A TEAM APPROACH TO OPTIMISING MEDICATION OUTCOMES IN PRIMARY CARE

A thesis submitted for the Degree of

Doctor of Philosophy

by

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ERRATA/ ADDENDUM

p 90, reference 67: should read: "Bolton PGM, Tipper SW, Tasker JL. Medication review by GPs reduces polypharmacy in the elderly: A quality use of medicines program. Aust J Prim Health. 2004;10(1):78-82."

p 125, Table 3.1 legend: add "DBI = Beck Depression Inventory"

p 133: Add at the start of page:

"Discussion

This systematic review and meta-analysis evaluated RCTs that investigated clinical services delivered by pharmacists co-located in general practice clinics. Findings from this review highlight the benefits of interprofessional communication and collaboration that occur with co-location."

p 212, Table 8.1: comment: Although the terms 'precaution' and 'contraindication' are not interchangeable, they have been combined in this table for simplicity of presentation.

p 214, line 5: should read: "A letter and information leaflet about Vitamin D were mailed by the researchers in consultation with the GPs and practice pharmacist to patients with a diagnosis of osteoporosis."

If there is an amateur reader still left in the world – or anybody who just reads and runs – I ask him or her with untellable affection and gratitude, to split the dedication of this book four ways with my parents and brother.

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List of abbreviations

ADE	adverse drug event
ADR	adverse drug reaction
APC	Ambulatory Payment Classification
AU$	Australian dollars
BBQ	Beliefs and Behaviour Questionnaire
BMD	bone mineral density
BMI	body mass index
CDM	chronic disease management
CENTRAL	Cochrane Central Register of Controlled Trials
CI	confidence interval
COPD	chronic obstructive pulmonary disease
CPD	continuing professional development
CPT	Current Procedural Terminology
CrCl	creatinine clearance
DBP	diastolic blood pressure
DUE	drug use evaluation
DVA	Department of Veterans Affairs
ED	emergency department
GDP	gross domestic product
GP	general practitioner
GPMP	GP Management Plan

HbA_{1C}	glycosylated haemoglobin
HDL	high-density lipoprotein
HEDIS	Healthcare Effectiveness Data and Information Set
HMR	Home Medicines Review
HRQoL	health-related quality of life
HRT	hormone replacement therapy
IMPACT	Integrating Family Medicine and Pharmacy to Advance Primary Care Therapeutics
IPA	International Pharmaceutical Abstracts
IQR	interquartile range
LDL	low-density lipoprotein
LPC	long patient consultation
MAI	Medicines Appropriateness Index
MAP	medication-related action plan
MBS	Medicare Benefits Schedule
MeSH	Medical Subject Heading
MRP	medication-related problem
MTM	medication therapy management
MTR	medication therapy review
NHS	National Health Service
NSAID	non-steroidal anti-inflammatory drug
OR	odds ratio
OTC	over-the-counter

PBS	Pharmaceutical Benefits Scheme
PCMH	patient-centred medical home
PCPCC	Patient-Centred Primary Care Collaborative
PHCT	primary healthcare team
PINCER	A pharmacist-led information technology intervention for medication errors
PIP	Practice Incentive Payment
PIPS	Pharmacists in Practice Study
PMR	personal medication record
PNIP	Practice Nurse Incentive Program
QUM	Quality Use of Medicines
RCT	randomised controlled trial
RESPECT	Randomised Evaluation of Shared Prescribing for Elderly people in the Community over Time
RMMR	Residential Medication Management Review
SBP	systolic blood pressure
SCRIPT	Successful Collaborative Relationships to Improve PatienT Care
SD	standard deviation
SMART	Seniors Medication Assessment Research Trial
SPC	short patient consultation
SPSS	Statistical Package for the Social Sciences
TABS	Tool for Adherence Behaviour Screening
TCA	Team Care Arrangement

TG	triglyceride
UK	United Kingdom
US$	American dollars
USA	United States of America
VA	Veterans Affairs
WHO	World Health Organization

Abstract

Background

Practice pharmacists often work in general and family practice clinics overseas, undertaking a variety of roles aimed at improving quality use of medicines by staff and patients. In Australia, the presence of pharmacists within general practice is uncommon and collaboration between general practitioners (GPs) and pharmacists in primary care remains low. There is currently limited Australian research evaluating the practice pharmacist role and stakeholder experiences with these services. Given that medication-related problems (MRPs) continue to be of concern in Australia, and quality use of medicines has been identified as an important quality indicator in general practice, the integration of pharmacists into Australian general practice warrants further investigation.

The overall aim of the PhD project was to develop and evaluate the role of a practice pharmacist within Australian general practice.

Methods

Firstly, a systematic review and meta-analyses of randomised controlled trials was undertaken to evaluate the effectiveness of pharmacist services delivered in general practice clinics on a variety of outcomes.

Secondly, semi-structured interviews with a purposive sample of GPs and pharmacists was undertaken to explore their views on the integration of pharmacists into the general practice setting.

Thirdly, a prospective, before-after study (the Pharmacists in Practice Study [PIPS]) was conducted at two primary healthcare clinics in Melbourne, Australia. The intervention consisted of a multi-faceted, collaborative service involving a part-time practice pharmacist co-located in each of the study clinics for six months. The practice pharmacists provided long and short patient consultations, drug information and education services, and quality improvement activities (a drug use evaluation [DUE] program for osteoporosis management). The main outcome measures were MRPs, medication adherence, quality of prescribing osteoporosis medicines, and experiences of staff and patients (explored both quantitatively and qualitatively using surveys, interviews, focus groups and narrative reports).

Key findings

The systematic review included 38 studies, and found that pharmacists co-located in general practice clinics delivered a variety of interventions, with favourable results seen in certain areas of chronic disease management and quality use of medicines. Seventeen studies were included in meta-analyses and found significant reductions in systolic blood pressure (-5.72 mmHg [95% CI, -7.05 to -4.39, $p<0.001$]), diastolic blood pressure (-3.47 mmHg [95% CI, -4.35 to -2.58, $p<0.001$]), glycosylated haemoglobin (-0.88% [95% CI, -1.15 to -0.62, $p<0.001$]), LDL-cholesterol (-18.72 mg/dL [95% CI, -34.10 to -3.36, $p<0.017$]), total cholesterol (-32.00 mg/dL [95% CI, -54.86 to -9.14, $p<0.006$]) and Framingham cardiovascular risk score (-1.83% [95% CI, -3.66 to 0.00, $p=0.05$]) following pharmacist intervention.

A total of 11 GPs and 16 pharmacists took part in the stakeholder interviews. The interviews revealed that although there was a positive professional relationship between GPs and pharmacists, there were limitations to the delivery of collaborative services.

Various roles and methods of integration for pharmacists in general practice were identified, and it was suggested that these roles could offer both advantages and disadvantages; however, a number of barriers and facilitators to integration would need to be considered to ensure viability of services.

In the PIPS, 82 patients received a long patient consultation and 62 (75.6%) were followed up over six months. After six months, the median number of MRPs fell from 2 (IQR 1, 4) to 0 (IQR 0, 1), $p<0.001$. The proportion of patients who were adherent to their medicines improved significantly, according to both the Morisky (44.1% versus 62.7%, $p=0.023$) and the TABS (35.6% versus 57.6%, $p=0.019$) scales. Patients were highly satisfied with the consultations, with 80.6% reporting they would like to have a pharmacist available in the clinic in the future. Twenty-five short patient consultations were undertaken, the majority of which addressed patient education (48.0%) and provided medication profiles (32.0%). The pharmacists documented 12 drug information queries and delivered four education sessions to staff. A total of 225 patients with a diagnosis of osteoporosis at baseline and 240 at the post-intervention audit 12 months later were part of the DUE program. The proportion of patients without documented contraindications to osteoporosis therapies who were prescribed an anti-osteoporosis medicine increased significantly from baseline at 12 months (134/225 [58.7%] vs. 168/240 [70.0%], $p=0.002$). Thirty-four participants were recruited to provide feedback on pharmacy services: 18 patients, 14 practice staff (9 GPs, 4 practice nurses, 1 practice manager), and two practice pharmacists. Five main themes emerged: environment; professional relationships and integration; pharmacist attributes; staff and patient benefits; and logistical challenges. Staff and patients were generally positive about the clinical pharmacy services.

Conclusions

This project demonstrated the feasibility and value of pharmacist roles in optimising medication use in Australian primary healthcare clinics, and their acceptability by stakeholders. These findings will guide further research in this area.

General Declaration

Declaration for thesis based or partially based on conjointly published or unpublished work

In accordance with Monash University Doctorate Regulation 17 Doctor of Philosophy and Research Master's regulations the following declarations are made:

I hereby declare that this thesis contains no material which has been accepted for the award of any other degree or diploma at any university or equivalent institution and that, to the best of my knowledge and belief, this thesis contains no material previously published or written by another person, except where due reference is made in the text of the thesis.

This thesis includes four original papers published in peer reviewed journals, one in press and two unpublished publications. The core theme of the thesis is the integration of pharmacists into primary health care clinics. The conception of ideas, their development and writing up of all the manuscripts in the thesis were the principal responsibility of myself, the candidate, working within the Centre for Medicine Use and Safety under the supervision of Dr Johnson George, Associate Professor Kay Stewart and Mr Rohan Elliott.

The inclusion of co-authors reflects the fact that the work originated from active collaboration between researchers and acknowledges input into team-based research.

In the case of **Chapters 3** to **9** my contribution to the work involved the following:

Thesis chapter	Publication title (publication status)	Nature and extent of candidate's contribution
3	Pharmacist services provided in general practice clinics: a systematic review and meta-analysis **(in press)**	Reviewed literature; designed methods; developed study materials and search strategies; undertook data extraction and synthesis; performed data analysis including meta-analysis; prepared manuscript
4	Integration of pharmacists into general practice in Australia: the views of general practitioners and pharmacists **(published)**	Reviewed literature; designed methods; coordinated the ethics application; developed study materials; carried out recruitment and interviews; performed data analysis; and prepared manuscript
5	An exploration of the role of pharmacists within general practice clinics: the protocol for the Pharmacists in Practice Study (PIPS) **(published)**	Reviewed literature; designed methods; developed study materials and protocol; established collaborations; and prepared manuscript
6	Pharmacist services provided in general practice clinics: an overview of the Pharmacists in Practice Study (PIPS) **(in preparation)**	Reviewed literature; designed methods; developed study materials; established collaborations; carried out recruitment; undertook data collection; performed data analysis; and prepared manuscript
7	Pharmacist consultations in general practice clinics: the	Reviewed literature; designed methods; developed study materials; established

Thesis chapter	Publication title (publication status)	Nature and extent of candidate's contribution
	Pharmacists in Practice Study (PIPS) **(published)**	collaborations; carried out recruitment; undertook data collection; performed data analysis; and prepared manuscript
8	Osteoporosis management in general practice: a practice-pharmacist led drug use evaluation program **(under review)**	Reviewed literature; designed methods; developed study materials; established collaborations; assisted with delivery of interventions; performed data collection and analysis; prepared manuscript
9	Stakeholder experiences with general practice pharmacist services: a qualitative study **(published)**	Reviewed literature; designed methods; coordinated the ethics application; developed study materials; carried out recruitment and interviews and focus groups; performed data analysis; and prepared manuscript

I have reformatted submitted or published papers in order to generate a consistent presentation within the thesis.

Signed: ……

Date: ……

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Communications

Journal publications

Published

Tan ECK, Stewart K, Elliott RA, George J. An exploration of the role of pharmacists within general practice clinics: the protocol for the Pharmacists in Practice Study (PIPS). *BMC: Health Services Research* 2012;12(1):246.

Tan ECK, Stewart K, Elliott RA, George J. Integration of pharmacists into general practice in Australia: the views of general practitioners and pharmacists. *Int J Pharm Pract.* Published Online First: 11 June 2013. doi: 10.1111/ijpp.12047

Tan ECK, Stewart K, Elliott RA, et al. Stakeholder experiences with general practice pharmacist services: a qualitative study. *BMJ Open* 2013;3:e003214. doi:10.1136/bmjopen-2013-003214

Tan ECK, Pharmacist consultations in general practice clinics: the Pharmacists in Practice Study (PIPS). *Res Social Adm Pharm*. Published Online First: 4 October 2013. doi:10.1016/j.sapharm.2013.08.005

In Press

Tan ECK, Stewart K, Elliott RA, George J. Pharmacist services provided in general practice clinics: a systematic review and meta-analysis. *Res Social Adm Pharm* (in press)

Under Review

Tan ECK, Elliott RA, Stewart K, George J. Improving osteoporosis management in general practice: a pharmacist-led drug use evaluation program. *Osteoporos Int* (under review)

In Preparation

Tan ECK, Stewart K, Elliott RA, George J. Pharmacist services provided in general practice clinics: an overview of the Pharmacists in Practice Study (PIPS). *Aust Fam Physician* (in preparation)

Conference Presentations

Tan ECK, Stewart K, Elliott RA, George J. Improving osteoporosis management in general practice: a pharmacist-led drug use evaluation program (submitted). Australasian Pharmaceutical Science Association, 8-11 December 2013, Dunedin

Tan ECK, Stewart K, Elliott RA, George J. An evaluation of clinical services provided by pharmacists co-located in general practice clinics: the Pharmacists in Practice Study (PIPS) (submitted). Australasian Pharmaceutical Science Association, 8-11 December 2013, Dunedin

Tan ECK, Stewart K, Elliott RA, George J. Improving osteoporosis management in general practice: a pharmacist-led drug use evaluation program (poster presentation). Pharmacy Australia Congress, 10-13 October 2013, Brisbane

Tan ECK, Stewart K, Elliott RA, George J. Integrating Pharmacists into Australian primary healthcare clinics: the Pharmacists in Practice Study (PIPS) (poster presentation). Pharmacy Australia Congress, 10-13 October 2013, Brisbane

Tan ECK, Stewart K, Elliott RA, George J. Pharmacist interventions provided in family practice: a systematic review (poster presentation). American Society of Health-System Pharmacists Midyear Clinical Meeting, 2-6 December 2012, Las Vegas

Tan ECK, Stewart K, Elliott RA, George J. Pharmacist integration into Australian primary healthcare clinics: the Pharmacists in Practice Study (PIPS) (oral presentation). Pharmacy Australia Congress, 18-21 October 2012, Melbourne

Tan ECK, Stewart K, Elliott RA, George J. Pharmacist integration into Australian primary healthcare clinics: the Pharmacists in Practice Study (PIPS) (oral presentation).7th Annual Postgraduate Research Symposium, Monash University, 26 September 2012, Melbourne

Tan ECK, Stewart K, Elliott RA, George J. Integration of pharmacists into Australian primary healthcare clinics: an introduction to the Pharmacists in Practice Study (PIPS) (oral presentation). National Medicines Symposium, 24-25 May 2012, Sydney

Tan ECK, Stewart K, Elliott RA, George J. Is there a role for pharmacists in general practice? (oral presentation). Australasian Pharmaceutical Science Association, 11-14 December 2011, Adelaide

Tan ECK, Stewart K, Elliott RA, George J. Collaboration between pharmacists and general practitioners (oral presentation). Pharmacy Australia Congress, 6-9 October 2011, Melbourne.

Tan ECK, Stewart K, Elliott RA, George J. Collaboration between pharmacists and general practitioners (oral presentation). 6th Annual Postgraduate Research Symposium, Monash University, 28 September 2011, Melbourne

Awards

2013 John Bertrand Leadership series, invited participant

2012 Pharmacy Australia Congress 2012, contributed paper presentation winner

2012 7th Annual Postgraduate Research Symposium, prize winner

2012 Faculty of Pharmacy and Pharmaceutical Sciences Three Minute Thesis, finalist

2012 Centre for Medicine Use and Safety Department Three Minute Thesis, winner

2010 Centre for Medicine Use and Safety Department Three Minute Thesis, winner

Chapter 1. Introduction

1.1 Problem statement

Patients living with chronic health conditions are best managed by a well prepared, proactive, multidisciplinary practice team;[1, 2] however, pharmacists often exist on the periphery of the primary healthcare team. This is unfortunate given the prevalence of medication-related problems (MRPs) in general practice and pharmacists' expertise in medication management and quality use of medicines.[3] Although collaborative services delivered by pharmacists and general practitioners do exist in the community, these are currently limited and underused due to various barriers such as geographical isolation, poor interprofessional communication and limited access to patient clinical information.[4, 5] A potential solution to overcoming these challenges is the co-location of pharmacists within primary healthcare clinics. Whilst practice pharmacists work in general and family practices overseas,[6] such a model of collaborative care is still uncommon within Australia and local evidence of scope and effectiveness is lacking. Thus, this model of healthcare delivery warrants further exploration.

1.2 Aim & Objectives

This PhD project aimed to explore, develop and evaluate the role of a practice pharmacist in the Australian primary healthcare clinic setting.

The specific objectives were to:

- Systematically review the literature on clinical services provided by pharmacists co-located within primary care clinics;
- Elucidate stakeholder views on the integration of pharmacists into general practice; and
- Implement and evaluate the impact of a pharmacist providing clinical services in a general practice clinic (including evaluation of clinical and humanistic outcomes)

1.3 Thesis overview

The thesis begins with a review of the literature on integration of pharmacists into primary healthcare teams. Chapter 2 provides a general review and summary of the literature about current theory and practice surrounding primary care; adverse drug events; quality use of medicines; primary health care teams and interprofessional collaboration; pharmacists as members of the primary health care team; stakeholder perceptions on integration; barriers and facilitators to integration; and service and funding models. Chapter 3 describes a systematic review and meta-analysis of randomised controlled trials of clinical interventions delivered by pharmacists co-located within primary care practices. A summary of findings from both reviews, and identification of gaps in the literature, is provided at the end of Chapter 3.

Chapter 4 explores stakeholder perspectives on pharmacist integration into Australian primary healthcare clinics through a series of interviews.

Findings from these initial chapters helped guide the development of the intervention evaluated in *the Pharmacists in Practice Study (PIPS)*, described in Chapter 5.

Chapter 6 presents a commentary on the main findings of the PIPS.

Chapter 7 presents a detailed analysis of the pharmacist long patient consultation (medication review) component of the PIPS.

Chapter 8 reports the pharmacist-led drug use evaluation component of the PIPS.

Feedback and experiences of stakeholders who participated in the PIPS are explored in Chapter 9.

Overall recommendations, directions for future research and final conclusions are made in Chapter 10.

1.4 References

1. Wagner EH. Chronic disease management: what will it take to improve care for chronic illness? *Eff Clin Pract.* 1998;1(1):2-4.

2. Wagner EH. The role of patient care teams in chronic disease management. *BMJ.* 2000;320(7234):569-72.

3. Miller GC, Britth HC, Valenti L. Adverse drug events in general practice patients in Australia. *Med J Aust.* 2006;184(7):321-4.

4. Dobson RT, Henry CJ, Taylor JG, Zello GA, Lachaine J, Forbes DA, et al. Interprofessional health care teams: attitudes and environmental factors associated with participation by community pharmacists. *J Interprof Care.* 2006;20(2):119-32.

5. Edmunds J, Calnan MW. The reprofessionalisation of community pharmacy? An exploration of attitudes to extended roles for community pharmacists amongst pharmacists and General Practioners in the United Kingdom. *Soc Sci Med.* 2001;53(7):943-55.

6. Fish A, Watson M, Bond C. Practice-based pharmaceutical services: a systematic review. *Int J Pharm Pract.* 2002;10:225-33.

Chapter 2. Literature review

2.1 Introduction

The purpose of this literature review is to provide a general overview regarding quality use of medicines in primary care and the integration of pharmacists into general practice. The review will begin with a snapshot of primary care in Australia (**Section 2.2**), including the challenges faced and the need for reform. In **Section 2.3**, a review of adverse drug events will be presented, followed by a discussion of quality use of medicines principles and the various strategies available to attain them in **Section 2.4**. Interprofessional collaboration and team-based care will be explored in **Section 2.5**, including the determinants of successful teams in primary care and the adoptability of pharmacists into these teams. A thorough review of studies investigating pharmacist integration into primary healthcare teams will then take place in **Section 2.6**, followed by an examination of stakeholder perceptions of pharmacist services in **Section 2.7**, including barriers and facilitators to integration (**Section 2.8**). **Section 2.9** reviews the various funding and service models for these services. **Section 2.10** then introduces the systematic review and meta-analyses (**Chapter 3)** that complements the findings of this chapter.

2.2 Primary Care in Australia

2.2.1 Definition

Primary care is first-contact, continuous, comprehensive, and coordinated care provided to populations undifferentiated by gender, disease, or organ system.[1] It may be defined in

several ways, in terms of functions, providers and funding sources.[2] The Australian Primary Health Care Research Institute defines primary health care as:

"Socially appropriate, universally accessible, scientifically sound first level care provided by health services and systems with a suitably trained workforce comprised of multi-disciplinary teams supported by integrated referral systems in a way that:

- gives priority to those most in need and addresses health inequalities;
- maximises community and individual self-reliance, participation and control; and
- involves collaboration and partnership with other sectors to promote public health.

Comprehensive primary health care includes health promotion, illness prevention, treatment and care of the sick, community development, and advocacy and rehabilitation."[3]

Health systems with strong primary care are more efficient, have lower rates of hospitalisations, fewer health inequalities and achieve better health levels, higher satisfaction and lower health service costs.[1, 3]

In Australia, primary health care comprises a range of different services including general practice, community health services (such as community nursing and aged care programs), pharmacy, dental and allied health services.[2]

2.2.2 General Practice and Other Primary Healthcare Services

General practice (family practice) provides person-centred, continuing, comprehensive and coordinated whole person health care to individuals and families in their communities.[4] It has been identified as the most suitable location for coordinating the care of individuals with complex and chronic conditions.[3] Around 83% of Australians visit a general practitioner (GP) at least once a year.[5] GPs commonly provide routine care of

acute and chronic conditions, in addition to acting as gate keepers to other health services in the community.[6]

Over the years, general practice has seen an increase in patients with multiple co-morbidities and complexity; however, consultation lengths have remained the same.[5] Practices are also becoming more multidisciplinary, with GPs working in larger clinics with the integration of practice nurses and allied health professionals.[2]

Accessibility of GP services is influenced mainly by affordability. There is a universal Government medical insurance scheme (managed by Medicare Australia), which covers all or most of a patient's costs for a GP visit.[5] This is known as bulk billing (when a provider bills Medicare directly for any medical or allied health service that the patient receives) and plays an important role in ensuring affordability of services.[7] The remuneration structure for general practitioners is largely fee-for-service, with exceptions being salaried medical practitioners working within community health centres.[2, 5] There are no compulsory patient lists or registration in general practice; individuals are free to see multiple practitioners and visit multiple practices of their choice. Reforms to the funding of GP services have occurred over the last decade, with the implementation of blended payment methods to encourage high-quality, preventive care and greater referrals to allied health professionals.

Aside from general practice, the Australian primary healthcare system comprises a range of other services. Community health services play an important role in the primary health system and aim to improve the health and wellbeing of individuals, particularly those with, or at risk of, poorer health.[8] These mainly involve publically funded community nursing and aged care programs which are funded on a targeted, non-universal basis.[2]

These services vary considerably across states, and there is no national strategy for their implementation.

Dental and allied health services provided in the community are mainly privately funded by individuals and private health insurance funds. The funding of pharmacy services provided in the community will be described later, in Section 2.8.1

2.2.3 Challenges in Primary Care

The challenges facing the primary health care sector are multi-faceted and inter-related.[2] Factors include:

- political issues, such as weak political support or public interest compared to other areas of healthcare;
- attributes of clients, especially vulnerable populations (including the elderly and those with multiple co-morbidities and disabilities), and the complexity of the intervention choices available for their care;
- organisational issues involving poor coordination of multiple, disparate services and poor collaboration between health providers;
- funding issues related to the multiple sources of Commonwealth and state funding and a lack of clear government responsibilities; and
- professional issues related to interprofessional rivalries, with health providers possessing different ideologies and having different training.

In a report produced by the Department of Health and Ageing*, Primary Health Care Reform in Australia – Report to Support Australia's First National Primary Health Care Strategy*,[3] a number of major challenges were highlighted as exerting pressure on Australia's health system. These included:

- demographic trends;
- burden of disease;
- changes in delivering care;
- increasing expectations;
- economic implications; and
- changes in the health workforce

Demographic trends

The ageing of the Australian population is set to continue at an accelerated rate. The Australian Bureau of Statistics (ABS) estimates that the proportion of people aged 65 years and over is projected to increase from 13% in 2007 to between 23% and 25% in 2056 and to between 25% and 28% in 2101.[9] Additionally, the proportion of Australians aged 85 years and over is projected to increase rapidly from 1.6% in 2007 to between 4.9% and 7.3% by 2056 and to between 5.8% and 9.3% by 2101.[9]

Older Australians are major users of GP services, with people aged 65 years and over taking up 29.7% of consultation time.[5] This cohort of patients also over present to their GP with more problems than younger people, are prescribed more medications per visit and have longer average consultations.[3, 5] Older Australians are also significant users of allied health and nursing services.[3]

Burden of disease

The increase in the proportion of older people in the community has contributed significantly to the high prevalence of chronic disease. More than three-quarters of Australians have at least one chronic health condition with more than 80% of those aged 65 years and older having three or more.[10] In addition to ill health and disability, chronic diseases are also a major economic burden, both on the patient and for the wider

community. In 2000–01 they accounted for nearly 70% of the total health expenditure that can be allocated to diseases.[10, 11]

Changes in delivering care

As the acute sector shifts towards attaining high throughput and reduced lengths of stay, there is greater pressure on post-acute and convalescent care. Patients on discharge from hospital often require greater and more complex care from primary health care providers. Additionally, some services traditionally provided within the hospital sector are now provided in the community (e.g. dialysis, chemotherapy and mental health services), thus further placing a burden on primary healthcare services.[3]

Increasing expectations

As consumers and health providers gain increasing awareness of what constitutes best practice care, coupled with the emergence of new technologies that can improve the way services are provided, their expectations of the health system also increase. Gaps in service provision, as a result of inequity in the provision of health services, is a major challenge.[3]

Economic implications

According to the Australian Government's *Intergenerational Report 2010*, health spending is projected to grow from 4.0 per cent of GDP in 2009–10 to 7.1 per cent of GDP in 2049–50.[7] Population ageing will contribute to spending growth; from 2009-10 to 2049-50, real health spending is expected to increase around seven-fold for those aged over 65 years and twelve-fold for those over 85 years. In addition, growth is projected to stem from increasing demand for health services and the funding of new technologies.[7]

Changes in the health workforce

In 2006, there were 548,400 health workers in Australia, an increase of 22.8% since 2001.[8] Over the same period, the health workforce aged with the proportion of workers in the 55 to 64 years age bracket increasing by 4 percentage points, coupled with a small decrease in the proportion aged 35 to 44 years (down by 1.8 percentage points).[8] There continues to be maldistribution of health professionals across Australia, with regional and remote areas experiencing medical workforce shortages, especially in general practice services. Workforce shortages are also increasingly being experienced in disadvantaged urban areas.[3, 8]

2.2.4 Chronic Care Model

Chronic disease poses major challenges for the current organisation of the Australian health care system. Current administrative arrangements do not encourage integration of health services, and payment mechanisms are largely based on acute or episodic care. This is unlike the United Kingdom (UK) and the United States of America (USA) which use capitation models of funding and patient enrolment with medical practices.[2] It has been shown that patients who receive structured, coordinated care of their chronic illnesses have improved outcomes. The Chronic Care Model developed by Wagner et al,[12] provides a framework for optimal care and consists of six elements:

- Community resources and policies;
- Health care organisation;
- Self-management support;
- Delivery system design;
- Decision support; and
- Clinical information systems.

Optimisation of the above elements will enable improved patient outcomes through productive interactions between an informed, activated patient and a prepared, proactive team.[13, 14] Whilst Australia has attempted to improve care coordination through programs such as Medicare Chronic Disease Management (CDM) items, there are limitations to these, and further reforms to service and funding models to encourage coordination and integration of general practice and other health services in the community are needed.

2.2.5 Reforms to the Primary Care System

To meet growing demands on the health system, many developed countries, including Australia, are undergoing significant reforms to their primary health care policies. This restructuring endeavours not only to manage the increased burden of an ageing population with complex and chronic diseases, but also to provide improved quality of care in the presence of workforce shortages, inequity and limited resources.[3, 15, 16]

As the number of patients on multiple medicines and complex medication regimens increases in the community, the odds of medication-related incidents also rise. This warrants appropriate medication management strategies to ensure safe and quality use of medicines in primary care. These issues will be discussed in the next section.

2.3 Adverse Drug Events in Primary Care

2.1.1 Definitions

Medication-related problems (MRPs) may be defined as "an event or circumstance involving a patient's drug treatment that actually, or potentially, interferes with the achievement of an optimal outcome."[17] Some MRPs lead to adverse drug events (ADEs), which may be defined as "medication incidents that cause harm to the patient".[18] ADEs encompass both harm that results from the intrinsic nature of the medicine (an adverse

drug reaction [ADR]) and harm that results from medication errors or system failures associated with the manufacture, distribution or use of medicines.[18]

Adverse drug events may be classified according to their severity and preventability. Generally, events may be described as mild (a reaction or other adverse outcome of limited duration which may or may not require further treatment and with minimum impact on daily activities), moderate (a reaction or adverse outcome of longer duration or which requires further treatment; and which limits daily activities), or severe (a reaction or other outcome of any duration which results in hospitalisation and/or long-term limitations of daily activities).[19]

An ADE may be considered preventable if it could have been avoided by any means currently available (unless that means is not considered standard care).[19, 20]

For example:

- Better communication between health professionals;
- Better communication between patient and health professionals;
- Better knowledge of a patient's medical history; and
- More appropriate choice of medicine or dose.

2.3.2 Adverse Drug Events Globally

Adverse drug events are a serious concern globally. In the USA, up to 25% of patients in the ambulatory care setting experience an ADE each year[21] with one-fourth being potentially serious or life-threatening.[22] Additionally, as many as 200,000 people may die from ADEs each year.[23] ADEs are estimated to cost at least US$200 billion annually; however, half of these ADEs are potentially preventable.[23]

In the UK, it is estimated that 4.5% to 5% of hospital admissions result from preventable drug-related morbidity, and that preventable harm from medication use could cost more than £750 million annually.[24] A report from the General Medical Council in the UK revealed that one in 20 prescriptions in general practice contain an error, affecting one in eight patients.[25] More than half of these were considered at moderate or severe risk for potential harm. A systematic review of studies addressing error rates in medicines management in primary care in the UK revealed that only 4% to 21% of patients achieve optimum benefit from their drug therapy.[26]

Kongkaew et al. conducted a systematic review of prospective and observational studies that used a consistent definition for ADRs. The review found that the prevalence rates of hospital admissions associated with ADRs ranged from 0.16% to 15.7% with an overall median of 5.3% internationally.[27] Higher rates of ADRs were found in elderly patients likely due to the use of multiple medicines for chronic disease management. The review also concluded that studies using more intensive forms of ADR detection, such as medical record review and patient interview, found higher prevalence rates for ADR admissions.

2.3.3 Adverse Drug Events in Australia

Adverse drug events are a significant burden on Australia's health system, particularly in the community setting. It is estimated that one in 10 patients who visit their GP have experienced an ADE in the previous six months, of which almost half were considered moderate or severe, with 8% requiring hospitalisation.[19] Approximately one in four of these events were considered preventable.

A review of Australian studies by Roughead and Semple concluded that 2% to 3% of hospitalisations (approximately 190,000 events annually) result from problems with medicines, and approximately 50% of these are preventable.[28] It was estimated that over

1.5 million Australians suffer an ADE each year, and that more than 400,000 ADEs may be managed in general practice annually.[28, 29] The cost to the community is significant, with estimates for medicine-related hospital admissions in 2008 at AU$660 million.[28] Medication-related incidents remain the second most common type of incident reported in Australian hospitals.[28]

These findings are consistent with previous reviews, which similarly found that 2% to 4% of all Australian hospital admissions were medication-related, increasing to 30% for patients over 75 years of age.[30-32] Additionally, three quarters of these admissions were potentially preventable.[32]

Roughead et al.[33] studied 1000 community-dwelling patients who were at risk of medication misadventure and had received medication management review services. The pharmacists who conducted the medication reviews identified MRPs, which were then categorised by the researchers. The study found that 90% of the included patients experienced some type of MRP, with a mean of 2.2 MRPs per patient. One in three people were observed to require additional monitoring, one in four required additional medication, and one in four were using wrong or inappropriate medication.[33] The retrospective nature of the study and missing information may have resulted in underestimation of MRPs.

In their study on actual and potential medication-related harm in general practice, Bhasale et al.[34] observed that 76% of the medication incidents reported were preventable and 27% had the potential for severe harm. Over half of these incidents were related to poor pharmacological management. Of these medication-related incidents, deaths were recorded in 3% and major harm in 15%.

2.3.4 Contributors to ADEs

Patient groups at an increased risk of ADEs in the community include the elderly, those taking multiple medicines and those taking high-risk medications.[35, 36] High-risk medications include cardiovascular drugs, antithrombotic agents, analgesics, antibiotics, oral antidiabetic agents, antidepressants, anti-epileptic drugs and chemotherapeutic agents.[35] ADEs associated with anticholinergics and benzodiazepines are common in the elderly.[35]

Poor communication has been identified as a common contributor to ADEs, in particular, poor communication between patients and health professionals, between general practitioners and pharmacists and between health professionals at the transfer of care.[21, 34, 36, 37] Poor communication may account for up to 60% of MRPs.[38] Better transfer of medical information between healthcare providers[34] and enhanced collaboration between GPs and pharmacists may improve medication safety.[39]

Other significant contributing factors included cognitive errors and deficiencies, and organisational or work-related factors such as insufficient staffing and poor workplace systems, particularly in the community pharmacy environment.[35]

2.4 Quality use of medicines

Following the World Health Organization (WHO) Conference of Experts on the Rational Use of Drugs held in 1985, the WHO prepared a document known as the 'Revised Drug Strategy'.[40] The following year, the 39th World Health Assembly endorsed this strategy, which encourages governments to employ a National Medicinal Drug Policy. Being a member of this assembly, Australia participated in the development of this strategy.[41] The

demand for a National Medicinal Drug Policy was further highlighted in the 'Health for All Australians' document jointly issued by all Australian Health Ministers in 1988.[41]

By the 1990s, a comprehensive policy was put in place, including a policy on Quality Use of Medicines (QUM), and in December 1999 a formal policy document, *Australia's National Medicines Policy*, was launched.[42]

Australia's National Medicines Policy is an established framework that aims to improve the health outcomes of Australians through their access to and wise use of medicines.[42] It consists of four, interdependent key objectives (See Fig 2.1):

- timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- medicines meeting appropriate standards of quality, safety and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable medicines industry.

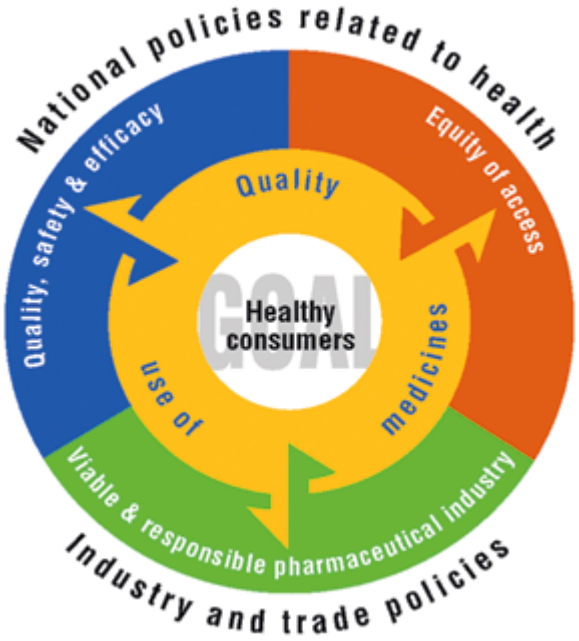


Figure 1.1. QUM and the National Medicines Policy[43]

A central component of this framework is QUM, which is defined as:

- *Selecting management options wisely* by considering the place of medicines in treating illness and maintaining health, and recognising that there may be better ways than medicine to manage many disorders;
- *Choosing suitable medicines if a medicine is considered necessary* so that the best available option is selected by taking into account the individual, clinical condition, pharmacotherapeutic considerations and costs; and
- *Using medicines safely and effectively* to get the best possible results by monitoring outcomes; minimising misuse, over-use and under-use; and improving people's ability to solve problems related to medication.[44]

The National Strategy for Quality Use of Medicines aims to improve QUM and is influenced by several key partners including healthcare consumers, their carers and the general community; health practitioners and health educators; health and aged-care facilities; medicines industries; media; healthcare funders and purchasers; and government. All partners have various responsibilities and must work in collaboration to achieve QUM.[44]

The National Strategy identifies the primacy of consumers; partnership; consultative, collaborative, multidisciplinary activity; support for existing activity; and systems-based approaches as being key principles when undertaking QUM activities.[44]

QUM is supported by six building blocks:

- policy development and implementation;
- facilitation and coordination of QUM initiatives;

- provision of objective information and assurance of ethical promotion of medicines;
- education and training;
- provision of services and appropriate interventions; and
- strategic research, evaluation and routine data collection.[44]

A multi-strategic, multi-level systems approach, which involves all partners at all stages of learning across all settings, has been identified as a key method for the implementation of actions to achieve QUM.[44]

2.4.1 Strategies to improve Quality Use of Medicines in Primary Care

Common strategies for improving QUM in the community include electronic prescribing, clinical decision support systems, educational outreach visits and other educational programs, audits and feedback, the provision of consumer information and medicines management services.[44]

In Australia, several of these services are government or not for profit organisation-led initiatives targeting consumers and health practitioners. Implementation of many QUM programs are driven by NPS MedicineWise (formally known as the National Prescribing Service) in partnership with general practice networks (Medicare Locals), and Department of Veterans Affairs (DVA).

A brief discussion on some common strategies, followed by a more in-depth review of medicines management services delivered by pharmacists in collaboration with GPs is provided below.

e-Health interventions

Computerised prescribing (electronic prescribing or e-prescribing) with clinical decision support and ADE alerts are some approaches used by GPs to reduce ADEs in the primary care setting.[18] Computerised prescribing systems are computer-based systems for ordering medications, which allow clinicians to enter medication orders directly, usually via a prepopulated list of medicines.[45, 46] Computerised clinical decision support systems are information systems designed to improve clinical decision making, and may be incorporated into computerised prescribing systems. Individual patient characteristics are matched to a computerised knowledge base, and software algorithms make recommendations specific to the patient.[47]

In Australia, over 90% of GPs use one of the 20 or so commercially available systems to write prescriptions, order pathology and other tests, record medical progress notes or communicate with other healthcare providers.[5, 47] Although such electronic systems are used widely in Australia, there is currently a lack of clear standards or guidelines for their development or implementation.[46] This has resulted in a variety of systems with markedly different capabilities, especially with regards to assisting GPs to prescribe safely and effectively.[47]

Systematic reviews of studies have shown that computerised prescribing systems can enhance the safety and quality of prescribing by ensuring complete and legible prescription orders, improving the detection of drug allergies and by reducing ADEs.[48, 49] However, these systems can also have negative effects on workflow and communications, and can compromise quality of prescribing. For example, they may introduce new types of errors[50, 51] and high levels of unhelpful alerts.

Most research, however, has been undertaken in hospital settings, and it is unknown how generalisable these findings are to primary care. Of the limited research undertaken in primary care, effects on ADEs have been disappointing. A systematic review[45] of 30 studies evaluating outpatient computerised prescribing found that of the four studies assessing safety, there was no significant effect on the number of ADEs. The authors concluded that there was no evidence that computerised prescribing systems enhance safety or reduce cost in outpatient settings. A systematic review[50] of 17 studies assessing the types and effectiveness of clinical decision support systems found that only nine studies had definitive positive effects on outcomes such as prescribing appropriateness, medication costs and attaining treatment goals. However, studies assessing the effect of clinical decision support systems on safety outcomes, including studies targeting oral anticoagulation dosing[52, 53] and heart disease management,[54] were found to have no significant effect on mortality, hospital admissions, ED visits and ADEs. It has also been shown that one in 10 electronic prescriptions include at least one MRP, of which a third are potentially harmful, a rate consistent with manually written prescription error rates.[55] Despite this, there are limitations to these studies. Error rates may vary across different systems and most studies are limited to single systems within one institution and are not easily generalisable to systems that are commercially available.[18]

Although there is some inconsistency in results, it is reported that the risk of unintended consequences and introduction of new errors result from poorly designed applications and failure to appreciate the organisational implications associated with their introduction.[48] Both Australian and international professional bodies endorse the implementation of electronic prescribing and clinical decision support systems in primary care.[46]

Educational Outreach (Academic Detailing)

The term educational outreach (academic detailing) is used to describe a personal 'face-to-face' visit by a trained person to health professionals in their own settings. These visits are usually conducted by specially trained clinical pharmacists or other physician "opinion leaders".[56] Soumerai and Avorn[57] describe the key techniques including:

1. conducting interviews to investigate baseline knowledge and motivations for current prescribing patterns;
2. focusing programs on specific categories of physicians as well as on their opinion leaders;
3. defining clear educational and behavioural objectives;
4. establishing credibility through a respected organizational identity, referencing authoritative and unbiased sources of information, and presenting both sides of controversial issues;
5. stimulating active physician participation in educational interactions;
6. using concise graphic educational materials;
7. highlighting and repeating the essential messages; and
8. providing positive reinforcement of improved practices in follow-up visits.

Educational outreach visits have the potential to change GPs' practice, particularly prescribing.[54, 57] A Cochrane review[58] of 69 studies evaluating educational outreach visits found them to improve the delivery of care to patients. With regards to changing prescribing practice, educational outreach visits were seen to consistently provide small to moderate changes in prescribing, which could be potentially important. Pharmacists working in educational outreach can have several roles including academic detailer,

reviewer of evidence for topics, developer of key messages and content/supporting tools, developer of the evaluation framework and trainer of other academic detailers.[59]

In Australia, NPS MedicineWise facilitators conduct educational outreach visits with GPs on relevant therapeutic topics that are linked to national activities and resources.[60] The facilitators are specially trained in health professional learning, clinical therapeutics and evidence-based medicine. The information and discussions are tailored to suit the individual GP, and participation in such visits may contribute to the GP's continuing professional development (CPD).[60]

Audit and Feedback

Audit and feedback involves measuring a health professional's performance and then comparing it to professional standards or targets. These data are then fed back to the individual with the aim of encouraging them to follow professional standards. This is a quality improvement process often used together with other interventions, such as educational meetings or reminders.[61]

A Cochrane review[61] of 140 studies found that audit and feedback generally leads to small but potentially important improvements in professional practice. The effectiveness of audit and feedback appears to depend on baseline performance and how the feedback is provided.[61] An exploratory analysis found that the largest effect was seen in prescribing appropriateness compared with other targeted behaviours such as the ordering of laboratory tests and management of diabetes or cardiovascular disease.

Drug Use and Evaluation (DUE) is a form of audit and feedback, targeting medicine prescribing or use. It is a systematic, criteria-based evaluation of medicine use within a health organisation that aims to improve medicine use.[62, 63] It is a cyclical, iterative process that consists of two phases: an investigative phase which involves an audit to

measure and define drug use, identify drug use problems and measure the impact of interventions; and an interventional phase which involves reviewing audit results, problem solving, consensus building and implementing strategies to improve drug use. [64]

DUE requires a multidisciplinary approach, usually involving physicians and pharmacists and sometimes other health professionals.[63] DUE has traditionally been conducted in hospital settings, but can be applied to any practice setting, including primary care. It can be used to evaluate the use of a specific drug or therapeutic class or management of a disease state or condition.[63]

In Australia, GPs may participate in NPS MedicineWise clinical audits which are free quality improvement activities that help GPs review their current prescribing practice for patients with certain conditions, compared with current best practice guidelines.[65] NPS MedicineWise also have DUE activities that focus on specific disease states or therapeutic areas for aged care homes and hospitals.[66]

GP Medication Reviews

A comprehensive GP-conducted medication review integrates a number of specific actions, including obtaining an accurate medication history, examination of the purpose and actual use of medications, shared GP-patient confirmation, reinforcement of expected outcomes, and follow-up as required.[67]

There is limited research investigating the effectiveness of medication reviews conducted solely by the GP. Bolton et al.[67] conducted an observational study in Australia involving 62 GPs and 694 patients (≥65 years and taking ≥5 medicines) from New South Wales and Western Australia. Patients received two medication reviews, six months apart. At the second review, a statistically significant reduction in the total number of medications ($p < 0.001$), and the dose ($p = 0.028$) and number ($p = 0.008$) of benzodiazepines was

observed. Limitations of this study included self-reporting by GPs, Hawthorne effect and loss to follow-up of participants.

A small prospective, randomised study involving 50 patients (≥ 65 years old, taking ≥ 2 medicines) who underwent a 10-minute medication review with their GP was conducted in Ireland.[68] The intervention resulted in significant reductions in the mean number of medications taken and inappropriate medicines prescribed ($p < 0.001$). Limitations of this study included the small sample and use of a single practice, which limit generalisability.

GP-conducted medication reviews have thus been shown to reduce polypharmacy and improve prescribing appropriateness; however, the clinical outcomes of these reviews have not been studied. With consultation times becoming progressively shorter,[69] GPs often do not have the time to undertake medication reviews. A qualitative analysis of 100 routine GP visits with patients (≥65 years old) in California, USA, found that comprehensive medication reviews or discussions about chronic medications are uncommon during visits.[70]

The prevention and resolution of ADEs in general practice is not the sole responsibility of the GP, so involvement of other health professionals, in consultation with their patients, is desirable.[29]

Multiple Strategies

An overview of 41 systematic reviews of interventions that aimed to change prescriber behaviour[71] found that passive approaches (e.g. dissemination of guidelines) are generally ineffective and unlikely to result in behaviour change. Most other interventions are effective under some circumstances, with educational outreach for prescribing and reminders seen as promising approaches. Multifaceted interventions targeting different barriers to change were concluded to be more effective than single interventions. The

avoidance and management of ADEs is a complex process, often requiring the use of multiple strategies.[35]

Pit et al investigated the combined effectiveness of the above mentioned QUM interventions in Australia.[72] A cluster RCT was carried out to evaluate the effectiveness of a QUM program delivered at the level of the general practice in the Hunter Region of Australia. Twenty GPs and 849 patients (≥65 years old and community dwelling) participated in the trial. The intervention comprised educational outreach visits by a clinical pharmacist, the provision of prescribing information and feedback, medication risk assessment of patients, and medication review by the GP facilitated by using a checklist. The intervention resulted in participants in the intervention group having significantly higher odds of having an improved composite score (reflecting use of benzodiazepines, NSAIDs and thiazide diuretics) than control-group participants (OR, 1.86; 95% CI, 1.21–2.85) and lower odds of using NSAIDs (OR, 0.62; 95% CI, 0.39–0.99) at 4-month follow-up but not at 12-month follow-up. There was a significant reduction in falls by 12-months (OR, 0.61; 95% CI, 0.41– 0.91), but no significant changes were found for health-related quality of life (HRQoL) or use of benzodiazepines or thiazide diuretics. Low participation rates of GPs (12%) may reduce generalisability of the findings; participation rates were higher in the intervention groups which may raise questions regarding the effectiveness of blinding, and high attrition rates meant the study was underpowered for detecting significant differences in the primary outcome.

2.4.2 Pharmaceutical care

Pharmacists have training and expertise in identifying and resolving MRPs and ADEs. Pharmacist interventions have been shown to have beneficial effects on prescribing behaviour and are important in improving medication safety in primary care.[73, 74] They

can contribute to optimising patient health outcomes by providing pharmaceutical care and ensuring successful drug therapy.[17]

Hepler and Strand[75] defined pharmaceutical care as "the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life." These outcomes include: the curing of a disease, the elimination or reduction of symptomatology, the arresting or slowing of disease progression, or preventing a disease or symptomatology. An updated definition describes pharmaceutical care as "a patient-centred practice in which the practitioner assumes responsibility for a patient's drug-related needs and is held accountable for this commitment".[76]

Pharmaceutical care is a process that involves the pharmacist cooperating with the patient and their other health professionals to effectively design, implement and monitor a therapeutic plan. The key functions of the pharmacist are to: identify actual and potential MRPs, resolve actual MRPs, and prevent potential MRPs.[75]

Pharmaceutical care can encompass various models, activities and definitions, and be delivered across a range of healthcare settings. Various terms such as clinical pharmacy services, cognitive services, medication management, medication therapy management (MTM) and medication review have been described as pharmaceutical care.[77] Pharmaceutical care interventions generally include: a one-to-one consultation between a patient and a pharmacist with a focus on managing health or resolving MRPs, development of a care-plan, and follow-up. Such interventions are patient-centred and are targeted towards those at high risk of medication misadventure.[77]

Pharmacist-led medication reviews

Pharmacist-led medication reviews, as part of a multidisciplinary team, are one of the most common means of providing pharmaceutical care in the community.[18] The goal of

pharmacist-led medication reviews are medication regimen optimisation and ADE prevention and resolution. In Australia, such services are typically carried out in the patient's home (Home Medicines Review [HMR]),[78] community pharmacy (Medscheck)[79] or aged care facility (Residential Medications Management Review [RMMR]).[80]

The HMR program was introduced in 2001 by the Australian Government with the aim of improving health outcomes for patients and promoting QUM.[81] It involves the patient, their GP, an accredited pharmacist, regular community pharmacy, and other healthcare professionals and carers if needed.[78] After the patient is identified as having a clinical need for an HMR, the GP writes a referral to either an accredited consultant pharmacist or the patient's nominated community pharmacy, and obtains patient consent to participate. The accredited pharmacist then visits the patient at their home and reviews their medicine. Information provided by the patient, community pharmacy and GP (with the HMR referral) are used to identify potential and actual MRPs. The accredited pharmacist then provides the GP (and community pharmacy) with a report of recommendations. The GP and patient then agree on a medication management plan at a follow-up appointment.[81]

Despite evidence of benefits from pharmacist-led medication management services in some studies, especially with regards to improved medicine use and surrogate clinical endpoints,[77] the effectiveness of this service on patient health outcomes in the community has been mixed. Previous rigorous studies of pharmacists' medication reviews in community-dwelling patients have shown mixed effects on patient outcomes for appropriateness of medication, drug knowledge, healthcare costs, rates of hospital admissions, GP visits, quality of life and mortality, as will be described below.

A large-scale, multicentre RCT involving 2454 patients (≥65 years old) from 190 community pharmacies was undertaken across seven European countries by Bernsten et al.[82] The study found that pharmaceutical care provided by community pharmacists had no significant effect on HRQoL, hospitalisations, patient-reported disease control or mean total cost per patient at 18 months. Some countries, however, found improvements in some outcomes such as patient compliance and self-reported problems with medicines.[83] Limitations of this study included the differences in healthcare systems between countries which hindered economic evaluation.

Sorensen et al.[84] conducted a RCT involving 92 GPs, 53 pharmacists and 400 patients (at risk of medication misadventure e.g. taking ≥5 medicines) across three Australian states. The intervention consisted of GP education, patient home visits, pharmacist-led medication reviews, team case conferences, GP implementation of action plans in consultation with patients, and follow-up visits for monitoring. The intervention did not have a significant effect on clinical outcomes (perceived disease severity, ADEs, hospitalisation or health-service use) or HRQoL, and produced modest cost savings at six months. Participants were highly satisfied with the model of care. The study benefited from the rigorous cluster design; however, it was limited by the short duration of follow-up for the chosen outcome measures.

The Randomised Evaluation of Shared Prescribing for Elderly people in the Community over Time (RESPECT) trial[85] utilised a multiple interrupted time-series design in five primary care trusts in the UK. The study involved 760 older patients (≥75 years old and taking at least five medications) who were recruited from 24 general practices and followed over three years. After interviewing patients and developing and implementing pharmaceutical care plans together with patients' GPs, community pharmacists undertook monthly medication reviews with patients for 12 months. The intervention had no

significant effect on appropriateness of prescribing or quality of life. Although the study used robust methods including cluster-randomisation and was well-powered, it was limited by self-selection of practices which might have introduced bias. The intervention was estimated to be cost-effective despite a lack of statistical significance in the effect.[86]

The HOMER trial,[87] a RCT which assessed home-based medication reviews in patients (>80 years old and taking two or more daily medicines) after discharge from hospitals in Norfolk and Suffolk in the UK, found a significantly higher rate of hospital readmissions but no significant improvement in quality of life or reduction in mortality at six months. The study was strengthened by the large sample size (n=872) and low attrition rate (3%), but the demographics of the sample (older and more ill) may limit generalisability to the general, medicine-taking community. Additionally, pharmacists did not have access to patient medical histories (only a discharge letter) which may have limited the effectiveness of the intervention.

Another RCT, involving 332 general practice patients (≥65 years and taking at least four medications) in Scotland, assessed the effectiveness of home-based medication reviews by 'clinically-trained' pharmacists. The study found no significant effect on medical costs, quality of life or health service use at three months.[88] Limitations of the study included potential contamination due to randomisation at the patient level, insufficient duration for implementation of pharmaceutical care plans and data collection by the study pharmacist introducing detection bias.

Systematic reviews and meta-analyses have revealed that whilst pharmacist-led medication reviews in primary care may improve process outcomes such as prescribing appropriateness, they are relatively ineffective in modifying outcomes such as hospital admissions.[89-91]

Royal et al.[89] undertook a systematic review and meta-analysis of interventions in primary care to reduce medication-related adverse events and hospital admissions. Of the 38 included studies, 17 included a pharmacist-led medication review component, of which 13 also reported on hospital admission data. Meta-analysis showed these interventions had a significant positive effect on reducing hospital admissions (OR 0.64, 95% CI 0.43 to 0.96) but this result was not significant when the meta-analysis was restricted to RCTs (OR 0.92, 95% CI 0.81 to 1.05).

Holland et al.[91] conducted a systematic review and meta-analysis of RCTs investigating pharmacist-led medication reviews in older people (mean age > 60 years) across all settings. Thirty-two studies fitted the inclusion criteria and meta-analysis of 17 trials revealed no significant effect on all-cause hospital admissions (p=0.92) or mortality (p=0.62). Thus, the authors concluded that these interventions cannot be assumed to have a beneficial clinical effect. Pharmacist-led medication reviews, however, may improve patient drug knowledge and adherence, and possibly reduce polypharmacy.

This evidence reveals that although studies have shown some positive effects of pharmacist-led medication management services, these do not necessarily translate to a reduction in morbidity or mortality for patients, at least in the short time frames that have been studied. The heterogeneity of these results may be explained by the methodological differences between studies, as well as variations in care delivery (e.g. training and experience of the pharmacists, level of access to medical histories, degree of communication/ interaction with prescribers), study population demographics and clinical conditions, duration of follow up and outcome measures.

Despite the evidence for major clinical outcomes being inconsistent, in Australia, professional bodies, consumer organisations and the government have recognised the

value of collaborative medication management services and as a result they are funded by the federal government and recommended in various guidelines (e.g. Australian Pharmaceutical Advisory Council *Guiding Principles for medication management in the community*[92]) and by organisations such as NPS MedicineWise.

Although these medication management services are free to consumers, research has consistently indicated that the uptake of HMRs has remained below the projected use, especially for at-risk individuals such as those with culturally and linguistically diverse backgrounds, older Australians and Indigenous Australians.[93, 94] Although most consumers are highly satisfied with these services, many are often unaware of their existence.[94, 95] Qualitative analysis has revealed that whilst GPs and pharmacists believe the program can successfully identify MRPs and improve the knowledge and adherence of patients to their medication regimen, there was still some ambivalence to undertaking these services.[96] Some also felt there was a lack of hard evidence to show this program improved outcomes significantly, especially with regards to reducing medication errors and hospitalisations.[96]

The lack of effect on some outcomes may result from the difficulties in implementing medication management services effectively in the community.[87] Successful implementation depends on the relationship between the pharmacist and GP; however, community pharmacists and independent consultant pharmacists often did not know the GP who initiated the referral or received their care plan, and often had difficulty meeting with GPs to discuss issues.[85, 91] Pharmacists were also unable to obtain complete and detailed medical histories, thus hindering the advice they could give or causing frustration in some GPs when their prescribing was questioned.[85] Others issues, such as administrative and logistical issues have also been raised as barriers to implementing efficient services.[85]

This suggests that greater contact and collaboration between pharmacists and GPs may be required. A cluster-RCT involving 738 older patients (≥75 years old on more than five medicines), 28 pharmacists and 77 GPs was conducted in the Netherlands to determine which method of medication review (case-conferencing between the community pharmacist and GP or written feedback) was more effective.[97] The study found that personal contact between the pharmacist and GP via case-conferencing resulted in significantly more medication changes with modest cost savings. Although this study was strengthened by cluster-randomisation, the convenience sampling of GPs may have introduced selection bias and limit generalisability. Collaborative medication reviews involving post-review discussions between the GP and pharmacist (face-to-face or phone) were also reported to improve the uptake of pharmacist recommendations from approximately 50% to 70% in aged care facilities in Tasmania, Australia.[98]

Interdisciplinary, collaborative care, facilitated by co-location of various health professionals (i.e. the physical presence of health professionals in the one setting), may be an approach to improve medication management services in the community.[85, 99] A review of selected studies investigating medication management services provided by pharmacists based within general practice clinic settings is provided in Section 2.6, and a systematic review in Chapter 3.

2.4.3 Summary

The previous sections (Sections 2.1 – 2.3) have established that medication misadventure remains a concern in primary care globally, and that various strategies may be implemented to improve QUM. Whilst various pharmaceutical care interventions, including pharmacist-led medication management services, have resulted in some positive outcomes, findings have been inconsistent. Greater interprofessional collaboration within primary care may be needed to improve the delivery of these services. A discussion of the

theory behind teamwork and the adoption of new health services is provided in the next section.

2.5 Interprofessional Collaboration and Team-based Care

2.5.1 Primary Healthcare Teams

As mentioned in Section 2.1, the primary healthcare systems of Australia and other countries are undergoing reforms to meet the needs of their populations.

Integrated and coordinated care provided by multidisciplinary teams has been identified as a key approach to managing the complex health needs of a changing population.[3, 6, 100, 101] Team-based models in primary care can contribute to creating a multidisciplinary skill mix within the primary care workforce enhance patient access to a diverse range of primary health providers; and improve the quality of service delivery.[16] At the primary care level, such strategies have the ability to regulate demands on the health system by managing patient needs within the community and reducing demands on the secondary and tertiary sectors.[6] Additionally, multidisciplinary care has been shown to benefit both provider behaviour and patient health outcomes, particularly in chronic disease management.[13, 102] Despite this, collaboration remains low in Australia[103] and it is estimated that 50% of patients with chronic disease do not receive best practice management.[104]

2.5.2 What is a Team?

Fried et al. described a team as "a group with a specific task or tasks, the accomplishment of which requires the interdependent and collaborative efforts of its members."[105] Xyrichis and Ream[106] further elaborated on this definition by describing teamwork in

healthcare as "a dynamic process involving two or more healthcare professionals with complementary backgrounds and skills, sharing common goals and exercising concerted physical and mental effort in assessing, planning, or evaluating patient care. This is accomplished through interdependent collaboration, open communication and shared decision-making. This in turn generates value-added patient, organisational and staff outcomes."

These definitions suggest that a team is not merely the unstructured grouping of individuals in the one setting. Individuals, with a range of diverse and complementary skills, must work together towards a common goal.

2.5.3 Effectiveness of Teams in Primary Care

Various factors influence the success of teams in primary care, including interprofessional education and learning,[107] organisational and management policies,[16] and practice support systems.[16, 108] Effective teamworking is also heavily influenced by team structure and team processes.[109]

Team structure may be influenced by several factors including the team premises, with co-location of team members seen as a facilitator.[109] The size and composition of a team may also have an effect: a range of disciplines, with individuals with different values and levels of power, may be barriers to effectiveness.[110] Hence, clear divisions of labour,[109, 111] adequate training,[111] positive personal qualities and commitment of staff [112] are imperative. Clinical and administrative systems,[111] and organisational support, which encourage innovation, the implementation of change and the development of creative working methods within the team are other positive elements.[109, 112]

Team processes are another important factor. Interprofessional communication has been identified as one of the most significant facilitators of team effectiveness.[111-114]

Individuals need to understand and respect team members' roles, recognise that teams require work and appreciate the nature of primary health care practice.[113, 114] Regular team meetings can improve communication, facilitate collaboration, clarify individual roles and responsibilities and avoid conflict.[109] Team meetings, both professional and social, are also important for the sustainability of teams in primary health care.[115]

Collaboration amongst team members is crucial. The concept of collaboration may be defined through the ideas of sharing, partnership, interdependency, power and process, and should include perspectives of both patients and professionals.[116] The determinants of successful collaboration include a range of systemic, organisational and interactional factors.[117] These may include interpersonal factors such as a willingness to collaborate, trust, mutual respect and communication. At the organisational level, organisational structure, philosophy, team resources, management and strong leadership are imperative.[117]

Clearly defined goals with measurable outcomes are another important element.[109, 111] Shared objectives have a significant effect on primary healthcare team (PHCT) effectiveness by allowing roles and responsibilities to be defined and providing the team with a vision.[109] Auditing of performance and the provision of feedback to individuals within the team are also important for recognition, and sustaining and improving performance.[109, 114]

Teamwork can lead to positive outcomes on several levels. For health professionals, teamwork can lead to professional satisfaction, individual recognition, and improved mental health.[109] Patients may benefit from improved quality of care, clinical outcomes, health-related quality of life and satisfaction.[109, 118] Healthcare organisations will gain a satisfied and committed workforce, cost control, and workforce retention.[109]

Although teams may be effective, there are challenges associated with this increased organisational complexity. Conflict within teams can arise as a result of a lack of understanding of the roles, scope of practice and accountability of other professions.[119] To overcome this, team leaders need to implement strategies for resolution, whilst individuals must engage in open and direct communication and maintain respect and humility.[119]

2.5.4 Adopting Practice Pharmacist Services

Rogers'[120] theory of diffusion of innovation may be used to explain the adoption of new health interventions.[121, 122] According to Rogers, the adoption and diffusion of an innovation is determined by five characteristics: relative advantage, compatibility, complexity, trialability and observability. "Relative advantage" is the degree to which an innovation is perceived as better than the idea it supersedes, the definition of which is dependent on the perceptions of the users. "Compatibility" is a measure of how an innovation is perceived as being consistent with the existing values, past experiences and needs of potential adopters. "Complexity" refers to the degree to which an innovation is perceived to be difficult to use or understand. "Trialability" is the degree to which an innovation can be experimented with and modified on a limited basis. "Observability" is a measure of how visible the results of the innovation are to others. According to Rogers, these five elements determine between 49 and 87 per cent of the variation in the adoption of innovations.[120]

Such a theoretical framework may be applied to the adoption of a practice pharmacist into the PHCT as illustrated by Pottie et al.[123] Such services need to offer a relative advantage to practitioners as well as clients, and be compatible with the values of the practice. The services should be simple to access and navigate, with minimal impact on practitioner workload. Such pharmacist services need to be tested for clinical effectiveness, as well as

acceptability by staff and clients, and to reduce uncertainty. The impact of these services needs to be visible, whether that is in terms of clinical, humanistic, economic or process benefits. By identifying and improving on each of these qualities, the adoption of these new services is more likely to take place.

Aside from the characteristics of the new intervention, another important concept is the social context in which these innovations are adopted. Users of an innovation may be divided into different categories depending on their propensity to adopt an innovation. These include: innovators, early adopters, early majorities, late majorities and laggards.[120] Systems that embrace a culture of creativity, have a relatively flat hierarchical structure, and are led by strong innovators are more likely to rapidly adopt new interventions.[122] This can be particularly challenging in a healthcare system, which is composed of hierarchies, bureaucracy and social norms that can hinder change. Additional determinants of successful adoption of new health interventions include the research evidence available and the method in which information is communicated. Face-to-face, interpersonal communication, involving individuals who share a high degree of professional resemblance, have been shown to be most effective.[122]

2.5.5 Summary

The use of interdisciplinary teams in primary care can potentially enhance patient access to a diverse range of primary health providers and improve the quality of service delivery. Various factors influence the success of health professional teams in primary care, as well as the adoption of new team members and their services. The next section explores pharmacist integration into general practice teams.

2.6 Pharmacists as Primary Healthcare Team Members

The role of pharmacists in healthcare is evolving. Traditionally the compounder and dispenser of medicines, the pharmacist's role has expanded to now encompass a wide range of clinical and pharmaceutical care services. Pharmacist involvement within multidisciplinary health care teams is an example of the profession adapting to further contribute to patient care. Despite this, pharmacist participation in primary care teams are low[124] and community pharmacists are often not viewed as a core part of the PHCT.[13, 125, 126] Evidence, however, suggests that a cooperative relationship between the pharmacist and physician can positively impact patient outcomes, highlighting the importance of multidisciplinary teamwork.[127] Moreover, the failure of pharmacists to become active team members could diminish their relevance by further isolating themselves from the other members of the PHCT.[128, 129]

Several different practice models for the delivery of team-based primary care in the community setting have been proposed and developed internationally. Models that incorporate pharmacists as part of the PHCT include:[130]

- The pharmacist as a member of the PHCT in a clinic setting or a physician's office
- Pharmacist managed or co-managed primary health care clinics
- The pharmacist as part of a remote/ virtual/ dispersed PHCT (not co-located), including:
    - the pharmacist as a provider of primary care services in community pharmacies;
    - the pharmacist as a consultant to a number of pharmacies, clinics or physicians' offices; and

- the pharmacist as a provider of remote monitoring services with the assistance of technology.

As the focus of the research presented in this thesis is the development of a practice pharmacist role based in general practice, the literature that involves this particular model of practice has been reviewed. The main studies involving pharmacist involvement in general practice are summarised below.

2.6.1 The Pharmacist as a Member of the Primary Healthcare Team in a Clinic Setting or a Physician's Office

Pharmacists have a diverse range of functions in general and family practices. Evidence reveals pharmacists can perform a range of duties in this setting at the level of the patient, health provider and practice.[130-132]

Patient-level activities include: patient education and counselling, performing medication reviews, assessing and optimising patient adherence, modifying and optimising drug regimens, drug and ADE monitoring, ordering and interpreting laboratory tests, running disease management clinics and prescribing (independent or supplementary).

