Doctor - Pharmacist Collaborative Prescribing in a Multidisciplinary Surgical Preadmission Clinic: Expanding the Role of the Preadmission Clinic Pharmacist

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BPharm (Hons)

A thesis submitted for the degree of Doctor of Philosophy at The University of Queensland in 2014
School of Pharmacy
Abstract
Non-medical prescribing has been introduced into several countries, with prescribing privileges being granted to health practitioners other than doctors, including pharmacists. The objectives behind the introduction of this new model of health care have been to create a more flexible system for the prescribing, dispensing and administration of medicines, increase access for the general public to safe and appropriate prescription medications, and to better utilise the skills of the current health workforce.
Current research on non-medical prescribing is predominantly qualitative, with little evidence as to the safety, appropriateness, effectiveness or cost effectiveness of the prescribing. Pharmacist prescribing is yet to be introduced in Australia, and in light of some resistance it is important to ensure that this potential model of care meets expectation, prior to implementation.
The overall aim of this thesis is to evaluate a model of pharmacist prescribing in an elective surgery pre admission clinic (PAC), using the validated National Health Performance Framework (NHPF), which was revised and approved by Australian Ministers in 2009. The framework uses six dimensions to assess how a health system performs; ‘effectiveness’, ‘safety’, ‘responsiveness’, ‘continuity of care’, ‘accessibility’ and ‘efficiency and sustainability’.
A randomised controlled trial was undertaken in PAC, with 400 patients randomised into either the intervention or control arm. Patients in the intervention arm were seen by a nurse, Resident Medical Officer (RMO), anaesthetist and the pharmacist prescriber. The pharmacist was responsible for the taking of a medication history, and prescribing the national inpatient medication chart (NIMC) to reflect the patient’s regular medications and the plan for medications peri operatively. Within the pharmacist’s agreed scope of practice was also the initiation of venous thromboembolism (VTE) prophylaxis, following a risk and contraindication assessment. Patients randomised into the control arm still saw the same four healthcare professionals, including a pharmacist for usual care duties. The prescribing of the medication chart, including VTE prophylaxis, was the responsibility of the Resident Medical Officer (RMO) from the treating surgical team. The primary end point of the study was the safety and accuracy of the NIMC. The secondary end point was the appropriateness of VTE prophylaxis prescribed in clinic.
Medications charts were audited against the medication history and plan for medication peri operatively. Medication charts in the intervention arm contained significantly fewer omissions of regular medications, significantly less prescribing errors involving selection of drug, dose or frequency and significantly fewer orders with at least one component of the prescription missing, incorrect or unclear. VTE risk assessments were documented, and prophylaxis was prescribed, significantly more appropriately in clinic.
The significant differences between arms in omissions of medication prompted an investigation into the appropriate of prescribing, and significance of omissions. A multidisciplinary panel was convened, and assessed the appropriateness of prescribing utilising a validated tool, the Medication Appropriateness Index (MAI). Panel members were asked to rate the appropriateness of medications prescribed, and the significance of medication omissions in terms of potential patient harm or ward inconvenience, from a random 5% sample of patients from the main study. For the appropriateness of prescribing, overall results were the same between arms, as judged by individual panel members. Medication charts in the control arm contained significantly more omissions than in the intervention arm, a number of which were rated by the panel members as having the potential for patient harm or ward inconvenience.

Patient satisfaction was evaluated using a questionnaire containing 12 closed questions on a 5 point Likert scale, which was given to the patient after the pharmacist appointment. The response rate in PAC was 182/200 (91%). Consultation satisfaction was high, and high percentages of patients agreed that they had a plan for medication explained clearly to them, that their understanding of the plan was checked, that any information given was easy to understand, any questions were answered in a way they easily understood, and their concerns about medications were understood. This led to a high percentage of patients that agreed that the pharmacist had helped prepare them for their surgery.

In conclusion, pharmacist prescribing in PAC has been shown to be as safe, effective and appropriate as usual care. Patient perceptions to the model of care appear not be a barrier to implementation. However, this was one pharmacist in one model of care. Future work should focus on the training and education requirements to reliably produce competent and fit for purpose pharmacist prescribers, who can replicate these results across different models of care, and ensure that pharmacists’ skills are utilised to their full potential in the Quality Use of Medicines (QUM).
Declaration by author

This thesis is composed of my original work, and contains no material previously published or written by another person except where due reference has been made in the text. I have clearly stated the contribution by others to jointly-authored works that I have included in my thesis. I have clearly stated the contribution of others to my thesis as a whole, including statistical assistance, survey design, data analysis, significant technical procedures, professional editorial advice, and any other original research work used or reported in my thesis. The content of my thesis is the result of work I have carried out since the commencement of my research higher degree candidature and does not include a substantial part of work that has been submitted to qualify for the award of any other degree or diploma in any university or other tertiary institution. I have clearly stated which parts of my thesis, if any, have been submitted to qualify for another award.
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Contributions by others to the thesis

Professor Lisa Nissen was the principal doctorial academic advisor, Associate Professor Ian Coombes was the associate advisor. Both advisors oversaw all aspects of data collection, interpretation and analysis.

In the initial stages the study was overseen by a steering committee made up of nurses, pharmacists and a senior doctor, who inputted into proposed outcomes and study design. The principal investigators were Dr Karen Whitfield and A/Prof Ian Coombes, with several associate investigators; Dr Julie Stokes, Professor Lisa Nissen, Elaine Lum, Trudy McGovern, Sue Turner, Dr Carmel Finn, Lynda Cardiff, Tony Hall, Renea Collins and Dr Harry Gibbs.

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List of Abbreviations

ACT Australian Capital Territory
ADRAC Adverse Drug Reaction Advisory Committee
AHMC Australian Health Ministers Conference
AHWAC Australian Health Workforce Advisory Committee
AHWOC Australian Health Workforce Official’s Committee
AHPA Allied Health Professionals Australia
AIHW Australian Institute of Health and Welfare
AMA Australian Medical Association
AMC Australian Medical Council
AMH Australian Medication Handbook
AMWAC Australian Ministers’ Workforce Advisory Committee
ANMC Australian Nursing and Midwifery Council
AQAR Annual Quality and Activity Return
BMA British Medical Association
CMS Center for Medicare and Medicaid Services
CNC Clinical Nurse Consultant
COAG Council of Australian Governments
CORA Council of Optometry Registration Authorities
CPA Canadian Pharmacists Association
CPD Continuing Professional Development
CSHP Canadian Society of Hospital Pharmacists
DMP Designated Medical Practitioner
GB Great Britain
GPhC General Pharmaceutical Council
GP General Practitioner
<table>
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<td>HEI</td>
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<td>Human Immunodeficiency Virus</td>
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<td>HQCC</td>
<td>Health Quality Complaints Commission</td>
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<td>HWA</td>
<td>Health Workforce Australia</td>
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<td>HWPC</td>
<td>Health Workforce Principal Committee</td>
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<td>HPPP</td>
<td>Health Professionals Prescribing Pathway</td>
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<td>IP</td>
<td>Independent Prescriber</td>
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<td>MAI</td>
<td>Medication Appropriateness Index</td>
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<td>MBBS</td>
<td>Bachelor of Medicine and Bachelor of Surgery</td>
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<td>NHISSC</td>
<td>National Health Information Standards and Statistics Committee</td>
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<td>NHMRC</td>
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<td>NHPF</td>
<td>National Health Performance Framework</td>
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<td>National Health Work Planning and Research Collaboration</td>
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<td>National Health Workforce Strategic Framework</td>
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<td>Quality Use of Medicines</td>
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<td>RAHWS</td>
<td>Rural Allied Health Workforce Study</td>
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RANZCO  Royal Australia and New Zealand College of Optometrists
RMO  Resident Medical Officer
RPSGB  Royal Pharmaceutical Society of Great Britain
SA  South Australia
SHPA  Society of Hospital Pharmacists of Australia
SP  Supplementary Prescriber
UK  United Kingdom
USA  United States of America
VMO  Visiting Medical Officer
VTE  Venous Thromboembolism
WA  Western Australia
WHO  World Health Organisation
1 Introduction

In light of an increasing demand on the healthcare workforce, a focus has been placed on the role of alternative workforce options, including non-medical prescribers within the healthcare system. Pharmacists, with extensive knowledge and skills in the application of pharmacology and therapeutics, are well placed to contribute to the prescribing process.

The main driver behind pharmacist, and other non-medical professions, prescribing has been the desire to:

• provide consumers with improved, responsible and safe access to prescription medicines
• optimise use of pharmacists’ and doctors’ skills and time
• reduce inefficient use of health resources.\[1\]

Following recommendations made in the Crown Reports to the government of the United Kingdom (UK) in 1999, changes were made in legislation resulting in the extension of prescribing privileges to non-medical professionals, including pharmacists.\[2, 3\]

There are two models of pharmacist prescribing in the UK:

1. **Supplementary prescribing** was introduced in 2003, and involves a voluntary partnership between the responsible independent prescriber, the supplementary prescriber and the patient, to implement an agreed patient-specific clinical management plan \[4\]
2. **Independent prescribing** was introduced in 2006, in this model the pharmacist has sole authority to make treatment decisions and is wholly responsible for the resultant outcomes\[5\]

An independent prescriber is defined as a ‘practitioner responsible for the assessment of patients with undiagnosed or diagnosed conditions and for decisions about the clinical management required, including prescribing’.\[6\]

Prescribing rights were also granted to several other health professionals in the UK following the Crown Report, including nurses, physiotherapists, radiographers, podiatrists and optometrists.

Pharmacist prescribing has been introduced in to several other countries, including the United States of America (USA), Canada and New Zealand (NZ), where pharmacists can prescribe medicines previously only prescribed by medical practitioners.

In Australia, pharmacist prescribing is yet to be introduced as a model of care. Several other health professionals have been granted prescribing rights, including podiatrists, optometrists, midwives and nurse practitioners. In 2010, nurse practitioners were granted full access to prescribe medicines on the Pharmaceutical Benefits Scheme (PBS).
The introduction of non-medical prescribing in Australia and other countries has also been accompanied by the development of curricula for undergraduate and postgraduate prescribing training courses, to ensure the reliable and sustainable production of competent prescribers. Despite the granting of prescribing rights to several other professions, including pharmacy, reviews have shown that there is a lack of evidence from studies as to the benefits in safety, efficacy, access to medicines, appropriateness and cost effectiveness of non-medical prescribing.[7, 8]

The views of the medical profession on non-medical prescribing have been mixed, with concerns expressed in Australia over the ‘task substitution’ that has been suggested in order to relieve the work pressure on doctors, and a reasonable call for evidence to prove that any new model of care is safe and of an acceptable quality.[9, 10]

The lack of evidence, and call from the medical profession to prove the safety of any new scope of practice, are the reasons why evaluation of the model of care through pilot studies is essential prior to implementation.

The broad practice of hospital pharmacy lends itself well to developing models of pharmacist prescribing for the Australian setting, as pharmacists have medicines knowledge and the skills inherent to prescribing, along with access to patient clinical records and experience in practising as part of a multidisciplinary team.

This research explores a trial of collaborative doctor pharmacist prescribing in a multidisciplinary surgical Pre-Admission Clinic (PAC), evaluated using a National Health Performance Framework (NHPF) to provide evidence across the indicators previously mentioned.[11]
1.1 The Current Healthcare Workforce, Access to Medicines and Healthcare

Healthcare is defined as the prevention, treatment, and management of illness and the preservation of mental and physical well-being through the services offered by medical and allied health professions. Healthcare embraces all the goods and services designed to promote health, including preventive, curative and palliative interventions, whether directed to individuals or to populations.[12] Healthcare workers are those people whose main activities are aimed at enhancing health.[13]

Healthcare workforce shortage is a well-documented global phenomenon. A 2006 report by the World Health Organisation (WHO) estimated that a 70% increase in the health workforce is required worldwide, including doctors, nurses and midwives in order to meet current demand. This figure increases to as high as a 139% increase required in the Africa region. The lowest scale of increase identified was a 40% workforce growth requirement in the Americas region.[14] In numbers, this equates to a predicted worldwide shortage of 4 million doctors, pharmacists, nurses, midwives and other healthcare workers, over the next decade.

Australia is no exception to this phenomenon of health workforce shortage, with several reports over recent years highlighting the shortages, reasons behind them and possible solutions.[15-17]

In 2003, Brooks et al. expressed concerns regarding doctor shortages, especially in rural areas, and suggested various methods that they felt merited further investigation, including: greater flexibility for entry of highly trained overseas doctors; increasing medical school student intake; and workplace practice alternatives, for example ‘task substitution’.[18]

In 2004 the Australian Health Minister’s Conference (AHMC) developed the National Health Workforce Strategic Framework (NHWSF). The NHWSF resulted from ministers’ recognition that addressing the health workforce shortage was a high priority for Australian Health Ministers.[19]

The framework defined the following vision for the direction in which national health workforce effort should be focused, and the guiding principles for strategic action in achieving the vision, and strategies to deliver that vision:

“Australia will have a sustainable health workforce that is knowledgeable, skilled and adaptable. The workforce will be distributed to achieve equitable health outcomes, suitably trained and competent. The workforce will be valued and able to work within a supportive environment and culture. It will provide safe, quality, preventative, curative and supportive care that is population and health consumer focused and capable of meeting the health needs of the Australian community.”
The report summarized that Australia is experiencing workforce shortages across a number of health professions; including doctors, nurses and pharmacists, and that those shortages were even more acute in rural and remote areas.

The framework was designed to guide national health workforce policy and planning throughout the decade, ensuring that actions were sustainable and linked to an overall direction. It was recognised that a collaborative, multidisciplinary approach was needed to effectively tackle workforce issues.

The key challenges driving the framework at the time of its release were health workforce shortages and misdistribution, and the future challenges that were recognised, including:

- demographic changes – focusing not just on the well known fact that Australia has a slowly growing, but ageing population but also on the key workforce impact of demographic change. In Australia in 2004 the workforce was growing at a rate of 17,000 per year, by 2020 it is predicted to be just 12,500 per year
- new technologies – the expectation for the next 20-30 years is that health care advances and innovations will be upon the healthcare system at an astounding rate, with demand for their prompt uptake by increasingly well informed consumers. The implications for that include a greater demand for services, the ability to provide more services and safer care, a change in the way services and care are provided, and an ever expanding need for training and regular skills updates throughout practitioner careers.
- empowered consumers – who will demand to know more about treatments, their effectiveness, and the track record of the practitioners involved in treating them. Consumers are likely to seek out the most advanced, safest, lowest cost care options.

The Australian Health Workforce Official’s Committee (AHWOC) produced its annual report in 2004/2005, a year in which the work of AHWOC had been dominated by consideration of reforms of the system and structures in which the health workforce operates.[20] The annual report considered the issues of workforce at the highest levels of government.

A number of reports made predictions of future workforce shortages. The Productivity Commission, in its 2005 report on Australia's health workforce, detailed shortages in the health workforce "in general practice, various medical specialty areas, dentistry, nursing and some key allied health areas." It suggested shortfalls of 800 to 1,300 GPs in 2002 (~5% of the GP workforce), and an anticipated shortfall of 10–12,000 nurses (~5% of the nursing workforce) in 2006 and 12–13,000 in 2010.

Also in 2005 the Australian Health Workforce Advisory Committee (AHWAC), the Australian Medical Workforce Advisory Committee (AMWAC) and AHWOC released a joint information paper entitled “A Models of Care Approach to Health Workforce Planning”, which
encouraged thinking and discussions about models of care health workforce planning.[21] The paper noted that the exploration of new approaches to health workforce planning was being driven by demographic shifts and broad health system changes. Workforce shortages and shrinkage in the available pool of potential new workers were added pressures, responsible for challenging Australian workforce planners to look for new, more consumer-focused and cost effective ways of using the health workforce, including the consideration of multi-health-professional and multi-functional approaches to health workforce planning. The report also stated that before a ‘models of care’ approach to health workforce planning can be undertaken, it may be necessary to define a ‘best practice model’, and in the absence of a defined optimal model of care the model of care approach to workforce planning involves:

- selecting a particular care group
- identifying and describing the most common prevailing models of care
- defining the multidisciplinary workforce currently associated with these models of care, including the occupations represented, what they do and the skills required
- estimating the growth in demand for a defined period using appropriate indicators
- calculating future workforce requirements based on models and growth in demand
- projecting future workforce supply
- analysing any mismatch in projected workforce requirements and supply estimates
- strategies to achieve a balance in workforce requirements and supply

The Australian Government Productivity Commission released a research report on 19th January 2006 which examined issues impacting on the health workforce, including the supply of, and demand for, health workforce professionals.[22] They proposed solutions to ensure the continued delivery of quality healthcare over the next 10 years, which included initiatives to boost supply through more education and training and strategies to improve retention and re-entry; strategies to moderate demand such as through a shift toward preventive medicine; and initiatives which maximise the effectiveness and productivity of the available pool of health workers.

Also in 2006, the Council of Australian Governments (COAG) agreed to a significant national health workforce reform package to enable the health workforce to better respond to the evolving needs of the Australian community, while maintaining the quality and safety of health services.[23]

The National Health Workforce Taskforce (NHWT) was established as part of these reforms, to undertake projects which inform development of practical solutions on workforce innovation and reform. It is a national body created under the Australian Health Ministers’ Advisory Council (AHMAC) committee structure and reports directly to the Chair of AHMAC’s Health Workforce Principal Committee (HWPC).
At the same time, the Australian Institute of Health and Welfare (AIHW) have published multiple studies across the issue of health workforce shortage with some reports ranging from as far back as 1992. The reports detailed demographics and labour force statistics in medicine, eye health, dental, nursing and midwifery, physiotherapy, occupational therapy, psychology and pharmacy.[24-31]

The 2006 Census of Population and Housing provided an overview of Australia’s current health workforce, covering four key occupational groups: Generalist medical practitioners, specialists, dental practitioners and nurses, including midwives, showing that there were 450,000 Australians employed in the health occupations, accounting for around 5% of the total workforce.[32]

More than half (54%) of the workforce were employed in nursing occupations, with medical professions (12%) and allied health professionals (eg pharmacists, physiotherapists, occupational therapists) (9%) of the workforce.

The report also stated that new models of care will be required, but did not specify what these models of care might be. It also suggested that with research and technology increasing diagnosis and treatment, growing community expectations and an ageing population, the demand for health workforces will increase while the available labour market will tighten.

Specifically in terms of allied health workforce, a report was published in March 2006 by AHWAC entitled “The Australian Allied Health Workforce – An Overview of Workforce Planning Issues”. [33] It provided an overview of the status of the allied health workforce, with a view to the possible need to commission specific national level workforce planning projects for the allied health workforce. It also provided details of a range of current workforce issues for possible further investigation, but acknowledged it was limited by not having future predictions on workforce requirements.

A ministerial report published by Allied Health Professionals Australia (AHPA) in February 2008 acknowledged significant national shortages in key allied health disciplines, affecting health services in the public, private and community sectors, in cities as well as in rural areas. They also offered theories for the high attrition rates being related to poor career paths and inadequate pay, called for a comprehensive and regular workforce study to be undertaken to enable the current workforce problems to be addressed, noted that rural and remote areas have less allied health professionals per head of population than urban areas, and indigenous communities in remote areas often have very little or no access to allied health services. Recommendations included strengthening of indigenous health services by increasing the number of allied health professionals, in order to tackle chronic conditions such as diabetes and obesity.[34]
In 2008, Keane et al published the ‘Rural Allied Health Workforce Study (RAHWS)’ which concluded that the absence of accurate data profiling the existing allied health workforce presents a major challenge for future workforce planning. [35]

The NHWT most recently released a report in April 2009, detailing the “Health Workforce in Australia and Factors for Current Shortages”.[15] Health workforce shortages cited were often linked to the ageing population in Australia driving:
- an increased demand for health care services and the health care workforce
- a reduced supply of health care professionals as the health workforce ages.

The NHWT report also identified many more factors that influenced workforce shortages, and found that the factors broadly relate to one of the following 3 themes:
- escalating demand for health care workers
- labour market competition
- a constrained training system with limited capacity to accommodate the increasing number of students entering the system.

NHWT also concluded that rural and remote services suffer from well documented shortages in health workforce. People in rural and remote areas often have more difficulty in accessing health workforce services, and the number of health professionals relative to population diminishes for communities located further away from the major cities.

Segal and Bolton, in 2009, also reported that on top of workforce shortages, the health workforce market is influenced by a much wider range of factors.[36] A number of factors were also identified that were increasing the demand for health workforce:
- burden of disease in the ageing Australian population
- changes in service delivery
- community expectation
- workforce expectations
- workforce specialisation
- unintended effects of workforce strategies (for example, hospital demand management strategies resulting in shifting demand from the acute to the community sector).

NHWT released a report in 2010 from the National Health Workforce Planning and Research Collaboration, Which was established in 2009 between The University of Queensland, The University of Melbourne and PricewaterhouseCoopers. The NHWT requested the Collaboration to undertake a project to explore the likely nature and contingencies for a nationally consistent approach to prescribing medications by non-medical health professionals.[37] The report concluded
that non-medical prescribing in Australia will improve equitable access to medicines for patients within a governance framework focused on safety and quality use of medicines.

In 2010, Health Workforce Australia (HWA) also commenced operations, established by COAG, who recognised that a national coordinated approach was needed to create a health workforce able to meet the current and future healthcare needs of all communities. HWA’s goal is to build a sustainable workforce in Australia, via the following objectives:

- Building capacity by delivering more health professionals more quickly and efficiently.
- Boosting productivity of the workforce with new workforce models that maximise the skills and flexibility of all health professionals across the entire workforce.
- Improving distribution to get the workforce to the places and specialties where it is needed.
- Building the evidence for national health workforce reform and innovation through planning, research and evaluation.
- Providing leadership to inform and influence national health workforce policy and program decisions.
- Working in collaboration with key stakeholders to deliver targeted programs to drive reform

In 2011, in a national call for action for workforce reform across the health and education sectors, HWA released The National Health Workforce Innovation and Reform Strategic Framework for Action 2011–2015.[38] Proposed future outcomes were a sustainable and affordable health system, increased equality in access to services and sustainable partnerships between health service providers and educators in preparing and developing the health workforce. It was stipulated that the framework may ‘seek to seed innovations and reforms not previously undertaken’.

In 2012, HWA released the first, long term national projections for doctors, nurses and midwives from now through to 2025; Health Workforce 2025.[39] The report’s overall goal is to ensure Australia’s health workforce meets the demands of the population.

One of the key objectives of HWA’s 2012-2013 work plan was to build workforce flexibility through expanding workforce scope initiatives.[40]

In line with this, another project currently being undertaken by HWA, and due for completion in late 2013, is the Health Professionals Prescribing Pathway Project (HPPP).[41] The HPPP aims to describe the key steps a health professional must complete to become a safe and competent prescriber within the scope of their professional practice, and deliver a standard approach to prescribing by health professionals, other than doctors. The report summarises that this will ensure Australians receive safe, high-quality healthcare when and where they need it.

One example of the problem with access to services and medication was highlighted in a study by Kowanko et al in 2004.[42] The authors sent out 225 surveys, of which 114 were completed (51% return rate), to workers and managers from approximately 30 health and human
service organisations across metropolitan, rural and remote areas of South Australia. The purposively selected sample had to have some involvement with Aboriginal people suffering from mental health disorders, and management of their medications. A number of issues influenced quality use of medicines in the patient population, including limited access to specialist services. The authors also concluded that the range of workers providing medication services was very wide, many of whom lacked adequate training or resources.

Another study by Gordon et al from Townsville Hospital in Queensland, Australia also highlighted the issue of access to services. In the study, involving a computer assisted telephone interview of 410 cancer patients, the authors found that over 46% of patients lived more than 100Km away from the hospital and 3% lived more than 600Km away. Average out-of-pocket expenses involved in attending hospital for treatment ranged between $563 and $6231, with a mean value of $4311.[43]

1.2 Training Requirements of Existing Australian Prescribers and Review of Literature Surrounding Suitability

1.2.1 Medical Practitioners

Between June 2007 and June 2008 the total number of prescriptions written, as reported by the Pharmaceutical Benefits Scheme (PBS), was 171,296,023. The numbers of PBS prescriptions dispensed has increased each year. In 2008 there was a 1.6 per cent increase in prescription items dispensed compared to 168.5million in 2007.[44]

The cost of these medicines was significant. Total Government expenditure on the PBS reached $7,034 million, which amounted to 83.3% of the total cost of medicines, and another $1,189.5 million in patient contributions.[44]

Due to legislated restrictions on both prescribing and dispensing authorisations in Australia, the ability for health professionals to prescribe or dispense under the PBS is limited. As a result, the majority of prescribing in Australia is done by medical professionals, with limited prescribing by other professions including dentists, optometrists, podiatrists and nurse practitioners.

In order to gain access to the rights to prescribe medicines and to prescribe within the PBS, the training and education required to become a registered medical practitioner is rigorous and lengthy. There are 2 types of initial degree in Australia undertaken; an undergraduate 6 year Bachelor of Medicine and Bachelor of Surgery (MBBS), and a 4 year graduate entry medical degree. Upon completion of the medical degree, graduates enter the medical workforce, primarily in major teaching hospitals, as interns, for a period of 12 months. Only on completion of this year do junior doctors receive full medical registration.
The intern year involves a series of rotations to specific clinical departments, and is governed by the State Postgraduate Medical Education Council (PMEC) in Queensland and other equivalent bodies in other states. The PMEC has attempted to provide training in order to expose the medical practitioner to a range of clinical situations and environments whilst under supervision. It is often referred to as Post Graduate Year 1, or PGY1.

After successful completion of the internship, junior medical practitioners usually spend a number of years rotating between clinical departments; and often rotate to regional and rural hospitals. Rural rotations serve two purposes; to meet the service and workforce needs and to expose the doctor to a greater variety of clinical settings. Doctors in this period are often referred to as Resident Medical Officers (RMOs). This term is known as Post Graduate Year 2 and 3 (PGY2 and PGY3).

In order to undertake specialisation, at the end of PGY2 or PGY3 medical practitioners may seek admission to a vocational “advanced” training program run by one of the medical colleges. These programs, some of which offer a ‘basic training program’, may be undertaken by a RMO in the lead up to applying for advanced training.

Once accepted into the college advanced training program, often after a “primary examination”, the junior doctor must apply for and secure employment in a registrar position. This position must be an accredited training position by the relevant college. This stage of training usually takes between 3-5 years.

Medical practitioners training in General Practice will undertake their advanced training in private GP training practices, as opposed to training for the majority of specialty medical fields, which is undertaken in the tertiary system.

Upon successful completion of the advanced training, doctors are awarded a Fellowship of the respective College and will be recognised as a specialist in that particular discipline, and their registration with the Medical Board is “endorsed” to reflect these qualifications.

Upon completion of specialist or GP training, the vocational options for medical practitioners broaden to include private practice, a combination of private and Visiting Medical Officer (VMO) engagement at public hospitals, or employment as a specialist in a public hospital.

Standards for education and training of medical practitioners are monitored by the Australian Medical Council (AMC). The AMC is an independent national body, set up under Commonwealth legislation, that sets standards for medical education and training. It has four core functions:

1. Assessment of medical courses and training programs (both medical school courses and the programs for training medical specialists) and accreditation of programs which meet AMC standards

2. Assessment of international medical graduates who wish to practise medicine in Australia
3. Advice to medical boards on uniform approaches to the registration of medical practitioners and the maintenance of professional standards

4. Advice to the Australian government on the recognition of medical specialties.

In summary, the process for obtaining rights to prescription only medicines in Australia is rigorous and contains many steps required by accrediting bodies. These checks and balances were designed to achieve a robust model of training and accreditation, aimed at ensuring competent and fit for purpose practitioners.

Under state and federal legislation in Australia, medical practitioners are authorised to prescribe as soon as graduating from university and registering with the relevant medical board. There are few legislative restrictions placed on intern prescribing. Those existing restrictions often arise from PBS requirements, for example, that restricted or authorised medications to be prescribed by a ‘specialist’ in that area.

1.2.2 Views on Suitability of Training as Preparation to Prescribe

In 2002, Pearson investigated the factors influencing intern prescribing, by interviewing 20 randomly selected interns from two hospitals in New South Wales, and found agreement that Medical school pharmacology and therapeutics training was highlighted as an example of ‘how not to teach prescribing’. The recurrent theme through responses was that medical school training provides ‘no practical experience’ and fails to ‘tell you what doses you should be using, how often you should be using the drug, the route you should be using’ and does not prepare students for the competing pressures interns encounter. A number of positive influences were identified, amongst which were nurses and pharmacists.

A 2007 study by Tobaiqy, in Scotland, aimed to determine whether first year foundation doctors believed that their undergraduate education in clinical pharmacology and therapeutics had prepared them to prescribe safely and rationally. A questionnaire was issued to all 90 first year doctors at Aberdeen Royal Infirmary Teaching Hospital, covering undergraduate and postgraduate training in pharmacology, experience of ADRs (Adverse Drug Reactions) and drug interactions, confidence in drug usage and any perceived deficiencies in training in clinical pharmacology. With a 71% return rate, the results showed only 8% of respondents rated their knowledge of clinical pharmacology as ‘good’, whereas 30% rated it as ‘poor’ or ‘very poor’. With regards to whether undergraduate training had equipped them to prescribe safely and rationally, 41% replied ‘no’. When asked about which topics in clinical pharmacology required more extensive coverage, the topics cited by more than 50% of respondents were: ‘prescribing for special patient groups, drug-drug interactions, ADRs and therapeutic drug monitoring’.
Similarly in 2007 in Australia, Coombes et al assessed the attitudes of 4th year medical students with regards to their readiness to prescribe, associated risks and perceptions of available support.[47] By surveying 101 students, the authors discovered that medical students felt unprepared to start prescribing. Most students, or 94%, felt that they would be able to prescribe for most ‘simple’ complaints and 82% felt they would be able to complete discharge prescriptions. High risk situations instilled less confidence in the students, with only 54% and 55%, respectively, confident with managing warfarin prescribing and a patient with diabetes. The authors concluded that more work is needed to prepare doctors to prescribe safely.

In 2008 in Australia, Coombes et al investigated factors behind intern prescribing errors by interviewing 14 interns involved in 21 prescribing errors.[48] The main finding was that lack of drug knowledge was not the single causative factor in any one error, and all errors were underpinned by a culture that saw prescribing as a low risk, repetitive chore.

Pillans, in Australia in 2009, recognised that prescribing is a core skill for every graduating medical student and their competence should be assessed before they are allowed to prescribe.[49] A study by Hilmer, in 2009 at Royal North Shore Hospital in Sydney aimed to assess the ability of new interns to prescribe medications safely and appropriately by giving 191 of them a clinical case scenario that tested prescribing ability.[50] The results showed that no intern completed all prescribing tasks correctly and no intern charted the patient’s regular medications on admission completely correctly. Only six wrote an accurate discharge list, and none wrote an accurate discharge list and a legal Schedule 8 discharge script.

This is in stark contrast to the findings by Coombes et al, discussed earlier, about the perceptions of students of their ability to complete these tasks.[47]

In a separate part of the study, the interns’ views of pharmacology training as an undergraduate were elicited via a questionnaire. None of the respondents strongly agreed that they felt adequately trained to prescribe medications in their intern year.

1.2.3 Dentists

Dentists are also established authorised prescribers of a limited number of prescription medicines in the Australian healthcare system. The number of approved items is a very small proportion of prescriptions compared to medical practitioners, attributable to their much narrower scope of practice.

Dentists trained in Australia are required to have met the entry requirements of one of the Australian institutions offering dental courses, and then complete the required full-time academic training (approximately five years) leading to a dental degree. If dentists wish to specialise, they must complete extra study after having had clinical experience.
Similar to doctors, dentists have prescribing rights straight from graduation. The authority to prescribe is governed by individual state legislation, which may vary from state to state. Dentists have a narrowed scope of practice, and as such, both state and federal PBS legislation permit a dentist to prescribe from a restricted drug list, and only specifically for a person’s dental treatment.

1.2.3.1 Views on Suitability of Training as Preparation to Prescribe

There is nothing to be found in the literature assessing the suitability of dentist training with regards to prescribing of prescription medications.

1.2.4 Optometrists

Optometrist training is accredited by the Optometry Council of Australia and New Zealand (OCANZ) and includes:

- undergraduate courses suitable for general registration
- undergraduate courses which include therapeutic training suitable for general registration and endorsement for scheduled medicines
- postgraduate courses in ocular therapeutics suitable for endorsement for scheduled medicines

Applicants seeking registration board approval for therapeutic practice, or prescribing rights, must hold one of the accredited qualifications, so either one of the two undergraduate courses with accredited therapeutics training, or the Postgraduate Certificate in Ocular Therapeutics.

Courses are accredited against the Accreditation Manual for Optometry Courses in Australia and New Zealand which defines the organisation, governance, educational goals and objectives and course curriculum.[51]

Optometrists have sought prescribing rights for therapeutic drugs independently in each state over the last 15 years; starting with Victoria in 1996. In 2005, the Optometrists Association of Australia issued a response to the productivity commission’s paper on the health workforce. The response surmised that

‘while the current Australian optometric workforce was sufficient to meet the eye care needs of the Australian community, there were several opportunities for improving the delivery of eye care, two of which were extending prescribing rights to optometrists in all states and territories, and extending the PBS to cover prescribing of certain medications by optometrists.’

Since 2005 optometrists in Victoria and Tasmania had been prescribing eye medications to treat eye infections, allergic reactions of the eye and, in some cases, glaucoma. Legislation to
similar effect had been passed in the Australian Capital Territory (ACT), New South Wales (NSW), the Northern Territory (NT) and Queensland, and is planned in South Australia (SA).

Prescribing rights vary between states, with no prescribing rights at all in Western Australia (WA); and with each state having individual legislation and slightly different formularies available. One of the major concerns has been that with this approach comes a lack of nationally consistent standards and principles to protect the public.

1.2.4.1 Views on Suitability of Training as Preparation to Prescribe

In recognition of this problem, the Royal Australian and New Zealand College of Ophthalmologists (RANZCO) released a position paper on optometrist prescribing to answer some of the concerns surrounding the lack of nationally consistent standards, with a view to setting a nationally consistent scope of practice, along with rigorous training and assessment methods to assess the competencies of prescribing optometrists.[52]

In 2008, the Council of Optometry Registration Authorities (CORA) also called for the states and territories to adopt a unified approach to avoid the problems of a discordant approach to prescribing, highlighting a main issue as the inconsistency between the states of patient access to medication.[53]

Optometrists were granted PBS access from 1st January 2008, and as with dentists, limited to prescribing only the items relevant to their scope of practice, as listed in the PBS optometrist section.

1.2.5 Podiatrists

Surgical podiatrists are also authorised to prescribe prescription only medicines; with regulations being slightly different in each state. They have access to a limited list of drugs to prescribe, mainly comprising of antibiotics, local anaesthetics and analgesics.

In order to gain prescribing rights, all podiatrists must complete a Bachelor of Podiatry and be registered to practise in the appropriate State. In some states, additional qualifications are legislatively required in order for podiatrists to be able to prescribe and supply of a range of prescription only medicines.

In Victoria in 2002, the Podiatrist’s Registration Board of Victoria and the Australian Podiatry Association proposed that regulation of podiatry prescribing be undertaken by the Podiatrist’s Registration Board and that the Board regulate prescribing by podiatrists in the following manner:
i. Approve courses of study offered by educational and professional bodies, that in the opinion of the Board, provide training which qualifies podiatrists for endorsement of their registration to prescribe

ii. Ensure that therapeutic competencies are monitored and maintained. This will be achieved through clinical audits and ongoing development of clinical pathways. Training programs will be modified appropriately in response to these activities.

iii. Maintain a register of individuals who have acquired and are maintaining competency as prescribers

iv. Keep the content of prescribing formulary under review and submit any proposals for change to the appropriate bodies.

A permanent sub-committee of the board is to be formed, for the purpose of:

1. Making recommendations to the board regarding:
   - Alteration to register, removing or adding prescribers
   - Adding or removing approved drugs
   - Academic requirements for prescription rights

2. Investigating complaints with regards to prescribing, as directed by the Board

3. Liaising directly as required with external bodies such as:
   - Adverse Drug Reaction Advisory Committee (ADRAC)
   - Poisons Advisory Committee, Department of Human Services”[54].

In Queensland in 2006, amendments were made to the Health (Drugs and Poisons) Regulation 1996 to allow recognised ‘surgical podiatrists (who hold fellowship with Australasian College of Podiatric Surgeons) to prescribe, supply or administer a limited formulary of Schedule 4 and one Schedule 8 drug.’

In Victoria, under the terms of the Health Professions Registration Act (2005) and the 2007 Regulation amendments to the Drugs, Poisons and Controlled Substances Act 1981, the Podiatrists’ Registration Board had been given authority to determine which Schedule 2, 3 and 4 medicines may be possessed, used, sold or supplied by its registrants following approval by the Health Minister. As a result, the Podiatrists’ Board was empowered to create a subset of registrants known as ‘authorised prescribers’. Final approval of the initial formulary was given by the Health Minister in June 2009.

Under the process of National Registration & Accreditation, local state and territory health professional registration boards were disbanded and replaced by national authorities. As such, the Podiatry Board of Australia was constituted in 2009, with the task of taking over the administration of registration and regulation of standards of practice for all Australian podiatrists in July 2010. Under the requirements of the Health Practitioner Regulation (Administrative Arrangements)
National Law Act 2008, the Board began consultation on the mechanisms for implementation of national standards for podiatric prescribing within Australia, submitted for approval by the Australian Health Workforce Ministerial Council.

The standard was approved on 31 March 2011, with approval taking effect from 1 July 2011. To be eligible to be granted an endorsement for scheduled medicines ie to administer, obtain, possess, prescribe, sell, supply or use Schedule 2, 3, 4 or 8 medicines for the treatment of podiatric conditions an applicant must have completed:

- an approved program of study in podiatric therapeutics, or
- a program of study determined by the Board to be substantially equivalent to an approved program of study, and

1. a period of postqualification experience (seven years clinical experience in an appropriate setting where active prescribing is occurring and two confirmatory references of applicant exposure to patient care involving restricted drugs), or
2. completion of web-based case studies approved by the Board (20 hours) and a specified period of supervised practice (40 sessions of supervision by an endorsed prescriber approved by the Board in an appropriate setting where active prescribing is occurring in a 12 month period).

1.2.5.1 Views on Suitability of Training as Preparation to Prescribe

The issue of podiatrist suitability to prescribe and scope of practice was highlighted in Victoria after legislation was passed allowing podiatrists to prescribe ‘drugs of addiction’, such as temazepam and codeine. Response from the Australian Medical Association was less than supportive, suggesting “podiatrists would be out of their depth”.[55]

Such media response has highlighted the importance of a formalised agreement of scope of practice for non-medical prescribers with all of the members of the healthcare team, especially the medical staff. Once the scope starts to stray from a perceived competency framework, implementation has become difficult and was met with objections, usually from the traditional prescribing workforce.

A 2010 paper from Australia, by Borthwick et al, used a range of published material and unpublished material in private possession to trace a chronological account of the development of podiatrist prescribing in both the UK and Australasia.[56] The paper concluded that the changes were met with resistance on the right to access, administer, supply and prescribe medicines from the traditional prescribing workforce. However, the broader policy agenda allowed workforce redesign to continue, and podiatry has assumed wider roles and responsibilities in prescribing.
1.2.6 Nurse Practitioners

Since 1998, a selected subset of nurses, midwives, have been able to order and interpret a limited range of tests and to subsequently prescribe specified drugs, under a very limited scope of care, to healthy women and their babies during uncomplicated pregnancy, childbirth and the early postnatal period. However, similar to optometrists and podiatrists, again a lack of consistency across states in legislation acts as a barrier to enabling these guidelines. Access to the PBS was not granted at this point in time, and medication was for administration in specified settings.

In some States and Territories amendments have been made to broaden the scope of such legislation to allow midwives to initiate (but not ‘prescribe’ in the full sense given above) the use of medications in some circumstances.

NSW was the first state to authorise the role of the nurse practitioner in 2000, Tasmania and the NT in July 2008 and March 2008 respectively.

A Nurse Practitioner is defined as

‘a registered nurse educated and authorised to function autonomously and collaboratively in an advanced and extended clinical role. Nurse practitioners are registered nurses with at least five years in their chosen area of practice post-registration and at least seven to nine years study, including masters-level university qualification. The nurse practitioner role includes assessment and management of clients using nursing knowledge and skills and may include but is not limited to, the direct referral of patients to other health care professionals, prescribing medications and ordering diagnostic investigations’.[57]

Latest figures suggest there are about 400 nurse practitioners in Australia, working primarily in illness prevention, chronic disease management, aged care, emergency care, wound care, diabetes education, sexual health and rural health. According to the 2006 AIHW report on Health and Community Services Labour Force 29% of nurse practitioners work outside of major cities.[58]

The nurse practitioner course is accredited by the Australian Nursing and Midwifery Council (ANMC), with the standards for course management and curriculum set out in the document “Nurse Practitioners – Standards and Criteria for the Accreditation of Nursing and Midwifery Courses leading to Registration, Enrolment, Endorsement and Authorisation in Australia – with Evidence Guide”.[59] Entrance criteria stipulates that a nurse must have 5 years experience as a registered nurse, with 3 years in a speciality and 1 year working at an advanced practice level within the speciality. Candidates must have a Bachelor of Nursing, or equivalent, and a postgraduate qualification in a speciality field that has prepared the student for advanced practice, either as a pre-requisite or integrated into the Masters degree. With regards to prescribing of medications the document states “that the curriculum addresses knowledge in advanced
pharmacology and therapeutic medication management for prescribers (or for nurse practitioners to prescribe competently, legally and ethically)"

The Nursing and Midwifery Board of Australia (NMBA) released guidelines in 2011 which outlined the educational requirements for courses suitable for attaining the qualifications required for a registered midwife to be recognised as an ‘eligible midwife’ and endorsed for scheduled medications.[60] There are six recommendations that a midwife has to be able to meet:

- current general registration as a midwife in Australia with no restrictions on practice
- midwifery experience that constitutes the equivalent of three years’ full-time post initial registration as a midwife
- current competence to provide pregnancy, labour, birth and postnatal care to women and their infants (the continuum of midwifery care)
- participation in an additional 20 hours per year of continuing professional development (i.e. a total of 40 hours) relevant to the continuum of midwifery care
- successful completion of an NMBA-approved professional midwifery practice review program for midwives working across the continuum of midwifery care (to be conducted every three years)
- formal undertaking to complete, within 18 months of recognition, an accredited and approved program of study determined by the Board to develop midwives’ knowledge and skills in prescribing, or a program that is substantially equivalent to such an approved program of study, also to be determined by the Board

1.2.6.1 Views on Suitability of Training as Preparation to Prescribe

In 1998 concerns were expressed in the Australian Nursing Journal over nurses’ lack of pharmacology training to enable them to prescribe safely and effectively, and that any training nurses undergo before prescribing must be tailored to this.[61]

In 2000 Offredy et al also raised concerns about the pharmacological knowledge and decision making skills of nurses in a study where 25 nurse prescribers were presented with a number of scenarios.[62] Only a minority were able to identify more than half of the pharmacological problems relevant to each case and to suggest an appropriate course of action. This resulted in Pulse, a weekly newspaper for GPs, to state that nurses are ‘floundering’ in their prescribing role.[63] This was echoed in many other articles in this particular publication.[64-75]

In 2003 Aronson, a clinical pharmacologist, wrote of the concerns of the nursing profession being adequately prepared, especially in the sciences of pharmacology and clinical pharmacology, as previously discussed by others.[76]
By 2003, the Australian Nursing Journal reported that the UK Nursing and Midwifery Council (NMC) had included training in prescribing medicines in the pre-registration curriculum for nursing students, to enable all nurses to become supplementary prescribers.[77]

In 2004 Banning prepared a review of the literature using MEDLINE, CINAHL, OVID, PUBMED, EBESCO and also the National Prescribing Service (NPS).[78] The search was limited to evidence published in England and relevant to nurse prescribing developments in the UK and papers between 1994–2003, the timeframe reflecting the year nurse prescribing was first implemented. Banning concluded that the review had drawn attention to the deficits in the scientific preparation of nurses in applied pharmacology and therapeutics and called for a more clinically-focused pre-registration and training programme to provide nursing students with the appropriate scientific and professional knowledge to act as a foundation for post graduate education.

