THE DEVELOPMENT AND PILOT TESTING OF A DOCTOR-PHARMACIST COLLABORATION INTERVENTION TO IMPROVE MEDICATION SAFETY FOR PATIENTS WITH CHRONIC DISEASES IN PRIMARY CARE

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ABSTRACT

Patients with chronic diseases are often prescribed with complex medication regimens. This puts them at a higher risk of adverse drug events, leading to poor disease control and increased health care costs. Previous studies have shown that the provision of pharmaceutical care by pharmacists as part of a multidisciplinary team, can improve disease control and medication safety. It is however unclear how these interventions were developed, and how the doctor-pharmacist working relationship affects patients' therapeutic outcomes.

The aim of this study was to systematically develop and pilot test a doctor-pharmacist collaboration intervention to improve medication safety for patients with chronic diseases in primary care.

This study was divided into 3 phases. In phase 1, qualitative interviews were conducted with primary care physicians (PCPs), pharmacists, and patients at a teaching hospital in Malaysia. These interviews aimed to explore the problems encountered by PCPs when prescribing, by pharmacists while dispensing, and by patients when using medications for chronic diseases. In phase 2, an intervention called the "Physician-Pharmacist Partnership for Patient Safety (4Ps)" was developed based on findings from phase 1, literature and conceptual framework. This intervention was reiteratively reviewed by a steering committee, and tested for feasibility and acceptability. The 4Ps consisted of briefings to the PCPs and pharmacists, identification of patients with potential drug related problems (DRPs) by the PCP, pharmacist's assessment of patients for DRPs, discussion between the PCP and pharmacist regarding the DRPs identified, feedback by the PCP to the pharmacist on patients' medication plan after the doctor-patient consultation, and medication dispensing and counselling by the pharmacist. To assess the level of doctor-

pharmacist collaborative working relationship, two instruments, the Physician-Pharmacist Collaborative Index (PPCI) for physicians, and the PPCI for pharmacists, were validated. Phase 3 was a pilot test of the 4Ps. Four PCP-pharmacist pairs provided this intervention once a week over three weeks. In addition to the PPCI, qualitative interviews were conducted with the PCPs and pharmacists to explore their experiences in establishing a collaborative working relationship with each other. The DRPs identified and resolved by the PCP-pharmacist pairs were also recorded.

Findings from Phase 1 highlighted the need to support PCPs' medication-prescribing practice, improve patients' medication knowledge and medication-taking behavior, create a system to engage pharmacists more actively in patient care, and improve interprofessional communication between PCPs and pharmacists. This led to the development of the 4Ps in phase 2. Both the PPCI for physicians and pharmacists were found to be valid and reliable in assessing doctor-pharmacist collaborative working relationship in Malaysia. Findings from phase 3 provided preliminary evidence that the 4Ps enhanced the collaborative working relationship between PCPs and pharmacists, to identify and resolve patients' DRPs. The 4Ps was well accepted by PCPs and pharmacists. However, its integration into routine practice will require a change in policy and practice.

In conclusion a doctor-pharmacist collaboration intervention was successfully developed based on needs assessment, evidence and theory. More rigorous evaluation is needed to confirm the effectiveness of the intervention in improving patients' medication safety.

ABSTRAK

Pesakit dengan penyakit kronik sering dibebani dengan rejimen ubat yang kompleks. Oleh itu, mereka berisiko tinggi untuk kesan sampingan ubat, yang juga boleh menyumbang kepada kawalan penyakit yang tidak memuaskan serta peningkatan kos kesihatan. Kajian telah menunjukkan bahawa penglibatan pegawai farmasi sebahagian daripada pasukan multidisiplin, boleh meningkatkan kawalan penyakit dan keselamatan ubat pesakit. Tetapi, ianya tidak jelas bagaimana penglibatan tersebut dilaksanakan, dan bagaimana kerjasama antara doktor dan pegawai farmasi memberi kesan kepada hasil terapeutik pesakit.

Kajian in bertujuan untuk membangunkan secara sistematik, dan menjalankan ujian perintis sebuah intervensi yang melibatkan kerjasama doktor-pegawai farmasi untuk meningkatkan keselamatan ubat bagi pesakit dengan penyakit kronik di peringkat penjagaan primer.

Kajian ini dibahagikan kepada 3 fasa. Dalam fasa 1, temubual kualitatif telah diadakan dengan doktor, pegawai farmasi, dan pesakit di sebuah hospital pengajar di Malaysia. Temubual tersebut bertujuan untuk meninjau masalah yang dihadapi oleh doktor apabila menulis preskripsi, pegawai farmasi apabila mendispens, dan pesakit apabila menggunakan ubat-ubatan untuk penyakit kronik. Dalam fasa 2, intervensi "Physician-Pharmacist Partnership for Patient Safety (4Ps)" telah dibangunkan berdasarkan penemuan daripada fasa 1, bukti daripada kajian terdahulu dan rangka kerja konseptual. Intervensi ini telah dipinda berulangkali berdasarkan maklumbalas daripada sebuah jawatankuasa, dan hasil daripada ujian kebolehlaksanaan dan kebolehterimaan. Intervensi 4Ps terdiri daripada taklimat kepada doktor dan pegawai farmasi, mengenal pasti pesakit yang berkemungkinan mempunyai masalah berkaitan dengan dengan ubat oleh doktor,

penilaian pesakit oleh pegawai farmasi untuk masalah berkaitan dengan ubat, perbincangan antara doktor dan pegawai farmasi mengenai masalah ubatan yang dikenal pasti, maklumbalas oleh doktor kepada pegawai farmasi mengenai pelan rawatan pesakit selepas rundingan doktor-pesakit, dan pendispensan dan kaunseling ubat oleh pegawai farmasi. Untuk menilai tahap kerjasama antara doktor dan pegawai farmasi, dua soal selidik, Physician-Pharmacist Collaborative Index (PPCI) bagi doktor dan pegawai farmasi, telah divalidasi. Fasa 3 merupakan ujian perintis 4Ps. Empat pasang doktor-pegawai farmasi terlibat dengan intervensi ini seminggu sekali, selama tiga minggu. Selain PPCI, temubual kualitatif telah diadakan dengan doktor dan pegawai farmasi untuk meneroka pengalaman mereka dalam mula berkerjasama dengan satu sama lain. Masalah berkaitan ubatan yang dikenal pasti dan diselesaikan oleh pasangan doktor-pegawai farmasi juga telah direkodkan.

Penemuan daripada fasa 1 menekankan keperluan untuk menyokong amalan menulis preskripsi doktor, meningkatkan pengetahuan pesakit mengenai ubat dan amalan pengambilan ubat oleh pesakit, mewujudkan satu sistem untuk melibatkan pegawai farmasi dengan lebih aktif dalam penjagaan pesakit, dan meningkatkan komunikasi antara doktor dan pegawai farmasi. Ini membawa kepada pembangunan intervensi 4Ps dalam fasa 2. Di samping itu, kedua-dua PPCI untuk doktor dan pegawai farmasi didapati sah dan boleh dipercayai dalam menilai tahap kerjasama doktor-pegawai farmasi di Malaysia. Penemuan daripada fasa 3 memberikan bukti awal bahawa intervensi 4Ps dapat meningkatkan kerjasama antara doktor dan pegawai farmasi, untuk mengenal pasti dan menyelesaikan masalah ubatan pesakit. Intervensi 4Ps telah diterima dengan baik oleh doktor dan pegawai farmasi. Walau bagaimanapun, integrasi 4Ps ke dalam amalan rutin akan memerlukan perubahan polisi.

Kesimpulannya, sebuah intervensi yang melibatkan kerjasama doktor-pegawai farmasi telah berjaya dibangunkan berdasarkan keperluan, bukti dan teori. Penilaian yang lebih menyeluruh diperlukan untuk mengesahkan keberkesanan intervensi ini dalam meningkatkan keselamatan ubat pesakit.

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$\chi 2/df$	:	Chi square/degree of freedom
4Ps	:	Physician-Pharmacist Partnership for Patient Safety
ACPS	:	Ambulatory care pharmacist service
ADE	:	Adverse drug event
ADR	:	Adverse drug reaction
AGFI	:	Adjusted-goodness-of-fit index
ATCI	:	Attitude Towards Collaboration Instrument
AVE	:	Average variance extracted
CDS	:	Clinical decision support
CFA	:	Confirmatory factor analysis
CFI	:	Comparative fit index
CPOE	:	Computerised physician order entry
CR	:	Composite reliability
CWR	:	Collaborative working relationship
DRP	:	Drug related problem
ED	:	Emergency department
e-prescribing	:	Electronic prescribing
FGD	:	Focus group discussion
GFI	:	Goodness-of-fit indices
GP	:	General practitioner
ICC	:	Inter-class correlation coefficient
IDI	:	In-depth interview
IT	:	Information technology
KMO	:	Kaiser-Meyer-Oklin

L	:	Factor loading
ME	:	Medication error
PCNE	:	Pharmaceutical Care Network Europe
PCP	:	Primary care physician
PIMS	:	Pharmacy information management system
PPCI	:	Physician-Pharmacist Collaborative Index
RCT	:	Randomised controlled trial
RMSEA	:	Root mean square error approximation index
TeAMM	:	Team Approach to Medication Management
UK MRC	:	United Kingdom Medical Research Council
UMMC	:	University Malaya Medical Centre

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CHAPTER 1: INTRODUCTION

Chronic diseases are a significant health problem globally. As of 2012, about half of the adults in the United States (49.8%, 117 million people) have one or more chronic health conditions (Ward, Schiller, & Goodman, 2014). In Malaysia, the prevalence of chronic diseases among Malaysian adults in 2006 was even higher at 70% (Amal, Paramesarvathy, Tee, Gurpreet, & Karuthan, 2011; Institute for Public Health, 2011). Patients with chronic diseases are at higher risk of adverse drug events (ADEs) as they are older, are taking a higher number of medications and have multiple co-morbidities (Chrischilles et al., 2007; Hajjar et al., 2003; Miller, Britth, & Valenti, 2006).

Medication safety is defined as "freedom from accidental injury during the course of medication use" (American Hospital Association; Health Research & Educational Trust; Institute for Safe Medication Practices, 2002). A medication error (ME) refers to "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use" (National Coordinating Council for Medication Error Reporting and Prevention). An ADE is said to occur when a patient is harmed as a result from the use of medication (Bates et al., 1995). There are two kinds of ADEs: preventable ADEs and non-preventable ADEs (Gurwitz et al., 2000; Leape, Kabcenell, Berwick, & Roessner, 1998). A preventable ADE is harm caused by MEs; whilst a non-preventable ADE occurs when a medication is prescribed and administered appropriately, but causes unwanted effects (Leape et al., 1998; Roswell, Van Diepen, Jones, & Hicks, 2001).

ME is the leading cause of death and injury in health care (Committee on Quality of Health Care in America, 1999). It accounts for approximately 7000 deaths, and harm to at least 1.5 million people every year in the United States (Committee on Identifying and Preventing Medication Errors, 2007; Phillips, Christenfeld, & Glynn, 1998). The rate of MEs in the general practice setting of United States was reported to be 23% (Miller et al., 2006). In Malaysia, a medical record review conducted at 12 public primary care clinics identified 41.1% MEs (Khoo et al., 2012).

ADEs that occur in the community have a significant clinical and economic impact. International studies have shown that ADEs might lead to up to 16.2% of general hospital admission (Nelson & Talbert, 1996), 33.2% of emergency department (ED) visits (Baena et al., 2006), 0.4% of outpatient clinic visits (Zhan et al., 2005), and 3.1% of death (Wester, Jonsson, Spigset, Druid, & Hagg, 2008). In Malaysia, 39% of admission to medical wards in a tertiary teaching hospital was due to ADEs (Karuppannan, 2012). In terms of costs, preventable ADEs at the outpatient setting resulted in roughly $887 million in extra medical costs in the year 2000 (Field et al., 2005). This figure is in fact an underestimate as the study only looked at a subset of clinic visitors, and did not take into account loss of wages and productivity or other indirect costs (Field et al., 2005).

A diverse array of interventions has been developed and tested to prevent ADEs and to improve medication safety in primary care. These include information technology (IT) interventions (Raebel, Charles, et al., 2007; Tamblyn et al., 2008), pharmacist-led medication reviews (A. V. Sorensen & Bernard, 2009; Touchette et al., 2012), medication review by other health care professionals (Olivarius, Beck-Nielsen, Andreasen, Hørder, & Pedersen, 2001; Piette et al., 2000), and patient education (Wu et al., 2006). However, the majority of these interventions did not demonstrate a significant impact on rates of

ADEs, health care utilisation, mortality and quality of life (Easton, Morgan, & Williamson, June 2009). Pharmacist-led medication reviews however, resulted in significant reduction in deaths (Gattis, Hasselblad, Whellan, & O'Connor, 1999), hospital admissions and re-admissions (McCombs et al., 1998; Taylor, Byrd, & Krueger, 2003), ED visits (Taylor et al., 2003), ADEs (J. P. Jameson & VanNoord, 2001) and improvement of quality of life (Schulz et al., 2001). In addition, pharmacist-led medication review combined with patient education and therapeutic recommendation to prescriber improved medication use outcomes such as medication appropriateness (Hanlon et al., 1996; Taylor et al., 2003), number of drugs (Blakey & Hixson-Wallace, 2000; Britton & Lurvey, 1991) and drug related problems (DRPs) (Sturgess, McElnay, Hughes, & Crealey, 2003). The effect is more evident when pharmacists provided these services as part of a multidisciplinary team (working closely with prescribers and nurses) (Kaur, Mitchell, Vitetta, & Roberts, 2009; Susan M. Patterson, Hughes, Kerse, Cardwell Chris, & Bradley Marie, 2012).

Doctor-pharmacist collaboration in primary care teams has produced favourable results in terms of improvement in chronic disease control such as blood pressure and diabetes (Carter, Ardery, Dawson, & et al., 2009; Z. Chen, Ernst, Ardery, Xu, & Carter, 2013; Codispoti, Douglas, McCallister, & Zuniga, 2004; Howard-Thompson et al., 2013). In addition, doctor-pharmacist collaboration improved medication safety by facilitating ME detection, improved medication appropriateness and resolution of DRPs (C. A. Brown, Bailey, Lee, Garrett, & Rudman, 2006; L. J. Bryant, Coster, Gamble, & McCormick, 2011; Dolovich et al., 2008; Gilbert, Roughead, Beilby, Mott, & Barratt, 2002). To date, pharmacists have not been involved in patient care at the primary care clinic of the University Malaya Medical Centre (UMMC). There is an untapped potential for pharmacists to work in collaboration with primary care physicians (PCPs) to improve

medication safety of patients with chronic diseases (Kaur et al., 2009; Susan M. Patterson et al., 2012; Smith Susan, Soubhi, Fortin, Hudon, & O'Dowd, 2012).

The main aim of this study was to develop and pilot test a doctor-pharmacist collaboration intervention to improve medication safety for patients with chronic diseases in primary care. This thesis is written in the article format where each chapter will answer a specific objective of the study:

1. To identify the challenges faced by PCPs in prescribing medications for patients with chronic diseases, and its impact on medication safety (Chapter 3).
2. To explore patients' experiences in taking medications for their chronic diseases, and how it affects medication safety (Chapter 4).
3. To explore the challenges faced by hospital outpatient pharmacists in dispensing medications for patients with chronic diseases, and its impact on medication safety (Chapter 5).
4. To explore the views of PCPs, patients and hospital outpatient pharmacists on the implementation of an ambulatory care pharmacist service for patients with chronic diseases in primary care (Chapter 6).
5. To systematically develop a doctor-pharmacist collaboration intervention based on needs, evidence and theories, to improve medication safety for patients with chronic diseases in primary care (Chapter 7).
6. To determine the validity and reliability of the Physician-Pharmacist Collaborative Index for pharmacists in assessing the doctor-pharmacist professional interactions in Malaysia (Chapter 8).

7. To determine the validity and reliability of the Physician-Pharmacist Collaborative Index for physicians in assessing the professional exchanges between doctors and pharmacists in Malaysia (Chapter 9).
8. To evaluate the effectiveness of the Physician-Pharmacist for Patient Safety intervention in improving doctor-pharmacist collaborative working relationship (Chapter 10).
9. To determine the effectiveness of the Physician-Pharmacist for Patient Safety intervention in the identification and resolution of DRPs (Chapter 11).

CHAPTER 2: LITERATURE REVIEW

This chapter begins with a literature review on the burden of chronic diseases, and its management in primary care. Next, terms related to patient safety and medication safety that are used throughout this thesis will be defined. This will be followed by a literature review on the prevalence and impact of ADEs and MEs, risk factors for ADEs, and causes of MEs in the outpatient setting. The next section provides an extensive review on interventions designed to improve medication safety in primary care, followed by an introduction to doctor-pharmacist collaboration. Next, research gaps pertaining to this study will be reported, and finally an introduction to the approach used to develop a complex intervention in this study.

2.1 What is a chronic disease?

A chronic disease is a non-communicable condition that is not passed from person to person (World Health Organization, 2014). It is of long duration and generally slow in progression (World Health Organization, 2014). Chronic diseases generally cannot be prevented by vaccines or cured by medication, and do not just disappear. Examples of chronic disease include heart disease, stroke, cancer, diabetes, obesity, and arthritis.

2.1.1 The epidemiology of chronic diseases globally

A total of 56 million deaths occurred worldwide in the year 2012 (World Health Organization, 2014). Of these, 38 million were due to chronic diseases (World Health Organization, 2014). Nearly three-quarter of these deaths occurred in low- and middle-income countries (World Health Organization, 2014). Cardiovascular diseases were responsible for most chronic diseases associated death (17.5 million, 46.2%), followed by cancers (8.2 million, 21.7%), respiratory diseases (4 million, 10.7%), and diabetes (1.5 million, 4%) (World Health Organization, 2014). Together, these four chronic diseases

were responsible for 82% of all deaths due to chronic diseases (World Health Organization, 2014).

The number of deaths attributable to chronic diseases increased worldwide and in every region since 2000; from 31 million in 2000 to 38 million in 2012 (World Health Organization, 2014). Deaths due to chronic diseases have increased the most in the South-East Asia Region, from 6.7 million in 2000 to 8.5 million in 2012, and in the Western Pacific Region, from 8.6 million to 10.9 million (World Health Organization, 2014).

2.1.2 The epidemiology of chronic diseases in the United States

As of 2012, about half of all adults (117 million people) in the United States had at least one chronic disease (Ward et al., 2014). Of these, one in four adults had more than two chronic health conditions (multimorbidities) (Ward et al., 2014). Chronic diseases were accountable for seven out of ten top causes of death in 2012, equivalent to 65% of all deaths in the United States (Heron, 2015). Heart diseases and cancers accounts for 46.5% of all deaths in the United States (Heron, 2015).

2.1.3 The epidemiology of chronic diseases in South-East Asia Region

Chronic diseases were responsible for 7.9 million (55%) of a total of 14.5 million deaths in this region in the year 2008 (World Health Organization, 2011). Cardiovascular diseases alone accounted for 25% of all deaths followed by chronic respiratory diseases (9.6%), cancers (7.8%) and diabetes (2.1%) (World Health Organization, 2011). In nine of the 11 member countries, the estimated percentage of chronic diseases deaths out of the total deaths already exceeded 50%; the highest percentage in Maldives (79%) followed by Thailand (71%) and Sri Lanka (66%) (World Health Organization, 2011). At

present, Timor-Leste and Myanmar are the only two countries in this Region where chronic diseases caused less than 50% deaths (World Health Organization, 2011).

2.1.4 The epidemiology of chronic diseases in Western Pacific Region

In 2012, 28.7% (10.9 million) of the 38 million deaths from chronic diseases worldwide were from the Western Pacific Region (World Health Organization, 2014). Disease registries are not widely available in this Region, making it difficult to assess disease specific morbidity and mortality data.

2.1.5 The epidemiology of chronic diseases in Malaysia

Malaysia falls under the Western Pacific Region according to the World Health Organization classification (World Health Organization, 2014). It is also rated as an upper-middle-income country by the World Bank Income Group Classification, 2013 (World Health Organization, 2014). It is estimated that 73% of all deaths in Malaysia are due to chronic diseases. Of these, the highest is cardiovascular diseases (36%), followed by cancers (15%), chronic respiratory diseases (7%) and diabetes (3%) (World Health Organization, 2014).

According to the latest National Health and Morbidity Survey 2015, the three major chronic diseases among Malaysian adults are hypercholesterolemia (47.7%), hypertension (30.3%) and diabetes (17.5%) (Institute for Public Health, 2015). The prevalence of chronic diseases among Malaysians is rising at an alarming rate; the prevalence of hypercholesterolemia increased from 32.6% in 2011 to 47.7%, a relative increase of 46% (Institute for Public Health, 2011, 2015). The prevalence of diabetes on the other hand increased by 15%, from 15.2% in 2011 to the 17.5% in 2015 (Institute for Public Health, 2011, 2015).

2.1.6 Burden of chronic diseases

Premature death (death under the age 70) is a major consideration when evaluating the impact of chronic diseases on a given population; premature deaths from chronic diseases result in loss of productivity and have an impact on the economy. In 2012, approximately 42% of all chronic disease deaths globally occurred before the age of 70 years (World Health Organization, 2014). This represents 16 million deaths, an increase from 14.6 million premature deaths in the year 2000 (World Health Organization, 2014). In low- and middle-income countries, a higher proportion (48%) of all chronic disease deaths are estimated to occur in people under the age of 70 years, compared with high-income countries (28%) (World Health Organization, 2014). In Malaysia, the probability of premature deaths due to the four main types of chronic diseases (cardiovascular diseases, cancers, diabetes and chronic respiratory diseases) is 20% (Health Informatics Centre, 2014).

The economic consequences of chronic diseases are felt by all countries but are particularly devastating in poor and vulnerable populations. During 2011–2025, cumulative economic losses due to chronic diseases under a "business as usual" scenario in low- and middle-income countries have been estimated at US$ 7 trillion (World Health Organization, 2014). This sum far outweighs the annual US$ 11.2 billion cost of implementing a set of high-impact interventions to reduce the chronic disease burden (World Health Organization, 2014). Furthermore, chronic diseases account for the majority of health care spending; in 2010, 86% percent of all health care spending in the United States was for people with one or more chronic medical conditions (Gerteis et al., 2014). In Malaysia, chronic diseases were responsible for 35% of hospital admissions in 2013 (Health Informatics Centre, 2014).

2.1.7 Why is it important to consider medication safety in patients with chronic diseases?

Despite being on drug therapy, more than 70% of patients with chronic diseases do not achieve adequate disease control requiring medical attention and hospitalisation (Health Informatics Centre, 2014; Rampal et al., 2010). In addition, patients with chronic diseases are at higher risk of ADEs due to increasing age, large number of medications and presence of multimorbidities (Chrischilles et al., 2007; Hajjar et al., 2003; Letchuman et al., 2010; Miller et al., 2006). Patients with chronic diseases are also at higher risk of ADEs due to the type of drugs prescribed for them; drugs such as cardiovascular drugs, antithrombotic agents, antidiabetic agents, antidepressants and anti-epileptic are associated with higher risk for ADEs (Karuppannan, 2012; McDonnell & Jacobs, 2002; Zhan et al., 2005). ADEs among patients with chronic diseases will further burden the Malaysian health care system due to increased health care utilisation and in serious cases death.

2.2 The role of primary care in chronic disease management

The complexity of chronic diseases which often involve more than one caregiver and institution, warrants a high level of coordinated medical care. Given the defining features of primary care (continuity, comprehensiveness and coordination) are well suited to care for these patients, the majority of patients with chronic diseases are managed at the primary care setting (Starfield, 1998; Yasin, Chan, Reidpath, & Allotey, 2012).

2.2.1 Primary care setting in Malaysia

Malaysia has a dual health care system. The public sector consists of public-funded hospitals and health clinics, which serve the majority of the population; whilst the private sector comprises fee-for-service hospitals and clinics.

Primary care services in Malaysia comprises private general practices, government health clinics in the community, and government primary care clinics within teaching hospitals. The private general practices are run by private family medicine specialists and general practitioners (GPs), while the government health clinics are run by family medicine specialists, family medicine trainees and medical officers. Family medicine specialist is a GP or a medical officer who has completed four years of training to become a specialist in family medicine. Patients are free to choose where they prefer to receive treatment.

2.2.2 Why is it important to look at medication safety in primary care patients?

Medication management in primary care is very complex. In inpatient setting, there is a close working relationship among healthcare professionals (such as doctors, nurses and pharmacists), and medication prescribing, administration and review occur in collaboration (Budnitz & Layde, 2007). In primary care, patients come into contact with these health care professionals at different times and places, and mostly self-administer their own medications (Budnitz & Layde, 2007). Patients may also frequent multiple health centres and pharmacies (T. K. Gandhi et al., 2005). This situation is further complicated by relying on patients to book and attend follow-up appointments (T. K. Gandhi et al., 2002). These factors present challenges for medication reconciliation and coordination in primary care, increasing the risk for MEs and ADEs (Anthony J. Avery et al., 2002).

2.3 Definition of terms used in this thesis

Terminologies related to patient safety and medication safety have been inconsistently used in literature. Hence, for the purpose of this thesis, the following terms will be defined.

2.3.1 Definition of patient safety

Patient safety is defined as the "freedom from accidental injuries during the course of medical care" (Committee on Quality of Health Care in America, 1999). This include activities to avoid, prevent, or correct adverse outcomes, which may result from the delivery of health care (American Hospital Association; Health Research & Educational Trust; Institute for Safe Medication Practices, 2002).

2.3.2 Definition of medication safety

Medication safety is defined as the "freedom from accidental injury during the course of medication use, which include activities to avoid, prevent, or correct ADEs which may result from the use of medications" (American Hospital Association; Health Research & Educational Trust; Institute for Safe Medication Practices, 2002).

2.3.3 Definition of medication error

A ME refers to "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use" (National Coordinating Council for Medication Error Reporting and Prevention). Examples of ME include wrong dosage prescribed, wrong dosage administered, or failure to give or take a medication.

A ME may or may not lead to patient harm; a ME that leads to patient harm is termed an "ADE", while a ME that does not lead to patient harm is termed a "near miss" or a "potential ADE" [Figure 2.1].

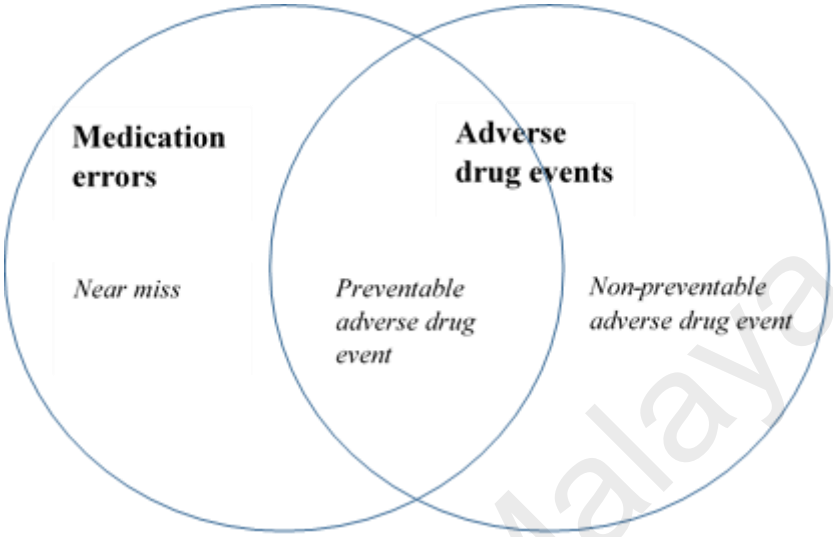


Figure 2.1: Relationship between medication errors, preventable adverse drug event and non-preventable adverse drug event, and near miss.

2.3.4 Definition of an adverse drug event

An ADE is "an injury, large or small, caused by the use (including non-use) of a drug". There are two types of ADEs: preventable and non-preventable ADEs (Gurwitz et al., 2000; Leape et al., 1998) [Figure 2.1].

2.3.4.1 Definition of a preventable adverse drug event

A preventable ADE is "an ADE associated with a ME" (Roswell et al., 2001). For example, a wrong dosage prescribed leading to injury such as rash or confusion.

2.3.4.2 Definition of a non-preventable adverse drug event

Non-preventable ADEs are called adverse drug reactions (ADRs) or side effects (Leape et al., 1998). It refers to patient harm that occur despite proper usage. In other words, it is an ADE that does not result from an error, but reflects the inherent risk of

drug use and cannot be prevented given the current state of knowledge (Otero & Schmitt, 2005). Examples of non-preventable ADEs are dermatological reactions from unknown allergens in the drug; known side effects without identified mitigation strategies; known side effects that are accepted for the benefit of the drug (i.e. nausea with chemo-therapy).

2.3.5 Definition of a near miss

A near miss is also known as a potential ADE (Leape et al., 1998). It refers to "an act of commission or omission that could have harmed the patient, but did not do so as a result of chance (e.g., the patient received a contraindicated drug, but did not experience an ADE), prevention (e.g., a potentially lethal overdose was prescribed, but a nurse identified the error before administering the medication), or mitigation (e.g., a lethal overdose was administered but discovered early, and countered with an antidote)" (Committee on Data Standards for Patient Safety, 2004).

2.3.6 Definition of a drug related problem

A DRP is an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes (Pharmaceutical Care Network Europe Foundation, 2010).

2.4 Prevalence of medication errors and adverse drug events

ME is the leading cause of death and injury in health care (Committee on Quality of Health Care in America, 1999). MEs account for approximately 7000 deaths, and harm at least 1.5 million people every year in the United States (Committee on Identifying and Preventing Medication Errors, 2007; Phillips et al., 1998). MEs occur frequently in hospitals. In an analysis of 289,411 medication orders written during one year period in a teaching hospital in the United States, the overall ME rate was 3.99 errors per 1000

orders (Lesar, Briceland, & Stein, 1997). In addition, the occurrence of an ADE was associated with increased length of stay of 1.91 days, an increased cost of $2262 and an almost two-fold increased risk of death (Classen, Pestotnik, Evans, Lloyd, & Burke, 1997).

However, hospital patients represent only a fraction of the total population at risk of MEs and ADEs. With the bulk of medication use occurring in the community, this increases the likelihood of MEs and ADEs (Committee on Quality of Health Care in America, 1999; Kunac & Tatley, 2011). For example, MEs were said to account for one in 131 outpatient deaths as compared to one in 854 inpatients deaths in the United States (Phillips et al., 1998); during a ten-year period from 1983 to 1993, the rate of outpatient deaths due to MEs rose 8.48 fold, compared with a 2.57-fold increase in inpatient deaths (Phillips et al., 1998).

Based on data from the United States, the prevalence of ADEs in the community was reported to be as high as 18% of adults in the general populations (T. K. Gandhi et al., 2000), and up to 22% of people aged 65 years and above (Chrischilles et al., 2007). Of these, the rate of MEs in the general practice setting was reported to be 23% (Miller et al., 2006). To our knowledge, there are two studies reporting on MEs in the outpatient setting of Malaysia. A medical record review conducted at 12 public primary care clinics found 41.1% of MEs (Khoo et al., 2012), while an earlier study conducted by screening prescriptions at the outpatient pharmacy of a teaching hospital found ME rate of 25.2% (Abdullah, Ibrahim, & Ibrahim, 2004).

2.5 Impact of adverse drug events in the outpatient setting

ADEs that occur in the community have a significant clinical and economic impact. International studies have shown that ADEs might lead to up to 16.2% of general hospital admission (Nelson & Talbert, 1996), 30.7% of admission in the elderly (Courtman & Stallings, 1995) and 3.1% of death (Wester et al., 2008). ADEs are also associated with up to 38% of hospital re-admissions (Witherington, Pirzada, & Avery, 2008), 33.2% of ED visits (Baena et al., 2006), and 0.4% of outpatient clinic visits (Zhan et al., 2005). In Malaysia, 39% of admission to medical wards in a tertiary teaching hospital was due to ADEs (Karuppannan, 2012). In terms of costs, preventable ADEs at the outpatient setting resulted in roughly $887 million in extra medical costs in 2000 (Field et al., 2005). This figure is in fact an underestimate as the study only looked at a subset of clinic visitors, and did not take into account loss of wages and productivity or other indirect costs.

2.6 Risk factors for adverse drug events

2.6.1 Patient characteristics

Older adults (≥ 65 years old) are at greater risk of (Bourgeois, Shannon, Valim, & Mandl, 2010; Miller et al., 2006; Zhan et al., 2005). This is due to the metabolic changes and decreased drug clearance associated with aging (Gurwitz & Avorn, 1991). In addition, the cognitive impairment or depression among the elderly leads to poor adherence (Sajatovic et al., 2011). The elderly are also associated with a higher incidence of polypharmacy (≥ 5 medications), which further increases their risk of ADEs (Chrischilles et al., 2007; Oladimeji, Farris, Urmie, & Doucette, 2008). Polypharmacy also increases the potential for drug-drug interactions (Chatsisvili et al., 2010; Gagne, Maio, & Rabinowitz, 2008). Besides, the toxicity of drug combinations may sometimes be synergistic, and be greater than the sum of the toxicity of either agent used alone. One study reported that patients concurrently receiving corticosteroids and nonsteroidal anti-

inflammatory drugs, had a risk of peptic ulcer disease that was 15 times greater than that of nonusers of either drug (Piper, Ray, Daugherty, & Griffin, 1991).

Other risk factors for ADEs in the community include multiple care providers, multiple pharmacies, multiple chronic conditions, multiple hospitalisations and multiple ED visits (Hajjar et al., 2003; Lu & Roughead, 2011; Oladimeji et al., 2008). The lack of coordination of care among the different health care providers can lead to ADEs due to drug duplications and drug-drug interactions (Green, Hawley, & Rask, 2007).

2.6.2 Medication classes

Patients taking drugs with a low therapeutic ratio (ratio of the maximally tolerated dose of a drug to the minimal curative or effective dose) are at higher risk of ADEs (Wester et al., 2008). The majority of studies identified drugs affecting the cardiovascular system (e.g. diuretics, angiotensin converting enzyme-inhibitor and digoxin), antithrombotic agents (e.g. warfarin), nonsteroidal anti-inflammatory drugs and antibiotics as the most common drugs associated with ADEs (Hafner Jr, Belknap, Squillante, & Bucheit, 2002; McDonnell & Jacobs, 2002; Trifiro et al., 2005; Wester et al., 2008; Zhan et al., 2005). Other medications reported include oral antidiabetics, antidepressants, antiepileptic and chemotherapeutic agents (Hafner Jr et al., 2002; McDonnell & Jacobs, 2002; Trifiro et al., 2005; Wester et al., 2008; Zhan et al., 2005).

Additionally, drugs such as anticholinergics, benzodiazepines, antipsychotics, sedatives and hypnotics increase the risk of ADEs in older outpatients (American Geriatrics Society Beers Criteria Update Expert Panel, 2015; Gurwitz et al., 2005; Hanlon et al., 2006). These drugs are associated with side effects such as sedation, delirium,

confusion and impaired balance, which can lead to falls and injury (Leipzig, Cumming, & Tinetti, 1999).

2.7 Causes of medication errors in outpatient setting

An understanding of causes of MEs is important in determining the potential target areas for intervention. However, there is relatively little information available on causes of MEs in the outpatient setting. This could be due to difficulties in establishing the origins and circumstances of such events (Easton et al., June 2009). Available studies examined contributing factors for a range of medication safety issues including medication dispensing, medication prescribing, prescription transcribing, ADEs leading to hospital admissions and all medication safety issues in the community in general (Easton et al., June 2009). Table 2.1 provides an overview of the causes of MEs in the outpatient setting, which will be discussed in the following sub-sections.

Table 2.1: Causes of medication errors in the outpatient setting

Patient-related factors	Lack of knowledge
	Patient's behaviour
Doctor-related factors	Lack of knowledge about patient
	Lack of knowledge about medication
	Failure to recognize signs and symptoms
	Doctor's behaviour
Pharmacist-related factors	Misidentification of medication
Health care system factors	Communication
	Computer system
	Work environment
	Medication availability and cost

2.7.1 Patient-related factors

Patient-related factors are an important source of MEs in the community. This is because in the community setting, patients are actively engaged in all aspects of their medication management, and may be solely responsible for one or more of this aspect (Budnitz & Layde, 2007). For example, in a hospital setting, medications are collected from the pharmacy and administered to patients by nurses; whereas in an outpatient setting, patients are solely responsible for collecting their medications from the pharmacy, and taking the medications according to instructions.

2.7.1.1 Lack of knowledge

Patients' lack of knowledge about their medication and disease is an important source of MEs; the lack of knowledge about drug indication may result in patients taking the wrong medication, while the lack of knowledge about drug dose and frequency may lead to patients taking the wrong amount of medication (Bhasale, Miller, Reid, & Britt, 1998; M. Brown, Frost, Ko, & Woosley, 2006; Teinila, Kaunisvesi, & Airaksinen, 2011). Studies have shown that patients who do not know or understand the importance of their medications, are less adherent to their medications (Bhasale et al., 1998; K. M. Nair, Levine, Lohfeld, & Gerstein, 2007).

2.7.1.2 Patient's behaviour

Some patients assume that their long term medication regimen will remain unchanged, and therefore do not read their medication instructions (M. Brown et al., 2006). This may lead to medication administration errors, and ADEs (M. Brown et al., 2006). Some patients intentionally decide not take their medication according to instructions, as they perceive that modern medications are injurious to health (K. M. Nair et al., 2007). Others do not seek help when experiencing ADEs, and self-medicate themselves with over-the-

counter medications without their doctor's knowledge (M. Brown et al., 2006; Howard, Avery, & Bissell, 2008; Teinila et al., 2011).

2.7.2 Doctor-related factors

2.7.2.1 Lack of knowledge about patient

Doctor's lack of knowledge about their patients may lead to prescribing errors (Y. F. Chen et al., 2005; Howard et al., 2008; Slight et al., 2013; Teinila et al., 2011; Witherington et al., 2008). For example, doctors who are not aware of their patients' co-medication, allergies and medical history prescribe contraindicated drug combinations, or drugs that might harm patients due to drug-drug interactions (Y. F. Chen et al., 2005; Teinila et al., 2011).

2.7.2.2 Lack of knowledge about medication

Doctor's lack of knowledge about medication may cause prescribing errors such as wrong dose, wrong frequency and wrong instructions (Y. F. Chen et al., 2005; Howard et al., 2008; Slight et al., 2013; Teinila et al., 2011).

2.7.2.3 Failure to recognise signs and symptoms

When a patient with polypharmacy presents with a rash, it could be due to the side effects of his/her current medications or a new indication for treatment. It is therefore up to the doctor's clinical judgment to recognise the signs and symptoms, and to prescribe appropriately for the patient. Prescribing errors occurr when a doctor fails to do this due to their inexperience, or lack of professional skills (Bhasale et al., 1998; Slight et al., 2013; Teinila et al., 2011).