Health provider and practice-level activities include: providing drug information and education sessions to health professionals; managing and developing formularies, drug budgets and practice information systems; conducting practice-based research; undertaking quality improvement activities and clinical audits; participating in various committees; liaising with other primary healthcare professionals including community pharmacists; and liaising with the secondary, tertiary and aged care sectors.[130-132] These roles are continually expanding, with practice pharmacists having newer and more involved responsibilities as healthcare systems evolve.[130]

The following sub-sections discuss studies investigating pharmacist integration into primary healthcare clinics in several countries, with a particular focus on medication management services. Studies that involve general practice patients with a range of health conditions (rather than targeting specific health conditions or populations) have been reviewed here, as this best reflects the generalist nature of the practice pharmacist. Further critical analysis of studies of pharmacists co-located in general practice clinics is presented in Chapter 3 as part of a systematic review and meta-analysis.

United Kingdom

Primary care clinic pharmacy in the UK developed after major reforms to the National Health Services (NHS) in the 1990s, which resulted in economic liberalisation, the creation of an internal market and fund-holding GPs.[133] As GPs were allocated drug budgets by government health authorities, GPs saw the need for assistance in making their prescribing more cost-effective. Thus, pharmacists were employed in general practices to act as pharmaceutical advisors – helping GPs to develop prescribing policies and formularies, switch to generic prescribing, manage repeat prescribing and implement evidence-based medicine.[133, 134] These arrangements led to pharmacists working alongside physicians as a part of a PHCT, and later roles were extended to include more clinical and patient-centred services.[135]

Poor management of repeat prescribing and a lack of ongoing reviews of long-term medications have been identified as issues in primary healthcare in the UK.[136] To remedy this, primary care pharmacy has increasingly been involved in individualised pharmacist-led medication reviews for patients with chronic diseases and on long-term therapy.[133] Several studies, described below, have shown the benefits of these reviews undertaken in general practice, including positive effects on drug use and cost.

Some studies[137, 138] investigated pharmacist-conducted medication reviews of repeat medications in general practice, but without a consultation with the patient. Pharmacists, however, had full access to patient histories and liaised closely with GPs and other practice staff, discussing MRPs at joint meetings.

Granas and Bates[137] conducted a RCT involving 511 repeat prescriptions containing at least three items. A community pharmacist visited the general practice once or twice a week to review repeat prescriptions and identify MRPs. A meeting between the pharmacist and GP immediately followed the identification of MRPs. A modified Delphi technique was also used to assess the clinical significance of MRPs. Compared with usual care, the intervention resulted in significant reductions in the number of MRPs associated with repeat prescriptions at 24 months. The pharmacist reduced the absolute risk of a MRP by 26% and for every 3.8 repeat prescriptions reviewed, a MRP was prevented. Although the study used a rigorous trial design, limitations included the use of a single pharmacist and practice limiting generalisability.

Goldstein et al. [138] conducted a larger-scale, observational study involving 1,564 patients (receiving at least six medicines) and 47 GP-community pharmacist partnerships from two health authorities in England. The pharmacists reviewed the GP notes and medical records of patients to identify MRPs. Discussions were held between the GP-pharmacist partners to resolve issues. A total of 9,762 potential MRPs were identified. By three months, GPs agreed with 58% of pharmacist-identified problems but only 56% of these 58% were acted upon. Focus groups at the end of the project revealed that various factors, including prescriber behaviour and "patient pressure", were contributors to low levels of change. Despite this, the study demonstrated the benefits of a collaborative GP-pharmacist relationship in identifying and resolving inappropriate prescribing. The study was robust, especially for a feasibility study.

Early studies[139-141] of medication review clinics involving pharmacist-patient consultations in British general practices lacked rigour and were limited by their failure to assess effects on health service utilisation, morbidity or mortality.

Mackie et al.[139] conducted a RCT involving 1,436 patients (≥20 years old and receiving four or more repeat prescription medicines) from six randomly selected practices in Greater Glasgow. Whilst both groups had pharmacists review medicines and identify MRPs, only the intervention group had pharmacist recommendations passed onto the GP. The study found that pharmacist-led medication review clinics resulted in a potential reduction in inappropriate prescribing, with pharmacists implementing more sustainable changes than GPs alone (87% v 34%, $p<0.001$) at 12 months. Referral rates were also high (83.0%) and rejection rates low (3.0%), indicating that GPs were receptive to pharmacist recommendations. As a full study report was not available (despite several attempts to contact the author), it is difficult to assess the quality of this study or the results of other reported outcomes. The authors, however, acknowledged that potential washover between groups may limit the findings of this study.

Chen and Britten[140] trialled the role of a primary care pharmacist as a medication counsellor, conducting medication reviews with patients in GP surgeries and in patients' homes. Twenty-five consultations were undertaken by three primary care pharmacists over a three-month period, and analysed qualitatively. Referrals from GPs were slow, but pharmacist-patient consultations were deemed rich and acceptable to patients. Patient perceptions of their medicines, including the efficacy and propensity for adverse effects, also emerged. The authors concluded that such a service was a feasible extension of the role of pharmacists as prescribing budget advisors in the UK. The study lacked methodological details, thus it is unknown whether data saturation was reached and what other potential biases may exist.

Burtonwood et al.[141] evaluated the effectiveness of a pharmacist-run repeat medication review clinic in a general practice in Wales. A clinical pharmacist performed face-to-face, semi-structured patient interviews and reviewed medication regimens of 245 patients (on ≥ six medicines) either in the clinic or as a home visit. Written feedback was then provided to the GP for follow-up. An average of 3.5 pharmacist interventions were made per patient, with the most common recommendation being the removal of medicines no longer required (12.9%). The majority (91%) of interventions recommended were accepted by the GP and were 64% confirmed to be maintained six months after implementation. Thirty per cent of interventions were deemed important to act upon. The interventions resulted in reductions in drug use and modest cost savings (£155 per patient per year). The authors concluded the activity to be an important quality control mechanism for repeat prescribing. However, the study was conducted in a single practice and lacked a control group, hence limiting generalisability.

Larger-scale, rigorously conducted RCTs[142, 143] of medication review services in general practice have also been conducted in the UK.

Zermansky et al.[142] conducted a RCT involving 1188 patients (≥65 years old and taking ≥1 repeat prescription medication) from four general practices in the UK. Pharmacists held consultations with the patients to review medical conditions and medicines. Although the intervention resulted in significantly more drug changes and some cost savings after 12 months, there was no effect on hospital admissions, health service utilisation or mortality rates. Limitations of this study included potential contamination due to randomisation at the patient level rather than the practice level, and reduced generalisability due to the involvement of a single pharmacist. A subsequent report[144] on these findings highlights the effectiveness of a clinical pharmacist conducting medication

reviews in general practice without increasing the workload of other members of the PHCT.

Avery et al.[143] recently conducted a pragmatic, cluster RCT involving 72 general practices in the UK. Whilst the control practices received computerised simple feedback for at-risk patients (i.e. any patient who had potentially been subjected to hazardous prescribing or medicines management), the intervention practices received a pharmacist-led information technology intervention (PINCER) comprising feedback, educational outreach and dedicated support including reviewing patient medical records, discussions with GPs and staff, recommending blood tests and undertaking patient medication reviews. At the six-month follow-up, there were significant reductions in inappropriate prescribing of non-steroidal anti-inflammatory drugs (NSAIDs), beta-blockers and angiotensin-converting enzyme (ACE) inhibitors. The intervention was also deemed to be cost-effective if the decision-maker's ceiling willingness to pay reached £75. The study was strengthened by the pragmatic design that utilised appropriate methods of block randomisation, allocation concealment and blinding of outcome assessment. A large number of practices and diverse range of specific outcome measures were other strengths. This study highlights the benefits of a multifaceted, systems-level approach that utilises information technology as well as pharmacist expertise and interprofessional rapport. The authors also reported that the intervention was acceptable, based on their qualitative work.[145]

United States of America

In the USA, the growth of managed care and integrated health systems over the last few decades has stimulated the adoption of primary care as a means of improving the management of patient health care needs and access to specialty services.[132] Pharmacists

involved in primary care participate with other team members in the management of patients for whom medications are a focus of therapy.[132] Pharmacists in the American primary care sector work in a diverse range of settings including Department of Veterans Affairs (VA) systems, ambulatory care and outpatient clinics, physicians' offices, community health centres, and primary care practices associated with medical schools or pharmacies.[146-149] Thus, extrapolating interventions and results of American studies to typical general practice clinics may be difficult.

As part of pharmaceutical care, American primary care pharmacists undertake medication therapy management (MTM). These services involve collaboration between pharmacists and other health professionals to deliver patient-centred care that optimises medication use and improves patient health outcomes.[150] MTM consists of five standard core elements:

1. Medication therapy review (MTR) (the systematic process of collecting patient-specific information, assessing medication therapies to identify MRPs, developing a prioritised list of MRPs, and creating a plan to resolve them);
2. Personal medication record (PMR) (a comprehensive record of the patient's medications including prescription and non-prescription medications, herbal products, and other dietary supplements);
3. Medication-related action plan (MAP) (a patient-centric document containing a list of actions for the patient to use in tracking progress for self-management);
4. Intervention and/or referral to other health professionals; and
5. Documentation and follow-up.[150]

Pharmacists working collaboratively with physicians have been shown to make MTM decisions that are clinically credible.[151]

Recently, the integration of pharmacists into the patient-centred medical home (PCMH) has been advocated, and is gradually occurring.[152] The PCMH is a model or philosophy of primary care that is patient-centred, comprehensive, coordinated, accessible and committed to quality and safety.[153] Although the medical home concept dates back to the 1960s,[154] PCMH has gained attention from American policy makers and health professionals in recent years due to health reform in the USA. The PCMH encompasses seven joint principles[154]:

- Personal physician;
- Physician-directed medical practice;
- Whole-person orientation;
- Coordinated and integrated care;
- Quality and safety;
- Enhanced access; and
- Payment recognises value of PCMH.

In 2009, a group of American pharmacy organisations released a document detailing the seven principles for the integration of pharmacists' clinical services within the framework of the PCMH. These include:

- Access to pharmacists' clinical services;
- Patient-focused collaborative care;
- Flexibility in medical home design;
- Development of outcome measures;
- Access to relevant patient information;
- Effective health information technology; and
- Aligned payment policies.

Subsequently, the Patient-Centred Primary Care Collaborative produced a resource document regarding the incorporation of medication management services into the medical home.[155] It highlighted the importance and value of comprehensive MTM services in this setting, and that services can be delivered to patients and fully integrated with the work of the PCMH team to achieve coordinated care.[155] Such medication management services also improve clinical outcomes, are cost-effective and acceptable to patients and physicians.[155]

Pharmacy services delivered within primary care and family medicine clinics have been shown to embody the joint principles of the PCMH.[155] Scott et al. illustrated this with the delivery of clinical pharmacy services to a family medicine clinic in North Carolina, where pharmacists were involved in the provision of MTM in a pharmacotherapy clinic, anticoagulation clinic and osteoporosis clinic. Aside from direct patient care services, the pharmacists also ensured patient access to community resources, assisted with transition of care, provided interprofessional education and continuous quality improvement.[156]

Several small, observational studies[147, 148, 157-159] have been conducted in the US assessing the feasibility of providing MTM to general medical patients of PCMHs. Whilst these studies showed positive effects for certain medication and clinical outcomes, and the feasibility of pharmacist integration, they suffered from some methodological limitations. These mainly comprised the lack of a control group, which might have compromised internal validity, and the use of a single pharmacist and/or practice limiting generalisability of findings.

Harris et al.[148] conducted a prospective, observational, cohort study to evaluate the role of the pharmacist providing medication therapy reviews and interventions in a family medicine clinic in Minnesota. Ninety-two patients (taking ≥5 medications; with multiple

medical conditions; and/or medical conditions that result in high use of the health care system e.g., asthma, diabetes) were included in the study. MRPs were identified in 90% of patients. Clinical status improved in 45% of patients following medication review, with significant improvements in those with hypertension, dyslipidaemia and asthma. Clinical status remained unchanged in 46% of patients with a decline in the remaining 9%. The use of aspirin post-myocardial infarction and inhaled steroids in asthma increased significantly. There was also a significant reduction in the average number of medications used per patient.

Nkansah et al.[147] conducted a retrospective, uncontrolled time series study investigating a pharmacist-run diabetes clinic in a private physician practice. Seventy-seven patients (≥18 years old, with type 1 or 2 diabetes mellitus, receiving oral and insulin therapy, and referred to the pharmacy clinic from 2001 to 2003) were included in the study. There was a significant reduction in HbA1C ($p<0.001$) but no effect on other outcomes at the six-month post-clinic visit. Internal validity and generalisability of results were compromised by the retrospective, uncontrolled study design, undertaken in a single site with a predominantly African-American population.

Roth et al.[157] conducted a six-month, prospective, observational pilot study in a community-based primary care practice. A clinical pharmacist provided MTM at baseline, three and six months to a convenience sample of 64 patients (≥65 years old and taking at least five medicines). The intervention resulted in significant reductions in MRPs (4.2 at baseline vs 1.0 at six months, $p<0.0001$), and modest reductions in acute health service utilisation. Physicians were positive about the service. The study was limited by the single site, small sample size, lack of a control group, and selection bias.

Taylor et al.[158] assessed the effects of pharmacist-provided MTM services to 69 patients (considered at high risk of medication misadventure) from three family medicine clinics in rural Alabama. The service resulted in a significant increase in the attainment of therapy goals in hypertension, diabetes, dyslipidaemia and anticoagulation at 12 months by the intervention group, while these became worse in the control group. Hospitalisations and emergency department (ED) visits decreased in the intervention group and remained unchanged in the control group. Inappropriate medication use decreased in the intervention group, but increased in the control group. There was no significant difference in HRQoL between groups. Compliance and medication knowledge increased in the intervention group but decreased in the control group. The study was limited by a small sample size, short follow-up period and potential contamination due to randomisation at the level of the patient rather than physician.

An observational study undertaken by Berdine and Skomo[159] involved a pharmacist delivering MTM clinical services to a primary care practice in Pittsburgh, Pennsylvania. Two hundred patients (mean age 52.8; most common medical conditions hypertension, dyslipidaemia and diabetes) were included in the study. The most common reasons for referral to the pharmacist were for diabetes self-management, weight management, and other (e.g. anticoagulation management, lifestyle issues). The pharmacist-led clinic resulted in statistically significant improvements in clinical parameters for lipids, HbA1C and body mass index (BMI) at one and two years. The study was limited by non-randomised single-cohort design, missing data and inconsistent follow-up of patients.

Larger, observational studies have also been conducted. Isetts et al.[160] conducted a prospective study investigating collaborative MTM services provided by pharmacists and other primary care providers in six ambulatory clinics in Minnesota. Two hundred and eighty-five patients (with ≥1 of 12 predefined health conditions) were included and

compared with a historical control group of 252 patients (126 with hypertension and 126 with hyperlipidaemia) from nine clinics without MTM services. The intervention resulted in 637 drug therapy problems being resolved and achievement of treatment goals increased (from 76% to 90%) in the 285 intervention patients. There was an improvement in the intervention group compared with the control in the Healthcare Effectiveness Data and Information Set (HEDIS) goals for hypertension (71% v 59%) and hyperlipidaemia (52% v 30%). Total health expenditures decreased from US$11,965 to US$8,197 per person ($n = 186$, $p < 0.001$), with the reduction in total annual health expenditures exceeding the cost of providing MTM services by more than 12 to 1. Selection bias, mainly related to the sampling of clinics and patients, was the main limitation of this study as acknowledged by the authors.

Altaveta et al.[161] conducted a prospective, controlled study comparing two primary care internal medicine practices in Rochester, New York. A total of 343 patients (with ≥1 risk factor: ≥1 chronic disease or event (e.g. ED visit), or aged 50 years or older; a scheduled visit to see a GP or a diagnosis of diabetes without a GP visit; need for optimisation of medication therapy as determined by a clinical pharmacist on the screening date; and 12 months of continuous insurance eligibility before enrolment) were recruited to the study. The intervention involved one clinical pharmacist embedded in the practice reviewing medical records and making recommendations to the primary care physician. Other activities, such as patient counselling or physician education were done on an as-needed basis. The same pharmacist reviewed the medical records of the comparison group but the recommendations were concealed from the physicians. The intervention resulted in no significant differences between groups in the primary outcome of medical (excluding pharmacy) costs ($p=0.711$), however there were some significant improvements in medication-related issues being addressed. The study was limited by a lack of

randomisation, a comparator group which was not matched, and the use of a single pharmacist.

Several RCTs[146, 162, 163] have been conducted, and some examples in general medical patients are discussed here. A RCT conducted by Hanlon et al.[162] involved a clinical pharmacist providing MTM services to elderly patients in a general medicine clinic of a VA medical centre. Two hundred and eight eligible patients (≥65 years old and taking at least five medicines) were recruited. The pharmacist-led medication review resulted in a reduction in inappropriate prescribing compared to usual care which was sustained at 12 months (decrease 28% v 5%, $p<0.001$). There was no effect on other outcomes including potential ADEs, HRQoL, patient compliance, medication knowledge and satisfaction. Physicians were receptive and the enactment of recommendations was higher for the intervention group (55.1% v 19.8%, $p<0.001$). The study, however, failed to provide any information on the clinical importance of the intervention. Some limitations included poorly described allocation concealment, the use of a single site which might have led to potential contamination, and the use of a single pharmacist and setting which reduced generalisability.

The Impact of Managed Pharmaceutical Care on Resource Utilisation and Outcomes in Veterans Affairs Medical Centres (IMPROVE) study was a large scale RCT, involving nine VA medical centres, 78 pharmacists and 1054 patients at risk of medication problems who were randomised to intervention or control groups.[146, 163] There was diversity in the roles and responsibilities of pharmacists depending on the clinic (e.g. ability to prescribe or order blood tests). Generally, pharmacists met intervention patients to perform a medication review and make recommendations to the physician. The level of collaboration between pharmacists and physicians also varied depending on the clinic. Compared to usual care, after 12 months, the intervention had no effect on patient

satisfaction, HRQoL or health expenditure. Post hoc analysis revealed some improvement in patients with dyslipidaemia. Whilst the study was strengthened by the large sample size, there were several limitations including the lack of allocation concealment as patient recruitment occurred after randomisation, the poor standardisation of methodology across the sites and the use of 'soft' surrogates and humanistic outcome measures.

Canada

The integration of pharmacists into family practices across Canada was in response to the federal and provincial governments wishing to create a sustainable healthcare system with community-based providers working in teams and undertaking a newer, diverse range of responsibilities in the early 2000s.[164] These primary health care reforms led to the development of the pharmacist's role on interdisciplinary PHCTs in family practices and clinics. The need for greater collaboration between physicians and pharmacists in order to improve medication management was also highlighted in a joint statement of the Canadian Medical Association and the Canadian Pharmacists Association.[165] There are currently over 300 pharmacists working within PCMH practice sites across Canada.[166] Although integration is still relatively new and sporadic, ongoing studies show the value of pharmacist-family physician collaboration in Canada.[166]

A cluster RCT, the Seniors Medication Assessment Research Trial (SMART), evaluated pharmacist consultation programs in family practices in Ontario.[167, 168] The study involved 24 sites, 48 physicians, and 889 community-dwelling, elderly (≥65 years old) patients taking five or more medicines. The authors found that pharmacist medication reviews and subsequent discussions with physicians did not have a significant effect on patient outcomes. There were no significant differences in the number and cost of medications, health care use and cost, or HRQoL between the intervention and control groups. Despite

this, pharmacists identified a mean of 2.5 MRPs per patient in the intervention group, and physicians were receptive of the pharmacists' recommendations, with physicians acting on over 70% of recommendations and stating that their knowledge had improved. The authors concluded that collaboration between pharmacists and physicians is possible, and participants described it as a good opportunity for learning. Although the study benefited from a rigorous design and large sample size, it was limited by a short time frame (five months) for the outcomes measured.

The Integrating Family Medicine and Pharmacy to Advance Primary Care Therapeutics (IMPACT) project[169] was a large-scale demonstration project that followed the SMART trial,[167] and involved the placement of pharmacists into seven family medical sites across Ontario over a 31-month period. The pharmacists provided various services that included patient medication assessments, education and academic detailing, drug information and enhancements to office systems.[169, 170] The intervention involved 969 patient assessments by the pharmacists over the first 24 months; the pharmacists identified an average of 4.4 MRPs per patient. Overall, the study resulted in the optimisation of prescribing and use of medicines in the practices. In conjunction with other local initiatives and policy reforms, the project facilitated the development of interdisciplinary family health teams (FHTs) in Ontario.[169] Although the IMPACT project involved a more comprehensive and continuous intervention than the SMART trial, the practices and pharmacists were conveniently sampled introducing selection bias and limiting generalisability. However, as this was a demonstration project, these limitations were expected.

Australia

In Australia, the role of the general practice pharmacist is currently underdeveloped, poorly defined and unfunded. In 1996, Greenhill[171] conducted an uncontrolled study

assessing medication reviews undertaken in a general practice by a single pharmacist in Western Australia. Lack of details of methods and statistical analysis make it difficult to interpret the results of this study. Sixty-two patients were recruited to the study and data from 53 were available for the final analysis. The intervention was found to have no effect on the number, timing and doses of regular medications or on number of GP surgery visits. Subjective assessment of compliance, drug knowledge and "wellness" demonstrated significant improvements; however, level of statistical significance was not reported. Annual cost savings from the pharmacist recommendations were estimated to be AU$4,430 (equivalent to AU$83.58 per medication review per year), of which the majority (96.1%) were savings for the Federal Government subsidised Pharmaceutical Benefits Scheme (PBS). A surprisingly high number of pharmacist observations, comments and recommendations (mean 13.3 per patient) were reported; however, poor reporting made it difficult to interpret what these were and the practicality of implementation. The study was limited by a lack of a control group, which compromised internal validity, poor reporting and limited generalisability given a single pharmacist in a single practice.

Whitehead evaluated the delivery of pharmacy services in general practice clinics in Western Australia.[172] A 'quasi-experimental combination' design, essentially a before-after study with a matched control, was used.[173] Ten community pharmacists and 37 GPs were conveniently sampled and recruited to the study. GPs could refer their patients for one of three levels of service provided by the on-site pharmacist: an adherence assessment (brief medication review); a medication management service (in-depth medication review); or a preventive care service (in-depth medication review with regular follow-up). One hundred and ninety-one patients were referred to the service. At the end of four months, there was a significant increase in the number and cost of medications, as well as

self-reported adherence, in the intervention group. There were no significant differences in the number, types and costs of medical services or the types of medications used. Study limitations included missing data, potential selection bias, and limited generalisability due to convenience sampling of pharmacists from a particular region of Australia.

In 2012, Freeman et al.[174] investigated the practice pharmacist role in Queensland, Australia. After some initial qualitative work[175, 176] (described later in this chapter), an ethnographic study was conducted[177] to document the range of activities undertaken by a practice pharmacist based in a primary care medical practice in Brisbane, Australia. Over a three month period, the pharmacist engaged mainly in medication review, "pharmaceutical opinion" (provision of therapeutic advice for a particular patient), student supervision, drug information and administrative duties. This study was restricted to a single medical centre, involved a single pharmacist for a short duration, and coding of roles and reflective entries was undertaken by one investigator.

Following on from this work, a retrospective analysis of medication reviews[174] found that the practice pharmacist could significantly reduce the time to complete the home medication review process (i.e. from the date the patient was referred for a medication review to the date the GP had a follow-up consultation with the patient) from a median of 56 days in the pre-intervention phase to 20 days in the post-intervention phase. The number of medication reviews never billed (to the Government funder) also decreased substantially from 56% to 7%. Another retrospective analysis of medication reviews[178] revealed that the types of MRPs identified by an external pharmacist were similar to those identified by the practice pharmacist, but that the practice pharmacist identified a lower rate of MRPs compared with the external pharmacists. The authors attributed this to the practice pharmacist having access to medical records hence less irrelevant MRPs (due to lack of patient data) were reported. Significantly more recommendations from the

practice pharmacist were implemented by the GP compared to recommendations from external pharmacists (71% compared with 56%, $p<0.001$) and this was explained by the greater opportunities for interprofessional communication and rapport with co-location. The types and numbers of MRPs did not differ whether the medication review was undertaken in the home or medical centre during the practice pharmacist phase. Whilst these studies provided support for pharmacist integration, the findings were limited by several factors, mainly the retrospective nature of the investigation, the main investigator being the practice pharmacist, introducing observation bias, and a single pharmacist working in a single medical centre limiting generalisability of findings.

2.6.2 Summary

Pharmacists based in general practice clinics can provide a range of medication management services that result in improvements in medication use, as well as in clinical, humanistic and economic outcomes. Most of these studies, however, were limited by selection bias and poor generalisability due to the use of single practice sites and conveniently sampled participants. These limitations, however, were expected especially as many of these studies were assessing feasibility. Stakeholder acceptability of these services is explored in the next section.

2.7 Perceptions of Pharmacist Roles and the Integration Process

A few studies have explored stakeholder views on pharmacist integration into primary healthcare clinics, including perceptions of potential integration, and experiences with actual integration. Studies exploring pharmacist roles, benefits and disadvantages, and

overall experiences with pharmacist integration will be reviewed here, followed by barriers to and facilitators of integration in the next section.

2.7.1 Canada

SMART Trial

As part of the previously mentioned SMART trial,[179] a qualitative analysis was undertaken to learn about the experiences of the pharmacists and family physicians involved in the program, and how the program could be improved.[168] In-depth interviews were conducted with a purposive sample of six physicians and six pharmacists based on their level of functioning within the pair (as determined by a satisfaction questionnaire). Interviews were semi-structured and face-to-face, and data were analysed thematically.

The interviews revealed that pharmacists saw advancing the profession, being more equal partners, and advising physicians on medication regimens as key aspects of their role in family practice. Pharmacists found reviewing medicines with access to additional patient information was satisfying; however, they felt confined by not being able to advise the patient directly, rather, they could only make recommendations about prescription medicines to the physician. Pharmacists found the extended role in family practice challenging initially and acknowledged that they needed to practice their skills and acquire additional training.

Physicians did not want pharmacists directly advising patients on medications other than over-the-counter (OTC) preparations and felt pharmacists should respect physicians' relationship with patients. Physicians saw quality control, assistance with OTC and herbal products, identification of potential drug interactions, academic detailing and adherence support as appropriate pharmacist roles. Physicians reported that patients enjoyed their interactions with the pharmacists, with patients appreciating the extra time with a

healthcare professional. Physicians reported learning new information from pharmacists that could be generalised to other patients, especially with regards to OTC products and adherence.

Both pharmacists and physicians felt the impact of the program was modest but helpful, and the implementation of the role could be improved with better targeting of patients. Co-location and repeated contact between pharmacists and physicians helped with the development of rapport. Development of a trusting relationship was deemed to be important for effective collaboration.

Study limitations included the artificial setting of a RCT, the interviewer knowing the level of functioning of the participant pairs, and the interviewer being involved in the RCT which may have influenced participant responses.

IMPACT project

The IMPACT project used various qualitative and quantitative analyses to explore the experiences and perceptions of physicians and pharmacists on pharmacist integration into family practices. Physician perceptions were explored using focus groups,[123] semi-structured interviews[123] and periodic questionnaires.[180] The initial four exploratory focus groups (each comprising four to nine physicians and the practice pharmacist), revealed physicians' concerns about medico-legal implications and the need to maintain integrity of patient-physician relationships.

The follow-up semi-structured interviews of physicians (n=12, purposively sampled based on demographics and perceived support of the pharmacist program) were conducted 12 months into the program. Thematic analysis of data was performed.

The findings revealed that physicians found operational challenges to be an issue, especially the need to adjust daily routines to include a pharmacist or find time to work with them. However, this improved twelve months into the study and physicians found that pharmacists sometimes helped save time.

Physicians found that clinical security had developed over time, and that initial medico-legal issues were no longer a concern. They also appreciated the pharmacists' provision of medicines information, fresh perspectives and clinical reassurance, which helped them feel more confident in prescribing. At the practice level, physicians felt the pharmacist could provide links with community pharmacists, provide group education and enhance the sense of a team. Some felt the pharmacist freed up physician time.

The authors acknowledged that a limitation of this study was that questions may have been phrased to elicit positive responses.

Another study assessed how family physicians perceived their own and pharmacists' contributions to medication processes during the integration process. Physicians were mailed a 22-item questionnaire (the Family Medicine Medication Use Processes Matrix) at the 3rd, 12th and 19th month of pharmacist integration and response rates were 36/48 (75%), 36/47 (77%) and 30/40 (75%) respectively. Initially, physicians perceived their own contributions to be significantly higher in the subscales of Diagnosis & Prescribing, Monitoring and Administration/Documentation and significantly lower in Education, compared to pharmacists. However, over time, physicians perceived a significant increase in the pharmacists' contributions to Diagnosis & Prescribing, Monitoring and Medication Review, whilst perceptions of their own contribution to Diagnosis & Prescribing and Education decreased significantly.

These findings suggest that physicians may initially underestimate the pharmacist's role in family practice, but gradually start to recognise their expertise and competence. Selection bias may be a limitation of all these studies as physicians were innovative and may not be reflective of the general population.

Narrative reports were used to qualitatively assess pharmacist experiences with integration and identity development within family practices.[170, 181, 182]

Seven practice pharmacists completed 63 monthly narrative reports over a one-year period during their integration into group family practices. The reports were analysed by four independent researchers using iterative grounded theory to determine themes. The initial reports (one to two months) revealed that pharmacists experienced emotional challenges with integration, including feeling disoriented, feeling like an outsider, feeling as though they worked too slowly and feeling undervalued.[170, 182] Pharmacist mentors were important in helping deal with uncertainty and complex care and influencing pharmacist identity development.[182]

In subsequent months (three to four months), pharmacists felt they needed to demonstrate value, and establish and build relationships with other team members. Gradually, pharmacists began to feel like part of the team and built confidence in their skills; however, there were still pressures associated with meeting the goals of both physicians and the project.[170, 182]

At later stages of integration (five months and beyond), staff became more comfortable working with the pharmacist, and pharmacists became more accustomed to the clinical setting. They also felt like the family practice environment offered certain benefits. Pharmacists had dual perspectives on the roles of pharmacists and physicians, and began to view the patient more holistically.[182] Pharmacists felt like this new role in family

practice enhanced their sense of professionalism as there was increased contact with other health professionals and patients. Access to patient information and more involvement in patient treatment were seen as key benefits.[182]

These findings reveal that pharmacist integration and identity development is a gradual process; however, pharmacists perceived this as a beneficial role. The open narrative reporting and rigorous analysis process used strengthen this study; however, the small sample and 'early adopter' nature of the participants limited generalisability of results.

2.7.2 United States of America

The SCRIPT Project

Kozminski et al.[183] conducted a qualitative study to determine the acceptance and attitudes of family medicine physicians, practice staff, pharmacists and patients during pharmacist integration into four medical homes in Pittsburgh, Pennsylvania (the Successful Collaborative Relationships to Improve PatienT Care [SCRIPT] project).

A combination of methods was used including individual interviews (all stakeholders), surveys (patients), monthly written logs (pharmacists), and weekly observations (pharmacists). A total of 84 interviews were conducted; 21 with physicians, 26 with clinical staff, 9 with nonclinical staff, 13 with patients, 6 with pharmacists (3 per pharmacist), and 8 with office managers (2 per office manager). A total of 62 pharmacist-patient and numerous pharmacist-staff observations were made, and 16 satisfaction surveys were completed by patients. Thematic analysis was used to explore data.

The interviews found some initial concerns with integration, such as logistical and operational challenges. However, these dissipated shortly after integration and the pharmacist was well accepted in the practices.

All stakeholders had a positive overall feeling about pharmacist integration into the family practice; the role created various clinical, educational, and time-saving benefits. Physicians and other staff felt that pharmacists were able to fill in gaps in patient care, especially with regards to patient education and follow-up post discharge, ensuring appropriate medication use, dealing with formulary issues and assisting with management of chronic disease. Pharmacists were viewed as a quick and reliable source of medicines information by clinical staff, and were seen as time saving. Patients liked having the pharmacist onsite in the family practice office as it gave the impression that health professionals were working collaboratively, and increased trust. Many physicians and staff wanted the pharmacist to be present onsite for more often.

Pharmacists felt accepted by the practices fairly quickly, and by six months felt fully incorporated into the team. They felt like they could be a valuable resource for the team, and enjoyed spending more time on patient care. They also provided a link between the family practice and community pharmacy. Initial challenges included having to explain to staff the role of the pharmacist, and having to work out their role within the practice and use their time efficiently. Building relationships with patients was also difficult as they saw them less frequently than in community pharmacy

The study was strengthened by the use of triangulation of various methods which increased the robustness of the findings by allowing verification and contextualisation. Limitations included the use of highly motivated pharmacists and practices which limited generalisabiltiy, and participants being familiar with the interviewers (lead investigators and themselves pharmacists) which might have biased their responses.

2.7.3 United Kingdom

MacRae et al.[184] assessed the views of GPs on pharmacist-led medication review clinics provided in general practices in Glasgow.[139] Semi-structured interviews with a purposive sample of six GPs (based on demographics, volume of referrals to the pharmacist and views towards clinics) guided the development of a postal questionnaire. The questionnaire was completed by 218/258 (84%) GPs from 76/82 (93%) practices involved in the pharmacist clinics. A combination of Likert scales and open and closed questions were used to elicit responses about the process, value, benefits, problems and areas for improvement for the pharmacist services.

Quantitative assessment indicated that most GPs (over 80%) found the pharmacist clinic processes to be acceptable – including the selection and referral of patients, and that the services positively impacted on patient care. Overall, 95% of respondents found the pharmacist clinics to be a useful service to their practice and that the benefits outweighed any problems.

Qualitative assessment of the free text responses revealed that most GPs felt the pharmacist-led medication review clinics offered several benefits. Responses indicated that most GPs perceived prescribing practice to have been improved or rationalised (n=114). Benefits to the patients (n=17) included improved therapeutics, increased patient knowledge, enhanced compliance and satisfaction. Some GPs felt the service increased GP knowledge and confidence (n=34), decreased workload (n=13) and encouraged better multidisciplinary working and communication (n=8).

However, a minority of GPs also reported problems with pharmacist clinics. Some found such services increased workload (n=25), required space that wasn't available (n=24),

crossed "role boundaries" (n=2) and caused fear of external scrutiny (n=2). Problems for patients (n=21) were also mentioned, including confusion and resistance to change.

This study was strengthened by the high response rates and initial methods for developing and validating the survey. Limitations of this study included that almost half of respondents were still receiving pharmacy services and hence may not have responded honestly, thus introducing potential social desirability bias. For those respondents who were no longer receiving pharmacy services, recall bias may have been an issue.

Patient perceptions

Patient perceptions on general practice-based pharmacist services have also been explored qualitatively in the UK.

Petty et al.[185] conducted focus groups to ascertain patients' views of pharmacist medication reviews undertaken in their general practice surgery as part of a study mentioned earlier.[142] A topic guide for focus groups was developed through consultation with patients, clinical pharmacists, a GP and a researcher. A purposive sample of 18 patients (based on demographics, number of medicines and medication changes made by the clinic pharmacist) was recruited for the three focus groups, conducted by an independent researcher. Thematic analysis was performed independently by two investigators who then compared their analyses to reach consensus.

The qualitative study found that patients had mixed perceptions about the purpose of the pharmacist-led medication review prior to attending. Some patients felt that the consultation would help them find out more about their medicines, including how they worked, whether they were effective or harmful, or whether they were necessary. Some participants valued the time and opportunity to discuss their medicines, which allowed for problems to be picked up sooner. Others, however, were suspicious of the medication

reviews, thinking they were implemented just to save the government money through stopping or changing medicines to cheaper alternatives. Some patients felt such reviews were the doctor's role, and others thought there was something suspicious about the pharmacist being in the practice.

Regarding patient reasons for attending the pharmacist appointment, these appeared to be largely altruistic. Several patients felt that their participation would help other patients and the researcher. Others expressed loyalty to their GP and wished to help the practice. Some attended for social contact or out of curiosity. Some saw it as a waste of time or thought it was intended for the teaching of students.

Patient experiences of the medication review clinics was also explored.[185] Some patients enjoyed the opportunity to have their health and medicine questions answered, whilst others felt such explanations were unnecessary as they had faith in their doctor. Some participants held strong beliefs about their health and did not accept advice provided by pharmacists. Some were disappointed with the service, arising from unrealistic expectations of the clinic including not having their illness cured or having their long-term medication stopped. Others did not like how the clinic was conducted and felt they did not get the information they wanted. Some patients felt that the pharmacist did not have authority to change medicines, and it was the duty of the specialist and GP.

Some patients were reluctant to attend a regular pharmacist review: they expressed feelings of guilt for attending the surgery too frequently, and others were happy with a medicine review provided by their GP.

The study[185] was strengthened by stringent methods used to develop and validate the focus group questions and perform analysis of data. Selection bias, leading to reduced

generalisability, was a potential limitation. It is also unknown whether data saturation had been reached.

2.7.4 Australia

In 2012, Freeman et al. published an investigation of stakeholder perceptions of potential practice pharmacist roles in Australia using both qualitative[175] and quantitative methods.[176]

A convenience sample of GPs (n=8), pharmacists (n=28), practice managers (n=4) and health care consumers (n=18) from South East Queensland took part in five focus groups and 18 semi-structured interviews.[175] Focus groups and interviews were face-to-face, conducted by two investigators and used seeding questions to facilitate discussion. Textual analysis was performed on the data. All participants felt that medication reviews, medication information, and education were positive roles for practice pharmacists. All stakeholder groups, with the exception of GPs, had mixed feelings about pharmacist prescribing, with some participants feeling repeat prescribing would be acceptable. GPs, however, viewed pharmacist prescribing negatively. All stakeholder groups viewed dispensing and diagnosis as negative roles for a pharmacist in the general practice setting.

All groups felt that pharmacist access to patient medical files, increased privacy and dedicated time for services were benefits of pharmacist integration, except for the GP group. The health professional groups felt that increased rapport and interprofessional communication were beneficial aspects of this role. GPs also reported that practice pharmacists would be viewed as being more independent and there would be greater acceptance of pharmacist services by patients in this setting.

Findings from this qualitative study are limited by a small, convenience sample of participants from a confined area which reduces generalisability.

Freeman et al. followed this qualitative study with a national internet survey to seek stakeholder views on integrating pharmacists into general practice.[176] A total of 1038 respondents completed the survey: 829 pharmacists, 167 consumers (Diabetes Australia and Lung Foundation members) and 42 GPs. The survey confirmed the findings of the qualitative study. Medication review, drug information for practice staff and consumers, medication counselling, medication reconciliation and ADR assessment were viewed as potential roles. Pharmacists (78%) and consumers (72%) supported supplementary prescribing, whilst GPs were ambivalent (31% agree, 38% disagree) and preferred a protocol model of prescribing.

The low response rates from GPs and consumers and sampling method limited generalisability of the findings.

2.7.5 Summary

The studies discussed above reveal that stakeholders are generally receptive to pharmacist services based in primary healthcare clinics and general practices. Whilst most stakeholders felt that medication review, medicines information and education, and adherence assessment were positive roles for a practice pharmacists, GPs in some countries, especially Australia, had reservations about pharmacists providing patient advice on prescriptions or participating in prescribing activities.

Pharmacists felt they benefitted from greater patient contact, access to greater patient information, improved confidence in their clinical skills, and felt like being part of the general practice team. Physicians and staff expressed advantages such as access to a reliable medicines information resource, optimised patient care and prescribing, and reduced workload. Patients appreciated being able to spend time with the pharmacist,

improving their medication knowledge and witnessing a collaborative working relationship between the pharmacist and physician.

However, some pharmacists found initial integration difficult and to be a steep learning curve. Some GPs felt that the pharmacist disrupted workflow and placed a burden on the practice and their time. Whilst patients in most countries were generally receptive of pharmacist services, some British patients were suspicious of the pharmacist's motives and preferred GPs reviewing their medicines.

The experiences of integration were similar across most countries where practice pharmacist services existed: integration was reported as a gradual process and one where stakeholders' perceptions change as they become used to the presence of a pharmacist in their clinics.

2.8 Barriers and Facilitators to Integration

Several of the studies described above reported various barriers and facilitators experienced or anticipated during the integration process.

2.8.1 Barriers to Integration

Operational and logistical issues were seen as barriers by some GPs, pharmacists and practice staff across countries.[123, 175, 180] A lack of permanent, accessible, or adequate office space was seen as a major barrier by both GPs and pharmacists across all countries.[170, 175, 176] The limited size of the practice was thus seen as a barrier.[175]

Prior to pharmacist integration, some physicians were concerned about the impact a new health professional would have on the practice's workflow.[183] Physicians who had worked with practice pharmacists found it initially difficult to adjust routines and find the

time to incorporate a pharmacist into their daily work.[123] In Canada and the US, GPs needed to learn about the pharmacist's role and work out how to include them effectively in clinical decision making.[123, 183] Pharmacists also needed to become familiar with the workflow in order to minimise disruptions.[183] Difficulties in gaining full access to communication tools or finding time to speak to busy physicians and staff were seen as barriers by some pharmacists.[170] Some patients felt that extra time spent in the clinic was a challenge.[183]

The negative perceptions of physicians were seen as a potential barrier for pharmacist integration by some stakeholders. Some GPs who had not worked with a practice pharmacist doubted the pharmacist's clinical abilities for taking on this role[176, 180] and admitted having negative preconceptions of the pharmacist's roles.[175] For example, physicians from the SMART trial were reluctant to support pharmacists beyond a traditional role.[168] Some consumers felt GPs may be reluctant to having a pharmacist working within their clinic.[175] Pharmacists in Australia felt that boundary encroachment was the biggest barrier that would be seen negatively by GPs; however, Australian GPs did not identify this as an issue.[175, 176]

Hughes et al.[186] explored the perceived interprofessional barriers between community pharmacists and GPs in 11 focus groups involving 22 GPs and 31 pharmacists in the UK. The study revealed that many GPs viewed the community pharmacist as a 'shopkeeper' and felt there was a conflict of interest between business and health care. The study additionally found that GPs in the UK perceived there to be a hierarchy in healthcare, and had concerns about community pharmacists taking on roles such as prescribing. Pharmacist participants also felt that boundary encroachment would be an issue and felt GPs lacked knowledge about pharmacists' training and role. Many GPs, however, saw a

practice pharmacist as the preferred model with regards to interprofessional working and prescribing support as this would remove any perceived commercial biases.

Moreover, health professionals other than GP who constitute the PHCT, may have concerns about the integration of a pharmacist into general practice. Practice nurses may be wary of pharmacists encroaching on their professional boundaries by undertaking additional roles that traditionally fall within the nurses' domain.[187] In contrast, nurses working with ward pharmacists in a hospital environment were accepting of this collaboration.[188]

Some pharmacists themselves also felt they lacked the clinical skills, knowledge or experience needed in this role, especially at initial integration.[168, 175, 176] Limited experience with team establishment and a lack of clear understanding of the role pharmacists can play in PHCTs were other barriers.[189]

As part of the previously described PINCER trial,[143] Cresswell et al. performed a qualitative analysis involving a combination of 52 longitudinal semi-structured telephone interviews, six focus groups and relevant documents. Participants included trial pharmacists, general practice staff, researchers and primary care trust staff. Data were analysed thematically using stringent methods to enhance validity. The study found that a major barrier identified by pharmacists was the sustainability of pharmacist interventions in general practice. This was expressed in light of the absence of an appropriate support network and career development pathways for pharmacists. Concerns about a lack of remuneration for pharmacist services was seen as a barrier by all stakeholder types in countries where integration had not yet been fully taken up.[176, 183]

2.8.2 Facilitators of Integration

Physical presence in the office was critical to building relationships with physicians and staff, and allowed staff to become familiar with the pharmacist and what they had to offer.[183] Face-to-face contact and relationship building between pharmacists and practice staff were important,[145] and trust tended to develop over time.[168] Participation of pharmacists in practice meetings or education sessions with colleagues was seen as conducive to rapport building.[170] Communication between the pharmacist and GP could also be improved by setting aside time for discussion.[184] Technological tools (such as electronic medical records) and communication tools (such as email and internal messaging systems) were important for maintaining interprofessional communication, especially when the pharmacist was offsite.[170, 183]

Previously established rapport with medical staff was seen as important by Australian GPs and consumers for ensuring successful integration.[176] Support from GPs was seen as an enabler by consumers.[175] Some GPs felt it would be useful for the pharmacist to have extended roles, such as the autonomy to make changes without constantly having to get GP agreement.[184]

Pharmacists needed to demonstrate credibility and value, and show they could save time for physicians. Willingness to collaborate increased once staff became aware of the pharmacist's value.[183] The success of the PINCER trial included the credibility and appropriateness of the pharmacist interventions made to identify and resolve prescribing errors.[145] Pharmacist flexibility and motivation were important to ensure smooth integration and avoid disruptions to workflow.[183]

Pharmacist services should be targeted towards certain patient groups (e.g. those with specific management difficulties)[168, 185] and frequency of consultations should be

considered depending on patient needs.[185] This may facilitate acceptance by consumers and reduce costs.

Training for the pharmacist was deemed an important facilitator by all stakeholder groups.[176] Pharmacists needed to practice their skills and acquire new ones in order to perform their roles effectively.[168] In Canada, competencies for pharmacists providing collaborative care in family practice have been developed and validated, and educational programs exist for pharmacists in this setting.[190]

Additionally, training for the medical centre, especially on the role of the pharmacist and how they fit in, was seen as an important facilitator by pharmacists and consumers in Australia.[175, 176] Practice managers felt that education and promotion of the benefits of pharmacist services to GPs and patients was needed to encourage uptake.[175]

Mentors (who acted as role models and provided support especially at initial integration) were seen as imperative for the integration process by pharmacists of the IMPACT project.[170] Professional mentors were also perceived to be facilitators by Australian GPs.[175] Support from allied health and accommodating doctors was also seen as necessary for success.[170]

Administrative support for the pharmacist was seen as necessary by GPs and patients in Australia,[175] and by pharmacists in Canada.[170]

Appropriate remuneration was seen as the most important facilitator by pharmacists, especially in Australia.[176] Potential and actual funding models will be discussed later in the chapter.

Kolodziejak et al.[191] summarised the overall factors that could facilitate the integration of a pharmacist into the primary care team. They performed a qualitative study to investigate

and provide guidance on the integration of a pharmacist into an already established PHCT (a student health centre) at the University of Saskatchewan, Canada. Action research was used to define the role of the pharmacist and then implement eight weeks of full-time clinical pharmacy services. Focus groups with members of the PHCT were held at the end of the intervention period and moderated by an external facilitator. Thematic analysis was performed on the data.

The focus group findings, coupled with the pharmacist's recommendations, formed a step-wise template for integration consisting of eight key steps:

1. Selecting a collaborative process;
2. Selecting an appropriate team;
3. Defining the role of the pharmacist;
4. Determining the logistics of providing care;
5. Establishing credibility;
6. Conducting patient consultations as they arise;
7. Re-evaluating the role as it evolves; and
8. Obtaining patient feedback.

The main limitations of this study were the short time frame and the use of a pharmacist who was also the researcher; poor description of the composition of focus groups and analysis methodology also made it difficult to interpret the quality of results.

2.8.3 Summary

Whilst pharmacist integration into general practice clinics is generally accepted by a range of stakeholders, various barriers to, and facilitators for, integration exist. The key barriers to integration included: logistical, attitudinal, professional and sustainability issues.

The main facilitators for integration included: communication, positive experiences, training of pharmacists and staff, administrative support and adequate remuneration. Such issues must be considered prior to implementation of pharmacist services. The final section (Section 2.9), looks at actual and potential funding mechanisms for this role across different countries.

2.9 Service and Funding Models

Clinical pharmacy services have been shown to produce not only health benefits but also economic benefits to the health system. Several of the studies mentioned earlier in the chapter resulted in cost savings through reduced medicine and health service use and increased cost-effective prescribing.[142, 143, 146, 160] Perez et al.[192] conducted a systematic review of studies published between 2001 and 2005 that measured the economic impact of clinical pharmacy services. Of the included studies, 20/93 (21.5%) were undertaken in ambulatory care clinics or physician's offices. The median benefit-to-cost ratio was 2.89 in ambulatory settings (ambulatory clinics and community pharmacies), meaning that for every $1 invested in the clinical pharmacy service, $2.89 was saved in costs or through other economic benefits. A limitation of the review was that many studies lacked data important for the analysis, and study design, setting and quality varied between studies.

Countries that have integrated pharmacists into primary care practices often do not have a single, standardised remuneration structure; various different funding models may be employed to suit the needs of the practice, population and pharmacist. Various parties may be involved in contributing to the remuneration of pharmacists in primary care clinics. Whilst the majority of countries rely on governmental funding, payment by patients and private health insurers also occurs.

A white paper developed by the American College of Clinical Pharmacy Task Force on Ambulatory Practice summarises some existing payment methods[193]:

Fee-for-service

In the USA, pharmacist services may be covered by Medicare. Physicians may directly bill Medicare for services provided by the pharmacist as "incident to physician services". Direct billing of Medicare using MTM Current Procedural Terminology (CPT) reimbursement codes can also be used. With the Medicare Part D, pharmacists are paid as providers and several health plans use this as a payment mechanism for pharmacists to provide advanced care to patients. Additionally, some states may have payment for MTM for Medicaid patients.

Capitation

In the USA, health maintenance organisations utilise a "per-member-per-month" model. This risk-sharing model involves a physician or provider agreeing to pay the pharmacist a certain amount per-member-per-month to avoid unnecessary emergency department visits or hospital admissions. A common example is the provision of anticoagulation services by a pharmacist.

Pay for performance

In this model, physicians or providers agree to pay a certain amount to have pharmacists assist the practice to achieve best practice and meet predetermined goals. In the USA, physicians or providers choosing this method are likely to have incentives from insurance carriers to achieve disease-state goals, and these savings may be passed on to the pharmacist.

Canada and the UK also use variations of the above funding models to remunerate pharmacists. In Canada, interdisciplinary family practices are usually compensated using a blended payment method comprised of the above models. The Ministry of Health provides the salaries for interdisciplinary team members of family health teams, including pharmacists. Each practice's governing board decides which professionals to be hired based on patient needs. Thus, pharmacists in these teams are generally paid through salary compensation, however other mechanisms are possible such as sessional or casual funding.[194] A similar payment method is adopted in the UK, where practice-based pharmacists are paid by the practice via NHS funding.[133]

2.9.1 Australia

Funding in Australian Primary Care Pharmacy

In the Australian primary care setting, pharmacists operate on a fee for service basis, mainly though government subsidy. In community pharmacy, remuneration occurs, for example, with each prescription dispensed or each professional service provided by the community pharmacist under the Fifth Community Pharmacy Agreement.[79] Pharmacies are entitled to receive pharmacy practice incentives for services including:

- clinical interventions (identifying a MRP and making a recommendation in an attempt to prevent or resolve it);
- multi-compartment dose administration aid preparation;
- staged supply of medicines (supplying medicines to consumers in periodic instalments of less than the total required or prescribed quantity at agreed intervals. It is aimed at improving the safety and efficacy of medicine use in vulnerable consumers who are unable to manage their medicines safely);

- community service support (providing medicine safety, harm minimisation and services to support the community e.g. needle and syringe programs, opioid substitution programs); and
- working with others (documenting collaborations with other (non-pharmacy) health professionals from at least three different health professional groups).

Medication management programs are also delivered by community pharmacists within the pharmacy. Medscheck and Diabetes Medscheck are in-pharmacy reviews of a consumer's medicines, focusing on education and self-management, and are similarly funded by the government.[79]

Accredited consultant pharmacists who undertake medication management programs (HMRs and RMMRs) are also remunerated on a fee-for-service basis through government subsidy. The GP may refer an eligible patient to the patient's preferred community pharmacy or an accredited pharmacist, and allows the patient to choose the most appropriate pharmacist to conduct the HMR review. The GP and accredited pharmacist (and community pharmacy if involved in the referral) receive a Medicare payment for each review undertaken.[78]

Other government funded collaborative arrangements involving GPs and pharmacists are limited in Australia. Team Care Arrangements (TCAs) involve the care of patients with a chronic or terminal medical condition and complex care needs delivered by a multidisciplinary team consisting of a GP and at least two other health or care providers, one of which could be a pharmacist. However, only GPs receive a Medicare rebate for coordinating and reviewing the arrangement.[195]

In Australia, a defined funding mechanism for the involvement of pharmacists in the general practice team currently does not exist. Freeman et al.[175, 176] identified that lack of appropriate or sustainable remuneration was a major barrier to integrating pharmacists into Australian general practices. Pharmacists, GPs, consumers and practice managers agreed that government subsidy for this new role would be the ideal remuneration model. However, various flexible and mixed models have been proposed including the use of government, patient co-payment, practice salary (paid by medical centre) and health insurance payments. According to their survey, 48% of GP respondents supported a combination of part government and part patient co-payment; 67% of pharmacists supported a part government and part practice salary; and 56% of consumers supported an entirely government funded model.[176]

Thus, as reported from other countries, and from local opinion,[176] a single funding model for practice pharmacists may not be possible, but rather, a range of flexible options should be explored. Discussion of potential funding models in Australia will take place in Chapter 10.

2.9.2 Summary

As pharmacy service models in primary care develop and change, so should the systems of funding. Such remuneration structures must be flexible, and will depend on the roles of the pharmacist, the needs of the practice and their patients, and the willingness of the consumers to pay. However, adequate evidence for the efficacy and effectiveness of pharmacist services provided in Australian general practice needs to be generated first, in order to justify the funding of such services in the future.

2.10 Next Chapter

To complement the findings of this literature review, and further explore the effectiveness of clinical services provided by pharmacists co-located in general practice clinics, a systematic review and meta-analyses were undertaken, and are reported in the next chapter. A summary of the collective findings of both reviews is provided at the end of Chapter 3.

2.11 References

1. Starfield B. Is primary care essential? *The Lancet.* 1994;344(8930):1129-33.

2. Duckett S, Willcox S. The Australian healthcare system. 4th ed. Melbourne: Oxford University Press; 2011.

3. Department of Health and Ageing. Primary health care reform in Australia - report to support Australia's first national primary health care strategy. Canberra: Department of Health and Ageing; 2009. Available from http://www.yourhealth.gov.au/internet/yourhealth/publishing.nsf/Content/nphc-draftreportsupp-toc/$FILE/NPHC-supp.pdf. (Accessed on 22 September 2013)

4. Royal Australian College of General Practitioners. What is general practice? 2012. Available from http://www.racgp.org.au/whatisgeneralpractice. (Accessed on 27 May 2013)

5. Britt H, Miller GC, Henderson J, Charles J, Valenti L, Harrison C, et al. General practice activity in Australia 2011–12. General practice series no.31. Sydney: Sydney University Press; 2012.

6. Mitchell GK, Tieman JJ, Shelby-James TM. Multidisciplinary care planning and teamwork in primary care. *Med J Aust.* 2008;188(8):S61-S4.

7. Australian Government. Intergenerational Report 2010. Canberra: Australian Government; 2010. Available from http://archive.treasury.gov.au/igr/igr2010/report/pdf/IGR_2010.pdf. (Accessed on 17 September 2013)

8. Australian Institute of Health and Welfare. Health and community services labour force. National health labour force series number 42. Cat. no. HWL 43. Canberra: AIHW; 2009.

9. Australian Bureau of Statistics. Population projections, Australia, 2006 to 2101. Canberra: Australian Bureau of Statistics; 2008. Available from http://www.ausstats.abs.gov.au/Ausstats/subscriber.nsf/0/0E09CCC14E4C94F6CA2574B9001626FE/$File/32220_2006%20to%202101.pdf. (Accessed on Accessed: 10 Septemeber 2013)

10. AIHW. Chronic diseases and associated risk factors in Australia, 2006. Canberra: AIHW; 2006. Available from http://www.aihw.gov.au/publications/phe/cdarfa06/cdarfa06.pdf. (Accessed on 10 September 2013)

11. AIHW. Health system expenditure on disease and injury in Australia, 2000–01. Canberra 2005. Available from http://www.aihw.gov.au/publications/hwe/hsedia00-01-2/hsedia00-01-2.pdf. (Accessed on 10 September 2013)

12. Wagner EH. Chronic disease management: what will it take to improve care for chronic illness? *Eff Clin Pract.* 1998;1(1):2-4.

13. Wagner EH. The role of patient care teams in chronic disease management. *BMJ.* 2000;320(7234):569-72.

14. Bodenheimer T, Wagner EH, Grumbach K. Improving primary care for patients with chronic illness. *JAMA.* 2002;288(14):1775-9.

15. Department of Health and Ageing. Building a 21st century primary health care system: Australia's first national primary health care strategy. Canberra: Department of

Health and Ageing; 2010. Available from http://www.yourhealth.gov.au/internet/yourhealth/publishing.nsf/Content/550436A8DA6839ECCA25771B00220E23/$File/6552%20NPHC%201205.pdf. (Accessed on 22 September 2013)

16. Naccarella L, Greenstock L, Brooks P. A framework to support team-based models of primary care within the Australian health care system. *MJA Open.* 2012;1(Suppl 3):22-5.

17. Strand LM, Morely PC, Cipolle RJ, Ramsey R, Lamsam GD. Drug-related problems: their structure and function. *Ann Pharmacother.* 1990;24:1093-7.

18. Australian Council for Safety and Quality in Healthcare. Second national report on patient safety - improving medication safety. Canberra: Australian Council for Safety and Quality in Healthcare; 2002. Available from http://www.safetyandquality.gov.au/former-publications/patient-safety-second-national-report-on-patient-safety-improving-medication-safety-pdf-923-kb/. (Accessed on 22 September 2013)

19. Miller GC, Britth HC, Valenti L. Adverse drug events in general practice patients in Australia. *Med J Aust.* 2006;184(7):321-4.

20. Thomas EJ, Brennan TA. Incidence and types of preventable adverse events in elderly patients: population based review of medical records. *BMJ.* 2000;320(7237):741-4.

21. Gandhi TK, Weingart SN, Borus J, Seger AC, Peterson J, Burdick E, et al. Adverse drug events in ambulatory care. *N Engl J Med.* 2003;348(16):1556-64.

22. Gandhi TK, Seger AC, Overhage JM, Murray MD, Hope C, Fiskio J, et al. Outpatient adverse drug events identified by screening electronic health records. *J Patient Saf.* 2010;6(2):91-6.

23. Simonson W, Feinberg JL. Medication-related problems in the elderly - Defining the issues and identifying solutions. *Drugs Aging.* 2005;22(7):559-69.

24. Department of Health. Pharmacy in England. Building on strengths - delivering the future. London: The Stationary Office; 2008.

25. Avery T, Barber N, Ghaleb M, Dean Franklin B, Armstrong S, Crowe S, et al. Investigating the prevalence and causes of prescribing errors in general practice: the PRACtICe study. London: General Medical Council; 2012. Available from http://www.gmc-uk.org/Investigating_the_prevalence_and_causes_of_prescribing_errors_in_general_practice___The_PRACtICe_study_Reoprt_May_2012_48605085.pdf. (Accessed on 22 September 2013)

26. Garfield S, Barber N, Walley P, Willson A, Eliasson L. Quality of medication use in primary care - mapping the problem, working to a solution: a systematic review of the literature. *BMC Medicine.* 2009;7(1):50.

27. Kongkaew C, Noyce PR, Ashcroft DM. Hospital admissions associated with adverse drug reactions: a systematic review of prospective observational studies. *Ann Pharmacother.* 2008;42(7):1017-25.

28. Roughead EE, Semple SJ. Medication safety in acute care in Australia: where are we now? Part 1: a review of the extent and causes of medication problems 2002-2008. *Aust New Zealand Health Policy.* 2009;6:18.

29. Roughead EE, Lexchin J. Adverse drug events: counting is not enough, action is needed. *Med J Aust.* 2006;184(7):315-6.

30. Roughead EE, Gilbert AL, Primrose JG, Sansom LN. Drug-related hospital admissions: a review of Australian studies published 1988-1996. *Med J Aust.* 1998;168(8):405-8.

31. Roughead EE. The nature and extent of drug-related hospitalisations in Australia. *J Qual Clin Pract.* 1999;19(1):19-22.

32. Runciman WB, Roughead EE, Semple SJ, Adams RJ. Adverse drug events and medication errors in Australia. *Int J Qual Health Care.* 2003;15:i49-i59.

33. Roughead EE, Barratt JD, Gilbert AL. Medication-related problems commonly occurring in an Australian community setting. *Pharmacoepidemiol Drug Saf.* 2004;13(2):83-7.

34. Bhasale AL, Miller GC, Reid SE, Britt HC. Analysing potential harm in Australian general practice: an incident-monitoring study. *Med J Aust.* 1998;169(2):73-6.

35. Easton K, Morgan T, Williamson M. Medication safety in the community: a review of the literature. Sydney: National Prescribing Service; 2009. Available from http://www.nps.org.au/__data/assets/pdf_file/0008/71675/09060902_Meds_safety_June_2009.pdf. (Accessed on 22 September 2013)

36. Chen YF, Avery AJ, Neil KE, Johnson C, Dewey ME, Stockley IH. Incidence and possible causes of prescribing potentially hazardous/contraindicated drug combinations in general practice. *Drug Saf.* 2005;28(1):67-80.

37. Witherington EM, Pirzada OM, Avery AJ. Communication gaps and readmissions to hospital for patients aged 75 years and older: observational study. *Qual Saf Health Care.* 2008;17(1):71-5.

38. Amercian Association of Critcal Care Nurses. AACN standards for establishing and sustaining healthy work environments: a journey to excellence. *Am J Crit Care.* 2005;14(3):187-97.

39. Teinila T, Kaunisvesi K, Airaksinen M. Primary care physicians' perceptions of medication errors and error prevention in cooperation with community pharmacists. *Res Social Adm Pharm.* 2011;7(2):162-79.

40. World Health Organisation. The rational use of drugs. Report of the conference of experts, Nairobi, 25 - 29 November 1985 Geneva: World Health Organization; 1987.

41. Hammad EA, Yasein N, Tahaineh L, Albsoul-Younes AM. A randomized controlled trial to assess pharmacist- physician collaborative practice in the management of metabolic syndrome in a university medical clinic in Jordan. *J Manag Care Pharm.* 2011;17(4):295-303.

42. Commonwealth Department of Health and Ageing. National medicines policy. Canberra: Commonwealth Department of Health and Ageing; 1999. Available from https://www.health.gov.au/internet/main/publishing.nsf/Content/National+Medicines+Policy-1. (Accessed on 22 September 2013)

43. Department of Health. The national strategy for Quality Use of Medicines (QUM) - executive summary. Canberra: Department of Health; 2004. Available from http://www.health.gov.au/internet/main/publishing.nsf/Content/46121C0B732612B9CA257BF0001CFED0/$File/execsumbro.pdf. (Accessed on 3 October 2013)

44. Commonwealth Department of Health and Ageing. The national strategy for quality use of medicines. Canberra: Commonwealth Department of Health and Ageing; 2002. Available from http://www.health.gov.au/internet/main/publishing.nsf/Content/nmp-pdf-execsumbro-cnt.htm. (Accessed on 22 September 2013)

45. Eslami S, Abu-Hanna A, de Keizer NF. Evaluation of outpatient computerized physician medication order entry systems: a systematic review. *J Am Med Inform Assoc.* 2007;14(4):400-6.

46. Australian Commission on Safety and Quality in Health Care. Electronic medication management systems - a guide to safe implementation (2nd edition). Canberra: Australian Commission on Safety and Quality in Health Care; 2012. Available from http://www.safetyandquality.gov.au/wp-content/uploads/2011/01/EMMS-A-Guide-to-Safe-Implementation-2nd-Edition-web-version.pdf. (Accessed on 22 September 2013)

47. Garg AX, Adhikari NK, McDonald H, Rosas-Arellano MP, Devereaux PJ, Beyene J, et al. Effects of computerized clinical decision support systems on practitioner performance and patient outcomes: a systematic review. *JAMA.* 2005;293(10):1223-38.

48. Ammenwerth E, Schnell-Inderst P, Machan C, Siebert U. The effect of electronic prescribing on medication errors and adverse drug events: a systematic review. *J Am Med Inform Assoc.* 2008;15(5):585-600.

49. Wolfstadt JI, Gurwitz JH, Field TS, Lee M, Kalkar S, Wu W, et al. The effect of computerized physician order entry with clinical decision support on the rates of adverse drug events: a systematic review. *J Gen Intern Med.* 2008;23(4):451-8.

50. Bryan C, Boren SA. The use and effectiveness of electronic clinical decision support tools in the ambulatory/primary care setting: a systematic review of the literature. *Informatics in primary care.* 2008;16(2):79-91.

51. Donyai P, O'Grady K, Jacklin A, Barber N, Franklin BD. The effects of electronic prescribing on the quality of prescribing. *Br J Clin Pharmacol.* 2008;65(2):230-7.

52. Vadher B, Patterson DL, Leaning M. Evaluation of a decision support system for initiation and control of oral anticoagulation in a randomised trial. *BMJ.* 1997;314(7089):1252-6.

53. Fitzmaurice DA, Hobbs FD, Murray ET, Holder RL, Allan TF, Rose PE. Oral anticoagulation management in primary care with the use of computerized decision support and near-patient testing: a randomized, controlled trial. *Arch Intern Med.* 2000;160(15):2343-8.

54. Tierney WM, Overhage JM, Murray MD, Harris LE, Zhou XH, Eckert GJ, et al. Effects of computerized guidelines for managing heart disease in primary care. *J Gen Intern Med.* 2003;18(12):967-76.

55. Nanji KC, Rothschild JM, Salzberg C, Keohane CA, Zigmont K, Devita J, et al. Errors associated with outpatient computerized prescribing systems. *J Am Med Inform Assoc.* 2011;18(6):767-73.

56. Soumerai SB, Avorn J. Principles of educational outreach ('academic detailing') to improve clinical decision making. *JAMA.* 1990;263(4):549-56.

57. Soumerai SB, McLaughlin TJ, Avorn J. Quality assurance for drug prescribing. *Qual Assur Health Care.* 1990;2(1):37-58.

58. O'Brien MA, Rogers S, Jamtvedt G, Oxman AD, Odgaard-Jensen J, Kristoffersen DT, et al. Educational outreach visits: effects on professional practice and health care outcomes. *Cochrane Database Syst Rev.* 2007(4):CD000409.

59. Jin M, Naumann T, Regier L, Bugden S, Allen M, Salach L, et al. A brief overview of academic detailing in Canada: Another role for pharmacists. *Can Pharm J.* 2012;145(3):142-6 e2.