In 2005 Avery, a professor of primary health care and Pringle, professor of general practice wrote in the BMJ along similar lines, and referred to both nurse and pharmacist prescribing when they said that to ensure safe and effective prescribing the practitioners must be trained appropriately, have access to all the tools they need to help them prescribe safely, and strong clinical governance is essential to identify any prescriber exceeding his or her competency.[79]

In 2005, Banning investigated these claims in an article exploring independent nurse prescribers’ views on the use of evidence based medicine and practice in nursing.[80] A cross section of 16 nurses from practice and district nursing, nurse practitioner, accident and emergency nurse practitioner, palliative care nurse, family planning nurse and health visitor participated. Two data collection methods were used, a short answer questionnaire and semi structured interviews using a focus group technique. All nurses completed the questionnaire. The findings of the study were that many nurses were not familiar with evidence based practice, and one recommendation was more focus on the exploration of evidence from randomized controlled trials in the training of independent nurse prescribers to enable maximum contribution to the medication management of patients.

In 2006 Banning followed this up by suggesting a variety of teaching and learning approaches which can be used by nurse prescribers to develop critical thinking skills, on the premise that critical thinking is an essential skill in making judgements and informed clinical decisions.[81]

In 2006 Aronson again wrote of an overall concern about the adequate teaching of all non-medical prescribers to prescribe, with the conclusion that if the correct amount of time and teaching was not put into training prescribers it would invariably lead to more patient harm.[82]

In 2007, Avery wrote again in the BMJ about nurse prescribers specifically, and suggested a new model of training, and moving away from the stand alone training package then on offer, to
train nurses to prescribe to incorporating the ‘task’ of prescribing within the broader framework of the recognised clinical role of nurse practitioners.[83]

In 2007, the National Prescribing Service (NPS) in Australia announced a two-year project aimed to provide nurse practitioners with resources to assist in the quality use of medicines, including four new educational packages.[84]

In 2010 Tuoi reviewed the evidence and debate that saw the role of nurse practitioner move to the doctoral level in America, in order to open the debate about whether it is timely for Australian universities to consider the need for a Doctor of Nursing Practice.[85]

In 2010, Latter et al evaluated several aspects of pharmacist and nurse independent prescribing, including educational courses and suitability, through a postal questionnaire to Nurse Independent Prescribers (NIPs) and Pharmacist Independent Prescribers (PIPs) asking specifically about any changes that may need to be made to existing courses.[86] Focus group discussions were also held with Higher Education Institution (HEI) leads and Designated Medical Practitioners (DMPs)

The study findings indicate that current educational programmes of preparation for nurse and pharmacist prescribing are operating largely satisfactorily, and provide fit-for-purpose preparation for current pharmacist and nurse prescribing roles. The report recommended that attention needs to continue to be given to nurses and pharmacists’ assessment and diagnostic skills which underpin their independent prescribing role.

1.3 Training Requirements of United Kingdom Pharmacist Prescribers

In 2010 the Royal Pharmaceutical Society of Great Britain (RPSGB) was replaced by the General Pharmaceutical Council (GPhC) as the regulator for pharmacy. As such, it is the responsibility of the GPhC to set the standards for education and training that regulate both provision of pharmacy degrees and pre-registration training to ensure competent and fit for purpose clinicians.

Since 1997, and in line with European Directive requirements the pharmacy degree was extended from three to four years, leading in to a one year pre-registration year. All undergraduate pharmacy schools were obliged to restructure their programmes and the degree award changed from a Bachelors to a Masters of Pharmacy (MPharm). After the one year pre-registration training graduates can then register with the GPhC.

In April 2008, the Government published a White Paper, ‘Pharmacy in England: building on strengths, delivering the future’, which recognised that in order to develop consistent and coherent high quality practice a number of aspects of education, training, career development and workforce planning needed to be addressed, and made specific recommendations as to how the
profession’s infrastructure ought to be modernised.[87] More particularly, areas for consideration included: post-registration education that supported continuous professional development within a coherent nationally recognised framework and called on the profession to rise to the challenge of modernising the profession.

Relevant courses to our research context that the GPhC recognise and accredit are:

- Master of Pharmacy degrees leading to pre-registration then pharmacist registration
- prescribing courses leading to pharmacist annotation

Accreditation relates to specific course providers where all processes are directly quality assured. Courses are mapped to the quality credit framework and are agreed national occupational standards. The standards define the prerequisites, outcomes, processes and structures expected of a Master of Pharmacy Course. The standards also contain an indicative syllabus under the subtitles; ‘the patient’, ‘medicines: drug action’, ‘medicines: the drug substance’, ‘medicines: the medicinal product’, ‘healthcare systems and the roles of professionals’ and ‘the wider context’

GPhC also accredits the pharmacist independent prescribing programmes, and the Pharmacist Independent prescribing – conversion programme, which is a condensed course aimed at pharmacists previously qualified as supplementary prescribers, wishing to become independent prescribers.

Governance, structure and content of courses is dictated by the Accreditation of Independent Prescribing Programmes manual.[88] The manual indicates what the learning outcomes and indicative content of the course should be to achieve accreditation.

The indicative content headings; ‘consultation, decision-making, assessment and review’, ‘influences on and psychology of prescribing’, ‘prescribing in a team context’, ‘applied therapeutics’, ‘evidence based practice and clinical governance’, ‘legal, policy, professional and ethical aspects; and ‘prescribing in the public health context’ are derived from the prescribing competencies first produced by the National Prescribing Centre (NPC) in 2003 and updated in 2006.[89]

For entry on to a prescribing course GPhC stipulates that pharmacists must:

- be a registered pharmacist with the GPhC or the Pharmaceutical Society of Northern Ireland (PSNI)
- have at least 2 years appropriate patient orientated experience in a UK hospital, community or primary care setting following their pre-registration year

Applicants must:

- have identified an area of clinical practice in which to develop their prescribing skills and have up to date clinical, pharmacological and pharmaceutical knowledge relevant to their intended area of prescribing practice
• demonstrate how they reflect on their own performance and take responsibility for own continuing professional development (CPD)

Additionally:

• the pharmacist must identify a designated medical practitioner (DMP) who has training and experience appropriate to their role. The DMP must have agreed to show supervision, support and shadowing opportunities for the student.

1.3.1 Views on Suitability of Training as Preparation to Prescribe

The feelings of some of the medical profession as to the suitability of the training for nurse and pharmacist prescribing was summed up, in 2005, by a quote in the BMJ from James Johnson, the British Medical Association (BMA) chairman.[90] Johnson said “It is difficult to see how healthcare professionals who are not trained to diagnose disease can safely prescribe appropriate treatment.”

In the same news article, Hamish Meldrum, the Chair of the BMA’s General Practitioners Committee said “This announcement (of extended prescribing rights) raises patient safety issues, and we are extremely concerned that the training provided is not remotely equivalent to the five or six years’ training every doctor has undertaken. While we support the ability of suitably trained nurses and pharmacists to prescribe from a limited range of medicines for specific conditions, we believe only doctors have the necessary diagnostic training and prescribing training that justifies access to the full range of medicines for all conditions”

In an editorial in 2005, McGavock cautioned the UK about independent prescribing for pharmacists, saying pharmacists were not trained to diagnose and that the specialty should be left to the more qualified medical practitioners.[91] He also said that pharmacists were appropriately qualified in pharmacology and should be used more in partnership with GPs in prescribing once the doctor had provided the correct diagnosis. He also added that nurses are not trained adequately in either diagnostics or pharmacology, leading to nurse prescribing being ‘fraught with risk’.

Weiss et al published a report through the RPSGB, in 2006 which interviewed pharmacist supplementary prescribers to explore their views on the education and training they had received to prepare them for the new role.[92] On the whole pharmacists found the training course useful, with the aspects they found most useful varying according to their background and place of work. Most felt that it was the practice based element of the course, with the DMP, that was most useful.

In 2008, Cooper et al sent a postal questionnaire to all 808 supplementary prescribers registered in England exploring training prescribing, safety culture and perceptions of supplementary prescribing (SP).[93] With a return rate of 51%, the results showed that 82% thought SP training was useful, 58% thought courses provided appropriate knowledge and 62% agreed that
the necessary prescribing skills were gained. More diagnostic training was thought to be important by 67% of respondents.

The findings of a review of Pharmacist Independent Prescribing (PIP) training from UK in 2010 by Latter et al are discussed previously.[86]

In 2010, in Australia, an article in The Medical Observer reported similar concerns to the initial concerns in UK.[94] Australia Medical Association (AMA) vice-president Dr Steve Hambleton was quoted as saying “Pharmacists have two choices if they want to prescribe. They can either complete medical degrees to become doctors, or they’re welcome to submit a training program to the Australian Medical Council (AMC) that would bring them up to the equivalence of doctors. Where is the evidence to suggest pharmacist-driven prescribing is safe? Why is it up to doctors to prove it is not?”

In 2011, McIntosh et al surveyed newly registered pharmacists in Great Britain (GB), for their views on potential future roles as prescribers.[95] A 5-point Likert scale questionnaire was sent out to all 1658 pharmacist entering on to the register in 2009, with a response rate of 25.2%. Most pharmacists (86.4%) registered an interest in in prescribing, with most agreeing that they should have 2 years of experience as a pharmacist prior to engaging in training. Training needs in clinical examination, patient monitoring and medico-legal aspects were acknowledged, with led the authors to conclude that a review of the undergraduate course may be necessary to incorporate these aspects of training.

1.4 Scopes of Practice

Dentists, optometrists, podiatrists and midwives have a limited and clearly defined scope of practice, or a limited formulary of drugs from which they can prescribe. Under the current disparate system, the different professions have developed multiple different training and education packages tailored to their narrow scope of practice. Assessment of competence for prescribing remains inconsistent and without transparency across professions, as highlighted by Morris in an editorial from Australia in 2011.[96]

Defining formularies limited to scope of practice has been achievable for these professions, as the drugs required to practice in their scopes are limited and often obvious. Medical practitioners have historically either specialised in one field, so effectively limiting their scope of practice in the same way, or become GPs.

The training, education, experience required and competency assessments for becoming a specialist or GP are well defined and accepted as producing fit for purpose clinicians who have a right to prescribe medications at the end of their training.
Nurse practitioners and pharmacists face a different challenge, which is predominantly due to the fact that they can practice in a wide range of clinical settings and may not have a defined specialist role, making defining a scope of practice for prescribing much more difficult, and a formulary basis for restriction untenable.

1.5 The Current Healthcare System

1.5.1 The Medication Management Pathway

The Australian Council for Safety and Quality in Healthcare recommended that “in order to recognise what can go wrong with the use of medicines we need to understand the processes that are involved”.[97]

There are multiple stages in this pathway originating from the decision to prescribe through to monitoring the outcome of that medication on the patient (See Figure 1). Medication errors have been shown to occur in every stage of this pathway; prescribing, medication order generation, reviewing, dispensing and administration processes.

**Figure 1 - The Medication Management Cycle**

1.5.2 Prescribing Process

The prescribing of a medication is the most frequent medical intervention a patient receives in hospital.[98] Whilst the literature suggests the standard of prescribing was reportedly generally
high, patients were most frequently harmed as a result of prescribing errors; the majority of which were preventable.

In 1994 the WHO published “A Guide to Good Prescribing: A Practical Manual”, which acknowledged that “at the start of clinical training most medical students find that they don't have a very clear idea of how to prescribe a drug for their patients or what information they need to provide.”[99] The main reason behind this was stated to be that undergraduate training did not prepare the medical student to prescribe, mainly as training was often diagnostic rather than therapeutic, and more specifically pharmacology training focused more on theory than practice. The guide states that the result of this is although pharmacological knowledge is acquired, practical prescribing skills remain weak. The consequence of bad prescribing habits is stated to be; ineffective and unsafe treatment, exacerbation or prolongation of illness, distress and harm to the patient and higher costs. The manual focuses of the process of prescribing.

The opinion of the guide with regards to lack of preparation of medical students to prescribe would appear to be backed up by the literature reviewed so far within this document. [47]

In 2007, Page undertook a qualitative study of the social and cultural influences on prescribing practices in two Australian teaching hospitals.[100] The research identified that prescribing was a complex process, which involved six stages:

- diagnose
- make primary decisions ie select treatment plan, drug if necessary
- select dose of drug, duration, communicate order
- check and review, revise decision if necessary
- educate patient
- monitor and review

It also outlines the actions undertaken by several different health professionals, including pharmacists, in the prescribing process and their key responsibilities.

In 2010, Coombes et al suggested a similar model of prescribing, involving a four stage process with each stage impacting on the next (See Figure 2):

- gathering patient and drug information including medication history, previous ADRs and an accurate diagnosis,
- making a clinical decision to select the correct drug, form, route, dose and duration of treatment depending on the patient’s characteristics and other concomitant diseases and drug therapy,
- communicating these decisions by generating instructions for the supply and administration of these drugs
- reviewing the outcome and revising the prescribing decisions.[101]
The suggested model has also been put forward as a suitable building block around which prescribing competencies can be developed in the Australian healthcare setting, which would in turn inform the training, development and credentialing of all clinicians.[96]

The guideline discussed earlier, produced by the Nursing and Midwifery Board of Australia, is the first official document in Australia to suggest use of the above prescribing competencies as a foundation for a suitable prescribing course.[60]

This thesis will attempt to evaluate the safety, efficacy and appropriateness of pharmacist involvement in various stages of the prescribing process in the pre-admission clinic (PAC) setting, when compared against usual care. This is novel research within the Australian healthcare system.

### 1.5.3 Prescribing Errors

Dean et al defined a prescribing error, through a two stage Delphi technique involving 34 UK judges, including physicians, surgeons, pharmacists, nurses and risk managers.[102] The definition developed from the process was:

“A clinically meaningful prescribing error occurs when, as a result of a prescribing decision or prescription writing process, there is an unintentional significant reduction in the probability of treatment being timely and effective or an increase in the risk of harm when compared with generally accepted practice.”

Consensus was also achieved that errors occur when there is: “a failure to communicate essential information; the use of drugs or doses is inappropriate for the individual patient; and transcription errors.”
According to what definition of ‘error’ is used, the literature reports very different error rates from studies.

A study from the UK in 2002 by Dean et al identified a 1.5% error rate from 36,200 medication orders written during the study period, which in numbers equated to 135 prescribing errors per week during a 4 week period.[103]

A study from United States of America (USA) by Potts et al showed, from a prospective trial of 514 paediatric patients, and 13,828 medication orders a medication prescribing error rate of 30.1%. [104] The main errors detected in the study were either omissions of core components (such as name, form, route, dose or frequency) or unsafe abbreviations.

1.6 Evidence of Healthcare Benefits of Non-Medical Prescribing Models

A review of the literature has identified a dearth of evidence for the benefits of non-medical prescribing. Most of the research so far has originated from the UK or USA, with pharmacist prescribing accounting for the largest number of articles.

1.6.1 Optometrists

Little research has been published on the safety and effectiveness of optometrist prescribing. A greater focus of publishing has been on professional surveys aimed at establishing the scope of practice of optometrists and the perceived barriers to implementation of prescribing; particularly from an education and training point of view.

Soroka has been responsible for a number of published journal articles evaluating the profession in USA, across both hospital and primary care, predominantly in terms of workforce shortages and scope of practice. In 1977, in a study of 4,156 patients, the referral patterns from an optometric clinic were analysed with a view to planning the staffing requirements of present and future optometric clinics.[105] Thirty percent of the patients examined required further testing and specialised services, suggesting that a group practice environment that provides comprehensive eye care of ophthalmologists and optometrists would ensure such services are readily available. This study did not recommend the prescribing of therapeutic agents, but provides insight into patient requirements and referral patterns.

In 1978, Soroka sent a questionnaire to all hospitals within the 5 counties of New York City, a total of 132 institutions.[106] A 77% return rate was achieved and found that 27% of the institutions had an optometrist associated with their institution and concluded that optometrists were used inadequately as a healthcare resource. The article highlighted a scope of practice that the optometry profession would be competent within, which when supported by appropriate education and training, optometry could work with ophthalmology to prevent duplication of services and to
improve the vision care of the patient population. It was suggested several system changes, including clear and distinct reporting relations of optometrists, optometrists triaging patients with ocular and visual complaints and development of service protocols for staff optometrists would all assist in preventing duplication of services, and contribute to an efficient and effective delivery of vision care. This article did not suggest prescribing rights for optometrists, but laid foundations for a clear scope of practice and referral system to ophthalmologists to facilitate the acceptance of optometry within the healthcare team.

In USA in 1990, McAlister surveyed Missouri optometrists who had not been certified to use therapeutic pharmaceutical agents, and found a lack of time to undertake extra educational requirements was the major barrier to taking on the extra scope.[107] In the same year, the same author assessed the effects of the expansion on scope of practice, and noted a majority of respondent optometrists reported they were comfortable in providing a prescribing service and reported an increase in income and patient retention. Over half of the respondents had received referrals from primary care physicians for therapeutic services.

By 1991, optometrists were licensed to use diagnostic drugs, those used to diagnose ocular disease, in all 50 states of the USA, and to prescribe therapeutic drugs for the treatment of ocular diseases in 25 of the states. Soroka assessed, via a national telephone survey of 1000 optometrists and 1003 ophthalmologists, the examination fees and availability of routine vision care by the 2 groups.[108] The survey showed that average fees were significantly less amongst optometrists than ophthalmologists; for a routine eye test, $42 compared to $61, and that the average wait for the earliest appointment was 5 days for optometrists and 20 days for ophthalmologists. Notably, whilst 3 out of 4 optometrists had evening or weekend hours for routine eye care, only 1 out of 4 ophthalmologists were available for this service during these times. Soroka concluded that changes to legislation to extend prescribing rights of therapeutic drugs in the remaining states would increase patient access to eye care. Similarly, a study in 1991, by Saroka again, compared average charges made by optometrists and ophthalmologists and found optometrist charges to be considerably lower.[109]

The advances made by the optometry profession in improving standards of patient care were demonstrated in an article written by Soroka et al in 1994 which aimed to develop an evidence based standard of optometric care for patients with diabetes mellitus to aid in the prevention, diagnosis, treatment, management, and rehabilitation of their patients.[110] In 1999, a study was conducted to determine how managed care plans were used by optometrists to provide vision and eye care across several different states.[111] The study found that optometry scope of practice was influenced by legal, financial and organisational factors. In some cases, care plans skills were underutilized relative to their legal authority, whilst in other care
plans the benefits of optometry were extended beyond the existent practice laws by creative, cooperative arrangements. In 2000, this was followed up by study that investigated the role of optometry in managed care plan.[112]

Both of the above studies looked at the appropriateness of optometric care, with the second study also assessing the extent to which optometrists provided various kinds of eye care independently, and whether referrals to ophthalmologists were appropriate. The latter study showed that optometrists provide a substantial range of eye care, which was reflective of the advances made by the optometric profession over the previous number of years during which prescribing was incorporated into their scope of practice in USA.

In Australia in 2000, Schmid et al surveyed Queensland optometrists to assess their level of education, scope of practice and the workforce preparedness to prescribe therapeutic agents.[113] A 45% response rate to the survey, 231 out of 517, was obtained. A majority (88%) wanted to be able to prescribe therapeutic agents and in line with like work, the profession felt comfortable within a narrow scope of practice; namely dry eye, blepharitis, allergic conjunctivitis, corneal abrasions and contact lens induced conjunctivitis. More than 90% felt competent to recommend topical lubricants and antihistamines, while 65% felt they were prepared to prescribe topical antibiotics. Education level, and in particular the completion of a therapeutic drug course, was the main factor that determined whether the respondents practised or were willing to practise at an advanced level.

In USA in 2001, Krumholz et al assessed the competence and prescribing patterns of optometrists newly qualified to prescribe.[114] Out of 8,936 initial visits in the study only 89 patients required ophthalmological referral and the most frequent diagnoses were related to allergies, conjunctivitis and blepharitis. On analysis, it was found the patterns of prescribing adhered to currently accepted clinical guidelines, and concluded that use of topical medicines by optometrists in New York State appeared to be safe.

In 2002, Mason and Mason investigated the potential for optometrist prescribing in UK via a national postal survey of optometrists.[115] The Anonymous Enquiry of the Scope for Optometrist Prescribing (AESOP) consisted of 22 questions in 5 sections, covering demographic details, nature of work and views on prescribing, reimbursement and audit. Surveys were sent to roughly 10% of the optometrist population, with 758 being mailed out achieving a response rate of 57%, or 432. Most respondents, 87%, thought optometrists should be able to train as therapeutic prescribers, with 67% wishing to participate personally in independent prescribing and 69% dependent. Results showed respondents, who were all optometrists, anticipated that referrals to GPs would be reduced by 39% and to ophthalmologists via a GP by 18% if they were permitted to prescribe. It was estimated optometrist prescribing could increase patient access to therapeutic ocular care by between 29% and 50%. Overall, it was suggested authorising UK optometrists to prescribe would
make good use of existing skills and improve access to eye care, while relieving pressure upon other healthcare providers.

In 2008, Needle et al surveyed the scope of practice of UK optometrists and attitudes towards an extended prescribing role via an online survey.[116] Registered optometrists were recruited by the College of Optometrists sending an e-mail to 5284 of its members. A total of 1288 responses were received, a return rate of 24.4%. As also found by Krumholz, the response showed blepharitis and dry eye were the most commonly managed conditions, managed frequently by 74% and 75% of responders respectively.[114] Over the counter preparations, such as lubricants and anti-allergy medications were supplied frequently by 87% and 32% respectively, with only 21% of respondents frequently supplying antibiotics. With regards to the extension of their scope of practice to prescribing, 75% of respondents felt they should be able to prescribe non-steroidal anti-inflammatory drugs (NSAIDs), 69% anti-glaucoma drugs, 84% further anti-infectives and 60% anti-virals, assuming further training is undertaken. A few barriers in undertaking further training for prescribing were identified, including; cost and time required, lack of remuneration for a prescribing role, and a fear of litigation. Only 14% of respondents showed no interest in undertaking further training.

In summary, the majority of optometrist evidence has been in the form of qualitative surveys to determine current scopes of practice and the willingness of the profession to undertake the extended role of prescribing, and within what scope. There has been little research in the form of pilots prior to application for prescribing rights, or evaluation once prescribing rights were granted to assess the safety, effectiveness, improvement in access or acceptability to either the patients or other members of the healthcare system.

1.6.2 Podiatrists

Minimal evidence on podiatrist prescribing has been reported in the literature with regards to safety and appropriateness. One study, in 2000 from London, by Kalra et al showed that where diagnosis, management and treatment was uncomplicated, the ability of authorised podiatrists to prescribe drug therapy would improve healthcare delivery and lessen inconvenience to patients receiving treatment for foot pathology.[117]

Several articles have discussed the notion of safe prescribing, however they have not assessed the quality of prescribing by podiatrists or podiatric surgeons in terms of frequency of prescribing errors.

Martin, in 2004, discussed strategies for optimal pharmacological management of foot pain, and touched on common errors in pain management and prescribing errors.[118]
In a similar manner, also in 2004, Wright and Warpula discussed prescribing in the elderly, more from the point of view of considerations that need to be made in order to prescribe safely and effectively, and again not actually assessing current practice.[119]

In 2005, Biederman discussed the use of non-steroidal anti-inflammatories (NSAIDs) in podiatry, and in particular the serious side effects associated with their usage, in an attempt to educate podiatrists in safe and effective prescribing.[120] Again, there was no assessment of current prescribing practice.

In 2005, Smith wrote an article on how to safely and effectively prescribe low molecular weight heparins for the prevention of venous thromboembolism, but again did not assess the safety of current practice.[121]

And in 2006, Smith also discussed pain management in podiatry patients, focusing on usage of opioid analgesics.[122] The article was a guide to aid the selection of opioids to treat lower extremity pain, but did not include any assessment of podiatrist prescribing.

1.6.3 Nurse Practitioners

Although nurse practitioners are able to prescribe medications, and have been granted access to the PBS, prescribing is only one element of their advanced scope of practice. PBS access may be regulated locally within the scope of practice of the individual or particular profession group and would remain in accordance with the state and territory legislation under which they work.

A number of articles have been written on registered nurse and nurse practitioner prescribing from various countries, in various clinical settings and assessing different models of prescribing. There has also been a mixture of qualitative and quantitative research.

In the UK, primary legislation to allow nurses to prescribe was passed as far back as 1992. In 1994, nurse prescribing began at 8 pilot sites and in 1998 a national roll out of nurse prescribing was announced. Initially, this applied only to district nurses and health visitors.

In 1998, Allen assessed the scope of practice of advanced practice psychiatric nurses via a postal survey, mailed out to a randomly selected 100 members of the Network for Psychiatric Nursing Research, and achieving a 78% return rate.[123] It was found that psychiatric diagnoses were undertaken by 55.8% of respondents, forming a good case for advanced practice roles. Prescribing of one off emergency doses and modifying doses prescribed by psychiatrists of various medications was also undertaken by significant numbers of nurses, for example short acting neuroleptics 50% and 56%, long acting neuroleptics 50% and 50% and anxiolytics 55% and 56%. There was no assessment of the appropriateness of the prescribing unearthed in the questionnaire and the study concluded that pilot sites should be established to test the effectiveness of an advanced role.
In 1998, a postal survey was also sent to senior nurses in all major accident and emergency departments in the UK in an attempt to identify scope of clinical activity, role configuration and training.\[124\] Response rate from 293 surveys posted out was 94\% or 274 replies. Sixty eight percent of departments allowed supply of ‘over the counter’ medications under local protocol, and 54\% ‘prescription only’ drug supplying from an agreed list. The article noted a wide variety in service organisation, training and scope of activity.

Similar to the optometrist articles from the USA, these articles are examples of essential work in a review of traditional role boundaries and ever evolving scopes of practice within a profession. Also, importantly, they aided in defining a niche in the healthcare system for the nursing staff that was acceptable to other members of the healthcare team according to training and perceived competence. This was a vital step in being able to expand scopes of practice further down the track.

In 1999, the Department of Health recommended that prescribing rights be extended to include other groups of nurses and other health professionals. In 2000 The NHS Plan, which emphasised that health services needed to change and modernise to improve service delivery, endorsed these recommendations and the Health and Social Care Act (2001) contained the necessary clauses to allow supplementary nurse prescribing.\[125, 126\] This meant that patients with more complex conditions such as chronic diseases and mental ill-health could be managed by a nurse practitioner after initial assessment of the patient by a medical practitioner.

In 1999, Nursing Management in England published a summary of the key points of the report on prescribing, supply and administration of medicines which recommended introducing a distinction between two new categories of prescribers, independent and dependent prescribers.\[127\] It also made a number of important recommendations for other groups of professionals considering prescribing. In particular it recommended that proposals for new professional groups to be considered as potential prescribers would be expected to come from nationally recognised organisations and that professional groups should ensure adequate arrangements are established for accrediting training programmes.

In 1999 in the UK, Bond et al explored the educational requirements for nurse practitioners in general practice, compared their performance against GPs and assessed their acceptability to patients.\[128\] After one year of working in a GP practice, the diagnoses and management decisions of the nurse practitioners were compared with GPs for 586 patients. The nurse diagnosis was found to agree in 94\% of diagnoses and 96\% of the time for clinical management decisions made. Patients were asked to complete a satisfaction survey, of which 80\% complied. While results illustrated that 38\% of patients would have preferred to see a GP, they rated the nurse consultations as good as or better then the GP.
In 2000, Venning reported on a randomised controlled study of patients in 20 general practices across England and Wales requesting same day appointments. The study recruited 1303 eligible patients and compared the cost effectiveness of general practitioners and nurse practitioners. Data was available for 652 general practitioner consults and 642 nurse practitioner consults. The study found the length of consultation of the nurses to be considerably longer than the GPs, 11.57 vs 7.28 minutes. There was no significant difference between prescribing patterns or health outcome status between groups. Patient satisfaction was assessed and patients were more satisfied with nurse consultations. There was no assessment of appropriateness of treatment, with the article focusing primarily on economic outcomes.

Wilmhurst et al, also in 2000, investigated the effect of nurse initiated thrombolysis, under a local protocol, on the time between arriving at hospital and starting thrombolytic treatment. Patients included in the study were all patients admitted with suspected myocardial infarction between 1995 and 1999. Prior to the initiation of the nurse initiated thrombolysis and a new chest pain protocol time from door to needle was assessed in seven periods, each of four months, during which time 437 patients were given thrombolytic treatment. Following introduction of nurse initiation, and during four periods totalling 20 months, 308 patients were given thrombolytic treatment. The median ‘door to needle time’ was reduced from 50-58 minutes before implementation to 25-30 minutes afterwards.

In 2001, Blue et al conducted a randomised controlled trial to determine whether nurse interventions improved outcomes in patients suffering from chronic heart failure, a model which is often cited as appropriate for a supplementary prescribing role due to the functions of dose initiation, titration and monitoring of effectiveness of treatment, lending themselves well to being guideline driven. Out of a cohort of 165 patients, it was found that fewer patients in the intervention group had fewer readmissions for any reason, for heart failure and also spent fewer days in hospital for heart failure.

In 2002, the publication *Emergency Nurse* reported that the A&E Nursing Association refuted claims by *The Lancet* that nurse prescribing was being rolled out too quickly and was ‘a dangerous uncontrolled experiment’. Dr Richard Horton, editor of The Lancet had questioned whether nurses could appraise evidence from clinical trials and whether nurse prescribing would make any difference.

In 2004, Albarran investigated the literature in order to examine the content of educational programmes, teaching methods and assessment strategies to prepare nurses to initiate thrombolytic therapy. The summary stressed there was a need for national consultation relating to guidelines, standards and accreditation of practice schemes.
In 2005 Seale et al compared nurse practitioner and General Practitioner (GP) consultations in nine general practices across England and Wales by taping 18 matched pairs of nurse and doctor consultations, form an original 55 recordings of consultations.[134] Similar to previous studies, they found that nurse practitioners spent twice as long with patients as doctors did, and wanted to show what the nurse practitioners did with that extra time. It was found that is was due predominantly to them spending more time discussing treatments. Some of the extra time was also due to the requirements of getting doctors to sign prescriptions which also prompted the authors to suggest it may be worthwhile investigating a system that afforded nurses more clinical autonomy.

In 2005, Allsop described the experiences of nine psychiatric nurses who were part of the first cohort in the UK to undertake the supplementary prescribing course.[135] Some of the proposed benefits of the nurses being able to prescribe included increased efficacy, an increased concordance with medication and an increased access to medication. No data were published to back these claims up.

Also in 2005, Allen evaluated a community aged care nurse practitioner service by inviting all new clients and carers visited by the Aged Care Nurse Practitioner Candidate (ACNPC) to participate in a semi-structured interview.[136] From 18 new clients invited, 15 agreed to be interviewed and 10 health care professionals on the aged care team were interviewed. The analysis of responses showed that the respondents thought the service would be of high quality and positively impact on client health outcomes to improve quality of life. Again, there was no evaluation of the service via any other means or hard data to back these claims up.

Evidence from USA is slightly more robust, with several trials assessing the effectiveness of nurse practitioners. Dunagan et al, in 2005, assessed the efficacy of a nurse led telephone follow up service, after their initial physician contact, for patients suffering from heart failure.[137] The intervention involved randomisation of 151 patients hospitalised with heart failure to either usual care, which was an educational package describing the causes of heart failure, the basic principles of treatment, their role in routine care and monitoring their condition, and appropriate strategies for managing an exacerbation of heart failure or intervention, which involved additional regular follow up telephone contact by specially trained nurses to assess self-management, diet, adherence to medications and any exacerbations of heart failure symptoms. The results showed that at 6 months the number of total admissions, hospital days and hospital costs were significantly lower that the control group. However, at 12 months the results were no longer statistically significant. Whilst the study did not directly assess prescribing, it did assess an intervention of an advanced level, specially trained nurse in the monitoring and treatment of a chronic disease.

Astles, in 2006, conducted a literature review of nurse practitioner services in elderly patients, which summarised that nurses are excellently placed to diagnose due to the long term
relationship many had developed with the patients.[138] This was theorised to reduce the time the patients waited for treatment and increased the cohesion within multidisciplinary teams. In the ‘key points’ summary the authors were confident in stating that nurse practitioners were ‘safe and effective diagnosters and prescribers’, but only pertaining to the limited scope of practice, and limited drug formulary for the treatment of elderly patients for a limited number of conditions.

One of the few authors to actually assess the appropriateness of prescribing, Latter et al, from the School of Nursing and Midwifery in Southampton, England in 2007 developed a methodology for testing which involved sending an audio recording of consultations to a panel of prescribing experts.[139] There were ten prescribing nurses selected from a range of sites, and the final cohort included six nurse practitioners and two practice nurses in general practice settings, two senior nurses in a walk in centre, two community midwives, a nurse consultant in secondary care, and a community palliative care nurse. To be included in the study each nurse had to have a reported prescribing rate above 10 items per week, and regular reported prescribing of antimicrobials. The expert panel consisted of seven experts who were known nationally for research in to medical prescribing, clinical expertise in prescribing and/or were in leadership positions in national or regional prescribing related organisations. Five were GPs and two were physicians/clinical pharmacologists. In the study 118 prescribing episodes were evaluated using a modified version of the Medication Appropriateness Index (MAI), a tool which had been used by both pharmacists and doctors to rate appropriateness of prescribed drugs, and showed good inter-rater and good intra-rater reliability coefficients in preliminary research. Findings from the panel highlighted that nurses in the study were generally making prescribing decisions that were clinically appropriate across a number of indicators.

In 2007 in USA, Barth et al undertook a descriptive review of 366 patients having 28,192 blood glucose measurements in three intensive care units, Surgical Trauma Intensive Care Unit, Medical and Coronary Care Unit to assess the effectiveness of a nurse initiated insulin infusion protocol.[140] Results showed that it was safe and effective in controlling BSLs and that deviations from protocol were uncommon in all three units.

Two articles by Stenner in 2008 explored nurses’ views on the benefits for patients of nurse prescribing for patients in pain, and secondly, the role of inter-professional relationships and support for nurse prescribing in acute and chronic pain.[141] [142] Twenty six nurses were interviewed and a number of benefits were reported, including faster access to treatment, improved quality of care, improved relations and communications with patients, greater efficiency and cost effectiveness. There was no evidence to back any of these claims up, bar anecdotal evidence and scenarios.
The same interviews were analysed for views on the role of inter-professional relationships and found the nurses believed that prescribing encouraged collaborative working with doctors, which served a number of functions including support and continuous learning. The biggest barrier to nurse prescribing was believed to be a lack of understanding of the nurses prescribing role amongst healthcare professionals.

In the lead up to the federal budget, in 2008, Dragon published a timely article which highlighted that despite the fact nurse practitioners can prescribe, order diagnostic tests and refer, few are working to potential capacity to the restrictions that not having access to the PBS places them under. [143]

Gardner, in 2009, mailed out a five section questionnaire in July 2007 to all 234 registered nurse practitioners in Australia achieving an 85% response rate. [144] Over 70% stated that lack of Medicare provider numbers and lack of authority to prescribe through the PBS was extremely limiting to their practice, which is a finding consistent with the international literature describing establishment of reformative health care roles.

In the 2009 Federal Budget, the Health Minister outlined her intention that nurse practitioners and midwives would be granted access to the PBS from 1 November 2010.

In 2012, Latter et al used a similar methodology to assess the appropriateness of both nurse and pharmacist prescribing decisions as previously to assess the appropriateness of nurse prescribing in 2007. [145] As in 2007, the study showed that nurses and pharmacists were generally making clinically appropriate prescribing decisions. Potential room for improvement was noted from qualitative comments in nurses and pharmacists history taking, assessment and diagnosis skills.

### 1.6.4 Pharmacists

The literature review identified the largest number of research papers published on non-medical prescribing were in the pharmacy profession. This included a number of published research papers focusing on clinical and economic outcomes of pharmacist supplementary prescribing in the UK.

Pharmacist prescribing is an established initiative in USA, with prescribing in some form having been implemented in 45 states.

In 1998 in USA, Martin et al explored pharmacist prescribing of antiemetic agents in patients receiving chemotherapy, with pharmacists managing antiemetic therapy for more than 1200 patient visits. [146] The authors reported that this model was accepted by both patients and other professionals in the clinic.

In 1998 in UK Bleiker and Lewis sought to ascertain views of GPs on a potential extension of the role of community pharmacists. [147] A questionnaire including attitude scales and open
ended questions was sent out to 368 GPs of the South and West Devon health commission area, achieving a 81.2% response rate. Overall there was a positive attitude towards pharmacists as part of the primary healthcare team, but there was little support for the idea of pharmacists undertaking screening and running therapeutic monitoring clinics, with only 14% agreeing to pharmacists running lithium monitoring clinics.

Also in 1998, Child et al investigated healthcare professionals’ views on hospital pharmacist prescribing, with questionnaires being sent to 195 doctors, 200 nurses and all 87 pharmacists working at 5 hospitals in Birmingham, England.[148] The combined response rate was 57.5%. Overall a high proportion of doctors and nurses responding agreed (78.7 per cent and 86.1 per cent respectively) that it would be useful to permit pharmacists to write prescriptions and prescribe drug treatment, though a majority believed that this should only include pharmacists with postgraduate education/training and that the pharmacist was routinely attached to the clinical area in question. Important issues highlighted as potential barriers to pharmacist prescribing included pharmacist willingness to accept the new role, education and training, familiarity with the patient, communication between healthcare professionals, professional and legal accountability and resource implications. If further training and education was made available for those who felt there was a need for it, 98.5% of pharmacists stated they would be happy to write a prescription for existing therapy.

Two studies, in 1998 and 2000 investigated the ‘repeat prescribing’ model for community pharmacists. Dowell recruited a convenience sample of five medical/pharmacy practice pairs across Tayside in Scotland.[149] A stratified, random sample of 156 adult patients receiving thyroxine, atenolol, oral hypoglycaemics or allopurinol were randomised to receive repeat dispensing or their usual service. After one year practices were allowed to expand the system as they wished. After the trial year a postal questionnaire (n=214) was sent out to evaluate patient opinion of the new scheme and professionals’ opinions were sought by interview. The results showed employing community pharmacists to streamline the process and provide clinical supervision was popular with patients and GPs, and worked well for patients in stable treatment regimes, however the evaluation does not provide robust data on quality of care.

In 2000, Bond et al conducted a much larger study comparing community pharmacy managed repeat prescribing system versus usual care across 19 general medical practices, 3074 patients and 62 community pharmacists in Grampian, Scotland.[150] The results showed that there were more adverse drug reactions, more hospital admissions and more compliance problems found in the arm managed by community pharmacists and significant savings made in the drug bill of patients by monitoring more closely the medications that were actually required by the patients. The
authors acknowledged anecdotal evidence of some patients being excluded from recruitment as the GPs may have classed them as ‘unsuitable’, which may have affected the study sample.

Jones explored the patient satisfaction element of the study by Bond in 2000, by sending questionnaires to 2667 patients, 1625 intervention and 1042 control patients.[151] Return rate was 73% and the results showed the pharmacist managed repeat system was preferred to the usual system by 81% of patients, although it was acknowledged that satisfaction was influenced positively by reduced waiting time and financial cost.

In 2000, Holden et al compared the effectiveness of pharmacist managed warfarin in the community against GPs by means of a retrospective analysis of patients who had been managed by GPs and subsequently referred to the pharmacist led outreach service within Gateshead and South Tyneside Health Authority.[152] The audit looked at individual international normalised ratio (INR) results, the time interval between tests and whether the INR was within therapeutic range. Both the GP and pharmacist managed care was audited and it was found, among the 51 eligible patients, that the pharmacy management was at least as effective, with the proportion of test results that were in range greater than with GP monitoring and the interval between tests was longer.

In 2000, Boddy investigated the effects of the involvement of a pharmacist on the quality of medical inpatient maintenance coagulation.[154] For 4 weeks warfarin dosing by doctors was investigated on 4 medical wards, and found delays in initiation of warfarin, failure to maintain INR, inappropriate frequency of measurement, delayed administration and poor continuity of care. Following circulation of prescribing guidelines to all consultants and junior doctors, the haematology pharmacist was responsible for warfarin dosing on 2 of the wards, while on the other 2 wards warfarin dosing was continued by the doctors. The study period was 12 weeks. The study found that in the pharmacist group INR control was improved, with 58% of INRs measured from day 4 onwards being in the therapeutic range, when compared with 17.7% of the doctor INRs. A higher percentage of patients reached therapeutic INR by day 8 (88% vs 72% and 77%). Fewer INRs were requested by the pharmacist, on average 2 INRs per 7 patient days compared to 4.5 INRs per 7 patient days by the doctors. Timing of warfarin dosing was more appropriate according to guidelines, with 90% of the doses prescribed by the pharmacist given within 1 hour of the 6pm administration time, compared to 15% of the doctors’ doses.

In 2004, another warfarin study was conducted by Burns, again evaluating the effectiveness of pharmacist dosing of warfarin for inpatients compared against usual care of junior doctors.[155] The study was undertaken at Brighton General Hospital, England and two medical wards were
under pharmacist control of warfarin dosing and three medical wards remained under the care of doctors. From all wards, 33 patients were recruited into both arms and results showed that patients in the intervention received more appropriate loading doses (100% vs 73%), so reached target INR quicker (93% at day 6 vs 73%), better INR control with only 67% of patients being out of range at some point during their stay in the intervention group, compared to 91% in the control group. There were also fewer adverse events in the intervention arm (2/33) than the control arm (4/33). The authors acknowledged a number of limitations, including small patient numbers.

In a short article in the pertaining to pharmacist prescribing in Northern Ireland, Maguire referred to three pilots; two where costs were not increased by using pharmacist prescribers, and one which referred to pharmacists independently prescribing from a limited formulary for coughs and colds.[156] Maguire held the view that the government in Northern Ireland was only supporting supplementary prescribing to make existing clinics, such as warfarin clinics, legal.

In 2004, Bellingham described three pharmacists providing supplementary prescribing services in an acute setting in hospital and one in an outpatient HIV clinic.[157] The three pharmacists in the acute setting prescribed total parenteral nutrition (TPN) and described supplementary prescribing of a way to legalising what pharmacists did before. The advantages of the supplementary prescribing role were listed as: uses pharmacists better; saves junior doctor time; provides junior doctors with a good role model for prescribing; and, the patient gets care from a skilled practitioner.

Australian literature on pharmacist prescribing is also limited, with the first discussion in 2004 by Hanes and Bajorek focusing on whether the Australian pharmacy profession was prepared to take on the role of prescriber, using a questionnaire to explore hospital pharmacists’ opinions of pharmacist prescribing.[158] Small numbers of hospital pharmacists (N=10) and teacher practitioners (N=5) rated the appropriateness of suggested models of pharmacist prescribing. The authors concluded that ‘discharge or specialist settings may be ideal to pilot pharmacist prescribing’.

In the same year, Kay and Brien encouraged discussion about future roles for pharmacists in Australia suggesting that new roles, such as prescribing, should be evaluated for impact on the profession and on health outcomes.[159]

In 2004 Weeks, in a letter to the editor, encouraged the pharmacy profession to start discussion and debate on pharmacist prescribing and lay the foundation for pharmacy practice reform.[160]

In a literature review in 2004, Kay et al identified only 18 studies conducted since the 1970’s which measured outcomes comparing pharmacist prescribing to standard care.[161] The summary reported positive outcomes associated with pharmacist prescribing included: improvement
in disease control; improvement in compliance; improved patient outcomes; reduced adverse effects; fewer drugs prescribed; reduced death rate; increased discharge rate; and, reduced resource utilisation.