2.7.2.4 Doctor's behaviour

Inadequate patient assessment and inadequate review for repeat prescriptions by doctors may lead to under- or over-treatment of patients (Bhasale et al., 1998; Y. F. Chen et al., 2005; Slight et al., 2013; Teinila et al., 2011). In addition, poor documentation of patients' current medication(s), and the lack of documentation on how a clinical decision is derived in medical records may lead to prescribing errors (Y. F. Chen et al., 2005). This is because the next attending doctor may not have enough information to prescribe appropriately for the patient (Y. F. Chen et al., 2005). Poor instructions to patients while prescribing may also result in patients taking their medications incorrectly due to the lack of information (Teinila et al., 2011). Being careless has also been reported as the cause for prescribing errors (Teinila et al., 2011).

2.7.3 Pharmacist-related factors

2.7.3.1 Misidentification of medication

Misreading of "sound-alike" and "look-alike" medications has resulted in the wrong medication being picked and dispensed (Knudsen, Herborg, Mortensen, Knudsen, & Hellebek, 2007; Peterson, Wu, & Bergin, 1999).

2.7.4 Health care system factors

2.7.4.1 Communication

Local health care system design that permits patients to visit multiple organisation and/or doctors for the same complaint has been identified as an important factor leading to MEs in the community (Teinila et al., 2011). Poor communication that leads to deficiencies in information flow is another important factor consistently reported in the literature. This include patient-doctor communication, communication among healthcare providers (including doctor-doctor and doctor-pharmacist) and patient-pharmacist

communication (Bhasale et al., 1998; C. A. Brown et al., 2006; M. Brown et al., 2006; Y. F. Chen et al., 2005; Howard et al., 2008; Slight et al., 2013; Teinila et al., 2011; Witherington et al., 2008). Patient-doctor communication and patient-pharmacist communication is often limited by the lack of time and high workload (M. Brown et al., 2006). On the other hand, the lack of doctor-pharmacist communication is often related to the lack of platform for such communication in the outpatient setting; in the outpatient setting, doctors and pharmacists often work in isolation due to the physical barrier of being attached to two separate organisations (C. A. Brown et al., 2006). Illegible handwriting on prescription may lead to miscommunication of orders, which in turn may lead to dispensing errors at the pharmacy (C. A. Brown et al., 2006; Knudsen et al., 2007; Peterson et al., 1999).

2.7.4.2 Computer system

Although the use of computer system in prescribing has improved prescription legibility and reduced MEs, it has also introduced new error-producing conditions in the medication trajectory (Ammenwerth, Schnell-Inderst, Machan, & Siebert, 2008). A few studies reported that possibility of choosing the wrong drug while prescribing or dispensing may be a factor contributing to MEs (Howard et al., 2008; Knudsen et al., 2007; Slight et al., 2013).

2.7.4.3 Work environment

Work environment-related factors leading to MEs include high workload, staffing issues, distractions and interruptions during medication prescribing and dispensing (Howard et al., 2008; Peterson et al., 1999; Slight et al., 2013; Teinila et al., 2011). High workload may contribute to fatigue and rushing while prescribing and dispensing. MEs (Bhasale et al., 1998; Knudsen et al., 2007; Peterson et al., 1999; Slight et al., 2013;

Teinila et al., 2011). In addition, the lack of privacy and noisy dispensary may lead to miscommunication of medication instructions during dispensing (Peterson et al., 1999).

2.7.4.4 Medication availability and cost

The use of generic medications may cause confusion among patients due to the change in brand name, physical appearance, and packaging of the medications (Hakonsen, Eilertsen, Borge, & Toverud, 2009). As a result, some patients may take their medications incorrectly, while some may not take their medications at all (Y. F. Chen et al., 2005; Teinila et al., 2011). Medication unavailability due to stock problem on the other hand, may result in patients not receiving their prescribed medications; while high medication cost affected patients' access to their medication and hence not taking their medications (Y. F. Chen et al., 2005; Teinila et al., 2011).

2.8 Interventions to improve medication safety in primary care

A search of published literature was conducted to determine the effectiveness of interventions to improve medication safety in ambulatory care setting. We did not conduct a systematic review as part of this study as several systematic reviews have been recently published in this area (Castelino, Bajorek, & Chen, 2009; Holland et al., 2008; Kaur et al., 2009; Lainer, Mann, & Sonnichsen, 2013; Nkansah et al., 2010; Pande, Hiller, Nkansah, & Bero, 2013; Saez-Benito et al., 2013). The majority of the systematic reviews reported on the effectiveness of specific type of intervention on medication safety outcomes (Holland et al., 2008; Lainer et al., 2013; Nkansah et al., 2010; Pande et al., 2013), while others focused on the effectiveness of interventions in reducing suboptimal prescribing and polypharmacy among elderly outpatients (Castelino et al., 2009; Kaur et al., 2009; S. M. Patterson et al., 2014; Saez-Benito et al., 2013). This literature review

section will serve to update and summarise individual studies meeting our inclusion and exclusion criteria, to inform the design of an intervention in our study.

2.8.1 Search strategy

Search was conducted primarily in PubMed and Embase; supplemented by reference mining. The search terms used were a combination of free text and medical subheadings [Table 2.2]. The search was limited to studies published in English, from 1990 to 2015. Search results were screened against the inclusion and exclusion criteria based on the title and abstract. Full text was retrieved and reviewed in case there was insufficient information available for selection based on title and abstract alone.

Table 2.2: Search terms used for the literature review

Setting	Outcome
primary care ambulatory care outpatient* clinic* primary health care general practice* family practice* family medicine	medication error* adverse drug event* preventable adverse event* medication* medicine* prescribing prescription* medication safety patient safety

2.8.1.1 Selection criteria

Studies conducted among adult outpatients in primary care centres, general practices, community pharmacies and hospital-based outpatient clinics were included. Outcomes of interest were MEs, ADEs, hospitalisations, ED visits, outpatient visits and mortality. Only randomised controlled trials (RCTs) were included, to allow us to determine the effectiveness of the interventions in improving the medication safety outcomes.

Excluded were non-RCTs, controlled and non-controlled trials and cohort studies. Studies conducted in inpatient setting, EDs, nursing home, residential care, home visits or among paediatric patients were not included in the review.

2.8.1.2 Summarising the evidence

The following information were extracted from the selected studies: title, author(s), year of publication, study design, target population criteria, description of intervention(s), duration of follow-up, and outcome(s).

A total of 50 RCTs that fulfilled the inclusion and exclusion criteria were identified. The interventions were grouped into IT interventions (14 studies), patient education (3 studies), medication review by GPs and nurses (9 studies), individual pharmacist-led medication reviews (19 studies) and pharmacist-led medication reviews in multidisciplinary teams (5 studies).

2.8.2 Information technology interventions

2.8.2.1 Computerised physician order entry system

Computerised physician order entry (CPOE) system is a computer-based system that allows doctors to enter medication orders and instructions electronically (as compared to traditional paper prescriptions). The purpose of this intervention was to prevent prescriber-related factors such as poor handwriting and misspelling of medication orders. Due to the lack of studies evaluating the impact of CPOE on ADE prevention, there is no conclusive evidence for CPOE as a stand-alone intervention in reducing ADEs and MEs in outpatient setting (Eslami, Abu-Hanna, & de Keizer, 2007). The use of CPOE however, was associated with new types of MEs; the use of CPOE improves prescription legibility

but does not prevent doctors from placing wrong orders (Horsky, Kuperman, & Patel, 2005; Nanji et al., 2011; Schiff et al., 2015).

2.8.2.2 Clinical decision support system

Clinical decision support (CDS) systems are active knowledge systems; it matches characteristics of individual patients to a computerised knowledge base and generate patient-specific therapeutic recommendations such as dosage, alternative medication and drug-drug interaction. This intervention therefore helps to overcome prescriber's lack of knowledge about patients and medications.

The combination of CPOE with CDS, was shown to significantly reduce inappropriate prescribing in outpatient setting (Berner et al., 2006; Tamblyn et al., 2003) [Table 2.3]. But it does not significantly impact on other safety outcomes such as ADEs, hospital admissions, ED visits and mortality (Fitzmaurice et al., 2000; Glassman et al., 2007; Tierney et al., 2003). Lainer et al. (2013) in their systematic review on IT interventions to improve medication safety in primary care concluded that, CDS was only effective when targeted at a limited set of potentially inappropriate drugs, or specific group of patients (e.g. patients with renal insufficiency). When CDS covers an extensive database, this leads to "alert-fatigue" among prescribers, causing them to pay less attention to the alerts and potentially missing important alerts (van der Sijs, Aarts, Vulto, & Berg, 2006).

Table 2.3: The effectiveness of the combination of computerised physician order entry and clinical decision support system to improve medication safety in primary care

Author (year), country	Setting	Duration	Participants	Intervention(s)	Control	Outcome(s)
Palen, Raebel, Lyons, and Magid (2006), US	General practice, 207 PCPs	12 months	34242 prescriptions, 26586 patients	CPOE + CDS (reminders for laboratory monitoring for selected medications)	CPOE	Laboratory monitoring performed as recommended: intervention 56.6% vs control 57.1% (p=0.31)
Glassman et al. (2007), US	Outpatient clinic	12 months	932 patients, 1024 medication profiles	CPOE + medication profiling + feedback to provider	CPOE	(i) ADE: intervention 37% vs control 45% (p=0.06) (ii) Non-serious ADE: intervention 58% vs control 51% (p=0.53) (iii) Preventable ADE: intervention 17% vs control 16% (p=0.79)
Berner et al. (2006), UK	Outpatient clinic, 68 residents	Not stated	189 patient encounters	CPOE + CDS (NSAID-risk rule)	CPOE + CDS	Mean proportion of unsafe prescribing of NSAIDs: intervention 23% vs control 45% (p<0.05)
Tamblyn et al. (2003), Canada	General practice, 107 PCPs	13 months	12560 patients >65 years	CPOE + CDS	CPOE	(i) New PIP per 1000 visits: intervention 43.8 vs control 52.2, RR=0.82 (0.62-0.98) (ii) Discontinued PIP per 1000 visits: intervention 71.4 vs control 67.4, RR=1.06 (0.89-1.26)

Table 2.3 continued

Author (year), country	Setting	Duration	Participants	Intervention(s)	Control	Outcome(s)
Tamblyn et al. (2008), Canada	General practice, 28 PCPs	6 months	3449 patients	CPOE + Automated CDS	CPOE + CDS on demand	Proportion of patients with one or more prescribing problems: automated 38.8% vs on demand 30.1 (p=0.17)
Fitzmaurice et al. (2000), UK	12 general practices	12 months	367 patients on warfarin	CPOE + CDS (warfarin dosing recommendations based on INR reading)	CPOE	(i) Serious ADEs: intervention 2.5% vs control 4.1% (NS) (ii) Mortality: intervention 2.5% vs control 2.5% (NS)
Tierney et al. (2003), US	Outpatient clinic	12 months	706 patients with heart failure, 3419 visits	CPOE + CDS (cardiac care suggestions)	CPOE	(i) ED visit: intervention 1.1 ± 1.4 vs control 1.0 ± 1.7 (NS) (ii) Hospital admissions: intervention 0.5 ± 1.1 vs control 0.5 ± 1.1 (NS) (iii) Mortality: NS (p>0.9)

US=United States; PCP=primary care physician; CPOE=computerised physician order entry; CDS=clinical decision support; ADE=adverse drug event; UK=United Kingdom; NSAID=nonsteroidal anti-inflammatory drug; PIP=potentially inappropriate prescription; RR=relative risk; INR=international normalized ratio; NS=not significant; ED= emergency department

2.8.2.3 Pharmacy information management system

Pharmacy information management system (PIMS) is an electronic intervention designed to automate the provision of pharmacy services such as interaction checking, allergy screening and contraindication alerts during dispensing (Lainer et al., 2013). This intervention aims to assist pharmacist in detecting prescribing errors and preventing it from reaching patients.

PIMS generated drug alert to pharmacist, plus pharmacist-prescriber discussion for safer medication alternative was effective at reducing inappropriate prescribing in elderly outpatients (Raebel, Charles, et al., 2007), and high-risk prescribing among pregnant women (Raebel, Carroll, et al., 2007) [Table 2.4]. Another recent study evaluating the effect of computer-generated feedback plus pharmacist-led educational outreach to prescribers reported that the intervention was effective in reducing MEs in general practice (A. J. Avery et al., 2012). Pharmacist-led educational outreach component of this intervention aimed to improve drug knowledge dissemination among prescribers (A. J. Avery et al., 2012). Although it is not clear which of the component in these interventions were effective in reducing MEs, these results seem to suggest that the detection of unsafe prescribing by pharmacist together with feedback to and discussion with physicians may be beneficial in reducing MEs in primary care (Lainer et al., 2013).

Table 2.4: The effectiveness of pharmacist-led information technology interventions to improve medication safety in primary care

Author (year), country	Setting	Duration	Participants	Intervention(s)	Control	Outcome(s)
Raebel, Carroll, et al. (2007), US*	General practice	3 months	11100 pregnant women	PIMS drug alert + pharmacist feedback to prescriber	Usual care	Proportion of patients dispensed inappropriate medication: intervention 2.9% vs control 5.5% (p<0.001), OR=0.52 (0.43-0.63)
Raebel, Charles, et al. (2007), US	General practice	12 months	59680 adults >65 years	PIMS drug alert + pharmacist feedback to prescriber	Usual care	Proportion of newly dispensed at least one inappropriate medication: intervention 1.8% vs control 2.2%, RR=16%, (p=0.002)
A. J. Avery et al. (2012), UK	General practice	12 months	72 general practices, 480942 patients	Computer-generated feedback + educational outreach and dedicated support by pharmacist	Computer-generated simple feedback	(i) History of peptic ulcer prescribed with non-selective NSAID without gastroprotection: intervention 3% vs control 4%, OR=0·58 (0·38–0·89) (ii) History of asthma prescribed with β blocker: intervention 2% vs control 3%, OR=0·73 (0·58–0·91) (iii) ACE inhibitor or loop diuretic without appropriate monitoring: intervention 5% vs control 8%, OR=0·51 (0·34–0·78)

US=United States; *this study was discontinued earlier due to false positive alerts owing to misidentification of contraindicated medications and misidentification of pregnancy; PIMS=pharmacy information management system; OR=odds ratio; RR=relative risk; UK=United Kingdom; NSAID=nonsteroidal anti-inflammatory drug; ACE=angiotensin converting enzyme

2.8.2.4 Telemedicine

Telemedicine involves the exchange of medical information from one site to another via electronic communication. This intervention aimed to reduce ADEs by improving prescriber-patient communication in outpatient setting. Spaeder et al. (2006) reported on the remote monitoring of medication titration in congestive heart failure patients, while Elkjaer et al. (2010) created a web program to support patients in recognising relapse in inflammatory bowel disease and starting medication [Table 2.5]. Both these studies did not show any significant improvement in ADEs compared to usual care (Elkjaer et al., 2010; Spaeder et al., 2006). More recently, Weingart et al. (2013) tested web generated messages to patients inquiring about any problems with their recent medications and patients' responses were forwarded to their respective physicians. This application facilitated physician-patient communication regarding medication-related issues but also did not show any improvement in ADEs rates (Weingart et al., 2013). These studies were however underpowered to detect any changes in ADEs.

Table 2.5: The effectiveness of telemedicine interventions to improve medication safety in primary care

Author (year), country	Setting	Duration	Participants	Intervention(s)	Control	Outcome(s)
Elkjaer et al. (2010), Denmark, Ireland	Outpatient clinic	12 months	333 patients with ulcerative colitis on 5-ASA treatment	Web-program providing disease specific education and self-treatment	Usual care	ADEs: intervention 11.5% vs control 14.1%, RR=0.82
Spaeder et al. (2006), US	Outpatient clinic	3 months	49 patients with NYHA class II/III left ventricular systolic dysfunction	TeleWatch system (remote monitoring of physiological parameters, heart failure symptoms, medication adherence and side effects) with clinic visits	Clinic visits	Serious ADEs: intervention (1%) vs control (1.2%) (p=0.29), OR=4 (0.48-33.1)
Weingart et al. (2013), US	General practice, 43 PCPs	3 months	738 patients	MedCheck; automated electronic message generated in a patient Internet portal asking patients if they had filled a recent prescription, and if they had experienced any problems with the medication. Patients' responses were forwarded automatically to PCPs	Usual care	ADEs: intervention 26.1% vs control 25.6%, p=0.89 Serious ADEs: intervention 0.8% vs control 0.0%, p=0.08 Preventable ADEs: intervention 1.6% vs 0.6%, p=0.22 *Health care utilisation: NS

5-ASA=5-aminosalicylic acid; ADE=adverse drug event; RR=relative risk; US=United States; NYHA=New York Heart Association; OR=odds ratio; PCP=primary care physician; NS=not significant; *telephone calls, patient site messages, PCPs appointments, specialist appointments, ED visits, hospital admissions, inpatient days

2.8.2.5 Web-based safety improvement system

IT interventions were also used as part of quality management strategies in primary care. Singh et al. (2012) evaluated a web-based team resource management system which employed cyclical safety improvement process facilitated by two online surveys: failure modes and effects analysis tool focusing on medication management, and ambulatory version of the safety attitude questionnaire. Each member of the intervention primary care practice completed both questionnaires anonymously, following which the staffs were grouped and the survey results were reviewed and discussed. The online tool provided automated analysis and visual presentation of the survey results. At the end of the discussion, staffs prioritised medication safety issues identified by the online survey. In subsequent meetings, staffs developed system changes to improve medication safety based on the issues identified earlier. The online tool monitored this process by prompting staffs to define their goals and objectives, assigning specific work steps to individual team members, tracking progress, coordinating meetings and reminding staffs of their commitments (Singh et al., 2012). This resulted in reduced ADE rates within the 12 months study period in intervention sites compared to controls (intervention 18.3% versus control 24.8%, p=0.05) (Singh et al., 2012). This study demonstrates the importance of stake holders' (in this case the primary care practice staffs) views and participation in addressing ADEs and MEs in primary care.

2.8.3 Patient education

Patient education has been one of the most common interventions to improve medication safety in primary care. This is because in outpatient setting, patients play a central role in taking their medications as per instructions (Bajcar, Kennie, & Einarson, 2005). In addition, patients' medication knowledge and believe influence their medication-taking behaviour (K. Nair et al., 2002; Raynor, Savage, Knapp, & Henley,

2004; Viswanathan & Lambert, 2005). Providing patients with information about their disease and medication will therefore help to prevent MEs that occur at patient homes (K. Nair et al., 2002; Viswanathan & Lambert, 2005). This intervention can be delivered either verbally, written or both. The majority of patient education interventions were delivered as part of medication reviews, which will be covered in section 2.8.4 (page 36). In this section, studies that reported on patient education as a stand-alone intervention will be described.

Wu et al. (2006) investigated the impact of pharmacist-provided telephone counselling for 502 out of 1011 non-adherent patients with polypharmacy (≥5 medications). At the end of the 24 months, the intervention significantly reduced mortality, but did not impact on hospital admissions and ED attendances (Wu et al., 2006) [Table 2.6]. Apart from the large sample size and long duration of follow-up, the impact on mortality in this study could be due to their patient selection criteria; the intervention was targeted at patients who were non-adherent to their medications (Wu et al., 2006). The other two studies investigated the impact of educating patients about their medications on hospital admission rates, but did not find any significance (Machtinger et al., 2007; Peveler, George, Kinmonth, Campbell, & Thompson, 1999) [Table 2.6].

Table 2.6: The effectiveness of patient education interventions to improve medication safety in primary care

Author (year), country	Setting	Duration	Participants	Intervention(s) *(frequency)*	Control	Outcome(s)
Wu et al. (2006), Hong Kong	Outpatient clinic	24 months	1011 Patients with ≥5 medications who were non-compliant to their medications	Pharmacist provided education to increase adherence through the telephone (including diet, exercise and self-monitoring) *(mid-point between clinic visits)*	Usual care	Hospital admissions: intervention 1 vs control 0 (p=0.316) ED attendances: intervention 0 vs control 1 (p=0.203) Mortality: intervention 25 vs control 38 (p<0.05); RR 0.59 (CI 0.35-0.97), p=0.039
Machtinger et al. (2007), US	Outpatient clinic	3 months	157 people using warfarin	A visual medication schedule with digitalized images of patient's warfarin regimen + brief patient education *(each visit)*	Usual care: pharmacist consultation	Hospital admissions: NS
Peveler et al. (1999), UK	General practice	12 weeks	213 people using tricylic antidepressants	Patient education by nurse (written and verbal)	Usual care	Hospital admissions: NS

ED=emergency department; RR=risk ratio; CI=confidence interval; US=United States; NS=not significant; UK=United Kingdom

2.8.4 Medication reviews

Medication review is a structured evaluation of a patient's medication with the aim to reach agreement with the patient about drug therapy, optimising the impact of medication, and minimising the number of DRPs (Holland et al., 2008). Most of the interventions designed to improve medication safety in primary care involved medications reviews, of which the majority was pharmacist-provided medication reviews (section 2.8.4.2 page 43, and section 2.8.4.3 page 50).

Medication review interventions in the literature vary in intensity and design making direct comparison between studies difficult. For example, some studies involved more than one session of medication review (Gattis et al., 1999; Taylor et al., 2003), while others only involved a single medication review session (Krska et al., 2001; L. Sorensen et al., 2004). In some studies, details on how and how many times the reviews were conducted were unclear (Bernsten et al., 2001; McCombs et al., 1998). This can significantly impact results as studies with more frequent medication reviews, will result in more identification and reduction in DRPs. In addition, some studies involved pharmacist discussion with physicians regarding DRPs and recommendations, while others only involved written recommendations to prescriber, without further follow-up. Pharmacist-physician discussion on DRPs and action plan is an important step in resolving the DRPs identified (Cipolle, Strand, & Morley, 2004). Sending written recommendations to prescriber without follow-up has high chances of prescriber ignoring the recommendations proposed, and DRPs remained unresolved.

Medication reviews were often targeted at "high risk" patients based on their age (eg, elderly) (Zermansky et al., 2001), disease state (eg, heart failure) (Bouvy et al., 2003; Gattis et al., 1999; Sadik, Yousif, & McElnay, 2005), drug therapy (eg, ≥5 medications)

(J. P. Jameson & VanNoord, 2001), or a combination of these factors (Lim et al., 2004). These are consistent with the risk factors for ADEs in outpatient setting (refer to section 2.6, page 16). However, due to the heterogeneity in target population selection among studies, direct comparison of results between studies is difficult and inappropriate.

A range of patient safety outcomes were investigated in medication review intervention studies: hospital admissions, ADEs, ADRs, ED visits, and mortality (Bond, Matheson, Williams, Williams, & Donnan, 2000; Hanlon et al., 1996; Olivarius et al., 2001). This is based on the grounds that the identification and resolution of DRPs through medication reviews can reduce ADEs and improve disease control. Improvement in disease control and ADEs will in turn result in reduction in health care utilisation such as hospital admissions and EED visits, as well as mortality.

2.8.4.1 Medication review by general practitioners and nurses

A total of nine studies were identified involving medication reviews by health care professionals other than pharmacists [Table 2.7]. In two of these studies, the medication reviews were conducted by GPs (Kendrick, Burns, & Freeling, 1995; Olivarius et al., 2001), while the remaining seven studies investigated the impact of nurse-led medication reviews in outpatient setting (Aubert et al., 1998; Cline, Israelsson, Willenheimer, Broms, & Erhardt, 1998; Doughty et al., 2002; Ekman et al., 1998; Newbury, Marley, & Beilby, 2001; Piette et al., 2000; Stromberg et al., 2003). GP and nurse-led medication reviews were delivered as part of multi-faceted interventions; the interventions generally involved medication review, patient education on treatment, diet and exercise, and patient monitoring (through clinic visit or through phone calls) (Aubert et al., 1998; Cline et al., 1998). Studies vary in the way the medication reviews were conducted; some studies used a structured tool such as checklist and protocol to conduct the reviews (Aubert et al.,

1998; Kendrick et al., 1995), while others did not specify the exact method used to conduct the reviews (Doughty et al., 2002; Newbury et al., 2001). The population targeted by these studies were the elderly (Newbury et al., 2001), people with mental illness (Kendrick et al., 1995), diabetes (Aubert et al., 1998; Olivarius et al., 2001; Piette et al., 2000) and heart failure (Cline et al., 1998; Doughty et al., 2002; Ekman et al., 1998; Stromberg et al., 2003).

Six studies investigated the impact of medication reviews by GPs and nurses on mortality (Cline et al., 1998; Doughty et al., 2002; Ekman et al., 1998; Newbury et al., 2001; Olivarius et al., 2001; Stromberg et al., 2003), out of which only one study showed significant impact (Stromberg et al., 2003). In this study, nurse-delivered medication review, patient education and continuous telephone support for heart failure patients significantly reduced mortality in the intervention group at the end of the 12 months follow-up period (7 vs 20, p=0.05) (Stromberg et al., 2003). This study also reported a significant reduction in hospital admissions at 3 months 33 vs 56, p=0.047), but this significance was lost at 12 months (82 vs 92, p=.031(Stromberg et al., 2003). None of the studies in this category reported a positive impact of the intervention on ED visits, and ADEs. Consistent with this, a meta-analysis by Royal, Smeaton, Avery, Hurwitz, and Sheikh (2006) on four GP and nurse-led medication review studies found no significant impact on ADEs (OR 1.05, 95% CI 0.57 to 1.94).

The lack of evidence for GPs and nurse-led medication reviews on patient safety outcomes is not explained by small sample size or short duration of follow-up of the studies. For example, Olivarius et al. (2001) conducted a GP-led medication review study involving 1316 patients with diabetes, who were followed up for six years. This study did not find any impact on hospital admissions, ADEs and mortality (Olivarius et al., 2001).

However, the lack of impact could be due to the intervention itself; in this study, the GPs were only prompted to do the medication reviews and no specific protocol was provided (Olivarius et al., 2001). Furthermore, the reviews were conducted by the patients' GP himself/herself, and no other health care professionals were involved (Olivarius et al., 2001). This could be a potential source of bias and the lack of impact of the study despite large sample size and long duration of follow-up.

Table 2.7: The effectiveness of general practitioners and nurse-led medication review interventions in improving medication safety outcomes

Author (year), country	Setting	Duration	Participants	Intervention(s) *(frequency)*	Control	Outcome(s)
Olivarius et al. (2001), Denmark	General practice	72 months	1316 people with Type-2 diabetes	Medication review by GP + education for GP based on clinical guidelines + prompting GP for diabetic screening and weight reduction + providing GP with report on measurements of risk factors, complications, current treatment goal, and pharmacological treatment for each patient *(every 3 months)*	Usual care	ADEs: intervention 17 vs control 1 (0.94) Hospital admissions: intervention 1 vs control 1 (p=0.79) Mortality: intervention 33.3% vs control 33.9 (p=0.82)
Kendrick et al. (1995), UK	16 general practices	24 months	440 patients with long term mental illness	GP were trained to conduct structured assessment of patient's mental illness to optimize treatment and asked to review patients 6 monthly *(6 monthly)*	Usual care; GPs were asked to review patients 6 monthly	Admission for drug overdose: intervention 0.5 vs control 0.23 (NS) Admission to psychiatric hospital; intervention 17.3% vs control 14.8% (NS)
Newbury et al. (2001), Australia	General practice	12 months	100 patients aged ≥75 years old	Medical assessment and medication review by nurse + feedback to prescriber *(once)*	Usual care	Mortality: NS

Table 2.7 continued

Author (year), country	Setting	Duration	Participants	Intervention(s) *(frequency)*	Control	Outcome(s)
Aubert et al. (1998), US	General practice	12 months	138 patients with Type-1 or Type-2 diabetes	Nurse-led case management using a protocol which include medication adjustment, meal planning and exercise reinforcement + follow-up calls 2 weekly + feedback to prescriber *(3 monthly in person, 2 weekly phone call)*	Usual care	ADEs: intervention 4.6% vs control 4.4% (p=0.158) Hospitalisation rate: intervention 6% vs control 6% (NS) ED attendances: intervention 2% vs control 6% (p>0.2)
Piette et al. (2000), US	General practice	12 months	280 patients with diabetes	Automated telephone call to identify problems with health and therapy + self-care education through telephone + follow-up call by diabetes nurse educator where problems identified *(bi-weekly)*	Usual care with access to triage nurse and diabetes education clinic	Hospital admissions: intervention 24% vs control 23% (p=0.9) ED attendances: intervention 48% vs 40% (p=0.2)
Cline et al. (1998), Sweden	Outpatient clinic	12 months	190 patients aged ≥65 years old with heart failure	Diabetic nurse-led diabetic care which include education on disease, medication and self-management strategies (including printed materials) + easy access follow up at outpatient clinic and telephone call *(continuous)*	Usual care (follow up at the outpatient clinic by cardiologist or primary care physician)	Mortality: intervention 30% vs control 28% (p=0.06) Hospital admissions: intervention 22 vs control 43 (p=0.08)

Table 2.7 continued

Author (year), country	Setting	Duration	Participants	Intervention(s) *(frequency)*	Control	Outcome(s)
Doughty et al. (2002), New Zealand	Outpatient clinic	12 months	197 patients with heart failure	Medication review + nurse provided patient education + written feedback to prescriber followed by discussion over the phone + group education by cardiologist and nurse *(clinic visit: 6 weekly)*	Usual care	Hospital admission: intervention 64 vs control 59 (NS) Mortality: intervention 19 vs control 24 (NS)
Ekman et al. (1998), Sweden	Outpatient clinic	6 months	158 patients aged ≥65 years old with heart failure with heart failure	Nurse-led clinic providing patient review (medication and symptoms) + individual care plan + patient education + telephone support *(continuous)*	Usual care	Hospital admissions: intervention 61% vs control 57% (NS) Mortality: intervention 27% vs control 22% (NS)
Stromberg et al. (2003), Sweden	Outpatient clinic	12 months	106 patients with heart failure	Nurse-led clinic with medication review and protocol-based medication changes + patient education (written and verbal) + telephone support *(continuous)*	Usual care	Hospital admissions at 3 months: intervention 33 vs control 56 (p=0.047) Hospital admission at 12 months: intervention 82 vs control 92 (p=0.31) Mortality: intervention 7 vs control 20 (p=0.05)

NS=not significant; UK=United Kingdom; GP=general practitioner; US=United States; ADE=adverse drug event; ED= emergency department

2.8.4.2 Individual pharmacist-led medication reviews

Pharmacists can provide medication review interventions either independently, or as part of a multidisciplinary team (L. Sorensen et al., 2004; Zermansky et al., 2001). Pharmacist-led medication reviews are based on the principles of pharmaceutical care, which is defined as the "responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life" (Hepler & Strand, 1990). This generally involved pharmacist reviewing patients' drug therapy based on information obtained via patient interview and/or individual's medical record. Following this, a pharmaceutical care plan was designed specifying the DRP(s) identified, action(s) proposed to solve each DRP and clinical target(s) (Cipolle et al., 2004). When necessary, drug therapy recommendations were made to prescriber either verbally or in writing. Patient education about disease and treatment were also provided. Finally, patients were followed up and monitored for DRPs, either through clinic visit or through the telephone.

The majority of studies did not show that individual pharmacist-led medication reviews reduce hospital admissions and ED visits (Sellors et al., 2003; Touchette et al., 2012; Zermansky et al., 2001), except for McCombs et al. (1998), Taylor et al. (2003), and Varma, McElnay, Hughes, Passmore, and Varma (1999) who reported significant reduction in hospital admissions and/or ED visits [Table 2.8]. This could be explained by the relatively large sample size (6000 patients) and longer study duration (24 months) employed by McCombs et al. (1998), and the relatively frequent medication review and patient contact (each visit) provided by the other two studies (Taylor et al., 2003; Varma et al., 1999). A meta-analysis by Royal et al. (2006) reported that random effects meta-analysis of hospital admissions data from 13 pharmacist-led medication review studies showed significant reductions in hospital admissions (OR 0.64, 95% CI 0.43 to 0.96). They also found significant heterogeneity between studies included in the analysis (Chi-

square 126.71, df 12, p<0.001) (Royal et al., 2006). Restricting the results to RCTs removed the heterogeneity between studies, but no longer found a statistically significant effect of the intervention on hospitalisations (OR 0.92, 95% CI 0.81 to 1.05) (Royal et al., 2006). Therefore, the authors concluded that there is a relatively weak evidence to indicate that pharmacist-led medication reviews are effective in reducing hospital admissions (Royal et al., 2006).

Only one study in this category reported on mortality, but did not find any significance (Bond et al., 2000).

One of the underlying objectives of pharmacist-led medication reviews were to reduce ADEs. Despite this, relatively few studies investigated the impact of the intervention on ADEs. Studies that compared ADE rates between intervention and control did not find any significance (Bond et al., 2000; Hanlon et al., 1996; Lim et al., 2004; Touchette et al., 2012). J. P. Jameson and VanNoord (2001) however, found that at the end of the six months follow up period, more patients in the interventions group had their ADE scores improved, and fewer had symptoms worsen than in the usual care group (p=0.024).

Table 2.8: The effectiveness of individual pharmacist-provided medication reviews to improve medication safety in primary care

Author (year), country	Setting	Duration	Participants	Intervention(s) *(frequency)*	Control	Outcome(s)
Kimberlin, Berardo, Pendergast, and McKenzie (1993), US	Community pharmacy, 102 pharmacists	3 months	762 patients aged ≥65 years old	Pharmacists were trained to identify and solve patients' DRP *(not specified)*	Usual care	Odds of hospital admission not significantly different between groups
Knowlton and Knapp (1994), US	Community pharmacy	9 months	18 pharmacies	Pharmacists were trained to communicate with patients and prescribers and to solve patients' DRP *(not specified)*	Usual care	Hospital admission rates/month: intervention 3.95% vs control 3.93% (NS)
Hanlon et al. (1996), US	Outpatient clinic	12 months	208 patients aged ≥65 years old	Pharmacist provided medication review + patient interview + pharmaceutical care plan + discussion with prescriber + patient education (oral and written) *(each visit)*	Medication review by nurse before and after (only when there are changes) doctor's visit	ADEs: intervention 30.2% vs control 40.0% (p=0.19)
McCombs et al. (1998), US	Community pharmacy	24 months	6000 patients	Model 1: Pharmacist consultation for new/changed medications or Model 2; Pharmacist consultation for selected high-risk patients *(not specified)*	Usual care	Hospital admissions: Model 1= OR 0.967, p<0.01 Model 2= OR 0.982, p<0.05

Table 2.8 continued

Author (year), country	Setting	Duration	Participants	Intervention(s) *(frequency)*	Control	Outcome(s)
Bond et al. (2000), UK	Community pharmacy, 62 pharmacists, 19 general medical practices	12 months	3074 patients,	Pharmacists reviewed patients' medication for each repeat prescription *(monthly)*	Usual care	ADRs: intervention 8.3% vs control 6.7% (p=0.291) Hospital admissions: intervention 6.0% vs control 5.7% (p=0.856) Mortality: intervention 3.6% vs control 3.8% (NS)
Malone et al. (2000), US	9 general practices	12 months	1054 patients at high risk of DRP	Medical care + medication review by clinical pharmacist *(each visit)*	Medical care	Increase in hospital admission: intervention 0.13 vs control 0.19 (NS)
Bernsten et al. (2001), multicenter (Europe)	190 community pharmacies	18 months	2454 patients ≥65 years old	Pharmacist assessed patients for DRP, formulated care plans to solve DRP and monitored patients *(continuous)*	Usual care	Hospitalisations: intervention 35.6% vs control 40.4% (p>0.05)
Krska et al. (2001), UK	General practice	3 months	381 patients aged ≥65 years old	Pharmacist provided medication review + formulated and implemented pharmaceutical care plan + written feedback to prescriber *(once)*	Usual care	Hospital admissions: intervention 6 vs control 8*

Table 2.8 continued

Author (year), country	Author (year), country	Author (year), country	Author (year), country	Author (year), country	Author (year), country	Author (year), country
Zermansky et al. (2001), UK	General practice	12 months	1188 patients aged ≥65 years old	Pharmacist provided medication review + discussion with GP (when needed) *(once)*	Usual care	Hospital admissions: intervention 19% vs control 17% (p=0.16)
J. Jameson, VanNoord, and Vanderwoud (1995), US	Outpatient clinic	6 months	64 patients at high risk of medication incidents	Pharmacist provided medication review + feedback to prescriber *(once)*	Usual care	ADEs: improved by 1.8 points in intervention group (NS)
J. P. Jameson and VanNoord (2001), US	General practice	6 months	340 patients with ≥5 medications	Pharmacist provided medication review + feedback to prescriber *(once)*	Usual care	Improvement in ADEs: intervention 54.0% vs control 37.6% (p=0.024)
Lim et al. (2004), Singapore	Outpatient clinic	2 months	136 patients at high risk of medication incidents	Pharmacist provided medication review + discussion with physician + patient education + supply of compliance aid (when necessary) *(once)*	Usual care	Decrease in residual ADRs: intervention 30.7 vs control 50.0% (NS)
Sellors et al. (2003), Canada	24 general practices, 48 physicians	5 months	889 patients aged ≥65 years old and on ≥5 medications	Pharmacist provided medication review + formulation of pharmaceutical care plan + discussion with prescriber + patient tele-monitoring *(continuous)*	Usual care	ED attendances: intervention 20% vs control 23% (p=0.28) Drug related hospital admissions: intervention 4% vs control 4% (p=0.08)

Table 2.8 continued

Author (year), country	Setting	Duration	Participants	Intervention(s) *(frequency)*	Control	Outcome(s)
Taylor et al. (2003), US	General practice	12 months	81 patients at high risk for medication incidents	Pharmacist provided medication review + therapeutic recommendation to prescriber (written or verbal) + patient education (including written materials) + provision of compliance strategies + monitoring *(each visit)*	Standard medical care	Hospitalisations: intervention 2 vs control 11 (p=0.003) ED attendances: intervention 4 vs control 6 (p=0.044)
Touchette et al. (2012), US	General practice	3 months	637 patients with high risk for medication incidents	Pharmacist provided medication review + screened and resolved DRP + patient education + feedback to prescriber (written or telephone) *(0 and 3 months)*	Medical care + routine pharmacist counselling	ADEs: intervention 27.9% vs control 33.7% (p=0.278) Hospitalisations: intervention 7.9% vs control 10.4% (p=0.370) ED attendances: intervention 20.0% vs control 20.3% (p=0.970)
Jaber, Halapy, Fernet, Tummalapalli, and Diwakaran (1996), US	Outpatient clinic	4 months	45 patients with Type-2 diabetes	Pharmacist provided diabetes education + medication counseling + instructions on dietary regulation, exercise, and home blood glucose monitoring + evaluation and adjustment of hypoglycemic regimen *(once)*	Usual care	Hospitalisations*: intervention 1 vs control 2

Table 2.8 continued

Author (year), country	Setting	Duration	Participants	Intervention(s) *(frequency)*	Control	Outcome(s)
Bouvy et al. (2003), Netherlands	Outpatient clinic	6 months	152 patients with heart failure	Clinical pharmacist medication review + reinforced adherence + written feedback to prescriber + monthly phone call *(monthly)*	Usual care	Hospital admissions: intervention 43% vs 54% (p=0.4)
Sadik et al. (2005), United Arab Emirates	Outpatient clinic	12 months	221 patients with heart failure	Pharmacist provided medication review + patient education on medication, self-monitoring, diet and exercise (including printed booklet) + discussion with prescriber regarding care plan *(three monthly)*	Usual care	Hospital admissions*: intervention 22 vs control 36 ED attendances*: intervention 33 vs control 25
Varma et al. (1999), Ireland	Outpatient clinic	12 months	83 patients aged ≥65 years old with congestive heart failure	Pharmacist provided patient education on disease, treatment, lifestyle and self-monitoring + reinforce adherence + simplification of medication regimen with physician if necessary *(each visit)*	Usual care	Hospital admissions: intervention 14 vs control 26 (p=0.006) ED attendances: NS

US=United States; DRP=drug related problem; NS=not significant; ADE=adverse drug event; OR= odds ratio; UK= United Kingdom; ADR=adverse drug reaction; *significance not reported; GP=general practitioner; ED=emergency department

2.8.4.3 Pharmacist-led medication reviews as part of a multidisciplinary team

Pharmacists also provided medication reviews as part of a multidisciplinary team consisting of a doctor, and/or a nurse, a dietician and a social worker. Three out of five studies in this category showed a significant impact on either one of the medication safety outcomes (hospital admissions, serious ADRs and mortality) (Gattis et al., 1999; Sadur et al., 1999; Schmader et al., 2004) [Table 2.9]. Gattis et al. (1999) reported that the provision of pharmaceutical care by a pharmacist in the heart failure management team significantly reduced mortality and non-fatal heart failure events by 78%; whilst Schmader et al. (2004) reported a 35% reduction in serious ADRs among patients receiving pharmacist-provided medication review in a multidisciplinary team consisting of geriatrician, nurse and social worker. The lack of effect of the remaining two studies can be explained by the frequency of the intervention; L. Sorensen et al. (2004) delivered the intervention only once, while the intervention by Coleman, Grothaus, Sandhu, and Wagner (1999) was delivered every three to four months.