60. National Prescribing Service. NPS MedicineWise facilitator visits. Sydney: National Prescribing Service; 2013. Available from http://www.nps.org.au/health-professionals/professional-development/nps-facilitator-visits. (Accessed on 15 September 2013)

61. Ivers N, Jamtvedt G, Flottorp S, Young JM, Odgaard-Jensen J, French SD, et al. Audit and feedback: effects on professional practice and healthcare outcomes. *Cochrane Database Syst Rev.* 2012;6:CD000259.

62. Holloway K, Green T. Drug and therapeutics committees - a practical guide. Geneva: World Health Organisation; 2003.

63. Society of Hospital Pharmacists of Australia Committee of Specialty Practice in Drug Use Evaluation. SHPA standards of practice for drug use evaluation in Australian hospitals. *J Pharm Pract and Res.* 2004;34(3):220-3.

64. Dartnell J. Understanding, influencing and evaluating drug use. Melbourne: Therapeutic Guidelines Ltd; 2001.

65. National Prescribing Service. NPS clinical audits for GPs. Sydney: National Prescribing Service; 2013. Available from http://www.nps.org.au/health-

professionals/professional-development/nps-facilitator-visits. (Accessed on 15 September 2013)

66. National Prescribing Service. Drug use evaluation (DUE) programs. Sydney: National Prescribing Service; 2013. Available from http://www.nps.org.au/health-professionals/professional-development/nps-facilitator-visits. (Accessed on 15 September 2013)

67. GM Bolton P, W Tipper S, L Tasker J. Medication review by GPs reduces polypharmacy in the elderly: A quality use of medicines program. *Aust J Prim Health.* 2004;10(1):78-82.

68. Walsh EK, Cussen K. "Take ten minutes": a dedicated ten minute medication review reduces polypharmacy in the elderly. *Ir Med J.* 2010;103(8):236-8.

69. Taylor M, Horey D, Livingstone C, Swerissen H. Decline with a capital D: long-term changes in general practice consultation patterns across Australia. *Med J Aust.* 2010;193(2):80-3.

70. Tarn DM, Paterniti DA, Kravitz RL, Fein S, Wenger NS. How Do Physicians Conduct Medication Reviews? *J Gen Intern Med.* 2009;24(12):1296-302.

71. Shojania KG, Jennings A, Mayhew A, Ramsay CR, Eccles MP, Grimshaw J. The effects of on-screen, point of care computer reminders on processes and outcomes of care. *Cochrane Database Syst Rev.* 2009(3):CD001096.

72. Pit SW, Byles JE, Henry DA, Holt L, Hansen V, Bowman DA. A Quality Use of Medicines prograrn for general practitioners and older people: a cluster randomised controlled trial. *Med J Aust.* 2007;187(1):23-30.

73. Avery AJ, Sheikh A, Hurwitz B, Smeaton L, Chen YF, Howard R, et al. Safer medicines management in primary care. *Br J Gen Pract.* 2002;52:S17-S22.

74. Nkansah N, Mostovetsky O, Yu C, Chheng T, Beney J, Bond CM, et al. Effect of outpatient pharmacists' non-dispensing roles on patient outcomes and prescribing patterns. *Cochrane Database Syst Rev.* 2010(7):CD000336.

75. Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. *Am J Hosp Pharm.* 1990;47(3):533-43.

76. Cipolle R, Strand L, Morley P. Pharmaceutical care practice: the clinician's guide. 2nd ed. New York: McGraw-Hill; 2004.

77. Roughead E, Semple S, Vitry A. Pharmaceutical care services: a systematic review of published studies, 1990 to 2003, examining effectiveness in improving patient outcomes. *Int J Pharm Pract.* 2005;13(1):53-70.

78. Department of Health and Ageing. Home medicines review. Canberra: Department of Health and Ageing; 2013. Available from http://www.medicareaustralia.gov.au/provider/pbs/fifth-agreement/home-medicines-review.jsp. (Accessed on 9 September 2013)

79. Pharmacy Guild of Australia. The fifth community pharmacy agreement: pharmacy practice incentives. Canberra: Pharmacy Guild of Australia; 2013. Available from http://www.5cpa.com.au/initiatives-programs/ppi. (Accessed on 9 September 2013)

80. Department of Health and Ageing. Residential medication management review (RMMR). Canberra: Department of Health and Ageing; 2013. Available from

http://www.medicareaustralia.gov.au/provider/pbs/fifth-agreement/residential-medication-management-review.jsp. (Accessed on 10 September 2013)

81. Pharmaceutical Society of Australia. Guidelines for pharmacists providing Home Medicines Review (HMR) services. Deakin: Pharmaceutical Society of Australia; 2011. Available from http://www.psa.org.au/download/practice-guidelines/home-medicines-review-services.pdf. (Accessed on 16 September 2013)

82. Bernsten C, Bjorkman I, Caramona M, Crealey G, Frokjaer B, Grundberger E, et al. Improving the well-being of elderly patients via community pharmacy-based provision of pharmaceutical care: a multicentre study in seven European countries. *Drugs Aging.* 2001;18(1):63-77.

83. Sturgess IK, McElnay JC, Hughes CM, Crealey G. Community pharmacy based provision of pharmaceutical care to older patients. *Pharm World Sci.* 2003;25(5):218-26.

84. Sorensen L, Stokes JA, Purdie DM, Woodward M, Elliott R, Roberts MS. Medication reviews in the community: results of a randomized, controlled effectiveness trial. *Br J Clin Pharmacol.* 2004;58(6):648-64.

85. RESPECT trial team. Effectiveness of shared pharmaceutical care for older patients: RESPECT trial findings. *Br J Gen Pract.* 2010;60(570):e10-9.

86. RESPECT trial team. Cost-effectiveness of shared pharmaceutical care for older patients: RESPECT trial findings. *Br J Gen Pract.* 2010;60(570):e20-7.

87. Holland R, Lenaghan E, Harvey I, Smith R, Shepstone L, Lipp A, et al. Does home based medication review keep older people out of hospital? The HOMER randomised controlled trial. *BMJ.* 2005;330(7486):293-5.

88. Krska J, Cromarty JA, Arris F, Jamieson D, Hansford D, Duffus PR, et al. Pharmacist-led medication review in patients over 65: a randomized, controlled trial in primary care. *Age Ageing.* 2001;30(3):205-11.

89. Royal S, Smeaton L, Avery AJ, Hurwitz B, Sheikh A. Interventions in primary care to reduce medication related adverse events and hospital admissions: systematic review and meta-analysis. *Qual Saf Health Care.* 2006;15(1):23-31.

90. Blenkinsopp A, Bond C, Raynor DK. Medication reviews. *Br J Clin Pharmacol.* 2012;74(4):573-80.

91. Holland R, Desborough J, Goodyer L, Hall S, Wright D, Loke YK. Does pharmacist-led medication review help to reduce hospital admissions and deaths in older people? A systematic review and meta-analysis. *Br J Clin Pharmacol.* 2008;65(3):303-16.

92. Australian Pharmaceutical Advisory Council. Guiding Principles for medication management in the community. Canberra: Australia Pharmaceutical Advisory Council; 2006. Available from http://www.health.gov.au/internet/main/publishing.nsf/Content/23D9459ECD60326FCA257391001C6CFF/$File/booklet.pdf. (Accessed on 20 September 2013)

93. White L, Klinner C, Carter S. Consumer perspectives of the Australian Home Medicines Review Program: benefits and barriers. *Res Social Adm Pharm.* 2012;8(1):4-16.

94. Consumer Health Forum. Consumer uptake of home medicines reviews (HMR): an analysis of the HMR program and its sustainability. Canberra: Consumer Health Forum of Australia; 2013. Available from https://www.chf.org.au/pdfs/rep/rep-HMR--Issues-Paper.pdf. (Accessed on 17 September 2013)

95. Carter SR, Chen TF, White L. Home medicines reviews: a quantitative study of the views of recipients and eligible non-recipients. *Int J Pharm Pract.* 2012;20(4):209-17.

96. Campbell Research & Consulting. Home medicines review program qualitative research project - final report. Canberra: Department of Health and Aging; 2008. Available from http://www.health.gov.au/internet/main/publishing.nsf/Content/B2992EBF12BE7E1ECA2573D8007F91F3/$File/HMR%20Final%20Report.pdf. (Accessed on 17 September 2013)

97. Denneboom W, Dautzenberg MG, Grol R, De Smet PA. Treatment reviews of older people on polypharmacy in primary care: cluster controlled trial comparing two approaches. *Br J Gen Pract.* 2007;57(542):723-31.

98. Jackson S, Tenni P, Naunton M. Collaborative RMMRs in aged care facilities. *Aust Pharm.* 2006;25:758.

99. Geurts MM, Talsma J, Brouwers JR, de Gier JJ. Medication review and reconciliation with cooperation between pharmacist and general practitioner and the benefit for the patient: a systematic review. *Br J Clin Pharmacol.* 2012;74(1):16-33.

100. Tieman J, Mitchell G, Shelby-James T, Currow D, Fazekas B, O'Doherty L, et al. Integration, coordination and multidisciplinary care: What can these approaches offer to Australian primary health care? *Aust J Prim Health.* 2007;13(2):56-65.

101. Southern DM, Young D, Dunt D, Appleby NJ, Batterham RW. Integration of primary health care services: perceptions of Australian general practitioners, non-general practitioner health service providers and consumers at the general practice-primary care interface. *Eval Program Plann.* 2002;25(1):47-59.

102. Dennis SM, Zwar N, Griffiths R, Roland M, Hasan I, Powell Davies G, et al. Chronic disease management in primary care: from evidence to policy. *Med J Aust.* 2008;188(8 Suppl):S53-6.

103. McDonald J, Davies GP, Harris MF. Interorganisational and interprofessional partnership approaches to achieve more coordinated and integrated primary and community health services: the Australian experience. *Aust J Prim Health.* 2009;15(4):262-9.

104. Oldroyd J, Proudfoot J, Infante FA, Davies GP, Bubner T, Holton C, et al. Providing healthcare for people with chronic illness: the views of Australian GPs. *Med J Aust.* 2003;179(1):30.

105. Fried B, Rundal T, Topping S. Groups and teams in health services organizations. In: Shortell S, Kaluzny A, editors. Health Care Management. Albany, NY: Delmar Thomson Learning; 2000.

106. Xyrichis A, Ream E. Teamwork: a concept analysis. *J Adv Nurs.* 2008;61(2):232-41.

107. Reeves S, Goldman J, Burton A, Sawatzky-Girling B. Synthesis of systematic review evidence of interprofessional education. *J Allied Health.* 2010;39(3):198-203.

108. Pullon S, McKinlay E, Dew K. Primary health care in New Zealand: the impact of organisational factors on teamwork. *Br J Gen Pract.* 2009;59(560):191-7.

109. Xyrichis A, Lowton K. What fosters or prevents interprofessional teamworking in primary and community care? A literature review. *Int J Nurs Stud.* 2008;45(1):140-53.

110. Irvine R, Kerridge I, McPhee J, Freeman S. Interprofessionalism and ethics: consensus or clash of cultures? *J Interprof Care.* 2002;16(3):199-210.

111. Grumbach K, Bodenheimer T. Can health care teams improve primary care practice? *J Am Med Assoc.* 2004;291(10):1246-51.

112. Molyneux J. Interprofessional teamworking: what makes teams work well? *J Interprof Care.* 2001;15:29-35.

113. Sargeant J, Loney E, Murphy G. Effective interprofessional teams: "contact is not enough" to build a team. *J Contin Educ Health Prof.* 2008;28(4):228-34.

114. Delva D, Jamieson M, Lemieux M. Team effectiveness in academic primary health care teams. *J Interprof Care.* 2008;22(6):598-611.

115. Brown JB, Lewis L, Ellis K, Beckhoff C, Stewart M, Freeman T, et al. Sustaining primary health care teams: what is needed? *J Interprof Care.* 2010;24(4):463-5.

116. D'Amour D, Ferrada-Videla M, San Martin Rodriguez L, Beaulieu MD. The conceptual basis for interprofessional collaboration: core concepts and theoretical frameworks. *J Interprof Care.* 2005;19 (Suppl 1):116-31.

117. San Martin-Rodriguez L, Beaulieu MD, D'Amour D, Ferrada-Videla M. The determinants of successful collaboration: a review of theoretical and empirical studies. *J Interprof Care.* 2005;19 (Suppl 1):132-47.

118. Lemieux-Charles L, McGuire W. What do we know about health care team effectiveness? A review of the literature. *Med Care Res Rev.* 2006;63(3):263-300.

119. Brown J, Lewis L, Ellis K, Stewart M, Freeman TR, Kasperski MJ. Conflict on interprofessional primary health care teams - can it be resolved? *J Interprof Care.* 2011;25(1):4-10.

120. Rogers E. Diffusion of innovations. 5th ed. New York: Free Press; 2003.

121. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of Innovations in Service Organizations: systematic review and recommandations. *Milbank Q.* 2004;82(4):581-629.

122. Sanson-Fisher RW. Diffusion of innovation theory for clinical change. *Med J Aust.* 2004;180(6):S55-6.

123. Pottie K, Farrell B, Haydt S, Dolovich L, Sellors C, Kennie N, et al. Integrating pharmacists into family practice teams: physicians' perspectives on collaborative care. *Can Fam Physician.* 2008;54(12):1714-7.

124. Dobson RT, Henry CJ, Taylor JG, Zello GA, Lachaine J, Forbes DA, et al. Interprofessional health care teams: attitudes and environmental factors associated with participation by community pharmacists. *J Interprof Care.* 2006;20(2):119-32.

125. Bradley F, Elvey R, Ashcroft DM, Hassell K, Kendall J, Sibbald B, et al. The challenge of integrating community pharmacists into the primary health care team: a case study of local pharmaceutical services (LPS) pilots and interprofessional collaboration. *J Interprof Care.* 2008;22(4):387-98.

126. Spencer J, Edwards C. Pharmacy beyond the dispensary: general practitioners' views. *BMJ.* 1992;304:1670-2.

127. Zillich A, McDonough RP, Carter BL, Doucette WR. Influential characteristics of physician/pharmacist collaborative relationships. *Ann Pharmacother.* 2004;38:764-70.

128. Dobson RT, Taylor JG, Henry CJ, Lachaine J, Zello GA, Keegan DL, et al. Taking the lead: Community pharmacists' perception of their role potential within the primary care team. *Res Social Adm Pharm.* 2009;5(4):327-36.

129. Ray MD. Shared borders: achieving the goals of interdisciplinary patient care. *Am J Health Syst Pharm.* 1998;55(13):1369-74.

130. Canadian Pharmacists Association. Pharmacists and primary health care. Ottawa, Ontario: Canadian Pharmacists Association; May 2004.

131. Bradley M. The role of the full-time practice pharmacist. *Primary Care Pharmacy.* 1999;1(1):14-5.

132. American Society of Health-System Pharmacists. ASHP statement on the pharmacist's role in primary care. *Am J Health Syst Pharm.* 1999;56(16):1665-7.

133. Silcock J, Raynor DKT, Petty D. The organisation and development of primary care pharmacy in the United Kingdom. *Health Policy.* 2004;67(2):207-14.

134. Mason P. A pharmacist in the surgery - what better prescription for the new age? *Pharm J.* 1996;256:192-5.

135. Kempner N. "GP Pharmacists": what do they do? *Pharm J.* 1996;256:196-7.

136. Zermansky AG. Who controls repeats? *Br J Gen Pract.* 1996;46(412):643-7.

137. Granås A, Bates I. The effect of pharmaceutical review of repeat prescriptions in general practice. *Int J Pharm Pract.* 1999;7:264-75.

138. Goldstein R, Hulme H, Willits J. Reviewing repeat prescribing - general practitioners and community pharmacists working together. *Int J Pharm Pract.* 1998;6:60-6.

139. Mackie CA, Lawson DH, Campbell A, Maclaren AG, Wright R. A randomised controlled trial of medication review in patients receiving polypharmacy in general practice. *Pharm J.* 1999;263(supp):R7.

140. Chen J, Britten N. 'Strong medicine': an analysis of pharmacist consultations in primary care. *Fam Pract.* 2000;17(6):480-3.

141. Burtonwood A, Hinchliffe A, Tinkler G. A prescription for quality: a role for the clinical pharmacist in general practice. *Pharm J.* 1998;261:678-80.

142. Zermansky AG, Petty DR, Raynor DK, Freemantle N, Vail A, Lowe CJ. Randomised controlled trial of clinical medication review by a pharmacist of elderly patients receiving repeat prescriptions in general practice. *BMJ.* 2001;6(20):1340-3.

143. Avery AJ, Rodgers S, Cantrill JA, Armstrong S, Cresswell K, Eden M, et al. A pharmacist-led information technology intervention for medication errors (PINCER): a multicentre, cluster randomised, controlled trial and cost-effectiveness analysis. *Lancet.* 2012;379(9823):1310-9.

144. Petty DR, Zermansky AG, Raynor DK, Lowe CJ, Freemantle N, Vail A. Clinical medication review by a pharmacist of elderly patients on repeat medications in general practice - pharmacist interventions and review outcomes. *Int J Pharm Pract.* 2002;10:39-45.

145. Cresswell KM, Sadler S, Rodgers S, Avery A, Cantrill J, Murray SA, et al. An embedded longitudinal multi-faceted qualitative evaluation of a complex cluster

randomized controlled trial aiming to reduce clinically important errors in medicines management in general practice. *Trials.* 2012;13:78.

146. Malone DC, Carter BL, Billups SJ, Valuck RJ, Barnette DJ, Sintek CD, et al. An economic analysis of a randomized, controlled, multicenter study of clinical pharmacist interventions for high-risk veterans: the IMPROVE study. *Pharmacotherapy.* 2000;20(10):1149-58.

147. Nkansah N, Brewer J, Connors R, Shermock K. Clinical outcomes of patients with diabetes mellitus receiving medication management by pharmacists in an urban private physician practice. *Am J Health Syst Pharm.* 2008;65:145-9.

148. Harris IM, Westberg SM, Frakes MJ, Van Vooren JS. Outcomes of medication therapy review in a family medicine clinic. *J Am Pharm Assoc.* 2009;49(5):623-7.

149. Cranor CW, Bunting BA, Christensen DB. The Asheville Project: long-term clinical and economic outcomes of a community pharmacy diabetes care program. *J Am Pharm Assoc* 2003;43(2):173-84.

150. American Pharmacists Association, National Association of Chain Drug Stores Foundation. Medication therapy management in pharmacy practice: Core elements of an MTM service model (version 2.0). *J Am Pharm Assoc.* 2008;48(3):341-53.

151. Isetts BJ, Brown LM, Schondelmeyer SW, Lenarz LA. Quality assessment of a collaborative approach for decreasing drug-related morbidity and achieving therapeutic goals. *Arch Intern Med.* 2003;163(15):1813-20.

152. Smith M, Bates DW, Bodenheimer T, Cleary PD. Why pharmacists belong in the medical home. *Health Aff.* 2010;29(5):906-13.

153. Patient-Centred Primary Care Collaborative. Defining the medical home. Patient-Centred Primary Care Collaborative; 2013. Available from http://www.pcpcc.org/about/medical-home. (Accessed on 21 August 2013)

154. American Academy of Family Physicians, American Academy of Pediatrics, American College of Physicians, Association AO. Joint principles of the patient-centered medical home. 2007. Available from http://www.aafp.org/dam/AAFP/documents/practice_management/pcmh/initiatives/PCMHJoint.pdf. (Accessed on 21 August 2013)

155. McInnis T, Strand L, CE W. The patient-centered medical home: integrating comprehensive medication management to optimize patient outcomes. Washington: Patient-Centred Primary Care Collaborative; 2012. Available from http://www.accp.com/docs/positions/misc/CMM%20Resource%20Guide.pdf.

156. Scott MA, Hitch B, Ray L, Colvin G. Integration of pharmacists into a patient-centered medical home. *J Am Pharm Assoc (2003).* 2011;51(2):161-6.

157. Roth MT, Ivey JL, Esserman DA, Crisp G, Kurz J, Weinberger M. Individualized medication assessment and planning: optimizing medication use in older adults in the primary care setting. *Pharmacotherapy.* 2013;33(8):787-97.

158. Taylor CT, Byrd DC, Krueger K. Improving primary care in rural Alabama with a pharmacy initiative. *Am J Health Syst Pharm.* 2003;60(11):1123-9

159. Berdine HJ, Skomo ML. Development and integration of pharmacist clinical services into the patient-centered medical home. *J Am Pharm Assoc.* 2003;52(5):661-7.

160. Isetts BJ, Schondelmeyer SW, Artz MB, Lenarz LA, Heaton AH, Wadd WB, et al. Clinical and economic outcomes of medication therapy management services: The Minnesota experience. *J Am Pharm Assoc.* 2008;48(2):203-11.

161. Altavela J, Jones M, Ritter M. A prospective trial of a clinical pharmacy intervention in a primary care practice in a capitated payment system. *J Manag Care Pharm.* 2008;14:831-43.

162. Hanlon JT, Weinberger M, Samsa GP, Schmader KE, Uttech KM, Lewis IK, et al. A randomized, controlled trial of a clinical pharmacist intervention to improve inappropriate prescribing in elderly outpatients with polypharmacy. *Am J Med.* 1996;100(4):428-37.

163. Malone DCP, Carter BLP, Billups SJP, Valuck RJP, Barnette DJP, Sintek CDMS, et al. Can clinical pharmacists affect SF-36 scores in veterans at high risk for medication-related problems? *Med Care* 2001;39(2):113-22.

164. Romanow R. Building on values: The future of Health Care in Canada. Ottawa, Ontario: Commission on the Future of Health Care in Canada; 2002. Available from http://dsp-psd.pwgsc.gc.ca/Collection/CP32-85-2002E.pdf. (Accessed on 22 September 2013)

165. Approaches to enhancing the quality of drug therapy. A joint statement by the CMA and the Canadian Pharmaceutical Association. Canadian Medical Association. *CMAJ.* 1996;155(6):784A-F.

166. Dolovich L. Ontario pharmacists practicing in family health teams and the patient-centered medical home. *Ann Pharmacother.* 2012;46(4):S33-9.

167. Sellors J, Kaczorowski J, Sellors C, Dolovich L, Woodward C, Willan A, et al. A randomized controlled trial of a pharmacist consultation program for family physicians and their elderly patients. *Can Med Assoc J.* 2003;169(1):17-22.

168. Howard M, Trim K, Woodward C, Dolovich L, Sellors C, Kaczorowski J, et al. Collaboration between community pharmacists and family physicians: lessons learned from the Seniors Medication Assessment Research Trial. *J Am Pharm Assoc.* 2003;43:566 - 72.

169. Dolovich L, Pottie K, Kaczorowski J, Farrell B, Austin Z, Rodriguez C, et al. Integrating family medicine and pharmacy to advance primary care therapeutics. *Clin Pharmacol Ther.* 2008;83(6):913-7.

170. Farrell B, Pottie K, Haydt S, Kennie N, Sellors C, Dolovich L. Integrating into family practice: the experiences of pharmacists in Ontario, Canada. *Int J Pharm Pract.* 2008;16:309-15.

171. Greenhill G. Clinical pharmacist review of medication for the elderly in a general practice setting. Final report for the Pharmacy Education Program (PEP). Perth;1996. Available from http://www.qummap.net.au/files/reports/12113278200963.pdf. (Accessed on 5 June 2013)

172. Whitehead P. Evaluation of a model of delivery of patient orientated pharmacy services by pharmacists based in general medical practices in Australia (doctoral thesis). Western Australia: Curtin University of Technology; 2005.

173. Whitehead PA, Sunderland VB, Benrimoj SI. The 'general practice' pharmacist. *Aust J Pharm.* 2003;84:24-7.

174. Freeman C, Cottrell WN, Kyle G, Williams I, Nissen L. Does a primary care practice pharmacist improve the timeliness and completion of medication management reviews? *Int J Pharm Pract.* 2012;20(6):395-401.

175. Freeman C, Cottrell W, Kyle G, Williams I, Nissen L. Integrating a pharmacist into the general practice environment: opinions of pharmacists, general practitioners, health care consumers, and practice managers. *BMC Health Serv Res.* 2012;12(1):229.

176. Freeman C, Cottrell W, Kyle G, Williams ID, Nissen L. Pharmacists', general practitioners' and consumers' views on integrating pharmacists into general practice. *J Pharm Pract and Res.* 2012;42(3):184-8.

177. Freeman C, Cottrell W, Kyle G, Williams I, Nissen L. Chronicles of a primary care practice pharmacist *Integrated Pharmacy Research and Practice.* 2012;1:13-8.

178. Freeman CR, Cottrell WN, Kyle G, Williams ID, Nissen L. An evaluation of medication review reports across different settings. *Int J Clin Pharm.* 2013;35(1):5-13.

179. Sellors J, Cosby R, Trim K, Kaczorowski J, Howard M, Hardcastle L, et al. Recruiting family physicians and patients for a clinical trial: lessons learned. *Fam Pract.* 2002;19(1):99-104.

180. Farrell B, Pottie K, Woodend K, Yao V, Dolovich L, Kennie N, et al. Shifts in expectations: evaluating physicians' perceptions as pharmacists become integrated into family practice. *J Interprof Care.* 2010;24:80 - 9.

181. Pottie K, Haydt S, Farrell B, Dolovich L, Sellors C, Hogg W. Narrative reports to monitor and evaluate the integration of pharmacists into family practice settings. *Ann Fam Med.* 2008;6(2):161-5.

182. Pottie K, Haydt S, Farrell B, Kennie N, Sellors C, Martin C, et al. Pharmacists' identity development within multidisciplinary primary health care teams in Ontario; qualitative results from the IMPACT project. *Res Social Adm Pharm.* 2009;5(4):319-26.

183. Kozminski M, Busby R, McGivney MS, Klatt PM, Hackett SR, Merenstein JH. Pharmacist integration into the medical home: qualitative analysis. *J Am Pharm Assoc (2003).* 2011;51(2):173-83.

184. MacRae F, Lowrie R, MacLaren A, Barbour R, Norrie J. Pharmacist-led medication review clinics in general practice: the views of Greater Glasgow GPs. *Int J Pharm Pract.* 2003;11:199 - 208.

185. Petty D, Knapp P, Raynor D, House A. Patients' views of a pharmacist-run medication review clinic in general practice. *Br J Gen Pract.* 2003;53:607-13.

186. Hughes C, McCann S. Perceived interprofessional barriers between community pharmacists and general practitioners: a qualitative assessment. *Br J Gen Pract.* 2003;53:600-6.

187. Gilbert L. The community pharmacist as a member of a primary health care team in South Africa - perceptions of pharmacists, doctors and nurses. *Int J Pharm Pract.* 1997;5:192-200.

188. Gillespie U, Morlin C, Hammarlund-Udenaes M, Hedstrom M. Perceived value of ward-based pharmacists from the perspective of physicians and nurses. *Int J Clin Pharm.* 2012;34(1):127-35.

189. Pharmacy Coalition on Primary Care. Role of the pharmacist in primary health care in Canada. Saskatchewan, Canada: Pharmacy Coalition on Primary Care; 2003. Available from

http://scp.in1touch.org/uploaded/web/site/PrimaryCare_PCPC_Submission_2003.pdf. (Accessed on 22 September 2013)

190. Kennie-Kaulbach N, Farrell B, Ward N, Johnston S, Gubbels A, Eguale T, et al. Pharmacist provision of primary health care: a modified Delphi validation of pharmacists' competencies. *BMC Fam Pract.* 2012;13:27.

191. Kolodziejak L, Rémillard A, Neubauer S. Integration of a primary healthcare pharmacist. *J Interprof Care.* 2010;24(3):274-84.

192. Perez A, Doloresco F, Hoffman JM, Meek PD, Touchette DR, Vermeulen LC, et al. ACCP: economic evaluations of clinical pharmacy services: 2001-2005. *Pharmacotherapy.* 2009;29(1):128.

193. Harris IM, Baker E, Berry TM, Halloran MA, Lindauer K, Ragucci KR, et al. Developing a business-practice model for pharmacy services in ambulatory settings. *Pharmacotherapy.* 2008;28(2):285.

194. Ministry of Health and Long-Term Care. Guide to interdisciplinary provider compensation. Ontario: Ministry of Health and Long-Term Care; 2010. Available from http://www.health.gov.on.ca/transformation/fht/guides/fht_inter_provider.pdf. (Accessed on 22 September 2013)

195. Department of Health and Ageing. Chronic disease management (CDM) Medicare items. Canberra: Department of Health and Ageing; 2013. Available from http://www.health.gov.au/internet/main/publishing.nsf/Content/mbsprimarycare-chronicdiseasemanagement. (Accessed on 10 September 2013)

Chapter 3. Systematic review and meta-analyses

3.1 Introduction

The previous chapter provided an overview of the literature regarding pharmacist integration into the PHCT. The review identified several gaps in the literature, including the lack of recent systematic reviews appraising the effectiveness of co-located pharmacist services provided in general practice settings.

This chapter presents a critical evaluation of RCTs that investigated interventions delivered by pharmacists working within general practice and primary healthcare clinics.

The key objectives of this systematic review were to:

- Evaluate the effectiveness of the interventions delivered by pharmacists in the general practice setting on primary outcomes;
- Assess the methodological quality of the included studies; and
- Determine which interventions and methods of delivery were the most effective.

A manuscript for this systematic review and meta-analyses has been accepted for publication by *Research in Social and Administrative Pharmacy* and is reproduced below.

Declaration for Thesis Chapter 3

Declaration by candidate

In the case of Chapter 3, the nature and extent of my contribution to the work was the following:

Nature of contribution	**Extent of contribution (%)**
Reviewed literature; designed methodology; developed study materials; screened articles; undertook data extraction and synthesis; performed data analysis including meta-analysis; prepared manuscript.	75%

The following co-authors contributed to the work:

Name	**Nature of contribution**
Assoc Prof Kay Stewart	Designed methodology; reviewed study materials; undertook data extraction; reviewed data and manuscript.
Mr Rohan Elliott	Designed methodology; reviewed study materials; undertook data extraction; reviewed data and manuscript.
Dr Johnson George	Designed methodology; reviewed study materials; undertook data extraction; reviewed data and manuscript.

Candidate's Signature		**Date**

Declaration by co-authors

The undersigned hereby certify that:

1. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors.
2. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. there are no other authors of the publication according to these criteria;
5. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
6. the original data are stored at the following location(s) and will be held for at least five years from the date indicated below:

Location(s)	**Centre for Medicine Use and Safety, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University, Parkville, Victoria 3052**

Signature 1	[redacted] Assoc Prof Kay Stewart	**Date** 8/10/13
Signature 2	[redacted] Mr Rohan Elliott	8/10/13
Signature 3	[redacted] Dr Johnson George	8/10/13

3.2 Article Synopsis

Integration of pharmacists into primary care general practice clinics has the potential to improve interdisciplinary teamwork and patient care. A systematic review and meta-analysis of the effectiveness of clinical pharmacist services delivered in general practice clinics found that pharmacists delivered a range of interventions, most commonly medication review, and that these services often had favourable impacts on various aspects of chronic disease management and quality use of medicines. Meta-analyses indicated that pharmacist interventions led to significant improvements in blood pressure, glycosylated haemoglobin, cholesterol and Framingham risk score.

3.3 Abstract

Background

Integration of pharmacists into primary care general practice clinics has the potential to improve interdisciplinary teamwork and patient care; however this practice is not widespread.

Objective

The aim of this study was to review the effectiveness of clinical pharmacist services delivered in primary care general practice clinics.

Methods

A systematic review of English language randomized controlled trials cited in the Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE and International Pharmaceutical Abstracts was conducted. Studies were included if pharmacists had a regular and ongoing relationship with the clinic; delivered an intervention aimed at

optimizing prescribing for, and/or medication use by, clinic patients; and were physically present within the clinic for all or part of the intervention, or for communication with staff. The search generated 1484 articles. After removal of duplicates and screening of titles and abstracts against inclusion criteria, 131 articles remained. Following review and assessment of full texts by two investigators, 38 studies were included in the review and assessed for quality. Seventeen studies had common endpoints (blood pressure, glycosylated hemoglobin, cholesterol and/or Framingham risk score) and were included in meta-analyses.

Results

Twenty-nine of the 38 studies recruited patients with specific medical conditions, most commonly cardiovascular disease (15 studies) and/or diabetes (9 studies). The remaining 9 studies recruited patients at general risk of medication misadventure. Pharmacist interventions usually involved medication review (86.8%), with or without other activities delivered collaboratively with the general practitioner (family physician). Positive effects on primary outcomes related to medication use or clinical outcomes were reported in 19 studies, mixed effects in six studies, and no effect in 13 studies. The results of meta-analyses favoured the pharmacist intervention, with significant improvements in blood pressure, glycosylated haemoglobin, cholesterol and Framingham risk score in intervention patients compared to control patients.

Conclusions

Pharmacists co-located in general practice clinics delivered a range of interventions, with favourable results in various areas of chronic disease management and quality use of medicines

3.4 Introduction

General practice is defined as "the provision of primary continuing comprehensive whole-patient medical care to individuals, families and their communities".[1] In the provision of primary care, much undifferentiated illness is seen; the primary care physician or general practitioner (GP) must deal with problem complexes and make a total assessment of a patient's condition in a range of clinical contexts. In managing the patient, general practice staff may make referral to other health care professionals and community services, including pharmacists.[1]

There is evidence that non-dispensing or clinical services provided by pharmacists in the outpatient setting may result in improved patient outcomes and prescribing patterns.[2] Despite this, the uptake of these services is low and collaboration between pharmacists and general practitioners is suboptimal.[3, 4] Limitations of most models of GP-pharmacist collaboration in primary care include geographical isolation, poor communication, and lack of time and remuneration for team activities.[5, 6]

In recent years, pharmacists have increasingly integrated into general practice clinics.[7, 8] Practice pharmacists have a range of functions including administrative and clinical duties related to their expertise in medication use and safety. Clinical services provided by these pharmacists include drug information, medication reviews, education and counselling, health promotion, and running disease management clinics.[9] The co-location of pharmacists with GPs in these settings has been shown to enable greater inter-professional communication and the development of collaborative working relationships.[10]

A systematic review by Fish et al.,[11] published in 2002, found that studies of general practice-based pharmaceutical services have largely been of poor methodological quality, with inconsistent results. Since that review was published, there has been a rise in the number of studies exploring the role of general practice-based pharmacists.

Other more recent systematic reviews of pharmacist interventions have focused on specific patient groups, disease states, interventions, and/or outcome measures in a diverse range of healthcare settings rather than in primary care general practice clinics specifically, thus making it difficult to apply findings to the general practice setting.[2, 12-15]

The aim of our systematic review was to evaluate the role of pharmacists co-located with GPs and other health professionals within primary care general practice clinics (e.g. family practice clinics, community health centers or primary healthcare centers). The review includes randomized controlled trials (RCTs) that explored a variety of pharmacist interventions covering different disease states and patient groups, and their effect on various health outcomes.

3.5 Methods

3.5.1 Search Strategy

A search of the literature was undertaken using the Cochrane Central Register of Controlled Trials (CENTRAL) (1966 – May 2013), MEDLINE (1966–May 2013), EMBASE (1966 – May 2013) and International Pharmaceutical Abstracts (IPA) (1970 – May 2013). In CENTRAL and MEDLINE, Medical Subject Headings (MeSH) related to pharmacy ("pharmacists" OR "pharmaceutical services") AND general practice ("family

practice" OR "primary health care" OR "family physicians" OR "physicians' offices" OR "community health centers" OR "community health services") were used. These were supplemented with truncated text words related to pharmacy ("pharmacist*") AND general practice ("family adj2 practi*" OR "general adj2 practi*" OR "primary adj2 care" OR "family adj2 physician" OR "clinic"). EMBASE was searched using a similar strategy; however, the Emtree subject headings "pharmaceutical care" and "pharmacy" were used instead of "pharmaceutical services", "general practice" and "general practitioners" were used instead of "family practice" and "family practitioners", and the term "physicians' offices" was excluded as it was not available. Searches were limited to randomized controlled trials (RCTs). IPA was searched using the key words "pharmacist*" AND "primary care" OR "primary health care" OR "primary health care" OR "general practice" OR "family practice" OR "family medicine" OR "community health" OR "office" OR "clinic" AND "control*" OR "random*". Descriptor terms were not utilized as these were considered to be too broad and non-specific. Searches were limited to English-language articles and excluded conference abstracts. Reference lists of studies identified, and other review articles related to pharmacist involvement in general practice, were screened for additional relevant studies.

3.5.2 Inclusion and Exclusion Criteria

Studies were included in the review if they met all of the following conditions:

- tested an intervention that included a pharmacist who
  - delivered one or more clinical pharmacy (non-dispensing) services aimed at improving prescribing and/or medication use in patients attending a general practice clinic;

  - had a regular and ongoing relationship with the clinic; and
  - was physically present within the clinic for all or part of the intervention, or for communication with clinic staff (however, may deliver interventions to individual patients remotely [e.g. via telephone or web] or in the patient's home [i.e. home visit]).
- had a control group;
- randomly assigned participants (patients or practices) to the study groups; and
- measured outcomes related to appropriateness of prescribing, medication use, health service use, clinical, functional, practice or economic outcomes.

Studies were excluded if they met any of the following conditions:

- tested infrequent or "once off" interventions such as academic detailing or similar interventions provided by an external group;
- the intervention was delivered in secondary or tertiary care hospital settings;
- tested interventions that did not target management of individual patients (e.g. the use of group education sessions or drug use evaluation only);or
- they did not report an *a priori* sample size calculation and the sample size was less than 50 subjects per group[1]

3.5.3 Study Selection

The titles and abstracts of studies were screened for relevance by one author (ET). Full-text copies were obtained if a study appeared to meet the inclusion criteria or it was unclear whether it would meet the criteria. Two authors independently reviewed the full

[1] Likely to be underpowered, with unacceptable risk of false negative findings.

text to assess studies' suitability for inclusion. Disagreements or uncertainties about study inclusion were resolved by discussion in the presence of all authors.

3.5.4 Data Extraction and Validity Assessment

Data were extracted independently by two authors using a standardised abstraction form. Data extracted included study setting, duration, study population, sample size, intervention tested, outcome measures and results. Methodological quality was assessed according to the Cochrane Handbook risk of bias assessment tool[16] and included examining the following criteria: method of randomisation, concealment of allocation, blinding of outcome assessment, addressing of incomplete outcome data and freedom from selective outcome reporting. Given the nature of the interventions assessed, blinding of the participants and personnel in the studies was not possible, and hence these criteria were not included in the quality assessment. Attempts were made to contact authors to clarify details of the studies as needed.

The primary outcome measures for the intervention and control groups at the end of study were compared; a p value <0.05 was considered statistically significant. A 'positive outcome' was defined as a significant difference in favour of the intervention group for the primary outcome at study-end, with a 'negative outcome' being the opposite. 'No effect' was defined as no statistically significant difference between the groups. For studies assessing multiple primary outcomes, a 'mixed result' was defined as a positive outcome on one primary outcome measure but not another.

3.5.5 Meta-Analysis

Where there were two or more studies that reported a similar primary outcome measure with appropriate extractable data, a meta-analysis was undertaken. Data extracted from

these studies included sample size, means and standard deviations; if these were not reported, other data (e.g. p-values) were recorded where possible. Meta-analysis was performed using Comprehensive Meta-analysis (Biostat, Inc, Englewood, NJ). Random effects models were used for pooling the data and I^2 statistics were used for exploring heterogeneity.[17, 18]. The effect size for the meta-analysis was calculated as the difference in means. Weighted averages were used to pool each study and significance tested using a Z-statistic.

3.6 Results

3.6.1 Search and Study Selection

The electronic database searches retrieved 1,484 articles. An additional eight articles were identified by a manual search of relevant review articles and reference lists. After removal of duplicates, the titles and abstracts of 986 studies were reviewed, of which 855 were excluded because they clearly did not meet the inclusion criteria. 131 articles were deemed suitable for the retrieval of full-text copies for further scrutiny; 93 of these were excluded after review by at least two investigators (Figure 1). A total of 38 studies were included in the final review and are summarised below and in Table 1.

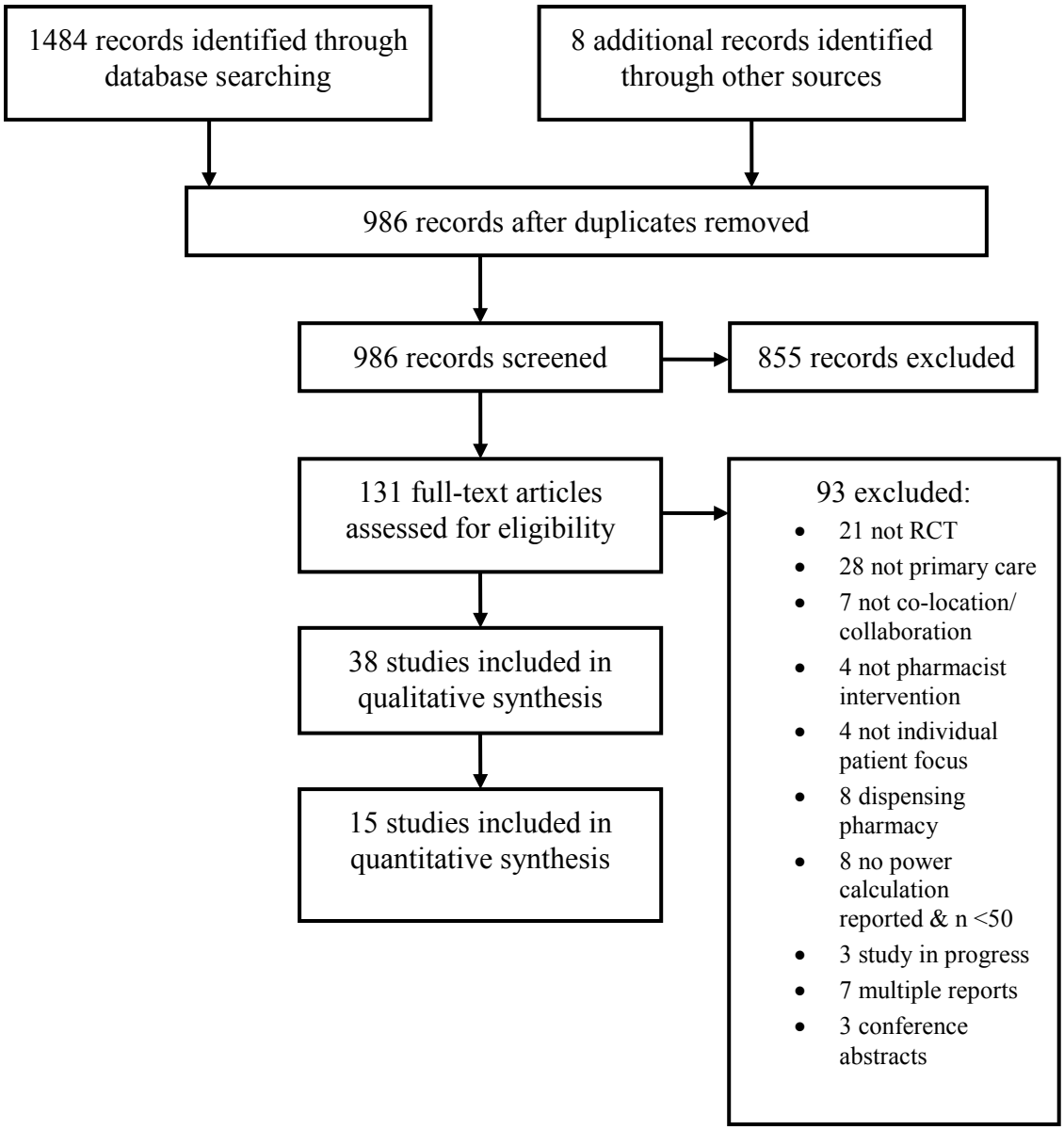


Figure 3.2. Selection of studies

3.6.2 Summary of Included Studies

The majority of studies were conducted in the United States of America (USA),[19-36] United Kingdom (UK)[37-43] or Canada.[44-49] Three studies were undertaken in South America[50-52] and four studies in Asia.[53-56] Twenty-nine trials included patients with

specific medical conditions including cardiovascular disease,[20, 23, 27, 28, 33, 38, 41, 42, 45, 51-55, 57] diabetes,[24, 27, 29, 31, 32, 34, 35, 49, 50] depression,[19, 21, 25] metabolic syndrome,[56] pain,[40] chronic obstructive pulmonary disease (COPD)[57] and menopause[44] as part of their inclusion criteria. The remaining nine studies included patients receiving polypharmacy,[26, 30, 39, 46, 48] patients prescribed at least one medication,[43] patients at risk of medication problems,[22] patients at risk of adverse health problems (e.g. had at least one emergency department visit in the past year, multiple co-morbidities etc.),[47] and any general practice patients.[37]

The pharmacist interventions mainly involved medication review, either face-to-face with the patient[19, 22-26, 28-31, 33-35, 37, 40-43, 45, 47-53, 55, 56] or based on clinic medical records only.[27, 32, 38, 39, 46] All studies described some form of collaboration between the pharmacist and the GP or primary care physician. Interprofessional communication was either verbal (face-to-face[19, 21, 23, 24, 26, 28-30, 35, 37, 39, 41, 42, 45, 47-49, 54-56] or by telephone[20, 25, 29, 34, 54]), written[19, 21, 24-29, 32, 34, 38, 40-46, 48, 50, 51, 53, 55, 56] or not specified.[22, 31, 36, 52] The pharmacist intervention resulted in positive outcomes in 19 studies,[23-26, 28, 33, 35, 37, 39, 41, 43, 47, 49-51, 53-56] mixed outcomes in six studies,[19, 20, 34, 36, 38, 52] and no effect in 13 studies (Table 3.1).[21, 23, 27, 29-32, 40, 42, 44-46, 48]

Table 3.1. Characteristics of included studies

Author, Year, country	Primary care population	Patient-directed activities							Communication with GP			Primary Outcome(s)	Effect(s)
		Med review	Education	Adherence assessment	Health/ lifestyle advice	Physical assessment (e.g. BP)	Monitor	Prescribe/ adjust/ administer	Face to face	Phone	Written		
Adler (2004),[19] US	≥18 years old with depression	✓	✓	✓	✓				✓		✓	Antidepressant use rates; Severity of depression (modified BDI)	Mixed (positive for antidepressant use; no effect BDI score)
Avery (2012),[37] UK	General practices with electronic prescribing	✓	✓				✓		✓			Prescribing appropriateness indicators	Positive
Bond (2007),[38] UK	Angina & Hypertension	✓ of MR									✓	Prescribing appropriateness indicators	Mixed
Borenstein (2003),[20] US	≥18 y.o, capitated medical insurance, uncontrolled hypertension		✓	✓	✓	✓				✓		BP	Mixed (positive in SBP; no in DBP)
Capoccia (2004),[21] US	≥ 18years old with new episode of depression, started on antidepressant medication		✓	✓	✓			✓	✓		✓	Depression symptoms (Hopkins SCL-20 score)	No effect
Carter (2001),[22] US	Patients at high risk of medication problems	✓	✓	✓			✓ Varied between sites	✓ Varied between sites				Patient satisfaction, Health care use & costs, HRQoL;	No effect
Carter (2008),[23]	21 – 85 years old	✓	✓	✓				✓	✓			BP & % patients	Positive

Author, Year, country	Primary care population	Patient-directed activities							Communication with GP			Primary Outcome(s)	Effect(s)
		Med review	Education	Adherence assessment	Health/ lifestyle advice	Physical assessment (e.g. BP)	Monitor	Prescribe/ adjust/ administer	Face to face	Phone	Written		
US	with hypertension											at target BP level	
Choe (2005),[24] US	Type 2 diabetes and most recent $HbA_{1C} \geq 8.0\%$	✓	✓		✓			✓	✓		✓	HbA1c	Positive
Deschamps (2004),[44] Canada	Peri- and post-menopausal female patients, 48-52 years old		✓								✓	Perception of being informed about HRT; decisional conflict; satisfaction with education & decision made regarding HRT; adherence to HRT	No effect
Evans (2010),[45] Canada	Cardiovascular risk (Framingham Risk Score ≥15%)	✓	✓		✓				✓		✓	Framingham risk score	No effect
Finley (2003),[25] US	Depression, newly starting antidepressant	✓	✓		✓			✓		✓	✓	Adherence to antidepressant drug therapy	Positive
Gourley (1998),[36, 57, 59] US	Adults with hypertension or COPD		✓	✓	✓							Medication compliance, health resource use, satisfaction, disease knowledge, QoL, clinical and process outcomes (primary outcome not specified)	Mixed

Author, Year, country	Primary care population	Patient-directed activities							Communication with GP			Primary Outcome(s)	Effect(s)
		Med review	Education	Adherence assessment	Health/ lifestyle advice	Physical assessment (e.g. BP)	Monitor	Prescribe/ adjust/ administer	Face to face	Phone	Written		
Granas (1999),[39] UK	Repeat prescriptions with ≥3 items	✓ of MR							✓			MRP resolution	Positive
Grymonpre (2001),[46] Canada	≥65 years, ≥2 medications	✓ of MR	✓								✓	Medication adherence	No effect
Hammad (2011),[56] Jordan	Metabolic syndrome	✓	✓	✓	✓		✓		✓		✓	Metabolic syndrome status	Positive
Hanlon (1996),[26] US	≥65 years, ≥5 medications	✓	✓	✓					✓		✓	MAI	Positive
Hay (2006),[40, 70] UK	≥55 years, pain/stiffness in knee	✓		✓			✓	✓			✓	WOMAC index	No effect
Heisler (2012),[27] US	Diabetes, poor BP control & adherence	✓ of MR	✓	✓		✓	✓	✓			✓	SBP	No effect
Hogg (2009),[47] Canada	At risk of health problems	✓	✓						✓			CDM QOC measures	Positive
Hunt (2008),[28] US	Hypertension	✓	✓	✓	✓	✓	✓	✓	✓		✓	BP	Positive
Jacobs (2012),[29] US	Type 2 diabetes; HbA1C >8%	✓	✓	✓	✓	✓	✓ With GP	✓ With GP	✓	✓	✓	Targets for HbA1C (≤7%), LDL (≤100	No effect

Author, Year, country	Primary care population	Patient-directed activities							Communication with GP			Primary Outcome(s)	Effect(s)
		Med review	Education	Adherence assessment	Health/ lifestyle advice	Physical assessment (e.g. BP)	Monitor approval	Prescribe/ adjust/ administer approval	Face to face	Phone	Written		
Jameson (2001),[30] US	≥5 chronic medicines	✓	✓	✓	✓				✓			Medical & drug costs	No effect
Jameson (2010),[30] US	≥18 years old, diabetes, HbA1C ≥9.0%	✓	✓	✓	✓			✓ (insulin)	?	?	?	HbA1C	No effect
Jamieson (2010),[41] UK	Adults, BP >140/85 and on treatment	✓	✓	✓	✓		✓		✓		✓	BP	Positive
Kirwin (2010),[32] US	≥18, Diabetes Mellitus (Type 1 or 2)	✓ of MR									✓	Rate of HbA1C testing	No effect
Lowrie (2012),[42] UK	≥18 years, left ventricular systolic dysfunction	✓	✓	✓	✓		✓	✓	✓		✓	Composite of death from any cause or hospital admission for worsening heart failure	No effect
Mourao (2013),[50] Brazil	≥18 yrs, post-prandial capillary glucose ≥180 mg/dL, HbA1C ≥7%	✓	✓	✓	✓						✓	HbA1C	Positive
Neto (2011),[51] Brazil	≥60 years, diabetes and/or hypertension diagnosis & on	✓	✓	✓	✓						✓	Framingham risk score	Positive

Author, Year, country	Primary care population	Patient-directed activities							Communication with GP			Primary Outcome(s)	Effect(s)
		Med review	Education	Adherence assessment	Health/ lifestyle advice	Physical assessment (e.g. BP)	Monitor	Prescribe/ adjust/ administer	Face to face	Phone	Written		
	therapy												
Okamoto (2001),[33] US	≥18 years old, essential hypertension	✓	✓			?	✓					SBP & DBP	Positive
Rothman (2005),[34] US	Type 2 diabetes	✓	✓					✓		✓	✓	BP, HbA1C, Total cholesterol	Mixed (positive for BP and HbA1C but not cholesterol)
Scott (2006),[35] US	≥18 years old, Type 2 diabetes	✓	✓		✓			✓ (vaccine)	✓			HbA1c	Positive
Sellors (2003),[48] Canada	≥ 65 years, ≥ 5 medications	✓							✓		✓	Number of daily doses	No effect
Simpson (2011),[49] Canada	Type 2 diabetes	✓				✓	✓		✓			BP	Positive
Sookaneknum (2004),[53] Thailand	≥18 years old, primary hypertension	✓	✓	✓	✓	✓					✓	BP	Positive
Tahaineh (2011),[55] Jordan	≥18 years, dyslipidaemia	✓	✓	✓	✓		✓		✓		✓	% patients at LDL cholesterol target level	Positive
Tobari (2010),[54] Japan	40 – 79 years, SBP 140-179 mmHg or DBP 90-109 mmHg or on		✓		✓		✓		✓	✓		BP	Positive

Author, Year, country	Primary care population	Patient-directed activities							Communication with GP			Primary Outcome(s)	Effect(s)
		Med review	Education	Adherence assessment	Health/ lifestyle advice	Physical assessment (e.g. BP)	Monitor	Prescribe/ adjust/ administer	Face to face	Phone	Written		
	antihypertensive												
Villa (2009),[52] Chile	≥18 years old, dyslipidaemia	✓	✓		✓							Lipid profile (total cholesterol, LDL, HDL, TGs)	Mixed (positive for all except HDL)
Zermansky (2001),[43] UK	≥65 years old, ≥1 prescription, living in community	✓	✓	✓							✓	Number of changes to repeat prescriptions over 12 months	Positive

BP = blood pressure; CDM QOC = chronic disease management quality of care; GP = general practitioner; HbA1C = glycosylated haemoglobin; HF = heart failure; LDL = low density lipoprotein; MAI = Medicines Appropriateness Index; MR = Medical record only; MRP = medication-related problem; SBP = systolic blood pressure; WOMAC = Western Ontario & McMaster Universities Arthritis Index

3.6.3 Methodological Quality of Studies

The quality assessment of studies is summarised in Table 3.2. Thirty-three studies had appropriate randomisation processes described, with the remaining five studies not explicitly stating the method of sequence generation used. Half of the studies did not clearly describe the methods used to conceal allocation of patients into groups and two studies did not use appropriate methods for allocation concealment (it appeared that patients were randomised before recruitment).[29, 58] Adequate blinding of outcome assessment was explicitly described in only 15 studies, with the remaining studies either failing to mention blinding or using the intervention pharmacist also to collect outcome data. Most studies (n =35) used intention to treat analysis for outcome assessment and/or explicitly reported attrition and exclusions. The remaining studies failed to adequately describe loss to follow up, or had differential attrition rates across groups. Almost all studies reported on outcomes as per their intended study protocol; however, one study also included extensive *post-hoc* analyses[59] and another may have selectively reported on additional *post hoc* measures.[22]

Table 3.2. Quality assessment of included studies

Reference	Sequence generation adequate	Allocation concealment adequate	Blinding of outcome assessment adequate	Incomplete outcome data addressed	Free from selective outcome reporting	Total 'Yes' (out of 5)
Adler (2004)[19]	Yes	Yes	Yes	No	Yes	4
Avery (2012[37]	Yes	Yes	No	Yes	Yes	4
Bond (2007)[38]	Yes	Yes	Yes	Yes	Yes	5
Borenstein (2003)[20]	Yes	No	No	Yes	Yes	3
Capoccia (2004)[21]	Yes	Unclear	Unclear	Yes	Yes	3
Carter (2001)[22, 58]	Yes	No	Unclear	Yes	Unclear	2
Carter (2008)[23]	Yes	Unclear	Unclear	Yes	Yes	3
Choe (2005)[24]	Unclear	Unclear	Yes	Yes	Yes	3
Deschamps (2004)[44]	Unclear	Unclear	Unclear	Yes	Yes	2
Evans (2010)[45]	Yes	Yes	No	Yes	Yes	4
Finley (2003)[25]	Yes	Yes	Yes	Yes	Yes	5
Gourley (1998)[36, 57, 59]	Yes	Unclear	No	Yes	No	2
Granas (1999)[39]	Yes	Yes	Unclear	Yes	Yes	4
Grymonpre (2001)[46]	Yes	Yes	Yes	Yes	Yes	5
Hammad (2011)[56]	Yes	Yes	No	Yes	Yes	4

Reference	Sequence generation adequate	Allocation concealment adequate	Blinding of outcome assessment adequate	Incomplete outcome data addressed	Free from selective outcome reporting	Total 'Yes' (out of 5)
Hanlon (1996)[26]	Yes	Unclear	Yes	Yes	Yes	4
Hay (2006)[40]	Yes	Yes	Yes	Yes	Yes	5
Heisler (2012)[27]	Yes	Yes	Yes	Yes	Yes	5
Hogg (2009)[47]	Yes	Yes	No	Yes	Yes	4
Hunt (2008)[28]	Yes	Unclear	Yes	Yes	Yes	4
Jacobs (2012)[29]	Yes	No	Unclear	Yes	Yes	3
Jameson (2001)[30]	Yes	Unclear	Unclear	No	Yes	2
Jameson (2010)[31]	Yes	Unclear	No	Yes	Yes	3
Jamieson (2010)[41]	Yes	Yes	No	Yes	Yes	4
Kirwin (2010)[32]	Yes	Yes	Yes	Yes	Yes	5
Lowrie (2012)[42]	Yes	Yes	Yes	Yes	Yes	5
Mourao (2013)[50]	Yes	Unclear	Unclear	Yes	Yes	3
Neto (2011)[51]	Yes	Unclear	Yes	Yes	Yes	4
Okamoto (2001)[33]	Unclear	Unclear	No	Yes	Yes	2
Rothman (2005)[34]	Yes	Yes	No	Yes	Yes	4
Scott (2006)[35]	Yes	No	No	Yes	Yes	3
Sellors (2003)[48]	Yes	Yes	Yes	Yes	Yes	5

Reference	Sequence generation adequate	Allocation concealment adequate	Blinding of outcome assessment adequate	Incomplete outcome data addressed	Free from selective outcome reporting	Total 'Yes' (out of 5)
Simpson (2011)[49]	Yes	Yes	Yes	Yes	Yes	5
Sookaneknum (2004)[53]	Unclear	Unclear	No	Yes	Yes	2
Tahaineh (2011)[55]	Yes	Yes	No	Yes	Yes	4
Tobari (2010)[54]	Yes	Yes	Yes	Yes	Yes	5
Villa (2009)[52]	Unclear	Unclear	No	Unclear	Yes	1
Zermansky (2001)	Yes	Unclear	No	Yes	Yes	3

Yes = low risk of bias; No = high risk of bias; Unclear = not explicitly/sufficiently described in paper to reach a conclusion and unable to verify with author

3.6.4 Meta-analysis

Meta-analysis was performed on eleven trials that reported blood pressure (BP) as an outcome measure,[20, 23, 28, 29, 33, 34, 41, 49, 53, 54, 56] five trials that reported glycosylated haemoglobin (HbA_1C),[24, 29, 34, 35, 50] three studies that reported cholesterol [29, 34, 52] and two studies that reported 10-year Framingham risk score as an outcome measure.[45, 51] Three studies that measured these endpoints were excluded as suitable data were not available for extraction.[27, 31, 55]

Statistical heterogeneity across the studies assessing BP was moderate (I^2 = 37.5%). All eleven studies reported data on systolic BP (SBP), while ten also reported diastolic BP (DBP). The results of the meta-analysis favoured the pharmacist intervention, revealing a significant reduction in both SBP and DBP in intervention patients (Figure 3.2a). The mean difference between intervention and control groups in SBP was -5.72 mmHg (95% CI, -7.05 to -4.39, p<0.001) and DBP was -3.47 mmHg (95% CI, -4.35 to -2.58, p<0.001).

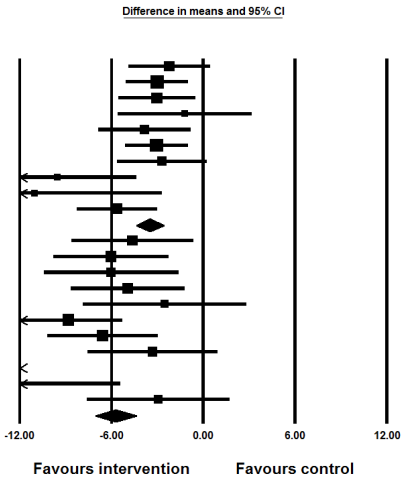
Statistical heterogeneity was low across the studies assessing HbA_1C (I^2 = 0%). The results of the meta-analysis favoured the pharmacist intervention, with significant reductions in HbA_1C (Figure 3.2b). The mean difference between groups was -0.88% (95% CI, -1.15 to -0.62, p<0.001).

Statistical heterogeneity was considerable across the studies assessing LDL-cholesterol (I^2 = 77.38%) and total cholesterol (I^2 = 53.93%). The results of the meta-analysis favoured the pharmacist intervention, with significant reductions in LDL-cholesterol by 18.72 mg/dL (95% CI, -34.10 to -3.36, p<0.017) and total cholesterol by 32.00 mg/dL (95% CI, -54.86 to -9.14, p<0.006) between groups (Figure 3.2c).

Of the two studies assessing 10-year Framingham risk score reduction, heterogeneity was moderate (I^2 = 40.5%). Pharmacist intervention resulted in a statistically significant reduction in 10-year Framingham risk score of -1.83% (95% CI, -3.66 to 0.00) between groups (Figure 3.2d).

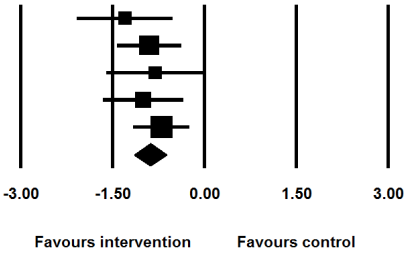
(a) Blood Pressure (mmHg)

Group by Subgroup within study	Study name	Subgroup	Difference in means	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
DBP	Hammad, 2011	DBP	-2.20	1.35	1.81	-4.84	0.44	-1.63	0.102
DBP	Hunt, 2008	DBP	-3.00	1.03	1.06	-5.01	-0.99	-2.92	0.003
DBP	Rothman, 2005	DBP	-3.00	1.28	1.64	-5.51	-0.49	-2.35	0.019
DBP	Tobari, 2010	DBP	-1.20	2.22	4.93	-5.55	3.15	-0.54	0.589
DBP	Carter, 2008	DBP	-3.80	1.54	2.36	-6.81	-0.79	-2.47	0.013
DBP	Okamoto, 2001	DBP	-3.02	1.04	1.09	-5.07	-0.97	-2.89	0.004
DBP	Sookaneknum, 2004	DBP	-2.68	1.48	2.19	-5.58	0.22	-1.81	0.070
DBP	Jamieson, 2010	DBP	-9.50	2.62	6.88	-14.64	-4.36	-3.62	0.000
DBP	Borenstein, 2003	DBP	-11.00	4.23	17.88	-19.29	-2.71	-2.60	0.009
DBP	Jacobs, 2012	DBP	-5.60	1.33	1.77	-8.20	-3.00	-4.21	0.000
DBP	All studies		-3.47	0.45	0.20	-4.35	-2.58	-7.65	0.000
SBP	Hammad, 2011	SBP	-4.60	2.01	4.06	-8.55	-0.65	-2.28	0.022
SBP	Hunt, 2008	SBP	-6.00	1.91	3.65	-9.75	-2.25	-3.14	0.002
SBP	Rothman, 2005	SBP	-6.00	2.24	5.01	-10.39	-1.61	-2.68	0.007
SBP	Simpson, 2011	SBP	-4.90	1.89	3.57	-8.60	-1.20	-2.60	0.009
SBP	Tobari, 2010	SBP	-2.50	2.72	7.40	-7.83	2.83	-0.92	0.358
SBP	Carter, 2008	SBP	-8.80	1.79	3.20	-12.31	-5.29	-4.92	0.000
SBP	Okamoto, 2001	SBP	-6.56	1.83	3.36	-10.15	-2.97	-3.58	0.000
SBP	Sookaneknum, 2004	SBP	-3.30	2.15	4.63	-7.52	0.92	-1.53	0.125
SBP	Jamieson, 2010	SBP	-26.50	7.32	53.54	-40.84	-12.16	-3.62	0.000
SBP	Borenstein, 2003	SBP	-22.00	8.46	71.53	-38.58	-5.42	-2.60	0.009
SBP	Jacobs, 2012	SBP	-2.90	2.37	5.61	-7.54	1.74	-1.22	0.221
SBP	All studies		-5.72	0.68	0.46	-7.05	-4.39	-8.43	0.000



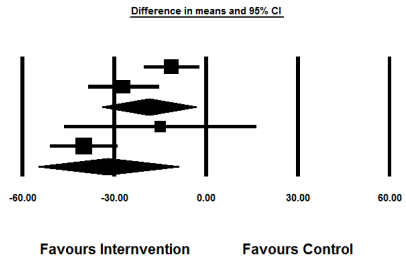
(b) Glycosylated Hemoglobin (%)

Study name	Difference in means	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
Choe 2005	-1.300	0.397	0.158	-2.079	-0.521	-3.273	0.001
Mourao 2013	-0.900	0.265	0.070	-1.420	-0.380	-3.393	0.001
Rothman 2005	-0.800	0.406	0.165	-1.595	-0.005	-1.972	0.049
Scott 2006	-1.000	0.331	0.109	-1.648	-0.352	-3.025	0.002
Jacobs 2012	-0.700	0.232	0.054	-1.155	-0.245	-3.014	0.003
All studies	-0.884	0.136	0.018	-1.150	-0.618	-6.516	0.000



(c) Cholesterol (mg/dL)

Group by Subgroup within study	Study name	Subgroup within study	Difference in means	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
LDL	Jacobs 2012	LDL	-11.300	4.609	21.239	-20.333	-2.267	-2.452	0.014
LDL	Villa 2009	LDL	-27.000	5.876	34.528	-38.517	-15.483	-4.595	0.000
LDL			-18.727	7.839	61.443	-34.090	-3.363	-2.389	0.017
Total	Rothman 2005	Total	-15.000	16.011	256.342	-46.380	16.380	-0.937	0.349
Total	Villa 2009	Total	-40.000	5.619	31.577	-51.014	-28.986	-7.118	0.000
Total	All studies		-31.995	11.664	136.042	-54.856	-9.135	-2.743	0.006



(d) 10 Year Framingham Risk Score (%)

Study name	Difference in means	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
Evans 2010	-0.300	1.522	2.317	-3.284	2.684	-0.197	0.844
Neto 2011	-2.400	0.555	0.309	-3.489	-1.311	-4.321	0.000
All studies	-1.828	0.935	0.874	-3.660	0.004	-1.956	0.050

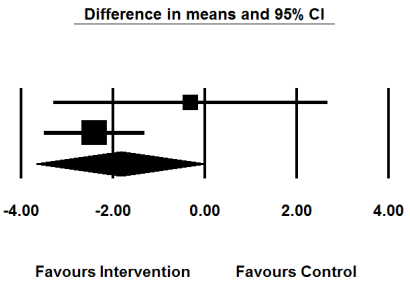


Figure 3.3a to d. Forest plots of studies

Most studies (25/38) reported positive effects on at least one primary outcome measure. Positive effects were more often seen in studies that involved a pharmacist delivering a multifaceted intervention in conjunction with follow-up of patients, rather than delivering medication reviews, education or drug information in isolation. When pharmacists provided only medication management reviews with written or no communication with the patient's primary care physician, a positive effect was less likely to be observed. Positive effects were seen when medication review was combined with interprofessional face-to-face verbal communication. Studies that incorporated additional pharmacist interventions such as adherence assessment, health and lifestyle advice, medication initiation or adjustment, and monitoring, in conjunction with verbal communication (telephone or face-to-face) with the GP were also more likely to demonstrate improved outcomes. The importance of verbal inter-professional communication, especially the opportunity for bidirectional, face-to-face communication, has been recognised previously.[60] One study[29] that used multiple pharmacist interventions and all forms of interprofessional communication resulted in significant improvements in BP, HbA1C and LDL cholesterol, but failed to achieve pre-defined targets for these parameters.