In 2004 in USA, Rapoport assessed the effectiveness of pharmacist involvement in the management of patients in a pain clinic.[162] It was found that waiting time for an appointment in the pain clinic was reduced and unscheduled visits for narcotic prescriptions were eliminated.

Also in USA in the same year, Lynn reported their assessment of pharmacist interventions to optimise pain management in a study of 22 patients reportedly expressed they were satisfied with the service and grateful the pharmacist had improved their level of comfort.[163]

In 2005, a much larger study funded through the Third Community Pharmacy Agreement in Australia by Bessell et al developed four theoretical prescribing models and assessed the applicability of each model in an Australian context via semi-structured interviews with 34 participants, including policy makers, medical practitioners, pharmacists and consumers.[1]

Rahman et al, in 2005, evaluated the quality of pharmacist written discharge prescriptions from a general surgical ward in a UK hospital by running a 2 phase study over 2 weeks.[164] In phase 1, doctors wrote the discharge prescriptions which were checked by the ward pharmacist. In phase 2, ward pharmacists wrote the discharge prescriptions which were then checked by the junior doctor. Both phases were subjected to a final check by the dispensary pharmacist, and all interventions were recorded on a data collection form. There were 128 doctor written discharges, compared to 133 pharmacist written. In total 755 interventions were recorded during the doctor written phase, compared to 76 during the pharmacist written phase. Pharmacist written discharge prescriptions contained fewer errors, omissions and unclear information in comparison to doctor written discharge prescriptions. The authors acknowledged the short study time, and the fact that both groups were aware of the assessment as major limitations.

In 2005 Shulman conducted a randomised controlled trial in an ICU setting to determine the level of adherence to guidelines of anti-infective agents in haemofiltered patients by pharmacist prescribers and doctor prescribers.[165] Results showed 53.7% of doctor prescriptions compared to 100% of supplementary pharmacist prescriber prescriptions were deemed appropriate.

In 2005, Ahmed described his experience as a supplementary prescriber; prescribing in the areas of hypertension, hypercholesterolaemia, hypothyroidism, epilepsy, ischaemic heart disease and pain management.[166] He made several claims in the article resulting from pharmacists prescribing, including better inter-professional relationships, more effective use of pharmacy skills, fewer drug errors and satisfaction from independent prescribers, patients, practice nurses and other staff. However, none of these claims were backed up by any evaluation or data.
Also in 2005 in USA, Bond assessed clinical and economic outcomes of pharmacist managed aminoglycoside or vancomycin therapy in a hospital setting, in a study population composed of 199,082 Medicare patients treated in 961 hospitals.[167] The author reported significant improvements in the management of both therapies; hospitals that did not have pharmacist managed vancomycin or aminoglycoside therapy, death rates were 6.71% higher, length of stay was 12.28% higher, drug charges were 8.15% higher. With regards to adverse effects, hearing loss was 46.42% higher and renal impairment was 33.95% higher.

Much of the qualitative research published from UK has involved pharmacists who were already supplementary prescribers. Most of the literature reported intra-professional perspectives, with little data reported exploring the perspectives of patients and other professions. One small study in 2006 by Smalley investigated patient perceptions of a pharmacist led supplementary hypertension clinic, via a postal questionnaire, sent out to 127 patients.[168] Following two mailouts, the response rate was 87% and the results indicated that there was a general acceptance of patients for non-medical prescribing, with 57% of patients feeling standard of care was better than they received previously, 86% of respondents said they understood more about their condition, and 92% saying supplementary prescribing by pharmacists was a good idea.

In 2006, Khoo et al aimed to identify opportunities for pharmacist prescribing activities in warfarin management in the hospital setting via an audit of pharmacist interventions in the management of patients’ warfarin therapy.[169] The authors concluded there was ample opportunity for pharmacist prescribing within this model, however the outpatient setting may be more appropriate for a trial of pharmacist prescribing due to significant practice change being required in hospital.

Dole et al in USA in 2007 assessed pharmacist prescribing in a pain setting and found that patients were effectively managed, using the pain score as the clinical measurable endpoint.[170] The pharmacist saw an average of 18 patients a day between June 2004 and June 2005. The study also looks at safety and economic outcomes, finding an improvement in both, with the clinic generating $107550 of actual revenue and saving the health plan over $450000.

Following on from the initial paper in 2001, in 2007 the Canadian Pharmacists Association (CPA) released a position statement on pharmacist prescribing which highlighted that in recent times that pharmacist scope of practice had widened to include a greater range of activities, including: modifying prescriptions written by another prescriber to either improve drug therapy or provide continuation of drug therapy; and, prescribing medications through delegated authority or under collaborative practice agreements [171].

In 2008, Vracar et al assessed Australian GP views on extended prescribing rights for pharmacists via a questionnaire and a semi-structured interview.[172] Some major issues were
raised by the GPs, including safety issues, lack of awareness of pharmacist capabilities, interference with the GP-patient relationship and remuneration. The authors concluded that the issues raised would need to be addressed before pharmacist prescribing could be pursued.

In a follow up of the 2004 letter, Weeks used a postal questionnaire in 2008 to assess the views of Society of Hospital Pharmacists of Australia (SHPA) members on collaborative prescribing, and the extent of ‘de facto’ prescribing within their institutions.[173] From 1367 invitations to participate, 551 pharmacists responded, with the results showing that there was strong support for development of collaborative prescribing in Australia, with hospital pharmacists already undertaking a range of ‘de-facto’ prescribing activities.

One of few studies, by Charrois et al, to assess clinical outcomes is underway in Canada.[174] The multi-centre study aims to assess the effect of pharmacist managed prescribing, and titration of antihypertensives, on change in systolic blood pressure between baseline and 24 weeks, with a view to providing high level evidence about pharmacist prescribing.

More patient perspectives were sought in 2011 by Stewart et al in UK, this time from patients who had experienced pharmacist prescribing in primary care.[175] All 1162 registered prescribers were asked to participate, by inviting up to five consecutive patients who had experienced their prescribing services to complete a questionnaire. From the 49 pharmacists eligible to participate, 143 patients were recruited, with a response rate of 73.4%, or 105 surveys. Overall patients were very satisfied with their pharmacist, and most would recommend seeing a pharmacist prescriber. However, due to small numbers, findings may not be generalizable.

In 2012, an Irish study by McCann et al evaluated views on pharmacist prescribing from patients, doctors and relevant stakeholders.[176] Interviews were conducted with 11 pharmacists, eight doctors who had acted as mentors during prescribing training, and 13 stakeholders who were viewed as having a vested interest in the development of pharmacist prescribing. Key themes to emerge from the semi structured interviews were effect on patient care, challenges facing pharmacist prescribers and the importance of the inter professional team. The main advantage in patient care was an enhanced medication focus during consultations, the main challenge was seen to be medical resistance, and the focus on the professional team was suggestive that a collaborative approach to prescribing was more favourable than the pharmacist acting independently, and possibly causing fragmentation of care.

A UK study in 2013 by Bruhn et al investigated chronic pain control in a three way randomised control study; pharmacist review with pharmacist prescribing, pharmacist review with feedback to GP or usual care.[177] Final numbers of patients who completed questionnaires was 152 across the three arms, with 50 in the pharmacist prescribing arm. Results showed a statistically significant improvement in the Chronic Pain Grade (CPG) in the pharmacist prescribing arm,
however the study acknowledged low numbers and the need to repeat the study on a larger scale, to achieve higher power.

A Canadian before-after design study in 2013, by Hamameh et al, assessed the effect of pharmacist prescribing on glycaemic control, in patients with poorly controlled type-2 diabetes, and an HbA1c of 7.5-11.[178] Results showed, in the 100 patients recruited in to the study, an average 1.8% reduction in HbA1c over the 26 week study period. Over half of the patients achieved an HbA1c of <7 by the end of the study period. The results were comparable to any previous studies of physician diabetes management, and provide evidence for a potential enhanced role for pharmacists in diabetes management

1.7 Evidence of Healthcare Benefits of Non-Medical Prescribing Models

The Australian Health Ministers’ Conference (AHMC) established the National Health Performance Committee (NHPC) in August 1999. This committee was responsible for the development and maintenance of a national health performance framework that could be used as the basis for its annual report to Health Ministers. The framework developed consisted of three tiers: health status and outcomes; determinants of health; and health system performance, and was endorsed by the Australian Health Minister’s Advisory Council in 2001. It was subsequently reviewed by the NHPC in 2007-08, with a revised framework agreed by the National Health Information Standards and Statistics Committee (NHISSC) and noted by Health Ministers in September 2009.[11]

Health system performance consists of six measures to assess the following criteria:

- How well does the health system perform?
- What is the level of quality of care across the range of patient care needs?
- Is it the same for everybody?
- Does the health system deliver value for money and is it sustainable?

The framework can also be used as a guiding structure when developing sets of performance indicators for more discrete components of the health system, such as a particular program, or a specific target group. The evaluation framework is proposed to attempt to demonstrate positive outcomes in as many of the six measures as possible:

1. Effectiveness
2. Safety
3. Responsiveness
4. Continuity of care
5. Accessibility
6. Efficiency and Sustainability
With this determination in mind, matching the literature on non-medical prescribing against this framework for health system performance has indicated that the quality of published research is generally poor when assessed against all measures.

A review of the literature has identified that all three of the main professions in the literature; pharmacy, nurses and nurse practitioners have attempted to demonstrate their ability to prescribe through studies and reports, looking at capability and effectiveness. Pharmacists also assessed the
safety and efficiency of their prescribing. Nurses and nurse practitioners mainly evaluated responsiveness, as well as sustainability and accessibility to services.

In the light of a gap in the literature of research into pharmacist prescribing within the Australian healthcare system assessing the impact of service quality against a defined and endorsed evaluation criteria, this thesis intends to investigate a pilot of pharmacist prescribing, using methodology designed to assess quality of the collaborative prescribing model in line with the national health performance framework.[11]

1.8 Independent Reviews of Non-Medical Prescribing Services

Pharmacists and nurses were found to be best represented in published trials of non-medical prescribing, from a literature review published by Cooper et al in 2008.[7] The authors searched the literature between 1997 and 2007, using MEDLINE, EMBASE, CINAHL IS web of Knowledge and Zetoc and found 35 published trials of nurse and pharmacist prescribing, 20 alluding to pharmacy and 15 to nursing. Studies were mainly qualitative in nature, and assessed the views of different members of the healthcare team with regards to the possible advantages of non-medical prescribing, without backing these theories up with prescribing audits and data. Few studies assessed clinical indicators as an evaluation of the quality of prescribing by non-medical prescribers.

The same authors, also in 2008 published a review of stakeholders’ views on nurse and pharmacist supplementary prescribing (SP), by undertaking semi structured interviews with 43 UK stakeholders, including pharmacist and nurse supplementary prescribers, doctors, patient group representatives, academics and policy developers.[179] Overall views were positive and the suggestion was that SP has the potential to fulfil the UK Governments objectives with regards to improved access to medicines and reducing delays in seeing healthcare professionals. In summary the authors suggested that several years after implementation in the UK that challenges, and a number of tensions still remained, which could potentially threaten the success of supplementary and other forms of non-medical prescribing.

The biggest implementation threat was perceived to be that patients remained largely unaware of SP, and that SP was introduced without adequate patient consultation and information. One of the tensions alluded to by several stakeholders was that some doctors may be threatened by SP, and several examples were provided of conflicts between nurses and pharmacists in practice.

In 2009, Winstanley suggested problems with the ongoing implementation and sustainability of pharmacist prescribing due to a lack of credible evaluation of the new service, either from a pilot phase or after implementation.[180]
In 2010, the National Health Workforce Planning and Research Collaboration (NHWPRC) undertook a thorough review of the literature, as already discussed previously.[37] The report concluded that whilst there is a sizable body of literature addressing non-medical prescribing, there is a lack of rigorous evaluation data published.

However, in 2010, Latter et al produced the largest and most comprehensive review of nurse and pharmacist independent prescribing through the University of Southampton.[86] The study used three phases.

Phase 1 included a national questionnaire survey of nurse (N=976/1462, 58% response rate) and pharmacist independent prescribers (N=208/358, 58.1% response rate), a telephone survey of non-medical prescribing Trust leads (N=86/168, 52% response rate) and focus group discussions, involving 23 people split into two focus groups of 9 and 12, with Higher Education Institutions non-medical prescribing program leads and Designated Medical Practitioners.

Phase 2 used case studies of practice, including analysis of the appropriateness of nurse and pharmacist prescribing using the MAI, case record analysis of nurse and pharmacist independent prescriber consultations against national prescribing standards (n=451), patient surveys (N=273, 141 from patients of nurse prescribers, 132 from patients of pharmacist prescribers) of experiences, outcomes and preferences and interviews with health care professionals (N=10).

Phase 3 was a multi stakeholder workshop where all stakeholders were invited to consider and prioritise the initial study findings.

Key points of the findings of the report were summarised, namely:

- between 2% and 3% of the current nursing and pharmacy workforce were qualified to prescribe medicines
- prescribing was predominantly in primary care
- study results indicated that prescribing was overall safe and appropriate
- current educational programmes were largely satisfactory and provide fit for purpose clinicians
- acceptability to patients is high
- most patients did not express a strong preference to their medical or non-medical prescriber
- nurse and pharmacist prescribing in England is becoming a well integrated and established means of managing a patient’s condition and providing access to medications

In 2011, Bhanbhro et al undertook an integrative review of the literature, using CINAHL, MEDLINE, BNI, AMED, ISI Web of Knowledge and Index to Theses.[8] The review found 19 papers, from 17 empirical studies, mainly from UK. Only 2 two papers investigated clinical outcome, seven reported only qualitative data and four studies had fewer than 10 participants. The literature review concluded that there were substantial gaps in the knowledge base to help evidence
based policy changes, and that the acceptability of non-medical prescribing is based only on the perceived value to the health care system.

In Australia there are published opinions suggesting that evidence already exists of resistance to change.[9, 94] There have been calls for evidence as to the effectiveness and safety of non-medical prescribing before implementation of this new initiative can be considered.[181]

Most recently, Gielen et al conducted a literature review of relevant studies, between January 2006 and January 2012, to assess the effects of nurse prescribing compared to physician prescribing on the quantity and types of medication prescribed, and on patient outcomes. The authors searched 11 databases for quantitative studies which had a comparative design to physician prescribing. Models of care included were patient group directions, supplementary and independent prescribing. Thirty five studies met the inclusion criteria, only 13 of which reported on clinical outcomes. Most of the 13 reported no differences between nurse and physician prescribing. One study in patients with hypertension and diabetes showed a larger drop in diastolic blood pressure in patients receiving prescriptions from nurses, whilst another study in diabetic patients showed better cholesterol control in patients treated by a medical specialist. The review concluded that due to methodological weaknesses in the studies that any conclusions are to remain tentative, the main one being that 24 of the 35 studies were not randomised controlled trials, and that more randomised controlled trials were needed to be able to draw firm conclusions about the effects of nurse prescribing.[182]
2 Chapter 2: Evaluation Framework for Non-Medical Prescribing

2.1 Chapter Introduction

Without robust and credible evidence for the benefits in health outcomes of non-medical prescribing, widespread implementation will be challenging. Our aim is to develop a consistent evaluation framework that could be applied to non-medical prescribing research.

An informal collaboration was initiated in 2008 by a group of pharmacists from Australia and New Zealand to assist in information sharing, pilot design, methodologies and evaluation for pharmacist prescribing.

Different pilots were using different models, methodologies and evaluation, it was agreed that the development of a consistent evaluation framework to be applied to future research on non-medical prescribing was required.

The framework would help to align the outcomes of different research pilots and enable the comparison of endpoints to determine the effectiveness of a non-medical prescribing intervention.

This article presents the results of a workshop held at The University of Queensland in January 2009. Participants were asked to consider how to evaluate the effectiveness of different models of pharmacist prescribing.

What is known about the topic? Little is known about the effectiveness and safety of non-medical prescribing services due to a lack of robust evidence.

What does this paper add? This paper adds a methodology for clinicians and healthcare managers to be able to evaluate any new service of non-medical prescribing, either in the pilot phase or once introduced as a new model of care.

What are the implications for practitioners? The implication for practitioners is the ability to prove to healthcare providers that non-medical prescribing services are at least as effective as usual care, so informing whether a change should be introduced in the way healthcare is delivered to patients.

2.2 Published Paper: An Evaluation Framework for Non-Medical Prescribing


This paper is reproduced in full in Appendix A
2.2.1 Introduction

Healthcare workforce shortage is a well-documented global phenomenon. A 2006 report by the World Health Organisation (WHO) estimated that a 70% increase in the health workforce is required worldwide, including doctors, nurses and midwives, in order to meet current demand. Australia is no exception to this phenomenon of health workforce shortage, with several reports over recent years highlighting the shortages, the reasons behind them and possible solutions.[15-17]

In 2003, Brooks et al. expressed concerns regarding doctor shortages, especially in rural areas, and suggested various methods that they felt merited further investigation, including: greater flexibility for entry of highly trained overseas doctors, increasing medical school student intake and workplace practice alternatives (e.g. example ‘task substitution’).[18, 183]

The supply of medicines and pharmaceutical-related services in Australia is guided by the National Medicines Policy and the Policy for the Quality Use of Medicines.[183] Both documents prioritise the need for timely access to safe, effective and efficient use of medicines.

Recent reviews suggest that health services in Australia may not be currently meeting these requirements.[184] The Quality in Australian Health Care Study identified the harm associated with medicine use in Australia over 13 years ago.[185] Major programs of work have subsequently been undertaken to improve medication safety, with one such example being the development and implementation of the National Inpatient Medication Chart. This program of work has improved the safety of prescribing in the hospital setting.[186] However, as two editorials in particular have highlighted, safety issues still remain, with Wilson and Van Der Weyden saying in 2005 that 10 years on from the original study, hospitals were no safer, noting the inadequacies of the organisational and political responses, and saying that Australia needs a patient safety initiative that captures the imagination of politicians, professionals and the public.[187] In 2008, Hughes also highlighted the ongoing problem of medication error in hospital, asking what could be done.[188]

Subsequent work has also shown high rates of preventable medication misadventure in the Australian community setting, with a review of 1000 patients showing 2222 medication-related problems, with 90% of patients experiencing at least one.[189] One in three people were found to require additional monitoring, one in four required additional medication, one in four were using the wrong or inappropriate medication and one in five were using insufficient medication.

Also in the community setting, in 2006, a study of 8215 patient encounters with general practitioners (GPs) reported 10.4% of patients had experienced an adverse drug event in the previous 6 months. GPs classified 23.2% of the adverse drug reactions as preventable, and the study concluded that adverse drug events were one of the most significant causes of morbidity in the Australian community.[190]
The issue of access to health services, in particular medicines, has seen several changes to the Pharmaceutical Benefits Scheme and health service provision, for example the Rural and Remote Section 100 program. In spite of these initiatives, the quality of medicine services remains an issue for many Australians, with access to medications still a problem, especially in the rural setting. In 2004, Kowanko et al sent out 225 surveys to workers and managers from ~30 health and human service organisations across metropolitan, rural and remote areas of South Australia.[42] The purposively selected sample had to have some involvement with Aboriginal people suffering from mental health disorders, and management of their medications. Several issues influenced quality use of medicines in the patient population, including limited access to specialist services. The authors also concluded that the range of workers providing medication services was very wide, and many workers lacked adequate training or resources.

Another study by Gordon et al from Townsville Hospital also highlighted the issue of access to services.[43] In the study, involving a computer-assisted telephone interview of 410 cancer patients, the authors found that over 46% of patients lived more than 100 km away from the hospital and 3% lived more than 600 km away. Average out-of-pocket expenses involved in attending hospital for treatment ranged between $563 and $6231, with a mean value of $4311. The National Health and Hospitals Reform Commission and the establishment of the National Health Workforce Taskforce have both recognised the need to reform the way healthcare services in Australia are delivered.[191]

2.2.2 International developments

Following recommendations made in the Crown Reports to the government of the United Kingdom (UK) in 1999, changes were made in legislation, resulting in the extension of prescribing privileges to non-medical professionals, including pharmacists.[2, 3] The UK Canada, USA and New Zealand have all extended prescribing of ‘prescription only medicines’ to healthcare professionals other than doctors.[192-197] In a literature review published by Cooper et al in 2008, pharmacists and nurses were found to be best represented in published trials of non-medical prescribing.[7] The authors searched the literature between 1997 and 2007, and found 35 published trials of nurse and pharmacist prescribing, 20 alluding to pharmacies and 15 to nursing. Studies were mainly qualitative in nature, and assessed the views of different members of the healthcare team with regards to the possible advantages of non-medical prescribing, without backing these theories up with prescribing audits and data. Few studies assessed clinical indicators as an evaluation of the quality of prescribing by non-medical prescribers. A lack of robust evidence of increased safety from the introduction of non-medical prescribing services into other countries has led to calls for evidence to prove the effectiveness of non-medical prescribing services and resistance to such change in Australia.[9, 181]
In recognition of a lack of evidence and the need for a nationally consistent framework to evaluate non-medical prescribing, a collaboration of pharmacists from Australia and New Zealand was established in 2008. This collaboration was born from the common goal of establishing an evidence base for the effectiveness of pharmacist prescribing being undertaken in a series of pilots in Australia. The objectives of the collaboration were to:

* Share information, methodologies, barriers and enablers of pilots of pharmacist prescribing;
* Establish an evidence base as to the effectiveness of pharmacist prescribing;
* Establish a framework for uniformly measuring effectiveness, so as to enable the alignment of research outcomes and comparison of data and evidence; and
* Develop a framework that could be used to measure the ongoing effectiveness of pharmacist prescribing services following the pilot phase.

It is hoped that if evidence can be provided in a robust, credible and consistent manner, it may address some of this resistance to change.

Evidence as to the effectiveness of non-medical prescribing may also avoid some of the suggested problems with the ongoing implementation and sustainability of pharmacist prescribing in the UK due to a lack of credible evaluation of the new service, either from a pilot phase or after implementation.[180] With significant changes to health service delivery pending, there is an urgent need to define a uniform framework for the evaluation of non-medical, including pharmacist, prescribing. The broad practice of hospital pharmacy lends itself well to developing models of pharmacist prescribing for the Australian setting, as pharmacists have medicinal knowledge and the skills inherent to prescribing, along with access to patient clinical records and experience in practising as part of a multidisciplinary team.

As highlighted by The Pharmacy Guild in ‘The Roadmap – The Strategic Direction for Community Pharmacy’, community pharmacists remain the most accessible of all health professionals, available for consultations at short notice and without appointment across a variety of locations all across Australia.[198] Without robust evidence for this new scope of practice, further development of this role is unlikely. This paper presents some of the outcomes of this informal collaboration.

### 2.2.3 Background

In 2000, the National Health Performance Committee developed the National Health Performance Framework for the Australian Health Minister’s Conference. The framework was reviewed in 2007–08, and a revised framework was agreed and noted by the Health Ministers in 2009.[11] This performance framework has been endorsed by each jurisdiction and was used as the basis for a pharmacist prescribing performance framework.
2.2.4 Objective
To develop an evaluation framework that can be utilised to assess the performance of non-medical prescribing services uniformly, in several different models.

2.2.5 Method
Groups of researchers undertaking pilots of pharmacist prescribing across Australia were identified. An open invitation was sent across Australia and New Zealand, to which 30 attendees responded from NSW, Victoria, South Australia, Queensland and New Zealand. A day-and-a-half workshop was held at University of Queensland, which involved presentations from the different sites on their planned pilots. From the presentations, it was clear that each site was assessing different models of pharmacist prescribing and subsequently using different evaluation methods. Following the presentations, attendees were split into five groups. Each group was given a different model of pharmacist prescribing and asked to consider how to evaluate these models:
* Pharmacist prescriber (global),
* Community generalist,
* Community specialist,
* Hospital generalist,
* Hospital specialist.

The models of care were chosen to reflect that the two most likely practice settings of pharmacists are either in a hospital or in the community. Within those settings, pharmacists may provide a generalist role (e.g. ward pharmacist on a general medical ward or a community pharmacist) or a specialist role (e.g. renal specialist pharmacist, pharmacist in a surgical preadmission clinic).

The groups were asked to consider the measures necessary to prove the effectiveness of each model. Data were collated by the project team and measures and indicators have since been aligned with the six dimensions of the National Health Performance Framework, namely:
* Accessibility
* Continuity
* Effectiveness
* Efficiency and sustainability
* Responsiveness
* Safety

Following development of the non-medical prescribing evaluation framework, the document was circulated to the collaboration for endorsement.
2.2.6 Results

The proposed non-medical prescribing evaluation framework is described below.

Australian Institute of Health and Welfare domains of health system performance

(1) Accessibility. People can obtain healthcare at the right place and time irrespective of income, physical location and cultural background.

(2) Continuity. The ability to provide uninterrupted, coordinated care or service across programs, practitioners, organisations and levels over time.

(3) Effectiveness. The care, intervention or action provided is relevant to the client’s needs and is based on established standards. The care, intervention or action achieves the desired outcome.

(4) Efficiency and sustainability. Achieving the desired results with cost-effective use of resources, and the capacity of the system to sustain the workforce and infrastructure, and to innovate and respond to emerging needs.

(5) Responsiveness. Service is client-orientated. Clients are treated with dignity and confidentiality, and encouraged to participate in choices related to their care.

(6) Safety. The avoidance of reduction to acceptable levels of actual or potential harm from healthcare management or the environment in which healthcare is delivered.

Table 1 shows examples of proposed different models of care and a small selection of some measures that might be evaluated to show that the model is as good as traditional models of care.

2.2.7 Discussion

The workshop identified several key points. There are several pilots being planned and undertaken in Australia and New Zealand. Each of these pilots is investigating a different model of pharmacist prescribing, each within a different setting. In order to address criticisms regarding the lack of evidence as to the benefit of pharmacist prescribing, a uniform framework to assess the benefits and performance of the pharmacist prescribing service is essential.

With a uniform framework, the profession will be able to take a common approach to lobby for the introduction of pharmacist prescribing services in the future, something that is essential for successful progression of the agenda nationally. International pharmacy experience and Australian experience in other professions, for example optometrists, has demonstrated the need for such a unified approach. In order for the profession to be ready for changes arising out of the establishment of the National Health Workforce Taskforce and the recommendations of the Health and Hospitals Reform Commission, strong leadership and clear direction is required from all areas of the profession. Where non-medical prescribing has been introduced in other countries without a
uniform framework for evaluation, issues have arisen retrospectively that could have been addressed earlier, and therefore pre-empted the need to continually justify services.[180] However, it is important that the framework adopted to measure the performance of non-medical prescribing in the pilot phase must also be appropriate to evaluate ongoing services. Although the settings, models and services may differ, unless safe access to medicines is assured within an effective, efficient and sustainable service, the objectives of the National Medicines Policy will not be met.

The framework outlines general principles that should be evaluated within several dimensions. There is some overlap between the dimensions and not all measures for all dimensions will be collectable or appropriate in each setting. Therefore, pilots should select appropriate measures to reflect each dimension adequately. The framework is intended to provide objective evaluation but be customisable to different settings and models. For example, the ‘sustainability’ of a pharmacist prescribing service in a pre-admission clinic may require cost justification based on efficiency, whereas ‘sustainability’ for other models may require an ongoing source of suitably trained pharmacists, such as in the setting of specialist HIV pharmacy services. Within different models, the relative importance of one dimension over another may differ. For example, ‘continuity’ is the major driving force behind the introduction of discharge medication services, whereas safe ‘access’ to medicines services in rural and remote areas is a major driver for health service reform. It is important to note that irrespective of the model or setting, patient safety is the underlying principle.

The collaboration strongly recommends the development of prescribing competencies that can be applied across the board irrespective of the professions involved. Given that training and competencies for pharmacist prescribing are determined by the performance requirements of the service, the authors propose that a competency and training framework for non-medical prescribing be developed.

Patient safety associated with medicine use remains the ultimate goal.

2.2.8 Conclusions

The National Health Performance Framework has provided the basis for a non-medical prescribing evaluation framework that can be applied to pilots and for the evaluation of future services and research. A collaboration of pharmacists from Australian and New Zealand recommend a consistent approach to measuring non-medical prescribing uniformly in order to establish an evidence base, professional consensus and the basis of requirements for national competency and the accreditation of prescribers.
Table 1 - Pharmacist Prescribing Evaluation Framework

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Measure</th>
<th>Model / examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Accessibility – obtaining healthcare at the right time and place</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Time to access to prescriber</td>
<td>Time to appointment</td>
<td>Community outpatient clinic eg HIV</td>
</tr>
<tr>
<td>• Ability to enrol new patients</td>
<td>Doctor time freed up by pharmacist taking patient load</td>
<td></td>
</tr>
<tr>
<td>2. Continuity - ability to provide uninterrupted, coordinated care / intervention / action across programs, practitioners, organisations and levels</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Prescribing on discharge</td>
<td>Accuracy of discharge medication list</td>
<td>Prescribing on discharge from hospital</td>
</tr>
<tr>
<td></td>
<td>Provision of information to allow continuity of care across healthcare settings</td>
<td></td>
</tr>
<tr>
<td>3. Effectiveness – care/intervention/action is relevant to the client's needs and based on established standards, and achieves desired outcome</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Appropriateness of prescribing according to guideline</td>
<td>Appropriate of VTE prophylaxis against agreed guidelines</td>
<td>Surgical pre-admission clinic</td>
</tr>
<tr>
<td>• Clinical Outcome</td>
<td>Blood pressure control</td>
<td>Outpatient hypertension clinic</td>
</tr>
<tr>
<td>4. Efficiency and Sustainability – achieving desired results with cost effective use of resources, capacity of system to sustain workforce and infrastructure, to innovate and respond to emerging needs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Technical efficiency</td>
<td>Accuracy of medication history and completeness of medication prescribing information</td>
<td>Emergency Department Pharmacist</td>
</tr>
<tr>
<td>• Sustainable workforce</td>
<td>Time with no pharmacist prescriber service</td>
<td>All models</td>
</tr>
<tr>
<td>5. Responsiveness – service is client orientated. Clients are treated with dignity, confidentiality, and encouraged to participate in choices about their care</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Patient satisfaction</td>
<td>Patient satisfaction surveys</td>
<td>All models</td>
</tr>
<tr>
<td>6. Safety – the avoidance or reduction to acceptable levels of actual or potential harm from health care management or the environment in which health care is delivered</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Prescribing errors and safety</td>
<td>Prescription audit of quality (errors) of individual medication order (inpatient or outpatient)</td>
<td>All models</td>
</tr>
</tbody>
</table>
3 Chapter 3 - Assessment of the Safety, Accuracy and Effectiveness of National Inpatient Medication Charts

3.1 Chapter Introduction

An elective surgery PAC was chosen for the doctor - pharmacist prescribing study for several reasons, all of which were considered prior to the study as critical success factors for the collaborative prescribing model of care. The PAC at PAH has a well-established pharmacy service, initiated in 1998, with evidence to show the effectiveness of the pharmacy service in providing improved quality of information as patients crossed healthcare settings.[199]

Due to the scope of practice of the PAC pharmacist, and involvement in the clinical decision making process with regards to medication management, the role is that of an advanced level pharmacy practitioner. It is envisaged that prescribing will be a role for advanced practice pharmacists in future, with post graduate qualifications a requirement prior to commencing prescribing training.

The PAC is a collaborative working environment, with good access for the pharmacist to surgical RMOs and senior anaesthetists, to enable discussion and referral of medication management decisions in a timely and efficient manner.

The issues with regards to medication management and prescribing of inpatient medication charts were known, as a result of an audit prior to the main study commencing, evaluating the quality of the existing model of care.[200] This allowed the research question to be formulated, as it was clear where improvements needed to be made in terms of medication management in PAC, and specifically with regards to the prescribing of the NIMC.

The scope of the prescribing in PAC allowed evaluation of a number of facets of prescribing; stopping medications permanently, withholding medications temporarily prior to surgery, therapeutic substitution of withheld medication where necessary, and initiation of new medications for the patient’s admission.

Chapter 2 called for a standardised methodology for evaluation of pilots of non-medical prescribing, via utilisation of the National Health Performance Framework.[11] This chapter of the thesis reports the results for the main outcome of the study, the safety and accuracy of national inpatient medication charts produced in both arms. The NHPF indicators assessed in this chapter are the continuity, effectiveness, efficiency and safety of the prescribing in the collaborative model of care, compared to usual care.

In the 2009 review of the framework, ‘effective’, ‘appropriate’ and ‘capable’ were combined in to the one indicator, ‘effectiveness’. This chapter also reports briefly on the appropriateness of
prescribing of venous thromboembolism (VTE) prophylaxis, giving more evidence as to the effectiveness of the model of care within that defined scope of practice.

3.2 Published Paper - Perioperative medication management: expanding the role of the preadmission clinic pharmacist in a single centre, randomised controlled trial of collaborative prescribing

This paper is reproduced in full in Appendix B

Abstract

3.2.1.1 Objective
Current evidence to support non-medical prescribing is predominantly qualitative, with little evaluation of accuracy, safety and appropriateness. Our aim was to evaluate a new model of service for the Australia healthcare system, of inpatient medication prescribing by a pharmacist in an elective surgery preadmission clinic (PAC) against usual care, using an endorsed performance framework.

3.2.1.2 Design
Single centre, randomised controlled, two-arm trial.

3.2.1.3 Setting
Elective surgery PAC in a Brisbane-based tertiary hospital.

3.2.1.4 Participants
400 adults scheduled for elective surgery were randomised to intervention or control.

3.2.1.5 Intervention
A pharmacist generated the inpatient medication chart to reflect the patient’s regular medication, made a plan for medication perioperatively and prescribed venous thromboembolism (VTE) prophylaxis. In the control arm, the medication chart was generated by the Resident Medical Officers

3.2.1.6 Outcome Measure
Primary outcome was frequency of omissions and prescribing errors when compared against the medication history. The clinical significance of omissions was also analysed.
Secondary outcome was appropriateness of VTE prophylaxis prescribing.

3.2.1.7 Results

There were significantly less unintended omissions of medications: 11 of 887 (1.2%) intervention orders compared with 383 of 1217 (31.5%) control (p<0.001). There were significantly less prescribing errors involving selection of drug, dose or frequency: 2 in 857 (0.2%) intervention orders compared with 51 in 807 (6.3%) control (p<0.001).

Orders with at least one component of the prescription missing, incorrect or unclear occurred in 208 of 904 (23%) intervention orders and 445 of 1034 (43%) controls (p<0.001). VTE prophylaxis on admission to the ward was appropriate in 93% of intervention patients and 90% controls (p=0.29).

3.2.1.8 Conclusion

Medication charts in the intervention arm contained fewer clinically significant omissions, and prescribing errors, when compared with controls. There was no difference in appropriateness of VTE prophylaxis on admission between the two groups.

3.2.1.9 Trial Registration

Registered with ANZCTR—ACTR Number ACTRN12609000426280

3.2.1.10 Article Summary

3.2.1.10.1 Article focus

• A doctor–pharmacist collaborative prescribing model provides as least as high a quality of care as usual care, with regard to safety, access, appropriateness, effectiveness, efficiency and consumer participation.
• Workforce shortages are prompting a review of the way the current workforce is utilised, and whether different roles could be taken on by healthcare professionals to alleviate some of the pressures within the system.
• Research on non-medical prescribing so far is predominantly qualitative in nature. Our study has analysed quantitative data on the safety, accuracy and appropriateness of prescribing to try and assess whether this model is at least as good as usual care
3.2.10.2 Key messages

- Pharmacists’ skills in medication management are currently underutilised, and with appropriate training and education they could be contributing to medication management much more effectively by taking on a prescribing role.
- The prescribing is collaborative and driven by guidelines and under the supervision of a medical team. Diagnosis is not within the scope of practice of the prescribing pharmacist.
- This model of care has been proved to be highly effective in this study, with an increased accuracy, safety and appropriateness of prescribing within the intervention arm.

3.2.10.3 Strengths and limitations of this study

- The results with regard to the accuracy and safety of medication charts produced in the study are emphatic and statistically significant.
- The intervention is reproducible in other settings with a pharmacist of appropriate experience, training and education.
- The study assessed one pharmacist prescriber versus a cohort of medical prescribers. While this has been accounted for in the analysis, it also reflects what usual practice would be in a model care such as this. The authors recognise and acknowledge it as a limitation.

3.2.2 Introduction

Prescribing involves four stages: information gathering, clinical decision-making, communication of decision and monitoring.[201] Taking a medication history, continuing, ceasing and withholding of medications and initiating new medications are critical components of prescribing associated with an admission for surgery. Medication errors are common, occur most often at the time of prescribing, and frequently on the day of hospital admission, resulting in discrepancies between regular medications and admission orders.[202-204] A small, but significant, proportion of errors result in adverse drug events (ADEs).[205] Errors have been defined as when there is “a failure to communicate essential information; the use of drugs or doses is inappropriate for the individual patient; and transcription error.”[102] To be able to communicate a clinical decision safely and effectively in the form of a written prescription, it is necessary to select the correct drug, together with the route, form, dose, frequency and duration.[206] Multiple interventions have been suggested in an attempt to improve prescribing, with suggestions that increased training of the individual, a controlled environment and a change in organisational culture are necessary.[207] Within hospital, the medication chart provides instructions for safe medication supply and administration, and ensures the patient access to medications as an inpatient. It is an integral part of communication
between doctors, pharmacists and nurses about prescribing decisions and is used as the primary source of information regarding medications on discharge. The pharmacy service in the Princess Alexandra Hospital (PAH) preadmission clinic (PAC) began in 1998 to provide timely, accurate and comprehensive information about medication as patients crossed between healthcare settings. It ensured accurate transfer of information at admission, during the inpatient stay and at discharge, the benefits of which were a reduction in both readmissions and contact with community healthcare providers postdischarge.[208] The importance of accurate transfer of information across the whole surgical care pathway from preadmission to discharge, including information about medications, has been highlighted in a recent study that reported how communication failures led to patient morbidity and mortality. Standardisation and systematisation of communication processes, along with other interventions targeted at the entire surgical pathway, were recommended with a view to improving information transfer and quality of care.[209]

Pharmacists in PACs have been shown to improve the accuracy of medication histories and medication orders, when compared with standard care, and the efficacy of prescribing perioperatively in line with recognised guidelines.[210, 211] Only with an accurate history of medication usage can decisions be made safely regarding the perioperative management of medications. Medication histories are elicited from a variety of sources of information: patient’s own medications, the patient or carer, general practitioner summaries, community pharmacies, previous hospital admissions and nursing home records. A number of sources may be consulted to build an accurate record of medication that the patient is taking, both regularly and occasionally. The range of prescribers has been expanded in a number of countries, with changes in legislation to allow for extension of prescribing privileges to non-medical professionals, including pharmacists. The objective of this was to make greater use of the skills and specialisation of pharmacists so that a more flexible system for the prescribing, supply and administration of medicines could be developed, while maintaining safe and appropriate access to medicines.[3, 193] In response to the documented workforce shortages in Australia, Brooks et al described possible solutions, including ‘task substitution’, and a focus has been placed recently on non-medical prescribers within the healthcare system.[15, 17, 18, 37, 40] Pharmacists, with training in pharmacology and therapeutics, are potentially well placed to undertake prescribing roles. An Australian study identified the main driver behind pharmacist prescribing as the desire to work collaboratively with medical and nursing staff to:

- Provide consumers with improved, responsible and safe access to prescription medicines;
- Optimise use of pharmacists’ and doctors’ skills and time;
- Reduce inefficient use of health resources.[1]
Evidence to support non-medical prescribing so far has been mainly qualitative, with minimal evaluation of access, safety and appropriateness. One recent review concluded that acceptability of non-medical prescribing services is based on the perceived value to the health service.[8] This lack of evidence has led to calls to prove the safety and effectiveness of non-medical prescribing services in Australia.[181] The aim of the data analysis discussed in this paper was to compare a doctor—pharmacist collaborative prescribing model with usual care, with regard to safety, access, appropriateness and effectiveness; the null hypothesis being that no difference exists between the two models of care.[11]

3.2.3 Methods

The study was conducted between June and September 2009 in the surgical PAC at PAH, a 750-bed tertiary teaching hospital in Queensland. The definition of error used in the study was: “a failure to communicate essential information; the use of drugs or doses is inappropriate for the individual patient; and transcription error.”[203] All patients who attended PAC and could provide written informed consent were considered for participation. Patients were excluded if they were under 18 years of age, unable to communicate due to language difficulties or undergoing day surgery (figure 4).

![Randomisation Flow Chart](image)

**Figure 4 - Randomisation Flow Chart**
Patients were approached on arrival at the clinic and written consent was obtained. After consent, patients were randomised using a computer generated randomisation list, in blocks of 10 (Microsoft Excel). Sealed envelopes (not prepared by the recruiting researcher) contained a zero or one as per the computer list; the next envelope was opened after consent to determine whether a patient entered the control or intervention arm, respectively. If a patient had been randomised and their surgery cancelled during PAC, the patient was removed from the study and not replaced. A previous pilot study in the PAC showed an error rate of 12% of orders.[200] Using an expected error rate of 8% in the intervention arm, a sample size of 932 orders per group was calculated to be required for a power of 80%. Assuming an average of five orders per patient, approximately 200 patients per arm would be required. Only one pharmacist in the PAC, with 3 years’ experience as a hospital pharmacist and having a postgraduate diploma in clinical pharmacy, was trained to be a prescriber. The pharmacist attended a prescribing course which was accredited by the General Pharmaceutical Council, UK as an Independent Pharmacist Prescribing Course.[212] Training included a minimum of 12 days of ‘period of learning in practice’ under a ‘designated medical practitioner’ (DMP), who was the consultant anaesthetist for PAC. The training included case studies and sessions on venous thromboembolism (VTE) prophylaxis with a consultant vascular physician and the clinical nurse consultant (CNC) for VTE prophylaxis at PAH. The DMP endorsed the pharmacist’s competency to prescribe before the study could start.

For the pilot, an amendment was facilitated to the Queensland Health (Drugs and Poisons) Regulation 1996 to allow ‘Pharmacists registered in Queensland who are employed or contracted to Queensland Health and working in the Pharmacist Prescribing Pilot’ to prescribe controlled drugs, restricted drugs and schedule 2 and 3 poisons.

3.2.3.1 Intervention Cohort

Patients were seen by a nurse, prescribing pharmacist, Resident Medical Officer (RMO) and anaesthetist. Patients had to be seen by the pharmacist before they were seen by the RMO to allow usual RMO duties and a countersignature of the pharmacist prescriptions, a site requirement. The pharmacist undertook all pharmacist duties as per usual care, as well as prescribing medications on the medication chart. The scope of prescribing was continuing or withholding regular medications and prescribing VTE prophylaxis according to local and national guidelines, following a risk and contraindication assessment. [213]

Directors of surgery were consulted prior to the start of the trial for permission to include patients in prescribing of VTE prophylaxis, according to their specific unit guidelines, which had been defined in advance in collaboration with the CNC for VTE prophylaxis at PAH. Urology and renal transplant patients were excluded (N=43 control, N=34 intervention) from VTE prophylaxis.
prescribing as the director of urology was unavailable to confirm the scope of the project, and the director for transplant requested exclusion on the grounds that VTE prophylaxis in these patients was driven more by consultant discretion as opposed to being driven by guidelines.

### 3.2.3.2 Control Cohort

Patients were seen by all four healthcare professionals in clinic, in no particular order, as per usual care. Either pharmacist in the clinic saw control patients for documentation of medication history. The prescribing of the medication chart was the responsibility of the RMO. In both arms, review and monitoring were undertaken, both by RMOs in clinic at countersignature and by RMOs and clinical pharmacists at the ward level, once the patient was admitted. Changes made by RMOs to intervention patient medication charts in clinic were recorded.

### 3.2.4 Outcome Measures

The primary endpoint for the study was the accuracy of medication charts, with regard to concordance of the medication chart with the medication history, the plan for medications perioperatively and the quality of the individual orders related to legality and safety for administration purposes. The secondary endpoint was the appropriateness of prescribing for both chemical and mechanical VTE prophylaxis according to local and national guidelines. Analysis of scanned copies of medication charts, for the primary outcomes of omissions and errors, was conducted in tandem by two assessors, one a member of the research team and the other an external assessor, both trained in the use of validated audit tools and blinded to randomisation. Any ambiguities were clarified by consensus.

