framework' (The Commonwealth Department of Health and Ageing 2005, p.6) for professional pharmacy programs and services. The committee's function was to provide advice and recommendations to the Minster of Health on professional pharmacy programs and services, including funding, management, objectives, eligibility criteria, performance outcome measures and monitoring. The fifth agreement greatly enhanced the funding allocated to professional programs and services and was more specific in defining the programs and services (The Commonwealth Department of Health and Ageing 2010). Direct payment per service was paid to pharmacies for

the first time and a pool of funding was provided as Pharmacy Practice Incentives (PPIs). Details of professional programs and service remuneration are provided Table 1.

In June 2015 the sixth Community Pharmacy Agreement was signed. For the first time major changes were introduced to pharmacy remuneration with the introduction of an Administrative, Handling and Infrastructure (AHI) fee to replace the pharmacy mark-up. In essence pharmacy remuneration was separated from medicine pricing, 'intended to support the sustainability of the community pharmacy sector while removing a barrier to future PBS reform' (The Commonwealth Department of Health and Ageing 2015, p.9). Another significant feature of the agreement was a further increase in funding professional pharmacy programs and services, but subject to a cost-effectiveness assessment to inform continuation and investment for the duration of the agreement.

Triggers for Australian community pharmacies to introduce and integrate professional services include the Government, economic pressure and competitive impetus. It can be seen as early as the third agreement that government health policy began to promote pharmacy services, in order to improve patient health outcomes, the rational use of medicines and provide cost-savings for the government. At the same time Australian community pharmacies were seeing declining profits from their dispensing function, largely as a result of separate government cost-saving approaches (e.g. expanded and accelerated price disclosure policy) (Quilty 2014). Furthermore, internal competitive pressure was being exerted within pharmacy due to the emergence of a discount pharmacy business model (Singleton & Nissen 2014). In essence there was a push from the top, at the government level, and trigger from bottom, at the pharmacy level, for pharmacy to change.

Support for pharmacies and pharmacists to introduce and integration professional services in Australia comes from academic research, universities training students in pharmacy practice and service provision, as well as professional organisations developing materials and providing continued professional development. Academic research in Australia has contributed to an ever expanding portfolio of services (Singleton & Nissen 2014) and implementation research, largely exploring the lack of implementation, has been conducted for over ten years (Berbatis et al. 2007; Roberts et al. 2003). Research has been funded by government, industry and Community Pharmacy Agreement. The sixth agreement has provided $50 million to 'trial new and expanded Community Pharmacy Programmes which seek to improve clinical outcomes for consumers and/or extend the role of pharmacists in the delivery of primary healthcare services through community pharmacy' (The Commonwealth Department of Health and Ageing 2015, p15). Universities and professional organisations have incorporated pharmacy practice, pharmaceutical care and professional pharmacy services into their curricula and continued professional development offerings. As such, graduates and registered pharmacists are emphasised as having a role as part of the healthcare team and system.

The implementation of professional services, despite the pharmacy environment appearing ready for change, has not been smooth (Berbatis et al. 2007; Jokanovic et al. 2015; McMillan et al. 2013). A contributing factor may be the lack of implementation knowledge and holistic implementation programs. In the third agreement implementation assistance for one the first professional services, the Consumer Medicines Information (CMI)

program, involved financial incentivises to register, to purchase a printer and initially an 11 cents remuneration per provision, which was later incorporated into the pharmacy remuneration per prescription. A statement signed by the pharmacy to verify they had provided the information was used as quality assurance. Unsurprisingly the registration rate for the CMI program was high, while rate of provision significantly lower (Benton 2004). The fourth agreement provided accreditation incentives for medication reviews as well as $29 million for medication review facilitators. In 2011, during the fifth agreement a subsidiary company of the Pharmacy Guild of Australia was formed to develop a software platform, GuildCare, to assist in the implementation and provision of professional pharmacy services. Despite these initiatives awareness of medication reviews has been shown as low among non-recipient patients and reach to those most in need (Jokanovic et al. 2015). It is unknown what implementation research and resources will be provided under the sixth agreement, apart from the $50 million set aside for the trials.

The Community Pharmacy Agreements and Pharmacy Guild of Australia came under scrutiny after an audit was conducted to assess the effectiveness of the development, administration and realisation of the fifth agreement (Australian National Audit Office 2015). The audit reported a lack of evaluation and internal auditing by the profession, which subsequently did not allow the government to assess performance or the value for money it received. In addition, the report referred to the rigidity of the profession's remuneration structure and not taking the opportunity to restructure away from being linked to the price of medications and shifting from volume sales to professional services.

> *"The then Government and department considered that the 5CPA offered an opportunity to improve health outcomes and value for money by restructuring pharmacy remuneration arrangements 'to diminish their link to the price of PBS medicines.' The Commonwealth anticipated doing so by shifting financial incentives from the volume driven sale of medicines to the delivery of value adding professional services. However, the structure of pharmacy remuneration remained essentially unchanged from the 4CPA to the 5CPA - based on defined mark-ups to the base price of pharmaceuticals and the addition of a variety of fees. Further, key wholesaler and pharmacy mark-ups continued at previous rates."*
>
> (Australian National Audit Office 2015, pp. 93-94)

The audit further commented on that 'the successful implementation of complex programs requires active management and a disciplined and co-ordinated approach to managing risks and challenges through the program life cycle—including the development, costing, negotiation and implementation phases' (Australian National Audit Office 2015, p.27). The audit exposed that the Government, along with a number of pharmacists, universities, and professional organisations were eager for services. As such in the sixth agreement the Government forced upon the professional body representing community pharmacy owners a funding restructure.

Australia has remuneration for an ever increasing number of professional services and pharmacy graduates are equipped with the principles of pharmacy practice, pharmaceutical care and professional pharmacy services. An IT software package to support service provision has been developed. Government policy supports and is pushing for services and increased pharmacy involvement in the health care system. However, practicality and viability of

a new business model for community pharmacy, orientated and supported by professional services, has proven difficult. Australia lacks theoretical guidance, long-term strategy, holistic programs for implementation and involvement and support from all stakeholder groups (such as patients and general practitioners). Some innovative pharmacies have emerged and bottom-up services have been developed internally by independent pharmacies or pharmacy banner groups, however pharmacists appear to be repeatedly clinging to their dispensing role (Mak et al. 2012).

Spanish situation

Spain has 21 854 community pharmacies, with an average catchment of 2 140 people per pharmacy (General Council of Official Pharmaceutical Associations 2014). Compared to Australia, Spain has almost double the number of pharmacies per capita. In total, there are 68 381 pharmacists, with almost 70% registered as community pharmacists, a figure increasing to 86.8% when only actively practicing pharmacists are counted (General Council of Official Pharmaceutical Associations 2014).

As in Australia, Spanish community pharmacies' primary task is medication distribution, for both government and non-government subsidised medications. Spanish community pharmacies are funded by reimbursement for medication based on the retail price of the product and a mark-up, i.e. a product orientated payment system, rather than a service or mixed payment system (Sandulli 2014). Since 2009, the pharmacy sector has seen a sharp decline in profits, beyond that of the economic crisis (Sandulli 2014). In the last two years alone, community pharmacy saw a 20% reduction in turnover, compared to 6-7% shrinkage of the overall economy. In addition, the regulation of public pharmaceutical coverage is causing a transformation of the business aspect of the pharmacy. There is increased competition between pharmacies and a growing dependence on non-National Health System (NHS) business which has acquired increasing importance in the economic survival of pharmacies. As a consequence, Spanish community pharmacies are looking for additional revenue streams, as well as wanting to improve health outcomes for the communities they serve. At this point there is limited payment for professional services, however, negotiation for remuneration of medication review with follow-up service, has begun in four provinces: Navarra, Las Palmas, Santa Cruz de Tenerife and Gipuzkoa.

At the national Government level in 2001, a group of experts formed by the Ministry of Health and Consumption met to discuss the notion of pharmaceutical care (Health and Consumer Ministry Expert Panel 2001). Their first Consensus defined pharmaceutical care as the

> *"Active participation of the pharmacist in patient care involving dispensing and monitoring of a pharmacological treatment, thereby cooperating with the physician and other health professionals to achieve results that improve the quality of life of patients. Also implies pharmacist involvement in activities that provide good health and prevent disease"*
>
> (Health and Consumer Ministry Expert Panel 2001, p. 5)

Five years later in 2006, Spain introduced a rational use of medicine law, which included dispensing with provision of pharmaceutical care, as an essential service for patients and its provision as the responsibility of the pharmacist (Law 29/2006, 26 July, safeguards and rational use of medicines and health products). This law laid the foundations for pharmacists to be included in the healthcare team and deliver professional services.

> *"Pharmacists, being responsible for the dispensing of medicines and medical devices to citizens, shall ensure adherence with the guidelines established by the patient's physician in the prescription, cooperating with said physicians in follow-up treatment through pharmaceutical care procedures, helping to ensure its effectiveness and safety. Similarly, they shall participate in the implementation of a series of activities designed for the rational use of medicinal products, specifically, through informed patient dispensing"*
>
> (Law 29/2006, 26 July, safeguards and rational use of medicines and health products, ss. 84)

However, despite the Spanish Government beginning to accept a greater role of community pharmacy and pharmacists, professional services are not remunerated. Unlike Australia the main triggers for professional service development, dissemination and implementation come from university research groups, professional organisations and their representative pharmaceutical care forums, rather than the Government and remuneration. In 1993, a research group on pharmaceutical care was formed at the University of Granada and in 1998 the first consensus of Granada defined and classified Drug Related Problems (DRPs) into 6 categories (Consensus Panel 1999). This was followed with second and third consensuses in 2002 and 2007 and the development of the Dader Method for conducting medication reviews (Consensus Committee 2007; Sabater-Hernández D, Silva Castro MM & Faus Dáder MJ 2007). This methodology was utilised to establish the professional pharmacy service: Medication review with follow-up.

Concurrently to the research by the University of Granada other organisations and groups began to explore pharmaceutical care and professional services. In 2004, the General Council of Official Pharmaceutical Associations of Spain promoted the formation of a working group composed of representatives of various institutions, across sectors (primary, hospital and community), with an interest in pharmaceutical care. The group became known as the Pharmaceutical Care Forum (Pharmaceutical Care Forum 2006a, 2006b). In 2006 they published their commitment to the profession and in 2008, their first consensus document set out their primary objective: To create a single message, to be communicated between pharmaceutical groups, other health professionals, society, etc., that would develop a practice model of pharmaceutical care services and agree on its concepts (Expert Group of Pharmaceutical Care Forum 2008). The Pharmaceutical Care Forum delves into five areas: justification, motivation, dissemination, training and tools for pharmaceutical care. The agreement resolved to define and optimise three services: dispensing, minor ailment management and medication review with follow-up.

Along with the research on professional services conducted by universities and research groups, the institutions involved in the Pharmaceutical Care Forum, with a specific interest in community pharmacy, considered it necessary to support the implementation of pharmaceutical care and professional pharmacy services specifically into community pharmacies. A new working group, known as Community Pharmacy Pharmaceutical Care Forum

(AF-FC Forum), was created. The aim of AF-FC Forum was to disseminate a unified, simple message centred on medications and medical devices to improve patient care and quality of life through the implementation of professional services in community pharmacy, in order to lay the groundwork for a new professional future (Community Pharmacy Pharmaceutical Care Forum 2009). In May 2010, they launched a practical guide to pharmaceutical care services in community pharmacy (Community Pharmacy Pharmaceutical Care Forum 2010). This guide presented procedures in a practical manner with case studies and introduced an IT support system to standardise the provision and recording of activities, with the aim being to enhance diffusion, dissemination, adoption and implementation of pharmaceutical care services in Spain. In 2011, a consensus was established to develop and implement the three main services nationally (dispensing, minor ailment management and medication review with follow-up), as well as resolving to add additional services in the portfolio (Community Pharmacy Pharmaceutical Care Forum 2012a, 2012b, 2015b). For example in 2015, the AF-FC Forum discussed working on an adherence service, and together with the Spanish Society for Hospital Pharmacists, to define a "Medication Reconciliation Service in Community Pharmacy", along with the next steps that must be taken for their implementation (Community Pharmacy Pharmaceutical Care Forum 2015a).

In 2013 and 2014, AF-FC Forum met with representatives of the faculties of pharmacy and pharmaceutical profession to discuss the current situation of pharmaceutical care in university. The meeting focused on three topics: teaching at university, research, and the relationship between profession organisations and universities. As a result in April 2015, a joint University-Pharmacy Profession committee was created, to develop objectives and content of teaching of pharmaceutical care at university (Portalfarma 2015). Currently professional development courses and Masters Courses are offered by the professional organisations and Universities.

Spain has a defined pathway for services, but is experiencing political resistance, indicated by the absence of remuneration. Furthermore implementation is hindered by resistance from the university sector, where neither pharmacy practice, social and administrative pharmacy, pharmaceutical care, or professional services are not included in undergraduate pharmacy degrees. On the other hand, Spain has the benefit of a working group who defines their services, procedures, dissemination and IT packages. This group provides a clear vision and direction for community pharmacies to follow. However at this stage the political and university system are slow to embrace the change required for professional pharmacy service provision.

Professional Pharmacy Service: Medication Review

Medication review services are a sound example to illustrate the evidence pathway and investigate the international evolution and current situation of professional pharmacy services. Furthermore it reveals lack of implementation research in pharmacy practice and therefore the applicability of studying and employing implementation science.

Medication reviews generally consist of an assessment of a patient's medications to improve quality use of medicine (including improving medication and health literacy, confidence and medication adherence), reduce medication related problems and optimise outcomes of medicine therapy, and enhance health and quality of life (Pharmaceutical Care Network Europe 2012; Zermansky et al. 2002). 'This entails identifying the risk, detecting medication-related problems and suggesting solutions' (Pharmaceutical Care Network Europe 2012, p. 1). Terms for medication reviews include Home Medicines Reviews (HMR), Residential Medication Reviews (RMMR), and MedsChecks [Australia], Clinical Medication Review and Medicines Use Review (MUR)[UK], Medication Therapy Management (MTM)[United States of America], Medicines Therapy Assessment (MTA) and Comprehensive Medicines Management (CMM)[New Zealand], Medication Review with follow-up (SFT)[Spain] (Hatah et al. 2014; Jokanovic et al. 2015; Sabater-Hernández D, Silva Castro MM & Faus Dáder MJ 2007). The focus, involvedness, duration, comprehensiveness, follow-up, and location of the review vary (Bulajeva et al. 2014; Hatah et al. 2014). The Pharmaceutical Care Network Europe recognises three basic types of medication review simple, intermediate and advanced, classified based on the amount of information available and evaluated by the pharmacist (Pharmaceutical Care Network Europe 2012). Remuneration for such services exists in some countries including Australia, New Zealand, United Kingdom and the United States of America (Hatah et al. 2014). Collaboration, referral, eligibility and remuneration structures also vary across countries (Chan et al. 2008).

Multiple clinical and cost-effectiveness evaluation studies have been conducted, with generally positive results (Blenkinsopp, Bond & Raynor 2012; Hatah et al. 2014; Jokanovic et al. 2015). Although it has been acknowledged that studies conducted in a manner to ensure lack of bias, such as having a registered and/or published study protocol, with subsequent process evaluation to assess fidelity, are lacking (Jokanovic et al. 2015; Patwardhan, Amin & Chewning 2014). In addition, multiple studies were completed retrospectively, not allowing real-time process evaluation to be conducted. Medication reviews are complex, multifaceted interventions and therefore these limitations mean that the components that are related to positive outcomes are yet to be deduced.

The lack of widespread dissemination and implementation of medication reviews has been discussed, including a concern for the representativeness of the pharmacies adopting and the patients being reached (Campbell Research & Consulting 2008; Glasgow, Vogt & Boles 1999; Mott et al. 2014). In other words there needs to be a focus on 'ensuring access by those consumers who could benefit most' (Campbell Research & Consulting 2008), not only should a number of patients be reached, but those reached should include those most in need (Glasgow, Vogt & Boles 1999). Furthermore, to achieve high "reach" pharmacies adopting and pharmacists providing the service should ideally be spread across diverse demographic and geographical areas. Dissemination studies to increase

patient and other healthcare professional uptake have been undertaken (Lee et al. 2011). With respect to implementation only research, barrier and facilitator assessments have been completed in many countries. A review of barriers reported accreditation costs, remuneration, consumer awareness, time constraints and rural locations to be barriers to service provision internationally (Jokanovic et al. 2015). Additional studies investigating consumer (White, Klinner & Carter 2012) and stakeholder (Lee et al. 2012) perspectives and those specific for sustainability (Kaae & Christensen 2012; Kaae et al. 2011; Kaae et al. 2010), which have expanded the list of barriers and facilitators.

In Australia advanced, clinical medication reviews (HMR and RMMR) exist concurrently with intermediate, pharmacy based medication reviews (MedsChecks). Effectiveness and cost-effectiveness of clinical medication reviews (HMRs and RMMRs) have been established (Jokanovic et al. 2015). Evaluation of intermediate, medication reviews, such as MedsChecks, appears limited. MedsChecks are a more basic form medication review services, similar to MURs, introduced in the fifth Community Pharmacy Agreement (The Commonwealth Department of Health and Ageing 2010). Unlike other remunerated services, MedsChecks are provided within community pharmacies and required distinct practice and organisational changes to be implemented. MedsChecks involve a consultation (estimated to be 30 minutes to 40 minutes), by a registered pharmacist who is not undertaking other professional duties at the time, face to face with the patient, in an area of a community pharmacy that is physically separated from the trading floor to ensure privacy and confidentiality. Diffusion strategies were employed in terms of a mass media campaign, and conference presentations. Dissemination involved using software providers as implementation facilitators. Adoption rates of the services by pharmacies, based on registration to the GuildCare platform, are reported as high (Sclavos 2012). The true implementation level in terms of representativeness of the pharmacies adopting, representativeness of the patient population reached, and fidelity of the service implementation and delivery remain largely unknown. In addition, the process of implementation in pharmacies and the influences across the different implementation stages have not been explored.

In Spain, the Dader methodology was created by the Pharmaceutical Care Research Group at the University of Granada as an approach for undertaking medication reviews and achieving pharmaceutical care (Sabater-Hernández D, Silva Castro MM & Faus Dáder MJ 2007). The methodology was subsequently used to develop a pharmacotherapy monitoring, medication Review with Follow-Up, service (Seguimiento Farmacoterapéutico (SFT)) [Table 2].

The SFT service is defined as

> *"professional practice in which the pharmacist is responsible for patient necessities with regard to medicines. Such a practice is carried out through the detection of drug related problems (DRP) for the prevention and solution negative outcomes associated with medication (NOM). This service implies a commitment, which should be provided on a continual basis in a systematic and documented way. Such a process should be carried out in collaboration with the patient himself and other professional health care staff, with the aim of achieving specific results that improve the patient's quality of life."*
>
> (Consensus Committee 2007, p. 16)

Table 2 - Concepts of medication review with follow-up service

Conceptual variable	***Operational definition***
Professional	Pharmacist must be able to use and apply their technical knowledge to assess and intervene in every situation
Commitment	Relationship is established and formal agreement is made between the pharmacy and participating patients.
Continuous	Continuous and indefinite-in-time monitoring and evaluation of effects of the drugs the patient uses and intervention results, including education and comprehensive treatment of the patients' health problems. Involves using a developed action plan.
Systematic	Adjustments to guidelines, made in an orderly fashion contributing to reach the goal via the design and development of procedures, for example using Dader method.
Documented	Development of documentation systems to facilitate adequate recording of service activities.
Collaboration	Necessary integration of the pharmacist's role in the multidisciplinary health team that cares for the patient. Pharmacist must know and define what their role entails in terms of the management and care of the patient's health problems and provide their clinical judgment, made from the perspective of the drug, when they see fit.
Patient-centred	Pharmacist must cooperate and collaborate with the patient to achieve preservation or improvement in the health status of the patient
Detection	Detect medication-associated problems in order to prevent and resolve medication-associated negative outcomes. SFT is a clinical activity in which the pharmacist will detect changes in the patient's health status attributable the use of medication. This involves the use and measurement of clinical variables for determining whether drug therapy is necessary, effective and/or safe.
Results	Assess and intervene in every situation to achieve preservation or improvement in the health status of the patient.

(Sabater-Hernández D, Silva Castro MM & Faus Dáder MJ 2007)

The SFT service was shown to be effective, for optimising prescribed medication and improving quality of life, and cost effective (Jódar-Sánchez et al. 2015). In addition the perception of pharmacists have been assessed (Gastelurrutia et al. 2011). Systems interventions are now required to gain political support and remuneration. In addition implementation science may assist in developing implementation programs and tools that may be used in the future.

On one end of the spectrum you have Australia, amongst the pioneers of medication review services, with service provision remunerated, taught at universities and successful implementation, or at least adoption, being declared. On the other you have countries such as Spain, who have sound conceptual development and evaluation of medication review with follow-up service and a strong foundation to communicate with the profession, however are yet to receive any government remuneration and thus implementation and achieving sustainability is

thwarted. Despite Spain being in a different position along the implementation path of professional pharmacy service, experiences and challenges are shared. Across the World there is movement to try and more actively incorporate pharmacists into the healthcare system and healthcare team. It appears the political will in both countries is to improve health outcomes and quality of life of patients, while reducing health expenditure with pharmacies and pharmacists being flagged as having a role. Yet the implementation challenge is real.

In summary, it can be seen that Australia could benefit from implementation science to assist in the evaluation, sustainability and scale-up of current services as well as grounding newly developed projects in implementation principles. While Spain, could use implementation science to hopefully achieve a smoother implementation journey from the onset.

Implementation Science

Internationally, across multiple disciplines there is a realisation of gaps in the take-up and the need to study and improve implementation. "Science to Service", "research to reality", "evidence to practice," "know-do", are all terms used to indicate gaps in the take-up and application of innovations (Brownson, Colditz & Proctor 2012; Proctor et al. 2009). More recently there has been discussion of an "implementation gap" and a "quality chasm" referring to services not being implemented and/or sustained over time and not being delivered with fidelity, as they were originally designed and intended (Fixsen et al. 2013). There is also an extension of this fidelity debate, of whether it is necessary to safeguard results achieved in controlled clinical trials by pushing fidelity, versus allowing and encouraging adaptation, which has been shown to assist introduction and integration (Durlak & DuPre 2008).

There is increasing recognition and priority being placed on dissemination and implementation research around the World (Eccles & Mittman 2006). Implementation science and knowledge translation has arisen to move innovations into practice, drive research utilisation and evidence-based practice (EBP), and by doing so improve the worth of research (Rycroft-Malone & Bucknall 2010). Implementation involves change, but is further complicated by necessitating change within and across multiple contextual levels, by multiple stakeholders (Wandersman et al. 2008). Implementation may require innovation adaptation/change, behavioural change, organisational change and systems change (Foster-Fishman & Watson 2012; Holmes et al. 2012; Michie et al. 2005; Stirman et al. 2013; Weiner 2009). In light of this, it is not surprising there is an implementation challenge nor that this challenge is not unique to pharmacy practice, but is shared among all human services (Fixsen 2005). Implementation science is a cross-disciplinary field that engages practitioners, service providers, policy makers and researchers from clinical, education, community and policy contexts (Eccles & Mittman 2006). Implementation science is about opening the "black-box" of implementation in order to develop logical, useable approaches that can be easily understood and utilised by researchers and practitioners to close the implementation "gaps" (Brownson, Colditz & Proctor 2012; Proctor et al. 2009).

Implementation science is a research field directed towards building evidence on how (effective implementation strategies and programs), by whom (facilitators/coaches, purveyors, intermediaries, stakeholders), where (enabling contexts including policy, clinical and community settings) and for whom, any innovation, in any given situation, may be introduced and integrated into practice (Fixsen 2005). Implementation research is needed for all these implementation questions, while incorporating implementation evidence across the whole research pipeline to create professional services that are more marketable, acceptable, and workable for the diverse professional networks (Powell et al. 2013).

Foundations of the discipline

The propagation of implementation science is widely attributed to Everett Rogers's seminal "Diffusion of Innovations," although its advent is traced to much earlier anthropology and social science research (Rogers 2003). Roger's work was based on initial research conducted in 1943 on the adoption, or lack thereof, of hybrid corn seed by farmers in Iowa USA, together with a synthesis of other studies, from diverse fields, which also utilised the diffusion of innovations theory (Rogers 2003). The diffusion of innovation paradigm is rooted in communications theory. The diffusion process and rate of adoption are explained by: innovation attributes, adopter innovativeness, innovation-decision process, communication channels, and the social system. The popularity of diffusion studies spread from rural sociologists into general knowledge utilisation by social and political scientists, where policymakers were the adopters, as well as to technology transfer and knowledge translation, in large organisations (Dearing & Kee 2012). At a similar time concepts and theories on research utilisation, and evidence-based medicine/practice were gaining momentum (Estabrooks et al. 2008).

In many ways the principles from diffusion theory have remained constant, but have been explored further and subsequently expanded, with research investigating the ensuing stages, post the adoption decision, of the implementation process (Rycroft-Malone & Bucknall 2010). With time and further evidence, multiple other approaches have been added to the communication based diffusion theory, and frameworks and models have proliferated (Tabak et al. 2012). Interest in diffusion of innovations continues, as is recognition of the importance of the ensuing introduction and integration stages post-awareness of the innovation. These stages have been termed the implementation process and the study of this process and strategies to improve successful implementation, called implementation science. Implementation science amalgamates different theories and various lenses are offered to view processes and outcomes. Regardless of the lens the notion is moving an innovation or knowledge among individuals and contexts by various means to achieve outcomes.

Terminology

Alongside implementation science the term knowledge translation is commonly used, particularly, in health and policy sectors in the Europe and Canada. Knowledge translation was used by the World Health Organisation (WHO), in their policy to close the 'know-do-gap' (World Health Organization 2006). Subsequently, WHO have released a practical guide to implementation research in health, blurring the terminology boundaries (Peters 2013). Other distinct, but similar terms and often used interchangeably to knowledge translation include research or knowledge utilisation, transfer, mobilisation or exchange (Ottoson & Hawe 2009). Within these fields the terminology and inclusion of concepts within their frameworks vary, however the goals, principles and theories are largely similar (see chapter 4).

The terminology of the implementation fields can be confusing. Not only does implementation science use different terms to knowledge translation, but within the fields and within the same disciplines different terms are

often used to mean the same thing (synonymy), or the same term is used to mean different things (homonymy) (McKibbon et al. 2010; Proctor, Powell & McMillen 2013; Rabin et al. 2008). For example the word "intervention" may refer to an "implementation intervention" or to a "clinical intervention". Another example is the end-user, which in implementation usually refers to the individual who will deliver the innovation (the implementer), whereas in pharmacy practice, other health services and public health disciplines the end-user is the individual receiving the innovation (i.e. patient). Throughout the thesis, including publications a typology of implementation terminology for pharmacy has been defined. These implementation science based pharmacy practice definitions have been published as appendices (chapter 4 and chapter 5).

Theoretical approaches

One of the interesting and valuable aspects of the implementation science is that it incorporates concepts from a large array of disciplines and theories to provide a more holistic view of the implementation process and its determinants. Disciplines drawn upon include sociology, psychology, political science, business and communications (Nilsen 2015), theories include cognitive, behavioural, and organisational (Davies, Walker & Grimshaw 2010) and systems thinking to cross social ecological boundaries (Foster-Fishman & Watson 2012). As mentioned pharmacy practice researchers have looked at implementation using a range of approaches, but it may be beneficial to consider implementation from a more holistically.

Along with realisation of the importance of the later phases of the evidence pathway, dissemination and implementation, as mentioned there has been insight that for successful implementation, implementation evidence should also be considered during the early, innovation or service development, phase (Kitson et al. 2013; Kothari & Wathen 2013). Examples of frameworks that incorporate principles of implementation into the development phases include: the medication research council of UK's Framework for Complex Interventions (Craig et al. 2008; Craig et al. 2013), knowledge translation frameworks that are based around theories of planned action such as Knowledge to Action (KTA) (Graham et al. 2006) and intervention mapping (Bartholomew, Parcel & Kok 1998). Nevertheless, such frameworks generally require additional, more specific theories to operationalise the implementation steps.

It was once assumed the diffusion, uptake and use of innovations would occur naturally. This was followed by empirically based implementation research, case studies, or use of anecdotal evidence (Glasgow, Green, et al. 2006). Eccles et al (2005) described this as an expensive version of trial and error. Mixed results persisted and the lack of theoretical backbone and poor reporting made explaining success or failure and replication of results difficult (Eccles et al. 2009). Theory is needed to test hypotheses and predict implementation success. As implementation science has gained momentum and funding, there has been increased recognition of the importance of using established change theories, models and/or frameworks, as well as developing theoretical bases from within the implementation science discipline. Theoretical grounding may be used to determine and assess factors, create and evaluate strategies and develop tools and measures in order to gain evidence into the

mechanisms of implementation and the ways in which implementation is more likely to succeed (The Improved Clinical Effectiveness through Behavioural Research Group 2006). It is largely accepted that research should to be theoretically driven and implementation research is no exception, however the debate on frivolous theory over common sense and empirical evidence lingers (Bhattacharyya et al. 2006; Oxman, Fretheim & Flottorp 2005).

The basis of generalised behavioural theories is that practitioners' behaviour is a form of human behaviour (Eccles et al. 2005). Diffusion of innovations was one of the first theories to link macro-level processes of systems change with micro-level processes of individuals' behavioural change (Dearing & Kee 2012). Individuals were shown to be influenced by social norms, while systems structures and rules are the result of individuals' actions. A second sociology grounded, classic theory, under the implementation umbrella, Normalisation Process Theory (NPT), was developed to understand the process of embedding practices (May 2010). In contrast to diffusion of innovations which explores up to the point of the adoption decision, NPT describes later integration stages of implementation process. The theory may be used to understand and evaluate implementation and how to adapt innovations to make them more "workable".

Implementation theories, models and frameworks have been classified as being concentrated towards, content and context (determinant frameworks, classic theories or implementation theories), process, or evaluation (Nilsen 2015). Within these classifications there are broach overarching frameworks (e.g. lists of factors, strategies or measures; stages, steps or evaluations across the entire implementation process; multi-level context derivations; general theory of implementation) as well as frameworks for specific concepts (e.g. fidelity, organisational readiness, implementation climate, adoption stage, sustainability stage). In addition, frameworks, models and theories from related fields are used (e.g. intervention development models such as intervention mapping; behavioural motivational, action or stage theories; organisational or quality improvement theories; systems thinking). There is occasion for all frameworks, models and theories depending on the research question, objective, contextual level being targeted, setting and point in the evidence pathway that is being investigated. This research seeks to review the implementation science literature on frameworks, models and theories and subsequently help select or create a framework for implementation in pharmacy practice (chapter 4).

Implementation research

The objective of implementation science is to understand the mechanisms required to improve implementation success (Proctor et al. 2009). Rabin described that implementation research 'seeks to understand the processes and factors that are associated with successful integration of evidence-based interventions within a particular setting' (Rabin 2008, p. 119). Implementation research is specific for researching the effect of implementation strategies and programs. This is distinct to health services research which focuses on the effect of the health innovation being implemented. In other words implementation science is focussed on the processes, influences and outcomes of implementation, rather than the processes, determinants or outcomes of the innovation. The study of implementation strategies need to be scientifically tested, as would a clinical intervention. To produce rigorous implementation evidence study designs, tools and analyses need to relate to implementation objectives and indicators (Landsverk 2012). Proctor et al (2013) describe the principles of naming, conceptually defining, and specifying (actor, action, target, temporality, dose, implementation outcome affected, justification) to operationalise and contextualise implementation strategies. An Effective Practice and Organisation of Care (EPOC) group was formed at the Cochrane Institute to evaluate effectiveness of implementation strategies (Cochrane Effective Practice and Organisation of Care Group 2010). Ideally, implementation strategies should follow an evidence path, from theory building to phase I modelling, Phase II exploratory studies before phase III implementation and phase IV sustainability trials (Eccles et al. 2005).

External validity and generalisability is central to implementation science, as research addresses the introduction and integration of innovations within real-world, complex, service systems. In many health service fields, including pharmacy practice research, internal validity has been emphasised, leading to testing in restricted populations with narrow interventions, and meta-analyses which exclude non-randomised trials. It follows that moving innovations into diverse settings is a haphazard process where it is unknown if the interventions will be workable and produce the outcomes shown in the controlled setting (Eccles et al. 2009). The Consolidated Standards of Reporting Trials (CONSORT) statement recommends researchers summarise the extent a study is pragmatic versus explanatory to increase the external validity data available for systematic reviews (Zwarenstein et al. 2008). The Pragmatic-Explanatory Continuum Indicator Summary (PRECIS) has been developed to provide guidelines (Loudon et al. 2015). In addition the extended Consolidated Standards of Reporting Trials statement (CONSORT statement) includes recording recruitment (reach) and maintenance (sustainability) details (Calvert 2013). It follows that future pharmacy practice research should also consider the addition of reporting implementation indicators and outcomes (chapter 6).

The interrelationships within and across social ecological levels require novel study designs for innovation and service development and testing, dissemination, and implementation (Lindamer et al. 2009; Mendel et al. 2008). Study designs for implementation research include an array of hybrid, staging, adaptive, and mixed method protocols. In particular it is being recommended that developers consider participatory action research to design services that are feasible, implementable and produce relevant outcomes for all stakeholders. Social network analysis, economic evaluations, studies of sustainability and longitudinal studies using stepped-wedge or

interrupted time-series designs are being suggested (Landsverk 2012). Realist evaluation is also beginning to be utilised in implementation science (Dalkin et al. 2015). This approach is based on program theory where the focus is on studying the mechanism or response implementation strategies trigger in stakeholders, and the resulting outcome (Dalkin et al. 2015). Realist evaluation investigates the causes, mechanism and factors associated with an outcome, rather than just the outcome, and therefore is an approach targeting the questions that consume implementation 'what works, for whom, in what circumstances?' (Salter & Kothari 2014, p. 2)

Evaluating complex interventions such as health programs and professional pharmacy services is challenging. There is often not a single outcome or stakeholder, but a large number of potential measures of success and groups and individuals with an interest (Ottoson & Hawe 2009). Funders are often interested in "reach," wanting to know the number of participants and if the service has reached those most in need. Program developers are often interested in milestone attainment of the stages of "adoption" and "implementation". These measures may be further augmented by indicating if practitioners accept the innovation and subsequently use the innovation, or provide the innovation with fidelity. To correctly attribute observed outcomes of an innovation to those achieved in efficacy or effectiveness studies, the researcher should have empirical evidence on the extent to which innovation components were implemented, the degree of fidelity. Only by understanding and measuring whether an intervention has been implemented with fidelity can researchers and practitioners gain a better understanding of how and why an intervention works, and the extent to which outcomes can be improved (chapter 7). At this stage in pharmacy practice research has only minimum reporting of implementation measures and the optimisation of services (Patwardhan, Amin & Chewning 2014). It is of extreme importance to assess service implementation prior to analysing program effectiveness. In a similar way it is important when conducting implementation research to assess the extent to which implementation program components were delivered, in order to attribute successful implementation to the program.

Implementation concepts

In basic terms implementation success is impacted by

- What is to be implemented (the innovation)
- Where and for whom is the innovation to be implemented (the context)
- How and by whom is the innovation to be implemented (the implementation program)

Figure 2 – Active implementation framework formula for success (Fixsen et al. 2013)

Developing evidence on what constitutes effective implementation, for which innovations, in which contexts, is the primary focus of implementation science (Fixsen et al. 2013; Salter & Kothari 2014). Knowledge translation has mirrored concepts, where successful implementation has been postulated to be calculated from evidence, context and facilitation in the Promoting Action on Research Implementation in Health Services (PARIHS) framework (Kitson et al. 2008). Similar components have also been voiced as the essential ingredients of change management and organisational change (Worren, Ruddle & Moore 1999). By being multiplications, the implementation equations signify that all components are imperative and must be considered, and that if any component equals zero, the outcome will be zero, i.e. unsuccessful implementation.

Related implementation influences may be grouped into domains or levels offering an alternative division for the implementation concepts presented above. In addition the complexity of the interrelationships between the levels should be depicted (Mendel et al. 2008; Wandersman et al. 2008). The contextual levels for pharmacy are determined in chapter 5. The division and terminology of domains are often discipline specific however some broad classifications include:

- Program/intervention design, external environment, implementation and sustainability infrastructure, recipients (organisation and patients) (Feldstein & Glasgow 2008)
- Innovation, organisation, environment, individual (Dobbins et al. 2009)
- Intervention characteristics, individual characteristics, inner setting, outer setting, process (Damschroder et al. 2009)
- Communities, providers and innovations, and aspects of the prevention delivery system (i.e., organisational functioning) and the prevention support system (i.e., training and technical assistance (Wandersman et al. 2008)

i) What is to be implemented?

Implementation science arose as innovations, including research evidence and knowledge, sat idle in academia and empirical evidence and knowledge were not spreading. Innovations are defined as a novel set of behaviours, routines, and ways of working within a setting (Greenhalgh et al. 2004). Innovations vary from a new technology

or guideline, to a service or program, or a novel way of working, such as continuous quality improvement initiatives or evidence-based practice. The characteristics of innovations influence the ease and likelihood of successful implementation. The innovation's attributes effect all stages of the implementation process, from exploring and appraising the service and deciding whether or not to implement (adoption decision), to how much preparation is required, how difficult the service is to introduce, the challenge of gathering support and integrating into practice, to finally influencing the spread across diverse settings.

It appears professional pharmacy services are largely developed prior to considering implementation and sustainability. It is therefore possible that the research conducted may be producing innovations that are not implementable. Integrated implementation would be desirable to increase their acceptability, implementability and sustainability. In addition investigating the components of services would be recommended so that adaptations to the innovation may be made, while ensuring the positive outcomes obtained in the trials are transferred to real-world practice. Pharmacy practice research could benefit from service development and optimisation studies, which incorporate implementation science, as well as implementation research on services that are already developed and available for implementation.

ii) Where and for whom is it to be implemented?

The context into which an innovation is to be implemented is gaining increasing attention in implementation science literature. The notion of contextual domains, groupings of related influences regarding the circumstances that surround the innovation to be implemented (Damschroder et al. 2009), is to acknowledge and embrace the complexity of the system and consider all social ecological levels, at all stages of the process. Generally one should consider the characteristics, readiness and agency of all stakeholders involved with an innovation and/or the implementation process, the conditions and characteristics of the setting(s) in which the innovation is to operate, the circumstances immediately surrounding the organisation(s) including the community, patients (for whom the innovation is targeting) and their social network, and finally the economic, political and professional milieu. Mendel et al (2008) use complexity theory in their framework including multiple levels of context and illustrating the importance of capacity building. The Interactive Systems Framework (ISF), a community service implementation framework, also focuses on building the capacity of the service delivery system and the service support system, plus the interrelationships between these levels (Wandersman et al. 2008). Their latest framework the Evidence-Based System for Innovation Support (EBSIS) builds on the ISF by delineating an implementation program specific for capacity building (Leeman et al. 2015). In addition implementation science is beginning to acknowledge the importance of considering and involving the community and patients in the process (Kitson et al. 2013).

Tools and theories of contextual factors are being developed and tested, such as implementation climate (Ehrhart, Aarons & Farahnak 2014; Weiner et al. 2011), leadership (Aarons, Ehrhart & Farahnak 2014), implementation citizenship behaviour (Ehrhart, Aarons & Farahnak 2015), organisational readiness (Weiner, Amick & Lee 2008), organisation context (Estabrooks et al. 2009; Helfrich, Sharp & Sales 2009)). Another implementation equation

exists for organisational readiness where 'readiness = motivation x general capacity x innovation-specific capacity ($R=mc^2$)' (Scaccia et al. 2015). This equation suggests readiness is dynamic, where for example an organisation such as a pharmacy might be 'ready' to adopt, but not ready to implement. Therefore readiness is required for all implementation stages.

Conceptual frameworks are a perpetually evolving through revisions and enhancements. In addition it is possible to contextualise and adapt frameworks for individual situations. For instance the context domains may be further divided depending on the desired analysis and research question. As an example a domain of the local setting surrounding a pharmacy, may be split into three sub-domains of its constituent parts, patients, community and local healthcare professionals. In the countries involved in this research, Australia and Spain, pharmacies show cultural and contextual differences. Compared to Australia, Spanish pharmacies are commonly owned by single proprietors, who can only own one pharmacy, are smaller in size and have longer employer tenure. Therefore, an example of theoretical adaptation would be considering that "team" based concepts may not be applicable or suitable for strategies or evaluations in Spanish pharmacy settings.

iii) How and by whom is it to be implemented?

The crux of implementation science is to answer the question, "How and by whom should an innovation in a particular context be implemented?" Or "What constitutes effective implementation?" The answer is not simple. Implementation consists of a complex process, often to implement complex innovations, across complex social systems.

The individuals involved in the implementation process have been shown as vital (Rycroft-Malone et al. 2013; Stetler et al. 2011). They are part of both effective implementation (who is delivering the implementation strategies?) as well as enabling contexts (who is delivering the innovation?). Staff selection, implementation teams and leadership are particularly prominent implementation topics (chapter 5). In addition the use of knowledge brokers, purveyors and intermediary organisations has received attention (Gagnon 2011; Oosthuizen & Louw 2013). Research, funding and use of implementation facilitators may be valuable for professional service implementation.

Process of Implementation

It is widely accepted that implementation is not a single event, but a long and complex process. The process is delineated into numerous different arrangements and typologies of stages. In addition, in some derivations, the stages are further divided into a series of activities or steps. In particular branded implementation programs and frameworks that include the development or synthesis phase, such as in knowledge translation, quality improvement and intervention mapping, appear to be more prescriptive of the implementation process.

Examples of the implementation process stages include:

- Knowledge, persuasion, decision, implementation and confirmation (Innovation-decision process up until point of adoption) (Rogers 2003)
- Orientation, Insight, Acceptance, Change (Grol 1992)
- Research information (synthesis, distillation, appraisal), credible dissemination (awareness, attitude, knowledge), implementation (information, negotiation, public pressure, incentives, regulation, catalysts), application (Lomas 1993)
- Problem identification, direction setting, implementation, stabilisation (Glisson & Schoenwald 2005)
- Knowledge creation (tailoring knowledge): knowledge inquiry, synthesis, product tools; Action cycle (application): identify problem, identify, review, select knowledge, adapt knowledge to local context, assess barriers to knowledge use, select, tailor, implement interventions, monitor knowledge use, evaluate outcomes, sustain knowledge use (Graham et al. 2006; Straus, Tetroe & Graham 2009)
- Recognised gap, initiation of innovation (stage 1 – new ideas), adoption (stage 2 – decision to adopt), implementation (stage 3 – extent of implementation) (Jantz 2011)
- Exploration, installation, initial implementation, full implementation (Fixsen 2005)
- Exploration, adoption, active implementation, sustainment (Aarons, Hurlburt & Horwitz 2011)
- Awareness, adoption, implementation, institutionalisation (Steckler et al. 1992)
- Training, adoption, implementation, practice improvement (Simpson & Flynn 2007)
- Initial contact and framing the issue, knowledge refining and testing, knowledge interpreting, contextualising and adapting, implementation and evaluation, embedding in context, translating to other contexts (Kitson et al. 2013)

The stages and steps are criticised for their ambiguous, linear derivation, as the process appears to be iterative. Frameworks, such as Greenhalgh et al. (2004), are less linear in appearance, where system antecedents and system readiness occurring parallel to diffusion and dissemination, both leading to adoption/assimilation, followed by implementation and finally consequences. It appears for illustrative and planning purposes many frameworks take a temporal, stage based approach. Ensuing is a general introduction to the stages of implementation.

Development/identification/knowledge creating/problem detection: To start with an innovation or service must be identified or created, synthesised, refined, evaluated and packaged (Graham et al. 2006). As the program and service development fields progress the importance of planning for implementation and sustainability from the beginning of the process is being emphasised. A recognised method, known as co-production or co-creation, involves support from stakeholders across multiple ecological levels. In addition, it is being emphasised that researchers should include, either quantitative or qualitative, implementation indicators in effectiveness studies, to assess the likelihood of future implementation.

Communication: After an innovation is developed it must be communicated and "sold". Communication is the process by which people learn and share information about a new innovation (Rogers 2003). Aim is to increase knowledge, awareness and perception of the innovation to increase the rate and level of adoption.

Diffusion: Is natural passive communication, spread or horizontal transmission through a social system that is untargeted and uncontrolled (Rabin et al. 2008; Rogers 2003). The onus is on the adopter to seek, absorb and act on the information. Examples of diffusion include presentations at conferences, publishing in journals and mass mailings.