Table 2.9: The effectiveness of pharmacist-led medication reviews in a multidisciplinary team on medication safety outcomes

Author (year), country	Setting	Duration	Participants	Intervention(s) *(frequency)*	Control	Outcome(s)
L. Sorensen et al. (2004), Australia	General practice, 92 GPs, 53 pharmacists	6 months	400 patients at high risk of medication incidents	GP education + GP and pharmacist home visits + pharmacist medication reviews + primary healthcare team conferences + GP implementation of action plans *(once)*	Usual care	ADEs: intervention 9.3% vs control 34.0% (NS)
Coleman et al. (1999), US	General practice	24 months	169 patients aged ≥65 years old	Extended visit with physician and nurse dedicated to planning chronic disease management + pharmacist visit that emphasized reduction of polypharmacy and high-risk medications + self-management/support group *(every 3-4 months)*	Usual care	Hospital admissions: intervention 58% vs control 59% (NS) ED attendances: intervention 23% vs control 27% (NS)
Schmader et al. (2004), US	Outpatient clinic	12 months	808 patients aged ≥65 years old	Pharmacist conducted regular medication reviews and provided therapeutic recommendations as part of a multidisciplinary team consisting of a geriatrician, nurse and social worker. *(not specified)*	Usual care	All ADRs: intervention 247 vs control 250, RR 1.03 (p=0.75) Serious ADRs: intervention 49 vs control 78, RR 0.65 (p=0.02)
Gattis et al. (1999), US	Outpatient clinic	6 months	181 patients with heart failure	Pharmacist medication review + verbal therapeutic recommendations to attending physician + patient education + follow-up telemonitoring *(0, 2, 12 and 24 weeks)*	Usual care	Mortality: intervention 4 vs control 16 (p=0.005); OR 0.22 (CI 0.07-0.65)

Table 2.9 continued

Author (year), country	Setting	Duration	Participants	Intervention(s) *(frequency)*	Control	Outcome(s)
Sadur et al. (1999), US	Outpatient clinic	12 months	185 patients with diabetes	Pharmacist provided medication review as part of a multidisciplinary team consisting of dietitian, behaviorist and led by diabetes nurse educator. *(monthly)*	Usual care	Hospital admissions: intervention 28 vs control 41 (p=0.04)

GP=general practitioner; ADE=adverse drug event; NS=not significant; US=United States; OR= odds ratio; CI=confidence interval; ED=emergency department; ADR=adverse drug reaction; RR=relative risk

2.8.4.4 Impact of medication review interventions on medication use outcomes

The lack of concrete evidence for medication review interventions in improving patient safety outcomes such as hospital admissions, mortality and ADEs could be related to the difficulties in detecting the impact of the intervention on those outcomes. Krska et al. (2001) reasoned that medication reviews were only likely to affect hospital admissions that were related to drug therapy. Also, a large sample size of approximately 2800 to 6000 will be required to detect the impact of medication reviews on preventable drug-related hospitalisations (Krska et al., 2001). It might therefore be more appropriate to consider outcomes such as ADEs. Unfortunately, sample size is still an issue when using this outcome as a minimum of 800 to 1400 elderly people would need to be randomised to detect a 25% reduction in ADEs (Hanlon, Lindblad, & Gray, 2004). In addition, it is difficult to objectively determine ADE rates; ADE rates in the literature are usually collected through self-reports from participants, and this can be very misleading due to its subjective nature (Jaber et al., 1996). Besides, the impact of interventions on outcomes such as mortality, ADEs and hospital admissions may require a long duration of follow which were mostly not met through available studies (Krska et al., 2001; Lim et al., 2004; Sellors et al., 2003).

Due to the difficulties in determining the impact of medication reviews on patient safety outcomes as discussed above, many researchers opted to use alternative outcomes such as numbers of DRPs, number of drugs, and medication appropriateness (Bernsten et al., 2001; Grymonpre, Williamson, & Montgomery, 2001; Krska et al., 2001; Stromberg et al., 2003). These outcomes reflect on the medication use process that may lead to ADEs. As one of the aim of medication review intervention is to prevent, identify and solve DRPs, it is expected that the intervention will lead to significant reduction in patient's DRPs. This is supported by a systematic review by Hanlon et al. (2004) who

reported that there was substantial evidence that clinical pharmacy interventions reduced the occurrence of DRPs in community dwelling older people. Similarly, as medication review involves optimisation of drug regimen, it is expected that this intervention will result in reduction of patient's number of medication by eliminating unwanted therapies. The evidence for this is provided by a systematic review by Holland et al. (2008) who found that pharmacist-led medication review interventions decreased the number of drugs prescribed in older people (weighted mean difference = -0.48, 95% CI -0.89 to -0.07).

In addition, Schmader et al. (2004) reported that medication reviews conducted by a team of doctor, pharmacist and nurse significantly improved the number of inappropriate drugs among elderly outpatients. Similar conclusion was reported by Susan M. Patterson et al. (2012) and Kaur et al. (2009) in their systematic reviews; the most successful type of intervention to reduce inappropriate prescribing in older people were those that had multidisciplinary involvement (mainly doctors and pharmacists).

2.8.4.5 Multidisciplinary versus individual led medication review interventions

Pharmacist-led medication reviews were more effective compared to GP and nurse-led reviews (Easton et al., June 2009). This could be because pharmacists have been trained specifically in drug therapy, and to deliver pharmaceutical care with the goal of optimising patients' drug therapy and improve quality of life (Hepler & Strand, 1990). In contrast, nurses are not professionally trained to focus on patients' medication regimen. Medication reviews by GPs on the other hand, were conducted by the patients' GP himself/herself rather than another independent GP (Kendrick et al., 1995). This was a potential source of bias and could have an impact on the effectiveness of the interventions.

In addition, pharmacist-led medication reviews were more effective when delivered as part of a multidisciplinary team, as compared to when delivered independently (Easton et al., June 2009). For a medication review to be effective, the medication management plan arising from the review needs to be implemented. However, this did not happen frequently when pharmacist provided medication reviews independently from the prescriber due to the lack of communication and collaboration between them (Gilbert et al., 2002). When pharmacist and prescriber work as part of a multidisciplinary team, this facilitates communication and collaboration; the medication management plan was discussed and drafted together, before being implemented (L. Sorensen et al., 2004). This therefore led to a greater improvement in patients' therapy compared to individual pharmacist-led medication reviews.

2.8.5 Doctor-pharmacist collaboration in primary care

Collaboration in health care refers to the process in which different professionals work together to positively impact health care (Zwarenstein, Goldman, & Reeves, 2009). It involves a negotiated agreement between professionals which values the expertise and contributions that various health care professionals bring to patient care (Zwarenstein et al., 2009). Two health care professionals that have been increasingly encouraged to work together are doctors and pharmacists (Canadian Pharmacists Association, 2007). As doctors and pharmacists have specialist knowledge of medications, they can complement each other's role in patient care. Besides, doctors and pharmacists are the two main health care professionals involved in medication management of patients in the outpatient setting (Bajcar et al., 2005). Collaboration and improved communication between them can help in the exchange of patient-specific information in a more timely manner, and resolve patients' drug therapy problems more effectively and efficiently (Randal P. McDonough & Doucette, 2001).

2.8.5.1 Benefits of doctor-pharmacist collaboration in primary care

Many health systems around the world are introducing pharmacists into their primary care teams (Ackermann, Douglas Williams, & Freeman, 2010; Bernsten et al., 2001; Bradley et al., 2008; Dolovich et al., 2008; Farrell et al., 2008). Pharmacists add value to these teams by providing medication reviews, patient education, acting as a drug information source to other members and implementing system-level practice enhancements such as a diabetes care monitoring system and a medication switching protocol (Dolovich et al., 2008). Interprofessional collaboration between doctors and pharmacists in primary care teams has produced favourable results in terms of ME detection, improved medication appropriateness and resolution of DRPs (C. A. Brown et al., 2006; L. J. Bryant et al., 2011; Gilbert et al., 2002). In addition, doctor-pharmacist collaborations in primary care have reported successful outcomes with regards to chronic disease control such as cholesterol reduction, blood pressure control, diabetes management, heart-failure management, depression management and pain control (Bogden, Koontz, Williamson, & Abbott, 1997; Chelminski et al., 2005; Z. Chen et al., 2013; Codispoti et al., 2004; Gattis et al., 1999).

2.8.5.2 Barriers to successful doctor-pharmacist collaboration in primary care

Integration of pharmacists into primary care teams has provided doctors and pharmacists a framework for collaboration. However, evidence suggest that minimal collaboration exists between them; most doctors and pharmacists continue to work as functionally separate solo practitioners (Dey, de Vries, & Bosnic-Anticevich, 2011; Dieleman et al., 2004; Zwarenstein et al., 2009). One of the reason for this is cultural barriers; the historical lack of close collaboration makes it difficult for doctors to accept that they can utilise the expertise of pharmacist to improve quality and safety of medication use (T. F. Chen & de Almeida Neto, 2007; Dey et al., 2011). Pharmacists are

often not viewed as a core part of the primary health care team, as their role has been traditionally characterised by dispensing prescription medications, and offering healthcare advice (Hughes & McCann, 2003).

The lack of face-to-face interactions between doctors and pharmacists is another barrier to successful collaboration (T. F. Chen & de Almeida Neto, 2007). Medication reviews by pharmacists are often undertaken separately from the doctors, with limited history of face-to-face contact. Information regarding patient care is exchanged in an impersonal manner through written reports, rather than face-to-face. Face-to-face interactions is important as it facilitates the establishment of trust, making it easier for doctors to accept input by pharmacist in the medication review process (Randal P. McDonough & Doucette, 2001).

Another important challenge to doctor-pharmacist collaboration is the lack of role definition within the relationship (Hughes & McCann, 2003; Jorgenson, Laubscher, Lyons, & Palmer, 2013). A clear role definition is important to avoid misunderstanding regarding responsibilities and authority (Randal P. McDonough & Doucette, 2001). In addition, doctors and pharmacists are often not aware of the shared expectations of the collaboration prior to starting. This further impedes collaboration between them (T. F. Chen & de Almeida Neto, 2007; Hughes & McCann, 2003).

2.8.5.3 Theoretical models for doctor-pharmacist collaborative working relationship

An understanding of the nature and context of interactions between doctors and pharmacists is critical to the development of strategies to enhance collaboration between them, and optimise their contribution to patient care. To date, two models have been

developed to describe the collaborative working relationship (CWR) between doctors and pharmacists (Bradley, Ashcroft, & Noyce, 2012; Randal P. McDonough & Doucette, 2001).

(a) *The Collaborative Working Relationship model*

The CWR model, proposed by Randal P. McDonough and Doucette (2001), is a general model for doctors and pharmacists. The model describes collaboration as an evolving process consisting of five stages: stage 0 – professional awareness, stage 1 – professional recognition, stage 2 – exploration and trial, stage 3 – professional relationship expansion and stage 4 – commitment to the CWR [Figure 2.2] (Randal P. McDonough & Doucette, 2001). The progressive shading of the stages (boxes) in the model represents the increasing collaboration and motivation to maintain the relationship between the doctors and pharmacists.

Interactions between the professionals are termed as exchanges, and at stage 0, exchanges are minimal and discrete (Randal P. McDonough & Doucette, 2001). For example, pharmacists calling doctors to clarify prescription problems encountered during dispensing process. These interactions are usually short and happen without much thought about developing a CWR or identifying new ways to improve patient care. At stage 1, efforts to establish CWR is unilateral and instigated by pharmacists (Randal P. McDonough & Doucette, 2001). For example, pharmacists approaching doctors for patient referrals upon starting of a new service such as medication review. At this stage, pharmacists view the relationship as necessary for the success of their new clinical service, while the doctors may not see the value or need of establishing CWR with pharmacists. As the relationship progresses, efforts to maintain the CWR becomes more bilateral. At Stage 4, commitment to the CWR by both practitioners has been achieved

with bilateral communication, mutual trust and respect (Randal P. McDonough & Doucette, 2001).

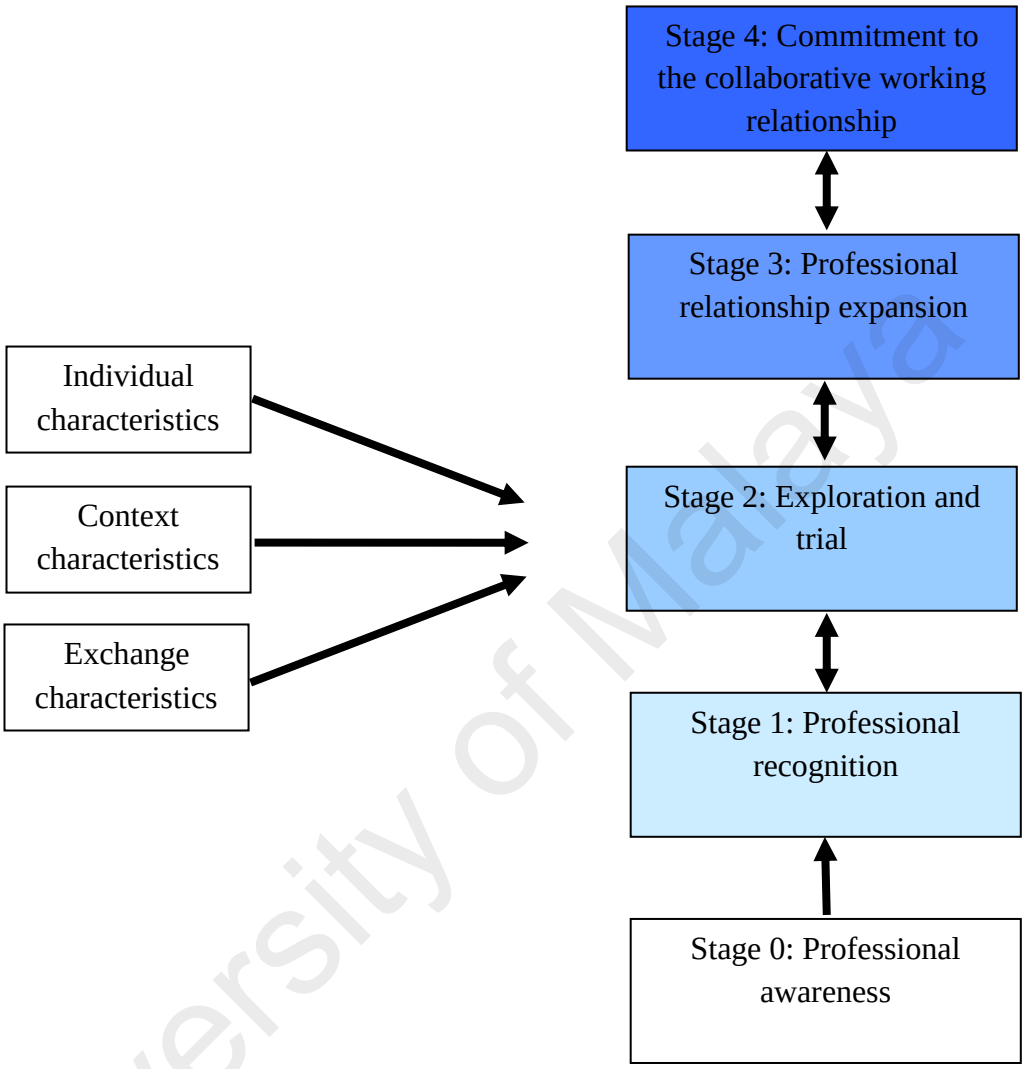


Figure 2.2: Staged approach to developing the physician-pharmacist collaborative working relationship (Randal P. McDonough & Doucette, 2001)

According to this model, factors that affect the development of CWR are individual characteristics (participants' personal and professional backgrounds), context characteristics (context of practice including patient characteristics and health system) and exchange characteristics (the nature and extent of professional interactions between the doctors and pharmacists) (Randal P. McDonough & Doucette, 2001; A. J. Zillich, McDonough, Carter, & Doucette, 2004).

The stages of the CWR model was synthesised from existing models of interpersonal relationships, including theories of social exchange, business relationships and collaborative care models primarily relating to nurses and physicians (Randal P. McDonough & Doucette, 2001). The proposed drivers of collaboration have been validated; the exchange characteristics of trustworthiness and role specification were reported to be the most significant factors influencing CWR for both professional groups (Snyder et al., 2010; A. J. Zillich et al., 2004).

(b) ***The conceptual model of general practitioner-community pharmacist collaboration***

More recently, Bradley et al. (2012) developed the conceptual model of GP-community pharmacist collaboration [Table 2.10]. This model consists of three stages: stage 1 – isolation, stage 2 – communication and stage 3 – collaboration tested (Bradley et al., 2012). Key components of collaboration were locality, service provision, trust, 'knowing' each other, communication, professional roles and respect tested (Bradley et al., 2012). The GP-community pharmacist collaboration model was derived from interviews with GPs and community pharmacists in the United Kingdom, and yet to be tested (Bradley et al., 2012). This model resonates with the CWR model by Randal P. McDonough and Doucette (2001), but does not explain how to operationalise, establish and develop doctor-pharmacist collaboration.

Table 2.10: The conceptual model of general practitioner-community pharmacist collaboration (Bradley et al., 2012)

	Level 1 – Isolation	Level 2 – Communication	Level 3 - Collaboration
Locality	Geographically separate	Mostly geographically separate but with some exceptions	Co-located or close geographically
Service Provision	Pharmacy provides limited or no additional services beyond dispensing	Pharmacy provides some additional services – the increased contact necessitated by these services has the potential to improve or worsen relationship	Pharmacy provides enhanced level services – working together on a service can formalise and cement relationships
Trust	GP has little trust in the pharmacist(s), with suspicion element of pharmacy. The need to trust GP is not considered by the pharmacist	Some trust has been built and is dependent on the pharmacist demonstrating they are trustworthy. GP distrust is associated with certain types of pharmacists. The need to trust GP is still given little consideration by the pharmacist	A historical relationship – mutual trust has been built up over time. Having had good relationships with pharmacists before, the GP is more inclined to trust the profession more widely
'Knowing' each other	GPs and pharmacists do not feel that they 'know' each other	GPs may feel that they 'know' some pharmacists in their locality, but are concerned that they do not know locums/sessional pharmacists and that their patients will not either	Both parties feel they 'know' each other. Some concerns on the GPs part that they would need to get to 'know' a new pharmacist – demonstrating a level of dependency
Communication	Limited communication which is mostly uni-directional from the pharmacist to the GP	Moderate communication. Still mostly uni-directional, with the pharmacist initiating most of the contact. Communication at the start of the service may have been good but it has not been sustained. Limited communication may be viewed as desirable as it indicates that there are few problems arising.	Regular reciprocal communication is the norm. Both parties are comfortable communicating with each other, informally and formally
Professional roles	Defined, separate and traditional roles. GP maintains a territorial approach. Pharmacist may be reluctant to expand their role.	GP believes the pharmacist can be useful in a substitute role, if appropriately trained, and their role should be limited to the management of minor ailments and helping ease workload etc. GP is somewhat still territorial. The pharmacist has a reactive rather than proactive and believes it is the GP's domain to select appropriate patients for a service	GP believes that pharmacists can offer an enhanced level of service as a result of their expertise. The GP views the pharmacist as a useful resource for them to consult for advice. Motivation for both is patient benefit, which is considered more important than professional territories
Professional respect	Limited evidence of professional respect for or confidence in pharmacy from the GP	Some evidence of respect for pharmacy by the GP, but this is caveated with a distinction between certain types of pharmacists – 'some are better than others'	Examples of mutual respect for both individuals and the professions generally

GP=general practitioner

(c) ***Reasons for selecting the Collaborative Working Relationship model***

The CWR model was selected to be used in this study as it outlines how to establish and develop CWR between an isolated doctor-pharmacist pair (Chapter 7, section 7.2.3, page 168) (Randal P. McDonough & Doucette, 2001). This model is also a generic model, applicable to CWR between doctors and pharmacists in any setting, as compared to the GP-community pharmacist collaboration model which was specifically developed to describe the interprofessional collaboration between GPs and community pharmacists (Bradley et al., 2012; Randal P. McDonough & Doucette, 2001). In addition, the CWR model has been validated and tested in several studies in the United States general practice setting (Snyder et al., 2010; A. J. Zillich et al., 2004).

2.9 Frameworks related to medication use in primary care

Theories or frameworks relevant to medication use in primary care were reviewed to provide a better understanding of medication management in primary care. Three frameworks were identified: the "Drug use process" (Smith & Knapp, 1992), the "Medication use process" (Bates et al., 1995), and the "Team Approach to Medication Management (TeAMM) model" (Bajcar et al., 2005).

2.9.1 Drug use process

The "Drug use process" framework outlines the steps involved in the process of drug use. This include perception of a need for a drug, selection of a specific drug product, choice of a treatment regimen, acquisition of the drug product, administration or consumption of the drug product and effect of drug therapy (Smith & Knapp, 1992). This framework is process oriented, and is focused on the drug product. It does not acknowledge the role played by patients in medication use in primary care setting.

2.9.2 Medication use process

The "Medication use process" framework describes the stages in which MEs may be corrected: prescribing, transcribing, dispensing, administration of drug, carer assistance, and the patient who may take or frequently does not take the medication according to instruction (Bates et al., 1995). This framework is also process oriented, but acknowledges the role of patients and carers in medication use. This role is however confined to the administration of medication and passively following doctor's instructions, without taking into account patients' opinion and preference with regards to their medication (Bates et al., 1995).

2.9.3 Team Approach to Medication Management

The TeAMM model specifies three primary, interrelated medication-related practices: medication-taking by patients, medication-prescribing by prescribers and medication-dispensing by pharmacists [Figure 2.3] (Bajcar et al., 2005). Within each practice, the model describes the roles and responsibilities of the individual who has the ultimate control over the practice in primary care.

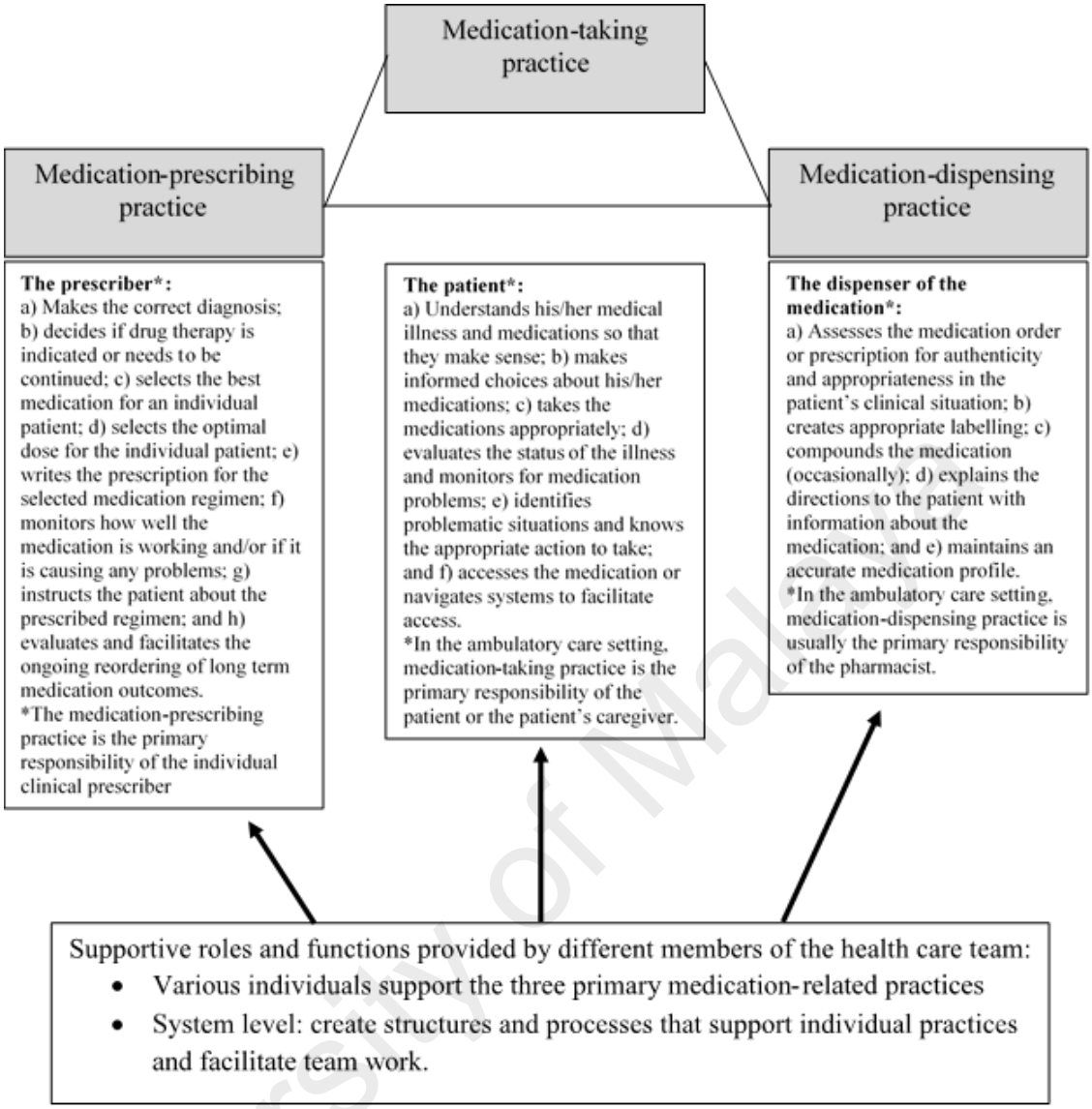


Figure 2.3: The Team Approach to Medication Management (TeAMM) model (Bajcar et al., 2005)

The TeAMM model acknowledges that the roles and responsibilities that are performed as part of the three primary practices are complex (Bajcar et al., 2005). Therefore, in addition to the primary responsibilities, health care team members are placed in supportive roles (Bajcar et al., 2005). For example, although the doctor is ultimately responsible for the prescribing of medications, pharmacists can play a supportive role in helping doctors obtain a patient's medication history or conduct a medication review. Similarly, the medication-dispensing practice of pharmacists and medication-taking practice by patients could be supported by diabetic education nurses

who conduct educational sessions for patients on sugar control and insulin use. Both primary and supportive roles are key to the overall safety and effective use of medication (Bajcar et al., 2005).

Another key feature of this model is that it stresses the importance on the medication-taking practice of patients, and places this practice at the core of the framework (Bajcar et al., 2005). This is based on the fact that in the outpatient setting, patients and/or their caregiver are the last link in the chain that leads to optimal use of medications. Patients are therefore given more active roles beyond administration and passive following of instructions (Bajcar et al., 2005).

2.9.4 Reasons for selecting the Team Approach to Medication Management model

The TeAMM model was selected to be used in this study, as it proposes collaboration between different team members to tackle the complexity of modern medication management in primary care (Bajcar et al., 2005). This was consistent with the aim of this study, which was to develop and pilot test a doctor-pharmacist collaboration intervention to improve medication safety in primary care. The TeAMM model provides a platform to discuss on individual roles and responsibilities (primary and supportive), and will help doctors and pharmacists to understand each other's roles in the relationship (Chapter 7, section 7.2.3, page 168) (Bajcar et al., 2005).

2.10 The pharmaceutical care practice

As medication-dispensing is becoming more automated and facilitated by the use of various technologies, this allows pharmacists to expand their clinical roles in recent years (Petrakaki, Cornford, Hibberd, Lichtner, & Barber, 2011). The concept of pharmaceutical care practice was introduced to guide pharmacists in assuming this responsibility. The

pharmaceutical care practice refers to the patient-centred practice in which pharmacists assume responsibility for meeting patients' drug related needs (Hepler & Strand, 1990). This include patient assessment for DRPs, formulating a care plan to address each of the DRPs identified and following up patients for monitoring and evaluation as summarised in Table 2.11.

Table 2.11: Activities and responsibilities in the pharmaceutical care practice (Cipolle et al., 2004)

	Activities	Responsibilities
Assessment	Meet the patient	Establish the patient-pharmacist relationship
	Elicit relevant information from the patient	Determine who your patient is as an individual by learning about the reason for the encounter, the patients' demographics, medication experience, and other clinical information
	Make rational drug therapy decisions	Determine whether the patient's drug related needs are being met (indication, effectiveness, safety, adherence), identify drug related problems
Care plan	Establish goal of therapy	Negotiate and agree upon endpoints and timeframe for pharmacotherapies with the patient
	Select appropriate interventions for: a) resolution of drug therapy problems; b) achievement of goals of therapy; c) prevention of drug related problems	Consider therapeutic alternatives Select patient-specific pharmacotherapy Consider non-drug interventions Educate patients
	Schedule a follow-up evaluation	Establish a schedule that is clinically appropriate and convenient for the patient
Follow-up evaluation	Elicit clinical and/or lab evidence of actual patient outcomes and compare them to the goals of therapy to determine the effectiveness of drug therapy	Evaluate effectiveness of pharmacotherapy
	Elicit clinical and/or lab evidence of adverse effects to determine safety of drug therapy	Evaluate safety of pharmacotherapy Determine patient adherence
	Document clinical status and any changes in pharmacotherapy that are required	Make a judgment as to the clinical status of the patient's condition being managed with drug therapy
	Assess patient for any new drug related problems	Identify any new drug related problems and their cause
	Schedule the next follow-up evaluation	Provide continuous care

2.11 Research gaps

There are relatively few studies that have explored factors contributing to MEs in primary care, as compared to secondary care (Committee on Quality of Health Care in America, 1999; Easton et al., June 2009). In addition, the studies identified were conducted in general practice and community pharmacy settings of Australia (Bhasale et al., 1998; Peterson et al., 1999), United States (M. Brown et al., 2006), United Kingdom (Y. F. Chen et al., 2005; Howard et al., 2008; Slight et al., 2013; Witherington et al., 2008), Denmark (Knudsen et al., 2007)and Finland (Teinila et al., 2011). This does not reflect the primary care setting of Malaysia. As health care system design itself was identified as a potential cause of MEs, there is a need to explore stakeholders' (mainly doctors, patients and pharmacists) needs in medication use for chronic diseases in Malaysian primary care setting (Y. F. Chen et al., 2005; Slight et al., 2013; Teinila et al., 2011). Furthermore, as Malaysia is a developing country, the patient population, their behaviour, attitude and knowledge towards medication might not be comparable to studies conducted at developed countries.

Although medication reviews involving pharmacists are increasingly implemented worldwide to improve quality of medication use and safety, the impact from this intervention has been variable (Geurts, Talsma, Brouwers, & de Gier, 2012). While differences in study population, medication review process and components could be the reason for these conflicting findings, it is possible that the extent of doctor-pharmacist collaboration in these medication review programmes are overlooked (T. F. Chen & de Almeida Neto, 2007). It is true that medication review in primary care setting has provided a framework for doctors and pharmacists to collaborate. However, the implementation of medication review interventions alone may not necessarily result in

effective collaboration between the two professionals (T. F. Chen & de Almeida Neto, 2007). There is a need to better understand how to effectively foster CWR between doctors and pharmacists involved in medication review interventions, and how this relationship affects patient outcomes.

While literature provides a description of the interventions that have been developed to tackle medication safety, details on how the interventions were developed is often lacking. This thesis will adopt the recommendations proposed by the United Kingdom medical Research Council (UK MRC) to develop and pilot test a doctor-pharmacist collaboration intervention systematically based on evidence, needs and theory (Craig et al., 2008).

2.12 Adaptation of the United Kingdom Medical Research Council framework to develop and pilot test a complex intervention.

A doctor-pharmacist collaboration intervention is a complex intervention. An intervention is considered complex when there is a range of possible outcomes, or when there are several population targets or when the intervention itself consists of several elements (Craig et al., 2008). Complex interventions are difficult to design, standardise, implement and evaluate (Craig et al., 2008). Hence, a framework for developing and evaluating complex health interventions was proposed by the UK MRC [Figure 2.4]; the initial framework was developed in 2000 and revised in 2008 (Campbell et al., 2000; Craig et al., 2008).

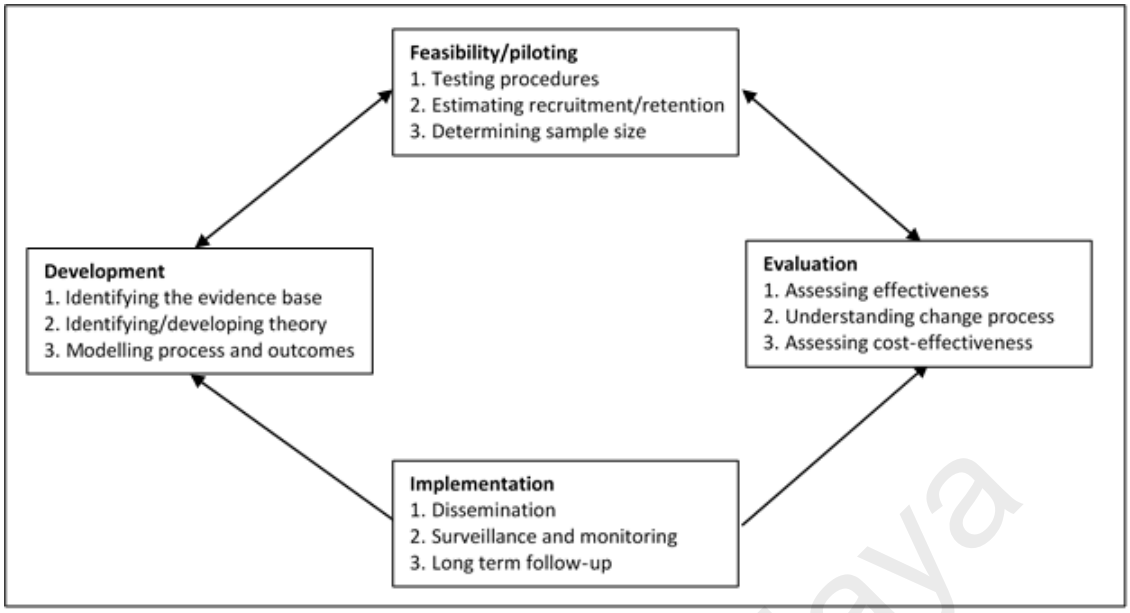


Figure 2.4: The development, evaluation and implementation process of a complex intervention as proposed by the United Kingdom Medical Research Council (Craig et al., 2008)

The UK MRC recommends that a complex intervention should be developed systematically based on evidence and theory (Craig et al., 2008). The intervention should be tested in a series of pilot tests each targeting a specific uncertainty in the design (Craig et al., 2008). This is then followed by an exploratory and definitive evaluation (Craig et al., 2008). The results of the evaluation should be disseminated widely and persuasively with further studies to assist and monitor the implementation process (Craig et al., 2008).

This thesis will focus on the development and pilot testing of a complex intervention, while evaluation and implementation of the intervention are beyond the scope of this study. Based on the UK MRC recommendation, a framework to guide the development of a doctor-pharmacist collaboration intervention to improve medication safety for patients with chronic diseases in primary care was developed [Figure 2.5]. Based on this framework, this study was divided into three phases: needs assessment (Chapter 3-6), development of intervention (Chapter 7-9) and pilot testing (Chapter 10-11).