Appropriateness of VTE prophylaxis prescribed in both arms in clinic was analysed using scanned copies of medication charts, in tandem by two assessors, one a member of the research team and the other a CNC for VTE prophylaxis at PAH. Prescribing was also assessed on admission to the ward to ensure that VTE prophylaxis was appropriate.

An expert panel, comprising a surgeon, a clinical pharmacologist, an anaesthetist, a RMO, a pharmacist and a nurse, was convened to assess the clinical significance of omissions in a randomly selected 5% sample of the total cohort of patients from both arms (N=10 control, N=9 intervention). Panel members were blinded to randomisation.

*Tables 2 and 3* describe the collection methods and definitions of these endpoints.
### Table 2 - Analysis to assess the accuracy and safety of medication charts generated in the study

<table>
<thead>
<tr>
<th>Measure</th>
<th>Definition</th>
<th>Method</th>
<th>Assessing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Omissions</strong></td>
<td>Medication in patient’s medication history not prescribed on medication chart, with no reason documented in patient chart</td>
<td>Every medication in patient’s medication history audited against medication chart - omissions from medication chart noted</td>
<td>Whether or not medication is prescribed</td>
</tr>
<tr>
<td><strong>Prescribing Errors</strong></td>
<td>Anomaly in drug name, strength, dose, frequency or route, with no documentation in patient chart</td>
<td>Every medication in patient’s medication history audited against medication chart – anomalies noted</td>
<td>Whether or not prescription is accurate in terms of drug name, strength, dose, frequency and route</td>
</tr>
<tr>
<td><strong>Communication Errors</strong></td>
<td>Unclear prescription in terms of name, route, dose, frequency, slow release medication notification or intermittent order prescribing</td>
<td>Every prescription written audited using validated audit tool – unclear prescribing noted, as agreed by both auditors</td>
<td>Whether or not prescription is safe for administration purposes</td>
</tr>
</tbody>
</table>

### Table 3 - Analysis to assess accuracy of VTE risk and contraindication assessments and appropriateness of VTE prescribing

<table>
<thead>
<tr>
<th>Measure</th>
<th>Definition</th>
<th>Method</th>
<th>Assessing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>VTE Risk Assessment</strong></td>
<td>Patient categorised in to low or high risk for VTE, as per guidelines</td>
<td>Every patient medical record audited for a documented VTE risk assessment</td>
<td>Risk assessment documented Y/N Risk assessment correct Y/N</td>
</tr>
<tr>
<td><strong>VTE Contraindication Assessment</strong></td>
<td>Patient highlighted as inappropriate for mechanical or chemical prophylaxis, as per guidelines</td>
<td>Every patient medical record audited for a documented contraindication assessment</td>
<td>Contraindication assessment documented Y/N Contraindication assessment correct Y/N</td>
</tr>
<tr>
<td><strong>VTE prescribing</strong></td>
<td>Whether patient prescribed mechanical and/or chemical VTE prophylaxis, as per guidelines</td>
<td>Prescribing of mechanical and chemical VTE prophylaxis audited against agreed local and national guidelines</td>
<td>VTE prescribing appropriate according to guidelines and individual patient factors Y/N</td>
</tr>
</tbody>
</table>

Categorical data were compared using \( \chi^2 \) tests for independence. When any one cell had a count of less than 10, Fisher’s exact test was substituted. Logistic regression was used to analyse the overall omissions between the two groups. The number of regular and ‘PRN’ medications that the patient
was currently taking was included as an explanatory variable in the model as it was deemed more likely that an individual medication would be omitted in a patient taking a large number of medications. Logistic regression was also used to analyse the overall communications prescribing errors between the two groups. The assumption of independence between observations is clearly violated as multiple observations exist for most patients. As such, robust SEs clustered by patient were calculated. No other covariates were adjusted for. All reported p values are two-sided using a level of significance of 0.05. All statistical analysis and sample size calculations were conducted using Stata V.11.2 (StataCorp, College Station, Texas, USA).

3.2.5 Results

The demographics of the patients randomised into the trial were similar, except for the higher number of medications taken by patients in the control arm (table 4)

**Table 4 - Characteristics of study population**

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Patients</td>
<td>190</td>
<td>194</td>
</tr>
<tr>
<td>Age ‡</td>
<td>57.6 [18-89]</td>
<td>55.8 [18-86]</td>
</tr>
<tr>
<td>Male (%)</td>
<td>58%</td>
<td>59%</td>
</tr>
<tr>
<td>*Regular Medications†</td>
<td>4[0-16]</td>
<td>3[0-18]</td>
</tr>
<tr>
<td>#When Required ‘PRN’ Medications†</td>
<td>2[0-7]</td>
<td>1[0-4]</td>
</tr>
<tr>
<td>Complementary and Alternative Medicines (CAM) †</td>
<td>(0)[0-9]</td>
<td>(0)[0-6]</td>
</tr>
<tr>
<td>Over The Counter (OTC) Medications†</td>
<td>(0)[0-2]</td>
<td>(0)[0-2]</td>
</tr>
<tr>
<td>Total Medications</td>
<td>1364</td>
<td>983</td>
</tr>
<tr>
<td>Total medications (regular and prn only)</td>
<td>1217</td>
<td>887</td>
</tr>
<tr>
<td>Medication Charts Prescribed</td>
<td>161 (85%)</td>
<td>194 (100%)</td>
</tr>
</tbody>
</table>

‡ mean [range]  
† median [range]  

*Regular medications are defined as medications prescribed with the intent to be taken on a regular basis  
#Pro Re Nata (PRN) medications are defined as medications prescribed with the intent to be taken only when required
3.2.5.1 Omissions

Total unintentional medication omissions from medication charts were higher for control patients (31.5%) compared with interventions (1.2%). The OR for an order in the control group to be omitted, compared with that for the intervention group, was 41.0 (95% CI 20.6 to 81.8; p<0.001 logistic regression) after adjusting for the number of medications the patient was currently taking (figure 5 and table 5). There were 59 prescribers in the control arm, 54 of whom reviewed patients who were currently taking regular or PRN medications at home, and as such had the opportunity to omit a patient’s medication. Of these 54 prescribers, the median percentage of medications that were omitted per prescriber in the control arm was 21 (range 0–100).

![Figure 5 - Percentage of Medication Omitted](image.png)
Table 5 - Medication omissions from medication chart

<table>
<thead>
<tr>
<th>Type of Medication and Perioperative Plan</th>
<th>Control (N)[%]</th>
<th>Intervention(N)[%]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Regular</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continue</td>
<td>179 (805)[22.2]</td>
<td>3 (620)[0.5]</td>
</tr>
<tr>
<td>Withhold prior to surgery</td>
<td>46(75)[7.4]</td>
<td>0(48)</td>
</tr>
<tr>
<td>Withhold on morning of surgery</td>
<td>21(54)[38.9]</td>
<td>0(39)</td>
</tr>
<tr>
<td>Adjust dose</td>
<td>1(5)[20.0]</td>
<td>0(5)</td>
</tr>
<tr>
<td>Review</td>
<td>1(7)[14.2]</td>
<td>0(6)</td>
</tr>
<tr>
<td>Cease</td>
<td>0(1)</td>
<td>0(2)</td>
</tr>
<tr>
<td><strong>PRN</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continue</td>
<td>128(248)[51.6]</td>
<td>6(142)[4.2]</td>
</tr>
<tr>
<td>Withhold prior to surgery</td>
<td>7(12)[58.3]</td>
<td>2(13)[15.4]</td>
</tr>
<tr>
<td>Adjust dose</td>
<td>0(2)[20.0]</td>
<td>0(1)</td>
</tr>
<tr>
<td>Review</td>
<td>0(8)[14.3]</td>
<td>0(11)</td>
</tr>
<tr>
<td><strong>Total Omissions</strong></td>
<td>383(1217)[31.5]</td>
<td>11(887)[1.2]</td>
</tr>
<tr>
<td>*Complementary and Alternative Medicines (CAMs)</td>
<td>126</td>
<td>87</td>
</tr>
<tr>
<td>*Over The Counter Medications (OTC)</td>
<td>21</td>
<td>9</td>
</tr>
</tbody>
</table>

*CAM and OTC medications were not classed as omissions in either arm if not prescribed on the inpatient medication chart

3.2.5.2 Clinical significance of omissions

Omissions from a randomly selected 5% of the total cohort were evaluated for clinical significance. Of the 89 regular medications in the patients’ medication histories in the control arm, 25 (28%) were omitted from the medication charts, compared with 1 of 55 (2%) in the control arm. When asked to assess the severity of omission, the average across the panel showed that 52% of omissions
in the control arm had the potential for patient harm or ward inconvenience (figure 6). Only one reviewer thought the omission in the intervention arm was significant.

Figure 6 - Assessment of clinical significance of omissions

3.2.5.3 Prescribing errors related to drug, dose and frequency selection

Overall, 53 errors were identified where the drug strength, dose or frequency prescribed did not match the medication history or perioperative plan (figure 7). This equates to 6.3% of control orders compared with 0.2% of intervention orders (p<0.001, Fisher’s exact test).
3.2.5.4 Communication errors

Communication errors, where prescriptions were rated as ambiguous or unclear, were significantly higher in the control arm compared with the intervention arm. The OR for an order in the control arm to have a communication error compared with an order in the intervention arm was 2.52 (95% CI 1.96 to 3.27; logistic regression p<0.001). As there were multiple orders per patient, robust SEs, clustered by patient, were utilised (table 6). Individually, communication errors were significantly higher in the control arm for all types of error except the route of administration (p=0.57 χ2 test). From the control arm prescribers, 44 of them prescribed medication on the medication charts, with a median number of orders of 21 (range 1–85). The median percentage of orders in the control arm that contained at least one communication error per prescriber was 38 (range 0–100).
Table 6 - Prescribing errors with an ambiguity in at least one component of the prescription

<table>
<thead>
<tr>
<th></th>
<th>Control Number of errors (% of total orders)</th>
<th>Intervention Number of errors (% of total orders)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Orders</td>
<td>1034</td>
<td>904</td>
<td></td>
</tr>
<tr>
<td>Orders with at Least One Communication Error</td>
<td>445(43)</td>
<td>208(23)</td>
<td>&lt;0.001 †</td>
</tr>
<tr>
<td>Prescribing Communication Errors</td>
<td>667</td>
<td>229</td>
<td>&lt;0.001 †</td>
</tr>
</tbody>
</table>

Prescribing Communication Errors

<table>
<thead>
<tr>
<th>Component</th>
<th>Control</th>
<th>Intervention</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug name</td>
<td>23 (2.1)</td>
<td>0</td>
<td>&lt;0.001 ‡</td>
</tr>
<tr>
<td>Route</td>
<td>79 (7.6)</td>
<td>76 (8.4)</td>
<td>0.57 †</td>
</tr>
<tr>
<td>Dose</td>
<td>48 (4.6)</td>
<td>5 (0.6)</td>
<td>&lt;0.001 ‡</td>
</tr>
<tr>
<td>Frequency</td>
<td>190 (18.4)</td>
<td>96 (10.6)</td>
<td>&lt;0.001 ‡</td>
</tr>
<tr>
<td>Administration times incorrect or missing</td>
<td>117 (14.9) (781 orders)</td>
<td>4 (0.5%) (762 orders)</td>
<td>&lt;0.001 ‡</td>
</tr>
<tr>
<td>prn max dose missing</td>
<td>178 (74.5) (241 orders)</td>
<td>47 (32.6) (142 orders)</td>
<td>&lt;0.001 ‡</td>
</tr>
<tr>
<td>Slow Release not specified</td>
<td>15 (30.0) (50 orders)</td>
<td>1 (1.5) (66 orders)</td>
<td>&lt;0.001 ‡</td>
</tr>
<tr>
<td>Intermittent order not specified</td>
<td>17 (57.5) (30 orders)</td>
<td>0 (38 orders)</td>
<td>&lt;0.001 ‡</td>
</tr>
</tbody>
</table>

Π Logistic regression

† Chi-Square

‡ Fisher’s Exact

3.2.5.5 VTE prophylaxis

Patients in the intervention arm were significantly more likely than controls to have appropriate VTE prophylaxis prescribed on the medication chart in PAC and to have documented VTE assessment (figure 8). On admission to the ward, approximately 90% of both intervention and control patients were prescribed appropriate VTE prophylaxis.
3.2.6 Discussion

This study has built on the findings from previous research of pharmacists prescribing in PAC settings, which have found improved accuracy of information gathered, and improved prescribing according to guidelines.[208, 214] Similar studies of pharmacist interventions in different settings have shown improvements in clinical endpoints such as blood pressure control, increased appropriateness of prescribing and reductions in ADEs, such as warfarin-associated bleeds.[155, 215]

The traditional scope of practice for the PAC pharmacist consists of taking a medication history, using guidelines, clinical judgement and referral to the surgical team to suggest a plan for medications perioperatively, and providing this information to the RMOs to generate the medication charts. This scope has been extended in our study by providing an appropriately trained pharmacist to generate the medication chart and prescribe VTE prophylaxis, which has led to a significant reduction in omissions and prescribing errors, ensuring that patients get the correct medication while in hospital. The evaluation of VTE prophylaxis prescribing was essential to assess the safety and appropriateness of initiation of a new medication, within guidelines, by the prescribing pharmacist. The results from this study have shown the prescribing to be as appropriate as usual.
care at the time the patient is admitted to the ward. Issues still remain with the prescribing, especially with the use of inappropriate abbreviations.[216] For example, a large proportion of communication errors in the intervention arm were due to the use of s/c to indicate subcutaneous, which has informed the researchers on future educational requirements of prescribers, especially with regard to safe prescribing. Electronic prescribing may be one solution to such errors involving legibility and inappropriate abbreviations, but studies have shown that the systems introduce errors of their own.[217] These errors need to be fully assessed and appreciated if the quality of prescribing is to be improved by the introduction of computerised prescribing into the healthcare system.

The results presented in this paper are part of a larger study. Further work is required to assess the appropriateness of prescribing of medication charts and consumer participation of this new model of care.[11] There are a number of limitations. Even though the trial was randomised, the total number of medications that the patients were taking was higher in the control arm (1364) compared with the intervention arm (983). The explanation for this is unknown but may in part be due to large randomisation block sizes, possibly meaning that a number of consecutive patients were randomised to the control arm during clinic sessions, where patients were more likely to have a higher burden of medication, for example, during a vascular surgery clinic. There was more opportunity for omissions from the control arm as a result of more medications needing to be continued, and this was allowed for in the analysis. RMOs in clinic during the study were aware of the intervention pharmacist’s role, which may have led to an increased number and quality of medication charts prescribed in the control arm. Even with this potential effect, the study still showed a significant improvement in the safety and accuracy of medication charts. Review of medication orders is not a role that an RMO routinely undertakes. All RMOs were educated with regard to the requirement of a countersignature of pharmacist orders, and to amend anything as required prior to sign off. In the trial, 10 charts were amended—5 changes were minor, 3 were addition of analgesics out of the pharmacist’s prescribing scope and 2 changes actually resulted in inappropriate VTE prophylaxis. Despite the legislative changes, countersignature of pharmacist orders was a local requirement owing to the concern that junior doctors may become deskilled as a result of being removed from the prescribing process. However, the authors suggest that having an appropriately trained prescribing pharmacist in clinic, for the RMOs to use as guidance and to provide feedback on any prescribing errors, may increase the effectiveness of the learning environment. Having only one pharmacist prescribing in the intervention arm and multiple RMOs prescribing in the control arm is a potential source of bias that is unavoidable where individual knowledge, skills and capabilities determine the quality of prescribing. It has been suggested that medical undergraduate training may not prepare graduates to prescribe, which if addressed may
reduce this individual variance.[218] The model of care tested in our study was successful as we were able to reduce the variance within a group by training one individual pharmacist to manage medications perioperatively, within a set scope of practice, and to include prescribing. It could be argued that the same results may have been obtained by providing the RMOs with extra prescribing training, and that the improved performance may not necessarily be solely due to the introduction of a new professional discipline.

The authors acknowledge that the improved results may well be multifactorial, but would also suggest that the underlying competencies of an experienced, ‘advanced level’ pharmacist, plus the prescribing training provided, have ensured appropriate competencies to prescribe in the model of care in which the prescribing took place.[219]

The order of consultation in the intervention arm was set by trial design. The order in the control arm was not set, which is a true reflection of usual care, where the patient could see the RMO prior to the pharmacist. This may have impacted on the quality of control medication charts prescribed by the RMO, without information available from the pharmacist history. While this could be classed as a limitation, this does reflect usual care in PAC and highlights the collaborative nature of the existing model of care. The prescribing pharmacist was able to see control patients for usual care duties of a medication history, which may be perceived as introducing bias. However, as both pharmacists have received the same undergraduate and general-level pharmacist training, the quality of medication history gathered for the RMO to use to prescribe the medication chart would be the same. Another limitation is the potential sustainability of the model of care, and capacity to train pharmacists as prescribers. This was only one pharmacist in one hospital who had received special training to be able to prescribe. Evaluation of the requirements of non-medical prescribing courses is underway, but substantial further thought needs to be applied to ensure reproducibility of these results in a larger sample and consistent production of safe and effective prescribers.[220]

Further work is required to address the actual and perceived medicolegal implications for both doctors and pharmacists in such collaborations.

3.2.7 Conclusion

Medication charts in the intervention arm were significantly safer and more accurate with regard to the patients’ regular medications than medication charts in the control arm. There was no difference in appropriateness of VTE prophylaxis prescribing between arms on admission to the ward. Our study has shown that the pharmacist in a PAC was able to effectively gather all the information required to collaboratively formulate a clinical decision in clinic within an agreed scope of practice, and communicate the decisions safely and accurately onto the medication chart.
A collaborative doctor–pharmacist prescribing model in a PAC was as safe and accurate as usual care in ensuring that patients were prescribed the medication required on admission for elective surgery.

3.2.8 Competing Interests

None

3.2.9 Acknowledgements

The authors would like to acknowledge the following people without whom the study would not have been possible. Professor Stephen Lynch, Chair of Surgery, Princess Alexandra Hospital, Associate Professor Lynette Loy, Director of Pharmacy, Princess Alexandra Hospital, Ms Ching-Ting Hung, Senior Pharmacist, Princess Alexandra Hospital, Ms Renea Collins, Clinical Nurse Consultant, VTE Prophylaxis, Princess Alexandra Hospital, all of the staff in Pre Admission Clinic.

3.2.10 Contributors

Contributors ARH, IDC, JS, KW, EM and LN contributed to the project concept and study design. ARH collected all data and was responsible for the running of the study. ARH, IDC, JS and LN were involved in the evaluation of data. ARH and DMD were responsible for database design, data evaluation and statistical reporting. All authors contributed significantly to the write-up of the project. All authors have read and approved the final manuscript.

3.2.11 Data Sharing Statement

Extra data can be accessed via the Dryad data repository at http://datadryad.org/ with the doi:10.5061/dryad.81tr1.

3.3 Next Steps

Large differences in the number of medication omissions in the results reported in Chapter 3 prompted the question about appropriateness of prescribing in both arms, and namely the appropriateness of medications prescribed (commissions) and the appropriateness and significance of medications omitted from the NIMC, both in terms of likelihood to cause ward inconvenience and patient harm.
4 Chapter 4 – Appropriateness of Prescribing and Significance of Omissions.

4.1 Chapter Introduction

The results in Chapter 3 showed a large difference between the control and intervention arms in the percentage of patients’ regular medications omitted from the NIMC. This raised the question of the importance of these omissions, and whether they were likely to be clinically significant, and hold any potential for patient harm from missing doses, or ward inconvenience in having to find a medical officer to prescribe them on to the NIMC on admission to the ward. It was crucial to assess the possible impact of omissions, and the appropriateness of the medications that had been prescribed on to the NIMC for the patient’s admission. This was to ensure the prescribing on the NIMC was not only safe and accurate, as shown in Chapter 3, but also appropriate.

A sub study methodology was designed, utilising an expert panel of clinicians relevant to a patient’s surgical pre admission and admission, and a validated tool for assessing appropriateness of prescribing, the Medication Appropriateness Index (MAI). The purpose of the panel was to assess a ‘snap shot’ of the prescribing in the study from both arms, as to whether medications that had been prescribed were appropriate and whether omissions of any patients’ regular medications from the NIMC were potentially significant, in terms of ward inconvenience or patient harm.

In the 2009 review of the National Health Performance Framework the effective, appropriate and capable dimensions were combined into one dimension effectiveness. Effectiveness is defined as the ‘intervention achieves the desired outcomes’, which in this case is an appropriately prescribed and complete medication chart. The medication chart provides information for administration of medications on the ward, and is also the number one source of information on discharge. A complete and accurate medication chart is important for inpatient access to medications, and continuity of care across healthcare settings.

4.2 Published Paper - A Pilot Study to Assess the Appropriateness of Prescribing From a Collaborative Pharmacist Prescribing Study in a Surgical Pre Admission Clinic

4.2.1 Abstract

4.2.1.1 Background

Current evidence to support non-medical prescribing is predominantly qualitative, with little evaluation of quality, safety or appropriateness of prescribing.

4.2.1.2 Objective

This study aims to evaluate the appropriateness of prescribing, and significance of omissions, from a doctor-pharmacist collaborative prescribing model.

4.2.1.3 Setting

An elective surgery pre admission clinic (PAC) in a Brisbane based tertiary hospital

4.2.1.4 Method

A modified version of the Medication Appropriate Index (MAI) was developed, piloted and subsequently used by an expert panel, comprised of a surgeon, anaesthetist, clinical pharmacologist, pharmacist, resident medical officer (RMO) and clinical nurse.

4.2.1.5 Main outcome measures

A modified version of the Medication Appropriate Index (MAI) was developed, piloted and subsequently used by an expert panel, comprised of a surgeon, anaesthetist, clinical pharmacologist, pharmacist, resident medical officer (RMO) and clinical nurse.

4.2.1.6 Results

When reviewer assessments were combined, 32 out of 294 (10.9%) medications assessed for appropriateness in the control arm were classed as inappropriate, compared to 13 of 266 (4.9%) in the intervention arm.

Out of 89 regular medications in the control arm, 25 (28%) were omitted from the medication charts, compared to 1 out of 55 (2%) in the intervention arm (p<0.001, fishers exact)

On average, 52% of omissions in the control arm were judged to have potential for patient harm or ward inconvenience.
4.2.1.7 Conclusion

For the appropriateness of prescribing, overall results were similar between arms, as judged by individual panel members. Medication charts in the control arm contained significantly more omissions than in the intervention arm, a number of which were rated by the panel members as having the potential for patient harm or ward inconvenience.

- Pharmacist prescribing is a model of care that has the potential to increase access, for the general public, to safe and appropriate medication usage, and better utilise the skills of the current healthcare workforce
- Research on pharmacist prescribing has been predominantly qualitative, with little assessment of quality, safety or appropriateness of prescribing.
- Our study analysed the safety, accuracy and appropriateness of prescribing within this model of care, to provide the more robust quantitative data required to aid in the implementation of pharmacist prescribing in Australia
- Pharmacist prescribing will make for a more efficient system; freeing up doctor time, whilst ensuring the knowledge and skills of pharmacists, in quality use of medicines, are utilised to their full potential.

4.2.2 Introduction

Inappropriate prescribing is the failure to provide the quality of care related to medication use that should be achieved in practice, and encompasses overprescribing, misprescribing, and underprescribing.[221] Inappropriate medicine use has been defined as that which poses greater risk of harms than benefits, especially when safer alternatives exist.[222] Elderly patients, in particular, are susceptible to the consequences of inappropriate prescribing, increasing the risk of adverse drug events and related morbidity and hospitalisations.[223, 224] Patients recently discharged from hospital are also at increased risk of medication misadventure, as medication is often reviewed and changed during an admission, and poorly communicated with community practitioners.[225] The importance of accurate transfer of information across the whole surgical care pathway from preadmission to discharge, including information about medications, was highlighted in a study that reported communication failures led to patient morbidity and mortality.[209] The Australian Commission on Quality and Safety in Health Care has highlighted medication reconciliation, and the accurate transfer of information about medication as a national priority.[226]

Within hospital, the medication chart provides a record of patient’s medication, instructions for safe medication supply and administration, and ensures patient access to medications as an inpatient. It is a communication tool between doctors, pharmacists and nurses about prescribing decisions, and
is used as the primary source of information regarding medications, both during the inpatient stay and on discharge. An appropriate and accurate medication chart is essential, and unless prescribing errors are found and corrected early, they can lead to errors in supply and administration.[227]

Pre admission clinic (PAC) at Princess Alexandra Hospital (PAH) is a multidisciplinary clinic, comprising of nurse, Resident Medical Officer (RMO), pharmacy and anaesthetic review. The pharmacy service in PAC was initiated in 1998, with the aim of improvement in the accuracy of information exchange as patients cross healthcare setting.[208] The benefits of pharmacy involvement in PAC on medication management and information transfer prior to admission and on discharge, and the associated risks of omissions of medications at these times, were highlighted as part of a randomised controlled trial.[199] Pharmacy in PAC is now a well-recognised role in Australia, with the Society of Hospital Pharmacists of Australia (SHPA) publishing a fact sheet on how pharmacists in PAC can contribute to better patient outcomes and quality of care.[228]

Several countries have extended the prescribing of prescription only medicines to health care professionals other than doctors, with the aim of increasing patients’ access and choice, and make best use of health professionals’ skills, whilst ensuring patient safety.[229] Health Workforce Australia has highlighted possible models of prescribing for non-medical health professionals within the Australian healthcare system.[37, 230] However, there is a lack of evidence to support this model of care. Current literature is predominantly qualitative, with little in the way of evaluation of quality, safety or appropriateness of prescribing. A recent review suggested that acceptance of the model of care was mainly based on the perceived value to the healthcare system.[8]

4.2.3 Aim of the study

To use a validated national health performance framework to compare a collaborative pharmacist prescribing model with usual care, with regards to effectiveness (incorporating appropriateness), safety, responsiveness, continuity, accessibility and efficiency.[11] The hypothesis was that no difference exists between the models of care. Results so far have shown pharmacist prescribing is as good as usual care in safety and accuracy of medication charts, and appropriateness of venous thromboembolism (VTE) prophylaxis.[231]

The significant difference in omissions of medications prompted further investigation in to the appropriateness of prescribing, and the significance of medications that had not been prescribed on to the national inpatient medication chart (NIMC). The aim of the data discussed in this paper is to assess a ‘snapshot’ of the appropriateness of prescribing, and the potential health impact or ward inconvenience of omissions from the NIMC.
4.2.4  Ethical approval

Ethics approval was obtained from the PAH Human Research Ethics Committee

4.2.5  Methods

The main study was conducted between June to September 2009 in the surgical, multidisciplinary PAC at PAH, a 750 bed tertiary teaching hospital in Queensland.

All patients who attended PAC and could provide written, informed consent were considered for participation. Patients were excluded if they were under 18 years of age, unable to communicate due to language difficulties or undergoing day surgery

A previous audit in PAH PAC showed an error rate of 12% of orders.[200] Using an expected error rate of 8% in the intervention arm a sample size of 932 orders per group was calculated to be required for a power of 80%. Assuming an average of 5 orders per patient, it was estimated that 200 patients per arm would be required for the main study.

4.2.5.1 Intervention Cohort

Patients were seen by a nurse, prescribing pharmacist, Resident Medical Officer (RMO) and anaesthetist. Patients were seen by the pharmacist before they were seen by the RMO to allow usual RMO duties and a countersignature of the pharmacist prescriptions, a site requirement. The pharmacist undertook all pharmacist duties as per usual care, as well as prescribing medications on the NIMC.

4.2.5.2 Control Cohort

Patients were seen by all four health care professionals in clinic, as per usual care. The prescribing of the NIMC was the responsibility of the RMO.

4.2.5.3 Sample of Patients for Panel Assessment of Appropriateness

Intervention and control patients from the main study were stratified in to 5 groups, from the first patient recruited to the last patient, in blocks of 40. Microsoft Excel random number generator was used to pick 2 numbers from each stratified group, giving a total of 10 patients (5%) from both arms. The rationale for the stratification was to enable a selection of patients from across the study timeline, and a selection of prescribers in the control arm, as the study spanned across two rotations of junior doctors. Patients identified in the medication history in PAC as not taking any medication were excluded, and another number was generated until a patient who was taking medication prior
to admission was selected. One patient was subsequently removed from the control group, due to being lost to follow up from the main study.

4.2.5.4 Panel Selection

The panel consisted of a number of different health professionals, recognising either their involvement in the care of surgical patients, prescribing expertise or both; a consultant anaesthetist, a consultant hepatobiliary surgeon, a consultant clinical pharmacologist, a senior pharmacist with previous PAC experience, a senior PAC nurse, and a RMO with previous surgical and PAC experience.

All panel members were independent to the research team.

4.2.5.5 Medication Appropriateness Index

Previous studies assessing appropriateness of prescribing, including non-medical prescribing, have identified the Medication Appropriateness Index (MAI) as the most suitable tool with which to assess appropriateness in an acute setting, with good inter and intra rater variability.[139] The tool consists of a 10-item rating system; indication, effectiveness, dose, correct directions, practical directions, drug-drug interactions, drug-disease interactions, duplication, duration and cost. Amendments were made to the MAI for our study; items regarding duration of therapy and cost effectiveness were not considered applicable, due to the scope of the pharmacist’s prescribing being medications that the patient was already taking. Additional questions were added, as the MAI does not assess underprescribing. Our finalised tool contained two questions to assess whether there had been an omission, and the significance in terms of potential ward inconvenience and patient harm.

With regards to appropriateness of prescribing, the final tool contained 8 items. The original three-point Likert scale was dichotomised to either appropriate or inappropriate, as the original midpoint (marginally appropriate) was considered too subjective, as per previous studies.[139]

Five patients were piloted by one member of the research team and one panel member prior to the panel assessment to assess whether the modified MAI could be applied to the patients appropriately, and to gain a rough estimate of an average time per patient. Time was an important factor, as this determined the number of patients that could be reasonably assessed, taking in to consideration panel members’ availability. A member of the research team met with all panel members prior to the panel sittings to discuss the modified MAI. Agreement was reached that it would be an appropriate tool to assess appropriateness and significance of omissions.
4.2.5.6 Assessment of Prescribing and Omissions

Panel members were provided with copies of patient’s PAC notes, including the medication history taken by the PAC pharmacist, and the NIMC. The panel was blinded as to whether the patients were control or intervention. Resources provided included the Australian Medicines Handbook (AMH), locally produced PAC medication guidelines containing recommendations for management of medications peri operatively, and individual consultant preferences obtained by clinic for management of certain groups of medications peri operatively, for example anticoagulants. The panel was convened for 2 sittings, and each individual panel member rated every medication prescribed on to the NIMC using the criteria set out by the amended MAI. An unintentional omission was defined as any medication from the medication history not prescribed on the medication chart, with no supporting documentation as to why. Omissions were noted and panel members rated each one as whether it had the potential for patient harm, ward inconvenience, or both. Due to clinical duties only three panel members, the surgeon, clinical pharmacologist and pharmacist were able to make both sittings, and review all 19 patients. The other three panel members were only able to make one of the 2 sittings and reviewed as many patients possible in that time.

4.2.5.7 Data Analysis

A medication was scored zero, and classed appropriate, if none of the 8 items on the MAI was rated as inappropriate. A medication was given a score of 1, and classed inappropriate, if one or more of the 8 items received a rating of inappropriate.

Each panel member’s ratings were evaluated individually, and ratings from all 6 panel members were combined, by adding the number of inappropriate reviews together. This gave the total number of medications that were rated as inappropriately prescribed, from the total number of reviews of medications that were undertaken by the panel.

All statistical analysis was conducted using Stata 11.2 (StataCorp, College Station, Tx). Categorical data was analysed by chi-square tests. When the value in any one cell was below ten a Fisher’s exact test was used as chi-square tests can become unreliable. A p-value of < 0.05 was considered statistically significant for the total number of omissions and individual reviewer assessment of appropriateness of prescribing.

4.2.6 Results

The sample included 19 patients, resulting in 294 medication assessments for appropriateness for the control arm, and 266 for the intervention arm, from the entire panel.
The demographics of patients selected for the appropriateness panel assessment were similar to those of patients from the main study. *(see Table 4)*

### 4.2.6.1 Appropriateness of Prescribing

Based on individual reviewer’s assessments only one reviewer, the pharmacist, showed statistical significance, 6/61 medications assessed in inappropriate in the control arm, compared to 0/54 in the intervention (p=0.029).

Reviewer assessments were combined by adding the results together, in an attempt to describe the overall appropriateness. Out of 294 medication assessments across the panel for appropriateness, 32 (10.9%) of the medications prescribed in the control arm were classed inappropriate, when compared to 13 out of 266 (4.9%) in the intervention arm.

From the entire panel, an average of 5.7% of reviews across both arms were judged as inappropriate, with a range of 0 – 18.8%. Nine of the 19 patients were judged as having no inappropriate prescribing, 4 from the control arm and 5 from the intervention arm.

There was a 78% agreement between panel members on inappropriateness of prescribing.

*Table 7* shows total medications reviewed by each panel member, and a breakdown of reasons why each reviewer thought an individual medication was prescribed inappropriately.
Table 7 - Number of Inappropriate Ratings and Reasons for Being Classed as Inappropriate by Reviewer (some data missing)

<table>
<thead>
<tr>
<th>Reason</th>
<th>Anaesthetist</th>
<th>Pharmacologist</th>
<th>Nurse</th>
<th>Pharmacist</th>
<th>RMO</th>
<th>Surgeon</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medications Reviewed</td>
<td>77</td>
<td>110</td>
<td>73</td>
<td>115</td>
<td>68</td>
<td>117</td>
</tr>
<tr>
<td>Inappropriate Medications (%)</td>
<td>4 (5)</td>
<td>10 (9)</td>
<td>6 (8)</td>
<td>6 (5)</td>
<td>6 (9)</td>
<td>13 (11)</td>
</tr>
<tr>
<td>Reason</td>
<td>C</td>
<td>I</td>
<td>C</td>
<td>I</td>
<td>C</td>
<td>I</td>
</tr>
<tr>
<td>Medication Indicated</td>
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<td>0</td>
<td>2</td>
<td>3</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Medication Effective</td>
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<td>1</td>
<td>3</td>
<td>0</td>
<td>1</td>
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<td>Dose Correct</td>
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<td>0</td>
<td>0</td>
<td>4</td>
<td>0</td>
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<tr>
<td>Directions Correct</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>0</td>
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<td>Directions Practical</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Drug–Drug Interaction</td>
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<td>3</td>
<td>0</td>
<td>4</td>
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<td>1</td>
<td>10</td>
<td>6</td>
<td>13</td>
<td>0</td>
</tr>
</tbody>
</table>

C = Control
I = Intervention
4.2.6.2 Omissions

There were significantly more omissions in the control arm, of which four panel members’ individual assessments showed significant numbers had the potential for either patient harm or ward inconvenience. Total unintentional medication omissions from the NIMC in the main study was significantly higher for control patients (31.5%) compared to intervention (1.2%) (p<0.001, chi-square). Omissions from the 5% sample of patients were reflective of these results. Out of 89 regular medications in the patients’ medication histories in the control arm, 25 (28%) were omitted from the NIMC, compared to 1 out of 55 (2%) in the control arm (p<0.001, exact). In the control group, all patients had at least one omission. The median number of omissions was 2, with a range between 1-7. When asked to assess the severity of omission, all the reviewers thought a percentage of the omissions had the potential for patient harm, ward inconvenience, or both. The lowest individual reviewer assessment was 40% and the highest 78%, with the average across the panel showing 52% of omissions in the control arm were assessed as having the potential for patient harm or ward inconvenience (figure 1). Only one reviewer thought the omission in the intervention arm was significant.

Difference of opinion regarding significance of an omission is inevitable, some of the examples of omissions that were rated as ‘potential for harm’ by all reviewers were; omission of aspirin from the medication chart in two patients, one of whom had a previous cerebrovascular accident (CVA) in 1995, and one of whom had a history of ischaemic heart disease (IHD); omission of esomeprazole 40mg from the medication chart of a patient who suffered from chronic gastro-oesophageal reflux disease (GORD), and omission of perindopril 2.5mg daily in a patient diagnosed with hypertension.

4.2.7 Discussion

Our study showed that the appropriateness of prescribing from a collaborative doctor – pharmacist approach to prescribing was similar to usual care prescribing, and produced medication charts that contained significantly fewer omissions of relevant medications.

Previous interventions to improve the appropriateness of prescribing have included an increase in clinical pharmacy involvement during the inpatient stay, which improved the prescribing of medicines.[232, 233] Since the introduction of non-medical prescribing in UK, studies of appropriateness where nurses and pharmacists have taken on the prescribing role have shown that nurse and pharmacists were making clinically appropriate prescribing decisions.[139, 234]

There are various methods and tools in the literature to assess the appropriateness of prescribing, each with their own limitations.[235, 236] The method chosen for our study was one of individual clinician, judgement based assessment. It has been suggested the results from this method may not
always be valid, reproducible or generalisable. However, the same authors suggested that these limitations were remediable by using detailed specifications, validated instruments to obtain data and by training data collectors.[221] The use of the MAI satisfied all of these remedial criteria, although amongst the 6 panel members differences of opinion as to the appropriateness of prescribing, or the significance of an omission is inevitable. Another approach could have been to ask the panel to use the MAI to rate each medication as a panel, rather than individually. The authors felt the issue of perceived seniority within the panel may have introduced bias into the final decision, hence it was felt more reliable to ask each panel member to rate autonomously.

From table 7, it can be seen that no one item from the assessment tool stood out as being the main reason why the prescribing was assessed as inappropriate across both arms. No indication, ineffective medications and duplication of medications can contribute to inappropriate polypharmacy, and increase the chance of medication misadventure.[223] Inappropriate doses and directions for medication increase the chance of incorrect administration of medication as an inpatient.[227] Omissions of medications from the inpatient medication chart, if not rectified during the inpatient stay, are likely to be omitted on any discharge information and summary as patients cross settings. This will expose the patient to an increased chance of poor outcomes, including unplanned 30 day readmission.[208]

The study is limited by the small numbers of patients assessed by the panel for appropriateness of prescribing, and the inability of all of the panel to review all the patients, due to time constraints. One of the recognised limitations of the MAI is that it is time consuming, however it was considered the best tool for the clinical setting in which the study was conducted. Panel members’ availability and the amount of time deemed reasonable for members to commit to the panel amongst other clinical commitments, limited the number of patients that it was possible to assess, which affected the statistical power of the study, and the ability to assess rater variability.

The summing of the individual reviewer assessments to describe overall appropriateness would be flawed in the event of a panel not agreeing on what makes prescribing inappropriate. However, the use of an objective, validated tool with good inter rater variability was used to counteract that concern. Difference of opinion is inevitable, but our panel reached 78% agreement, with regards to inappropriate prescribing.

It can be challenging to link inappropriate prescribing to important outcome measures, such as mortality, morbidity and adverse drug events. However, from what is known on the subject of polypharmacy, and omissions of medication, there is little doubt that a review of medications on admission, a complete and accurate medication chart during the inpatient stay, and accurate transfer
of information on discharge are all essential components of effective medication management and quality use of medicines.[208, 223, 225, 226]

Results from this small snapshot of prescribing are encouraging, and merit repeating the panel assessment on a larger scale. Larger numbers and more robust statistical analysis are necessary to enable any sound conclusions to be drawn, and for the results to be extrapolated and generalised outside of our small study.

4.2.8 Conclusion

For the appropriateness of prescribing, observed results were similar between arms, as judged by individual panel members. Medication charts in the control arm contained significantly more omissions than in the intervention arm, a number of which were rated by the panel members as having the potential for patient harm or ward inconvenience.

A larger sample size is required to make statistical significance or non-inferior conclusions between the two arms.

4.2.9 Acknowledgments

The authors would like to thank the following people for their involvement in the study:

Ms Ching-Ting Hung
Dr Thomas O’Rourke
Dr Elizabeth Maycock
Dr Gary Foo
Ms Elaine Brown

4.2.10 Conflict of interests

There are no conflicts of interest to be declared for any of the authors

4.3 Next Steps

Evaluation of the prescribing of patients’ regular medications in the study was crucial to show that, within the collaborative model, the pharmacist could make appropriate clinical decisions with regards to what medications were to be withheld and continued prior to surgery, and that this could be communicated accurately and safely on to the inpatient medication chart. Results in Chapters 3
and 4 have proved that this to be the case, with the end result being a more accurate and safer medication chart to provide the patient with access to appropriate medication, as an inpatient.

It was equally important to show that, within the collaborative model of care and with the use of agreed guidelines, that the pharmacist was capable of initiating a new medication in PAC appropriately and safely. From the pre study audit that was undertaken, it was clear that there were 3 main classes of medication initiated in PAC by the RMOs in preparation for the patient’s admission to the ward; perioperative analgesia, perioperative nausea and vomiting treatment and venous thromboembolism (VTE) prophylaxis.[200]

Prior to the study commencing, when agreeing the prescribing pharmacist’s scope of practice during the study, it was agreed by hospital executive that the pharmacist in clinic could initiate VTE prophylaxis, due to the fact that Princess Alexandra Hospital had agreed guidelines for each surgical unit, which clearly highlighted which patients were to be treated as low and high risk, and the appropriate treatment options once a patient had been risk assessed.

Chapter 5 reports the results of VTE risk assessments and VTE prophylaxis prescribing in both arms in PAC.
Chapter 5 – Appropriateness of Venous Thromboembolism (VTE) Prophylaxis Prescribing.

5.1 Chapter Introduction

Recording of a VTE risk assessment and prescribing of appropriate VTE prophylaxis are essential parts of a patient’s admission to hospital, especially considering surgery is often a risk factor for VTE. The secondary outcome for our study was a pre-determined analysis of the appropriateness of VTE prophylaxis prescribing on both arms, with the hypothesis being that the pharmacist would be as appropriate in their prescribing as the control arm.

The NHPF domains assessed during this part of the evaluation are;

- **effectiveness**, in ensuring that the care provided is relevant to the patient’s needs and based on established standards, or in this case agreed guidelines as to what is considered best practice
- **safety**, in ensuring there is a reduction in potential harm by appropriate use of medications to avoid VTE

Evaluation of VTE prescribing was crucial to show that an appropriately trained pharmacist was appropriate in the initiation of a new medication for the patient’s admission. This appropriateness can be translated to initiation of medications across many different models of care, and different settings, where guidelines provide recommendations for treatment options. This chapter of the study shows that appropriate training, to enable interpretation of individual patient parameters, in addition to the use of guidelines, and referral to medical officers where appropriate, can improve prescribing of important new medications required for a patient admission, to improve patient outcomes.

5.2 Published Letter to the Editor: Pharmacist Prescribing of Venous Thromboembolism Prophylaxis in a Surgical Pre Admission Clinic

Hale A, Gibbs H, Coombes I, Collins R, Maycock E, Nissen L.


The letter is reproduced in full in Appendix G.

5.2.1 Abstract Summary

Our study evaluated a potential new model of care for the Australian healthcare system, collaborative doctor-pharmacist prescribing of venous thromboembolism (VTE) prophylaxis in a pre admission clinic (PAC). The model of care seeks to better utilise the skills within the current
multidisciplinary team, and free up doctor time to allow for more efficient processes, whilst ensuring safe and appropriate access to medications.

Four hundred adults scheduled for elective surgery were randomised to either intervention; a pharmacist generated the inpatient medication chart and prescribed VTE prophylaxis following a risk and contraindication assessment, or control; prescribing of the medication chart and VTE prophylaxis was the responsibility of Resident Medical Officers (RMO). Secondary outcome was appropriateness of VTE prophylaxis prescribing.