Studies included in this review showed that pharmacist services provided in general practice clinics can improve management of chronic conditions such as cardiovascular disease and diabetes. This is evidenced by improved BP, HbA1C and cholesterol levels and attainment of health goals more often in the intervention groups compared with usual care. Our meta-analyses found improvements to cardiovascular parameters in favour of the intervention group, including a mean difference in SBP reduction of 5.72 mmHg between intervention and control groups. Although modest, a reduction of this magnitude equates to a decrease in the risk of cardiovascular events by 20% over five years.[61] Meta-

analysis also revealed a 0.88% reduction in HbA1C in favour of the intervention group. A decrease of this magnitude is associated with a relative risk reduction of 25% for microvascular endpoints.[62] Pharmacist interventions in general practice clinics were also shown to improve the quality of prescribing and medication appropriateness. This was evidenced in positive effects on outcomes such as medication adherence, resolution of medication-related problems and indicators of quality of care. Pharmacist interventions tended to have limited or no effect on outcomes related to symptoms, quality of life, patient satisfaction and medical costs.

Our review differs from previous systematic reviews and meta-analyses in that they tended to focus on specific interventions or outcomes,[13, 63-66] or delivery of pharmacist interventions across a range of settings, whereas ours focussed on pharmacists co-located with GPs and explored a broader range of pharmacist roles and outcomes, taking into account the generalist nature of the clinical pharmacist as a healthcare provider in primary care. This allowed for a broader assessment of the pharmacists' role in general practice, however heterogeneity in the nature of the interventions delivered (roles, format, duration and frequency of follow up of patients) and outcomes measured, made it difficult to compare studies and perform meta-analyses for all outcome measures. This was particularly evident in the various outcome measures for medication appropriateness, adherence and satisfaction. Standardisation of outcome measures, as has been suggested in previous systematic reviews,[2] could assist in the comparison of interventions across multiple studies.

This systematic review and meta-analyses has some limitations. Although broad search strategies and manual checking of reference lists were undertaken to ensure all relevant studies were included, unpublished studies and studies published in languages other than

English were not sought. Additionally, there were limitations to the studies included in this review. Several studies were conducted in single clinics or multiple clinics that were part of one organisation or healthcare group, and interventions were often delivered by a single pharmacist or specially trained pharmacist, limiting their external validity. Contamination of participants and Hawthorne effect could also not be ruled out. Pharmacists may have had existing relationships with the health professionals at these sites, thus influencing the ease of integration and acceptance of the pharmacist's role. Therefore the results of these studies may not be easily inferred in other settings. The outcomes assessed in these studies tended to be surrogate endpoints (e.g. BP) rather than direct endpoints of morbidity or mortality. Only one study[42] assessed death and hospitalisation as primary outcomes, on which the pharmacist intervention had no effect. Further research in this area is needed, using outcome measures such as hospitalisation and mortality to confirm beneficial outcomes for patients and practitioners, as well as cost-effectiveness.[11, 13]

Additionally, our review found a lack of rigour in methodological quality of some included studies and difficulty comparing studies due to heterogeneity. These limitations have also been identified by other reviews.[2, 11, 15] Adequately powered multi-centre trials that use cluster randomisation, with sufficient follow up, blinding of outcome assessment and objective outcome measures to enhance the validity of the data are warranted. Additionally, explicit reporting of quality criteria, especially allocation concealment, is needed to ensure that studies produce evidence of high quality and reliability.

The positive impact of pharmacist co-location within general practice clinics identified in this review has implications for practitioners and policy makers regarding the structure and dynamics of the primary healthcare workforce. Interdisciplinary medication

management services within general practice clinics, especially for patients with cardiovascular disease and diabetes, would be valuable. Positive experiences from new models of collaborative practice in primary care involving pharmacists also support such services.[67, 68] However, more support in terms of infrastructure, integration into the healthcare team, and sustainable funding models are critical for the adoption of pharmacists into general practice teams more widely.[69]

3.7 Conclusion

Pharmacists co-located in primary care general practice clinics delivered a variety of interventions, with favourable results seen in the management of cardiovascular disease, diabetes and some measures of quality use of medicines. Interventions were most effective when they were multifaceted and involved interprofessional collaboration with face-to-face communication. Co-location of pharmacists within general practice clinics may be an effective approach for delivery of patient-centered interdisciplinary medication management services.

3.8 Summary (Chapters 2 and 3)

In summary, the general literature review in Chapter 2 and the systematic review and meta-analysis reported in this chapter have shown that the role of a practice pharmacist is acceptable to stakeholders and that it can be effective in improving patient outcomes. As most of the studies were conducted outside of Australia, such a role warrants further exploration within the Australian context.

Increasingly, both in Australia and overseas, there is recognition of the need to strengthen and improve the delivery of primary health care in order to manage increasing demands on the health system. Adverse drug events are a serious concern in primary care worldwide, and the implementation of strategies to improve QUM are needed. Current strategies, including pharmacist-led medication reviews, have shown mixed results especially when undertaken in isolation, highlighting the need for greater collaboration between health professionals, especially GPs and pharmacists.

The use of multidisciplinary, team-based care may improve the quality of service delivery in primary care, and various factors can influence the success of team effectiveness and adoptability of new services in this setting. Various models exist for the integration of pharmacists into primary care teams, including co-location within general practice clinics.

Pharmacists can be valuable members of the co-located PHCT, with evidence from overseas and Australia highlighting the potential for this role. The international literature highlights the various barriers and facilitators that need to be considered when implementing pharmacist services into general practice, including potential funding models. The systematic review, in particular, found that multi-faceted interventions coupled with face-to-face interprofessional communication, led to positive effects on outcomes. The results of the meta-analyses also favoured pharmacist intervention, with

significant improvements in blood pressure, glycosylated haemoglobin, cholesterol and Framingham risk score in intervention patients compared to control patients. These findings highlight the beneficial effect practice pharmacists can have in providing medicines management services to general practice patients with chronic disease.

This literature review has also identified several gaps in the knowledge regarding a practice pharmacist role in Australian general practices. The main gaps include:

- Limited research exploring stakeholder opinions about the potential for pharmacist integration into general practice;
- Limited research exploring the effectiveness of multifaceted pharmacist roles in general practice and the effect of this role on clinical and humanistic outcomes;
- No research exploring stakeholders' first-hand experiences with a practice pharmacist, from the perspectives of the consumer, practice staff and practice pharmacist; and
- A lack of a defined practice pharmacist role and model of service delivery within Australian primary care.

The research undertaken in this thesis was thus conducted to address the above knowledge gaps to improve the quality and safe use of medicines by both patients and practice staff.

3.9 References

1. Royal Australian College of General Practitioners. What is general practice? 2012. Available from http://www.racgp.org.au/whatisgeneralpractice. (Accessed on 27 May 2013)

2. Nkansah N, Mostovetsky O, Yu C, Chheng T, Beney J, Bond CM, et al. Effect of outpatient pharmacists' non-dispensing roles on patient outcomes and prescribing patterns. *Cochrane Database Syst Rev.* 2010:CD000336.

3. Bell J, Kalisch L, Ramsay E, Pratt N, Barratt J, LeBlanc T, et al. Prescriber feedback to improve quality use of medicines among older people: the veterans' MATES program. *J Pharm Pract Res.* 2001;41:316-9.

4. Pojskic N, MacKeigan L, Boon H, Ellison P, Breslin C. Ontario family physician readiness to collaborate with community pharmacists on drug therapy management. *Res Soc Adm Pharm.* 2011;7:39-50.

5. Dobson RT, Henry CJ, Taylor JG, Zello GA, Lachaine J, Forbes DA, et al. Interprofessional health care teams: attitudes and environmental factors associated with participation by community pharmacists. *J Interprof Care.* 2006;20:119-32.

6. Edmunds J, Calnan MW. The reprofessionalisation of community pharmacy? An exploration of attitudes to extended roles for community pharmacists amongst pharmacists and General Practioners in the United Kingdom. *Soc Sci Med.* 2001;53:943-55.

7. Dolovich L. Ontario pharmacists practicing in family health teams and the patient-centered medical home. *Ann Pharmacother.* 2012;46:S33-9.

8. Bradley F, Elvey R, Ashcroft DM, Hassell K, Kendall J, Sibbald B, et al. The challenge of integrating community pharmacists into the primary health care team: a case study of local pharmaceutical services (LPS) pilots and interprofessional collaboration. *J Interprof Care.* 2008;22:387-98.

9. Farrell B, Ward N, Dore N, Russell G, Geneau R, Evans S. Working in interprofessional primary health care teams: What do pharmacists do? *Res Social Adm Pharm.* 2013;9:288-301.

10. Dolovich L, Pottie K, Kaczorowski J, Farrell B, Austin Z, Rodriguez C, et al. Integrating family medicine and pharmacy to advance primary care therapeutics. *Clin Pharmacol Ther.* 2008;83:913-7.

11. Fish A, Watson M, Bond C. Practice-based pharmaceutical services: a systematic review. *Int J Pharm Pract.* 2002;10:225-33.

12. Hanlon JT, Lindblad CI, Gray SL. Can clinical pharmacy services have a positive impact on drug-related problems and health outcomes in community-based older adults? *Am J Geriatr Pharmacother.* 2004;2:3-13.

13. Geurts MM, Talsma J, Brouwers JR, de Gier JJ. Medication review and reconciliation with cooperation between pharmacist and general practitioner and the benefit for the patient: a systematic review. *Br J Clin Pharmacol.* 2012;74:16-33.

14. Haynes RB, Ackloo E, Sahota N, McDonald HP, Yao X. Interventions for enhancing medication adherence. *Cochrane Database Syst Rev.* 2008:CD000011.

15. Chisholm-Burns MA, Kim Lee J, Spivey CA, Slack M, Herrier RN, Hall-Lipsy E, et al. US pharmacists' effect as team members on patient care: systematic review and meta-analyses. *Med Care.* 2010;48:923-33.

16. Higgins J, Altman D, Sterne J. (editors) Chapter 8: Assessing risk of bias in included studies. In: Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

17. Higgins JP, Thompson SG, Deeks JJ, Altman DG. Measuring inconsistency in meta-analyses. *BMJ.* 2003;327:557-60.

18. Borenstein M, Hedges L, Rothstein H. Meta-analysis: fixed effect vs. random effects. 2007. Available from http://www.meta-analysis.com/downloads/Meta-analysis%20fixed%20effect%20vs%20random%20effects.pdf. (Accessed on 30 August 2013)

19. Adler DA, Bungay KM, Wilson IB, Pei Y, Supran S, Peckham E, et al. The impact of a pharmacist intervention on 6-month outcomes in depressed primary care patients. *Gen Hosp Psychiatry.* 2004;26:199-209.

20. Borenstein JE, Graber G, Saltiel E, Wallace J, Ryu S, Archi J, et al. Physician-pharmacist comanagement of hypertension: a randomized, comparative trial. *Pharmacotherapy.* 2003;23:209-16.

21. Capoccia KL, Boudreau DM, Blough DK, Ellsworth AJ, Clark DR, Stevens NG, et al. Randomized trial of pharmacist interventions to improve depression care and outcomes in primary care. *Am J Health Syst Pharm.* 2004;61:364-72.

22. Carter BL, Malone DC, Billups SJ, Valuck RJ, Barnette DJ, Sintek CD, et al. Interpreting the findings of the IMPROVE study. *Am J Health Syst Pharm.* 2001;58:1330-7.

23. Carter BL, Bergus GR, Dawson JD, Farris KB, Doucette WR, Chrischilles EA, et al. A cluster randomized trial to evaluate physician/pharmacist collaboration to improve blood pressure control. *J Clin Hypertens* 2008;10:260-71.

24. Choe HM, Mitrovich S, Dubay D, Hayward RA, Krein SL, Vijan S. Proactive case management of high-risk patients with type 2 diabetes mellitus by a clinical pharmacist: a randomized controlled trial. *Am J Manag Care.* 2005;11:253-60.

25. Finley PR, Rens HR, Pont JT, Gess SL, Louie C, Bull SA, et al. Impact of a collaborative care model on depression in a primary care setting: a randomized controlled trial. *Pharmacotherapy.* 2003;23:1175-85.

26. Hanlon JT, Weinberger M, Samsa GP, Schmader KE, Uttech KM, Lewis IK, et al. A randomized, controlled trial of a clinical pharmacist intervention to improve inappropriate prescribing in elderly outpatients with polypharmacy. *Am J Med.* 1996;100:428-37.

27. Heisler M, Hofer TP, Schmittdiel JA, Selby JV, Klamerus ML, Bosworth HB, et al. Improving blood pressure control through a clinical pharmacist outreach program in patients with diabetes mellitus in 2 high-performing health systems: the adherence and intensification of medications cluster randomized, controlled pragmatic trial. *Circulation.* 2012;125:2863-72.

28. Hunt JS, Siemienczuk J, Pape G, Rozenfeld Y, MacKay J, LeBlanc BH, et al. A randomized controlled trial of team-based care: impact of physician-pharmacist collaboration on uncontrolled hypertension. *J Gen Intern Med.* 2008;23:1966-72.

29. Jacobs M, Sherry PS, Taylor LM, Amato M, Tataronis GR, Cushing G. Pharmacist Assisted Medication Program Enhancing the Regulation of Diabetes (PAMPERED) study. *J Am Pharm Assoc* 2012;52:613-21.

30. Jameson JP, VanNoord GR. Pharmacotherapy consultation on polypharmacy patients in ambulatory care. *Ann Pharmacother.* 2001;35:835-40.

31. Jameson JP, Baty PJ. Pharmacist collaborative management of poorly controlled diabetes mellitus: a randomized controlled trial. *Am J Manag Care.* 2010;16:250-5.

32. Kirwin JL, Cunningham RJ, Sequist TD. Pharmacist recommendations to improve the quality of diabetes care: a randomized controlled trial. *J Manag Care Pharm.* 2010;16:104-13.

33. Okamoto MP, Nakahiro RK. Pharmacoeconomic evaluation of a pharmacist-managed hypertension clinic. *Pharmacotherapy.* 2001;21:1337-44.

34. Rothman RL, Malone R, Bryant B, Shintani AK, Crigler B, Dewalt DA, et al. A randomized trial of a primary care-based disease management program to improve cardiovascular risk factors and glycated hemoglobin levels in patients with diabetes. *Am J Med.* 2005;118:276-84.

35. Scott DM, Boyd ST, Stephan M, Augustine SC, Reardon TP. Outcomes of pharmacist-managed diabetes care services in a community health center. *Am J Health Syst Pharm.* 2006;63:2116-22.

36. Gourley DR, Gourley GA, Solomon DK, Portner TS, Bass GE, Holt JM, et al. Development, implementation, and evaluation of a multicenter pharmaceutical care outcomes study. *J Am Pharm Assoc.* 1998;38:567-73.

37. Avery AJ, Rodgers S, Cantrill JA, Armstrong S, Cresswell K, Eden M, et al. A pharmacist-led information technology intervention for medication errors (PINCER): a multicentre, cluster randomised, controlled trial and cost-effectiveness analysis. *Lancet.* 2012;379:1310-9.

38. Bond CM, Fish A, Porteous TH, Reid JP, Scott A, Antonazzo E. A randomised controlled trial of the effects of note-based medication review by community pharmacists on prescribing of cardiovascular drugs in general practice. *Int J Pharm Pract.* 2007;15:39-46.

39. Granås A, Bates I. The effect of pharmaceutical review of repeat prescriptions in general practice. *Int J Pharm Pract.* 1999;7:264-75.

40. Hay EM, Foster NE, Thomas E, Peat G, Phelan M, Yates HE, et al. Effectiveness of community physiotherapy and enhanced pharmacy review for knee pain in people aged over 55 presenting to primary care: pragmatic randomised trial. *BMJ.* 2006;333:995.

41. Jamieson L, Scally A, Chrystyn H. A randomised comparison of practice pharmacist-managed hypertension providing level 3 medication review versus usual care in general practice. *J App Ther Res.* 2010;7:77-86.

42. Lowrie R, Mair FS, Greenlaw N, Forsyth P, Jhund PS, McConnachie A, et al. Pharmacist intervention in primary care to improve outcomes in patients with left ventricular systolic dysfunction. *Eur Heart J.* 2012;33:314-24.

43. Zermansky AG, Petty DR, Raynor DK, Freemantle N, Vail A, Lowe CJ. Randomised controlled trial of clinical medication review by a pharmacist of elderly patients receiving repeat prescriptions in general practice. *BMJ.* 2001;6:1340-3.

44. Deschamps MA, Taylor JG, Neubauer SL, Whiting S, Green K. Impact of pharmacist consultation versus a decision aid on decision making regarding hormone replacement therapy. *Int J Pharm Pract.* 2004;12:21-8.

45. Evans CD, Eurich DT, Taylor JG, Blackburn DF. The Collaborative Cardiovascular Risk Reduction in Primary Care (CCARP) study. *Pharmacotherapy.* 2010;30:766-75.

46. Grymonpre RE, Williamson DA, Montgomery PR. Impact of a pharmaceutical care model for non-institutionalised elderly: results of a randomised, controlled trial. *Int J Pharm Pract.* 2001;9:235-41.

47. Hogg W, Lemelin J, Dahrouge S, Liddy C, Armstrong CD, Legault F, et al. Randomized controlled trial of anticipatory and preventive multidisciplinary team care: for complex patients in a community-based primary care setting. *Can Fam Physician.* 2009;55:e76-85.

48. Sellors J, Kaczorowski J, Sellors C, Dolovich L, Woodward C, Willan A, et al. A randomized controlled trial of a pharmacist consultation program for family physicians and their elderly patients. *Can Med Assoc J.* 2003;169:17-22.

49. Simpson SH, Majumdar SR, Tsuyuki RT, Lewanczuk RZ, Spooner R, Johnson JA. Effect of adding pharmacists to primary care teams on blood pressure control in patients with type 2 diabetes: a randomized controlled trial. *Diabetes Care.* 2011;34:20-6.

50. Mourao AO, Ferreira WR, Martins MA, Reis AM, Carrillo MR, Guimaraes AG, et al. Pharmaceutical care program for type 2 diabetes patients in Brazil: a randomised controlled trial. *Int J Clin Pharm.* 2013;35:79-86.

51. Neto PR, Marusic S, de Lyra Junior DP, Pilger D, Cruciol-Souza JM, Gaeti WP, et al. Effect of a 36-month pharmaceutical care program on the coronary heart disease risk in elderly diabetic and hypertensive patients. *J Pharm Pharm Sci.* 2011;14:249-63.

52. Villa LA, Von Chrismar AM, Oyarzun C, Eujenin P, Fernandez ME, Quezada M. Pharmaceutical care program for dyslipidemic patients at three primary health care centers: impacts and outcomes. *Lat Am J Pharm.* 2009;28:415-20.

53. Sookaneknun P, Richards RME, Sanguansermsri J, Teerasut C. Pharmacist involvement in primary care improves hypertensive patient clinical outcomes. *Ann Pharmacother.* 2004;38:2023-8.

54. Tobari H, Arimoto T, Shimojo N, Yuhara K, Noda H, Yamagishi K, et al. Physician-Pharmacist Cooperation Program for Blood Pressure Control in Patients With Hypertension: A Randomized-Controlled Trial. *Am J Hypertens.* 2010;23:1144-52.

55. Tahaineh L, Albsoul-Younes A, Al-Ashqar E, Habeb A. The role of clinical pharmacist on lipid control in dyslipidemic patients in North of Jordan. *Int J Clin Pharm.* 2011;33:229-36.

56. Hammad EA, Yasein N, Tahaineh L, Albsoul-Younes AM. A randomized controlled trial to assess pharmacist- physician collaborative practice in the management of metabolic syndrome in a university medical clinic in Jordan. *J Manag Care Pharm.* 2011;17:295-303.

57. Solomon DK, Portner TS, Bass GE, Gourley DR, Gourley GA, Holt JM, et al. Clinical and economic outcomes in the hypertension and COPD arms of a multicenter outcomes study. *J Am Pharm Assoc (Wash).* 1998;38:574-85.

58. Carter BL, Malone DC, Valuck RJ, Barnette DJ, Sintek CD, Billups SJ. The IMPROVE study: background and study design. Impact of Managed Pharmaceutical Care on Resource Utilization and Outcomes in Veterans Affairs Medical Centers. *Am J Health Syst Pharm.* 1998;55:62-7.

59. Gourley GA, Portner TS, Gourley DR, Rigolosi EL, Holt JM, Solomon DK, et al. Humanistic outcomes in the hypertension and COPD arms of a multicenter outcomes study. *J Am Pharm Assoc* 1998;38:586-97.

60. Zillich A, McDonough RP, Carter BL, Doucette WR. Influential characteristics of physician/pharmacist collaborative relationships. *Ann Pharmacother.* 2004;38:764-70.

61. Glynn RJ, L'Italien GJ, Sesso HD, Jackson EA, Buring JE. Development of predictive models for long-term cardiovascular risk associated with systolic and diastolic blood pressure. *Hypertension.* 2002;39:105-10.

62. UK Prospective Diabetes Study (UKPDS) Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *The Lancet.* 1998;352:837-53.

63. Holland R, Desborough J, Goodyer L, Hall S, Wright D, Loke YK. Does pharmacist-led medication review help to reduce hospital admissions and deaths in older people? A systematic review and meta-analysis. *Br J Clin Pharmacol.* 2008;65:303-16.

64. Collins C, Limone BL, Scholle JM, Coleman CI. Effect of pharmacist intervention on glycemic control in diabetes. *Diabetes research and clinical practice.* 2011;92:145-52.

65. Morgado MP, Morgado SR, Mendes LC, Pereira LJ, Castelo-Branco M. Pharmacist interventions to enhance blood pressure control and adherence to

antihypertensive therapy: Review and meta-analysis. *Am J Health Syst Pharm.* 2011;68:241-53.

66. Santschi V, Chiolero A, Burnand B, Colosimo AL, Paradis G. Impact of pharmacist care in the management of cardiovascular disease risk factors: A systematic review and meta-analysis of randomized trials. *Arch Intern Med.* 2011;171:1441-53.

67. Guillaume L, Cooper R, Avery A, Mitchell S, Ward P, Anderson C, et al. Supplementary prescribing by community and primary care pharmacists: an analysis of PACT data, 2004-2006. *J Clin Pharm Ther.* 2008;33:11-6.

68. George J, McCaig DJ, Bond CM, Cunningham IT, Diack HL, Watson AM, et al. Supplementary prescribing: early experiences of pharmacists in Great Britain. *Ann Pharmacother.* 2006;40:1843-50.

69. Tan ECK, Stewart K, Elliott RA, George J. Integration of pharmacists into general practice clinics in Australia: the views of general practitioners and pharmacists. *Int J Pharm Pract.* Published Online First: 12 June 2013. doi:10.1111/ijpp.12047

70. Phelan M, Foster NE, Thomas E, Hay EM, Blenkinsopp A. Pharmacist-led medication review for knee pain in older adults: content, process and outcomes. *Int J Pharm Pract.* 2008;16:347-55.

Chapter 4. Stakeholder consultation

4.1 Introduction

The findings reported in Chapters 2 and 3 highlight the potential benefits of the pharmacist's role in general practice, especially in chronic disease and medicines management. In Australia, the role of the practice pharmacist is still uncommon, and it is unknown how local stakeholders perceive this service.

Thus this chapter describes a study that explored the views of Australian GPs and pharmacists on pharmacist integration into general practice clinics.

The key objectives of this study were to:

- Explore the current relationship between GPs and pharmacists;
- Identify potential roles for a pharmacist working in general practice;
- Determine the perceived advantages and disadvantages of integration; and
- Elucidate the barriers to and facilitators of integration.

A qualitative study using semi-structured, individual interviews with GPs and pharmacists was conducted to investigate the feasibility, acceptability and appropriateness of this potential new health service.

A manuscript, detailing the findings from this qualitative study, has been published in the *International Journal of Pharmacy Practice* and is reproduced below.

Note: This work was approved by the Monash University Human Research Ethics Committee (Appendix 1), and copies of the participant recruitment material, explanatory statement and consent form are provided in Appendix 2.

4.2 Publication

Tan E, Stewart K, Elliott RA, George J. Integration of pharmacists into general practice in Australia: the views of general practitioners and pharmacists. *Int J Pharm Pract.* 2013 Published Online First: 11 June 2013. doi: 10.1111/ijpp.12047

Declaration for Thesis Chapter 4

Declaration by candidate

In the case of Chapter 4, the nature and extent of my contribution to the work was the following:

Nature of contribution	**Extent of contribution (%)**
Reviewed literature; designed methodology; applied for ethics; developed study materials; carried out recruitment and interviews; performed data analysis; and prepared manuscript.	80%

The following co-authors contributed to the work:

Name	**Nature of contribution**
Assoc Prof Kay Stewart	Designed methodology; reviewed ethics application, study materials, data analysis and manuscript.
Mr Rohan Elliott	Designed methodology; reviewed ethics application, study materials, data analysis and manuscript.
Dr Johnson George	Designed methodology; reviewed ethics application, study materials, data analysis and manuscript.

Candidate's Signature		**Date**

Declaration by co-authors

The undersigned hereby certify that:

7. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors.
8. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
9. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
10. there are no other authors of the publication according to these criteria;
11. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
12. the original data are stored at the following location(s) and will be held for at least five years from the date indicated below:

Location(s)	**Centre for Medicine Use and Safety, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University, Parkville, Victoria 3052**

Signature 1	[redacted] Assoc Prof Kay Stewart	**Date** 8/10/13
Signature 2	[redacted] Mr Rohan Elliott	8/10/13
Signature 3	[redacted] Dr Johnson George	8/10/13

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Integration of pharmacists into general practice clinics in Australia: the views of general practitioners and pharmacists

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Keywords
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Abstract

Background Pharmacists working collaboratively with general practitioners (GPs) in primary-care settings can improve patient outcomes; however, there are challenges to the implementation of collaborative services. A possible solution is the co-location of pharmacists within general practice clinics.

Objective To elicit the views of GPs and pharmacists on the integration of pharmacists into general practice in Australia.

Methods Semi-structured, individual interviews with a sample of 11 GPs and 16 pharmacists.

Key findings Four major themes emerged: the current GP–pharmacist relationship; the role of the general practice pharmacist; the pros and cons of integration; and the barriers to and facilitators for integration. Most participants had experienced positive inter-professional relationships, though there were limitations in the collaborative services currently provided. Various methods of integration were discussed, including the co-location of pharmacists within practices. The potential roles for practice pharmacists were deemed to be multifaceted and in some cases allowed for role expansion. Although these roles were thought to offer potential benefits to practice staff, patients and pharmacists, they were also perceived to be potentially disadvantageous. The integration of pharmacists into general practice was believed to be hindered by limited funding and infrastructure and by practitioner perceptions. Various facilitating factors were proposed that could help ensure viability of the role.

Conclusions Various roles and methods of integration were identified for pharmacists in general practice; however, a number of barriers and facilitators to integration would need to be considered to ensure viability of services. Future research should explore different methods of collaboration and trial their implementation.

Introduction

General practice has been identified as the most suitable location for coordinating care of patients with complex and chronic conditions in the community.[1] Co-location of nurses and allied health professionals in general practices is becoming more accepted. In countries such as the UK, the USA and Canada, pharmacists are increasingly becoming part of primary healthcare teams in family and general practices. Such arrangements have resulted in improved medication and health outcomes and reduction in health-service use and costs.[2–4] Co-location has also been shown to enable greater communication and collaboration among health professionals, and to strengthen inter-professional relationships.[5] Elsewhere, however, pharmacists are often on the periphery of the primary healthcare team. Given that medication misadventure is a serious concern in general practice,[6,7] pharmacists have the potential to be valuable members of the team.

In Australia, the majority of pharmacists (85%) work in community pharmacies,[8] undertaking dispensing and other professional services. Community pharmacists generally do

not have access to patients' medical records and have minimal interaction with general practitioners (GPs). A small proportion of pharmacists in primary care (11.8%) work as consultant pharmacists,[9] providing medication management services to patients either in their home or in government subsidised aged-care facilities on referral from GPs. These pharmacists usually work independently or are employed by a community pharmacy; co-location within general practices is rare.

In recent years, reforms to Australian primary healthcare policy have recommended that GPs and other health professionals work in multidisciplinary teams to manage the health needs of an ageing population.[1] Collaborative medicines management services delivered by pharmacists and GPs have already been successful in identifying and resolving medication-related problems, improving patient outcomes, and optimising drug use and costs.[10,11] Such services include Home Medicines Reviews (HMRs),[12] where an accredited consultant pharmacist, on referral from a patient's GP, visits the patient at home, reviews their medicines management, and provides the GP with a report. The GP and patient then agree on a medicines management plan. However, these services are underused.[13] Barriers to the delivery of effective collaborative services in the community include geographical isolation of pharmacists, limited pharmacist access to patient medical records, lack of time for team activities and a health policy that is not conducive to such arrangements.[14] Additionally, communication between GPs and community pharmacists is currently sporadic and reactive, risking fragmentation of patient care.[15]

Few studies have explored stakeholder views on pharmacist integration into general practices to date, none of which have explored the views of Australian GPs and pharmacists. The aim of this study was to elicit the views of Australian GPs and pharmacists on the integration of pharmacists into the general practice setting, the proposed roles for a general practice pharmacist, and the factors influencing integration.

Methods

Recruitment

Advertisements and letters of invitation were disseminated through the Victorian Divisions of General Practice (a support network for GPs in Victoria, Australia), the Australian Association of Consultant Pharmacy (AACP) (the credentialing and accreditation body for Australian consultant pharmacists) and key informants in the area. A combination of purposive, snowball and convenience sampling was used to ensure a broad sample from the two health professional groups. Participants were selected according to their role in the profession and whether they had previous experience working with or as an on-site general practice pharmacist, or a pharmacist closely associated with a general practice.

Data collection

General practice staff and pharmacists were interviewed one-to-one, using a semi-structured interview guide developed from the literature (Table 1). Face and content validity were established by discussion with pharmacists and the guide was pilot tested on two interviewees. Interviews occurred over the period from December 2010 to June 2011; written consent was obtained from all participants prior to the interview. All interviews were conducted by the same interviewer (ET), either face-to-face or by telephone, according to participant preference, at a mutually convenient place and time. Recruitment and interviews continued until data saturation was reached (i.e. when no new, relevant themes were emerging). Interviews were audio-recorded and transcribed verbatim by an independent, professional transcribing service.

Data management and quality assurance

All transcripts were verified against audio recordings by ET. Data management was facilitated using Nvivo 9.0 software (QSR, Melbourne). Interview transcripts, recordings and field notes were entered into the software. Data were analysed and coded for emergent themes using the framework approach, whereby a draft thematic framework, based on *a priori* issues, was applied to the data.[16] The framework was structured according to the interview guide and checked independently by all authors. This aided subsequent detailed analysis and interpretation. Coding and emerging themes were discussed at regular meetings involving all the authors, where discrepancies in the initial coding were resolved.

Ethics approval

This study was approved by the Monash University's Human Research Ethics Committee.

Results

Eleven GPs and 16 pharmacists were individually interviewed. Participants' characteristics are shown in Table 2. Four major themes emerged from the interviews and are supported by illustrative quotes in Boxes 1–4.

Current GP–pharmacist relationship (Box 1)

General practitioners recognised the role of pharmacists as centring on quality use of medicines (Box 1.1); however, they expressed mixed views on the level of knowledge and skills possessed by pharmacists (Box 1.2–1.4). Participants cited

Table 1 Semi-structured interview guide for general practitioners and pharmacists

Topic area 1:
The potential role(s) for a practice pharmacist:
• What is your perception of the skills and knowledge of pharmacists?
• What are the potential roles of pharmacists in health care?
• Have you had any experience working with a pharmacist?
◦ (Previous experience with community/HMR pharmacists/team care arrangements?)
◦ How did you find this?
• What do you think of pharmacists working in general practice?
• Have you had experience working with a practice pharmacist?
• What roles could the pharmacist undertake in general practice?
◦ Do you see these as collaborative roles with other staff or as an individual role?
◦ Are there any other tasks or activities that the pharmacist could undertake besides those you mentioned?
• Which patients do you think would benefit from a pharmacist working in general practice?
◦ How could a pharmacist improve the level of care these patients receive?
◦ Do you think patients would be receptive to seeing a pharmacist?
• What may be some of the advantages/disadvantages of having a pharmacist working in general practice?
Topic area 2:
The integration of a pharmacist into the general practice team:
• How do you think members of the general practice will feel about having a pharmacist join the team?
◦ Do you think general practice staff will benefit from having a pharmacist?
◦ Do you think pharmacists will reduce staff workload?
• What are some of the factors that may make it difficult for pharmacists to integrate?
◦ Would staff support a pharmacist as a new member of the team? If yes/no – why?
• What are some of the factors that may make it easier for pharmacists to integrate?
Topic area 3:
The logistics of integrating a pharmacist into general practice:
• Do you think general practices have the resources to support a practice pharmacist?
◦ Office space
◦ Administrative support
• Should pharmacists have access to medical records/patient data?
• How should patients be identified and referred to the pharmacist?
• What sort of hours do you think the pharmacist should be available (full-time/part-time/sessional)?
• How should practice pharmacists be funded or reimbursed?
• Do you think pharmacists in this new role require additional training?
◦ What sort of training do you think they should receive?
• Do pharmacists in this new role need certain attributes/characteristics?
• Do you see pharmacists working in general practice as a viable role in the future?
◦ How could it be made viable?

HMR, Home Medicines Review.

positive experiences with pharmacists overall, several drawing on relationships they had with local community and hospital pharmacists (Box 1.5–1.6). National Prescribing Service (NPS)[17] facilitators (usually pharmacists, who provide academic detailing to general practice staff) were deemed to be trustworthy sources of information and pharmacist-conducted medication review services were generally well regarded (Box 1.7–1.8).

Both GP and pharmacist participants felt that professional isolation and minimal face-to-face contact were barriers to effective communication and collaboration in the current model of practice (Box 1.9). Community pharmacists felt that lack of time, focus on retail duties and poor access to patient clinical information were challenges to effective collaboration (Box 1.10).

While the current medication review model provides opportunities for collaboration between GPs and pharmacists, poor uptake means these opportunities have not been fully realised. Barriers to uptake identified by GP participants included time constraints or insufficient incentives to refer; the paperwork involved; use of often unfamiliar consultant pharmacists; and variability in the quality of review reports (Box 1.11). Some pharmacists felt there was a lack of implementation of and feedback about their recommendations,

Table 2 Demographic characteristics of participants ($n = 27$)

Characteristic		GPs $n = 11$	Pharmacists $n = 16$
Gender	Male	7	5
	Female	4	11
Age*		50.6 (32–63)	39.6 (25–65)
Current role†	GP	9	
	GP academic	2	
	Community pharmacist		11
	Pharmacy academic		1
	Consultant pharmacist		9
	Other pharmacist‡		8
Years of experience*		20.2 (3–36)	11 (3–45)
Previous experience with/as a practice pharmacist		2	3
Location	Metropolitan	9	8
	Regional/rural	2	8

*Mean (range).
†Some pharmacists fit multiple categories.
‡Hospital $n = 1$, National Prescribing Service facilitator $n = 3$, practice pharmacist (dispensing $n = 1$ and non-dispensing $n = 3$).
GP, General practitioner.

and that conducting HMRs was not an independently sustainable form of work given their irregularity (Box 1.12).

Role of the general practice pharmacist (Box 2)

Participants expressed views on new methods of collaborative practice that could overcome these barriers. The suggestion of a practice pharmacist co-located within the clinic received mixed views from participants. Some interviewees felt physical presence would ensure accessibility and facilitate communication; however, lack of office space and funding mechanisms were limitations to this model (Box 2.1). A consultant pharmacist contracted with several clinics in the area and a pharmacist as part of a virtual general-practice team were other options mentioned (Box 2.2–2.3).

The practice pharmacist was thought to be able to undertake various roles in general practice including medication reviews; medication education and advice for clinical staff and patients; mentoring new prescribers; quality assurance and drug safety activities; case conferencing; and liaison across the health sectors Box 2.4–2.8). Some pharmacist participants saw the practice pharmacist position as an opportunity for role expansion to include repeat prescribing and running disease management clinics, whilst others saw these roles as threats to integration as they may be perceived as professional boundary encroachment by GPs (Box 2.9–2.11).

Participants agreed that the ideal practice pharmacist should be competent, knowledgeable and personable, being able to work both independently and as part of a team (Box 2.12). There were mixed views on the level of training pharmacists should receive prior to working in general practice. Most felt that clinical experience and additional, ongoing training would be essential (Box 2.13).

The majority of participants thought a part-time or sessional position would be realistic for the practice pharmacist (Box 2.14). Most participants felt that the practice pharmacist should have full access to patient medical records and be bound by confidentiality requirements similar to other practice staff (Box 2.15). Most thought GP referral to the pharmacist was needed, whereas others thought referrals could be made by other staff or by patients themselves (Box 2.16). Practice pharmacists could additionally assist with identifying suitable patients by screening records for those at risk of medication misadventure or with particular disease states (Box 2.17). Participants identified various funding options to remunerate the practice pharmacist, including practice salary, patient co-payments, patient private health insurance, government funding (including existing and new Medicare Benefits Scheme (MBS)[18] items); or combinations of these (Box 2.18–2.21).

Pros and cons of integration (Box 3)

Participants felt that practice staff could benefit from more efficient communication, improved drug knowledge, sharing of care and clinical reassurance when managing complex patients. Optimised quality of prescribing, up-to-date medication records and reductions in workload for practice staff were other suggested benefits (Box 3.1–3.3). Patients prone to medication misadventure were felt to be able to potentially benefit from improved medication use and health outcomes (Box 3.4). Pharmacists would also benefit from an increased scope of practice, greater integration into the primary healthcare team, credibility and professional satisfaction (Box 3.5–3.6).

Some participants, however, thought the practice pharmacist would be unnecessarily duplicating GP services or increasing GP workload by wishing to engage GPs in case conferencing or other time-consuming activities (Box 3.7). Others perceived this new role as undermining the community pharmacist, potentially inciting competition or territorial issues and risking fragmentation of care (Box 3.8). It was suggested that patients could also potentially receive conflicting information from different pharmacists, affecting patients' perceptions of their therapy, and that some patients may not want to see a clinic pharmacist (Box 3.9–3.10). Some

Box 1 Current GP–pharmacist relationship

1.1 'Well, I think their [the pharmacist] role is their traditional role, which is prescription provision and checking and making sure that the doctor hasn't made mistakes and things are appropriate. I think their other roles encompass advice and medication for, as I said, plus minor medical problems that they're able to prescribe or suggest treatment for and probably a counselling role with their customers in regard to their diseases and treatment protocols and so forth.' (GP 10)

1.2 'I have great respect for pharmacists. They certainly know a lot of details and useful details and information on drugs and application of drugs and also they would have basic handy tips and ideas on the use of medication that we don't have.' (GP 6)

1.3 'They [pharmacists] come from a fairly academic point of view and obviously don't have a close relationship with the patient and I think they often forget that we actually negotiate a lot with the patient about what we're going to treat them with and why, and what are the patient's priorities.' (GP 4)

1.4 'I think a lot of pharmacists see a clear line in the fact that they've got a pharmacy and a business. They think they need to help themselves for the business rather than the etiquette of being a pharmacist.' (GP 8)

1.5 'I'm on the phone to my pharmacist, my local pharmacist, probably two or three times a day. I often pop across there at lunch time.' (GP 4)

1.6 'I work with a pharmacist one-on-one in the X Palliative Care Unit, so we discuss the patients 1 day a week there. We would individually discuss new patients and their medication. We discuss means of giving the medication and we quite often would discuss with the patient how they're coping with the medications and so forth.' (GP3)

1.7 'You know, I trust her [National Prescribing Service facilitator] implicitly so I get my information from her.' (GP 3)

1.8 I've done a fair bit of work with pharmacists through medication management reviews . . . and I've been quite impressed by the feedback I get from them . . . Their clinical knowledge is actually quite good, so I find it quite helpful. (GP 9)

1.9 'It's kind of like quite distant, both physically and also, they've got their role and we've got ours and we don't really perhaps talk as much as we should or could.' (GP 9)

1.10 'People look at us as shopkeepers rather than pharmacists. We don't seem as professional as doctors' (Pharmacist 6)

1.11 'At the moment . . . it [HMR] is a paper shuffling exercise often where some [person] you've never met, don't know, is going to do a medicines review.' (GP 3)

1.12 'Well the current HMR model – from a business point of view – it's unsustainable. There's no regularity of work. It's very hit and miss . . . so from that point of view it would be fantastic to have a regular position in a practice.' (Pharmacist 7)

GP, general practitioner; HMR, Home Medicines Review.

interviewees thought that the role may prove less financially rewarding for pharmacists than other roles (Box 3.11).

Barriers to and facilitators for integration (Box 4)

Some participants felt that there was no need for a practice pharmacist and that, although international evidence may exist, local evidence was lacking. There were reservations about their role not being clearly defined (Box 4.1). Another concern was that there would be insufficient work for the pharmacist and that pharmacist services are a lower priority compared to other potential services in the GP setting (Box 4.2). The initial uptake of this role by GPs may also be slow, with GP and practice staff perceptions and attitudes posing another challenge (Box 4.3). Boundary encroachment, previous bad experiences and a perceived conflict of interest for pharmacists were raised (Box 4.4). Practical challenges, such as smaller practices with insufficient infrastructure and limited funding, were a recurring theme (Box 4.5). The views held by organisations representing the medical and pharmacy professions were also foreshadowed as a potential barrier, with participants feeling the apparent goals of these organisations would not align with such integration (Box 4.6–4.7).

To overcome these barriers, interviewees felt that a clear need for this position, and a well-defined role supported by local evidence, would be imperative (Box 4.8). Initial and ongoing stakeholder consultation regarding the new role would be necessary (Box 4.9). Some participants felt that an existing, positive relationship with a pharmacist would be beneficial and pharmacists themselves needed to portray credibility and competence when integrating (Box 4.10). Previous positive integration of other practice staff was another facilitating factor. External funding for the pharmacist's role and a rigorous business model were seen as major facilitators, with practices embracing a multidisciplinary approach perceived as being more accommodating of a practice pharmacist (Box 4.11). Collaboration with and endorsement from professional organisations, as well as the specialist colleges, were recommended (Box 4.12).

Box 2 Role of the general practice pharmacist

2.1 'You could certainly get much better advice about medications from them if they're on the spot and you had face-to-face contact with them.' (GP 11)
2.2 'They don't need to be based in one clinic; they need to be attached or affiliated with several clinics and that would make them viable.' (GP 6)
2.3 '. . . a video link or a web cam, is something that you can offer to remote practices, because you may not want to travel, but if you can have a regular link up and both of you will get paid for your time.' (GP 3)
2.4 'Reviewing medications . . . You need someone to sit down and talk to them about their medications and how they work.' (GP 11)
2.5 'He's available if we have any pharmacological questions that we can e-mail him or talk to him directly and he's very helpful with giving us answers to those questions.' (GP 7, working with practice pharmacist)
2.6 'Say 2 or 3 years of a new practitioner's life, getting them to take on good habits, quality use of medicines principles and just double check what they're up to would be good. That would help the burden of supervision that GPs increasingly will have.' (GP 4)
2.7 'I think it would be an opportunity for practices to do a bit of self-analysis; what their prescribing patterns are and things of that nature, which we don't have the time for now.' (GP 10)
2.8 'You could have case conferences about people . . . so you could conceivably have the GP, the pharmacist, the dietician and the diabetic educator sitting around talking about the management of that particular patient.' (GP 11)
2.9 'They're looking at . . . giving pharmacists the ability to do repeat prescribing, so I think that's a fairly good opportunity for pharmacists to be involved with a GP. They could screen and see if the patient needs to see the doctor for their script for Lipitor or if you had a protocol for it you could say [I can prescribe that for you].' (Pharmacist 1)
2.10 'Someone with the right qualifications could run a hypertension clinic or a warfarin clinic [etc.] . . . using clinical pathways that have been set up with the help of the doctors.' (Pharmacist 8)
2.11 'Well the pharmacist working in a GP practice I think having prescribing rights would be divisive, seen as a threat to the GP so in that situation I'd say a definite no.' (Pharmacist 15)
2.12 'They need to be good at managing professional relationships. They need to be flexible and professional and adaptable and good communicators . . . All of the things we'd like all of our staff to be, or ourselves as well.' (GP 5)
2.13 'I could not have graduated and walked into a GP's surgery and started working, because I've had to really change my attitude over the last 10 years working with GPs . . . I think we'd certainly have to do something . . . maybe not knowledge . . . but certainly some skills and some attitudes.' (Pharmacist 5)
2.14 'Because I find it very helpful, I guess every day would be ideal but 2 to 3 days is still quite good because most medication questions can wait a day or so.' (GP 7, working with practice pharmacist)
2.15 'Well they'd have to have, to a large extent, unlimited access because they need to know what's going on and they'd have to have access to the drugs they'd been prescribed and various other information – alcohol habits and smoking habits.' (GP 11)
2.16 'I would be preferring, if they were functioning in our clinic, then the doctor would refer them or suggest that they see the patient.' (GP 10)
2.17 'I would like the pharmacist to be taking a more active role in identifying the patient [for medication review]. And saying, 'Look here's a list of patients that I generated from your data' – I think they probably all could benefit from it' (GP 5)
2.18 'I think it would have to be on a salary basis.' (GP 11)
2.19 'And most patients, not all, but most patients won't pay so I think government subsidy is the only way.' (Pharmacist 3)
2.20 'And when you've got private health insurance that would be the other way to try and get cover by extras because a lot of our patients would have that.' (GP 4)
2.21 'I think the Extended Primary Care plan, has funding for other allied health professionals as well, I don't know if you can mix it in with that . . . with so many visits allowed a year for free.' (Pharmacist 16)

GP, general practitioner.

Discussion

This study identified several benefits of having a pharmacist co-located in the practice, including improved collaboration and communication amongst the primary healthcare team and improved quality use of medicines by both patients and staff. Overall, pharmacist participants were collectively supportive of this role, whereas GPs had mixed views. Those GPs

Box 3 Pros and cons of integration

3.1 'It's like working with the physios or the dietician or the podiatrist here, if you have a problem you can talk to them, actually talk to them and discuss it and something that takes minutes to fix and solve a problem rather than days or weeks.' (GP 7, working with practice pharmacist)
3.2 'Just sharing information and sharing the workload as well.' (GP 11)
3.3 'I also think that I'm a valuable check so to see okay are the blood pressure goals being met or is the HBA1c goal being met. You know have they had all their vaccinations. I guess I'm fortunate I can focus on the smaller part of the patient where the doctor has to focus on all of the patient.' (Pharmacist 10, practice experience)
3.4 'The outcome would be better use of medicines; better outcomes for patients and less harm from medicine; less inadequate treatment; less iatrogenic illness.' (GP 5)
3.5 'Just work wise challenging; I would see that as being a more fulfilling role perhaps than some other pharmacy roles. It would appeal to me personally.' (Pharmacist 7)
3.6 'I think being valued as a part of the team was pretty much top of the list, the first time in my life as a pharmacist I've actually felt that way, as being part of a team, it was just fantastic.' (Pharmacist 2, practice experience)
3.7 'We're somewhat besieged by patients, by allied health professionals who want to chat . . . It's all nice and each individual thing is probably quite useful but there is a real time issue here for which we're often not paid.' (GP 4)
3.8 'The only disadvantage would be if they were somehow undermining the community pharmacist who you do not want to put off-side . . . over many years you build up a very good rapport with them so there's that issue.' (GP 3)
3.9 'There may be a conflict in the advice that they're given so what they've been told by the pharmacist working in a medical clinic setting may be different from the advice given by the local pharmacist that they have the medication filled . . . So it may adversely affect how they perceive the therapy.' (GP 6)
3.10 'One of the barriers is the patient is just not interested in spending another half hour at the surgery with a health professional.' (Pharmacist 16)
3.11 'I can see though some people might not see it as a future for making as much money . . . some pharmacists might think it might be a drop in wage.' (Pharmacist 5)

GP, general practitioner.

who had previously worked with a practice pharmacist were more supportive of this role. However, the need for a practice pharmacist was felt to be insufficiently well defined and lacking in evaluated evidence to drive uptake. Various approaches to pharmacist integration were suggested by participants, reflecting the spectrum of models proposed or followed in other countries.[19] It was apparent that barriers, mainly practitioner perceptions, insufficient funding and infrastructure, would need to be overcome before the successful broad implementation of pharmacy services into Australian general practices.

This study has strengths and limitations. Participants interviewed were from a range of backgrounds and data saturation was achieved. Some participants had already worked in multidisciplinary teams, thus offering a richness and diversity of views. Two GPs had previous experience working within pharmacy (one as a pharmacist, the other as a sales assistant). It may be that participants interviewed had a pre-existing interest in this topic; however, they expressed varying views, highlighting the complex and divisive nature of the subject. The majority of pharmacists interviewed were consultant pharmacists, accredited to undertake collaborative medicines management reviews. We believed that consultant pharmacists would be the most suitable candidates for a role in general practice given their additional training and existing working relationship with GPs, and thus they were approached for this study. Although this may have introduced selection bias, the pharmacists interviewed had experience in multiple other roles within the profession, including traditional roles in community and hospital pharmacy, and thus were able to offer insights from different perspectives.

The interviewer was a registered pharmacist but took care to remain neutral throughout the interview, and did not emphasise the fact he was a pharmacist. Being a qualitative study, caution should be exercised in generalising these results because of the non-probabilistic nature of the sample. Although this study explored the views of GPs and pharmacists, input from other stakeholders such as consumers and major professional organisations is critical before recommending any changes to the current model.

Studies in other counties have shown that integrated pharmacists have been perceived by stakeholders to benefit both practice staff and pharmacists.[20,21] Our study revealed some concerns about potential negative impacts of the role on the community pharmacist. Some GPs felt this new role may undermine the current role of the community pharmacist, possibly reflecting the positive relationship between these GPs and their local pharmacists; however, most pharmacists

Box 4 Barriers and facilitators to integration

4.1 'For them to be there, it can't just be something because somebody said it's a good idea, we've actually got to define a role and what they're going to do.' (GP 8)
4.2 'I have more concerns about using our space for a pharmacist, I can think of more useful people I'd have.' (GP 4)
4.3 'Well first of all, clinical respect – it takes a while for doctors to really assess how good the pharmacist's clinical knowledge is and where they can fit in to the day-to-day business of the practice.' (Pharmacist 15)
4.4 'Well there would be all those inter-professional cultural sort of barriers that would take a long time to overcome for many GPs.' (GP 5)
4.5 'I just don't think general practice at the moment has enough space to accommodate everything we're being asked to accommodate.' (GP 4)
4.6 'I know that the AMA [Australian Medical Association] will be protective and negative because they're like a union.' (GP 3)
4.7 'The Pharmacy Guild will put up some sort of problems with this because they protect their shops and they wouldn't like the fact that the pharmacies might be bypassed for some of this sort of service.' (Pharmacist 8)
4.8 'We've just got to get the money sorted. And the other thing we could do . . ..is have some pilots and run a few things and see how it works.' (GP 3)
4.9 'Probably at the beginning to actually have communication so everybody knows why they're there and what their role is and what they're doing.' (GP 7, working with practice pharmacist)
4.10 'I guess if I had someone coming into my practice I'd feel more positive about it if it was someone I knew, like one of the pharmacists that I regularly work with anyhow.' (GP 5)
4.11 'Only ones that are purpose built with enough rooms, that have deliberately already integrating allied health professionals in their building.' (Pharmacist 5)
4.12 'Well I guess support at a high level, so you know, you see the colleges working together and you know statements and guidelines for stuff for sort of – you know say this is a good idea and this is how it could work and some commitment to putting the funding and infrastructure in place.' (GP 5)

GP, general practitioner.

in our study, including those working within community pharmacy, felt the role would be beneficial to the pharmacy profession overall.

The opinion that a non-dispensing, co-located practice pharmacist was more credible than a community pharmacist is a view shared by GPs in the UK.[22] Similarly to other studies, the GPs interviewed in our study felt that pharmacists mainly have a role in support and advisory functions.[14] Pharmacist participants, however, felt that role expansion and greater clinical involvement would be desirable and these views are reflected in the international literature.[14,23] The diversity of views regarding the role of the pharmacist working within general practice suggests that such a position may take various forms. The practice pharmacist may be akin to a clinical pharmacist working within a hospital setting, performing a combination of clinical, administrative and medication safety duties, but tailored to the primary-care setting. Others perceived it as an extension of the current consultant pharmacist role, with a greater focus on medication review and education. Overall, it appeared that the role would be multifaceted, with different models and scopes of practice suiting different clinics, depending on the nature and needs of the individual practice.

The barriers to and facilitators for integration are consistent with the international literature.[21,24] Slow uptake by GPs and other operational challenges were similarly mentioned. Some GP participants expressed their concerns with introducing yet another member into their practice without adequate evidence of need, and GPs in our study explained this in light of the slow initial uptake of practice nurses into Australian general practices. Local evidence was preferred by GPs to support this new role. Although Australian evidence is sparse, new research is emerging focusing on inter-professional collaboration between GPs and pharmacists[25] and the co-location of pharmacists in general practices.[26] Some participants felt GPs may feel threatened by this new role, an opinion shared by GPs in international studies.[14,22] The reluctance to allow pharmacists to be more involved may be the result of a poor understanding of their training, a barrier mentioned by some participants and elicited from other studies.[27] This highlights the need for inter-professional education and the development of collaborative working relationships.

A variety of funding models were suggested, including models specific to the current Australian healthcare setting such as government subsidised programmes. This included

reimbursement for pharmacists as part of existing MBS primary-care items such as Chronic Disease Management (CDM) items like team care arrangements (TCAs). Using and building on current HMR funding may be viable depending on the pharmacist's role. These potential funding mechanisms are advantageous within the Australian context given their existence for other health professionals.[28] Alternatively, salaries, which practice pharmacists overseas commonly receive, could be implemented similarly to how practice nurses and other allied health staff are currently remunerated in Australian general practice.[29]

Previous studies have highlighted the reluctance of some GPs to allow pharmacists to access patient medical records, most feeling patient confidentiality would be compromised.[14,22] The majority of participants in our study, however, felt that full access to patient medical records was a necessity for the pharmacist in order to provide optimal care. A reason for this discrepancy may be that Australian GPs are familiar with sharing patient information with pharmacists, especially those using the HMR programme.

Conclusion

The integration of pharmacists into the general-practice setting was well accepted, and various methods of integration are possible. Important barriers and facilitators of integration should be considered when implementing services. Future research should further explore the methods of collaboration and trial their implementation.

Declarations

Conflict of interest

The Author(s) declare(s) that they have no conflicts of interest to disclose.

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Author contributions

ET (PhD candidate) participated in recruitment and interviewing of all participants. All Authors participated in study design, data analysis, and preparation of the manuscript. All Authors state that they had complete access to the study data that support this publication, and read and approved the final manuscript.

References

1. Department of Health and Ageing. *Primary Health Care Reform in Australia – Report to Support Australia's First National Primary Health Care Strategy*. Canberra: Department of Health and Ageing, 2009.
2. Dolovich L *et al.* Integrating family medicine and pharmacy to advance primary care therapeutics. *Clin Pharmacol Ther* 2008; 83: 913–917.
3. Borenstein JE *et al.* Physician-pharmacist comanagement of hypertension: a randomized, comparative trial. *Pharmacotherapy* 2003; 23: 209–216.
4. Zermansky AG *et al.* Randomised controlled trial of clinical medication review by a pharmacist of elderly patients receiving repeat prescriptions in general practice. *BMJ* 2001; 6: 1340–1343.
5. Farrell B *et al.* Shifts in expectations: evaluating physicians' perceptions as pharmacists become integrated into family practice. *J Interprof Care* 2010; 24: 80–89.
6. Miller GC *et al.* Adverse drug events in general practice patients in Australia. *Med J Aust* 2006; 184: 321–324.
7. Avery T *et al. Investigating the prevalence and causes of prescribing errors in general practice: the PRACtICe study*. Project Report. London: General Medical Council, 2012.
8. Long M *et al. Pharmacy Workforce Planning Study*. Canberra: Department of Health and Ageing and The Pharmacy Guild of Australia, 2011. http://www.guild.org.au/iwov-resources/documents/The_Guild/PDFs/CPA%20and%20Programs/4CPA%20General/Pharmacy%20Workforce%20Planning/Full%20Final%20Report%20FINAL.pdf (accessed 24 October 2012).
9. Ridoutt L. *Analysis of Secondary Data to Understand Pharmacy Workforce Supply*. Initial Supply Report. Sydney: Human Capital Alliance, 2008. http://www.humancapitalalliance.com.au/documents/Initial%20Supply%20Report%20final%20-%2022102008.pdf (accessed 24 October 2012).
10. Gilbert AL *et al.* Collaborative medication management services: improving patient care. *Med J Aust* 2002; 177: 189–192.
11. Stafford L *et al.* Drug-related problems identified in post-discharge medication reviews for patients taking warfarin. *Int J Clin Pharm* 2011; 33: 621–626.
12. Medicare Australia. Home Medicines Review [online]. Canberra: Department of Human Services, 2012. http://www.medicareaustralia.gov.au/provider/pbs/fourth-agreement/hmr.jsp (accessed 21 June 2012).
13. Bell J *et al.* Prescriber feedback to improve quality use of medicines among older people: the veterans' MATES program. *J Pharm Pract Res* 2001; 41: 316–319.
14. Edmunds J, Calnan MW. The reprofessionalisation of community pharmacy?

An exploration of attitudes to extended roles for community pharmacists amongst pharmacists and General Practioners in the United Kingdom. *Soc Sci Med* 2001; 53: 943–955.
15. Chen T *et al.* Collaboration between community pharmacists and GPs – impact on interprofessional communication. *J Soc Adm Pharm* 2001; 18: 83–90.
16. Pope C *et al.* Qualitative research in health care. Analysing qualitative data. *BMJ* 2000; 320: 114–116.
17. National Prescribing Service. NPS Medicinewise [online; home page]. Canberra: Department of Health and Ageing, 2012. http://www.nps.org.au/ (accessed 21 June 2012).
18. Department of Health and Ageing. Medicare Benefits Schedule Online [online]. Canberra: Department of Health and Ageing, 2012. http://www.health.gov.au/internet/mbsonline/publishing.nsf/Content/Medicare-Benefits-Schedule-MBS-1 (accessed 21 June 2012).
19. Silcock J *et al.* The organisation and development of primary care pharmacy in the United Kingdom. *Health Policy* 2004; 67: 207–214.
20. Pottie K *et al.* Integrating pharmacists into family practice teams physicians' perspectives on collaborative care. *Can Fam Physician* 2008; 54: 1714–1717. e5.
21. MacRae F *et al.* Pharmacist-led medication review clinics in general practice: the views of Greater Glasgow GPs. *Int J Pharm Pract* 2003; 11: 199–208.
22. Hughes C, McCann S. Perceived interprofessional barriers between community pharmacists and general practitioners: a qualitative assessment. *Br J Gen Pract* 2003; 53: 600–606.
23. Pottie K *et al.* Pharmacist's identity development within multidisciplinary primary health care teams in Ontario; qualitative results from the IMPACT project. *Res Soc Adm Pharm* 2009; 5: 319–326.
24. Kolodziejak L *et al.* Integration of a primary healthcare pharmacist. *J Interprof Care* 2010; 24: 274–284.
25. Bereznicki BJ *et al.* Pharmacist-initiated general practitioner referral of patients with suboptimal asthma management. *Pharm World Sci* 2008; 30: 869–875.
26. Ackerman E *et al.* Pharmacists in general practice. *Aus Fam Physician* 2010; 39: 163–164.
27. Bond C *et al.* Pharmacists: a resource for general practice? *Int J Pharm Pract* 1995; 3: 85–90.
28. Department of Health and Ageing. Chronic Disease Management (CDM) Medicare Items [online]. Canberra: Department of Health and Ageing, 2013. http://www.health.gov.au/internet/main/publishing.nsf/Content/mbsprimarycare-chronicdiseasemanagement (accessed 25 May 2013).
29. Department of Human Services. *Practice Nurse Incentive Program guidelines, July 2012*. Canberra: Department of Human Services.

Chapter 5. The Pharmacists in Practice Study (PIPS): Study protocol

5.1 Introduction

Findings presented in Chapters 3 and 4 demonstrated that the delivery of health services by a practice pharmacist co-located in general practice clinics can be effective in improving patient health outcomes, and that this potential model of clinical pharmacy service delivery is well accepted by Australian stakeholders. These chapters also highlighted the various roles pharmacists can have in this setting, the challenges and enablers to the implementation of such services, and the need to trial these services in a local (Australian) environment.

These results helped guide the development of a multi-faceted practice pharmacist role in Australian primary care practices. This role was trialled as part of a prospective, before-after intervention study, which also included a concurrent qualitative evaluation.

This study, known as the PIPS (Pharmacists in Practice Study), aimed to investigate the effectiveness and feasibility of a practice pharmacist role in the Australian setting.

The key objectives of this study were to:

- Implement the practice pharmacist intervention to improve quality use of medicines by patients and staff;
- Evaluate the effectiveness of the intervention on medication-related problems; medication adherence; quality of prescribing and adherence to clinical guidelines; satisfaction; and general health and health service use; and

- Explore stakeholder experiences with practice pharmacist services, including perceived feasibility and acceptability.

The protocol for this study has been published in *BMC Health Services Research* and is reproduced below. The appendices also provide copies of the ethics approval (Appendix 3); grant award (Appendix 4); participant explanatory statement, consent form and recruitment materials (Appendix 5); the patient questionnaires (Appendix 6), additional promotional material (Appendix 7) and pharmacist service record forms (Appendix 8). Detailed findings from the study are presented in Chapters 6 to 9.

5.2 Publication

Tan E, Stewart K, Elliott RA, George J. An exploration of the role of pharmacists within general practice clinics: the protocol for the Pharmacists in Practice Study (PIPS). *BMC: Health Services Research* 2012;12(1):246.

Declaration for Thesis Chapter 5

Declaration by candidate

In the case of Chapter 5, the nature and extent of my contribution to the work was the following:

Nature of contribution	**Extent of contribution (%)**
Reviewed literature; designed methodology; developed study materials; established collaborations; coordinated and led progress meetings with study sites and pharmacists; carried out recruitment; and prepared manuscript	75%

The following co-authors contributed to the work:

Name	**Nature of contribution**
Assoc Prof Kay Stewart	Designed methodology; attended site visits/progress meetings; reviewed study materials and manuscript
Mr Rohan Elliott	Designed methodology; attended site visits/progress meetings; reviewed study materials and manuscript
Dr Johnson George	Designed methodology; attended site visits/progress meetings; reviewed study materials and manuscript

Candidate's Signature		**Date**

Declaration by co-authors

The undersigned hereby certify that:

13. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors.
14. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
15. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
16. there are no other authors of the publication according to these criteria;
17. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
18. the original data are stored at the following location(s) and will be held for at least five years from the date indicated below:

Location(s)	**Centre for Medicine Use and Safety, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University, Parkville, Victoria 3052**

Signature 1	[redacted] Assoc Prof Kay Stewart	**Date** 8/10/13
Signature 2	[redacted] Mr Rohan Elliott	 8/10/13
Signature 3	[redacted] Dr Johnson George	 8/10/13

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BMC Health Services Research

STUDY PROTOCOL Open Access

An exploration of the role of pharmacists within general practice clinics: the protocol for the pharmacists in practice study (PIPS)

Edwin Tan[1], Kay Stewart[1], Rohan A Elliott[1,2] and Johnson George[1*]

Abstract

Background: Medication-related problems are a serious concern in Australian primary care. Pharmacist interventions have been shown to be effective in identifying and resolving these problems. Collaborative general practitioner-pharmacist services currently available in Australia are limited and underused. Limitations include geographical isolation of pharmacists and lack of communication and access to patient information. Co-location of pharmacists within the general practice clinics is a possible solution. There have been no studies in the Australian setting exploring the role of pharmacists within general practice clinics.
The aim of this study is to develop and test a multifaceted practice pharmacist role in primary care practices to improve the quality use of medicines by patients and clinic staff.

Methods/design: This is a multi-centre, prospective intervention study with a pre-post design and a qualitative component. A practice pharmacist will be located in each of two clinics and provide short and long patient consultations, drug information services and quality assurance activities. Patients receiving long consultation with a pharmacist will be followed up at 3 and 6 months. Based on sample size calculations, at least 50 patients will be recruited for long patient consultations across both sites. Outcome measures include the number, type and severity of medication-related problems identified and resolved; medication adherence; and patient satisfaction. Brief structured interviews will be conducted with patients participating in the study to evaluate their experiences with the service. Staff collaboration and satisfaction with the service will be assessed.