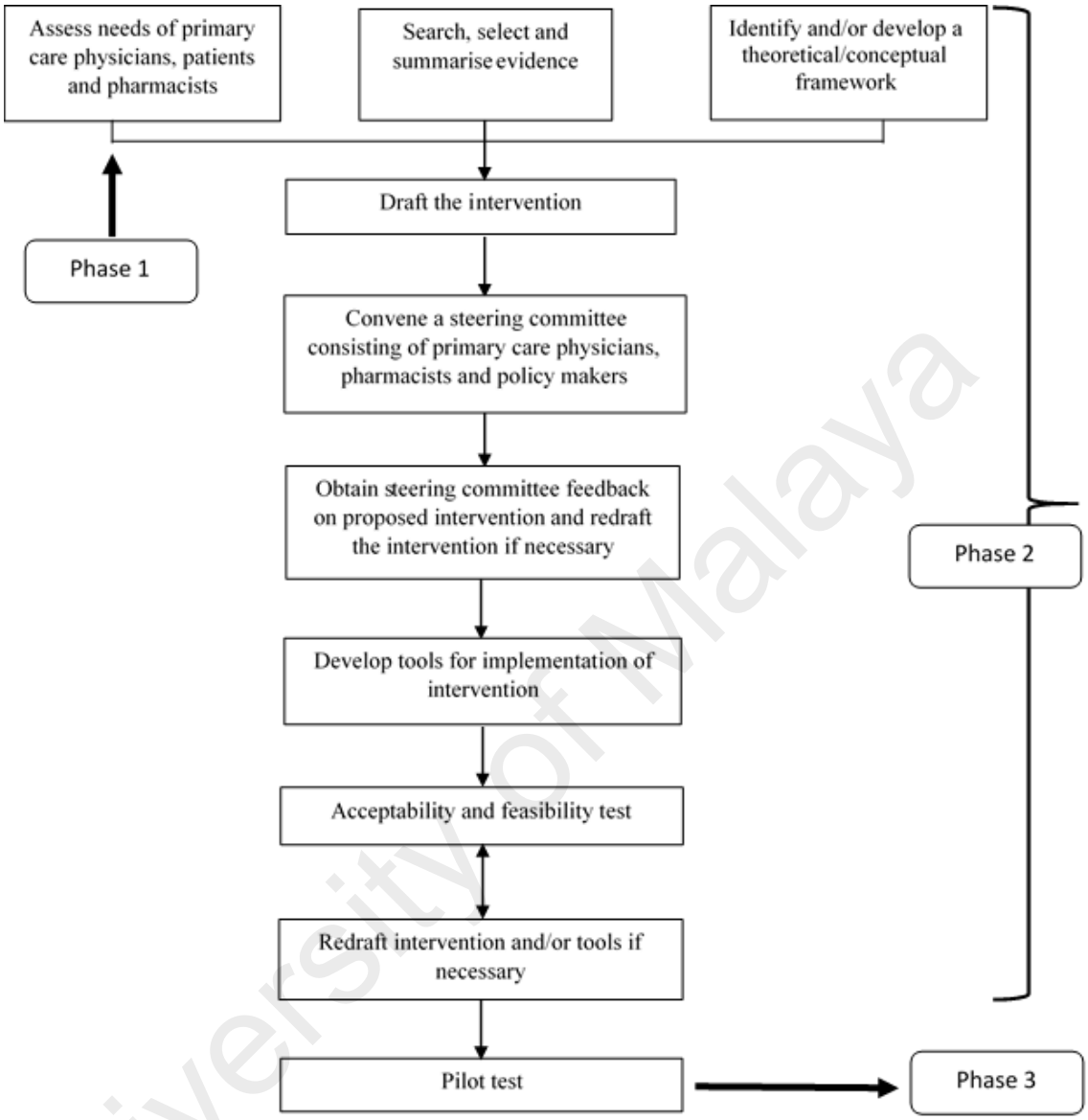


Figure 2.5: Framework for the development and pilot testing of a complex intervention to improve medication safety in primary care

CHAPTER 3: CHALLENGES FACED BY PRIMARY CARE PHYSICIANS WHEN PRESCRIBING FOR PATIENTS WITH CHRONIC DISEASES IN A TEACHING HOSPITAL IN MALAYSIA: A QUALITATIVE STUDY

Studies indicate that there is a high incidence of MEs in the primary care setting of Malaysia (Ahmad, Ismail, & Yusof, 2006; Khoo et al., 2012). However, there is a lack of information on why these MEs occur. It is important to conduct a needs assessment to find out the causes of MEs from the stakeholders (patients, doctors and pharmacists), and address the problem. Needs assessment is a systematic method of identifying unmet health and healthcare needs of a population and making changes to meet these unmet needs (Wright, Williams, & Wilkinson, 1998).Designing interventions to meet local population needs is imperative in ensuring effective and successful implementation of the intervention (Craig et al., 2008). In addition, a needs assessment will also help in engaging the stakeholders early on in the development process, and increases the likelihood of uptake of the intervention in future (Craig et al., 2008).

Needs assessment was therefore conducted with PCPs at the primary care clinic of UMMC, patients with chronic diseases attending the clinic, and pharmacists at the outpatient pharmacy of UMMC. This chapter will report on the challenges faced by PCPs when prescribing for patients with chronic diseases, and how these challenges affect medication safety. Findings from this chapter, together with findings from the rest of the needs assessment studies (Chapters 4, 5 and 6) were used to identify the target for an intervention to improve medication safety (Chapter 7, section 7.2.1, page 167).

3.1 Introduction

Prescribing medications for patients with chronic diseases has become increasingly challenging (Barnett et al., 2012; L. M. Hunt, Kreiner, & Brody, 2012). With the rising

prevalence of patients with multimorbidities, their medication regimens are getting more complex (Roberts, Green, & Kadam, 2014). Clinical practice guidelines often only provide recommendations for disease-specific conditions but do not guide prescribers in prescribing for patients with multimorbidities (Boyd et al., 2005). The rapid expansion of drug choices further complicates the situation as prescribers need to carefully deliberate the suitability of each treatment option for a particular patient in terms of cost, effectiveness and side effects (JillHill, 2010).

These challenges might lead to inappropriate prescribing for patients with chronic diseases which in turn lead to ADEs and poor disease control (Tejal K. Gandhi et al., 2003; Kunac & Tatley, 2011; Sarkar et al., 2010). Moreover, the majority of patients with chronic diseases are the elderly, who are at a higher risk for ADEs (Gurwitz et al., 2003; Olaniyan, Ghaleb, Dhillon, & Robinson, 2014). Inappropriate prescribing for chronic diseases also has a significant economic impact due to increased hospitalisation, number of outpatient visits and medical costs (Akazawa, Imai, Igarashi, & Tsutani, 2010; Kuo, Phillips, Graham, & Hickner, 2008; D. T. Lau, Kasper, Potter, Lyles, & Bennett, 2005). This is a major concern in the delivery of healthcare (Kohn, Corrigan, & Donaldson, 1999).

In many countries, chronic care is shifting from secondary care to primary care, with the aim to mitigate rising healthcare burdens in hospitals, as well as to improve the cost-effectiveness of health care delivery (Rothman & Wagner, 2003; Starfield, 1998). Patients with chronic diseases often receive care from multiple practitioners and institutions and this requires a high level of coordination (Rothman & Wagner, 2003; Vogeli et al., 2007). Primary care practice plays an important role in integrating the care of these patients as a whole without focusing on a specific disease, organ or system. PCPs are therefore

responsible for managing complex medication regimens prescribed by different healthcare providers.

There is a considerable amount of literature available on the prevalence and factors associated with inappropriate prescribing in primary care around the world (Ahmad et al., 2006; Y. F. Chen et al., 2005; Dhabali, Awang, & Zyoud, 2011). Others focused on specific disease conditions (eg dementia) (D. T. Lau et al., 2010), specific target groups (eg elderly) (Akazawa et al., 2010; Carey et al., 2008; Gurwitz et al., 2003) or specific medications (eg antidepressant) (Coupland et al., 2011). This failed to capture the real challenges faced by PCPs in managing patients with chronic diseases who are mostly the elderly with multimorbidities. Therefore, this study aimed to identify the challenges faced by PCPs in prescribing for patients with chronic diseases, and its impact on medication safety.

3.2 Methods

3.2.1 Design

A qualitative methodology was selected to explore the challenges faced by PCPs when prescribing for their patients with chronic diseases. Qualitative research studies things in their natural settings, and attempts to make sense of or interpret phenomena in terms of the meanings people bring to them (Denzin & Lincoln, 2011). This was a suitable research method for this study because it allowed PCPs to share their prescribing challenges from their own perspective.

Focus group discussion (FGD), a common qualitative interview method was used in this study. A FGD is a group of 6-12 people, who meet in an informal setting to talk about a particular topic set by the researcher (Bowling, 2010; Morgan, 1997). The moderator

keeps the group on the topic, but at the same time allows participants to explore the issue from as many angles as they wish. Often, the researcher will construct a group which is as homogenous as possible. This is to simulate discussion among a group of people with things in common, so that they feel comfortable talking to each other. The interaction among participants during a FGD produces a 'synergistic' effect. Participants are not only able to express their personal views and thoughts, but hearing what other says during a group discussion can also trigger more thought, which they can challenge or clarify with one another (Morgan, 1997). FGDs also allow the researcher to gather the opinions of a large number of people in lesser time and minimal expense.

In this study, the PCPs were grouped according to their years of clinical experience. This eventually created groups consisting of colleagues and friends, and the FGDs created a platform for them to share their prescribing experiences.

3.2.2 Setting

Primary care services in Malaysia comprise of private general practices, government primary care clinics in the community, and government primary care clinics within teaching hospitals. This study was conducted at the primary care clinic of the UMMC, a tertiary teaching hospital located in the urban city centre of Kuala Lumpur, Malaysia.

Patients attending the primary care clinic presented with a broad range of chronic conditions. Patients however may be attending other specialist clinics or health institutions located within or outside the UMMC for other chronic conditions. For example, a patient may be seen by an endocrinologist for his/her diabetes, a psychiatrist for depression and a PCP for hypertension. PCPs prescribed electronically but maintained paper-based medical records, which were kept separately and not shared with other

clinicians within the hospital. Patients collected their prescribed medications from the hospital outpatient pharmacy at a subsidised rate.

3.2.3 Duration

This study was conducted between July and August 2012.

3.2.4 Participants and sampling

All PCPs attached to the clinic during the study period were eligible to participate in this study. This included service medical officers, postgraduate family medicine trainees and family medicine specialists, where family medicine trainees formed the majority. Family medicine trainees are medical officers who are pursuing their four-year training as a specialist in family medicine, while service medical officers are doctors who are employed to provide clinical services at the primary care clinic. Purposive sampling was performed to include PCPs with various lengths of clinical experience. This was to ensure that a range of prescribing experiences can be captured; as PCPs with different lengths of clinical experience may face different types of prescribing challenges. We invited potential participants in person or through text message explaining the objectives, date, time and venue of the FGD.

3.2.5 Sample size

Twenty-two PCPs were approached, of which 19 agreed to participate. Three potential participants were not able to participate in the FGDs, as they were not free at the given date and time. We ceased recruitment once no new themes emerged from the analysis (thematic saturation).

3.2.6 Instruments used

A topic guide [Appendix A1] was developed based on a conceptual framework [Figure 3.1]. This conceptual framework was mapped using information derived from literature on the types and causes of MEs in primary care, as well as available solutions (Lainer et al., 2013; Susan M. Patterson et al., 2012; Royal et al., 2006; Teinila et al., 2011). PCPs were provided with a participant information sheet [Appendix A2] prior to obtaining written consent [Appendix A3]. We also collected the demographic data of the PCPs [Appendix A4].

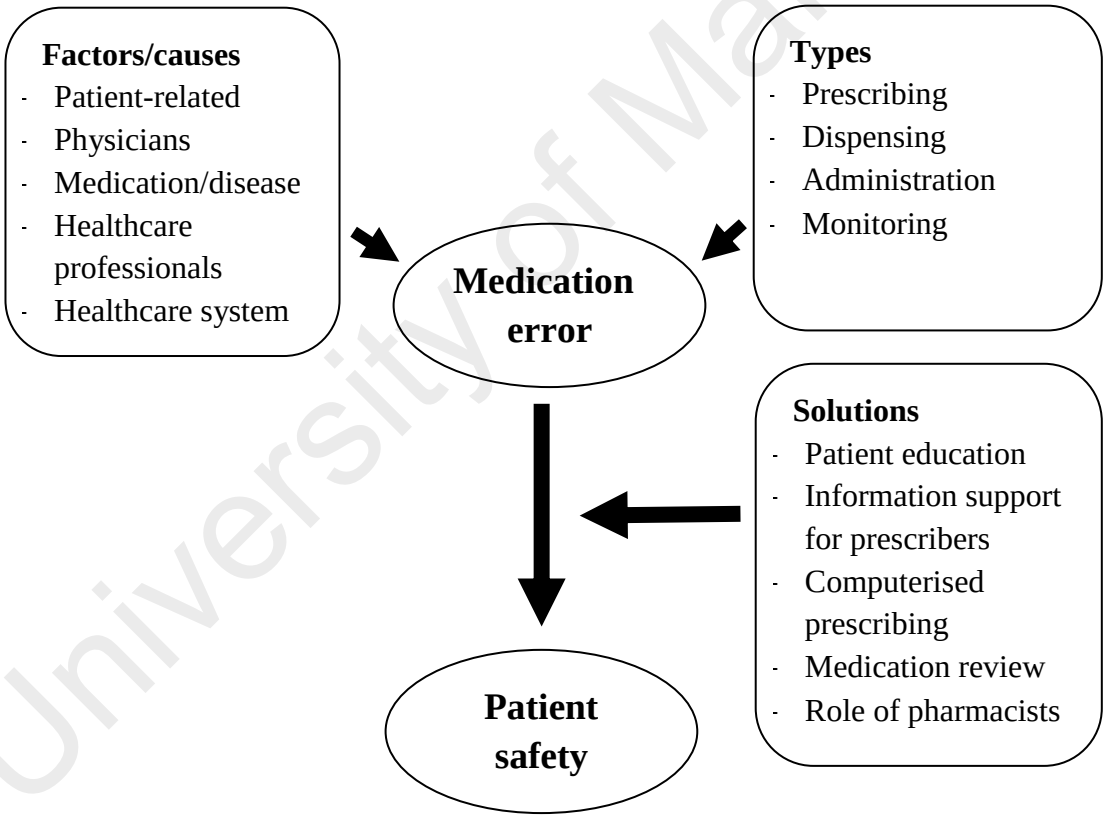


Figure 3.1: Conceptual framework of types and causes of medication errors in primary care, and available solutions

3.2.7 Data collection

An academic family medicine specialist affiliated to the primary care clinic of the study site conducted the first FGD (CJN). The remaining two FGDs were conducted by

RS, a trained researcher who was not an academic staff, and would therefore not be seen as an authoritative figure by participants. They were reminded to discuss based on their experiences in managing patients with chronic diseases, and were assured that anonymity will be maintained throughout reporting. We asked open-ended questions and prompted them when important issues were not mentioned. All FGDs were conducted in English, audio-recorded and transcribed verbatim. Checked transcripts were used as data for analysis. Researchers documented relevant impressions and thoughts after each FGD while a research assistant took field notes on non-verbal cues during the FGDs.

3.2.8 Data analysis

We used a descriptive-interpretive approach to analyse the data, which involved describing interpretively what the researcher learned and understood about the meanings of the situations (St. George, 2010; Thorne, Kirkham, & O'Flynn-Magee, 2004). The researchers' backgrounds (as a clinician and pharmacist) therefore influenced how they interpreted the data, and also how their interactions with the participants during the FGDs were influential in constructing the data (St. George, 2010; Thorne et al., 2004). A computer-assisted qualitative data analysis software Nvivo10 (QSR International Pty Ltd, Doncaster, Victoria, Australia) was used to manage the data. Data was analysed inductively starting with the first transcript. RS familiarised herself with the data by reading the first transcript to identify and index the themes (Pope, Ziebland, & Mays, 2000). All data relevant to each theme were identified and examined through constant comparison (Pope et al., 2000). These themes were further refined and reduced in number by grouping them into larger categories (Pope et al., 2000).The research team (RS, CJN and PSML) met over several meetings to discuss the list of themes and categories, which were refined iteratively through consensus until the team agreed on the final coding framework. RS used the final coding framework to code the remaining two transcripts.

New themes that emerged were added to the list upon consultation with the research team. Thematic saturation occurred at the third FGD.

The research team consisted of a family medicine specialist (CJN) and two pharmacists (PSML and RS). All researchers were conscious of their personal and professional biases, and therefore constantly reflected and debated during data collection and analysis to improve the credibility of the data.

3.2.9 Ethics

Ethics approval was obtained from the UMMC Medical Ethics Committee prior to the commencement of this study (approval No. 890.104) [Appendix A5].

3.3 Results

Three FGDs were conducted, each lasting 50-100 minutes. Eight male and 11 female PCPs participated in this study, aged from 30-62 years old [Table 3.1]. Their years of clinical experience ranged from 5-37 years. Participants were grouped into year 3 family medicine trainees (n=7), year 4 family medicine trainees (n=7) and service medical officers (n=5).

Table 3.1: Demographic profile of the primary care physicians interviewed

Participant ID	Age	Sex	Ethnicity	Professional background	Years of clinical experience
D01	32	Female	Malay	Year 3 family medicine trainee	8
D02	38	Male	Indian	Year 3 family medicine trainee	7
D03	30	Male	Chinese	Year 3 family medicine trainee	5
D04	32	Male	Chinese	Year 3 family medicine trainee	6
D05	32	Female	Malay	Year 3 family medicine trainee	8
D06	34	Female	Malay	Year 3 family medicine trainee	10
D07	34	Female	Malay	Year 3 family medicine trainee	10
D08	30	Male	Malay	Year 4 family medicine trainee	6
D09	32	Female	Malay	Year 4 family medicine trainee	8
D10	34	Male	Indian	Year 4 family medicine trainee	9
D11	33	Male	Malay	Year 4 family medicine trainee	9
D12	35	Female	Malay	Year 4 family medicine trainee	8
D13	31	Female	Malay	Year 4 family medicine trainee	7
D14	33	Female	Indian	Year 4 family medicine trainee	7
D15	48	Female	Indian	Service medical officer	26
D16	62	Male	Burmese	Service medical officer	37
D17	59	Male	Burmese	Service medical officer	35
D18	57	Female	Indian	Service medical officer	29
D19	56	Female	Indian	Service medical officer	29

The challenges faced by PCPs in prescribing for patients with chronic diseases are summarised in Table 3.2.

Table 3.2: Challenges faced by primary care physicians when prescribing for chronic diseases

Health care system-related
Lack of communication among healthcare providers
Transition from paper to electronic prescribing
Deficiencies in the electronic prescribing system
Medication supply problems
Patient-related
'Doctor and pharmacy hopping' by patients
Patients' changing living and care arrangements
Dealing with patients' beliefs, demands and medication-taking behaviour
Patients' lack of knowledge about medication
Physician-related
Providing medication advice to patients
Managing complex drug regimen and side effects

3.3.1 Health care system-related challenges

3.3.1.1 Lack of communication among healthcare providers

Patients with multiple chronic diseases attended several specialists' clinics as well as the primary care clinic for different conditions. A lack of communication between specialists and PCPs was a challenge when prescribing medications as changes in medication regimen by specialists were often not communicated to PCPs. For example, PCPs were not informed of any changes made to patients' medications during admission to the hospital. This increased the risk of drug duplications and drug interactions, which might affect patient safety.

"I have a patient that was actually under another clinic and under me. He was started on an ARB (angiotensin receptor blocker) and I was not aware of it. I started ACE (angiotensin-converting-enzyme) inhibitor. It happened because I did not know what was going on with the other clinic follow up. So, yeah! I am causing more harm to the patient because of poor records."

[D01]

"When a patient is discharged from the ward, a lot of things can happen in the ward. They (doctors in the ward) changed the medication for example. When they (patients) come (to see me), they do not have the records. So, we are quite stuck there."

[D14]

There was also a lack of communication between PCPs and hospital outpatient pharmacists. Patients were sometimes asked to be the 'middle person' to convey messages regarding unavailable medications to the PCPs; patients were directed from the pharmacy back to the clinic to ask the prescriber for an alternative medication. Patients were unhappy to do this and it also disrupted PCPs consultation with other patients.

"Just ah... two weeks ago, one patient was very upset. He asked me how come the medicine is not available? So... I gave (prescribed) him with an alternative. Then the patient asked me again, how if that second medicine is also not available. For that I said, I really don't know. Why don't the pharmacist or the pharmacy staff call me directly to inform that the medicine was not available and we can talk about it. This patient told me that he is not a dispatch boy and he is not there to do these kind of things, going up and

down from the pharmacy to the clinic. I was seeing another patient at that time and it was... awkward."

[D16]

PCPs faced difficulties in contacting the pharmacists in case of any medication-related queries. Although there is an option in the electronic prescribing (e-prescribing) system for PCPs to insert additional notes for pharmacists, these notes might not be read by the pharmacists and hence messages were not conveyed to patients during dispensing.

"Sometimes when we try to contact the pharmacy (through telephone) to get some clarification about medications, it is so difficult to get through. I rather walk to the pharmacy to find out."

[D19]

"Actually there is a column in the e-prescribing saying instructions for pharmacists. I used to type whatever instructions I have for the pharmacists when dispensing, I was doing it so religiously but now I stopped. Because when the patients don't seem to get the message, I called the pharmacists and asked how come they didn't convey the message to the patient? Then I got to know that they don't read those notes. Wasting my time! (all the PCPs laughed)."

[D08]

3.3.1.2 Transition from paper to electronic prescribing

The primary care clinic was the only specialty within the hospital which has fully adopted e-prescribing. The other specialties (e.g. internal medicine, surgery etc.) still practiced paper prescribing, and these manual prescriptions were transcribed into

electronic form prior to dispensing by the pharmacy personnel. Sometimes, the medications prescribed manually did not appear in the electronic records. This further impedes communication regarding patients' medications among the doctors from different specialties within the hospital.

"Not everyone (doctors from other specialties) in the hospital is using e-prescribing. And when they use manual prescriptions, the medications are not updated in the computer. We then don't know what are being prescribed by them (doctors from other specialties)."

[D13]

The transition from paper to e-prescribing created a dual record system for patients' medications and this became a challenge when prescribing. When PCPs prescribed electronically, they often did not document the medications that they had prescribed in the paper-based medical records. This became a problem when the e-prescribing system was inaccessible, as PCPs could not retrieve information on patients' medication history. There were also some instances when the medication list on the paper records and the electronic records differed, and PCPs faced a dilemma as to which one was the correct information to follow.

"Some of us may not write down exactly what the patient is taking anymore because we are doing two jobs. We need to write the medication in the folder and prescribe in the computer. But when patients have ten medications or so, it is quite a hassle to write down everything."

[D17]

"And when the e-prescribing system is down, you check the patient folders and you find that it (medication list) is not updated. You then do not know what medications the patient is on."

[D19]

"Sometimes, the medication list on e-prescribing and the notes (medical folders) is not the same and you don't know which one to trust."

[D04]

3.3.1.3 Deficiencies in the electronic prescribing system

Patients' medication histories displayed in the e-prescribing system were often incomplete. PCPs were also unable to determine certain medications were stopped or initiated. PCPs therefore had problems in deciding which medications to prescribe for patients.

"Sometimes the previous doctor will start on some medications and it is not updated in the e-prescribing system. So, you are not sure… whether to continue… or to stop… or what medication the patient is on!"

[D04]

"I had a problem when a patient came for insulin Glargine. It was not stated anywhere in the notes. And when I looked at the computer, it (insulin Glargine) was cancelled by another doctor. And when cancelled, I don't know whether it was stopped, changed or what? The computer doesn't capture the reason for that. And then there was unnecessary

argument with the patient as she wanted the medicine. At that point, I don't know whether to trust the notes, the computer or the patient!"

[D02]

3.3.1.4 Shortage of medication supply

Patients often complained to PCPs that they have not been supplied with adequate amount of medication to last until their next visit to the doctors. PCPs were unsure why this was occurring. Sometimes, medications were not supplied as the medication was out of stock. Patients were supposed to come back to collect the medication another day once the stock has arrived, but some patients did not make this extra trip and ended up not taking their prescribed medications.

"So many patients come back complaining that they don't have enough medicines. We always prescribe until their next appointment. Either they didn't come to take their balance medications, or the pharmacy gave them the wrong amount. But they don't realise that they can come earlier to get the medicines. So they will just wait until the appointment and go without medicines till then!"

[D19]

"We prescribe three or four medicines, one or two sometimes are out of stock. Patients do not get their medicines, and we do not know that. Some smart patients call up after a few days and collect their medicines when stocks are available. But some patients do not come back. They wait until the next appointment. This leads to poor compliance."

[D16]

3.3.2 Patient-related challenges

3.3.2.1 'Doctor and pharmacy hopping' by patients

Some patients were "doctor and pharmacy hopping". They visited different doctors and community pharmacies for the same symptom. This became a problem when PCPs did not know what medications patients were prescribed (or supplied with), giving rise to drug duplication.

"There are patients who are given some medications from our hospital pharmacy, and then they go outside of the hospital to get more medications. So that one you really can't control. We don't know what they are on. Sometimes they have duplicate medications. The brand is different, so they think it is a different medication."

[D13]

3.3.2.2 Patients' changing living and care arrangements

In line with the Asian culture, most elderly patients live with their children. However, elderly patients that have several children are sometimes 'rotated' between different children's homes. These elderly patients may then be accompanied by different carers to different doctors for their follow-up visits at different healthcare, resulting in lack of continuity of care. Prescribing for this group of patients then becomes a challenge.

"I have a few patients who stay at their children's place of one month here, one month there and so on. And they don't bring their medication with them. So what happens is the son brings to one clinic and the daughter brings to another clinic. The patients end up with so many duplicate medications. They then come back to us with all those medications and we do not know which one is which anymore!"

[D10]

3.3.2.3 Dealing with patients' beliefs, demands and medication-taking behaviour

Patients had their own beliefs and preferences in starting, maintaining or changing their medications. While some patients requested more medications, some believed that modern medications are injurious to health and therefore reduced or stopped their medications on their own accord. Some patients also refused to follow their PCPs' advice in altering the medications prescribed by specialists, as they believed that the specialists knew better.

"Sometimes patients say, I want medicine for this, I want medicine for that. And if we don't prescribe them, they become so upset. They are already on many medicines plus with all these medicines they want to take, there can be a lot of interactions."

[D10]

"When you tell them (patients) to take four tablets, they think it is a large dose and will harm them. So they (patients) reduce the dose themselves."

[D19]

"We are supposed to be the coordinator of their medication, but patients sometimes are reluctant to change the medication given by specialists. I have a patient attending the skin clinic for urticaria and treated with cetirizine. (Patient) also has allergic rhinitis, seen by ENT specialist and given loratadine. So I told the patient to take either one but she refused because the medications were given by specialists and they (specialists) know the best."

[D04]

Patients' medication-taking behaviour further complicates PCPs prescribing practice. Patients did not take their medications according to instructions due to various reasons such as convenience and belief that their disease has been 'cured'. Some patients took their spouses' medication when they ran out of medications.

"Sometimes we prescribe half a tablet daily... and they take one tablet every other day as they find it inconvenient to break the tablet into half."

[D02]

"When we tell them (patients) that their cholesterol levels are normal, they will stop their (cholesterol) medication. They think that once it's normal, it will stay normal. So, they will stop themselves. They don't listen to our advice."

[D12]

"Some patients even take their spouses' medication when they run out of their own medication."

[D06]

3.3.2.4 Patients' lack of knowledge about medication

Many patients did not know the indications for their medications, while some were not aware of medication dosage changes and therefore were taking their medications incorrectly. Elderly patients who were on many medications were particularly difficult to manage as they often got confused with medication indications and administration times.

"First of all they do not know what medications they are taking. Sometimes they may confuse diabetic medications for high blood pressure medications."

[D18]

"For example Diamicron MR. Previously (it was) 30mg, now we do not have (the) 30mg anymore. We have (the) 60mg. So, patient will say… I am taking one tablet. But it is 60mg now. They are not aware of the dosage change and they do not read the label. They think it is the same."

[D04]

"Especially with the elderly. You give them seven, eight medications, they will get confused. Everything looks white, everything looks yellow to them. So, they wouldn't know which one is once a day, which one is twice a day."

[D01]

3.3.3 Physician-related challenges

3.3.3.1 Providing medication advice to patients

PCPs generally agreed that their role as a prescriber includes advising patients on their medications. PCPs however struggled to do this due to lack of time during the consultation or lack of knowledge on proper use of medication.

"During busy clinics we have no time to tell the patient what are the possible side effects of the medications. That can be considered as a prescribing error."

[D15]

"Sometimes I do not know… when they are supposed to take the medicine, whether it is before meal or after meals. So I will tell them (patients) to check with the dispenser later."

[D01]

PCPs were also not aware of the dosage available at the pharmacy. The same medication that the patient is on might be dispensed at different strengths based on drug availability at the pharmacy. This has led to confusion among patients and drug administration errors at patient homes.

"I feel that doctors should explain to the patient about what you are giving to the patient. But the problem is we (PCPs) don't know what is the dosage strength supplied to the patient. For example we prescribe 8mg but patients are given 4mg tablets. Since we told them (patients) to take 1 tablet, they took 1 tablet of the 4mg and ended up with sub-optimal treatment."

[D07]

3.3.3.2 Managing complex drug regimen and side effects

The more co-morbidities a patient has, the more complex his or her medication regimen becomes. When patients developed side effects to any of these medications, PCPs faced difficulties in identifying the causative agent and managing the side effects.

"Side effect due to medication is a major problem, especially when the patient is on so many medications for a long time. It is very, very difficult for us to really identify which medication is causing the side effect."

[D03]

3.4 Discussion

Our study highlighted the prescribing challenges faced by PCPs in their daily practices when managing patients with chronic diseases. A lack of communication among healthcare providers, the transition from paper to e-prescribing, deficiencies in the e-prescribing system and shortage of medication supply were examples of health care system-related challenges. In addition, patients' help-seeking behaviour, social context, belief and demands about medications, non-adherence to medication instructions and lack of knowledge about their medications influenced PCPs' prescribing pattern. PCPs also faced difficulties in advising patients about medications and managing side effects due to complex medication regimens.

Lack of effective communication among different specialties within the hospital made prescribing difficult as PCPs were not able to get a complete picture about patients' medical and medication history. PCPs were therefore unable to coordinate the care of patients with chronic diseases effectively, potentially leading to prescribing errors (Y. F. Chen et al., 2005; Ramaswamy et al., 2011; Slight et al., 2013). This problem however is not unique to the Malaysian health care system. Previous studies have identified that there was a communication gap between primary and secondary care due to poorly documented and disorganised medical records (Y. F. Chen et al., 2005; Kripalani et al., 2007; Ramaswamy et al., 2011). Electronic medical records and patient-held records could be the possible solutions for this problem (DesRoches et al., 2008; Ko, Turner, Jones, & Hill, 2010). These technological interventions can assist PCPs role in coordinating the care of patients with multimorbidities, by facilitating information sharing and improving the communication among different specialties (DesRoches et al., 2008; Ko et al., 2010).

Besides doctor-doctor communication, participants also mentioned about the lack of communication between PCPs and pharmacists. These two professionals have varying roles in the medication management for patients with chronic diseases; PCPs as the prescribers and pharmacists as the dispensers (Bajcar et al., 2005). Ideally, PCPs and pharmacists should work together along with the patients to optimise medication management for chronic diseases. PCPs in our hospital however were not able to convey messages to the pharmacists regarding patient prescriptions and vice versa. This highlights the lack of a platform for them to communicate. Integration of pharmacists into primary healthcare team is one way to create a platform for these two professionals to interact and collaborate (Dolovich et al., 2008).

Pharmacists can complement PCPs' role in educating patients about their medications and to address the patient-related problems highlighted in this study such as patients' lack of knowledge about medication, non-adherence to medication instructions and their belief about medical treatment (Bernsten et al., 2001; Hanlon et al., 1996; V. B. Petkova, 2008). These are important issues to be addressed as it can lead to poor disease control and ADEs (Kunac & Tatley, 2011; Rasmussen, Chong, & Alter, 2007; Stempel, Roberts, & Stanford, 2004). PCPs however struggled to do this during consultation due to the lack of time, high workload and lack of knowledge on proper drug use (Ostbye et al., 2005; Tarn et al., 2006). Apart from patient education, other potential pharmacist roles include patient medication review, medication recommendation to PCPs and patient follow-up for DRPs (Bernsten et al., 2001; Hanlon et al., 1996). These pharmacist-provided services were proven to impact positively on chronic diseases control such as asthma, hypertension and heart failure (Gattis et al., 1999; Roughead, Semple, & Vitry, 2005). Interprofessional collaboration between PCPs and pharmacists may also help to foster knowledge exchange

and enhance safety netting in reducing MEs (Dolovich et al., 2008; Williams et al., 2004; Zarowitz, Stebelsky, Muma, Romain, & Peterson, 2005).

Another important factor that affects patient's medication use is their social circumstances. Patients are more likely to comply with treatment regimen which causes little change to their present lifestyle (K. M. Nair et al., 2007; Vermeire, Hearnshaw, Van Royen, & Denekens, 2001). This was illustrated in one of the participants' response on how one patient self-adjusted his medication dose as it was inconvenient to break the tablet into half. Another example is when an elderly patient is cared for by different children brought to different institutions for medical treatment leading to duplicate medications. PCPs therefore should explore, consider and address patients' social circumstances prior to prescribing to avoid MEs (Bajcar et al., 2005).

Multimorbidities and the resulting increase in number of prescribed medication were identified as risk factors for ADEs (Akazawa et al., 2010; Y. F. Chen et al., 2005; Guthrie et al., 2011; Hanlon et al., 1997; Laroche, Charmes, Nouaille, Picard, & Merle, 2007). It was therefore not surprising that PCPs faced difficulties in identifying and managing side effects due to complex medication regimen. But this could also mean that PCPs lacked the knowledge and skills for doing so (Y. F. Chen et al., 2005; Ramaswamy et al., 2011; Slight et al., 2013). PCPs should therefore be provided with adequate training in prescribing for patients with multi-morbidities and complex medication regimen to improve management of chronic diseases in primary care.

Previous studies have reported that computer system created problems to doctors in placing new drug orders and increased the risk for prescribing errors (Slight et al., 2013). But our study highlights the problems associated with implementing a new computer

system into practice. Slow uptake of e-prescribing by doctors has been reported in the literature (Gagnon, Nsangou, Payne-Gagnon, Grenier, & Sicotte, 2013). Our findings show that this became a problem for PCPs in coordinating the care of patients with chronic diseases and created room for MEs. It is therefore important to create awareness among these "late adopters" of the potential risk of their behaviour and encourage them to prescribe electronically, as well as provide adequate training and support for them to do so (Gagnon et al., 2013). At the same time, it is important to look into the flaws within the e-prescribing system as mentioned by our study participants, and rectify them to make it more user friendly and "attractive" for the doctor's to use.

With the introduction of the e-prescribing system, PCPs felt burdened as they needed to record patients' medication twice, and therefore tended to skip the paper-records due to limited time. This became a problem when the two records did not tally or when the e-prescribing system was not accessible. In future, PCPs adopting e-prescribing into practice should be made aware of this potential challenge during the transition phase, and the importance of proper paper-records should be emphasised until the e-prescribing is fully adopted into practice.

To our knowledge, this is the first study in Malaysia to explore the challenges faced by PCPs in prescribing for patients with chronic diseases. This is an important first step in order to improve the care of this patient group. However, it should be noted that being part of a teaching hospital, there are more teaching involved and junior PCPs are constantly under the guidance and supervision of more senior PCPs and family medicine specialist. This could limit the applicability of our findings as the setting is different from the majority of primary care practices elsewhere. In addition, the use of FGD may have hindered PCPs in sharing some personal prescribing challenges in front of their

colleagues to avoid embarrassment. This could have affected the comprehensiveness of our finding.

No family medicine specialists were interviewed in this study and their challenges and views could have been different from the medical officers and trainees that participated in our study. This study was part of a larger study which aimed to look at the problems and needs of PCPs, pharmacists and patients in mediation use for chronic diseases in primary care. Many of the issues reported by PCPs in this study were related to pharmacists and patients. Therefore, the views from pharmacists and patients themselves are important to provide a clearer picture of the real challenge in medication use for chronic diseases in primary care. These findings will be reported in subsequent chapters (Chapter 4 and 5).

3.5 Conclusion

PCPs faced multiple challenges related to health care system, patients and themselves when prescribing for patients with chronic diseases. These challenges have a significant implication on patient safety. As many of the issues raised were related to patients and pharmacists, there is a need to investigate the medication experiences of patients and pharmacists to obtain a clearer picture, and search for an effective intervention to improve medication safety of patients with chronic diseases in primary care.

CHAPTER 4: THE MEDICATION EXPERIENCES OF PATIENTS WITH CHRONIC DISEASES: A QUALITATIVE STUDY

This chapter is the second part of the needs assessment. Chapter 3 highlighted many patient-related challenges faced by PCPs when prescribing for their patients with chronic diseases. There is a need to look at these medication-related problems from the patients' perspective. This chapter will therefore focus on exploring the medication experiences of patients with chronic diseases.

4.1 Introduction

Patients with chronic diseases are often burdened with many medications to take on a regular and long term basis (Roberts et al., 2014). This puts them at a higher risk for ADEs, affecting their safety (Baena et al., 2006; Bourgeois et al., 2010). ADEs have a significant clinical and economic impact. International studies have shown that ADEs were responsible for up to 16.2% of general hospital admissions (Nelson & Talbert, 1996), 30.7% of admission in the elderly (Courtman & Stallings, 1995) and 3.1% of death (Wester et al., 2008). ADEs were also associated with up to 38% of hospital re-admissions (Witherington et al., 2008), 33.2% of ED visits (Baena et al., 2006), and 0.4% of outpatient clinic visits (Zhan et al., 2005). In Malaysia, ADEs were associated with 39% of admission to medical wards in a tertiary hospital (Karuppannan, 2012).

Approximately 16% to 41% of ADEs in the community is preventable (i.e. due to an error) (Tache, Sonnichsen, & Ashcroft, 2011). While MEs can occur at any stage of the medication use process (prescribing, dispensing, administration and monitoring), the most common type of MEs are prescribing errors and administration errors (Kunac & Tatley, 2011). Administration errors in the community occur at patients' homes.

Understanding patients' medication experiences will help to identify the root cause of the problem and tackle it.

Medication experience refers to an individual's subjective experience of taking a medication in his daily life (Shoemaker & Ramalho de Oliveira, 2008). There are many factors that influence how patients take their medications. This include patients' socio-economic status, their knowledge and attitude about medication, disease severity, treatment complexity and patient-provider relationship (World Health Organization, 2003). Though many studies have examined the meaning of medications from the patients' perspective, most have focused on specific diseases (Viswanathan & Lambert, 2005) or classes of drugs (Carrick, Mitchell, Powell, & Lloyd, 2004). Additionally, most of these studies focused on patient-related factors such as patients' medication knowledge (F. W. Chan, Wong, So, Kung, & Wong, 2013) and medication adherence (Turner, Hollenbeak, Weiner, Ten Have, & Roberts, 2009). There is a lack of studies that look at the health system and provider associated factors that could have an impact on patients' medication experiences.

The aim of this study was to explore patients' experiences in taking medications for their chronic diseases, and how it affects medication safety. We explored patients' medication experiences, following them through the whole process, which includes the prescribing of medications by their doctor, the dispensing of medications by the pharmacist, and the administration of medications at home. We also explored patients' beliefs and opinions about their medications. This provided us with a complete picture of patients' medication experiences, as it did not just focus on their medication-taking behaviour. This information was useful in identifying patients' needs in taking their long term medications appropriately.

4.2 Methods

4.2.1 Design

A qualitative methodology was selected to explore the medication experiences of patients with chronic diseases. This research method provided an in-depth understanding of patients' experiences, practices and opinions about their long term medications.

Individual in-depth interviews (IDI), a common qualitative interview method was used in this study. IDIs are described as 'conversations with a purpose' (Webb & Webb, 1975). It allows the researcher to construct knowledge about a problem, based on interactions between the interviewer and interviewee (Rorty, 2009). Semi-structured IDIs combine flexibility with structure. Although the interviewer prepares a set of pre-determined questions, the interview is conducted in a conversational manner, where participants are allowed to explore issues that they feel are important (Bowling, 2010). Semi-structured IDIs were used in this study because medication experiences of patients vary between individuals, and IDIs will allow the researcher to explore these experiences more deeply.

4.2.2 Setting

This study was conducted at the primary care clinic of the UMMC, a tertiary teaching hospital located in the urban city centre of Kuala Lumpur, Malaysia. Doctors prescribed electronically and patients collected their prescribed medications from the hospital outpatient pharmacy at a subsidised rate. The electronically transmitted prescriptions were screened, filled and dispensed by trained pharmacy technicians and trainee pharmacists, under the supervision of pharmacists.

4.2.3 Duration

The IDIs were conducted between January and April 2013.