The primary outcome was the safety and accuracy of medication charts prescribed in clinic. Secondary outcome was the appropriateness of VTE prophylaxis prescribing in clinic, which is crucial to ensure a patient’s probability of VTE is minimised whilst in hospital.

The rate of documented VTE risk assessment and documented contraindication assessments were also evaluated, due to the evidence that suggests that appropriateness of VTE prophylaxis is more likely in the presence of a documented risk assessment. Healthcare services in other countries are subject to targets of VTE risk assessment being set, and linked to financial incentives. Financial penalties are also imposed in the event of any 30 day post-operative readmission to hospital for VTE, on the grounds they are considered preventable errors.

Our study highlights some concerns if similar initiatives are to be considered within the Australian healthcare system, and suggests a new model of care to increase both documented risk and appropriateness of prophylaxis.

VTE risk assessment was documented in significantly more patients in the intervention arm, 153/160 (96%), compared to 1/147 (1%) in the control arm (p=<0.0001), and when undertaken was correct 94% of the time.

VTE prophylaxis was appropriately prescribed in clinic in 150/160 (94%) intervention patients, and 94/147 (64%) control (p<0.0001)

The documentation of risk assessment, and prescribing of VTE prophylaxis by the pharmacist in clinic, was significantly more appropriate.

Trial Registration: Registered with ANZCTR—ACTR Number ACTRN12609000426280

5.2.2 Introduction

Venous thromboembolism (VTE) is the term used to describe the disease process which presents as either deep vein thrombosis (DVT) or pulmonary embolism (PE). VTE is a major cause of death and disability worldwide, and places a large financial burden on health care systems.[237]
In 2003, VTE was a more common cause of death than the most common types of cancer, and 7% of all deaths in hospital were due to VTE.[238] In 2008 there were almost 15000 cases of VTE in Australia, at a financial cost of $1.72 billion, or 0.15% of the GDP. A recent systematic review of the literature has shown that initial episodes of DVT or PE are associated with significant healthcare costs, estimated at $3,000-9,500 in the United States (US), and € 2,000-4,000 in Europe.[239] Multiple risk factors have been identified for development of VTE, including hospitalisation for acute medical illness or surgery.[240] Appropriate use of prophylaxis, using anticoagulants and/or mechanical devices has been shown to reduce the development of VTE. Studies have achieved a 80% reduction in VTE, and reduction in some of the long term morbidity associated with VTE, which can include chronic venous insufficiency, oedema and recurrent venous ulceration.[241, 242] Despite the availability of clear, evidence based guidelines which outline the appropriate use of prophylaxis, these recommendations are underutilised.[243]

Documentation of VTE risk assessment is a critical part of any patient admission, driven by evidence that a risk assessment is a trigger for the VTE prevention pathway, and thinking about the risks of VTE and bleeding in each patient will improve outcomes by ensuring appropriate prophylaxis.[244] Such is the perceived importance of a documented risk assessment, that in United Kingdom (UK), a financial incentive is offered through the Commissioning for Quality and Innovation (CQUIN) for organisations that document a risk assessment for at least 90% of patients admitted to hospital.[245]

Several barriers have been identified for undertaking VTE risk assessment, including lack of awareness by healthcare professionals about incidence of VTE, lack of education about the risk assessment, disagreement with best practice clinical guidelines and inadequate system support for conducting VTE assessments, such as no clear delegation for the responsibility of completing the risk assessment.[246]

Pharmacist prescribing has been successfully implemented in a number of countries, the objectives being to make better use of the skills of the current multidisciplinary team, and that a more flexible system for the prescribing, supply and administration of medicines could be developed, while maintaining safe and appropriate access to medicines.[3] Evidence so far suggests pharmacists are making clinically appropriate prescribing decisions, acceptability to patients is high and the role is generally viewed positively by other healthcare professionals.[247]

The overall aim of our main study was to compare a doctor – pharmacist collaborative prescribing model with usual care, with regards to safety, access, effectiveness (incorporating appropriateness), efficiency and responsiveness.[248] Results so far have showed improvements in accuracy and safety of medication charts prescribed by the pharmacist.[231]
We have previously reported the appropriateness of VTE prophylaxis in a cohort of patients on admission to hospital.[231] Given the importance, from the literature, and potential efficiency benefits of undertaking risk assessments and prescribing VTE prophylaxis in clinic, we undertook an analysis of the rate of risk assessments and appropriate of prescribing in a larger cohort of patients at the end of clinic. The aim of the data in this paper is to assess how this new model of care may assist in the rate of documentation of VTE risk and contraindication assessments, and appropriateness of VTE prophylaxis prescribed in pre admission clinic.

5.2.3 Method

This main study was conducted between June to September 2009 in the surgical PAC of a 750 bed tertiary teaching hospital in Queensland. Ethics approval was obtained from the PAH Human Research Ethics Committee, research protocol approval number 2009/050.

All patients who attended PAC and could provide written, informed consent were considered for participation. Patients were excluded if they were under 18 years of age, unable to communicate due to language difficulties or undergoing day surgery. After consent, patients were randomised using a computer generated randomisation list, in blocks of 10 (Microsoft Excel). Sealed envelopes (not prepared by the recruiting researcher) contained a zero or one as per the computer list; the next envelope was opened after consent to determine whether a patient entered the control or intervention arm, respectively. Patients were randomised to have their medications prescribed on the National Inpatient Medication Chart (NIMC) in PAC by either a clinical pharmacist, and countersigned by a Resident Medical Officer (RMO), or to usual care, where the medications were prescribed by the RMO. If a patient had been randomised and their surgery cancelled during PAC, the patient was removed from the study and not replaced.

The primary outcome for the main study was the combined accuracy and safety of medication charts produced by the prescribing pharmacist in clinic, compared to usual care. Statistical power was calculated from a previous pilot study in PAC.[200] After loss of patients due to cancellation of surgery in clinic, the final cohort for the main study was 384 patients; 190 control and 194 intervention. This paper was a predetermined sub-study of the main study, and the effect of a prescribing pharmacist on documented risk assessments, and appropriateness of VTE prophylaxis prescribed in clinic was evaluated. Appropriate VTE prophylaxis was defined as the guideline recommended prophylaxis for the surgical unit under which the patient was to be admitted. Each surgical unit has a VTE prophylaxis guideline which is available on the hospital intranet, and which is given to RMOs during their unit orientation. These guidelines differ due to local input and opinion from individual surgical units, but are based on international guidelines.[213] The locally
produced guidelines define criteria that determine the need for anticoagulant and/or mechanical methods of VTE prophylaxis in high risk patients, and also contraindications to their use.

Training for the prescribing pharmacist included a minimum of 12 days of ‘period of learning in practice’ under a ‘designated medical practitioner’ (DMP), who was the consultant anaesthetist for PAC. The training included case studies and sessions on VTE prophylaxis with a consultant vascular physician and the clinical nurse consultant (CNC) for VTE prophylaxis at PAH. The DMP endorsed the pharmacist’s competency to prescribe before the study could commence.

5.2.3.1 Intervention Cohort

Patients were seen by a nurse, prescribing pharmacist, Resident Medical Officer (RMO) and anaesthetist. Patients had to be seen by the pharmacist before they were seen by the RMO to allow usual RMO duties and a countersignature of the pharmacist prescriptions, a site requirement. The pharmacist undertook all pharmacist duties as per usual care, as well as prescribing medications on the medication chart. The scope of prescribing was to continue or withhold regular medications, according to the plan for medications perioperatively, and to prescribe VTE prophylaxis according to local and national guidelines, following a risk and contraindication assessment.

5.2.3.2 Control Cohort

Patients were seen by all four health care professionals in clinic, in no particular order, as per usual care. The prescribing of the medication chart, and VTE prophylaxis, was the responsibility of the RMO.

Patient charts were assessed for a documented VTE risk assessment, documented mechanical and anticoagulant contraindication assessments, and appropriateness of VTE prescribing in clinic by the CNC for VTE prophylaxis and the project manager for the research team.

5.2.3.3 Data Analysis

All statistical analysis was conducted using Stata 11.2 (StataCorp, College Station, Tx). Categorical data was analysed by chi-square tests. When the value in any one cell was below ten a Fisher’s exact test was used as chi-square tests can become unreliable. All reported p values are two-sided using a level of significance of 0.05.
5.2.4 Results

Table 8 - Summary of Results of VTE Assessments and Appropriateness of Prescribing

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<thead>
<tr>
<th>Intervention n(%)</th>
<th>Control n(%)</th>
<th>p</th>
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<tbody>
<tr>
<td>VTE Risk Assessment Documented</td>
<td>153 (96)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Anticoagulant Contraindication Documented</td>
<td>109 (68)</td>
<td>0</td>
</tr>
<tr>
<td>Mechanical Contraindication Documented</td>
<td>133 (83)</td>
<td>0</td>
</tr>
<tr>
<td>Appropriate VTE Prophylaxis</td>
<td>150 (94)</td>
<td>94 (64)</td>
</tr>
</tbody>
</table>

Directors of surgery were consulted prior to commencement of the trial for permission to include patients in prescribing of VTE prophylaxis, according to their specific unit guidelines. Urology and renal transplant patients were excluded (N=34 intervention, N=43 control) from VTE prophylaxis prescribing as the director of urology was unavailable to confirm the scope of the project, and the director for transplant requested exclusion on the grounds that VTE prophylaxis in these patients being more consultant discretion as opposed to guideline driven.

Figure 9 - Randomisation Flow Chart
5.2.4.1 VTE Risk Assessment

In the intervention arm, out of 160 patient charts assessed a VTE risk assessment was documented 153 times (96%). In the control arm, out of 147 patient charts assessed, a risk assessment was documented on one occasion (p=<0.0001, exact)

In the intervention arm, the risk assessment was assessed as being correct on 144 occasions, or 94% of the time. All 9 risk assessments that were evaluated as incorrect were documented as high risk by the pharmacist, when they should have been low risk, according to guidelines.

5.2.4.2 Contraindication Assessments

In the intervention arm contraindication assessments to anticoagulant and mechanical prophylaxis were documented 109 (68%) times and 133 (83%) times, respectively. All contraindication assessments were assessed as being correct.

In the control arm, no contraindication assessments, to either mechanical or anticoagulant prophylaxis, were documented.

5.2.4.3 VTE Prophylaxis Prescribed in Clinic – Mechanical

In the intervention arm, out of 160 patients assessed for mechanical prophylaxis, 125 (78%) were prescribed compression stockings, which was assessed as being 100% appropriate. Patients not prescribed stockings were assessed as being contraindicated for various reasons.

In the control arm, 38 out of 147 (26%) patients had stockings prescribed. Out of the 109 patients not prescribed stockings, 40 (37%) were assessed as requiring them, according to risk stratification.

5.2.4.4 VTE Prophylaxis Prescribed in Clinic – Anticoagulant

Table 9 - Summary of Appropriateness of Anticoagulant Prescribing

<table>
<thead>
<tr>
<th></th>
<th>Intervention n (%)</th>
<th>Control n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=160</td>
<td>n=147</td>
</tr>
<tr>
<td>Anticoagulant prescribed</td>
<td>77 (48)</td>
<td>40 (27)</td>
</tr>
</tbody>
</table>
| Anticoagulant prescribed 
  inappropriately               | 6 (8)              | 6 (15)        |
|                               | 3 by RMO           |               |
| Reason for Anticoagulant Not 
  Prescribed                   |                    |               |
| Low risk                      | 46 (55)            | 51 (48)       |
| Contraindication              | 33 (40)            | 35 (33)       |
| Omitted                       | 4 (5)              | 21 (20)       |
In the intervention arm, 77 out of 160 (48%) patients had anticoagulants prescribed. Out of the 77 patients, 71 had prophylaxis prescribed by the pharmacist, and six by an RMO. Five of these were following referral from the pharmacist, requesting a final decision on whether heparin was required for that particular patient, due to individual patient factors outside of guidelines which were perceived by the pharmacist to require medical input.

There were 6 patients prescribed heparin who should not have been, either due to being low risk or having contraindications.

Out of 83 patients not prescribed anticoagulants, 46 were assessed as low risk, 33 were assessed as having contraindications, and 4 had heparin omitted from their medication chart when it should have been prescribed.

Out of the 10 patients with inappropriate prophylaxis, 3 had heparin prescribed by the RMO, when it was originally appropriately not prescribed by the pharmacist.

In the control arm, 40 out of 147 (27%) patients had anticoagulants prescribed, 6 of whom should not have had heparin, either due to being low risk or having contraindications. Out of the 107 patients not prescribed heparin, 51 were assessed as low risk, 35 were assessed as having contraindications and 21 had heparin omitted from their medication chart when it should have been prescribed.

The intervention arm had an overall appropriateness for VTE prophylaxis prescribing in clinic of 150/160 (94%), compared to the control arm appropriateness of 94/147 (64%) (p<0.0001)

5.2.5 Discussion

In line with previous research on pharmacist prescribing, our study has shown a pharmacist in a collaborative prescribing model has made a high percentage of appropriate clinical decisions, in this case with regards to the prescribing of VTE prophylaxis.[145] VTE risk assessment documentation is documented more than usual care, and above the target set by CQUIN in UK, at which financial incentives are paid to organisations.[245] Appropriateness of VTE prophylaxis prescribed in clinic was more appropriate than usual care, the benefits of which are a reduction in probability of VTE whilst an inpatient[237].

In 2003, the National Health and Medical Research Council’s (NHMRC) National Institute of Clinical Studies (NICS) developed a national program to improve the prevention of VTE in hospitalised patients in Australia.[249] A system based approach to patient VTE risk assessment and management was one approach highlighted that would account for significant improvements in compliance with best practice guidelines. In 2009, the Australian Institute of Health and Welfare
produced recommendations for a set of 55 national indicators of safety and quality in healthcare, one of which was the proportion of admitted patients who have a documented VTE risk assessment.[250] In 2010 in the United Kingdom (UK), the National Institute for Clinical Excellence (NICE) released a guideline, the key priorities of which were to assess patients for risk of VTE on admission to hospital, assess patients for bleeding risk and evaluate the risks and benefits of prescribing VTE prophylaxis.[251] In 2012, the Health Quality and Complaints Commission (HQCC) in Australia produced standards with a view to minimise VTE rates in hospitalised patients.[252] The first reporting requirement was the proportion of admitted patients with a documented VTE risk, with all Queensland hospitals required to report data to HQCC through and Annual Quality and Activity Return (AQAR), with the information used to drive healthcare quality improvement. Also in 2012, the Australian Commission on Safety and Quality in Health Care produced the Medication Safety Action Guide, which set several proposed outcomes for health care, focusing on a small number of key safety and quality challenges which, if improved, would have a significant impact on the health and wellbeing of individuals, or on the healthcare system as a whole.[226] One of the outcomes was adults receive less venous thromboembolisms associated with hospitalisation, and the document highlighted possible actions by healthcare providers required to ensure all adult inpatients are assessed for risk of VTE on admission, and receive appropriate prophylaxis.

In the US, institutions are financially penalised in an attempt to ensure appropriate VTE prophylaxis is considered and prescribed. The Centers for Medicare and Medicaid Services (CMS) refuses to reimburse for hospital treatment of a primary diagnosis for VTE following recent (30 day) total hip or knee arthroplasty, on the grounds they are considered the result of preventable medical errors.[253] If similar financial penalties were to be introduced in Australia, new methods to maximise appropriate VTE prophylaxis would become even more crucial.

In line with results from studies in the UK, prior to guidelines and mandatory reporting of documented VTE risk assessments, the documented risk assessments in the current model of care in PAC are far from reaching the recommended level of 95% stipulated by NICE, or the 90% required by CQUIN in UK for financial incentives to be paid[245, 251]. Subsequent guidelines released in Australia by AIHW and HQCC have not gone so far to recommend a target percentage that should have a documented risk assessment, and as of yet there are no financial incentives linked to performance in Australia. Should this model ever be adopted, that there was only one documented risk assessment in the control arm, out of 147 patients, is an area for grave concern.[250, 252]

The lack of documented risk assessment is reflected in the appropriateness of VTE prescribing, and a previous study has shown that a documented risk assessment is more likely to lead to appropriate
choice of prophylaxis by acting as a trigger for the VTE prevention pathway.[244] With the systems that are in place in hospital, such as VTE advocates on the ward, nurse assessment of VTE risk on admission, and ward pharmacy review on admission and during the inpatient stay, the appropriateness of VTE prophylaxis in the control arm should increase. However, the efficiencies of a pharmacist documenting risk and prescribing prophylaxis in clinic are apparent. The initiative will save clinician time, both in PAC and the ward, and ensure more patients receive appropriate prophylaxis on admission to the ward in a timely manner.

The medication safety document produced by the Australian Commission on Safety and Quality in Health Care recommended possible actions by healthcare providers to ensure appropriate prophylaxis.[226] These included routinely assessing all adults admitted to hospital for VTE risk, assessing bleeding risk and ordering appropriate prophylaxis where indicated, development of VTE prevention policies and clinical pathways, and to train staff in VTE risk assessment, risk of bleeding, contraindications to prophylaxis and appropriate prophylaxis prescribing.

Guidelines for VTE prophylaxis were previously facilitated between the individual surgical units in the hospital and the CNC for VTE prophylaxis. The authors believe the model of care evaluated in this paper, in having an appropriately trained pharmacist delegated to focus on VTE risk assessment and prophylaxis prescribing, as part of a defined scope of practice, has facilitated the other recommendations, and counteracted all of the barriers mentioned previously.[246]

Whilst guidelines provide support for clinicians in their clinical decision making and prescribing, they are not objective tools, with many patients requiring individualised consideration due to unique patient factors.[254] Guidelines do not cover every patient, or clinical scenario, and this was highlighted in the study with the referrals made from the pharmacist to the RMO in clinic, requesting a final decision on whether chemical prophylaxis was appropriate to be prescribed. This ability to refer is a crucial part of a collaborative model of care, requiring recognition of limitations in scope of practice on behalf of the pharmacist, and access to medical officers to be able to discuss individual cases when necessary.

A common reason for inappropriate prophylaxis in both arms was overprescribing of heparin in patients who were assessed as not requiring chemical prophylaxis. This is a concern when prescribing anticoagulants perioperatively, and may be a symptom of the increased awareness and push within organisations for VTE prophylaxis to be prescribed.[255, 256]

Limitations of the study include this being one pharmacist in one hospital, and further work must be undertaken to ensure the underlying skills and knowledge of an advanced level pharmacist, along
with appropriate postgraduate prescribing training, can reliably produce competent and fit for purpose prescribers, irrespective of model of care or scope of practice.

The fact that the study is reliant on a surrogate endpoint of appropriateness of prescribing, as opposed to actual clinical outcomes of events is also a limitation. However, numbers required to show a difference in either VTE or bleeds would be unrealistic for the scope of our study. Reviews have shown probabilities of poor outcomes, with regards to VTE, to be higher in surgical patients who do not receive appropriate prophylaxis.[257]

VTE is a costly outcome, both in terms of a financial burden to the healthcare system, and quality of life for the patient.[238, 239] The saving of doctor time will be offset by an increased time requirement for the pharmacist to complete the assessment and prescribe prophylaxis. Further work is required to assess the cost effectiveness of this new model of care, and to assess whether any increased cost of the new model of care would be justified in terms of healthcare costs saved and health benefits gained.

Whilst a figure of 94% appropriateness is an improvement, the end goal, irrespective of model of care, should be appropriate VTE prophylaxis in all patient

5.2.6 Conclusion

Documentation of VTE risk assessment and VTE prophylaxis prescribing was more appropriate in this new model of care. A multidisciplinary approach and investigation of new roles for existing healthcare professionals may be approaches to consider, in an attempt to primarily ensure patients receive appropriate VTE prophylaxis.

5.2.7 Competing Interests

No external funding and no competing interests declared

5.3 Next Steps

Chapters 3, 4 and 5 have established that a pharmacist, with appropriate training and education, can make clinically appropriate decisions in the PAC setting, and communicate these accurately and safely on to the NIMC. The hypothesis that the pharmacist is as good as usual care when it comes to producing a safe and accurate medication chart, and prescribe appropriate VTE prophylaxis, has been proved.

Now it is crucial to assess whether the patients in the study were satisfied with the service they received in clinic and with the model of care, and whether there are any major concerns which might be a barrier to implementation of pharmacist prescribing in Australia.
6 Chapter 6 – Submitted Paper. Patient Satisfaction from Two Studies of Collaborative Doctor – Pharmacist Prescribing in Australia

6.1 Chapter Introduction

The NHPF stipulates as part of any evaluation of a health service, responsiveness should be assessed, namely whether the service is client orientated, and whether clients are treated with dignity, confidentiality and encouraged to participate in choices related to their healthcare.

The importance of patient views is acknowledged in developing services, and the healthcare sector has used a variety of methods to assess patient feedback, which can be divided in to individual or group based approaches.[258] Examples of individual approaches include questionnaires to assess a patient’s needs before a consultation, shared decision making, one-to-one interviews and surveys to be filled out by patients after a consultation. Examples of group based approaches include focus groups, consensus mapping, consensus panels and public meetings. Methods need to be examined in terms of validity, effectiveness and implementation. In our studies, it was predominantly the ease of implementation that defined the methodology selected. Whereas focus groups may allow for more scope to express different preferences, by using more open ended approaches, it was considered not feasible to convene groups as part of our study, due to the inconvenience that would have been caused to patients by having to return to hospital again. Questionnaires allowed patient views to be elicited in a timely and efficient manner, while the consultation experience was still recent. Previous international literature utilising the same methodology also allows us to compare results within similar cohorts of patients.

Patients in the PAC study were requested to complete a satisfaction survey at the end of their clinic appointment, the results of which are reported in Chapter 6.

The data analysis in this chapter also includes the patient satisfaction results from another pilot of pharmacist prescribing, in a different model of care. The pilot took place in an outpatient sexual health clinic, and aimed to assess the safety and effectiveness of a pharmacist managing the ongoing treatment and medication of medically stable patients with a diagnosis of HIV (Human Immunodeficiency Virus), under an agreed care plan made between pharmacist, patient, and the patient’s usual medical specialist.
6.2 Patient Satisfaction from Two Studies of Collaborative Doctor - Pharmacist Prescribing in Australia

6.2.1 Abstract

6.2.1.1 Background
Pharmacist prescribing has been introduced in several countries, and is a possible future role for pharmacy in Australia.

6.2.1.2 Objective
To assess whether patient satisfaction and patient experiences in two settings of collaborative doctor pharmacist prescribing may be barriers to implementation of pharmacist prescribing in Australia.

6.2.1.3 Design
Surveys containing closed questions, and Likert scale response options, were completed in both settings to investigate patient satisfaction after each consultation. A further survey investigating attitudes towards pharmacist prescribing, after multiple consultations, was completed in the sexual health clinic study only.

6.2.1.4 Setting and Participants
A surgical pre admission clinic (PAC) in a tertiary hospital, and an outpatient sexual health clinic attached to a university hospital. Two hundred patients scheduled for elective surgery, and 17 patients diagnosed with HIV, respectively, recruited in to the pharmacist prescribing arm of two collaborative doctor pharmacist prescribing studies.

6.2.1.5 Results
Consultation satisfaction response rates in PAC and the sexual health clinic were 182/200 (91%) and 29/34 (85%), respectively. In the sexual health clinic, the attitudes towards pharmacist prescribing survey response rate was 14/17 (82%).

Consultation satisfaction was high in both studies, most patients (98% and 97% respectively) agreed they were satisfied with the consultation.

In the sexual health clinic, all patients (14/14) agreed that they trusted the pharmacist's ability to prescribe, the care was as good as usual care, and they would recommend seeing a pharmacist prescriber to friends.
6.2.1.6 Discussion and Conclusion

Most of the patients from both studies had a high satisfaction with pharmacist prescriber consultations, and a positive outlook on the collaborative model of care in the sexual health clinic.

6.2.2 Introduction

Non-medical prescribing is one proposed strategy to assist in meeting growing demand in Australia for healthcare, and improving access to medicines. The Health Workforce Australia (HWA) Health Professionals Prescribing Pathway (HPPP) Project is developing a national pathway to prescribing by health professionals other than doctors.[259] The first stage is complete, with the recommendations for implementation approved at a national policy level in November 2013. Key issues such as regulatory practice, education, training and accreditation requirements will now be addressed with key stakeholders. There is little evidence in Australia of patient perspectives and opinions on non-medical prescribing, will also be important to inform the implementation of this new model of healthcare.

Previous exploration of Australian patient views about pharmacist prescribing were based on surveys about a hypothetical role, utilising a theoretical framework to examine opinions on the expanded role, and any factors that contributed positively to their perception of trust in pharmacists.[260] Hoti et al showed that most clients indicated trust in pharmacists assuming an extended role, where doctors made the primary diagnosis, and the recommendation was made that any introduction be made in a way that facilitates the already established relationships between doctors and patients. Before now, no study in Australia has examined patient perspectives after experiencing the pharmacist prescribing model of care.

The National Health Performance Framework (NHPF) provides indicators; effectiveness, safety, responsiveness, continuity of care, accessibility and efficiency, and sustainability, that were used as a guide for evaluation of the two pilots of collaborative doctor-pharmacist prescribing discussed in this paper.[11] The study in preadmission clinic (PAC) has shown benefits in safety, effectiveness and appropriateness.[231] Both studies examined patient satisfaction, with the experience as a measure of responsiveness. The need to involve patients in decision making, especially in prescribing, has also become an integral part of healthcare.

Non-medical prescribing has been introduced in a number of countries and evidence so far suggests acceptability to patients is high.[247] In Australia a focus has been placed recently on non-medical prescribers within the healthcare system, and in light of some resistance it is important to have evidence that this potential new model of care meets satisfies any concerns.[17, 37, 40, 181, 261]
This data discussed in this paper describes what elements of prescriber behaviour during a consultation lead to patient satisfaction in the two models of care. Attitudes towards pharmacist prescribing are investigated, to assess whether this may be a barrier to expansion of the pharmacist role in Australia, and implementation of collaborative doctor-pharmacist prescribing.

6.2.3 Method

6.2.3.1 Pharmacist Training

Both pharmacists attended a prescribing course, accredited by the General Pharmaceutical Council, UK as an Independent Pharmacist Prescribing Course.[262]

6.2.3.2 Pre Admission Clinic

Four hundred patients scheduled for elective surgery were recruited into the study, and randomised to intervention or control (N=200 intervention, N=200 control). Intervention patients were seen by a nurse, prescribing pharmacist, resident medical officer (RMO) and anaesthetist. The pharmacist was responsible for taking a medication history, plus the prescribing of the inpatient medication chart. This was to ensure continuation of the patient’s regular medications on admission, and that the medication chart reflected the plan for medication perioperatively, including initiation of venous thromboembolism (VTE) prophylaxis. The pharmacist was unknown to the intervention patients, unless there was a small chance they had previously been thorough clinic and met the pharmacist at a prior appointment. This is possible, but unlikely to have happened often enough to influence the data. Control patients were seen by the same four health professionals in clinic, but the prescribing of the inpatient medication chart was the responsibility of the RMO. Intervention patients were asked to complete a satisfaction questionnaire after their appointment with the prescribing pharmacist, in order to be able to assess the prescribing pharmacist’s consultation behaviours, and how these impacted on patient satisfaction and views of pharmacist prescribing.

6.2.3.3 Sexual Health Clinic

Thirty three patients with a diagnosis of Human Immunodeficiency Virus (HIV), and judged to be medically stable by the sexual health staff specialist in the clinic, were recruited in to the study and randomised to intervention or control (N=17 intervention, N=16 control). Patients were excluded if they had any contact with the pharmacist prior to the study. The patient’s first appointment was with both the medical specialist, and the prescribing pharmacist, for the development of an agreed care plan. Second and third appointments in the study were undertaken by the prescribing pharmacist alone. The pharmacist’s scope of practice included ongoing management and prescribing of regular HIV medicines, with referral to the medical specialist still possible at the
pharmacist’s discretion, and in particular for anything outside of the care plan. Intervention patients were asked to complete a consultation satisfaction questionnaire at the end of each appointment with the pharmacist, in order to assess consultation behaviours of the pharmacist, and how these impacted on patient satisfaction. At the end of their last appointment intervention patients were also asked to complete an attitudes towards pharmacist prescribing questionnaire, to assess their attitudes towards the new collaborative pharmacist prescribing model of care they had experienced during the study.

6.2.3.4 Questionnaire Development

Patient satisfaction is an important outcome of care, and satisfied patients are more likely to cooperate with treatment (ref Kincey J, GP). For this reason patient satisfaction was evaluated as a consultation goal in both studies. Patient satisfaction questionnaires were developed for both pilots, with relevant statements chosen from a scale developed initially for general practitioners (ref Baker R- GP in general practice) Relevant statements on attitudes towards pharmacist prescribing were chosen from a scale developed previously in the UK.[263]

Statements were developed to assess important elements of the scope of practice of the pharmacist in both settings that would contribute towards consultation goals, for example an assessment of the explanation of the plan for the patient’s medication before their operation in PAC.

One questionnaire was developed for the PAC trial which focused on satisfaction and preparedness for surgery, elicited from experiences related to the delivery of the consultation. There were 12 questions in total, with information collected on a 5 point Likert scale, from strongly agree to strongly disagree.

Pre admission clinic services prepare patients for their admission for elective surgery, aiming to ensure patients are admitted in the best possible state of health. Questionnaires were designed to assess whether the pharmacist has assisted in the patient feeling ‘prepared for surgery’. One questionnaire was developed for the PAC trial which focused on the goals of satisfaction and preparedness, elicited from experiences related to the delivery of the consultation. There were 12 questions in total, with information collected on a 5 point Likert scale, from strongly agree to strongly disagree.

Consultation goals in the sexual health clinic were satisfaction, and the extent to which patient felt involved in decisions about their healthcare, as evidence suggests that a patient centred approach contributes to the goals of treatment for patients with chronic disease; to reduce hospital admission and improve quality of life. (ref Q Health strategy for chronic disease). Two questionnaires were
developed for the sexual health clinic, one focusing on consultation satisfaction, quality and patient involvement in treatments as the goals of consultation, and the other on attitudes towards the pharmacist prescriber model of care. There were 15 questions in the appointment questionnaire, and 10 in the attitudes towards pharmacist prescribing questionnaire. Both questionnaires collected information on a 5 point Likert scale, from strongly agree to strongly disagree.

Ethics approval for the PAC and the sexual health questionnaires was sought from the Princess Alexandra Hospital and the Gold Coast Health Service District Human Research Ethics Committees, respectively. Changes were requested to the PAC questionnaires, and for questions 2, 4, 6 and 9 to be changed to make the questionnaire a mixture of positive and negative responses. For example, question 2 was changed from “The pharmacist listened to what I had to say” to “The pharmacist did not listen to me”. No changes were requested to the sexual health clinic questionnaires.

Following ethics approval, all questionnaires were piloted on 5 non study patients in each clinic prior to the studies commencing, with respondents asked about ease of completion, understanding and length. On the basis of the pilot, no changes were made to any of the questionnaires.

**6.2.3.5 Statistical Analysis**

For reporting purposes, the 5 point Likert scale in all questionnaires was collapsed in to a 3 point scale; agree (strongly agree/agree), disagree (strongly disagree/disagree) and neutral. Cronbach’s alpha coefficient was used to evaluate the internal consistency reliability for the different themes in surveys. For these calculations, the 5 point Likert scales were used.

The consultation behaviours associated with achievement of consultation goals in both settings were examined using the Spearman’s rank correlation test.

**6.2.4 Results**

**6.2.4.1 Pre Admission Clinic**

The patient response rate was 91% (182/200). Respondents had a median age of 56 (range 18-86) and 60% were male. At the time of the PAC appointment, 83% (148/178) were taking regular medications. *(Table 10)*
Consultation Goals – Satisfaction and Preparedness for Surgery

Responses showed a very high level of satisfaction with the consultation, 98% of patients agreed that they were satisfied with the consultation provided by the pharmacist. Importantly, 92% of patients agreed the information the pharmacist had given them helped prepare them for surgery.

Consultation Experience

High percentages of patients agreed that the pharmacist explained their role in clinic (98%), that the pharmacist listened to them (92%), that they had a plan for medications, both before and after their operation, clearly explained to them (85% and 81% respectively).

With regards to responsiveness to patients, high percentages agreed that the pharmacist checked their understanding of the plan for medication (98%), and that the pharmacist answered questions in a way that was easily understood (97%) and understood their concerns about medications (96%).

High percentages of patients agreed that any information they were given was easy to understand, and 88% of patients agreed they trusted the pharmacist’s ability to provide them with a plan.

Spearman correlation results highlighted elements of the consultation which are most strongly associated with feelings of patient satisfaction and preparedness for surgery. Both goals shared the highest ranked elements, namely the pharmacist explaining their role clearly, checking the patient understanding, understanding patient concerns and answering any questions the patient had effectively. This would suggest effective listening and communication, information provision and empathy are all important in ensuring patient satisfaction and preparedness. (Table 11)

The independence of the pharmacist caused most ambivalence, and uncertain responses (14%), amongst respondents was whether patients would like the plan given to them by the pharmacist to be checked by the doctor.

The independence of the pharmacist caused most ambivalence, and uncertainty (14%), amongst respondents, as indicated by responses to the question whether patients would like the plan given to them by the pharmacist checked by the doctor?

6.2.4.2 Sexual Health Clinic

Consultation Satisfaction

The patient response for appointment feedback was 85%, with one patient only completing one questionnaire after the first pharmacist appointment, and two patients not completing either. Median age was 49 (range 33-65) and 87% were male. (Table 12)
Consultation Goals – Consultation Satisfaction, Quality and Patient Empowerment

There was a high satisfaction with the consultation, patients agreed they were satisfied for 97% of appointments, and only after 3% of consultations did they agree that some things could have been better. All of the patients agreed the pharmacist allowed them the opportunity to be involved in decisions about their care.

Professional Care

All of the patients agreed that the prescriber told them everything about their treatment during the appointment, checked that they understood their medications, and how to take them, and that any information given to them by the pharmacist was relevant and easy to understand. After their appointment, 72% of patients agreed that they understood their illness more, and 79% agreed that they understood their medications, and how to take them more. Overall, all of the patients agreed that they would follow the pharmacist’s advice because he/she was absolutely right.

Empathy

All of the patients agreed the pharmacist understood their health problem, listened to them, took time to answer any questions and appeared genuinely caring and concerned for their well-being.

In line with results from PAC, the Spearman’s correlation showed that elements of the consultation behaviour that were most strongly associated with patient satisfaction were those concerning effective listening and answering of questions, information provision, and checking of patient understanding. The highest correlation with satisfaction was patients feeling they were involved in decisions concerning their treatment. *(Table 13)*

Attitudes Towards Pharmacist Prescribing

The response rate for the attitudes towards pharmacist prescribing questionnaire was 82% (14/17). Respondents’ median age was 49 (range 33-65), and 87% were male. *(Table 14)*

The Consultation

Consistent with the consultation satisfaction questionnaire, all of the patients were satisfied with the consultations provided by the pharmacist. All patients agreed that they had enough time to discuss medication related issues.
**Provision of Information and Understanding of Treatment Plan**

All patients who had changes to their treatment plan or medication agreed that changes had been explained to their satisfaction.

**Trust in Pharmacist**

All of the patients trusted the pharmacist’s ability to prescribe, and thought that care provided was as good as usual care. This was all reflected in the overall willingness to engage with a pharmacist prescriber; 93% agreed they would consider seeing a pharmacist prescriber for ongoing management of their condition and medication, and all patients would recommend seeing a pharmacist prescriber to other people.

One question that caused most ambivalence amongst respondents was as to whether they were more interested in the quality of care than the profession of the person who provides it; 63% agreed, 21% disagreed and 14% were unsure.

End of consult goals were consistent with overall study satisfaction.
Table 10 - Patient Satisfaction Pre Admission Clinic

<table>
<thead>
<tr>
<th>Consultation Experience</th>
<th>Strongly Agree 5</th>
<th>Agree 4</th>
<th>Uncertain 3</th>
<th>Disagree 2</th>
<th>Strongly Disagree 1</th>
<th>Median Score (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The pharmacist explained to me clearly what his/her role was in Pre-Admission Clinic</td>
<td>98 (54%)</td>
<td>80 (44%)</td>
<td>3 (1)</td>
<td>1 (1)</td>
<td>0</td>
<td>Median 1 (2-5)</td>
</tr>
<tr>
<td>The pharmacist did not listen to me</td>
<td>5 (3%)</td>
<td>5 (3%)</td>
<td>5 (3)</td>
<td>47 (27)</td>
<td>115 (65)</td>
<td>Median 1 (1-5)</td>
</tr>
<tr>
<td>The pharmacist did not explain clearly what to do with my medications before my operation</td>
<td>10 (6%)</td>
<td>15 (8)</td>
<td>1 (1)</td>
<td>40 (23)</td>
<td>110 (62)</td>
<td>Median 1 (1-5)</td>
</tr>
<tr>
<td>The pharmacist did not explain clearly what to do with my medications after my operation</td>
<td>7 (4%)</td>
<td>16 (9)</td>
<td>11 (6)</td>
<td>44 (25)</td>
<td>101 (56)</td>
<td>Median 1 (1-5)</td>
</tr>
<tr>
<td>The pharmacist checked that I understood what to do with my medications</td>
<td>99 (55%)</td>
<td>78 (43)</td>
<td>1 (1)</td>
<td>2 (1)</td>
<td>1 (1)</td>
<td>Median 5 (1-5)</td>
</tr>
<tr>
<td>Any information the pharmacist gave me was irrelevant and difficult to understand</td>
<td>5 (3%)</td>
<td>7 (4)</td>
<td>3 (2)</td>
<td>54 (30)</td>
<td>109 (61)</td>
<td>Median 1 (1-5)</td>
</tr>
<tr>
<td>The pharmacist answered any questions I asked in a way I easily understood</td>
<td>95 (53%)</td>
<td>80 (44)</td>
<td>3 (2)</td>
<td>1 (1)</td>
<td>1 (1)</td>
<td>Median 5 (1-5)</td>
</tr>
<tr>
<td>I felt the pharmacist understood any concerns I had about my medications</td>
<td>81 (45%)</td>
<td>91 (51)</td>
<td>4 (2)</td>
<td>2 (1)</td>
<td>1 (1)</td>
<td>Median 4 (1-5)</td>
</tr>
<tr>
<td>I did not trust the pharmacist’s ability to provide me with a plan for the management of my medication</td>
<td>6 (3%)</td>
<td>11 (6)</td>
<td>5 (3)</td>
<td>49 (28)</td>
<td>106 (60)</td>
<td>Median 1 (1-5)</td>
</tr>
<tr>
<td>To make sure the pharmacist is giving me the right plan I would like it to be checked by a doctor in the clinic</td>
<td>22 (12%)</td>
<td>44 (25)</td>
<td>24 (14)</td>
<td>48 (27)</td>
<td>39 (22)</td>
<td>Median 3 (1-5)</td>
</tr>
</tbody>
</table>

Cronbach’s Alpha: 0.612

<table>
<thead>
<tr>
<th>Consultation Goals</th>
<th>Strongly Agree 5</th>
<th>Agree 4</th>
<th>Uncertain 3</th>
<th>Disagree 2</th>
<th>Strongly Disagree 1</th>
<th>Median Score (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I am satisfied by the consultation provided by the pharmacist</td>
<td>104 (57%)</td>
<td>74 (41)</td>
<td>4 (2)</td>
<td>0</td>
<td>0</td>
<td>Median 1 (3-5)</td>
</tr>
<tr>
<td>The information the pharmacist gave me has helped me prepare for my surgery</td>
<td>72 (40%)</td>
<td>95 (52)</td>
<td>13 (7)</td>
<td>2 (1)</td>
<td>0</td>
<td>Median 2 (2-5)</td>
</tr>
</tbody>
</table>
Table 11 - Spearman’s Rank Correlation with Consultation Goals-Pre Admission Clinic

<table>
<thead>
<tr>
<th></th>
<th>I am satisfied by the consultation provided by the pharmacist</th>
<th>The information the pharmacist gave me has helped me prepare for my surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>The pharmacist explained to me clearly what his/her role was in Pre-Admission Clinic</td>
<td>0.712**</td>
<td>0.574**</td>
</tr>
<tr>
<td>The pharmacist did not listen to me</td>
<td>-0.381**</td>
<td>-0.277**</td>
</tr>
<tr>
<td>The pharmacist did not explain clearly what to do with my medications before my operation</td>
<td>-0.334**</td>
<td>-0.213**</td>
</tr>
<tr>
<td>The pharmacist did not explain clearly what to do with my medications after my operation</td>
<td>-0.400**</td>
<td>-0.284**</td>
</tr>
<tr>
<td>The pharmacist checked that I understood what to do with my medications</td>
<td>0.632**</td>
<td>0.583**</td>
</tr>
<tr>
<td>Any information the pharmacist gave me was irrelevant and difficult to understand</td>
<td>-0.360**</td>
<td>-0.314**</td>
</tr>
<tr>
<td>The pharmacist answered any questions I asked in a way I easily understood</td>
<td>0.637**</td>
<td>0.554**</td>
</tr>
<tr>
<td>I felt the pharmacist understood any concerns I had about my medications</td>
<td>0.615**</td>
<td>0.618**</td>
</tr>
<tr>
<td>I did not trust the pharmacist’s ability to provide me with a plan for the management of my medication</td>
<td>-0.428**</td>
<td>-0.319**</td>
</tr>
<tr>
<td>To make sure the pharmacist is giving me the right plan I would like it to be checked by a doctor in the clinic</td>
<td>-0.185*</td>
<td>-0.085</td>
</tr>
<tr>
<td>The information the pharmacist gave me has helped me prepare for my surgery</td>
<td>0.581**</td>
<td>-</td>
</tr>
</tbody>
</table>

** Correlation is significant at the 0.01 level (2-tailed)

*Correlation is significant at the 0.05 level (2-tailed)
<table>
<thead>
<tr>
<th>Professional Care</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Uncertain</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
<th>Median Score (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The prescriber told me everything about my treatment.</td>
<td>27 (93%)</td>
<td>2 (7)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(4-5)</td>
</tr>
<tr>
<td>I understand my illness more after seeing the prescriber than I did beforehand.</td>
<td>9 (31%)</td>
<td>12 (41)</td>
<td>7 (24)</td>
<td>1 (3)</td>
<td></td>
<td>4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(2-5)</td>
</tr>
<tr>
<td>I understand my medications and how to take them more after seeing the prescriber than beforehand.</td>
<td>13 (45%)</td>
<td>10 (34)</td>
<td>5 (17)</td>
<td>0</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(1-5)</td>
</tr>
<tr>
<td>The prescriber checked that I understood my medications and that I would take them correctly.</td>
<td>25 (86%)</td>
<td>4 (14)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(4-5)</td>
</tr>
<tr>
<td>Any information the prescriber gave me was relevant and easy to understand.</td>
<td>23 (79%)</td>
<td>6 (21)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(4-5)</td>
</tr>
<tr>
<td>I will follow this prescriber’s advice because I think he/she is absolutely right.</td>
<td>19 (66%)</td>
<td>10 (34)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(4-5)</td>
</tr>
<tr>
<td>The prescriber was interested in me as a person, not just my illness.</td>
<td>20 (69%)</td>
<td>8 (28)</td>
<td>1 (3)</td>
<td>0</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(3-5)</td>
</tr>
<tr>
<td>I felt the prescriber appeared to understand my concerns about medication.</td>
<td>18 (62%)</td>
<td>9 (31)</td>
<td>2 (7)</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(3-5)</td>
</tr>
<tr>
<td>Cronbach’s Alpha: 0.70</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Empathy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The prescriber understood my health problem.</td>
<td>26 (90%)</td>
<td>3 (10)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(4-5)</td>
</tr>
<tr>
<td>The prescriber listened to what I had to say.</td>
<td>25 (86%)</td>
<td>4 (14)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(4-5)</td>
</tr>
<tr>
<td>The prescriber took time to discuss any questions or worries I had.</td>
<td>22 (76%)</td>
<td>7 (24)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(4-5)</td>
</tr>
<tr>
<td>The prescriber appeared genuinely caring and concerned for my well-being.</td>
<td>26 (90%)</td>
<td>3 (10)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(4-5)</td>
</tr>
<tr>
<td>Cronbach’s Alpha: 0.85</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consultation Goals</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I am totally satisfied with my visit to the prescriber.</td>
<td>24 (83%)</td>
<td>4 (14)</td>
<td>1 (3)</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(3-5)</td>
</tr>
<tr>
<td>Some things about my consultation with the prescriber could have been better.</td>
<td>1 (3%)</td>
<td>2 (7)</td>
<td>2 (7)</td>
<td>5 (17)</td>
<td>19 (66)</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(1-5)</td>
</tr>
<tr>
<td>The prescriber allowed me an opportunity to be involved in making decisions about my care.</td>
<td>24 (83%)</td>
<td>5 (17)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(4-5)</td>
</tr>
</tbody>
</table>
Table 13 - Spearman’s Rank Correlation with Consultation Goals-Sexual Health Clinic