Dissemination: Is an active approach of communicating and spreading innovations to a recipient audience via determined channels, using planned strategies (Greenhalgh et al. 2004; Rabin et al. 2008). Different approaches may be used to target the messages, by taking into account the innovation and contextual factors of the audience. Examples of dissemination strategies include use of opinion leaders, interactive educational sessions and targeted media campaigns.

Exploration/awareness/knowledge & persuasion/innovative-decision process/adoption:
The diffusion and dissemination process leads to an end-user being aware of or discovering an innovation, which then requires appraisal to clarify, asses pros and cons, feasibility etc. In diffusion theory, the process has been called the "innovation-decision process," whereby the end-user(s) appraises the innovation concluding with a decision to either to accept/adopt or reject. The stage occurs from first awareness of an intervention (or identification of an issue, need and/or new innovation), progressing through knowledge, persuasion, opinion and finally adoption decision (Rogers 2003).

Preparation/adoption: Prior to innovation use there is a period of preparing the innovation and context (individuals, organisation, local environment and external system)(Fixsen 2005). Developing and ensuring organisational readiness prior to moving to provide the innovation is thought to be essential (Scaccia et al. 2015; Shea et al. 2014; Weiner 2009).

Implementation/application/operation: The implementation stage is a transition period during which the innovation is in use and is in the process of being integrated into routine practice through active and planned approaches (implementation strategies). Practitioners are increasing their skills, confidence, efficiency, consistency and commitment to its use (Century, Rudnick & Freeman 2010; Rabin et al. 2008).

Sustainability/institutionalisation/full implementation/innovation/practice improvement/ confirmation/ stabilisation/maintenance/post-implementation: Maintaining the innovation is a dynamic process of continued innovation use integrated as routine practice, ongoing capacity and environment sufficient to support innovation use and persistence of benefits. Moving from operation to sustainability occurs when three conditions are met: service deliver continues, after any implementation program (or external assistance) has ceased, there is sufficient capacity (supportive context) for this ongoing delivery and service benefits are maintained (Goodman et al. 1993; Pluye, Potvin & Denis 2004; Shediac-Rizkallah & Bone 1998).

Scale-up/replication/Spread: Depending on the discipline there is discussion of scaling-up as the proceeding stage post sustainability. Scale-up is a particularly prevalent in public health (Milat, Bauman & Redman 2015).

This stage is focussed on increasing adoption, to a greater number of organisations, and reach, to a larger patient population.

Implementation Elements

During the implementation process, when conducting implementation research or developing implementation programs, implementation factors, strategies and evaluations should be discussed and taken into account. These three "implementation elements" should be considered for each domain, that is the innovation to be implemented and the contextual or ecological levels of the environment into which the innovation is being introduced, at each stage.

Factors

Factors are the variables that may affect the implementation process. Also termed influences, facilitators and barriers or determinants of practice (Flottorp et al. 2013). List-style frameworks of factors include the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al. 2009), integrated checklist to identify determinants of practice (TICD checklist) (Flottorp et al. 2013), and Theoretical Domains Framework (TDF) (Michie et al. 2005), Behavioural Change Wheel (BCW) (Michie 2014). Some researchers have narrowed down the scope of the factors and developed models that link to aid in the selection of strategies, such as the PRECEDE-PROCEED (Green 1999).

The use of factor frameworks assists reflection within all domains, enables consistent terminology to be used across disciplines, may be used to link to theories to tailor suitable strategies, and allows for implementation impact evaluation (where determinants of implementation are evaluated). Factors may act as moderators, where they modify direction or strength of an effect, or as mediators, where they account for part of an effect (Flottorp et al. 2013). Once relevant factors, such as components of a behaviour or influences of a behaviour, have been determined, appropriate strategies may be chosen, including the operationalisation and reasoning of the strategy, such that the proposed mechanism of action, which may be tested (Dalkin et al. 2015; Eccles et al. 2005). As mentioned, barriers and facilitators to professional pharmacy service implementation have been tested, however using a typology that links to strategies, and assessing the factors influencing the implementation by multiple stakeholders, at different time points may advance implementation evidence for the implementation of professional pharmacy services.

Strategies

Implementation strategies are the efforts (method, technique or activity) designed to enhance the movement of an innovation into use and being integrated into routine practice (Curran et al. 2012; Flottorp et al. 2013). 'Implementation strategies are inherently complex social interventions, as they address multifaceted and complicated processes within interpersonal, organisational, and community contexts' (Proctor, Powell & McMillen 2013, p. 3). In a similar vein as clinical interventions being designed to affect behavioural or environment determinants of patients' health, implementation strategies are designed to affect the behavioural or environmental determinants of practitioners' practice. Strategies may need to adapt or translate innovations, change behaviour, impact organisational structure, climate, and culture; shift perceptions of communities or enable policy amendments. Implementation strategies include:

> *'how to translate interventions to encourage uptake and implementation in ways that preserve scientifically validated components of evidence-based practices, how to obtain buy-in of various stakeholders in settings over which researchers have little control, and how to sustain interventions beyond initial demonstrations and funding, particularly in settings with highly constrained resources'.*
>
> (Mendel et al. 2008, p. 22)

Taxonomies and frameworks of implementation strategies include the EPOC checklist (Cochrane Effective Practice and Organisation of Care Group 2010), Behavioural Change Techniques (BCT) (Michie et al. 2013) and Expert Recommendations for Implementing Change (ERIC) discrete strategies list (Powell et al. 2015). Other frameworks have been termed branded, manualised, multi-faceted implementation strategies or implementation programs (Proctor, Powell & McMillen 2013), which combine a number of discrete strategies. These include the Availability, Responsiveness and Continuity model (ARC) (Glisson & Schoenwald 2005), Replicating Effective Programs (REP) (Kilbourne et al. 2007), Getting to Outcomes (GTO) (Chinman et al. 2004), and Quality Implementation Framework (QIF) (Meyers, Durlak & Wandersman 2012). Examples of commonly used implementation strategies include education, audit & feedback, outreach (opinion leaders, knowledge brokers, facilitators/coaches, purveyors) infrastructure & technology, and financial incentives.

Implementation science has shown that single implementation factors or strategies are generally not sufficient for successful, sustained implementation (Grimshaw et al. 2001; Scott et al. 2012). In other words, factors such as a strong desire, motivation and knowledge alone are not sufficient to drive implementation (Green et al. 2009). Neither are strategies such as payment, training, continued professional development (CPD) including conferences, or mass mailings of clinical guidelines (Forsetlund et al. 2009; Grimshaw et al. 2001; Hakkennes & Dodd 2008). In pharmacy practice it was widely believed that payment and CPD would be sufficient to drive implementation. From the experiences in many countries it can now be seen that although a benefit must be realised for the pharmacy business, remuneration and training alone are not going to lead to implementation success. This is clearly visible in Australia, which has funding for a number of services, has conducted mass media campaigns, provided implementation incentives and delivered education, but achieving profession-wide implementation, is still an issue (Jokanovic et al. 2015; Lingam 2013). Implementation science deems that

theoretically driven strategies are needed to target key factors that influence implementation for a particular setting for a particular service (Palinkas et al. 2011). On the contrary, the evidence for tailored interventions is currently mixed (Baker et al. 2015).

A research team headed by Susan Michie at University College London have combined psychological frameworks and models for determining factors and tailoring implementation strategies. The factors determined from the Theoretical Domains Framework (TDF) or Behavioural Change Wheel (BCW) may be mapped to the COM-B model (Capability, Opportunity, Motivation – Behaviour) (French et al. 2012; Michie 2014). This model determines whether greater Capability, increased Opportunity, or stronger Motivation is required to drive behavioural change. From the results, strategies and finally techniques, the active ingredients that may achieve the desired change to the determinants, are identified (Michie 2014). Although they have been used in policy and organisational contexts, as the name suggests, the BCW and associated models are largely focussed on behaviour. Quality improvement approaches such as UK's Institute for Healthcare Improvement (IHI) breakthrough series (Institute for Healthcare Improvement 2003) and US Department of Veteran's Affairs, Quality Enhancement Research Initiative (QUERI) projects (Stetler et al. 2006) are particularly helpful at the organisational level. Alternatively an option is to follow an intervention development framework (such as the Medical Research Council (MRC) guidance, intervention mapping, IHI etc.), but for the development of an implementation strategy or program, rather than the clinical intervention.

The design of implementation strategies should be deliberated, strategically and systematically, and this design process explicitly reported. When researching implementation programs it is essential to report each strategy as would a clinical intervention. In this way the fidelity of implementation and essential strategies for a particular innovation in a particular context may be evaluated. In addition, it allows for replication and meta-analyses (Michie et al. 2009; Proctor, Powell & McMillen 2013). Recommendations have been made by the Workgroup for Intervention Development and Evaluation Research (WIDER) group for reporting of behavioural change interventions including implementation strategies, including the provision of manuals and protocols, or Standards for Quality Improvement Reporting Excellence (SQUIRE checklist) for quality improvement interventions. A study in pharmacy has equally shown poor reporting of implementation strategies and therefore is an area with room for improvement (Patwardhan, Amin & Chewning 2014).

Evaluations

An implementation program or protocol should include a plan to evaluate the impact of the chosen approach, including ways to measure success. Implementation evaluation measures the effects of implementation and may include process evaluation of progression, impact evaluation of factors, formative and summative evaluation of strategies as well as the degree of implementation and innovation outcomes (Curran et al. 2012; Glasgow, Vogt & Boles 1999; Proctor et al. 2011). Frameworks based on implementation evaluations include Green & Kreuter (2005) and Lehman et al. (2011), Proctor et al. (2011), Stekler et al. (1992) and Stetler et al. (2006).

Formative evaluation is an assessment process designed to identify influences on the progress and effectiveness of implementation efforts to guide tailoring implementation strategies with the aim of enhancing implementation success. Formative evaluation is often used as part of an audit and feedback implementation strategy or in quality improvement. Four progressive, integrated stages of formative evaluation are described by Stetler et al. (2006): developmental evaluation prior to implementation to explore and assess current practice, determinants of current practice, barriers and facilitators for implementation, and feasibility and tailoring of implementation strategy; process focussed evaluation to monitor the progress; implementation focussed evaluation to reduce type III errors and enhance result analysis, assess modifiable barriers to refine implementation strategies and innovation adaptation, assess critical factors and/or strategies to replicate outcomes; interpretative evaluations post implementation to explain the summative implementation and innovation outcomes, assess evidence for the factors and strategies, develop tools for wider spread and scale-up and hypotheses for future studies.

RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance), is an implementation evaluation framework that may be used to guide both implementation science protocol design and measurement (Glasgow, Klesges, et al. 2006; Glasgow et al. 2005; Glasgow, Vogt & Boles 1999). This framework includes effectiveness testing (of the professional service and/or implementation program), in combination with reach (participation rate and representativeness of the participants), organisational measures of adoption (uptake by providers and organisations, including proportion and representativeness), implementation (quality, consistency and integrity of provision) and maintenance of both health benefits in patients (or determinants of benefits such as behavioural changes) and changes in the organisation in terms of integrating the service as routine. Another useful tool is the Stages of Implementation Completion (SIC), which may be used as both a formative and summative tool to measure the rate and depth of implementation (Chamberlain, Brown & Saldana 2011). It may be used to investigate which steps or strategies are essential for implementation success. These frameworks have been used to help guide the development of an evaluation model for implementation programs and pharmacy services (chapter 6).

In recent years implementation science has focussed heavily on the development and testing of implementation tools and measures and large databases have been developed as repositories (Lewis et al. 2015; Rabin et al. 2012). Over 500 measures have been described. Literature reviews on implementation tools have been conducted (Cook et al. 2012), tools developed for particular implementation concepts (e.g. Stages of Implementation Completion (Chamberlain, Brown & Saldana 2011)), specific factors (e.g. implementation climate (Ehrhart, Aarons & Farahnak 2014; Weiner et al. 2011)), theory suitable for formative evaluation of normalisation (May 2010) and models of

particular outcomes (e.g. implementation fidelity (Carroll et al. 2007)). Many tools and measures remain discipline specific and therefore unsuitable for pharmacy. Pharmacy specific and service specific tools are required (chapter 7).

Chapter 2

Synopsis

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Rationale

Internationally professional pharmacy services are being developed, disseminated and beginning to be implemented; however there appears to be a pervasive challenge to achieving widespread support and integration into routine pharmacy practice (Kansanaho et al. 2005; Patwardhan, Amin & Chewning 2014; Rosenthal, Austin & Tsuyuki 2010). Lack of integrated implementation, implementation research and implementation evidence may be implicated (Kaae et al. 2009; Kitson et al. 2013; Kothari & Wathen 2013). A major implication of a knowledge gap on the process and influences affecting implementation is suboptimal support to assist pharmacy practice move services research into reality. Evidence-based practice, programs and services must be widely available and offered to achieve improved outcomes.

The use of implementation science to study and conceptualise implementation in community pharmacy, followed by contextualisation and application could aid implementation success and future scale-up. Conducting implementation studies, using an implementation framework, and measuring implementation indicators may assist community pharmacy move toward the ultimate goal of integrated service provision and improved health outcomes for the communities they serve. A framework for the implementation of services in pharmacy, incorporating all concepts involved in the complex process of implementation, including a catalogue of implementation measures, is needed.

Objectives

The thesis covers the synthesis, analysis and development of knowledge concerning implementation science as well as its contextualisation and utility for the implementation of professional services in community internationally. The research conceptualises and defines the process, influences and indicators for the implementation of professional pharmacy services. To approach implementation science in the community pharmacy context, specific objectives were defined:

Specific objectives

- Identify the extent to which existing implementation frameworks include implementation concepts and determine if frameworks vary depending on the innovation they target.
- Explore the implementation process occurring in community pharmacy and to assess the factors, strategies and evaluations influencing this process, in order to tailor a framework for the implementation of services in pharmacy.
- Develop two tools to measure fidelity, specifically an adherence index and a patient responsiveness scale for medication review with follow-up service.

Apart from the specific objectives that guided the main research, this thesis includes two theoretical works that contribute to the development of the science of implementation and pharmacy services. Specifically, these theoretical papers deal with (1) defining the innovation to be implemented in the field of pharmacy (i.e. professional pharmacy services) and (2) developing a model for the evaluation of such services and their implementation.

Research Overview

Mixed methodologies were employed to investigate the implementation of professional pharmacy services in community pharmacy internationally. Following the introduction provided in chapter 1, chapter 2 presents an overview of the dissertation. The subsequent chapters present a series of works, each chapter addressing a specific objective or theoretical work [Figure 3].

- Chapter 3 is a theoretical paper based on reviews of pharmacy practice literature to define professional pharmacy services - the innovation in which pharmacy practice is endeavouring to implement.
- Chapter 4 uses a systematic review methodology to study the implementation literature to determine the concepts involved in the implementation of innovations in healthcare (core implementation concepts).
- Chapter 5 describes a qualitative study involving semi-structured interviews of pharmacists in community pharmacies across three states of Australia. Framework and thematic analyses of the data were employed to investigate the process and influences (factors, strategies and evaluations) implicated in implementation of professional pharmacy services.
- Chapter 6 is a theoretical paper based on reviews of health services and implementation literature to develop a practical model for the evaluation of implementation programs and professional pharmacy services.
- Chapter 7 is a mixed methodology study, using both an expert panel followed by statistical analysis, conducted in Spain, to develop two questionnaires and test their reliability and validity as measures of the implementation outcome, fidelity.

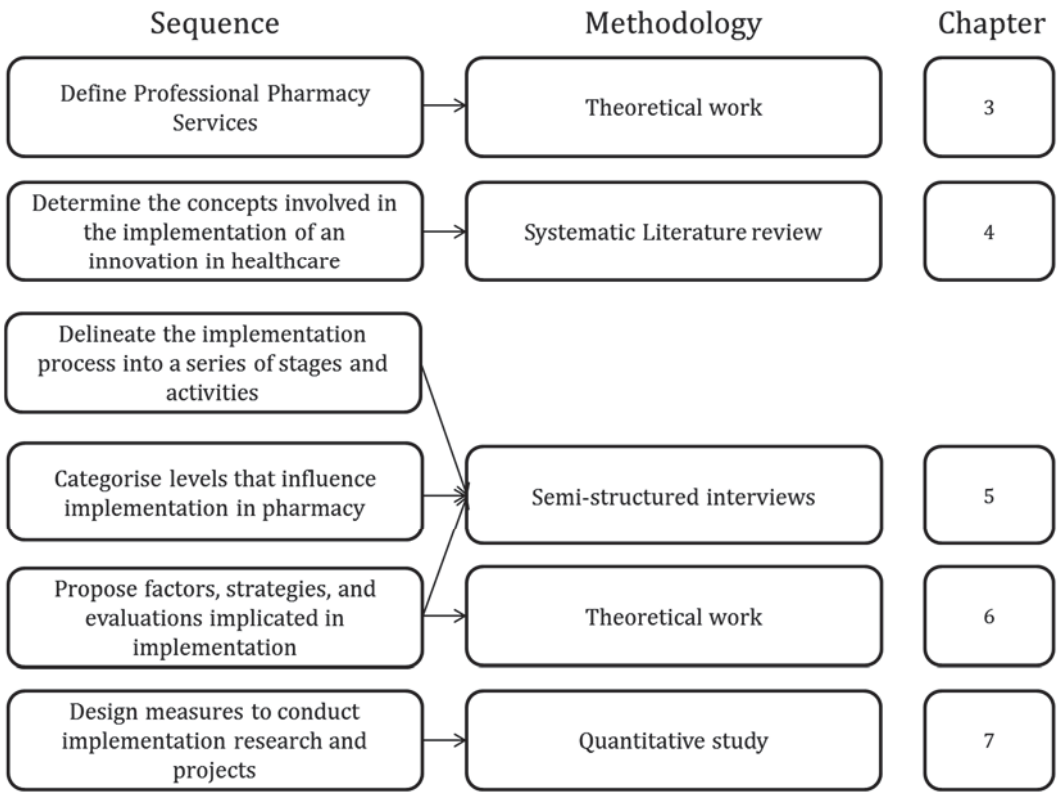


Figure 3 - Research Structure

Defining Professional Pharmacy Services (chapter 3)

The first part of the thesis involved defining profession pharmacy services - the innovation in which pharmacy practice is endeavouring to implement.

An overarching community pharmacy centric service definition was required as community pharmacies provide an accessible health network, delivering a wider range of health services and by a wider range of healthcare providers, than generally acknowledged. As community pharmacy transforms to a service provider model a broader definition would assist in researching the types of services and impact of service quality, performance and implementation. In addition the definition may facilitate recognition by the community, stakeholders and government of community pharmacy's role and the value pharmacies provide as a healthcare network. Wider recognition of community pharmacy as a healthcare institution may consequently lead to a greater inclusion in health policy.

A preliminary literature review was conducted using online databases (PubMed, MEDLINE, with no date limits), texts and conference proceedings, along with bibliographic searching, to identify the scope of current pharmacy service definitions. It appeared there was no universally accepted definition in the pharmacy practice literature that encompassed the entire scope of activities, services, and programs provided by community pharmacy.

A professional pharmacy service definition was constructed conceptually around Donabedian's framework for evaluating the quality of medical care (Donabedian 2005). In the context of a professional pharmacy service the constituents are the pharmacy setting/resources i.e. structure, provider and client behaviours of the process of care, and health outcomes. Health outcomes are primarily seen as the ultimate measure of healthcare services, yet some of the modifiable elements for improvement are the professional practice and environment surrounding the service.

A **professional pharmacy service** was defined as *"an action or set of actions undertaken in or organised by a pharmacy, delivered by a pharmacist or other health practitioner, who applies their specialised health knowledge personally or via an intermediary, with a patient/client, population or other health professional, to optimise the process of care, with the aim to improve health outcomes and the value of healthcare."*

Professional pharmacy services were seen to fit within the overall service offering of a pharmacy [Figure 4]. A pharmacy may provide a range of pharmacy services, some professional others non-professional in nature. In contrast to professional services, non-professional services do not involve the application of any 'specialised health knowledge', do not 'optimise the process of care' nor are directed towards 'improving health outcomes and the value of healthcare'. Professional pharmacy services can be delineated further into services provided by a pharmacist, and those provided by other healthcare providers and pharmacist services even further into those relating to medication (pharmaceutical service) and other healthcare services.

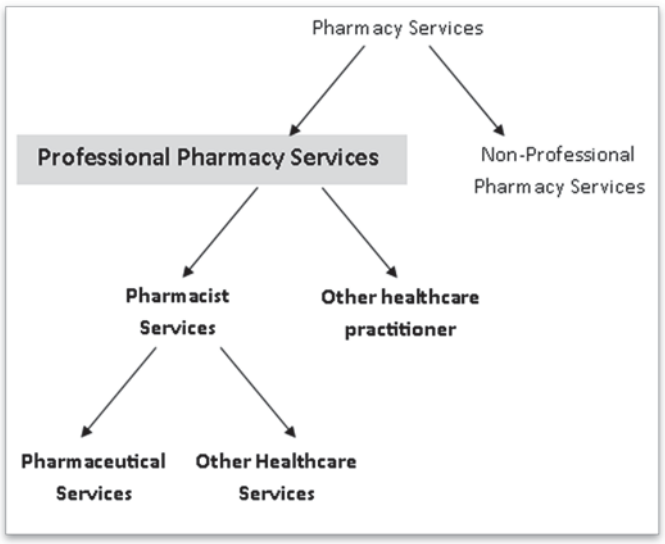


Figure 4 – Model of Pharmacy Service Provision

For this research the innovation of interest is the implementation of professional pharmacy services, particularly pharmacist services. The configuration of the professional pharmacy service definition facilitates the selection of suitable dimensions and indicators. A service may be evaluated on three core indicators, process, structural (impact indicators of changes in determinants of patient behaviour including the organisation and environment), and outcome. Implementation efforts may then be targeted towards achieving these indicators. Furthermore a service evaluation may include the implementation measures so that a pharmacy may be assessed in terms of service implementation and provision as well as overall outcomes.

Systematic Review of Implementation Frameworks of Innovations in Healthcare and Resulting Generic Implementation Framework (chapter 4)

The successive part of the research was to review the implementation literature for a suitable framework for the implementation of professional pharmacy services in community pharmacy. Multiple countries were struggling with implementation and consequently services were not able to achieve their potential impact and outcomes. Internationally it appeared there was no overarching theory driving implementation efforts in community pharmacy.

A theoretical base is needed to be chosen for the research. The decision included whether to select a single or to combine multiple implementation frameworks. Numerous implementation frameworks, models and theories have been developed, targeting a diverse array of innovations. As such it was plausible that not all of the frameworks included the full range of concepts thought to be involved in implementation. To aid the selection decision of an applicable, holistic structure that may be used for community pharmacy a literature review was conducted to assess the comprehensiveness of existing implementation frameworks of innovations in healthcare.

A systematic search was undertaken in PubMed to identify implementation frameworks of innovations in healthcare published from 2004 (post a comprehensive literature review of implementation studies conducted by Greenhalgh et al (2004)) to May 2013. In addition titles and abstracts from *Implementation Science* journal and references from identified papers were reviewed. The orientation, type, presence of stages and domains, along with the degree of inclusion and depth of analysis of factors, strategies and evaluations of implementation of included frameworks were analysed.

The database search identified 1397 articles and a further 621 were sourced from *Implementation Science* journal. From the 2018 articles screened, 1764 articles were eliminated after title and abstract screening and a further 223 after examination of the full-text articles. The references of the remaining 31 articles were screened resulting in the identification of an additional 18 frameworks. In the end a total of 49 implementation frameworks of an innovation in healthcare were included in the systematic analysis

Out of the 49 implementation frameworks only five comprehensively included the range of items within any one element with justification for their inclusion. Overall, there was limited degree and depth of analysis of implementation concepts. Therefore it was seen as beneficial for the both pharmacy practice and field of implementation science to collate the core implementation concepts across the frameworks to form a Generic Implementation Framework (GIF) [Figure 5].

The GIF is a conceptual framework consisting of the following concepts:

- Implementation occurs as a non-linear, iterative process
- Each implementation effort has a range of unique influencing factors
- A set of strategies, also termed implementation interventions, should be decided as part of the implementation plan and interventions tailored to the determined influencing factors
- Measures should be used to evaluate the implementation process, impact and outcomes along with innovation evaluations
- Influences (factors, strategies and evaluations) relate to the innovation in which the implementation effort is targeting and may vary throughout the implementation process
- In addition to innovation influences contextual influences, factors at multiple ecological levels and strategies and evaluations targeting the factors at each level, exist and may be grouped into context domains

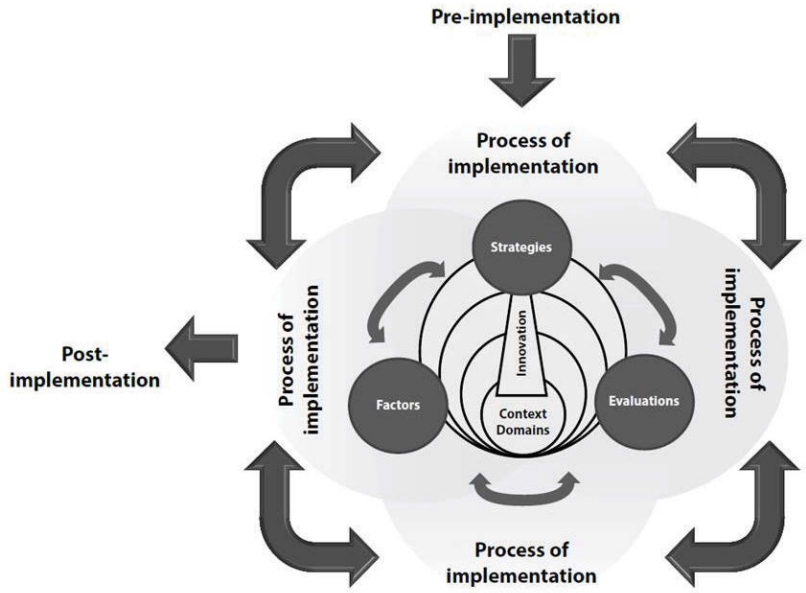


Figure 5 – Generic Implementation Framework (GIF)

The GIF collates the key concepts that need attention to conduct implementation work. It is a skeletal structure into which meta-frameworks, model of theories are required for each of its constituent parts, both from the systematic literature review and wider implementation literature.

- The *process* of implementation has been divided into various numbers of *stages*. Widely used are those defined by Greenhalgh et al (2004), Aarons et al (2011), and/or the National Implementation Research Network (NIRN) (Fixsen 2005). The stages may be further divided into a series of *steps or activities* (Meyers, Durlak & Wandersman 2012; Meyers et al. 2012).

- The breakdown of *domains* varies and may be subject to discipline specificity. Commonly used are those derived in the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al. 2009) and those of the Interactive Systems Framework for Dissemination and Implementation (ISF) (Wandersman et al. 2008). The domains include both the innovation and the contextual levels.

- To assess the *factors* influencing a particular implementation effort a number of comprehensive frameworks exist. Literature reviews of implementation factors led to the CFIR (Damschroder et al. 2009) and the Integrated Checklist of Determinants of Practice (TIDC) (Flottorp et al. 2013). Alternatively the behavioural influences are outlined in the Theoretical Domains Framework (TDF) (Michie et al. 2005), and COM-B model of Behavioural Change Wheel (BCW) (Michie, van Stralen & West 2011), which may be used in to enhance the behavioural influences in the multi-level implementation factor lists.

- Typologies of implementation *strategies* include those from The Cochrane Effective Practice and Organisation of Care group (EPOC) (Cochrane Effective Practice and Organisation of Care Group 2010), Mazza et al. (2013), Powell et al. (Powell et al. 2015; Powell et al. 2012). The Behaviour Change Techniques Taxonomy (BCT) (Michie et al. 2013) and corresponding Behavioural Change Wheel (BCW) (Michie, van Stralen & West 2011), are particularly detailed at an individual level and characterise interventions based on their mechanism rather than components along with methodologies such as intervention mapping (Bartholomew et al. 2011). These strategies need to be further detailed as would a clinical intervention (Michie et al. 2009; Proctor, Powell & McMillen 2013).

- Finally frameworks for implementation *evaluations* include those by Glasgow et al (RE-AIM (Glasgow, Vogt & Boles 1999)), Proctor et al. (2011), Lehman et al. (2011), Steckler et al. (1992) and Green & Kreuter (2005). In addition to measuring outcomes, literature reviews on implementation tools have been conducted (Cook et al. 2012), tools developed for particular implementation concepts (e.g. Stages of Implementation Completion (Chamberlain, Brown & Saldana 2011), formative evaluation of normalisation (May 2010) and models of particular outcomes (e.g. implementation fidelity (Carroll et al. 2007)).

Qualitative study on the implementation of professional pharmacy services in Australian community pharmacies using framework analysis (chapter 5)

To be applied in practice the Generic Implementation Framework (GIF) required contextualisation and operationalisation. As such to create the foundation of a theoretical framework for pharmacy service implementation the concepts of GIF required investigation specifically for community pharmacy. Qualitative methodologies were used to delineate the implementation process, into stages and activities, and investigate the influences on the process (factors, strategies and evaluations).

The study investigated the process of implementation occurring in twenty-one Australian community pharmacies. Purposeful sampling was used to investigate the process used across a range of levels of implementation. The analysed components of the systematic literature review and concepts of the GIF were used to design an eight question interview guide. Twenty-five semi-structured interviews were conducted and examined using a framework analysis methodology. Data was charted into a framework matrix, where data were coded under the implementation stages as overarching themes and then each stage thematically analysed. Interpretation of the matrix was used to investigate the implementation process, which concurrently exposed the concept of overarching influences that appeared as vital drivers to implementation efforts. Secondary analyses were performed of the factors (barriers and facilitators), and implementation strategies. Evaluations were lacking. Finally the results set the foundation of a Framework for the Implementation of Services in Pharmacy (FISpH) that may be used by all stakeholders involved in service development, implementation and evaluation.

Six stages emerged, labelled as development or discovery, exploration, preparation, testing, operation and sustainability. The pre-implementation stage, of development or discovery, naturally emerged in the discourse, where a pharmacy or pharmacy group had to internally develop services and/or discover externally developed services. Following this pharmacies entered exploration.

Exploration occurs after a pharmacy is aware of the service, and they are appraising or considering the service, and deciding whether or not they want to adopt it. If the decision is to adopt, they move to preparation or planning. During this stage the pharmacy, pharmacist and all other factors are prepared for service delivery. The next stage the service is trialled, operated for a defined period or with limited numbers, before moving to the operation stage and the service is beginning to be integrated into routine practice. The testing and operation stages may initially be felt as awkward or difficult, as they staff are not confident with the change and can easily convert back to their old habits and way of working.

Finally moving from operation to sustainability occurs when three conditions are met: (1) service deliver continues, after any implementation program (or external assistance) has ceased, (2) there is sufficient capacity (supportive context) for this ongoing delivery and (3) service benefits are maintained (Goodman et al. 1993; Pluye, Potvin & Denis 2004; Shediac-Rizkallah & Bone 1998). Sustainability is therefore the stage when the service is integrated as a routine in the pharmacy, when there is ongoing support and capacity and outcomes persist, both for the patients and from the business perspective. Few pharmacies had reached sustainability.

During the stages a range of activities were exposed from the interview data. The activities were *Exploration*: Organisational fit assessment, value assessment (relative advantage), service assessment (service characteristics), organisational capacity assessment (supporting conditions & staff capacity), community fit assessment, decision; *Preparation*: Assign leader, research requirements, organise supporting conditions, plan service procedure, rearrange workflow, staff arrangements, team communication (buy-in and foster climate), training, community awareness & recruitment; *Testing*: Initial adaptations, familiarisation & improve staff conviction, test patient demand; *Operation*: Modification of plans & procedures, maintain patient demand, staffing, teamwork, team input and internal communication, integration tactics, ongoing training, goal setting, monitoring, adaptation, improvement; *Sustainability*: Few pharmacies had reached sustainability however activities would be posited as continuing the last three activities of the operation stage: monitoring, adaptation and improvement.

The interpretation of the framework matrix of the interview data, highlighted that there were overlaps between stages, variation in duration of stages, movement back and forth between stages, differences in the order of performing implementation activities and that not all activities were necessarily completed. In other words process was not always linear, but iterative. Pharmacies could move back and forth between stages or even skip a stage. There was a trend towards the greater the number of activities considered, the greater the apparent integration into the pharmacy organisation. The activities have been termed steps in other implementation frameworks however due to the non-linear nature the word activities has been embraced.

Within the process, five overarching influences (pharmacy's direction and impetus, internal communication, staffing, community fit and support) were identified. As a result of a secondary analysis of the data a refined list of implementation factors for community pharmacy was developed. In addition it was seen that the factors that influence implementation vary at the different stages of the process. Implementation strategies employed by pharmacies varied widely. Evaluations were lacking.

Domain levels were confirmed, as previously defined in the systematic review of implementation frameworks. Specifically from the perspective of pharmacy the domains may be defined as:

- Innovation: the pharmacy service to be implemented
- Individuals: the people involved in the implementation process including the pharmacy owner, the service provider (often a pharmacist), and other pharmacy staff such as technicians and assistants. It may also include individuals from the pharmacy group, such as professional services manager, or external assistance sought to aid the implementation effort
- Organisation: the pharmacy and may also include the characteristics of a group of pharmacies
- Local context: the environment surrounding the pharmacy including patients, friends and relatives, clientele, the community and other healthcare professionals
- System: the political and economic context, as well as the professional situation (such as the pharmacy bodies and the organisations of other healthcare professionals)

The foundation of an innovative Framework for the Implementation of Services in Pharmacy (FISpH), was tailored from the qualitative results [Figure 6].

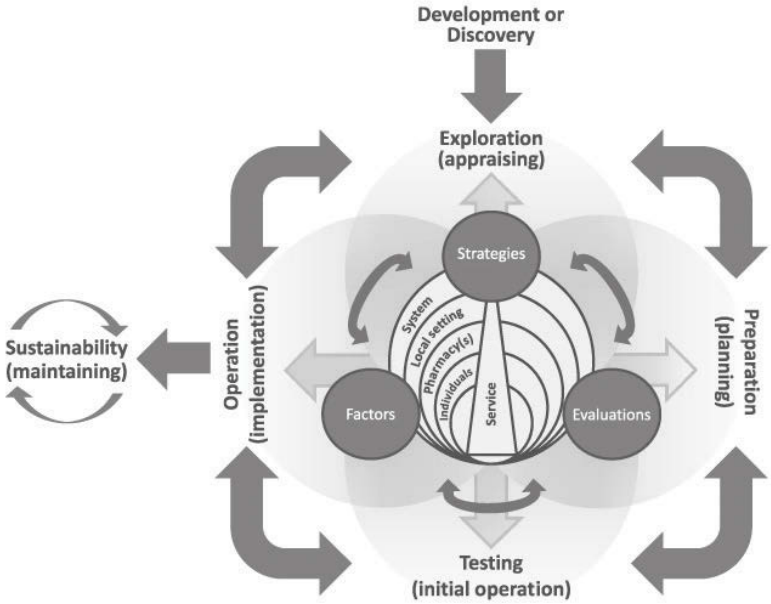


Figure 6 – Framework for the Implementation of Services in Pharmacy (FISpH)

Model for the evaluation of implementation programs and professional pharmacy services (chapter 6)

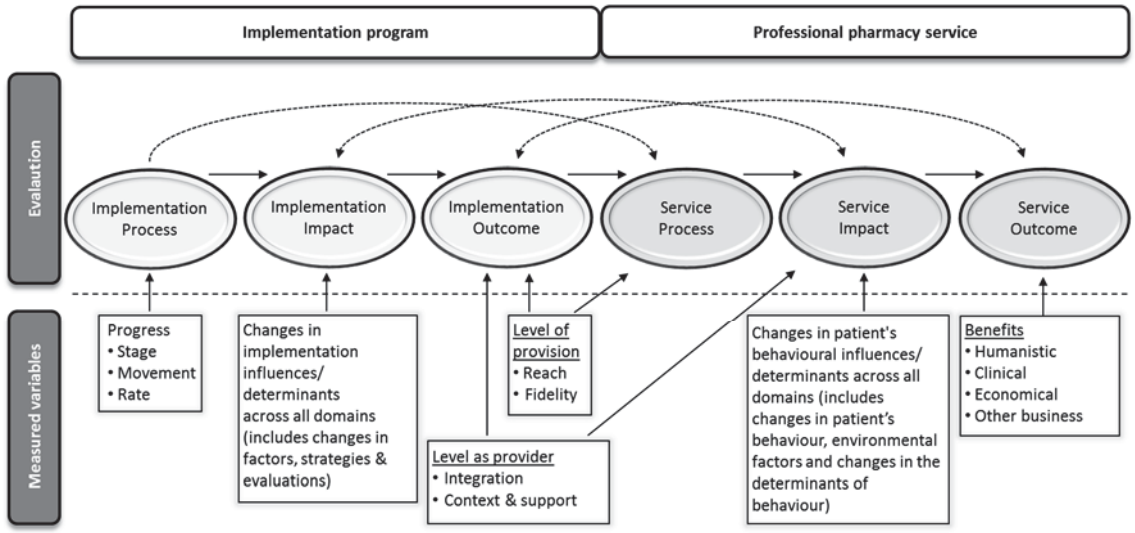
The qualitative study set the foundation of a Framework for the Implementation of Services in Pharmacy (FISpH). Interview data settled a six stage implementation process from development or discovery to sustainability [Figure 6], as well as distinguishing a range of implementation activities pharmacies completed as they moved through the stages. In addition overarching influences were revealed and preliminary lists of implementation factors and strategies utilised by pharmacy were investigated. The remaining concept of the framework, evaluations, appeared widely lacking. As such, a theoretical based, yet practical model for the evaluation of implementation programs and professional pharmacy services was required.

Along with the poor evaluation conducted internally by community pharmacies in Australia, there appeared to be limited implementation evaluation conducted by professional organisations and researchers (Australian National Audit Office 2015; Patwardhan, Amin & Chewning 2014). In order to satisfy policy-makers, funders and subsequently practitioners with viable remuneration packages, pharmacy practice research and service evaluations have been predominantly focused on patient outcomes and cost-effectiveness. Research studies have been largely conducted in controlled conditions, prior to implementation and there appears to be a dearth of process or implementation indicators reported (Patwardhan, Amin & Chewning 2014). Poor monitoring by pharmacists and a lack of implementation evaluation (process, impact and outcome) in pharmacy practice has been discussed as an issue in Australia, including by government policy makers (Australian National Audit Office 2015; Patwardhan, Amin & Chewning 2014). This push for evaluation is also being seen in academia with a move internationally to include impact data in research proposals and reports (Research Excellence Framework 2014).

Evaluations are required for all aspects of implementation including indicators of movement through the implementation stages (formative and summative implementation process evaluation), measures of influencing factors and change in factors over-time (implementation impact), assessment of strategies and/or implementation program and overall measures to generate a level of implementation (implementation outcomes).

Based on the FISpH and implementation science literature (Carroll et al. 2007; Glasgow, Vogt & Boles 1999; Lehman et al. 2011; Proctor et al. 2011; Slaghuis et al. 2011; Steckler et al. 1992) a model for the evaluation of implementation programs and professional pharmacy services was proposed [Figure 7]. The implementation evaluation model involves indicators for implementation process, impact, and outcome evaluations as well as service process, impact and outcome. The service evaluation component was described in the first study and is widely accepted (Green & Kreuter 2005; Kozma, Reeder & Schulz 1993), therefore the focus was on describing the implementation evaluation section. Implementation evaluation may be used to assess implementation programs and in service evaluations. The arrows indicate the flow of affect, while the curved arrows hypothesised relationships between the implementation and service evaluations.

Figure 7 – Model for the evaluation of implementation programs and professional pharmacy services



Note: Domains are the divisions or categories of the implementation influences and determinants of patient behaviour. They include the characteristics of the service being implementation, and the context (individuals, organisation/pharmacy(s), local setting and system).

The level of implementation of a professional pharmacy service can be estimated from the level of service delivery (reach and fidelity) and level as a service provider (integration and strength of support in the service environment). The level of service provision is 'how much and how well' the service is being delivered. The level as a service provider is related to the degree the service is part of the pharmacies principles and routine practice and the capability and support in the service environment, across all contextual domains. This overall outcome named level of implementation can be looked at from various ecological perspectives. For example you could measure the outcome for an individual staff member (micro level), the pharmacy as a whole or for a group of pharmacies (meso level). Alternatively measures can be aggregated to look at a service's implementation outcomes nationally (macro or system level).

To conduct evaluations and implementation research, tools need to be developed and tested for the implementation indicators in pharmacy.

Development and testing of two implementation tools to measure components of professional pharmacy service fidelity (chapter 7)

To conduct implementation research, quality assurance, performance assessment and for service evaluation and optimisation, practical tools to measure implementation indicators are required. To begin developing a catalogue of implementation tools, two tools, one for measuring the way in which the service is delivered and one for the way it is received, were developed. Specifically, as part of an overall fidelity measure an adherence index and a patient responsiveness scale for medication review with follow-up service were designed and tested in Spain. Spain was at the point of negotiating for remuneration and investigating the implementation of their first professional pharmacy service, medication review with follow-up. As such it was a suitable setting for designing and testing implementation tools and an implementation program.

Fidelity is the degree to which a service, or other innovation, intervention or program, is implemented in practice as it was originally designed and intended (Carroll et al. 2007; Dane & Schneider 1998). Fidelity is based on the notion of measuring core components, the features of a service that make it effective (Blase 2013; Fixsen et al. 2013). As professional pharmacy services are being implemented into practice there is a need for impact, process and implementation outcome evaluations. The service medication review with follow-up has shown positive results in patient outcome studies. The concepts of the service were defined but the core components, active ingredients and dose necessary to realise these positive patient outcomes were unknown.

Fidelity evaluation may be used for service optimisation by associating service components to patient outcomes (Allen 2012). Once established only the core components would be expected to be implemented with fidelity, while the remaining 'adaptive periphery' of a service, may be adjusted by individual providers or pharmacies to fit the context into which it is being implemented (Allen 2012; Fixsen et al. 2013; Stirman et al. 2013). There appears to be a positive relationship between fidelity and service outcomes (Durlak & DuPre 2008), while allowing for adaptation, appears to increase successful implementation (Stetler et al. 2006; Winter & Szulanski 2001). Collaborating with end-users (e.g. pharmacists and patients) and measuring fidelity during development, service assessment and implementation studies helps create services that are feasible, implementable and acceptable (Mihalic 2004; Stirman et al. 2013).

Adherence to the service's components, dose of the service and how patients respond are measures of fidelity. Dose may be assessed using service records, while tools to measure adherence and patient responsiveness are required. The procedure described by DeVellis (2012) was followed to develop an adherence index and patient responsiveness scale. Due to conceptual differences between indexes and scales, the item generation and evaluation for each questionnaire varied (DeVellis 2012; Diamantopoulos & Winklhofer 2001). Both tools were developed and tested in Spain, using Spanish versions of the questionnaires (English translations are provided in the paper). The questionnaires were administered as part of an ongoing study investigating the implementation of medication review with follow-up, at the six month time point. In total, 190 service providers from 128 pharmacies, across 11 provinces of Spain, responded to the questionnaires.

To generate items for the adherence index, the medication review with follow-up service was divided into the service phases, as proposed by the Dader methodology (Pharmaceutical Care Research Group 2006), while taking into account the service definition and objectives. An adherence index of 39 items was developed to cover the full scope of the medication review with follow-up protocol. An initial assessment of item functionality was performed using descriptive statistics and item discrimination. Respondents rated the acceptability of the questionnaire as high. Responses to the items were concentrated towards high adherence with a mean total adherence score of 4.3 out of 5 (SD: 0.9).

For the patient responsiveness scale the item pool was created, based on the definition that patient responsiveness consists of and may be measured by the service providers perception of patients' participation and enthusiasm to the aspects of the service protocol that require their involvement. A 16 item patient responsiveness questionnaire was developed and psychometric properties tested. Acceptability of the questionnaire was high. The scale's internal consistency was validated by calculating Cronbach's alpha coefficient and inter-item correlations. Decision on number of factors was based on Kaiser Criterion, parallel analysis and Catell's scree test. The length of the scale was optimised guided by iterative Exploratory Factor Analysis (EFA), using Principle Component Analysis (PCA) extraction with oblique rotation. After five EFA iterations, four items were removed, resulting in a final scale of 12 items loading on two factors, with correlation of 0.321. Total percentage of variance explained was 53.9% (42.7% by factor 1 and 11.2% by factor 2). Factor 1 (Participation), consisted of 9 items, had a Cronbach's alpha of 0.888 and inter-item correlation of 0.473. Factor 2 (enthusiasm), consisted of three items, had a Cronbach's alpha of 0.586, and inter-item correlation of 0.327.