4.2.4 Participants and sampling

Patients diagnosed with chronic disease(s) and on medical treatment were eligible for this study. Excluded were patients who could not converse in English, Malay or Tamil, and patients with cognitive impairment and active mental illness. Patients were selected purposively to ensure maximum variation in terms of age, number of medications and educational level. This was to ensure that a variety of medication experiences was captured; individual patient's opinion, belief and practice might differ according to their socio-demographic background. One researcher (RS) approached potential participants while they were waiting for their doctor's appointment. RS explained the objectives and duration of the interview, inviting them to participate. Patients who agreed to participate were interviewed in a separate room at the clinic.

4.2.5 Sample size

All 12 patients approached agreed to participate in the study. We ceased recruitment once no new themes emerged from the analysis (thematic saturation). Data reached thematic saturation at the tenth interview. Two additional IDIs were conducted to ensure that no new themes emerge and the data was indeed saturated.

4.2.6 Instruments used

A topic guide [Appendix B1 and B2] was developed based on a conceptual framework [Figure 4.1], which was mapped using information derived from the literature. This framework covers each stages of the medication use process and factors influencing patients' medication taking behaviour (World Health Organization, 2003). Patients were provided with a participant information sheet [Appendix B3 and B4] prior to obtaining their written consent [Appendix B5 and B6] and demographic profile [Appendix B7 and B8].

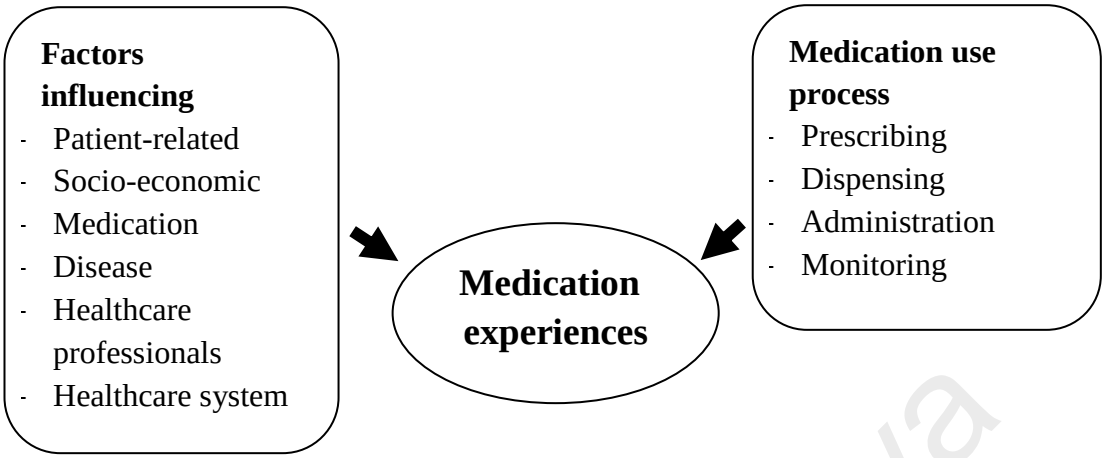


Figure 4.1: Conceptual framework on stages of the medication use process, and factors influencing patients' medication taking behaviour in the outpatient setting

4.2.7 Data collection

The IDIs were conducted by RS, a trained researcher. The IDIs were conducted in English, Malay or Tamil according to patient's preference. We asked patients open-ended questions and prompted them when some important issues were not mentioned. Patients were assured that anonymity will be maintained throughout reporting. Interviews were audio-recorded and transcribed verbatim in its original language. Checked transcripts were used as data for analysis. Quotes from interviews performed in Malay and Tamil were analysed in its original language and translated into English during reporting. The researcher documented relevant impressions and thoughts after each IDI.

4.2.8 Data analysis

We used descriptive-interpretive approach to analyse the data (St. George, 2010; Thorne et al., 2004). A computer-assisted qualitative data analysis software Nvivo10 (QSR International Pty Ltd, Doncaster, Victoria, Australia) was used to manage the data. Data was analysed inductively starting with the first transcript. RS familiarised herself with the data by reading the first transcript to identify and index the themes (Pope et al.,

2000). All data relevant to each theme were identified and examined through constant comparison (Pope et al., 2000). These themes were further refined and reduced in number by grouping them into larger categories (Pope et al., 2000).The research team (RS, CJN and PSML) met over several meetings to discuss the list of themes and categories, which were refined iteratively through consensus until the team agreed on the final coding framework. RS used the final coding framework to code the remaining eleven transcripts. New themes that emerged were added to the list upon consultation with the research team.

The research team consisted of a family medicine specialist (CJN) and two pharmacists (PSML and RS). All researchers were conscious of their personal and professional biases, and therefore constantly reflected and debated during data collection and analysis to improve the credibility of the data.

4.2.9 Ethics

Ethics approval was obtained from the UMMC Medical Ethics Committee prior to the commencement of this study (approval. No. 890.104) [Appendix A5].

4.3 Results

A total of 12 IDIs were conducted, each lasted from 18 to 43 minutes. Six IDIs were conducted in English, five in Malay and one in Tamil. Three male and nine female patients aged 53 to 82 years old were interviewed individually. Demographic characteristics of patients who participated in the IDIs are presented in Table 4.1.

Table 4.1: Demographic profile of the patients interviewed

Participant ID	Age	Sex	Ethnicity	Highest level of education	Number of chronic diseases	Number of chronic medications
Pt01	75	Female	Chinese	Secondary school	2	3
Pt02	62	Female	Chinese	Secondary school	2	3
Pt03	64	Male	Indian	Secondary school	4	7
Pt04	67	Male	Chinese	Secondary school	3	9
Pt05	67	Female	Malay	Secondary school	4	4
Pt06	64	Female	Indian	Primary school	3	8
Pt07	56	Female	Malay	Secondary school	3	5
Pt08	70	Female	Chinese	Secondary school	2	3
Pt09	64	Female	Malay	Primary school	3	6
Pt10	82	Female	Malay	Primary school	5	8
Pt11	65	Female	Chinese	Secondary school	3	4
Pt12	53	Male	Chinese	Secondary school	2	3

The medication experiences of patients with chronic diseases are summarised in Table 4.2.

Table 4.2: The medication experiences of patients with chronic diseases

Lack of knowledge and awareness about medications
Information seeking behaviour
Information sources
Beliefs about medications and medical treatment
Medication adherence
Experiences with medication side effects
Experiences with the health care system
Frequent change in medication brand
Inconsistent dispensing practice at the pharmacy
Shortage of medication supply

4.3.1 Lack of knowledge and awareness about medications

When asked about their medications, some patients were not able to tell the name, strength or indication of their medications. Some were not informed and therefore not aware of changes in their medication regimen. However, these patients decided not to question the doctors' decision as they felt that it would make the doctors unhappy and therefore affect the medical care that they receive.

"Hmm… that one (tablet to be taken at night)? I do not understand. I just follow the instruction on the label. I have been taking (the medicine) for so long. But I do not know what is it for." (translated from Malay)

[Pt12]

"Before this I was given more than three supplements, folic acid and some other vitamins. Few months ago, they (doctor) cut on it (stopped prescribing). I do not know

the reason and I do not ask. I try not to argue upon it you see. Because I want to have a good service, so I would not argue with the doctor."

[Pt05]

4.3.2 Information seeking behaviour

While some patients wanted to know more about their medications, some patients had very low expectations. This group of patients think doctors 'know best" and hence it was not important for them to know about their medications.

"I need the information. I would like to know what I am taking because these medicines are very important. I want to know about their side effects and how to take it. I also want to know what it does to my body and what will happen if I don't take it."

[Pt03]

"I never thought about it. I see the doctor for my disease. She (the doctor) gives me the medicines and I feel better. I see the doctor regularly. So I think she knows what to do. I never wanted to know more about my medicines. In fact, I never even thought about it until you asked." (translated from Tamil)

[Pt06]

4.3.2.1 Information sources

Patients obtained information regarding their medications from different sources: hospital pharmacy technicians, community pharmacists, doctors and relatives or friends working in the healthcare sector. However, none had the opportunity to speak to the hospital pharmacists regarding their medications due to the high patient load at the pharmacy.

"I usually ask the dispensers (pharmacy technician) when they give the medicine to me. How to take the medicine, before or after meal?"

[Pt11]

"Erm… last year when I went to see the psychiatrist, I was not too sure about the medicine given. So I consulted a pharmacist outside (private pharmacy) and asked more about the medicine. And recently, I went there again to tell about my appetite and she recommended multivitamins for me."

[Pt05]

"I have been taking these medicines for so long so, I know what is it for. The doctor told me which one is for diabetes, which one is for high blood pressure and cholesterol."

[Pt04]

"If I have any doubt about my medicines, I will ask my daughter. She is a pharmacist, working in Singapore. I will call and ask her to confirm before taking any medicine."

[Pt11]

"The pharmacist? No. I have not spoken to the (hospital outpatient) pharmacist. Because you have to understand there are so many people taking their medicines. You cannot blame them (hospital outpatient pharmacists). By right they (hospital outpatient pharmacists) should explain something but I do not feel offended or what not. It is alright. You just give us the medicine, I am very happy. That's all. Because the next visit we can just ask the doctor."

[Pt02]

4.3.3 Beliefs about medications and medical treatment

A few patients developed negative impression about modern medications being injurious to their body and therefore stopped taking their medications.

"Some people told me, if I take too many medicines, I will have problems. For example, swollen heart, kidney disease and anything can happen. So I do not take the medicine anymore. I take USANA (health supplement)." (translated from Malay)

[Pt12]

Some stopped taking their chronic medications as they believed that their disease has been cured, or that lifestyle changes could "cure" their disease. A few substituted prescribed medications with health supplements based on their own judgment.

"I have been seeing the doctor here for the past two years. But since this year, I am not sick anymore. I have finished taking the medicines, and I did not come to take more because I know I am not sick. I always check my blood pressure at the pharmacy (community) and they told me it is normal. Not high anymore." (translated from Malay)

[Pt12]

"I stopped eating the simvastatin. I took on and off and still no improvement. I still have leg cramps. So I just control my diet. I take Quaker oats and I do not eat fatty food (laughs). I know what is good and bad for me."

[Pt01]

"I am not taking the simvastatin at all. I take this one (health supplement). Because it says er… for healthy cholesterol. This one is the oil from red fish. It is krill oil."

[Pt01]

4.3.4 Medication adherence

Patients adhere to their medications for various reasons. While some took medications to avoid disease complications, some felt unwell without their medication. These patients also associated medication taking with their daily routines and therefore did not find it difficult to adhere to the medication schedule.

"The high blood pressure medication? I never miss that. I am afraid if my blood pressure goes up, I will get stroke (laughs). I am scared of that." (translated from Malay)

[Pt08]

"I take my medications on time! If I don't take it, I feel uncomfortable."

(translated from Tamil)

[Pt06]

"No, not difficult. Because I take it (medication) right after my meal, At night, I take it (medication) before I got to bed." (translated from Malay)

[Pt10]

Some patients however self-adjusted their medication doses due to the lack of knowledge and awareness about their medications.

"Sometimes if I don't take my pressure medicine, I get headache. And when I take two tablets as instructed, sometimes I feel like taking more. If I take more than instructed, the doctor will scold me saying that I should not take extra and it will affect my heart. But I will still take two tablets extra." (translated from Tamil)

[Pt06]

"Sometimes when I wake up later, I skip breakfast. I was thinking if I skip breakfast, I don't have to take my medicine. But I was wrong. When I told the doctor, he said that it is not good to do so. I had to ask him (doctor). He didn't tell me earlier."

[Pt03]

Participants mentioned several other reasons for medication non-adherence such as cost of medication, forgetfulness, travel and ran out of medications.

"I am not wealthy, so I don't buy (the medication) often. So do not eat it (medication) continuously. I stopped taking it (medication)."

[Pt01]

"Now that I am getting old, I sometimes forget to take my medicine. I am already 65 years old (laughs)."

[Pt11]

"Sometimes I do forget. Like when I go travelling, I forget to bring my medicine along." (translated from Malay)

[Pt09]

"I came for my appointment at the eye clinic today. At the same time I am here (in primary care clinic) to ask for more medicine. I missed my previous appointment. So I ran out of medicine for so long. It is not easy to come so often." (translated from Malay)

[Pt09]

4.3.5 Experiences with medication side effects

Patient experienced side effects such as weight gain, leg swelling and headache at one point or another after taking their long term medication. Fortunately, they sought medical help and had the medication changed. Sometimes patients were uncertain whether a particular symptom was due to the disease itself or medications, as they were on multiple medications and it was difficult to identify which one was the cause of the problem.

"There was once when the doctor changed my high blood pressure medicine, I took it and my legs started to swell. I came back to see the doctor and she changed my medicine. Now I do not have the problem." (translated from Malay)

[Pt08]

"My legs are very itchy and my lips are very dry. For the past one week, very dry and itchy. I have been scratching. It could be the medicine as I don't know what is the culprit. I am taking a lot of tablets and all these chemicals have side effects. My diet… I have not changed anything. So could be the medicines I am taking."

[Pt03]

4.3.6 Experiences with the health care system

4.3.6.1 Shortage of medication supply

Patients sometimes were not supplied with enough medications to last till their next appointment with the doctor. When the hospital outpatient pharmacy ran out of stock for certain medication, the patients were asked to come at a later date to collect the medication once the stock becomes available. Some patients however found it inconvenient to make the extra trip to the hospital and therefore did not take the medication.

"I have previous experience with daonil. I think about two months back. Every time they gave me less daonil, more metformin. I had to come back and complain to the doctor. Now they (pharmacy) are giving me enough, they have corrected it."

[Pt03]

"Once I was prescribed with eye drop, they (pharmacy personnel) told me out of stock. They asked me to come another day, and to call first and check if the stock has arrived. But at the end I did not take the medication at all! It is difficult for me to come again another day." (translated from Malay)

[Pt08]

4.3.6.2 Frequent change in medication brand

Many patients commented on the frequent change of brand of their chronic medications. This led to changes in the physical appearances of the medication and caused confusion among patients as to whether they were given the right medication or not. One patient said she felt different after taking the new medication, but eventually got accustomed to it.

"The cholesterol medication, sometimes they (pharmacy) give me a medicine with a different name. But they (pharmacy personnel) say for cholesterol. Just now I spoke to my doctor. Usually they give me simvastatin, but this (medicine) is different. The doctor said it is the same medicine of a different brand." (translated from Malay)

[Pt07]

"The high blood pressure medication, I was taking from a different box. Then they (pharmacy) changed it to a different one, different tablet. When I asked the doctor why is it different, she told me it comes in this form now. And I have to take it. So I took it. Initially I felt different, but after a while it felt normal again." (translated from Tamil)

[Pt06]

4.3.6.3 Inconsistent dispensing practice at the pharmacy

Patients had mixed experiences while collecting medications at the hospital outpatient pharmacy. Some said they were given basic instructions on how to take their medications by the dispenser, while others were not given any information at all.

"They (pharmacy personnel) gave it (medication) to me and explained this medicine is for what, ah... for how long, how many times to take, the name of the medicine, ah... that is all they tell me. They tell me my next appointment date (for medication refill), to come at this date to take the second time. That is after one month, ah two months."

[Pt02]

"Even the pharmacy personnel, they don't explain. They just push the medicine to you. I tell you, at the pharmacy, they (pharmacy personnel) just ask for the name (patients' name), and give the medicine. That is all they say. They don't give information."

[Pt03]

4.4 Discussion

This qualitative study reported on medication experiences of patients with chronic diseases which covered a broad range of themes including patients' medication knowledge and beliefs, their information seeking behaviour, their medication-taking practices as well as their experiences with medications and the health system.

Medication experiences of individual patients vary greatly. While some knew about their medications and took initiative to obtain medication information from trusted sources such as doctors and community pharmacists, some thought it was not important for them to know. Others believed that medications had a detrimental effect on their health and stopped taking their medications while the rest believed that the medications were helping them in disease control. This implies that interventions that aim to improve patients' medication-taking behaviour need to be personalised according to individual patients' needs, as it is impossible to design one intervention that caters for all patients (World Health Organization, 2003). It would also be more cost and time efficient to identify and target patients who require help, rather than providing an intervention for all patients with chronic diseases (Olaniyan et al., 2014).

Literature suggests that patients who did not know about their medications and disease state were more likely to be non-adherent (Alm-Roijer, Stagmo, Udén, & Erhardt, 2004). We however found that this was not necessarily the case, as some patients took their

medications according to instructions, even though they did not know the indications of the medications. This was probably due to the respect and trust they had on the doctors. Speaking up and asking questions to the doctors were considered as disrespectful and rude (Hrisos & Thomson, 2013). This mindset needs to be changed to encourage patients to self-manage their chronic diseases (Department of Health, 2001). Patients need to realise their role in managing their own disease, and should be empowered to do so by providing them with the necessary information about their medical condition and treatment

Similar to a previous study, we found that patients "take what works for them" based on their knowledge and belief about their medications and medical conditions (K. M. Nair et al., 2007). This again emphasises the need for patient education and awareness. Changing their mindset and the associated medication-taking practice will require time and patience which the primary care doctors are struggling to achieve within a short consultation and in a high patient load environment of primary care (Ostbye et al., 2005). Doctor-pharmacist collaboration could be one solution for this. Pharmacists can complement doctors' role in patient care by addressing patients' medication-related concerns through the provision of medication reviews and patient counseling (Dolovich et al., 2008). This has shown to positively impact on patients' medication adherence, improve chronic disease control as well as reduce the occurrence of MEs (Z. Chen et al., 2013; Dolovich et al., 2008; Howard-Thompson et al., 2013; Lindenmeyer et al., 2006; Schlenk, Bernardo, Organist, Klem, & Engberg, 2008).

An important local health system issue that was apparent in this study was the lack of pharmacist involvement in patient care. On average, the outpatient pharmacy in our setting receives 2000 prescriptions per day. However, there are only eight pharmacists

working in the outpatient pharmacy. Hence, dispensing of medications are performed by trained pharmacy technicians and trainee pharmacists. As a result, patients had little or no access to hospital pharmacists. In fact, patients had very little awareness of the role of the pharmacists in ambulatory care. This is disappointing given the evolving role of pharmacists in healthcare worldwide (Pearson, 2007). Pharmacists have the potential to complement the role of PCPs in promoting the safe and effective use of medication in chronic disease management (C. A. Brown et al., 2006; Carter et al., 2009). Policymakers should therefore look into ways in creating opportunities for pharmacists to be more actively involved in patient care to improve medication safety in the outpatient setting (Murray, Ritchey, Wu, & Tu, 2009).

Health system issues affecting patients' medication adherence were apparent in this study. For example hospital pharmacy running out of stock for certain medications and changes in the physical outlook of medications supplied have led to some patients temporarily stop taking their medications (Hakonsen et al., 2009). Another issue was the inconsistent dispensing practice at the pharmacy. It was disturbing to note that some pharmacy technicians and trainee pharmacists did not provide the necessary information (on how medications should be taken) during dispensing. Basic medication instructions given to patients while dispensing are necessary to ensure that patients take their medications appropriately (Teinila et al., 2011). Therefore, there should be adequate training and monitoring of pharmacy technicians and trainee pharmacists in order to avoid variations in the delivery of healthcare in future.

A limitation of our study was that the participants in this study were aged 50 years and above and attended up to secondary school only. The medication experiences of younger

patients and those of higher level of education might be different from those reported in this study and worth exploring in future studies.

The strength of our study was that it explored the complete medication-taking experiences of patients without just focusing on patient-related factors. Based on this, we were able to point out some local health system issues that need to be addressed in order to create a safe and effective medication management for chronic diseases in primary care.

4.5 Conclusion

Patients' with chronic diseases display a broad range of medication experiences including their knowledge, belief, information seeking behavior and medication-taking practices. Besides creating awareness among patients about their role in self-management, there is a need to educate patients to improve their knowledge and safety. Health system issues such as lack of medication supply and inconsistent dispensing practices at the pharmacy should also be addressed to avoid negative impact on patients' medication adherence and safety.

CHAPTER 5: CHALLENGES FACED BY PHARMACISTS IN DISPENSING MEDICATIONS FOR PATIENTS WITH CHRONIC DISEASES: A QUALITATIVE STUDY

Pharmacists play an important role in health care through the medications they supply and the counselling they provide. A pharmacist's responsibilities include a range care for patients from ensuring that the medications prescribed by doctors are appropriate, to dispensing medications, monitoring and maximising patients' response to medications. Pharmacists also educate patients on the use of medications, and advise doctors and other health care professionals on drug decisions. The needs assessment would be incomplete if the perceptions and experiences of pharmacists in carrying out these duties were not explored. This chapter will report on the challenges faced by pharmacists in screening and dispensing medications for patients with chronic diseases.

5.1 Introduction

Medication management for chronic diseases involves three parties: the doctor, the patient and the pharmacist (Bajcar et al., 2005). It is important that all three parties work together in unity towards the safe and effective use of medications. While the doctor is responsible for prescribing appropriately for the patient, the pharmacist's role is to confirm that the medication prescribed is appropriate, and to dispense the medication(s) to the patient with the correct instructions (on how to take the medications), in the correct strength and quantity. It is also the pharmacist's role to counsel the patient on how to take the medication. Ultimately, it is the patient's responsibility to take the medication as prescribed to achieve the desired outcome. Error in any component of this medication trajectory will have an adverse effect on the patient (Gurwitz et al., 2003; Lund, Carnahan, Egge, Chrischilles, & Kaboli, 2010).

While prescribing for patients with chronic diseases has become increasingly challenging (as described in Chapter 3), dispensing medications for this group of patient is also a difficult task. At present, there is no dispensing separation practiced in Malaysia. The doctors in the community are allowed to prescribe and dispense without the presence of a pharmacist. Hence, community pharmacies do not stock up on prescription medications. Therefore, most hospital patients will obtain their medications from the hospital outpatient pharmacy. The outpatient pharmacy of the UMMC dispenses approximately 2000 prescriptions daily, with only eight available pharmacists. With the increasing prevalence of multimorbidities, patients often attend several specialist clinics for their treatment and end up with prescriptions from different doctors (Ashman & Beresovsky, 2013). This increases the chance of drug duplication and drug interactions (Green et al., 2007). It is the pharmacist's responsibility to detect and prevent these errors. This is a challenging task given the high patient load and the lack of manpower at the outpatient pharmacy.

A search of published literature revealed that many studies have looked into doctors' prescribing practice and patients' medication-taking behaviour (Y. F. Chen et al., 2005; K. Nair et al., 2002; K. M. Nair et al., 2007; Ramaswamy et al., 2011). However, not many studies have been conducted on the pharmacists' experiences in dispensing for patients with chronic diseases. It is important to explore the pharmacists' views and experiences as they are directly involved in patients' medication management in the outpatient setting. The aim of this study was to explore the challenges faced by hospital outpatient pharmacists in dispensing medications for patients with chronic diseases, and its impact on medication safety. By doing this, we hope to identify any gaps and needs to improve medication management for chronic diseases in primary care.

5.2 Methods

5.2.1 Design

A qualitative methodology (combination of IDIs and FGDs) was used to explore the challenges faced by pharmacists when dispensing medications for patients with chronic diseases. This research method allowed an in-depth understanding of the experiences, challenges and dispensing practices of the pharmacists.

5.2.2 Setting

This study was conducted at the UMMC, a tertiary teaching hospital located in the urban city centre of Kuala Lumpur, Malaysia. The outpatient pharmacy received approximately 2000 prescriptions per day from all specialties within the hospital. The PCPs prescribed electronically and the prescriptions were screened, filled and dispensed by trainee pharmacists or pharmacy technicians, under the pharmacists' supervision.

5.2.3 Duration

This study was conducted between March and April 2013.

5.2.4 Participants and sampling

Convenient sampling was employed where all outpatient pharmacists were eligible to participate in this study. This included the head of outpatient pharmacy, and seven outpatient pharmacists. The researcher (RS) sent an invitation via email to all the outpatient pharmacists, explaining the details of what this study was on, its objectives and the duration of the interview.

5.2.5 Sample size

All eight outpatient pharmacists were invited to participate in this study. However, only seven pharmacists were interviewed, as one pharmacist was unavailable during the data collection period. This pharmacist was of similar characteristics (in terms of age and years of clinical experience) as the other six pharmacists who were interviewed. Therefore, her unavailability to participate would not have affected the results.

5.2.6 Instruments used

A topic guide [Appendix C1] was developed based on a conceptual framework [Figure 5.1]. This conceptual framework was mapped based on literature review on stages of the dispensing process, and the factors contributing to dispensing errors (Teinila, Gronroos, & Airaksinen, 2008). The pharmacists were provided with a participant information sheet [Appendix C2] prior to obtaining written consent [Appendix A3]. We also collected the pharmacists' demographic data [Appendix C3].

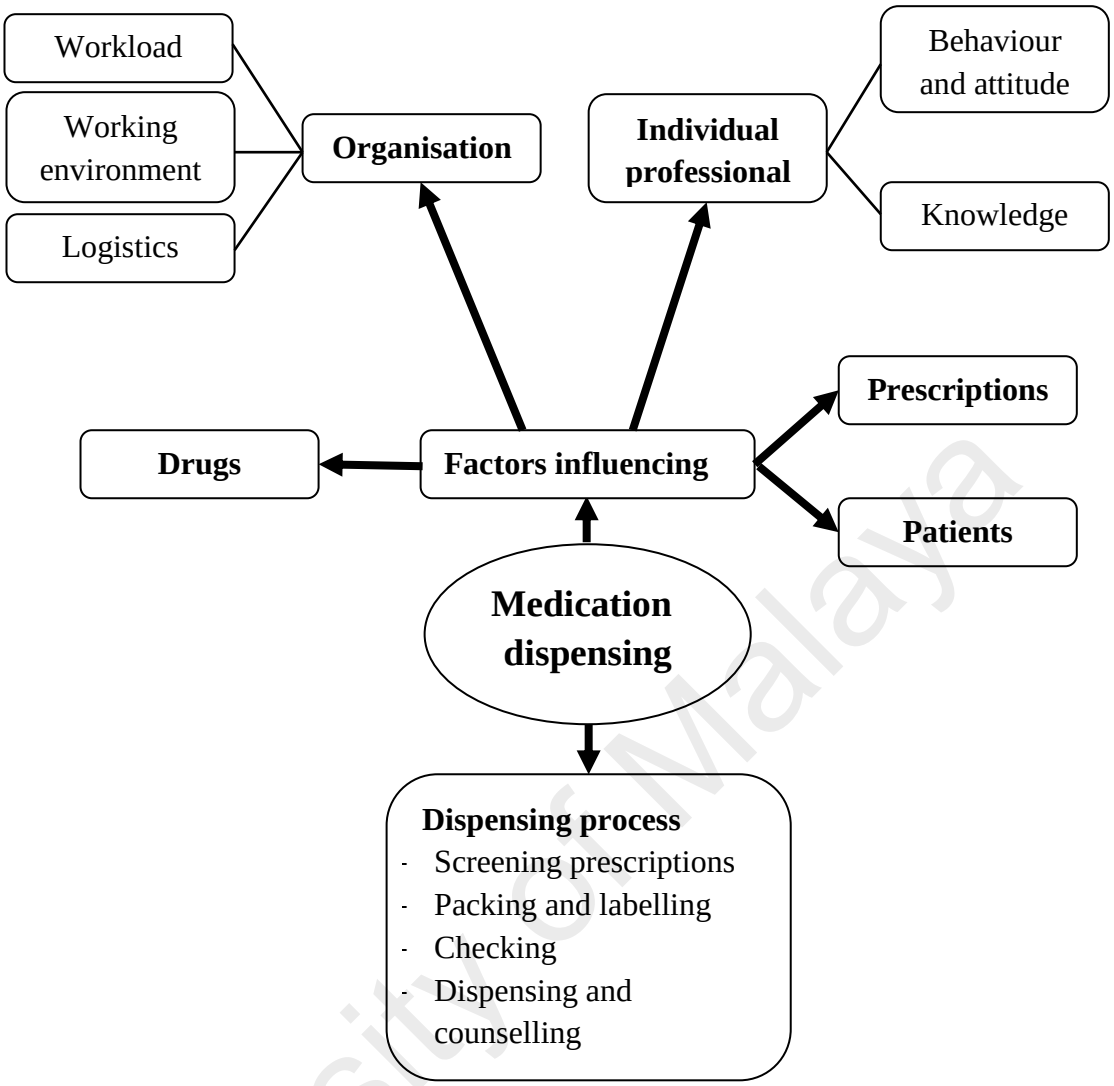


Figure 5.1: Conceptual framework on factors contributing to dispensing errors, and stages of the dispensing process

5.2.7 Data collection

A combination of FGDs and IDIs were used in this study. This was necessary as it was difficult to gather all the outpatient pharmacists simultaneously for an FGD due to their busy schedule. However, the head of outpatient pharmacy had to be interviewed separately as he was more senior compared to the other pharmacists, and preferred to speak in Malay. This mixed method of data collection also allowed data triangulation between the FGDs and IDIs.

Five pharmacists were grouped into two FGDs (two and three pharmacists respectively), according to their availability. The remaining two pharmacists were interviewed individually. The interviews were conducted by RS, a trained researcher not known to the pharmacists. One IDI and two FGDs were conducted in English, while one IDI was conducted in Malay. The pharmacists were asked to speak about their experiences in dispensing medications for patients with chronic diseases from the primary care clinic. We asked the pharmacists open-ended questions and prompted them when some important issues were not mentioned. Interviews were audio-recorded and transcribed verbatim in its original language. Checked transcripts were used as data for analysis. Quotes from interviews performed in Malay were analysed in its original language and translated to English during reporting. The researcher documented relevant impressions and thoughts after each interview session, while a research assistant took field notes on non-verbal cues during the FGDs.

5.2.8 Data analysis

We used descriptive-interpretive approach to analyse the data (St. George, 2010; Thorne et al., 2004). A computer-assisted qualitative data analysis software Nvivo10 (QSR International Pty Ltd, Doncaster, Victoria, Australia) was used to manage the data. Data was analysed inductively starting with the first transcript, which was an FGD. RS familiarised herself with the data by reading the first transcript to identify and index the themes (Pope et al., 2000). All data relevant to each theme were identified and examined through constant comparison (Pope et al., 2000). The research team (RS, CJN and PSML) met over several meetings to discuss the list of themes, which were refined iteratively through consensus until the team agreed on the final coding framework. RS used the final coding framework to code the remaining three transcripts (one FGD and two IDIs). New themes that emerged were added to the list upon consultation with the research team. Data

reached thematic saturation after two FGDs and one IDI. We however conducted one additional IDI to ensure that no new themes emerge and the data was indeed saturated.

The research team consisted of a family medicine specialist (CJN) and two pharmacists (PSML and RS). All researchers were conscious of their personal and professional biases, and therefore constantly reflected and debated during data collection and analysis to improve the credibility of the data.

5.2.9 Ethics

Ethics approval was obtained from the UMMC Medical Ethics Committee prior to the commencement of this study (approval No. 890.104) [Appendix A5].

5.3 Results

Each interview lasted for about 29-58 minutes. Three male and four female pharmacists, aged 25-45 years old were interviewed. Their clinical experience ranged from 2-12 years. Demographic characteristics of the pharmacists who participated in this study are presented in Table 5.1.

Table 5.1: Demographic profile of hospital outpatient pharmacists participated

Participant ID	Age	Sex	Ethnicity	Years of clinical experience
Ph01	25	Female	Chinese	3
Ph02	27	Female	Chinese	2
Ph03	27	Male	Chinese	3
Ph04	30	Female	Indian	4
Ph05	29	Male	Chinese	5
Ph06	45	Male	Malay	12
Ph07	28	Female	Chinese	6

The challenges faced by pharmacists in dispensing medications for patients with chronic diseases are listed in Table 5.2.

Table 5.2: The challenges faced by pharmacists in dispensing medications for patients with chronic diseases

Lack of pharmacists
High work load
Lack of clinical information to screen prescriptions
Difficulties in contacting the prescriber
Difficulties in addressing patients' medication-related problems
Barriers to medication counselling

5.3.1 Lack of pharmacists

The small number of outpatient pharmacists at the hospital was a challenge in providing services to patients with chronic diseases. There are only eight outpatient pharmacists, five trainee pharmacists and 31 pharmacy technicians, who dispense approximately 2000 prescriptions a day. On average, a prescription will have four items. This means that a total of 8000 items are dispensed daily. Majority of the dispensing tasks; screening of prescriptions, packing and labelling of medications, and medications dispensing were performed by trainee pharmacists and pharmacy technicians. This increased the risk of prescription errors not being picked up during dispensing.

"Because... we don't have enough staff (pharmacists), not all the processes (screening, packing, checking and dispensing) are owned by us (pharmacists). Every day, one pharmacist will be in charge of one process, for example screening. So, there is a possibility that not every prescription has gone through a pharmacist."

[Ph01]

"Because we have so many patients, at some point it can be very mechanical. It is only when the prescription comes to one of us, the pharmacists or a senior dispenser (pharmacy technician) that somebody picks up something (error). If not the prescription just goes out and comes back again without anyone noticing the error."

[Ph04]

"When a patient tell us that they do not need the medication as they have plenty at home, we try to talk to them to make sure that they are taking it (medication) as instructed. But if the screener is a pharmacy technician, then they (pharmacy technician) may not realise and may not inquire more. The problem is most of our front liners are pharmacy technicians." [Ph03]

5.3.2 High workload

The pharmacists found it difficult to screen each prescription thoroughly prior to dispensing due to the large prescription volume received by the pharmacy daily. Time was another factor; patients wait approximately one hour for their prescriptions to be filled and if the pharmacist took longer time to screen, then then waiting time will be increased further. It was also difficult to counsel patients comprehensively about their medications while dispensing due to the same reasons.

"We try to check but the amount of prescriptions… it is quite hard for us actually. So, we try to check as much as possible."

[Ph05]

"When we dispense, most of the time we just tell them (patients) how and when to take the medication. Because it is very crowded and there is not much time!"

[Ph03]

High workload also led to dispensing errors. When it was really busy at the pharmacy, the risk of selecting the wrong medication that 'look alike' and 'sound alike' was very high. The challenge was to prevent these errors from reaching patients, or if the errors were to occur, to detect them before the medication reach the patient.

"Packing errors occur because we have multiple dosages in our pharmacy. Different doses but similar names, similar colour of the medication and we get all that wrong. And when it is really busy, there is a high chance that we may pick the wrong drug. The problem is when we dispense it without checking" (translated from Malay)

[Ph06]

5.3.3 Lack of clinical information to screen prescriptions

The pharmacists were also concerned about not able to pick up prescribing errors by just looking at the prescription alone. As the hospital practiced paper-based records, pharmacists had no access to patients' medical records and therefore were unable to determine accurately if the prescription was appropriate for a particular patient.

"Say the doctor transcribed from the file (medical record) wrongly. For example, patient is on amlodipine 5mg but he prescribed amlodipine 10mg. Because it (amlodipine 10mg) is a common dose, we might not check it. We will just assume that the doctor has increased the dose. It is difficult for us because the doctors don't er… annotate on the prescription whether they have increased or decreased the dose. So, if it (the dose) is

within a normal range, we might not check. Unless it is an overdose, then of course we will call the doctor to confirm."

[Ph07]

"Sometimes it is hard to discuss with the doctor because we don't have the patient files (medical records)."

[Ph02]

5.3.4 Difficulties in contacting the prescriber

Contacting doctors to clarify prescriptions was a tedious process as the pharmacists had to go through the hospital telephone operators to get the doctor's mobile number, or the clinic staff to find out the doctor's consultation room extension number. Contacting the doctor in this manner took longer than necessary, and resulted in the patient waiting for a longer time at the pharmacy. Sometimes by the time the pharmacists managed to contact the doctors, the patient folders may have been dispatched to medical records, or the doctor may have left the clinic. The discussion will then be based on the doctor's recall memory, which may increase the risk of ME.

"Right now we cannot dial straight to the doctor from the pharmacy. We have to call the (hospital) operator if we want to call to the doctors' mobile phone. Or we have to call the clinic (receptionist) and then call the doctor's room and back to the clinic (receptionist), if the doctor is not in his room. If we can get direct access to the doctor, then it will be so much faster and easier. We can speak directly and settle the problem almost immediately. Sometimes we have so many prescriptions waiting to be dispensed

because we cannot contact the doctor to clarify the prescriptions. We have to keep calling again and again!"

[Ph04]

"And when finally we got them (doctors) on the line, it might be a bit too late. The file (medical folders) may not be in the clinic anymore. It will take a while for them to get the file. Sometimes, the doctor will just follow our suggestions and we are not sure if he knows which patient we are talking about."

[Ph05]

"I think this may affect the patient care. They (patients) might not get the proper therapy that they need. Say if the doctor actually intended to increase it (medication dose) and we were just calling to check on the change of dose. If they (doctors) didn't check the file and tell us to stick with the old dose, the patients might not get the optimum therapy."

[Ph01]

5.3.5 Difficulties in addressing patients' medication-related problems

Detecting and addressing patients' medication-related problems during the dispensing process can be a difficult task. Many patients have multiple co-morbidities. It is not uncommon for such a patient to consult with different specialists, and receive prescriptions from several doctors. This became a problem when patients were prescribed with the same medications by different doctors, but the instructions on how to take these medications differ in terms of dose and frequency. It was difficult to notice this error during dispensing, especially when the prescriptions were dispensed on different days.

"A patient with multiple prescriptions from different clinics for the same medicine is a headache! So much of polypharmacy, so much of non-compliance! They have 11 medications on one sheet and another five on another sheet, another three from another doctor, which may overlap. Especially say a patient attending the diabetic clinic, the heart clinic and some even go to RUKA (primary care clinic). All three prescriptions with same medications, different dosages and worst sometimes we don't notice it because they come on different days. So we just keep supplying all of them (prescriptions)."

[Ph04]

Some patients complained about the side effects of their medications to the pharmacists, and refused to take certain medications. When advised to consult the doctor, patients were often reluctant due to the fear of the doctor, or the hassle of waiting to see the doctor. This could possibly lead to non-adherence and medication wastage. Some patients even self-medicated themselves to treat the side effects, which could be harmful to them.

"Sometimes when we tell them (patients) to go back to the doctor, they do not listen and decide to stop the medication themselves. They (patients) refuse to see the doctor. Or sometimes, they (patients) won't even talk to us about it. They will actually stop it themselves. So when they (patients) come to collect their medication, they tell us they don't want certain drug. When we ask further, then we realise they have not been taking it. They (patients) might also self-medicate themselves with other medication to treat the side effects." [Ph03]

Patients also often complained to pharmacists about not being supplied with enough medications. Based on their experience, the pharmacists realised that this could be due to

several reasons such as patients taking their medication incorrectly, misplacing their medications or sharing their medications with family members. It could also be due to dispensing the wrong amount to patients.

"We need to be careful when addressing this complain (insufficient medication). Sometimes the patient takes extra medications than prescribed. For example, instead of taking one tablet, the patient actually takes two. That is how the patient ends up with not enough medication." (translated from Malay)

[Ph06]

"Sometimes this (insufficient medication) happens because the patient is actually taking the wrong dose. Other times they might have misplaced the medication or we could have given the patient the wrong amount."

[Ph03]

"When I asked further, the patient then told me that she gave the calcium tablets to her daughter (everyone laughed). That is why she was short of the tablets."