<table>
<thead>
<tr>
<th></th>
<th>I am totally satisfied with my visit to the prescriber</th>
<th>Some things about my consultation with the prescriber could have been better</th>
<th>The prescriber allowed me an opportunity to be involved in making decisions about my care</th>
</tr>
</thead>
<tbody>
<tr>
<td>I am totally satisfied with my visit to the prescriber</td>
<td>-</td>
<td>-.639**</td>
<td>.764**</td>
</tr>
<tr>
<td>Some things about my consultation with the prescriber could have been better</td>
<td>-</td>
<td>-</td>
<td>-.413*</td>
</tr>
<tr>
<td>The prescriber told me everything about my treatment.</td>
<td>0.632**</td>
<td>-0.443*</td>
<td>0.596**</td>
</tr>
<tr>
<td>I understand my illness more after seeing the prescriber than I did beforehand</td>
<td>-0.088</td>
<td>0.056</td>
<td>0.185</td>
</tr>
<tr>
<td>I understand my medications and how to take them more after seeing the prescriber than beforehand</td>
<td>-0.078</td>
<td>-0.067</td>
<td>0.158</td>
</tr>
<tr>
<td>The prescriber checked that I understood my medications and that I would take them correctly</td>
<td>0.583**</td>
<td>-0.474**</td>
<td>0.612**</td>
</tr>
<tr>
<td>Any information the prescriber gave me was relevant and easy to understand</td>
<td>0.674**</td>
<td>-0.614**</td>
<td>0.668**</td>
</tr>
<tr>
<td>I will follow this prescriber’s advice because I think he/she is absolutely right</td>
<td>0.627**</td>
<td>-0.570**</td>
<td>0.629**</td>
</tr>
<tr>
<td>The prescriber was interested in me as a person, not just my illness</td>
<td>0.458*</td>
<td>-0.226</td>
<td>0.453*</td>
</tr>
<tr>
<td>I felt the prescriber appeared to understand my concerns about medication.</td>
<td>0.343</td>
<td>-0.487**</td>
<td>0.338</td>
</tr>
<tr>
<td>The prescriber understood my health problem</td>
<td>0.474**</td>
<td>-0.481**</td>
<td>0.444*</td>
</tr>
<tr>
<td>The prescriber listened to what I had to say</td>
<td>0.883**</td>
<td>-0.523**</td>
<td>0.876**</td>
</tr>
<tr>
<td>The prescriber took time to discuss any questions or worries I had</td>
<td>0.601**</td>
<td>-0.388*</td>
<td>0.596**</td>
</tr>
<tr>
<td>The prescriber appeared genuinely caring and concerned for my well-being</td>
<td>0.763**</td>
<td>-0.481**</td>
<td>0.744**</td>
</tr>
</tbody>
</table>

** Correlation is significant at the 0.01 level (2-tailed)

*Correlation is significant at the 0.05 level (2-tailed)
Table 14 - Patient responses relating to experience of pharmacist prescribing in the sexual health clinic (n = 14)

<table>
<thead>
<tr>
<th></th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Uncertain</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
<th>Median Score (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I trusted the pharmacist's ability to prescribe.</td>
<td>12</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5 (4-5)</td>
</tr>
<tr>
<td></td>
<td>(86%)</td>
<td>(14)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I was satisfied by the consultation(s) provided by the</td>
<td>11</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5 (4-5)</td>
</tr>
<tr>
<td>pharmacist prescriber.</td>
<td>(79%)</td>
<td>(21)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I think the care provided by the prescribing pharmacist was as</td>
<td>10</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5 (4-5)</td>
</tr>
<tr>
<td>good as my usual care.</td>
<td>(71%)</td>
<td>(29)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I think the pharmacist prescriber improved the health care I</td>
<td>5</td>
<td>6</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>4 (3-5)</td>
</tr>
<tr>
<td>received.</td>
<td>(36%)</td>
<td>(43)</td>
<td>(21)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Changes to my treatment plan were explained to my satisfaction.</td>
<td>9</td>
<td>2</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>5 (3-5)</td>
</tr>
<tr>
<td></td>
<td>(64%)</td>
<td>(14)</td>
<td>(21)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Changes to my medication were explained to my satisfaction</td>
<td>8</td>
<td>2</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>5 (3-5)</td>
</tr>
<tr>
<td></td>
<td>(57%)</td>
<td>(14)</td>
<td>(29)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I had enough time with the pharmacist prescriber for discussing</td>
<td>13</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5 (4-5)</td>
</tr>
<tr>
<td>medication related issues.</td>
<td>(93%)</td>
<td>(7)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I am more interested in the quality of care than the profession</td>
<td>8</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>3</td>
<td>5 (1-5)</td>
</tr>
<tr>
<td>of the person who provides it.</td>
<td>(57%)</td>
<td>(7)</td>
<td>(14)</td>
<td></td>
<td>(21)</td>
<td></td>
</tr>
<tr>
<td>I would recommend seeing a pharmacist prescriber to other</td>
<td>11</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5 (4-5)</td>
</tr>
<tr>
<td>people.</td>
<td>(79%)</td>
<td>(21)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I would consider seeing a pharmacist prescriber for ongoing</td>
<td>9</td>
<td>4</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>5 (3-5)</td>
</tr>
<tr>
<td>management, under an agreed care plan, of my condition and</td>
<td>(64%)</td>
<td>(29)</td>
<td>(7)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>medication.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
6.2.5 Discussion

In line with previous research on patient perspectives of non-medical prescribing, patients in PAC and the sexual health clinic were highly satisfied with the consultations, and patients in the sexual health clinic positive about their experiences in the model of care.[168, 247, 263]

A recent review suggested consultations with patients need to be treated as partnerships, and patients must be given the confidence, skills and knowledge to be partners.[264] A questionnaire for assessing satisfaction with General Practitioner (GP) consults was developed in 1990, with the appreciation that patient satisfaction is an important outcome of care, and in light of previous research which showed satisfied patients are more likely to cooperate with treatment.[265, 266]

United Kingdom (UK) guidelines have since highlighted key consultation characteristics that support adherence to medication, including rapport, being given relevant information about medicines, being understood by the prescriber and being involved in decisions about their medicines, and a previous literature review reported that most of the studies reviewed demonstrated correlation between effective physician-patient communication and improved patient health outcomes.[267, 268] Giving patients the opportunity to feed back on the health care they receive is an important part of any healthcare program, and if used effectively, can drive improvements in healthcare delivery.[269, 270]

The two models of care in our studies differ significantly, with PAC being an acute, single meeting between patient and prescriber, and the sexual health clinic being a chronic model of care, with repeat appointments. Desired outcomes for the models of care are different, with the main goal in PAC ensuring the patient’s medication is optimised prior to surgery, and that the patient understands and follows a clear plan for their medications perioperatively. Not following the plan for medications, especially with regards to anticoagulants, for example, increase the likelihood of surgery cancellation, and patient morbidity and mortality.[271, 272] The positive responses in PAC with regards to the pharmacist explaining their role, listening, providing effective information, effectively answering any questions and understanding of concerns are suggestive of the pharmacist managing to build a good rapport within a relatively short space of time. Most patients agreed the pharmacist explained instructions clearly, and also checked their level of understanding. From previous research, these are all key components in forming an effective partnership with a patient, and maximising the chance of cooperation and adherence with treatment plans.[264-267]

From the Spearman’s correlation, it was also shown that these elements of the questionnaire were the most strongly correlated to both the overall feeling of consultation satisfaction, and the feeling of being prepared for surgery.
In models of care such as the sexual health clinic a patient centred approach, which empowers individuals to manage their health and health care, contributes to the goals of treatment; to reduce hospital admissions and improve quality of life for people with chronic disease.[273] Patients in the sexual health clinic were highly satisfied with the consultation, with the consistently high positive feedback across all questions again suggestive that an effective partnership was built between prescriber and patient. Patients felt like they were understood, given effective information and involved in treatment decisions, all keys to patient empowerment and indicators for adherence and positive health outcomes.[267, 268] There were some reservations in PAC with regards to the trust in the pharmacist to take on the extended role over the usual model of care, which again was in line with UK research in 2006 which explored patient perspectives, as part of a study of pharmacist prescribers in both primary and secondary care.[274] The results showed positive consultation experiences, and positive attitudes towards pharmacist prescribing. However, 65% of patients reported they would rather see a doctor. There question in PAC which divided opinion, and had the highest percentage of ‘unsure’ respondents; whether the patients would like a doctor to double check the plan for medications. This would suggest that patients are not altogether comfortable to relinquish contact with a medical officer within clinic, when it comes to the medication related aspect of their appointment, which is also in line with the Australian survey of pharmacy clients’ attitudes to pharmacist prescribing.[260] The advantage of the collaborative prescribing model of care proposed within this study is that having to choose between health care professionals is not a requirement, and it facilitates the already established relations between doctors and patients by ensuring lines of referral between pharmacist and doctor are readily available. A recent study from a UK study ascertained views from patients on the impact of prescribing by nurse and pharmacist prescribers, including satisfaction with the consultation and the impact on choice, access, quality of care, knowledge, adherence and control of their condition.[275] The results showed a high satisfaction with their last consultation, and a good relationship with, and high confidence in, their non-medical prescriber. When comparing non-medical prescribing and doctor prescribing, most patients reported no difference in their experience of care provided. The difference between the results in this study with regards to willingness to engage with non-medical prescribers in previous UK studies may be explained by a maturation of attitudes within the general public, as non-medical prescribing becomes an accepted model of care with time. Consistent with other research, patients in the sexual health clinic were also highly satisfied with the concept of pharmacist prescribing, having experienced it over multiple appointments.[168] The trust that patients had in the pharmacist’s abilities to prescribe was high, patients were willing to engage with the pharmacist prescriber on an ongoing basis, and all patients thought that care was as
good as usual care, with some believing the standard of care was better. Almost two thirds of patients were more interested in the quality of care provided, than the profession of the person who provided it. From the results, the authors would suggest an effective patient centred model of care was achieved, maximising the chances of positive health outcomes.[273] The difference between the two models in terms of willingness to engage with a pharmacist over medical staff may well be a reflection of the chronic nature of the sexual health clinic model, in that the pharmacist was able to build a relationship with the patients through several appointments, when compared to the acute model of a single appointment in PAC. The collaborative model of care that seems so important to patients in the early stages of pharmacist prescribing implementation may have been more obvious to patients in the sexual health clinic than those in the PAC.[260, 274] The results from our studies bode well for any future introduction of pharmacist prescribing in to the Australian health care system, and suggest initially that models of care which are more obviously collaborative would be most acceptable to patients.

Limitations include small numbers of patients in the sexual health clinic, with 14 respondents to the overall satisfaction questionnaire, however the authors suggest the emphatic nature of the results overcome this. In PAC, it was difficult to ascertain views on the pharmacist prescribing model of care in the same way as in the sexual health clinic, due to the acute nature and also because, from the patient’s perspective, the appointment differed in no way from usual care. Generalisability of the results from this study to pharmacist prescribing in general may be limited. This is partly due to the questionnaires containing normative questions, which tend to define how things should be according to the researchers. Questions of this nature may not always provide a totally unbiased picture of patient views.[182]

Recognising these limitations of the study is important, however the trustworthiness of findings is supported by the use of an evaluation framework which means evidence can be added to that from other studies, to strengthen the overall evidence base. The findings of our study are consistent with previous studies undertaken in Australia and UK.[260, 274] There is also a strong consistency in the results between our two studies, and strong internal consistency in the results of the sexual health clinic study. This study is also in keeping with findings from other studies where patient perception of service quality has a positive relationship with satisfaction and behavioural intent.[257] In both models, there are consistent responses between ratings of satisfaction and behavioural intent (preparedness for surgery in PAC and recommending the pharmacist prescriber to other in the sexual health clinic).

Our studies trialled a single pharmacist prescriber in a designated scope of practice. Communication and consultation skills are a key component of the UK pharmacist prescribing course, as directed by the General Pharmaceutical Council guide on learning outcomes and indicative content.[262]
Prescribing competencies have recently been produced in Australia, to guide and direct learning outcomes for prescribers, and to be used in the development, or revision, of prescribing curricula.[276] The results of our study show that effective listening and communication, empathy, effective information provision and empowerment of the patient in their treatment would seem to be the most important behaviours which are responsible for patient satisfaction, and the associated benefits. The challenge lies in ensuring training and education requirements for any future collaborative prescribing course are appropriate, and courses consistently and reliably produce competent and fit for purpose prescribers, who can replicate these results and outcomes on an ongoing basis.

6.2.6 Conclusion

Most patients were highly satisfied with the consultations with pharmacists in both studies, with positive attitudes on the model of care from patients in the sexual health clinic. The results suggest that patient satisfaction and willingness to engage will not be barriers to the implementation of collaborative doctor pharmacist prescribing models in Australia.

6.3 Next Steps

Previous chapters have described an analysis, via use of the NHPF, of how the collaborative prescribing model of care was at least as good as usual care with regards to effectiveness, safety, responsiveness, continuity of care and access to medications.

As the review by Bhanbhro has highlighted, in 2011, there have been few assessments of the cost effectiveness of this new model of care.[8] The last domain of the NHPF which required evaluation was ‘efficiency and sustainability’. Efficiency is defined as ‘achieving the desired results with the most cost effective use of resources.’

Sustainability is defined the ‘capacity of the system to sustain workforce and infrastructure, to innovate and respond to emerging needs’. Efficiency and sustainability were not rigorously assessed as part of this thesis, but is discussed in Chapter 7 under ‘Future Research’
7 Chapter 7 – Overall Discussion and Conclusion

7.1 Chapter Introduction

This final chapter discusses the overall findings of the previous chapters, and describes how the body of work in this thesis has added to pre-existing knowledge. It also describes the limitations of the work, and recommends future directions for research in the area.

The thesis set out to investigate the outcomes of a collaborative doctor-pharmacist prescribing model in an elective surgical PAC, using the validated national health performance framework utilised by Australian Institute of Health and Welfare, to assess how health services are performing at a national level.[248] The framework can also be used as a guide when developing performance indicators for a particular program, and was used as such in the design of our pilot. The framework consists of six domains; effectiveness, safety, responsiveness, continuity of care, accessibility and efficiency and sustainability (Figure 3)

Chapter 1 of this thesis provides an insight into the current evidence base on non-medical prescribing, and in particular pharmacist prescribing. The recurrent themes throughout the literature, and indeed the literature reviews, are a lack of robust evidence and substantial gaps in the knowledge base.[7, 8] Our study has addressed some of these gaps by providing robust evidence, from a randomised controlled trial, on the safety, effectiveness, appropriateness and responsiveness of a collaborative doctor – pharmacist prescribing model of care.

Data collection and evaluation was designed to show our pilot was as good as usual care, as per the hypothesis, across as many domains as possible within this scope of practice. The advantage of using an objective framework in the evaluation of non-medical prescribing, both pre- and post-implementation, is that different models of care can utilise the framework in the same manner, and tailor evaluation to relevant domains of the framework, as described in Chapter 2. The aim is to provide an understanding of the scope of this proposed new model of care and how it might best align, and work with current healthcare services to provide improved access to safe and appropriate medication usage, and more efficient usage of the time and skills of the current multidisciplinary team.

7.2 Discussion

7.2.1 Safety and Accuracy of Medication Charts

Under usual care, the scope of practice of the PAC pharmacist is the eliciting of a complete and accurate medication history, and assistance in the formulation of a plan for medications perioperatively, namely which medications to continue, withhold and stop prior to surgery. Although
predominantly driven by guidelines, there is the need for individual clinical assessment and decision making outside of guidelines. Surgical RMOs are readily available for consult in clinic for confirmation of any plan, with this availability being one reason why PAC lends itself well to a collaborative prescribing model of care.

Under usual care, the pharmacist provides the information from the medication history to the relevant RMO for confirmation of a plan as necessary, and to prescribe the inpatient medication chart, in preparation for the patient's admission to hospital. The advantage of the pharmacist seeing the patient prior to the RMO was shown during a small pre study audit, which showed that out of 19 patients only four saw the RMO first. Out of those four, only one (25%) had a medication chart prescribed, compared to 11 out of 15 (73%) who saw the pharmacist first. The same audit showed a number of issues with the prescribing of medication charts in clinic, namely prescribing omissions and errors.[200]

The advanced scope of practice evaluated in our study was the production of the inpatient medication chart by the prescribing pharmacist in clinic, with our hypothesis being that the pharmacist would be as good as usual care, with regards to medication chart accuracy and safety. Results showed significantly less unintended omissions of medications: 11 of 887 (1.2%) intervention orders compared with 383 of 1217 (31.5%) control (p<0.001). There were significantly less prescribing errors involving selection of drug, dose or frequency: 2 in 857 (0.2%) intervention orders compared with 51 in 807 (6.3%) control (p<0.001).

Orders with at least one component of the prescription missing, incorrect or unclear occurred in 208 of 904 (23%) intervention orders and 445 of 1034 (43%) controls (p<0.001).

Our results have shown an improvement in the safety and accuracy of medication chart prescribing, and is the first study to do so in the PAC setting.[231] The evidence from our study has enabled progression of the pharmacist prescribing agenda in Australia, looking to drive legislation and policy change from dissemination of the results to relevant stakeholders, to enable pharmacists to undertake a prescribing role. The proposed benefits to patients and the healthcare system of such an initiative are evident in the results from this study.

7.2.2 Appropriateness of Prescribing

The large difference in the number of omissions of medication from the NIMC between control arm and intervention arm (31% vs 1.2%) prompted further investigation as to the appropriateness of commissions and omissions. Whilst this was not a pre-determined sub study, an ‘expert panel’ methodology was devised from a similar study in the literature assessing the appropriateness of
nurse prescribing [139]. Individual panel members were asked to rate a selection of commissions and omissions from a randomly selected 5% sample of the total cohort of patient, using an amended and validated version of the Medication Appropriateness Index (MAI).

Results showed the appropriateness of prescribing in both arms was the same. From the 5% sample there were significantly more omissions of medication from the NIMC in the control, and each panel member was requested to rate each omission as whether it had potential for patient harm, ward inconvenience, both or neither. Out of 89 regular medications in the control arm, 25 (28%) were omitted from the medication charts, compared to 1 out of 55 (2%) in the intervention arm (p<0.001, fishers exact)

When reviewer assessments were combined, 32 out of 294 (10.9%) medications assessed for appropriateness in the control arm were classed as inappropriate, compared to 13 of 266 (4.9%) in the intervention arm.

On average, 52% of omissions in the control arm were judged to have potential for patient harm or ward inconvenience.

Whilst the sub study lacked statistical power, it provided a useful ‘snap shot’ of the prescribing, to show that the appropriateness of prescribing by the pharmacist assessed in the study was the same as usual care, and is described in Chapter 4.

Few studies have assessed the appropriateness of non-medical prescribing, and the results from this part of the study are the first time that the appropriateness of a pharmacist’s prescribing has been evaluated. Whilst Chapter 3 assessed the medication chart as safe and accurate, according to the patient’s medication history, there was no evaluation of whether inclusion of medications on the medication chart were appropriate, or how much of an impact any omission from the medication chart may have had. The results from this part of the study show that the clinical decision making by the pharmacist with regards to what to continue, withhold and omit from the NIMC, was appropriate.[277]

7.2.3 Appropriateness of Venous Thromboembolism (VTE) Prophylaxis

Whilst prescribing of patients’ regular medications for an inpatient stay is essential, it was also important as part of our study to evaluate the initiation of a new medication. Surgery is a known risk factor for VTE and a routine part of any admission should be assessment of individual patient VTE risk and prescribing of VTE prophylaxis, as per guideline.[213] VTE prophylaxis lends itself well to a collaborative prescribing model, due to the availability of national and local guidelines,
which clearly defined criteria for assessment of patient risk and contraindications, and definitive treatment paths for low and high risk patients.

It was agreed by hospital executive and the Designated Medical Practitioner that the pharmacist’s prescribing scope could include VTE prophylaxis, following a documented risk and contraindication assessment. With patients that fall outside of guidelines, there is access for the pharmacist to surgical RMOs for confirmation of VTE prophylaxis requirements. This is another reason why this is a good example of a scope of practice suitable for a collaborative prescribing model. The hypothesis was that the pharmacist would be as appropriate as usual care. Results showed that VTE risk assessment was documented in significantly more patients in the intervention arm, 153/160 (96%), compared to 1/147 (1%) in the control arm (p=<0.0001), and when undertaken was correct 94% of the time.

VTE prophylaxis was appropriately prescribed in clinic in 150/160 (94%) intervention patients, and 94/147 (64%) control (p<0.0001)

The documentation of risk assessment, and prescribing of VTE prophylaxis by the pharmacist in clinic, was significantly more appropriate.

Chapter 5 describes the results of the prescribing of VTE prophylaxis, and is the first time pharmacist prescribing of VTE prophylaxis has been evaluated.[278] This outcome has significant potential for improving patient outcomes peri operatively, both in terms of patient morbidity and mortality, and reducing the high healthcare costs associated with hospital associated thromboembolus.[238]

Importantly, results can also be translated in to other models of care, where initiation and management of medications are guideline driven. Our results show that an appropriately trained pharmacist can initiate a medication, via guidelines, safely and appropriately. In the context of many chronic diseases, for example asthma, which are managed by treatment guidelines, this presents an opportunity for future research on the evaluation of chronic disease management by pharmacist prescribers within a collaborative model of care. Our study would suggest translation in to other models of care and scopes of practice would be feasible.

7.2.4 Assessment of Unplanned 30 Day Readmissions

Unplanned hospital readmission within 30 days of discharge is an undesirable outcome, and can be used as an indicator to gauge quality of hospital care.[279] Pharmacists in PAC have been shown to improve the accuracy of medication histories and medication orders, when compared with standard care.[210] The pharmacy medication liaison
service (MLS) in the preadmission clinic (PAC) at Princess Alexandra Hospital (PAH) was introduced and evaluated in 1998, with a view to increasing the accuracy of information exchange as patients crossed healthcare settings, via medication reconciliation at pre admission and at discharge, and increased communication with community healthcare providers.[208] The study followed up post discharge outcomes, with the MLS associated with an almost significant 20% reduction in unplanned 30 day readmissions to hospital.[199] The MLS patients also experienced significantly fewer unplanned healthcare professional visits per subject in the 30 days post discharge. Omission of one medication on discharge was shown to have a 2.3 times increased risk of 30 day readmission.

Similar to the MLS, our study expanded the role of the PAC pharmacist for intervention patients, but at the admission stage of the patient journey only. Part of our study assessed 30 day post discharge outcomes for patients. Patients were contacted 30 days post discharge by telephone, and asked whether they had experienced 30 day unplanned readmissions to hospital, presentations to the Emergency Department (ED) and any unscheduled contact with General Practitioners (GP). From the control arm, 164/190 (86%) patients were able to be contacted, with 170/194 (88%) from the intervention arm.

Results showed no significant difference in rates of 30 day GP visits, ED visits or unplanned readmissions

**Table 15 - Unscheduled 30 Day Post Discharge Readmissions, GP and ED Contact**

<table>
<thead>
<tr>
<th></th>
<th>Control N=164 (%)</th>
<th>Intervention N=170 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unscheduled visit to GP</td>
<td>35 (21%)</td>
<td>38 (22%)</td>
</tr>
<tr>
<td>ED visit</td>
<td>16 (10%)</td>
<td>19 (11%)</td>
</tr>
<tr>
<td>Unplanned readmission</td>
<td>10 (6%)</td>
<td>7 (4%)</td>
</tr>
</tbody>
</table>

Despite significant differences in omissions and prescribing errors on the medication charts produced at the end of PAC, this may not be an unexpected outcome. Results from Chapter 4, and the expert panel assessment of omissions, showed that an average of 52% of omissions were judged to have potential for patient harm or ward inconvenience. These were omissions that required remedial action whilst the patient was in hospital, otherwise the accuracy of information exchange across settings would be compromised, resulting in increased chance for the associated bad outcomes for patients, including unplanned 30 day readmission.
Patients in both arms have a pharmacist medication history from PAC, and would still be subject to all the usual interventions in hospital and on discharge of multidisciplinary pharmaceutical review. It may be expected that the safety barriers in place within the current system would fix any significant errors and omissions from admission, resulting in an accurate record on discharge in both arms (see Figure 10). The advantage in the pharmacist prescribing model of care is the assumed efficiency gains in ensuring that the medication history and medication chart, which is then used as the primary source of information on discharge, are complete and correct on admission. Although this wasn’t assessed as part of our study, there would be less of a requirement to correct any of the clinically significant omissions and prescribing errors, freeing up pharmacist and doctor time whilst the patient was in hospital and on discharge.

**Figure 10 - Current Model of Pharmaceutical Care Impacting on Safety at Discharge**
7.2.5 Patient Satisfaction

High percentages of patients, from the 182 that responded via a questionnaire at the end of their clinic appointment, were satisfied with the consultation provided by the pharmacist in clinic, and thought that the information the pharmacist had given them helped prepare them for their surgery. Previous literature has suggested that satisfied patients, and patients who feel involved in treatment options, are more likely to comply with treatment plans.[266] With regards to medication management peri-operatively, this is important to avoid surgery cancellations, and to reduce chances of patient morbidity and mortality.

Results suggest that the attitudes and experiences of patients who experienced the pharmacist prescribing model of care would not be a barrier to the implementation of pharmacist prescribing in Australia. These are encouraging results, especially given that the patients in PAC did not know the pharmacist, and there was little time to build a rapport between pharmacist and patient. Many proposed scopes of practice and models of care where pharmacist prescribing may benefit patients, for example chronic disease management, would present more of an opportunity for the pharmacist to build a relationship with the patient through repeat appointments and longer term management.

7.3 Overall Results

By relating our results to the model of prescribing suggested by Coombes et al (see Figure 2), the first three quadrants of the model have been assessed during our study, and found to be as effective as usual care.

7.3.1 Information Gathering

Previous studies have shown that pharmacists in PAC take more accurate medication histories, to be able to inform peri-operative clinical decisions.[210] As such, our study did not assess the accuracy of histories taken in clinic, but the accuracy of transfer of information gathered across the healthcare transition from pre admission to admission.

With regards to VTE risk and contraindication assessments and prescribing, the information gathered by the pharmacist to enable VTE prophylaxis to be prescribed, was shown to be documented more appropriately.

7.3.2 Clinical Decision Making

Appropriate clinical decisions, regarding which medications to continue, withhold, stop and initiate have been made by the pharmacist and doctors in this collaborative model of care. With regards to
VTE prophylaxis prescribing, clinical decisions on mechanical and anticoagulant prophylaxis made by the pharmacist in clinic were more appropriate than usual care.

7.3.3 Communication

The information regarding regular medications, and plan for medication peri operatively, was more safely and effectively communicated by the pharmacist in PAC than the RMOs in the control arm. This was reflected in more accurate and safer medication charts, for administration of medications to inpatients during their hospital admission.

7.3.4 NHPF Framework

As per the hypothesis, our evaluation has shown a doctor pharmacist collaborative prescribing model to be at least as good as usual care in effectiveness, safety, continuity of care and accessibility. Whilst responsiveness wasn’t compared against the control arm, patient feedback showed the service was client orientated and met patients’ needs.

7.4 Limitations

The main limitation of the overall study is that the results of the thesis report on the prescribing of one pharmacist, in one hospital, working in one specific scope of practice. Whilst this is true, prescribing involves a core set of competencies which, following appropriate training and education, should be able to be applied to other models, practice settings and scopes of practice.[276]

7.5 Future Research Directions

7.5.1 Training and Credentialing of the Pharmacist

The Health Practitioners Prescribing Pathway Project, run by Health Workforce Australia is seeking to deliver a national approach to prescribing by health professionals, other than doctors.[259] The first stage of the project was approved by the Standing Council on 8 November 2013, and HWA will now commence work on implementation.

One of the first challenges for education providers is to define what baseline experience and qualifications are required by a pharmacist prior to undertaking a postgraduate prescribing course. The Advanced Pharmacy Practice Framework Steering Committee (APPFSC) is undertaking work to develop an advanced pharmacy practice recognition model.

Advanced level practice in pharmacy within a certain speciality entails knowledge, skills and attitudes in a particular scope, gained through a combination of work experience and clinical
postgraduate clinical qualifications. However, there is no mandatory approach as to levels of clinical experience, post graduate qualifications and accreditation a pharmacist must undertake before they can be recognised as an ‘advanced level practitioner’. This body of work is essential to the progression of advanced scopes of practice, such as prescribing, to objectively define who is appropriate to be able to undertake a prescribing course.

The prescribing course should not be responsible for clinical knowledge, but more focused on the skills required to be able to prescribe safely, effectively and appropriately within a collaborative model of care. The UK and NZ have produced definitive curricula, which may act as a guide for Australia for any future prescribing courses.[262] As well as the academic content, both courses incorporate a prescribing practicum element in to the training, which is under the guidance of a supporting senior medic, or designated medical practitioner (DMP). Only with completion to satisfaction of the academic content, the required hours of practicum, and following sign off on prescribing competencies by the DMP, can the pharmacist be registered to be a prescriber.

The challenge is to ensure that education providers tailor courses to satisfy prescribing competencies, and reliably produce competent and fit-for-purpose prescribers.[276] The prescribing competencies should align and complement other clinical knowledge and competencies gained as an advanced level clinician, to allow for safe and appropriate prescribing.

Future research should also focus on translation of these skills and competencies in to different models of care, practice settings and clinical specialities, and continued evaluation of pharmacist prescribing post implementation to show the benefits to patients, and the healthcare system alike.

7.5.2 Cost Effectiveness of Collaborative Prescribing

As highlighted by a previous review, evidence for the cost effectiveness of non-medical prescribing is lacking.[8] Future analysis to be undertaken includes the cost effectiveness modelling of this new model of care. The improvements shown in the intervention arm, in both the primary and secondary endpoints in the study, would suggest there are financial benefits to be gained from implementing pharmacist prescribing in the PAC setting. With regards to significantly more accurate and safer medication charts, the reduction in medication errors and the associated patient harm would reduce costs to the healthcare system. VTE prescribing was also more appropriate in the intervention arm. The reduction in cost to the healthcare system and the reduction in patient harm that would prevail from the associated reduction in peri operative emboli with appropriate prophylaxis, merits further investigation.
7.5.3 Factors for Success

Barriers and facilitators to running the pilot of pharmacist prescribing have informed the wider agenda, and given an idea of what pharmacist prescribing should look like to maximise the chances of success in implementation.[280]

Medical resistance was overcome partly by a clear scope of practice for the prescribing, that was acceptable to the relevant senior medics and clear proposed outcomes, focusing on the ability to assist doctors make more efficient use of their time.

A senior, advanced level pharmacist who had undergone accredited education and training to prescribe was essential to gain the support from a senior medical officer to act as a DMP.

Initially, as shown by the patient satisfaction results, it is vital that the scope of practice be obviously collaborative with medical staff. It would appear that a maturation of attitudes from the general public may be required with regards to the acceptability of pharmacist prescribing, as shown in UK with time.

7.6 Conclusion

The results of our pilot show that pharmacist prescribing within an elective surgery PAC is a feasible concept.

The study has demonstrated increased safety and accuracy of medication chart prescribing and increased appropriateness of VTE prophylaxis prescribing.

It has been demonstrated that a pharmacist who undertakes appropriate training, education and assessment has the skills to be able to competently prescribe within a clearly defined scope of practice of collaborative prescribing.

The findings of this project will help in forming the basis of a new model of care for Australian pharmacy practice, which will be of benefit to patients, the healthcare system and the profession alike.
8 References


53. Council Of Optometry Registration Authorites Inc (CORA), *Council of Optometry Registration Authorities (CORA) response to the Consultation Paper on Issues Supplementary to the Intergovernmental Agreement on a National Registration and Accreditation Scheme for the health professions to be included in the first bill*. 2008: Warragul. p. 3


60. Nursing and Midwifery Board of Australia, *Guidelines for Education Requirements for Recognition as Eligible Midwives and Accreditation Standards for programs of study leading to endorsement for scheduled medicines for Eligible Midwives*. 2011.


63. *Nurses are 'floundering' in their new prescribing role*. Pulse, 2007. 67(12): p. 3-3.

64. *I'm petitioning Downing Street on nurse prescribing*, in *Pulse*. 2007, United Business Media. p. 22-22.


75. **RCGP voices concerns over plans to extend controlled drug prescribing.** Pulse, 2007. 67(37): p. 11-11.


216. Australian Commission on Safety and Quality in Health Care, *National terminology, abbreviations and symbols to be used in the prescribing and administering of medicines in Australian hospitals*. 2006.


9 Appendices

9.1 Appendix A – Letter to the Editor, Australian Health Review

Evaluation of non-medical prescribing

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The supply and access to safe, effective and efficient use of medicines is guided by the National Medicines Policy and the Policy for the Quality Use of Medicines. Evidence suggests that health services in Australia may not be currently meeting these requirements1,2,3.

The access to health services, and medicines, has resulted in changes to the PHS and health service provision, such as the Rural and Remote Section 100 program.

The National Health and Hospitals Reform Commission and the establishment of the National Health Workforce Taskforce have recognised the need to reform the way health care services in Australia are delivered.

In an effort to improve access to medicines in the UK, Canada, USA and New Zealand non-medical prescribing has been introduced. However, resistance to such change exists in Australia.

There have also been understandable calls for evidence to prove the effectiveness of non-medical prescribing services.4 This evidence must be provided in a robust, credible and consistent manner in order to address some of this resistance to change, and a uniform framework for the evaluation of non-prescribing is required.

In 2008, the Australian Institute of Health and Welfare prepared a set of performance indicators across the healthcare system.5 To ensure the quality and safety of non-prescribing, it is proposed that the dimensions within this framework (better health, focus on prevention, access, appropriateness, safety, continuity, responsiveness, efficiency and sustainability), could be applied to future research.

Although the framework would not provide definitive outcome measures, it would provide guidance on the domains that should be considered when assessing the quality of healthcare service delivery. It may be possible to measure ‘safety’ in several different ways, depending on the model of non-medical prescribing. For example, ‘safety’ in one model may mean an assessment of the numbers of prescribing errors, whereas in a different model of care may be assessment of the numbers of adverse drug reactions.

It may also not be possible, or indeed necessary, for each pilot to cover every domain within the framework, for example some pilots may be designed to solve an ‘access’ problem, whereas others may be more suited towards solving a ‘safety’ issue. Outcomes from pilots could be compared and combined to provide an evidence base, which may see as essential to the successful implementation of this new Australian initiative.

References

4 Feed P. Medication prescribing – not a task for non-medical health practitioners. JPIPR 2008; 38: 256.

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Pharmacist prescribing – making steps towards the future

To the Editor,

Non-medical prescribing is a hot topic in Australia at the moment. Optometrists have been granted access to the Australian Pharmaceutical Benefits Scheme; the first nurse practitioners in Queensland have been authorised to prescribe; and several pilot studies of physician assistants are running across the country.5

Prescribing, as part of an advanced scope of practice, is a role for which the pharmacy profession considers itself well placed. Pharmacist prescribing has been investigated in a recent article in the *Journal of Pharmacy Practice and Research*, for which the authors collated the views of the members of the Society of Hospital Pharmacists of Australia. Pharmacist prescribing has also been explored in a large study funded through the Third Community Pharmacy Agreement in 2005.5

There is a dearth of Australian evidence on pharmacist prescribing. Therefore, the initial emphasis for implementing pharmacist prescribing must be on the production of evidence to support this new role, and the development of robust, credible methods to produce competent and fit-for-purpose clinicians.

In August 2008, an informal teleconference was instigated between practitioners across Australia and New Zealand who were undertaking work on the advanced scope of practice of pharmacy practitioners. Prescribing is a major component of that scope. The teleconference served as a useful forum for discussions and a valuable method of sharing ideas, projects and progress. Based on the collaboration developed over subsequent teleconferences, the group agreed that a face-to-face workshop was needed to explore issues further.

An open invitation was sent to teleconference participants to attend a two-day workshop at The University of Queensland in January 2009. Thirty people with interests in academia, clinical pharmacy and pharmacy regulation from Queensland, Victoria, New South Wales, South Australia and New Zealand attended the workshop. A teleconference participant from Western Australia was unable to attend the workshop.

The workshop focused on the various pharmacist prescribing models, pilot studies, practitioner competencies and training. Participants heard presentations from people running pilot studies in New South Wales, Victoria and Queensland addressing the facilitators and barriers for pilots.

It became evident that the pilot studies were using different models, methods and evaluation frameworks. As a result, the attendees agreed that the development of a consistent ‘evaluation framework’ was a priority. The evaluation framework would set the agenda for future research on pharmacist prescribing, allowing the alignment of research outcomes and enable multiple small trials to be combined into a powerful evidence base. Without professional unity and such an evidence base, wide adoption of pharmacist prescribing models would be faced with ongoing scepticism.

There is a clear need to continue a forum for professional interaction and consensus. In the absence of formal mechanisms, it was proposed that this initial national and trans-Tasman collaboration continue. The collaboration will continue to provide an opportunity...
for an aligned approach to introducing pharmacist prescribing and overseeing pharmacy issues and barriers.

For the pharmacy profession to adopt such an advanced scope of practice (seen by many as essential
to the profession), a more formal progression of the
agenda will be required. The profession will need to speak
with one voice, yet address many different models of
care. The call for such professional unity from the
workshop was strongly supported.

The authors would like to acknowledge the voice
and dedication of all the participants of the in-person
workshops.

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References
5. Bowes DM, Mackay RJ, Isleley ADJ, Terhorst L. Australian medical review: improving Australian access to

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Pharmacist prescribers

Non-medical prescribing is currently a hot topic in New Zealand and Australia. In New Zealand midwives and optometrists have been authorised to prescribe within their professional practice and most recently nurse practitioners were granted authorisation to prescribe specified medicines within their scope of practice. The Ministry of Health is also consulting on designated prescribing authority for podiatrists. In Australia optometrists can prescribe specific medicines; the first Queensland nurse practitioners have been authorised to prescribe; and several pilot studies of physicians’ assistants are underway.
Prescribing is a role for which the pharmacy profession is preparing itself, as part of an advanced scope of practice. Designated prescribing authority for pharmacists was proposed by the Pharmacy Council of New Zealand (PCNZ) in 2007. Stakeholder feedback to this regulatory framework for advanced practitioners was positive; however collaborative practice was identified as the preferred model. Pharmacists participating as prescribers within a multidisciplinary health care team. Other research exploring feedback on the Ten-year vision for pharmacists in New Zealand: 2004–2014 also found that pharmacists were positive in their agreement about undertaking enhanced clinical and collaborative roles alongside the more traditional roles. However, significant barriers to a future role extension by pharmacists included a perceived lack of leadership and a unified pharmacy voice.

With little Australian evidence, the initial emphasis for implementing pharmacists prescribing must be on the accrual of evidence to support this new role, and the development of robust, credible methods to produce competent and fit-for-purpose practitioners.

In August 2008, an informal teleconference was initiated between individual pharmacist practitioners across Australia and New Zealand currently working on the advanced scopes of practice. Prescribing is a major component of that scope. The teleconference served as a useful forum for interaction, sharing ideas, projects and progress. Based on the collaboration developed over subsequent teleconferences, the group agreed that a face-to-face workshop was needed to explore issues further.

A two-day workshop at the University of Queensland was held in January 2009. Thirty people attended with interests in academia, clinical pharmacy and regulation from New Zealand and Australia. The workshop focused on pharmacist prescribing models, pilot studies, practitioner competencies and training. It became evident from presentations that pharmacist prescribing pilot studies were using different models, methodologies and evaluation frameworks. As a result, the attendees agreed that a consistent ‘evaluation framework’ was needed. The framework could act as a guide for future pharmacist prescribing research and enable the alignment of research outcomes and for small studies to be combined as a more substantive evidence base. Without professional unity and such an evidence base, widespread adoption of pharmacist prescribing models would be faced with ongoing scepticism.

Participants felt there was a need to continue a forum for professional interaction and consensus. In the absence of more formal mechanisms, it was proposed that the trans-Tasman collaboration continue, providing an opportunity for an aligned approach to introducing pharmacist prescribing and overcoming the many issues and barriers. For example, a lack of information on the potential role of advanced pharmacists in mental health was identified and New Zealand participants proposed to explore this further over the coming year to inform the local evidence base. The collaboration can also provide informal support and feedback as the PCNZ prepares to lodge an application with the Ministry of Health for a new scope of practice (the Pharmacist Prescriber) in the later part of 2010.

For the pharmacy profession to adopt such an advanced scope of practice, the profession will need to speak with one voice, yet address many different models of care. The call for professional unity from the workshop was strongly supported.

We would like to acknowledge the vision and dedication of all teleconference and workshop participants. The New Zealand participants also acknowledge support from The University of Auckland and the Mental Health Pharmacy Special Interest Group to attend the workshop in Australia.

Dr Amanda Wheeler, Mr Andrew Hale, Miss Marie Jensen, Dr Ian Goobies, Dr Julie Stoles, Dr Danielle Szwarcz, Dr Lisa Nissen

References
An evaluation framework for non-medical prescribing research

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Abstract. Without robust and credible evidence for the benefits in health outcomes of non-medical prescribing, widespread implementation will be challenging. Our aim is to develop a consistent evaluation framework that could be applied to non-medical prescribing research. An informal collaboration was initiated in 2008 by a group of pharmacists from Australia and New Zealand to assist in information sharing, pilot design, methodologies and evaluation for pharmacist prescribing. Different pilots used different models, methodologies and evaluation. It was agreed that the development of a consistent evaluation framework to be applied to future research on non-medical prescribing was required. The framework would help to align, the outcomes of different research pilots and enable the comparison of endpoints to determine the effectiveness of a non-medical prescribing intervention.

This article presents the results of a workshop held at The University of Queensland in January 2009. Participants were asked to consider how to evaluate the effectiveness of different models of pharmacist prescribing.

What is known about the topic? Little is known about the effectiveness and safety of non-medical prescribing services due to a lack of robust evidence.

What does this paper add? This paper adds a methodology for clinicians and healthcare managers to be able to evaluate any new service of non-medical prescribing, either in the pilot phase or once introduced as a new model of care.

What are the implications for practitioners? The implication for practitioners is the ability to prove to healthcare providers that non-medical prescribing services are at least as effective as usual care, so informing whether a change should be introduced in the way healthcare is delivered to patients.

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Introduction
Healthcare workforce shortage is a well-documented global phenomenon. A 2006 report by the World Health Organisation (WHO) estimated that a 70% increase in the health workforce is required worldwide, including doctors, nurses and midwives, in order to meet current demand. Australia is no exception to this phenomenon of health workforce shortage, with several reports over recent years highlighting the shortages, the reasons behind them and possible solutions. In 2003, Brooks et al. expressed concerns regarding doctor shortages, especially in rural areas, and suggested various methods that they felt merited further investigation, including: greater flexibility for entry of highly trained overseas doctors, increasing medical school student intake and workplace practice alternatives (e.g. example “task substitution”).
The supply of medicines and pharmaceutical-related services in Australia is guided by the National Medicines Policy and the Policy for the Quality Use of Medicines. Both documents prioritise the need for timely access to safe, effective and efficient use of medicines.