Along with data collected to measure other concepts of fidelity, such as dose, the adherence and patient responsiveness scores may be summated to generate a fidelity score. The tools developed and calculated fidelity scores may be used in implementation and service evaluations including quality assurance, quality improvement, and service optimisation procedures and therefore are beneficial for researchers, pharmacists, professional bodies and government agencies.

Chapter 3

Defining Professional Pharmacy Services

Moullin J.C., Sabater-Hernández D., Fernandez-Llimos F., & Benrimoj, S.I. 2013, 'Defining professional pharmacy services in community pharmacy', *Res Social Adm Pharm*, vol. 9, no. 6, pp. 989-95.
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RESEARCH IN SOCIAL & ADMINISTRATIVE PHARMACY

Commentary

Defining professional pharmacy services in community pharmacy

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Summary

Multiple terms and definitions exist to describe specific aspects of pharmacy practice and service provision, yet none encompass the full range of professional services delivered by community pharmacy. The majority of current pharmacy service definitions and nomenclature refer to either the professional philosophy of pharmaceutical care or to specific professional pharmacy services; particularly pharmaceutical services provided by pharmacists with a focus on drug safety, effectiveness and health outcomes. The objective of this paper is therefore to define a professional pharmacy service within the context of the community pharmacy model of service provision. A *professional pharmacy service* is defined as "an action or set of actions undertaken in or organised by a pharmacy, delivered by a pharmacist or other health practitioner, who applies their specialised health knowledge personally or via an intermediary, with a patient/client, population or other health professional, to optimise the process of care, with the aim to improve health outcomes and the value of healthcare." Based on Donabedian's framework, the professional pharmacy service definition incorporates the concepts of organizational structure, process indicators and outcome measures. The definition will assist in many areas including recognition of the full range of services provided by community pharmacy and facilitating the identification of indicators of professional pharmacy service implementation and sustainable provision. A simple conceptual model for incorporating all services provided by community pharmacy is proposed.

Keywords: Professional services; Pharmacy services; Community pharmacy; Definition; Pharmaceutical care

Rationale

Current definitions of pharmacy services do not cover the complete community pharmacy service offering as they focus on defining services arising from the pharmaceutical care concept, or alternatively are restricted to services specifically delivered by pharmacists (Appendix A). Pharmaceutical care is one of the key terms used to describe pharmacy practice beyond the field of dispensing.[1–5] The pharmaceutical care philosophy was transformed into a service-based definition, where drug-related services were provided

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by pharmacists "specialised knowledge by pharmacists for the patient or health care professionals for purpose of promoting effective and safe drug therapy."[4] Subsequent authors modified the idea and coined the term cognitive pharmaceutical services, which again kept pharmacists at the core, but broadened the outcome to patient health rather than drug therapy alone, for example "professional services provided by pharmacists, who use their skills and knowledge to take an active role in contributing to patient health, through effective interaction with both patients and other health professionals."[6] The term cognitive pharmaceutical services (CPS) was further adapted to incorporate aspects lacking in previous definitions such as, health services at a local community or population level and acknowledging the role of other pharmacy staff, "CPS can be seen as a range of healthcare-related activities (some of them including pharmaceutical care) to enhance public health and the quality of drug therapy, promoted by the pharmacy staff."[7]

Although pharmaceutical care may remain the primary focus for pharmacist driven services, a broader definition is needed to acknowledge the wider role that the community pharmacy network and community pharmacies individually play in healthcare. In many ways, pharmaceutical care definitions have narrowed the role of community pharmacy as they predominantly focus on drug safety, effectiveness and optimizing health outcomes arising from medications. As the role of profession expands and develops, it is important to identify and document the extensive array of services provided by both pharmacists (incorporating specializations and diverse settings), and equally community pharmacies (incorporating other health practitioners and healthcare services).

In recent years, both the role of pharmacists and the professional and business operations of community pharmacy have been changing and expanding. Pharmacists are diversifying the settings in which they practice, and specializations are emerging.[8] Concurrently, community pharmacies are incorporating professional pharmacy services, into both their professional practice and business model.[8] Ongoing expansion and differentiation of pharmacists' role is clearly professionally advantageous. Similarly expansion and differentiation of community pharmacy practices are vital for their survival. This is particularly evident in the current international environment where economic pressure is being exerted on the traditional business model. On an international basis, an emerging trend is for governments, health insurance companies and/or patients being willing to remunerate for a range of pharmacy services aimed at contributing to improved patient outcomes.[9]

There is no universally accepted definition in the pharmacy practice literature that encompasses the entire scope of activities, services, and programs provided by community pharmacy. A preliminary literature review was conducted using online databases (PubMed, MEDLINE, with no date limits), texts and conference proceedings, along with bibliographic searching, to identify the scope of current pharmacy service definitions. The examination revealed multiple terms and definitions used to describe pharmacist services, as well as aspects of pharmacy practice and service provision, yet none included the full range of services delivered by community pharmacy (Appendix A).

An overarching community pharmacy centric service definition is required as community pharmacies provide an accessible health network delivering a wider range of health services and by a wider range of healthcare providers than generally acknowledged. As community pharmacy transforms to a service provider model a broader definition will assist in researching the types and full impact of service quality, performance and implementation. Finally, a broader definition would facilitate recognition by the community, stakeholders and government of community pharmacy's role and the value pharmacies provide as a healthcare network. Wider recognition of community pharmacy as a healthcare institution may consequently lead to a greater inclusion in health policy.

Defining a professional pharmacy service

In order to gain an understanding of the full suite of professional pharmacy services that are or may be offered by community pharmacy, the following definition is proposed:

A *professional pharmacy service* is an action or set of actions undertaken in or organized by a pharmacy, delivered by a pharmacist or other health practitioner, who applies their specialized health knowledge personally or via an intermediary, with a patient/client, population or other health professional, to optimize the process of care, with the aim to improve health outcomes and the value of healthcare.

The professional pharmacy service definition is constructed conceptually around Donabedian's framework for evaluating the quality of medical care.[10] In the context of a professional pharmacy service, the constituents are the pharmacy setting/resources i.e., structure, provider and client behaviors of the process of care, and health outcomes. Health outcomes are primarily seen as the ultimate measure of healthcare services, yet some of the modifiable elements for improvement are the professional practice and environment surrounding the service.

The important components that reside within this definition are:

1. Based on the Oxford dictionary, 'service' is described 'as an action, set of actions,' or a series of defined activities, synonymously termed a program.[11] The focus is on the value, benefit or experience that a service creates.[12]
2. A community 'pharmacy' is a registered premise, approved and licensed dependent on individual country's legislation and regulations. This organizational 'structure' provides the capacity, influence, and enablers for the process of care, which includes facilities, staff, administrative processes and equipment.[10] These components may be useful in the evaluation of a service. For a service to be classified as a professional pharmacy service, it may be 'undertaken in or organized by a pharmacy,' and performed on or offsite. Regardless of location, if a service fits the pharmacy's professional practice and uses the pharmacy's resources and/or skills of the pharmacy setting and/or staff, it warrants being a professional 'pharmacy' service. A common example would be a medication management service, where this service can be provided either onsite or offsite, for example in an aged care facility or patient's home.[13] Another example illustrating how services could be extended is health promotion activities, such as a pharmacist delivering an educational presentation to parents of a childcare center, or to staff of a medical center on prescribing practices.[14–16] It can be seen that a professional pharmacy service must be connected to a pharmacy, but in contrast to definitions proposed until now, is not restricted to being performed within the pharmacy premises.
3. A professional pharmacy service is not restricted to being 'delivered by a pharmacist,' but also may be performed by 'other health practitioner' (Fig. 1). This is a significant differentiator from previous definitions, which are centered on the pharmacist rather than the pharmacy (Appendix A). With the inclusion of other healthcare professionals in the definition, a professional pharmacy service could include a nurse practitioner leading a vaccination program (such as flu clinic) or baby consultation, or a dietician undertaking a weight loss program or providing nutritional advice to diabetics.[17] The definition stimulates the question whether the legal and/or professional responsibility for all professional pharmacy services is ultimately with the pharmacy owner(s) and/or those with whom technical responsibility lies.
4. To be 'professional,' a professional pharmacy service must involve the application of a pharmacist's or other healthcare practitioner's 'specialized health knowledge.'[18–20] It would be optimal that the specialized health knowledge is applied using an evidence-based approach and be an integral part of the process of care provided. Importantly, this specialist knowledge is not restricted to medication. Pharmacists are medication specialists, but they also possess broad health knowledge and many pharmacists are now specializing in less traditional fields.[16] For example, a key role in good pharmacy practice is to identify, manage or triage health-related problems.[21] By inclusion and clarification of the word 'professional' in the definition, we in effect exclude services that are not professional in nature. Examples include posting or delivery of medication to patient's homes, ear piercing, photo printing, beauty services and product sale without assistance or advice. These services do not use any health-related specialized knowledge yet are provided by pharmacies and therefore are to be considered a type of pharmacy service, but would be outside the scope of a professional pharmacy service.
5. There are many points of service delivery, and therefore, to restrict delivery to direct face-to-face patient/client interactions would not suffice. The broadening of the definition is also responding to criticism of pharmacy for solely focusing on the individual client.[17,22] A professional pharmacy service may be directed toward an individual, a patient or someone on behalf of the patient ('patient/client'), a community or group ('population'), or 'other health professional.' 'Personally' refers to

direct interaction between the healthcare practitioner and patient/client, population or other health professional, whereas an 'intermediary' permits indirect knowledge application. Intermediaries include supervised pharmacy staff members, or a technology, such as an automated machine or a web site. In all cases, an intermediary's knowledge comes from, and is under the supervision or review of the healthcare practitioner, who takes responsibility for the process of care provided. A qualified/trained pharmacy staff member would fit under other health professional. There are many examples of professional pharmacy services provided by intermediary staff members including blood pressure monitoring, compression stocking sizing, and weight management.[17] Examples of technologies include health information websites.[23,24]

6. A core aspect of a professional pharmacy service is to 'optimize the process of care.' The medical care process consists of at least two sets of behaviors, provider and client, that converge in the form of service participation to produce health outcomes.[25] The process of care itself consists of three components; identification of a need (including prevention), use of the service and modification of the need. Client (including patients, carers and third parties) behaviors are recognition of a need, decision to seek care, process of seeking care and assumption of the sick role in order to maintain care.[25] Provider behaviors (including liaising with other healthcare professionals) include recognition of need, and diagnostic and decision making in terms of modification of the need. The aim is to make the most effective use of the professional pharmacy service by adjusting any of the behaviors or components in the process of care.
7. The overall objective of a professional pharmacy service is to 'improve health outcomes' (prevent negative, maintain positive or improve economic, clinical, or humanistic outcomes) and 'increase the value of healthcare' (maximizing health outcomes for the dollars spent).[26,27] Along with pharmacy setting professional and business measures, processes of care behaviors (provider and client) and patient health outcomes, are health indicators, which can be measured to potentially predict outcomes. Quality is often used to indicate process measures such as fidelity to evidence-based practice guidelines, while outcomes in healthcare are often seen as safety and effectiveness parameters.[26] Value, a relatively new concept in healthcare, is determined on the total cycle of patient care for a specific condition, usually involving multiple settings, services and costs to achieve outcomes. Performance improvement and increasing the value in healthcare should drive progress, shifting the focus from volume to value, however, the structure of the health system makes the measurement of the value difficult.[27] There remains a need to measure both process and outcomes.

Model of pharmacy service provision

Professional pharmacy services fit within the overall service offering of a pharmacy (Fig. 1). There are a wide variety of pharmacy services provided by community pharmacy, both professional and non-professional. In contrast to professional services, non-professional services do not involve the application of any 'specialized health knowledge,' do not 'optimize the process of care' nor are directed toward 'improving health outcomes and the value of healthcare.'

Pharmacy practice research has concentrated largely on the services provided by pharmacists (Pharmacist Services 1.3). A pharmacy may have other healthcare practitioners provide services and these should be included in the professional service offering of a pharmacy (Other Healthcare Practitioner Services 1.4). In an attempt to convert the concept of pharmaceutical care to practice, a heterogeneous mix of ideas, terms, definitions, services and classification schemes, without apparent conceptual bases, have been created (Appendix A). The aforementioned mix can be categorized under Pharmacist Services (1.3). Pharmacist Services are divided into Pharmaceutical Services (1.5), (those relating to drug therapy including pharmaceutical care services, medication management services, clinical services and cognitive pharmaceutical services), and Other Healthcare Services (1.6), (such as those relating to health promotion and primary care). The key focus of pharmacists will remain centered on their area of speciality – drug therapy, but all services that use their diverse skills and knowledge base to improve the value of healthcare, should be acknowledged (1.1).

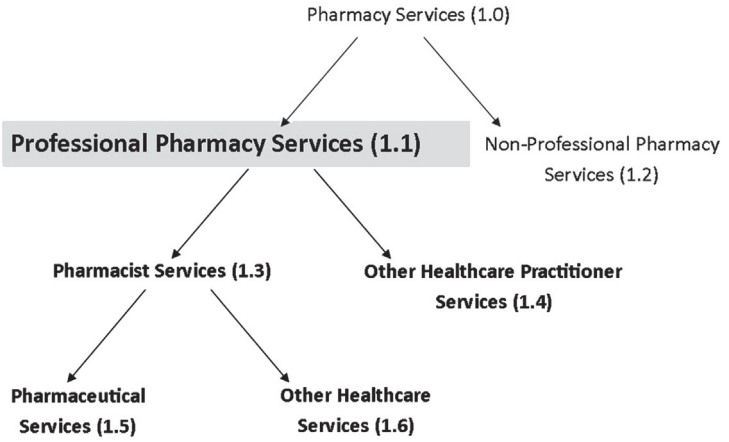

Fig. 1. Model of pharmacy service provision.

Conclusion

Defining the range of professional pharmacy services facilitates a holistic understanding of the role and value community pharmacies provide as part of the healthcare system both independently and as a collective network. Furthermore, application of the definition allows for professional pharmacy services to be identified, and subsequently measured. This will assist the community pharmacy network to be evaluated in terms of the value created for the healthcare system. Pharmacies individually may be assessed on their total offering, rate and depth of service implementation and quality of service provision. A pharmacy or group of pharmacies can be identified as professional service provider(s) once they have successfully implemented professional pharmacy services. Pharmacies will be able to be differentiated on the number, type, level or quality of services they provide, as part their overall offering, that is, the aggregate of any good, service or combination of these that is offered to their clients.[28] The ultimate goal is for community pharmacy to be appropriately recognized as providers not only of products but also providers of professional pharmacy services.

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Appendix A
Definitions related to pharmacy services and pharmaceutical care

- Pharmaceutical care: "The care that a given patient requires and receives which assures safe and rational drug usage."[1]
- "Pharmaceutical care includes the determination of the drug needs for a given individual and the provision not only of the drugs required but also of the necessary services (before, during or after treatment) to assure optimally safe and effective therapy. It includes a feedback mechanism as a means of facilitating continuity of care by those who provide it."[29]
- "Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life."[2]
- "Pharmaceutical care is that component of pharmacy practice which entails the direct interaction of the pharmacist with the patient for the purpose of caring for that patient's drug-related needs."[3]
- "Pharmaceutical care is a patient-centered practice in which the practitioner assumes responsibility for a patient's drug-related needs and is held accountable for this commitment."[4]
- Pharmaceutical care services: "The use of specialized knowledge by pharmacists for the patient or healthcare professionals for the purpose of promoting effective and safe drug therapy."[4]
- From a systematic review of literature used of classify services in Australia, pharmacist services were "broadly defined to include any pharmacist activity aimed at promoting the quality use of medicines and improving patient outcomes."[30]
- "The European understanding is that pharmaceutical care basically is 'the professional care for the individual patient in a pharmacy.' It can be described as follows: Pharmaceutical care is a practice philosophy for pharmacy."[5]
- Cognitive pharmaceutical services: "Professional services provided by the pharmacist, who use their skills and knowledge to take an active role in contributing to patient health, through effective interaction with both patients and other health professionals."[6]
- "Enhanced pharmacy services refer to those offered in community pharmacies requiring additional or special skills, knowledge and/or facilities and are provided to sub-groups with

special needs. While community pharmacies worldwide routinely provide the safe, effective and rational use of medically prescribed, pharmacy- and self-selected medicines to all people, there is a growing diversity of additional services which are being developed and remunerated in developed countries."[31]

- "Pharmacist clinical care services were defined as those that enhanced a patient's medication therapy or overall health and did not include medication preparation, distribution, or any tasks delegated to a typical Canadian pharmacy technician with basic training."[9]
- In the United Kingdom, 'pharmacy services' are divided into three categories, essential, advanced and enhanced. Each particular service within these categories is described individually. The public by the NHS and to the profession in the pharmaceutical services.[32]
- Good pharmacy practice: "The practice of pharmacy that responds the needs of the people who use the pharmacist's services by providing optimal, evidence-based care. To support this practice it is essential that there be an established national framework of quality standards and guidelines."[21]
- "Pharmaceutical care is a professional patient care practice, which, when provided as an organized service, is experienced, documented, evaluated, and paid for as medication management services."[33]
- "Medication management services are the identifiable events in practice surrounding the professional responsibility of managing a patient's medications."[33]
- "Professional Services means the provision of services within a pharmacy, which require the specific supervision and active involvement of the pharmacist. Professional pharmacy services may be offered outside of the pharmacy but are outside the scope of this standard."[34]

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Chapter 4

Systematic Review of Implementation Frameworks of Innovations in Healthcare and Resulting Generic Implementation Framework

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HEALTH RESEARCH POLICY AND SYSTEMS

REVIEW Open Access

A systematic review of implementation frameworks of innovations in healthcare and resulting generic implementation framework

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Abstract

Background: Implementation science and knowledge translation have developed across multiple disciplines with the common aim of bringing innovations to practice. Numerous implementation frameworks, models, and theories have been developed to target a diverse array of innovations. As such, it is plausible that not all frameworks include the full range of concepts now thought to be involved in implementation. Users face the decision of selecting a single or combining multiple implementation frameworks. To aid this decision, the aim of this review was to assess the comprehensiveness of existing frameworks.

Methods: A systematic search was undertaken in PubMed to identify implementation frameworks of innovations in healthcare published from 2004 to May 2013. Additionally, titles and abstracts from *Implementation Science* journal and references from identified papers were reviewed. The orientation, type, and presence of stages and domains, along with the degree of inclusion and depth of analysis of factors, strategies, and evaluations of implementation of included frameworks were analysed.

Results: Frameworks were assessed individually and grouped according to their targeted innovation. Frameworks for particular innovations had similar settings, end-users, and 'type' (descriptive, prescriptive, explanatory, or predictive). On the whole, frameworks were descriptive and explanatory more often than prescriptive and predictive. A small number of the reviewed frameworks covered an implementation concept(s) in detail, however, overall, there was limited degree and depth of analysis of implementation concepts. The core implementation concepts across the frameworks were collated to form a Generic Implementation Framework, which includes the process of implementation (often portrayed as a series of stages and/or steps), the innovation to be implemented, the context in which the implementation is to occur (divided into a range of domains), and influencing factors, strategies, and evaluations.

Conclusions: The selection of implementation framework(s) should be based not solely on the healthcare innovation to be implemented, but include other aspects of the framework's orientation, e.g., the setting and end-user, as well as the degree of inclusion and depth of analysis of the implementation concepts. The resulting generic structure provides researchers, policy-makers, health administrators, and practitioners a base that can be used as guidance for their implementation efforts.

Keywords: Diffusion, Framework, Implementation, Knowledge translation, Model, Systematic literature review, Theory

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Background

Implementation of innovations into practice is a complex process [1]. The importance and acceptance of implementation research is growing and as a result is rapidly evolving [2]. The fields of implementation science and knowledge translation have arisen to drive change and move an array of innovations into practice [3-5].

Implementation and knowledge translation frameworks have predominantly developed within disciplines. This discipline-specific approach in the targeted innovations, settings, and end-users, has resulted in multiple and potentially disparate frameworks being developed and used [4,6-12]. Variations in implementation frameworks include the presence of disparate terminology and classification of implementation concepts. Implementation concepts are designated as including the process of implementation (divided into a series of stages or steps), domains (groups or levels of influences), and three elements: factors (also called barriers and enablers or determinants of practice), strategies (approaches to address the factors and implement the innovation), and evaluations. As implementation science advances, researchers have attempted to consolidate nomenclature and develop multidisciplinary frameworks [13-15]. Yet, it is unknown to what extent frameworks continue to focus on one concept alone or be innovation-specific.

Selecting an implementation framework is a challenging task. If an organisation or provider is interested in implementing a particular innovation, they must decide if an implementation framework for the innovation to be implemented is the most suitable, or should a framework or combination of frameworks, potentially created for the implementation of different innovation(s), be considered? In other words, as implementation frameworks vary in their orientation, it is plausible, by design or otherwise, that not all frameworks targeting a particular innovation cover all implementation concepts. The diversity of frameworks leads to a second question: do implementation frameworks across the range of innovations in healthcare consist of the same concepts, covered to the same degree and depth, and if not, how do they vary? Core implementation concepts have been posited and so it would appear for those with an objective to implement an innovation, rather than, for example, study a particular concept, the consequences of using a framework lacking degree or depth of an implementation concept may be poor results [9]. Therefore, the answers to such questions of framework comprehensiveness may aid users in their selection of a suitable implementation framework or whether to combine multiple implementation frameworks to aid their implementation efforts.

In 2004, Greenhalgh *et al.* [16] conducted a comprehensive literature review of implementation studies for innovations in service delivery and organisation. The work was focused predominantly in healthcare and used a snowballing technique to locate studies, as formal search techniques at this time drew a poor yield. Their landmark review located and analysed research areas that provided evidence of implementation research, in addition to collating findings to create a conceptual framework for implementation. The review elicited attributes of innovations, receiving organisations and their surrounding contexts; the complex, stop-start nature of the implementation process (from diffusion and dissemination, to adoption/assimilation and implementation/routinisation); as well as positing preliminary links amongst implementation concepts. In the ensuing 9 years, the field has expanded considerably and further taxonomies, checklists, conceptual frameworks, theories, and models of implementation have been developed [10,13,14,17,18]. A number of literature reviews of implementation frameworks have also been conducted, concentrating on particular implementation concepts, such as a particular stage, or specifically on either the factors, strategies or evaluations, rather than addressing all the concepts that could affect an innovation's implementation [13,17,19-26]. There seems to be no literature review covering the comprehensiveness of the frameworks [26].

With the expansion of implementation literature and maturation of the implementation field, it is now possible to conduct a formal search strategy solely within healthcare. The focussed results will increase the study's relevance and applicability to those comparing and selecting implementation frameworks for innovations in healthcare. It therefore appears timely to conduct a systematic review to analyse the comprehensiveness of implementation frameworks of innovations in healthcare. The present systematic review aimed to identify the extent to which existing implementation frameworks include core implementation concepts and determine if frameworks vary depending on the innovation they target.

Methods

Search strategy

A systematic literature search was undertaken to identify all frameworks of implementation of innovations in healthcare published from 2004 to May 2013. A search of literature was conducted using PubMed without language restrictions. The search strategy used was: ("Models, Educational" [MH] OR "Models, Nursing" [MH] OR "Models, Organizational" [MH] OR "Models, Psychological" [MH]) AND ("Diffusion of Innovation" [MH] OR "Organizational Innovation"[MH] OR "Capacity Building" [MH] OR "Decision Making, Organizational" [MH] OR "Organizational Culture" [MH] OR "Information Dissemination" [MH]) AND has abstract AND (model [TIAB] OR models [TIAB] OR theory [TIAB] OR theories [TIAB] OR framework* [TIAB]). In addition, titles and abstracts

of all *Implementation Science* journal articles (Feb 2006 to May 2013) and references from identified papers were reviewed for implementation frameworks.

Inclusion/exclusion criteria

Papers were included if they proposed an implementation framework of an innovation in healthcare. The inclusion criteria were defined as follows (Additional file 1):

- *Implementation* was defined as the process of putting to use or integrating innovations within a setting [14]. Frameworks needed to include concepts related to the either the stage of 'operation' (where the innovation is in use and is in the process of being integrated into routine practice) and/or 'sustainability' (the process of maintaining innovation use, capacity and benefits).
- *Framework* was defined as a graphical or narrative representation of the key factors, concepts, or variables to explain the phenomenon of implementation [27-30], and as a minimum needed to include the steps or strategies for implementation. Papers were included if they proposed a framework, model, or theory of implementation. Eligible papers needed to describe a new, or make change(s) to an existing, implementation framework.
- *Innovation in healthcare* was defined as a novel idea or set of behaviours, routines, and/or ways of working that involve a change in practice within a healthcare setting [6,16].

Frameworks were excluded if they were:

- Focussed on one specific domain, factor, or strategy (for example, organisational context, climate, or behavioural change).
- Studies applying or validating a framework without proposing a change to the framework.
- Based on a single case study.
- Quality improvement frameworks.
- For the implementation of a culture (for example, safety culture or green culture within an organisation).
- A model of patient care.
- To develop the fields of implementation science and knowledge translation (for example, the training of students in implementation).
- Concentrating on collaborative education as a method for change and models for curricula reform.

Data collection

A single reviewer (JCM) assessed titles and abstracts. For those that appeared to meet the inclusion criteria, the full paper was obtained and assessed. Any papers the reviewer was unsure about were discussed with a second member of the research team (SIB) and agreed upon for inclusion or exclusion.

Data extraction

The literature was critically analysed, by the same reviewer (JCM), to evaluate the frameworks according to the definitions provided and subsequently extract the following features from the frameworks:

i. The orientation of the framework: the kind of innovation (as described by the authors), the healthcare setting in which the innovation was to be implemented, the planned end-user(s), and a summary of the overall aim for which the framework was developed.
ii. The type of the framework: descriptive, prescriptive, explanatory, or predictive [31,32].
   - Descriptive frameworks describe the properties, characteristics, and/or qualities of implementation.
   - Prescriptive frameworks provide direction on the implementation process via a series of steps or procedures.
   - Explanatory frameworks specify the linkage and/or relationships between framework concepts.
   - Predictive frameworks hypothesise or propose directional relationships between the concepts of implementation.
iii. The implementation stages covered by the framework. Stages were designated based on Greenhalgh et al. conceptual framework (diffusion and dissemination, adoption/assimilation, and implementation) [16]. In addition, the pre-implementation stage of 'development' (innovation creation, refinement, and impact evaluation) from knowledge translation [12], and post-implementation stage of 'sustainability', which had not been included in the review by Greenhalgh et al. [16] due to lack of studies at that time focussing on this stage, were added. Diffusion and dissemination were combined under the heading of 'communication' (process by which people share information about a new innovation to increase awareness) as the terms often appear concurrently. The adoption/assimilation phase was divided into two sub-stages of 'exploration' (the innovation-decision process, whereby the end-user(s) appraise the innovation to decide whether to adopt) and 'installation' (the course of preparation, prior to use) [33-35]. The final stages included in the review table for analysis were development, communication, exploration, installation, operation, and sustainability. A framework was marked as including a stage if process components fitted the definitions of stage as provided in Additional file 1.

iv. The domains addressed in the framework. The domains were based on the Consolidated Framework for Implementation Research (intervention characteristics, outer setting, inner setting, characteristics of individuals, and process) [13]. The outer setting was divided into two, the 'external system' (economic, political, and professional milieu) and 'local environment' (circumstances surrounding the organisation(s) including patient, community, network) as it has been suggested the local environment has been lacking emphasis in previous frameworks [36,37]. In addition, the inner setting was termed 'organisation' and intervention called 'innovation' for greater clarity. The process factors were included under the 'strategies element' rather than as a domain. The final domains included in the review table for analysis were innovation, individuals, organisation, local environment, and external system. A framework was marked as including a domain if the influences fitted the definitions as provided in Additional file 1.

v. a) The degree of inclusion of the three elements: influencing factors, strategies, and evaluations (Additional file 1 for definitions), coded based on the substantiation provided for their inclusion. That is, where a smaller range of factors, strategies, and/or evaluations were provided, not a comprehensive range, the article was classified based on the justification of inclusion rather than number. These were assessed through classification into three levels:
   - + The framework itemises a range of factors, strategies, or evaluations with no explanation for their inclusion;
   - ++ The framework itemises a range of factors, strategies, or evaluations with some form of justification for their inclusion;
   - +++ The framework itemises a comprehensive range of factors or strategies based on a literature review or evaluations covering each of the concepts included in the framework.

   b) The depth of analysis of the three elements: influencing factors, strategies, and evaluations. These were assessed through classification into three levels:
   - ^ Factors, strategies, or evaluations provided as a list without descriptions;
   - ^^ Factors, strategies, or evaluations provided with descriptions;
   - ^^^ Factors, strategies, or evaluations provided with descriptions which included the relationships between or within the elements (factors, strategies, and evaluations) or mechanisms for operationalization.

Synthesis of results

A table was constructed to incorporate all of the data extracted (Additional file 2). Frameworks were ordered based on the innovation for which the framework was orientated and, secondly, on the setting. The classification of innovations into groups was based on the terminology used in the articles rather than by *ad hoc* definitions.

Results

The database search identified 1,397 articles and a further 621 were sourced from *Implementation Science* journal. From the 2,018 articles screened, 1,764 articles were eliminated after title and abstract screening and a further 223 after examination of the full-text articles. The references of the remaining 31 articles were screened, resulting in the identification of an additional 18 frameworks. Finally, a total of 49 implementation frameworks of an innovation in healthcare were included in the systematic analysis (Figure 1).

Frameworks were synthesised into tabular format (Additional file 2). Innovations were classified into groups: interventions (including those termed interventions, programs, innovations, complex interventions/innovations, shared-decision making, technologies, evidence-based practices, and telehealth; n = 22) [13,15,16,29,33-37,39-56], guidelines (including clinical-practice, best-practice, and evidence-based guidelines; n = 4) [57-61], knowledge (including knowledge, evidence, and research; n = 15) [12,62-68], evidence-based practice model (EBP model; n = 5) [69-74], and packaged implementation programs for innovations (n = 3) [75-77]. For implementation frameworks of 'EBP model' and 'packaged implementation programs', the innovation to be implemented is the model or program itself, which when implemented allows for the implementation of further innovations. Examples of the different types of innovations within each group as per the corresponding articles are provided in Additional file 2.

In many cases, within the innovation groups the frameworks' settings were similar (Additional file 2). Guidelines, knowledge, and EBP model frameworks were largely for clinical practice settings, while implementation programs were for community, public health, or human service settings. Interventions could be divided into two sub-groups; 12 were in community settings and 10 in clinical settings.

Key variations were seen between the innovation groups and the corresponding framework 'types' (descriptive, prescriptive, explanatory, and predictive) (Table 1). The 'type' of implementation framework for the innovation groups of interventions, guidelines, and implementation programs were often descriptive, in comparison to frameworks for knowledge and EBP model. Prescriptive frameworks, whereby the steps involved in the process of implementation were detailed, were rarely found for frameworks to implement guidelines or interventions, but were prevalent

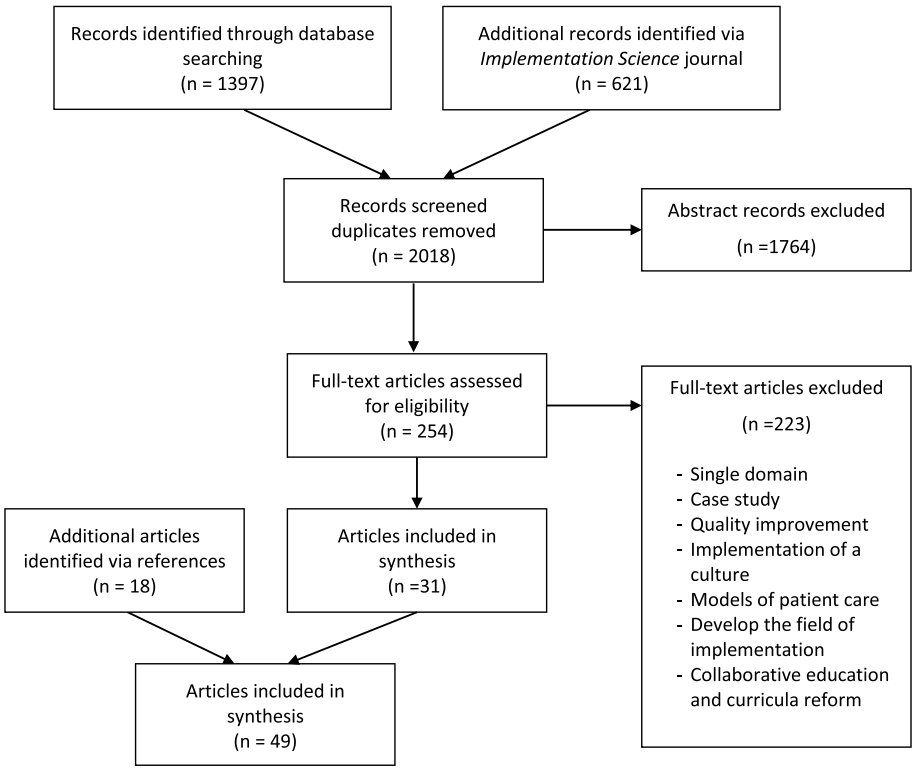

Figure 1 PRISMA flow chart of framework selection [38].

for implementation programs, EBP model, and knowledge frameworks. Overall, there were a larger number of descriptive and explanatory frameworks compared to prescriptive and predictive.

The process of implementation was depicted in various forms, including an array of linear, non-linear, recursive, or reiterative series of processes, steps, stages, or phases. The breakdown, categorisation, nomenclature, and order of the stages also varied. For example, eight frameworks did not explicitly mention stages [13,15,42,44,46,49,50,64,74], and the terminology ranged from 'orientation, insight, acceptance, change, and maintenance' [52], to 'implement, assess, adopt, disseminate, integrate, implement, maintain' [73] or 'unfreezing, moving, refreezing' [72]. Additional stages included innovation (in this situation meaning adaptation or reinvention) [34] and pilot testing [58].

The stage of operation (implementation) was found in all but three frameworks (94%), which were focused solely on sustainability. The pre-implementation stages of innovation development and communication were included in 24% and 37% of frameworks, respectively. The exploration stage was reported in 45% of frameworks and both the installation and sustainability stages were included in 63% of frameworks (Table 2).

When looking at the innovation groups, frameworks for the implementation of implementation programs covered the largest number of stages. Frameworks for the implementation of guidelines and knowledge included the

Table 1 Framework types

Innovation group	Type of framework			
	Descriptive	Prescriptive	Explanatory	Predictive
Interventions (n = 22)	16 (73%)	1 (5%)	14 (64%)	7 (32%)
Guidelines (n = 4)	3 (75%)	–	–	1 (25%)
Knowledge (n = 15)	4 (27%)	7 (47%)	8 (53%)	–
Evidence-based practice model (n = 5)	1 (20%)	3 (60%)	1 (20%)	1 (20%)
Implementation programs (n = 3)	3 (100%)	2 (67%)	1 (33%)	–
TOTAL (n = 49)	**27 (55%)**	**13 (24%)**	**24 (49%)**	**9 (18%)**

Percentages were calculated using the total number of frameworks at each innovation group in the denominator. Percentages are not accumulative because each framework could be fit into multiple 'type' categories.

Table 2 Framework stage analysis by innovation groups

Innovation group	Stages					
	Development	Communication	Exploration	Installation	Operation	Sustainability
Interventions (n = 22)	3 (14%)	6 (27%)	9 (41%)	13 (59%)	19 (86%)	17 (77%)
Guidelines (n = 4)	1 (25%)	3 (75%)	1 (25%)	1 (25%)	4 (100%)	2 (50%)
Knowledge (n = 15)	6 (40%)	8 (53%)	8 (53%)	9 (60%)	15 (100%)	7 (47%)
Evidence-based practice model (n = 5)	1 (20%)	0 (0%)	2 (40%)	5 (100%)	5 (100%)	2 (40%)
Implementation programs (n = 3)	1 (33%)	1 (33%)	2 (67%)	3 (100%)	3 (100%)	3 (100%)
TOTAL (n = 49)	**12 (24%)**	**18 (37%)**	**22 (45%)**	**31 (63%)**	**49 (94%)**	**31 (63%)**

Percentages calculated as the number of frameworks (which included a stage or domain) divided by the number of frameworks in each innovation group.

communication stage more often than for those for implementation programs, interventions, and EBP model (75% and 53% vs. 33%, 27%, and 0%, respectively). In contrast, frameworks for implementation programs and interventions incorporated sustainability more frequently (100% and 77%, compared to 50% for guidelines, 47% for knowledge, and 40% for EBP model frameworks). Frameworks for the implementation of knowledge included the development stage most frequently (40% of frameworks), while frameworks for guidelines focussed largely on communication and operation only (Table 2).

The categorisation and explicit presence of domains also differed across the frameworks. For example, May's [49] framework described only two domains (agency and context), and Aaron *et al.*'s [33] framework detailed three domains (outer context, inner context, and innovation); however, the components within the framework fitted four domains as per the definitions of analysis provided in Additional file 1. Three frameworks did not explicitly mention domains at all [35,54,56].

The organisational domain was covered most frequently in the 88% of frameworks, followed by the characteristics of the individuals involved in the process (76%), the innovation itself (73%), the local environment surrounding the implementation (55%), and the external system (45%). Frameworks for the implementation of implementation programs included all domains most often, followed by frameworks for interventions. Implementation frameworks for EBP model focussed largely on the individual and organisational domains, whereas frameworks for guidelines were more directed towards the guideline, or innovation itself, and the characteristics of the individuals (Table 3).

Out of the 49 implementation frameworks five comprehensively included the range of items within any one element with justification for their inclusion (as indicated by +++) and provided descriptions which included the relationships between or within the elements or mechanisms for operationalization (as indicated by ^^^) (Table 4). These frameworks were Damschroder *et al.* [13] covering factors, Kilbourne *et al.* [76] and Stetler *et al.* [55] for strategies, and Stetler *et al.* [55] and Lehman *et al.* [53] on evaluations. In total, only 6% of the frameworks covered the degree of any one element comprehensively (+++), while 20% covered factors, 29% strategies, and 14% evaluations in depth (^^^) (Table 4).

When analysed by innovation group, implementation frameworks of interventions most comprehensively covered the factors influencing implementation. Seventeen of the 22 intervention implementation frameworks (77%) included either a range of factors with some justification for inclusion (++) or comprehensive justification (+++); 16 of the 22 intervention implementation frameworks (73%) included factor descriptions (^^) and/or with relationships or operationalization (^^^). On the other hand, frameworks for implementation programs covered both the degree and depth of implementation strategies and evaluations, but were less detailed on factors. Frameworks for the implementation of guidelines, knowledge, and EBP model had lower levels of inclusion of evaluations, but were more comprehensive on strategies. Over a quarter of

Table 3 Framework domain analysis by innovation groups

Innovation group	Domains				
	Innovation	Individuals	Organisation	Local environment	External system
Interventions (n = 22)	15 (68%)	15 (68%)	21 (95%)	14 (64%)	12 (55%)
Guidelines (n = 4)	4 (100%)	3 (75%)	2 (50%)	2 (50%)	2 (50%)
Knowledge (n = 15)	12 (80%)	11 (73%)	13 (87%)	7 (47%)	5 (33%)
Evidence-based practice model (n = 5)	2 (40%)	5 (100%)	4 (80%)	1 (20%)	1 (20%)
Implementation programs (n = 3)	3 (100%)	3 (100%)	3 (100%)	3 (100%)	2 (67%)
TOTAL (n = 49)	**36 (73%)**	**37 (76%)**	**43 (88%)**	**27 (55%)**	**22 (45%)**

Percentages calculated as the number of frameworks (which included a stage or domain) divided by the number of frameworks in each innovation group.

Table 4 Framework element analysis (degree and depth)

			Factors (n = 49)	Strategies (n = 49)	Evaluations (n = 49)
Degree	+++		3	3	3
	++		28	30	15
	+		17	16	18
	nil		1	–	13
Depth	^^^		10	14	7
	^^		19	22	13
	^		19	13	16
	nil		1	–	13
Combined	+++	^^^	1	2	2
	++	^^^	8	10	3
	+	^^^	1	2	2
	+++	^^	2	1	1
	++	^^	14	18	8
	+	^^	3	3	4
	+++	^	–	–	–
	++	^	6	2	4
	+	^	13	11	12
	nil		1	–	13

+ Degree and substantiation of inclusion; ^ Depth of analysis.

frameworks did not include any evaluations (13 of 49 frameworks).

Discussion

Not surprisingly, and possibly due to a discipline effect, variations exist between both implementation frameworks for different healthcare innovations and implementation frameworks for the same healthcare innovation. The literature review sought to determine if frameworks varied depending on the innovation they were targeting. What is evident is that differences exist across frameworks regardless of whether frameworks are classified by a definition of the innovation or by terminology used to describe the innovation in the article. As such, the selection process for which framework(s) to use for a particular implementation program or study should not only be based on the type of innovation, but consider other aspects of the framework's orientation as well as the degree of inclusion and depth of analysis of all implementation concepts.

Frameworks for particular innovations existed largely within particular settings, targeting certain users, and were often of a similar framework 'type', that is, they are often still tacitly discipline-specific. A disadvantage of this specificity is that end-users of the implementation framework may inadvertently follow the framework configuration of their discipline and/or innovation in which they are interested, potentially missing concepts from other implementation frameworks. As an example, if a care worker was considering to implement a guideline within their community practice and found implementation frameworks for guidelines, the frameworks would be primarily directed towards nurses, health administrators, and researchers working in hospitals or clinical settings. However, a framework for a prevention program (classified as intervention) may be more appropriate, as these are often in community settings and therefore would address influencing factors more comparable to their setting. Alternatively, a combination of frameworks may be required to cover the depth of each element.

In terms of framework 'type' overall there was a lack of predictive and prescriptive frameworks, which may indicate the relatively early stage of development for the implementation and knowledge translation fields. As implementation science develops one would expect that new implementation studies should lead to the development and testing of predictive framework hypotheses.

Frameworks differed in their depiction and inclusion of implementation stages. Each stage along the implementation continuum has been studied and many stages have their own frameworks, such as frameworks for diffusion up to the point of adoption or sustainability frameworks [6,40-42]. It is therefore not surprising that the pre-implementation stages (development and communication) were included less frequently; this probably reflects that adoption is often considered to be a separate field of study. Interestingly, this was particularly prevalent in the frameworks for implementation of guidelines and knowledge. Recently, a further sustainability framework has been published, which expands on the idea of adaptation and innovation improvement as being central [78].

Categorisation and focus of implementation domains also varied widely across frameworks. It appears reasonable that the nomenclature and categorisation of the domains are not critical, but rather it is important that elements at a range of levels are considered for successful implementation and sustainability to ensue. For example, in hospital settings, the organisation in some occasions was further divided to include a team or unit domain [64], and particular end-users may prefer for patients to be separate from the local environment domain [52]. Frameworks for EBP model and knowledge were particularly low on the outer settings, both the local environment and external system domains, and may benefit from investigating elements from other frameworks in future implementation efforts.

There was a limited degree of inclusion and depth of analysis across the three elements in the frameworks reviewed. It was observed that implementation frameworks for particular innovations focused more on a particular element.

When implementing an innovation, there are core concepts requiring attention. When selecting a framework to implement an innovation the user should ensure all concepts are covered or alternatively they could select a range of frameworks. In other words, concepts that should be considered include those relating to the process of implementation (the stages and steps), the innovation to be implemented, the context in which the implementation is to occur (divided into various numbers of domains), influencing factors, strategies, and evaluations. As an example, it stands to reason that an organisation wanting to implement a program may desire a more prescriptive framework that spans all the implementation stages as well as being particularly detailed on strategies and evaluations. As such, a packaged implementation program for innovations, e.g., the Replication Effective Programs Framework, may be an option [76]. On the other hand, a researcher conducting an implementation study may be wanting to focus primarily on concept of implementation, e.g., on the factors affecting implementation, and therefore the Consolidated Framework for Implementation Research would be suitable [13].