[Ph02]

5.3.6 Barriers to medication counselling

Language was identified as a barrier to proper medication counseling for patients. Malaysia is a multi-racial country and many older patients do not speak the national language (Malay) or English. These patients therefore might not fully understand their medication instructions and require a translator while dispensing.

"Communication is another problem. Some patients do not understand English or Malay. So they just want to get their medication. They will then take the medication as they wish, not according to the instructions." [Ph02]

There was also no designated private space at the outpatient pharmacy for medication counselling. Counselling was given across the dispensing counter, which in itself was a barrier. In addition, each window is only partitioned by the frame. This does not provide enough privacy as conversations can be overheard by patients collecting medications from adjacent counters. Counselling patients in this kind of environment was a challenge.

"Sometimes they (patients) are not paying attention and it is very noisy. It is not a conducive place to actually counsel on medication. If you actually look at the (pharmacy) counter, patient A stands on the left and patient B on the right. When you explain to patient A, patient B also listen. You dispense to patient B, patient A also listen. This lead to confusion. It is so crowded that patients don't have a personal space by themselves." [Ph07]

5.4 Discussion

The hospital outpatient pharmacists faced several challenges in screening and dispensing medications for patients with chronic diseases. The main issue was the lack of pharmacists and the high workload as these affected their ability to detect and prevent MEs. The pharmacists were also unable to screen prescriptions effectively based on the limited clinical information available on prescriptions and when they did notice any problems, they were unable to communicate effectively with the prescriber. Counseling and addressing patients' medication-related problems while dispensing was also a

challenge due to language barrier, time factor and unconducive environment at the pharmacy.

The workload at the outpatient pharmacy is high; the ratio of staff to items dispensed daily is approximately 1:180. The lack of pharmacists and high work load means that the pharmacists had little time to specifically focus on patients with chronic diseases from the primary care clinic. They were also not able to screen prescriptions for medication appropriateness based on the information provided on the prescription alone. In order to this, they will need to look at patients' medical records and medication history as well as interview patients (Bradley et al., 2008). This will then allow them to perform a complete medication review and assist in identifying and addressing patients' medication-related problems (Lim et al., 2004; Taylor et al., 2003). This will require a lot of time and needs to be done on a one-to-one basis, which is not achievable in the busy setting of the outpatient pharmacy (A. C. Tan, Emmerton, & Hattingh, 2012). Rather, there should be designated pharmacists stationed at the primary care clinics to do this. They could therefore screen the prescriptions for error before reaching the pharmacy for dispensing. Besides reducing MEs, this could also reduce the burden at the outpatient pharmacy.

Some patients were not taking their medications correctly while some experienced side effects due to their medications. These findings concurred with our interviews conducted with the PCPs (Chapter 3, section 3.3, page 79) and patients with chronic diseases (Chapter 4, section 4.3, page 102) earlier. Unfortunately, the pharmacists faced difficulties in identifying and addressing these issues during dispensing due to time pressure, high workload, lack of access to patients' clinical information and lack of privacy at the pharmacy (A. C. Tan et al., 2012). By having the pharmacists as part of the primary care team, they could then help both the PCPs and patients in addressing these

medication-related problems (Dolovich et al., 2008). It is however impossible to do this for all patients with chronic diseases attending the primary care clinic. It will be more feasible to provide pharmacist counseling and medication review for patients with problems as identified by the PCPs during consultation, or the high risk patient group such as the elderly with multi-morbidities (Sturgess et al., 2003; Taylor et al., 2003). This will then ensure effective use of pharmacists' time and healthcare resources.

The integration of pharmacists into primary healthcare teams specifically for chronic diseases management has shown to have a significant positive impact on patients' health outcomes such as asthma, diabetes, hypertension as well as heart failure (Gattis et al., 1999; Roughead et al., 2005). Its effect on patients' safety outcomes such as medication appropriateness and incidence of ADEs has also been promising (Bernsten et al., 2001; Hanlon et al., 1996; V. B. Petkova, 2008; V B Petkova, 2009). However, this will require a two-way communication between the doctors and pharmacists. As mentioned by the PCPs (Chapter 3 section 3.3.1.1, page 81) and the pharmacists (Chapter 5 section 5.3.4, page 127) in this study, currently there was minimal interaction between the two professionals. PCPs were unable to reach the pharmacists for any medication-related queries and vice versa. There is therefore a need to address this communication gap between the two professionals to improve the medication management for chronic diseases in primary care.

The small number of outpatient pharmacists interviewed in this study is a limitation as it could affect the transferability of our findings.

5.5 Conclusion

The hospital outpatient pharmacists were burdened with heavy dispensing task at the pharmacy, and were therefore unable to provide active clinical services to patients with chronic diseases. There were also very minimal professional interactions between PCPs and pharmacists. This may increase the risk of MEs and patient harm. There is a need to look into ways to actively involve the pharmacists in chronic diseases management in primary care and at the same time improve the working relationship between PCPs and pharmacists.

CHAPTER 6: VIEWS OF PRIMARY CARE PRACTITIONERS, PATIENTS AND PHARMACISTS ON THE IMPLEMENTATION OF AN AMBULATORY CARE PHARMACIST SERVICE

Chapters 3, 4 and 5 explored the challenges and needs of PCPs, patients and pharmacists in the use of medication for chronic diseases in primary care and highlighted that there was a need to:

- Support PCPs' medication-prescribing practice to prevent MEs
- Improve patients' medication knowledge and medication taking-behaviour to improve chronic diseases management and prevent MEs.
- Create a platform to engage pharmacists more actively in patient care at the primary care clinic
- Improve the interprofessional communication between PCPs and pharmacists to improve medication safety

An ambulatory care pharmacist service (ACPS) was proposed as an intervention to address these needs. Implementing ACPS at the primary care clinic of the UMMC will create a platform for PCP-pharmacist communication, which was lacking previously. Pharmacists can complement PCPs' role in patient care by conducting medication reconciliation and updating patients' medication record. At the same time, pharmacists can conduct medication reviews to optimise patients' medication regimen. Pharmacists can also provide patient education to improve patients' drug knowledge and adherence. This chapter will explore the opinion of the stakeholders (PCPs, patients and pharmacists) on the implementation of an ACPS at the primary care clinic for patients with chronic diseases.

6.1 Introduction

Ambulatory care pharmacy practice involves the provision of direct patient care by pharmacists to address medication needs of patients in the community (Board of Pharmacy Specialties, 2015). This includes pharmacists working in the community pharmacies as well as institutions such as primary care practices and hospital-based ambulatory clinics. Among the services offered include conducting medication review, preparing personalised patient medication record, formulating individualised medication-related plan, addressing patients' medication related problems, providing recommendations to prescribers, and providing patient education and follow-up (American Pharmacists Association & National Association of Chain Drug Stores Foundation, 2008).

In primary care, the provision of pharmaceutical care by pharmacists improved disease control and reduced disease complications (Gattis et al., 1999; Pauley, Magee, & Cury, 1995). This translates into reduced overall health care costs due to decreased outpatient visits and hospitalisations (Ellis et al., 2000; Pauley et al., 1995). It also showed a positive impact on patients' medication adherence, knowledge about medications and satisfaction with medical care received (Carter & Helling, 2000). In many cases, the involvement of pharmacists in chronic disease management has reduced medication-related problems, inappropriate use of medications as well as prescribing and administration errors (Carter & Helling, 2000; Ellis et al., 2000; Hanlon et al., 1996).

This lead to the integration of pharmacists into primary health care teams in many health systems around the world (Gilani et al., 2013; J. S. Hunt et al., 2008; Kolodziejak, Remillard, & Neubauer, 2010). Each country however has a unique primary health care system, chronic diseases burden and patient population. Therefore, it is essential to tailor

the ACPS to meet the local health care demand and system (Jorgenson, Dalton, Farrell, Tsuyuki, & Dolovich, 2013; Kolodziejak et al., 2010). It is also important to get stakeholders' views and opinions regarding issues surrounding the implementation such services; whether it is acceptable, what are their concerns and what are their suggestions. This will help in informing the design of the ACPS and at the same time engaging stakeholders in the development of the service (Craig et al., 2008).

The aim of this study was to explore the views of PCPs, patients and hospital outpatient pharmacists on the implementation of an ACPS for patients with chronic diseases in primary care.

6.2 Methods

6.2.1 Design

A qualitative methodology was selected to explore the views of PCPs, patients and pharmacists on the implementation of the ACPS. This research method allowed an in-depth understanding of participants' views and opinions about the ACPS.

6.2.2 Setting

This study was conducted at the primary care clinic of the UMMC, a tertiary teaching hospital located in the urban city centre of Kuala Lumpur, Malaysia. Doctors prescribed electronically and patients collected their prescribed medications from the hospital outpatient pharmacy at a subsidised rate. The electronically transmitted prescriptions were screened, filled and dispensed by trained pharmacy technicians and trainee pharmacists, under the supervision of the pharmacists.

6.2.3 Duration

This study was conducted from July 2012 to April 2013.

6.2.4 Participants and sampling

All PCPs attached to the clinic during the study period were eligible to participate in this study. This included the service medical officers, postgraduate family medicine trainees and family medicine specialists, where family medicine trainees form the majority. Family medicine trainees are medical officers who are pursuing their four-year training as a specialist in family medicine, while service medical officers are doctors who are employed to provide clinical services at the primary care clinic. Purposive sampling was performed to include PCPs with various lengths of clinical experience. This was to ensure that a range of views can be captured; PCPs with different lengths of clinical experience may have different views about role of pharmacist in primary care. We invited potential participants in person or through text message explaining the objectives, date, time and venue of the FGD.

Patients diagnosed with chronic disease(s) and on medical treatment were eligible for this study. Excluded were patients who could not converse in English, Malay or Tamil, and patients with cognitive impairment and active mental illness. Patients were selected purposively to ensure maximum variation in terms of age, number of medications and educational level. This was to ensure that a variety of views was captured; individual patient's views and opinion about pharmacists' role in their health might differ according to their socio-demographic background. One researcher (RS) approached potential participants while they were waiting for their doctor's appointment. RS explained the objectives and duration of the interview, inviting them to participate. Patients who agreed to participate were interviewed individually in a separate room at the clinic.

All outpatient pharmacists were eligible to participate in this study. This included the head of the outpatient pharmacy, and seven other pharmacists. The researcher (RS) sent an invitation via email to all the outpatient pharmacists, explaining the details of what this study was on, its objectives and the duration of the interview.

6.2.5 Sample size

Twenty-two PCPs were approached, of which 19 agreed to participate. Three potential participants were not able to participate in the FGDs due to unavailability at the given FGD date and time.

All 12 patients approached agreed to participate in the study.

All eight outpatient pharmacists were invited to participate in this study. However, only seven pharmacists were interviewed, as one pharmacist was unavailable during the data collection period. This pharmacist was of similar characteristics (in terms of age and years of clinical experience) as the other six pharmacists who were interviewed. Therefore, her unavailability to participate would not have affected the results.

Sample size was determined by thematic saturation (no new themes emerged from the analysis). Data reached thematic saturation at the third FGD for the PCPs, tenth patient IDI and after two FGDs and one IDI with the pharmacists. We however conducted two additional patient IDIs and one pharmacist IDI to ensure that the data was indeed saturated.

6.2.6 Instruments used

Literature review on issues related to the implementation of an ACPS for patients with chronic diseases in primary care were mapped into a conceptual framework (Bradley et al., 2008; Farrell et al., 2008; Kolodziejak et al., 2010; K. Pottie et al., 2008). This include acceptability and feasibility of the ACPS, the ACPS pharmacist role, target patients for the ACPS, PCP-pharmacist communication within the ACPS and patient follow up by the ACPS pharmacist [Figure 6.1]. This framework was used to develop three different topic guides for each participant group: PCPs, patients and pharmacists [Appendix A1, B1, B2 and C1]. Participants were provided with a participant information sheet [Appendix A2, B3, B4 and C2] prior to obtaining their written consent [Appendix A3, B5 and B6] and demographic profile [Appendix A4, B7, B8 and C3].

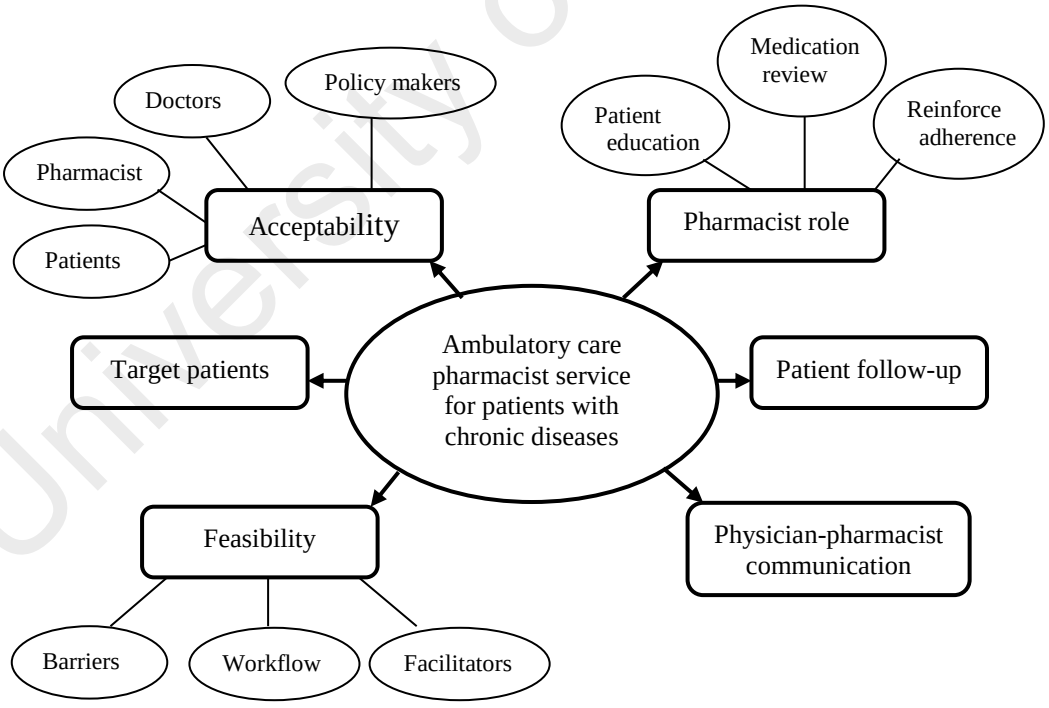


Figure 6.1: Issues related to the implementation of an ambulatory care pharmacist service for patients with chronic diseases in primary care

6.2.7 Data collection

A combination of FGDs and IDIs were used in this study to allow data triangulation. The PCPs were grouped into three FGDs according to their years of clinical experience: year 3 family medicine trainees (n=7), year 4 family medicine trainees (n=7) and service medical officers (n=5). The patients were interviewed individually. The pharmacists were interviewed in two FGDs and two IDIs, as it was difficult to gather all of them for a single FGD during working hours.

An academic family medicine specialist (CJN) affiliated to the primary care clinic of the study site conducted the first FGD with the PCPs. The remaining interviews were conducted by RS, a trained researcher who was not an academic staff, and would therefore not be seen as an authoritative figure by participants. Participants were given a brief introduction to the ACPS prior to the start of the interview. The interviews were conducted in English, Malay and Tamil according to participants' preference. We asked the participants open-ended questions and prompted them when some important issues were not mentioned. Interviews were audio-recorded and transcribed verbatim in its original language. Checked transcripts were used as data for analysis. Quotes from interviews performed in Malay and Tamil were analysed in its original language and translated to English during reporting. Researchers documented relevant impressions and thoughts after each interview session while a research assistant took field notes on non-verbal cues during the FGDs.

6.2.8 Data analysis

A descriptive-interpretive approach was used to analyse the data (St. George, 2010; Thorne et al., 2004), which was managed using Nvivo10 (QSR International Pty Ltd, Doncaster, Victoria, Australia). Data was analysed inductively starting with the first

transcript, which was the FGD with the PCPs. RS familiarised with the data by reading the transcript repeatedly to identify and to index themes (Pope et al., 2000). All data relevant to each theme were identified and examined through constant comparison (Pope et al., 2000). These themes were further refined and reduced in number by grouping them together into larger categories (Pope et al., 2000). All three researchers (RS, PSML and CJN) then met over several meetings to discuss the list of themes and categories, which were refined iteratively through consensus until the final coding framework was agreed. RS used the final coding framework to code the remaining 19 transcripts. Any new themes that emerged were added to the list upon consultation with the research team.

The research team consisted of a family medicine specialist (CJN) and two pharmacists (PSML and RS). All researchers were conscious of their personal and professional biases, and therefore constantly reflected and debated during data collection and analysis to improve the credibility of the data.

6.2.9 Ethics

Ethics approval was obtained from the UMMC Medical Ethics Committee prior to the commencement of this study (approval No. 890.104) [Appendix A5].

6.3 Results

A total of 19 PCPs, 12 patients and seven pharmacists were interviewed. Demographic characteristics of the participants are summarised in Table 6.1, 6.2 and 6.3.

Table 6.1: Demographic profile of the primary care physicians interviewed

Participant ID	Age	Sex	Ethnicity	Professional background	Years of clinical experience
D01	32	Female	Malay	Year 3 family medicine trainee	8
D02	38	Male	Indian	Year 3 family medicine trainee	7
D03	30	Male	Chinese	Year 3 family medicine trainee	5
D04	32	Male	Chinese	Year 3 family medicine trainee	6
D05	32	Female	Malay	Year 3 family medicine trainee	8
D06	34	Female	Malay	Year 3 family medicine trainee	10
D07	34	Female	Malay	Year 3 family medicine trainee	10
D08	30	Male	Malay	Year 4 family medicine trainee	6
D09	32	Female	Malay	Year 4 family medicine trainee	8
D10	34	Male	Indian	Year 4 family medicine trainee	9
D11	33	Male	Malay	Year 4 family medicine trainee	9
D12	35	Female	Malay	Year 4 family medicine trainee	8
D13	31	Female	Malay	Year 4 family medicine trainee	7
D14	33	Female	Indian	Year 4 family medicine trainee	7
D15	48	Female	Indian	Service medical officer	26
D16	62	Male	Burmese	Service medical officer	37
D17	59	Male	Burmese	Service medical officer	35
D18	57	Female	Indian	Service medical officer	29
D19	56	Female	Indian	Service medical officer	29

Table 6.2: Demographic profile of the patients interviewed

Participant ID	Age	Sex	Ethnicity	Highest level of education	Number of chronic diseases	Number of chronic medications
Pt01	75	Female	Chinese	Secondary school	2	3
Pt02	62	Female	Chinese	Secondary school	2	3
Pt03	64	Male	Indian	Secondary school	4	7
Pt04	67	Male	Chinese	Secondary school	3	9
Pt05	67	Female	Malay	Secondary school	4	4
Pt06	64	Female	Indian	Primary school	3	8
Pt07	56	Female	Malay	Secondary school	3	5
Pt08	70	Female	Chinese	Secondary school	2	3
Pt09	64	Female	Malay	Primary school	3	6
Pt10	82	Female	Malay	Primary school	5	8
Pt11	65	Female	Chinese	Secondary school	3	4
Pt12	53	Male	Chinese	Secondary school	2	3

Table 6.3: Demographic characteristics of the hospital outpatient pharmacists participated in this study

Participant ID	Age	Sex	Ethnicity	Years of clinical experience
Ph01	25	Female	Chinese	3
Ph02	27	Female	Chinese	2
Ph03	27	Male	Chinese	3
Ph04	30	Female	Indian	4
Ph05	29	Male	Chinese	5
Ph06	45	Male	Malay	12
Ph07	28	Female	Chinese	6

Six main categories emerged from the analysis: acceptability to ACPS, barriers to implementation of ACPS, role of ACPS pharmacists, target patient group for ACPS, physician-pharmacist communication and suggestions for implementation of ACPS.

6.3.1 Acceptability to ACPS

The idea of starting a new pharmacist service at the primary care clinic was well accepted by the PCPs and pharmacists. PCPs stated that having pharmacists as part of the primary care team will be beneficial in terms of preventing MEs. It was also seen as an opportunity to develop inter-professional relationship and foster knowledge exchange between pharmacists and PCPs.

"Why not? It is good to have pharmacists to check our prescriptions. We can also make mistakes. If the pharmacists are there, then they can help us on that (checking prescriptions). The pharmacists can then tell us what is the problem and we will be more aware of our mistakes. It is a good idea!"

[D15]

"It will be good if the pharmacists can inform the doctor when they find any prescription error. So that we are more aware and we will not repeat the same mistake. At the same time we are learning from them (pharmacists)."

[D11]

Hospital outpatient pharmacists on the other hand, regarded the ACPS as an opportunity to expand their professional roles. They were keen to be actively involved in patient care rather than their current role, which was limited to medication dispensing. The pharmacists felt that medication reviews can potentially prevent mediation errors and simplify patients' medication regimen. Educating patients on their medications will help patients to understand their medical treatment. The pharmacists also felt that they could help in reducing PCPs workload by addressing patients' medication-related problems.

"It is a very good opportunity for pharmacists to enhance our knowledge. We are looking forward to enhance the pharmacists' role as well."

[Ph04]

"I really look forward for the pharmacist service in RUKA (primary care clinics) because it will be so good to see the effect of the medication on the patient rather than just dispensing medication to them."

[Ph02]

"It would be such a good idea if we could go through their medications. I know that there will be lots of things (medication-related problems) that we will pick up."

[Ph03]

"We can also help to reduce patients' medication. For example, the diabetic doctor prescribes two anti-hypertensives and the renal doctor prescribes another two anti-hypertensives. The medications sometimes overlap in some way."

[Ph07]

"It is quite beneficial for the patients as well. They will know the correct way to take their medications and the consequences of not taking the medications."

[Ph05]

"The doctors might not have the time to interact with patients. So basically when the pharmacists actively review patients' medications, it will actually uhm... cause less burden to the doctors."

[Ph01]

Patients however gave mixed responses regarding the implementation of the ACPS. A few patients regarded pharmacists counselling as an opportunity for patients to gain knowledge about their medications, while others claimed that they did not need any help. Patients with previous encounters with pharmacists (with community pharmacists or family members who were pharmacists) said they preferred to speak to pharmacists regarding their medications as they felt that doctors were pressed for time during consultation. Patients who were not aware of the role of pharmacists however preferred to speak to the doctors rather than the pharmacists to discuss about their medications.

"It (pharmacist counselling) is good. You (pharmacists) should do it often. It will help most of us. We need help actually. We need information like this (about medication). So when we go back, we know what to do."

[Pt03]

"For me, I feel more comfortable to speak to a pharmacist rather than the doctor about my medicines. The doctors are so busy and I don't want to take up their time."

[Pt05]

"Erm… if it (pharmacists counselling) is too long also quite boring (laughs). We are old you know!"

[Pt01]

"No! I don't want to listen to the pharmacist teaching me how to take my medicines. When it comes to medicines, we can't take it lightly. I will only take (medicines) if the doctor tells me to do so!" (translated from Malay)

[Pt08]

6.3.2 Barriers to implementation of ACPS

The main barrier discussed by participants was time and workload; PCPs and patients were concerned about patients spending a longer time at the hospital (with the ACPS pharmacist), on top of their doctors' appointment. In addition, participants were concerned if the number of pharmacists is sufficient to match the large number of patients attending the primary care clinic daily.

"Most of the patients, once they see us, they just want to collect their medications and rush back. They don't want to do anything extra. To come here (the hospital), parking is a problem, transportation is a problem. For some, their children might be waiting in the car. So whether they want to spend the time might be a problem."

[D19]

"Yeah time is very important! I have to get out of this hospital before four o'clock. I depend on public transport. I need to get on the bus before the office hours. Time is very important! That is why I come early to get the number (to see the doctor) and go back early." [Pt03]

"Imagine we have 30 rooms in our clinic, one doctor per room. Each doctor has so many patients and if we all refer to one pharmacist, I can't imagine how the pharmacist can handle it (laughed)."

[D01]

"At this point, I don't think it is possible for the outpatient pharmacists to be involved (in the ACPS). Unless we get more pharmacists."

[Ph05]

"Actually you all (the pharmacists) can do this (patient counselling) but can you find the time to do it? (laughed). On a regular basis you know! (laughed)."

[Pt01]

PCPs also admitted that some of them may not be comfortable working with pharmacists, and will require some time to adjust.

"It will take some time. Not all the doctors have the same attitude. Some may not feel good about pharmacists querying their decision. So it (the ACPS) should start small and extend the service slowly."

[D15]

The outpatient pharmacists on the other hand, had concerns about not getting enough patient referrals from PCPs. This was based on their previous experiences in providing pharmaceutical care services at other specialist clinics within the hospital.

"The problem with my adherence clinic (at the specialist clinic), hmm… the doctors are not doing active referrals. So I end up with no patients. This is a major issue actually."

[Ph04]

6.3.3 Role of ACPS pharmacists

PCPs felt the ACPS pharmacists could complement their role in caring for patients with chronic diseases by providing medication education, teaching medication administration techniques and enhance patients' medication adherence. They were also comfortable with the ACPS pharmacists screening patients' medication prescriptions for errors and at the same time reinforce doctors' advice and instructions. Similarly, patients were also expecting information regarding their drug therapy from the ACPS pharmacists.

"If pharmacists can explain to them (patients) why their kidneys are failing, why their liver is affected, I think it will be really good. Sometimes we really have to spend lot of time explaining to them about their medications and what it is doing to their body."

[D19]

"Technique is very important especially in asthmatics. So the pharmacists can help us in checking patients' technique and teach them (patients) if necessary."

[D16]

"We have to depend on the medications to give its effect. So, we need somebody to help us enhance patients' compliance to medication, so that the treatment is effective."

[D04]

"When a patient is on a lot of medicines, there might be some interactions. So probably the pharmacist can help us to check. We might think that it is OK as it has been used for long time, but actually it is not."

[D10]

"After doctor's consultation, patients can go to the pharmacists to reassess their understanding. If a medication got changed, then the pharmacists can help us to reinforce our advice."

[D03]

"The pharmacists can explain to us regarding our medicines. We are not good at it. If you don't tell us, we will just take our medications as we wish." (translated from Malay)

[Pt10]

"Being a pharmacist you can explain to the patients because you know about medicines better. You tell them what is the side effect, why they need to take it (medicines), how to take it and all that."

[Pt02]

The family medicine trainees had a clearer picture of potential roles for ACPS pharmacists in primary care, as compared to the service medical officers. One service medical officer admitted that she was unsure about the professional training received by pharmacists, and the extent to which pharmacists could assist the PCPs in caring for patients with chronic diseases.

"Actually we don't know how far the pharmacist can help us (D17 laughed). How far you can help us? (D16 laughed). I don't know whether you (pharmacists) have done therapeutics in your training?"

[D18]

6.3.4 Target patient group for ACPS

There seemed to be a consensus among the PCPs and the pharmacists that although it is best to provide pharmaceutical care services to all patients with chronic diseases, it is best to start the ACPS by targeting a specific patient group.

"I prefer to have the pharmacists to review all patients. I don't really agree that only patients with long list of the mediations will do mistakes. Error takes place everywhere."

[D02]

"Maybe it is difficult for the pharmacist to screen all patients as we have lots of patients every day. So, maybe we can identify patients with problems and send to them (pharmacists)."

[D09]

The pharmacist felt that the ACPS should primarily focus on older patients as these are the patients with multi-comorbidities, taking many medications and often have trouble remembering to take their medications correctly. In addition, the PCPs said that any patient who needs assistant with their medications should be seen by the ACPS pharmacists as well as patients started on new drug therapies.

"The elderly I feel are the ones with multi-disciplinary diseases. So they go to several clinics (of different specialties). They will be on so many medications simultaneously, prescribed from each one of those clinics. They also tend to forget taking their medications."

[Ph04]

"I think that is when the role of the ambulatory care pharmacist comes in especially for patients who have problems with their medications. We can send those patients to see the pharmacists so that they (pharmacists) can go through each medication with the patient to hopefully reduce medication errors."

[D08]

"Patients started on new medicines need education. They (patients) should be seen by the pharmacists."

[D12]

6.3.5 Physician-pharmacist communication

PCPs preferred face to face communication with the ACPS pharmacists as they considered it as time saving and more effective. Most were also open to receiving phone calls from the ACPS pharmacists regarding their prescriptions. In addition, pharmacists

mentioned that formal documentation by the ACPS pharmacists should be included in patient's medical folders as it is important to ensure continuity of care; and that the next PCP and ACPS pharmacist will be able to know the complete medical and medication history of the patient.

"They (pharmacist) can just come in (to the consultation room). Tell us what is the problem and discuss. We can communicate better that way. It is a team work actually."

[D15]

"Written (notes) will take a long time. Better verbal. Just call and check with us if there is any problem with the prescription."

[D18]

"I would prefer phone call. Just call and tell me what is the problem."

[D11]

"I think the best is to have a standard document that we can include in patients' medical folders. So when the doctors are reviewing the patients, they can read our notes and immediately know what is the problem. For example, if we identified that the patient is experiencing any side effect from the medication, we can document it for the doctors. It will save their time in interviewing the patient to identify any issues."

[Ph05]

"If the doctor is still there (in the consultation room), we can just enter and discuss with the doctor. If not, we have to either call them or write a note to them."

[Ph03]

6.3.6 Suggestions for implementation of ACPS

PCPs felt that a regular pharmacist's availability (ideally daily) will help them in adapting the ACPS into practice. They also mentioned that a reminder in the form of short notes will help them to utilise the service better. There should also be more than one pharmacist involved in the ACPS to cater for the large number of patients seen by the PCPs daily.

"If you have it (the ACPS) everyday then it would be helpful because we know the service is always there."

[D13]

"It will take some time from our side (to adopt into practice). So maybe ah… a note in our table to say, these types of patients, please refer (to the pharmacists). That will help."

[D15]

"If we are going to send patients to the pharmacists, we have to ensure that it's not too crowded, not too many people. The waiting time (for the patients) is just nice. And if you are going to cater for the whole of RUKA (primary care clinic), maybe we need more than one pharmacist. If not patients might hesitate to go to see the pharmacist."

[D14]

Majority of PCPs attached to the primary care clinic were family medicine trainees and part of their training requirements, they had to rotate between government health centres and the primary care clinic of the hospital. This means that there is a high turnover of PCPs at the hospital. Therefore, it is important to conduct regular briefings for the new PCPs to ensure the sustainability of the ACPS. Similarly, the PCPs felt that the ACPS

pharmacists should be briefed to prevent any disagreement between the information provided by the pharmacists and the PCPs. It is also important to involve PCPs in the development of the ACPS; to consider and incorporate their input into the design of the ACPS.

"The clinical masters candidates (family medicine trainees) here are on rotation. So every time a new batch comes in, you have to orientate them. Tell them about the service (ACPS)."

[D18]

"I think the first thing which is very important is we (PCPs and pharmacists) need to have a common ground. There should not be any contradiction in the information that we are sharing. If we are telling A and the pharmacists are telling B, patients will be coming back to us and say the pharmacist told me this. Very difficult for us to answer them (patients). Pharmacists are also our colleagues and we can't tell the patients that the pharmacist is wrong."

[D03]

"I think before you start (the ACPS), we need to have a discussion. Decide on our role, your (pharmacists) role, and how we will work together."

[D17]

Some PCPs and pharmacists suggested that patients should be seen by the ACPS pharmacist before their doctor's appointment to screen for any medication-related problems. This will save PCPs' time during consultation as well as ensure efficient use of patients' time while waiting for the doctors. A majority of PCPs and pharmacists were

in agreement that patients should be referred to the ACPS pharmacists, after PCPs' consultation; they suggested that patients should meet the ACPS pharmacist after collecting their medications, so that the pharmacist can provide an individualised medication counselling for these patients.

"Maybe the pharmacist can pick up patients who are waiting for the doctors. They could go through the patients' ah… investigations. For example if they find that the HbA1c is high, not well controlled in a diabetic patient, they can go through the medications with the patient. Check if they (patients) are taking it (medication) correctly, the dosage and timing. They can address those issues so that the doctor doesn't have to go through it in the (consultation) room later."

[D02]

"An important point D02 brought up was to see the patients before they see us. After waiting for two to three hours to see us and then we send them to the pharmacists, maybe they (patients) will just go back home."

[D06]

"Seeing patients before the doctors is the best. You can then correct any previous mistakes and write a note to the doctor informing him of what is happening. For example, we identified that the patient is seeing doctors at three different clinics and receiving three different anti-diabetics. So it reduces the time that the doctor has to spend with the patient and it helps us to cut down the number of medications."

[Ph07]

"After doctors' consultation, patients get the medicines and see the pharmacist. If they (patients) see the pharmacist before getting their medicines (D12 nodding), it is not going to be very helpful. It is better to counsel patients based on their medicines."

[D13]

Some patients said they preferred to see the ACPS pharmacists while waiting for their doctors, while most preferred doctor's referral as they trust the doctors knew what will be best for them. Patients preferred meeting the ACPS pharmacists on the same day as their doctor's appointments, so that they did not have to make an extra trip to the hospital.

"Erm… Say my appointment is at two o'clock. I usually come early to take the number (to see the doctor). So maybe you can have it (pharmacist counselling) while we are waiting for the doctor to occupy our time."

[Pt05]

"If I am here for my appointment, then I don't mind to see the pharmacist. But to come here another day, no! It is very difficult to get car parking."

[Pt01]

"Of course if the doctor recommends is much better. They are professionals, they know better. If you ask me to walk in here (to see the pharmacist), I rather sit outside (laughed). If the doctor refers, she knows better and we will take her advice. We are here to see the doctor."

[Pt03]

"How if the doctor doesn't like it (counselling by pharmacist)? So better if the doctors refer (patients to see the pharmacist). They are the ones in charge here."

(translated from Malay)

[Pt10]

While most PCPs wanted the ACPS pharmacists to be located within the primary care clinic, some thought it will be more convenient for patients if the ACPS pharmacists are located near/at the outpatient pharmacy.

"It will be nice to have a one room within the clinic with one pharmacist in charge daily."

[D08]

"Put a mark on the patient's prescription and tell the patient to meet the pharmacist after collecting their medications. So the pharmacist will talk to the patients at the pharmacy itself rather than having the patients to go to the pharmacy to collect their medications and back to RUKA (primary care clinics) to see the pharmacist."

[D14]

6.4 Discussion

This study explored the views of PCPs, patients and pharmacists on the implementation of ACPS for patients with chronic diseases at primary care. The PCPs, patients and pharmacists spoke of their acceptability of the ACPS, barriers to implementation of ACPS and potential ACPS pharmacists' role. Participants also discussed their opinion on target patients, PCP-pharmacist communication means and provided some suggestions for the implementation of the ACPS to ensure sustainability.

The ACPS was well received by the healthcare professionals. The PCPs viewed it as an opportunity to ease their workload and at the same time improve medication safety. This finding is quite different from the views of GPs about having community pharmacists providing pharmaceutical care services to patients in their practice (Bradley et al., 2008). Although those GPs were generally supportive towards pharmacists' extended role, some felt uncomfortable having pharmacists to review their patients' medication as they thought it indicated shortcomings in their management (Bradley et al., 2008). Most GPs in the study were also guarded about allowing pharmacists access to patients' medical folders and this prevented pharmacists from conducting a comprehensive medication review (Bradley et al., 2008). This difference in attitude is because essentially GP and community pharmacist belong to two separate health institutions while in our study the PCPs and outpatient pharmacists belong to the same institution, and at many instances the PCPs spoke of the pharmacists as "colleagues".

However, as mentioned by our participants, there might be some delay in the uptake of the ACPS by some PCPs due to unfamiliarity with the professional competencies of pharmacists. As suggested by previous studies, such delay should be anticipated as PCPs need time to build trust and become aware of the professional skills of pharmacists (Bradley et al., 2008; Doucette, Nevins, & McDonough, 2005; Jorgenson, Laubscher, et al., 2013; A. J. Zillich et al., 2004). Other implementation issues that were mentioned by PCPs include pharmacist availability, briefing of new PCPs, involving the PCPs in the design of the ACPS and defining PCPs' and pharmacists' role in patient care. These issues were previously highlighted by others as the barriers faced by pharmacists for successful integration into primary care teams, and therefore should be addressed before the implementation of ACPS (Jorgenson, Laubscher, et al., 2013).

Patients gave mixed opinions on the implementation of ACPS. This was mostly due to the low level of awareness on the professional role of pharmacists among Malaysian patients as compared to other parts of the world (Al-Arifi, 2012; Khan et al., 2013). Many did not have any contact with the pharmacists (Chapter 4, section 4.3.2.1, page 105) and were not able to distinguish between the pharmacy technicians and the pharmacists at the hospital pharmacy. What was apparent however, was the uptake of the ACPS by patients relies heavily on PCPs' recommendation as many patients were not happy to be seen by the pharmacists without their PCPs' knowledge. Besides being not certain of pharmacist's role in their health care, patients perceived that PCPs were their main care provider and therefore were in power of making decisions regarding their medical care.

Potential pharmacists' roles that were identified in this study include providing medication education, teaching medication administration techniques, promoting patients' adherence to medications, reinforcing medication instructions to patients and screening prescriptions for errors. The ACPS should therefore focus on addressing these needs as a start to meet the stakeholders' demands as well as to build the PCPs and patients' trust in their professional competencies (Jorgenson, Dalton, et al., 2013; Kolodziejak et al., 2010). These roles should not however be fixed and should be regularly reviewed by relevant stakeholders to meet the current demand and ensure sustainability of the service (Jorgenson, Dalton, et al., 2013; Kolodziejak et al., 2010). Most participants acknowledged that it is not feasible to provide the ACPS for all patients with chronic diseases due to man power and time constraints. Rather, the service should be targeted to "high-risk" patient population such as the elderly with multi-morbidities and polypharmacy (Olaniyan et al., 2014). This too should be taken into account during the initial design of the ACPS and should be reviewed regularly to meet the PCPs' and patients' needs.

Participants gave some contradictory suggestions pertaining to the implementation of the ACPS, each with its own logic and explanation. What was clear was that patients' convenience and safety was the priority. For example many suggested for patients to be seen by pharmacist prior to PCP's appointment to reduce waiting time. Others raised concerns about patients waiting too long to be seen by the pharmacists. Some suggested for patients to be seen by pharmacists after medication collection for effective medication counseling. The design of the ACPS should therefore take into considerations these factors and if necessary tested in an iterative manner until the best suited design is identified prior to implementation into routine practice (Craig et al., 2008).

A possible limitation of this study is it was conducted in a university-affiliated primary care clinic, and this could limit the applicability of the findings to other primary care settings.

6.5 Conclusion

The findings from this study suggested that the ACPS is well accepted by the stakeholders, and implementable into practice. PCPs and pharmacists were supportive of the implementation of an ACPS for patients with chronic diseases in primary care. Most patients however were uncertain of the benefits of the ACPS and preferred the PCPs to make decision on what is best for them. Issues such as regular pharmacist availability, briefing of new PCPs, and agreement on PCP and pharmacist role need to be addressed prior to the setting up of the service. The ACPS pharmacist should focus on addressing the medication needs of "high risk" patient population such as the elderly with multimorbidities. The logistic design of the ACPS should to take into account of patients' convenience.