Discussion: This intervention has the potential to optimise medication use in primary care clinics leading to better health outcomes. This study will provide data about the effectiveness of the proposed model for pharmacist involvement in Australian general practice clinics, that will be useful to guide further research and development in this area.

Trial registration: Australian New Zealand Clinical Trials Registry: ACTRN12612000742875

Keywords: Pharmacists, Primary healthcare, General practice, Multidisciplinary, Family practice

Background

Medication misadventure remains a serious concern in Australian primary care [1,2]. It is estimated that one in 10 patients who visit their general practitioner (GP) experience a medication-related problem (MRP), of which almost half are considered moderate or severe, with 8% requiring hospitalization [1]. Approximately one in four of these are preventable. These data are consistent with studies from other countries. For example, a recent UK study revealed that one in 20 prescription items in general practice contained an error, affecting 1 in 8 patients [3]. Poor communication has been identified as a major contributing factor towards MRPs, [2] highlighting the need for greater collaboration between GPs, pharmacists and other primary health professionals to ensure optimal patient care.

Collaborative medication reviews, undertaken by pharmacists and GPs, have been successful in identifying and

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resolving medication-related problems, improving quality of prescribing, and optimizing drug use and costs [4,5]. These collaborative services, however, are currently limited and underused due to factors including geographical isolation, limited access to patient medical records, a lack of time for team activities and a health policy that is not conducive to such collaborative arrangements [6]. Additionally, communication between GPs and pharmacists in the community setting is sporadic and reactive, risking fragmentation of patient care [7].

A possible solution to these problems is the integration of pharmacists into general practices and primary healthcare clinics. In countries such as the United Kingdom, Canada and the United States, practice pharmacists work in close collaboration with GPs (family physicians) to undertake a range of clinical and administrative tasks [8,9]. Some studies suggest the implementation of these roles can result in improved medication use and health outcomes and reduced health service use and cost [10-12]. Co-location has also been shown to enable greater communication and cooperation between health professionals, and strengthen the primary health care team [13].

The aim of this study is to develop and test a multifaceted practice pharmacist role in primary care practices in Australia to improve the quality use of medicines by patients and clinic staff.

Methods/design

This is a multi-centre, prospective intervention study with a pre-post design and a qualitative component, involving two general practice (primary care) clinics in Melbourne, Australia.

Recruitment of practices and pharmacists

Primary care clinics will be invited to participate through advertisements and consultation with the Victorian Divisions of General Practice and key informants in Melbourne, Australia. Primary care practices that have the space to accommodate a co-located pharmacist will be targeted. An independent practice pharmacist with significant clinical experience and accreditation to conduct Government funded collaborative Home Medicines Reviews (HMRs) will be identified for each clinic through advertisements and key informants.

Intervention

The intervention will consist of a multi-faceted, collaborative service targeting patients and practice staff. A practice pharmacist will be co-located in each of the study clinics for at least eight hours per week for six months. The practice pharmacist will undertake the following tasks:

1. Long patient consultations
2. Short patient consultations
3. Drug information and education service for clinic staff; and
4. Quality assurance activities

Long patient consultation

Recruitment of participants

Participants for the long patient consultations will be practice patients who may be at an increased risk of MRPs [14].

Inclusion criteria

- Using five or more medicines
- Using one or more medicines that require therapeutic drug monitoring (e.g. warfarin, phenytoin, lithium)
- Using medicines for three or more medical problems
- Have had a recent unplanned hospital admission/ emergency department visit
- Having other reason(s) for being at risk of medication misadventure (e.g. adherence issues, language barriers, multiple prescribers)

Exclusion criteria

- Have had a HMR in the previous 12 months with no subsequent significant change in clinical status or medication regimen
- Are unable to provide written informed consent
- Are under 18 years of age
- Are unavailable for follow up for six months after recruitment

Patients meeting one or more of the eligibility criteria will be considered for referral to the study by their general practitioner or clinic staff. Those patients who are referred to the study will be provided with an introductory letter and plain language statement in person during their clinic visit. Patients will be asked by the GP/clinic staff if they are willing to be contacted by the research team. If patients agree, the GP/clinic staff will provide the research team with the patient's contact details.

The research assistant will contact patients who agreed to provide their contact details. Suitable and willing participants will be recruited by obtaining initial verbal consent. Written consent will be obtained at the time of the appointment with the practice pharmacist.

Baseline data collection

Baseline data will be collected by the research assistant using a structured questionnaire, either in person (at the clinic or the person's home) or by telephone, and will include demographic information (age, sex, ethnicity,

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education, socioeconomic status, living arrangements etc.), health information (general health, health service use, health literacy [15] etc.), and medicines information (medication risk [14] adherence [16,17] etc.). The research assistant will then organize for the participant to meet the practice pharmacist for a long consultation.

Long patient consultation process

All participants will receive a 30–60 minute consultation with the pharmacist in a private room at the clinic (or a home visit if they prefer or are housebound) to perform a comprehensive medication review and identify medication-related problems (MRPs). Prior to the consultation, the pharmacist will discuss any health or medication-related issues with the GP or clinic staff, if needed. The pharmacist will also review participants' general practice medical record (including progress notes, medication lists and pathology results) and dispensing histories if needed. The pharmacist will obtain written informed consent from the participant. In addition to reviewing the participant's medication regimen, the pharmacist will assess medication adherence and knowledge. The pharmacist will provide counseling and education as needed on medication management and the use of medication devices, and reinforce lifestyle advice related to their health problems and medications. The pharmacist may provide the participant with a complete medication list and refer them to their community pharmacy for adherence aids (e.g. pill boxes, administration aids), if needed. Additionally, referral may be made to the GP or other health professionals as required. After the consultation, the pharmacist will write a short report outlining MRPs and recommendations, and provide this to the participant's GP either electronically (via secure email or directly into the practice's electronic medical record) or as a paper-based report, depending on the GP's preference. The pharmacist may update the medication history within the practice's medical record as needed. Following this, the pharmacist will discuss any issues with the GP, other staff and community pharmacist, if needed. Case conferencing may be organized where appropriate.

Monitoring and follow up

Participants will be followed up by the research assistant at three and six months either in the clinic or by telephone to collect data about implementation of pharmacist recommendations, resolution of MRPs identified by the practice pharmacist, participant's medication adherence and participant's general health and wellbeing.

Sample size

Based on an expected average number of 2.5 MRPs per participant at baseline, an expected average reduction of 1 MRP (i.e. 40%) per participant with a within-participant standard deviation of 2.1 MRPs (assuming a correlation coefficient of 0.5), [18,19] a power of 80% and a two-tailed alpha of 0.05, the required sample size is 37 participants. Allowing for a dropout/loss to follow-up rate of 25%, at least 50 participants will be recruited. This was calculated using PS Power and Sample Size Calculations (Version 3.0, Dupont & Plummer, 2009).

Short patient consultation

Patients with potential medication issues (e.g. nonadherence, newly prescribed medicines) who do not require a comprehensive review of their complete medication regimen may receive a short consultation with the pharmacist. Data will be collected about these consultations, but the patients will not be consented for the study (no personal or identifying data will be collected). Referrals may be made by GPs or clinic staff, or patients may self-refer. The short patient consultation will last 15–30 minutes and provides an opportunity for the pharmacist to provide brief education and counseling on specific needs or answer questions. Short patient consultations will only be undertaken in the clinic. After the consultation, the pharmacist will write brief notes directly into the electronic medical record, and update records as needed. Examples of services to be provided in these consultations include: new medication counseling, adherence assessment, assessment of and education on device technique (e.g. using asthma inhalers), and provision of a medication list. Patient satisfaction will be assessed by an anonymous questionnaire to be given to each patient by the pharmacist along with a reply-paid envelope addressed to the researchers.

Drug information and education service

The practice pharmacist will provide a drug information service for practice staff. Queries can be made to the pharmacist in person, by telephone or via email. All queries (and responses) will be documented by the pharmacist. Practice staff will also be invited to attend pharmacist-led group education sessions targeting topics relevant to them (e.g. new therapy or treatment protocols), and a weekly drug information newsletter may also be produced by the pharmacist and provided to staff.

Quality assurance activities

The practice pharmacists will undertake a Drug Use and Evaluation (DUE) program in the clinic. The pharmacists will review current prescribing patterns, evaluate these against current best practice guidelines, and implement an intervention to address deficiencies identified using established DUE methodology [20]. A pharmacotherapeutic area of concern or importance will be identified by the pharmacist in conjunction with the GPs

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and clinic staff. The practice team, with assistance from the research team, will decide upon audit criteria and measurement instruments will be derived from published clinical practice guidelines. The pharmacist will collect and evaluate data relevant to medication use in this area by retrospectively reviewing electronic medical records. Confidentiality of data will be ensured by de-identifying all information collected. Results and feedback will be provided to staff. Multifaceted strategies to improve the quality of prescribing in the selected area will be developed and implemented by the interdisciplinary team, and re-evaluated at the end of the study period. Patients will not be recruited or consented to this part of the study, and no identifying data will be collected.

Monitoring and follow up

Actions arising from the DUE program (e.g. development and implementation of clinical guidelines, criteria, treatment protocols, education programs) will be assessed for effectiveness after six months by repeating the prescribing audit to complete the DUE cycle [20].

Outcomes

Outcomes of long patient consultations

Medication-related problems The primary outcome of the long consultations will be the number of MRPs identified by practice pharmacists and the number of identified MRPs that are resolved as a result of the pharmacists' interventions. The number of MRPs, number of recommendations made by the pharmacists and the number of recommendations accepted/implemented will be recorded and determined by chart audit and/or patient interview, conducted by a research assistant. The types of problems will be categorized by the research team according to the criteria described by Strand et al [21]. The severity of the MRPs and the likely consequences if they had not been addressed will be assessed by an expert panel using a risk classification system [22].

Medication adherence Participants' medication adherence will be measured using two methods – the Morisky Scale [16] and the Tool for Adherence Behaviour Screening (TABS) [17] at baseline, three and six months. The Morisky Scale is a validated 4-item scale that asks patients four 'yes/no' questions regarding patterns of medication use. A patient is considered non-adherent if they answer 'yes' to any of the questions. The TABS is a validated and reliable sub-scale of the Beliefs and Behaviour Questionnaire (BBQ). The TABS consists of two, 4-item subscales for adherence and non-adherence. It screens for medication non-adherence that is both intentional and unintentional and assesses the respondent's agreement with a series of statements that are scored on a five-point Likert scale. The total score for 'nonadherence' will be subtracted from that of 'adherence'; a differential of ≥15 will be considered as good adherence and ≤14 will be considered as suboptimal adherence [23].

General health Patient general health and wellbeing, including use of health services, will be assessed via patient self-report at baseline, three and six months.

Other outcomes

Satisfaction

Patient satisfaction with the practice pharmacist will be determined by a structured, satisfaction questionnaire adapted from a previously validated patient satisfaction survey by Baker regarding physician consultations [24,25]. The questionnaire will be anonymous and provided at the end of any interaction with the pharmacist (including long patient consultations and short patient consultations). Participants will be requested to complete and return the questionnaire before they leave the practice or at their earliest convenience, using a reply-paid envelope.

Quality of prescribing and medication use

The effectiveness of the DUE program will be assessed by re-evaluating medication use in the targeted population at the end of the study and comparing this to baseline data.

Drug information queries

The number of drug information queries made and answered, the type of queries made and by whom, will be evaluated at six months.

Short patient consultations

General information regarding the nature of the short consultations will be recorded, including the reason for referral, type of service provided and average time spent.

Experiences and feedback

The views of a sample of stakeholders on their experiences with this new service will be explored using interviews and/or focus groups at the study's conclusion. Patients and staff will have the opportunity to share their thoughts on the perceived benefits and challenges of the service and how it could be improved and developed further.

Data analysis

Data will be entered into the Statistical Package for Social Sciences (SPSS) for Windows Version 19.0 (IBM, New York, USA) and analyzed using standard descriptive methods. Bivariate analysis will be performed

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between pre- and post-intervention data, using paired t-tests for continuous variables, McNemar chi-square tests for categorical variables, and Wilcoxon matched-pairs signed-ranks tests for ordinal variables. Comparisons between practices may be done using repeated measures analysis of variance (ANOVA). Binary logistic regression may be performed to identify independent predictors of having medication-related problems and effects on adherence and other outcomes.

Qualitative data management will be facilitated using NVivo® (Version 9, Qualitative Solutions & Research International, Melbourne, Vic). Interview transcripts will be read by two independent researchers and coded for emergent themes. Any discrepancies will be discussed and sorted in team meetings in the presence of a third researcher. A framework approach may be utilized whereby a thematic framework, based on *a priori* issues, will be applied to the data [26]. This will allow data to be easily indexed and charted, thus aiding subsequent interpretation.

Ethics

This study has been approved by the Monash University Human Research Ethics Committee.

Discussion

To the best of our knowledge, this is the first study in Australia to evaluate an interdisciplinary, multifaceted practice pharmacist role to improve the quality use of medicines by both patients and clinic staff. The comprehensive nature of this intervention aims to optimise medicine use at several levels. Although the study will be conducted with a pre-post design, subjects will serve as their own controls, thus eliminating inter-subject variability and reducing confounding. Additionally, the study will be conducted in more than one primary care clinic allowing for inter-practice comparison and improving external validity.

The study involves mixed methods to capture and measure a variety of data to explain the impact of the intervention. Additionally, a range of process, health, medication management and humanistic outcomes will be collected. By using both quantitative and qualitative methods, a deeper exploration of the intervention can occur. This will enable a more comprehensive exploration of the various intricacies involved in both types of settings, thus allowing identification of the optimal models of pharmacist integration for various primary care clinics.

Limitations

The before and after design, which lacks a concurrent control group, may compromise the internal validity of the study and limit the conclusions drawn from the results. Non-random sampling means external validity is also compromised. However, this design is the most suitable and practical given the nature of the intervention; a controlled trial with randomization at the level of the patient would be severely limited by contamination, and a cluster randomized controlled trial would require multiple practices, which is not feasible in the context of limited resources.

Conclusion

The integration and co-location of a practice pharmacist into Australian primary healthcare clinics is uncommon and has not been evaluated. This study will implement and evaluate a new collaborative pharmacist role and assess its effects on optimizing medication outcomes at various levels. The study will provide useful data to guide further research and development in this area.

Abbreviations

MRP: Medication-related Problem; GP: General Practitioner; HMR: Home Medicines Review; DUE: Drug Use Evaluation; TABS: Tool for Adherence Behaviour Screening; BBQ: Beliefs and Behaviour Questionnaire.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

ET (PhD candidate) participated in the design of the trial, recruitment and manuscript preparation, and has an ongoing role in carrying out the trial. JG, RAE and KS participated in the design of the trial and study methodology, and review of the manuscript. All authors read and approved the final manuscript.

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References

1. Miller GC, Britth HC, Valenti L: **Adverse drug events in general practice patients in Australia.** *Med J Aust* 2006, **184**:321–324.
2. Bhasale AL, Miller GC, Reid SE, Britt HC: **Analysing potential harm in Australian general practice: an incident-monitoring study.** *Med J Aust* 1998, **169**:73–76.
3. Avery T, Barber N, Ghaleb M, Dean Franklin B, Armstrong S, Crowe S, Dhillon S, Freyer A, Howard R, Pezzolesi C, *et al*: **Investigating the prevalence and causes of prescribing errors in general practice: the PRACtICe study.** *Gen Med Council* 2012.
4. Gilbert AL, Roughead EE, Beilby J, Mott K, Barratt JD: **Collaborative medication management services: improving patient care.** *Med J Aust* 2002, **177**:189–192.
5. Stafford L, Stafford A, Hughes J, Angley M, Bereznicki L, Peterson G: **Drug-related problems identified in post-discharge medication reviews for patients taking warfarin.** *Int J Clin Pharm* 2011, **33**:621–626.
6. Edmunds J, Calnan MW: **The reprofessionalisation of community pharmacy? An exploration of attitudes to extended roles for community pharmacists amongst pharmacists and General Practioners in the United Kingdom.** *Soc Sci Med* 2001, **53**:943–955.

7. Farris K, Cote I, Feeny D, Johnson J, Tsuyuki R, Brilliant S, Dieleman S: **Enhancing primary care for complex patients. Demonstration project using multidisciplinary teams.** *Can Fam Physician* 2004, **50**:998–1003.
8. Silcock J, Raynor DKT, Petty D: **The organisation and development of primary care pharmacy in the United Kingdom.** *Health Policy* 2004, **67**:207–214.
9. American Society of Health-system Pharmacists: **ASHP Statement on the Pharmacist's Role in Primary Care.** *Am J Health-Sys Ph* 1999, **56**:1665–1667.
10. Dolovich L, Pottie K, Kaczorowski J, Farrell B, Austin Z, Rodriguez C, Gaebel K, Sellors C: **Integrating family medicine and pharmacy to advance primary care therapeutics.** *Clin Pharmacol Ther* 2008, **83**:913–917.
11. Borenstein JE, Graber G, Saltiel E: **Physician-Pharmacist Comanagement of Hypertension: A Randomized, Comparative Trial.** *Pharmacotherapy* 2003, **23**:209–216.
12. Zermansky AG, Petty DR, Raynor DK, Freemantle N, Vail A, Lowe CJ: **Randomized controlled trial of clinical medication review by a pharmacist of elderly patients receiving repeat prescriptions in general practice.** *Brit Med J* 2001, **6**:1340–1343.
13. Farrell B, Pottie K, Woodend K, Yao V, Dolovich L, Kennie N, Sellors C: **Shifts in expectations: Evaluating physicians' perceptions as pharmacists become integrated into family practice.** *J Interprof Care* 2010, **24**:80–89.
14. Barenholtz Levy H: **Self-administered medication-risk questionnaire in an elderly population.** *Ann Pharmacother* 2003, **37**:982–987.
15. Chew LD, Bradley KA, Boyko EJ: **Brief questions to identify patients with inadequate health literacy.** *Fam Med* 2004, **36**:588–594.
16. Morisky DE, Green LW, Levine DM: **Concurrent and predictive validity of a self-reported measure of medication adherence.** *Med Care* 1986, **24**:67–74.
17. George J, Mackinnon A, Kong DC, Stewart K: **Development and validation of the Beliefs and Behaviour Questionnaire (BBQ).** *Patient Educ Couns* 2006, **64**:50–60.
18. Sellors J, Kaczorowski J, Sellors C, Dolovich L, Woodward C, Willan A, Goeree R, Cosby R, Trim K, Sebaldt R, *et al*: **A randomized controlled trial of a pharmacist consultation program for family physicians and their elderly patients.** *Can Med Assoc Jl* 2003, **169**:17–22.
19. Soendergaard B, Kirkeby B, Dinsen C, Herborg H, Kjellberg J, Staehr P: **Drug-related problems in general practice: results from a development project in Denmark.** *Pharm World Sci* 2006, **28**:61–64.
20. SHPA Committee of Specialty Practice in Drug Use Evaluation: **SHPA Standards of Practice for Drug Use Evaluation in Australian Hospitals.** *J Pharm Pract and Res* 2004, **34**:220–223.
21. Strand LM, Morely PC, Cipolle RJ, Ramsey R, Lamsam GD: **Drug-related problems: their structure and function.** *Ann Pharmacother* 1990, **24**:1093–1097.
22. Elliott R, Woodward M: **Assessment of risk associated with medication-related problems in elderly outpatients.** *J Pharm Pract and Res* 2009, **39**:109–113.
23. Lau R, Stewart K, McNamara KP, Jackson SL, Hughes JD, Peterson GM, Bortoletto DA, McDowell J, Bailey MJ, Hsueh A, George J: **Evaluation of a community pharmacy-based intervention for improving patient adherence to antihypertensives: a randomized controlled trial.** *BMC Health Serv Res* 2010, **10**:34.
24. Baker R: **Development of a questionnaire to assess patients' satisfaction with consultations in general practice.** *Br J Gen Pract* 1990, **40**:487–490.
25. Stewart DC, George J, Bond CM, Cunningham IT, Diack HL, McCaig DJ: **Exploring patients' perspectives of pharmacist supplementary prescribing in Scotland.** *Pharm World Sci* 2008, **30**:892–897.
26. Pope C, Ziebland S, Mays N: **Qualitative research in health care. Analysing qualitative data.** *Brit Med J* 2000, **320**:114–116.

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Chapter 6. The Pharmacists in Practice Study (PIPS): Summary of Findings

6.1 Introduction

Having described the study protocol for the PIPS in the previous chapter, this chapter provides an overview of the key findings from the PIPS. More detailed results for specific roles can be found in Chapters 7 to 9.

A manuscript providing a commentary and overall findings from the PIPS is in preparation for submission to the *Australian Family Physician* as a "professional article", and is reproduced below.

Declaration for Thesis Chapter 6

Declaration by candidate

In the case of Chapter 6, the nature and extent of my contribution to the work was the following:

Nature of contribution	**Extent of contribution (%)**
Reviewed literature; designed methodology; developed study materials; established collaborations; carried out recruitment; undertook data collection; performed data analysis; and prepared manuscript	80%

The following co-authors contributed to the work:

Name	**Nature of contribution**
Assoc Prof Kay Stewart	Designed methodology; reviewed study materials, data and prepared manuscript
Mr Rohan Elliott	Designed methodology; reviewed study materials, data and prepared manuscript
Dr Johnson George	Designed methodology; reviewed study materials, data and prepared manuscript

Candidate's Signature		**Date**

Declaration by co-authors

The undersigned hereby certify that:

19. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors.
20. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
21. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
22. there are no other authors of the publication according to these criteria;
23. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
24. the original data are stored at the following location(s) and will be held for at least five years from the date indicated below:

Location(s)	**Centre for Medicine Use and Safety, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University, Parkville, Victoria 3052**

Signature 1	[redacted] Assoc Prof Kay Stewart	**Date** 8/10/13
Signature 2	[redacted] Mr Rohan Elliott	8/10/13
Signature 3	[redacted] Dr Johnson George	8/10/13

6.2 Title

Integrating pharmacists into Australian general practice

6.3 Abstract

Pharmacists in some countries have integrated into general practices, providing a range of clinical services to improve quality use of medicines. International research has provided evidence that supports the integration of pharmacists into primary care clinics. Although practice pharmacists are rare in Australia, local evidence is beginning to emerge. The Pharmacists in Practice Study was a prospective, before-after study conducted at two general practice clinics in Melbourne over six months, to evaluate the role of practice pharmacists. Pharmacists provided medication review, medicines information, education, and quality improvement services. These resulted in significant reductions in medication-related problems, medication non-adherence, and under-prescribing of osteoporosis medicines. Qualitative evaluation of staff and patient experiences revealed they were positive about the practice pharmacist services. The feasibility and value of integrating pharmacists into Australian general practice clinics to optimise medication use was highlighted.

6.4 Background

Pharmacists overseas often work in general practice clinics to provide clinical services.[1] Practice pharmacists have a variety of roles aimed at optimising medicines use by patients and staff (see Box 6.1).[2, 3] International evidence reveals that practice pharmacist services can improve medicines use and health outcomes, and reduce health service utilisation and costs.[1, 4, 5] Given that medication-related problems (MRPs) continue to be of concern in Australia,[6] and quality use of medicines (QUM) has been identified as an important quality indicator in general practice,[7] the integration of pharmacists into Australian general practice warrants further investigation. In Australia, the presence of pharmacists within general practice is uncommon, although their potential role has been suggested[8] and there is growing support for this role.[9]

6.5 Evidence supporting the integration of pharmacists into the Australian general practice team

Recent Australian research has shown that practice pharmacists can improve the nature and timeliness of medication reviews and reports.[10, 11] The concept of pharmacist integration is well accepted by stakeholders; however, various barriers and facilitators need to be considered before implementing services.[12, 13] There is limited research evaluating the practice pharmacist's roles and stakeholders' experiences with these services in Australia.

Box 6.1. The roles of practice pharmacists overseas

Patient-level activities:

- patient education and counselling;
- medication reviews;
- assessing and optimising medication adherence;
- therapeutic drug monitoring;
- adverse drug event monitoring;
- ordering and interpreting laboratory tests;
- involvement in disease management clinics; and
- prescribing (independent, dependent or collaborative).

Health provider and practice-level activities:

- providing medicines information and education sessions to health professionals;
- managing and developing formularies, drug budgets and practice information systems;
- conducting practice-based quality use of medicines research;
- undertaking quality improvement activities and clinical audits;
- participating in medicines-related committees;
- liaising with other primary healthcare professionals including community pharmacists; and
- liaising with the secondary, tertiary and aged care sectors about medicines-related issues.

6.5.1 The Pharmacists in Practice Study

The Pharmacists in Practice Study [PIPS] was a prospective, before-after study undertaken at two general practice clinics in Melbourne, Australia.[14] The intervention comprised a multi-faceted, collaborative clinical pharmacy service targeting patients and practice staff. A pharmacist was co-located in each clinic for at least eight hours per week for six months (December 2011 and to July 2012).

The practice pharmacists provided the following services:

Long patient consultations (LPCs) (medicines review)

Eligible clinic patients (see Box 6.2) were referred by their GP for a pharmacist consultation.[15] Consultations were undertaken in a private consulting room at the clinic or in the patient's home, lasting approximately 30 to 60 minutes. The pharmacist reviewed the patient's medicines and adherence, with full access to their medical record, provided patient education, and produced a report for the GP. Discussion between the GP and pharmacist occurred, if needed.

Short patient consultations (SPCs)

Patients were referred or could self-refer for a short consultation with the pharmacist in the clinic. These involved a brief medicines review or patient education, and lasted approximately 15 to 30 minutes.

Medicines information and education sessions

The pharmacist was available to answer medicines information queries from staff, and also held staff education sessions and prepared a weekly medicine information newsletter.

Quality improvement

A drug use evaluation (DUE) program focussing on osteoporosis management[16] was undertaken based on national clinical guidelines.[17] An intervention was implemented comprising prescriber feedback and education, individual case-conferences with prescribers, and patient education mail-outs.

Box 6.2. Eligibility criteria for long patient consultations (LPCs)

Meeting one or more of the following:

- using five or more medicines;
- using one or more medicines that require therapeutic drug monitoring (e.g. warfarin, phenytoin, lithium);
- using medicines for three or more medical problems;
- having had a recent unplanned hospital admission/emergency department visit; or
- having other risks for medication misadventure (e.g. adherence issues, language barriers, multiple prescribers).

6.5.2 Evaluation of the PIPS

The PIPS was evaluated using quantitative and qualitative methods to assess the feasibility, effectiveness and acceptability of practice pharmacist services. The primary

outcome for the long consultations (medicines review) was the number of MRPs identified by the pharmacist, and the number that remained unresolved six months after the pharmacist consultation. Secondary outcomes included medication adherence (Morisky scale and Tool for Adherence Behaviour Screening [TABS]),[18, 19] health service use, and patient satisfaction.[20]

The primary outcome for the DUE program was the change in proportion of patients with a diagnosis of osteoporosis who were appropriately prescribed an anti-osteoporosis medicine (i.e. those without contraindications to anti-osteoporosis medicines). Use of calcium and vitamin D supplements were secondary outcome measures.

Feedback and experiences with the pharmacist services were explored using semi-structured telephone interviews with patients, focus groups with practice staff, and semi-structured interviews with and periodic narrative reports from practice pharmacists.[21]

Long patient consultations (medicines review)

Eighty-two patients were referred to the practice pharmacists for a medicines review. The median number of MRPs per patient identified by the pharmacist was 2 (interquartile range [IQR] 1, 4). Six months after review, this fell to 0 (IQR 0, 1), $p<0.001$. The proportion of patients who were adherent to their medications improved significantly, according to both the Morisky (44.1% versus 62.7%, $p=0.023$) and the TABS (35.6% versus 57.6%, $p=0.019$) scales. There was no significant effect on health service use. Patients were highly satisfied with their pharmacist consultations.[15]

Short patient consultations

Twenty-five short patient consultations were undertaken, many of which addressed patient medicine education (48.0%) and provided up-to-date medication profiles (32.0%).

Drug information and education sessions

The pharmacists documented 12 drug information queries and delivered four education sessions during the intervention period. Topics included new medicines and medication management issues, illustrated with the use of case studies.

Quality improvement

A total of 225 patients had a documented diagnosis of osteoporosis at the time of the baseline audit, and 240 at the post-intervention audit 12 months later. The proportion of patients without documented contraindications to all osteoporosis therapies who were prescribed an anti-osteoporosis medicine increased significantly (134/225 [58.7%] vs. 168/240 [70.0%], p=0.002). The proportion of patients for whom vitamin D and/or calcium supplement use was documented also increased significantly (145/225 [64.4%] vs. 205/240 [85.4%], p=0.002).[16]

Feedback

Thirty-four participants (18 patients, 14 practice staff [9 GPs, 4 practice nurses, 1 practice manager], and two practice pharmacists) participated in the qualitative study. Five main themes emerged: environment; professional relationships and integration; pharmacist attributes; staff and patient benefits; and logistical challenges. Participants reported that co-location and the interdisciplinary environment of general practice enabled better

communication and collaboration compared to traditional pharmacy services. Participants felt that pharmacists needed to possess certain attributes to ensure successful integration, including being personable and proactive. The pharmacist services were felt to result in clinical benefits for patients and improved QUM practices by staff, with medication reviews being the most well received role. Attitudinal, professional and logistical barriers were identified but were able to be overcome with planning and dialogue.[21]

6.6 Implications

The PIPS trialled clinical services delivered by pharmacists co-located in general practice clinics. Pharmacist consultations with patients resulted in resolution of MRPs and improved medication adherence. The DUE program improved prescribing for osteoporosis. The pharmacist's role was well accepted by patients, staff and pharmacists. Overall, the results of this study support the benefits and feasibility of practice pharmacists in the Australian health system, and may help inform local policy and debate on this topic.

6.6.1 Comparison with other studies

The positive effect of practice pharmacist consultations on MRPs, adherence and satisfaction are consistent with previous overseas studies;[1, 4, 22] however, few studies have assessed a multifaceted practice pharmacist role targeting a diverse range of patients as we did in our study.[4, 5] The study included both long and short patient consultations, education services and a quality improvement component, utilising the diverse skill set of pharmacists and their role in QUM. The qualitative analysis of stakeholder experiences produced findings similar to those from other studies.[23-25] A range of clinical and humanistic benefits from the pharmacist services were demonstrated, complementing

previous Australian research that evaluated process outcomes such as efficiency of completing the home medicines review (HMR) process.[10]

6.6.2 Strengths and limitations

Although it was a small study, it was sufficiently powered for detection of changes in the primary outcomes. A before-after study design was used, and therefore we cannot be certain that improvements were the result of the intervention alone. The small number of clinics and potential selection bias means that larger multicentre studies are needed for better generalisability. Outcome assessment was not blinded and this may have introduced observation and detection bias.

6.7 The way forward

The findings of this study show that practice pharmacist services are feasible and acceptable to clinic staff and patients in Australia; however, the results should be confirmed in a larger, cluster-randomised controlled multi-centre trial with a longer follow-up period. Appropriate business models for pharmacist services in general practice should also be explored and their sustainability and cost-effectiveness should be assessed. Training and credentialing programs for pharmacists wishing to undertake advanced clinical roles in general practice should also be developed. Recommendations for integrating pharmacists into Australian general practice are summarised in Box 6.3.

The integration of pharmacists into Australian general practice clinics is feasible and beneficial for improving QUM. Efforts should be directed to establishing the long-term clinical benefits and cost-effectiveness of clinical services provided by co-located pharmacists.

Box 6.3. Recommendations for integrating pharmacists into general practice

The following key elements are needed to ensure successful integration:

- strong leadership and commitment, especially from practice managers and senior GPs, including shared goals of providing optimal patient care;
- a well-defined scope of practice for the pharmacist that is communicated to all practice staff and local community pharmacists;
- a variety of roles for the practice pharmacist focusing on quality use of medicines, including medication review, medicines education/information, and quality improvement activities such as drug use evaluation; and
- a career structure and funding model for practice pharmacists.

6.8 Summary

- Practice pharmacist services can improve the quality of medicine prescribing and use in general practice
- Practice pharmacists can have a variety of roles in general practice
- Integration is facilitated by co-location, communication and positive pharmacist characteristics

6.9 References

1. Tan E, Stewart K, Elliott R, George J. Pharmacist services provided in general practice clinics: a systematic review and meta-analysis. *Res Social Adm Pharm.* 2013 (in press).

2. Bradley M. The role of the full-time practice pharmacist. *Primary Care Pharmacy.* 1999;1(1):14-5.

3. Canadian Pharmacists Association. Pharmacists and primary health care. Ottawa, Ontario: Canadian Pharmacists Association; May 2004.

4. Dolovich L, Pottie K, Kaczorowski J, Farrell B, Austin Z, Rodriguez C, et al. Integrating family medicine and pharmacy to advance primary care therapeutics. *Clin Pharmacol Ther.* 2008;83(6):913-7.

5. Avery AJ, Rodgers S, Cantrill JA, Armstrong S, Cresswell K, Eden M, et al. A pharmacist-led information technology intervention for medication errors (PINCER): a multicentre, cluster randomised, controlled trial and cost-effectiveness analysis. *Lancet.* 2012;379(9823):1310-9.

6. Roughead EE, Semple SJ. Medication safety in acute care in Australia: where are we now? Part 1: a review of the extent and causes of medication problems 2002-2008. *Aust New Zealand Health Policy.* 2009;6:18.

7. Royal Australian College of General Practitioners. Standards for general practices: a template for quality care and risk management in contemporary Australian general practices. Melbourne: Royal Australian College of General Practitioners; 2010.

8. Ackermann E, Williams I, Freeman C. Pharmacists in general practice - a proposed role in the multidisciplinary team. *Aust Fam Physician.* 2010;39:163 - 4.

9. Morton B. Involving pharmacists in general practice. Australian Medicine March 2013. Available from https://ama.com.au/ausmed/involving-pharmacists-general-practice. (Accessed on 14 August 2013)

10. Freeman C, Cottrell WN, Kyle G, Williams I, Nissen L. Does a primary care practice pharmacist improve the timeliness and completion of medication management reviews? *Int J Pharm Pract.* 2012;20(6):395-401.

11. Freeman CR, Cottrell WN, Kyle G, Williams ID, Nissen L. An evaluation of medication review reports across different settings. *Int J Clin Pharm.* 2013;35(1):5-13.

12. Tan ECK, Stewart K, Elliott RA, George J. Integration of pharmacists into general practice clinics in Australia: the views of general practitioners and pharmacists. *Int J Pharm Pract.* Published Online First: 12 June 2013. doi:10.1111/ijpp.12047.

13. Freeman C, Cottrell W, Kyle G, Williams I, Nissen L. Integrating a pharmacist into the general practice environment: opinions of pharmacists, general practitioners, health care consumers, and practice managers. *BMC Health Serv Res.* 2012;12(1):229.

14. Tan ECK, Stewart K, Elliott RA, George J. An exploration of the role of pharmacists within general practice clinics: the protocol for the pharmacists in practice study (PIPS). *BMC Health Serv Res.* 2012;12(1):246.

15. Tan E, Stewart K, Elliott R, George J. Pharmacist consultations in general practice clinics: the Pharmacists in Practice Study (PIPS). *Res Social Adm Pharm.* Published Online First: 4 October 2013. doi:10.1016/j.sapharm.2013.08.005.

16. Tan E, George J, Stewart K, Elliott R. Improving osteoporosis management in general practice: a pharmacist-led drug use evaluation program. Proceedings of the Pharmacy Australia Congress; 10-13 October 2013; Brisbane.

17. The Royal Australian College of General Practitioners. Clinical guideline for prevention and treatment of osteoporosis in postmenopausal women and older men. South Melbourne: RACGP; 2010.

18. Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self-reported measure of medication adherence. *Med Care.* 1986;24(1):67-74.

19. George J, Mackinnon A, Kong DC, Stewart K. Development and validation of the Beliefs and Behaviour Questionnaire (BBQ). *Patient Educ Couns.* 2006;64(1-3):50-60.

20. Stewart DC, George J, Bond CM, Cunningham IT, Diack HL, McCaig DJ. Exploring patients' perspectives of pharmacist supplementary prescribing in Scotland. *Pharm World Sci.* 2008;30(6):892-7.

21. Tan ECK, Stewart K, Elliott RA, George J. Stakeholder experiences with general practice pharmacist services: a qualitative study. *BMJ Open.* 2013;3(9):e003214.

22. Sellors J, Kaczorowski J, Sellors C, Dolovich L, Woodward C, Willan A, et al. A randomized controlled trial of a pharmacist consultation program for family physicians and their elderly patients. *Can Med Assoc J.* 2003;169(1):17-22.

23. Farrell B, Pottie K, Haydt S, Kennie N, Sellors C, Dolovich L. Integrating into family practice: the experiences of pharmacists in Ontario, Canada. *Int J Pharm Pract.* 2008;16:309-15.

24. Pottie K, Farrell B, Haydt S, Dolovich L, Sellors C, Kennie N, et al. Integrating pharmacists into family practice teams: physicians' perspectives on collaborative care. *Can Fam Physician.* 2008;54(12):1714-7.

25. Petty D, Knapp P, Raynor D, House A. Patients' views of a pharmacist-run medication review clinic in general practice. *Br J Gen Pract.* 2003;53:607-13.

Chapter 7. The Pharmacists in Practice Study (PIPS): Long Patient Consultations (LPCs)

7.1 Introduction

This chapter describes in more detail the results of the Long Patient Consultations (LPCs) provided to patients by the practice pharmacists. This particular role was one of the pharmacist's main duties in the clinics, and hence was subjected to more thorough evaluation.

The key objectives of this study were to:

- Develop and implement pharmacist consultations, involving a comprehensive medication review, for general practice patients;
- Determine the prevalence, types and risk of medication-related problems (MRPs) identified by the pharmacists, and the recommendations made by pharmacists to resolve issues; and
- Evaluate the effect of the pharmacist consultations on patient MRPs, medication adherence, health service utilisation and satisfaction.

A manuscript has been accepted for publication in *Research in Social and Administrative Pharmacy* and is reproduced below.

7.2 Publication

Tan ECK, Stewart K, Elliott RA, George J. Pharmacist consultations in general practice clinics: The Pharmacists in Practice Study (PIPS). *Res Social Adm Pharm*. Published Online First: 4 October 2013. doi:10.1016/j.sapharm.2013.08.005.

Declaration for Thesis Chapter 7

Declaration by candidate

In the case of Chapter 7, the nature and extent of my contribution to the work was the following:

Nature of contribution	**Extent of contribution (%)**
Reviewed literature; designed methodology; developed study materials; established collaborations; carried out recruitment; undertook data collection; performed data analysis; and prepared manuscript	80%

The following co-authors contributed to the work:

Name	**Nature of contribution**
Assoc Prof Kay Stewart	Designed methodology; reviewed study materials, data and manuscript
Mr Rohan Elliott	Designed methodology; reviewed study materials, data and manuscript
Dr Johnson George	Designed methodology; reviewed study materials, data and manuscript

Candidate's Signature		**Date**

Declaration by co-authors

The undersigned hereby certify that:

25. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors.
26. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
27. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
28. there are no other authors of the publication according to these criteria;
29. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
30. the original data are stored at the following location(s) and will be held for at least five years from the date indicated below:

Location(s)	**Centre for Medicine Use and Safety, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University, Parkville, Victoria 3052**

Signature 1	[redacted] Assoc Prof Kay Stewart	**Date** 8/10/13
Signature 2	[redacted] Mr Rohan Elliott	 8/10/13
Signature 3	[redacted] Dr Johnson George	 8/10/13

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RESEARCH IN SOCIAL & ADMINISTRATIVE PHARMACY

Original Research

Pharmacist consultations in general practice clinics: The Pharmacists in Practice Study (PIPS)

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Abstract

Background: Medication-related problems (MRPs) are a concern in primary care settings. Pharmacists based in the community or community pharmacies are able to identify, resolve and prevent MRPs; however, the lack of a formal partnership with physicians and poor access to patients' medical records are limitations. In Australia, delivery of pharmacist services within general practice clinics is rare.

Objectives: To evaluate the effectiveness of consultations by pharmacists based within primary care medical practices.

Methods: A prospective, before-after intervention study was conducted at two primary health care (general practice) clinics in Melbourne, Australia. Participants were clinic patients who had risk-factors for MRPs (e.g. polypharmacy). Patients received a consultation with the pharmacist in a private consulting room at the clinic or in their home. The pharmacist reviewed the patient's medication regimen and adherence, with full access to their medical record, provided patient education, and produced a report for the general practitioner. The primary outcome was the number of MRPs identified by the pharmacist, and the number that remained unresolved 6 months after the pharmacist consultation. Secondary outcomes included medication adherence, health service use, and patient satisfaction.

Results: Eighty-two patients were recruited and 62 (75.6%) completed the study. The median number of MRPs per patient identified by the practice pharmacist was 2 (interquartile range [IQR] 1, 4). Six months after review, this fell to 0 (IQR 0, 1), $P < 0.001$. The proportion of patients who were adherent to their medications improved significantly, according to both the Morisky (44.1% versus 62.7%, $P = 0.023$) and the Tool for Adherence Behaviour Screening (TABS) (35.6% versus 57.6%, $P = 0.019$) scales. There was no significant effect on health service use. Patients were highly satisfied with the pharmacist consultations.

Conclusions: Consultations undertaken by pharmacists located within primary health care clinics were effective in identifying and resolving MRPs. The consultations were well received by patients and were associated with improvements in medication adherence.

Keywords: Pharmacists; General practice; Primary health care; Medication reviews; Pharmaceutical care

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Background

A medication-related problem (MRP) can be defined as "an event or circumstance involving medication therapy that actually or potentially interferes with an optimum outcome for a specific patient."[1] Medication-related problems are a serious concern in primary care globally.[2–5] They result in adverse drug events in up to 18% of general practice patients each year,[5] of which nearly a quarter are preventable.[2] Poor communication between health professionals has been recognized as a significant contributor toward MRPs[3,5] highlighting the need for greater collaboration between general practitioners [GPs] (family physicians), pharmacists and other primary health professionals to ensure optimal patient care.

Whilst it is uncertain whether pharmacist-led medication reviews for community dwelling patients prevent hospitalizations or improve quality of life,[6,7] such services have been effective in identifying and resolving MRPs, improving prescribing quality, and optimizing medicine use and costs.[8,9] Barriers to the uptake and effective delivery of pharmacist medication reviews for community dwelling patients include geographical separation of pharmacists from physicians, poor inter-professional communication, limited pharmacist access to patient medical records, time restrictions, and health policies that are not conducive to such collaborative arrangements.[10]

The integration of pharmacists into primary health care (general practice) clinics offers a potential solution to these barriers. In countries such as Canada, the United Kingdom, and the United States, pharmacists based in general practice clinics ('practice pharmacists') work with GPs to undertake a range of clinical, educative and administrative activities.[11,12] Medication review (medication therapy management) is an important component of the practice pharmacist's role and can lead to improvements in medication use and health outcomes, and reductions in health service utilization and cost.[13–17] Co-location of pharmacists (i.e. their physical presence within general practice clinics) can also improve communication and cooperation between health professionals, and strengthen the sense of a primary health care team.[18] However, the presence of pharmacists within general practices is still uncommon in many developed countries, and there has been limited research exploring the effectiveness of medication reviews undertaken in this setting.[19]

In Australia, most pharmacists (85%) work in community pharmacies,[20] providing dispensing and other professional services. Some pharmacists (12%) work as consultant pharmacists,[21] providing medication management and review services to patients either in their home or in aged-care facilities on referral from GPs. Co-location of pharmacists within general practice clinics is rare, and there is currently no formal service or funding model for this role. The Pharmacists in Practice Study (PIPS) aimed to evaluate the feasibility and effectiveness of a multifaceted pharmacist role within primary care practices in Melbourne, Australia, where practice pharmacist services are currently rare. The aim of the role was to improve the quality and safety of medicines use by patients and clinic staff. The role comprised long patient consultations (once-off comprehensive medication reviews and patient education, lasting approximately 30–60 min), short consultations (once-off brief reviews and patient education, lasting approximately 15–30 min), medicines information and education services for clinic staff, and quality assurance activities.[22] The aim of this paper was to evaluate one aspect of the role – long patient consultations, and their effect on MRPs.

Methods

Study design

A prospective, before–after intervention study was conducted at two general practice clinics in Melbourne, Australia, between December 2011 and January 2013.[22] Each practice consisted of four to five full time equivalent GPs who all participated in the study. A pharmacist was employed by the research team at each clinic for at least 8 h/week, on the same day(s) each week. The pharmacists were accredited to undertake Home Medicines Reviews (HMRs) (a government subsidized program where a consultant pharmacist conducts a medicines review in the patient's home),[23] and had at least 8 years of experience undertaking these. They received no additional training prior to working in the clinics (except for general induction and guidance on using practice software). The study was approved by the Monash University Human Research Ethics Committee.

Recruitment of patients

Participants were practice patients who had one or more risk-factors for MRPs.[24] General practitioners or other clinic staff referred potentially

eligible patients to the study if they met one or more of the inclusion criteria and the GP thought they would benefit from a long patient consultation with the pharmacist (intervention).

Inclusion criteria were: using five or more medicines; using one or more medicines that require therapeutic drug monitoring (e.g. warfarin, phenytoin, lithium); using medicines for three or more medical problems; having had a recent unplanned hospital admission/emergency department visit; or having other risks for MRPs (e.g. adherence issues, language barriers, multiple prescribers).

Exclusion criteria for patients included: had an HMR in the previous 12 months and no subsequent significant change in clinical status or medication regimen; unable to provide written informed consent; under 18 years of age; or likely to be unavailable for follow-up for 6 months from baseline.

An introductory letter and explanatory statement were provided to referred patients, and permission to be contacted by the research team was obtained by clinic staff. An appointment for a long patient consultation with the practice pharmacist was organized by administrative staff at the clinic. Patients were recruited to the study by initially obtaining verbal consent via telephone by a researcher (ET). Written consent was obtained at the time of the appointment with the practice pharmacist.

Baseline data collection

Baseline data were collected from patients by one of the researchers (ET) using a structured questionnaire, which included demographic information (age, sex, ethnicity, education, socioeconomic status, living arrangements etc.), health information (general health, health service use, health literacy[25] etc.), and medicines information (medication risk-factors,[24] adherence[26,27] etc.).

Intervention

Patients received a face-to-face consultation lasting approximately 30–60 min with the pharmacist in a private consulting room at the clinic or in their home to identify MRPs. Prior to the consultation, the pharmacist discussed patient-related issues with the GP and/or clinic nurse, if necessary. The pharmacist also reviewed patients' medical records and, in some cases, dispensing histories from the patient's community pharmacy. The pharmacist interviewed the patient to compile an accurate medication history, discussed their medication management, and reviewed their medication regimen. Medical translators were available for patients who did not speak English. The pharmacist also assessed medication adherence and knowledge. The pharmacist provided individualized education and counseling on medication management, the use of medication administration devices, and health-related lifestyle factors (e.g. nutrition and diet, exercise, smoking cessation), and provided the patient with a personal medication list, if needed, to facilitate medication adherence. Any MRPs that were identified and could be addressed by the practice pharmacist (e.g. non-adherence or over-the-counter medicine issues) were discussed at the time of the consultation. When necessary, the pharmacist referred the patient to their community pharmacy for adherence aids (e.g. pill boxes, administration aids). Additionally, referral was made to the GP or other health professionals as required for management of other patient issues identified during the appointment (e.g. social, psychological, medical issues). After the consultation, the pharmacist produced a report for the patient's GP outlining MRPs and recommendations to resolve them. Report format and style were tailored to suit the needs of the GPs. For urgent issues and/or to provide clarity, the pharmacist also discussed issues verbally with the GP, clinic staff and the patient's community pharmacist, when needed. Patients attended a follow-up appointment with their GP to discuss issues identified and develop a management plan.

Outcomes

Primary outcomes

Medication-related problems. The primary outcome was the number of MRPs identified by practice pharmacists at baseline, and the number of identified MRPs that remained unresolved 6 months after the pharmacist consultation. Six months was chosen as the timeframe to allow the GP sufficient time to review the pharmacist report and implement/trial pharmacist recommendations to resolve MRPs. In Australia, patients on long-term medicines need to be reviewed by their doctor at least every 6 months to obtain new prescriptions.[28] The number of MRPs at baseline, and resolution of MRPs at 6 months, was determined by chart audit and patient interview, conducted by one researcher (ET). Resolution of MRPs was defined as implementation of the

pharmacists' recommendations (e.g. if the MRP was 'dose too high,' and the GP reduced the dose then the MRP was considered resolved). The types of MRPs were categorized according to the criteria described by Strand et al[29] with the additional category of "improper storage." The types of pharmacist recommendations were also categorized. The drugs involved in MRPs were classified according to the Anatomical Therapeutic Chemical (ATC) classification system (first level).[30] A selection of MRPs (at least 50% from each site, selected using computer-generated random numbers) was reviewed for severity and likelihood of potential adverse consequences if they had not been addressed.[31] The MRPs were reviewed by an independent panel consisting of a GP and a clinical pharmacist, using a validated risk classification system.[31]

Secondary outcomes

Medication discrepancies. Discrepancies between the pharmacist-obtained medication history and the medication list in the GPs' medical records were identified by reviewing the pharmacists' reports. Medicines included both prescription and over-the-counter products.

Non-pharmacological disease management. Non-drug issues related to disease management or social factors that were identified by the pharmacists were also obtained from the pharmacist reports (e.g. the need for weight and diet management, exercise, social support or counseling).

Medication adherence. Medication adherence was measured using two methods – the Morisky Scale[26] and the Tool for Adherence Behaviour Screening (TABS)[27] at baseline and 6 months. The Morisky Scale asks patients four 'yes/no' questions regarding patterns of medicines use. A patient is considered nonadherent if they answer 'yes' to any of the questions. The TABS, a subscale of the Beliefs and Behaviour Questionnaire (BBQ), consists of two, 4-item subscales for 'adherence' and 'nonadherence' and assesses the respondent's agreement with a series of statements that are scored on a five-point Likert scale. The total score for 'nonadherence' was subtracted from that of 'adherence'; a differential of ≥ 15 was considered as good adherence and ≤ 14 was considered as suboptimal adherence.[32]

General health. Patients self-reported their general health and wellbeing at baseline and six months on a five-point Likert scale (from 1 = 'excellent health' to 5 = 'poor health'). Use of health services (GP/specialist visits and hospitalizations) 6 months before and after the intervention was assessed by patient self-report.

Satisfaction. Patient satisfaction with the consultations was determined by an anonymous, structured questionnaire adapted from a previously validated patient satisfaction survey for physician consultations.[33,34] At the end of each consultation, patients were provided with the questionnaire and requested to complete and return it to the researchers in a reply-paid envelope.

Sample size

Based on an estimated mean number of 2.5 MRPs per patient at baseline, to demonstrate a mean reduction of 1 MRP (i.e. 40%) per patient with a within patient standard deviation of 2.1 MRPs (assuming a correlation coefficient of 0.5),[35,36] a power of 80% and a two-tailed α of 0.05, the required sample size was 37 patients. Allowing for 25% dropout/loss to follow up, at least 50 patients were required. This was calculated using PS Power and Sample Size Calculations (Version 3.0, Dupont & Plummer, 2009). In order to enable the pharmacist service to become well established and to continue over the six month study period, recruitment continued beyond the minimum required sample size.

Statistical analysis

Analysis (per protocol) was performed using the Statistical Package for Social Sciences (SPSS) for Windows Version 19.0 (IBM, New York, USA). The median number of MRPs identified at baseline and remaining unresolved at 6 months were assessed using Wilcoxon signed rank tests. The proportions of patients who were adherent at baseline and 6 months were examined using McNemar's tests. Health service utilization was evaluated 6 months before and after the intervention using Wilcoxon signed rank tests. General health scores at baseline and 6 months were examined using Wilcoxon Signed Rank Tests. Standard descriptive methods were used to evaluate other outcomes.

Results

Patient characteristics

A total of 82 patients were recruited (Fig. 1). Follow-up data were available for 71 patients

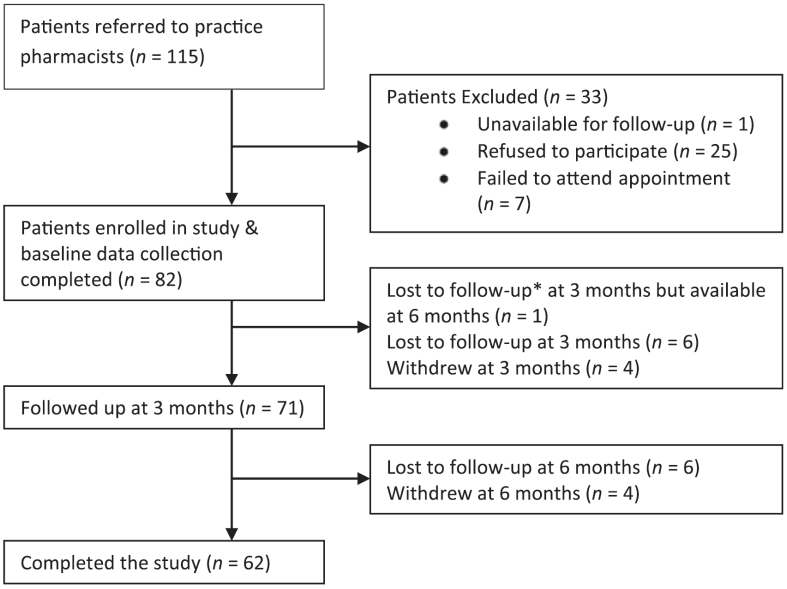

Fig. 1. Study flow. *Patient not contactable.

(86.6%) at 3 months and 62 (75.6%) at 6 months. Baseline characteristics are summarized in Table 1.

Primary outcomes

Medication-related problems

Outcomes of the pharmacist consultations are summarized in Table 2. A total of 251 MRPs were identified at baseline, of which 166 MRPs related to patients who completed the study. The median (interquartile range [IQR]) number of MRPs was 2 (IQR 1, 4) in patients who completed the study, and 3 (IQR 2, 7) in those who were lost to follow-up; this difference was not significant ($P = 0.06$) and the demographic characteristics of groups were comparable. At the six-month follow-up, 122/166 (73.5%) of MRPs identified by the pharmacists at baseline had been resolved and the median number of unresolved MRPs per patient had fallen to 0 (IQR 0, 1) ($P < 0.001$). Of the 49 patients who had an MRP at baseline, 21 (42.9%) had all their MRPs resolved at 6 months.

Table 1
Baseline characteristics of patients ($n = 82$)

Characteristic	*N* (%) of patients[a]
Age in years, mean ± SD	71.7 ± 11.2
Female	50 (61.0%)
Overseas born	29 (35.4%)
English not primary language	15 (18.3%)
Secondary education or higher	32 (39.0%)
Lives alone	41 (51.0%)
Adequate health literacy (self-reported)	67 (81.7%)
Number of medication risk-factors[24] median (IQR)	3 (2, 4)
Number of medicines,[b] median (IQR)	11.5 (9,15)
Previous medicines review by a pharmacist – HMR or MUR	13 (15.9%)

IQR, interquartile range; SD, standard deviation; HMR, home medicines review (undertaken by clinical pharmacist in patient's home); MUR, medicines use review (brief review undertaken by community pharmacist in pharmacy).

[a] Unless otherwise indicated.

[b] Includes prescription and over-the-counter medicines.

Types of medication-related problems

The most commonly identified MRP was nonadherence (35.9%) followed by untreated indication (15.5%) and inappropriate drug (11.6%) (Table 3). Nonadherence was most commonly associated with drugs used for the alimentary tract and metabolism (31.9% of this MRP type); cardiovascular disease (in particular thromboprophylaxis in patients at risk of a cardiovascular event) was the most common untreated indication (39.5%); β-blockers and complementary medicines were identified as the most common inappropriate drugs for the patient's given condition (13.8% each).

Overall, the drugs most frequently associated with MRPs were alimentary tract and metabolism

Table 2
Summary of outcome measures

Outcome measure	No. of patients (*N*)	Baseline, *n* (%)	Six month, *n* (%)	Change from baseline to 6 months (95% CI)	*P*-value
Proportion of patients with at least one MRP	62	49 (79.0%)	28 (45.2%)	33.8% (22.0–45.6%)	<0.001[a]
Number of MRPs	62	2 (1, 4)[c]	0 (0, 1)[c]	1 (1–2)[d]	<0.001[b]
Proportion adherent (Morisky)	59	26 (44.1%)	37 (62.7%)	18.6% (7.6–29.6%)	0.035[a]
Proportion adherent (TABS)	59	21 (35.6%)	34 (57.6%)	22.0% (5.7–38.4%)	0.019[a]
General health score	60	3.5 (3, 4)[c]	3 (3, 4)[c]	0.5 (0–0)[d]	0.627[b]
Health service use in previous 6 months					
Number of GP/specialist visits	54	6 (5, 10)[c]	6 (5, 9)[c]	0 (−1 to 0)[d]	0.319[b]
Number of unplanned hospitalizations	55	0 (0, 1)[c]	0 (0, 1)[c]	0 (0–0)[d]	0.105[b]

[a] McNemar's test baseline to 6 months.
[b] Wilcoxon signed rank test baseline to 6 months.
[c] Median (IQR).
[d] Median of individual differences between baseline and 6 months.

drugs (25.2%), followed by cardiovascular (24.8%) and nervous system (11.9%) drugs.

Pharmacist recommendations

A total of 320 recommendations were made by practice pharmacists to address MRPs (Table 4). The most common recommendation was initiation of a new drug (13.8%) followed by patient education (including adherence counseling) (13.4%) and monitoring or investigative testing (12.2%).

Medication-related problem risk

Of the 251 MRPs, 154 (61.4%) were randomly selected and reviewed. Of these, 45 (29.2%) MRPs were deemed to be associated with high or extreme risk of an adverse outcome and 41 (26.6%) with moderate risk, if not addressed. Examples are provided in Table 5.

Secondary outcomes

Medication discrepancies and other issues

Discrepancies existed between the GP record and the medication history obtained by the pharmacist. At least one medicine was omitted from the GP record for 57 (69.5%) patients (median 1.0; IQR 0, 3; range 0–18) and 44 (53.7%) patients had at least one medicine recorded in the GP record that they were no longer using (median 1.0; IQR 0, 3; range 0–5).

Table 3
Medication-related problems[29] ($n = 251$)

Category	Description	*N* (%)
Failure to receive drug (nonadherence)	The patient did not receive or is not taking the drug as prescribed	90 (35.9%)
Untreated indication	The patient has a medical condition that requires drug therapy (a drug indication) but the patient is not receiving a drug for that indication	39 (15.5%)
Wrong/inappropriate drug	The patient has a medical condition for which the wrong/inappropriate drug is being taken/contraindicated	29 (11.6%)
Adverse drug reaction	The patient has a medical condition resulting from a potential adverse drug reaction	23 (9.2%)
Drug interaction	The patient has a medical condition resulting from a potential drug–drug, drug–food, drug–laboratory interaction	20 (8.0%)
Dose too high	The patient has a medical condition for which too much of the correct drug is prescribed	18 (7.2%)
Unnecessary drug	The patient is taking a drug for which there is no valid medical indication	15 (6.0%)
Dose too low	The patient has a medical condition for which too little of the correct drug is prescribed	12 (4.8%)
Improper storage	Drug is not properly stored according to manufacturer's directions or drugs are being hoarded	5 (2.0%)

Table 4
Pharmacist recommendation types ($n = 320$)

Category	N (%)
Start medication	44 (13.8%)
Patient education/counseling on medications (incl. administration technique, adherence counseling)	43 (13.4%)
Monitoring or investigative test	39 (12.2%)
Change medication	35 (10.9%)
Stop/hold medication	32 (10.0%)
Change dose	30 (9.4%)
Refer to another health care professional	26 (8.1%)
Implement specific adherence strategies (incl. routines, dose administration aids etc.)	24 (7.5%)
For GP information/update records	23 (7.2%)
Non-pharmacological treatment education	13 (4.1%)
Change dose form	6 (1.9%)
Change timing	5 (1.6%)

Non-pharmacological disease management

Aside from MRPs, pharmacists identified at least one non-drug-related issue in 25 (30.5%) patients. The most common non-drug issue was the need for weight management (40.5%), either through changes to diet and/or exercise.

Medication adherence

Following pharmacist intervention, the proportion of patients who were adherent to their medication regimens improved significantly, according to both the Morisky (44.1% versus 62.7%, $P = 0.023$) and the TABS (35.6% versus 57.6%, $P = 0.019$) scales.

General health and health service use

There was no significant difference in self-reported general health from baseline to 6 months or health service utilization 6 months before and after the pharmacist intervention.

Patient satisfaction

Satisfaction questionnaires were completed by 36 patients (43.9%) who attended a consultation. Respondents had a mean age of 70.8 (SD 8.6) years and the majority were female (26, 72.2%). All respondents agreed or strongly agreed that they were totally satisfied with their visit to the practice pharmacist and 32 (91.4%) agreed or strongly agreed that the pharmacist told them everything about their treatment. The majority of patients agreed or strongly agreed that the pharmacist was interested in them as a person (33, 91.7%); that they had a better understanding of their illness after seeing the pharmacist (28, 77.8%); and that the pharmacist really knew what they were thinking (29, 80.6%). Twenty-one patients (58.3%) disagreed or strongly disagreed that some things about their consultation could have been better, and that they would find it difficult telling the pharmacist about some private things. Twelve patients (33.3%) agreed or strongly agreed that they wanted to spend more time with the pharmacist. Overall, 29 respondents (80.6%) felt they would like a pharmacist to be available in the clinic in the future.

Discussion

This study trialled medication consultations by a pharmacist co-located with GPs in Australian general practice clinics. The intervention identified and resolved MRPs and improved patients' medication adherence. It also provided GPs with a more accurate medication list. Patients were highly satisfied with the pharmacist consultations.

The practice pharmacist identified a median of two MRPs per patient. This aligns with the findings of other studies assessing pharmacist medication reviews undertaken in clinic settings.[19,35,37] The high rate of implementation of recommendations (73.5%) in this study is comparable to other studies,[19,35,36] and is higher than in most studies evaluating medication reviews conducted outside of clinic settings.[19,38] Increased rapport between pharmacists and GPs, opportunities for face-to-face communication and access to patient medical files enabling more targeted reports are potential reasons why implementation rates are higher with co-location of pharmacists within clinics.[19]

The most common type of MRP identified in this study was nonadherence, which the pharmacists addressed mostly through patient education and counseling. These actions were associated with improvements in medication adherence. The impact pharmacists can make in improving medication adherence is well documented in the literature.[39–41] The most common recommendation made by the practice pharmacists was the need for additional therapy, and this is comparable to other studies undertaken in similar settings.[19,42]

The intervention did not have a significant effect on patients' self-reported general health or health service utilization, and this finding is consistent with other medication review studies.[6] Follow-up duration may not have been long enough to detect changes in these parameters. Review by an independent GP and pharmacist found that almost 30% of MRPs were of high

Table 5
Risk associated with medication-related problems

Risk	*N* (%), *n* = 154	Example	Pharmacist recommendation	Potential clinical consequence
Extreme risk	9 (5.8%)	79 year-old male with a history of diabetes and hyperlipidemia; not receiving cardiovascular risk reduction therapy	Commence antiplatelet therapy	Myocardial ischemia
High risk	36 (23.4%)	75 year-old female with osteoporosis and vitamin D deficiency; ceased cholecalciferol approximately 1 month ago prior to a procedure. Has not recommenced and GP is unaware. Severe osteoporosis (T-score −3.2 femur, vitamin D deficient) & has not been prescribed an osteoporosis medication. Patient at high risk of fractures	Recommence cholecalciferol and assess possible role for anti-resorptive medication (e.g. strontium or bisphosphonate)	Osteoporosis
Moderate risk	41 (26.6%)	77 year-old female with a history of congestive cardiac failure and osteoarthritis; receiving combination of a diuretic, agent affecting angiotensin and a non-steroidal anti-inflammatory, which may predispose to sudden deterioration of renal function.	Consider cessation of Celecoxib and use of paracetamol in its place	Renal dysfunction
Low risk	35 (22.7%)	70 year-old female with asthma exhibits poor Seretide Accuhaler technique	Reinforced proper inhaler technique with patient	Asthma
No risk	33 (21.4%)	71 year-old female with osteoporosis takes risedronate 35 mg once weekly separately from other packed medicines and food	Change to risedronate 35 mg EC that can be packed in dose administration aid and administered with other medicines and food to aid adherence	No clinical significance

or extreme risk, suggesting that adverse events and health care intervention would have been likely if these MRPs were left unresolved.

This study suggests that pharmacists co-located within primary care clinics may improve medication outcomes for patients at risk of MRPs, and that these services are acceptable to consumers. The service was also well received by clinic staff who provided positive feedback on the practice pharmacist role and the opportunity for collaboration (data reported elsewhere).[43] These findings have implications for GPs, pharmacists, other primary health care professionals and policy makers by providing evidence for a model that may help to improve the structure and dynamics of the primary health care workforce and improve access to interdisciplinary, medication management services. There are currently no remuneration structures for the delivery of pharmacist services within Australian general practice clinics, so these findings may also inform development of business models.

This study had some limitations. The before–after design, which lacks a concurrent control group, may compromise the internal validity of the study and limit the conclusions drawn from the results. This design, however, allowed subjects to serve as their own controls, thus eliminating inter-subject variability and reducing confounding. Although external validity was enhanced by conducting the study in more than one site, the small number of clinics and potential selection bias means that larger multi-center studies are needed for better generalizability. Non-random sampling of patients may also be a limitation; however, the patient selection method mimicked the real life situation with regards to patient referrals for

pharmacist medication reviews. Although the sample size was not large, the study was sufficiently powered for the primary outcome. Outcome assessment was not completely blinded and some outcomes were based on patient self-report. Potential bias was limited by supplementing patient-reported information with objective clinical data extracted from GP medical records where possible. Impact of the intervention on condition-specific clinical outcomes (e.g. pain control, blood pressure) was not assessed, because of the diverse range of patients and conditions managed in the general practice environment. The development of potential new MRPs at follow-up was not assessed as the pharmacist consultation was a "once-off" intervention. Pharmacists used their discretion to determine whether verbal communication about MRPs was needed in addition to the written GP report. Although verbal communication may have led to an increased implementation of recommendations compared with just the provision of a written report, this reflected real world practice.