It should be noted that many implementation frameworks, models, and theories, including a number in this review, are not created to be holistic, but rather target a specific implementation concept, such as a stage, or either the factors, strategies, or evaluations. Consequently, if an all-inclusive implementation framework is desired, an alternative to selecting a comprehensive, holistic innovation-specific framework might be to choose a combination of frameworks to cover the depth of each element. This would be done by looking for framework(s) that include a range of each element the user is interested in with at least some justification for inclusion (++) or comprehensive justification (+++), plus descriptions (^^) or with relationships or operationalization (^^^).

Emergence of a generic implementation framework

As implementation frameworks vary, it is valuable for researchers, policymakers, health administrators, and practitioners to have guidance of the basic components required for their implementation efforts. Across the multiple frameworks, core implementation concepts have emerged and detailed models of variables within these concepts explored; however, there seems no simple high level illustration of these overarching concepts. Furthermore, as many frameworks are not holistic, by design or otherwise, without knowledge or illustration of the core implementation concepts that should be considered, it is difficult to determine if a single or multiple meta-frameworks or models are required. A Generic implementation framework (GIF) has been proposed to depict the core concepts of implementation (Figure 2). Foremost to implementation is the non-linear and recursive nature of the implementation process (illustrated by the double arrows and overlapping circles). This process is then able to be divided into a series of stages and/or steps. At the centre of the framework is the innovation to be implemented and surrounding the

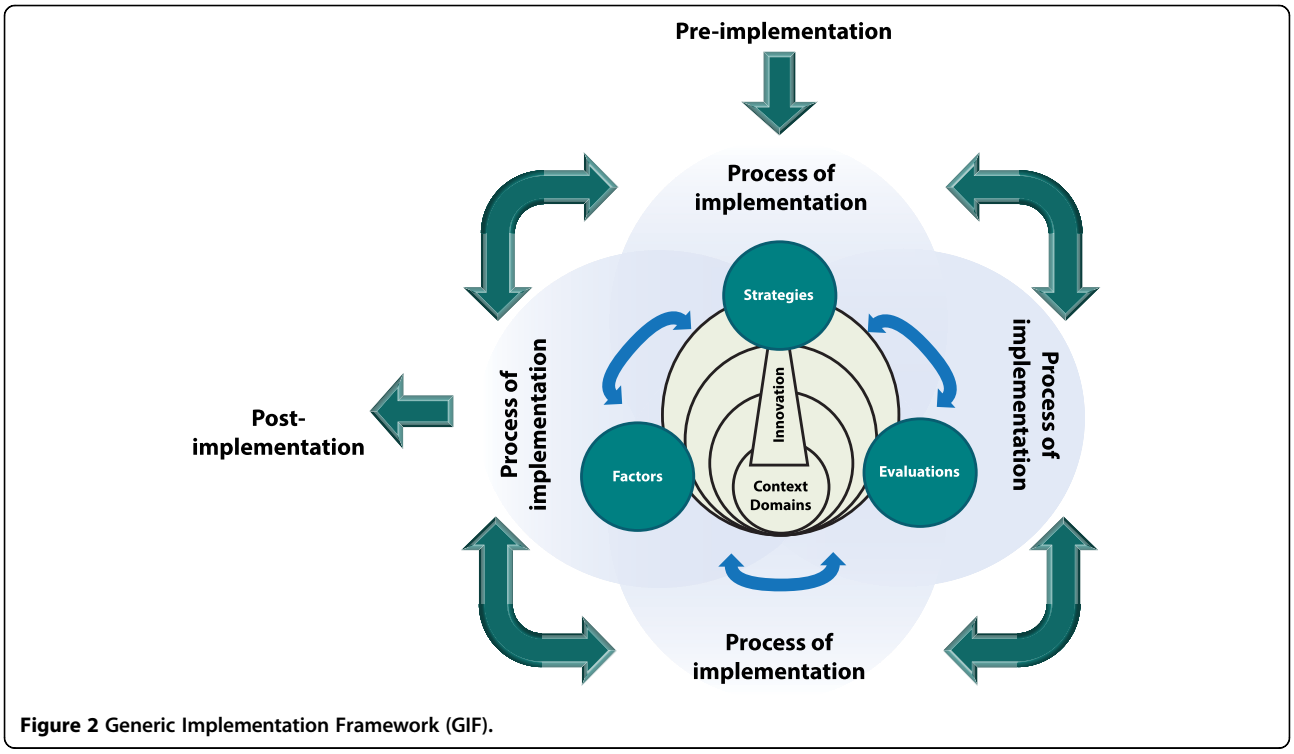

Figure 2 Generic Implementation Framework (GIF).

innovation are the contextual domains or levels of influence. Throughout the implementation process, at each stage and for each domain, there are factors, strategies, and evaluations that will influence the course of implementation and should be considered. It is important to note that the GIF is not a new framework but rather a composite of what is represented in most, if not all, other frameworks. Using the GIF as a starting point or checklist ensures the framework(s) chosen cover the core implementation concepts.

The GIF may be used as a memory aid, to ensure that, when an implementation effort (investigation, protocol, or program) is being designed, all concepts are considered and that the selection of framework(s) sufficiently covers them all. In this way, the GIF may be utilised as a base for the development of implementation protocols or programs and then tailored for use, depending of the innovation, user, setting, discipline, and objective. Meta-frameworks, models, or theories and particular discipline, innovation, or setting-specific variables may be added accordingly to each concept. The framework analysis may assist a user to choose an appropriate framework or combination of frameworks for their particular study or project. This may be done by using the table of analysis as a decision-support tool, whereby the end-user factors in their circumstances and objectives and compares this to the frameworks' targeted innovation, setting, type, and aim, along with the stages and domains it addresses and the degree and depth in which the elements are covered. For instance, guideline implementation frameworks, were essentially descriptive, based on clinical settings, were largely focussed on two domains, the innovation (the characteristics of the guideline to be implemented) and individuals, often did not include the stages of exploration and installation, and lacked comprehensiveness (degree and depth) of the evaluations element. Therefore, following on with the previous example of a care worker considering the implementation of a clinical guideline within their community practice, they may benefit from looking outside of the guideline implementation literature to frameworks for implementation programs which cover the missing stages and evaluations element to a greater extent. Furthermore, combining such a framework with a prevention program framework to address the factors associated with the user's orientation as a care worker in the community could be considered.

Limitations

Studies applying frameworks were not included unless a new framework was proposed. As such, further details to constructs may have been added to a framework, but not included in the review. Similarly, only the original reference per framework was included, unless subsequent changes were made to the framework, even if the depth of analysis was expanded in later papers. These exclusions could have affected the degree and depth of analysis; however, this has not affected the explanation of the framework or the resulting GIF. Moreover, it means that influential frameworks within implementation science published prior to 2004 are omitted, but these have been analysed in previously published literature reviews [79-81].

Classifying innovations based on definitions would have impacted the groupings and overall analysis (for example, by definition, clinical guidelines are used to implement evidence based practices and therefore could be classified as a health intervention rather than have their own group). This could be seen as a limitation, but it does not reduce the validity of the results, as the objective of analysis was to determine if an end-user was choosing a framework for a particular innovation would the frameworks targeting this innovation be the most suitable, or would a framework, created for the implementation of a different innovation, add further details on implementation concepts.

Finally, both the article inclusion and data extraction was performed by a single reviewer (JCM), with assistance from a secondary member when doubts arose (SIB). This may have influenced the coding of comprehensiveness of the frameworks (if different reviewers' were to have arrived at different classifications of the evaluative components degree and depth); however, the definitions for data extraction were developed to minimise uncertainties.

Conclusions

The literature review revealed variations in implementation frameworks of innovations in healthcare. Core concepts of implementation should be considered for every implementation effort, yet differences were seen in the structure and order in which the implementation process and domains were depicted, as well as the comprehensiveness of factors, strategies, and evaluations. Concepts that should be considered for successful implementation include those relating to the process of implementation (the stages and steps), the innovation to be implemented, the context in which the implementation is to occur (divided into various numbers of domains), influencing factors, strategies, and evaluations. The GIF was developed to ensure chosen frameworks, meta-frameworks, models, or theories as well as particular discipline, innovation, or setting-specific variables, cover the core implementation concepts.

Additional files

Additional file 1: Definitions.

Additional file 2: Table of analysis.

Abbreviations

EBP: Evidence-based practice; GIF: Generic implementation framework.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions
FFL contributed to the design of the systematic review: determined the search strategy and contributed to the methodology section. SIB participated in the systematic review of full text articles when doubts of inclusion arose, data analysis, and review of the manuscript. DSH contributed to study concept, drafting, and review of the manuscript. JCM systematically reviewed the articles, analysed the data, and wrote the manuscript. All authors read and approved the final manuscript.

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Additional File 1: Definitions

Implementation	The process of commencing to use and integrating innovations within a setting [1].
Framework	Graphical or narrative representation of the key factors, concepts, or variables in order to explain the phenomenon of implementation [2].
Innovation	Novel set of behaviours, routines, and ways of working within a setting[3].
PROCESS OF IMPLEMENTATION	Non-linear, recursive, reiterative progression of implementation.
STAGES OF IMPLEMENTATION	The breakdown of the complete implementation process.
Development	Innovation, identification or creation, synthesis, refinement, evaluation and packaging [4].
Communication	Process by which people learn and share information about a new innovation to increase awareness [5].
Diffusion	Passive, untargeted, unplanned and uncontrolled spread of new innovations [1]. Diffusion is a horizontal or natural process where the onus is on the adopter to seek, absorb and act on the information. Examples of diffusion include mass mailings, publishing in journals and conference presentations. Aim is to increase knowledge and awareness of the innovation.
Dissemination	Active approach using planned strategies via determined channels to persuade the target audience to adopt new innovations [1, 3]. Targeted approach takes into account such things as the type of evidence, the end-user(s) needs, and organisational culture and climate. Aim is to increase knowledge, awareness and perception of the innovation.
Exploration (appraisal)	The innovation-decision process whereby the end-user(s) appraise the innovation concluding with a decision to either to accept/adopt or reject. Involves progression through awareness (or an issue, need and/or new innovation), knowledge, persuasion, opinion and decision regarding the innovation [5].
Installation (preparation)	The course of preparation (innovation, individuals, organization, local environment and external system) prior to innovation use [6].
Operation (implementation)	Innovation is in use and is in the process of being integrated into routine practice through active and planned approaches[1].
Sustainability (maintenance)	Process of maintaining the innovation through continued innovation use integrated as routine practice, ongoing capacity and supportive environment sufficient to support innovation use and persistence of benefits [7].
DOMAINS	Groupings or levels of related implementation influences (and by which factors may be categorised and strategies and evaluations targeted). Domains may vary in number and way in which they are divided.
Innovation Domain	A grouping of related influences regarding the characteristics of the innovation to be implemented [8].
Context Domains	Groupings of related influences regarding the circumstances that surround the innovation to be implemented [8].
Individuals	Characteristics and agency of the people involved with the innovation and/or implementation process.
Organisation	Conditions and characteristics of the setting(s) in which the innovation is to operate.
Local environment	Circumstances immediately surrounding the organisation(s) including the community, patients and network.
External system	Broad economic, political and professional milieu.
ELEMENTS OF IMPLEMENTATION	Core considerations affecting the implementation process.
Factors	Variables that may affect the implementation process. Also termed facilitators and barriers or determinants of practice [9].
Strategies	Targeted efforts (method, technique or activity) designed to enhance moving of an innovation into use and integrating into routine practice [9, 10]. Package of implementation strategies often form an implementation program.
Evaluations	Measures of the effects of implementation including process evaluation of course and factors, formative evaluation of strategies, and summative evaluation of implementation and innovation outcomes [10-12].

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Additional File 2: Framework analysis

Innovation category	Framework		Orientation				Type	Stages						Domains					Elements		
	Title	Reference	Innovation	Setting	User(s)	Aim	Descriptive Explanatory Predictive	Development	Communication	Exploration	Installation	Operation	Sustainability	Innovation	Individuals	Organisation	Local environment	External system	Factors	Strategies	Evaluations
Interventions	Conceptual framework for sustainability of public health programs	Scheirer MA & Dearing JW. 2011[1]	Funded programs of healthcare, health promotion & disease prevention interventions	Health organisations and community settings	Researchers and funders	Provide guidance, for research and evaluation, of health program sustainability	Predictive						✓	✓		✓	✓	✓	++ ^^	+ ^	+++ ^^
Interventions	Sustainability planning model	Johnson K et al. 2004[2]	Substance abuse prevention innovations, programs and strategies	Organisational, community, state or national level substance abuse prevention systems	Researchers and practitioners	Highlight the key factors relating to sustaining innovations and how to address them	Prescriptive Explanatory						✓	✓		✓			++ ^^^	++ ^^	++ ^^
Interventions	Capacity for sustainability framework	Schell SF et al. 2013[3]	Public health programs (prevention)	Community practice settings	Researchers, funders and practitioners	Aid public health programs in conceptualizing their capacity for sustainability	Descriptive						✓	✓		✓	✓	✓	++ ^	+ ^	+ ^
Interventions	Interactive Systems Framework for dissemination and implementation (ISF)	Wandersman A et al. 2008[4]	Prevention innovations (programs, policies, processes & principles)	Organisational, community, state or national level	Multiple stakeholders (e.g. funders, practitioners, researchers)	Heuristic to help clarify the issues related to how to move what is known about prevention into widespread use	Descriptive Explanatory		✓	✓	✓	✓			✓	✓	✓	✓	+ ^	++ ^^	nil

Innovation category	Framework		Orientation				Type	Stages						Domains					Elements		
	Title	Reference	Innovation	Setting	User(s)	Aim	Descriptive Explanatory Predictive	Development	Communication	Exploration	Installation	Operation	Sustainability	Innovation	Individuals	Organisation	Local environment	External system	Factors	Strategies	Evaluations
Interventions	TCU Program Change Model	Simpson DD & Flynn PM. 2007[5]	Community drug treatment programs and health service innovations	Community-based organisations	Researchers	Organize and summarize implementation results	Descriptive Explanatory			✓	✓	✓	✓	✓	✓	✓			++ ^^^	++ ^^	++ ^^^
Interventions	Ecological framework for understanding effective implementation	Durlak JA & DuPre EP. 2008[6]	Promotion and prevention programs/ interventions	Community settings	Researchers	Framework to depict the factors that affect implementation	Explanatory Predictive		✓	✓	✓	✓	✓	✓	✓	✓	✓		+++ ^^	++ ^^	++ ^^
Interventions	Core implementation components	Fixsen DL et al. 2009[7]	Research-based prevention and treatment services, interventions and programs	Human service settings	Researchers and practitioners	Present the critical links of implementation stages and core components in the science to service chain	Descriptive			✓	✓	✓	✓		✓	✓		✓	++ ^	+++ ^^	+ ^
Interventions	Model of sustaining innovations in their effectiveness	Racine DP. 2006[8]	Health and human service innovations	Human and health services	Creators, funders, adopters, researchers	Describe factors that appear to play important roles in whether innovations are replicated and sustained in their effectiveness	Explanatory Predictive			✓		✓	✓	✓		✓	✓	✓	++ ^^^	++ ^^	nil
Interventions	Framework of dissemination in health services intervention research	Mendel P et al. 2008[9]	Evidence-based health interventions (mental health)	Community healthcare settings	Health services researchers	Evaluation and capacity focus (stakeholder/ community partnerships)	Descriptive Explanatory				✓	✓	✓		✓	✓	✓	✓	+ ^^^	+ ^	++ ^^^

Innovation category	Framework		Orientation				Type	Stages						Domains					Elements		
	Title	Reference	Innovation	Setting	User(s)	Aim	Descriptive Explanatory Predictive	Development	Communication	Exploration	Installation	Operation	Sustainability	Innovation	Individuals	Organisation	Local environment	External system	Factors	Strategies	Evaluations
Interventions	Conceptual model of implementation phases and factors affecting implementation in public service sectors	Aarons GA, Hurlburt M and McCue Horwitz S. 2011[10]	Evidence-based practices (mental health services and human service technologies)	Public sector systems serving children and families (child welfare)	Multiple stakeholders	Framework which includes the importance of variables at each implementation phase	Descriptive Explanatory			✓	✓	✓	✓	✓	✓	✓	✓	✓	++ ^^^	+ ^	nil
Interventions	Integrated 2-phase TCU approach to strategic system change	Lehman WEK et al. 2011[11]	Evidence-based practices (technologies)	Substance abuse treatment services	Researchers and organisations	Present a biphasic framework for innovation planning and implementation	Explanatory	✓		✓	✓	✓	✓	✓	✓	✓			++ ^^	++ ^^	+++ ^^^
Interventions	ATTC Network model of technology transfer in the innovation process	Addiction Technology Transfer Center Network Technology Transfer Workgroup. 2011[12]	Evidence based practices (technologies)	Substance abuse treatment organisations	Stakeholders (funders, organisations educational institutions, practitioners) and researchers	Field-driven conceptual model of innovation process and to provide a comprehensive taxonomy	Descriptive	✓	✓	✓		✓		✓	✓	✓			+ ^	+ ^	nil
Interventions	Practical, Robust Implementation and Sustainability Model (PRISM)	Feldstein AC & Glasgow RE. 2008[13]	Health interventions (programs, technologies, evidence-based practices)	Healthcare practices	Researchers and healthcare managers	Integrate key features of program design, predictors of implementation and diffusion, and appropriate outcomes measures	Descriptive Explanatory				✓	✓	✓	✓	✓	✓	✓	✓	++ ^^^	++ ^^^	++ ^

Innovation category	Framework		Orientation				Type	Stages						Domains					Elements		
	Title	Reference	Innovation	Setting	User(s)	Aim	Descriptive Explanatory Predictive	Development	Communication	Exploration	Installation	Operation	Sustainability	Innovation	Individuals	Organisation	Local environment	External system	Factors	Strategies	Evaluations
Interventions	Consolidated Framework of Implementation Research (CFIR)	Damschorder LJ et al. 2009[14]	Health interventions	Multiple contexts	Health services researchers	Consolidate all factors that may be encountered, promote theory development and guide formative evaluations	Descriptive		✓		✓	✓		✓	✓	✓	✓	✓	+++ ^^^	+ ^^	+ ^^^
Interventions	A model of diffusion in service organizations	Greenhalgh T et al. 2004[15]	Health service innovations	Healthcare service organisations	Researchers	Depict how to spread and sustain innovations in health service delivery and organisation	Descriptive Explanatory	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	+++ ^^	++ ^^	nil
Interventions	Factors that determine the rate of adopting of innovations from research into practice	Bradley EH et al. 2004[16]	Clinical programs and innovations	Multiple settings. Hospital, nursing home, paediatrics, pharmacy	Researchers	Describe the factors and steps learned about diffusing innovations into practice	Descriptive Explanatory					✓	✓	✓		✓		✓	++ ^^	++ ^^	+ ^
Interventions	Conceptual framework of complex innovation implementation	Helfrich CD et al. 2007[17]	Complex innovations	Healthcare organisations	Researchers, managers and practitioners	Adapt an organisational framework of innovation implementation for utility in healthcare	Predictive					✓				✓			++ ^^^	+ ^^^	+ ^^^
Interventions	Normalisation Process Theory (NPT)	May C & Finch T. 2009[18]	Complex practices: Business processes or complex interventions	Organisations or institutions	Researchers	Propose a working model of implementation, embedding and integration	Descriptive Explanatory Predictive				✓	✓	✓	✓	✓	✓	✓		++ ^^	++ ^^	++ ^^

Innovation category	Framework		Orientation				Type	Stages						Domains					Elements		
	Title	Reference	Innovation	Setting	User(s)	Aim	Descriptive Explanatory Predictive	Development	Communication	Exploration	Installation	Operation	Sustainability	Innovation	Individuals	Organisation	Local environment	External system	Factors	Strategies	Evaluations
Interventions	Normalisation Process Theory (NPT)	May C. 2013[19]	Innovations: Shared decision making in doctor and nurse-patient interactions	Healthcare organisations	Researchers	Specify specific set of activities involved in implementation (process) and embedding (state) of innovations	Descriptive Explanatory Predictive				✓	✓	✓						nil	++ ^^	++ ^
Interventions	General theory of implementation	May C. 2013[20]	Complex interventions	Clinical settings	Researchers and practitioners	Foundation for understanding, designing, predicting, and evaluating dynamic implementation processes	Descriptive Explanatory Predictive					✓		✓	✓	✓	✓	✓	++ ^^	+ ^^^	nil
Interventions	Model for success and breakdown factors of shared governance	Ballard N. 2010[21]	Shared governance	Practice settings	Nursing leaders	Summarise human and structural factors that contribute to success or breakdown of shared governance practice models	Descriptive				✓	✓	✓		✓	✓	✓		+ ^	++ ^^	nil
Interventions	Model and checklist for telehealth	Joseph V et al. 2011[22]	Telehealth	Healthcare organisations	Practitioners	Identify the key challenges for telehealth projects (trials) & produce a model and checklist to ensure success	Descriptive				✓	✓	✓		✓	✓	✓		++ ^^	++ ^^	+ ^
Guidelines	Three phase implementation model	Carey M, Buchnan H & Sanson-Fisher R. 2009[23]	Evidence-based guideline recommenda-tions	Healthcare	Guideline developers	Provide strategies targeting factors associated with behavioural change in a logical sequence	Descriptive	✓	✓		✓	✓		✓	✓	✓	✓		+ ^	++ ^^^	+ ^

Innovation category	Framework		Orientation				Type	Stages						Domains					Elements		
	Title	Reference	Innovation	Setting	User(s)	Aim	Descriptive Explanatory Predictive	Development	Communication	Exploration	Installation	Operation	Sustainability	Innovation	Individuals	Organisation	Local environment	External system	Factors	Strategies	Evaluations
Guidelines	Contingency model of innovation adoption	Berta W et al. 2005[24]	Clinical practice guidelines to improve quality of care	Long-term care facilities	Researchers	Describe factors that contribute to capacity building at each stage of innovation adoption	Predictive		✓			✓	✓	✓	✓	✓	✓	✓	++ ^^	+ ^	nil
Guidelines	Model matrix of factors in implementation of practice change	Hader JM et al. 2007[25]	Clinical practice guidelines	Doctors in clinical practice	Guideline developers	Insights into the determinants of change which may help identify means to increase successful implementation	Descriptive		✓	✓		✓	✓	✓	✓			✓	++ ^^	+ ^	nil
Guidelines	Guideline implementability framework	Gagliardi AR et al. 2011[26]	Guidelines	Healthcare	Guideline developers	Identify and define features that facilitate guideline use	Descriptive					✓		✓					+ ^	+ ^	+ ^
Knowledge	10-step model for inducing change in professional behaviour	Grol R & Wensing M. 2004[27]	Evidence (Change in practice)	Health services	Researchers	How to identify, categorize and use barriers and incentives to change practice, to tailor interventions and to facilitate desired change	Prescriptive		✓	✓		✓	✓	✓	✓	✓		✓	++ ^^	++ ^	nil
Knowledge	John Hopkins Quality and Safety Research Group translating evidence into practice model	Pronovost P, Berenholtz S & Needham D. 2008[28]	Evidence (evidence-based therapies & interventions)	Hospitals - clinical practice	Researchers and clinicians	Embed a method of knowledge translation in a collaborative team model	Prescriptive	✓			✓	✓	✓						+ ^	+ ^^	+ ^^
Knowledge	Promoting Action on Research Implementation in Health Services (PARIHS)	Kitson AL et al. 2008[29]	Evidence	Hospital	Researchers and practitioners	Heuristic to frame research or knowledge translation endeavours as two stage diagnostic and evaluative approach	Explanatory				✓	✓		✓	✓	✓			++ ^^^	++ ^^^	++ ^^

Innovation category	Framework		Orientation				Type	Stages						Domains					Elements		
	Title	Reference	Innovation	Setting	User(s)	Aim	Descriptive Explanatory Predictive	Development	Communication	Exploration	Installation	Operation	Sustainability	Innovation	Individuals	Organisation	Local environment	External system	Factors	Strategies	Evaluations
Knowledge	Revised PARIHS framework for a task-orientated approach to implementation	Stetler CB et al. 2011[30]	Evidence based practices	Veterans Health Administration healthcare settings or similar	Researchers	Revising PARIHS framework for use in task-orientated implementation	Explanatory				✓	✓		✓	✓	✓			++ ^^^	+++ ^^^	+++ ^^^
Knowledge	Promoting Action on Research Implementation in Health Services (PARIHS)	Rycroft-Malone J et al. 2013[31]	Evidence	Hospital	Researchers and practitioners	Represent the process of implementation of evidence to practice	Explanatory				✓	✓		✓	✓	✓			++ ^^	++ ^^^	++ ^
Knowledge	Critical Realism & the Arts Research Utilization Model (CRARUM)	Kontos PC & Poland BD. 2009[32]	Knowledge	Healthcare settings	Researchers	Incorporate the interpretive dimension of evidence and complexity of healthcare settings into a Knowledge Translation model	Descriptive Explanatory			✓	✓	✓	✓	✓	✓	✓	✓		++ ^^	++ ^^^	++ ^^
Knowledge	Analytic framework: moving knowledge into action	Best A, Hiatt RA & Norman CD. 2008[33]	Cancer control strategies (knowledge)	Cancer control systems	Practitioners	Integrate knowledge into the system (decisions, practices and policies) with communication as a central role	Descriptive		✓	✓		✓		✓	✓	✓	✓	✓	+ ^	++ ^^	nil
Knowledge	Knowledge to Action (KTA)	Graham ID et al. 2006[34]	Knowledge (research)	Healthcare practice	Healthcare practitioners, policymakers, patients, and the public	Conceptual map of the Knowledge-To-Action process	Prescriptive	✓	✓	✓	✓	✓	✓	✓	✓	✓			+ ^	+ ^	++ ^^^
Knowledge	Sticky knowledge	Elwyn G, Taubert M & Kowalczuk J. 2007[35]	Knowledge (evidence)	Primary care	Clinicians and management	Demonstrate sticky knowledge may play a role in helping overcome barriers to transfer	Descriptive			✓	✓	✓	✓	✓	✓	✓			++ ^^	+ ^	nil

Innovation category	Framework		Orientation				Type	Stages						Domains					Elements		
	Title	Reference	Innovation	Setting	User(s)	Aim	Descriptive Explanatory Predictive	Development	Communication	Exploration	Installation	Operation	Sustainability	Innovation	Individuals	Organisation	Local environment	External system	Factors	Strategies	Evaluations
Knowledge	Joint Venture Model of Knowledge Utilization (JVMKU)	Edgar L et al. 2006[36]	Knowledge	Nursing and healthcare	Nurses	Practical guide for critical reflection on issues affecting the process of knowledge utilisation	Descriptive Explanatory		✓			✓		✓	✓	✓	✓	✓	++ ^	++ ^	+ ^
Knowledge	Knowledge-value chain	Landry R et al. 2006[37]	Knowledge (research)	Public Health organisations (e.g. WHO)		Use of knowledge management for the capability to acquire, create, share and apply knowledge	Descriptive	✓	✓			✓		✓		✓			+ ^	+ ^	+ ^
Knowledge	Multisystem model of knowledge integration and translation	Palmer D & Kramlich D. 2011[38]	Knowledge	Healthcare	Nurse researchers	Generation, integration and implementation of knowledge into practice based on concepts of communities of practice	Descriptive Explanatory Prescriptive	✓	✓	✓	✓	✓	✓		✓	✓	✓		+ ^	++ ^^^	+ ^
Knowledge	Knowledge Use in Pain Care (KUPC)	Latimer MA, Ritchie JA & Johnston CC. 2010[39]	Knowledge (pain care for children)	Nursing practice in hospitals	Healthcare administrators clinical leaders, researchers	Link theory and evidence from clinical and administrative perspectives to implementation activities	Descriptive					✓			✓	✓	✓	✓	++ ^^	++ ^^	nil
Knowledge	Collaborative model of knowledge translation in clinical Settings	Baumbusch JL et al. 2008[40]	Research findings	Clinical settings		Provide an interactive model of knowledge translation	Explanatory	✓	✓	✓	✓	✓	✓	✓			✓	✓	++ ^	+ ^^	+ ^
Knowledge	Knowledge integration model	Gauthier N et al. 2005[41]	Knowledge/ evidence	Clinical settings	Researchers, clinicians and decision makers	Illustrate the dynamic and reiterative nature of knowledge integration supported by on-going dialogue	Descriptive	✓	✓	✓		✓		✓		✓	✓		+ ^	++ ^^	+ ^

Innovation category	Framework		Orientation				Type	Stages						Domains					Elements		
	Title	Reference	Innovation	Setting	User(s)	Aim	Descriptive Explanatory Predictive	Development	Communication	Exploration	Installation	Operation	Sustainability	Innovation	Individuals	Organisation	Local environment	External system	Factors	Strategies	Evaluations
Evidence based practice	Trinity model of evidence-based practice	Vratny A & Shriver D. 2007[42]	Evidence based practice model of care	Medical centre (hospital)	Nursing administrators	Use a tree metaphor to depict the core components to overcome barriers and encourage EBP implementation	Descriptive				✓	✓		✓	✓	✓	✓	✓	++ ^^	++ ^^^	++ ^^
Evidence based practice	Process for the use of evidence-based practice model for staff nurses	Reavy K & Tavernier S. 2008[43]	Evidence based practice model	Medical centre (hospital)	Staff nurses	Staff nurses to recognize ownership of their practice and role in changing practice	Prescriptive	✓		✓	✓	✓	✓		✓				+ ^	++ ^^	+ ^^
Evidence based practice	Tyler collaborative model for evidence-based practice	Olade RA. 2004[44]	Evidence based practice	Healthcare settings	Nurses and other healthcare professionals	Guide collaborative efforts toward evidence-based nursing practice	Prescriptive			✓	✓	✓	✓		✓	✓			++ ^	++ ^^	+ ^^
Evidence based practice	Steps in building an EBP Program	MacRobert M. 2008[45]	Evidence based practice	Case management practice setting	Case managers	Describe steps and strategies to move EBP into practice	Explanatory Prescriptive				✓	✓		✓	✓	✓			+ ^	++ ^^^	++ ^
Evidence based practice	Advancing Research and Clinical Practice Through Close Collaboration Model (ARCC)	Melnyk BM et al. 2010[46]	Evidence based practice	Hospitals and healthcare systems	EBP implementers	Guide system-wide implementation and sustainability of EBP to improve quality of care and patient outcomes	Predictive				✓	✓			✓	✓			+ ^^	++ ^^	+ ^^

Innovation category	Framework		Orientation				Type	Stages						Domains					Elements		
	Title	Reference	Innovation	Setting	User(s)	Aim	Descriptive Explanatory Predictive	Development	Communication	Exploration	Installation	Operation	Sustainability	Innovation	Individuals	Organisation	Local environment	External system	Factors	Strategies	Evaluations
Implementation programs	Replicating Effective Programs Framework (REP)	Kilbourne AM et al. 2007[47]	Program for implementing clinical and health service interventions	Community-based organisations	Researchers, intervention developers, stakeholders	Framework that can be applied to implement interventions	Descriptive Prescriptive	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	++ ^	+++ ^^^	++ ^^
Implementation programs	CHANGE model (customised, holistic, analytical, network-building, grassroots, evaluatory)	Vega MY. 2009[48]	Program for implementing packaged prevention interventions	Community-based organisations	Practitioners and researchers	Approach to provide skills to implement and capacity to reorient to interventions	Descriptive Prescriptive				✓	✓	✓	✓	✓	✓	✓	✓	+ ^^	++ ^^^	++ ^^
Implementation programs	ARC organisational and community intervention model	Glisson C & Schoenwald SK 2005[49]	Program for implementing social and mental health treatments and services for children	Isolated community practice settings	Practitioners and researchers	Address the 'fit' between the social context and service technology, address technical, social and strategic factors.	Descriptive Explanatory				✓	✓	✓	✓	✓	✓	✓		+ ^^	++ ^^^	++ ^^

\+ The framework itemizes a limited range of factors, strategies or evaluations with no explanation for their inclusion
++ The framework itemizes a range of factors, strategies or evaluations with some justification for their inclusion
+++ The framework itemizes a comprehensive range of factors, strategies or evaluations based on a literature review or expert consensus
^ Factors, strategies or evaluations provided as a list without description
^^ Factors, strategies or evaluations provided with definitions
^^^ Factors, strategies or evaluations provided with explanations which include the relationships between or within the elements (factors, strategies and evaluations) or mechanisms for operationalization

EBP = Evidence based practice model of practice; EBPs – Evidence-based practices; TCU – Texas Christian University

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Chapter 5

Qualitative study on the implementation of professional pharmacy services in Australian community pharmacies using framework analysis

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Qualitative study on the implementation of professional pharmacy services in Australian community pharmacies using framework analysis

Background

Implementation research is evolving, but studies using implementation theory and investigation of the implementation influences, over the course of implementation during each implementation stage, is scarce in both pharmacy and other disciplines [1, 2]. Knowledge of pharmacy's implementation process, combined with the use of a suitable implementation framework(s), could aid widespread adoption, implementation, sustainability and eventual scale-up of professional pharmacy services. Correspondingly as professional pharmacy services incorporate the principles and practices of pharmaceutical care and clinical pharmacy [3, 4] an improvement in patient outcomes would be predicted. Examples of professional pharmacy services include conducting reviews of patients' medications, counselling on new and/or chronic medications (to improve health literacy, knowledge, adherence and prescribing behaviour), the provision of immunisations and involvement in public health promotional campaigns [3, 5, 6]. In Australia these services may be Government funded, such as medication reviews, which may be adopted by any pharmacy, introduced by pharmacy groups, which may be optional or 'mandatory' for branches to provide, or developed and introduced at individual pharmacy level.

Internationally community pharmacy is attempting to implement professional services into routine practice [7-9]. In several countries professional pharmacy services are being remunerated and pharmacies are beginning to implement, however the implementation process pharmacies are undergoing is largely unknown [10]. Pharmacy practice research remains predominantly focused on clinical and cost effectiveness of the professional services [11], barriers and facilitators [12-15], pharmacy culture [16], perception of pharmacy [10, 17], and remuneration [18, 19].

There is increasing consensus in implementation science and knowledge translation regarding the concepts involved in implementation [20]. Implementation is the process of commencing to use and integrating innovations within a setting [21]. This process is described as a non-linear, iterative and complex that may be divided into a number of stages [22-24] and activities/steps [25, 26]. Throughout each stage of the implementation process, three fundamental elements or influences should be considered: factors, strategies and evaluations. Specifically those wishing to implement should consider the factors that are influencing the implementation effort (also termed determinants of practice or barriers and facilitators) [27-30], which strategies may assist (including implementation interventions) [30-35] and what evaluations should be conducted (encompassing tools, measures and outcomes) [36-40]. Finally the constituents within the factors, strategies and evaluations may be grouped into contextual domains or ecological levels [27, 41]. In other words factors exist at multiple levels and strategies and evaluations should be targeted towards each level. In brief, implementation may be summarised as involving: (1) an innovation, (2) a process, influenced across (3) contextual domains by (4) factors (5) strategies (6) and evaluations.[20] There are a range of frameworks, models or theories that

target the concepts individually as well as holistically [Table 1] [20, 42]. See Additional File 1 for implementation definitions.

The Generic Implementation Framework (GIF) has been suggested as an overarching, broad framework that collates and illustrates the core implementation concepts, suitable across disciplines [Figure 1] [20]. The GIF is a skeletal structure into which specific, detailed meta-frameworks, models or theories, such as those detailed in Table 1, should be chosen for each concept: innovation, process, contextual domains, factors, strategies and evaluations. To tailor the GIF to pharmacy practice it is therefore necessary to investigate and determine the contents for each of the aforementioned implementation concepts.

Table 1: Examples of meta-frameworks and models

Concept	Framework examples
Process	
Stages	Greenhalgh et al. [22], Fixsen et al. [24], Aarons et al. [23]
Steps	Meyers et al. [25, 26]
Domains	Greenhalgh et al. [22], Damschroder et al. [27], Wandersman et al. [41]
Factors	Damschroder et al. [27], Flottorp et al. [28], Michie et al [29, 30]
Strategies	
Discrete	EPOC [31], Mazza et al. [32], Powell et al. [33, 34], Michie [30, 35]
Multifaceted	Glisson et al. [64], Chinman et al. [52], Kilbourne et al. [53], Institute for Healthcare Improvement [67, 68]
Evaluations	Proctor et al. [37], Glasgow et al. [36], Steckler et al. [39], Lehman et al. [38], Stetler et al. [40] Green et al. [69]

Aim of study

The general objective was to explore the concepts of the GIF in community pharmacy in order to tailor a framework for the implementation of services in pharmacy. The primary objective was to investigate the process of professional service implementation occurring in practice and secondarily to assess over the course of this process the factors, strategies and evaluations.

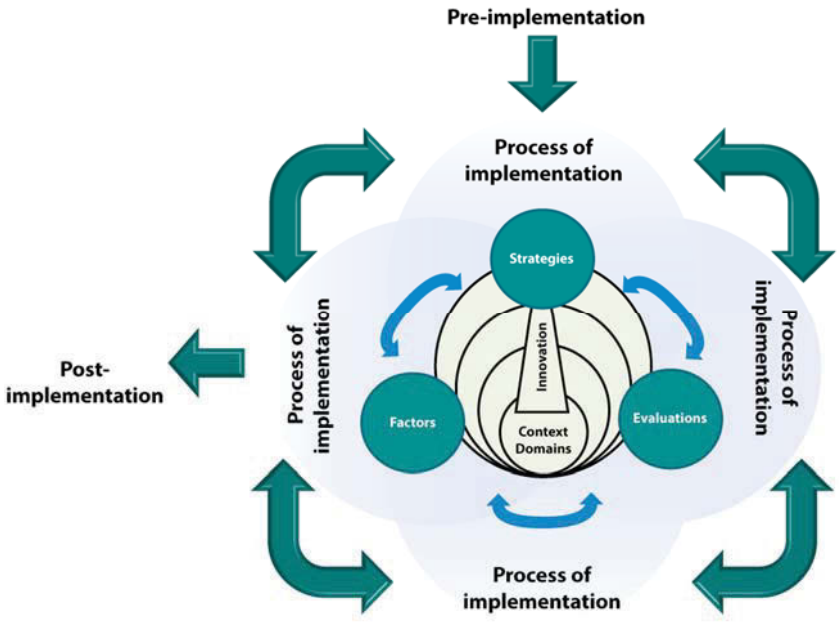

Figure 1: Generic Implementation Framework (GIF)[20]

Methods

Semi-structured interviews were conducted and analysed using framework methodology.

Interview Design

Face to face semi-structured interviews were chosen to enable a confidential exploration of pharmacists' experiences, behaviours, practice, process and perceptions in the implementation of professional pharmacy services. An eight question interview guide was developed and used [Additional File 2]. The structure and questions of the interview guide were derived from a systematic review of implementation frameworks and the resulting GIF concepts [20]. The guide examined across the stages of exploration, preparation, operation and sustainability, the steps or activities pharmacies conducted, factors that influenced, strategies used and evaluations conducted, if any. The interview guide was piloted in two pharmacies to establish face validity. These pilot pharmacies were not included in the purposeful sampling process and therefore were not included in the analysis.

Sampling and Recruitment

Purposeful sampling was used to maximise variation in pharmacies' level of service implementation across three states of Australia. De-identified data from a pharmacy service software provider, servicing over 60% of Australian pharmacies, was used to locate pharmacies that appeared to be at various stages of the implementation process, based on the number of MedsCheck services they were currently providing (<10, 11-100, 101-400 or >400 MedsChecks in the period twelve month period between December 2012 and November 2013). The number of MedsChecks was used to select pharmacies as it was a service introduced in 2012, remunerated, provided within community pharmacies and required distinct practice and organisational changes to be implemented. MedsChecks are basic medication review services, similar to Medicines Use Review (MUR)[43], that involve a consultation (estimated to be 30 minutes to 40 minutes), by a registered pharmacist who is not undertaking other professional duties at the time, face to face with the patient, in an area of a community pharmacy that is physically separated from the trading floor to ensure privacy and confidentiality. Pharmacies had to be within a two hours' drive from a capital city to be included in the study.

Pharmacies were contacted by the software provider to ask permission for the research team to communicate. Pharmacies who agreed to be contacted were recruited in December 2013 by phone and an interview time arranged with a consenting pharmacist. Information was offered to be emailed at this time and was given to all participants, along with signing a written consent in person, prior to the interview. Pharmacy owners, managers and employee pharmacists, involved in the implementation and/or provision of professional pharmacy services were interviewed [Participant demographics see Table 2]. In four pharmacies a second pharmacist was available and consented to being interviewed on the day.

Setting, data collection and data management

Interviews were conducted within a quiet area of the community pharmacies between January and February 2014. All interviews were audiotaped and subsequently transcribed in full and managed by QRS nVIVO 10.

Data analysis

A constructivist qualitative methodology, framework analysis, was used to analyse the data [44-46]. Framework analysis allowed for assessment of the data both across the interview cases and within the stages. The first phase of the framework methodology was familiarisation of the raw data by listening to audiotapes, to confirm accuracy of transcripts, and to note key ideas and recurrent themes. The data was then coded under the stages of implementation as the overarching themes, according to definitions in Additional File 1, and charted into a framework matrix. Charting is where data is rearranged and summarized, each column being a theme (stages of implementation) and each row a case (pharmacists interviewed) [44], to facilitate a detailed view of the implementation stages and the constituents within each stage for each interview case.

Thematic analysis was performed on the data under each stage of implementation to identify the steps/activities and influences on the process [44, 45]. This analysis was performed by open coding the transcript line-by-line, using a constant comparison approach of coding and recoding the interviews, until each pharmacists' interview data was coded across all applicable implementation stages and the key activities and influences in the implementation process emerged. Additional codes were added as the data extraction continued allowing the framework to be developed further [45]. The interpretation of the chart was used to confirm the implementation process, the influences and their relationships [44, 45].

A basic secondary analysis was performed to examine the influences using established implementation frameworks of the elements (factors, strategies and evaluations) across the domain levels [Additional File 1]. Specific implementation frameworks, which fit within the overarching concepts of the GIF, were used to structure the analysis. Instead of the largely inductive thematic analysis performed of the influences within the framework matrix, a more deductive approach was utilised to further investigate and advance the frameworks. Factors were assessed at each stage of implementation using the Consolidated Framework for Implementation Research (CFIR) [27]. CFIR was augmented with factors not included, or implied within broad constructs of the framework, in order to make them more explicit. Additional factors included behavioural influences from Theoretical Domains Framework and Behavioural Change Wheel [29, 47], and previous pharmacy practice research, such as remuneration [48]. Other adaptations included dividing the outer setting into two, the "external system" (economic, political and professional milieu) and "local environment" (circumstances surrounding the organisation(s) including patient, community, network) and the inner setting was termed "organisation" and intervention called "innovation" for greater clarity. These changes were based on implementation literature [49, 50] assessments of CFIR [51], and pharmacy practice literature [48]. The list of factors was further expanded with those that emerged from the interview data. Terminology was kept as consistent as possible to enable future comparative studies to be conducted. The strategies utilised by pharmacies were considered using with the more detailed Expert Recommendations for Implementing Change (ERIC) discrete implementation strategy compilation [34], rather than the general "process" construct of CFIR. As an initial analysis factors or strategies were marked in the analysis if they appeared in the interview data, thematic saturation and the degree of influence were not assessed. No further investigation of evaluations concept was conducted.

Ethical, consent and permissions

This study was approved by University of Technology Sydney Ethics Committee (UTS HREC REF NO. 2013000670). A written consent of interviewees was obtained in person, prior to the interview.

Results

Out of the 28 community pharmacies invited, 21 agreed to participate, with 25 interviews taking place. At this point thematic saturation of activities appeared to have been achieved, with no new activities emerging for any implementation stage, and therefore no further sampling was conducted [44]. Interviews ranged from 20 to 50 minutes. Participant characteristics are provided in Table 2. There was a range of levels of service provision, however all pharmacies had provided at least one service. The pharmacists interviewed spoke primarily about MedsCheck, but also the implementation of a range of other services including clinical interventions, sleep apnoea, health promotions (e.g. clean and check days for blood glucose monitors, community health talks, stroke prevention campaigns, flu vaccination), health screening or monitoring (blood pressure, blood glucose, cholesterol, iron, hearing), adherence, new to therapy, opioid replacement and mental health services. All pharmacies were conducting or considering at least one other service.