CHAPTER 7: DEVELOPMENT OF THE 'PHYSICIAN-PHARMACIST PARTNERSHIP FOR PATIENT SAFETY' INTERVENTION

This chapter will describe the systematic development of a doctor-pharmacist collaboration intervention to improve medication safety for patients with chronic diseases in primary care. The UK MRC framework for developing and evaluating complex health interventions was used to guide the development of this intervention, and its subsequent pilot test (Chapter 2, section 2.12, page 69). This chapter will provide a detailed description of the methods used to develop the intervention and the conceptual framework underpinning the design of the intervention. Additionally, it will also describe the outcome of each of the steps in the development process: i.e. how the first draft of the intervention was developed, feedback from the steering committee regarding the first draft, findings from acceptability and feasibility tests, and a detailed description of the final intervention. This will be followed by a discussion on the approach used to develop a doctor-pharmacist collaboration intervention in this study, and its conclusion.

7.1 Introduction

Doctor-pharmacist collaborations in primary care have reported successful outcomes in improving medication appropriateness, resolution of DRPs and detection of MEs (C. A. Brown et al., 2006; L. J. Bryant et al., 2011; Dolovich et al., 2008; Gilbert et al., 2002). In addition, the collaborations between doctors and pharmacists have been shown to improve disease control such as hypertension and cholesterol levels (Carter et al., 2009; Howard-Thompson et al., 2013).

In line with this, many primary health care systems around the world have moved towards the integration of pharmacists into their primary health care teams (Bradley et al., 2008; Dolovich et al., 2008; Farrell et al., 2008). However, pharmacists often face

difficulties in successfully integrating into primary care (Farrell et al., 2008; Jorgenson, Laubscher, et al., 2013). Team members (physicians and nurses) are often unclear of the pharmacist's role and therefore do not know what to expect out of the presence of a pharmacist in the team (Farrell et al., 2008; Kozminski et al., 2011). Similarly, pharmacists are often unfamiliar with other team members' role, and the primary care practice environment (Goldman, Meuser, Rogers, Lawrie, & Reeves, 2010). Lack of pharmacists' assertiveness, confidence and training are examples of challenges faced by pharmacists to successfully work part of primary care teams (Kozminski et al., 2011; Kevin Pottie et al., 2008). Evidence also suggests that minimal collaboration exists between doctors and pharmacists in primary care teams, and they continue to work as solo practitioners (Dey et al., 2011; Dieleman et al., 2004; Zwarenstein et al., 2009). This impedes the effectiveness of pharmacist-provided services within the primary care teams.

Many of these issues can be avoided with careful planning and testing of the intervention during its development (Craig et al., 2008). Unfortunately, most studies only focus on the implementation and the evaluation of the intervention, and the details on the development of the intervention is often lacking (Carter et al., 2009). In addition, there is a paucity of information on how the interprofessional relationship between doctors and pharmacists affects patients' therapeutic outcome, or how the relationship is developed. The aim of this study was to systematically develop a doctor-pharmacist collaboration intervention based on needs, evidence and theories, to improve medication safety for patients with chronic diseases in primary care.

7.2 Methods

The steps involved in the development of a doctor-pharmacist collaboration intervention in this study are illustrated in Figure 7.1. Each of these steps will be explained further in the following subsections.

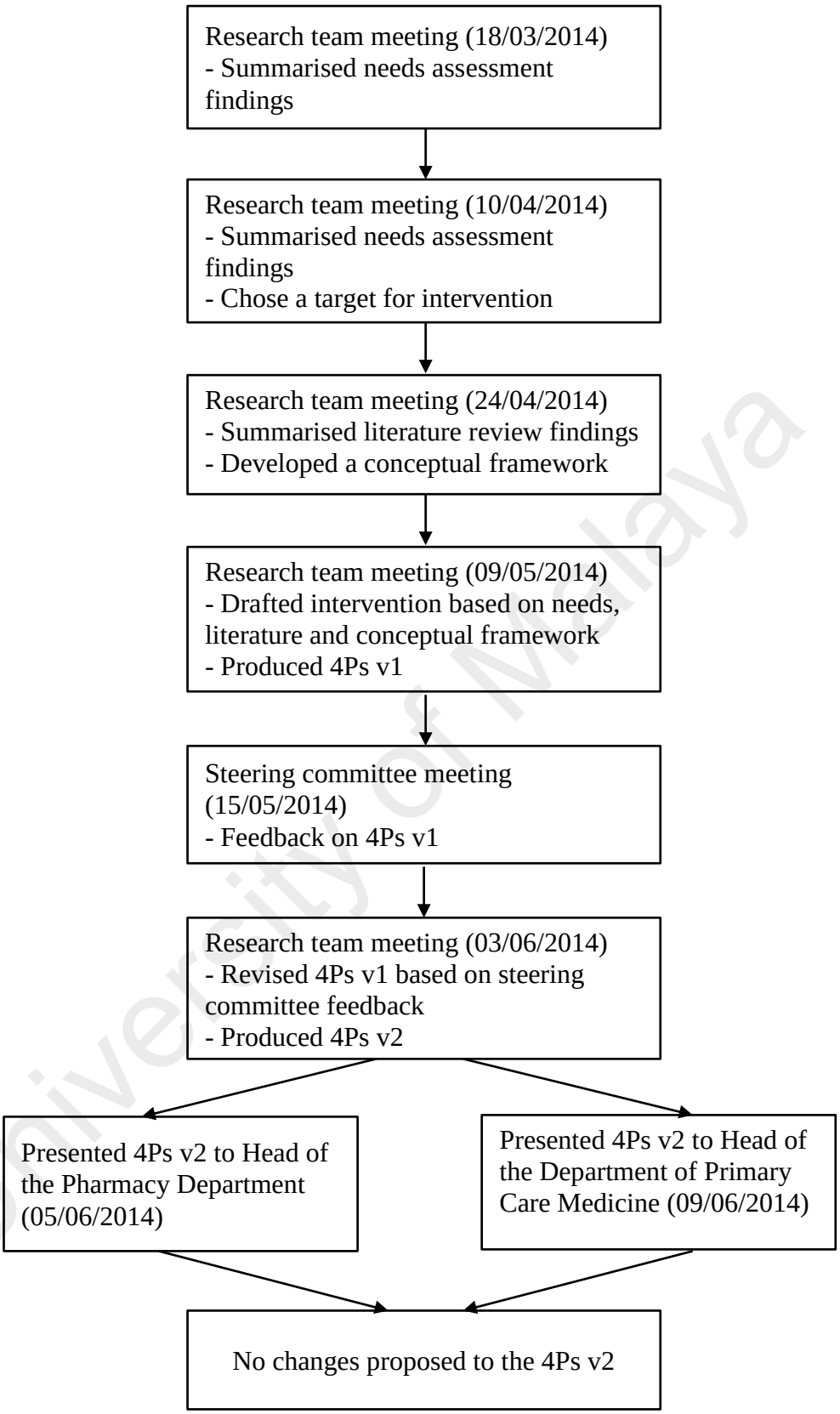
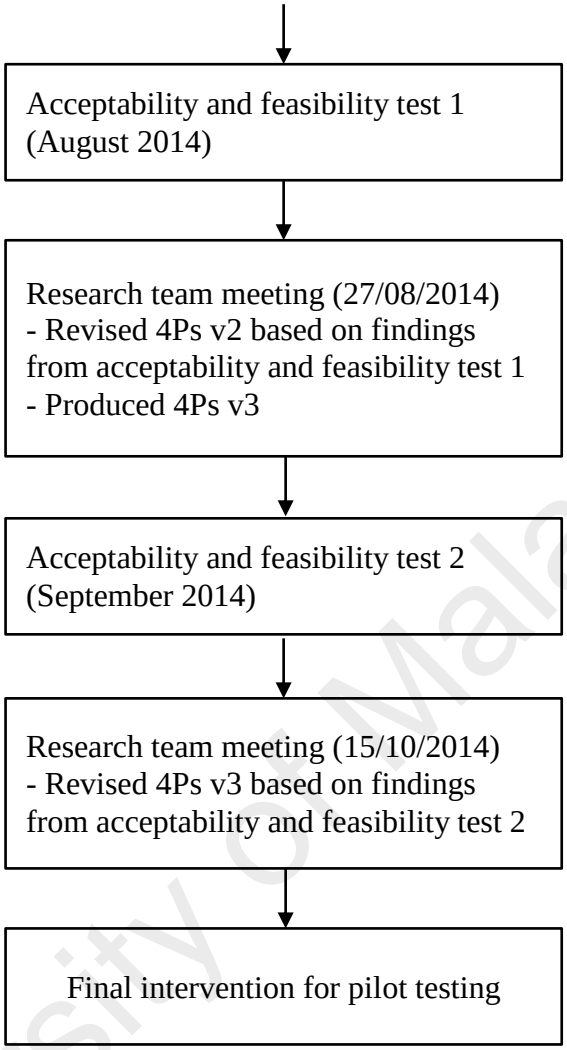


Figure 7.1: The development of the Physician-Pharmacist for Patient Safety intervention

Figure 7.1 continued



7.2.1 Summarising needs assessment findings

The research team met over two meetings in March and April to summarise findings from phase 1 (the needs assessment), and to choose a potential intervention target. Team members consisted of two pharmacists (RS and PSML) and a family medicine specialist (CJN). Details on the conduct and findings of the needs assessment have been described in Chapters 3, 4, and 5. Briefly, the research team identified that there was a need to improve the interprofessional communication between PCPs and pharmacists in addressing patients' medication-related problems and preventing MEs.

7.2.2 Summarising evidence from literature

Findings from literature review have been discussed in Chapter 2 (section 2.8, page 23). In summary, there was enough evidence to suggest that pharmacist-led medication review in collaboration with doctors, was effective in improving quality of medication use, medication safety and chronic disease control. However, there is a gap in knowledge about the CWR between doctors and pharmacists involved in the medication review interventions. It is not clear how the doctors and pharmacists develop CWR, or how the CWR between them affects patient outcomes. Therefore, this study focused on the development of CWR between PCPs and pharmacists in primary care, and the effect of the intervention on medication safety.

7.2.3 Developing a conceptual framework for a doctor-pharmacist collaboration intervention to improve medication safety in primary care

A doctor-pharmacist collaboration intervention is a complex intervention. A complex intervention is difficult to design, evaluate and implement due to the presence of several interacting components. The use of theory will help in predicting what change is expected and how to bring about this change (Craig et al., 2008). Three frameworks (TeAMM model, pharmaceutical care practice and CWR model) were combined into a conceptual framework, which was used to guide the design of the intervention in this study [Figure 7.2].

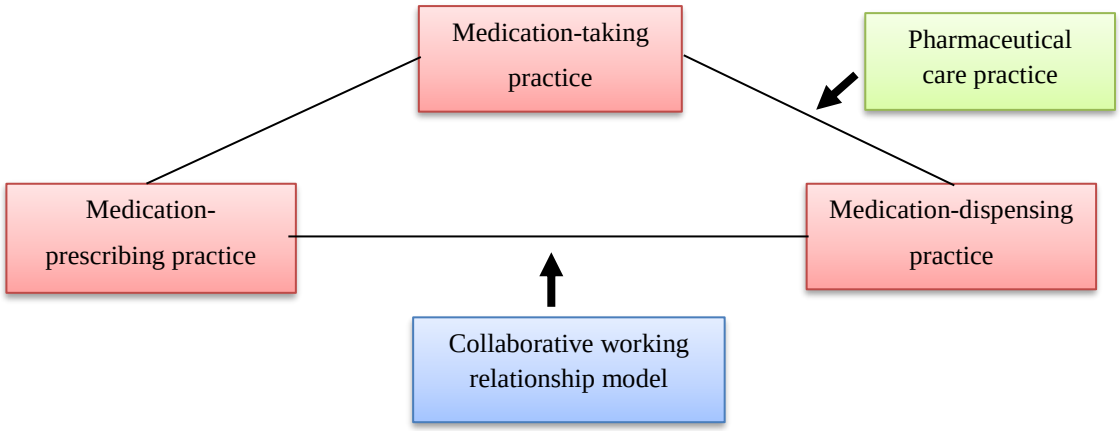


Figure 7.2: The conceptual framework of the Physician-Pharmacist Partnership for Patient Safety intervention

The TeAMM model provides a guide to the roles and responsibilities of prescribers (doctors), patients and pharmacists for medication use in a primary care context, and proposes that collaboration among team members is necessary for an effective and safe medication practice (Chapter 2, section 2.9.3, page 63) (Bajcar et al., 2005). On the other hand, the pharmaceutical care practice concept allows an understanding on the potential roles of pharmacists in supporting the medication-taking practice of patients (Chapter 2, section 2.10, page 65) (Cipolle et al., 2004). While these two concepts provide an understanding of individual roles of team members, the CWR model guides the development of CWR between doctors and pharmacists in this context (Chapter 2, section 2.8.5.3(a), page 58) (Randal P. McDonough & Doucette, 2001). This is important as doctors and pharmacists are two different professionals who have been trained to work within their specialities, are now brought together to complement and support each other's role towards safe medication practice in primary care. An understanding of this is necessary to ensure effective collaborative approach to medication management as suggested by the TeAMM model. The intervention was named the 'Physician-Pharmacist Partnership for Patient Safety' (4Ps).

7.2.4 Drafting, reviewing and revising the intervention

Based on findings from the needs assessment, evidence from literature and the conceptual framework, the research team developed the first draft of the 4Ps intervention (4Ps v1). Figure 7.3 outlines the main components of the 4Ps v1 intervention, while Table 7.1 provides justification for each component based on needs assessment, evidence and theory.

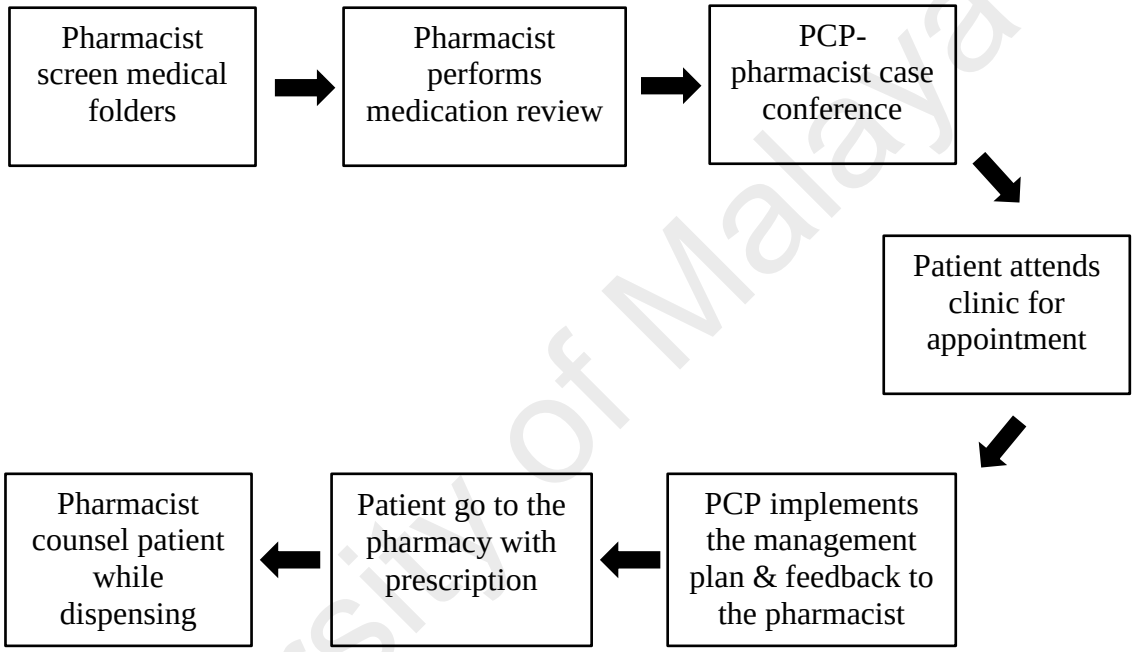


Figure 7.3: The Physician-Pharmacist for Patient Safety intervention version 1

Table 7.1: Main components of the Physician-Pharmacist Partnership for Patient Safety intervention version 1, and justifications for each of the component

Component	Objectives	Process/Content	Justification		
			Needs assessment	Evidence	Theories
Patient selection by pharmacist	To identify patients with high risk for medication-related problems.	Pharmacist screens medical folders of patients who are due for appointment with 1 to 3 PCPs at the family clinic. This is performed in the morning of the patients' appointment, based on a set of selection criteria A maximum of 5 patients to be selected daily	The patient load at the family clinic is very high. As there will be only one pharmacist delivering the intervention daily, choosing patients with high risk for medication-related problems will ensure efficient use of the pharmacist's time	Targeting the more susceptible population groups (such as the elderly, patients on polypharmacy, patients taking high-risk medications) may be more effective and efficient in reducing medication errors	According to the CWR model, the development of doctor-pharmacist CWR is influenced by context characteristics, and this includes patient characteristics. Selecting patients with high risk for medication-related problems will mean that the pharmacist will have a higher chance of identifying and resolving DRPs. This will impact on the development of CWR between PCPs and pharmacists, as PCPs will start to see the benefit from working together with the pharmacists, and help to move their CWR to higher stages faster.
Medication review by pharmacist	To identify patients' DRP	Pharmacist performs medication review for selected patients based on information available on medical records and the Pharmacy Information System. This is done right after patient selection, in the morning of the patients' appointment.	A medication review by pharmacists will help to address PCPs' needs identified in the needs assessment study: access to patients' updated medication list and prescription checking by pharmacist for medication appropriateness and errors.	Medication review by pharmacists was effective at improving medication use and patient health outcomes	Medication review is part of the provision of pharmaceutical care. Referring to the TeAMM model, medication review could be one way in which the pharmacists can support PCPs' medication prescribing practice

Table 7.1 continued

Component	Objectives	Process/Content	Justification		
			Needs assessment	Evidence	Theories
PCP-pharmacist case conference	To discuss DRPs identified and formulate plan of action	PCPs of the selected patients will meet with the pharmacist in a case conference prior to patients' appointment. The pharmacist will present each patient case, along with medication review findings. This include any DRPs identified and recommendations to address the DRPs. All PCPs and pharmacist present at the case conference will participate in a discussion to agree on a plan of action for each individual patient.	PCPs encouraged pharmacists to feedback to them about any DRPs identified during medication review. This include face-to-face discussion, and through the telephone	Pharmacist-providing medication review in collaboration with physicians was effective at improving medication use and safety outcomes.	According to TeAMM model, the doctor is responsible for the medication-prescribing practice, and the pharmacist's role is to support the doctor. Therefore any DRP identified should be discussed with the PCP and it is best to design a plan of action together Besides serving as a platform to communicate and build CWR, the PCP-pharmacist case conference will enhance knowledge exchange between participants.
PCP-patient consultation	To implement a plan of action to resolve DRPs	PCP decides on a management plan for the patient based on PCP-patient consultation, and PCP-pharmacist discussion the during case conference			The doctor is responsible for the medication-prescribing practice of the patient. The management plan for individual patients will therefore depend on the PCP's clinical judgment and patient's views following PCP-patient consultation. According to the TeAMM approach, the patient holds an important role in medication use in the ambulatory setting. Therefore, patients should be well informed about any plan in changing their medication regimen, and allowed to participate actively in decision making.

Table 7.1 continued

Component	Objectives	Process/Content	Justification		
			Needs assessment	Evidence	Theories
PCP's feedback to pharmacist	To update the pharmacist on the latest medication plan for the patient, and to convey any messages for the pharmacist to counsel during medication dispensing.	PCP will call the pharmacist	This step is necessary because the needs assessment highlighted that due to communication barriers between PCPs and pharmacists, any changes in prescription were not communicated to the pharmacists, and this prevented them from counselling patients effectively. Also, PCPs can relay any information they would like the pharmacist to inform patients during dispensing of medication.	Doctor's feedback to pharmacist regarding the latter's therapeutic recommendations helps the pharmacist to assess their performance and improve their future recommendations to prescriber.	This is important to establish a two way communication between the PCP and pharmacist, and to facilitate the development of CWR.
Medication dispensing and counselling	To improve patients' medication knowledge and adherence, and reinforce PCP's instructions.	At the outpatient pharmacy	This step will address the needs identified earlier: the need for individual medication counselling by pharmacist	Patient education is an important component of many interventions that aimed to improve medication use and safety in the outpatient setting	In line with the TeAMM model, this step will allow the pharmacist to support the medication-taking practice of patients by providing them with necessary information and help to take their medication as prescribed.

PCP=primary care physicians; CWR=collaborative working relationship; DRP=drug related problem; TeAMM=Team Approach to Medication Management

This draft was subjected to an iterative review and revision process. The purpose of this iterative review and revision process was to ensure that the intervention was acceptable to the stakeholders (PCPs, pharmacists and patients), and feasible to be implemented in the primary care clinic setting. The intervention was first reviewed by a steering committee, revised by the research team and presented to the steering committee again for approval. Following this, the intervention was tested for acceptability and feasibility test 1. Problems identified during this test were used to revise the intervention and re-tested the second time in a similar manner (acceptability and feasibility test 2). This iterative review revision was performed until no new issues were identified and the research team agreed that no further amendments were required to the intervention (which was after acceptability and feasibility test 2). This process is described in the following subsections.

7.2.4.1 Convening and obtaining feedback from the steering committee

A steering committee was formed to review and provide feedback on the acceptability and feasibility of the 4Ps v1. The steering committee consisted of two PCPs, two pharmacists, and three policy makers (Head of the Pharmacy Department, Head of the Department of Primary Care Medicine and the primary care clinic coordinator). Once the steering committee members were identified, they were invited for a meeting through email. The steering committee met once during the development phase. This meeting was attended by two PCPs, two pharmacists and a primary care clinic coordinator. The Head of Pharmacy Department and Head of Primary Care Medicine Department were unable to attend this meeting due to prior commitments. The research team was present during this meeting to introduce the intervention, answer questions from the steering committee and take research notes.

7.2.4.2 Feedback from steering committee on the Physician-Pharmacist Partnership for Patient Safety version 1

The steering committee members present agreed that the intervention should be delivered to selected patients, and agreed with the patient selection criteria proposed. However, they suggested that patient selection should be done by the PCPs, as PCPs are more familiar with their own patients. PCPs present at the meeting thought that it would not be a problem for the PCPs to select a patient, as this task can be performed earlier.

The steering committee felt that conducting medication review based on information on medical record from the primary care clinic and Pharmacy Information System alone would not be very helpful. They felt that access to hospital medical records were important in order to obtain the patient's complete medication history. However, tracing the medical records from the hospital's records office might require time and effort. As an alternative, the pharmacists suggested to include pharmacist-patient interaction prior to PCP-pharmacist discussion. This will allow them to explore more on patients' medication history, medication experiences and medication-taking behaviour.

These two important points raised meant that the flow of the intervention had to be revised, as the patient needed to be present for assessment by the pharmacist.

7.2.4.3 Revising the Physician-Pharmacist Partnership for Patient Safety version 1 based on steering committee feedback

The research team met and revised the intervention based on feedback received from steering committee members. This led to the 4Ps v2. Figure 7.4 provides and outline of the components proposed for 4Ps v2.

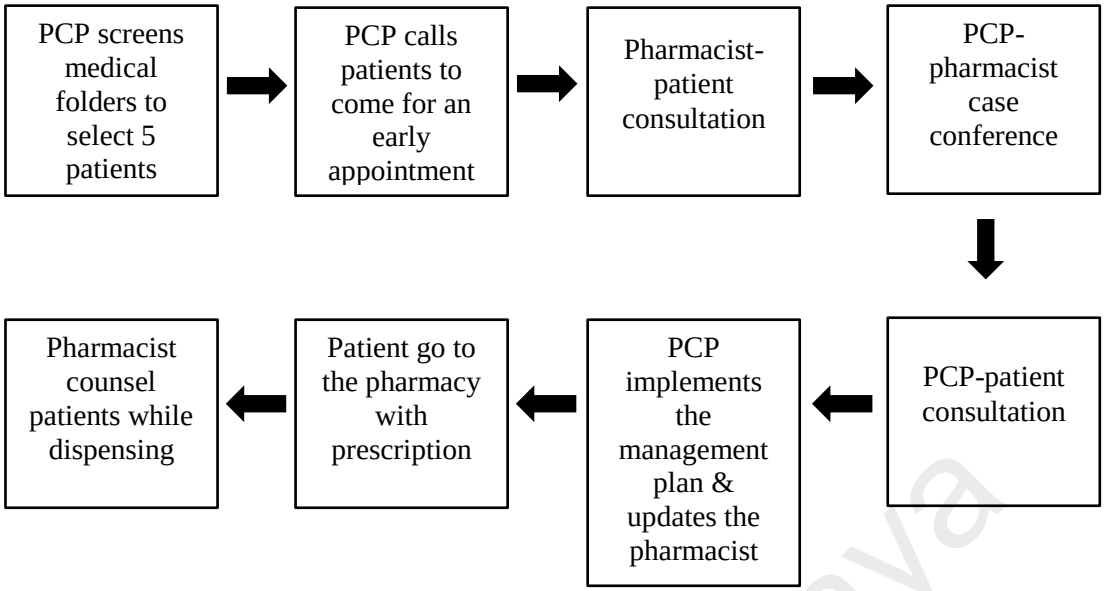


Figure 7.4: The Physician-Pharmacist for Patient Safety intervention version 2

Briefly, the PCPs will select and call their patients a few days earlier to reschedule their appointment in the morning at 9am, instead of their usual 2pm appointment at the family clinic. The PCPs felt that patients will be more comfortable with receiving a phone call from their doctor, instead from an unknown person. The 4Ps intervention will be delivered in the morning taking into account that the outpatient pharmacy's workload is lesser in the morning, and therefore the pharmacists will be able to deliver the intervention at the family clinic. One PCP and one pharmacist will be involved in the 4Ps intervention daily except for Tuesdays (family clinic does not attend to follow up patients on Tuesdays). On the day of patients' appointment, the pharmacist will see all study patients individually and assess them for any DRPs. Following this, the pharmacist meets with the PCP to present any DRP identified, provide recommendations to address the DRPs, and discuss and design a plan of action for each patient together with the PCP. The pharmacist then returns to the outpatient pharmacy, while the PCP start seeing the patients one by one. After each PCP-patient consultation, the PCP will call the pharmacist at the outpatient pharmacy to feedback on patient's latest management plan, and request for any additional counselling by pharmacist during dispensing. When the patient arrives at the

pharmacy, the pharmacist will dispense and counsel patients on their medications, according to the PCP's instructions.

7.2.4.4 Feedback from the policy makers

The 4Ps v2 was presented to the Head of the Pharmacy Department by RS and PSML, and to the Head of the Primary Care Medicine Department by RS and CJN on two separate occasions. The Head of the Department of Pharmacy was satisfied with the intervention proposed and gave his consent for the hospital outpatient pharmacists to be involved in testing of the intervention. The Head of the Department of Primary Care Medicine provided some feedback on the implementation of this intervention into routine practice, and provided consent for the intervention to be tested at the family clinic. No changes were made to the 4Ps v2 following these two meetings with the policy makers. This draft was then assessed for its acceptability and feasibility as described below.

7.2.4.5 Acceptability and feasibility test 1

Following the systematic development of a complex intervention, the UK MRC framework recommends a series of pilot tests to address any uncertainty in the design or conduct of the intervention (Craig et al., 2008). This is to ensure that the intervention will be delivered as intended. We therefore tested the intervention iteratively to determine the acceptability of the intervention and the tools; and to test out the procedures of the intervention identifying any practical issues to be addressed during implementation of the intervention. After each round of test, the research team met and made necessary revision before testing the intervention again. This was done twice, until no major changed were required. Following are details on the conduct of the acceptability and feasibility tests.

(a) ***Design***

This was a qualitative, non-participatory observational study to test the acceptability and feasibility of the 4Ps v2, and the tools developed.

(b) ***Setting***

This study was conducted at the family clinic of the UMMC, involving patients with chronic diseases who attended their afternoon follow-up appointments. One consultation room was allocated for the study which was used for patient assessment by pharmacist, PCP-pharmacist case conference and PCP-patient consultation. Medication dispensing was done at the outpatient pharmacy.

(c) ***Duration***

The study was conducted in August 2014, over a period of one week (Monday, Wednesday, Thursday and Friday). The family clinic does not attend to follow up patients on Tuesdays.

(d) ***Participants and sampling***

Purposive sampling was applied to identify the PCPs and pharmacists. Four PCPs (year 3 family medicine trainees) were approached to participate in this study. Year 3 family medicine trainees were selected as they were at that time attached to the UMMC primary care clinic as part of their training rotation. They were also already working for at least six months at the hospital and were familiar with their regular follow-up patients. Two outpatient pharmacists were purposely selected based on their availability to participate in this study. Only 2 outpatient pharmacists were recruited as compared to 4 PCPs as there were only 8 outpatient pharmacists available at the hospital. All four PCPs and two pharmacists approached agreed to participate in this study. Participants were

provided with participant information sheet [Appendix D1 and D2], following which written consent were obtained [Appendix D3].

Each PCP was assigned to one day of the week, while each pharmacist was assigned to work with 2 PCPs (i.e. two days of the week) [Table 7.2].

Table 7.2: Pairing of the primary care physicians and pharmacists for acceptability and feasibility test 1

Day	Pairing
Monday	PCP 1 and Pharmacist 1
Wednesday	PCP 2 and Pharmacist 1
Thursday	PCP 3 and Pharmacist 2
Friday	PCP 4 and Pharmacist 2

The primary care clinic team leader of the month was informed of the four PCPs' participation in the study. The team leader was asked to excuse the study PCPs from attending to walk-in patients at the family clinic from 9-11am on the respective dates, and to allocate one room at the family clinic to be used for the purpose of this study.

(e) ***Instruments used***

i Patient selection criteria checklist

This form was used by PCPs to document reason(s) on why they selected a particular patient to be included in the intervention [Appendix D4]. The list of patient criteria was derived from needs assessment and literature review. In the needs assessment study, majority of the PCPs and pharmacists proposed that the intervention should be delivered to patients with medication-related problems, to ensure efficient use of PCP and pharmacist time (Chapter 6, section 6.3.4, page 152). They also identified that the high

risk patient population is the elderly with multi-morbidities, who are taking large number of medications (Chapter 6, section 6.3.4, page 152). These suggestions were in agreement with literature, which also highlighted that the elderly on polypharmacy are at a higher risk of ADEs (Chapter 2, section 2.6.1, page 16). In addition, among the prescribing challenges reported by PCPs were failure to obtain complete medication history of patients with multiple follow up with several practitioners, poor medication knowledge of patients and adherence issues (Chapter 3, section 3.3, page 79). These led to the following criteria of patients to be selected for the 4Ps intervention: elderly (≥ 65 years old), polypharmacy (≥5 medications), incomplete medication history, non-adherence to treatment, and poor medication knowledge. In addition, PCPs were allowed to select patients with inadequate disease control (based on their assessment) to have their medication reviewed and optimised through the 4Ps intervention. This include uncontrolled hypertension, uncontrolled diabetes, uncontrolled hyperlipidaemia, uncontrolled asthma/COPD.

ii Patient assessment form version 1

This form was used by pharmacists to document patients' personal details, medication history, DRPs identified, cause(s) of the DRPs, action(s) proposed and outcome after PCP-patient consultation [Appendix D5]. The form was designed based on DRP classification by the Pharmaceutical Care Network Europe (PCNE) V 6.2 (Pharmaceutical Care Network Europe Foundation, 2010) [Appendix D6].

(f) *Data collection*

Each PCP-pharmacist pair provided the 4Ps v2 intervention on allocated days. Following are the detailed steps of the intervention:

i Patient selection

This was done one week before the intervention on Tuesday afternoon, during the PCPs' training day. PCPs reviewed the medical folders of their patients who were due for appointment with them the coming week on the allocated days. Each PCP selected a maximum of five patients based on the criteria mentioned above, and called the selected patients to reschedule their appointment from 2pm to 9am (on the same day).

ii Follow-up call by researcher

As this was a research study, the researcher made follow-up calls to inform patients about the study. Patients were informed that on the day of their appointment, they will be seen by a pharmacist, prior to their doctor's appointment. Patients were also requested to bring a sample of all their medications from home for review by the pharmacist.

iii Patient assessment by pharmacist for drug related problem

On the day of the appointment, the researcher provided study patients with participant information sheet [Appendix D7 and D8], and obtained written consent [Appendix D9 and D10]. Patients were then directed to the consultation room at the family clinic allocated for the study. All patients scheduled for the particular day were seen by the pharmacist on a first-come-first-serve basis. For each patient, the pharmacist obtained relevant personal details, medical and medication history. Based on the information obtained, medical records and patient interviews, the pharmacist assessed the patient for any DRP and designed recommendations to address each DRP identified. This process was documented in the patient assessment form v1.

iv Primary care physician-pharmacist case conference

Once the pharmacist had finished seeing all study patients for the day, he/she met with the PCP for a discussion. The pharmacist presented each patient case individually, along with his/her DRP assessment findings and recommendations. The PCP and pharmacist discussed to agree on a management plan, which the PCP documented on patient's medical records. This process was repeated for all patients seen by the pharmacist. Once finished, the pharmacist returned to the outpatient pharmacy, while the PCP continue seeing the study patients one by one in the same order seen by the pharmacist earlier.

v Primary care physician-patient consultation

This was a usual doctor-patient consultation. For each patient, the PCP decided on a suitable management plan based on the discussion with the pharmacist, and his/her clinical judgment following consultation with the patient. This was documented in patients' medical folders.

vi Primary care physician feedback to pharmacist

PCP called the pharmacist to update on patient's latest medication plan, and conveyed any message for the pharmacist to reinforce while dispensing medications to the patient.

vii Medication dispensing and counselling by pharmacist

The study patients' medications were dispensed by the pharmacist at the outpatient pharmacy. The pharmacist counselled patients on each of their medications, and reinforced any instructions given by the PCP over the telephone.

The researcher was present throughout the process of the intervention as a silent observer, and took research notes on the participants' (PCPs, pharmacists and patients) expressions, conversations and actions. The researcher informed and obtained consent from patients, pharmacists and PCPs prior to each consultation/discussion to ensure that the participants were comfortable with the presence of the researcher. In addition, any problems encountered in the delivery and flow of the intervention were noted.

(g) ***Data analysis***

The research notes taken during the delivery of the intervention served as the data for this study. The researcher analysed the data to determine the acceptability of the 4Ps v2 intervention and instruments used, and the feasibility of the 4Ps v2 intervention.

7.2.4.6 Findings from the acceptability and feasibility test 1

(a) ***Acceptability***

The 4Ps v2 intervention was well accepted by patients. They felt happy to talk and discuss their medications with the pharmacist. Many patients admitted that they gained new information about their medication, and understood its function and side effects better. All nine patients contacted brought their medications from home for review by the pharmacist, and this helped the pharmacist to assess patients' medication knowledge and medication-taking behaviour.

The PCPs were surprised with the DRPs identified by the pharmacists, especially with their regular patients that have been admitting to taking their medications according to instructions. They were glad that the 4Ps v2 intervention managed to identify and address some of their patients' DRP.

The pharmacists were able to conduct the patient assessment for DRP as planned, but found the patient assessment form v1 too complicated. They were not able to complete the form while doing patient assessment, and took some time after the session to do this. They said that they would prefer the form to contain more free text area for them to record down patient assessment findings and their recommendations, rather than a checklist.

(b) ***Feasibility***

The PCPs did not face any difficulties in selecting patients according to the selection criteria. Most PCPs however were reluctant to call the patients via the telephone as they had to go through the hospital telephone operator to make the phone call, and this was too time consuming. Some resorted to using their own mobile phones. In addition, patients' phone numbers were not updated in the hospital registry. Therefore, 11 out of 22 selected patients cannot be contacted. Two patients refused participation as it was inconvenient for them to come in the morning. All remaining nine patients contacted by the PCPs agreed to participate in the study, and turned up for their appointments.

On the day of the intervention, patients' waiting time was the main problem encountered. The first patient especially had to wait very long (approximately >60 minutes) for their PCP consultation (as this patient had to wait for all patients to be seen by the pharmacist, and for the PCP-pharmacist discussion). The PCPs also felt that they were wasting their time while the pharmacist was conducting patient assessment and suggested that the flow is revised.

Although the PCP-pharmacist discussion provided a platform for the PCPs and pharmacists to collaborate, there appeared to be a communication breakdown between the PCPs and pharmacist after PCP-patient consultation. The PCPs did not call the

pharmacist to update on patients' latest medication plan, as they found it troublesome to pick up the telephone and make a phone call. This prevented the pharmacist from providing the follow up medication counselling to patients effectively. Also, some patients did not go and collect their medications immediately from the pharmacy. The pharmacist therefore had no idea when the patient will come, and this disrupted his/her work at the pharmacy.

7.2.4.7 Revising the Physician-Pharmacist Partnership for Patient Safety version 2 based on findings from acceptability and feasibility test 2

The research team met to discuss on findings from acceptability and feasibility test 2. The 4Ps v2 was revised during this discussion, producing the 4Ps v3 intervention. The changes made are summarised in Table 7.3, while Figure 7.5 provides an overview of the 4Ps v3.

Table 7.3: Changes made to the Physician-Pharmacist Partnership for Patient Safety intervention version 2 based on findings from acceptability and feasibility 1

Component	Process	Justification for change
Patient selection	The researcher will call the patients selected by PCPs to inform about the study, reschedule their appointment and ask them to bring their medications from home.	This will reduce PCPs' burden in retrieving patients' phone numbers and calling patients. In addition, it is not unusual for patients to be contacted by hospital personnel other than a doctor regarding their appointment.
Patient assessment and PCP-patient consultation	The pharmacist and PCP will see patients concurrently. This means that after the pharmacist conducts DRP assessment for the first patient, he/she will meet with the PCP for a discussion, following which the PCP will continue seeing the first patient and the pharmacist will see the second patient. Therefore, there will be two rooms required for the provision of the 4Ps intervention. The PCP will see patients in his/her normal consultation room as allocated by the clinic team leader, while the pharmacist will occupy the room adjacent to the PCP's consultation room.	This will address the long patient waiting time issue encountered in acceptability and feasibility test 1.
PCP's feedback to pharmacist	Once the PCP decides on a management plan for the first patient, the PCP will feedback to the pharmacist face-to-face regarding patient's latest medication plan, and inform the pharmacist in case of any additional information to be delivered during medication dispensing and counselling.	This will ensure that the pharmacist is updated on patient's latest medication plan, and efficient two-way communication between the PCP and pharmacist.
Medication dispensing	Medication dispensing and counselling will be conducted at the family clinic itself. The pharmacist room at the clinic is located right above the outpatient pharmacy, connected by a flight of stairs. The pharmacist therefore will go to the outpatient pharmacy to collect patients' medication, and dispense it at the family clinic.	This will prevent patients from leaving the hospital without collecting their medications, and for pharmacist to provide medication counselling as instructed by the PCPs.