This study found that the clinic-based model allowed for greater opportunities for interprofessional communication and the timely resolution of MRPs identified by the pharmacist. The findings of this study should be confirmed in a larger, cluster-randomized controlled multicenter trial with a longer follow-up period. Cluster randomization (i.e. randomization at the level of the practice) would avoid potential contamination; a control group would allow for comparison of the intervention against usual care and improve the internal validity; multiple sites would improve the external validity; and longer duration would allow assessment of long-term clinical and economic outcomes.

Conclusion

Pharmacist consultations in primary health care clinics in Australia identified and resolved MRPs and were associated with improved medication adherence in patients at risk of medication misadventure. Interdisciplinary practice pharmacist services were well received by patients and staff. Future research should confirm these findings in larger, controlled trials.

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References

1. American Society of Health-System Pharmacists. ASHP statement on pharmaceutical care. *Am J Health Syst Pharm* 1993;50:1720–1723.
2. Miller GC, Britth HC, Valenti L. Adverse drug events in general practice patients in Australia. *Med J Aust* 2006;184:321–324.
3. Bhasale AL, Miller GC, Reid SE, Britt HC. Analysing potential harm in Australian general practice: an incident-monitoring study. *Med J Aust* 1998;169:73–76.
4. Avery T, Barber N, Ghaleb M, et al. *Investigating the Prevalence and Causes of Prescribing Errors in General Practice: The PRACtICe Study*. General Medical Council; 2012.
5. Gandhi TK, Weingart SN, Borus J, et al. Adverse drug events in ambulatory care. *N Engl J Med* 2003;348:1556–1564.
6. Blenkinsopp A, Bond C, Raynor DK. Medication reviews. *Br J Clin Pharmacol* 2012;74:573–580.
7. Holland R, Desborough J, Goodyer L, Hall S, Wright D, Loke YK. Does pharmacist-led medication review help to reduce hospital admissions and deaths in older people? A systematic review and meta-analysis. *Br J Clin Pharmacol* 2008;65:303–316.
8. Gilbert AL, Roughead EE, Beilby J, Mott K, Barratt JD. Collaborative medication management services: improving patient care. *Med J Aust* 2002;177:189–192.
9. Stafford L, Peterson GM, Bereznicki LR, et al. Clinical outcomes of a collaborative, home-based postdischarge warfarin management service. *Ann Pharmacother* 2011;45:325–334.
10. Edmunds J, Calnan MW. The reprofessionalisation of community pharmacy? An exploration of attitudes to extended roles for community pharmacists amongst pharmacists and general practitioners in the United Kingdom. *Soc Sci Med* 2001;53:943–955.
11. Silcock J, Raynor DKT, Petty D. The organisation and development of primary care pharmacy in the United Kingdom. *Health Policy* 2004;67:207–214.
12. American Society of Health-system Pharmacists. ASHP statement on the pharmacist's role in primary care. *Am J Health Syst Pharm* 1999;56:1665–1667.
13. Dolovich L, Pottie K, Kaczorowski J, et al. Integrating family medicine and pharmacy to advance primary care therapeutics. *Clin Pharmacol Ther* 2008;83:913–917.
14. Borenstein JE, Graber G, Saltiel E, et al. Physician-pharmacist comanagement of hypertension: a randomized, comparative trial. *Pharmacotherapy* 2003;23:209–216.
15. Zermansky AG, Petty DR, Raynor DK, Freemantle N, Vail A, Lowe CJ. Randomised

controlled trial of clinical medication review by a pharmacist of elderly patients receiving repeat prescriptions in general practice. *BMJ* 2001;6:1340–1343.
16. Carter BL, Ardery G, Dawson JD, et al. Physician and pharmacist collaboration to improve blood pressure control. *Arch Intern Med* 2009;169:1996–2002.
17. Adler DA, Bungay KM, Wilson IB, et al. The impact of a pharmacist intervention on 6-month outcomes in depressed primary care patients. *Gen Hosp Psychiatry* 2004;26:199–209.
18. Farrell B, Pottie K, Woodend K, et al. Shifts in expectations: Evaluating physicians' perceptions as pharmacists become integrated into family practice. *J Interprof Care* 2010;24:80–89.
19. Freeman CR, Cottrell WN, Kyle G, Williams ID, Nissen L. An evaluation of medication review reports across different settings. *Int J Clin Pharm* 2013;35:5–13.
20. Long M, Ridoutt L, Bagnulo J, et al. *Pharmacy Workforce Planning Study*. Department of Health and Ageing and The Pharmacy Guild of Australia, 2011. Available from: http://www.guild.org.au/docs/default-source/public-documents/services-and-programs/research-and-development/Fourth-Agreement-R-and-D/Pharmacy-Workforce-Planning/full-final-report.pdf?sfvrsn=0. Accessed 24.08.13.
21. Ridoutt L. *Analysis of Secondary Data to Understand Pharmacy Workforce Supply (Initial Supply Report)*, 2008. Available from: http://www.humancapitalalliance.com.au/documents/Initial%20Supply%20Report%20final%20-%2022102008.pdf. Accessed 24.08.13.
22. Tan ECK, Stewart K, Elliott RA, George J. An exploration of the role of pharmacists within general practice clinics: the protocol for the pharmacists in practice study (PIPS). *BMC Health Serv Res* 2012;12:246.
23. Medicare Australia. *Home Medicines Review*. Department of Human Services, 2012. Available from: http://www.medicareaustralia.gov.au/provider/pbs/fourth-agreement/hmr.jsp. Accessed 21.06.12.
24. Barenholtz Levy H. Self-administered medication-risk questionnaire in an elderly population. *Ann Pharmacother* 2003;37:982–987.
25. Chew LD, Bradley KA, Boyko EJ. Brief questions to identify patients with inadequate health literacy. *Fam Med* 2004;36:588–594.
26. Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self-reported measure of medication adherence. *Med Care* 1986;24:67–74.
27. George J, Mackinnon A, Kong DC, Stewart K. Development and validation of the Beliefs and Behaviour Questionnaire (BBQ). *Patient Educ Couns* 2006;64:50–60.
28. Department of Health and Ageing. *Prescribing Medicines – Information for PBS Prescribers*. Department of Health and Ageing, 2013. Available from: http://www.pbs.gov.au/info/healthpro/explanatory-notes/section1/Section_1_2_Explanatory_Notes#Maximum-quantities.
29. Strand LM, Morely PC, Cipolle RJ, Ramsey R, Lamsam GD. Drug-related problems: their structure and function. *Ann Pharmacother* 1990;24:1093–1097.
30. WHO Collaborating Centre for Drug Statistics Methodology. *ATC Classification Index with DDDs, 2013*. Oslo; 2012.
31. Elliott RA, Woodward M. Assessment of risk associated with medication-related problems in elderly outpatients. *J Pharm Pract Res* 2009;39:109–113.
32. Lau R, Stewart K, McNamara KP, et al. Evaluation of a community pharmacy-based intervention for improving patient adherence to antihypertensives: a randomised controlled trial. *BMC Health Serv Res* 2010;10.
33. Baker R. Development of a questionnaire to assess patients' satisfaction with consultations in general practice. *Br J Gen Pract* 1990;40:487–490.
34. Stewart DC, George J, Bond CM, Cunningham IT, Diack HL, McCaig DJ. Exploring patients' perspectives of pharmacist supplementary prescribing in Scotland. *Pharm World Sci* 2008;30:892–897.
35. Sellors J, Kaczorowski J, Sellors C, et al. A randomized controlled trial of a pharmacist consultation program for family physicians and their elderly patients. *Can Med Assoc J* 2003;169:17–22.
36. Soendergaard B, Kirkeby B, Dinsen C, Herborg H, Kjellberg J, Staehr P. Drug-related problems in general practice: results from a development project in Denmark. *Pharm World Sci* 2006;28:61–64.
37. Elliott RA, Woodward MC. Medication-related problems in patients referred to aged care and memory clinics at a tertiary care hospital. *Australas J Ageing* 2011;30:124–129.
38. Sorensen L, Stokes JA, Purdie DM, Woodward M, Elliott R, Roberts MS. Medication reviews in the community: results of a randomized, controlled effectiveness trial. *Br J Clin Pharmacol* 2004;58:648–664.
39. Morgado MP, Morgado SR, Mendes LC, Pereira LJ, Castelo-Branco M. Pharmacist interventions to enhance blood pressure control and adherence to antihypertensive therapy: review and meta-analysis. *Am J Health Syst Pharm* 2011;68:241–253.
40. Rubio-Valera M, Serrano-Blanco A, Magdalena-Belio J, et al. Effectiveness of pharmacist care in the improvement of adherence to antidepressants: a systematic review and meta-analysis. *Ann Pharmacother* 2011;45:39–48.
41. Chisholm-Burns MA, Kim Lee J, Spivey CA, et al. US pharmacists' effect as team members on patient care: systematic review and meta-analyses. *Med Care* 2010;48:923–933.
42. Castelino RL, Bajorek BV, Chen TF. Are interventions recommended by pharmacists during Home Medicines Review evidence-based? *J Eval Clin Pract* 2011;17:104–110.
43. Tan ECK, Stewart K, Elliott RA, George J. Stakeholder experiences with general practice pharmacist services: a qualitative study. BMJ Open 2013;3:e003214. doi:10.1136/bmjopen-2013-003214.

ARTICLE SYNOPSIS

A prospective, before–after intervention study was conducted at two primary health care (general practice) clinics to evaluate pharmacist consultations. Patients received a single consultation with the pharmacist in a private consulting room at the clinic or in their home. The pharmacist reviewed the patient's medication regimen and adherence, with full access to their medical record, provided patient education, and produced a report for the general practitioner. Six months after the intervention, there were significant reductions in medication-related problems and improvements in adherence. There was no significant effect on health service use. Patients were highly satisfied with the pharmacist consultations.

Chapter 8. The Pharmacists in Practice Study (PIPS): Drug Use Evaluation (DUE)

8.1 Introduction

As discussed in Chapter 2, Drug Use Evaluation (DUE) can be an effective strategy for improving quality use of medicines in health organisations, especially with regards to appropriate prescribing practices. Although DUE is commonly conducted in hospital and aged care settings, there are limited Australian studies of DUE in general practice clinics.

This chapter provides a detailed description of the DUE program implemented at the study sites. A pharmacist-led DUE program, designed to improve adherence to clinical guidelines for osteoporosis management, was undertaken.

The key objectives of this study were to:

- Design and implement a DUE program in two general practice clinics and
- Develop and evaluate a multifaceted strategy to improve the management of patients with osteoporosis.

A manuscript has been submitted for publication to *Osteoporosis International* and is currently under review. The manuscript is reproduced below.

A copy of the data collection form is provided in Appendix 9. Examples of strategies targeting patients and staff can be found in Appendix 10.

Declaration for Thesis Chapter 8

Declaration by candidate

In the case of Chapter 8, the nature and extent of my contribution to the work was the following:

Nature of contribution	**Extent of contribution (%)**
Reviewed literature; designed methodology; developed data collection form and other study materials; performed data collection and analysis; established collaborations; assisted with delivery of interventions (presentations, case-conferences, mail outs etc); prepared manuscript.	75%

The following co-authors contributed to the work:

Name	**Nature of contribution**
Assoc Prof Kay Stewart	Designed methodology; developed data collection form; reviewed other study materials, data and manuscript.
Mr Rohan Elliott	Designed methodology; developed data collection form; reviewed other study materials, data and manuscript.
Dr Johnson George	Designed methodology; developed data collection form; reviewed other study materials, data and manuscript.

Candidate's Signature		**Date**

Declaration by co-authors

The undersigned hereby certify that:

31. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors.
32. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
33. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
34. there are no other authors of the publication according to these criteria;
35. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
36. the original data are stored at the following location(s) and will be held for at least five years from the date indicated below:

Location(s)	**Centre for Medicine Use and Safety, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University, Parkville, Victoria 3052**

Signature 1	[redacted] Assoc Prof Kay Stewart	**Date** 8/10/13
Signature 2	[redacted] Mr Rohan Elliott	8/10/13
Signature 3	[redacted] Dr Johnson George	8/10/13

8.2 Abstract

Purpose

To evaluate the impact of a drug use evaluation (DUE) program on osteoporosis management in general practice.

Methods

A DUE program, led by pharmacists integrated into two general practice clinics in Melbourne, Australia, was undertaken as part of the Pharmacists in Practice Study. Data on use of anti-osteoporosis medicines and calcium and vitamin D supplements were collected at baseline and 12 months. Following the baseline audit, an intervention comprising prescriber feedback, group education and individual case-conferences with prescribers, and patient education mail-outs was implemented. The primary outcome was the proportion of patients with a diagnosis of osteoporosis and without contraindications to anti-osteoporosis medicines who were prescribed an anti-osteoporosis medicine. Feedback from practice staff and pharmacists was explored qualitatively to evaluate acceptability of the program.

Results

The proportion of patients without documented contraindications to osteoporosis therapies who were prescribed an anti-osteoporosis medicine increased significantly (134/227 [59.0%] vs. 168/240 [70.0%], p=0.002). The proportion of patients for whom vitamin D and/or calcium supplement use was documented also increased significantly (145/227 [63.9%] vs. 205/240 [85.4%], p=0.002). Practice staff and pharmacists were generally positive about the DUE program.

Conclusions

A practice pharmacist-led DUE program improved the management of osteoporosis in general practice.

8.3 Mini Abstract

Osteoporosis is often undertreated. A pharmacist-led intervention involving drug use evaluation, case-conferencing and prescriber and patient education significantly improved prescribing of anti-osteoporosis medicines and supplements. This collaborative approach can improve the management of patients with osteoporosis in primary care.

8.4 Introduction

Osteoporosis is a major health burden.[1] Although a range of effective drug therapies is available,[2, 3] osteoporosis remains undertreated,[4-6] with less than 30% of women with a postmenopausal fracture[7, 8] and less than 10% of men with osteoporosis receiving anti-osteoporosis medications and/or calcium and vitamin D supplements when these are indicated.[9, 10]

Various strategies may be used to improve prescribing, including the implementation of quality assurance activities that include audit and feedback, such as drug use evaluation (DUE).[11, 12] DUE is a systematic, criteria-based evaluation of medicines use within a health organisation that aims to ensure that medicines are used appropriately.[13, 14] It is a cyclical, iterative process that consists of two phases: an investigative phase which involves an audit to measure and define drug use, identify drug use problems and measure the impact of interventions; and an interventional phase which involves reviewing audit

results, problem solving, consensus building and implementing strategies to improve drug use.[15]

DUE requires a multidisciplinary approach, usually involving physicians and pharmacists and sometimes other health professionals.[14] DUE has traditionally been conducted in hospital settings, but can be applied to any practice setting. It can be used to evaluate the use of a specific drug or therapeutic class or management of a disease state or condition.[14]

Previous audits of osteoporosis management in primary care have been conducted in nursing homes and aged care facilities and generally did not include an intervention phase.[16, 17]

Strategies directed at both physicians and patients may be used to improve osteoporosis therapy in primary care.[18] Pharmacist-led interventions have been shown to be useful in improving compliance with osteoporosis guidelines.[19] These services were mainly delivered from community pharmacies; however, there is some evidence that pharmacist interventions based in primary care medical clinics may be effective.[20]

In primary care, osteoporosis management, particularly the use of pharmacotherapy and supplements, may be a target for a DUE program, to improve concordance between patient management and clinical guidelines. To date, there have been no studies exploring the impact of DUE on osteoporosis in primary care clinics, nor the delivery of such programs by pharmacists based in this setting.

As part of the Pharmacists in Practice Study (PIPS), which was designed to evaluate the role of pharmacists based in primary care clinics in Australia,[21] a DUE program targeting osteoporosis was implemented. This paper describes the methodology and outcomes of the DUE program – the aim of which was to improve management of osteoporosis in

general practice, particularly prescribing of anti-osteoporosis medications and use of supplements.

8.5 Methods

Two primary care (general practice) clinics in Melbourne, Australia were recruited; one private practice and one community health centre, both serving approximately 3000 clients with interdisciplinary practice teams consisting of general practitioners, nursing staff and allied health professionals. The osteoporosis DUE program was led by two practice-based pharmacists who worked in the clinics for eight hours per week over a six month period (January 2012 to July 2012).[21] As part of the PIPS the pharmacists also provided medicines reviews for individual patients, on referral from general practitioners (GPs), and medicines information and education sessions for practice staff – these services were broad in scope and did not focus on osteoporosis management.

8.5.1 DUE Program

The DUE program involved the following steps, as recommended by the World Health Organisation[13]:

1. Establishing responsibility

The decision to target osteoporosis was made in collaboration with the GPs, pharmacists and other practice staff at each site, and was based on the fact that osteoporosis is under-treated in Australia,[4, 7, 9, 22] and has been nominated by the Australian Government as a National Health Priority Area.[23] The research team worked with practice staff to develop the DUE program including audit criteria, data collection methods and analysis. The

practice pharmacist at each site was given shared responsibility for implementing, monitoring and supervising the DUE program at their clinic.

2. Developing the scope of activities and defining the objectives

Patients aged 50 years or older with an established osteoporosis diagnosis recorded in their medical record were included. The focus was on anti-osteoporosis medicine prescriptions and documentation of vitamin D and calcium supplement use in patient records.

3. Establishing criteria for review of the medicine

Outcome measures for the audit were based on current Australian clinical guidelines for osteoporosis management.[24] The primary outcome of interest was the proportion of patients diagnosed with osteoporosis who did not have a contraindication to all classes of osteoporosis medicines and who were prescribed an anti-osteoporosis medicine. Secondary outcomes included vitamin D supplement use, vitamin D use in patients with documented vitamin D deficiency, and calcium supplement use and their documentation in medical records.

4. Data collection

A retrospective review of the electronic medical records of active patients (at least three clinic visits in the previous two years) was performed by the practice pharmacists with guidance and assistance from a researcher (ET). All eligible patients on 31 December 2011 were included in the baseline audit. A standard form was use to collect the following data: age; sex; date of osteoporosis diagnosis; latest bone mineral density (BMD) scan date and results; latest vitamin D level date and result; anti-osteoporosis pharmacotherapy including treatment start dates, whether therapy had been trialled

previously and reasons for cessation; and potential precautions and contraindications to any anti-osteoporosis therapy (Table 8.1).

5. Data Analysis

Results of the baseline audit were tabulated and the nature and extent of deviations from the predefined criteria were summarised.

Table 8.1. Potential precautions and contraindications to anti-osteoporosis therapies[25]

Medicine	Contraindication/precaution
All anti-osteoporosis drugs	Previous adverse drug reaction (ADR) Pregnancy or breastfeeding
Bisphosphonates	Oesophageal disorders Inability to sit upright for at least 30 minutes Hypocalcaemia Upper gastrointestinal tract conditions Renal impairment (CrCl <35 ml/min) At risk of osteonecrosis Osteomalacia Concurrent use of non-steroidal anti-inflammatory drugs (NSAIDs)
Denosumab	Hypocalcaemia Renal impairment (CrCl <30 ml/min)
Raloxifene	History or risk of venous thromboembolism Oestrogen-dependent tumour With or risk of coronary heart disease Hepatic impairment
Strontium	Renal impairment (CrCl <30 ml/min) History or risk of venous thromboembolism Phenylketonuria
Teriparatide	Paget's disease of bone Hyperparathyroidism Urolithiasis Renal impairment (CrCl <30 ml/min) Skeletal malignancies History of skeletal radiation treatment Unexplained increases in alkaline phosphatase levels
Calcitriol	Hypercalcaemia Vitamin D toxicity

CrCl = Creatinine clearance

6. Feedback to the prescribers and making a plan of action

Findings from the baseline audit were presented to the general practice clinic staff, by the practice pharmacists and a researcher (ET), at a group education session in June 2012. Strategies to improve osteoporosis management at several levels were implemented in June and July 2012 as follows:

Group prescriber level

Baseline audit results and general information on evidence-based osteoporosis management and clinical guidelines[24, 26] were provided to GPs during a presentation by the practice pharmacist.

Individual prescriber level

Individual case-conferences between the pharmacists and GPs were undertaken to discuss cases where patient management did not adhere to clinical guidelines. Patients with a documented diagnosis of osteoporosis, and without documented precautions or contraindications to all anti-osteoporosis medicines available in Australia at the time of the study who were not prescribed an anti-osteoporosis medicine were targeted. Anti-osteoporosis therapies included bisphosphonates (alendronate, risedronate, zoledronic acid, etidronate), raloxifene, denosumab, strontium, calcitriol and teriparatide. Hormone replacement therapy (HRT) was excluded as it is not recommended as an anti-osteoporosis therapy in the absence of other indications for HRT.[25] The practice pharmacist arranged case-conferences with GPs at mutually convenient times. Multiple patients were discussed during each conference. Aside from anti-osteoporosis prescriptions, other issues discussed were BMD test results and/or need for BMD testing, vitamin D levels and/or need for vitamin D levels, and the use and documentation of vitamin D and calcium supplementation. Pharmacists also 'flagged' the medical records

of discussed patients by placing a pop-up alert in the electronic medical record that would act as a reminder when the GP opened the patient's record to improve the implementation of recommendations.

Patient level

A letter and information leaflet about vitamin D were mailed to patients with a diagnosis of osteoporosis. The letter explained the need for patients to inform their doctor of whether they were taking supplements and the need for that information to be recorded in their medical notes at their next appointment. Patients unsure of whether they required supplements were encouraged to speak with their GP.

7. Follow-up

The medical record audit was repeated on 31 December 2012 (12 months after the baseline audit; 6 months post-intervention) to identify changes in osteoporosis management in the clinic populations.

8.5.2 Feedback from staff

Feedback from practice staff and pharmacists regarding the practice pharmacist's role, including the DUE program, was explored qualitatively to assess stakeholder acceptability of the service.[27]

8.5.3 Data Analysis

Analysis was performed using the Statistical Package for Social Sciences (SPSS) for Windows Version 19.0 (IBM, New York, USA). Chi squared tests were used to compare proportions in the pre- and post-intervention groups. Student's t-tests were used to compare continuous variables. A p-value of <0.05 was considered statistically significant.

Ethics approval for the study was granted by the Monash University Human Research Ethics Committee. Being a quality assurance process, informed consent from patients was not necessary.

8.6 Results

A total of 225 patients had a documented diagnosis of osteoporosis at the baseline audit, and 240 at the post-intervention audit 12-months later (213 patients were included at both time points). Demographic and clinical characteristics were similar at the two audit time points (Table 8.2).

Table 8.2. Characteristics of patients with a diagnosis of osteoporosis

Characteristic	Baseline – Dec 2011 (N=225) n (%)	Post-intervention – Dec 2012 (N=240) n (%)	p value
Mean age (SD) in years	74.9 (10.8)	75.1 (10.4)	0.839[a]
Female	176 (78.2%)	190 (79.2%)	0.842[b]
Previous BMD test	139 (61.8%)	160 (66.7%)	0.261[b]
T-score < -2.5[c]	90/134 (67.2%)	119/155 (76.8%)	0.069[b]
Previous Vitamin D level	186 (82.7%)	202 (84.2%)	0.695[b]
Vitamin D <60nmol/L	59/186 (31.7%)	71/202 (34.1%)	0.573[b]
Does not have documented precautions/ contraindications to all anti-osteoporosis medicine[d]	225 (100.0%)	240 (100.0%)	0.694[b]

SD, standard deviation; BMD, bone mineral density; a. Student's t-test; b. χ^2 test; c. Not all patients had a documented test result; d. i.e. eligible for at least one anti-osteoporosis medicine

8.6.1 Primary outcome

Based on information documented in the medical records no patient had precautions or contraindications to all anti-osteoporosis medicines, and therefore all could potentially have been prescribed one or more of these medicines. The proportion of patients currently prescribed an anti-osteoporosis medicine increased significantly from baseline to 12

months (58.7% vs. 70.0%, p=0.002) (see Table 8.3). The most commonly prescribed anti-osteoporosis agents at baseline and 12 months were the bisphosphonates (49.8% and 54.2%) (Table 8.4). Previous anti-osteoporosis therapy had been trialled in 63 (28.0%) patients at baseline. Reasons for cessation included unknown (27, 12.0%), adverse drug reaction (15, 6.7%), patient refusal (7, 3.1%), stable condition (7, 3.1%), contraindication (5, 2.2%) and ineffectiveness (2, 0.9%).

Table 8.3. Prescription of anti-osteoporosis medicines and documentation of vitamin D and/or calcium supplement use

Characteristic	Baseline – Dec 2011 (N=225) n (%)	Post-intervention – Dec 2012 (N=240) n (%)	p value
Prescribed anti-osteoporosis medicine	132/225 (58.7%)	168/240 (70.0%)	0.002
Taking a vitamin D supplement	126/225 (56.0%)	196/240 (81.7%)	<0.001
Documented vitamin D deficiency and taking a vitamin D supplement	37/59 (62.7%)	62/71 (87.3%)	0.002
Taking a calcium supplement	80/225 (35.6%)	136/240 (56.7%)	<0.001

Table 8.4. Anti-osteoporosis medicines prescribed

Medicine	Baseline – Dec 2011 (N=225)	Post-intervention – Dec 2012 (N=240)
Bisphosphonates	112 (49.8%)	130 (54.2%)
Raloxifene	8 (3.6%)	12 (5.0%)
Denosumab	2 (0.9%)	9 (3.8%)
Strontium	7 (3.1%)	14 (5.8%)
Calcitriol	3 (1.3%)	2 (0.8%)
Teriparatide	0 (0.0%)	1 (0.4%)

8.6.2 Secondary outcomes

The proportion of patients for whom vitamin D and/or calcium supplement use was documented increased significantly from baseline to 12 months (63.6% vs. 85.4%, p=0.002). In particular, documentation of vitamin D supplement use increased from 56.0% to 81.7% (p<0.001) (Table 8.3). This increase remained significant when including only those patients with vitamin D deficiency (62.7% vs. 87.3%, p=0.002). Documentation of calcium supplement use also increased significantly (35.6% vs. 56.7%, p<0.001).

Feedback from practice staff and pharmacists about the PIPS pharmacist's role, including the DUE program was positive.[27] The DUE program was considered to be useful and to provide good outcomes for patients. Most practice staff felt that the pharmacist was skilled in this area and such a service was feasible and acceptable in general practice.

8.7 Discussion

Our study was an innovative quality assurance program that made use of pharmacist expertise to audit and improve osteoporosis management in two primary care clinics. Audit criteria were based on national, evidence-based clinical guidelines, and significant improvements were seen in the prescription of anti-osteoporosis medications and documentation of the use of vitamin D and calcium supplements. The multifaceted intervention, involving prescriber education and feedback at both group and individual levels and communication with patients, was well received by practice staff and led to improvements in osteoporosis management. These outcomes may translate to improvements in health outcomes for clinic patients, including fracture prevention and reduced health service utilisation.[24]

Other studies have investigated the effectiveness of interventions to improve treatment of osteoporosis in primary care. A systematic review and meta-analysis[18] found that the majority of interventions were multifaceted and included patient and physician education and physician notification about patients' osteoporosis and fracture risk. The interventions generally resulted in a significant increase in the initiation of osteoporosis treatment for high-risk patients.

A systematic review of pharmacist-led interventions to improve osteoporosis management[19] concluded that pharmacists can potentially identify individuals at high-risk of osteoporosis, and improve rates of BMD testing and use of calcium supplements, findings which are reflected in our study. However, these studies did not have any effect on the initiation of anti-osteoporosis medicines whilst ours did. A study using mixed methods found that community pharmacists and public health authorities believed pharmacists should play a significant role in osteoporosis and falls prevention; however, there were barriers to delivering services in community pharmacies.[29] Many of these barriers, including a lack of time and coordination with other health professionals and geographical separation[29] are overcome by co-location of pharmacists in primary healthcare clinics, which was the setting for our study.

A small before and after study from the United States of America (involving 22 patients) concluded that a pharmacist-run osteoporosis service in a family medicine clinic could improve compliance with osteoporosis treatment guidelines.[20] The pharmacists in that study conducted patient consultations and had a broader scope of practice with regards to initiating and modifying medications and ordering tests than in our study. In our study, pharmacists interacted with prescribers in an advisory role. Despite these differences, significant improvements in the prescription and documentation of anti-osteoporosis medicines and supplements were seen in both studies.

Practice staff were generally receptive of the pharmacist's role including the DUE program.[27] Personal case-conferencing with immediate plans to action recommendations was seen by GPs and pharmacists as effective. Feedback from some GPs revealed that the patient information mail out caused a degree of confusion, raising concerns in some patients who were properly managed. We included all patients with osteoporosis in the mail out who may benefit from vitamin D supplementation, rather than specifically targeting those who were not prescribed the medication, as we wished to raise awareness of the importance of adhering to vitamin D supplements and improve documentation of vitamin D use in medical records. In Australia, vitamin D is not subsidised and is relatively expensive, so it may be under-used by some patients. Additionally, Vitamin D does not require a prescription, so its use is sometimes not documented in patients' medical records. We felt it was important that patients talked to their GPs to ensure medical records were updated with regards to their Vitamin D intake. Proper recording would ensure Vitamin D levels were interpreted appropriately. In the future, more targeted strategies should be implemented.

Our study had some limitations. It was a before and after study, and therefore we cannot be certain that improvements were the result of the intervention alone, as they may have been influenced by factors such as potential Hawthorne effect or exposure of prescribers to other sources of education or information about osteoporosis management.

In addition to the DUE-related interventions, the pharmacists based in the participating clinics conducted medication reviews for individual patients on referral from GPs and provided a medicines information service.[21] However, these additional interventions were only provided to a limited number of patients (e.g. only 82 patients received a medication review from approximately 6000 patients across both clinics), and were not focused on

osteoporosis; hence are unlikely to have contributed significantly to the large improvements in osteoporosis management observed in this study.

As we relied on information available in the medical records, there is the potential that nonprescription medications, such as supplements available over-the-counter, were not properly documented. Hence the observed increases in supplement documentation may not reflect increased use by patients. We did not assess adherence to medications in this study and thus do not know whether patients were taking medications as prescribed.

We only evaluated patients with established osteoporosis and did not explore the use of preventive or lifestyle measures. The data collectors were the same at baseline and follow-up, thus limiting variability in data collection; however, they were not blinded and this may have introduced potential observation bias.

The research team provided guidance and assistance to the practice pharmacists to facilitate the planning and conduct of the DUE. This was largely due to the pharmacist only working onsite for eight hours per week and having other roles to fulfil such as medicine reviews. For the program to be implemented at other practices, pharmacists may require similar support unless they are experienced with the conduct of such programs and have the time to plan and implement them.

There has been debate surrounding the use of calcium supplements and increased risk of adverse cardiovascular events, especially myocardial infarction.[30, 31] Hence, increases in calcium supplementation could pose health risks to some patients. Despite this, it has been concluded that calcium supplements are beneficial for those who are not getting enough calcium through their diet. Patients should be individually assessed for risk versus benefit.[32, 33]

8.8 Conclusion

A pharmacist-led DUE program improved prescriber adherence to clinical guidelines for the management of osteoporosis in general practice clinics, including significant improvements in the prescribing of anti-osteoporosis medicines and documentation of the use of vitamin D and calcium supplements. The DUE program was well received by staff.

8.9 References

1. Johnell O, Kanis JA. An estimate of the worldwide prevalence and disability associated with osteoporotic fractures. *Osteoporos Int.* 2006;17(12):1726-33.

2. Kanis JA, McCloskey EV, Johansson H, Cooper C, Rizzoli R, Reginster JY. European guidance for the diagnosis and management of osteoporosis in postmenopausal women. *Osteoporos Int.* 2013;24(1):23-57.

3. Kanis JA, Borgstrom F, Zethraeus N, Johnell O, Oden A, Jonsson B. Intervention thresholds for osteoporosis in the UK. *Bone.* 2005;36(1):22-32.

4. Bell JS, Blacker N, Edwards S, Frank O, Alderman CP, Karan L, et al. Osteoporosis - pharmacological prevention and management in older people. *Aust Fam Physician.* 2012;41(3):110-8.

5. Siris ES, Miller PD, Barrett-Connor E, Faulkner KG, Wehren LE, Abbott TA, et al. Identification and fracture outcomes of undiagnosed low bone mineral density in postmenopausal women: results from the National Osteoporosis Risk Assessment. *JAMA.* 2001;286(22):2815-22.

6. Giangregorio L, Papaioannou A, Cranney A, Zytaruk N, Adachi JD. Fragility Fractures and the Osteoporosis Care Gap: An International Phenomenon. *Seminars in Arthritis and Rheumatism.* 2006;35(5):293-305.

7. Eisman J, Clapham S, Kehoe L. Osteoporosis prevalence and levels of treatment in primary care: the Australian BoneCare Study. *J Bone Miner Res.* 2004;19(12):1969-75.

8. Gehlbach SH, Avrunin JS, Puleo E, Spaeth R. Fracture risk and antiresorptive medication use in older women in the USA. *Osteoporos Int.* 2007;18(6):805-10.

9. Bleicher K, Naganathan V, Cumming RG, Seibel MJ, Sambrook PN, Blyth FM, et al. Prevalence and treatment of osteoporosis in older Australian men: findings from the CHAMP study. *Med J Aust.* 2010;193(7):387-91.

10. Papaioannou A, Kennedy CC, Ioannidis G, Gao Y, Sawka AM, Goltzman D, et al. The osteoporosis care gap in men with fragility fractures: the Canadian Multicentre Osteoporosis Study. *Osteoporos Int.* 2008;19(4):581-7.

11. Commonwealth Department of Health and Ageing. The national strategy for quality use of medicines. Canberra: Commonwealth Department of Health and Ageing; 2002.

12. Ivers N, Jamtvedt G, Flottorp S, Young JM, Odgaard-Jensen J, French SD, et al. Audit and feedback: effects on professional practice and healthcare outcomes. *Cochrane Database Syst Rev.* 2012;6:CD000259.

13. Holloway K, Green T. Drug and therapeutics committees - a practical guide. Geneva: World Health Organisation; 2003.

14. Society of Hospital Pharmacists of Australia Committee of Specialty Practice in Drug Use Evaluation. SHPA standards of practice for drug use evaluation in Australian hospitals. *J Pharm Pract and Res.* 2004;34(3):220-3.

15. Dartnell J. Understanding, influencing and evaluating drug use. Melbourne: Therapeutic Guidelines Ltd; 2001.

16. Kamel HK. Underutilization of calcium and vitamin D supplements in an academic long-term care facility. *J Am Med Dir Assoc.* 2004;5(2):98-100.

17. Bernett GB, Feldman S, Martin H, Smith BC, Raineri BD. An opportunity for medication risk reduction, healthcare provider collaboration, and improved patient care: a retrospective analysis of osteoporosis management. *J Am Med Dir Assoc.* 2003;4(6):329-36.

18. Laliberte MC, Perreault S, Jouini G, Shea BJ, Lalonde L. Effectiveness of interventions to improve the detection and treatment of osteoporosis in primary care settings: a systematic review and meta-analysis. *Osteoporos Int.* 2011;22(11):2743-68.

19. Elias MN, Burden AM, Cadarette SM. The impact of pharmacist interventions on osteoporosis management: a systematic review. *Osteoporos Int.* 2011;22(10):2587-96.

20. Hall LN, Shrader SP, Ragucci KR. Evaluation of compliance with osteoporosis treatment guidelines after initiation of a pharmacist-run osteoporosis service at a family medicine clinic. *Ann Pharmacother.* 2009;43(11):1781-6.

21. Tan ECK, Stewart K, Elliott RA, George J. An exploration of the role of pharmacists within general practice clinics: the protocol for the pharmacists in practice study (PIPS). *BMC Health Serv Res.* 2012;12(1):246.

22. Ewald D. Osteoporosis - prevention and detection in general practice. *Aust Fam Physician.* 2012;41(3):104-8.

23. Australian Institute of Health and Welfare. National health priority areas. Canberra: AIHW; 2013. Available from http://www.aihw.gov.au/national-health-priority-areas/. (Accessed on 16 June 2013)

24. The Royal Australian College of General Practitioners. Clinical guideline for prevention and treatment of osteoporosis in postmenopausal women and older men. South Melbourne: The RACGP; 2010.

25. Australian Medicines Handbook 2013. Australian Medicines Handbook. Adelaide: Australian Medicines Handbook Pty Ltd; 2013.

26. Osteoporosis Australia. Think Osteoporosis! (Flow chart for GPs). Osteoporosis Australia; 2011. Available from http://www.osteoporosis.org.au/health-professionals/general-practitioners/. (Accessed on 20 June 2013)

27. Tan ECK, Stewart K, Elliott RA, George J. Stakeholder experiences with general practice pharmacist services: a qualitative study. *BMJ Open 2013;3:e003214. doi:10.1136/bmjopen-2013-003214*.

28. Australian Institute of Health and Welfare 2011. A snapshot of osteoporosis in Australia 2011. Arthritis series no. 15. Cat. no. PHE 137. Canberra: AIHW.

29. Laliberté MC, Perreault S, Damestoy N, Lalonde L. The role of community pharmacists in the prevention and management of osteoporosis and the risk of falls: results of a cross-sectional study and qualitative interviews. *Osteoporos Int.* 2012:1-13.

30. Bolland MJ, Grey A, Avenell A, Gamble GD, Reid IR. Calcium supplements with or without vitamin D and risk of cardiovascular events: reanalysis of the Women's Health Initiative limited access dataset and meta-analysis. *BMJ.* 2011;342:d2040.

31. Reid IR, Bolland MJ, Avenell A, Grey A. Cardiovascular effects of calcium supplementation. *Osteoporos Int.* 2011;22(6):1649-58.

32. Rejnmark L, Avenell A, Masud T, Anderson F, Meyer HE, Sanders KM, et al. Vitamin D with calcium reduces mortality: patient level pooled analysis of 70,528 patients from eight major vitamin D trials. *J Clin Endocrinol Metab.* 2012;97(8):2670-81.

33. Ebeling PR, Daly RM, Kerr DA, Kimlin MG. An evidence-informed strategy to prevent osteoporosis in Australia. *Med J Aust.* 2013;198(2):90-1.

Chapter 9. The Pharmacists in Practice Study (PIPS): Stakeholder feedback and experiences

9.1 Introduction

The findings presented in Chapters 6 to 8, demonstrate that a practice pharmacist can improve medication use for general practice patients, by identifying and resolving MRPs, improving patients' medication adherence, and improving prescribers' adherence to clinical guidelines. According to the survey described in Chapter 7, patients were also satisfied with consultations with the practice pharmacist.

Having determined the effectiveness of the practice pharmacist role, an exploration of stakeholders' experiences with the practice pharmacist was conducted to determine overall feasibility and acceptability of the role. A qualitative study, using a combination of research techniques, was undertaken to allow for a deeper and more meaningful exploration. These methods included semi-structured interviews, focus groups and narrative reports.

This study aimed to ascertain the views of pharmacists, general practice staff and patients on their experiences interacting with a practice pharmacist in general practice. The key objectives of this study were to:

- Explore stakeholder experiences with the pharmacist services;
- Identify factors that influenced pharmacist integration;
- Determine whether practice pharmacist services are feasible within Australian general practice; and

- Apply theoretical frameworks to explain findings.

A manuscript has been published in *BMJ Open* and is reproduced below.

The supplementary online files referred to in the published manuscript are reproduced in the appendices. The appendices contain copies of the consent and explanatory statement forms (Appendix 11), interview and focus group guides (Appendix 12), narrative report templates (Appendix 13) and theoretical framework (Appendix 14).

9.2 Publication

Tan ECK, Stewart K, Elliott RA, et al. Stakeholder experiences with general practice pharmacist services: a qualitative study. *BMJ Open* 2013;3:e003214. doi:10.1136/bmjopen-2013-003214

Declaration for Thesis Chapter 9

Declaration by candidate

In the case of Chapter 9, the nature and extent of my contribution to the work was the following:

Nature of contribution	**Extent of contribution (%)**
Reviewed literature; designed methodology; applied for ethics; developed study materials; recruited for and moderated interviews and focus groups; performed data analysis; and prepared manuscript.	75%

The following co-authors contributed to the work:

Name	**Nature of contribution**
Assoc Prof Kay Stewart	Designed methodology; reviewed ethics application, study materials, data and manuscript; facilitated conduct of focus groups.
Mr Rohan Elliott	Designed methodology; reviewed ethics application, study materials, data and manuscript; facilitated conduct of focus groups.
Dr Johnson George	Designed methodology; reviewed ethics application, study materials, data and manuscript; facilitated conduct of focus groups.

Candidate's Signature		**Date**

Declaration by co-authors

The undersigned hereby certify that:

37. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors.
38. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
39. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
40. there are no other authors of the publication according to these criteria;
41. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
42. the original data are stored at the following location(s) and will be held for at least five years from the date indicated below:

Location(s)	**Centre for Medicine Use and Safety, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University, Parkville, Victoria 3052**

Signature 1	[redacted] Assoc Prof Kay Stewart	**Date** 8/10/13
Signature 2	[redacted] Mr Rohan Elliott	 8/10/13
Signature 3	[redacted] Dr Johnson George	 8/10/13

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Stakeholder experiences with general practice pharmacist services: a qualitative study

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ABSTRACT

Objectives: To explore general practice staff, pharmacist and patient experiences with pharmacist services in Australian general practice clinics within the Pharmacists in Practice Study.

Design: Qualitative study.

Setting: Two general practice clinics in Melbourne, Australia, in which pharmacists provided medication reviews, patient and staff education, medicines information and quality assurance services over a 6-month period.

Participants: Patients, practice staff and pharmacists.

Method: Semi-structured telephone interviews with patients, focus groups with practice staff and semi-structured interviews and periodic narrative reports with practice pharmacists. Data were analysed thematically and theoretical frameworks used to explain the findings.

Results: 34 participants were recruited: 18 patients, 14 practice staff (9 general practitioners, 4 practice nurses, 1 practice manager) and 2 practice pharmacists. Five main themes emerged: environment; professional relationships and integration; pharmacist attributes; staff and patient benefits and logistical challenges. Participants reported that colocation and the interdisciplinary environment of general practice enabled better communication and collaboration compared to traditional community and consultant pharmacy services. Participants felt that pharmacists needed to possess certain attributes to ensure successful integration, including being personable and proactive. Attitudinal, professional and logistical barriers were identified but were able to be overcome. The findings were explained using D'Amour's structuration model of collaboration and Roger's diffusion of innovation theory.

Conclusions: This is the first qualitative study to explore the experiences of general practice staff, pharmacists and patients on their interactions within the Australian general practice environment. Participants were receptive of colocated pharmacist services, and various barriers and facilitators to integration were identified. Future research should investigate the feasibility and sustainability of general practice pharmacist roles.

ARTICLE SUMMARY

Article focus

- Exploration of general practice staff, pharmacist and patient experiences with practice pharmacist services in Australian general practice clinics.

Key messages

- Integration was facilitated by colocation, communication and positive pharmacist characteristics, including credibility, adaptability and proactivity.
- Strong leadership, shared goals and the creation of benefits for patients and staff were imperative for successful implementation of pharmacist services.
- Logistical issues, especially time and adequate office space, were barriers to integration of a pharmacist into the clinics, but they were capable of being overcome.

Strengths and limitations of this study

- The study involved a private general practice and a community health clinic, representing the two main models of primary care practice in Australia.
- The study used multiple qualitative methods and recruited practice staff, patients and pharmacists, providing a rich exploration of stakeholders' experiences.
- The clinics and participants may not be representative of the general population because the practices had established interdisciplinary teams.

BACKGROUND

Pharmacists are increasingly becoming part of general or family practice clinic teams.[1] Integration of pharmacists into colocated primary care teams has resulted in improved medication, health and economic outcomes.[2–4] In Australia, the colocation of pharmacists within general practice is rare,[5] although such a role has been suggested.[6] Given the prevalence of medication-related problems in general practice patients,[7] the integration of pharmacists into the general practice team warrants further exploration.

Several studies have explored the opinions of general practitioners (GPs), pharmacists and patients about their interactions with pharmacists in primary care clinics,[8–13] but in Australia such evaluation is sparse, given the novelty of this role. Recently, Australian stakeholders' views about integration have begun to

emerge;[14–16] however, these studies mostly explored the opinions of stakeholders who had not experienced a practice pharmacist. The opinions expressed in these studies may thus be based on personal assumptions and theory rather than actual experience. Hence, knowledge of first-hand stakeholder experiences with actual integration of pharmacists in Australian general practice is warranted.

The Pharmacists in Practice Study (PIPS)[17] was a prospective, prepost intervention study investigating the integration of pharmacists into general practice clinics in Australia. This paper describes a qualitative evaluation of the PIPS, the aim of which was to explore general practice staff, pharmacist and patient experiences with pharmacist services provided in general practice clinics.

METHODS

The PIPS methodology and the practice pharmacist role have been described previously.[17] Briefly, pharmacists were located in two general practice clinics—one private practice and one community health centre—in Melbourne, Australia. Privately run general practice clinics and community health centres are the two main models of primary care medical practice in Australia. In private clinics, GPs are paid on a fee-for-service basis and patients may have to contribute copayments. Community health centres are government funded and offer a range of community health services to local residents, with a focus on health promotion and disease prevention and management. GPs are predominantly salaried and fees are charged for services according to the client's ability to pay.

The PIPS pharmacists provided short-patient and long-patient consultations, drug information and quality assurance activities on a part-time basis (approximately 8 h/week) over 6 months (January–July 2012). Long-patient consultations involved pharmacists performing a comprehensive medication review, on referral from the GP, usually in the clinic but sometimes in the patient's home. Pharmacists had full access to patient medical records and could discuss issues with the GP before and/or after the patient consultation. Short-patient consultations were briefer appointments where the pharmacists provided medicines information or education on specific patient needs. Drug information services included a regular medicines newsletter and answering questions from clinic staff. Quality assurance activities included a drug use evaluation programme addressing osteoporosis pharmacotherapy, a topic selected in consultation with clinic staff.

Experiences of general practice staff, practice pharmacists and patients were explored using several qualitative methods

- Semistructured telephone interviews (patients);
- Focus groups (practice staff);
- Semistructured interviews (practice pharmacists);
- Periodic narrative reports (practice pharmacists).

Recruitment and data collection

Patients

A purposive sample of patients, reflecting a range of demographic and therapeutic characteristics, who had a long-patient consultation with the practice pharmacist were approached. Semistructured telephone interviews were conducted by one investigator (ET) within 2 weeks of the pharmacist consultation. Individual interviews were used because discussions could involve personal or sensitive information about the patient's health or medicines. These were conducted by telephone for the participant's convenience. A topic guide was used to facilitate discussion (see online supplementary file 1). Recruitment continued until data saturation was reached.

Practice staff

One focus group with practice staff was conducted at each clinic during lunch breaks at the end of the PIPS. All practice staff who had worked with the practice pharmacist during the study period were invited. Focus groups were chosen in order to gain a multidisciplinary perspective by stimulation of group discussion, as well as being logistically convenient for participants. Focus groups were moderated by one investigator (ET) who facilitated the discussion using a topic guide (see online supplementary file 2); a note-taker and an observer were also present.

Practice pharmacists

Practice pharmacists participated in individual, semistructured interviews at study end, at a mutually convenient time and place (see online supplementary file 3). Narrative reports were also completed prospectively by the pharmacists at 1, 2, 4 and 6 months. A set of reflective questions adapted from a previous study[18] was provided to the pharmacists to assess processes, functions and personal experiences (see online supplementary file 4). Periodic narrative reports were used as they enabled the prospective capture of experiences and issues encountered by pharmacists during the establishment of the service, rather than relying on recall at the end of the study, thus allowing the researchers to observe the pharmacists' progression and development throughout the study.

Interview and focus group guides were developed by the research team based on the literature and the nature of the practice pharmacist roles. Interviews and focus groups were audio-recorded and transcribed verbatim by a professional transcribing service. Written, informed consent was obtained from all participants.

Data analysis

Transcripts were verified against audio recordings by one investigator (ET). Data management was facilitated using NVivo V.9.0 (QSR, Melbourne). Interview transcripts, recordings, narrative reports and field notes were entered into the software. All data were collected, entered and then analysed together. Two investigators

(ET and KS) read the transcripts and independently analysed the data inductively, coding the data for emergent themes.[19] The initial coding and emerging themes were then discussed between ET and KS to reach a general consensus. Results were then presented at meetings involving all authors, where discrepancies were resolved and themes finalised. Following thematic analysis, theoretical frameworks were used to explain the findings. Illustrative quotes that represent a range of stakeholders and points of view were selected for reporting.

RESULTS

Participant characteristics

Eighteen individual interviews were conducted with patients, 11 of whom were women. The mean age of participants was 72.6 years (range 52–85 years), the median number of medicines was 11 (range 6–16) and the median number of medication-related problems identified by the practice pharmacist was 2 (range 0–8). Participants had a range of chronic medical conditions (eg, asthma, depression, diabetes, hypertension and osteoporosis). Twelve patients were recruited from the private practice and six from the community health centre. This corresponded to roughly 20% of participants from each site.

Practice staff focus group 1 had six participants (5 GPs, 1 practice nurse) and focus group 2 had eight (4 GPs, 3 practice nurses, 1 practice manager). Of the practice staff participants, eight were women, the mean age was 49.4 years (range 37–64) and the median duration of general practice work experience was 27 years (range 3–33). All practice staff who had worked with the practice pharmacist and were working on the day of the focus group participated. One practice manager from the private practice was unavailable, while a nurse and GP from the community health centre were not available. No staff refused to participate.

The two practice pharmacists had at least 8 years of experience undertaking home medicines reviews.[20]

Major themes

Five major themes that illustrate the experiences of the participants emerged: environment; professional relationships and integration; pharmacist attributes; staff and patient benefits and logistical challenges.

Environment

Patients felt comfortable seeing the pharmacist in the clinic and appreciated the privacy in consulting rooms. By being affiliated and present within the clinic, rapport and trust with the pharmacist were more easily built.

> I could have asked the pharmacist that I usually see exactly the same questions but you actually don't ever get the chance to have that two way dialogue with that pharmacist [in the community pharmacy] and the other thing was, in the clinic you were in a private room,… which meant that we could sort of chat. (patient 7)

> I think people are comfortable seeing other health professionals here. I think they know the clinic, they feel comfortable here. It's not invading their home if they're not keen for that. (GP5)

> I think there's a greater acceptance from the client because the pharmacist is part of the team. (practice manager 1)

> I've found the patients have a different mindset when attending a consultation at the clinic. They seem to approach the service with a greater degree of respect and appreciation. I believe this is due to the professional environment and a more tangible association with their GP. (pharmacist 1)

Pharmacists enjoyed working with a diverse mix of staff in the clinic and perceived delivery of services in the clinic environment as more clinical and professional in nature than services provided outside the clinic (eg, within a community pharmacy).

> I loved having…access to a lot of different health professionals. There was the dietician that I often had discussions with and physiotherapists. The nursing staff certainly, and obviously the medical staff. So it was great to be able to have that professional interaction with a variety of different health professionals. (pharmacist 2)

The presence of the pharmacist within the clinic improved access to medicines information and enabled verbal communication about medication-related issues (rather than written communication that typically occurs between GPs and pharmacists with the Australian home medicines review programme).[20] It encouraged medication issues to be discussed and resolved in a timely manner and facilitated referrals to the pharmacist. This ease of communication also aided in the development of rapport.

> Having someone on site even just to ask quick questions to —I thought the pharmacist was really helpful on occasion. Obviously they have an overall idea of medications…so it was nice to have [the pharmacist] there. (GP4)

> You always work better with people when you eyeball them. (nurse 1)

> Patient-specific conversations [with GPs] often take place before [patient] consultation and problem areas identified to be focused on. (pharmacist 1, narrative report 1 month)

> Certainly on a one-to-one communication verbally you do have greater chance of explaining why you are making certain recommendations [to the GP], and you can justify it and then have that discussion about…the recommendations. (pharmacist 2)

> We'd bump into each other in the tea room or in the hallway—so there weren't any barriers to communication [with practice staff] given that we were under the same roof and that's the major advantage. (pharmacist 1)

Integration and professional relationships

Pharmacists mostly had positive experiences with integrating into the primary care practices. Positive experiences were facilitated by supportive staff who already worked within established interdisciplinary teams and, in the case of one pharmacist, a previous working relationship with some GPs in the clinic (as a result of having conducted home medicines reviews for the clinic).

> I had a pre-existing relationship with a couple of the GPs there, which certainly was a factor, but just basically their culture. They have a psychologist,…a diabetes educator, …pathology, so they already had experience in incorporating other disciplines—so I think that helped as well. … So I think it was a combination of those factors and that they also saw value in what we were doing, which is a very important part of them embracing it. (pharmacist 1)

Initial challenges faced by pharmacists included some staff lacking experience of working with pharmacists previously and thus not being familiar with the expertise or role of a non-dispensing pharmacist and therefore not utilising them fully.

> Each staff member is very different…Some of them were a little bit more resistant than others. (pharmacist 2)

To overcome cultural and professional barriers to integration, pharmacists had to be flexible, familiarise themselves with individual staff members and learn how to complement their roles.

> I think it was really important to get to know each staff member and what their agenda…and what their needs were. To see how I could support them in what they were trying to do. (pharmacist 2)

These initial challenges to integration generally dissipated once the pharmacist was used to the practice environment and staff became familiar working with a pharmacist. Pharmacists felt that this would continue to develop over time.

> The nursing staff were quite quick to embrace the expertise of the pharmacist whilst the GPs took a little more time, not really being sure at the outset of what the clinic pharmacist's skills and/or knowledge would be. The role developed over time and I believe started to hit its straps as the allocated time came to an end, with the GPs becoming more used to using me as an information source. (pharmacist 2, narrative report 6 months)

The integration of pharmacists into the practice allowed rapport to be built between the pharmacist and other staff. Staff were able to learn about the pharmacist's role and started to view them as a team member. Pharmacists also enjoyed working within a team environment.

> You just see the pharmacist more as part of the team rather than someone who dispenses the script…you have got a bit more collegiality, and more bouncing things off one another. A bit more interactive and educative for the both of us. (GP6)

> I loved being part of a team. (pharmacist 2)

The practice pharmacists also developed good relationships with the local community pharmacies. This facilitated continuity of care and was appreciated by the clinic staff.

> They were great, and very, very supportive…the pharmacies around the place. I didn't have ever one pharmacy refuse to send a dispensing history or to discuss a person's medication. They were quite comfortable with that. It's good to keep them in the loop. (pharmacist 2)

> [The practice pharmacist] usually followed up with the [community] pharmacists as well. Sort all that out too with the local pharmacist…It was brilliant. (practice manager 1)

The relationship between patients and practice pharmacists were deemed to be positive. Patients appreciated being able to spend time with the practice pharmacist specifically discussing their medications, compared with their GP or community pharmacist who were often viewed as being too busy. Patients also felt that the practice pharmacist would not adversely affect their relationship with the GP and might improve interprofessional communication and relationships.

> You go to the doctor and they're pressed for time always and they'll explain things to you but not in such detail as what the pharmacist did. (patient 1)

> Because if you are in the busy pharmacy, it's very difficult for the pharmacist and for you and usually there's no time to ask. (patient 18)

> [The pharmacist] had more time to spend with them one-on-one especially with respect to their medications. So I found patients get confused with their medications quite easily and I guess they tell you they are taking them fine, but when you really press them they're not. I guess I don't have time to really press them… (GP4)

Although patients were generally receptive to seeing the practice pharmacist, there were some challenges. These included patients being initially confused about the purpose of seeing the practice pharmacist or being reluctant to attend yet another appointment with a health professional. Some patients preferred consulting their GP rather than talking to the practice pharmacist about their medicines.

> I have also identified varying attitudes towards the service. Most patients have embraced it wholeheartedly, whilst others have felt inconvenienced and arrive with an attitude of 'this is pointless' or 'I am doing this as a favour for my GP who is a good bloke'. (pharmacist 1, narrative report 1 month)

> The doctor just told me 'I'm going to do an appointment for you to see the pharmacist' and that's it and I haven't any idea what's going on, just they told me 'bring all your tablets with you'. (patient 11)

> Once you've got a doctor tell you what to do and then prescribe your tablets, if something is not working you're talking to your doctor, you're not talking to your pharmacist. The pharmacist …what can he do? He can only say get a blood test…Your doctor—he's the best man you can get. (patient 17)

> I think it's a good thing to have…every so often it's a good thing to be able to sit down and go through things with a pharmacist. (patient 9)

It was felt by the pharmacists that these challenges could be overcome with adequate promotion of pharmacist services. Additionally, most negative receptivity disappeared once patients experienced the benefits of the practice pharmacist services.

> I didn't really have a lot of resistance. There was just that comment that 'I don't know why I am here. I know what I am doing with my medicines'. But usually at the end of the consultation they were very positive to say 'Oh I actually did learn something about my medicines'. (pharmacist 2)

Pharmacist attributes

Participants felt that the success of pharmacist integration into the clinic setting was influenced by the pharmacist's personality, skills and attributes. In particular, practice pharmacists needed to be personable, flexible and have sound interpersonal and communication skills.

> [The practice pharmacist] was very, very patient and she gave the impression she really knew what she was talking about…she could explain everything. (patient 18)

> She was very good, assertive with the GPs, but very gentle with the clients I thought. From day one, she had authority, she had that sort of presence, so it sort of made you respect her. (GP4)

> …you also need to work in a team environment so there's a certain type of person that can do that. You need to be good with people obviously, because you're consulting one-on-one, so a 'people person' as well, so there is a particular personality type that would be best suited to the role. (pharmacist 1)

> I think you have to go in there with an open mind and look at the needs of the clinic rather than going in with your fixed ideas…Be flexible, be open-minded… (pharmacist 2)

The success of the role also relied on the pharmacist being proactive and actively engaging with staff and identifying potential clients.

> She was good because she didn't let any opportunities slip by. If there was a discussion that involved medication of clients, her ears would prick up and then she'd get involved appropriately. (nurse 1, mental health)

> The role requires a proactive pharmacist who takes an active role in seeking out relationships with GPs, nursing staff, allied health professionals and the admin staff – all crucial in the success of the position. (pharmacist 2, narrative report 6 months)

Staff and patient benefits

Staff benefited from sharing patient care with the pharmacist; pharmacists could offer reassurance and feedback to staff, especially as they had time to explore medication issues in depth.

> I used to refer to [practice pharmacist] if a patient didn't need to see a doctor because they didn't need a script but over-the-counter medication…because there wasn't a doctor available for a consult. (nurse 2)

> I thought it was a logical conclusion to have someone who has that view of therapeutics. We are all competent at prescribing and considering interactions…But it's… helpful to have a second opinion, a second pair of eyes, because we don't have a mortgage on knowledge. (GP7)

> [The practice pharmacist] actually had the time, did a lot of research and ringing the pharmacy down the road and doing the home visits, so it really helped with compliance because…we don't always have the time, she took it to another level I guess than what I would normally do. (nurse 1)

Staff also benefited from an increased awareness of the actual medicine taking practices of their patients. The findings from the consultations also encouraged GPs to not only consider the pharmacist's recommendations, but also think of other patient issues and update their records.

> I think it would definitely increase the GP's knowledge of what their patients were doing. Because it was very, very rare for the GP's list of medications to reconcile with what the patient was actually taking. So if nothing else, at least I am feeding back to the GP this is what you have prescribed but actually this is what they are taking. (pharmacist 2)

> Oh it was great, and then to go back to the doctor's to get the feedback from what the pharmacist and I had talked about. The doctor didn't know that I didn't know that about my medication, it sort of hadn't arisen before, so it was actually a really good two way street. (patient 8)

> I think it also makes you update your [patient's] health summary…in a way that it's very clear as to what the patient has got, therefore why they are on the treatment. (GP5)

The practice pharmacist also assisted staff with improving the quality of prescribing and medicines information and management within the clinic.

> I think one of the good things…is that it's worked…for the clinicians, and I think they're spending a heap more time on their medications now. (practice manager 1)

Participants felt that the pharmacist improved the patients' understanding and awareness of their medicines, provided reassurance, encouraged compliance, rationalised drug therapy and optimised health outcomes.

> It was a benefit…it makes you feel like you are doing the right thing…making sure you're up with the tablets. (patient 14)

> Just having somebody to go over the medications and discuss [them] with the patients and explain to them what they were for, and actually confirm that they were actually taking the stuff, checking their compliance etc. (GP1)

> [The appointment with the pharmacist was] very informative. It probably helped me understand the medication more clear [sic] than I had in the past because I knew that I was taking medication for certain things, but I probably had a couple of the tablets mixed up. (patient 7)

Being within the clinic and part of the healthcare team, the pharmacist also began to see the patient more holistically and became involved in the patient's overall management plan.

> I found that I had more contribution to the overall management of a patient rather than just their medicines. So their social circumstances impacted on their medication management but sometimes their social circumstances were more of an immediate issue that needed to be addressed. (pharmacist 2)

Logistical challenges

While the presence of the pharmacists within the clinics was well received, the logistics of accommodating them, including office space, posed an issue.

> My shifts are often divided between different rooms. (pharmacist 1)

> There were problems when [the pharmacist] couldn't get a room. She didn't always have a room to work in. (practice manager 1)

Time was an issue for practice staff and patients. Staff were busy with their day-to-day routine and did not always have time to engage fully with the pharmacist.

> [The pharmacist] was fantastic with the patients she saw, but I just felt guilty the whole time she was here because I actually didn't have time to really access her or refer people to her. (GP2)

> The biggest challenge is modifying the GPs' behaviours. All of the services need to be driven by the GPs. They are very time poor and can be in automatic pilot mode. Support staff and software programs can assist the identification of eligible patients, but the onus still remains with the GP at the point of consultation. (pharmacist 1)

Some patients found attending appointments burdensome.

> …just another one of the millions of other appointments I have regarding what's going on with me at the moment. (patient 3)

Pharmacists were only available for a limited number of hours each week and on particular days, which was viewed as a disadvantage. They found it challenging to manage their time within busy practices. Their workload would often fluctuate from week to week.

> My greatest challenge…time! (pharmacist 2, narrative report 2 months)

> Well [the pharmacist] has got a fixed day and times, as opposed to after hours or multiple days to pick from. (GP5)

> There were often days that she wasn't really busy at all. (GP4)

> …but she might not be there on the day that you need them. (patient 10)

> The difficulty of course is that I was only there once a week…each week you have to regenerate that role that you have and that presence that you have. (pharmacist 2)

The findings from this qualitative evaluation of colocation of pharmacists in general practice may be explained using two theoretical frameworks that describe interprofessional collaboration and the adoption of new services. The structuration model of interprofessional collaboration,[21] which has its basis in organisational sociology, consists of four interrelated dimensions including: shared goals and vision; internalisation; formalisation and governance. The dimension of shared goals and vision was attained by the pharmacists' and practices' common desire to provide optimal patient care through improved medication management. The dimension of internalisation, characterised by mutual acquaintanceship and trust, was exemplified by the processes of pharmacist integration and relationship building with staff and patients. Once the staff became familiar with the pharmacists' skills, trust was built and a sense of team established. The dimension of formalisation, which encapsulates the structuring of clinical care, was highlighted in the way the pharmacist's role was centred on medicines management, allowing staff to share roles

and patient care. Information exchange also occurred easily given the interdisciplinary environment. The dimension of governance, which involves the leadership functions that support collaboration, was achieved by appropriate guidance from practice managers and head GPs who provided support for innovation and teamwork. Logistical issues, especially limited time for interprofessional interaction, posed an underlying barrier (see diagram in online supplementary file 5).

According to Rogers's 'diffusion of innovation theory',[22] the adoption and diffusion of an innovation is determined by five characteristics: relative advantage, compatibility, complexity, trialability and observability. Relative advantage—the degree to which an innovation is perceived to be better than what it supersedes—is exemplified in our study by the improved positive outcomes and opportunities for interprofessional communication and collaboration compared to existing services. The practice pharmacist services displayed compatibility with the practices' existing values of client-focused and team-based care, and built on staff's previous positive experiences with consultant pharmacists. The complexity of the intervention—particularly the study processes for identification and referral of patients to the pharmacist—was minimised by having pharmacists who were proactive and adaptable to suit the needs of individual staff members. The pharmacy service was successfully trialled and the results of the innovation were observable by patients and staff through the pharmacists' contribution to quality use of medicines.

DISCUSSION

This study explored the perspectives of patients, staff and practice pharmacists on the role of pharmacists colocated within the Australian general practice setting. Participants reported that colocation and the interdisciplinary environment of general practice enabled better communication and collaboration compared to traditional pharmacy services. Participants felt that pharmacists needed to possess certain attributes to ensure successful integration. Pharmacist services were perceived to provide benefits for patients and staff; however, attitudinal, professional and logistical challenges posed barriers. Application of D'Amour's structuration model of interprofessional collaboration and Rogers's diffusion of an innovation theory helped to explain our findings and the successful integration of the practice pharmacist into the interdisciplinary primary care team.

This study has strengths and limitations. Its strengths were that it involved two types of general practice clinic—one private practice and one community health centre—and used a combination of qualitative methods. The study's limitations were that it involved a small number of clinics, which had established interdisciplinary teams and were receptive to adding a pharmacist to their team, so it may not be representative of all general practice clinics. Additionally, the pharmacists were experienced and, in one case, had a previous working relationship with the practice (not colocated). Study constraints, including short duration and limited pharmacist hours, were also limitations.

Other studies have explored stakeholder views on pharmacist integration into co-located primary healthcare teams. Pottie *et al*[12] explored Canadian physicians' perceptions of pharmacist integration through focus groups and interviews. While physicians reported similar benefits and concerns to those identified in our study, the issues of security and medicolegality were elucidated only in their study. This may be because many Australian GPs, including those in our study, had experience of working with consultant pharmacists and were comfortable that the practice pharmacist would not cross ethical and legal boundaries. Consultant pharmacists are independent pharmacists accredited to undertake medicines reviews, but are not co-located in GP clinics. Canadian pharmacist narratives[8 18] revealed similar concerns in the early stages of integration, which gradually diminished with time. Similar to our study, other studies have found that colocation, existing working relationships and trust development were important factors for pharmacist integration.[23–25] Petty *et al*[13] explored patients' views of pharmacist-conducted medication review clinics within a general practice surgery in the UK. Similar to our study, patients had a range of positive and negative views before and after seeing the practice pharmacist.