Table 2: Participant characteristics

		Pharmacists n=25	Pharmacies n=21
Staff Type	Employee	9	
	Services Manager	2	
	Pharmacy manager	7	
	Owner	7	
State of Australia	NSW	17	13
	VIC	1	1
	WA	7	7
Number of MedsCheck Services*	< 10	9	7
	11-100	7	6
	101-400	4	3
	> 400	5	5
Pharmacy Size**	Small	6	5
	Small-medium	8	6
	Medium	6	6
	Large	5	4
Pharmacy Type ***	Independent	6	5
	Banner group	12	11
	Discount chain	7	5
Pharmacy Location	Local shopping strip	12	10
	Central Business District	4	3
	Shopping centre (mall)	9	8

*Provided for the year between December 2012 – and November 2013

**Size determined by number of pharmacists on duty majority of the time: Small = 1, Small-medium = 2, Medium = 3-4, Large = ≥5

*** Banner groups: pharmacies who act as a franchise for marketing, management and purchasing purposes; Discount chains: banner groups marketed as discounters

Process of implementation

Six implementation stages emerged from the data, the four stages of the interview guide (exploration, preparation, operation and sustainability) and a further two stages. The additional stages were a pre-implementation stage of development or discovery and a testing stage prior to operation. Pharmacies also spoke of a range of implementation activities they completed as they moved through the stages [results presented in Table 3]. Quotes supporting the stages and activities of the implementation process are provided in Additional File 3. Analysis across the cases of the framework matrix revealed a trend towards the greater the number of activities considered, the greater the apparent integration into the pharmacy organization. The interpretation of the framework matrix highlighted that there were overlaps between stages, variation in duration of stages, movement back and forth between stages, differences in the order of performing implementation activities and that not all activities were necessarily completed. For this reason, to appear less linear, the term activities were chosen rather than steps.

Table 3: Resulting stages and activities of the implementation process of professional pharmacy services in community pharmacy

Development or Discovery

Exploration
- Organisational fit assessment
- Value assessment (relative advantage)
- Service assessment (service characteristics)
- Organisational capacity assessment (supporting conditions & staff capacity)
- Community fit assessment
- Decision

Preparation
- Assign leader
- Research requirements
- Organise supporting conditions
- Plan service procedure
- Rearrange workflow
- Staff arrangements
- Team communication (buy-in and foster climate)
- Training
- Community awareness & recruitment

Testing
- Initial adaptations
- Familiarisation & improve staff conviction
- Test patient demand

Operation
- Modification of plans & procedures
- Maintain patient demand
- Staffing
- Teamwork, team input and internal communication
- Integration tactics
- Ongoing training
- Goal setting
- Monitoring
- Adaptation
- Improvement

Sustainability
- Monitoring*
- Adaptation*
- Improvement*

*Few pharmacies had reached sustainability, these activities appeared in the few that had continued service delivery after funding changes, however require further assessment.

A trigger was often involved to move pharmacies into the stages of development or exploration. Triggers included a new employee (generally at managerial level), financial stress, pressure from the pharmacy group, attendance of a workshop or conference and/or a representative visit from a pharmaceutical company or software provider.

Development or Discovery

A pre-implementation stage emerged in the discourse where a pharmacy or pharmacy group had to develop services within their pharmacy or group of pharmacies, and/or discover externally developed services. Services developed internally were primarily testing (screening or monitoring) or health promotions. The majority of pharmacists appeared to hear about an externally developed service (company sponsored and government programs), from either a Pharmacy Guild of Australia (membership body), through internal group communications (if part of a pharmacy group), or through a personal initiative, such as speaking to colleagues or attending a conference. Poor communication and awareness of government programs was an issue raised by pharmacists.

Exploration

During the exploration stage the service was assessed to see if was aligned with the pharmacy's orientation [Activity: *organisational fit assessment* [See Table 3 for activities and Additional File 3 for quotations]]. Pharmacies also looked at the potential benefits the service would offer, including financial, business (such as increasing customer loyalty and rapport), patient and/or professional [activity: *value assessment (relative advantage)*]. Service benefits were balanced against the 'implementability' and 'workability' of the service in most cases. That is pharmacies assessed the service itself (duration of service and follow-up, degree of change etc.) [activity: *service assessment (service characteristics)*] and their capacity (cost of resources, staffing levels, training etc.) [activity: *organisational capacity assessment (supporting conditions & staff capacity)*]. Some pharmacies considered their community's needs, demographics, rapport and estimated demand based on how they believed their patients' perceive pharmacy and would perceive the service [activity: *community fit assessment*].

The exploration or appraisal stage was often informal, without set structure or systems, but a few of pharmacies did a more formal, objective assessment. A decision was subsequently made, by the owner or the owner in consultation with senior pharmacist(s)/manager, to adopt or reject the service [activity: *decision*].

Preparation

After deciding to adopt a service in many cases a staff member was assigned to be in charge of the service, informally or formally, explicitly or implicitly [activity: *assign leader*]. This person was most often a pharmacist employee, but also included the owner, pharmacy technician or pharmacy assistant. Some pharmacies had one staff member in charge across multiple services, while other pharmacies delegated different employees to particular services. The leader's tasks included conducting training, recruiting patients, providing the service and overall driving the implementation effort. Another activity was to investigate the legalities and necessities of the service [activity: *research requirements*] and making the required changes to ensure the conditions were satisfactory [activity: *organise supporting conditions*].

Planning a procedure of how to deliver the service was generally carried out by the leader of the service [activity: *plan service procedure*]. All pharmacies considered logistics, but this was a particularly significant activity for smaller pharmacies with few staff or those with acutely busy periods of the day, such as those working in the city centre. As part of procedure planning some pharmacies developed an individualised protocol for the delivery of the service, while others relied on external guidelines, support provided by their pharmacy group, or support from an external body such as a pharmaceutical company. Along with the procedure of the specific service, for some pharmacies, preparation involved considering the workflow of the dispensary or the whole pharmacy [activity: *rearrange workflow*]. As an example one pharmacy moved a pharmacist to the front counter to interact with patients and hand-out prescriptions rather than dispense.

Staffing was a major consideration including changing staff roles and responsibilities, analysing staff numbers (to facilitate provision and meet regulatory requirements) and staff selection if new staff were required [activity: *staff arrangements*]. There was wide variability in the level of team input and teamwork [activity: *team communication (buy-in and foster climate)*]. Internal communication channels were fairly equally spread between formal meetings, informal conversations or lacking altogether.

Training was one of the most quoted activities undertaken to prepare for service delivery [activity: *training*]. While another consideration were methods to increase community awareness and commence patient recruitment [activity: *community awareness & recruitment*]. Both activities were led by the individual pharmacy, the pharmacy group, and/or supported by an external party.

Testing

A few pharmacies showed a distinct stage where they were trialling the service, operating for a defined period or with limited numbers. The testing or initial operation stage was about refinement of procedures [activity: *initial adaptations*], familiarisation of the procedures and software, to increase staff members' confidence, comfort and conviction with their role in the service [activity: *familiarisation & improve staff conviction*], and trialling the fit of service to the community in terms of patient perception and demand [activity: *test patient demand*].

Operation

As pharmacies moved to providing the service, procedures were further refined, including the protocol, logistics, recruitment process and/or data management system (for example if the computer programs were inadequate moving from computer, to iPad, to paper) [activity: *modification of plans & procedures]*. Service provision involved the new task of recruiting and enrolling patients and the implementation activity of maintaining patient demand emerged as a critical theme [activity: *maintain patient demand*]. The activity was approached in a number of ways including revising the dispensary procedure to include identifying patients, developing a uniform approach for asking patients, delegating to a staff member, using reminders and organising mail-outs. Most pharmacies had regular patients who they were able to enrol, however after this initial recruitment, most pharmacies struggled to maintain patient demand.

Staffing issues were deliberated by all pharmacies [activity: *staffing*]. Increasing staff skills and confidence, in providing the service and in the recruitment/selling of the service, as well as redefining roles and responsibilities of the pharmacy team were considered [activity: *teamwork team input and internal communication*]. Most pharmacies initiated techniques to assist breaking habits and to improve the integration of the service into routine practice [activity: *integration tactics*]. Tactics included reminders, providing incentives or disincentives and conducting performance reviews. In addition ongoing training for staff members was raised but was absent in the majority of cases [activity: *ongoing training]*.

Goal setting was prevalent in pharmacies more progressed in implementation [activity: *goal setting*]. A small number of pharmacies believed goals took away from the purpose of the service or that self-motivation was sufficient, some developed Key Performance Indicators (KPIs) for individual staff members, while others set pharmacy team targets. Goals were always based on number of patients or services provided.

Formal monitoring systems to record number of patients only emerged in a few pharmacies where it was organised by their pharmacy group [activity: *monitoring]*. Occasionally this was linked to pharmacy finances. The monitoring of customer feedback was seen as important to improve implementation and service provision as well to judge the relative advantage of the service. In addition there was informal monitoring of service procedures, such as time to conduct the service. Based on the monitoring a few pharmacies adapted the service, such as moving the location or time of the service, so it was done immediately rather than using an appointment system [activity: *adaptation*]. The final activity of operation was minor adjustments or improvements that were made to increase efficiency and proficiency, without changing the service [activity: *improvement*].

Sustainability

Few pharmacies had reached sustainability, that is ongoing service provision, maintenance of supportive conditions and persistence of service outcomes. Services were sustained only in those pharmacies that were able to adjust the service sufficiently to overcome changes in funding to maintain financial profitability and/or experienced relative advantage of the service in aspects other than from a financial perspective. An example of an adjustment was a service that had been reinvented from government program to a private fee-for-service.

Implementation influences

Five influences recurred in the thematic analysis of the implementation process: direction and impetus, internal communication, community fit, staffing and support. These influences affected a number of stages and activities, both positively and negatively, depending on their presence. For example increased staff capacity was positively associated to pharmacies progressing through implementation, whilst insufficient staff had negative effects on the adoption of change.

The importance of the pharmacy's direction and impetus, which includes both the pharmacy's vision and the top level leadership provided by the owner or manager, was a the first influence to emerge. A shift or change in a pharmacy's

vision, if this was not the existing orientation, was frequently the first requirement for the implementation process. This appeared to be an overarching prerequisite for further implementation. Top level leadership needed to include support, drive and push from the owner and/or manager. This type of leadership was necessary in addition to the role and responsibilities of an internal leader or champion.

The second influence was the internal communication within the pharmacy, including team-input and teamwork. Pharmacies ranged from having almost no communication surrounding services to formal buy-in and input of all staff throughout the process. Internal communication affected the pharmacy culture, implementation climate and subsequently the overall implementation effort.

The third influence was staff. Staff capacity (manpower, skills, and confidence) was particularly linked with the assessment decision during the exploration stage, but influenced all stages. Selecting staff and staff members' beliefs regarding the innovation were major influences. For example pharmacists who saw services as something they already provided or did not see their value, appeared to struggle with implementation.

Community fit influenced all stages of the implementation process. Initially in exploration the community's demographics (patient needs and resources) was considered by a few pharmacies. As pharmacies moved through the implementation process the number of pharmacies thinking about community fit increased, as they became aware of the influence of community awareness, perception and demand.

The final overarching influence was support, which included having a professional network, pharmacy group support and/or external support. This support affected a number of implementation activities including establishing favourable conditions, developing a service procedure, training, goal setting, monitoring and adaptations.

Secondary analysis

As a result of a secondary analysis of the data a refined list of implementation factors for community pharmacy was developed [Additional File 4]. In total seventeen additional factors were added to the CFIR, eleven factors derived from implementation and pharmacy practice literature and six from the interview analysis. The domains , as previously defined in a systematic review of implementation frameworks [20], were endorsed by the factors fitting within its structural arrangement. Factors varied across the implementation stages. The initial analysis of factors at each stage of implementation is provided in Additional File 5. Not surprisingly factors relating the characteristics service to be implemented (innovation domain) were particularly prominent during exploration, when pharmacies were deciding whether or not to adopt. Beliefs about the service (such as pharmacists not seeing value in it, or that it was a task they already performed and implementation was just documenting the task), staff personalities and self-efficacy were prominent factors relating to staff (individual factor domain), and could have both a positive and negative influence on the implementation process. All factors related to the pharmacy (organisational domain) were implicated during the operation stage, but the majority also during all stages. Quality assurance and data management systems were widely lacking. As mentioned pharmacy's patient population, their needs and subsequently the demand for the service were

dominant community factors. Furthermore during development and exploration stages peer pressures from other pharmacies, either mimetic or competitive to differentiate, were factors. For factors relating to the external system (political, economic and regulatory environment) the funding model, political stability and external support by professional bodies and companies were the most pronounced and predominant influence on sustainability.

Implementation strategies employed by pharmacies to aid adoption and integration varied widely. Many pharmacies were struggling with implementation, yet out the 73 discrete implementation strategies described by Powell *et al.* [34], 51 were implicated by at least one pharmacy [Additional File 6]. Despite the large number of strategies used, generally only one or two pharmacies utilised any one strategy.

During the framework analysis evaluations, of any form, were shown to be generally lacking or informal and therefore no secondary analysis was performed. All pharmacies looked at numbers of services provided (sometimes linking to economic outcomes) and patient feedback was used to gauge service, humanistic outcomes. There appeared to be no performance, implementation or clinical evaluations.

Discussion

Pharmacies in Australia, appeared to pass through stages of implementation and completed many implementation activities [Table 3] as described in the literature [25, 26, 52, 53], although there was variation the order of performing and number of implementation activities completed. As an example, planning a procedure of how the service would operate in the pharmacy was done by some pharmacies before deciding to adopt the service, as part of exploration stage, whilst the majority of pharmacies completed this activity as part of the preparation stage, after the adoption decision.

Reasons some pharmacies struggled with implementation or moved backwards between stages (such as stopping for a period of time) included, skipping important implementation activities, being deficient in a fundamental influence, or having barriers and lacking strategies to overcome them. For instance although all pharmacies appeared to have a driver for change, such as financial pressure, some lacked communication and teamwork, or top level leadership, which were revealed as vital drivers. Moreover whilst in some cases not all activities were required, in other cases activities were missed at the detriment of successful implementation. Interestingly a trend was seen that those pharmacies who considered more activities were more advanced in implementation, either by number of services being provided (reach) or the perceived integration of service into practice. In agreement with implementation literature, it therefore appears that the implementation activities and influences are complementary and integrative, where strength in one area may counter-balance a weakness in another [24]. It would be recommended for those wishing to implement to consider the feasibility of each activity and then concentrate on the pharmacy's strengths, to overcome barriers in the implementation process.

Pharmacies were providing a range of services. Services included those focussing on medicines, such as MedsCheck, services focussed on monitoring, as well as services directed towards a more healthy population, such as screening and

health promotions. The analysis did not distinguish between services and it may be possible that different services would require distinct implementation considerations. On the other hand, it appeared that the implementation process and influences were often similar, regardless of service. For example across a number of services it was found pharmacies "struggled to maintain patient demand". Demand may be influenced by multiple factors including: lack of stakeholder involvement, particularly during the service development stage, lack of pharmacy team involvement and buy-in, poor leadership at system and/or pharmacy level, low awareness or a perception of pharmacy at a local level that is at odds with service provision. Co-design, that necessitates stakeholder contribution, should be considered for the development of future professional pharmacy services.

Pharmacies receiving service support, from being part of a pharmacy group, appeared advantaged compared to those working independently. This appeared to be the case particularly for government funded services and services developed across a group. Generally such pharmacies emerged more knowledgeable on services available, aware earlier of new services and received assistance in implementation activities including procedure planning, training, and monitoring. On the contrary some factors were not affected by type of pharmacy including having open communication channels between the pharmacy team.

Evaluations and the activities related to monitoring have been important themes in implementation literature, yet like other disciplines [54] were underdeveloped. Outcome evaluation and staff performance monitoring, in terms of performance quality or fidelity, was lacking in all cases. Interestingly quality assurance although not measured was a topic pharmacists widely discussed. There was concern about the lack of monitoring and auditing and the consequence this has had on funding and the sustainability of the services. Pharmacists largely did not take personal responsibility to address this, but rather awaited policy changes or action from the professional bodies.

Framework for the Implementation of Services in Pharmacy (FISpH)

The qualitative study has enabled the implementation concepts of the generic implementation framework to be tailored for the implementation of services in pharmacy [Figure 2]. The data analysis revealed the implementation stages, preceded by development or discovery, as well as the delineation of these stages into a series of activities [Figure 3]. The data analysis also revealed overarching influences (direction and impetus, internal communication, community fit, staffing and support). A preliminary analysis of the factors that may influence the process at each stage, was also conducted [Additional Files 4 and 5], and results may be used as a sub-model for the factors concept of the FISpH. The secondary analysis of factors also verified the domains or ecological levels of influence for implementation professional pharmacy services [20]. Modest investigation of pharmacies utilisation of implementation strategies [Additional File 6] was conducted, but the concept requires further investigation as do implementation evaluations, which were not performed adequately to be studied in detail.

It has been acknowledged there is a lack of theory used in implementation research [2]. This qualitative study provides pharmacy researchers, strategists and practitioners with the foundation of a conceptual framework that may be used

as a base for future implementation efforts. The stages and activities may be used to plan implementation programs or protocols, while the influences and list of factors may be used to develop tools, questionnaires or interview guides.

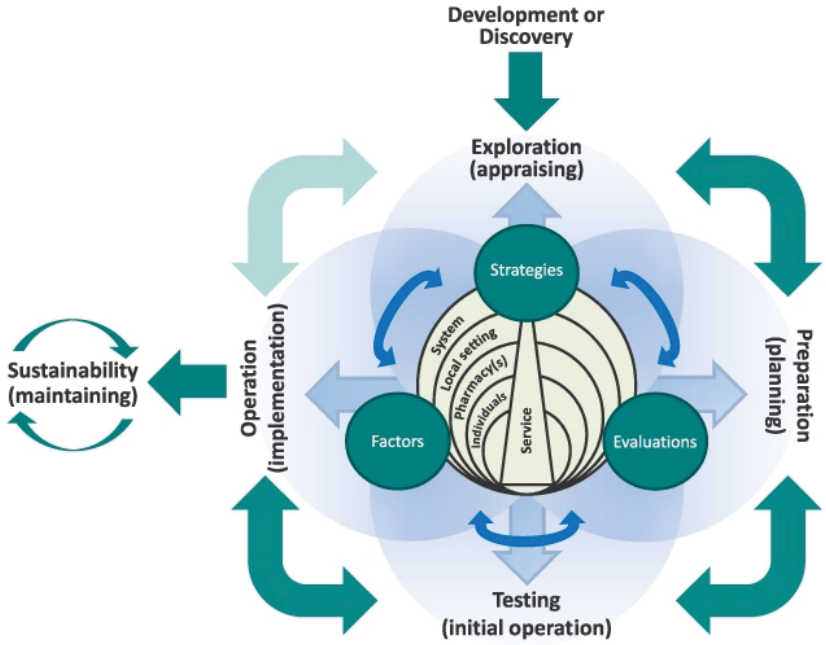

Figure 2: Framework for the Implementation of Services in Pharmacy (FISpH]

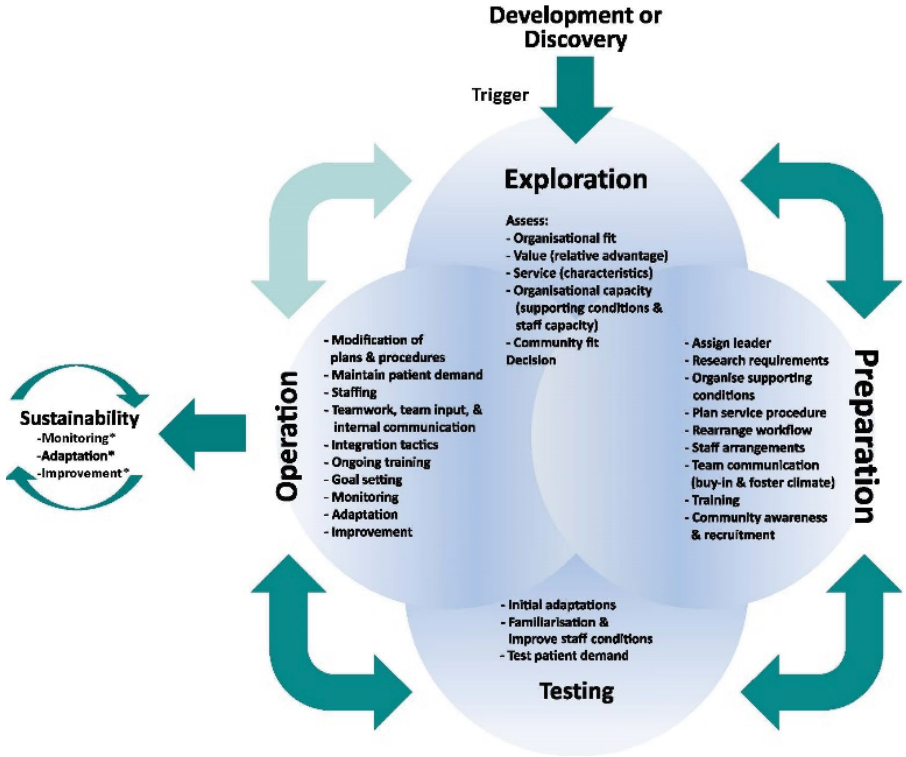

Figure 3: Process of Implementation in Community Pharmacy

Considerations for policy, practice and future research

The research revealed that factors vary across the stages and therefore a consideration for practice and future research might be for factor assessments to be conducted at multiple time points, rather than just initially. The adjusted CFIR list has kept the typology and terminology to enable future research and analysis across contexts. The additions require further validation. The list of discrete implementation strategies, along with other change frameworks, may subsequently assist in the selection of suitable approaches, to address or utilise the corresponding factors, both in practice and research projects. To allow implementation strategies to be studied and replicated they must be theoretically derived and reported, as would a clinical intervention [55-57]. It would be recommended that monitoring and evaluation of clinical outcomes, formative evaluations and implementation outcomes be prioritised, by researchers and policy-makers, to facilitate external policy support and the services' sustainability [58-61].

Subsequent appraisal of the framework depends on its utility, assessed by evaluating programs, that were based on the framework, and if they induced the desired implementation outcome. In other words it is the implementation program that may be validated, which in term evaluates the framework [62].

Strengths and Limitations

Framework analysis showed potential as a methodology for implementation research. In this study the implementation stages were used as overarching themes and thematic analysis performed for the data under each stage. The framework analysis allowed for assessment of the data both across the interview cases and within the stages. Alternatively interviews could be designed and coded using themes from an implementation factor, strategy or evaluation framework, which would offer interesting insights. A potential limitation of the framework approach is that unless applied in a flexible way, it may inhibit the development or refinement of models. This was prevented by the use of detailed thematic analysis of the activities and influences in addition to the matrix charting. Targeted interview guides based on the meta-frameworks of factors, strategies or evaluations across the stages of the implementation process, could useful for future assessment of these concepts.

A potential source of bias worthy of discussion is effects of a single-coder (JCM) conducting the data collection and analysis [63], although complete consensus has not been reached regarding the use of coding teams [64]. To minimise such affect full thematic and framework analyses were discussed and provided to the co-authors for review with the manuscript. Further studies to confirm and advance the framework and concepts for pharmacy would be recommended.

Purposeful sampling was based on pharmacies level of MedsChecks service provision, while interviews included exploring other services. As a variation in the degree of implementation was seen during the interviews across the range of services and thematic saturation was achieved across the range of services discussed, no further sampling was deemed necessary. Another sampling limitation is that the study was conducted in Australian pharmacies within two hours from a capital city and 68% of the interviews in the state of NSW. Although the results are in line with implementation literature they will require further investigation in other states of Australia, rural and remote areas, as well as in other countries. The FISpH however does appears generalizable and understandable by a range of stakeholders, and is currently being used in both Australia and Spain to develop implementation programs and protocols [65].

Conclusion

The implementation process defined in the literature is largely consistent for implementation in a pharmacy context. The stages and activities of the implementation process appeared as compensatory and did not follow a strict consecutive order, although there was a trend towards the greater the number of activities considered, the greater the integration. Overarching influences were revealed (direction and impetus, internal communication, community fit, staffing and support) and acted as vital drivers to implementation efforts. Improving implementation and service evaluations appeared a critical issue for policy, practice and future research. In addition, future research would be recommended to advance the Framework for the Implementation of Services in Pharmacy (FISpH).

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Additional File 1: Implementation definitions

Implementation	The process of commencing to use and integrating innovations within a setting [1].
Framework	Graphical or narrative representation of the key factors, concepts, or variables in order to explain the phenomenon of implementation [2].
Innovation	Novel set of behaviours, routines, and ways of working within a setting [3].
PROCESS OF IMPLEMENTATION	Non-linear, recursive, reiterative progression of implementation.
STAGES OF IMPLEMENTATION	The breakdown of the complete implementation process.
Development	Innovation, identification or creation, synthesis, refinement, evaluation and packaging [4].
Communication	Process by which people learn and share information about a new innovation to increase awareness [5].
Diffusion	Passive, untargeted, unplanned and uncontrolled spread of new innovations [1]. Diffusion is a horizontal or natural process where the onus is on the adopter to seek, absorb and act on the information. Examples of diffusion include mass mailings, publishing in journals and conference presentations. Aim is to increase knowledge and awareness of the innovation.
Dissemination	Active approach using planned strategies via determined channels to persuade the target audience to adopt new innovations [1, 3]. Targeted approach takes into account such things as the type of evidence, the end-user(s) needs, and organisational culture and climate. Aim is to increase knowledge, awareness and perception of the innovation.
Exploration (appraisal)	The innovation-decision process whereby the end-user(s) appraise the innovation concluding with a decision to either to accept/adopt or reject. Involves progression through awareness (or an issue, need and/or new innovation), knowledge, persuasion, opinion and decision regarding the innovation [5].
Preparation (planning)	The course of preparation (innovation, individuals, organization, local environment and external system) prior to innovation use [6].
Operation (implementation)	Innovation is in use and is in the process of being integrated into routine practice through active and planned approaches [1].
Sustainability (maintenance)	Process of maintaining the innovation through continued innovation use integrated as routine practice, ongoing capacity and supportive environment sufficient to support innovation use and persistence of benefits [7].
DOMAINS	Groupings or levels of related implementation influences (and by which factors may be categorised and strategies and evaluations targeted). Domains may vary in number and way in which they are divided.
Innovation Domain	A grouping of related influences regarding the characteristics of the innovation to be implemented [8].
Context Domains	Groupings of related influences regarding the circumstances that surround the innovation to be implemented [8].
Individuals	Characteristics and agency of the people involved with the innovation and/or implementation process.
Organisation	Conditions and characteristics of the setting(s) in which the innovation is to operate.
Local environment	Circumstances immediately surrounding the organisation(s) including the community, patients and network.
External system	Broad economic, political and professional milieu.
ELEMENTS OF IMPLEMENTATION	Core considerations affecting the implementation process.
Factors	Variables that may affect the implementation process. Also termed facilitators and barriers or determinants of practice [9].
Strategies	Targeted efforts (method, technique or activity) designed to enhance moving of an innovation into use and integrating into routine practice [9, 10]. Package of implementation strategies often form an implementation program.
Evaluations	Assessment of factors, formative evaluation of strategies, process evaluation and summative evaluation of implementation and innovation outcomes [10-12].

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Additional File 2: Interview Guide

1. Do you currently provide any professional services in your pharmacy?

If planning or providing services:
What would you say is your most successful service, or what service are you planning. Please answer the following questions in regards to this service or services generally.

2. After hearing about the service what drove you to provide the service? [Exploration]
   - *When considering the service what were you looking for?*

3. Do you have any decision process?
   - *How long after hearing about the service did you decide you were going to provide it?*
   - *How did you decide if it is a good idea?*
   - *Did you feel any pressure to adopt services? And if so, from whom?*
   - *Who made the decision to provide the service(s)?*

4. After deciding you wanted to provide a service, what were your next steps? [Preparation]
   - *Did you start providing the service immediately after making the decision to adopt?*
   - *Is someone leading the implementation process? Are all staff involved or particular staff?*
   - *Do you have any specific support for services? (consultants, service manager)*
   - *Have you used, adapted or created any procedures?*
   - *How were you able to accommodate services in your business?*
   - *How did you decide if you were ready to start delivering?*
   - *Any barriers you hit? And how did you overcome them*

5. Once you began delivering the service what did you do in terms of maintaining or improving its provision? [Operation]
   - *Is someone in particular responsible for provision of services?*
   - *How do you identify/recruit patients for services?*
   - *Since commencing have you adjusted the service or workflow in anyway?*
   - *Any barriers you hit? And how did you overcome them?*

6. Do you have any method to evaluate or measure the success of the services you offer? [Operation]
   - *Have you found any unintended benefits or consequences to implementing services?*
   - *Do you use any documentation system?*

7. Would you describe the service provision as routine day-to-day practice? [Sustainability]
   - *What (would) make it routine?*

If you could now think about another service that you do not provide

8. What would cause to decide you want to provide this professional service?

9. After you decided to provide the service what process would you go through or what steps would you to start providing the service?

10. Once the service was being delivered how would you decide whether or not to continue providing the service?

If not providing services:

2. What are your thoughts or opinion about providing professional services?

3. Is there something that would cause you to change your mind and decide you want to provide professional services?

4. After you decided to provide the service what process would you go through or what steps would you to start providing the service?

5. Once the service was being delivered how would you decide whether or not to continue providing the service?

Additional File 3: Quotes supporting the implementation process of professional pharmacy services in community pharmacy

Exploration

Organisational fit

"If we want to implement that, yes, it is definitely going to be required, yes, it is good for the customer because we focus on customer service and if it is, if we say that we focus on customer service and we don't have this service then what does that mean." (Interview 10)

Value assessment (relative advantage)

"The main goal in the pharmacy is that we are here to help people, to assist people. So as long as the service offers them some sort of health benefit, it will be implemented in the pharmacy. Not only that we do have to consider the business as well. I mean the owners; the services aren't going to pay for themselves. You know, so you have to consider the value of the service to the pharmacy as well." (Interview 5)

Service assessment (service characteristics)

"Has to be easy to follow through on GuildCare [software package] and easy to talk to customers about and doesn't take too long." (Interview 4)

Organisational capacity assessment (supporting conditions & staff capacity)

"*It was a way to get back some funds into the pharmacy, what we were losing through the dispensary, and I thought as a valuable service to the community and to the patients, and something that we could actually implement without too much drama."* (Interview 2)

Community fit assessment

"*We just didn't have the right clientele. We haven't the right socioeconomic for that."* (Interview 20)

"How are going to ever charge for providing a consultation, you know people are so used to walking into the pharmacy and getting it for free." (Interview 8)

Decision (communication, team input and buy-in)

"We work in a way that we seek approval from the team before we roll it out." (Interview 10)

Preparation

Assign leader

"*I would approach the person and ask if they are happy to do it first, and if they are happy then I will change their job description, but they are not happy to do it and they have a reason, I feel that if the person doesn't want to do it there's no point in pushing, so I won't push."* (Interview 10)

"If depends, one of the pharmacy assistants, this is sort of her area. She was in charge of it, so she organised the training for all of us. Something like MedsChecks, which I'm in charge of, I trained all the girls about it. It just depends who is in charge of what." (Interview 22)

"Guess that is where your champion, and you know that gets bandied around a lot, but it is really important to have that person, and for us it is probably our Tech, who then says lets ok, let's get so-and-so, lets book in a few, and start identifying who are the people who are going to do it." (Interview 2)

Research requirements

"*We check to see if we meet the criteria, say a private room or things like that, we want to make sure that we have the resources and everything."* (Interview 10)

"We assign someone, we give a week for that pharmacist – we explain to that pharmacist, that pharmacist does the research and gets back to us with all the requirements, all the information and things like that" (Interview 10)

"Make sure we know exactly what paperwork, what procedures need to be done" (Interview 12)

Organise supporting conditions

"First is, you need to actually get your resources up and running. Whatever resources…so what actually is required to implement it, whether it is equipment, software." (Interview 9)

"We got the program and everything sorted and also the registration with Medicare as well." (Interview 14)

"I had to have my pharmacy redone, so I've got a consulting room where I can provide that sort of service in the right environment" (Interview 20)

Plan service procedure

"Developing the procedure helped me to sort of understand how I was going to approach this otherwise I'd have no idea how it was going to work. And I think that was the main thing, the procedure, having that procedure, writing out what I think should be done, at what point it should be done, who should be involved." (Interview 8)

"We stick to the guidelines, but have our own procedures" (Interview 10)

"Because we are in the city, we needed to do it in a lunch break. Because it really is the only time people would be able to or would be convenient for them to come in" (Interview 1)

"We have a work calendar, and then every month we have a specific topic to focus on and then anything else we just bring that in as well" (Interview 11)

"[Pharmacy group] is really good in that they write up the whole protocol for you already" (Interview 22)

Rearrange workflow

"And because of all these new initiatives, that for us we actually had to change the dispensary flow of things. So for a medium size pharmacy it's challenging because you don't… the pharmacist has to go back and forth a lot." (Interview 25)

Staff arrangements

"We had to get all our timing schedule, I've employed another pharmacist so we've got two pharmacists here now, so before I didn't have the flexibility of senior pharmacists, it's impossible, it's just impossible to do these sort to things" (Interview 20)

"You need to choose a person who is comfortable in doing that. That helps. If you've got someone who is sort of says 'yeah I'll do that,' compared to, there are people where it is out of their comfort zone a little bit." (Interview 2)

"It was mainly employing the right people, who will actually fit in the team, being a good core team…I think before we were so desperate for staff, the previous manager hired sort of anyone" (Interview 22)

"Not exactly new staff, but changing the roles of current staff. So for example, we have a few girls that went from shop floor to dispensary to help dispense so that more pharmacists can get out, get out of the dispensary and talk to patients." (Interview 5)

Team communication (buy-in and foster climate)

"You have to communicate what you're doing so people, when they go up the front counter and go what's happening back there, they need to understand what's happening. We do have more specific, we'll have dispensary meetings and sometimes in dispensary, for certain things, but then we'll bring everyone in on the full staff meetings" (Interview 6)

"So basically everyone – we sort of got together like on a Thursday afternoon it might have even been, it was a bit quiet like now and said how are we going to do this? Get some ideas. Have a think about it. Come back to us and we will go from there. And basically that's how we worked it out." (Interview 8)

"We have poor communication within our staff." (Interview 1)

Training

"An evening with the staff where we can just get… they can get a fundamental knowledge of it" (Interview 19)

"We make sure we're all trained for it and then we implement that training and then we reinforce everyone's knowledge on it, so we have staff meetings to make sure everyone knows what they're doing. And if you know one or two people feel like they're not comfortable with doing it then we'll go through it with them another time and just make sure everyone knows." (Interview 5)

"So what happen is when we go to training... I haven't been to the pain yet, because that's a new one. But with all this training is of course they were explaining to the novel basic theory definitely, so why we want to do it and what benefits it will bring to the patient." (Interview 21)

"The main thing is the training, so we've got [pharmacy group] rep who came around. They do a bit of online training too" (Interview 15)

"We made sure everyone of us knew what was involved in that service. We had a lady [software provider] come and show us and demonstrate what to do."(Interview 5)

Community awareness & recruitment

"Getting the word out, for the patients, it was a bit of a challenge but… sometimes you verbally say, like tell them but it doesn't happen that often, but we have a lot of pamphlets." (Interview 18)

"We've contacted the council, sent out letters to local businesses, things like that." (Interview 25)

"And then normally it depends what sort of program, we might have to like have to say, look out for these sort of patients that's coming through because they will be the ones tied at this program –recruit people." (Interview 14)

"They'll [pharmacy group] start pushing it through catalogues" (Interview 16)

Testing

Initial adaptations

"What I do is I give it a go. I just give it a couple of goes to see what happens. Kind of muddle. I like to give it a go before I can... put anything on the pharmacist. I prefer to kind of take it, and then at least I know what I'm talking about, and people can't say you fobbed it off on me…So I'd probably give it a go, have a bit of a read of the literature, what you have to do and what you have to achieve it in, and then I'd give it a go, see what works, what doesn't work" (Interview 6)

Familiarisation & improve staff conviction

"After the first two that that I'd seen, and then, they were probably our hardest, so after that, we so when we decided we were going to do it" (Interview 1)

Test patient demand

"We usually test it for three months at the start. If customers' not interested we usually then we usually find out to what is sort of required, and then after a few months we will look at rolling out again to see how it goes." (Interview 10)

Operation

Modification of plans & procedures

"We've got like a communal timetable like when to book in the patients. Like it's a very small window, like for example, with Tuesday 10 o'clock to 2:30 only. The little window that we can book them in, that's when the two pharmacists are on duty." (Interview 22)

"Part of our process in terms of you know the dispensary, so if you notice that they need a MedChecks and they fit the criteria you know four or five medications, haven't had one in the last year then yeah, everyone gets a MedChecks. If they approve. But everyone is offered that MedChecks. So it's just part of our dispensing procedure, so in terms of adapting it in to our thing." (Interview 7)

"It´s just a matter of finding the time for it and doing it properly. You don't want to do jobs half-way, you want to do it properly." (Interview 12)

"Because of all these new initiatives, that for use we actually had to change the dispensary flow of things." (Interview 25)

Maintaining patient demand

"We discuss that amongst ourselves as well and so far we've found, you know, certain approaches work on some people and others don't. Some don't… some of our patients don't quite get it at first, do you know what I mean and that sort of thing. So we've tried bags, leaflets, we've tried… we've tried all of that and none of it seems to have worked that well. We have found actually face to face has probably been the best and inviting." (Interview 18)

"A little bit of oversight just trying to figure out how to approach people. That was probably the slowest thing but once we sort of figured out how we were all going to ask the same way." (Interview 4)

"Yeah so we just use the GuildCare program, it will pop up and we can check when they had it last and then we can approach them again." (Interview 3)

Staffing

"Again the accredited pharmacist, she was quite happy, she was quite keen to do it type of thing, although she wasn't quite keen on the sales, trying to get people in thing. But once she was there she was fine. Others just didn't feel comfortable, they... I suppose they didn't feel their knowledge base was strong enough, it was hard to kind of find what the barrier was. And that was... we were kind of in the process of working through those" (Interview 6)

"There was one month where I was tired of… it's like being a salesperson in a way and we didn't do any that month and then afterwards I was like 'OK, I've got to do this.'"(Interview 18)

Teamwork, team input and internal communication

"It is important to have someone who can sell. And as pharmacists ourselves, as pharmacists, we are probably all that good at doing that. So if you've got a Tech or somebody who can do that, I think they're the person to actually do it. Cos as pharmacists we tend to answer questions and give information, but under-sell ourselves if anything. So I think it important if you can identify somebody to/can, and when I say to sell, to actually get the customer or the patient to commit" (Interview 2)

"We all work together, because if you have one pharmacist doing one particular service and that's all that they do and they don't do any other service it kind of traps them in that role. So it's better I think in the pharmacy that we actually have each pharmacist running different types of services, keeps your mind going, engages the patient. You don't get bored doing just that one thing and yeah you have, you know you can practise your different skill sets along all the other different types of services that are available." (Interview 5)

"Yeah depends on the, most of the services there has at least part involvement, obviously the assistants cannot do the MedsCheck but they do know what is everything, what it is about…so when the customer asks they'll know what is it but they'll get someone else." (Interview 24)

Integration tactics

"We just would, like constantly remind them yeah…You just ask them just constantly, every single checking script "Did they qualify? Did they qualify? Did they qualify?" and they'd have to double check it again." (Interview 3)

"If you don't have it at the top of your priority on the list of your tasks, you will spend the whole day and won't even think of it once." (Interview 9)

"We have a system where they will readily have it in their pocket and it's something that is triggers them." (Interview 10)

"We have this note, OK. We put it in every basket. So we have all the programs that we provide. OK. So it's just as a reminder for us, pharmacist and the customers really." (Interview 21)

"You've got to have some sort of lead in to it, if you know what I mean? I mean in our case we've got the Guild Care program, which gives you a lot of... it flashes at you when the person has done five medications, or it'll tell you... it'll flash at you if somebody is on a puffer and they need." (Interview 16)

"We've just implemented the health screening, it's not… I mean I haven't actually screened anyone because it's kept in a file and it's kept in the drawer, and you don't remember it." (Interview 25)

"So accountability. So at the end of every week I wanted the report emailed. So that was even messed up a couple of times. So I was like just as you get paid every week with your weekly roster you need to send me a weekly account of how many clinical interventions you are doing." (Interview 9)

"Mandating it as part of their performance reviews. To make sure they actually do" (Interview 7)

Ongoing training

"Then we reinforce everyone's knowledge on it, so we have staff meetings to make sure everyone knows what they're doing." (Interview 5)

"We just find our own examples. Say for example if something that I come across with the customers I would then use it as an example to tell the team that that is a clinical intervention." (Interview 10)

"I just go the GuildCare lady coming in and showing the interns how to do them again." (Interview 4)

Goal setting

"*You have to get the message right to everyone…and then we set a weekly team target…so I guess as we break it down it seems like less, you know easier for the staff as well to focus on."* (Interview 11)

"KPIs are a good thing to be able to be able to share with staff, and I think that, and the staff do they understand that we get paid for these and they understand that this contributes towards their wages" (Interview 2)

"With my other pharmacist I've said to him I want you to do one a week, OK, I want you to really try to do one a week. So I put a bit of pressure on him to do one a week, and I said I'll do one as well. And if we can do that I think that's a good start. I think if you start doing it right then it starts to build and it becomes routine." (Interview 20)

"Only by physically doing them myself did I realise what is an achievable goal. People will actually say to you, I'm too busy, oh I can't pick up an intervention, you can hear a lot of reasons why it is not being implemented within your store. But you need to actually to have the grass roots yourself, know if you goals are set too high or you have goals that are achievable or not achievable." (Interview 9)

Monitoring

"So clinical interventions [type of service] are the same, we are rolling out well and then there will be a time where the team will go a bit down and then we will see the numbers drop because we know at least it will be that. Say for example we have 200 customers a day – I would say that as a minimum I would have clinical intervention would be 5% - really at least five customers that we would have certain intervention, but if anything that is dropping below that it triggers me to say hey it's time to perhaps realign the team again or we do the training again" (Interview 10)

"As far as monitoring we do look at how many we are doing, how many we are doing on a monthly basis and whatever and if we are not doing enough consistently than we talk about well how we are going to get them going again." (Interview 2)

"The data is from all the branches. It's not like from the sessions that you have in one branch, it's all branches, and then they collect like the data." (Interview 21)

"If anything we would probably look at on those days when we do have a health service how are we going with sales in store and if sales increase you have got a pretty good indication that it's because you have got something going on to get the customers in." (Interview 12)

"We will still take feedback as we go and then make it better and better" (Interview 11)

"A few negative feedback won't stop us from stopping the service altogether. It is more a bit of say after we've done it and then come back and found OK this is how much time we spent on it, this is what we got out of it, like and then we decide whether it was worthwhile to do it. Sometimes we don't do it like all year – we just choose a few months in the year to do it." (Interview 11)

"The guidelines always say it's between 20-30 minutes, but sometimes it can drag on a bit longer, so that is the thing…Usually if I see something like that I would sit down with the Pharmacist and say, look it has been taking a bit longer than the time we can assign for what we can do now." (Interview 10)

"You know what I base it on? The effect it has on my patients, do you know what I mean, in terms of how much they thought it was of value to them, and you normally can tell by the end of the thing. Because of the feedback that you get from them, do you know what I mean? And also then the follow up when I see them again" (Interview 20)

Adaptation

"It was theoretical, it didn't work in practice with the appointments, with consent forms." (Interview 3)

"When we first started approaching people on the spot we would only get maybe two out of ten who were happy to actually do it straight away, so we thought how can we go about this another way and that is how we thought of it we do it bit by bit by only taking up five or ten minutes of their time each time, then they're generally happy to do it that way." (Interview 6)

"And then give and take, is it working, if it's not we've got to change something. So like MedsCheck is not really working for us, so we've got to try and get a formula for instigating it, do you know what I mean?" (Interview 18)

"MedsCheck and diabetes I rarely do appointments, because people don't want to come back for it, I usually try and get it on the spot if I can." (Interview 18)

Improvement

"Yeah, and feedback. It's just, it's little things like we should have all the paperwork printed off ready so that we don't have to go and do that afterwards, do you know what I mean, the claiming sheets and all that sort of things, so we can do it all in one nice unit, and then it's done and we can fax it off and things like that. So that sort of thing. Printing out all their background

before they come in, so we've got it all ready, we've looked at it we're a bit familiar with it, and then so that when they come it's correct" (Interview 20)

"You get more comfortable in the speech of selling it, you become more comfortable with the programs you are using, the amount of time they take becomes shorter, so more manageable I guess. Don't get me wrong, some take a longer time, and some a shorter time." (Interview 2)