Recent reviews suggest that health services in Australia may not be currently meeting these requirements.

The Quality in Australian Health Care Study identified the harms associated with medicine usage in Australia over the last 10 years. Major programs of work have subsequently been undertaken to improve medication safety, with one such example being the development and implementation of the National Inpatient Medication Chart. This program of work has improved the safety of prescribing in the hospital setting. However, as two editors have highlighted, the safety issues still remain, with Wilson and Van De Woestijne saying in 2004 that 16 years after the original study, hospitals were no safer, noting the inadequacies of the organisational and political responses, and saying that Australia needs a patient safety initiative that captures the imagination of politicians, professionals and the public.

In 2008, Hughes also highlighted the ongoing problem of medication error in hospital, asking what could be done.

Subsequent work has also shown high rates of preventable medication misuse in the Australian community setting, with a review of 1000 patients showing 222 medication-related problems, with 90% of patients experiencing at least one. One in three people were found to require additional monitoring, one in four required additional medication, one in four were using the wrong or inappropriate medication and one in five were using insufficient medication.

Also in the community setting, in 2006, a study of 8215 patient encounters with general practitioners (GPs) reported 10.4% of patients had experienced an adverse drug event in the previous 6 months. GPs classified 23.2% of the adverse drug reactions as preventable, and the study concluded that adverse drug events were one of the most significant causes of morbidity in the Australian community.

The issue of access to health services, in particular medicines, has seen several changes to the Pharmaceutical Benefits Scheme and health service provision, for example the Rural and Remote Section 100 program.

In spite of these initiatives, the quality of medicine services remains an issue for many Australians, with access to medications still a problem, especially in the rural setting.

In 2004, Komisno and colleagues sent 225 surveys to workers and managers from 93 health and human service organisations across metropolitan, rural and remote areas of South Australia. The purposefully selected sample had to have some involvement with Aboriginal people suffering from mental health disorders, and management of their medications. Several issues influenced quality use of medicines in the patient population, including limited access to specialist services. The authors also concluded that the range of workers providing medications services was very wide, and many workers lacked adequate training or resources.

Another study by Gordon et al. from Toowoomba Hospital also highlighted the issue of access to services. In the study, involving a computer-assisted telephone interview of 410 cancer patients, the authors found that over 46% of patients lived more than 100 km away from the hospital and 3% lived more than 600 km away. Average out-of-pocket expenses involved in attending hospital for treatment ranged between $562 and $6231, with a mean value of $4311.

The National Health and Hospitals Reform Commission and the establishment of the National Health Workforce Taskforce have both recognised the need to reform the way healthcare services in Australia are delivered.

International developments

Following recommendations made in the Crown Reports to the government of the United Kingdom (UK) in 1999, changes were made in legislation, resulting in the extension of prescribing privileges to non-medical professionals, including pharmacists.

The UK, Canada, USA and New Zealand have all extended prescribing of 'prescription only medicines' to healthcare professionals other than doctors.

In a literature review published by Cooper et al. in 2008, pharmacists and nurses were found to be best represented in published trials of non-medical prescribing. The authors searched the literature between 1997 and 2007, and found 35 published trials of nurse and pharmacist prescribing, 20 involving pharmacists and 15 to nursing. Studies were mainly qualitative in nature, and assessed the views of different members of the healthcare teams with regards to the possible advantages of non-medical prescribing, without backing these theories up with prescribing audits and data. Few studies assessed clinical indicators as an evaluation of the quality of prescribing by non-medical prescribers.

A lack of robust evidence of increased safety from the introduction of non-medical prescribing services into other countries has led to calls for evidence to prove the effectiveness of non-medical prescribing services and resistance to such change in Australia.

In recognition of a lack of evidence and the need for a consistently consistent framework to evaluate non-medical prescribing, a collaboration of pharmacists from Australia and New Zealand was established in 2008. This collaboration was born from the common goal of establishing an evidence base for the effectiveness of pharmacist prescribing being undertaken in a series of pilots in Australia.

The objectives of the collaboration are to:

- Share information, methodologies, barriers and enablers of pilots of pharmacist prescribing;
- Establish an evidence base as to the effectiveness of pharmacist prescribing;
- Establish a framework for uniformly measuring effectiveness, so as to enable the alignment of research outcomes and comparison of data and evidence; and
- Develop a framework that could be used to measure the ongoing effectiveness of pharmacist prescribing services following the pilot phase.

It is hoped that if evidence can be provided in a robust, credible and consistent manner, it may address some of this resistance to change.

Evidence as to the effectiveness of non-medical prescribing may also address some of the suggested problems with the ongoing
implementation and sustainability of pharmacist prescribing in the UK due to a lack of credible evaluation of the new service, either from a pilot phase or after implementation.28

With significant changes to health service delivery pending, there is an urgent need to define a uniform framework for the evaluation of non-medical, including pharmacist, prescribing.

The broad practice of hospital pharmacy lends itself well to developing models of pharmacist prescribing for the Australian setting, as pharmacists have medicinal knowledge and the skills inherent to prescribing, along with access to patient clinical records and experience in practicing as part of a multidisciplinary team.

As highlighted by the Pharmacy Guild in 'The Roadmap - The Strategic Direction for Community Pharmacy', community pharmacists remain the most accessible of all health professionals, available for consultations at short notice and without appointment across a variety of locations all across Australia.29

Without robust evidence for this new scope of practice, further development of this role is unlikely.

This paper presents some of the outcomes of this informal collaboration.

Background
In 2009, the National Health Performance Committee developed the National Health Performance Framework for the Australian Health Minister's Conference.30 The framework was reviewed in 2007-08, and a revised framework was agreed to by the Health Ministers in 2009. This performance framework has been endorsed by each jurisdiction and was used as the basis for a pharmacist prescribing performance framework.

Objective
To develop an evaluation framework that can be utilised to assess the performance of non-medical prescribing services uniformly, in several different models.

Method
Groups of researchers undertaking pilots of pharmacist prescribing across Australia were identified.

An open invitation was sent across Australia and New Zealand to which 30 attendees responded from NSW, Victoria, South Australia, Queensland and New Zealand.

A day-and-a-half workshop was held at University of Queensland, which involved presentations from the different sites on their plans pilots. From the presentations, it was clear that each site was assessing different models of pharmacist prescribing and subsequently using different evaluation methods.

Following the presentations, attendees were split into five groups. Each group was given a different model of pharmacist prescribing and asked to consider how to evaluate these models:

- Pharmacist prescriber (global).
- Community generalist.
- Community specialist.
- Hospital generalist.
- Hospital specialist.

The models of care were chosen to reflect that the two most likely practice settings of pharmacists are either in a hospital or in the community. Within these settings, pharmacists may provide a generalist role (e.g. ward pharmacist on a general medical ward or a community pharmacist) or a specialist role (e.g. renal specialist pharmacist, pharmacist in a surgical premedication clinic).

The groups were asked to consider the measures necessary to prove the effectiveness of each model.

Data were collated by the project team and measures and indicators have since been aligned with the six dimensions of the National Health Performance Framework, namely:

- Accessibility.
- Continuity.
- Effectiveness.
- Efficiency and sustainability.
- Responsiveness.
- Safety.

Following development of the non-medical prescribing evaluation framework, the document was circulated to the collaboration for endorsement.

Results
The proposed non-medical prescribing evaluation framework is described below.

Australian Institute of Health and Welfare domains of health system performance

1. Accessibility. People can obtain healthcare at the right place and time irrespective of income, physical location and cultural background.

2. Continuity. The ability to provide uninterrupted, coordinated care or service across programs, practitioners, organisations and levels over time.

3. Effectiveness. The care, intervention or action provided is relevant to the client's needs and is based on established standards. The care, intervention or action achieves the desired outcome.

4. Efficiency and sustainability. Achieving the desired results with cost-effective use of resources, and the capacity of the system to sustain the workforce and infrastructure, and to innovate and respond to emerging needs.

5. Responsiveness. Service is client-oriented. Clients are treated with dignity and confidentiality, and encouraged to participate in choices related to their care.

6. Safety. The avoidance of reduction to acceptable levels of actual or potential harm from healthcare management or the environment in which healthcare is delivered.

Table 1 shows examples of proposed different models of care and a small selection of some measures that might be evaluated to show that the model is as good as traditional models of care.

Discussion
The workshop identified several key points. There are several pilots being planned and undertaken in Australia and New Zealand. Each of these pilots is investigating a different model of pharmacist prescribing, each within a different setting. In order to address criticisms regarding the lack of evidence as to the benefit of pharmacist prescribing, a uniform framework to assess
<table>
<thead>
<tr>
<th>Domain</th>
<th>Indicator</th>
<th>Measure</th>
<th>Model or examples</th>
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<tbody>
<tr>
<td>(1) Accessibility – obtaining healthcare at the right time and place</td>
<td>• Time to access to prescriber</td>
<td>• Time to appointment</td>
<td>Community outpatient clinic (e.g. HIV clinic)</td>
</tr>
<tr>
<td>(2) Continuity – ability to provide uninterrupted, coordinated care, intervention or action across programs, practitioners, organizations and levels</td>
<td>• Ability to enrol new patients</td>
<td>• Doctor time freed up by pharmacist taking patient load</td>
<td>Prescribing on discharge from hospital</td>
</tr>
<tr>
<td>(3) Effectiveness – the care, intervention or action is closest to the client’s needs and based on established standards, and achieves the desired outcome</td>
<td>• Prescribing on discharge</td>
<td>• Accuracy of discharge medication list</td>
<td>Surgical preadmission clinic</td>
</tr>
<tr>
<td>(4) Efficiency and sustainability – achieving the desired results with cost effectiveness of resources, and the capacity of system to sustain workforce and infrastructure, and to innovate and respond to emerging needs</td>
<td>• Appropriateness of prescribing according to guidelines</td>
<td>• Appropriate of various diszenrisabil prophylaxis against acquired guidelines</td>
<td>Quality hypertension clinic</td>
</tr>
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<td>(5) Responsiveness – service is client oriented. Clients are treated with dignity and sensitivity, and encouraged to participate in choices about their care</td>
<td>• Clinical outcome</td>
<td>• Appropriateness of antiretroviral prophylaxis against acquired guidelines</td>
<td>Emergency department pharmacist</td>
</tr>
<tr>
<td>(6) Safety – the avoidance or reduction to acceptable levels of actual or potential harm from healthcare service in which healthcare is delivered</td>
<td>• Technical efficiency</td>
<td>• Clinical outcome of medication history and completeness of medication prescribing information</td>
<td>All models</td>
</tr>
<tr>
<td></td>
<td>• Sustainable workforce</td>
<td>• Time with no pharmacist prescriber service</td>
<td>All models</td>
</tr>
<tr>
<td></td>
<td>• Patient satisfaction</td>
<td>• Patient satisfaction surveys</td>
<td>All models</td>
</tr>
<tr>
<td></td>
<td>• Prescribing errors and inactivation</td>
<td>• Prescriber audit of quality (e.g., of individual medication and the number of errors)</td>
<td>All models</td>
</tr>
</tbody>
</table>

The benefits and performance of the pharmacist prescribing service is essential.

With a uniform framework, the profession will be able to take a common approach to lobby for the introduction of pharmacist prescribing services in the future, something that is essential for the success of the agenda. International pharmacy experience and Australian experience in other professions, for example optometrists, has demonstrated the need for such a unified approach.

In order for the profession to be ready for changes arising from the establishment of the National Health Workforce Taskforce and the recommendations of the Health and Hospitals Reform Commission, strong leadership and clear direction is required from all areas of the profession.

Where non-medical prescribing has been introduced in other countries without a uniform framework for evaluation, issues have arisen retrospectively that could have been addressed earlier, and the reformed prescriber the need to continually justify services.

However, it is important that the framework adopted to measure the performance of non-medical prescribing in the pilot phase must also be appropriate to evaluate ongoing services. Although the settings, models and services may differ, unless safe access to medicines is assured within an effective, efficient and sustainable service, the objectives of the National Medicines Policy will not be met.

The framework outlines general principles that should be evaluated within several dimensions. There is some overlap between the dimensions and not all measures for all dimensions will be applicable and appropriate in each setting. Therefore, pilots should select appropriate measures to reflect each dimension adequately. The framework is intended to provide objective evaluation but be customisable to different settings and models. For example, the ‘sustainability’ of a pharmacist prescribing service in a pre-admission clinic may require cost justification based on efficiency, whereas ‘sustainability’ for other models may require an ongoing source of suitably trained pharmacists, such as in the setting of specialist HIV pharmacy services.

Within different models, the relative importance of each dimension over another may differ. For example, ‘continuity’ is the major driving force behind the introduction of discharge medication services, whereas safe ‘access’ to medicines services in rural and remote areas is a priority for health service reform.

It is important to note that irrespective of the model or setting, patient safety is the underlying principle. The collaboration strongly recommends the development of prescribing competencies that can be applied across the board irrespective of the professions involved. Given that training and competencies for
pharmacist prescribing are determined by the performance requirements of the service, the authors propose that a competency and training framework for non-medical prescribing be developed.

Patient safety associated with medicine use remains the ultimate goal.

Conclusions

The National Health Performance Framework has provided the basis for a non-medical prescribing evaluation framework that can be applied to pilots and for the evaluation of future services and research. A collaboration of pharmacists from Australian and New Zealand recommend a consistent approach to measuring non-medical prescribing uniformity in order to establish an evidence base, professional consensus and the basis of requirements for national competency and the accreditation of prescribers.

Competing interests

The authors declare there are no competing interests.

References


24 Manchester A. Nurses gain right to prescribe. Wellington 1998.


Appendix E – Invite to Attend Supplementary Prescribing Workshop

PHARMACIST SUPPLEMENTARY PRESCRIBING
CONCEPT TO REALITY?

Thursday 15th January 12 – 4pm (Registration 11.30am, lunch 12-1)
Friday 15th January 9am – 4pm (Registration 8.30am)
University of Queensland, St Lucia, Brisbane

Expressions of interest are being sought for a two day workshop at The University of Queensland, Brisbane.

Are you one of the following and interested in attending?

- Clinical or academic staff with an interest in the progression of supplementary pharmacist prescribing in Australia and New Zealand
- Involved currently in pilots investigating outcomes of supplementary pharmacist prescribing
- Have previous experience in supplementary prescribing from overseas

The workshop will seek to:

1) Initiate discussions on:
   - the strengths, weaknesses, threats and opportunities to the success of a wider roll out of a supplementary pharmacist prescribing program
   - the knowledge, skills and attitudes (competencies) required to enable pharmacists to prescribe safely and effectively in a supplementary prescribing role
   - the training, education and competency assessment required to enable pharmacists to prescribe safely and effectively in a supplementary prescribing role

2) Share methods, evaluation and outcome measures on current pilot projects being undertaken nationally on the subject of supplementary pharmacist prescribing.

Please RSVP to andrew.hale@health.qld.gov.au before 7th January 2009

Places are limited so be quick!!
Perioperative medication management: expanding the role of the preadmission clinic pharmacist in a single centre, randomised controlled trial of collaborative prescribing

A R Hale,1 J D Coombes,2 J Stokes,3 D McDougall,1 K Whitfield,4 E Maycock,5 L Nissen1

ABSTRACT

Objectives: Current evidence to support non-medical prescribing is predominantly qualitative, with little evaluation of accuracy, safety and appropriateness. Our aim was to evaluate a new model of service for the Australian healthcare system, of inpatient medication prescribing by a pharmacist in an elective surgery preadmission clinic (PAC) against usual care, using an extended performance framework.

Design: Single centre, randomised controlled, two-arm trial.

Setting: Elective surgery PAC in a Brisbane-based tertiary hospital.

Participants: 400 adults scheduled for elective surgery were randomised to intervention or control.

Intervention: A pharmacist generated the inpatient medication chart to reflect the patient’s regular medication, made a plan for medication perioperatively and prescribed venous thromboembolism (VTE) prophylaxis. In the control arm, the medication chart was generated by the Resident Medical Officers.

Outcome measures: Primary outcome was frequency of omissions and prescribing errors when compared against the medication history. The clinical significance of omissions was also analysed. Secondary outcome was appropriateness of VTE prophylaxis prescribing.

Results: There were significantly less unintended omissions of medications: 11 of 887 (1.2%) intervention orders compared with 383 of 11217 (31.5%) control (p<0.001). There were significantly less prescribing errors involving selection of drug, dose or frequency: 2 in 857 (0.2%) intervention orders compared with 51 in 807 (6.3%) control (p<0.001). Orders with at least one component of the prescription missing, incorrect or unclear occurred in 220 of 1994 (11%) intervention orders and 445 of 1934 (23%) control orders (p=0.001). VTE prophylaxis on admission to the ward was appropriate in 92% of intervention patients and 80% controls (p=0.098).

Conclusions: Medication charts in the intervention arm contained fewer clinically significant omissions, and prescribing errors, when compared with controls. There was a difference in appropriateness of VTE prophylaxis on admission between the two groups.

ARTICLE SUMMARY

Article focus

- A doctor-pharmacist collaborative prescribing model provides so long as high a quality of care as usual care, with regard to safety, access, appropriateness, effectiveness, efficiency and consumer participation.

- Workforce shortages are prompting a review of the way the current workforce is utilised, and whether different roles could be taken on by healthcare professionals to alleviate some of the pressures within the system.

- Research on non-medical prescribing so far is predominantly qualitative in nature. Our study has analysed quantitative data on the safety, accuracy and appropriateness of prescribing to try to assess whether this model is at least as good as usual care.

Key messages

- Pharmacists’ skills in medication management are currently underutilised, and with appropriate training and education they could be contributing to medication management much more effectively by being on a prescribing role.

- The prescribing is collaborative and driven by guidelines and under the supervision of a medical team. Diagnosis is not within the scope of practice of the prescribing pharmacist.

- This model of care has been proved to be highly effective in this study, with an increased accuracy, safety and appropriateness of prescribing within the intervention arm.

Total Registration: Registered with ANZCTR—ACTR Number ACTRN12605000420290
Expanding the role of the preadmission clinic pharmacist

ARTICLE SUMMARY

STrengths and limitations of this study
- The results with regard to the accuracy and safety of medication charts produced in the study are emphatic and statistically significant.
- The intervention is reproducible in other settings with a pharmacist of appropriate experience, training, and education.
- The study assessed one pharmacist per venue versus a cohort of medical prescribers. While this has been accounted for in the analysis, it also reflects what usual practice would be in a model care such as this. The authors recognise and acknowledge this as a limitation.

INTRODUCTION

Prescribing involves four stages: information gathering, clinical decision-making, communication of decision and monitoring. Taking a medication history, continuing, ceasing and withholding of medications and initiating new medications are critical components of prescribing associated with an admission for surgery. Medication errors are common, occur most often at the time of prescribing, and frequently on the day of hospital admission, resulting in discrepancies between regular medications and admission orders.

A small, but significant, proportion of errors result in adverse drug events (ADEs). Errors have been defined as when there is "a failure to communicate essential information; the use of drugs or doses is inappropriate for the individual patient; or transcription error." To be able to communicate a clinical decision safely and effectively in the form of a written prescription, it is necessary to select the correct drug, together with the route, form, dose, frequency and duration. Multiple interventions have been suggested in an attempt to improve prescribing, with suggestions that increased training of the individual, a controlled environment and a change in organisational culture are necessary.

Within hospital, the medication chart provides instructions for safe medication supply and administration, and ensures the patient access to medications as an inpatient. It is an integral part of communication between doctors, pharmacists and nurses about prescribing decisions and is used as the primary source of information regarding medications on discharge. The pharmacy service in the Princess Alexandra Hospital (PAH) pre-admission clinic (PAC) began in 1998 to provide timely, accurate and comprehensive information about medication as patients crossed between healthcare settings. It ensured accurate transfer of information at admission, during the inpatient stay and at discharge, the benefits of which were a reduction in both readmissions and contact with community healthcare providers post-discharge.

The importance of accurate transfer of information across the whole surgical care pathway from preadmission to discharge, including information about medications, has been highlighted in a recent study that reported how communication failures led to patient morbidity and mortality. Standardisation and systematisation of communication processes, along with other interventions targeted at the entire surgical pathway, were recommended with a view to improving information transfer and quality of care.

Pharmacies in PACs have been shown to improve the accuracy of medication histories and medication orders, when compared with standard care, and the efficacy of prescribing peroperatively in line with recognised guidelines. Only with an accurate history of medication usage can decisions be made safely regarding the perioperative management of medications. Medication histories are elicited from a variety of sources of information: patient's own medications, the patient or their care, general practitioner summaries, community pharmacies, previous hospital admissions and nursing home records. A number of sources may be consulted to build an accurate record of medication that the patient is taking, both regularly and occasionally.

The range of prescribers has been expanded in a number of countries, with changes in legislation to allow for extension of prescribing privileges to non-medical professionals, including pharmacists. The objective of this was to make greater use of the skills and specialisation of pharmacists so that a more flexible system for the prescribing, supply and administration of medicines could be developed, while maintaining safe and appropriate access to medicines.

In response to the documented workforce shortages in Australia, Brooks et al described possible solutions, including 'task substitution', and a focus has been placed recently on non-medical prescribers within the healthcare system. Pharmacists, with training in pharmacology and therapeutics, are potentially well placed to undertake prescribing roles. An Australian study identified the main driver behind pharmacist prescribing as the desire to work collaboratively with medical and nursing staff to:

- Provide consumers with improved, responsible and safe access to prescription medicines;
- Optimise use of pharmacists' and doctors' skills and time;
- Reduce inefficient use of health resources.

Evidence to support non-medical prescribing so far has been mainly qualitative, with minimal evaluation of access, safety and appropriateness. One recent review concluded that acceptability of non-medical prescribing services is based on the perceived value to the health service. This lack of evidence has led to calls to prove the safety and effectiveness of non-medical prescribing services in Australia. The aim of the data analysis discussed in this paper was to compare a doctor—pharmacist collaborative prescribing model with usual care, with regard to safety, access, appropriateness and effectiveness; the null hypothesis being that no difference exists between the two models of care.

METHODS

The study was conducted between June and September 2009 in the surgical PAC at PAH, a 754-bed tertiary teaching hospital in Queensland.

The definition of error used in the study was: "a failure to communicate essential information, the use of drugs or doses is inappropriate for the individual patient; and transcription error."  

All patients who attended PAC and could provide written informed consent were considered for participation. Patients were excluded if they were under 18 years of age, unable to communicate due to language difficulties or undergoing day surgery (see figure 1).

Patients were approached on arrival at the clinic and written consent was obtained. After consent, patients were randomised using a computer generated randomisation list, in blocks of 10 (Microsoft Excel). Sealed envelopes (not prepared by the recruiting researcher) contained a zero or one each time the computer list; the next envelope was opened after consent to determine whether a patient entered the control or intervention arm, respectively. If a patient had been randomised and then surgery cancelled during PAC, the patient was removed from the study and not replaced.

A previous pilot study in the PAC showed an error rate of 12% of orders. Using an expected error rate of 8% in the intervention arm, a sample size of 932 orders per group was calculated to be required for a power of 80%. Assuming an average of five orders per patient, approximately 200 patients per arm would be required.

Only one pharmacist in the PAC, with 3 years' experience as a hospital pharmacist and having a postgraduate diploma in clinical pharmacy, was trained to be a prescriber. The pharmacist attended a prescribing course which was accredited by the General Pharmaceutical Council, UK as an Independent Pharmacist Prescribing Course. Training included a minimum of 12 days of 'period of learning in practice' under a designated medical practitioner (DMP), who was the consultant anaesthetist for PAC. The training included case studies and sessions on venous thromboembolism (VTE) prophylaxis with a consultant vascular physician and the clinical nurse consultant (CNC) for VTE prophylaxis at PAH. The DMP endorsed the pharmacist's competency to prescribe before the study could begin.

For the pilot, an amendment was facilitated to the Queensland Health (Drugs and Poisons) Regulation 1996 to allow 'Pharmacist registered in Queensland who are employed or contracted to Queensland Health and working in the Pharmacist Prescribing Pilot' to prescribe controlled drugs, restricted drugs and schedule 2 and 3 poisons.

Intervention cohort

Patients were seen by a nurse, prescribing pharmacist, Resident Medical Officer (RMO) and anaesthetist. Patients had to be seen by the pharmacist before they were seen by the RMO to allow usual RMO duties and a common signature of the pharmacist prescriptions, a site requirement.

The pharmacist undertook all pharmacist duties as per usual care, as well as prescribing medications on the medication chart. The scope of prescribing was continuing or withholding regular medications and prescribing

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Figure 1: Randomisation flow chart

Assessed Eligibility (n=424)

Excluded (n=24)
- Not meet inclusion criteria (n=7)
- Declined to participate (n=17)

Randomised (n=400)

Allocated to intervention (n=200)

Surgery cancelled in PAC (n=6)

Final intervention cohort (n=194)

Allocated to control (n=200)

Surgery cancelled in PAC (n=10)

Final control cohort (n=190)
Expanding the role of the preadmission clinic pharmacist

VTE prophylaxis according to local and national guidelines, following a risk and consultation assessment.5,6

Doctors of surgery were consulted prior to the start of the trial for permission to include patients in prescribing of VTE prophylaxis, according to their specific unit guidelines, which had been defined in advance in collaboration with the CNC for VTE prophylaxis at PHL. Urology and renal transplant patients were excluded (N=43 control, N=34 intervention) from VTE prophylaxis prescribing as the director of urology was unavailable to confirm the scope of the project, and the director for transplant requested exclusion on the grounds that VTE prophylaxis in these patients was driven more by consultant discretion as opposed to being driven by guidelines.

Control cohort

Patients were seen by all four healthcare professionals in clinic, in no particular order, as per usual care. Either pharmacist in the clinic saw control patients for documentation of medication history. The prescribing of the medication chart was the responsibility of the RMO. In both arms, review and monitoring were undertaken, both by RMOs in clinic at countersignature and by RMOs and clinical pharmacists at the ward level, once the patient was admitted. Changes made by RMOs to intervention patient medication charts in clinic were recorded.

Outcome measures

The primary endpoint for the study was the accuracy of medication charts, with regard to concordance of the medication chart with the medication history, the plan for medications peripheratively and the quality of the individual orders related to legality and safety for administration purposes. The secondary endpoint was the appropriateness of prescribing for both chemical and mechanical VTE prophylaxis according to local and national guidelines.70

Analysis of scanned copies of medication charts, for the primary outcomes of omissions and errors, was conducted in tandem by two assessors, one a member of the research team and the other an external assessor, both trained in the use of validated audit tools and blinded to randomisation. Any ambiguities were clarified by consensus.

Appropriateness of VTE prophylaxis prescribed in both arms in clinic was analysed using scanned copies of medication charts, in tandem by two assessors, one a member of the research team and the other a CNC for VTE prophylaxis at PHL. Prescribing was also assessed on admission to the ward to ensure that VTE prophylaxis was appropriate.

An expert panel, comprising a surgeon, a clinical pharmacologist, an anaesthetist, a RMO, a pharmacist and a nurse, was convened to assess the clinical significance of omissions in a randomly selected 5% sample of the total cohort of patients from both arms (N=40 control, N=60 intervention). Panel members were blinded to randomisation.

Tables 1 and 2 describe the collection methods and definitions of these endpoints.

Categorical data were compared using χ2 tests for independence. When any one cell had a count of less than 10, Fisher’s exact test was substituted. Logistic regression was used to analyse the overall omissions between the two groups. The number of regular and PRN medications that the patient was currently taking was included as an explanatory variable in the model as it was deemed more likely that an individual medication would be omitted in a patient taking a large number of medications. Logistic regression was also used to analyse the overall communications prescribing errors between the two groups. The assumption of independence between observations is clearly violated as multiple observations exist for most patients. As such, robust SEm clustered by patient were calculated. No other covariates were adjusted for. All reported p values are two-tailed using a level of significance of 0.05. All statistical analysis and sample size calculations were conducted using Stata V11.2 (StataCorp, College Station, Texas, USA).

<table>
<thead>
<tr>
<th>Measure</th>
<th>Definition</th>
<th>Method</th>
<th>Assessing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omissions</td>
<td>Medication in patient’s medication history not prescribed on medication chart, with no reason documented in patient chart</td>
<td>Every medication in patient’s medication history checked against medication chart—omissions from medication chart noted</td>
<td>Whether or not medication is prescribed</td>
</tr>
<tr>
<td>Prescribing errors</td>
<td>Anomaly in drug name, strength, dose, frequency or route, with no documentation in patient chart</td>
<td>Every medication in patient’s medication history checked against medication chart—anomalies noted</td>
<td>Whether or not prescription is accurate in terms of drug name, strength, dose, frequency and route</td>
</tr>
<tr>
<td>Communication errors</td>
<td>Unclear prescription in terms of name, route, dose, frequency, slow release medication notification or intermittent order prescribing</td>
<td>Every prescription written checked using a validated audit tool—unclear prescription noted, as agreed by both researchers</td>
<td>Whether or not prescription is safe for administration purposes</td>
</tr>
</tbody>
</table>

RESULTS
The demographics of the patients randomised into the trial were similar, except for the higher number of medications taken by patients in the control arm (see Table 5).

Omissions
Total unintentional medication omissions from medication charts were higher for control patients (31.5%) compared with interventions (1.2%). The OR for an order in the control group to be omitted, compared with that for the intervention group, was 4.5 (90% CI 20.0 to 61.3; p<0.001 logistic regression) after adjusting for the number of medications the patient was currently taking (see Table 4 and Figure 2). There were 59 prescribers in the control arm, 54 of whom reviewed patients who were currently taking regular or PRN medications at home, and as such had the opportunity to omit a patient’s medication. Of these 54 prescribers, the median percentage of medications that were omitted per prescriber in the control arm was 21 (range 0–100).

Clinical significance of omissions
Omissions from a randomly selected 5% of the total cohort were evaluated for clinical significance. Of the 89 regular medications in the patients’ medication histories in the control arm, 25 (28%) were omitted from the medication charts, compared with 1 of 55 (2%) in the control arm. When asked to assess the severity of omission, the average across the panel showed that 52% of omissions in the control arm had the potential for patient harm or ward inconvenience (see Figure 3). Only one reviewer thought the omission in the intervention arm was significant.

Prescribing errors related to drug, dose and frequency selection
Overall, 53 errors were identified where the drug strength, dose or frequency prescribed did not match the medication history or perioperative plan (see Figure 4). This equates to 6.3% of intervention orders compared with 0.2% of intervention orders (p<0.001; Fisher’s exact test).

Communication errors
Communication errors, where prescriptions were noted as ambiguous or unclear, were significantly higher in the control arm compared with the intervention arm. The OR for an order in the control arm to have a communication error compared with an order in the intervention arm was 8.5 (95% CI 2.5–29.5; p<0.001 logistic regression).

Table 2: Analysis of accuracy of VTE risk and contraindication assessments and appropriateness of VTE prescribing

<table>
<thead>
<tr>
<th>Measure</th>
<th>Definition</th>
<th>Method</th>
<th>Assessing</th>
</tr>
</thead>
<tbody>
<tr>
<td>VTE-risk assessment</td>
<td>Patient categorised into low or high risk for VTE, as per guidelines</td>
<td>Every patient medical record checked for a documented VTE risk assessment</td>
<td>Risk assessment documented</td>
</tr>
<tr>
<td>VTE contraindication assessment</td>
<td>Patient highlighted as inappropriate for mechanical or chemical prophylaxis, as per guidelines</td>
<td>Every patient medical record checked for a documented contraindication assessment</td>
<td>Risk assessment correct (Y/N)</td>
</tr>
<tr>
<td>VTE prescribing</td>
<td>Whether patient prescribed mechanical and/or chemical VTE prophylaxis, as per guidelines</td>
<td>Prescribing of mechanical and chemical VTE prophylaxis checked against agreed local and national guidelines</td>
<td>Contraindication assessment documented (Y/N)</td>
</tr>
<tr>
<td></td>
<td>VTE events fatal, other VTE events</td>
<td>VTE prescribing appropriate according to guidelines and individual patient factors (Y/N)</td>
<td></td>
</tr>
</tbody>
</table>

Table 3: Characteristics of study population

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Intervention</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Total patients</td>
<td>150</td>
<td>194</td>
<td></td>
</tr>
<tr>
<td>Age*</td>
<td>57.6 (18–86)</td>
<td>55.8 (18–86)</td>
<td></td>
</tr>
<tr>
<td>Male (%)</td>
<td>56</td>
<td>59</td>
<td></td>
</tr>
<tr>
<td>Regular medications†‡</td>
<td>4 (0–16)</td>
<td>3 (0–18)</td>
<td></td>
</tr>
<tr>
<td>When required PRN medications†‡</td>
<td>2 (0–7)</td>
<td>1 (0–4)</td>
<td></td>
</tr>
<tr>
<td>Complementary and alternative medicines (CAM)†</td>
<td>(0) (0–0)</td>
<td>(0) (0–0)</td>
<td></td>
</tr>
<tr>
<td>Over the counter (OTC) medications*</td>
<td>(0) (0–2)</td>
<td>(0) (0–2)</td>
<td></td>
</tr>
<tr>
<td>Total medications</td>
<td>1364</td>
<td>985</td>
<td></td>
</tr>
<tr>
<td>Total medications (regular and PRN only)</td>
<td>1217</td>
<td>937</td>
<td></td>
</tr>
<tr>
<td>Medication charts prescribed</td>
<td>161 (85%)</td>
<td>194 (100%)</td>
<td></td>
</tr>
</tbody>
</table>

*Mean (range).
† Regular medications are defined as medications prescribed with the intent to be taken on a regular basis.
‡PRN (Pro Re Nata) medications are defined as medications prescribed with the intent to be taken only when required.
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Table 4  Medication omissions from medication chart

<table>
<thead>
<tr>
<th>Type of medication and perioperative plan</th>
<th>Control (N) [%]</th>
<th>Intervention (N) [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regular</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continue</td>
<td>179 (809) [22.2]</td>
<td>3 (620) [0.5]</td>
</tr>
<tr>
<td>Withhold prior to surgery</td>
<td>48 (70) [17.4]</td>
<td>0 (48)</td>
</tr>
<tr>
<td>Withhold morning of surgery</td>
<td>21 (56) [38.9]</td>
<td>0 (59)</td>
</tr>
<tr>
<td>Adjust dose</td>
<td>1 (5) [20.0]</td>
<td>0 (5)</td>
</tr>
<tr>
<td>Review</td>
<td>1 (7) [14.2]</td>
<td>0 (6)</td>
</tr>
<tr>
<td>Cease</td>
<td>0 (1)</td>
<td>0 (2)</td>
</tr>
<tr>
<td>PRN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continue</td>
<td>128 (248) [51.6]</td>
<td>6 (142) [4.2]</td>
</tr>
<tr>
<td>Withhold prior to surgery</td>
<td>7 (12) [30.3]</td>
<td>2 (13) [15.4]</td>
</tr>
<tr>
<td>Adjust dose</td>
<td>0 (2) [20.0]</td>
<td>0 (1)</td>
</tr>
<tr>
<td>Review</td>
<td>0 (8) [14.3]</td>
<td>0 (11)</td>
</tr>
<tr>
<td>Total omissions</td>
<td>383 (1217) [31.5]</td>
<td>11 (837) [1.2]</td>
</tr>
<tr>
<td>Complementary and alternative medicines (CAMs)*</td>
<td>126</td>
<td>87</td>
</tr>
<tr>
<td>Over-the-counter medications (OTC)*</td>
<td>21</td>
<td>9</td>
</tr>
</tbody>
</table>

*CAM and OTC medications were not classed as omissions in either arm if they were not prescribed on the inpatient medication chart.

arm was 2.82 (95% CI 1.96 to 3.77; logistic regression p<0.001). As there were multiple orders per patient, robust SEs, clustered by patient, were utilized (see Table 5). Individually, communication errors were significantly higher in the control arm for all types of error except the route of administration (p=0.57 χ² test).

From the control arm prescribers, 44 of them prescribed medication on the medication charts, with a median number of orders of 21 (range 1-85). The median percentage of orders in the control arm that contained at least one communication error per prescriber was 38 (range 0-100).

VTE prophylaxis

Patients in the intervention arm were significantly more likely than controls to have appropriate VTE prophylaxis prescribed on the medication chart in PAC and to have documented VTE assessment (see Figure 5). On admission to the ward, approximately 50% of both intervention and control patients were prescribed appropriate VTE prophylaxis.

DISCUSSION

This study has built on the findings of previous research of pharmacists practicing in PAC settings, which have found improved accuracy of information gathered, and improved prescribing according to guidelines.15 Similar studies of pharmacist interventions in different settings have shown improvements in clinical endpoints such as blood pressure control, increased appropriateness of prescribing and reductions in ADRs, such as warfarin-associated bleed.20-25

The traditional scope of practice for the PAC pharmacist consists of taking a medication history using
Expanding the role of the preadmission clinic pharmacist

Figure 3 Assessment of clinical significance of omissions.

<table>
<thead>
<tr>
<th>Role</th>
<th>Harm &amp; inconvenience</th>
<th>Patient harm alone</th>
<th>Inconvenience alone</th>
<th>Neither inconvenience nor harm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgeon</td>
<td>G</td>
<td>F</td>
<td>E</td>
<td>C</td>
</tr>
<tr>
<td>RMO</td>
<td>D</td>
<td>C</td>
<td>B</td>
<td>A</td>
</tr>
<tr>
<td>Pharm</td>
<td>A</td>
<td>D</td>
<td>E</td>
<td>F</td>
</tr>
<tr>
<td>Nurse</td>
<td>C</td>
<td>A (red)</td>
<td>B</td>
<td>D</td>
</tr>
<tr>
<td>C Phrm</td>
<td>B</td>
<td>D</td>
<td>E (green)</td>
<td>F (yellow)</td>
</tr>
<tr>
<td>Anaes</td>
<td>E</td>
<td>F</td>
<td>G</td>
<td>H</td>
</tr>
</tbody>
</table>

% of omissions rated

guidelines, clinical judgement and referral to the surgical team to suggest a plan for medications perioperatively and providing this information to the RMOs to generate the medication chart. This scope has been extended in our study by providing an appropriately trained pharmacist to generate the medication chart perioperatively. VTE prophylaxis, which has led to a significant reduction in omissions and prescribing errors, ensuring that patients get the correct medication while in hospital. The evaluation of VTE prophylaxis prescribing was essential to assess the safety and appropriateness of initiation of a new medication, within guidelines, by the prescribing pharmacists. The results from this study have shown the prescribing to be as appropriate as usual care at the time the patient is admitted to the ward. Issues still remain with the prescribing, especially with the use of inappropriate abbreviations. For example, a large proportion of communication errors in the intervention arm were due to the use of s/c to indicate subcutaneous, which has informed the researchers on future educational requirements of prescribers, especially with regard to safe prescribing.

Electronic prescribing may be one solution to such errors involving legibility and inappropriate abbreviations, but studies have shown that the systems introduce errors of their own. These errors need to be fully assessed and appreciated if the quality of prescribing is to be improved by the introduction of computerised prescribing into the healthcare system.

The results presented in this paper are part of a larger study. Further work is required to assess the appropriateness of prescribing of medication charts and consumer participation of this new model of care. There are a number of limitations. Even though the trial was...
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Table 5 Prescribing errors with an ambiguity in at least one component of the prescription

<table>
<thead>
<tr>
<th></th>
<th>Control number of errors (% of total orders)</th>
<th>Intervention number of errors (% of total orders)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total orders</td>
<td>10.9</td>
<td>9.4</td>
<td>&lt;0.001†</td>
</tr>
<tr>
<td>Orders with at least one communication error</td>
<td>4.4 (43)</td>
<td>2.0 (23)</td>
<td></td>
</tr>
<tr>
<td>Prescribing communication errors</td>
<td>267</td>
<td>0</td>
<td>&lt;0.001‡</td>
</tr>
<tr>
<td>Prescribing communication errors</td>
<td>22</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Drug name</td>
<td>23 (2.1)</td>
<td>23 (2.1)</td>
<td>0.57‡</td>
</tr>
<tr>
<td>Route</td>
<td>79 (7.6)</td>
<td>79 (8.4)</td>
<td></td>
</tr>
<tr>
<td>Dose</td>
<td>48 (4.6)</td>
<td>5 (0.6)</td>
<td>&lt;0.001‡</td>
</tr>
<tr>
<td>Frequency</td>
<td>190 (15.4)</td>
<td>96 (10.5)</td>
<td>&lt;0.001‡</td>
</tr>
<tr>
<td>Administration times incorrect or missing</td>
<td>117 (14.9) (781 orders)</td>
<td>4 (0.5%) (762 orders)</td>
<td>&lt;0.001‡</td>
</tr>
<tr>
<td>PRN maximum dose missing</td>
<td>178 (7.45) (241 orders)</td>
<td>47 (8.2%) (142 orders)</td>
<td>&lt;0.001‡</td>
</tr>
<tr>
<td>Slow release not specified</td>
<td>15 (30.0) (50 orders)</td>
<td>1 (1.5%) (66 orders)</td>
<td>&lt;0.001‡</td>
</tr>
<tr>
<td>Intermittent order not specified</td>
<td>17 (37.5) (50 orders)</td>
<td>0 (0.0%) (38 orders)</td>
<td></td>
</tr>
</tbody>
</table>

*Logistic regression.
†Fisher’s exact test.
‡Fisher’s exact test.

randomised, the total number of medications that the patients were taking was higher in the control arm (1304) compared with the intervention arm (883). The explanation for this is unknown but may in part be due to larger randomisation block sizes, possibly meaning that a number of consecutive patients was randomised to the control arm during clinic sessions, where patients were more likely to have a higher burden of medication, for example, during a vascular surgery clinic. There was more opportunity for omissions from the control arm as a result of more medications needing to be continued, and this was allowed for in the analysis.

RMOs in clinic during the study were aware of the intervention pharmacist’s role, which may have led to an increased number and quality of medication charts prescribed in the control arm. Even with this potential effect, the study still showed a significant improvement in the safety and accuracy of medication charts.

Review of medication orders is not a role that an RMO routinely undertakes. All RMOs were educated with regard to the requirement of a countersignature of pharmacist orders, and to amend anything as required prior to sign off. In the trial, 10 charts were amended—5 changes were minor, 5 were addition of analgesics out of the pharmacist’s prescribing scope and 2 changes actually resulted in inappropriate VTE prophylaxis. Despite the legislative changes, countersignature of pharmacist orders was a local requirement owing to the concern that junior doctors may become skilless as a result of being removed from the prescribing process.

Figure 5 Various thromboembolism prophylaxis assessments and prescribing.
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CONCLUSION

Medication charts in the intervention arm were significantly safer and more accurate with regard to the patients’ regular medications than medication charts in the control arm. There was no difference in appropriateness of VTE prophylaxis prescribing between arms on admission to the ward.

Our study has shown that the pharmacist in a PAC was able to effectively gather all the information required to collaboratively formulate a clinical decision in clinic within an agreed scope of practice, and communicate the decisions safely and accurately onto the medication chart.

A collaborative doctor-pharmacist prescribing model in a PAC was as safe and accurate as usual care in ensuring that patients were prescribed the medication required on admission for elective surgery.

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Contributors
AHK, IDC, JS, YA, BM and UN contributed to the project concept and study design. AHK collected all data and was responsible for the running of the study. AHK, IDC, JS and UN were involved in the evaluation of data. AHK and UN were responsible for database design, data evaluation and statistical reporting. All authors contributed significantly to the write-up of the project. All authors have read and approved the final manuscript.

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Competing interests
None.

Ethics approval
Princess Alexandra Hospital Human Ethics Research Committee

Provenance and peer review
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Data sharing statement
Data sets can be accessed via the Dryad data repository at http://dx.doi.org/10.5061/dryad.8r11f.