Previous Australian studies[14 15] on this topic generally have not involved participants who have experienced a practice pharmacist. Those studies suggested various potential benefits of colocation, such as patient privacy, improved access to patient information and increased interprofessional rapport and communication, and these perceived benefits were confirmed in our study.[14 15] Additionally, some proposed desirable pharmacist attributes and logistical challenges raised in the previous studies aligned with our findings.[14 15] Compared with other studies, the practice pharmacists in this study highlighted some additional benefits of working in this role. These included the ability to work with a diverse range of staff, including nursing and allied health, emphasising the interdisciplinary nature of the role; that interprofessional communication could occur prior to consultations, resulting in improved delivery of services; and the way the pharmacists now viewed patients more holistically and felt integrated into their overall management. While previous studies found that some participants were concerned about the potential negative effect that the practice pharmacist role would have on relationships with GPs and the role of community pharmacists, we did not observe this.[14]

This study highlights various barriers and facilitators that need to be considered by practitioners and policymakers when integrating a pharmacist into the primary healthcare team. Integration is facilitated by colocation, communication and positive pharmacist characteristics, including credibility, adaptability and proactivity. Supportive staff, shared goals and the creation of

benefits for patients and staff are imperative. Logistical issues, especially time and office space, are barriers to be considered. Future research should investigate the feasibility, sustainability and financial viability of general practice pharmacist roles and evaluate the impact on patient outcomes in larger controlled studies.

CONCLUSION

To our knowledge, this is the first qualitative study to explore the experiences of general practice staff, practice pharmacists and patients on their interactions within the Australian general practice environment. Overall, participants were receptive of colocated pharmacist services. The interdisciplinary environment enabled interprofessional collaboration. Integration and relationship formation developed over time. Patients and staff benefited from these services; however, logistical challenges posed a barrier.

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REFERENCES

1. Fish A, Watson M, Bond C. Practice-based pharmaceutical services: a systematic review. *Int J Pharm Pract* 2002;10:225–33.
2. Borenstein JE, Graber G, Saltiel E, *et al.* Physician-pharmacist comanagement of hypertension: a randomized, comparative trial. *Pharmacotherapy* 2003;23:209–16.
3. Dolovich L, Pottie K, Kaczorowski J, *et al.* Integrating family medicine and pharmacy to advance primary care therapeutics. *Clin Pharmacol Ther* 2008;83:913–17.
4. Zermansky AG, Petty DR, Raynor DK, *et al.* Randomised controlled trial of clinical medication review by a pharmacist of elderly patients receiving repeat prescriptions in general practice. *BMJ* 2001;6:1340–3.
5. Yates R, Wells L, Carnell K. General practice based multidisciplinary care teams in Australia: still some unanswered questions. A discussion paper from the Australian general practice network. *Aust J Prim Health* 2007;13:10–17.
6. Ackermann E, Williams I, Freeman C. Pharmacists in general practice—a proposed role in the multidisciplinary team. *Aust Fam Physician* 2010;39:163–4.
7. Australian Council for Safety and Quality in Healthcare. *Second national report on patient safety—improving medication safety.* Canberra: Australian Council for Safety and Quality in Health Care, 2002.
8. Farrell B, Pottie K, Haydt S, *et al.* Integrating into family practice: the experiences of pharmacists in Ontario, Canada. *Int J Pharm Pract* 2008;16:309–15.
9. Farrell B, Pottie K, Woodend K, *et al.* Shifts in expectations: evaluating physicians' perceptions as pharmacists become integrated into family practice. *J Interprof Care* 2010;24:80–9.
10. Kolodziejak L, Rémillard A, Neubauer S. Integration of a primary healthcare pharmacist. *J Interprof Care* 2010;24:274–84.
11. MacRae F, Lowrie R, MacLaren A, *et al.* Pharmacist-led medication review clinics in general practice: the views of greater Glasgow GPs. *Int J Pharm Pract* 2003;11:199–208.
12. Pottie K, Farrell B, Haydt S, *et al.* Integrating pharmacists into family practice teams: physicians' perspectives on collaborative care. *Can Fam Physician* 2008;54:1714–17.
13. Petty D, Knapp P, Raynor D, *et al.* Patients' views of a pharmacist-run medication review clinic in general practice. *Br J Gen Pract* 2003;53:607–13.
14. Tan E, Stewart K, Elliott RA, *et al.* Integration of pharmacists into general practice clinics in Australia: the views of general practitioners and pharmacists. *Int J Pharm Pract.* Published Online First: 12 June 2013. doi:10.1111/ijpp.12047
15. Freeman C, Cottrell W, Kyle G, *et al.* Pharmacists', general practitioners' and consumers' views on integrating pharmacists into general practice. *J Pharm Pract Res* 2012;42:184–8.
16. Freeman C, Cottrell W, Kyle G, *et al.* Integrating a pharmacist into the general practice environment: opinions of pharmacist's, general practitioner's, health care consumer's, and practice manager's. *BMC Health Serv Res* 2012;12:229.
17. Tan E, Stewart K, Elliott RA, *et al.* An exploration of the role of pharmacists within general practice clinics: the protocol for the pharmacists in practice study (PIPS). *BMC Health Serv Res* 2012;12:246.
18. Pottie K, Haydt S, Farrell B, *et al.* Narrative reports to monitor and evaluate the integration of pharmacists into family practice settings. *Ann Fam Med* 2008;6:161–5.
19. Liamputtong P. Qualitative data analysis: conceptual and practical considerations. *Health Promot J Austr* 2009;20:133–9.
20. Medicare Australia. Home medicines review. 2012. http://www.medicareaustralia.gov.au/provider/pbs/fourth-agreement/hmr.jsp
21. D'Amour D, Goulet L, Labadie J-F, *et al.* A model and typology of collaboration between professionals in healthcare organizations. *BMC Health Serv Res* 2008;8:188.
22. Rogers E. *Diffusion of innovations.* New York: Free Press, 1983.
23. Jesson JK, Wilson KA. One-stop health centres: what colocation means for pharmacy. *Health Place* 2003;9:253–61.
24. Zillich A, McDonough RP, Carter BL, *et al.* Influential characteristics of physician/pharmacist collaborative relationships. *Ann Pharmacother* 2004;38:764–70.
25. Bradley F, Elvey R, Ashcroft DM, *et al.* The challenge of integrating community pharmacists into the primary health care team: a case study of local pharmaceutical services (LPS) pilots and interprofessional collaboration. *J Interprof Care* 2008;22:387–98.

Chapter 10. Summary of findings and conclusions

10.1 Summary of findings

This thesis has presented findings of a series of studies on the integration of pharmacists into general practice clinics. The overall aim of this thesis was to explore, develop and evaluate the clinical role of a practice pharmacist in the Australian primary healthcare clinic setting.

To address information gaps related to this model of health service delivery, especially from a local perspective, key objectives were set. The main findings in relation to these objectives are summarised below.

Systematically review the literature on clinical services provided by pharmacists co-located within primary care clinics

The systematic review (**Chapter 3)** affirmed that pharmacists co-located in general practice clinics can deliver a variety of interventions, with favourable results seen in certain areas of chronic disease management and quality use of medicines. Positive effects were more often seen in studies that involved a pharmacist delivering a multifaceted intervention in conjunction with regular follow-up of patients and verbal communication with the GP. The meta-analyses found significant reductions in BP, HbA_{1C}, cholesterol and Framingham risk score after pharmacist intervention. These results highlight the effectiveness of delivering collaborative, clinical pharmacist services in general practice clinics.

Elucidate stakeholder views on the integration of pharmacists into general practice

Stakeholder interviews, prior to the PIPS, (**Chapter 4)** found that the current relationship between GPs and pharmacists was generally positive; but that there were barriers to the delivery of collaborative services. Co-location of pharmacists in general practice clinics was discussed, with participants having mixed views. Pharmacists practising in this setting were deemed to have multiple potential roles, with the possibility for role expansion in some cases. Pharmacist integration was seen to offer both advantages and disadvantages at the level of the patient, staff and pharmacist. To ensure successful integration, various barriers and facilitators need to be considered. The results of the interviews highlighted the importance of assessing the need for a practice pharmacist and clearly defining their role within the clinic; good communication with stakeholders to ensure understanding of the pharmacist's role; and adequate financial, logistical and organisational support to ensure viability of services.

Implement and evaluate the impact of a pharmacist providing clinical services in a general practice clinic (including evaluation of clinical and humanistic outcomes)

Findings from **Chapters 3 and 4** guided the development of the intervention that was evaluated in the prospective, before-after study outlined in **Chapter 5**. Overall study results have been summarised in **Chapter 6**. The practice pharmacist undertook several clinical roles including long and short patient consultations, drug information and education services, and quality improvement activities focusing on medicines use. The long patient consultations resulted in significant reductions in MRPs and improved medication adherence, with no effect on general health or health service use (**Chapter 7**). Patients were very satisfied with these consultations. The drug use evaluation (DUE) program improved prescriber adherence to clinical guidelines for osteoporosis, resulting

in significantly increased prescription and documentation of anti-osteoporosis medicines and supplements in patients with established osteoporosis (**Chapter 8**). The DUE program was well received by staff. The qualitative evaluation of pharmacist services (**Chapter 9)** revealed that the practice pharmacists' role was well accepted by patients, staff and pharmacists. Participants reported that co-location and the interdisciplinary environment of general practice enabled better communication and collaboration compared to traditional pharmacist roles in the community. Strong leadership, shared goals, a proactive approach by pharmacists and the creation of benefits for patients and staff were imperative for successful integration. Attitudinal, professional and logistical barriers were identified but were able to be overcome with careful planning and communication.

Findings from this study showed that the integration of pharmacists into general practice clinics was a feasible and acceptable model of healthcare delivery that could improve the medication outcomes of general practice patients.

10.2 What this Research Adds

10.2.1 Comparisons with the International Literature

The collective findings of this thesis have added to the growing body of evidence supporting the integration of pharmacists into general practice clinics worldwide. The systematic review and meta-analyses, which was more focused and up-to-date than previous reviews,[1, 2] confirmed the effectiveness of the practice pharmacist interventions and potential for this role. The findings of the local stakeholder consultations were consistent with those in the literature;[3, 4] however, additional issues that had not been previously identified were elicited, such as concerns regarding the potential negative effects integration may have on community pharmacists and the need for local evidence

and professional organisations to support this role. The positive effect of practice pharmacist medication reviews on MRPs, adherence and satisfaction are consistent with previous studies;[5, 6] however, few studies have assessed a multifaceted practice pharmacist role targeting a diverse range of patients as our study did.[5, 7, 8] The PIPS included both long and short consultations, education services and a substantial quality improvement component, emphasising the diverse skill set of the pharmacist and their role in QUM. The qualitative analysis of stakeholder experiences as part of the PIPS produced findings similar to other studies;[4, 9, 10] however, the use of theoretical frameworks helped explain the findings and strengthen the conclusions made.

10.2.2 Comparisons with the Local Literature

At the time this research was being developed and undertaken, Freeman et al.[11] concurrently conducted a similar study exploring a practice pharmacist role in Australia. However, the studies used different methods, interventions and outcome measures, and were conducted in different states in Australia. Our study involved an initial systematic review and meta-analyses[12] that helped affirm and guide the development of the intervention, whilst the study by Freeman et al. did not. Stakeholder consultations from both studies highlight that Australian stakeholders are generally receptive to practice pharmacist services.[13, 14] Medication reviews, medication information, and education were viewed as positive roles for practice pharmacists, with prescribing receiving generally mixed views. Dispensing and diagnosis were perceived as negative roles for a pharmacist in the general practice setting. Similar barriers and facilitators to integration were identified in both studies, mainly related to remuneration, logistical and attitudinal factors.

The roles of the practice pharmacists in both studies had some similarities; however, the differences highlight the breadth of services that practice pharmacists could offer and how

the pharmacist services were designed to suit the needs of the individual clinics.[15, 16] For example, whilst the pharmacists in both studies had medication review and medicines information as prominent roles, other roles differed. The pharmacist in the study by Freeman et al. was also engaged in student supervision, committee meetings, software development, disease-focused clinics and medical centre research, whilst the pharmacists in our study were not. The pharmacists in our study, however, provided both long and short patient consultations. Additionally, greater time was spent with quality improvement activities including the implementation of the DUE program and associated interventions; the pharmacist in the Freeman et al. study committed only 3% of their time to this type of activity.

Both studies evaluated MRPs as an outcome measure, with similar rates and types of MRPs identified and recommendations implemented. In addition, Freeman et al.[17] mainly assessed process outcomes, such as the time to complete the HMR process and the number of HMRs billed to Medicare. In our study, a broader range of humanistic and clinical outcomes were assessed, such as medication adherence, patient satisfaction, health service use and appropriateness of prescribing.

The study design used by Freeman et al.[11, 17] had some limitations, mainly the retrospective nature of the investigation, the primary investigator also being the practice pharmacist (introducing observation bias), and a single pharmacist working in a single medical centre, which limits generalisability of findings. Several of these limitations were overcome in our study by using a prospective before-after study design. Additionally, the study was undertaken in two general practice clinics and involved practice pharmacists who were independent of the research team.

Freeman et al. did not evaluate the experiences of consumers, staff or practice pharmacists with regards to their actual interactions within general practice. As part of the PIPS, a multimodal qualitative evaluation of stakeholder experiences and feedback was undertaken, providing important additional information with regards to acceptability of services, and the barriers and facilitators experienced.[18] The qualitative assessment also highlighted various additional benefits to integration, including the interdisciplinary nature of the role; the fact that interprofessional communication could occur prior to consultations thus improving delivery of services; and the way pharmacists benefited from gaining a more holistic view of the patient and were more integrated into overall patient management.

Together, these two independently conducted studies complement one another, and help strengthen and validate the positive findings from each. This further supports the benefits and feasibility of practice pharmacists in the Australian health system, and will help inform local policy and debate on this topic.

10.3 Strengths and Limitations

This study developed a new service model based on a systematic review and meta-analyses and stakeholder consultation, followed by evaluation of a variety of roles undertaken by the practice pharmacist using both qualitative and quantitative techniques. To our knowledge, this is the first study to use this combination of methods to investigate the role of the practice pharmacist in Australia.

Although this study overcame some of the limitations of previous research, there were still limitations. A before-after study design was used, and therefore we cannot be certain

that improvements were the result of the intervention alone. This design, however, allowed subjects to serve as their own controls, thus eliminating inter-subject variability and reducing confounding. Although external validity was enhanced by conducting the study in more than one site, the small number of clinics and potential selection bias means that larger multicentre studies are needed for better generalisability. Although this was a small study, it was sufficiently powered for the primary outcome. Outcome assessment was not blinded and this may have introduced potential observation and detection bias. Study constraints, including short duration, limited pharmacist hours and limited funding and resources, were other challenges. These restrictions meant a more rigorous study design, such as a cluster-RCT involving multiple sites and a longer follow-up period, was not feasible. Nevertheless, this study design was suitable for testing the initial feasibility and acceptability of practice pharmacist integration. Recommendations to overcome these issues in future research are described below (Section 10.5).

10.4 Recommendations

As can be seen, an 'optimal' service model for the practice pharmacist will vary between different clinics based on the practice and patient needs. The results of this thesis collectively highlight certain considerations that should be made when implementing practice pharmacist services in primary care clinics in Australia.

The following general recommendations are made:

- Strong leadership and commitment, especially from practice managers and principal or partner GPs, combined with shared goals of providing optimal patient care, are important for driving the adoption of pharmacist services in general practice;

- The practice pharmacist's role and scope of practice should be well-defined and communicated to all staff within the practice and local community pharmacists to avoid potential perceived boundary encroachment or territorial issues;
- The practice pharmacist should undertake a variety of roles focusing on quality use of medicines, including medication review, medicines education/information, and quality improvement activities such as DUE, as these roles are acceptable and beneficial to the practices and their clients, and within the pharmacist's expertise. Depending on the hours worked at the clinic, this will also ensure the pharmacist is productively occupied;
- The practice pharmacist should deliver services in collaboration with the GP and other staff, and ensure verbal, face-to-face communication (including both formal and informal conversations) is used wherever possible;
- Pharmacists should possess attributes including credibility, adaptability and a proactive approach, to ensure successful integration and adoption of this new role;
- Pharmacists should endeavour to create benefits for patients and staff, including improvements in clinical, humanistic and health system outcomes to demonstrate effectiveness and quality improvement;
- Logistical issues, especially time and adequate office space, should be considered and prepared for with careful planning and dialogue;
- Practice standards, and educational and promotional resources for health professionals and consumers regarding these services are needed to create awareness and guidance in adopting new practice pharmacist services;
- Formal training programs and credentialing for pharmacists wishing to practice in this area are needed to ensure pharmacists are confident and competent to deliver services at a suitable standard;

- Interprofessional education programs in universities, involving pharmacy and other healthcare disciplines at the undergraduate level should be implemented, to foster communication and a culture of teamwork from an early stage; and
- Appropriate funding for practice pharmacists should be addressed at a health policy level to ensure viability of this role. Potential funding models could be based on existing remuneration structures for pharmacists and GPs (e.g. home medicines reviews [HMR], chronic disease management [CDM] Medicare item numbers, team care arrangements [TCAs] and practice incentive program [PIP] payments) or new funding models could be developed (e.g. Medicare provider numbers for practice pharmacists). Aside from government subsidy, other payers could be used such as private health insurance, practice salaries, patient co-payments or blended payment options).

10.5 Future research directions

Future research should endeavour to do the following:

- Consult other stakeholders (e.g. consumers, policy makers including government, funding and professional bodies) regarding pharmacist integration into general practices to ensure optimal service models are developed and implemented;
- Explore and trial other roles for pharmacists in the general practice setting (e.g. disease management clinics, patient education groups, collaborative prescribing and mentoring of other health professionals and trainees etc.) to determine how the pharmacist's time is best spent;
- Conduct larger-scale, multi-state, multicentre, cluster-randomised controlled trials evaluating clinical services provided by pharmacists co-located in general practice clinics to confirm the findings of this study. Cluster randomisation (i.e.

randomisation at the level of the practice) would avoid potential contamination; a control group would allow for comparison of the intervention against usual care and improve the internal validity; multiple sites would improve the external validity; and longer duration would allow assessment of long-term clinical and economic outcomes, thus providing evidence for efficacy on a broader range of harder outcomes; and

- Assess the cost-effectiveness of practice pharmacist services and develop appropriate business models to ensure sustainability of this role.

10.6 Conclusions

Australian primary care is undergoing reform, which warrants change in the nature and delivery of pharmacy services. Once a contentious issue, the integration of pharmacists into Australian general practice has received growing support from both the medical and pharmacy professions in recent times.[19-21] This thesis has demonstrated that the integration of pharmacists into Australian general practice is feasible and acceptable to patients, general practice staff and pharmacists, and is effective in improving QUM in general practice, thus providing the much-needed preliminary evidence to support the need for change. These findings will further contribute to the development of the practice pharmacist role in Australian general practice.

10.7 References

1. Fish A, Watson M, Bond C. Practice-based pharmaceutical services: a systematic review. *Int J Pharm Pract.* 2002;10:225-33.

2. Nkansah N, Mostovetsky O, Yu C, Chheng T, Beney J, Bond CM, et al. Effect of outpatient pharmacists' non-dispensing roles on patient outcomes and prescribing patterns. *Cochrane Database Syst Rev.* 2010(7):CD000336.

3. Hughes C, McCann S. Perceived interprofessional barriers between community pharmacists and general practitioners: a qualitative assessment. *Br J Gen Pract.* 2003;53:600-6.

4. Pottie K, Farrell B, Haydt S, Dolovich L, Sellors C, Kennie N, et al. Integrating pharmacists into family practice teams: physicians' perspectives on collaborative care. *Can Fam Physician.* 2008;54(12):1714-7.

5. Dolovich L, Pottie K, Kaczorowski J, Farrell B, Austin Z, Rodriguez C, et al. Integrating family medicine and pharmacy to advance primary care therapeutics. *Clin Pharmacol Ther.* 2008;83(6):913-7.

6. Sellors J, Kaczorowski J, Sellors C, Dolovich L, Woodward C, Willan A, et al. A randomized controlled trial of a pharmacist consultation program for family physicians and their elderly patients. *Can Med Assoc J.* 2003;169(1):17-22.

7. Malone DCP, Carter BLP, Billups SJP, Valuck RJP, Barnette DJP, Sintek CDMS, et al. Can clinical pharmacists affect SF-36 scores in veterans at high risk for medication-related problems? *Med Care.* 2001;39(2):113-22.

8. Avery AJ, Rodgers S, Cantrill JA, Armstrong S, Cresswell K, Eden M, et al. A pharmacist-led information technology intervention for medication errors (PINCER): a

multicentre, cluster randomised, controlled trial and cost-effectiveness analysis. *Lancet.* 2012;379(9823):1310-9.

9. Farrell B, Pottie K, Haydt S, Kennie N, Sellors C, Dolovich L. Integrating into family practice: the experiences of pharmacists in Ontario, Canada. *Int J Pharm Pract.* 2008;16:309-15.

10. Petty D, Knapp P, Raynor D, House A. Patients' views of a pharmacist-run medication review clinic in general practice. *Br J Gen Pract.* 2003;53:607 - 13.

11. Freeman CR, Cottrell WN, Kyle G, Williams ID, Nissen L. An evaluation of medication review reports across different settings. *Int J Clin Pharm.* 2013;35(1):5-13.

12. Tan E, Stewart K, Elliott R, George J. Pharmacist services provided in general practice clinics: a systematic review and meta-analysis. *Res Social Adm Pharm.* 2013 (in press).

13. Freeman C, Cottrell W, Kyle G, Williams I, Nissen L. Integrating a pharmacist into the general practice environment: opinions of pharmacists, general practitioners, health care consumers, and practice managers. *BMC Health Serv Res.* 2012;12(1):229.

14. Tan ECK, Stewart K, Elliott RA, George J. Integration of pharmacists into general practice clinics in Australia: the views of general practitioners and pharmacists. *Int J Pharm Pract.* Published Online First: 12 June 2013. doi:10.1111/ijpp.12047

15. Freeman C, Cottrell W, Kyle G, Williams I, Nissen L. Chronicles of a primary care practice pharmacist *Integrated Pharmacy Research and Practice.* 2012;1:13-8.

16. Tan ECK, Stewart K, Elliott RA, George J. An exploration of the role of pharmacists within general practice clinics: the protocol for the pharmacists in practice study (PIPS). *BMC Health Serv Res.* 2012;12(1):246.

17. Freeman C, Cottrell WN, Kyle G, Williams I, Nissen L. Does a primary care practice pharmacist improve the timeliness and completion of medication management reviews? *Int J Pharm Pract.* 2012;20(6):395-401.

18. Tan ECK, Stewart K, Elliott RA, George J. Stakeholder experiences with general practice pharmacist services: a qualitative study. *BMJ Open.* 2013;3(9):e003214.

19. Morton B. Time for a new take on where pharmacists work? Australian Medicine March 2013. Available from https://ama.com.au/ausmed/time-new-take-where-pharmacists-work. (Accessed on 14th August 2013)

20. Morton B. Involving pharmacists in general practice. Australian Medicine March 2013. Available from https://ama.com.au/ausmed/involving-pharmacists-general-practice. (Accessed on 14 August 2013)

21. Pharmaceutical Society of Australia. GP-pharmacist collaboration under spotlight. Canberra: Pharmaceutical Society of Australia; 2013. Available from http://www.psa.org.au/media-releases/gp-pharmacist-collaboration-under-spotlight. (Accessed on 19 September 2013)

Appendices

APPENDIX 1

CHAPTER 4: ETHICS APPROVAL FOR STAKEHOLDER CONSULTATION

MONASH University

Monash University Human Research Ethics Committee (MUHREC)
Research Office

Human Ethics Certificate of Approval

Date:	**22 November 2010**
Project Number:	**CF10/2998 - 2010001656**
Project Title:	**A team approach to optimising medication outcomes in primary care: Stakeholder views and perspectives**
Chief Investigator:	**Dr Johnson George**
Approved:	**From: 22 November 2010 To: 22 November 2015**

Terms of approval

1. The Chief investigator is responsible for ensuring that permission letters are obtained, if relevant, and a copy forwarded to MUHREC before any data collection can occur at the specified organisation. **Failure to provide permission letters to MUHREC before data collection commences is in breach of the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research**.
2. Approval is only valid whilst you hold a position at Monash University.
3. It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by MUHREC.
4. You should notify MUHREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
5. The Explanatory Statement must be on Monash University letterhead and the Monash University complaints clause must contain your project number.
6. **Amendments to the approved project (including changes in personnel):** Requires the submission of a Request for Amendment form to MUHREC and must not begin without written approval from MUHREC. Substantial variations may require a new application.
7. **Future correspondence:** Please quote the project number and project title above in any further correspondence.
8. **Annual reports:** Continued approval of this project is dependent on the submission of an Annual Report. This is determined by the date of your letter of approval.
9. **Final report:** A Final Report should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected date of completion.
10. **Monitoring:** Projects may be subject to an audit or any other form of monitoring by MUHREC at any time.
11. **Retention and storage of data:** The Chief Investigator is responsible for the storage and retention of original data pertaining to a project for a minimum period of five years.

[redacted]

Professor Ben Canny
Chair, MUHREC

cc: Assoc Prof Kay Stewart, Mr Rohan Elliott, Mr Edwin Tan

Postal – Monash University, Vic 3800, Australia
Building 3E, Room 111, Clayton Campus, Wellington Road, Clayton
Telephone +[redacted] Facsimile +61 3 9905 3831
Email [redacted] www.monash.edu/research/ethics/human/index/html
ABN 12 377 614 012 CRICOS Provider #00008C

APPENDIX 2

CHAPTER 4: ADVERTISEMENTS, LETTER OF INVITATION, EXPLANATORY STATEMENT AND CONSENT FORM

MONASH University
Pharmacy and Pharmaceutical Sciences

A Team Approach to Optimising Medication Outcomes in Primary Care

GPs, General Practice Staff and Pharmacists Needed

We are looking for **general practitioners, general practice staff and pharmacists** interested in taking part in a study investigating strategies to improve medication use in primary care patients.

As a participant in this study, you will be invited to share your thoughts in **one-to-one interviews** or **focus groups**. An exploration of stakeholder opinions on the integration of pharmacy services into general practice and the delivery of collaborative patient care will take place.

Your experience and opinions will be greatly valued and will assist us in developing new ways to improve medication use among primary care patients.

The discussion will be organised at a place and time convenient for you. Individual interviews will run for approximately 30 minutes. Focus groups will run for approximately 2 hours and will involve 5 – 12 other stakeholders. In appreciation for your time, you will receive an **honorarium** of $50 (individual interviews) or $75 (focus groups). Refreshments will also be provided during focus groups.

Note: This study has received ethics approval from the Monash University Human Research Ethics Committee

For more information, please contact:
Edwin Tan (PhD scholar)
Department of Pharmacy Practice, Monash University, 381 Royal Pde, Parkville, VIC 3052
Phone: **(03) 9903 9170** • Fax: **(03) 9903 9629** • Email: **edwin.tan@monash.edu**

Interested in participating? Please complete the slip below, and fax/email/post it back and we will contact you

Yes, I am interested in participating in this study

Title: _____ Name: _____

I am a: ☐ GP ☐ Practice Nurse ☐ Practice Manager ☐ Other _____
☐ Pharmacist working in ☐ Community (please specify, ☐ Owner ☐ Manager ☐ Employee)
☐ Hospital ☐ Consultant ☐ Other_____

Contact phone number: _____ Suitable time for contact: _____

Email address: _____

Name of work place: _____ Suburb: _____

I would prefer to attend a: ☐ One-to-one interview ☐ Focus group/group discussion

Via: ☐ Face-to-Face ☐ Telephone/teleconference

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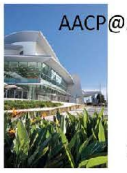

Click here if you want to register for APP 2011
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Monash Requires Pharmacists and GPs

A pharmacist in general practice?

We are looking for GPs, general practice staff and pharmacists interested in taking part in focus groups and/or individual interviews exploring stakeholder opinions on the integration of pharmacy services into general practice and the delivery of collaborative patient care. Individual interviews will run for approximately 30 minutes. Focus groups will run for approximately 2 hours and will involve 5 – 12 other stakeholders (more information). You will receive an honorarium of $50 (individual interviews) or $75 (focus groups). Refreshments will also be provided during focus groups. For more information, please see the attached flyer or contact Edwin Tan on 9903 9170 or email edwin.tan@monash.edu

'An Accredited pharmacist's journey'

Penny Kraemer was this year's joint winner of the AACP Pfizer Consultant Pharmacist of the year. If you missed her article in the November 2010 issue of The Australian Journal of Pharmacy (Vol. 91 November 2010) you can access a copy by clicking on this link. Penny has been accredited since 1997, establishing her own RMMR business in 2006, so her journey will be of interest to all accredited pharmacists. The article is reproduced with the permission from the Australian Journal of Pharmacy.

Are you receiving the All-Associate *Fortnightly Email Updates*?

If not, its probably because your email address is out of date.

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	Nge, Siv-ly
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	Gujral, Gina
	Leong, Jamie
VIC	Attia, Sherine
	Burt, Csilla
	Manassa, Trysha

MONASH University

Faculty of Pharmacy and Pharmaceutical Sciences

Dr. <insert name>
Medical Centre
STREET
SUBURB VIC 3000

16th March 2011

Dear Dr. <insert name>,

You are cordially invited to take part in our study *A Team Approach to Optimising Medication Outcomes in Primary Care*.

What is the purpose of this study?
The aim of this study is to elucidate your views on the integration of a clinical pharmacist into general practice. It is estimated that over 400,000 adverse drug events may be managed in general practice each year, with around 140,000 hospitalisations resulting from medication-related problems[1]. It is envisioned that by having a pharmacist working collaboratively as part of the general practice team, medication use and safety can be optimised. We would like to hear your views on this potential collaboration within the context of the Australian general practice setting.

Who are the researchers?
Edwin Tan is conducting this research project under the supervision of Dr Johnson George, Associate Professor Kay Stewart, and Rohan Elliott towards a Doctor of Philosophy (PhD) degree at Monash University.

This project has the support of: Dr. Grant Russell, Professor of General Practice Research, Monash University; Mr. Ken Mansbridge, Dr. Peter Eizenberg & Dr. Jenny Gowan, North East Valley Divisions of General Practice; and the Pharmacy Department of Austin Health.

What are the benefits of taking part?
This study presents a unique opportunity for you to voice your opinion on pharmacist integration into general practice. By helping us identify gaps in current practice, define the practice pharmacist's role and determine its feasibility, recommendations for policy change can be made which can lead to improved health care delivery to patients and potentially reduced GP workload and health costs.

An honorarium of $50 - $75 will be provided to participants as a small token of our appreciation.

What does the research involve?
You can take part in either an individual interview or focus group with other stakeholders such as practice staff, pharmacists, and consumer representatives. Individual interviews will last approximately 30 minutes and focus groups will last approximately 90 minutes. Discussions will take place either face-to-face or by telephone/teleconference at a time and venue suitable for you.

Should you wish to participate or require further information, please contact me on the details below or complete the attached expression of interest form. I look forward to hearing from you.

Yours sincerely,

Edwin Tan

PhD Scholar
Department of Pharmacy Practice
Centre for Medicine Use and Safety
Faculty of Pharmacy and Pharmaceutical Sciences
Monash University (Parkville campus)
381 Royal Parade
Parkville VIC 3052, Australia

[redacted]

1. Second National Report on Patient Safety Improving Medication Safety, published by Australian Council for Safety and Quality in Health Care, July 2002.

Explanatory Statement for Focus Groups/Interviews
A Team Approach to Optimising Medication Outcomes in Primary Care

This information sheet is for you to keep.

Dear _____,

My name is Edwin Tan and I am conducting a research project under the supervision of Dr Johnson George, Associate Professor Kay Stewart, and Mr Rohan Elliott towards a Doctor of Philosophy (PhD) degree at the Department of Pharmacy Practice at Monash University. This means that I will be writing a thesis which is the equivalent of a short book. I am supported by a Monash University scholarship.

What is the purpose of this study?
The aim of this study is to elucidate your views on integration of pharmacy services into general practice. Evidence from overseas has revealed that pharmacists can work successfully in close collaboration with other primary health care professionals as part of multidisciplinary teams. Such arrangements have resulted in improved patient care and the delivery of cost-effective health services. The overall aim of this study is to define and develop the role of the primary care pharmacist within the context of Australian general practice setting.

Why have I been chosen?
We are approaching health professionals such as general practitioners, pharmacists, and practice nurses involved in the care of general practice patients; practice managers and other staff involved in coordinating patient care; consumers and community-dwelling general practice patients; and representatives of professional organisations to take part in this study. Potential study participants have been identified in consultation with various health professionals and organisations. Given your experience and expertise in the research topic, you have been identified as a potential participant and we invite you to participate in this study.

What are the possible benefits of taking part?
By taking part in this study, you will help to give us a better understanding of the processes and issues associated with integrating a pharmacist into the general practice. You will help us identify gaps in current services and how these can be improved, define the role of the practice pharmacist and determine the feasibility of delivering pharmacy services through general practice. This information will help us to make recommendations to policy makers and/or suggest changes in policy to optimise medication use and improve the delivery of care to Australian general practice patients.

What does the research involve?
Participation in this study involves a one-to-one interview (face-to-face or by telephone) with a researcher and/or focus group with representatives of various stakeholder groups such as general practitioners, pharmacists, nurses, practice managers, other general practice staff, consumers and representatives of professional organisations. Five to twelve stakeholder representatives will be invited for the discussion, which will last approximately 2 hours. One-to-one interviews are likely to last approximately 15 to 30 minutes. The group discussion will take place at a venue and time convenient for all the participants. I will be moderating the focus group. Another member of the research team will also be present to take written notes of the group discussion.

The interviews and group discussion will be audio-recorded to make sure that we do not miss any valuable information provided by the participants. The interviews and group discussion will be transcribed verbatim and analysed for major themes. You will be identified only by a unique code in the transcript; any personal information that could reveal the identity of individual participants will be removed from the transcript.

MONASH University
Pharmacy and Pharmaceutical Sciences

Will I receive a payment for participating?
In recognition of your contributions to the study, an honorarium will be provided to you at the end of the discussion. Participants of one-to-one interviews and focus groups will receive gift vouchers worth $50 and $75, respectively. Refreshments will also be provided during focus groups.

What if I choose not to take part?
Participating in this study is voluntary – it is your decision whether to take part or not. If you choose not to take part, this will not affect your relationship with Monash Univeristy, the researchers or other stakeholders. However, your participation will be very useful to us. Even after you consent to participate, you may withdraw at any time without being disadvantaged in anyway.

Will my taking part in the study be kept confidential?
All the information collected from individual participants throughout the course of this study will be kept confidential. To ensure your participation remains anonymous and confidential, we will ask all participants in the group discussion to sign a confidentiality declaration statement form prior to commencement.

How will my data be stored?
Storage of the information will adhere to Monash University's regulations. Audio files and transcripts will be kept on the University premises in a locked cabinet for 5 years and electronic data or files will be stored on a password protected computer.

Will my data be used for other purposes?
A report of the study may be submitted for publication in a healthcare journal and/or presentation at a conference. However, individual participants will not be named or identified in such a report or in any publications resulting from the study.

How do I access the results of the study?
If you would like to be informed of the aggregate research findings, please contact Edwin Tan on (03) 9903 9057 or Dr Johnson George on (03) 9903 9178.

If you would like to contact the researchers about any aspect of this study, please contact the Chief Investigators:	If you have a complaint concerning the manner in which this research **CF10/2998-2010001656** is being conducted, please contact:
Dr Johnson George (Lecturer) Monash University (Parkville Campus) Department of Pharmacy Practice 381 Royal Parade VIC 3052 Tel: (03) 9903 9178 Fax: (03) 9903 9629 Email: johnson.george@monash.edu.au [redacted]	Executive Officer Monash University Human Research Ethics Committee (MUHREC) Building 3e Room 111 Research Office Monash University VIC 3800 [redacted]

Thank you,

Edwin Tan

MONASH University
Pharmacy and Pharmaceutical Sciences

Consent Form for Interview/Focus Group

A Team Approach to Medication Optimisation in Primary Care

NOTE: **This consent form will remain with the Monash University researcher for their records**

I agree to take part in the Monash University research project specified above. I have had the project explained to me, and I have read the Explanatory Statement, which I keep for my records.

1) I understand that agreeing to take part means that:

   - I agree to be interviewed by the researcher ☒ Yes ☐ No
   - I agree to the interview being audio-taped ☒ Yes ☐ No

2) I understand that my participation is voluntary, that I can choose not to participate in part or all of the project, and that I can withdraw at any stage of the project without being penalised or disadvantaged in any way.

3) I understand that any data that the researcher extracts from the interview / focus group for use in reports or published findings will not, under any circumstances, contain names or identifying characteristics.

4) I understand that I will be given a transcript of data concerning me for my approval before it is included in the write up of the research.

5) I understand that any information I provide is confidential, and that no information that could lead to the identification of any individual will be disclosed in any reports on the project, or to any other party.

6) I understand that data from the focus group/ transcript/ audio-tape will be kept in a secure storage and accessible to the research team. I also understand that the data will be destroyed after a 5 year period unless I consent to it being used in future research.

Participant's name: _____

Signature: _____ Date: _____

Please return the consent form in the reply paid envelope to Edwin Tan, Monash University, 381 Royal Parade, Parkville, VIC 3052; or fax to (03) 9903 9629; or email to edwin.tan@monash.edu

Thanks for your participation!

APPENDIX 3

CHAPTER 5: ETHICS APPROVAL FOR PIPS

MONASH University

Standing Committee on Ethics in Research Involving Humans (SCERH)
Research Office

Human Ethics Certificate of Approval

Date:	**1 April 2008**
Project Number:	**2008000201 - CF08/0429**
Project Title:	**A team approach for optimising medication outcomes in primary care**
Chief Investigator:	**Dr Johnson George**
Approved:	**From 1 April 2008 to 1 April 2013**

Terms of approval

1. Approval is only valid whilst you hold a position at Monash University.
2. It is the responsibility of the Chief Investigator to ensure that all pending information (such as permission letters from organisations) is forwarded to SCERH. Research cannot begin at an organisation until SCERH receives a permission letter from that organisation.
3. It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by SCERH.
4. You should notify SCERH immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
5. The Explanatory Statement must be on Monash University letterhead and the Monash University complaints clause must contain your project number.
6. **Amendments to the approved project:** Requires the submission of a Request for Amendment form to SCERH and must not begin without written approval from SCERH. Substantial variations may require a new application.
7. **Future correspondence:** Please quote the project number and project title above in any further correspondence.
8. **Annual reports:** Continued approval of this project is dependent on the submission of an Annual Report. This is determined by the date of your letter of approval.
9. **Final report:** A Final Report should be provided at the conclusion of the project. SCERH should be notified if the project is discontinued before the expected date of completion.
10. **Monitoring:** Projects may be subject to an audit or any other form of monitoring by SCERH at any time.
11. **Retention and storage of data:** The Chief Investigator is responsible for the storage and retention of original data pertaining to a project for a minimum period of five years.

[redacted]

Professor Ben Canny
Chair, SCERH

Cc: Prof Colin Burton Chapman; Dr Jane Elizabeth Opie; Mr Gregory Weeks; Ms Susan Stewart

Postal – Monash University, Vic 3800, Australia
Building 3E, Room 111, Clayton Campus, Wellington Road, Clayton
Telephone +[redacted] Facsimile +61 3 9905 1420
Email [redacted] www.monash.edu/research/ethics/human/index.html
ABN 12 377 614 012 CRICOS Provider #00008C

APPENDIX 4

CHAPTER 5: WINDERMERE FOUNDATION GRANT FOR PIPS

THIS AGREEMENT is made this 17th day of December 2007

BETWEEN: Windermere Foundation Limited (ACN 004 990 827)
Level 2, 306 Little Collins Street, Melbourne Vic 3000 (**"Windermere Foundation"**)

AND **Monash University** (**"Grantee"**)

AWARD OF GRANT

Windermere Foundation has agreed to make a grant of $15,000 during 2008 ('the Grant') to the Grantee for **"A team approach for optimising medication outcomes in primary care"** being the project described in the application from the Grantee and approved by Windermere Foundation ('the Application').

TERMS AND CONDITIONS OF THE GRANT

1 GRANTEE'S OBLIGATIONS

1.1 General obligations

The Grantee undertakes that it will:

(a) apply the whole of the Grant for the purposes outlined in the Application;

(b) only vary the substance of the Application with the prior approval of Windermere Foundation;

(c) if the project has not commenced prior to the Grantee being notified of the award of the Grant, commence the project within three months from the time of receipt of the Grant;

(d) complete the project for which the Grant is given within the period specified in the Application;

(e) acknowledge the assistance of Windermere Foundation in appropriate display or published material arising from the project; and

(f) expend the Grant only within Victoria.

1.2 Progress report

If requested by Windermere Foundation, the Grantee will provide Windermere Foundation at the halfway point of the project with a brief summary of the progress of the project and a statement of the expenditure of the Grant.

1.3 Completion

Within three months of completion of the project the Grantee will provide Windermere Foundation with a brief report on the results of the project. This report will contain:

(a) a description of the project's aim, processes and outcomes, including an evaluation of the project as a whole;

(b) copies of any publications or products developed in the course of the project; and

(c) a signed and dated financial statement showing expenditure of the Grant.

In addition, the Grantee will provide Windermere Foundation Limited copies of any subsequent publications arising from the Grant as they go to press.

2 INDEMNIFICATION

The Grantee indemnifies Windermere Foundation, its officers, employees and agents (the 'indemnified') against all liability, costs, loss and damage of any kind arising directly or indirectly from any claim, action or proceeding against the indemnified arising directly or indirectly in relation to the project.

3 ETHICS

3.1 Conduct of research

All research carried out with funding from the Grant will be conducted:

(a) for research involving humans, in accordance with the National Health and Medical Research Council's 'National Statement on Ethical Conduct in Research involving Humans';

(b) for research involving animals, in accordance with the 'Australian Code of Practice for the Care and Use of Animals for Experimental Purposes'; and

(c) for research that requires clearances from the Grantee's ethics committee, or another ethics committee, in accordance with the approval of the ethics committee.

3.2 Clearances

Funding under the Grant will not be released until all required clearances or approvals have been received and a copy of the clearance certification has been provided to Windermere Foundation. Provisional clearances or approvals will not be accepted.

4 INSURANCE

The Grantee must effect and maintain the following types of insurance as long as any obligations remain in connection with this Agreement:

(a) workers' compensation in the amount required by Victorian legislation;

(b) public liability insurance of $10 million; and

(c) professional indemnity insurance of not less than $5 million.

5 TAXES

All taxes, duties and government charges imposed or levied in connection with this agreement will be paid by the Grantee, or as the Grantee might arrange.

6 TERMINATION FOR DEFAULT

6.1 Termination

A Grant will be terminated if the Grantee does not observe the conditions of the Grant (and set out in this Agreement or in the Application).

6.2 Repayment of Grant

When a Grant is terminated under clause 6.1, the Grantee at the request of Windermere Foundation will immediately:

(a) return to Windermere Foundation any unexpended portion of the Grant; and

(b) remit to Windermere Foundation an amount equivalent to the portion of the Grant that has been spent.

EXECUTED as an agreement

SIGNED by **Ian Leonard Evans** as authorised representative for **WINDERMERE FOUNDATION LIMITED** in the presence of:

[redacted]

Signature of witness

[redacted]

Name of witness (block letters)

[redacted]

By executing this agreement the signatory warrants that the signatory is duly authorised to execute this agreement on behalf of **WINDERMERE FOUNDATION LIMITED**

SIGNED by [redacted] as authorised representative for **MONASH UNIVERSITY** in the presence of:

[redacted]

Signature of witness

[redacted]

Name of witness (block letters)

[redacted]

By executing this agreement the signatory warrants that the signatory is duly authorised to execute this agreement on behalf of **MONASH UNIVERSITY**

Professor Maxwell L King
Acting Deputy Vice-Chancellor (Research)
Monash University

APPENDIX 5

CHAPTER 5: PARTICIPANT EXPLANTORY STATEMENT, CONSENT FORM AND RECRUITMENT MATERIALS

MONASH University
Pharmacy and Pharmaceutical Sciences

29th November 2011

Pharmacists in Practice Study (PIPS)

Explanatory Statement for Patients

This information sheet is for you to keep.

Dear participant,

My name is Edwin Tan and I am conducting a research project under the supervision of Dr Johnson George, Associate Professor Kay Stewart, and Mr Rohan Elliott towards a Doctor of Philosophy (PhD) degree at the Department of Pharmacy Practice at Monash University. This means that I will be writing a thesis which is the equivalent of a short book. I am supported by a Monash University scholarship.

Why did you choose this particular person/group as participants?
We are contacting you through the clinic staff at your general practice. We haven't obtained any of your personal details. We are approaching patients attending this general practitioner (GP) surgery who are eligible for a medicines review by a pharmacist. We are not including patients who have had a pharmacist-conducted medicines review in the last 12 months, are unavailable for follow-up for the duration of the study, are under 18 years of age and those who are unable to provide written informed consent.

What is the purpose of the research?
The aim of this study is to evaluate the role of a pharmacist working in close collaboration with the GP and other staff within the surgery to improve the quality and safe use of medicines. We are conducting this research to find out whether such a team approach could help patients to access more efficient services and get the most out of their medications. This study has been funded by the Windermere Foundation.

What are the possible benefits of participating?
We anticipate that having a pharmacist working in close collaboration with GPs in the clinic will improve use of medicines. This project could lead to policy changes resulting in funding for pharmacists to be part of the general practice team. However, we cannot guarantee any direct benefit for you from your participation in this study.

What does the research involve?
The study involves your GP firstly making a referral and appointment for you to see the study pharmacist. A research assistant employed by the research team will then contact you and get you to complete a questionnaire about your health and use of medicines. You will then meet the pharmacist at your scheduled appointment either in a private consulting room at the GP surgery or at home depending on your preference. You will be asked to complete and sign a consent form to show your agreement to participate in the study. The pharmacist will then sit with you and go through your medicines with you. You will then have a follow up appointment with your GP.

This is not a compulsory medical review and your participation is voluntary. If you decide to participate, you will be asked to provide your contact details so that you can be contacted after 3 and 6 months to schedule follow up visits or phone calls with a research assistant employed by the

research team. During your follow up visits or phone calls the research assistant will ask you to complete another questionnaire about your health and use of medicines. If needed, you may arrange additional follow up appointments with the study pharmacist during the study period.

You may also be invited to participate in an interview to provide feedback on the pharmacist services you have received. You can decline to participate in the interview.

How much time will the research take?
Your initial meeting/phone call with the research assistant could take approximately 15-30 minutes. Your meeting with the pharmacist could take approximately 30-60 minutes. Your second and third meeting/phone call with the research assistant will last approximately 15-30 minutes. The interview to provide feedback on the pharmacy service may take 10 – 15 minutes.

What inconvenience/discomfort may I experience?
You may have to come to see the pharmacist at the GP surgery and the pharmacist will ask you questions about your health and use of medicines. We do not foresee any inconvenience or discomfort for you by participating in this study other than this. You may choose to avoid answering questions which are felt too personal or intrusive.

Will I receive payment?
At completion of the study and upon submission of receipts, we will reimburse your travel expenses up to $20.00 for visits to see the pharmacist/research assistant in the GP surgery.

Can I withdraw from the research?
Being in this study is voluntary and you are under no obligation to consent to participation. However, if you do consent to participate, you may only withdraw prior to your second interview with the researcher by contacting the researchers. If you decide not to participate in this study or withdraw after you consent, you will continue to receive standard care from your General Practitioner as before.

Will my information be kept confidential?
You will be identified only by a code and only the researchers will have access to the data collected. Only group data will be used in publications and presentations and no personal details that could reveal your identity will be reported. In the course of the study, if medicine-related problems are identified, your General Practitioner will be informed.

How will data be stored?
Storage of the data collected will adhere to the University regulations and kept on University premises in a locked cupboard/filing cabinet for 5 years. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report. You may request a copy of this report by contacting the chief investigator.

Will data be used for other purposes?
Data collected as part of this study will not be used for any other purpose.

Will I have access to results of this research?
If you would like to be informed of the aggregate research finding, please contact Dr Johnson George on 03 [redacted] or fax [redacted] or e-mail [redacted] The findings are accessible for a period of five years from the date of completion of this study.

If you would like to contact the researchers about any aspect of this study, please contact:	If you have a complaint concerning the manner in which this research <insert project number here> is being conducted, please contact:
Dr Johnson George Centre for Medicine Use and Safety Victorian College of Pharmacy 381 Royal Parade Parkville; VIC 3052 [redacted] Mr Edwin Tan (PhD scholar) Monash University (Parkville Campus) Centre for Medicine Use and Safety 381 Royal Parade VIC 3052 [redacted]	Human Ethics Officer Standing Committee on Ethics in Research Involving Humans (SCERH) Building 3e Room 111 Research Office Monash University VIC 3800 [redacted]

Thank you,

[redacted]

Edwin Tan
PhD candidate
Centre for Medicine Use and Safety
Monash University

MONASH University
Pharmacy and Pharmaceutical Sciences

Pharmacists in Practice Study (PIPS)

Patient Consent Form

NOTE: This consent form will remain with the Monash University researcher for their records

I agree to take part in the Monash University research project specified above. I have had the project explained to me, and I have read the Explanatory Statement, which I keep for my records. I understand that agreeing to take part means that I am willing to:

I agree to the pharmacist reviewing my medicines ☐ Yes ☐ No

I agree to the pharmacist/researcher accessing my medical records ☐ Yes ☐ No

I agree to complete questionnaires asking me about my health and medicine use ☐ Yes ☐ No

I agree to the pharmacist discussing my treatment with my General Practitioner ☐ Yes ☐ No

I agree to make myself available for a further interview after 3 and 6 months ☐ Yes ☐ No

I agree to be contacted after 6 months for an interview to give feedback on the pharmacist service ☐ Yes ☐ No

and

I understand that my participation is voluntary, that I can choose not to participate in part or all of the project, and that I can withdraw at any stage of the project prior to the second interview without being penalised or disadvantaged in any way.

and

I understand that any data that the researcher extracts from the interview / questionnaire for use in reports or published findings will not, under any circumstances, contain names or identifying characteristics.

and

I understand that data from the interviews/questionnaires will be kept in a secure storage and accessible only to the research team. I also understand that the data will be destroyed after a 5 year period unless I consent to it being used in future research.

Participant's name: _____

Signature: _____ Date: _____

MONASH University
Pharmacy and Pharmaceutical Sciences

A TEAM APPROACH TO OPTIMISING MEDICATION OUTCOMES IN PRIMARY CARE

A PILOT STUDY

WHAT IS THIS STUDY ABOUT?

The aim of this study is to pilot test the integration of a **clinical pharmacist** into general practice. It is estimated that over 400,000 adverse drug events may be managed in general practice each year, with around 140,000 hospitalisations resulting from medication-related problems[1]. It is envisioned that by having a pharmacist working collaboratively as part of the general practice team, medication use and safety can be optimised.

WHO ARE THE RESEARCHERS?

Edwin Tan is conducting this research project under the supervision of Dr Johnson George, Associate Professor Kay Stewart, and Rohan Elliott towards a Doctor of Philosophy (PhD) degree at Monash University.

WHAT ARE THE BENEFITS OF TAKING PART?

By taking part in this pilot study, you will help to give us a better understanding of the processes and issues associated with integrating a pharmacist into the general practice. Your practice may also benefit from:

- Reduced medication-related issues in your patients leading to better medication knowledge, compliance and health outcomes (see Box 1)
- Improved staff drug knowledge and quality of prescribing
- Greater opportunities for pharmacists to be part of your team with a view to increasing team care arrangements

Box 1. Examples of Patients Who May Benefit:

- Taking multiple medications or doses
- Had significant changes to their medicines including recent discharge from hospital
- Has difficulty managing their own medicines
- Has multiple co-morbidities
- Has specific chronic diseases (e.g. diabetes, heart failure etc)

WHAT IS INVOLVED?

After extensive consultation with your team, the study protocol will be finalised in the context of your practice. Your practice staff will assist in:

- Determining the logistics of integration and the roles of the pharmacist (see Box 2)
- Identifying patients meeting the agreed upon inclusion criteria
- Providing an invitation letter along with project information and consent form to selected patients
- Facilitating the project pharmacist to see the selected patients at your surgery and liaise with you on any medication issues identified.

Box 2. Examples of Practice Pharmacist Roles:

- In-clinic medicines reviews
- Medication education sessions
- Drug information services
- Drug Use Evaluation
- Liaison with other healthcare sectors
- Disease management clinics (e.g. smoking cessation, diabetes, asthma, heart failure etc)

WHERE CAN I OBTAIN FURTHER INFORMATION?

For further information, please contact Edwin Tan on the details below

Department of Pharmacy Practice, Monash University, 381 Royal Pde, Parkville, VIC 3182
phone (03) 9903 9170 | fax 9903 9629 | edwin.tan@monash.edu

1. Second National Report on Patient Safety Improving Medication Safety, published by Australian Council for Safety and Quality in Health Care, July 2002

PHARMACISTS IN PRACTICE STUDY (PIPS)

AN INTRODUCTORY GUIDE FOR GPs
AND PRACTICE STAFF

A Team approach to Optimising Medication Outcomes in Primary Care

About the study

The aim of this study is to pilot test the integration of a **clinical pharmacist** into general practice. It is estimated that over 400,000 adverse drug events are managed in general practice each year, and that around 140,000 hospitalisations result from medication-related problems[1]. It is envisioned that by having a pharmacist working collaboratively as part of the general practice team, medication use and safety can be optimised.

The roles of the practice pharmacist

LONG PATIENT CONSULTATIONS (LPCs)

Patients requiring a full review of their medications should be referred for a long patient consultation (LPC). Patients will receive a 30-60 minute consultation with the pharmacist in a private room of the clinic (or a home visit if patients prefer or are housebound).

Prior to the interview, the pharmacist will discuss any patient health or medication-related issues with the GP or clinic staff if needed. The pharmacist will also review patient medical records, medication lists, dispensing histories and pathology results.

The pharmacist will undertake a comprehensive review of the patient's medications and assess patient adherence and knowledge of medications. The pharmacist will then provide counselling and education as needed on medication management, the use of medication devices and reinforcing lifestyle issues. The pharmacist will provide the patient with a complete medication list and refer them to their community pharmacy for adherence aids (e.g. Dosettes, administration aids) if needed.

After the consultation, the pharmacist will write a report either directly into the electronic medical record or send it via secure email. Following this, the pharmacist will discuss any patient issues with the GP, other staff and community pharmacist if needed.

GPs will also be able to claim for MBS Item 900 payments after a subsequent meeting with the patient to discuss their medication management plan.

THE RESEARCH TEAM

Edwin Tan is conducting this research project under the supervision of Dr Johnson George, Associate Professor Kay Stewart, and Rohan Elliott towards a Doctor of Philosophy (PhD) degree at Monash University.

STUDY DESIGN & DURATION

This is a multi-centre, prospective intervention study with a pre-post design and qualitative component. It will run for approximately six months from December 2011 to June 2012.

PHARMACIST CO-LOCATION

Co-location has been found to facilitate communication and collaboration. The practice pharmacist will be on-site at the clinic for two, four-hour sessions each week. They will also perform home visits outside of these hours.

1. Second National Report on Patient Safety Improving Medication Safety, published by Australian Council for Safety and Quality in Health Care. July 2002

PIPS

OUTCOMES & FOLLOW UP

LPC patients will be followed up at 3 & 6 months. The primary outcome measure is the number of medication-related problems at six months. Other outcome measures include the type & severity of medication-related problems; the number of pharmacist recommendations made & implemented; medication regimen complexity; medication adherence; and quality of life. Staff & patient satisfaction will also be assessed.

FEEDBACK

At the conclusion of the study, staff will be invited to share their experiences with working with the practice pharmacist. This may involve the completion of questionnaires and/or involvement in interviews or focus groups

PATIENT RECRUITMENT

Only patients eligible for a LPC will be recruited and consented to the study (to enable data collection and follow-up). Patients participating in SPCs, group education sessions or quality assurance programs will not be recruited or consented to the study because no specific or identifying patient data will be collected and no follow-up will be done.

SHORT PATIENT CONSULTATIONS (SPCs)

Patients who do not require a full review of their medicines, may be referred for a short patient consultation (SPC) in the clinic with the pharmacist. The SPC will last 15-30 minutes and provides an opportunity for the pharmacist to provide education and counselling on specific needs or answer patient questions. After the consultation, the pharmacist will write brief notes directly into the electronic medical record. Examples of services provided in these consultations include: new medication counselling, adherence counselling or education on device technique.

EDUCATION SESSIONS

Patients will have the opportunity to attend group education sessions covering relevant topics related to their health conditions and medication management. Groups sessions will be led by the practice pharmacist but may also be run in conjunction with other staff (e.g. allied health, nursing) as part of other chronic disease management programs.

The pharmacist may also run education sessions for practice staff, targeting topics relevant to them (e.g. new therapy or treatment protocols etc).

DRUG INFORMATION SERVICE

The practice pharmacist will provide an ongoing drug information service for the practice staff. Queries can be made to the pharmacist in person, by phone or via email. All queries will be documented and answered in a timely manner.

QUALITY ASSURANCE ACTIVITIES

The practice pharmacist will undertake a Drug Use and Evaluation (DUE) program in the clinic. A pharmacotherapeutic area of concern or importance will be identified by the pharmacist in conjunction with the GPs and clinic staff. The team will decide upon audit criteria and the pharmacist will collect and evaluate data relevant to the medication use in this area. Multifaceted strategies to improve the quality of prescribing in this area will be developed and implemented by the interdisciplinary team, and re-evaluated at the end of the study period.

PIPS

WHO TO REFER

***INCLUSION CRITERIA FOR LPC**

- USING 5 OR MORE MEDICINES
- USING 1 OR MORE MEDICINES REQUIRING THERAPEUTIC DRUG MONITORING
- USING MEDICINES FOR 3 OR MORE MEDICAL PROBLEMS
- HAD RECENT UNPLANNED HOSPITAL ADMISSION/ED VISIT
- OTHER REASON FOR BEING AT RISK OF MEDICATION MISADVENTURE (ADHERENCE ISSUES, LANGUAGE BARRIERS, MULTIPLE PRESCRIBERS ETC)

EXCLUSION CRITERIA FOR LPC

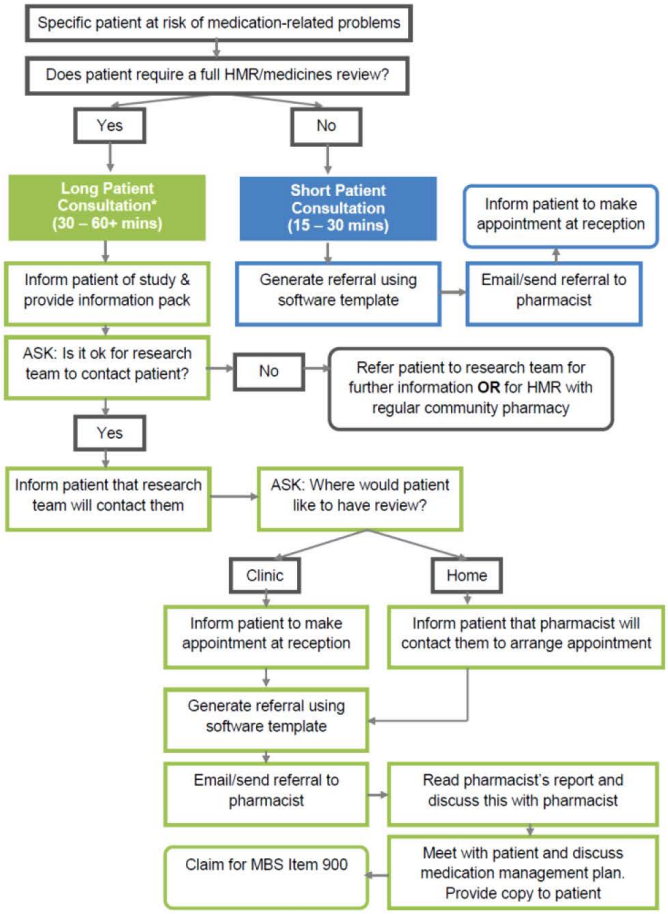
- HAD A HOME MEDICINES REVIEW (HMR) IN THE PREVIOUS 12 MONTHS WITH NO SUBSEQUENT SIGNIFICANT CHANGE IN CLINICAL STATUS OR MEDICATION REGIMEN

EXCLUSION CRITERIA FOR STUDY

- ARE UNABLE TO PROVIDE WRITTEN INFORMED CONSENT
- ARE UNDER 18 YEARS OF AGE
- UNAVAILABLE FOR FOLLOW-UP FOR THE DURATION OF THE STUDY

How to refer to the practice pharmacist

Identification and referral of patients is illustrated below. Any clinic staff and the pharmacist themselves may identify potential patients for consults, however the GP must approve & generate referrals for all LPCs. Only eligible patients (see left) may be recruited to the study and referred to the practice pharmacist for an LPC. Any patient may be referred for an SPC.



PIPS

FAQs

Are there any concerns about confidentiality or privacy to consider?
Pharmacists are bound by their code of ethics to maintain the confidentiality of information acquired in the course of practice. They must treat patients' information according to the same standards that apply to you and other team members. Pharmacists will sign any relevant confidentiality forms you require of all staff at your site.

How will the pharmacist protect patient information?
Pharmacists may maintain a separate electronic database with patient information, or keep separate charts or reports to assist them in providing clinical care. They are responsible for the safekeeping and security of all records. Electronic files will be password protected, and hard copies will be kept in a locked file when not in use. The regular processes used by all team members at your site will be followed.

How was this model of pharmacist integration into general practice chosen?
Extensive literature review and stakeholder consultation occurred to develop the current model of pharmaceutical care. Studies overseas have provided examples of successful models of integration, and interviews with Australian health professionals have offered guidance. It should be noted that this project is still largely exploratory, and hence some degree of flexibility remains.

Why does a pharmacist need a computer and internet access?
Pharmacists need an internet connection to access current drug information and be informed of any pharmaceutical issues (e.g. recalls or alerts). Additionally, the pharmacists will generate reports, answer drug information queries and access patient information electronically.

How much time should be booked for an interview or consult?
This may vary according to the complexity of the patient. Generally a LPC will last one hour, and a SPC or follow up interview will last 15-30 minutes. However, adjustments can be made. Home visits will be arranged by pharmacists themselves.

Based on iMPACT Lead Physician & Site Manager Toolkit 2006

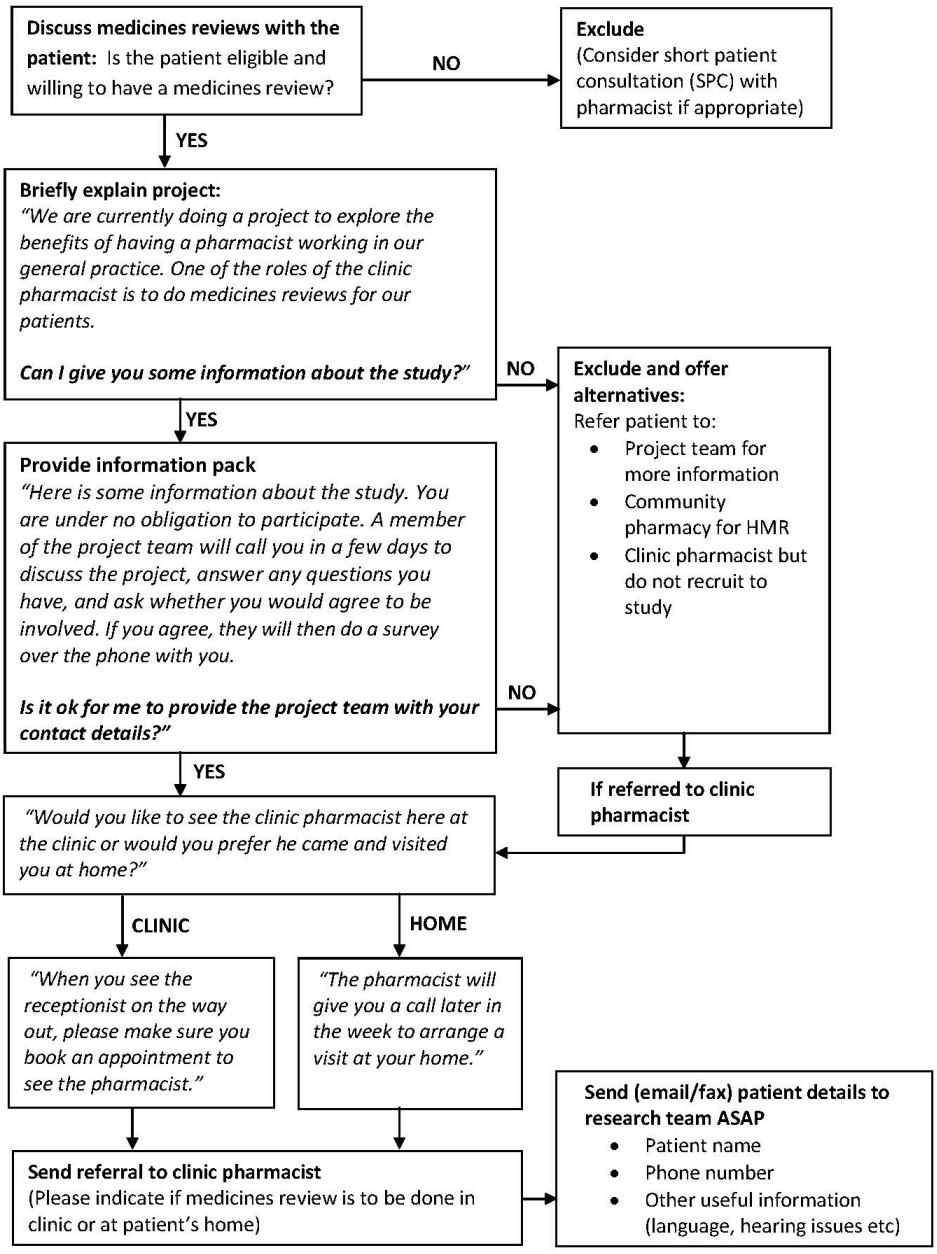
A Team Approach to Optimising Medication Outcomes in Primary Care

PIPS: Pharmacists in Practice Study

CONTACT:
Edwin Tan
Centre for Medicine Use and Safety
Monash University
381 Royal Pde
Parkville VIC 3052

Tel: (03) 9903 9170
Fax: (03) 9903 9629
Email: edwin.tan@monash.edu.au

PIPS Long Patient Consultation (LPC) Intake Protocol
GP Information



PIPS QUICK GUIDE FOR GPs

WHO TO REFER:

LONG PATIENT CONSULTATIONS (LPC) **(30-60+ minute complete medicines review)**

INCLUSION CRITERIA FOR LPC

- Using 5 or more medicines
- Using 1 or more medicines requiring therapeutic drug monitoring
- Using medicines for 3 or more medical problems
- Had recent unplanned hospital admission or emergency department visit
- Other reason for being at risk of medication misadventure (adherence issues, language barriers, multiple prescribers etc.)