"Once you get it builds into a more routine, much more streamlined. And so we have got the paperwork ready, we've got everything ready to go, so it's not a big deal" (Interview 20)

"Basically just more of like a teamwork, and more procedure wise and make sure everyone was up to date on how everything worked and how everything is meant to be done, so rather than having one person do something one way and one another way, everyone is on the same page." (Interview 8)

Sustainability

"It became everyday thing now. It's more routine…that's why we don't really separate that. It's like a routine that we make sure everybody does." (Interview 10)

""The MedChecks was getting to be part of routine practice, and we've all used it, and people are accepting of it. We had done, some of our database the first year, and we're kind of on to our second year of doing them, and we're increasing our tool with it, like new diagnosis, new patients, and things like that. People that really need to be told well what's happening here." (Interview 6)

"It's not new. So what happen is like, things like type 2 diabetes program, we had training since 2012 I think, when they start wanting to do this, and they put in a system how to do it. It's from 2012. And at that time, because I wasn't in this store yet, I was in bigger store, and at the time we do it for free. But then now there's a charge for it." (Interview 21)

"Well the thing is, you almost have to do a shorter time frame to access more people, because if you're going to make a difference to your practice you're going to need to... you know it's alright to… what´s my analogy, you can hug one person, but if you're better off having a handshake with ten people, and get more people involved so they can actually get exposed to it. Otherwise you don't actually make a difference. You can't just do it to a small selective, you've got to get a physical, critical mass to get through. So maybe you've got to bring it down to 15 minutes. And do more people in a day." (Interview 6)

"Yeah we are kept going. I mean the main aim of MedChecks is to help patients. And you're not going to stop helping patients because you're not going to be paid for that any more. I mean it's harder to afford to have the amount of pharmacists that we do without getting that funding but you know there are ways about it. You have to just be smart about it, conduct it in ways that are quicker, be more efficient about it, make sure patients are engaged in their you know they know what they're doing and they understand their medications." (Interview 5)

Additional File 4: List of implementation factors for community pharmacy adjusted from the Consolidated Framework for Implementation Research [1]

Domains & Factors

	INNOVATION (SERVICE) (b)	**Definition**
1	Source (a)	Perception of key stakeholders about whether the innovation is externally (for example by a professional body, university, pharmaceutical company, or government) internally (individual pharmacy or pharmacy group) developed (b) [1]
2	Evidence strength & quality (a)	Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the innovation will have desired outcomes (a) [1]
3	Relative advantage (a)	Stakeholders' perception of the advantage or value of the innovation versus an alternative solution (b, e) [1]
	3a. Direct financial benefits (e)	Direct financial compensation for example from government, company or patient
	3b. Other organisational benefits (e)	Business benefits as a result of the innovation such as increasing patient loyalty, return rates, community rapport, sales, efficiency etc.
	3c. Patient benefits (e)	Improved patient outcomes such as health, quality of life, adherence, knowledge confidence etc.
	3d. Professional/personal benefits (e)	Professional or personal reward such as increased satisfaction or motivation
4	Adaptability (a)	The degree to which an innovation can be adapted, tailored, refined, or reinvented to meet local needs (a) [1]
5	Trialability (a)	The ability to test the innovation on a small scale in the organization, and to be able to reverse course (undo implementation) if warranted (a) [1]
6	Implementation complexity (b)	Perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement (a) [1]
7	Design quality & packaging (a)	Perceived excellence in how the innovation is bundled, presented, and assembled (a) [1]
8	Cost (a)	Costs of the innovation and costs associated with implementing the innovation including investment, supply, and opportunity costs (a) [1]
9	Nature of innovation (e)	Nature of the service in terms of degree of change from previous habit (organisational practices and work routines) including innovation difficulty and extent of other healthcare professionals' involvement (c, e) [2]
10	Duration (e)	Duration of innovation including frequency of follow-up and regularity throughout the year
11	Quality assurance system (e)	Method to assess quality of the innovation's implementation and provision

	INDIVIDUALS (a)	
1	General knowledge (c)	Domain or general knowledge acquired from education, training, or accreditations on conditions, pharmacology, scientific rationale or the pharmacy environment and management (c) [2]
2	Knowledge about the innovation (b)	Individuals' comprehension with facts, requirements truths, principles and practices related to the innovation (b) [1]
3	Beliefs about the innovation (b)	Individuals' agreement with the innovation in terms of their attitude towards, value placed and expected outcomes or consequences (b, c) [1,2]
4	Self-efficacy (a)	Individual belief in their own capabilities to execute courses of action to achieve implementation goals (a) [1]
5	Individual state of change (a)	Characterisation of the phase an individual is in, as he or she progresses toward skilled, enthusiastic, and sustained use of the innovation (a) [1]
	5a. Technical skills (experience, capacity & competence) (c)	Familiarity, ability and expertise in performing the tasks involved in innovation provision including interpretation of results (c) [2]
	5b. Interpersonal skills (experience, capacity & competence) (c)	Communication skills and ability to relate and interact with patients, colleagues and other healthcare professionals (c) [2]
6	Individual identification with organisation (a)	A broad construct related to how individuals perceive the organisation and their relationship and degree of commitment with that organisation (a) [1]
7	Other personal attributes (a)	A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, learning style, emotions and coping strategies) (b, c) [1,2]
8	Values & motivation (b)	A person's professional identity, satisfaction, and intrinsic motivation which may be portrayed as intention and goals (c) [2]
9	Leadership skills (d)	Ability to inspire and motivate others as well as make sound decisions
10	Memory, attention and decision processes (c)	The ability to remember and retain information, focus selectively on aspects of the environment and choose between two or more alternatives, dedicate which may be lead to cognitive overload, tiredness, time dedicated to the service and its implementation and self-monitoring (c) [2]

ORGANISATION (PHARMACY(S)) (b)

1	Structural characteristics (a)	The social architecture, age, maturity, size, script volume and location of an organisation (b) [1]
2	Staff (d)	Sufficient and qualified staff/manpower
3	Layout & workflow (d)	Physical arrangement of the organisational environment
4	Networks & internal communication (b)	The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization (a) [1]
5	Teamwork (d)	Combined action of a group each doing their own part to aid effectiveness and efficiency
6	Autonomy (d)	Right to self-regulate, work and make decisions independently
7	Culture and vision (b)	Norms, values, and basic assumptions of a given organization including organisational direction (b) [1]
8	Implementation climate (a)	The absorptive capacity for change, shared receptivity of involved individuals to an innovation and the extent to which use of that innovation will be rewarded, supported, and expected within their organisation (a) [1]
	8a. Tension for change (a)	The degree to which stakeholders perceive the current situation as intolerable or needing change (a) [1]
	8b. Compatibility (a)	The degree of tangible fit between meaning and values attached to the innovation by involved individuals, how those align with individuals' own norms, valued and perceived risks and needs, and how the intervention fits with existing workflows and systems (a) [1]
	8c. Relative priority (a)	Individuals' shared perception of the importance of the implementation within the organization (a) [1]
	8d. Organisational incentives & rewards (a)	Extrinsic incentives such as goal-sharing awards, performance reviews, promotions, and raises in salary and less tangible incentives such as increased stature or respect (a) [1]
	8e. Goal setting (b)	Establishing targets and objectives for the innovation
	8f. Feedback (b)	The degree to which goals are clearly communicated, acted upon, and fed back to staff and alignment of that feedback with goals (a)
	8g. Learning climate (a)	A climate in which: a) leaders express their own fallibility and need for team members' assistance and input; b) team members feel that they are essential, valued, and knowledgeable partners in the change process; c) individuals feel psychologically safe to try new methods; and d) there is sufficient time and space for reflective thinking and evaluation. (a) [1]
9	Readiness for implementation (a)	Tangible and immediate indicators of organizational commitment to its decision to implement an innovation (a) [1]
	9a. Leadership engagement (a)	Commitment, involvement, and accountability of leaders and managers with the implementation (a) [1]
	9b. Available resources & training (a)	The level of resources dedicated for implementation and on-going operations including money, training, education and time (b) [1]
	9c. Access to knowledge & information (a)	Ease of access to digestible information and knowledge about the intervention and how to incorporate it into work tasks (a) [1]
10	Data management system (d)	Recording system for the innovation and information related to its implementation and provision
11	Quality assurance system (c)	Method or activities to assess quality of innovation implementation and/or provision
12	Environmental stressors (c)	Balance between competing demands and/or conflicting roles and available resources, including time
13	Organisational support and/or assistance (e)	Support provided by the organisational group or head office such as advertising, training, monitoring etc.
14	Experience (e)	Degree of observation or participation with the innovation or similar innovations previously

	LOCAL SETTING (d)	
1	Interprofessional network & communication (b)	The degree to which an organisation is networked and interacts within their profession (b) [1]
2	Intraprofessional network & communication (b)	The relationship, social networks and profile an organisation has with other local healthcare professionals and organisations (b) [1]
3	Community's perception about innovation and organisation (d)	Local population's knowledge, beliefs and expectations regarding the innovation
4	Relationship with patients and community (e)	Profile of the organisation within the community and rapport with their patients
5	Demand (d)	Perception of key stakeholders´ about the level of demand or interest in the innovation including the ease of recruiting patients in the service.
6	Patient needs & resources (a)	The extent to which patient needs, as well as barriers and facilitators to meet those needs are accurately known and prioritised by the organisation (a) [1]
7	Peer Pressure (a)	Mimetic or competitive pressure to implement an innovation; typically because most or other key peer or competing organizations have already implemented (a) [1]

	EXTERNAL SYSTEM (b)	
1	Laws, policies or regulations (b)	Includes policy and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives, public or benchmark reporting, or accreditation systems (b) [1]
2	Remuneration (b)	Model and degree of funding
3	Healthcare budget & contracts (b)	Payer polices including the duration and stability of contracts
4	Intraprofessional networks & communication (b)	The degree to which the profession is networked with other healthcare professions and their organisations (cosmopolitism) (b) [1]
5	Interprofessional relations & leadership (e)	The degree of consolidarity within the profession and their professional organisations
6	Stakeholder buy-in (e)	Acceptance of service from pharmacy organisations, other healthcare professional organisations and government
7	External support and/or assistance(d)	Support for professional organisations, companies or government in terms of materials, software, guidelines, training

(a) Direct from consolidated framework for implementation research [1] (b) Modified from consolidated framework for implementation research
(c) Adapted from theoretical domains framework [2] (d) Derived from pharmacy practice research [3] (e) Resulting from qualitative thematic analysis of implementation process for professional pharmacy services in community pharmacy

References

1. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC: **Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science**. *Implement Sci* 2009, **4**(1):50-50.
2. Michie S, Atikins L, West R: **The behavioural change wheel: a guide to designing interventions**. Great Britain: Silverback; 2014.
3. Roberts AS, Benrimoj SI, Chen TF, Williams KA, Aslani P: **Implementing cognitive services in community pharmacy: a review of models and frameworks for change**. *Int J Pharm Pract* 2006, **14**(2):105-113.

Additional File 5: Analysis of influencing factors across the stages of implementation

		Stages					
	INNOVATION (SERVICE)	**Development or discovery**	**Exploration**	**Preparation**	**Testing**	**Operation**	**Sustainability**
1	Source	X	X				X
2	Evidence strength & quality		X			X	
3	Relative advantage	X	X		X	X	X
	3a. Direct financial benefits		X			X	X
	3b. Other organisational benefits		X		X		
	3c. Patient benefits		X		X		
	3d. Professional/personal benefits		X			X	
4	Adaptability				X	X	X
5	Trialability			X	X		
6	Implementation complexity		X	X	X	X	
7	Design quality & packaging		X	X	X	X	
8	Cost		X	X		X	
9	Nature of innovation		X		X	X	
10	Duration		X	X	X	X	
11	Quality assurance system		X	X		X	X
	INDIVIDUALS						
1	General knowledge	X	X	X	X	X	X
2	Knowledge about innovation	X	X	X	X	X	
3	Beliefs regarding innovation		X	X	X	X	X
4	Self-efficacy		X		X	X	
5	Individual state of change		X	X	X	X	X
	5a. Technical skills (experience, capacity & competence)		X		X	X	
	5b. Interpersonal skills (experience, capacity & competence)			X	X	X	
6	Identification with organisation					X	X
7	Other personal attributes	X		X		X	
8	Values & motivation		X		X	X	X
9	Leadership skills		X	X	X	X	X
10	Memory, attention & decision processes				X	X	
	ORGANISATION (PHARMACY(S))						
1	Structural characteristics	X	X	X		X	
2	Staff	X	X	X	X	X	X
3	Layout & workflow		X	X	X	X	
4	Networks & internal communication	X	X	X	X	X	X
5	Teamwork		X	X	X	X	
6	Autonomy	X	X		X	X	

		Development or discovery	Exploration	Preparation	Testing	Full operation	Sustainability
7	Culture and vision	X	X	X	X	X	X
8	Implementation climate	X	X	X	X	X	
	8a. Tension for change	X	X	X		X	X
	8b. Compatibility		X		X	X	
	8c. Relative priority		X	X	X	X	
	8d. Organisational incentives & rewards		X		X	X	
	8e. Goal setting			X	X	X	
	8f. Feedback				X	X	
	8g. Learning climate		X	X	X	X	
9	Readiness for implementation		X	X	X	X	
	9a. Leadership engagement	X	X	X	X	X	X
	9b. Available resources		X	X	X	X	
	9c. Access to knowledge & information			X		X	
10	Data management system		X	X	X	X	X
11	Quality assurance system		X			X	X
12	Environmental stressors		X		X	X	
13	Organisational support and/or assistance	X	X	X		X	X
14	Experience		X		X	X	

LOCAL SETTING

1	Interprofessional network & communication	X	X	X			
2	Intraprofessional network & communication			X	X	X	X
3	Community's perception about innovation and organisation	X	X	X	X	X	X
4	Relationship with patients and community		X		X	X	X
5	Demand	X	X	X	X	X	X
6	Patient needs & resources	X	X	X	X	X	X
7	Peer Pressure	X	X				X

EXTERNAL SYSTEM

1	Laws, policies or regulations	X		X			X
2	Remuneration		X		X	X	X
3	Healthcare budget & contracts		X			X	X
4	Intraprofessional networks & communication						X
5	Interprofessional relations & leadership			X			X
6	Stakeholder buy-in	X				X	X
7	External support and/or assistance	X	X	X	X	X	

Additional File 6: Analysis of implementation strategies

	Strategy [1]	Utilised	Not-utilised
1	Access new funding	X	
2	Alter incentive/allowance structures	X	
3	Alter patient/consumer fees	X	
4	Assess for readiness and identify barriers and facilitators	X	
5	Audit and provide feedback	X	
6	Build a coalition	X	
7	Capture and share local knowledge	X	
8	Centralize technical assistance	X	
9	Change accreditation or membership requirements	X	
10	Change liability laws		X
11	Change physical structure and equipment	X	
12	Change record systems	X	
13	Change service sites	X	
14	Conduct cyclical small tests of change	X	
15	Conduct educational meetings	X	
16	Conduct educational outreach visits	X	
17	Conduct local consensus discussions		X
18	Conduct local needs assessment	X	
19	Conduct ongoing training	X	
20	Create a learning collaborative	X	
21	Create new clinical teams	X	
22	Create or change credentialing and/or licensure standards	X	
23	Develop a formal implementation blueprint	X	
24	Develop academic partnerships	X	
25	Develop an implementation glossary		X
26	Develop and implement tools for quality monitoring		X
27	Develop and organize quality monitoring systems		X
28	Develop disincentives	X	
29	Develop educational materials	X	
30	Develop resource sharing agreements	X	
31	Distribute educational materials	X	
32	Facilitate relay of clinical data to providers	X	
33	Facilitation	X	
34	Fund and contract for the clinical innovation	X	
35	Identify and prepare champions	X	
36	Identify early adopters		X
37	Increase demand	X	
38	Inform local opinion leaders		X
39	Intervene with patients/consumers to enhance uptake and adherence	X	
40	Involve executive boards		X
41	Involve patients/consumers and family members		X

42	Make billing easier		X
43	Make training dynamic		X
44	Mandate change	X	
45	Model and simulate change	X	
46	Obtain and use patients/consumers and family feedback	X	
47	Obtain formal commitments		X
48	Organize clinician implementation team meetings	X	
49	Place innovation on fee for service lists/formularies	X	
50	Prepare patients/consumers to be active participants		X
51	Promote adaptability	X	
52	Promote network weaving	X	
53	Provide clinical supervision		X
54	Provide local technical assistance	X	
55	Provide ongoing consultation		X
56	Purposely reexamine the implementation		X
57	Recruit, designate, and train for leadership	X	
58	Remind clinicians	X	
59	Revise professional roles	X	
60	Shadow other experts	X	
61	Stage implementation scale up	X	
62	Start a dissemination organization		X
63	Tailor strategies	X	
64	Use advisory boards and workgroups		X
65	Use an implementation advisor		X
66	Use capitated payments	X	
67	Use data experts		X
68	Use data warehousing techniques	X	
69	Use mass media	X	
70	Use other payment schemes		X
71	Use train-the-trainer strategies	X	
72	Visit other sites	X	
73	Work with educational institutions	X	

Reference

1. Powell B, Waltz T, Chinman M, et al. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. *Implement Sci.* 2015;10(1):21.

Additional File 7: Consolidated criteria for reporting qualitative research (COREQ checklist)

No.	Item	Description
Domain 1 : Research team and reflexivity		
Personal Characteristics		
1	Interviewer/facilitator	One author (JCM) conducted the interviews
2	Credentials	B.Pharm
3	Occupation	PhD candidate
4	Gender	Female
5	Experience and training	Australian Consortium for Social and Political Research (ACSPRI) Course: Introduction to Qualitative Research and Evaluation Course
Relationships with participants		
6	Relationship established	The interviewer spoke with the interviewee by telephone and face-to-face upon arrival prior to the interview to establish the relationship and provide information
7	Participant knowledge of the interviewer	The participants received an information sheet that contained: Who was doing the research; What the research was about; What would be involved; What were the risks/inconvenience; Why they had been asked; Did they need to say yes; What would happen if they say no; Could they change their mind; What to do if they have a concern or complaint.
8	Interviewer characteristics	The information sheet included the interviewer's characteristics and reason for conducting the research
Domain 2: Study design		
Theoretical framework		
9	Methodological orientation and theory	Framework method of analysis
Participant selection		
10	Sampling	Purposeful sampling
11	Method of approach	Telephone
12	Sample Size	25 pharmacists across 21 pharmacies
13	Non-participation	7 pharmacists were unable to participate as a suitable time was not available or they did not have the time to participate
Setting		
14	Setting of data collection	Data was collected in a private area of the pharmacies
15	Presence of non-participants	Other staff and patients were in the pharmacies, but not within listening distance
16	Description of sample	Interviews were conducted in January and February 2014. Patient characteristics are provided in Table 2
Data collection		
17	Interview guide	Interview guide is provided as Additional File 2. The guide was pilot tested
18	Repeat interviews	No repeat interviews were conducted
19	Audio/visual recording	The interviews were audio recorded
20	Field notes	Field notes were taken
21	Duration	Interviews ranged from to 20 to 50 minutes
22	Data saturation	Data saturation is discussed in the first paragraph of the results
23	Transcripts returned	Transcripts were not returned to participants for checking
Domain 3: Analysis and Findings		
Data analysis		
24	Number of data coders	One
25	Description of the coding tree	The reviewers were provided with the definitions of the codes.
26	Derivation of themes	As per framework analysis the themes were identified in advance, however new themes were added from the data
27	Software	QRS nVIVO 10
28	Participant checking	No feedback was provided by participants
Reporting		
29	Quotations presented	Quotations to support the findings are provided in Additional File 3. The quotations are identified by interview number.
30	Data and findings consistent	The data supports the findings of the study
31	Clarity of major themes	The major themes are clearly presented in the findings
32	Clarity of minor themes	There was variability in responses and a secondary analysis was done on minor themes. These are presented in the article.

Tong A, Sainsbury P, Craig J: Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care 2007, 19(6):349.

Ethics approval

Chapter 5

- Ethics approval: UTS HREC 2013000670
    - Consent form
    - Information sheet
    - Information letter
    - Recruitment process

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UTS CRICOS PROVIDER CODE 00099F

6 November 2013

Professor Charlie Benrimoj
Graduate School of Health
CB07.04.39
UNIVERSITY OF TECHNOLOGY, SYDNEY

Dear Charlie,

UTS HREC 2013000670 – Professor Charlie Benrimoj, Dr Daniel Hernandez (for Ms Joanna Moulin, PhD student) – "Implementation of Professional Pharmacy Services"

The UTS Human Research Ethics Committee reviewed your application titled, "Implementation of Professional Pharmacy Services", and agreed that the application 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. 2013000670
Your research is valid for five years from the date of this letter.

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, 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.

If you have any queries about your ethics clearance, or require any amendments to your research in the future, please do not hesitate to contact the Ethics Secretariat at the Research and Innovation Office, on 02 9514 9772.

Yours sincerely,

M R Haas

Professor Marion Haas
Chairperson
UTS Human Research Ethics Committee

UNIVERSITY OF TECHNOLOGY SYDNEY

UTS:PHARMACY

Consent Form

Implementation of Professional Services

I _____ agree to participate in the research project 'Implementation of Professional Services' being conducted by Joanna Moullin, mobile: 0426 266 156, of the University of Technology, Sydney for her doctoral degree in Pharmacy Practice Research.

I understand that the purpose of this study is to evaluate a framework of implementation and assess the adoption and provision of professional services with the aim to improve the implementation and future of provision of professional pharmacy services across the profession.

I understand that I have been asked to participate in this research because I have been identified as a professional service provider or potential provider and that my participation in this research will involve a short (20–30 minute) interview with Joanna regarding my experiences and views of the process required for service provision. I am aware that this interview will be audiotaped and transcribed, but that this will be de-identified to ensure privacy and confidentiality. In addition any publications using the information provided will not contain any identifiable data.

I am aware that I can contact Joanna Moullin (9514 9225; Joanna.moullin@uts.edu.au) or her supervisor Professor Charlie Benrimoj (9514 4013; Shalom.benrimoj@uts.eud.au) 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 Joanna Moullin has answered all my questions fully and clearly.

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.

UNIVERSITY OF TECHNOLOGY SYDNEY

UTS:PHARMACY

Information Sheet

Implementation of Professional Services

WHO IS DOING THE RESEARCH?

My name is Joanna Moullin and I am a student at UTS. My supervisor is Professor Charlie Benrimoj.

WHAT IS THIS RESEARCH ABOUT?

It has been widely acknowledged that Community Pharmacy Practice is in a period of unprecedented change. This has been paralleled by a move towards service provision. Research has been dedicated to defining services and demonstrating the value of pharmacy to gain remuneration. However, both nationally and internationally implementation and sustainability of services is a major challenge.

This research project aims to evaluate a framework of implementation and assess the adoption and provision of professional services with the aim to improve the implementation and future of provision of professional pharmacy services across the profession

IF I SAY YES, WHAT WILL IT INVOLVE?

A discussion about your views and experiences of the process required for service provision (about 20-30minutes) in your pharmacy or suitable convenient location. The interview will be audiotaped and transcribed. The data will be de-identified to ensure privacy and confidentiality. Any publications using the information provided will not contain any identifiable information.

ARE THERE ANY RISKS/INCONVENIENCE?

Potential risks include inconvenience and slight discomfort. Inconvenience may occur due to time away from your usual work commitments. In addition possible discomfort may occur based on the questions. The aim however is to assess the process in which implementation occurs in community pharmacy of professional services. The quantity and/or quality in which they provide services are not being judged.

WHY HAVE I BEEN ASKED?

You have been identified as a professional service or potential professional service provider.

DO I HAVE TO SAY YES?

You don't have to say yes.

WHAT WILL HAPPEN IF I SAY NO?

Nothing. I will thank you for your time so far and won't contact you about this research again.

IF I SAY YES, CAN I CHANGE MY MIND LATER?

You can change your mind at any time, withdraw, and you don't have to say why. I will thank you for your time so far and won't 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 or my supervisor can help you with, please feel free to contact us on 9514 9225; Joanna.Moullin@uts.edu.au (Joanna) or 9514 4013; Shalom.Benrimoj@uts.edu.au (Charlie).

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.

UNIVERSITY OF TECHNOLOGY SYDNEY

UTS:PHARMACY

Information Letter

Implementation of Professional Services

Dear Pharmacist

My name is Joanna Moullin and I am a doctoral student under the supervision of Professor Charlie Benrimoj at the University of Technology, Sydney.

I am conducting research into the implementation of professional services and would welcome your assistance. Participation will involve a short interview to discuss your views and experiences of the process required to implement services. It should take no more than 30 minutes of your time. The interview will be audiotaped and transcribed. The data will be de-identified to ensure privacy and confidentiality. Any publications using the information provided will not contain any identifiable information. I have asked you to participate as you have been identified as a provider or potential provider of professional services.

My research project aims to evaluate a framework of implementation and assess the adoption and provision of professional services, both nationally and internationally, with the aim to improve the implementation and future of provision of professional pharmacy services across the profession. Your input would be greatly appreciated to help shape my research, which I hope will contribute to moving pharmacy to a more patient and service orientated professional.

Potential risks include inconvenience and slight discomfort. Inconvenience may occur due to time away from your usual work commitments. In addition possible discomfort may occur based on the questions. The aim however is to assess the process in which implementation occurs in community pharmacy of professional services. The quantity and/or quality in which they provide services are not being judged.

If you are interested in participating, I would be glad if you would contact me on the details below.

You are under no obligation to participate in this research.

Yours sincerely,

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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.

UNIVERSITY OF TECHNOLOGY SYDNEY

UTS:PHARMACY

Recruitment Process

Email template

Dear pharmacist,

My name is Joanna Moullin and I am a doctoral student under the supervision of Professor Charlie Benrimoj at the University of Technology, Sydney.

I am conducting research into the implementation of professional services and would welcome your assistance. I am writing to invite you participate in my research. Participation will involve a short interview to discuss your views and experiences of the process required to implement services. I have asked you to participate as you have been identified as a provider or potential provider of professional services. Please see the attached information sheet for further details.

My research project aims to evaluate a framework of implementation and assess the adoption and provision of professional services, both nationally and internationally, with the aim to improve the implementation and future of provision of professional pharmacy services across the profession. Your input would be greatly appreciated to help shape my research, which I hope will contribute to moving pharmacy to a more patient and service orientated professional.

If you are interested in participating, I would be glad if you would contact me on the details below.

You are under no obligation to participate in this research.

Yours sincerely,

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NOTE:
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UNIVERSITY OF TECHNOLOGY SYDNEY

Telephone transcript

Hello,

My name is Joanna Moullin and I am a doctoral student under the supervision of Professor Charlie Benrimoj at the University of Technology, Sydney.

I am conducting research into the implementation of professional services and would welcome your assistance.

I am calling to ask if you would be willing for me to come visit your pharmacy and conduct a short 20-30 minute interview.

The interview is to discuss your views and experiences of the process required to implement services.

My research project aims to evaluate a framework of implementation and assess the adoption and provision of professional services, both nationally and internationally, with the aim to improve the implementation and future of provision of professional pharmacy services across the profession.

Your input would be greatly appreciated to help shape my research, which I hope will contribute to moving pharmacy to a more patient and service orientated professional.

The interview will be audiotaped and transcribed. The data will be de-identified to ensure privacy and confidentiality. Any publications using the information provided will not contain any identifiable information.

I am happy to send across an information sheet for you to read, or answer now any questions you may have.

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Chapter 6

Model for the evaluation of implementation programs and professional pharmacy services

Moullin J.C., Sabater-Hernández D., & Benrimoj S.I., 2016, 'Model for the evaluation of implementation programs and professional pharmacy services', *Res Social Adm Pharm*, vol. 12, no. 3, pp. 515-22.

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Research in Social and Administrative Pharmacy ■ (2015) ■–■
RESEARCH IN SOCIAL & ADMINISTRATIVE PHARMACY

Commentary

Model for the evaluation of implementation programs and professional pharmacy services

Joanna C. Moullin, B.Pharm.[a,*], Daniel Sabater-Hernández, Ph.D.[a,b], Shalom I. Benrimoj, Ph.D.[a]

[a]*Graduate School of Health, University of Technology Sydney, Level 4, Building 7, 67 Thomas St Ultimo, P.O. Box 123 Broadway, 2007 NSW, Australia*

[b]*Academic Centre in Pharmaceutical Care, Pharmaceutical Care Research Group, Faculty of Pharmacy, University of Granada, Campus Universitario de Cartuja s/n, C.P. 18071, Granada, Spain*

Summary

Pharmacy practice and pharmaceutical care research of professional services has largely focused on patient outcomes and cost-effectiveness. Research studies have been, for the most part, conducted in controlled conditions prior to full scale implementation. There appears to be a dearth of process and evaluation of implementation reported. Conducting implementation research or adding implementation measures to an impact study, adds external validity to service and patient outcomes. Evaluations are required for all aspects of implementation including indicators of movement through the implementation stages (formative and summative implementation process evaluation), measures of influencing factors (barriers and facilitators) and change in factors over time (implementation impact), assessment of strategies and/or the implementation program, and overall measures to generate a level of implementation (implementation outcomes). The level of implementation of a professional pharmacy service can be estimated from the level of service delivery (reach and fidelity) and level as a service provider (integration and strength of support in the service environment). The model may be used for evaluating professional pharmacy services and for evaluating implementation programs.

Keywords: Program evaluation [MeSH]; Health services administration [MeSH]; Health plan implementation [MeSH]; Pharmaceutical services [MeSH]

Background

Governments and health care practitioners share common goals to improve patients' clinical outcomes, quality of life and the rationale use of medicines. In light of this, community pharmacy stakeholders have become increasingly interested in implementable, cost-effective, evidence-based, patient-centred professional pharmacy services. As an example in Australia there is an increasing pool of funds available for professional services in community pharmacy.[1] Since 1990 the professional body representing pharmacy owners (Pharmacy Guild of Australia) has negotiated five year

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Community Pharmacy Agreements with the Commonwealth Government for remuneration.[2] The sixth agreement has recently been signed. There is a significant change in the funding arrangements for community pharmacies, removing the mark-up on products and doubling the funding available for professional pharmacy services.[1] This movement to introduce and integrate services into the practice of community pharmacy is echoed around the World.[3–7]

Implementation gap

The implementation of new innovations, such as professional pharmacy services, is a complex process. No single strategy appears to be sufficient to drive successful implementation.[8–10] High quality service provision cannot be assumed to occur. Internationally, across multiple disciplines there is a realization of translational gaps and the need to study and improve implementation. "Science to service," "research to reality," "evidence to practice," "know-do," are terms used to indicate gaps in the take-up and application of innovations.[11] More recently there has been discussion of an "implementation gap" and a "quality chasm" referring to services not being sustained over time and/or not being delivered as they were originally designed and intended.[12] Pharmacy practice is similarly struggling with implementation. The use of implementation theory, knowledge and tools may offer some much needed guidance.

The core concepts of implementation are (1) a process to implement (2) an innovation (professional pharmacy service), which is influenced across (3) contextual domains by (4) factors, (5) strategies and (6) evaluations.[13] A Framework for the Implementation of Services in Pharmacy (FISpH) has been developed using the core concepts and contextualized to the community pharmacy setting.[14] Meta-frameworks, models or theories are necessary to operationalize each concept. To generate the foundation for the FISpH, a qualitative study investigated the process and influences of implementation in Australian community pharmacies.[14] Analysis of the interview data produced a six stage implementation process from development or discovery to sustainability (Fig. 1), as well as distinguishing a range of implementation steps pharmacies completed as they moved through the stages. Contextual domains or the ecological levels of implementation influences and determinants of patient behavior, include individuals (pharmacy staff, external help), organization/pharmacy(s),

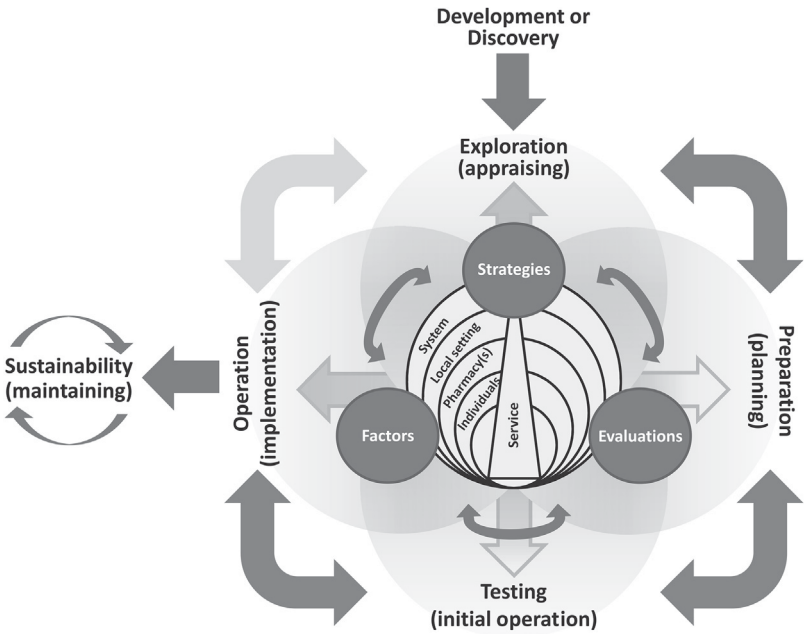


Fig. 1. Framework for the Implementation of Services in Pharmacy (FISpH).[14]

local setting (e.g. patients, community and health care professionals) and system. Across these domains overarching influences were revealed and preliminary lists of implementation factors (barriers and facilitators e.g. readiness for change, perception, competence, appropriateness, relative-advantage etc.) and strategies (e.g. training, changing roles and responsibilities) utilized by pharmacy were investigated. The remaining concept of the framework, evaluations, appeared widely lacking.[14] As such, a theoretical based, yet practical model for the evaluation of implementation programs and professional pharmacy services is required.

Current focus of evaluation

Along with the poor evaluation conducted internally by community pharmacies in Australia,[14] there appears to be limited evaluation of implementation of services and programs conducted by professional organizations and researchers.[15,16] To satisfy policymakers, funders and subsequently practitioners with viable remuneration packages, pharmacy practice research and service evaluations have been predominantly focused on patient outcomes and cost-effectiveness. Research studies have been largely conducted in controlled conditions, prior to implementation and there appears to be a dearth of process or implementation indicators reported.[16]

A systematic review on intervention research in pharmacy practice reported a lack of pharmacist behavior indicators, such as fidelity measures.[16] Fidelity is an implementation outcome that measures the degree to which a service is implemented and delivered as it was designed. As such it includes evaluating the behavior of the pharmacist, as the service provider. Of the 50 studies that evaluated the impact of professional pharmacy services, only 21 reported on pharmacists' behavior. Of these 21, only four studies measured both patient outcomes and pharmacists' behavior. It was further noted that many of the studies, despite claiming to report on behavior, used measures of adoption, that is number of pharmacists or pharmacies registered to deliver a program, rather than measures such as fidelity, or other quality or performance measures.[16]

Poor monitoring by pharmacists and a lack of evaluation of implementation in pharmacy practice has been discussed as an issue in Australia, including among government policymakers.[15,16] An audit of the effectiveness of the development, administration and outcomes of the fifth agreement in Australia reported that there was a lack of evaluation and internal auditing by the profession, which subsequently did not allow the government to assess value for money or performance of the agreement.[15] Consequently a requirement in the preceding sixth agreement (2015–2020) is for improved accountability and evaluation.[1] This push for evaluation is also being seen in academia with a move to include impact data in research proposals and reports.[17]

Implementation measures

Along with service and patient outcomes it is vital that pharmacy researchers begin to evaluate implementation. Evaluations are required for all aspects of implementation including indicators of movement through the implementation stages (formative and summative implementation process evaluation), measures of influencing factors and change in factors over time (implementation impact), assessment of strategies and/or implementation program and overall measures to generate a level of implementation (implementation outcomes).

Implementation research, involves investigating an implementation program or implementation strategy/intervention and its effects on implementation indicators and level of implementation success, while service research involves investigating the effects of a service or clinical intervention on patient's health, quality of life and other service outcomes. Therefore measures of implementation serve as indicators of implementation processes, impact and outcomes (implementation success) as well as intermediate outcomes in relation to service process, impact and outcomes.[18] As such implementation indicators may be used as process, impact and outcome measures of an implementation program or as intermediate process indicators in relation to the service, social and clinical outcomes.

Frameworks and models have been developed that include implementation evaluations, including those by Glasgow et al.,[19] Proctor et al.,[18] Green et al.,[20] Lehman et al.,[21] and Steckler et al.[22] In addition to measuring implementation indicators, literature reviews on implementation tools have been conducted,[23] tools developed for particular implementation concepts (e.g. Stages of Implementation Completion,[24] formative evaluation of normalization[25])

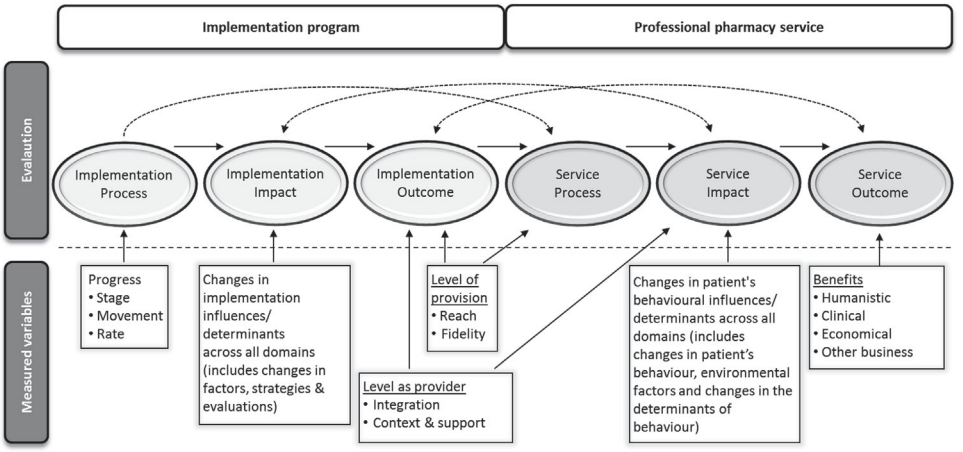
and models of particular outcomes (e.g. implementation fidelity[26]). In recent years the field of Implementation Science has focused heavily on the development and testing of implementation tools and measures and large databases have been developed as repositories.[27,28] Many tools and measures remain discipline specific, however provide guidance for pharmacy.

Model for the evaluation of implementation programs and professional pharmacy services

Conducting implementation research or adding implementation measures to an impact study as a hybrid design, or to a service or implementation program assessment, will add external validity to the service and patient outcomes.[11,29] Based on the FISpH[14] and implementation science literature[18,19,21,22,26,30] a model for the evaluation of implementation programs and professional pharmacy services is proposed (Fig. 2). To conduct implementation research and evaluations, tools for the implementation indicators in pharmacy will need to be developed and tested.

The implementation evaluation model involves both indicators for implementation process, impact, and outcome and service process, impact and outcome. The service evaluation component is widely accepted,[20,31] and therefore the focus will be on describing the implementation evaluation section. Implementation evaluation may be used to assess implementation programs and in service evaluations. The arrows indicate the flow of affect, while the curved arrows hypothesized relationships between the implementation and service evaluations. These relationships may be used to develop prescriptive models and theories for hypothesis testing.

Implementation process evaluation consists of indicators of progress, such as stage attainment (the implementation stage in which pharmacies are situated), and the movement and rate of movement through these stages. Assessing the progress through the stages involves determining: is a pharmacy aware of the service, indicating they are in exploration stage (exploration indicator: awareness); have they decided to adopt the service, indicating they are in preparation stage (preparation indicator: adoption); are delivering the service to a limited extent, indicating they are testing (testing indicator: limited provision); are delivering the service to full capacity, indicating that they are in operation (operation indicator: full provision); or are continuing to provide the service, maintaining the capacity and support for its provision and benefits over an extended period of time after any external support has ceased, indicating they are in sustainability (sustainability



Note: Domains are the divisions or categories of the implementation influences and determinants of patient behaviour. They include the characteristics of the service being implementation, and the context (individuals, organisation/pharmacy(s), local setting and system).

Fig. 2. Model for the evaluation of implementation programs and professional pharmacy services.

indicators: continued delivery, capacity and benefits)? (See explanation below). In addition to stages, steps or activities conducted as part of the implementation process, may be designed into a measurement tool to assess the movement and rate of movement through the stages.

The evaluation of implementation impact involves assessing the influences affecting implementation. The FISpH framework states that there are factors, strategies and evaluations involved in and affecting the implementation of pharmacy services. All influences act as indicators of the impact of the implementation effort on the attainment of implementation and service and patient outcomes. Factors include features of the service and characteristics and determinants of behavior, of pharmacy staff, the pharmacy(s), local setting, and system. Strategies are targeted efforts (method, technique or activity) designed to enhance moving of an innovation into use and integrating into routine practice.[29,32] Evaluations include all indicators in the model. Tools to assess implementation influences may be used in a formative capacity to aid successful implementation.[33] The formative use of evaluations may be assessed as part of implementation impact.

Implementation outcomes are depicted as the level of provision and the level as provider (Fig. 2). The level of service provision is 'how much and how well' the service is being delivered. This is determined by two primary measures: Reach, which is the number of services performed (or patients participating) as a proportion of the potential population for the service and the representativeness of this group[19]; and fidelity, which refers to the degree to which the service is performed as it was originally designed.[34] Fidelity includes adherence to the components of the service, the dose (for example are all follow-up sessions completed), the quality, patient responsiveness, program differentiation or how much it differs from other existing services, and how it was adapted.[34]

The level as a service provider is related to support in the service environment and the level of integration. Service integration includes routinization, which is the degree to which the new service has become part of the pharmacy's principles and everyday practice, and institutionalization measures the pharmacy's ability to support and enable ongoing service delivery and improvement. Support includes measures of context (such as culture, climate, and capacity) to measure the pharmacy's ability to maintain the service and the value the staff place in its provision. Support and perception may be evaluated at an individual, pharmacy, local, and system level (staff, pharmacists, owner, patient, community, other health care professionals, politicians etc.).

A level of service implementation may be estimated from the level of service delivery (reach and fidelity) and level as a service provider (integration and strength of support in the service environment). This overall outcome can be looked at from various ecological perspectives. For example, one could measure the outcome for an individual staff member (micro level), the pharmacy as a whole or for a group of pharmacies (meso level). Alternatively measures can be aggregated to look at a service's implementation outcomes nationally (macro or system level).

Final stage attainment – sustainability

Sustainability is the final phase of the implementation process in the FISpH (Fig. 1). As such, the level of implementation, as calculated through measurement of implementation outcomes, is related to reaching and maintaining sustainability of service provision. The measurement of sustainability is based on three ideas;

1. The definition of sustainability is conceptualized as consisting of three constructs: routinization, (repetitive, recognizable pattern of the new service) institutionalization (supporting conditions), and maintenance of benefits.[35–37] These three constructs are depicted in the implementation part of the evaluation model (Fig. 2). Routinization consists of the integration or delivery of the new service, institutionalization as the individual, organizational and system context,[38–41] including support and capacity for continued delivery and maintenance of benefits as service and patient outcomes. Benefits incorporate economic, clinical and humanistic outcomes and measures such as quality of life, satisfaction, efficiency etc. In addition to economic outcomes for the health care system and organizations, pharmacies are also interested in other potential business benefits such as differentiating their pharmacy from the market, improved customer loyalty and professional satisfaction.
2. Implementation of professional services in pharmacy involves the process of implementing a service, as well as changing the business model and professional practice to an

environment to one that is supported and conducive to service delivery. Therefore looking at only the level of service provision does not account for the change in nature or in the future maintenance of the service environment. There has been increased appreciation for the importance of context and the need for qualitative and quantitative measures to help understand and predict implementation outcomes.[42]

3. Local setting and system factors are imperative when considering the attainment of complete sustainability and measuring implementation from a systems perspective. Complete sustainability cannot be achieved without stakeholder buy-in, political support and funding.[39,43]

Implications for practice and research

The model provides a structure for choosing measures and outcomes for implementation programs, implementation studies or service research. The implementation indicators should be measured at various stages of the implementation process to evaluate the process, impact and outcomes. During the first stage, exploration, the service is being appraised by the pharmacy, and therefore indicators of implementation influences may be measured to aid the adoption decision, to assist in the tailoring of implementation strategies and in agreeing on implementation objectives for future formative evaluations of influences. Subsequently evaluation may include measuring the movement from exploration to preparation and to later stages. Process indicators at an individual or pharmacy level may include the rate of movement and number of activities of an implementation program completed during a stage, while at a systems level the rate and number of pharmacies may be evaluated. During the following stages changes in the implementation influences may be used to evaluate the implementation program's impact. Once service delivery begins the level of provision may be assessed. This may be used as an implementation outcome evaluation and as a service process evaluation. Finally the integration of the service into routine practice and the environment support may be chosen to be evaluated (pharmacy, local setting and system levels). These implementation indicators may be included in an implementation study or as a hybrid study where both service and implementation evaluations are conducted concurrently.