REFERENCES
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9.7 Appendix G. Chapter 4. Published Paper, Journal of Pharmaceutical Care and Health Systems

A Pilot Study to Assess the Appropriateness of Prescribing From a Collaborative Pharmacist Prescribing Study in a Surgical Pre Admissions Clinic

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Abstract

Background: Current evidence to support non-medical prescribing is predominantly qualitative with little evaluation of appropriateness. This study aims to evaluate the appropriateness of prescribing, and significance of omissions, from a doctor pharmacist collaborative prescribing model in an elective surgery pre admission clinic (PAC).

Method: A modified version of the Medication Appropriateness Index (MAI) was developed, piloted and subsequently used by an expert panel, comprised of a surgeon, based pharmacist, clinical pharmacist, pharmacist, and medical observers. The tool was used to rate the appropriateness of prescribing, and the significance of omissions in a 15% sample (n=19) of the total cohort from a random sample, continuing two arms of an arm trial of doctor pharmacist collaborative prescribing.

Results: Twenty reviewer assessments were combined, 12 out of 234 (10.5%) medications assessed for appropriateness in the control arm were assessed inappropriate, compared to 13 of 236 (4.7%) in the intervention arm. Out of 19 regular medications in the control arm, 25 (25%) were omitted from the medication chart, compared to 1 out of 55 (2%) in the intervention arm (p<0.001, Fisher’s exact) on average, 52% of medications in the control arm were judged to have potential patient harm or want convenience.

Conclusion: For the appropriateness of prescribing, overall results were similar between arms, as judged by individual panel members. Medication charts in the control arm contained significantly more errors than the intervention arm, a number of which were raised by the panel members as having the potential for patient harm or want convenience.

Keywords: Non-medical prescribing, Pharmacy, Pharmacist prescribing, Safe prescribing, Appropriate prescribing

Introduction

Inappropriate prescribing is the failure to provide the quality of care related to medication use that should be achieved in practice, and encompasses overprescribing, misprescribing and under prescribing [1]. Inappropriate medication use has been defined as that which poses greater risk of harm than benefits, especially when safer alternatives exist [2]. Elderly patients, in particular, are susceptible to the consequences of inappropriate prescribing, incurring the risk of adverse drug events and related morbidity and hospitalisations [3,4]. Patients recently discharged from hospital are also at increased risk of medication misadventure, as medication is often reviewed and changed during an admission, and poorly communicated with community practitioners [5]. The importance of accurate transfer of information across the whole care pathway from hospitalisation to discharge, including information about medications was highlighted in a study that reported communication failings led to patient mortality and mortality [6]. The Australian Commission on Quality and Safety in Health Care highlighted medication reconciliation, and the accurate transfer of information about medication as a national priority [7].

Within hospitals, the medication chart provides a record of patient’s medications, instructions for safe medication supply and administration, and ensures patient access to medications as an

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and on discharge, and the associated risks of admissions of medications at these times were highlighted as an important controlled trial [16]. Pharmacy in PACs is a well-recognized role in Australia, with the Society of Hospital Pharmacists of Australia (SHPA) publishing a fact sheet on how pharmacists in PACs can contribute to better patient outcomes and quality of care [11].

Several countries have extended the prescribing of prescription only medicines to health care professionals other than doctors, with the aim of increasing patients' access and choice, and make best use of health professionals' skills, whilst ensuring patient safety [12]. Health Workforce Australia has highlighted possible models of prescribing for non-medical health professionals within the Australian healthcare system [13,14]. However, there is a lack of evidence to support this model of care. Current literature is predominantly qualitative, with little in the way of evaluation of quality, safety or appropriateness of prescribing. A recent review suggested that acceptance of the model of care was mainly based on the perceived value to the healthcare system [15].

**Aim of the Study**

To use a validated national health performance framework to compare a collaborative pharmacist prescribing model with usual care, with regards to effectiveness (appropriateness), safety, responsiveness, continuity, accessibility and efficiency [16]. The hypothesis was that no difference exists between the models of care. Results so far have shown pharmacist prescribing is as good as usual care in safety and accuracy of medication charts, and appropriateness of venous thromboembolism (VTE) prophylaxis [17].

The significant difference in emissions of medications prompted further investigation into the appropriateness of prescribing, and the significance of medications that had not been prescribed on the National Inpatient Medication Chart (NIMC). The aim of the data discussed in this paper was to assess a 'snapshot' of the appropriateness of prescribing from a pilot study and the potential health impact of ward inconveniences of emissions from the NIMC. If the methodology utilised in the pilot proves feasible and yields meaningful data, this study will provide guidance for future assessment of appropriateness of prescribing from collaborative non-medical prescribing studies. Ethics approval was obtained from the PAH Human Research Ethics Committee.

**Materials and Methods**

The main study was conducted between June and September 2009 in the surgical, multidisciplinary PAC at PAH’s 750-bed tertiary teaching hospital in Queensland.

All patients who attended PAC and could provide written, informed consent were considered for participation. Patients were excluded if they were under 18 years of age, unable to communicate due to language difficulties or undergoing eye surgery. A previous audit in PAH PAC showed an error rate of 12% of orders [18]. Using an expected error rate of 0% in the intervention arm a sample size of 952 orders per group was calculated to be required for a power of 80%.

Assuming an average of 5 orders per patient, it was estimated that 200 patients per arm would be required for the main study.

**Intervention cohort**

Patients were seen by a nurse, prescribing pharmacist, Resident Medical Officer (RMO) and anaesthetist. Patients were seen by the pharmacist before they were seen by the RMO to allow usual RHO duties and a countersignature of the pharmacist prescription, a site requirement. The pharmacist undertook all pharmacist duties as per usual care, as well as prescribing medications on the NIMC.

**Control cohort**

Patients were seen by all four health care professionals in clinic, as per usual care. Patients in the control arm were still seen by a pharmacist, for usual care duties of a medication history, which was documented in the PAC assessment form and on the front of the NIMC. There was no set order in the control arm, meaning the patient could see the RMO first. The prescribing of the NIMC was the responsibility of the RMO.

**Sample of patients for panel assessment of appropriateness**

Intervention and control patients from the main study were stratified into 5 groups, from the first patient recruited to the last patient, in blocks of 4. Microsoft Excel random number generator was used to pick 2 numbers from each stratified group, giving a total of 10 patients (5%) from both arms. The rationale for the stratification was to enable a selection of patients from across the study timeline, and a selection of prescribers in the control arm, as the study spanned across two rotations of junior doctors. Patients identified in the medication history in PACs not taking any medication were excluded, and another number was generated until a patient who was taking medication prior to admission was selected. One patient was subsequently removed from the control group, due to having been lost to follow-up from the main study.

**Panel selection**

The panel consisted of a number of different health professionals, recognising each other’s involvement in the care of surgical patients, prescribing expertise or both; a consultant anaesthetist, a consultant laparoscopic surgeon, a consultant clinical pharmacologist, a senior pharmacist with previous PAC experience, a senior PAC nurse, and a RMO with previous surgical and PAC experience. All panel members were independent to the research team.

**Medication appropriateness index**

Previous studies assessing appropriateness of prescribing, including non-medical prescribing, have identified the Medication Appropriateness Index (MAI) as the most suitable tool with which to assess appropriateness in an acute setting, with good inter and intra-rater variability [19]. The tool consists of a 10-item rating system: indication, effectiveness, dose, correct directions, practical directions, drug-drug interactions, drug-food interactions, duplication, duration and cost. Assessments were made on the MAI for our study; items regarding duration of therapy and cost effectiveness were not considered applicable due to the scope of the pharmacist’s prescribing being medications that the patient was already taking. Additional questions were added, as the MAI does not assess under prescribing.

Our finalised tool contained two questions to assess whether there had been an omission, and the significance in terms of potential ward inconvenience and patient harm. With regards to appropriateness of prescribing, the final tool contained 8 items. The original three-point Likert scale was dichotomized to either appropriate or inappropriate, as the original midpoint (marginally appropriate) was considered too subjective, as per previous studies [19].

Five patients were plotted by one member of the research team and one panel member prior to the panel assessment to assess whether the modified MAI could be applied to the patients appropriately, and to gain a rough estimate of an average time per patient. Time was in...
important factor, as this determined the number of patients that could be reasonably assessed, taking into consideration panel members' availability. A member of the research team met with all panel members prior to the panel meetings to discuss the modified MAI. Agreement was reached that it would be an appropriate tool to assess appropriateness and significance of omissions.

Assessment of prescribing and omissions

Panel members were provided with copies of patient's PAC notes, including the medication history taken by the PAC pharmacist, and the NIMHC. The panel was blinded as to whether the patients were control or intervention. There was a possibility that panel members may have been able to identify whether the patient was in the control arm or intervention arm from the handwriting of the prescriber, as they were provided with the original medication charts. However, this risk of bias was judged to be minimal due to the multiple prescribers in the control arm, and the patients being presented to the panel in a random order. Signatures were considered to be a more obvious risk to unblinding, and as such they were removed from the NIMHC that was given to the panel members. Resources provided included the Australian Medicines Handbook (AMH), locally produced PAC medication guidelines containing recommendations for management of medications post-operatively, and individual consultant preferences obtained by clinic for management of certain groups of medications post-operatively, for example anticoagulants. The panel was convened for 2 meetings, and each individual panel member rated every medication prescribed on the NIMHC using the criteria set out by the amended MAI. An unintentional omission was defined as any medication from the medication history not prescribed on the medication chart, with no supporting documentation as to why. Omissions were noted and panel members rated each case as whether it had the potential for patient harm, caused inconvenience, or both. Due to clinical duties only three panel members, the surgeon, clinical pharmacist and pharmacist were able to be present for both meetings and review all 39 patients. The other three panel members were only able to make one of the 2 sittings and reviewed as many patients possible in that time.

Data analysis

A medication was scored zero, and classed appropriate, if none of the 8 items on the MAI was rated as inappropriate. A medication was given a score of 1, and classed inappropriate, if one or more of the 8 items received a rating of inappropriate. Each panel members' ratings were evaluated individually, and ratings from all 8 panel members were combined, by adding the number of inappropriate ratings together. This gave the total number of medications that were rated as inappropriate prescribed, from the total number of reviews of medications that were undertaken by the panel. All statistical analysis was conducted using stata 14.2 (Stata Corp, College Station, TX). Categorical data was analyzed by chi-square tests. When the value in any one cell was below ten a mather's exact test was used as chi-square tests can become unreliable.

A p-value of <0.05 was considered statistically significant for the total number of omissions and individual reviewer assessment of appropriateness of prescribing.

Results

The sample included 19 patients, resulting in 294 medication assessments for appropriateness for the control arm, and 265 for the intervention arm, from the entire panel.

The demographics of patients selected for the appropriateness panel assessment were similar to those of patients from the main study [17] (Table 1).

Appropriateness of prescribing

Based on individual reviewer's assessments only one reviewer, the pharmacist, showed statistical significance, yet medications assessed inappropriate in the control arm, compared to 6/75 in the intervention (p=0.0.629).

Reviewer assessments were combined by adding the results together, in an attempt to describe the overall appropriateness. Out of 294 medication assessments across the panel for appropriateness, 32 (10.9%) of the medications prescribed in the control arm were classed inappropriate, when compared to 13 out of 265 (4.9%) in the intervention arm.

From the entire panel, an average of 5.7% of reviews across both arms were judged as inappropriate, with a range of 0-38.8%. Nine of the 19 patients were judged as having an inappropriate prescribing, 4 from the control arm and 5 from the intervention arm.

There was a 79% agreement between panel members on inappropriate prescribing.

Table 2 shows total medications prescribed by each panel member, and a breakdown of reasons why each reviewer thought an individual medication was prescribed inappropriately.

Omissions

There were significantly more omissions in the control arm, of which four panel members' individual assessments showed significant numbers had the potential for either patient harm or wasted inconvenience. Total unintentional medication omissions from the NIMHC in the main study was significantly higher for control patients (31.5%) compared to intervention (1.2%) (p=0.004, chi-square). Omissions from the 5% sample of patients were reflective of these results. Out of 89 regular medications in the patients' medication histories in the control arm, 25 (28%) were omitted from the NIMHC.

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Intervention</th>
<th>Control</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name Study</td>
<td>190</td>
<td>196</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>Sub Set</td>
<td>8%</td>
<td>10%</td>
<td>1%</td>
<td>0%</td>
</tr>
<tr>
<td>Age (years)</td>
<td>8.5 (5-88)</td>
<td>9.5 (6-85)</td>
<td>5.5 (6-83)</td>
<td>5.5 (6-77)</td>
</tr>
<tr>
<td>Male (%)</td>
<td>58%</td>
<td>59%</td>
<td>87%</td>
<td>67%</td>
</tr>
<tr>
<td>'Regular Medications'</td>
<td>45/126</td>
<td>42/132</td>
<td>4/112</td>
<td>3/100</td>
</tr>
<tr>
<td>'Other Required PRN'</td>
<td>2/71</td>
<td>1/40</td>
<td>2/66</td>
<td>0/0</td>
</tr>
<tr>
<td>Complementary and Alternative Medicine (CAM)</td>
<td>(0/51)</td>
<td>(0/43)</td>
<td>(0/71)</td>
<td>(0/54)</td>
</tr>
<tr>
<td>OTC/Medication (OTCM)</td>
<td>(0/53)</td>
<td>(0/62)</td>
<td>(0/11)</td>
<td>(0/11)</td>
</tr>
<tr>
<td>Total medications</td>
<td>194</td>
<td>193</td>
<td>19</td>
<td>56</td>
</tr>
<tr>
<td>Total medications (regular and PRN only)</td>
<td>1217</td>
<td>887</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Medication Charts Prescribed</td>
<td>16/1 (95%)</td>
<td>19/1 (100%)</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

2 mean [median] T median [range] 
 Regular medications are defined as medications prescribed with the intent to be taken on a regular basis. 
 PRN medications are defined as medications prescribed with the intent to be taken only when required.

Table 1: Characteristics of Study Population
Table 2: Number of Inappropriate Ratings and Reasons for Being Classed as Inappropriate by Reviewer

<table>
<thead>
<tr>
<th>Reason</th>
<th>Anesthetist</th>
<th>Pharmacist</th>
<th>Nurse</th>
<th>Pharmacist (RNO)</th>
<th>Surgeon</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication indicated</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Medication effective</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Dose correct</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Directions correct</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Drug-Drug interaction</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Drug-Disease interaction</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Duplication</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>3</td>
<td>1</td>
<td>6</td>
<td>13</td>
<td>10</td>
</tr>
</tbody>
</table>

NB: Medications may have been assessed as inappropriate for more than one reason. C = Control; I = Intervention.

Discussion

Our study showed that the appropriateness of prescribing from a collaborative doctor- pharmacist approach to prescribing was similar to usual care prescribing and produced medication charts that contained significantly fewer omissions of relevant medications.

Previous interventions to improve the appropriateness of prescribing have included an increase in clinical pharmacy involvement during the inpatient stay, which improved the prescribing of medicines [35,31]. Since the introduction of non-medical prescribing in UK, studies of appropriateness where nurses and pharmacists have taken on the prescribing role have shown that nurse and pharmacists were making clinically appropriate prescribing decisions [19,22].

There are various methods and tools in the literature to assess the appropriateness of prescribing, each with their own limitations [25,34]. The method chosen for our study was one of individual clinician judgement based assessment. It has been suggested that the results from this method may not always be valid, reproducible or generalizable. However, the same authors suggested that these limitations were remediable by using detailed specifications, validated instruments to obtain data and by training data collectors [1]. The use of the MAI satisfied all of these remitual criteria, although amongst the 6 panel members differences of opinion as to the appropriateness of prescribing, or the significance of an omission is inevitable. Another approach could have been to ask the panel to use the MAI to rate each medication as a panel, rather than individually. The authors felt the issue of perceived seniority within the panel may have introduced bias into the final decision, hence it was felt more reliable to ask each panel member to rate autonomously.

From Table 2, it can be seen that no one item from the assessment tool stood out as being the main reason why the prescribing was assessed as inappropriate across both arms. No indication, ineffective medications and duplication of medications can contribute to inappropriate polypharmacy, and increase the chance of medication misuse/va [3]. Inappropriate doses and directions for medication increase the chance of incorrect administration of medication as an inpatient [11]. Omissions of medications from inpatient medication chart, if not rectified during the inpatient stay, are likely to be omitted on any discharge information and summary as patients cross settings. This will expose the patient to an increased chance of poor outcomes, including unplanned 30-day readmissions [9].

The study is limited by the small numbers of patients assessed by the panel for appropriateness of prescribing, and the inability of the entire panel to review all the patients, due to time constraints. One of the recognised limitations of the MAI is that it is time-consuming, however, it was considered the best tool for the clinical setting in which the study was conducted. Panel members’ availability and the amount of time deemed reasonable for members to commit to the panel amongst other clinical commitments, limited the number of patients that it was possible to assess, which affected the statistical power of the study, and the ability to assess inter rater reliability. Future studies should bear in mind the requirement for all panel members to see all patients, to ensure consistency in the number of medications reviewed by each panel member.

The summing of the individual reviewer assessments to describe overall appropriateness of prescribing would be flawed in the event of a panel not agreeing on what makes prescribing inappropriate. However, the use of an objective, validated tool with good inter rater variability was used to counteract that concern. Difference of opinion is inevitable, but our panel reached 78% agreement, with regards to inappropriate prescribing.

It can be challenging to link inappropriate prescribing to important outcome measures, such as mortality, morbidity and adverse drug events. However, from what is known about the subject of polypharmacy, and omission of medication, there is little doubt that a review of
medications on admission, a complete and accurate medication chart during the inpatient stay, and accurate transfer of information on discharge are all essential components of effective medication management and quality use of medicines [5, 6, 7].

A methodology had been developed that provides guidance for future assessments of the appropriateness of prescribing in any study of non-medical prescribing. Results from this small snapshot of prescribing are encouraging, and merit repeating the panel assessment on a larger scale. Larger numbers and more robust statistical analysis are necessary to enable any sound conclusions to be drawn, and for the results to be extrapolated and generalised outside of our small study.

Conclusion

For the appropriateness of prescribing, observed results were similar between arms, as judged by individual panel members. Medication charts in the control arm contained significantly more omissions than in the intervention arm, a number of which were rated by the panel members as having the potential for patient harm or ward inconvenience.

A larger sample size is required to make statistical significance or non-inferior conclusions between the two arms.

Acknowledgements

The authors would like to thank the following people for their involvement in the study:

Ms Ching Ting Hung
Dr Thomas O’Rourke
Dr Elisabeth Maysock
Dr Gary Fox
Ms Elaine Brown

References


Appendix H. Chapter 5. Letter to the Editor, Anaesthetics and Intensive Care

Correspondence

Pharmacist prescribing of venous thromboembolism prophylaxis in a surgical pre-admission clinic

Venous thromboembolism (VTE) is the term used to describe the disease process which presents as either deep vein thrombosis or pulmonary embolism. It is a major cause of death and disability worldwide and places a large financial burden on healthcare systems. Multiple risk factors have been identified for the development of VTE, including hospitalisation for acute medical illness and surgery. Documentation of VTE risk assessment is a critical part of any patient admission, driven by evidence that a risk assessment is a trigger for VTE prophylaxis to be considered. Several barriers have been identified for undertaking VTE risk assessment, including lack of awareness by healthcare professionals about the incidence of VTE, lack of education about the risk assessment, disagreement with best practice clinical guidelines and no clear delegation for the responsibility of the risk assessment. Appropriate prescribing of VTE prophylaxis, with the associated reduction in the probability of VTE, is the ultimate goal. The ENDORSE (Epidemiologic International Day for the Evaluation of Patients at Risk of Venous Thrombosis in the Acute Hospital Care Setting) study showed that out of 17,084 surgical patients who were at risk of VTE only 52.5% received appropriate prophylaxis.

Pharmacist prescribing has been successfully implemented in a number of countries, some of the objectives being to make better use of the skills of the current multidisciplinary team and to optimise the use of clinicians' time. Given that this is a model of care not yet introduced in Australia, we would like to draw attention to the results of a randomised controlled trial of pharmacist prescribing that we have previously published.

The study was conducted in the surgical pre-admission clinic of a 750-bed tertiary teaching hospital in Queensland; the intervention pharmacist's scope of practice was the prescribing of inpatient medication charts, including VTE prophylaxis risk assessment documentation and prescribing. Appropriate VTE prophylaxis was defined as the guideline-recommended prophylaxis for the surgical unit under which the patient was admitted. Each surgical unit had a VTE prophylaxis guideline previously agreed between the Clinical Nurse Consultant for VTE and the doctors of each surgical unit. The locally produced guidelines define criteria that determine the need for anticoagulant and/or mechanical methods of VTE prophylaxis in high-risk patients and also contraindications to their use. Training for the prescribing pharmacist, as part of a supervised prescribing practicum, included case studies and sessions on VTE prophylaxis with a consultant vascular physician and the Clinical Nurse Consultant for VTE prophylaxis.

Control arm patients had their medication charts and VTE prophylaxis prescribed by the resident medical officer of the surgical team, as per usual care. In the intervention arm, out of 160 patients, a VTE risk assessment was documented 13 times (9%), of which 144 (94%) were assessed as being correct. In the control arm, out of 147 patients, a risk assessment was documented on one occasion (P <0.0001, exact). The intervention arm had an overall appropriateness for VTE prophylaxis prescribing in clinic of 150/160 (94%), compared to the control arm appropriateness of 94/147 (64%) (P <0.0001).

The Australian Commission on Safety and Quality in Healthcare has produced a medication safety action plan, which recommends possible actions by healthcare providers to ensure appropriate prophylaxis. These include routinely assessing all adults admitted to hospital for VTE risk; assessing bleeding risk and ordering appropriate prophylaxis where indicated; developing VTE prevention policies and clinical pathways; and training staff in VTE risk assessment, risk of bleeding, contraindications to prophylaxis and appropriate prophylaxis prescribing.

The model of care evaluated in this study, that of delegating VTE risk assessment and VTE prophylaxis prescribing to an appropriately trained pharmacist, as part of a defined scope of practice, has facilitated these recommendations and counteracted all of the barriers mentioned previously.

With the systems that are in place in hospitals—such as VTE advocates on the ward, nurse assessment of VTE risk on admission and ward pharmacy review on admission and during the inpatient stay—the appropriateness of VTE prophylaxis in the control arm should increase. This study showed the efficiencies that can be gained by a pharmacist documenting risk and prescribing prophylaxis in

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The initiative will save clinician time, both in the pre-admission clinic and the ward, and ensure more risk assessments are documented and that more patients receive appropriate prophylaxis on admission to the ward in a timely manner.

Documentation of VTE risk assessment and VTE prophylaxis prescribing was more appropriate in this new model of care. A multidisciplinary approach and investigation of new roles for existing healthcare professionals may be methods to consider in an attempt to ensure patients receive appropriate VTE prophylaxis.

A. Hale
H. Gibbs
I. Coombes
R. Collins
E. Maycock
L. Nissen
D. Brisbane, Queensland

References
9.9 Appendix I – Commissioned Editorial, Journal of Pharmacy Practice and Research

Hospital Pharmacists’ Views on Collaborative Prescribing

In 2008, Weeks et al. published the results of a postal survey, which explored the views of the Society of Hospital Pharmacists of Australia’s (SHPA) members on collaborative prescribing, and the extent of de facto prescribing in their institution. Since then, significant work has been undertaken on non-medical prescribing, such as pilots of pharmacist prescribing across Australia and a National Health Workforce report on developing a nationally consistent approach to prescribing by non-medical health professionals. The first stage of the Health Workforce Australia Health Practitioners Prescribing Pathway project is complete and the recommendations for implementation have been approved by the Standing Council in November 2013. New Zealand pharmacists obtained prescribing rights in 2013, and the first cohort of 14 prescribers have completed the postgraduate pharmacist prescribing course (jointly run by the Otgo and Auckland University of Technology). At the 39th SHPA national conference (19 to 22 September 2013), the Saturday breakfast session (‘Picking together the pharmacist prescribing puzzle – more than just paper and pills’) gave an overview of results from an Australian prescribing pilot, the collaboration between Australia and New Zealand and Australia’s current position in the pharmacist prescribing agenda. To make the session interactive, seven questions were interspersed throughout the presentation for the audience to answer via a smart phone application. Five questions from the Weeks et al. (2008) survey were utilized (to compare results and two new questions were added (to ascertain opinions on educational requirements for pharmacist prescribers). The 2008 survey elicited 551 responses, while at the conference 868 responses were received. In 2008, 95% of respondents compared to 98% (p = 0.4, exact) at the conference had witnessed system delays or pressure points where they believed collaborative prescribing could assist service delivery. The definition of de fact’ prescribing used in the 2008 paper was provided to the audience prior to question 2, namely ‘initiation, cessation, transcription, amendment or pre-protocol change of a medication order, excluding verbal orders from medical practitioners’. In 2008, 37% of pharmacists thought they were de facto prescribing compared to 84% in 2013 (p = 0.001, chi-square). This suggests there has either been an increase in the number of pharmacists taking on extended roles in the last 5 years or pharmacists are now more aware that the tasks they have always done could be classified as de facto prescribing. A higher proportion in 2013 (83%) would consider becoming a prescriber in a clinical area if there was a legal and credentialing framework compared to 75% in 2008 (p = 0.04, chi-square). This is encouraging, as there were concerns that low numbers would potentially make a prescribing course difficult to sustain. Similar proportions of respondents thought that a prescribing role would be important for the future development of hospital pharmacy practice: 79% in 2013 versus 77% in 2008 (p = 0.72, chi-square). A lower proportion in 2013 (57%) compared to 71% in 2008 (p = 0.007, chi-square) thought that the emergence of a prescribing role was important to attract and retain hospital pharmacists. The audience were presented training requirements from UK and New Zealand, and asked how many years of workplace experience should pharmacists have before being eligible to undertake a postgraduate prescribing course? The majority favoured a time period of more than 2 years, supporting the proposal that pharmacist prescribing be an ‘advanced practitioner’ role. 9% suggested prescribing should be taught at an undergraduate level, 3% thought pharmacists with 0 to 2 years experience, 48% believed 2 to 5 years was appropriate, and 39% suggested that more than 5 years was necessary. Opinions on the study burden of the New Zealand course were also investigated: 76% agreed that it was ‘just right’, 7% that more study was required and 17% opined the burden was too high. This is reassuring, because the majority of respondents (83%) would undertake significant extra training to be able to take on a prescribing role. Experience suggests that one of the biggest challenges the profession faces is the paradigm shift from reviewer to prescriber of medicines, and the realization of the different mindset and competencies required for this new role. This needs to be addressed as part of any future prescribing course.

Barriers to the set up and running of pharmacist prescribing pilots in Queensland were presented and the solutions were used to describe what the research team believed are facilitators to successfully progress the pharmacist prescribing agenda in Australia. The facilitators included:

- a senior ‘advanced level’ clinician with appropriate postgraduate qualifications
- accredited prescribing training to satisfy concerns over competence to prescribe
- recruitment of supportive, senior medical staff prior to commencement of the pilots, to be responsible for sign off of prescribing competencies and supervision
- clear collaborative scope of practice that had been agreed with the appropriate senior medical staff
- clear proposed outcomes and benefits of the service, with an emphasis on freeing up patient time, and better utilisation of skills within the existing multidisciplinary team
- overarching principle of providing patients with access to safe and appropriate medication usage.

Future proposed scope of practice and prescribing models for pharmacists to operate within as prescribers, need to be mindful of these requirements to ensure the best chance of success.

A unified approach from the entire pharmacy profession is essential, with agreement on proposed models of care, scope of practice, and training and education requirements to sustainably produce competent prescribers. Without this, progression of the new role, and ensuring the knowledge and skills of pharmacists are utilized to their full potential, will be a major challenge.

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9.10 Appendix J – Ethics Approval, Princess Alexandra Hospital

APPROVAL LETTER – Princess Alexandra Hospital

Research Protocol: 2009/050

Evaluation of the Impacts of a Doctor-Pharmacist Collaborative Prescribing Model in a Multidisciplinary Surgical Pre-Admission Clinic

NEAP Protocol

Participant Information and Consent Form:

Appointment Satisfaction Survey:
Pre-Admission Clinic Resident Medical Officer
Questionnaire: Pre Project and Post Project

At a meeting of the Princess Alexandra Hospital Human Research Ethics Committee (PAH HREC) held on 30/3/2009, the Committee reviewed the above research Protocol. The Princess Alexandra Hospital Human Research Ethics Committee is duly constituted, operates in accordance and complies with the current National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research 2007.

On the recommendation of the Human Research Ethics Committee approval is granted for your project to proceed. This approval is subject to researcher(s) compliance throughout the duration of the research with certain requirements as outlined in the National Statement on Ethical Conduct in Human Research 2007 and Australian Research Code for the Responsible Conduct of Research.

The following links have been provided for your convenience:

Some requirements are briefly outlined below. Please ensure that you communicate with the PAH HREC on the following:
- **Protocol Changes**: Substantial changes made to the protocol require HREC approval.
- **Problems and SAEs**: The HREC must be informed of any problems that arise during the course of the study which may have ethical implications. Serious Unexpected Adverse Events must be...
notified to the HREC as soon as possible in accordance with Good Clinical Practice (CPMP/ICH-E13/09).

- **Lapsed Approval:** If the study has not commenced within twelve months approval will lapse requiring resubmission of the study to the HREC.
- **Annual Reviews:** All studies are required by the NHMRC to be reviewed annually. To assist with reporting obligations an Annual Report template is available on the PAH HREC website. This form is required to be completed and returned to the HREC within the 12 month reviewing period.

As this research involves the recruitment of patients from the Princess Alexandra Hospital Health Service District (PAH-HSD), it is my responsibility to remind you of your ongoing duty of care for all patients recruited into projects or clinical trials whilst public patients. All conditions and requirements regarding confidentiality of public information and patient privacy apply. You are required to comply at all times with any application requirements of Australian Law including the Health Services Act, the Privacy Act and other relevant legislation, other obligations and guidelines which may be applicable to the PAH-HSD from time to time including, without limitation, any requirement in respect of the maintenance, preservation or destruction of patient records.

When the study involves patient contact, it is your responsibility as the principal investigator to notify the relevant consultant and request their approval.

Should you have any problems, please liaise directly with the Chair of the HREC early in the program.

A copy of this letter should be presented when required as official confirmation of the approval of the Princess Alexandra Hospital Human Research Ethics Committee.

We wish you every success in undertaking this research.

Yours sincerely,

[Signature]

Dr David Thallo Snr
DISTRICT CHIEF EXECUTIVE OFFICER
METRO SOUTH DISTRICT

[Date]
9.11 Appendix K – Temporary Change in Legislation for Prescribing Pilots

HEALTH (DRUGS AND POISONS) REGULATION 1996

APPROVAL UNDER SECTION 18(1)

I, Jeannette Rosita Young, delegate of the Chief Executive, Queensland Health, approve the following persons:

Pharmacists Registered in Queensland who are employed or contracted to Queensland Health and working in the Pharmacist Prescribing Pilot Project

to perform the function/s listed in the table below for the scheduled drugs and poisons listed in the corresponding column:

<table>
<thead>
<tr>
<th>Function</th>
<th>Class of Drug and Poisons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescribe</td>
<td>Controlled drugs, Restricted drugs and Schedule 2 and 3 poisons</td>
</tr>
<tr>
<td>Give an oral or written instruction to administer the drug or poison, to a person who is authorised under the Health(Drugs and Poisons) Regulation 1996 to administer the drug or poison</td>
<td>Controlled drugs, Restricted drugs and Schedule 2 and 3 poisons</td>
</tr>
</tbody>
</table>

subject to the following conditions:

1. The approval is limited to those named pharmacists participating in the Pharmacist Prescribing Pilot Project and in accordance with the project’s administrative guidelines. These guidelines are those that have been endorsed in writing by the Senior Director Medication Services Queensland on behalf of the Ministerial Working Group for Pharmacist Prescribing and must address:

   ▪ Appropriate medical mentoring;
   ▪ Fitness for the role; and
   ▪ Any limitations deemed appropriate.
2. The functions must be performed in accordance with any relevant sections of the *Health (Drugs and Poisons) Regulation 1996*.

3. The duration of this approval is from the date of signature below for a period of two years, unless sooner suspended, cancelled, replaced or surrendered, whichever occurs first.

Given under my hand this 5th day of August 2008.

Dr Jeanette Young
Delegate of the Chief Executive
Queensland Health

Approval No. EH-ATH-3853

Please note that no expiry reminder advice will be issued. Should you wish this approval to be reissued then a fresh application should be made.

---

NOTICE

*HEALTH (DRUGS AND POISONS) REGULATION 1996*

Section 18(3)

Notice is given to the approval holder that the conditions included on approval No. EH-ATH-3853 have been imposed for the reasons stated below.

REASONS:

*Condition 1:* Limits the approval to pharmacists participating in the Pharmacist Prescribing Pilot Project and that they use appropriate guidelines in the use of the scheduled drugs and poisons.

*Condition 2:* Ensures compliance with relevant sections of the *Health (Drugs and Poisons) Regulation 1996*.

*Condition 3:* Limits the life of the approval.

You may appeal against the imposition of these conditions within 28 days to a Magistrates Court.
9.12 Appendix L – Patient Information and Consent Form

APPENDIX 1

PATIENT INFORMATION SHEET
Medication Services Queensland

LOCAL PROJECT SPONSORS: Dr Elizabeth Maycock – Consultant Anaesthetist
Miss Ching Ting Hung – Senior Pharmacist

FULL PROJECT TITLE: A study to evaluate the impact of a collaborative doctor–pharmacist joint prescribing care plan on medication management in a surgical Pre-Admission Clinic.

What is the Project Trying to Assess?
This project aims to assess the quality of care of a pharmacist prescriber being responsible for the management and prescribing of your regular medications, by working under the guidance of the surgical doctors and anaesthetists in Pre-Admission Clinic.

Is Pharmacist Prescribing A New Initiative?
Pharmacist prescribing is an initiative that has been running in The United Kingdom, The United States and Canada for a number of years. Pharmacist prescribing is a new model of patient care for Australia, and if patient care and outcomes are shown to benefit from this practice, it may act as a demonstration model for pharmacists in other settings.

What Will Participation In This Project Mean For Me?
By agreeing to participate in this research project, you will be randomly allocated into one of two possible groups:

1. The pharmacist you see in Pre-Admission Clinic will take a medication history and provide you with a plan for your medications before and after your operation, under the guidance of the surgical doctors and anaesthetist. They will also prescribe your medication chart for use when you are admitted to the ward, and medication to reduce the chance of a blood clot after your surgery, if necessary.

2. The pharmacist you see in Pre-Admission Clinic will take a medication history, provide you with a plan for your medications before and after your operation under the guidance of the surgical doctors and anaesthetist, but the prescribing of your medication chart for use when you are admitted to the ward will be the responsibility of the surgical doctors.

If I Am Being Seen By The Prescribing Pharmacist Will I Still See My Doctor?
Yes, there will be no other difference to your clinic appointment. You will also still see a nurse, surgical doctor and anaesthetist for assessment prior to your surgery.

Will I Have to Make More Trips To The Clinic Than Normal?
No, being seen by the pharmacist prescriber does not mean you will have to make any more visits to hospital or clinic than usual.

Will I Have to Give More Blood Than Normal?
No, you will not be asked to provide any blood samples apart from the tests that are done routinely as part of your usual pre-surgical assessment.
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So What Will Be Different From Usual?

We will also ask you to complete a questionnaire after your appointment with the pharmacist on your satisfaction with the pharmacy service. The questionnaire will take approximately 5 minutes.
We will also phone you approximately 30 days after you have been discharged from hospital to ask you a few questions about your experiences in hospital and since you were discharged. This phone call should take no longer than 10 minutes.

Will I Benefit Directly From Participating In The Project?

We cannot guarantee or promise that you will receive any benefits from this research, however your involvement may produce improvements in the quality of patient care and service delivery by allowing alternative work practices in the clinic.

Will I Be Placed Under Any New Risks From Participating In This Project?

We do not envisage that your participation in this project will involve more risk to you than usual care.

Do I Have To Agree To Participate In The Project?

Participation in this research project is entirely voluntary. If you do not wish to take part you do not have to give a reason and your participation chart will be prescribed by your usual doctor.
If you decide not to participate, or decide to withdraw from the project at a later date, this will not affect your ongoing care or relationship with the clinic staff or the hospital.

If I Have Any Questions About The Project?

Please call the investigator contact number below should you have any questions about the project, if you wish to withdraw, or you are interested in the results of the research.
All efforts will be made to protect your privacy.
Any information obtained in connection with this research project that can identify you will remain confidential and will only be used for the purpose of this research project.
In any publication and/or presentation, information will be provided in such a way that you cannot be identified.
Information about your participation in this research project may be recorded in your health records.

PRINCIPAL RESEARCHERS: Dr Ian Coombes
Dr Karen Whitfield

INVESTIGATOR CONTACT NAME: Andrew Hale, Project Co-ordinator,
Pharmacist Prescribing Project

INVESTIGATOR CONTACT ADDRESS: Medication Services Queensland
Royal Brisbane Hospital,
Block 7, Level 13,
Hasten,
Brisbane

INVESTIGATOR CONTACT NUMBER: 07 3658 9139
Mon – Fri, 9am – 5pm

If you have any complaints about any aspect of the project, the way in which it is being conducted or any questions about being a research participant in general, then you may also contact:

ETHICS MANAGER,
Princess Alexandra Human Ethics and Research Committee,
Level 2, Building 35, Princess Alexandra Hospital,
Ipswich Road, Woolloongabba, 4102.
Telephone: 07 3240 5566

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PATIENT CONSENT FORM

PROJECT TITLE: A study to evaluate the impact of a doctor–pharmacist joint prescribing care plan on the management of medications in a surgical pre-admission clinic.

I have read, or have had read to me in a language that I understand, this document and I understand the purposes, procedures and possible risks of this research project as described within it and I agree to take part.

I understand that I may not directly benefit from taking part in this project.

I understand that, while information gained during the study may be published, I will not be identified and my personal results will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I understand that I can withdraw from the study at any stage and that it will not affect my medical care, now or in the future.

I understand that should I wish to withdraw from the study, the research team may use data collected up to that point.

I understand that I will be given a signed copy of this document to keep.

Participant’s name (printed) .................................................................

Signature  
Date

Name of witness to participant’s signature (printed) ....................................................

Signature  
Date

Declaration by recruiting person: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Recruiting Person’s name (printed) .................................................................

Signature  
Date

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PHARMACIST APPOINTMENT SATISFACTION SURVEY

PATIENT TRIAL ID ______________________

Age _____ Gender: Male/Female (delete as appropriate)

Surgical Speciality ________________________________

Are you taking any regular medication? (circle as appropriate) YES / NO

We are interested in your experiences and satisfaction with the appointment that you just had in the clinic with the pharmacist. Please circle one response for each of the following statements that best reflects how you feel.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Uncertain</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>I am satisfied by the consultation provided by the pharmacist</td>
<td>SA</td>
<td>A</td>
<td>U</td>
<td>D</td>
<td>SD</td>
</tr>
<tr>
<td>The pharmacist explained to me clearly what his/her role was in Pre-Admission Clinic</td>
<td>SA</td>
<td>A</td>
<td>U</td>
<td>D</td>
<td>SD</td>
</tr>
<tr>
<td>The pharmacist did not listen to me</td>
<td>SA</td>
<td>A</td>
<td>U</td>
<td>D</td>
<td>SD</td>
</tr>
<tr>
<td>The pharmacist did not explain clearly what to do with my medications before my operation</td>
<td>SA</td>
<td>A</td>
<td>U</td>
<td>D</td>
<td>SD</td>
</tr>
<tr>
<td>The pharmacist did not explain clearly what to do with my medications after my operation</td>
<td>SA</td>
<td>A</td>
<td>U</td>
<td>D</td>
<td>SD</td>
</tr>
<tr>
<td>The pharmacist checked that I understood what to do with my medications</td>
<td>SA</td>
<td>A</td>
<td>U</td>
<td>D</td>
<td>SD</td>
</tr>
<tr>
<td>Any information the pharmacist gave me was irrelevant and difficult to understand</td>
<td>SA</td>
<td>A</td>
<td>U</td>
<td>D</td>
<td>SD</td>
</tr>
<tr>
<td>The pharmacist answered any questions I asked in a way I easily understood</td>
<td>SA</td>
<td>A</td>
<td>U</td>
<td>D</td>
<td>SD</td>
</tr>
<tr>
<td>I felt the pharmacist understood any concerns I had about my medications</td>
<td>SA</td>
<td>A</td>
<td>U</td>
<td>D</td>
<td>SD</td>
</tr>
<tr>
<td>I did not trust the pharmacist’s ability to provide me with a plan for the management of my medication</td>
<td>SA</td>
<td>A</td>
<td>U</td>
<td>D</td>
<td>SD</td>
</tr>
<tr>
<td>To make sure the pharmacist is giving me the right plan I would like it to be checked by a doctor in the clinic</td>
<td>SA</td>
<td>A</td>
<td>U</td>
<td>D</td>
<td>SD</td>
</tr>
<tr>
<td>I am more comfortable discussing medication related issues with the pharmacist than the doctor in the clinic</td>
<td>SA</td>
<td>A</td>
<td>U</td>
<td>D</td>
<td>SD</td>
</tr>
<tr>
<td>The information the pharmacist gave me has helped me prepare for my surgery</td>
<td>SA</td>
<td>A</td>
<td>U</td>
<td>D</td>
<td>SD</td>
</tr>
</tbody>
</table>
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Any other comments about the pharmacy service or would you like to elaborate on any of your answers above?

_________________________________________
_________________________________________
_________________________________________
_________________________________________
_________________________________________
_________________________________________
_________________________________________
_________________________________________

Any other comments about ways in which this service could be improved?

_________________________________________
_________________________________________
_________________________________________
_________________________________________
_________________________________________
_________________________________________
_________________________________________
_________________________________________

Thankyou for taking the time to complete this questionnaire
30 DAY POST-DISCHARGE TELEPHONE INTERVIEW

PATIENT TRIAL ID____________________

Introduction

Good morning/afternoon <Patient’s name>, this is <Caller’s name> from the pharmacist prescribing project at the Pre-Admission Clinic, Princess Alexandra Hospital. I was wondering if now was a good time to ask you a few questions about your experiences since you have been home from hospital after your surgery? It should take no more than 5 minutes.

NO → Arrange to call again at a more convenient time

YES

↓

Questions

1. In the time since your discharge from hospital after surgery have you had to visit your GP for any reason?

NO → Go to question 2
YES → Was it a planned visit, or for something unexpected?

Planned/routine → Go to next question 2 (after confirming not medication related)

Unexpected →
What was the reason for having to visit your GP?

Was the reason you had to visit your GP medication related?

YES → Provide further details
NO → Go to question 2

2. **In the time since your discharge from hospital after surgery have you had to visit the Emergency Dept at any hospital for any reason?**

NO → Go to question 3
YES → **What was the reason for having to visit ED?**

Was the visit to ED medication related?

YES → Provide further details

NO – go to question 3

↓

3. **Have you been re-admitted to hospital at all since discharge after your surgery?**

NO → Go to question 4
YES → **Was it a planned readmission, or was it unexpected?**

Planned/expected → Go to question 4 *(after confirming not medication related)*

Unexpected →

**What was the reason for your readmission to hospital?**
Was the reason for admission medication related?

YES → Provide further details

NO – go to question 4 if appropriate

↓

For question 4, the person calling will have access to the patient’s plan for medication peri-operatively, so will know whether any medications, and in particular anti-coagulants, were withheld pre-operatively.

4. Are you now taking the medication that was withheld before your operation – (confirm medication name with patient eg aspirin, clopidogrel?)

YES – When did you re-start the medication, and who gave you the instruction to re-start? Was it in hospital or after you left hospital?

NO – Is this for any particular reason eg more planned surgery, or have you been told not to restart the medication?

If the patient is not taking medication of significance (eg anti-coagulants) withheld prior to surgery, and the reason is not apparent, it will be followed up with the relevant surgical team.

Thankyou for your time and agreeing to participate in the study.

Do you have any questions with regards to the study?

End Phone Call