EXCLUSION CRITERIA FOR LPC

- Had a home medicines review (HMR) in the previous 12 months with no subsequent significant change in clinical status or medication regimen

EXCLUSION CRITERIA FOR STUDY

- Are unable to provide written informed consent
- Are under 18 years of age
- Unavailable for follow-up for the duration of the study (6 months)

SHORT PATIENT CONSULTATIONS (SPC) **(15-30 minutes)**

Any patient may be referred for a SPC. Here are some examples of patients who may benefit:

- Suspected adverse drug event
- Adherence/ medicine taking issues
- Initiation of new medicines/changes to regimen
- Poor understanding of medicines
- Poor control of health condition(s)

IF YOU HAVE A QUESTION:

For **patient-related, drug information or clinical queries**, please contact your study pharmacist:

Philip Grasso

[redacted]

In-person at clinic:
Tuesdays 9:00am – 1:00pm
Thursdays 12:30pm – 4:30pm

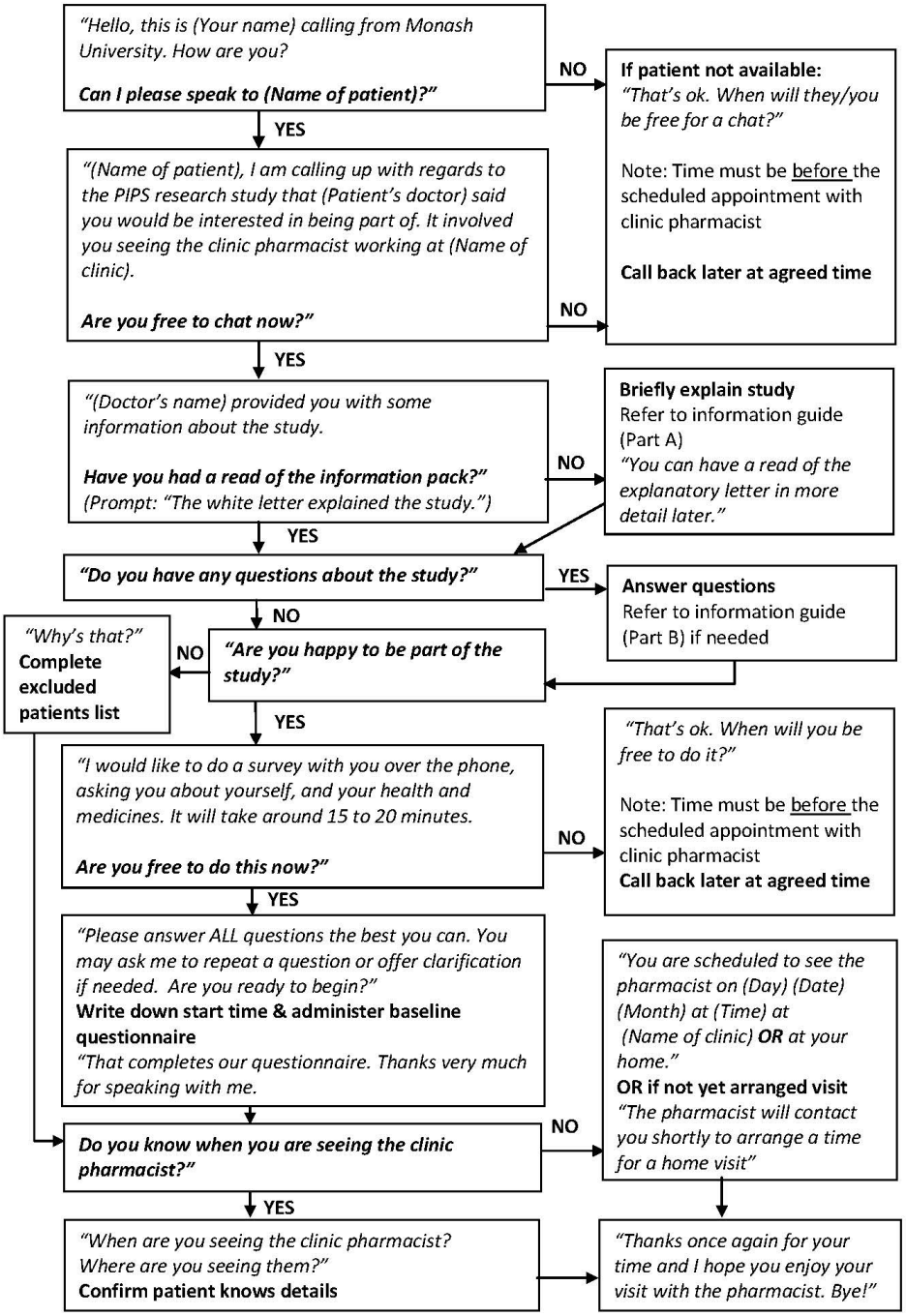
For queries about the **study**, please contact the PIPS research team:

Edwin Tan

[redacted]

Mob: 0421 315 502
In case: Johnson George (03) 9903 9178

LONG PATIENT CONSULTATION (LPC) PATIENT BASELINE PHONE INTERVIEW
SCRIPT FOR RESEARCH ASSISTANT



BRIEF STUDY INFORMATION TO EXPLAIN TO PATIENTS

PART A. Brief overview

"This study is looking at having a pharmacist working within the clinic, to help doctors and patients get the most out of their medicines. One of the roles of the pharmacist is to do a review of patients' medicines. Your doctor referred you to this study because they think you would benefit from a medicines review.

The study will involve you meeting with the clinic pharmacist, where they will sit and go through your medicines with you. The appointment will last around 30 to 60 minutes. You will then have a follow up appointment with your GP about 1-2 weeks later. Before seeing the pharmacist, you will do a survey with me, and then in 3 months and 6 months time I will repeat the survey with you. These surveys will last around 15 minutes.

Your participation in the study is voluntary. If you agree to participate in the study, you will need to sign a consent form when you see the pharmacist.

To thank you for your time, at the end of the study you will be reimbursed up to $20 for any travel costs to see the pharmacist in the clinic."

PART B. Frequently Asked Questions (adapted from explanatory statement)

– if unable to answer question, refer to Edwin or other member of research team

Why did you choose me?
Your GP gave us your contact details because he or she thought you would benefit from a medicines review.

What is the purpose of the research?
The aim of this study is to evaluate the role of a pharmacist working in collaboration with the GP and other staff within the surgery to improve the use of medicines. We are conducting this research to find out whether such a team approach could help patients to access more efficient services and get the most out of their medications.

What are the possible benefits of participating?
You can benefit from a pharmacist who can spend time with you going through your medicines. This can lead to you having a better understanding of your medicines so you are taking them safely and with confidence. This project could also lead to policy changes resulting in funding for pharmacists to be part of the general practice team.

What does the research involve?
The study involves your GP firstly making a referral and appointment for you to see the study pharmacist. A research assistant, that's me, employed by the research team will then contact you and get you to complete a questionnaire about your health and use of medicines. You will then meet the pharmacist at your scheduled appointment either in a private consulting room at the GP surgery or at home depending on your preference. You will be asked to complete and sign a consent form to show your agreement to participate in the study. The pharmacist will then sit with you and go through your medicines with you. You will then have a follow up appointment with your GP.

Your participation is voluntary. If you decide to participate, you will be asked to provide your contact details so that you can be contacted after 3 and 6 months to schedule follow up visits or phone calls with a research assistant employed by the research team. During your follow up visits or phone calls

the research assistant will ask you to complete another questionnaire about your health and use of medicines. If needed, you may arrange additional follow up appointments with the study pharmacist during the study period.

You may also be invited to participate in an interview to provide feedback on the pharmacist services you have received. You can decline to participate in the interview, but still get the pharmacist to go through your medicines.

How much time will the research take?
Your initial meeting/phone call with the research assistant could take approximately 15-30 minutes. Your meeting with the pharmacist could take approximately 30-60 minutes. Your second and third meeting/phone call with the research assistant will last approximately 15-20 minutes. The interview to provide feedback on the pharmacy service may take 15-30 minutes.

What inconvenience/discomfort may I experience?
You may have to come to see the pharmacist at the GP surgery and the pharmacist will ask you questions about your health and use of medicines. We do not foresee any inconvenience or discomfort for you by participating in this study other than this. You may choose to avoid answering questions which are felt too personal or intrusive.

Will I receive payment?
At completion of the study and upon submission of receipts, we will reimburse your travel expenses up to $20.00 for visits to see the pharmacist/research assistant in the GP surgery.

Can I withdraw from the research?
Being in this study is voluntary and you are under no obligation to consent to participation. However, if you do consent to participate, you may only withdraw prior to your second phone interview with the researcher* by contacting the researchers. If you decide not to participate in this study or withdraw after you consent, you will continue to receive standard care from your General Practitioner as before. *(*wording in explanatory statement is different)*

Will my information be kept confidential?
Information about you will be identified only by a code, The research team will not record your name, address or other identifying information. Only the researchers will have access to the data collected. Only group data will be used in publications and presentations and no personal details that could reveal your identity will be reported. In the course of the study, if medicine-related problems are identified, your General Practitioner will be informed.

How will data be stored?
Storage of the data collected will adhere to the University regulations and kept on University premises in a locked cupboard/filing cabinet for 5 years. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report. You may request a copy of this report by contacting the chief investigator.

Will data be used for other purposes?
Data collected as part of this study will not be used for any other purpose.

Will I have access to results of this research?
If you would like to be informed of the aggregate research finding, please contact Dr Johnson George on [redacted] or e-mail [redacted] The findings are accessible for a period of five years from the date of completion of this study.

APPENDIX 6

CHAPTER 5: BASELINE AND FOLLOW UP QUESTIONNAIRES

Baseline telephone survey

PATIENT BASELINE QUESTIONNAIRE ***PIPS STUDY***		
Study ID:	**Date:** **Start time:**	**Data collected by:**

SECTION A: Questions about you in general

The following questions are about you and your background in general.

1. What is your age in years? _____ ***(OR year of birth if can't remember)***
2. What is your sex? ☐ Male ☐ Female ***(May be pre-filled by interviewer)***
3. In which country were you born? _____
4. Are you of Aboriginal or Torres Strait Islander origin?
   - ☐ No
   - ☐ Yes, Aboriginal *(go to question 6)*
   - ☐ Yes, Torres Strait Islander *(go to question 6)*
5. What is your ethnic background (you can select several options)?
   - ☐ Australian ***(Do not need to read out options. Just use as prompts if needed)***
   - ☐ Chinese
   - ☐ English
   - ☐ German
   - ☐ Greek
   - ☐ Indian
   - ☐ Irish
   - ☐ Italian
   - ☐ Maori
   - ☐ Polynesian/Pacific Islander
   - ☐ Scottish
   - ☐ Other, specify _____
6. What is your current living arrangement?
   - ☐ Home alone
   - ☐ Home with others
   - ☐ Other, specify _____
7. What language do you speak mostly at home?
   - ☐ English
   - ☐ Other, specify _____
8. What is the highest level of education you have completed? ***(if unsure, write down their qualification/certificate etc)***
   - ☐ No formal schooling
   - ☐ Primary school
   - ☐ Secondary education (part)
   - ☐ Secondary education (completed yr 12)
   - ☐ Vocational training (TAFE/VET)
   - ☐ University education

Baseline telephone survey

9. Do you have an Australian Healthcare concession card?
   - ☐ No
   - ☐ Yes ➔ Which type?
     - ☐ Healthcare card
     - ☐ Pensioner concession card
     - ☐ Commonwealth Seniors Health card
     - ☐ Repatriation Pharmaceutical Benefits card

SECTION B: Questions about your use of health services

The following questions are about your use of health services.

1. Have you ever had a pharmacist-conducted medication review (where a pharmacist sat down with you for at least half an hour to discuss all your medicines and check for side effects and interactions)?
   ☐ No ☐ Yes ➔ When was the last review? _____

2. In the last 6 months, how many times have you seen a:

   a) Doctor _____ ***(includes GPs, specialists etc)***
   b) Nurse _____
   c) Pharmacist _____ ***(includes community/ hospital pharmacist, collecting scripts etc)***

3. In the last 6 months, how many times have you been admitted to a hospital unexpectedly or visited an emergency department? _____
   (prompt: unplanned, taken by ambulance etc)

The following is a list of statements about your use of health services. Please tell us about how often these apply to you. You may choose from five (5) options: never, rarely, sometimes, often or always.

	Never	Rarely	Sometimes	Often	Always
4. When you collect your prescriptions, how often does your community pharmacist speak to you about your medicines?					
5. How often do you have someone help you read health materials?					
6. Are you confident filling out medical forms by yourself?					
7. How often do you have problems learning about your medical condition because of difficulty understanding written information?					

Baseline telephone survey

SECTION C: Questions about your medicines

The following questions are about your medicines. Please answer 'yes' or 'no'.

1. Do you currently take 5 or more medications?

   ☐ Yes ☐ No

2. Do you take 12 or more medication doses each day?

   ☐ Yes ☐ No

3. Do you take any of the following medications: ***(Use brand names as prompts if needed)***
   - carbamazepine *(Tegretol)*
   - lithium *(Lithicarb or Quilonum)*,
   - phenytoin (*Dilantin)*,
   - warfarin (*Coumadin or Marevan)*,
   - digoxin (*Lanoxin)*
   - theophylline *(Nuelin)*?

   ☐ Yes ☐ No

4. Does more than 1 doctor prescribe medications for you on a regular basis?

   ☐ Yes ☐ No

5. Are you currently taking medications for 3 or more medical problems?

   ☐ Yes ☐ No

6. Do you get your prescriptions filled at more than 1 pharmacy?

   ☐ Yes ☐ No

7. Does someone else bring any of your medications to your home for you?

   ☐ Yes ☐ No

8. Is it difficult for you to follow your medication regimen or do you sometimes choose not to?

   ☐ Yes ☐ No

9. Have your medications or the instructions on how to take them been changed in the past 3 months?

   ☐ Yes ☐ No

10. Are there any medicines that you do not know why you are taking?

    ☐ Yes ☐ No

Baseline telephone survey

SECTION D: Questions about your medicine taking

The following questions are about your medicine taking. Please answer 'yes' or 'no'.

1. Do you ever forget to take your medicine?
   ☐ Yes ☐ No
2. Are you careless at times about taking your medicine?
   ☐ Yes ☐ No
3. When you feel better do you sometimes stop taking your medicine?
   ☐ Yes ☐ No
4. Sometimes if you feel worse when you take the medicine, do you stop taking it?
   ☐ Yes ☐ No

The following is a list of statements about your medicine taking. Please tell us about how often these apply to you. You may choose from five (5) options: never, rarely, sometimes, often or always.

	Never	Rarely	Sometimes	Often	Always
5. I have strict routines for using my medication					
6. I keep my medications close to where I need to use them					
7. I ensure I have enough medications so that I do not run out					
8. I strive to follow the instructions of my doctors					
9. I get confused about my medications					
10. I make changes in the recommended management to suit my lifestyle					
11. I vary my recommended management based on how I am feeling					
12. I put up with my medical problems before taking any action					

13. How would you rate the difficulty using or taking ALL your medicines as prescribed on a scale of 1 (very simple) to 5 (very complex)?

(Very simple) 1---------2---------3---------4---------5 (Very complex)

Baseline telephone survey

SECTION E: General health

In general, would you say your health is:

Excellent 1

Very good 2

Good 3

Fair 4

or Poor 5

SECTION F: Your expectations about the visit

Lastly, with regards to your visit to the clinic pharmacist:

1. What do you expect to get out from your visit with the clinic pharmacist?
(prompts if needed:
- ***What are your thoughts on seeing the pharmacist in the clinic?***
- ***What would you like the pharmacist to do for you?)***

Please write patient response below (try and get exact "quotes" if possible):

Baseline telephone survey

END OF QUESTIONS

That completes our survey. Thank you very much for speaking with me.

Do you know when you are seeing the clinic pharmacist?

☐ Yes ➔ When? Confirm correct day and time ➔ Where? Confirm correct venue

☐ No ➔ Tell patient the day, time and venue of the pharmacist consultation if known

➔ *OR* pharmacist will contact them shortly to arrange a time

Thanks once again for your time and I hope you enjoy your visit with the pharmacist.

Research Assistant Notes:

Finish time: _____

3-month telephone survey

PATIENT 3-MONTH FOLLOW UP QUESTIONNAIRE ***PIPS STUDY***		
Study ID:	**Date:** **Start time:**	**Data collected by:**

Prior to phone interview:

- Have LPC report &/or MRP record form ready
- Complete the Issue & GP columns of the MRP Table below

SECTION A: Questions about your medicines review

About 3 months ago, you had an appointment with the pharmacist.

1. Did your GP discuss the findings from the pharmacist interview with you?
   ☐ Yes ☐ No

2. Have any of your medicines changed as a result of the pharmacist interview?
   ☐ Yes ☐ No ➔ *Verify with MRP Table & clarify if necessary*
   ↓
   2.a What changes have been made? (*Verify with MRP Table & clarify if necessary)*

MRP Table (From LPC Report/ MRP form)

At Baseline	**By 3 months**		
MRP/Issue & recommendation *Describe briefly*	**GP accepted recommendation**	**Recommendation implemented**	
	According to GP	**According to GP**	**According to patient**
☐ No MRPs present			
MRP 1	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
MRP 2	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
MRP 3	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
MRP 4	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
MRP 5	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
MRP 6	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
MRP 7	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

3-month telephone survey

3. Has the way you take or manage your medicines changed?
☐ Yes ☐ No
↓
3a. What has changed?

Use of **adherence aids**:
☐ Medicines list
☐ Alarm beeper
☐ Calendar
☐ Diary
☐ Medicines box/Dosette/Webster
Packed by: ☐ Self ☐ Community pharmacy ☐ Carer/partner ☐ Other:_____
☐ Other (specify) _____

Use of **dose administration aids**:
☐ Eye drop aid
☐ Inhaler aid
☐ Pill cutter
☐ Blood pressure monitor
☐ Blood glucose monitor
☐ Other (specify) _____

SECTION B: Questions about your use of health services

The following questions are about your use of health services.

1. In the last 3 months, how many times have you seen a:

a) Doctor _____ ***(includes GPs, specialists etc)*** b) Nurse _____ c) Pharmacist _____ ***(includes community/ hospital, collecting scripts)***

2. In the last 3 months, how many times have you been admitted to a hospital unexpectedly or visited an emergency department? _____
(prompt: unplanned, taken by ambulance etc)

3-month telephone survey

SECTION C: Questions about your medicine taking (Adherence)

The following questions are about your medicine taking **in the last 3 months**. Please answer 'yes' or 'no'.

1. Do you ever forget to take your medicine?
   ☐ Yes ☐ No
2. Are you careless at times about taking your medicine?
   ☐ Yes ☐ No
3. When you feel better do you sometimes stop taking your medicine?
   ☐ Yes ☐ No
4. Sometimes if you feel worse when you take the medicine, do you stop taking it?
   ☐ Yes ☐ No

The following is a list of statements about your medicine taking **in the last 3 months**. Please tell us about how often these apply to you. You may choose from five (5) options: never, rarely, sometimes, often or always.

	Never	Rarely	Sometimes	Often	Always
5. I have strict routines for using my medication					
6. I keep my medications close to where I need to use them					
7. I ensure I have enough medications so that I do not run out					
8. I strive to follow the instructions of my doctors					
9. I get confused about my medications					
10. I make changes in the recommended management to suit my lifestyle					
11. I vary my recommended management based on how I am feeling					
12. I put up with my medical problems before taking any action					

13. How would you rate the difficulty using or taking ALL your medicines as prescribed on a scale of 1 (very simple) to 5 (very complex)?

(Very simple) 1---------2---------3---------4---------5 (Very complex)

3-month telephone survey

SECTION D: General health

In general, would you say your health is:

Excellent 1

Very good 2

Good 3

Fair 4

or Poor 5

END OF QUESTIONS

- That completes our survey. Thank you very much for speaking with me.
- Did you have any questions regarding the study?
- I will give you a call in 3 months time to repeat the survey.

Research Assistant Notes:

Finish time: _____

6-month telephone survey

PATIENT 6-MONTH FOLLOW UP QUESTIONNAIRE ***PIPS STUDY***		
Study ID:	**Date:** **Start time:**	**Data collected by:**

Prior to phone interview:

- Have LPC report &/or MRP record form ready
- Complete the Issue & GP columns of the MRP Table below

SECTION A: Questions about your medicines review

About 6 months ago, you had an appointment with the pharmacist.

1. If **no MRPs**, then go straight to **Section B**

2. If **MRPs** identified at 3 months:
I want to check whether the medication issues we talked about last time I spoke with you (3 months ago) are still the same:
The pharmacist recommended...

MRP Table (From LPC Report/ MRP form)

At Baseline	**By 6 months**		
MRP/Issue & recommendation *Describe briefly*	**GP accepted recommendation**	**Recommendation implemented**	
	According to GP	**According to GP**	**According to patient**
☐ No MRPs present			
MRP 1	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
MRP 2	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
MRP 3	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
MRP 4	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
MRP 5	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
MRP 6	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
MRP 7	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

6-month telephone survey

3. Has the way you take or manage your medicines changed?
☐ Yes ☐ No
↓
3a. What has changed?

Use of **adherence aids**:
☐ Medicines list
☐ Alarm beeper
☐ Calendar
☐ Diary
☐ Medicines box/Dosette/Webster
Packed by: ☐ Self ☐ Community pharmacy ☐ Carer/partner ☐ Other:_____
☐ Other (specify) _____

Use of **dose administration aids**:
☐ Eye drop aid
☐ Inhaler aid
☐ Pill cutter
☐ Blood pressure monitor
☐ Blood glucose monitor
☐ Other (specify) _____

SECTION B: Questions about your use of health services

The following questions are about your use of health services.

1. In the last 3 months, how many times have you seen a:

a) Doctor _____ ***(includes GPs, specialists etc)*** b) Nurse _____ c) Pharmacist _____ ***(includes community/ hospital, collecting scripts)***

2. In the last 3 months, how many times have you been admitted to a hospital unexpectedly or visited an emergency department? _____
(prompt: unplanned, taken by ambulance etc)

6-month telephone survey

SECTION C: Questions about your medicine taking (Adherence)

The following questions are about your medicine taking **in the last 3 months**. Please answer 'yes' or 'no'.

1. Do you ever forget to take your medicine?
   ☐ Yes ☐ No
2. Are you careless at times about taking your medicine?
   ☐ Yes ☐ No
3. When you feel better do you sometimes stop taking your medicine?
   ☐ Yes ☐ No
4. Sometimes if you feel worse when you take the medicine, do you stop taking it?
   ☐ Yes ☐ No

The following is a list of statements about your medicine taking **in the last 3 months**. Please tell us about how often these apply to you. You may choose from five (5) options: never, rarely, sometimes, often or always.

	Never	Rarely	Sometimes	Often	Always
5. I have strict routines for using my medication					
6. I keep my medications close to where I need to use them					
7. I ensure I have enough medications so that I do not run out					
8. I strive to follow the instructions of my doctors					
9. I get confused about my medications					
10. I make changes in the recommended management to suit my lifestyle					
11. I vary my recommended management based on how I am feeling					
12. I put up with my medical problems before taking any action					

13. How would you rate the difficulty using or taking ALL your medicines as prescribed on a scale of 1 (very simple) to 5 (very complex)?

(Very simple) 1---------2---------3---------4---------5 (Very complex)

6-month telephone survey

SECTION D: General health

In general, would you say your health is:

Excellent 1

Very good 2

Good 3

Fair 4

or Poor 5

END OF QUESTIONS

- That completes our survey. Thank you very much for speaking with me.
- Did you have any questions regarding the study?
- That's our final survey. Thanks for taking part in this study.

Research Assistant Notes:

Finish time: _____

PIPS PATIENT SATISFACTION QUESTIONNAIRE

1. What did you see the clinic pharmacist for?
   - ☐ Medicines review in the clinic
   - ☐ Medicines review at home
   - ☐ One-to-one education/information session
   - ☐ Group education session
   - ☐ Other _____

2. What is your age in years? _____ 3. What is your sex? ☐ Male ☐ Female

4. Who referred you to the clinic pharmacist?
   ☐ GP ☐ Nurse ☐ Other: _____ ☐ Don't know

The following is a list of items about your views on this visit you made to the pharmacist. For each item please (✓) the box that is nearest your opinion. Please answer all of them. *Neutral* means you have no feelings either way.

Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
I am totally satisfied with my visit to this pharmacist					
This pharmacist told me everything about my treatment					
Some things about my consultation with the pharmacist could have been better					
This pharmacist was interested in me as a person, not just my illness					
I understand my illness much better after seeing this pharmacist					
I felt this pharmacist really knew what I was thinking					
I wish it had been possible to spend a little more time with the pharmacist					
I would find it difficult to tell this pharmacist about some private things					
I would like a pharmacist to be available in the clinic in the future					

Any other comments about your visit to the pharmacist:

Please return the completed survey to the research assistant, pharmacist or other clinic staff in person, or mail it back in the reply-paid envelope at your earliest convenience.

APPENDIX 7

CHAPTER 5: OTHER PROMOTIONAL MATERIALS

THE CLINIC PHARMACIST IS IN TODAY

SERVICES PROVIDED:

- Medicines reviews
- Medicines information
- Device use assessment (including asthma puffers & monitors)
- Healthy lifestyle advice
- Italian speaking

PLEASE ASK ABOUT A FREE CONSULTATION

MONASH University

West Brunswick Clinic
YOUR HEALTH CARE TEAM

HAVE A QUESTION ABOUT YOUR MEDICINES?
ASK OUR CLINIC PHARMACIST

OUR ONSITE PHARMACIST CAN HELP YOU GET THE MOST OUT OF YOUR MEDICINES.

THIS IS A **FREE SERVICE** AVAILABLE
FRIDAYS 8:30AM TO 4:30PM
PLEASE ASK AT RECEPTION

MONASH University

DouttaGalla CommunityHealth

(PRESENTED AS POSTCARD AND POSTER FORMATS)

APPENDIX 8

CHAPTER 5: PHARMACIST RECORD FORMS

PIPS DRUG INFORMATION QUERY RECORD FORM

Requested by: ☐ GP ☐ Nurse ☐ Other: _____		Date/time of Query: Date/time required:
Name of enquirer:		Date/time answered:
Method of enquiry: ☐ Phone ☐ Email ☐ In-person	Method of reply ☐ Phone ☐ Email ☐ In-person	Query type: ☐ Patient-related ☐ General enquiry

Query:

Answer*:

Resources used:

☐ Own knowledge/experience

☐ References (please specify): _____

☐ Other:_____

Other information:

Notes:

*Only complete this field for your own records if you wish

PIPS SHORT PATIENT CONSULTATION (SPC) RECORD FORM

Patient Name*:	Date of consultation:
Date of birth:	Start time:
GP name:	End time:

Referred by:
☐ GP
☐ Nurse
☐ Other: _____

Reason for consultation:

Pharmacist interventions provided:

Recommendations:
☐ No further action needed

☐ Practice pharmacist follow-up of patient
☐ Phone ☐ In-person When: _____

☐ Refer to: _____
For:

Other information:

Community pharmacy details:	Phone: Fax:
Notes:	

*Please de-identify copies of completed forms prior to giving to research team

APPENDIX 9

CHAPTER 8: DATA COLLECTION FORM

Date: _____ **Initials:** _____
Clinic: WBC/DGCHS

OSTEOPOROSIS DUE DATA COLLECTION TOOL

Patient clinic code: _____ **Age:** _____ **Gender:** ☐ male ☐ female

Osteoporosis diagnosis? ☐ no ☐ yes, date: _____

Low trauma fracture (or suspected or confirmed vertebral fracture)

since age 50? ☐ no ☐ yes, site(s): _____ date: _____
site(s): _____ date: _____

BMD Scan? ☐ no ☐ yes, date of latest: _____ ☐ Previous scans done

T score (femoral neck): _____ T score (vertebrae): _____

BMD (femoral neck): _____ BMD (vertebrae): _____

Vitamin D level? ☐ no ☐ yes, date of latest: _____ ☐ Previous levels taken

Result: _____

Drug Therapy

Is the patient currently using anti-osteoporotic drug therapy?
☐ yes ☐ no

Current anti-osteoporotic drug therapy:

☐ alendronate (Alendro, Fosamax)
☐ risedronate (Actonel)
☐ zoledronic acid (Aclasta)
☐ etidronate (Dicrocal)
☐ raloxifene (Evista)
☐ denosumab (Prolia)
☐ strontium (Protos)
☐ calcitriol
☐ hormone replacement therapy (oestrogen/ progestogen)
☐ teriparatide (Forteo)
☐ other (specify): _____

Treatment started: ☐ ≤ 6 months ago ☐ > 6 months ago ☐ unknown

If no,

Previous anti-osteoporotic drug therapy:	**Cease date:**	**Reason for ceasing:**
_____	_____	_____
_____	_____	_____

Potential precautions and contraindications to anti-osteoporotic drug therapies:

☐ ADR to anti-osteoporotic drug (specify drug & reaction:_____)
☐ oesophageal disorders (active oesophagitis, oesophageal ulceration, stricture, achalasia)
☐ risk of osteonecrosis of jaw (history of dental surgery or trauma, cancer, chemotherapy, radiotherapy, corticosteroid treatment, poor oral hygiene, anaemia, periodontal disease)

Date: _____ **Initials:** _____
Clinic: WBC/DGCHS

Continued from previous:

- ☐ oestrogen-dependent tumour (e.g. breast or endometrial cancer)
- ☐ hypocalcaemia
- ☐ urolithiasis
- ☐ pregnancy or breastfeeding
- ☐ history of breast cancer
- ☐ severe hepatic impairment
- ☐ phenylketonuria
- ☐ hyperparathyroidism
- ☐ concurrent use of NSAIDs
- ☐ skeletal malignancies
- ☐ osteomalacia
- ☐ inability to sit upright for at least 30 minutes
- ☐ history or risk of venous thromboembolism (VTE)
- ☐ with or risk of coronary heart disease
- ☐ renal impairment (CrCl/eGFR: _____)
- ☐ Paget's disease of bone
- ☐ upper GI conditions (e.g. dysphagia, gastritis)
- ☐ history of skeletal radiation treatment
- ☐ unexplained increases in alkaline phosphatase levels

Risk factor assessment

Drugs associated with osteoporosis:

- ☐ corticosteroids (drug, dose & duration: _____)
- ☐ anti-androgens (e.g. cyproterone)
- ☐ thyroxine (excessive dose)
- ☐ loop diuretics
- ☐ thiazolidinediones
- ☐ proton pump inhibitors
- ☐ long-term heparin
- ☐ aromatase inhibitors (e.g. anastrozole, exemestane, letrozole)
- ☐ selective serotonin reuptake inhibitors (SSRI's)
- ☐ anti-epileptics (phenytoin, carbamazapine, primidone, valproate)

Medical conditions associated with osteoporosis:

- ☐ Rheumatoid arthritis
- ☐ Premature menopause (<45 years)
- ☐ Osteogenesis imperfecta in adults
- ☐ Hyperparathyroidism
- ☐ Chronic malnutrition
- ☐ Chronic renal disease
- ☐ Malabsorption syndromes (coeliac disease, gastric/bowel resection)
- ☐ Type 1 diabetes
- ☐ Sex hormone deficiency (e.g. hypogonadism)
- ☐ Hyperthyroidism (long standing & untreated)
- ☐ Cushing syndrome
- ☐ Chronic liver disease
- ☐ Weight loss (e.g. anorexia nervosa)

Other risk factors

Weight: _____ Height: _____

Family history of osteoporosis, hip fracture, minimal trauma fracture	☐ Y	☐ N	☐ Unknown
Falls in last 12 months	☐ Y	☐ N	☐ Unknown
Current smoker	☐ Y	☐ N	☐ Unknown
Alcohol intake >2 std drinks/day	☐ Y	☐ N	☐ Unknown
Inadequate physical activity	☐ Y	☐ N	☐ Unknown
Caucasian or Asian ethnicity	☐ Y	☐ N	☐ Unknown
Dark skin or covered skin for religious/cultural reasons	☐ Y	☐ N	☐ Unknown
Housebound or RACF	☐ Y	☐ N	☐ Unknown
Low calcium intake (<3 serves/day)	☐ Y	☐ N	☐ Unknown

Other risk factor/s (specify): _____

APPENDIX 10

CHAPTER 8: INTERVENTION MATERIALS FOR PATIENTS AND STAFF

VITAMIN D TABLETS FOR HEALTHY BONES

Our records show that you have bone problems **or** low levels of vitamin D, and may benefit from vitamin D tablets. Low vitamin D levels may increase your risk of bone fractures.

If you are taking vitamin D tablets, it is important that your doctor knows which **brand** and **how much** you are taking. Please let your doctor know at your next appointment.

If you are not sure whether you should be taking vitamin D tablets, please ask your doctor at your next appointment.

If you have questions about vitamin D tablets, please speak to your doctor or pharmacist.

English
March 2006

osteoporosis australia

Calcium, Vitamin D and Osteoporosis

What is osteoporosis?
Osteoporosis is a disease in which the bones become fragile and brittle. They fracture more easily than normal bone. Even a minor bump or fall can cause a serious fracture. Half of all women and one-third of men over 60 in Australia will have a fracture due to osteoporosis.

Calcium and bones
Calcium is important for building strong bones in childhood and helping protect us from developing osteoporosis later in life.

Having osteoporosis means we are more likely to fracture a bone, particularly at the wrist and hip. Osteoporosis can also cause fractures in the bones (vertebrae) of the spine. These are called 'crush' fractures and they cause the spine to shrink, making a person lose height.

In the first 30 years of life, our bones are at their strongest. Getting enough calcium is especially important in childhood and adolescence. Later in life, when the body loses calcium, there's an increased need for calcium, especially for women around menopause. As men also lose calcium as they get older, they need to get enough calcium too.

Getting enough vitamin D is important too – it helps the body absorb calcium from the diet.

Vitamin D and bones
Vitamin D deficiency in older adults can increase the risk of osteoporosis, falls and fractures.

In Australia, the main source of vitamin D is sunlight. Most people get enough vitamin D during typical day-to-day outdoor activities. To get enough sunlight for your body to make vitamin D, you need to expose your hands, face and arms (or equivalent area of skin) to sunlight for about 5-15 minutes 4-6 times a week. Elderly people and people with darker skins need more sunlight exposure – about 15 minutes 5-6 times a week.

However, it's important to stay out of the sun between 10am and 2pm in the summer months (11am-3pm in daylight saving time) because of the risks of sunburn and skin cancer. This outweighs any possible benefits from vitamin D production.

The Australian Government has provided funding to support this publication; however, the views expressed in this document are those of the authors, based on current research, and do not necessarily represent the views of the Australian Government.

Many people in Australia are deficient in vitamin D, especially older people living in residential care.

Vitamin D deficiency in children can result in rickets, a condition causing bone and muscle weakness and bone deformities. Low levels of vitamin D in adults may lead to fractures caused by osteoporosis, as well as bone and joint pain, muscle weakness and falls.

How much calcium and vitamin D do you need?

Calcium
Dairy products are a good source of calcium. There are also small amounts in other foods including breads, cereals, fruits and vegetables, fish with edible bones (e.g. tinned salmon and sardines), tahini, almonds, figs and foods fortified with calcium. If you find it difficult to get enough calcium from food ask your doctor or dietitian about taking a calcium supplement.

If you can't tolerate dairy products or don't enjoy them, there are some calcium-enriched products available such as calcium-enriched orange juice, cereals and soy milk. However calcium added to soy drinks may not be as well absorbed as from dairy foods, so you may need larger servings of soy drinks.

People need different amounts of calcium at different ages – the food table at the end of this fact sheet shows you how to get calcium from food.

- **Children (5 to 11 years)** - 2 to 3 serves of calcium rich foods each day (600-1000 mg daily from high calcium foods).
- **Adolescents (11 to 18 years)** - at least 3 serves of calcium rich foods each day (800-1000 mg daily from high calcium foods).
- **Women after menopause** -at least 3 serves of calcium rich foods each day (1000 to 1300 mg daily from high calcium foods),
- **Other adults -** at least 3 serves of calcium rich foods each day (1000 to 1300 mg daily from high calcium foods).
- **Adults over 70** - at least 3 serves of calcium rich foods each day (1300mg daily from high calcium foods).

Vitamin D
We need at least 400 to 600 IUs (international units) of vitamin D daily. If you don't get enough exposure to sunlight, you need a vitamin D supplement of at least 400 IUs daily. If you think you may be deficient in vitamin D, talk to your doctor.

Some calcium supplements and multivitamin preparations contain vitamin D, but their levels maybe too low to treat vitamin D deficiency.

There are small quantities of vitamin D in a few foods, such as fatty fish (salmon, herring and mackerel). It is also in liver, eggs and fortified foods such as margarine. There are very small amounts in some low-fat milks.

Most people are unlikely to get enough vitamin D from diet alone. Cod liver oil contains vitamin D but also vitamin A. This can be toxic in large amounts, and may even increase the risk of fracture.

Always discuss calcium or vitamin D supplements with your doctor before taking them.

Who is most at risk of vitamin D deficiency?

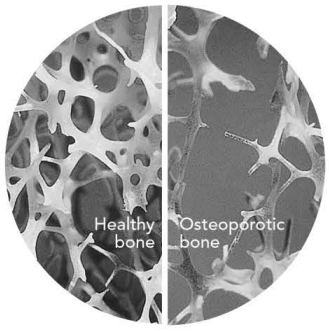
- elderly people - especially those who are housebound or in residential care
- people with certain skin conditions who need to avoid the sun
- people with dark skin
- women who wear veils and cover most of their bodies
- people with diseases which make it difficult to absorb enough vitamin D

Food	Standard Serving Size	Calcium (mg)	Kilojoules
Rump Steak (lean)	100g	5	883
Apples	1 medium (156g)	7	323
Lamb Chop (lean)	100g	8	1000
Bread – mixed grain	30g (slice)	15	272
Bread – wholemeal	30g (slice)	16	282
Chicken – roasted no skin	100g	16	783
Broccoli	60g	18	61
Strawberries	1 cup (145g)	19	118
Eggs – boiled	1 large (48g)	21	303
Baked Beans	100g	34	285
Oranges	1 medium (122g)	35	190
Apricots – dried	50g	35	410
Spinach	100g	50	80
Tahini	20g (1 tbsp)	65	520
Soy beans (boiled)	100g	76	540
Custard	100g	100	393
Almonds	50g	110	1235
Ice Cream	100g	133	800
Tofu (calcium set)*	100g	150	479
Salmon – tinned, red	100g	220	814

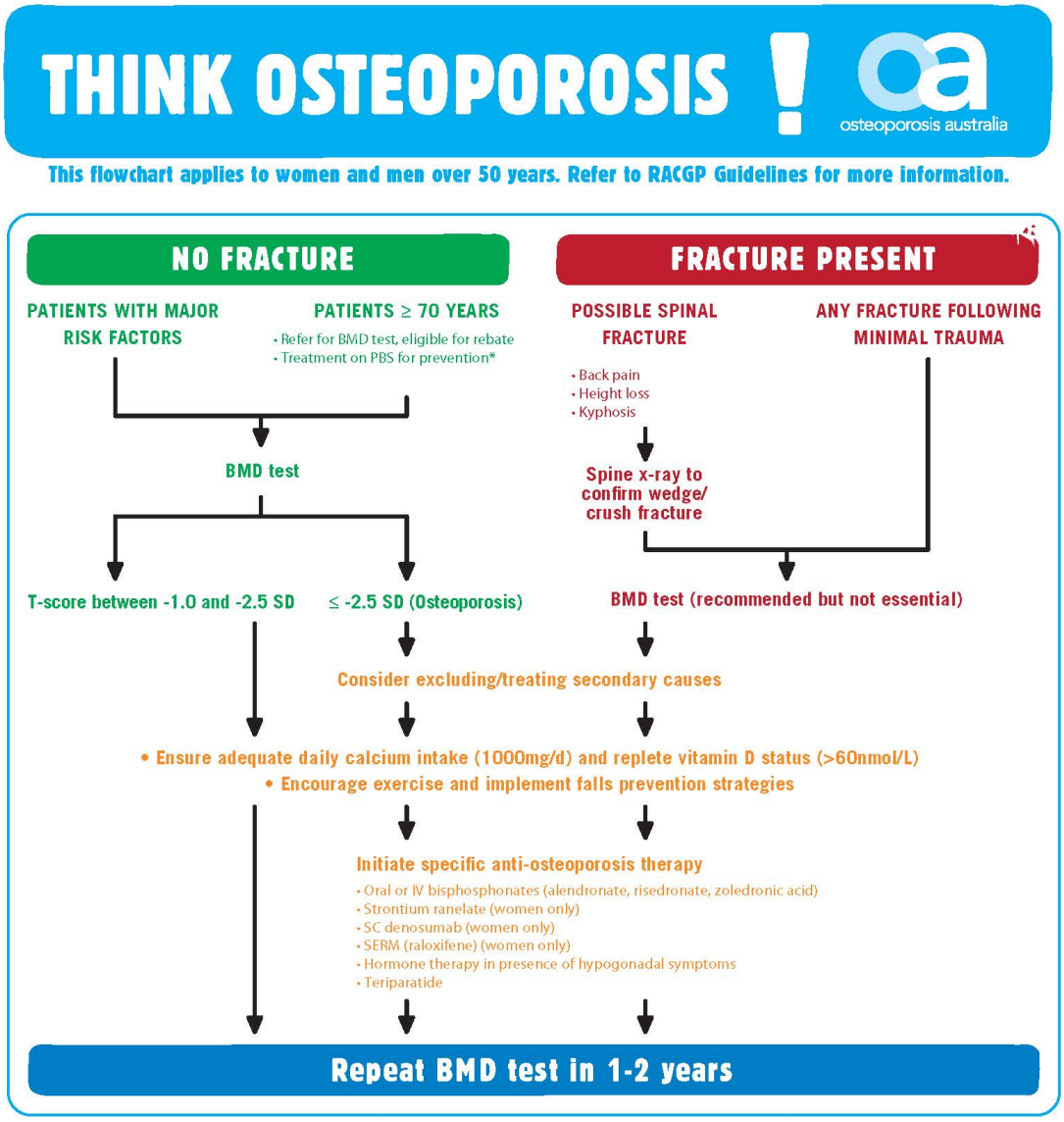
Food	Standard Serving Size	Calcium (mg)	Kilojoules
Sardines – canned	100g	380	951
Cheese	40g (piece)	300	676
Cheddar (reduced fat)	40g (2 slices)	323	548
Cheddar Cheese	40g (2 slices)	327	575
Parmesan Cheese	40g (piece)	460	740
Haloumi Cheese	40g (piece)	248	408
Feta Cheese	40g (piece)	130	468
Yogurt – Flavoured	200g (std tub)	316	738
Yogurt – Plain	200g (std tub)	390	716
Milk – Reduced Fat	250ml (std glass)	352	525
Milk – Regular	250ml (std glass)	285	698
Milk - Skim	250ml (std glass)	320	377
Milk – calcium fortified	250ml (std glass)	353	523

*Not all tofu is set with calcium – check the nutrition panel to make sure the product contains calcium, or contact the manufacturer.
* Foods such as rice, pasta, beans and lentils do not contain significant amounts of calcium.

Tip: You can add a calcium 'boost' to soups, smoothies, curries and sauces by adding skim milk powder.



Healthy bone Osteoporotic bone



*People ≥70 years with a BMD T-score ≤-2.5 or ≤-3.0 (depending on medication prescribed) can receive treatment on the PBS, without having sustained a fracture (ie for primary prevention).

- Patients of any age with osteoporosis who have sustained a minimal-trauma fracture can also receive treatment on the PBS.
- Patients on prolonged (at least 3 months), high dose (≥7.5 mg per day prednisolone or equivalent) corticosteroid treatment with a BMD T-score ≤-1.5 can receive treatment on the PBS.

Medicare Item Numbers – BMD testing for diagnosis and monitoring of osteoporosis

Item 12323	Males or females aged 70 years or over
Item 12306	One or more fractures after minimal trauma Monitoring of low BMD (proven by previous bone densitometry)
Item 12321	Monitor BMD after change in osteoporosis treatment (change in class of drugs rather than dosage)

Item 12312	Prolonged glucocorticoid therapy Female hypogonadism (lasting > 6 months before age 45) Male hypogonadism Cushing's syndrome
Item 12315	Primary hyperparathyroidism Chronic liver disease Chronic renal disease Proven malabsorption with vitamin D deficency or proven coeliac disease Conditions associated with thyroxine excess Hyperthyroidism Rheumatoid arthritis

Note: Where item numbers do not apply, the test is available at most large hospitals, many private radiology clinics and at nuclear medicine practices. Some specialists also offer this service.

RISK FACTORS

MAJOR FACTORS

- Presence of any spinal or minimal trauma fracture
- Low BMD (≤-2.5 SD)
- Age – over 60 years

MEDICAL CONDITIONS & MEDICATIONS

- Prolonged corticosteroid use (longer than 3 months) or Cushing's syndrome
- Malabsorption disorders (eg: coeliac disease)
- Inflammatory conditions (RA)
- Hypogonadism
- Hyperparathyroidism/hyperthyroidism
- Chronic liver or kidney disease
- Multiple myeloma
- Premature menopause
- Organ or bone marrow transplant
- Certain anti-epileptic drugs
- Aromatase inhibitors

LIFESTYLE & FAMILY HISTORY

- Family history of minimal trauma fractures
- Smoking / excessive alcohol consumption
- Diet lacking in calcium
- Vitamin D deficiency
- Sedentary lifestyle over many years
- Low body weight
- Recurrent falls

CALCIUM

More than half of Australian adults do not get their recommended intake of calcium.
Recommended daily calcium intake: 1000mg calcium per day for adults. 1300mg per day for women 50 years +, men 70 years + and for patients with osteoporosis.

Calcium & Diet

- To ensure sufficient daily calcium: 3 serves per day of high-calcium foods (eg: milk, cheese, yoghurt, tinned sardines, tinned red salmon). Many calcium-enriched products are now available for those who cannot tolerate dairy products.

Calcium Supplements

Recommended for:

- people with insufficient dietary calcium
- people on corticosteroids for more than 3 months
- treatment of postmenopausal osteoporosis

Note:

- Supplements containing calcium carbonate require gastric acidity for optimal absorption and should therefore be taken with meals.
- Supplements containing calcium in other forms, such as citrate, do not require gastric acidity.
- There is data suggesting calcium supplements may be more effective if taken at night eg. with evening meal.

VITAMIN D

Vitamin D Deficiency

Vitamin D deficiency is associated with a lower bone density as well as a higher risk of falling.

- Groups most at risk:
  - the elderly
  - naturally dark-skinned people
  - those who cover their skin for cultural or religious reasons
  - people housebound or in residential care

Vitamin D Supplementation

- A supplement of at least 800IU (20 micrograms) per day is recommended for people who do not get adequate sun exposure for a variety of reasons.
- Vitamin D replacement is safe, generally not causing hypercalcaemia or hypercalciuria, even in higher doses.

EXERCISE

Exercise for Bone Health

30-40 minutes of weight-bearing and resistance exercise 4-6 times per week can help maintain better bone density.

- Weight bearing:
  - aerobic exercise (eg: brisk walking, tennis, dancing) at moderate to high intensity
  - high impact (eg: jogging, skipping, netball, basketball)
- Resistance exercise (eg: lifting weights with hands or legs, using gym equipment) at high intensity

Bones like:

- short high intensity bursts of exercise rather than long, slower low impact exercise
- exercise that gets progressively harder
- variety in exercise routines to vary the forces placed upon bone

Note: Non weight bearing exercise (eg: swimming, cycling) does not enhance bone density

FALLS PREVENTION

A range of interventions has demonstrated a reduction in risk of falls.

Exercise Programs

- Balance Training (eg: group and home based physio or Tai Chi)
- Muscle strengthening

Home & Personal Changes

- Home modifications: remove mats, improve lighting, install hand rails, remove electrical cords
- Correct footwear: flat shoes, firm fitting
- Correct eyewear: to improve vision
- Walking aids as needed

Medical Review

- Management of conditions associated with falls eg: vitamin D deficiency, arthritis, use of psychotropic medications, gait and balance deficits, depression, cognitive impairment.

The Australian Government has provided funding to support this project. Based on RACGP guidelines.

APPENDIX 11

CHAPTER 9: CONSENT AND EXPLANATORY STATEMENT FORMS

MONASH University
Pharmacy and Pharmaceutical Sciences

Pharmacists in Practice Study (PIPS)

A team approach for optimising medication outcomes in primary care

Staff Consent Form

NOTE: This consent form will remain with the Monash University researcher for their records

I agree to take part in the Monash University research project specified above. I have had the project explained to me, and I have read the Explanatory Statement, which I keep for my records. I understand that agreeing to take part means that:

I agree to the research assistant employed by the researchers interviewing me about my views on the services provided by the primary care pharmacist ☐ **Yes** ☐ **No**

and

I agree to the research assistant audio-recording the interview/focus group ☐ **Yes** ☐ **No**

and

I understand that my participation is voluntary, that I can choose not to participate in part or all of the project, and that I can withdraw at any stage of the project without being penalised or disadvantaged in any way.

and

I understand that any data that the researcher extracts from the interview for use in reports or published findings will not, under any circumstances, contain names or identifying characteristics.

and

I understand that data from the **focus group** will be kept in a secure storage and accessible only to the research team. I also understand that the data will be destroyed after a 5 year period unless I consent to it being used in future research.

Participant's name: _____

Signature: _____

Date: _____

MONASH University
Pharmacy and Pharmaceutical Sciences

Pharmacists in Practice Study (PIPS)

A team approach for optimising medication outcomes in primary care

Explanatory Statement – Practice Staff

This information sheet is for you to keep.

My name is Edwin Tan and I am conducting a research project under the supervision of Dr Johnson George, Associate Professor Kay Stewart, and Mr Rohan Elliott towards a Doctor of Philosophy (PhD) degree at the Department of Pharmacy Practice at Monash University. This means that I will be writing a thesis which is the equivalent of a short book. I am supported by a Monash University scholarship.

Why did you choose this particular person/group as participants?
We are approaching you for participation in this study because your clinic participated in the pilot project: *Pharmacists in Practice Study (PIPS) – A team approach to optimising medication outcomes in primary care*.

The aim/purpose of the research
The aim of this study is to evaluate the role of a pharmacist working in close collaboration with the general practice staff within the GP surgery in optimising medicines use and outcomes. We are conducting this research to find out whether such a team approach could offer chronic disease management services and medicines reviews more efficiently. We are interested in getting feedback from you about the new service. This study has been funded by the Windermere Foundation.

Possible benefits
We anticipate that medicines review by pharmacists working in close collaboration with general practice staff will improve use of medicines by patients. This project could lead to policy changes resulting in funding for pharmacists to be part of the General Practice team. However, we cannot guarantee any direct benefit for you from your participation in this study.

What does the research involve?
The study involves the pharmacist (a research assistant employed by the research team) reviewing the medicines of your patients having complex medication regimens either in the clinic or the patient's home. Each patient will complete a questionnaire about their health and their use of medicines. Patients participating in the study will be contacted after 3 and 6 months to schedule follow up phone calls/visits with a research assistant to repeat the questionnaire. Any medication-related issues identified during the review will be brought to your attention. The pharmacist will also provide additional roles include drug information/education, and quality assurance activities.

At the end of the project a research assistant will conduct a focus group with you and your colleagues to get your views on the new service. This group discussion will be organised at a place and time convenient for you. To make sure that the research assistant does not miss any valuable information provided by you during the interview, the interview will be audio-recorded.

How much time will the research take?
The focus group with the research assistant will take approximately 60 minutes.

Inconvenience/discomfort
We do not foresee any inconvenience or discomfort for you by participating in this study. You may choose to avoid answering questions during the discussion which are felt too personal or intrusive.

Payment
There is no payment for you to participate in the discussion, however lunch will be provided.

Can I withdraw from the research?
Being in this study is voluntary and you are under no obligation to consent to participation.

Confidentiality
The focus group will be transcribed verbatim. Any personal details that could reveal your identity will be removed from the transcripts. You will be identified only by a code and only the researchers will have access to the data collected. Only group data will be used in publications and presentations and no personal details that could reveal your identity will be reported.

Storage of data
Storage of the data collected will adhere to the University regulations and kept on University premises in a locked cupboard/filing cabinet for 5 years. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report. You may request a copy of this report by contacting the chief investigator.

Use of data for other purposes
Data collected as part of this study will not be used for any other purpose.

Results
If you would like to be informed of the aggregate research finding, please contact Dr Johnson George on [redacted] or e-mail [redacted]. The findings are accessible for a period of five years from the date of completion of this study.

If you would like to contact the researchers about any aspect of this study, please contact the Chief Investigator:	If you have a complaint concerning the manner in which this research 2008000201 - CF08/0429 is being conducted, please contact:
Mr Edwin Tan (PhD scholar) Monash University (Parkville Campus) Department of Pharmacy Practice 381 Royal Parade VIC 3052 Tel: (03) 9903 9170 Fax: (03) 9903 9629 Email: edwin.tan@monash.edu Dr Johnson George Department of Pharmacy Practice Victorian College of Pharmacy 381 Royal Parade Parkville; VIC 3052 [redacted]	Human Ethics Officer Standing Committee on Ethics in Research Involving Humans (SCERH) Building 3e Room 111 Research Office Monash University VIC 3800 [redacted]

Thank you,
Edwin Tan

APPENDIX 12

CHAPTER 9: INTERVIEW AND FOCUS GROUP GUIDES

PATIENT INTERVIEW GUIDE

The broad topic areas to be covered in the semi-structured interviews (duration 10 to 15 minutes)

1. How did you feel about being asked to attend the pharmacist appointment?
    a. What did you think would happen at the appointment?/What did you think the pharmacist would do?
    b. Did you have any concerns about the purpose of the visit?

2. How did you find your appointment with the pharmacist?
    a. What did you like about it?
    b. What did you actually achieve?
    c. Did you find it useful? What in particular?
    d. What did you not like about it?

3. Did your visit to the clinic pharmacist meet your expectations? In what way?
    a. Was anything not achieved that you hoped would be?

4. What could have been improved and how?

5. What are the benefits of having a pharmacist working in the GP surgery?

6. What are the disadvantages of having a pharmacist working in the GP surgery?

7. Did you have any concerns about discussing medication issues with a pharmacist rather than with the doctor?
    a. Were you comfortable?
    b. Do you think discussing your medicine with the pharmacist could have affected your relationship with the doctor?

8. In relation to having your medicines reviewed and receiving medicines information, would you prefer to see a pharmacist in the clinic, a pharmacist at your local community pharmacy or your doctor?
    a. Do you think anything extra could be achieved by seeing the clinic pharmacist that would not have been by seeing your doctor or community pharmacist in the normal way?

9. Would you prefer to see the pharmacist in the clinic or at home?

10. Do you see a role for pharmacists in the GP surgery/clinic?

Ref: Petty D et al. Patients' views of a pharmacist-run medication review clinic in general practice. British Journal of General Practice, 2003, 53, 607-613.

FOCUS GROUP INTERVIEW GUIDE

Question 1.
What did you think about having a pharmacist working in your clinic?

- What do you see as the advantages/disadvantages of having a pharmacist working in your clinic? What could be improved?

Specific roles
The pharmacist performed a few different roles in your clinic. These included:

- Long Patient Consultations (HMRs); Short Patient Consultations (SPCs); drug information and education; and quality assurance activities (including a drug use evaluation).

Question 2.
How did you find the long patient consultations (LPCs)?

Question 3.
How did you find the short patient consultations (SPCs)?

Question 4.
How did you find the drug information or education he provided?

Question 5.
How did you find the osteoporosis drug use evaluation (DUE)?

Question 6.
Was there anything else that the pharmacist did in the clinic that you found useful (or not)?

Question 7.
Now that we have discussed each of the roles:

- What do you think was the most useful role? Why?
- Which was the least useful? Why?
- What other roles would you have liked a pharmacist to have done in your clinic?

STUDY PHARMACIST INTERVIEW GUIDE

General feedback

How did you find your experience working at (West Brunswick Clinic)?

- Like/ dislike?
- Benefits/disadvantages?
- Meet initial expectations?
- Challenges/Eased integration?

Staff

How did you find the staff at the clinic?

- Relationships
- Supportive
- Challenges
- Communication – opportunities?

Patients

How would you describe the types of patients you consulted?

- Similar to HMR clients?
- Receptive to seeing you in clinic?
- Benefited?

Specific Roles

How did you find the **long patient consultations (LPCs)?**

- Differences with normal HMR style?
- Communicating referrals – written/verbal?
- Presentation of reports/findings – content/communication?
- Acceptance of recommendations – differences?

Short patient consultations (SPCs)?

- Useful/How improve?

Drug information/education you provided to staff?

Drug use evaluation (DUE)?

- Audit
- Case conference

Which roles:

- Enjoy the most? Why?
- Most effective or useful for staff/patients
- Could have been improved? How?
- Other potential roles in this setting?

Future

How do you see the role of pharmacists in general practice in the future?

- Advice for other pharmacists?

APPENDIX 13

CHAPTER 9: PHARMACIST NARRATIVE REPORT TEMPLATES

Study Pharmacist's Monthly Narrative Report
1 month

Instructions

- Narrative reports offer a great way for you to document and reflect on your experiences as you integrate into the practice.
- **You are required to complete the narrative report and hand it to the research team at each monthly progress meeting.**
- It will be easiest to make notes in your logbook about specific observations, experiences or events **as they occur**
- Please write honestly and freely
- Please avoid writing business-like reports – these do not need to be written in a precise style or use perfect grammar
- We are interested in **your story**

PART A. Time log:
Reflect on your last 4 weeks in the practice and estimate how much time you spent on each of the following program activities:

Pharmacist activity	**Percentage of office time spent on tasks (Should total 100)**
Orientation	
Long patient consultations	
Short patient consultations	
Drug information & Education sessions	
Quality assurance (Drug use evaluation)	
Administrative work	
Other (please specify):	

PART B. Reflective Questions:

1. Describe your personal observations of the practice and how your current or proposed pharmacist activities may enhance or hinder the current practice system.
2. What are your thoughts on your integration into the practice? Please highlight your personal approach and ideas for integration, in the short term and long term.
3. Describe experiences that illustrate specific challenges and/or barriers that you encountered during the last month (both personally and professionally).
4. Describe experiences that illustrate specific successes and/or breakthroughs that you made during the last month (both personally and professionally).
5. Describe any other "lessons learned", success stories, feedback you have received, or any items or concerns that would be worth discussing with the other pharmacists.

Study Pharmacist's Monthly Narrative Report
2 months

Instructions

- Narrative reports offer a great way for you to document and reflect on your experiences as you integrate into the practice.
- **You are required to complete the narrative report and hand it to the research team at each monthly progress meeting.**
- It will be easiest to make notes in your logbook about specific observations, experiences or events **as they occur**
- Please write honestly and freely
- Please avoid writing business-like reports – these do not need to be written in a precise style or use perfect grammar
- We are interested in **your story**

PART A.

Time log:
Reflect on your last 4 weeks in the practice and estimate how much time you spent on each of the following program activities:

Pharmacist activity	**Percentage of office time spent on tasks (Should total 100)**
Orientation	-
Long patient consultations	62
Short patient consultations	5
Drug information & Education sessions	3
Quality assurance (Drug use evaluation)	10
Administrative work	20
Other (please specify):	-

Reflective Questions:

1. Describe your personal observations of the practice and how your current or proposed pharmacist activities may enhance or hinder the current practice system.
2. What are your thoughts on your integration into the practice? Please highlight your personal approach and ideas for integration, in the short term and long term.
3. Describe experiences that illustrate specific challenges and/or barriers that you encountered during the last month (both personally and professionally).
4. Describe experiences that illustrate specific successes and/or breakthroughs that you made during the last month (both personally and professionally).
5. Describe any other "lessons learned", success stories, feedback you have received, or any items or concerns that would be worth discussing with the other pharmacists.

Study Pharmacist's Monthly Narrative Report
4 Months

Instructions

- Narrative reports offer a great way for you to document and reflect on your experiences as you integrate into the practice.
- **You are required to complete the narrative report and hand it to the research team at each monthly progress meeting.**
- It will be easiest to make notes in your logbook about specific observations, experiences or events **as they occur**
- Please write honestly and freely
- Please avoid writing business-like reports – these do not need to be written in a precise style or use perfect grammar
- We are interested in **your story**

PART A. Time log:
Reflect on your last 4 weeks in the practice and estimate how much time you spent on each of the following program activities:

Pharmacist activity	**Percentage of office time spent on tasks (Should total 100)**
Long patient consultations	
Short patient consultations	
Drug information & Education sessions	
Quality assurance (Drug use evaluation)	
Administrative work	
Other (please specify):	

PART B. Reflective Questions:

1. Describe how your role as a practice pharmacist has developed and evolved over the last 4 months.
2. How does your role as a clinic-based practice pharmacist compare with that of a HMR pharmacist? Describe the advantages and disadvantages of both.
3. What are your thoughts on the way clinic staff attitudes and/or processes have changed to accommodate you as a practice pharmacist so far?
4. Describe experiences that illustrate specific challenges and/or barriers that you encountered during the last couple of months (both personally and professionally).
5. Describe experiences that illustrate specific successes and/or breakthroughs that you made during the last couple of months (both personally and professionally).
6. Describe any other "lessons learned", success stories, feedback you have received, or any items or concerns that would be worth discussing with the other pharmacists.

Study Pharmacist's Monthly Narrative Report
6 Months

Instructions

- Narrative reports offer a great way for you to document and reflect on your experiences as you integrate into the practice.
- **You are required to complete the narrative report and hand it to the research team at each monthly progress meeting.**
- It will be easiest to make notes in your logbook about specific observations, experiences or events **as they occur**
- Please write honestly and freely
- Please avoid writing business-like reports – these do not need to be written in a precise style or use perfect grammar
- We are interested in **your story**

PART A. Time log:
Reflect on your last 4 weeks in the practice and estimate how much time you spent on each of the following program activities:

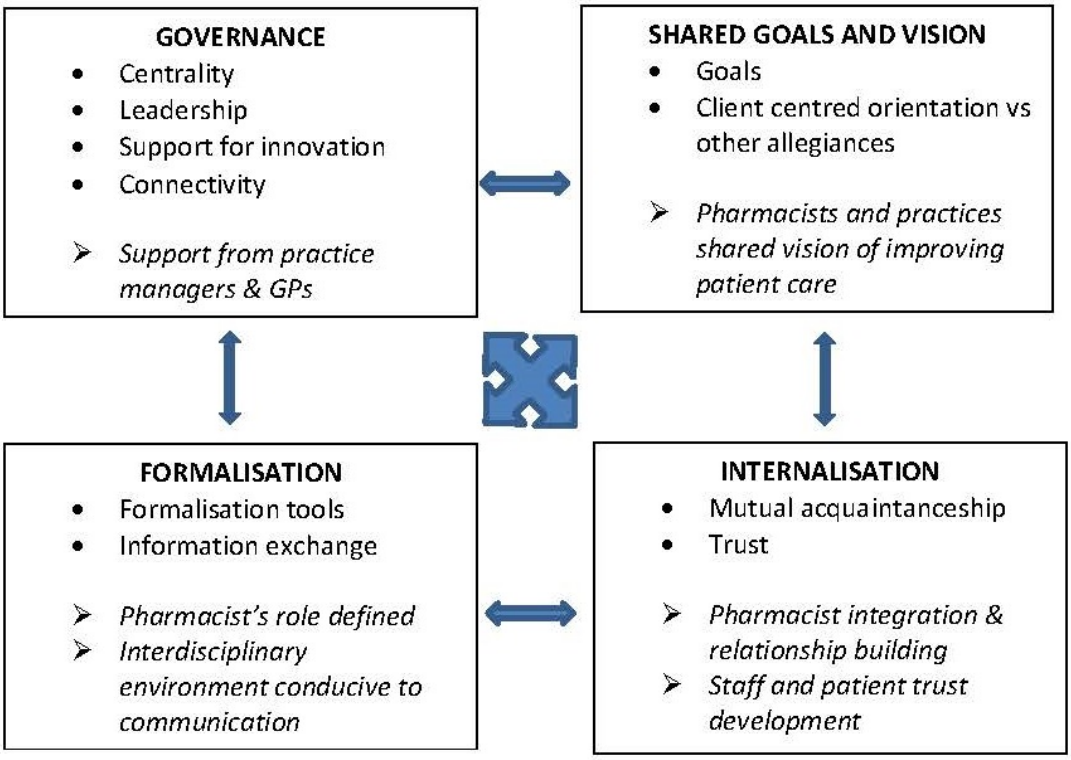
Pharmacist activity	**Percentage of office time spent on tasks (Should total 100)**
Long patient consultations	
Short patient consultations	
Drug information & Education sessions	
Quality assurance (Drug use evaluation)	
Administrative work	
Other (please specify):	

PART B. Reflective Questions:

1. Describe your overall experience working in the clinic over the last six months and whether it met your initial expectations.
2. What advice would you give to pharmacists wishing to undertake a similar role in general practice?
3. Describe your experiences with the short patient consultations (SPCs) and their effectiveness. In what way could they have been improved?
4. Describe your experiences with the drug use evaluation (DUE) and the effectiveness of the strategies implemented. In what way could they have been improved?
5. Describe the biggest challenges/barriers you encountered during the last 6 months (both personally and professionally).
6. Describe the major successes that you made during the last 6 months (both personally and professionally).

APPENDIX 14

CHAPTER 9: THEORETICAL FRAMEWORK OF FINDINGS



Four Dimensional Model of Collaboration with study findings (in italics)

Based on: D'Amour D, Goulet L, Labadie J-F, et al. A model and typology of collaboration between professionals in healthcare organizations. BMC Health Serv Res 2008;**8**(1):188