A second application of the model is to assist in the design of implementation research questions. As an example of an implementation research study, assessing an implementation strategy or program, the dependent variable may be the degree of integration of the service (routinization and institutionalization), and independent variables reach (number of patients receiving the service and their representatives of the target population) and fidelity (delivery of the service as it was designed). Additionally, process indicators (such as number of pharmacies moving through the stages or change in influences) may be added, and these measures may be used formatively to try and increase the implementation. An alternative is a hybrid design evaluating both the implementation and effectiveness of a service. Adjustments to the Consolidated Standards of Reporting Trials (CONSORT) statement have been made to enhance external validity.[44,45] It has been suggested this should be further extended to include implementation measures.[46] The model for the evaluation of implementation and professional pharmacy services would suggest inclusion of implementation and sustainability measures as outcomes.

Conclusion

A model for the evaluation of implementation and professional pharmacy services is proposed. The model recommends the inclusion of implementation indicators (process, impact and outcome) along with service evaluations. To confidently attribute patient outcomes to the service being evaluated it is imperative that implementation measures are also evaluated. Furthermore, doing so allows program and service evaluators to assess the true level of service implementation and quality of service delivery. The model may also be used to guide formative evaluation to enhance implementation success and to conduct implementation research.

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Chapter 7

Development and testing two tools for measurement of implementation fidelity

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Development and testing of two implementation tools to measure components of professional pharmacy service fidelity

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Keywords
health plan implementation, health services research, patient acceptance of health care, pharmaceutical services, process assessment (health care), validation studies as topic

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Abstract

Rationale, aims and objectives There is a need to evaluate both service process and implementation outcomes as professional services are being implemented into pharmacy practice. Fidelity is an implementation outcome, which may be used for service optimization, by associating service components to patient outcomes, as well as use in process evaluation. The objective of this study was to develop tools to measure components of fidelity, specifically, an adherence index (adherence of the service provider to the elements of the service) and a patient responsiveness scale for the professional pharmacy service, *medication review with follow-up*.

Methods The procedure described by DeVellis was followed to develop the tools. An expert panel was used to create items and establish content validity. Primary data were collected from 190 service provider pharmacists from 128 pharmacies across 11 provinces of Spain using Spanish version tools as part of an ongoing implementation study (English translations appended to the online version of the article as supplementary material). An initial assessment of item functionality was performed using descriptive statistics and item discrimination for both tools. The patient responsiveness scale's internal consistency was confirmed by calculating Cronbach's alpha coefficient and inter-item correlations. In addition, for the patient responsiveness scale, the number of factors to retain was based on Kaiser criterion, parallel analysis and Cattell's scree test and the number of items was optimized as guided by iterative exploratory factor analysis (EFA).

Results Acceptability of both tools was high. An adherence index of 39 items was developed. After five EFA iterations, four items were removed, resulting in a reliable, 12-item, two-factor patient responsiveness scale, explaining 53.9% of total variance.

Conclusions Two tools for measuring implementation fidelity, an adherence index and a patient responsiveness scale, have been developed and tested. Future assessment, in particular to establish criterion validity, is recommended.

Introduction

The objective of developing and implementing a health service is to benefit a patient, population, health care practitioner, health care organization and/or health care system. Researchers, professional organizations and practitioners have made significant progress in defining professional pharmacy services [1]. In addition, the impact of professional services has been studied demonstrating improved clinical and humanistic patient outcomes [2,3], and that these services are cost-effective for both the pharmacy and the health care system [4]. Patients, however, cannot benefit from these services unless they are widely implemented and delivered with high fidelity [5], as there appears to be a positive relationship between fidelity and service outcomes [6].

Fidelity is the degree to which a service, or other innovation, intervention or programme, is implemented in practice as it was

Table 1 Conceptual variables of fidelity

Conceptual variable	Operational definition
Adherence [6–8,19,20]	Process: The extent service delivery is consistent with the designed service process and protocol. Structure: The extent to which the environmental aspects and foundation from which the service is delivered are implemented.
Dose [6–8,19,20]	The amount (intensity), frequency and duration of service components and phases.
Patient responsiveness [7,19,20]	Degree of patient participation and enthusiasm to aspects of the service protocol that require their involvement.
Adaptation* [6,19]	Unintentional drift or intended changes made to the components of the service.
Quality* [6–8,19,20]	The manner in which the service is delivered towards the theoretical ideal. Dimensions may include provider enthusiasm, facilitation of responsiveness, preparation, knowledge and confidence/self-efficacy.
Differentiation* [6–8,19,20]	Degree to which the critical components are present including comparing what patients receive with the service to what they receive with normal practice.

*Conceptual variables that may not be considered dimensions of fidelity, but as moderators. They should be measured, but may or may not be included in fidelity measurement itself [8].

originally designed and intended [7,8]. Collaborating with end-users (e.g. pharmacists and patients) and measuring fidelity during development, impact and implementation studies helps create services that are feasible, implementable and acceptable [9,10]. Fidelity is based on the notion of measuring core components, the features of a service that make it effective [11,12].

The identification, validation and implementation of a service's core components are of great importance for widespread service implementation, replication and sustainability [11]. The service, *medication review with follow-up*, has shown positive results in impact studies and is in the process of being implemented in Spain [4,13,14]. The service is defined as 'the professional service having the goal of detecting problems related to medicinal products, for the prevention and resolution of negative outcomes associated with the medicine. This service requires considerable commitment and should be provided on a continual basis, in a systemized and documented manner, in collaboration with the patient and other healthcare professionals, in order to attain specific results that will improve the patient's quality of life' [15]. The core components (i.e. 'active ingredients' and 'dose' of the service) necessary to produce positive outcomes require validation. Fidelity evaluation is one methodology that may be used for service optimization by associating service components to patient outcomes [9]. Once the core components have been established, only these components need to be implemented with fidelity, whereas the remaining non-core components or 'adaptive periphery' of a service may be adjusted to fit the context into which it is being implemented [9,12,16]. Allowing for adaptation is believed to increase successful implementation and sustainability [17,18]. As a first step for such service optimization, tools to measure fidelity are needed.

Fidelity consists of six conceptual variables: adherence, dose, patient responsiveness, adaptation, quality and differentiation of the service components (definitions provided in Table 1) [6–8,19,20]. Adherence, dose and patient responsiveness may be considered measures of the core components, whereas adaptation, quality and differentiation are said to be moderators or subdivisions of fidelity, which should be measured, but may or may not be included in the overall fidelity score [8].

Across multiple disciplines, including pharmacy practice, there is inadequate measurement of fidelity, possibly due to poor understanding of the concept and/or a lack of validated tools [9,21–24]. Implementation of services involves both process and structure elements [25]. The process is the delivery and integration of the service into practice. Structural elements are the environmental aspects and foundation from which the service is delivered such as having sufficient staff, budget, frequency of contacts etc. Although tools to measure the structural element of implementation may be included as part of the adherence conceptual variable of fidelity measures, they are often assessed separately as part of organizational readiness, context and/or integration measures [25,26]. On the other hand, a tool to measure adherence to the process element is needed. 'Dose' may be measured by service records. The theory of patient responsiveness is that core components of the service are dependent not only on the service provider but that service effectiveness also requires patients to be involved and engaged [19,26]. Patient responsiveness may be measured by questionnaires answered by either the patients themselves or a third party observing or involved in the service delivery [27].

Objective

The objective was to develop two tools to measure fidelity, specifically an adherence index and a patient responsiveness scale, for the *medication review with follow-up* service.

Methods

The procedure described by DeVellis was followed for the index and scale development: (1) define what is to be measured (latent variable); (2) generate items; (3) determine format for measurement; (4) review of items by expert panel; (5) administer to sample; (6) evaluate items; and (7) optimize length [28]. A scale consists of 'effect indicators' where the item value/responses are caused by the latent variable, whereas an index is made up of 'cause indicators', or items that determine the level of a construct [28,29]. Because of these conceptual differences between indexes and scales, the item generation and evaluation for each questionnaire varied [28,29].

Both tools were developed and tested in Spain using Spanish versions of the questionnaires (see Appendices S1 & S2) (English translations are provided in Table 2 & Table 3). In addition, both

Table 2 Descriptive statistics of the adherence index (n = 190)

Item	Percentage frequency of responses						
	Never (1)	Rarely (2)	Sometimes (3)	Often (4)	Always (5)	Mean	SD
Service offer							
1. Patients who could benefit from the service are identified.	1.1	3.2	28.4	48.9	18.4	3.81	0.809
2. The service is offered to the patients who could benefit from the service.	1.6	6.8	37.9	34.7	18.9	3.63	0.921
3. An appointment for the first interview is agreed with the patient.	1.1	4.2	10.0	16.8	67.9	4.46	0.912
4. Patients are asked to bring to the first interview all the medicines they have at home.	1.1	1.6	0.5	4.2	92.6	4.86	0.596
5. Patients are asked to bring to the first interview all medical reports that they have.	1.1	1.1	2.6	7.9	87.4	4.79	0.638
6. Patients are asked to bring to the first interview all test results that they have.	1.1	2.1	2.1	8.9	85.8	4.76	0.691
First interview							
7. All the patients' health problems are identified.	2.1	1.6	14.7	43.7	37.4	4.13	0.874
8. Information on the degree of control of the identified health problems is collected.	1.6	0.5	9.5	43.2	44.7	4.30	0.790
9. Additional information (diagnoses, clinical parameters, etc.) is requested when necessary to identify and/or better understand the control of their health problems.	1.6	1.6	9.5	22.6	64.2	4.47	0.854
10. All prescription drugs used by the patient are recorded.	1.6	0.5	0.5	7.4	89.5	4.84	0.610
11. All the pharmacist recommended medicines or medicines self-administered by patients are recorded.	2.1	1.1	5.8	25.3	65.3	4.51	0.829
12. Information on the patients' medication use (dosage, directions, pattern, adherence, dosage form, etc.) is collected.	1.6	0.5	0.0	13.2	83.7	4.79	0.627
Determination of current status							
13. All health problems and current medications of the patient are recorded in the status report.	1.6	1.1	2.1	20.5	73.2	4.65	0.727
14. All information relating to medicines (date, pattern, etc.) is recorded in the status report.	1.6	1.1	6.8	29.5	58.9	4.46	0.806
15. All information relating to health issues (date, etc. control) is recorded in the status report.	1.6	1.1	6.8	36.3	51.6	4.39	0.801
16. Health problems not treated pharmacologically and/or medications without associated health problems are recorded in the status report.	2.1	2.1	11.1	25.8	55.8	4.36	0.923
Study phase							
17. Questions in relation to the clinical situation of patients are posed.	2.1	0.5	11.6	42.6	39.5	4.21	0.841
18. The posed clinical questions are resolved using appropriate information sources.	2.1	1.1	7.4	47.9	37.9	4.23	0.813
19. Interventions that can potentially improve health outcomes of patients are identified.	2.2	0.5	4.9	43.4	48.9	4.36	0.794
20. Information on the use and administration of patients' medications is identified.	2.1	1.6	2.6	33.2	56.8	4.46	0.817
Evaluation phase							
21. The need, effectiveness and safety of each of the patients' medications are evaluated.	2.1	1.1	2.6	14.2	76.3	4.68	0.777
22. Drug-related problems that could be associated or cause of poor control of health problems are identified.	2.1	1.1	3.2	22.6	67.4	4.58	0.800
23. A list of the identified negative clinical outcomes associated with medications is prepared.	3.7	5.8	8.4	26.8	51.6	4.21	1.08
Intervention phase							
24. A number of objectives are set to improve, maintain and/or avoid potential risk of the health of the patient.	2.1	2.6	9.5	34.2	47.9	4.28	0.910
25. The objectives are prioritized according to the situation and needs of the patient.	2.6	2.1	4.2	30.5	56.3	4.42	0.893
26. Interventions are planned to achieve the set objectives.	2.6	2.6	6.3	42.6	41.6	4.23	0.899
27. Interventions are scheduled over time (short, medium and long term).	5.3	7.4	20.5	42.1	20.5	3.68	1.07
28. Patients are educated about their health problems and medications as necessary.	2.1	0.5	6.8	26.8	59.5	4.47	0.832
29. The planned interventions are performed with the relevant recipient (e.g. patient, doctor).	2.1	2.6	14.7	22.6	53.7	4.29	0.972
30. All interventions (including the acceptance and outcome) are recorded in the designated system.	4.2	2.1	7.4	17.4	64.7	4.42	1.03
Successive interviews and evaluation of results							
31. Following any required intervention, patient appointments are scheduled to check their progress.	3.7	2.6	12.6	27.4	49.5	4.21	1.03
32. Information on the acceptance of interventions by the recipient (patient, doctor, etc.) is obtained.	3.7	4.2	10.0	32.6	44.2	4.16	1.04
33. Information on the outcome (health) of the interventions is obtained.	3.7	1.6	10.5	32.1	46.3	4.23	0.988
34. The action plan established for each patient is modified based on the results of the interventions and evaluation of the patient over time.	3.7	2.6	9.5	38.4	40.5	4.16	0.985
35. Health status of the patient is periodically re-evaluated.	3.2	2.1	8.9	25.8	54.2	4.34	0.977
36. When a patient has a change in their health status or medications, a visit is arranged to check the situation.	3.7	4.7	12.1	23.2	51.1	4.19	1.09
General service aspects							
37. Patients' informed consent is obtained.	1.1	1.6	2.6	4.7	86.3	4.80	0.667
38. The service process is followed orderly.	2.1	4.7	10.5	22.6	56.3	4.31	0.998
39. Performed activities are documented while conducting the different phases of the service.	1.1	5.3	11.1	26.3	52.6	4.29	0.948

SD, standard deviation.

Table 3 Factor structure and reliability analysis of the patient responsiveness scale (n = 190)

Item	Factor analysis				Reliability		
	Factor loadings*		Communalities	Percentage of variance explained†	Cronbach's alpha	Inter-item correlation	Corrected item–total correlation
	Factor 1	Factor 2					
Participation				38.9	0.888	0.473	
13. Patients go to the doctor when referred by the pharmacist.	0.755		0.507				0.640
7. Patients actively participate during meetings with the pharmacist.	0.746		0.645				0.725
15. During the service, patients come to appointments scheduled by the pharmacist.	0.746		0.499				0.582
10. Patients comply with the interventions proposed by the pharmacist.	0.744		0.535				0.600
11. When interventions are directed towards modifying a medication plan (change in medication, dose, schedule, etc.), patients adhere to them.	0.739		0.545				0.606
14. Patients keep the pharmacist informed of any changes in their medication or health status.	0.719		0.521				0.596
5. Patients provide information about all the medicines they use (e.g. medicine cabinet, list of medications).	0.719		0.499				0.579
12. When education is provided (e.g. use of medications, adherence, non-pharmacological advice), patients adhere to the interventions.	0.713		0.565				0.639
8. Patients collaborate in deciding an action plan and prioritizing the interventions.	0.596		0.461				0.587
Enthusiasm				15.0	0.586	0.327	
1. Patients request the service.		0.791	0.572				0.213
4. Patients are proactive in asking the pharmacist questions.		0.691	0.587				0.468
16. Through other people (e.g. patients' family, friends), I am aware that patients speak positively about the service.		0.672	0.534				0.371
Total scale				53.9	0.861	0.354	

Extraction method: principal component analysis. Rotation method: Oblimin with Kaiser normalization. Rotation converged in four iterations.

Items deleted: 2. Patients agree to receive the service. 3. Patients respond to questions posed by the pharmacist. 6. Patients provide recent clinical parameters (e.g. blood pressure, blood test results) and medical reports (e.g. diagnoses). 9. Patients openly express their concerns about their health problems and/or medications.

*Pattern matrix with oblique rotation (oblimin).

†Rotation sums of squared loadings.

tools used the same expert review panel and respondent group of pharmacists. The expert panel consisted of four researchers who developed the service and have experience in implementation science and/or pharmacy practice [25]. Questionnaires were administered to *medication review with follow-up* service provider pharmacists, who was recruited as part of an ongoing implementation study [30]. A description of the service has been presented previously [31]. The recruitment process consisted of a written invitation to participate in the study, which was sent from pharmacy colleges (pharmacy professional organizations at provincial/state level) to all pharmacies in their provinces (ranging from 150 pharmacies in Guadalajara province to 1200 in Valencia). After a structured, introductory, 2-day training session, pharmacy owners indicated their interest in their pharmacy participating in the 12-month implementation study [30]. Those who expressed an interest had their pharmacies coded, by a researcher from the pharmaceutical care research group of the University of Granada, and 11 pharmacy codes per province were randomly selected. From each pharmacy, the pharmacists who would provide the service attended a structured, interactive, 5-day training course. In addition, as part of this ongoing study investigating the implementation of *medication review with follow-up*, facilitators visited pharmacies monthly to provide implementation assistance according to the individual needs of each pharmacy [30]. As part of their 6-month visit, these facilitators delivered and collected the questionnaires, which were self-completed during the visit by the service provider pharmacists. Informed consent was received in written form for the study and questionnaire administration.

The study was approved by Research Centre of Granada Ethics Committee (Comité de Ética de la Investigación de Centro de Granada, Consejería de Salud – Servicio Andaluz de Salud).

Data were prepared and analysis performed in SPSS version 22 (IBM Corp., Armonk, NY, USA). The study was based on individual pharmacist-level analyses of the data, rather than aggregating to a pharmacy or province levels. All items were screened using descriptive statistics, for univariate and bivariate normality, to detect outliers and conduct missing values analysis.

Tool no. 1: adherence index

The latent variable, adherence, was defined (see Table 1) and the scope of the index identified as the process aspects of all seven phases of *medication review with follow-up* service (see Table 2) according to the Dader methodology [15,31]. The procedure described by Bond *et al*. [32] was followed for item generation of the adherence index. In this procedure, a member of the team who developed the service methodology identified all the processes within each phase of the service protocol. Next, while considering the definition and objectives of the service, they delineated items corresponding to each of the identified service processes [15]. This process ensured theoretical underpinnings were included in the operational definitions of the items [29].

The response format determined was a 5-point Likert scale, to which respondents indicated the frequency with which they performed each component of the service protocol, where: 1 = never, 2 = rarely, 3 = sometimes, 4 = often, 5 = always [28]. An individual respondent's adherence score was calculated as the sum of their responses [28]. Each item was given equal weight in the adherence score.

Content validity of the items were independently tested by the expert panel. Two rounds of comments were collected, via email, on items' relevance, clarity, ease to respond as well as recommendations for alternative wording and other suggestions [28]. The questionnaire's content was further assessed by two practising pharmacists. Their responses were further used as an initial test of acceptability and to ensure contextualization and cultural suitability. After each feedback round, the questionnaire was revised.

As a further assessment of content validity and acceptability, additional questions were included at the conclusion of the questionnaire to be completed by the responding pharmacists. Three yes/no questions were added to assess content validity: (1) Do you think there are additional items that should be included? (2) Do you have any alternative wording suggestions for any of the items? (3) Are there any items that you have not answered? To test acceptability, three statements were included, scored by means of a 5-point Likert scale from 'strongly disagree' to 'strongly agree': (1) ease in responding to the items; (2) relevance of the items; and (3) clarity of the items. Space for additional free text comments was provided. Acceptability was also examined by how long it took to complete the questionnaire and inspecting the frequency of missing data for items within each questionnaire.

An initial assessment of item functionality was performed using descriptive statistics and item discrimination, looking at the level of missing data, outlier responses, response frequencies, response mean and response standard deviation (SD) for each item.

Tool no. 2: patient responsiveness scale

The first part of the scale development process was to define a theoretical structure for the latent variable, patient responsiveness from a service provider's perspective [28]. This was achieved through reviewing the literature and creating items for the two components of the patient responsiveness definition, participation and enthusiasm [7,19,20]. The item pool was built taking into account the service definition, the phases of the service process where patients are explicitly or implicitly/indirectly involved and the hypothesized aspects affected by the patients' responsiveness. A 5-point Likert format was chosen where 1 = never, 2 = rarely, 3 = sometimes, 4 = often, 5 = always.

The same process as per the adherence index was used to assess the content validity and acceptability of the patient responsiveness items. Internal consistency, the degree to which the items measure the same underlying construct, was determined using Cronbach's alpha coefficient and inter-item correlation [33]. Item to total correlations were checked to assess the contribution of each item to the scale.

Guided by exploratory factor analysis (EFA), the underlying structure of the scale was determined and the number of items of the scale optimized. The suitability of the data for factor analysis was checked by assessing the frequency of missing data, descriptive statistics (outlier responses, response frequencies, response mean and response SD for each item) and inter-item correlations, ensuring a significant Bartlett's test of sphericity ($P < 0.001$) [34], and that Kaiser–Meyer–Olkin (KMO) measure of sampling adequacy and individual item measures of sampling adequacy were above 0.6 [35]. Factors were extracted using principal component analysis (PCA) with oblique rotation using Oblimin [36]. Oblique rotation was chosen as it was expected that the factors

were related. Orthogonal (varimax) rotation was used to check the structure. The decision on the number of factors to retain was based on Kaiser criterion, Horn's parallel analysis [37] and Cattell's screeplot [38]. Parallel analysis was conducted using 100 replications in the computer program Monte Carlo PCA for parallel analysis and confirmed with parallel analysis using the 95th percentile of 5000 replications in SPSS [39]. The PCA-obtained eigenvalues were compared with those from a randomly generated data file of the same size and factors were retained only if their eigenvalues were above the value obtained from the parallel analysis. Fitting with the factor solution, after each EFA iteration, items were removed one at a time. Items were considered for deletion based on ability to discriminate, communalities and cross-loadings.

Results

In total, 190 service providers of *medication review for follow-up* (138 females and 52 males) from 128 pharmacies, across 11 provinces of Spain, responded to the questionnaires. The median number of service provider pharmacists per pharmacy was 1.0 [mean = 1.5 pharmacists, SD = 0.732, with a minimum of 1 and maximum of 5], the mean age for the sample was 40.6 years (SD = 10.5 years, youngest 24 years and oldest 69 years) and median duration of employment at the current pharmacy was 7.0 years (mean = 9.5 years, SD = 9.4 years, ranging from less than 1 year up to 44 years). The sample consisted of 101 employee pharmacists, 79 pharmacy owners and 10 managers. The average number of patients receiving the service at time of response was 5.0 (SD = 1.6, ranging from 1 to 13 patients). Because of the administration by facilitators, the response rate from the service provider pharmacists participating in the implementation study was 100%.

Tool no. 1: adherence index

A questionnaire of 39 items was developed to cover the full scope of the *medication review with follow-up* protocol. Respondents rated the acceptability of the questionnaire as high, with a mean score for relevance of the items 4.3 out of 5 (SD: 0.9), clarity of the items 4.4 out of 5 (SD: 0.8) and ease of responding 4.4 out of 5 (SD: 0.8). The mean time estimated by respondents to complete the questionnaire was 8.0 minutes (SD: 4.8 min). Missing data ranged from 0 to 5.5%. There were no missing data for items in the first phase, service offering, increasing up to a maximum of between 4.2 and 5.8% for items in the last phase, successive interviews and evaluation of results. In terms of content, the primary suggestions were to include additional items on patient acceptance and patients' adherence to the process.

Responses to the items tended towards high adherence (Table 2), with the mean total adherence score, for pharmacists at month 6 of implementation, being 173 out of 195 (SD: 14.7; Fig. 1). Four outlier cases with a total score less than 100 were removed. A score of 100 means that the majority of items were rarely or never implemented. This was a mean adherence score of 4.4 out of 5 (total score by 39 items). The mean response for items ranged from 3.63 (item 2) to 4.86 (item 4). Components of the programme that appeared less well implemented, based on lower response mean, were item 2 (3.63), item 1 (3.81) and item 27 (3.86).

Tool no. 2: patient responsiveness scale

A 16-item questionnaire was developed and administered to the sample. Acceptability of the questionnaire was high with a mean score of the clarity of the items 4.6 out of 5 (SD: 0.8), ease of responding 4.5 out of 5 (SD: 0.8), relevance 4.4 out of 5 (SD: 0.8) and time to complete 5.0 minutes (SD: 3.8 min). Additional items

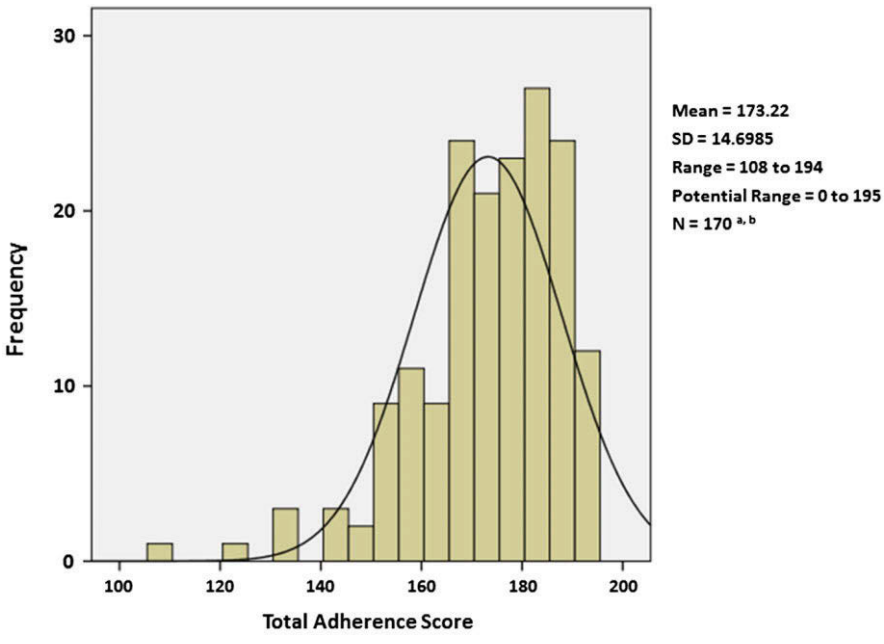

Figure 1 Histogram of spread of total adherence score. [a]Missing data = 16 cases. [b]Outliers = 4 cases removed.

suggested by respondents included items surrounding value/perception/attitude of patients towards the service and items regarding caregivers/relatives.

The following analysis indicated the data set was suitable for factor analysis. The sample size of 190 service providers gave a ratio of 11.9 responses per item, above the recommended number for item analysis [28,36,40]. A total of 159 cases remained, for reliability and validity analyses, after removal of cases with missing data (listwise deletion). The percentage of missing data ranged from 0 to 6.3% per item, with the greatest amount of missing data for item 11 (4.7%), item 13 (6.4%) and item 16 (5.8%). Each item had a minimum of one coefficient in the correlation matrix above 0.3. The KMO measure of sampling adequacy was 0.906 exceeding the recommended value [35,41]. Bartlett's test of sphericity, to test the hypothesis that items are not related, was statistically significant ($P < 0.001$) [34]. Individual measures of sampling adequacy (MSA), indicating the strength of the correlation with other items, were also all above the recommended level [35]. Cronbach's alpha for the full 16-item scale was 0.895, indicating very good internal consistency for the scale within the sample [28].

In the EFA, the Kaiser criterion presented a three-factor solution for eigenvalues exceeding 1, whereas the Horn's parallel test suggested rejecting the third factor (eigenvalue 1.056), as did Cattell's scree plot. Furthermore, the three-factor component correlation matrix showed a strong correlation of –0.527 between factors 1 and 3, suggesting the factors could be combined, whereas the correlation was 0.377 when a two-factor solution was forced. A two-factor solution was chosen. The same items appeared on each factor using oblique and orthogonal rotations with no cross-loadings, after item deletion was conducted. Based on the items within each factor, the factors were maintained as participation and enthusiasm, participation being the degree of involvement in the activities of the service and enthusiasm the degree of interest in or approval of the service.

Based on the two-factor solution, four items were removed. Item 3 was first deleted based on lack of discriminability, as only two response categories accounted for over 90% of responses (mean response 4.5; SD: 0.712). Subsequently, item two was removed due to low communality (0.301), item 9 due to cross-loading (factor 1: 0.555; factor 2: 0.368) and finally item 6 due to low communality (0.425). Item 8 had the next lowest communality at 0.461, but was an item theoretically necessary for the objectives of the service, that it was delivered over time. In addition, at this point, there were no cross-loadings of items across factors. After five iterations, the 12 items loaded on two factors. The correlation between the two factors was 0.321, indicating they are separate but related factors. The total percentage of variance explained after rotation was 53.9% (38.9% by factor 1 and 15.0% by factor 2) (Table 3). Internal consistency and inter-item correlations of the final 12-item scale and factors are presented in Table 3.

Discussion

Tool no. 1: adherence index

The developmental and validation status of the index according to DeVellis [28] and Diamantopoulos and Winklhofer [29] was the process of *medication review with follow-up* was delineated into a questionnaire, the questionnaire administered to a sample of service providers and the content validity and acceptability assessed. To further improve the adherence index, future testing is required of response process, item collinearity and external validity (e.g. predictive validity) [29,42]. As an index, decisions about the inclusion or exclusion of items should be largely related to their importance to the programme and not about correlations with other items [29]. By relating adherence items, the index as a whole or sub-indices of service phases, to a dependent variable (such as patient outcomes or number of interventions), the tool may be used to determine which items are correlated to service endpoints and therefore defined as the core components of the service [29]. Subsequently, these core components would be expected to be implemented with high fidelity (as they were originally designed and intended), whereas other items may be adapted by individual providers or pharmacies. High fidelity has been shown to increase patient outcomes [6], while allowing for adaptation appears to increase successful implementation [17,18].

There was little distribution seen across the questionnaire's responses. Six items (4–6,10,12,37) showed noticeably low discrimination with over 80% of respondents answering 5 (always) to the item and having a SD of responses <0.7. Accordingly, to improve the measurement of the response variance, the response format for subsequent administration and validation was adjusted from a 5-point to a 10-point continuous scale (from 0 indicating never to 10 indicating always; See Appendix S3). Further testing of the index is required using the 10-point response format and with respondents who have been providing the service for a longer period and are further down the implementation path.

The results indicate that, 6 months after adopting the *medication review with follow-up* service, providers believed they were highly adherent to the service process. This may be a true reflection of high adherence or the results may be high in the short term, as service providers continue to receive implementation assistance via facilitator visits as part of the implementation study. In the open commentary section of the questionnaire, 19 respondents felt they had been delivering the service for a short period of time, lacked experience and were yet to complete all phases of the service. This was further indicated by the increase in missing data in the later phases of the service process. Another possibility is respondent fatigue due to the length of the questionnaire. Interestingly, the items with the poorest implementation (items 1, 2, 27) were not those with missing data, but those that required capacity for ongoing delivery and integration of the service into the routine practice of the pharmacy. With time, the service may drift and adherence may diminish, or conversely with experience fidelity may remain high. Additional items were suggested regarding patients' acceptance and adherence; however, such items would assess patients' behaviour rather than assessing the behaviour and process of the provider and as such were included in the second tool, the patient responsiveness scale.

The adherence index may be used for quality assurance purposes to be used by professional bodies or funders to incorporate into service standards and subsequent auditing procedures. In addition to being a summative outcome, the index may be used formatively during implementation to improve service design as well as a continuous quality improvement strategy to enhance adherence performance by use as monitoring and feedback tool.

However, it is important to note the index only includes process indicators, and actual performance quality will also affect service outcomes.

Tool no. 2: patient responsiveness scale

The two factors of patient responsiveness, defined as 'participation' and 'enthusiasm', fit the concept that fidelity implicates the involvement and engagement of both providers and patients [19,26]. A patient-centred approach is necessary for pharmacy services to achieve positive patient outcomes and equally a lack of participation from patients would be thought to negatively impact service outcomes. As such, it is important to measure patients' response and engagement with the service, from the perspective of the service provider and subsequently its relationship to outcomes.

Pharmacists appear to be well trusted and respected, at least in countries such as Australia [43], and therefore it is unsurprising that item 3, patients respond to questions posed by the pharmacist, showed low discrimination and was able to be removed. The low communality of item 2 may reflect that the item is associated to acceptance of the service rather than participation and enthusiasm, whereas the low communality of item 6 appears reflective of requiring resources outside the patient's control, and therefore not a true indication of participation or enthusiasm. Item 9, the final item omitted, cross-loaded on both participation and enthusiasm and appeared unnecessary as item 7 also encompassed the concept of active participation.

The patient responsiveness scale showed strong reliability and construct validity for measuring providers' perceptions of patient participation and enthusiasm to the aspects of the service protocol that require patient involvement. The final tool consisted of two subscales. The Cronbach's alpha was marginally low for factor 2; however, the inter-item correlation, which is not dependent on scale length, was within the optimal level of homogeneity. In some fidelity frameworks and definitions, patient responsiveness has been described as being or including patient acceptability [8,44]. Respondents also suggested the addition of acceptability items. It is proposed that acceptability, awareness and understanding (of patients, providers and other health care professionals) are important influences on implementation and sustainability and may act as a moderator of fidelity, rather than a constituent. A separate tool to measure these and other implementation influences would be valuable.

As validity is incremental, future testing would be recommended, particularly external validity, to test the hypothesis of a positive relationship to service outcomes. In addition, a patient responsiveness scale may be tested for use in other contexts and for other services.

Limitations

Facilitators employed to provide ongoing assistance as part of an implementation study were used to administer and collect the questionnaires. This is potentially a confounding factor if providers and/or facilitators believed they were being assessed. It would be recommended that response process validity be tested in the future, establishing evidence of fit between adherence and the responses given by respondents on the item(s) developed to measure the concept [42]. Another option would be to use an alternative approach to access pharmacists, such as mailing questionnaires. To minimize the risk of bias being introduced, the questionnaires were completed anonymously and were not used in a formative capacity as part of performance assessment or quality improvement.

Implications for practice

Attempts should be made to maximize and measure fidelity as they moderate service outcomes. Two tools for measuring implementation fidelity, an adherence index and a patient responsiveness scale, have been developed and tested. The notion is that the components of fidelity may be combined in some form to produce an overall fidelity score. These tools and fidelity scores may be used in quality assurance, quality improvement and service optimization and therefore are beneficial for researchers, pharmacists, professional bodies and government agencies.

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Supporting information

Additional supporting information may be found in the online version of this article at the publisher's web site.

Spanish versions of the questionnaires are provided for electronic access:

Appendix S1 Índice de adherencia: servicio de seguimiento farmacoterapéutico (SFT) (original version).
Appendix S2 Escala de receptividad del paciente.
Appendix S3 Índice de adherencia: servicio de seguimiento farmacoterapéutico (SFT) (new version).

Appendix S1

Código de la provincia: __ __ **Código de la farmacia: __ __** **Fecha: __ /__/__**

Tipo de empleado: __ (1-4) **Años de trabajo en esta Farmacia: __ __** **Edad: __ __** **Sexo: __ (V/M)**

1. Titular y proveedor del SFT
2. Regente y proveedor del SFT
3. Sustituto y proveedor del SFT
4. Farmacéutico adjunto y proveedor del SFT

Índice de adherencia del Servicio de Seguimiento Farmacoterapéutico (SFT)

Como parte del proyecto de investigación conSIGUE estamos muy interesados en conocer su opinión sobre la implantación del **Servicio de Seguimiento Farmacoterapéutico** (**SFT)** en su farmacia y, es por ello que hemos desarrollado una serie de cuestionarios para poder evaluarla. La información que se obtenga será utilizada por los investigadores para poder mejorar el proceso de implantación en el futuro y también repercutirá en su farmacia.

Concretamente, este **índice de adherencia al servicio** tiene como objetivo medir el grado en que los proveedores del servicio se ajustan o adaptan las pautas del servicio.

Para completar el cuestionario, por favor, indique **LA FRECUENCIA** con la que sucede cada una de las siguientes afirmaciones. Tenga en cuenta la frecuencia puede variar de **NUNCA (1) a SIEMPRE (5)**.

		Nunca [1]	Casi nunca [2]	A veces [3]	A menudo [4]	Siempre [5]
OFERTA DEL SERVICIO						
1	Se identifican los pacientes que pueden beneficiarse del servicio.					
2	Se oferta el servicio a los pacientes que pueden beneficiarse del servicio.					
3	Se acuerda la cita para la primera entrevista con los pacientes.					
4	Se solicita a los pacientes que traigan a la primera entrevista todos los medicamentos que tienen en casa.					
5	Se solicita a los pacientes que traigan a la primera entrevista los informes médicos que posean.					
6	Se solicita a los pacientes que traigan a la primera entrevista los parámetros que posea.					
PRIMERA ENTREVISTA						
7	Se identifican todos los problemas de salud del paciente.					
8	Se recaba información sobre el grado de control de los problemas de salud identificados.					
9	Se solicita información adicional (diagnósticos, parámetros clínicos, etc.) cuando es necesario para identificar y/o conocer el control los problemas de salud de mejor forma.					
10	Se registran todos los medicamentos de prescripción médica que utiliza el paciente.					
11	Se registran todos los medicamentos de indicación farmacéutico o automedicación que utiliza el paciente.					
12	Se recaba información sobre el uso que hacen los pacientes de sus medicamentos (dosis, indicaciones, pauta, adherencia, forma de administración etc.).					

		Nunca [1]	Casi nunca [2]	A veces [3]	A menudo [4]	Siempre [5]
ESTADO DE SITUACIÓN						
13	Todos los problemas de salud y medicamentos actuales del paciente se registran en el estado de situación.					
14	Se ha registrado toda la información relativa a los medicamentos (fecha, pauta etc.).					
15	Se ha registrado toda la información relativa a los problemas de salud (fecha, control etc.).					
16	Los problemas de salud no tratados farmacológicamente y/o los medicamentos sin problema de salud asociado a su uso también se registran en el estado de situación.					
FASE DE ESTUDIO						
17	Se plantean las dudas que surgen en relación a la situación clínica de los pacientes.					
18	Se resuelven las preguntas clínicas planteadas utilizando fuentes de información apropiadas para ello.					
19	Se identifican aquellas intervenciones que potencialmente pueden mejorar los resultados en salud de los pacientes.					
20	Se identifica información sobre el uso y administración de los medicamentos de los pacientes.					
FASE DE EVALUACIÓN						
21	Se evalúa la necesidad, efectividad y seguridad de cada uno de los medicamentos de los pacientes.					
22	Se identifican los PRM que podrían ser causa de un mal control de los problemas de salud.					
23	Se elaboran listados de los RNM identificados.					
FASE DE INTERVENCIÓN						
24	Se establecen una serie de objetivos para mejorar y/o preservar el estado de salud del paciente o evitar posibles riesgos.					
25	Los objetivos se priorizan según la situación particular y necesidades del paciente.					
26	Se planifican intervenciones para conseguir los objetivos planteados.					
27	Se programan varias intervenciones en el tiempo (a corto, medio y largo plazo).					
28	Se realiza educación al paciente sobre sus problemas de salud y medicamentos siempre que es necesario.					
29	Las intervenciones planificadas son realizadas con el correspondiente destinatario (ej. paciente, médico, etc.)					
30	Todas las intervenciones (incluido su aceptación y resultado final) se registran mediante algún sistema destinado a ello.					

		Nunca [1]	Casi nunca [2]	A veces [3]	A menudo [4]	Siempre [5]
ENTREVISTAS SUCESIVAS						
31	Tras las correspondientes intervenciones se programan citas con el paciente para comprobar su evolución.					
32	Se obtiene la información sobre la aceptación de las intervenciones por parte del destinario (paciente, médico, etc.).					
33	Se obtiene la información sobre el resultado (en salud) de las intervenciones					
34	El plan de actuación establecido para cada paciente se va modificando en base al resultado de las intervenciones y evaluación del paciente en el tiempo.					
35	Se reevalúa el estado de salud del paciente de forma periódica.					
36	Cuando el paciente presenta un cambio en su estado de salud o en su medicación, se fija una visita para comprobar la situación.					
ASPECTOS GENERALES SOBRE EL PROCESO						
37	Se obtiene el consentimiento informado del paciente					
38	El proceso del servicio se sigue de forma ordenada.					
39	Se documentan las actividades conforme se realizan las distintas etapas del servicio.					

Appendix S2

Cuestionario a completar por el farmacéutico proveedor

Código de la provincia: __ __ **Código de la farmacia: __ __** **Fecha: __ /__/__**

Tipo de empleado: __ (1-4) **Años de trabajo en esta Farmacia: __ __** **Edad: __ __** **Sexo: __ (V/M)**

1. Titular y proveedor del SFT
2. Regente y proveedor del SFT
3. Sustituto y proveedor del SFT
4. Farmacéutico adjunto y proveedor del SFT

Escala de receptividad del paciente

Como parte del proyecto de investigación conSIGUE estamos muy interesados en conocer su opinión sobre la implantación del **Servicio de Seguimiento Farmacoterapéutico** (**SFT)** en su farmacia y, es por ello que hemos desarrollado una serie de cuestionarios para poder evaluarla. La información que se obtenga será utilizada por los investigadores para poder mejorar el proceso de implantación en el futuro y también repercutirá en su farmacia.

Concretamente, esta **escala de receptividad del paciente** tiene como objetivo medir la percepción del paciente sobre el servicio, valorando su aceptación, entusiasmo y compromiso.

Para completar el cuestionario, por favor, indique **LA FRECUENCIA** con la que sucede cada una de las siguientes afirmaciones. Tenga en cuenta la frecuencia puede variar de **NUNCA (1) a SIEMPRE (5)**.

		Nunca [1]	**Casi nunca [2]**	**A veces [3]**	**A menudo [4]**	**Siempre [5]**
1	Los pacientes demandan el servicio.					
2	Los pacientes aceptan recibir el servicio.					
3	Los pacientes responden a las preguntas del farmacéutico.					
4	Los pacientes toman la iniciativa de formular preguntas al farmacéutico.					
5	Los pacientes aportan información sobre todos los medicamentos que utilizan (ej. botiquín con medicamentos, hoja de tratamientos actual, etc.).					
6	Los pacientes aportan parámetros clínicos recientes (ej. cifras de presión arterial, analíticas) e informes médicos sobre sus problemas de salud (ej. diagnósticos médicos).					
7	Los pacientes participan activamente durante los encuentros con el farmacéutico.					
8	Los pacientes colaboran en la realización del plan de acción y en la priorización de las intervenciones					
9	Los pacientes manifiestan abiertamente sus preocupaciones respecto a sus problemas de salud y tratamientos farmacológicos.					
10	Los pacientes cumplen con las intervenciones propuestas por el farmacéutico.					
11	Cuando las intervenciones están orientadas a cambiar la estrategia farmacológica (dosis, pauta, cambio de medicamentos, etc.) los pacientes cumplen con ellas					
12	Cuando se realiza educación al paciente (ej. uso de los medicamentos, promoción de la adherencia, medidas no farmacológicas), los pacientes cumplen las intervenciones.					
13	Los pacientes acuden al médico cuando el farmacéutico los deriva.					
14	Los pacientes mantienen al farmacéutico informado de cualquier cambio en su medicación y/o en su estado de salud.					
15	Durante el servicio, los pacientes acuden a las citas programadas por el farmacéutico.					
16	A través de otras personas (familiares, amigos de los pacientes) puedo darme cuenta de que los pacientes hablan positivamente del servicio.					

Appendix S3

Cuestionario a completar por el farmacéutico proveedor

Código de la provincia: __ __ **Código de la farmacia: __ __** **Fecha: __ /__/__**

Tipo de empleado: __ (1-4) **Años de trabajo en esta Farmacia: __ __** **Edad: __ __** **Sexo: __ (V/M)**

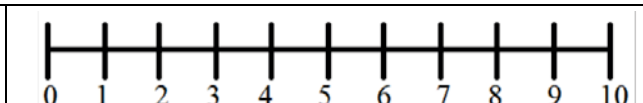
1. Titular y proveedor del SFT
2. Regente y proveedor del SFT
3. Sustituto y proveedor del SFT
4. Farmacéutico adjunto y proveedor del SFT

Índice de adherencia del Servicio de Seguimiento Farmacoterapéutico (SFT)

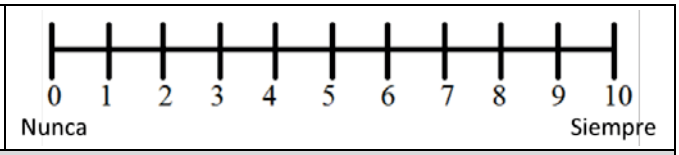
Como parte del proyecto de investigación conSIGUE estamos muy interesados en conocer su opinión sobre la implantación del **Servicio de Seguimiento Farmacoterapéutico** (**SFT)** en su farmacia y, es por ello que hemos desarrollado una serie de cuestionarios para poder evaluarla. La información que se obtenga será utilizada por los investigadores para poder mejorar el proceso de implantación en el futuro y también repercutirá en su farmacia.

Concretamente, este **índice de adherencia al servicio** tiene como objetivo medir el grado en que los proveedores del servicio se ajustan o adaptan las pautas del servicio.

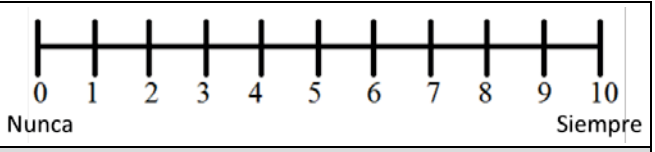
Para completar el cuestionario, por favor, indique con un número de cero a diez **LA FRECUENCIA** con la que sucede cada una de las siguientes afirmaciones, si cero representa nunca y diez representa siempre.

												
OFERTA DEL SERVICIO												
1	Se identifican los pacientes que pueden beneficiarse del servicio.	0	1	2	3	4	5	6	7	8	9	10
2	Se oferta el servicio a los pacientes que pueden beneficiarse del servicio.	0	1	2	3	4	5	6	7	8	9	10
3	Se acuerda la cita para la primera entrevista con los pacientes.	0	1	2	3	4	5	6	7	8	9	10
4	Se solicita a los pacientes que traigan a la primera entrevista todos los medicamentos que tienen en casa.	0	1	2	3	4	5	6	7	8	9	10
5	Se solicita a los pacientes que traigan a la primera entrevista los informes médicos que posean.	0	1	2	3	4	5	6	7	8	9	10
6	Se solicita a los pacientes que traigan a la primera entrevista los parámetros que posea.	0	1	2	3	4	5	6	7	8	9	10
PRIMERA ENTREVISTA												
7	Se identifican todos los problemas de salud del paciente.	0	1	2	3	4	5	6	7	8	9	10
8	Se recaba información sobre el grado de control de los problemas de salud identificados.	0	1	2	3	4	5	6	7	8	9	10
9	Se solicita información adicional (diagnósticos, parámetros clínicos, etc.) cuando es necesario para identificar y/o conocer el control los problemas de salud de mejor forma.	0	1	2	3	4	5	6	7	8	9	10
10	Se registran todos los medicamentos de prescripción médica que utiliza el paciente.	0	1	2	3	4	5	6	7	8	9	10
11	Se registran todos los medicamentos de indicación farmacéutico o automedicación que utiliza el paciente.	0	1	2	3	4	5	6	7	8	9	10
12	Se recaba información sobre el uso que hacen los pacientes de sus medicamentos (dosis, indicaciones, pauta, adherencia, forma de administración etc.).	0	1	2	3	4	5	6	7	8	9	10

Cuestionario a completar por el farmacéutico proveedor

												
ESTADO DE SITUACIÓN												
13	Todos los problemas de salud y medicamentos actuales del paciente se registran en el estado de situación.	0	1	2	3	4	5	6	7	8	9	10
14	Se ha registrado toda la información relativa a los medicamentos (fecha, pauta etc.).	0	1	2	3	4	5	6	7	8	9	10
15	Se ha registrado toda la información relativa a los problemas de salud (fecha, control etc.).	0	1	2	3	4	5	6	7	8	9	10
16	Los problemas de salud no tratados farmacológicamente y/o los medicamentos sin problema de salud asociado a su uso también se registran en el estado de situación.	0	1	2	3	4	5	6	7	8	9	10
FASE DE ESTUDIO												
17	Se plantean las dudas que surgen en relación a la situación clínica de los pacientes.	0	1	2	3	4	5	6	7	8	9	10
18	Se resuelven las preguntas clínicas planteadas utilizando fuentes de información apropiadas para ello.	0	1	2	3	4	5	6	7	8	9	10
19	Se identifican aquellas intervenciones que potencialmente pueden mejorar los resultados en salud de los pacientes.	0	1	2	3	4	5	6	7	8	9	10
20	Se identifica información sobre el uso y administración de los medicamentos de los pacientes.	0	1	2	3	4	5	6	7	8	9	10
FASE DE EVALUACIÓN												
21	Se evalúa la necesidad, efectividad y seguridad de cada uno de los medicamentos de los pacientes.	0	1	2	3	4	5	6	7	8	9	10
22	Se identifican los PRM que podrían ser causa de un mal control de los problemas de salud.	0	1	2	3	4	5	6	7	8	9	10
23	Se elaboran listados de los RNM identificados.	0	1	2	3	4	5	6	7	8	9	10
FASE DE INTERVENCIÓN												
24	Se establecen una serie de objetivos para mejorar y/o preservar el estado de salud del paciente o evitar posibles riesgos.	0	1	2	3	4	5	6	7	8	9	10
25	Los objetivos se priorizan según la situación particular y necesidades del paciente.	0	1	2	3	4	5	6	7	8	9	10
26	Se planifican intervenciones para conseguir los objetivos planteados.	0	1	2	3	4	5	6	7	8	9	10
27	Se programan varias intervenciones en el tiempo (a corto, medio y largo plazo).	0	1	2	3	4	5	6	7	8	9	10
28	Se realiza educación al paciente sobre sus problemas de salud y medicamentos siempre que es necesario.	0	1	2	3	4	5	6	7	8	9	10
29	Las intervenciones planificadas son realizadas con el correspondiente destinatario (ej. paciente, médico, etc.)	0	1	2	3	4	5	6	7	8	9	10
30	Todas las intervenciones (incluido su aceptación y resultado final) se registran mediante algún sistema destinado a ello.	0	1	2	3	4	5	6	7	8	9	10

Cuestionario a completar por el farmacéutico proveedor

												
ENTREVISTAS SUCESIVAS												
31	Tras las correspondientes intervenciones se programan citas con el paciente para comprobar su evolución.	0	1	2	3	4	5	6	7	8	9	10
32	Se obtiene la información sobre la aceptación de las intervenciones por parte del destinario (paciente, médico, etc.).	0	1	2	3	4	5	6	7	8	9	10
33	Se obtiene la información sobre el resultado (en salud) de las intervenciones	0	1	2	3	4	5	6	7	8	9	10
34	El plan de actuación establecido para cada paciente se va modificando en base al resultado de las intervenciones y evaluación del paciente en el tiempo.	0	1	2	3	4	5	6	7	8	9	10
35	Se reevalúa el estado de salud del paciente de forma periódica.	0	1	2	3	4	5	6	7	8	9	10
36	Cuando el paciente presenta un cambio en su estado de salud o en su medicación, se fija una visita para comprobar la situación.	0	1	2	3	4	5	6	7	8	9	10
ASPECTOS GENERALES SOBRE EL PROCESO												
37	Se obtiene el consentimiento informado del paciente	0	1	2	3	4	5	6	7	8	9	10
38	El proceso del servicio se sigue de forma ordenada.	0	1	2	3	4	5	6	7	8	9	10
39	Se documentan las actividades conforme se realizan las distintas etapas del servicio.	0	1	2	3	4	5	6	7	8	9	10

Ethics Approval

Chapter 7

- Ethics Approval: Research Centre of Granada Ethics Committee (Comité de Ética de la Investigación de Centro de Granada, Consejería de Salud – Servicio Andaluz de Salud)

D. Miguel Ángel Calleja Hernández Secretario del Comité de Ética de la Investigación de Centro de Granada (CEI-GRANADA)

CERTIFICA

Que este Comité ha analizado la propuesta de el Grupo de Atencion Farmaceutica de la Universidad de Granada (Dr. Fernando Martínez Martínez) de enmienda,por extensión del proyecto de investigacion titulado: " Medida del Impacto clinico, economico y humanistico del Seguimiento Farmacoterapeutico en Pacientes Polimedicados aprobado el 25/11/09 por el CEIC del HUVN, para que se realice el proyecto titulado: "Programa para la implantación y futura sostenibilidad del Servicio de Seguimiento Farmacoterapéutico en la farmacia comunitaria española" y considera que:

Se cumplen los requisitos necesarios de idoneidad del proyecto en relación con los objetivos del estudio.

La capacidad del investigador y los medios disponibles son apropiados para llevar a cabo el estudio.

Entendiendo que dicho estudio se ajusta a las normas éticas esenciales y criterios deontológicos que rigen en este centro.

Y que este Comité acepta que dicho estudio sea realizado por los Dres Mª Jose Faus Dáder y Fernando Martínez Martínez junto con el Grupo de Investigacion en Atención Farmaceutica como investigadores principales en el mismo y colaboradores.

Lo que firmo en Granada a veinte de diciembre de dos mil trece.

Dr. Miguel Angel Calleja Hernández

Firmado:

CONSEJERÍA DE SALUD
Consejería de Salud
Comité de Ética de la Investigación
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D. Miguel Ángel Calleja Hernández Secretario del Comité de Ética de la Investigación de Centro de Granada (CEI-GRANADA)

CERTIFICA

Que este Comité ha analizado la propuesta del Grupo de Atención Farmacéutica de la UGR (Dr. Fernando Martínez Martínez) para que se realice la modificación por ampliación de obtención de datos relativos al proyecto *"Programa de implantación y futura sostenibilidad del Servicio de Seguimiento Farmacoterapeutico en la farmacia española comunitaria"* que fue evaluado favorablemente por este Comité con fecha 20 de diciembre de 2013 y considera que:

Se cumplen los requisitos necesarios de idoneidad del proyecto en relación con los objetivos del estudio por lo que puede llevarse a cabo dicha modificación.

Entendiendo que dicho estudio se ajusta a las normas éticas esenciales y criterios deontológicos que rigen en este centro.

Lo que firmo en Granada a dieciséis de febrero de dos mil quince.

Dr. Miguel Ángel Calleja Hernández

CONSEJERÍA DE SALUD Granada Comité de Ética de la Investigación Servicio Andaluz de Salud

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Chapter 8

Discussion and conclusions

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Discussion

This thesis introduces, synthesises, analyses and augments the field of implementation science and subsequently contextualises and applies the knowledge to pharmacy practice, specifically to area of implementing professional services in community pharmacy. The work builds on previous research that developed and evaluated the impact and outcomes of professional pharmacy services as well as research that has investigated professional pharmacy service implementation through other conceptual lenses, such as change management and organisational flexibility. The compilation of works addresses the specific objectives of the research and in doing so lays a sound theoretical and experimental foundation from which implementation research may be conducted and implementation programs developed for the introduction and integration of services into community pharmacy practice.

As implementation frameworks vary, it is valuable for researchers, policymakers, health administrators, and practitioners to have guidance of the basic components required for their implementation efforts. The systematic review of the implementation literature saw variation across implementation frameworks. Consequently, the core concepts observed, were collated as a generic implementation framework (chapter 4). Implementation was summarised as involving: (1) an innovation, (2) a multi-level context, (3) a complex multi-stage process, influenced by a range of (4) factors (5) strategies (6) and evaluations (formative and summative).

A qualitative study was performed to contextualise implementation science concepts to pharmacy and gain a deep understanding of the current implementation processes and influences (chapter 5). Qualitative methods were used as they are intended to identify subjective meanings and generate explanations (Pope 2006). The interview data was analysed using framework thematic analyses which allowed examination across cases, as well as thematically. The resulting Framework for the Implementation of Services in Pharmacy contextualises and operationalises the concepts of the Generic Implementation Framework by defining the innovation as a professional pharmacy service, delineating the implementation process, outlining the contextual domains, and beginning to demarcate sub-models for the factors, strategies and evaluation elements. The framework appears to be a practical base for implementation programs and protocols and well understood by a range of pharmacy stakeholders. Subsequent appraisal of the framework depends on its utility. This may be assessed by evaluating programs that were based on the framework, and if they induced the desired implementation outcome. In other words implementation programs may be validated, which in turn evaluates the framework (Rycroft-Malone & Bucknall 2010). Currently the framework is being applied in Australia (Garcia-Cardenas 2015; Roberts et al. 2015), and Spain (Moullin, Sabater- Hernández & Benrimoj 2014), to develop mixed methodology, hybrid design implementation protocols and programs.

The difference between theories, models and frameworks is pertinent. Theories are generally specific and predictive, with directional relationships between concepts, and therefore suitable for hypothesis testing and validation (Rycroft-Malone & Bucknall 2010). Models are similarly narrow in scope, however are more often prescriptive, for example delineating a series of steps. Frameworks on the other hand are explanatory or

descriptive covering the range and relationships between concepts involved in a phenomenon, such as implementation. As such, the GIF and FISpH do not predict successful implementation, but rather are frameworks to assist in the selection of meta-frameworks, models or theories for its constituent concepts. Evaluating the framework depends fundamentally on its use, the quality depends on measuring whether its use in developing a program induces the desired outcome of implementation. The concepts of the FISpH investigated were the implementation process (stages and steps), adjusted CFIR list, and the model for evaluation. It is these sub-models that may facilitate the development of implementation research questions.

A definition was sought for the innovation of interest, professional pharmacy services (chapter 3). The definition was organised by process, structure, and outcomes to facilitate coordinated identification, implementation and evaluation of services. As identified in later works, implementation evaluation is an issue within pharmacy practice. Use of the definition in combination with implementation measurements, such as fidelity, may assist in the determination of the core structural and process components of services. Subsequently this may reduce implementation burden, whilst simultaneously assisting in value assessment. In addition, to assist with the implementation of existing, established services, the characteristics of the new, yet to be defined services should be considered right from the beginning, in the development stage. Multiple stakeholders should be involved in the development, co-creation or co-production, to improve implementabilility, achieve support and buy-in, and subsequently enhance implementation across all contextual domains (Kitson et al. 2013).

Professional pharmacy services were placed within an overall model of pharmacy services to support a holistic understanding of the role and value community pharmacy provides as part of the healthcare system (chapter 3). Moreover a value assessment of services may promote support at a political level and from other healthcare professional organisations, a factor known to affect implementation and sustainability (Schell et al. 2013).

Implementation as a process is the crux of implementation science. Implementation has been included in frameworks for decades, however was often labelled as a single step or event. Quality improvement, organisational change or program planning for examples all include a step titled “implementation”, without tools to guide the process, formal approach to facilitate the introduction or integration of the innovation or methods to adapt the innovation to other situations and contexts. This simplification and lack of evidence of “how” to operationalise the implementation step, is attributed as one of the reasons for past struggles and implementation failure (Wandersman et al. 2008). Implementation science voice the process as sufficiently long to be divided into multiple stages and steps and sufficiently complex to warrant a research discipline. The process as defined in this research includes that at each stage, factors or determinants hindering or enabling the forward movement through the process should be assessed, strategies accordingly applied and indicators of process, impact and outcomes evaluated (formative and summative). In addition implementation programs following the framework would incorporate the steps identified in the qualitative study (chapter 5).

The importance of context is recognised in implementation science and knowledge translation. The factors, strategies and evaluations that influence the implementation of one innovation or service will vary from between

settings and individuals. Contextual considerations and subsequent adaptations of the service and implementation program will need to occur for different countries, different provinces/states within the same country, different pharmacies within the same region and even for different staff members within the same pharmacy. Individual staff members, even within a pharmacy, have different personalities, attitudes, knowledge, skills, experience etc. Pharmacies vary in size, business orientation, vision, etc. The demographics of the patient population, community and opinion of other healthcare practitioners vary in the local setting surrounding pharmacies as do the political, economic situations and professional organisations capability and capacity. Moreover, there is a complex web of interrelationships between each of these contextual domains which influence the overall environment and thus implementation outcomes. This research used the experiences from Australia to develop the foundations of a pharmacy implementation framework, which is now being applied, to evaluate the cross-cultural and contextual applicability internationally, through the development of implementation programs and tools in both Australia (Garcia-Cardenas 2015; Roberts et al. 2015) and Spain (Moullin, Sabater-Hernandez & Benrimoj 2014).

The factor and strategy elements of the framework are deserving of further study. There is a fairly large base of research on implementation barriers and facilitators, but these determinants have not been explored across the implementation stages nor have they been targeted by tailored strategies. An analysis of factors at across the stages of implementation could be incorporated as part of future implementation programs and/or research, allowing implementation strategies to be selected for the factors at every implementation stage. Interestingly environmental stressors (such as lack of time), a barrier that has arisen in previous research (Roberts et al. 2008), was mentioned more in smaller pharmacies, compared to pharmacies with a greater number employee pharmacists. Similarly the relationship and communication with local doctors did arise, but was less prevalent than in previous studies (Roberts et al. 2005). This may be explained by the lower level of multidisciplinary coordination required for the most recently implemented services in Australia, in particular MedsChecks. It also indicates how components of implementation will vary for different services/innovations, and therefore implementation programs need to involve assessment of implementation factors and strategies tailored accordingly. The external system arose as an influence on integration and sustainability, and logically would have impacted the initial availability and funding for the service. As the service had funding available, and therefore a degree of political support, this did not appear as a theme, however the sustainability literature would suggest this is an overarching driver (Kaae et al. 2009; Schell et al. 2013). An investigation into the degree of influence of each factor would be useful with a more detailed and specific interview guide tailored to the list of factors.

During each stage, at each step of the implementation process, implementation strategies are necessary. The initial look at implementation strategies shows that the list by Powell et al (2015) will be useful for further investigation in future implementation studies as well as in implementation program development (chapter 5). A large number of strategies could be coded to the interviews, however they were often loosely used, and by only one pharmacy. Strategies should be named, defined and specified/operationalised in sufficient detail for evaluation and replication. For example, during training, what 'type' of training and 'how' the training will be/was conducted, what is the 'target of the action' etc. (Proctor, Powell & McMillen 2013). Studying the effectiveness of

implementation strategies to develop evidence based implementation programs for professional pharmacy services and developing or using theory that links implementation strategies to determined implementation factors, are areas for future research.

Implementation strategies, employed by pharmacies to aid adoption and integration, varied widely. Most common strategies were conducting education meetings, distributing education materials, increasing demand and reminding clinicians. Strategies involved all domain levels, although the strategies not utilised were largely related to the external system, such as changing liability laws, identifying early adopters and opinion leaders, and starting a dissemination organisation. This lack of strategies seen at the external system level may be because the interviews did not include strategists, or may indicate a true gap in strategies at the system level and thus should be considered in future implementation efforts. As a consequence of these results, the project in Spain developed using the FISpH, has incorporated strategies across all contextual levels (Moullin, Sabater-Hernandez & Benrimoj 2014). By increasing the level of knowledge and buy-in the aim is to improve the ability to sustain the service and scale-up its provision across the profession.

For the final chapters of the research, the remaining implementation concept of the FISpH, evaluation, was contemplated. A lack of implementation evaluation and systems for quality monitoring is seen in both the qualitative study and published literature (Chaudoir, Dugan & Barr 2013). Evaluations serve multiple purposes in the implementation process. For example, implementation evaluation may be used to influence the implementation process by being used as part of quality improvement cycles to assess small incremental changes (Institute for Healthcare Improvement 2003) or formative evaluations of fidelity for service optimisation and adaptation (French et al. 2015; Stetler et al. 2006). An important message from the evaluation model (chapter 6), is that implementation indicators should not only be included when conducting implementation research, but also involved as intermediate outcomes in service evaluations. A second implication is that an overall level of implementation may be visualised, in alignment with the model of pharmacy services presented in chapter 3. The use of the evaluation model may enable a pharmacist, pharmacy or group of pharmacies, or pharmacy network (system) to be assessed and subsequently differentiated on the number, type and level of their service implementation. An aspiration for community pharmacy is to be appropriately recognised as providers not only of products but also providers of professional services.

To apply the evaluation model tools are needed for the implementation indicators. Two fidelity tools were developed and are in various points of the accumulative validation process (chapter 7). The development of such tools will facilitate an increase in data management and monitoring at a pharmacy level (as shown lacking in the qualitative interviews, chapter 5), and quality assurance at profession level, to alleviate concerns raised at policy level (such as those presented in the audit in Australia of professional service administration in community pharmacy) (Australian National Audit Office 2015). Further tools are required for other components of fidelity as well as other implementation indicators. As part of the study being conducted in Spain that applied this research, a tool to measure service integration is being developed.

Methodological reflections and limitations

Multiple methodologies were employed across the thesis to explicate facets of implementation and to develop, test and evaluate the implementation framework, models and tools. Furthermore, studies were set in both Australia and Spain to increase the generalisability of the results and to develop a framework that has international application. Australia and Spain are at different positions along the implementation pathway and approaching the move into services in fundamentally different ways. While Australia has remuneration, it lacks a coherent service portfolio and plan. Spain on the other hand, is still pushing for political acceptance and remuneration, but already has a sound theoretical foundation for services.

Medication reviews appear to be one of, if not the most widely investigated professional pharmacy service. Therefore by using medications reviews as a base, the research aimed to be applicable in other countries that provide medication review services. In Australia, the number of MedsChecks was used to sample pharmacies for the qualitative study, and in Spain, medication review with follow-up was used to develop implementation tools and an implementation program. It would also be proposed that the results are generalisable to other services, as considerable implementation theory is shared between diverse disciplines and innovations. A wide range of pharmacy services are being introduced around the world, professional and non-professional, provided by pharmacists and other healthcare professionals, and related to medications or other healthcare issues (chapter 3). Professional pharmacy services were chosen as the innovation of interest to demonstrate to stakeholders the full value offered by pharmacy, both services by pharmacists and other healthcare professionals. In reality, the focus of pharmacy based implementation research is currently on pharmacist delivered services, both pharmaceutical and other healthcare services.

The central theoretical underpinning of the thesis was implementation science. A range of suppositions from implementation science were included: the iterative, complex multi-stage process, the ecological model in the multi-level interacting contextual domains and the influences on change, in terms of factors, strategies and evaluations. Implementation science provides a logical conceptual base as it is a new field developed to tackle the issues of implementation holistically. The holistic nature and early development of the implementation science disciple is its strength, but also is a limitation. Implementation may be approached in many ways, and the journey may begin at many stages along the evidence pathway. Implementation science considers this and exploits multiple change theories to provide an overarching lens to investigate the introduction and integration of innovations. Implementation science attempts to investigate and build evidence of the implementation part of the evidence pathway and thus subsequently enhance research impact by increasing its translation into practice. However, it needs to be considered that complete theories are built on small sections of the implementation process or single implementation concepts and therefore trying to use one holistic framework, model or theory may not be feasible (chapter 4). All the implementation frameworks, models and theories are useful depending on the research question and objectives. As such, the FISpH is designed to present the big picture. Within the framework each concept requires a specific model or theory, such as the developed stages and steps of the implementation process, list of implementation factors, system for selecting strategies and model of evaluation.

To attain an overview of the current implementation literature a systematic review methodology was chosen (chapter 4). A systematic approach, versus a narrative approach, has both advantages and disadvantages. Narrative reviews are considered appropriate for summarising and synthesising the literature to draw conclusions about "what we know" about the subject. Narrative reviews yield qualitative results, with strengths in capturing diversities and pluralities of understanding (Jones 2004). The methods of narrative reviews, however do not allow for replication or future additions to the study (Rother 2007). The literature review was undertaken to investigate the comprehensiveness of implementation frameworks, in order to aid the selection of theoretical framework(s) when designing implementation studies of professional pharmacy services. A narrative literature review was conducted at a similar time to the systematic review of this research (Nilsen 2015) and drew similar conclusions of the state of implementation theories. This independent research using different methods provides convergent evidence of the range of implementation frameworks, models and theories in the field as presented in the Generic Implementation Framework (GIF).

Qualitative methods were used to explore implementation steps and influences at each stage of the implementation process (chapter 5). A wide range of stakeholders affect pharmacies and influence the implementation of professional services. Stakeholders include government policy-makers and funders, professional organisations board members and employees, patients and community members, pharmacy owners and pharmacy employees, and researchers. The perspective and opinion of each of these stakeholders is important. Their input would influence each stage of the implementation process and the factors, strategies and evaluations that should be incorporated into sub-models of the framework. The qualitative study involved semi-structured interviews with pharmacists only, and therefore it is important to bear in mind the results are from pharmacists' perspective. A second methodological consideration is the urban Australian community pharmacy setting. As deliberated earlier, consideration of the context of implementation is vital for success. Therefore further studies to confirm and/or enhance the delineation of the implementation process and exposed influences, in other contexts would be beneficial.

Multiple methodologies were utilised to analyse the qualitative data. Framework analysis was employed for the primary objective, to investigate the process of professional service implementation occurring in practice. This methodology is well suited to implementation research as it facilitates exploration 'across' interview cases and thematically 'down' themes (Pope 2006). Analysis was both deductive (using the implementation stages as themes) and inductive (open-coding for reoccurring steps, influences and noteworthy ideas of interest). The secondary objective was to assess over the course of this process the factors, strategies and evaluations. The data was thematically analysed, using established implementation frameworks for the codes, of the corresponding element. The CIFR was inductively modified based on the data (chapter 5). As discussed, these secondary analyses produced appealing results that warrant further investigation.

A model of implementation evaluation was developed, theoretically based on health services and implementation literature, particularly literature of implementation evaluation, outcomes and tools (chapter 6). Information should to be gathered on pharmacies present implementation status to determine areas requiring work. Strategies

may then be put in place improve the implementation indicators and increase implementation and service provision.

The final study in this thesis entailed the development of two implementation tools, to measure components of the implementation outcome, fidelity (chapter 7). The tools may be used longitudinally for formative evaluations and for summative evaluations. The adherence index consisted of process items for the medication review with follow-up service being implemented in Spain. A separate tool to assess capacity, context and support (structural items) would be beneficial. The timing of administration was at six months, which is considered early in the implementation process, future administration at more distant time-points, correlation to external variables and observation would also be recommended. The patient responsiveness scale had reliability, acceptability, content and construct validity tested. The tool was designed to be completed by the pharmacist providing the service, but it would be reasonable to further test this tool against a patient administered questionnaire to check response process validity. The tools were developed in Spain in Spanish, for the SFT service (medication review with follow-up). The patient responsiveness scale may be applied to other medication review services (after back translation). Adherence indices however, are by nature only for the service in which they are developed as they delineate the process of providing the service. It may be possible in the future once core components of services are established that these are validated across a range of medication review services.

The works have a shared limitation in the data collection, synthesis and analysis, in that all studies were conducted by a single researcher. In particular it is possible for a qualitative study to be affected by this limitation, as multiple researchers are needed for interviewer and analysis triangulation, to support results being grounded in data and reduce the risk of bias being introduced. Procedures were put in place in each of the three principal studies to minimise the impact and ensure rigor: Systematic review definitions for data extraction were developed to minimise uncertainties (chapter 4); In the qualitative study co-authors were provided with the interview data to check the findings and discussion were substantiated (chapter 5); For the tool development an expert panel was used to gather an item pool and validate the content and for the analysis of the questionnaire responses an external statistician confirmed the procedure used and solutions obtained (chapter 7).

A final reflection across the research is the terminology used by the different disciplines, implementation science, knowledge translation and pharmacy practice. Pharmacy practice research has largely used medical, clinical terminology. For example, interventions would be referring to clinical interventions that target patients, and determinants usually refer to behaviours of the patient or other influences that impact their health. In implementation science however the term interventions refers to the interventions that target the providers of the service or the service environment (i.e. implementation strategies), and determinants are those of practitioners' practice (i.e. implementation factors). Similarly, in pharmacy practice research, impact evaluation usually refers to changes in patients' determinants of health, their health, and subsequent economic, clinical or humanistic outcomes. In implementation science, impact evaluation refers to assessing the influences/determinants affecting implementation, such as improved knowledge of the service, skills, organisational culture etc. and then implementation outcomes. Introducing the terminology of implementation is

an issue for pharmacy, as well as in other disciplines. It is important for pharmacy practice researchers conducting implementation research or including implementation factors, strategies or evaluations in their studies to try to be clear and consistent with terms chosen. To try and encourage consistency from the onset, a number of typologies were developed and the definitions assumed for the research were included with each study.

Implications: policy, professional practice, economic and research

For almost twenty years concerns have been voiced regarding the translation and implementation of services into pharmacy practice (Dader Faus 1999; Farris et al. 1999; Odedina et al. 1996). This concern has been investigated from a number of theoretical perspectives, however the challenge persists. This thesis investigated the issue through an implementation science lens, which has policy, professional practice, economic and research implications. Research implications are presented, followed by recommendation for future research.

Policy Implications

Internationally policy-makers, at governmental and organisational levels, are increasingly interested in cost-effective, evidence-based, patient-centred professional pharmacy services. The drivers of this interest are equally to save the healthcare system money and to improve patient clinical outcomes, quality of life and the rationale use of medicines. However, as the results of this thesis confirm, the process of implementation is multifaceted and thus require conscientious support throughout the implementation process at the political level and from the professional organisations representing pharmacy. Specific implementation policy research may be warranted (Kaae et al. 2009; Nilsen et al. 2013). The thesis presents the merit of including funding, as part of the overall remuneration provided for services, for implementation research and implementation programs. For example in Spain the FISpH is being used to develop and research an implementation program with the intention that it may be scaled-up to a national level (Moullin, Sabater-Hernandez & Benrimoj 2014).

The qualitative study serves to remind policy-makers, both government and those working for professional pharmacy organisations, of the complexity and time involved in implementation. Political lifecycles and policies are generally short, ranging from three to five years. As a result, government workers and those reliant on government funding, require outcomes, or at least indicators, within this time. In terms of implementation this timeframe is considered short and results achieved in this timeframe may not be valid for integration. Implementation literature states the implementation process is two to four years (Fixsen 2005), information the qualitative study reinforces. An implication for policy is therefore to be contingent of the time required for successful implementation and set realistic targets that will be useful for policy makers, but also allow for long-term sustainable results. One possible solution is developing implementation programs that include organisational readiness and capacity building support. Subsequently when results are required in a short time frame, pharmacies that show 'readiness' may be selectively chosen, while readiness is built in those still in the pre-implementation, exploration and/or preparation stages, to allow for future scale-up.

A fundamental influence revealed in the qualitative study, across all implementation stages, was the importance of support. Support primarily came from the professional body, Pharmacy Guild of Australia, in terms of pharmacies becoming aware of the service, and providing initial training. However the rate of awareness was raised as an issue and therefore professional bodies should consider additional dissemination strategies. In addition, professional bodies may think of developing implementation programs as part of the administration of professional services. These programs should include the stages of implementation and ongoing support, as this has been shown to be crucial for sustainability. If support is not maintained the implementation of future services may be impaired. In Australia implementation programs have primarily involved single implementation strategies, such as training or one off incentive payments for pharmacies to register as service providers. Implementation science, previous pharmacy practice evidence and this research show that this is not sufficient to drive implementation and sustained change. Strategies should be theoretically based and are required across a number of contextual levels and over time. The interviews showed pharmacies were experimenting with a variety of implementation strategies, but they lacked depth and coherence across the industry.

The interviews also showed evaluations were lacking, supporting the findings of the Australian Government audit (Australian National Audit Office 2015). Currently the degree of adoption is the prime measure of implementation used by professional organisations to portray success; however, this does not link to patient or service outcomes. Implementation outcomes, such as reach (including representativeness) and fidelity, should to be added. The model of measurement may be incorporated into policy as a requirement for service providers, audit evaluations and research proposals. Current research proposals submitted for funding should be required to include "impact reporting" that includes implementation evaluation. The tools produced may be of assistance for those working in Spain and may be back-translated, contextualised and then tested for use in Australia and other countries.

Finally, as indicated by the model of pharmacy services (chapter 3), community pharmacy as a network across a country forms a unique part of the healthcare system, that provide a range of services to the communities they serve. Not only are pharmacies providers of pharmaceutical services such as dispensing, counselling and medication management, they also provide or have the capability to provide other healthcare services such as health promotion, vaccination and minor ailment schemes. As an accessible healthcare destination pharmacies may also support services provided by other healthcare professionals in addition to non-professional services that aid the overall quality of care of patients, such as medication delivery. Stakeholders should be aware of the wide service offering provided by pharmacy and support its maintenance, continued improvement, and adaptation of both current and novel pharmacy services to aid their dissemination, implementation and sustainability.

Professional Practice and Economic Implications

Around the world the current scope of pharmacy practice remains heavily focused on medication dispensing and provision. This is despite pharmaceutical care and service delivery being seen as the future of community pharmacy for more than two decades (Carr & Benrimoj 1996; Hepler & Strand 1990). The move to a service provider business model and the introduction and integration of professional pharmacy services is a major role

change for the profession (Martins, van Mil & da Costa 2015; Singleton & Nissen 2014). Without strategic guidance to increase the scope of pharmacy practice, as well as holistic support for the implementation process, successful, wide-spread, sustained implementation is unable to occur.

It is has been acknowledged previously, and was reaffirmed in by this research (chapter 5), community pharmacies are increasingly searching for alternative income streams, to minimise the reliance on product sales and government remuneration. Overall there appears to be a desire to be less reliant on the government, due to reduced and unpredictable healthcare budgets, as well as the industry, due to price fluctuations. In addition pharmacists are aspiring to apply their knowledge and skills and be included in the healthcare team. A more diverse community pharmacy network has resulted from pharmacies choosing different professional and business paths. The Model of Pharmacy Services may be used by pharmacies and pharmacy groups to differentiate, by aiding the adoption decision on which types of services to embrace (chapter 3).

In Australia a large number of independent pharmacies now operate under banner groups. Broad division of banner groups are discount pharmacies and service orientated pharmacies. Initially these groups' primary offer was improved buying power. Over the years the groups offering and vision have diversified. Along with improved purchasing terms groups now offer business support, and increasingly service implementation assistance. Many groups develop their own services and provide service support such as resources, training materials, on-site coaches/facilitators, and marketing and advertising to improve both staff and community perception of the pharmacies and their services on offer. The importance of the support offered by pharmacy groups (as well as any other external assistance) was apparent in the interview data. Pharmacies that were part of pharmacy groups appeared more knowledgeable of services and aware of government remunerated services earlier. As such the results suggest that independent pharmacies should seek a form implementation support, such as through professional bodies or professional networks, while banner groups should continue to develop their implementation programs. Other key influences, which should be considered at a practice level, were internal communication and staffing arrangements, and impetus and drive, where the owner needed to be supportive of services and their implementation, while orientating the vision of the pharmacy towards service delivery.

As for policy-makers, another implication of this research for pharmacy groups, owners and practitioners, is to understand the complexity of the implementation process and time involved. The FISpH and incorporated models of implementation concepts may support the development of implementation programs, assist in the decision of a timeline for each stage and step, and support the assessment of factors, tailoring of strategies and establishment of suitable evaluations over the course of implementation process. It would be suggested pharmacies should measure success in terms of implementation, business, service and patient outcomes.

Research Implications

The Framework for the Implementation of Services in Pharmacy (FISpH), and its incorporated definitions, models and tools, are useful for guiding the development of implementation programs and protocols. Thus far the research conducted as part of this thesis has been applied in both Australia (Garcia-Cardenas 2015; Roberts et al.

2015) and Spain (Moullin, Sabater-Hernandez & Benrimoj 2014). The implementation programs currently using the FISpH incorporate the stages and a number of the steps, plus implementation strategies, which include assessing factors, and conducting implementation evaluations.

In Spain, a national study used FISpH to develop an implementation program and study protocol for their medication review with follow-up service (Moullin, Sabater-Hernandez & Benrimoj 2014). The implementation study used a hybrid design (Curran et al. 2012), consisting of a 3 month pilot and a 15 month main study. Implementation strategies employed include stakeholder meetings to ensure buy-in from professional organisations at provincial level, interactive training sessions with pharmacy owners and service providers, monthly outreach facilitator visits and the assignment of an internal pharmacy champion to take over control of the implementation effort as implementation progresses. The facilitators' and champions' role included analysing barriers and facilitators and subsequently tailoring interventions to overcome or utilise the realised factors. Outcomes being measured include the movement of pharmacies through implementation stages, service benefits, reach, fidelity and integration.

In addition the sub-models of the implementation framework may be used to create research questions and investigate particular implementation constructs. For this reason the evaluation model is inclusive of indicators of implementation impact along with implementation process and outcome measures. The application of the evaluation model is that across the implementation stages, it may be used to hypothesise and predict implementation success and service and client outcomes with the addition of particular factors or strategies (Proctor et al. 2011). Formative tools looking at implementation activities and factors may be added to aid the implementation process as part of an implementation program.

In summary the Generic Implementation Framework appears to be an applicable base to tailor to pharmacy practice. The consequent Framework for Implementation of Services in Pharmacy is appropriate to develop implementation protocols and programs and is well understood by stakeholders at policy, professional organisation, pharmacy owner and employee staff levels.

Recommendations for future research

The thesis provides a foundation from which pharmacy practice implementation research may be conducted. Firstly, general implementation science principles suggest, researchers should attempt to include policy-makers and other stakeholders (patients, professional organisations, pharmacists and other healthcare professionals) in all phases of the evidence pathway. Additionally during all phases the concepts of implementation should be considered by posing questions such as: Will people adopt? Is the service implementable? Is it sustainable? It is recommended these principles are incorporated more widely in professional pharmacy services research.

Further recommendations are for future research to advance the pharmacy implementation framework, models and tools. The developed Framework for the Implementation of Services in Pharmacy is descriptive. The literature review revealed that in terms of framework 'type' across implementation science there is a lack of predictive and prescriptive frameworks. This may be indicative of a relatively early stage of development for the implementation and knowledge translation fields. As implementation science develops, including within pharmacy, one would expect that new implementation studies will lead to the design and testing of predictive framework hypotheses. Similarly it would be recommended within pharmacy that the models of FISpH's concepts, be used to explore hypotheses.

Although not predictive itself, the FISpH and its sub-models may assist in the developing implementation research questions. Implementation research may focus on whether different implementation strategies will improve implementation process impact or outcome indicators. In addition it is possible to test the relationship between two implementation impact indicators (factors) or the effect an implementation factor has on implementation process, implementation outcome or any service indicator. Finally hypotheses on the effect of implementation outcomes on service outcomes may be tested (Landsverk 2012). These are all questions of implementation and should be accompanied by appropriate study design, tools and analysis. Eventually such testing may lead to the establishment of a theory of implementation for services in pharmacy.

Across the domains, the stages and steps of the implementation framework may be used to plan implementation programs or protocols, while the influencing factors may be used to develop tools, questionnaires or interview guides. A recommendation would be for future research to develop formative tools on the factors and strategies, to aid implementation and assess the rate, completion and importance of the implementation steps. A tool to measure service integration is being developed in Spain. Additional tools are still necessary for the proposed hypotheses testing to be conducted, for different services, in diverse settings. One intention of the evaluation model was to alert policy-makers, evaluators and researchers of the importance of including and where to include implementation measures, as comprehensive evaluation of service, patient and implementation outcomes currently appears to be an issue. It is recommended implementation outcomes, particularly a fidelity assessment to be added to studies of pharmacy services. This will add effectiveness data to the implementation strategies as well as generalisability evidence to the service data.

In the qualitative study different factors appeared to influence different stages of the implementation process. Each stage along the implementation continuum has been studied and many stages have their own frameworks, for example frameworks for diffusion up to the point of adoption (Rogers 2003; Wisdom et al. 2014), or sustainability frameworks (Johnson et al. 2004; Rogers 2003; Scheirer & Dearing 2011; Schell et al. 2013; Slaghuis et al. 2011). However, it is unknown in pharmacy what predicts integration of a service and whether a pharmacy will reach sustainability? Are these the same factors that predict a pharmacy will be an early adopter? Can these factors be targeted as part of the implementation strategy to increase implementation success? Once factors that influence a particular stage are determined these may be related to implementation outcomes (Gaglio, Shoup & Glasgow 2013). Further research, to quantify the factors, determine the relative importance of the indicators at various stages of the implementation cycle using component analysis, and explore the interrelationships using structural equation modelling, would be beneficial to further the evidence of the determinants of pharmacy implementation. One possibility would be to look at services that were implemented in the past and assess the characteristics of those who continue to deliver, as successful implementers. This may then be used to define implementation and determine further indicators.

There have been numerous reviews of implementation barriers and facilitators of professional pharmacy services, as well as a number of frameworks listing implementation factors. Instead of further reviews of factors generally, it is suggested that factor assessments are required for each implementation effort, in each setting, across each contextual domain, to tailor implementation strategies as part of implementation programs. As suggested it would also be recommended that the assessments be repeated at various time points throughout the implementation process. The FISpH demarcates the stages of the process and the contextual domains (the ecological levels) at its core. Other frameworks and theories are then required for the factor, strategy and evaluation elements. It has been noted that the use of theoretical frameworks for interventions targeting pharmacists' behaviour is limited (Patwardhan, Amin & Chewning 2014). This research tailored the Consolidated Framework for Implementation Research (CFIR) for community pharmacy (chapter 5). The original CFIR is in the process of being linked to the Expert Recommendations for Implementing Change (ERIC) list of discrete strategies, which will add the selection of strategies. Another option, as introduced in the background, is the Normalisation Process Theory (NPT), which is a classic theory that may be used to describe the factors that affect the embedding of a practice. The evaluation of the factors using NPT may be repeated throughout the process and the results used formatively. The theory at this stage does not link directly to implementation strategies. A third option would be the Theoretical Domains Framework (TDF) or Behavioural Change Wheel (BCW) to assess factors and then link to Behavioural Change Technique Taxonomy (BCT) to design strategies. Finally a selection of indicators from the model for the evaluation of implementation programs and professional services are needed.

The steps delineated in the qualitative study require evaluation for their importance in the process. An option may be to utilise the stages and steps to develop a tool, similar to the Stages of Implementation Completion (Saldana 2014), for pharmacies. Pharmacies would complete the date they completed steps to keep a track of their progress and rate of progress through implementation. This may then be evaluated to determine which steps are linked to implementation and/or service impact and outcomes.

Finally it would be recommended for pharmacy to begin disentangling the effectiveness of implementation strategies. As with complex clinical interventions with patients, implementation strategies are complex interventions with pharmacists or other stakeholders across the ecological contextual domains. Therefore delineating the core components of implementation strategies is an area requiring attention. A prerequisite for this to occur is for implementation strategies to be recorded and reported in detail as would clinical interventions (Bartholomew et al. 2011; Michie et al. 2009; Proctor, Powell & McMillen 2013). This also will facilitate future replication, comparison and assessment across studies. In addition, different study designs may be necessary to assess the effects of the components of implementation programs and the individual implementation strategies (Brown & Lilford 2006; Craig et al. 2008; Curran et al. 2012; Kane et al. 2014; Landsverk et al. 2011; Leykum et al. 2009; Loudon et al. 2015; Pawson et al. 2005; Rycroft-Malone et al. 2012; Thorpe et al. 2009).

Conclusions

- Professional pharmacy services fit within the overall service offering of a pharmacy described in a model of pharmacy service provision. (chapter 3)

- There is variability in the concepts included and the depth of their exploration within implementation frameworks of diverse innovations in healthcare. Core implementation concepts are collated in the cross-disciplinary, overarching Generic Implementation Framework (GIF). (Chapter 4)

- The core concepts, explored in Australian community pharmacies, resulted in the implementation process of professional pharmacy services being delineated into six broad iterative stages, accompanied by a series of activities. Five overarching influences appeared to be fundamental for successful implementation. In addition a list of implementation factors (barriers and facilitators) has been tailored for the pharmacy profession from an existing framework. Implementation strategies varied widely and lacked profundity. The exploration of the core implementation concepts has laid the foundation of a Framework for the Implementation of Services in Pharmacy (FISpH). (Chapter 5)

- A model for the evaluation of professional pharmacy services has been designed to incorporate indicators of implementation process, impact and outcomes in conjunction with service and patient measures. The level of service implementation can be calculated from the level of service delivery (reach and fidelity) and the level as a service provider (integration and strength of support the service environment). (Chapter 6)

- Two questionnaires to measure fidelity have been developed and tested, as formative and summative evaluation tools to assist the implementation of professional pharmacy services. Specifically, an adherence index and a patient responsiveness scale have been created for a medication review with follow-up service being implemented in Spain. (Chapter 7)

- Application of the framework, models and tools in practice includes the development of implementation programs and implementation research protocols.

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