PCP=primary care physician; DRP=drug related problem

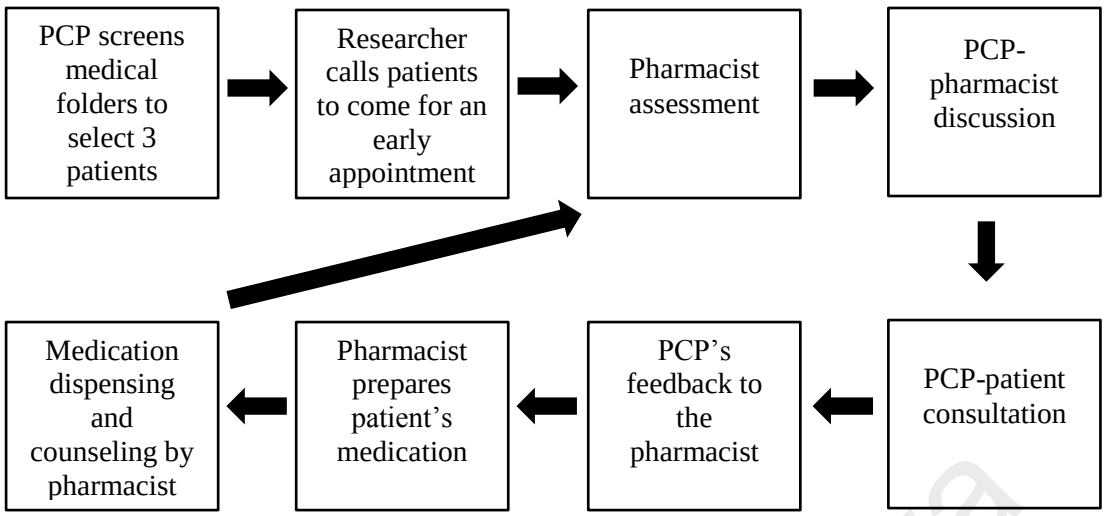


Figure 7.5: The Physician-Pharmacist for Patient Safety intervention version 3

7.2.4.8 Acceptability and feasibility test 2

This test was similar to acceptability and feasibility test 1, and only steps that were different will be reported.

(a) ***Setting***

Two rooms, located side by side were allocated for the study. This is because PCP and pharmacist were seeing patients simultaneously as compared to earlier test where the pharmacist saw all the patients first, followed by the PCP. The consultation room was for PCP-pharmacist discussion and PCP-patient consultation, while patient assessment by pharmacist and medication dispensing were conducted at the adjacent pharmacist room.

(b) ***Duration***

This study was conducted for two days (Monday and Wednesday) in September 2014.

(c) ***Participants and sampling***

Two PCPs and one pharmacist who participated in acceptability and feasibility test 1 were invited to participate in this study. Following are the pairing of PCPs and pharmacist for this study.

Table 7.4: Pairing of the primary care physicians and pharmacists for acceptability and feasibility test 2

Day	Pairing
Monday	PCP 1 and Pharmacist 1
Wednesday	PCP 2 and Pharmacist 1

(d) ***Instruments used***

Patient assessment form v2 was used in this study. This form was revised from patient assessment form v1 following feedback received during acceptability and feasibility test 1 [Appendix D11].

(e) ***Data collection***

i Patient selection

PCPs were not required to call patients as part of patient selection procedure to save their time.

ii Primary care physician-pharmacist discussion

Once the pharmacist had finished seeing the first patient, he/she met with the PCP for a discussion. This was documented by the pharmacist on the patient assessment form v2 [Appendix D11]. Once finished, the pharmacist returned to his/her room to see the next patient, while the PCP saw the first patient.

iii Primary care physician's feedback to pharmacist

PCP met with the pharmacist after each PCP-patient consultation to update the pharmacist on patient's latest medication plan, and conveyed any message for the pharmacist to reinforce while dispensing medications to the patient. This process was documented by the pharmacist on the patient assessment form v2.

iv Medication dispensing and counselling by pharmacist

Patients' medications were dispensed by the pharmacist at the family clinic. As PCPs prescribed electronically, the prescription was electronically transmitted to the pharmacy and was prepared by the pharmacy staff. Once ready, the pharmacist went down to collect the medication from the pharmacy, and dispensed it to the patient at the family clinic. The pharmacist counselled patients on each of their medications, and reinforced any instructions given by the PCP. This process was also documented in the patient assessment form v2.

7.2.4.9 Findings from the acceptability and feasibility test 2

(a) ***Acceptability***

Similar to acceptability and feasibility test 2, the intervention content was well accepted by the PCPs, pharmacist and patients. In addition, the phone calls made by the researcher to reschedule patients' appointment were well accepted by patients. All patients contacted attended the appointment as scheduled. Patients were also happy to get their medications at the family clinic itself, with one-to-one counselling from the pharmacist.

The PCPs and pharmacist found that having their rooms near to each other at the family clinic was convenient, as they could communicate easily should the need arise. The PCPs'

feedback to pharmacist after PCP-patient consultation was helpful for the pharmacist in providing follow up counselling to patients during medication dispensing. This step also allowed the PCP to convey any additional message to the pharmacist that needed to be stressed to the patient while dispensing.

The pharmacist found the patient assessment form v2 satisfactory, and easy to complete.

(b) ***Feasibility***

The room occupied by the pharmacist was shared with other patients who were receiving acute treatment at the family clinic. The environment was therefore a little noisy and disruptive for the pharmacist-patient discussion. However, there is little can be done to this as there is limited room available at the family clinic, and the treatment room is ideal for the pharmacists' use as it was very near to the outpatient pharmacy entrance. There is also computer with access to lab results and pharmacy information system available at the room.

Both the PCPs and pharmacist were happy with the flow of the 4Ps v3 intervention, and thought that it is feasible to be implemented into routine care. There were however a few instances where they were unsure of the next step of the intervention, and had to consult the researcher for help. Also one PCP thought that there was a clash of roles between her and the pharmacist, as she did not know what the pharmacist's role with the patient was. Based on the researcher's observation, there were inconsistencies with the way the pharmacists provided pharmaceutical care, and interacted with the PCPs.

7.2.4.10 Revising the Physician-Pharmacist Partnership for Patient Safety version 2 based on findings from acceptability and feasibility test 2

Based on the issues and feedback encountered in acceptability and feasibility test 2, the research team identified that there was a need to conduct a formal briefing session with the participants prior to the intervention. The PCPs and pharmacists need to be briefed on the steps involved in the 4Ps intervention, and each other's role in the intervention. This will ensure smooth running of the intervention, and facilitate the building of CWR between PCPs and pharmacists.

The pharmacist will be briefed first, followed by the PCPs and pharmacists briefing together. Based on the CWR model proposed by Randal P. McDonough and Doucette (2001), the pharmacists should be the driver of the CWR at early stages. Therefore, the researchers felt that it was necessary to brief and engage the pharmacists first, before the PCPs and pharmacists briefing. This session will also be used to train and motivate the pharmacists to provide consistent, high quality pharmaceutical care in order to gain the PCPs' trust in them (Randal P. McDonough & Doucette, 2001).

Next, the PCPs and pharmacists will be briefed together. This briefing will serve as an ice breaking session between the two professionals. In addition, a pharmacist representative will be elected to propose the services that will be provided by the pharmacists as part of the 4Ps intervention, and obtain feedback from the PCPs. This session will provide a platform for PCPs and pharmacists to familiarise with each other's role in the 4Ps intervention, to facilitate a CWR working relationship between them (Bajcar et al., 2005; Randal P. McDonough & Doucette, 2001).

Two additional tools were developed as part of this revision which was the guide for PCP and the guide for pharmacist. The purpose of these guides was to ensure consistency and smooth delivery of the provision of the 4Ps intervention by the PCPs and pharmacists. These guides will be provided to the PCPs and pharmacists during the briefing sessions.

(a) ***Guide for primary care physician***

The 4Ps intervention guide for primary care physician [Appendix D12] is divided into two main sections: PCPs' role in supporting the provision of pharmaceutical care by pharmacists, and establishing a CWR with the pharmacists. This guide was developed based on the researcher's observation during acceptability and feasibility tests 1 and 2, and the CWR model as proposed by Randal P. McDonough and Doucette (2001).

(b) ***Guide for pharmacist***

The 4Ps intervention guide for pharmacist [Appendix D13] was also divided into two sections; pharmacists' role in providing pharmaceutical care and their role in establishing a CWR with the PCPs. Pharmacists' role in providing pharmaceutical care was developed based on the pharmaceutical care concept as introduced by Cipolle et al. (2004), and the International Pharmaceutical Federation guide for pharmacists on Counselling, Concordance and Communication (Guirguis, 2012). Pharmacists' role in developing CWR with the PCPs was developed based on the recommendations provided by Randal P. McDonough and Doucette (2001).

At this point, the research team reached a consensus that no more changes was needed to the intervention, and it can be finalised and ready for pilot testing. Details on the conduct and findings of the pilot test will be described in detail in later chapters of this thesis (Chapter 10 and 11).

7.3 Results

7.3.1 The final Physician-Pharmacist Partnership for Patient Safety intervention

Figure 7.6 represents the final 4Ps intervention that was systematically developed using needs, evidence and theory.

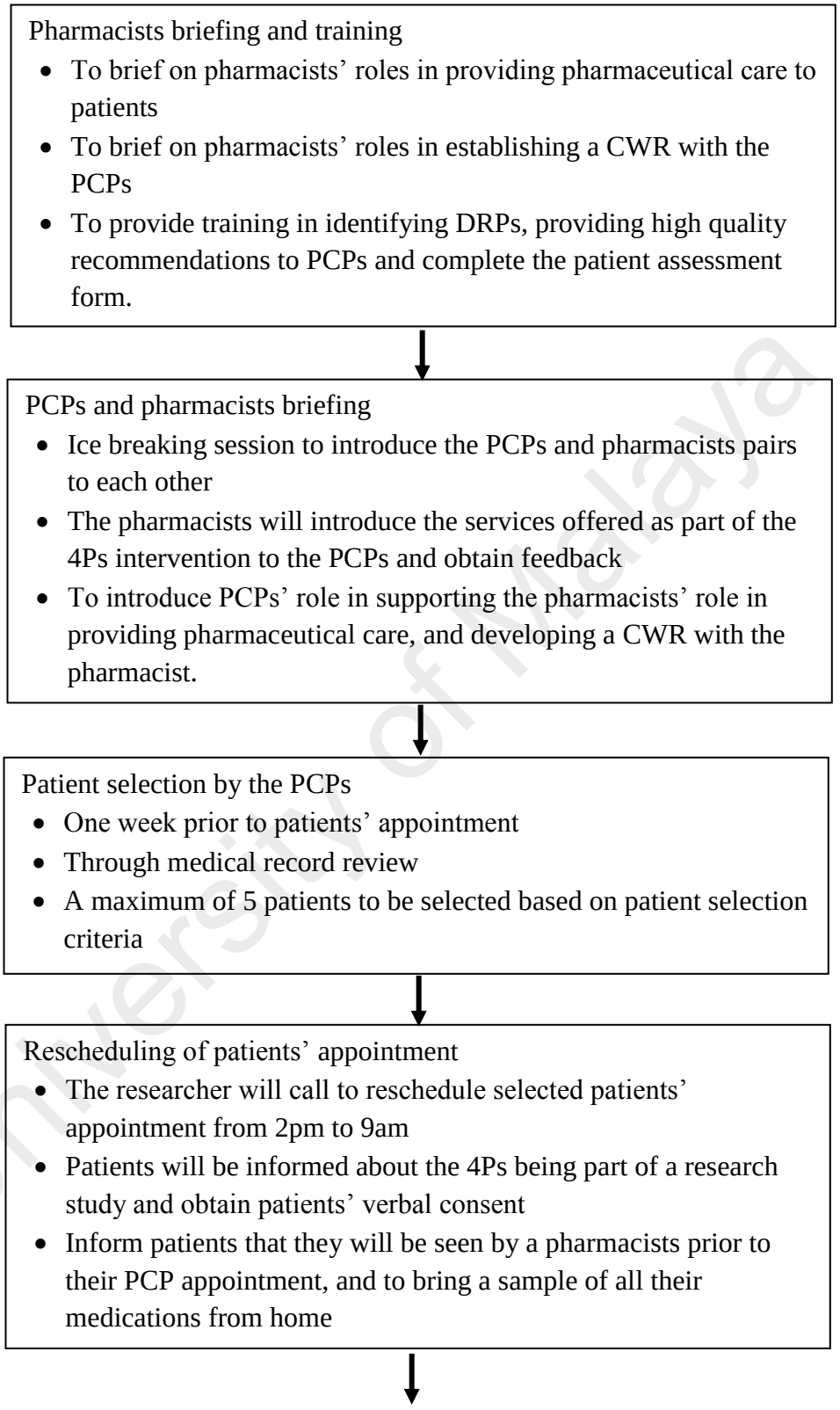
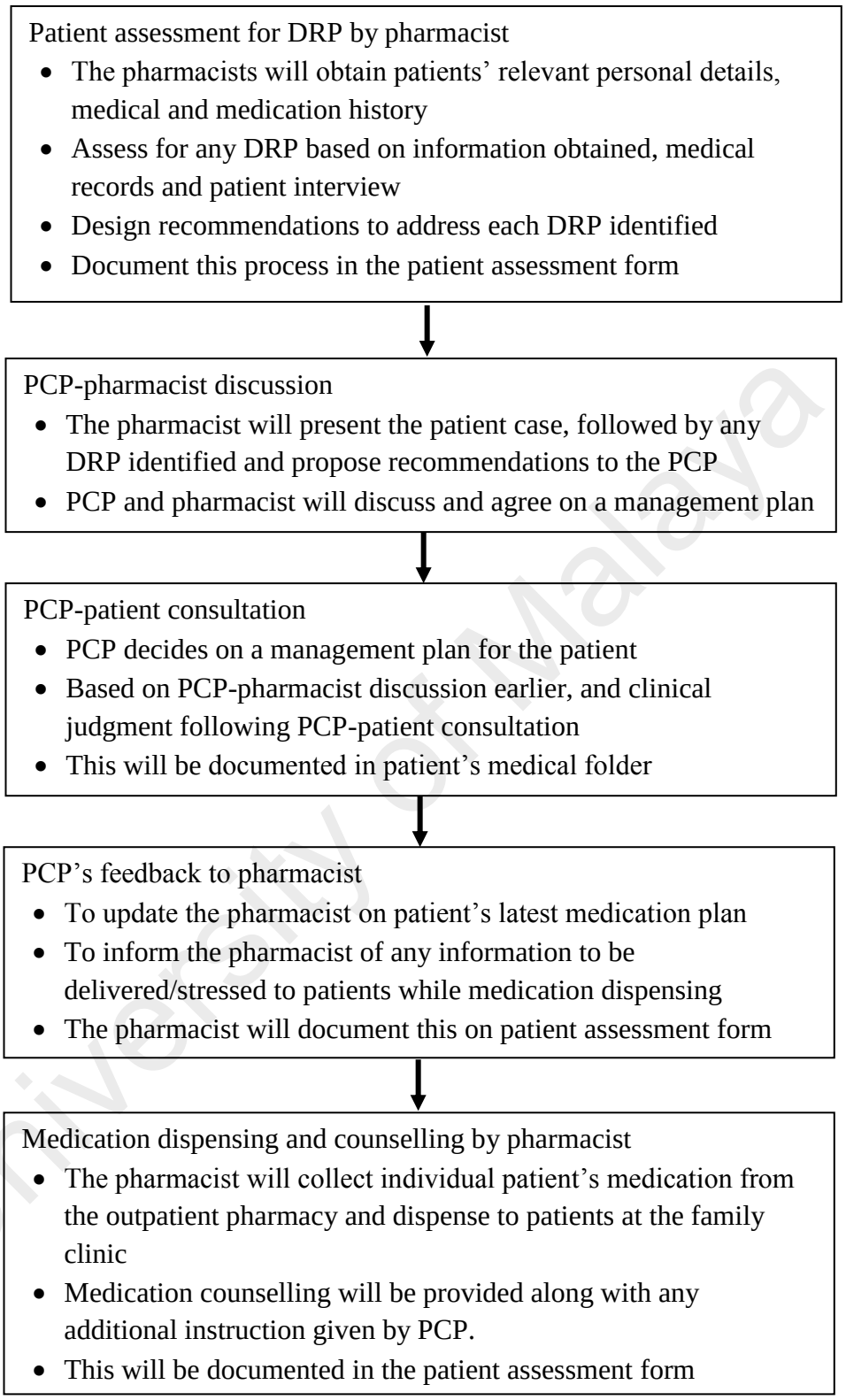


Figure 7.6: The final Physician-Pharmacist Partnership for Patient Safety intervention for pilot testing

Figure 7.6 continued



7.4 Discussion

This article outlines a systematic way of developing a doctor-pharmacist collaboration intervention using the UK MRC framework (Craig et al., 2008). The 4Ps intervention was developed based on needs assessment (Chapter 3, 4, 5 and 6), evidence from literature and a conceptual framework. The intervention was subjected to an iterative review and revision process, which included review by a steering committee and two rounds of acceptability and feasibility tests. This produced a final intervention that is ready for pilot testing.

Despite the current global trend towards pharmacists integration into primary care, details on the development of such services are often lacking. There is however a considerable amount of literature reporting pharmacists' experiences, and barriers faced to successfully integrate into primary care teams (Bradley et al., 2008; Farrell et al., 2008; Kozminski et al., 2011). Based on this, Jorgenson, Dalton, et al. (2013) proposed a set of guidelines for pharmacists integrating into primary care teams. Although these guidelines are useful for pharmacists who plan to work as part of an existing primary care team, it does not explain how to develop such services. The use of UK MRC framework in this study was able to guide us through the development process systematically. We cannot however tell for certain if the intervention was successful in improving medication safety for patients with chronic diseases without a rigorous evaluation.

The use of user needs, literature and a conceptual framework in the design of the intervention was found to be essential. The use of qualitative research methods for needs assessment allowed an in-depth understanding of medication safety issues in the outpatient setting. However, it also revealed a broad range of problems faced by the stakeholders (Chapters 3-5). The problems were mostly complex and interrelated i.e. one

problem often led to another problem. For example, the health care system allowed patients to visit different health institution for different complaints. This presented a challenge to PCPs to coordinate patients' care and prescribe safely. As a result, patients were at risk for drug duplications and drug-drug interactions. When patients were not informed or aware of the duplicate medications, they might take the same medication twice, leading to ADEs. The researchers realised that it was not possible to tackle all the problems in a single intervention, and it was important to identify the most significant cause of ADEs and MEs. This was a very challenging step which required several rounds of discussion and deliberation among the research team.

Literature review was conducted to identify the types, and effectiveness of interventions designed to improve medication safety in the outpatient setting. It was a challenge to synthesise and summarise the broad range of interventions identified. In addition, majority of the intervention were complex, consisting of several components. It was not clear which component was important and which one was responsible for the observed effect. Furthermore, majority of studies were not large enough to detect any difference in medication safety outcomes such as MEs, ADEs, hospitalisation and mortality. Therefore, the researchers had to consider alternative outcomes such as medication appropriateness and DRPs to identify the most effective intervention to improve medication safety in outpatient setting.

Three different frameworks (the TeAMM model, the Pharmaceutical care practice concept and the CWR model) were identified and combined to form the conceptual framework for the 4Ps intervention. This was an important step in the development of the 4Ps. Initially, only the TeAMM model and the 'Pharmaceutical care practice' concept were identified (Bajcar et al., 2005; Cipolle et al., 2004). However, the research team

realised that there is a need to look at the professional interaction between doctors and pharmacists to ensure the success of the TeAMM approach, and the effective delivery of pharmaceutical care. This led to the search for theories on doctor-pharmacist CWR and identification of the CWR model (Randal P. McDonough & Doucette, 2001). This model proved to be the most important link in the design of the 4Ps intervention, as it was used to establish and develop CWR between PCPs and pharmacists. Without the CWR model, it would have been difficult to get the two professionals to start working together which could have affected the delivery of the intervention.

Feedback from steering committee was very useful in the development of the 4Ps intervention. In fact, the intervention underwent significant change following feedback from the steering committee. However, there were mixed opinions provided during the meeting. For example, some preferred the patients to be seen by the pharmacists first, while some preferred the pharmacist to dispense and counsel patients after their PCP's consultation. Similar conflicting opinions were reported during the needs assessment (Chapter 6, section 6.3.6, page 155). The researchers faced difficulties in deciding which suggestion to incorporate in the design of the intervention, and this justified the need for acceptability and feasibility test to determine the most suitable and feasible method.

The 4Ps was tested for acceptability and feasibility twice, and many issues were identified. These issues needed to be ironed out earlier to improve the feasibility and smooth delivery of the intervention during later stages (pilot testing and evaluation) (Craig et al., 2008). The acceptability and feasibility tests that were conducted had many limitations, one of which was the presence of the researcher could have affected the interaction between participants. However, these tests combined with researcher's direct

observation were necessary to refine the 4Ps intervention. Alternatively, a video recording or one-way mirror could have been used.

The 4Ps intervention is different from the other interventions available in the literature. In most studies, the integration of pharmacist into primary care focuses on the roles and responsibilities of pharmacists, and the impact of pharmaceutical care on patient outcomes or process outcomes (Carter et al., 2009; Williams et al., 2004). But little has been said about the working relationship between the doctors and pharmacists. In this study, through the use of the TeAMM and CWR model, we highlighted the need to focus on developing a successful CWR between doctors and pharmacists, to ensure a successful collaborative medication management in primary care. Future evaluation of the 4Ps intervention should also aim to study the impact of the intervention on doctor-pharmacist CWR, and how this affects patients' therapeutic outcome.

The development of the 4Ps intervention however, should not stop here. In line with the UK MRC framework recommendation, it should be continuously assessed and improved (Craig et al., 2008; Jorgenson, Dalton, et al., 2013). This will ensure that it meets the current needs of stakeholders. One way is to have regular feedback sessions involving stakeholders, in which the performance of the 4Ps intervention is assessed, and any problems encountered are discussed and resolved.

7.5 Conclusion

A doctor-pharmacist collaboration intervention was successfully developed based on needs assessment, evidence and theory. Further evaluation is needed to determine the effectiveness of the intervention in improving doctor-pharmacist CWR, and medication safety.

CHAPTER 8: VALIDATION OF THE PHYSICIAN-PHARMACIST COLLABORATIVE INDEX FOR PHARMACISTS IN MALAYSIA

Following the development of the 4Ps intervention (Chapter 7), the intervention was pilot tested to determine its impact on doctor-pharmacist CWR and medication safety. Two questionnaires were selected to measure the extent of PCP-pharmacist professional exchanges during the pilot test: the Physician-Pharmacist Collaborative Index (PPCI) for pharmacists and the PPCI for physicians. This chapter will report on the validation of the PPCI for pharmacists in Malaysia.

8.1 Background

Multidisciplinary team approach to patient care was introduced to ensure effective and efficient delivery of health care (Codispoti et al., 2004). It essentially involves two or more health care professionals utilising their skills and knowledge for the wellbeing of a patient (Canadian Pharmacists Association, 2007). The two groups of healthcare professionals that have been increasingly encouraged to work together are doctors and pharmacists (Canadian Pharmacists Association, 2007).

Previous studies have shown the positive impact of pharmacists working together with doctors on patients' health and safety outcomes. This include improvement in surrogate endpoints such as blood pressure (Carter et al., 2009), cholesterol levels (Howard-Thompson et al., 2013) and glycosylated haemoglobin (Codispoti et al., 2004). Doctor-pharmacist collaboration also ensures medication safety by improving medication appropriateness (L. J. Bryant et al., 2011) and reducing the number of patients' DRPs (Gilbert et al., 2002). One study showed an improvement in combined all-cause mortality and non-fatal heart failure-related events in patients with heart failure (Gattis et al., 1999). However, the magnitude of impact was variable between studies, which might be due to

different levels of collaboration between doctors and pharmacists. There is a need to understand the CWR between doctors and pharmacists, and how it affects patient outcomes.

Randal P. McDonough and Doucette (2001) was the first to shed some light on doctor-pharmacist CWR by introducing the CWR model. This model proposes that doctor-pharmacist relationship progresses in stages, driven by their individual characteristics, contextual factors and the professional exchanges between them (Randal P. McDonough & Doucette, 2001). Following this, several studies were conducted to explore the nature and extent of collaboration between GPs and community pharmacists in the United States (A. J. Zillich et al., 2004), Canada (Dieleman et al., 2004), United Kingdom (Bradley et al., 2012) and Australia (C. Van, Mitchell, & Krass, 2011). These studies identified that professional exchanges such as open communication, trust, respect and understanding of roles were the strongest driver of doctor-pharmacist CWR (Bradley et al., 2012; Dieleman et al., 2004; C. Van et al., 2011; A. J. Zillich et al., 2004).

To date, two measures have been developed to quantify the professional exchanges between a doctor and a pharmacist: the PPCI (Alan J. Zillich, Doucette, Carter, & Kreiter, 2005; A. J. Zillich, Milchak, Carter, & Doucette, 2006) and the Attitude Towards Collaboration Instrument (ATCI) (Connie Van, Costa, Abbott, Mitchell, & Krass, 2012; C. Van, Costa, Mitchell, Abbott, & Krass, 2013). The PPCI is a generic instrument that can be used in any setting. It was developed and validated among GPs and community pharmacists in the United States (Alan J. Zillich et al., 2005; A. J. Zillich et al., 2006). On the other hand, the ATCI was developed specifically for GPs and community pharmacists. The final version of the ATCI consists of 13 items, and was validated among GPs and community pharmacists in Australia (Connie Van et al., 2012; C. Van et al.,

2013). The PPCI was selected as we wanted to assess the CWR among doctors and pharmacists in a teaching hospital in Malaysia.

The PPCI was developed into two versions; one for doctors and one for pharmacists. The PPCI for pharmacists has been tested for sensitivity and criterion validity among 25 pharmacists in the United States (A. J. Zillich et al., 2006). However, it has not been validated in Malaysia. Although English is widely spoken and understood by many Malaysians, the English used in the United States may not necessarily be interpreted the same way in Malaysia (Lai, 2013). The aim of this study was to determine the validity and reliability of the PPCI for pharmacists in assessing the doctor-pharmacist professional interactions, in Malaysia.

8.2 Methods

8.2.1 Study design

This was a validation study to determine the validity and reliability of the PPCI for pharmacists in assessing the doctor-pharmacist professional interactions in Malaysia.

8.2.2 Setting

This study was conducted at an urban teaching hospital in Kuala Lumpur, Malaysia.

8.2.3 Duration

Data collection was conducted from June to August 2014.

8.2.4 Participants and sampling

At the time of the study, there were 27 pharmacists in our hospital; out of which 9 were clinical pharmacists in the intensive care, infectious disease, geriatric, nephrology,

hematology, respiratory, upper gastrointestinal surgery, endocrine and oncology wards. Clinical pharmacists participated in ward rounds, screened prescriptions and handled all medication-related enquiries. If doctors had any medication-related enquiries, they would liaise with their clinical pharmacists. Similarly, if a clinical pharmacist detected any problem, he/she would liaise with the doctor. Doctor-pharmacist interactions occurred approximately 2-5 times per day per pharmacist via the telephone, email or face to face. Medication-related enquiries included questions regarding drug indications, drug dosages, drug-drug interactions, adverse effects, and drug incompatibility.

The remaining 15 pharmacists worked as outpatient, inpatient, manufacturing and store pharmacists. These pharmacists contacted doctors via telephone to clarify any medication-related enquiries at the point of dispensing or preparing medications. Doctors from wards without a clinical pharmacist called the general pharmacy telephone line when they had any medication-related enquiries. Wards that did not have a clinical pharmacist were the rehabilitation medicine, orthopaedics, psychological medicine, ophthalmology, emergency medicine and obstetrics and gynaecology wards. These calls were attended by any random non-clinical pharmacist assigned to answer the telephone for the day. In Malaysia, clinical pharmacists are not required to have postgraduate qualifications or additional specialisation. Hence, no difference exists in terms of the level of education and the years of working experience between clinical and non-clinical pharmacists.

In addition, there were 25 trainee pharmacists who were undergoing their one year compulsory training at the hospital.

We recruited all pharmacists from the pharmacy department of the hospital. Outpatient pharmacists were excluded as they would be involved in the pilot testing of the 4Ps intervention (Chapter 10). We also excluded trainee pharmacists as they were not in a position of making decisions regarding patient care without prior consultation with registered pharmacists. The pharmacists were grouped into "collaborators" and "non-collaborators" based on the differences in their working pattern with a doctor. "Collaborators" were defined as clinical pharmacists who worked together with doctors in their ward; while "non-collaborators" were defined as pharmacists who interacted with any random doctor over the telephone, to solve medication-related problems.

8.2.5 Sample size

An ideal sample size to perform confirmatory factor analysis would be participant-to-item ratio of 5:1 (F. B. Bryant & Yarnold, 1995). Since the total number of items in the PPCI for pharmacists was 14, the number of pharmacists required was 14*5=70. Allowing for a loss to follow up of 20%, the total number of pharmacists required was 84. However, since there were only 27 pharmacists at the hospital, we aimed to recruit all pharmacists who met the inclusion and exclusion criteria into the study.

8.2.6 Instruments used

8.2.6.1 Demographic form

A demographic form was designed to capture the individual and contextual characteristics of the pharmacists such as age, gender, years of clinical experience, post graduate qualifications, job description (clinical pharmacist, store pharmacist etc.) and the average number of prescriptions screened per day [Appendix E1].

8.2.6.2 Physician-Pharmacist Collaborative Index for pharmacists

The original English version of the PPCI for pharmacists was used in this study [Appendix E2]. It consists of three domains and 14 items: trustworthiness (6 items), role specification (5 items) and relationship initiation (3 items) (Snyder et al., 2010; A. J. Zillich et al., 2006). Responses were assessed using a seven-point Likert scale from 1 (very strongly disagree) to 7 (very strongly agree) (Snyder et al., 2010; A. J. Zillich et al., 2006). A higher total score of the PPCI for pharmacist indicated a higher level of doctor-pharmacist collaboration (Snyder et al., 2010; A. J. Zillich et al., 2006)

8.2.7 Data collection

Collaborators (clinical pharmacists) and non-collaborators (non-clinical pharmacists) were approached personally to participate in the study, and provided with a participant information sheet [Appendix E3]. After providing written informed consent [Appendix E4], participants completed the demographic form and the PPCI for pharmacists. Collaborators were asked to complete the PPCI for pharmacists based on their relationship with one particular doctor that they work closely with in their respective wards. Non-collaborators were asked to consider their relationship with any one doctor whom they have interacted previously, and to respond to each item based on their interactions with this particular doctor. Two weeks later, all participants were required to complete the PPCI for pharmacists in a similar manner to assess for reliability. The survey was answered anonymously as the researcher assigned a unique participant identification number for each participant.

8.2.8 Data analysis

Data was analysed using IBM SPSS Statistics version 20 (IBM Corp., Armonk, New York). Continuous variables were presented as mean, standard deviation, median and

range; whilst categorical variables were presented as frequency and percentage. Normality was assessed using the Shapiro-Wilk test (Ghasemi & Zahediasl, 2012). As data was found to be not normally distributed, the Mann-Whitney U test was used to compare continuous variables between groups. Categorical variables were compared using the Chi-square test.

The process of validation consists of 2 steps: validity and reliability. Validity can be further divided into face validity and construct validity (factor analysis, convergent validity and discriminative validity) (Terwee et al., 2007); whilst reliability is divided into internal consistency and test-retest reliability (Terwee et al., 2007). In this study, we assessed the face validity, discriminative validity, internal consistency and stability of the PPCI for pharmacists. Confirmatory factor analysis was not performed due to the insufficient sample size.

8.2.8.1 Face validity

The face validity of the PPCI for pharmacists was assessed by an expert panel consisting of 2 pharmacists and 1 family medicine specialist. This involved assessing the layout, language, instructions, response format and clarity of the items in the PPCI for pharmacists. In addition, a pilot study was conducted on 2 clinical pharmacists, 2 inpatient pharmacists and 1 outpatient pharmacist from an urban government hospital in Malaysia. Participants were invited to read the questions, to evaluate verbally if the items were difficult for them to comprehend, and to recommend items for deletion or modification.

8.2.8.2 Construct validity

The correlation between the mean scores of the domains was determined using Spearman's rho; Spearman's rho values of 0.10-0.29 were defined as small, 0.30-0.49 as medium and >0.50 as large (J. Cohen, 1988).

(a) ***Discriminative validity***

We hypothesised that collaborators would have higher scores in all the PPCI for pharmacists domains compared to non-collaborators, due to the fact that collaborators worked in closer proximity with doctors and had more frequent professional interactions with them, than non-collaborators. The scores between the two groups were compared using Mann-Whitney U test.

8.2.8.3 Reliability

(a) ***Internal consistency***

Internal consistency was determined using Cronbach's alpha for each domain within the PPCI for pharmacists, and the total score. Cronbach's alpha measures the average correlation between items. Values of 0.70-0.79 was considered fair, 0.8-0.89 was good, and >0.90 suggested redundancy in some items (Terwee et al., 2007). Cronbach's alpha if item is deleted was computed to check if the Cronbach's alpha can be improved significantly by deleting any of the item in the domain.

Corrected item-total correlation was computed to identify items that were not in good agreement with the rest of the items in a particular domain. Correlation values of individual items should be between 0.3-0.9; a value of <0.3 indicates that the item does not belong to the domain and a value of >0.9 indicates a redundant item in the domain

(Tabachnick & Fidell, 2007). The effect of removing a single item on the Cronbach's alpha was also determined.

(b) ***Test-retest reliability***

Test-retest reliability is the extent to which the repeated scores from the same participant remains unchanged over time (Lidwine B. Mokkink et al., 2012). For instruments with a Likert scale such as the PPCI for pharmacists, weighted kappa is the preferred statistical method for determining test-retest reliability for individual items (J. Cohen, 1968). As the total score was a continuous variable, it was assessed for test-retest reliability using inter-class correlation coefficient ($ICC_{agreement}$) (Terwee et al., 2007). A weighted kappa or ICC value of 0.7 was considered acceptable (Terwee et al., 2007). Test-retest was evaluated after 14 days as it was long enough to prevent participants from recalling their previous answers, and short enough to prevent any significant change in their relationship with the doctor they evaluated previously (Terwee et al., 2007).

8.2.9 Ethics

Ethics approval was obtained from the UMMC Medical Ethics Committee (approval No: 20144-150) [Appendix E5].

8.3 Results

A total of 23 pharmacists (9 collaborators and 14 non-collaborators) were recruited. 24 pharmacists were approached, of which 23 responded (response rate=96%). The demographic characteristics of the participants are presented in Table 8.1. There was no significant difference between the demographic profiles of the collaborators and the non-collaborators, except for gender and the average number of prescriptions screened per day. The collaborators were all females (100%), while 64.3% of non-collaborators were

female. Majority of the collaborators (55.6%) screened >150 prescriptions per day, while a majority of the non-collaborators (44.9%) screened <50 prescriptions per day.

Table 8.1: The demographic profile of collaborators (clinical pharmacists) and non-collaborators (non-clinical pharmacists)

Characteristics	Collaborators n (%) (n=9)	Non-collaborators n (%) (n=14)	p-value
Mean age ± SD [years] Median (range) [years]	32.7±9.4 30.0 (27-57)	33.9±8.7 32.5 (25-53)	0.612[a]
Gender			0.043[b]*
Male	0	5 (35.7)	
Female	9 (100.0)	9 (64.3)	
Mean clinical experience ± SD Median (range) [years]	9.3± 9.8 6.0 (4-35)	10.6±8.2 9.0 (2-29)	0.483[a]
Postgraduate qualification			0.825[b]
Yes	1 (11.1)	2 (14.3)	
No	8 (88.9)	12 (85.7)	
Prescriptions screened/day			0.005 [b]*
≤50	0	7 (44.9)	
51-100	3 (33.3)	4 (41.8)	
101-150	1 (11.1)	3 (2.0)	
>150	5 (55.6)	0	

[a]Mann-Whitney U test, [b]Person's chi square test, *statistically significant at p<0.05

8.3.1 Face validity

All 5 participants from the pilot study did not face any difficulties in understanding and completing the questionnaire. Hence, no changes were made to the original instrument.

8.3.2 Construct validity

The correlation of the mean domain scores ranged from 0.571-0.671 [Table 8.2].

Table 8.2: Correlation of the mean scores between domains

Construct	Trustworthiness	Role specification	Relationship initiation
Trustworthiness	1.000	0.612	0.671
Role specification	0.612	1.000	0.571
Relationship initiation	0.671	0.571	1.000

8.3.2.1 Discriminative validity

Collaborators scored slightly higher compared to non-collaborators in all domains as well as the total score of the PPCI for pharmacists, but these differences were not statistically significant [Table 8.3].

Table 8.3: Physician-Pharmacist Collaborative Index scores of collaborators and non-collaborators

Domains	Range	Collaborators (n=9)		Non-collaborators (n=14)		Mann Whitney U test	
		Median	Mean ± SD	Median	Mean ± SD	z score	p-value
Trustworthiness	6-42	33.0	34.0 ± 3.5	32.0	32.9 ± 5.5	-0.601	0.548
Role specification	5-35	25.0	25.3 ± 2.9	24.0	24.3 ± 3.1	-1.339	0.181
Relationship initiation	3-21	15.0	16.4 ± 2.2	15.0	14.7 ± 2.2	-1.228	0.220
Total score	14-98	73.0	75.8 ± 7.7	70.5	71.9 ± 9.1	-1.168	0.243

8.3.3 Reliability

8.3.3.1 Internal consistency

The Cronbach alpha for total score of the PPCI for pharmacists was 0.912, while the Cronbach alpha for the individual domains ranged from 0.715-0.930. Corrected item total correlation values were all >0.3 [Table 8.4].

8.3.3.2 Test-retest reliability

All 14 items had weighted kappa values of 0.541-0.878 [Table 8.4]. The $ICC_{agreement}$ of total PPCI for pharmacists score was 0.825.

Table 8.4: Internal consistency and test-retest reliability of the Physician-Pharmacist Collaborative Index for pharmacists

Domain	Item no.	Corrected item-total correlation	Cronbach alpha if item deleted	Cronbach alpha	Test (n=23)		Re-test (n=23)		Kappa with quadratic weighting
					Mean ± SD	Median	Mean ± SD	Median	
Trustworthiness	2	0.825	0.913	0.930	5.65 ± 0.98	6.00	5.57 ± 0.79	5.00	0.715
	3	0.737	0.924		5.57 ± 0.84	5.00	5.43 ± 0.66	5.00	0.805
	4	0.725	0.926		5.52 ± 0.90	6.00	5.52 ± 0.99	5.00	0.595
	9	0.898	0.903		5.57 ± 1.04	5.00	5.43 ± 0.95	5.00	0.703
	10	0.864	0.908		5.61 ± 0.99	5.00	5.65 ± 0.98	6.00	0.696
	11	0.734	0.925		5.39 ± 0.78	5.00	5.39 ± 0.99	5.00	0.657
Role specification	1	0.519	0.758	0.783	5.00 ± 0.91	5.00	5.04 ± 0.56	5.00	0.580
	5	0.442	0.777		4.39 ± 0.72	4.00	4.52 ± 0.59	5.00	0.548
	6	0.574	0.739		4.87 ± 0.92	5.00	4.83 ± 0.83	5.00	0.541
	7	0.609	0.727		5.30 ± 0.77	5.00	5.13 ± 1.01	5.00	0.834
	8	0.675	0.706		5.13 ± 0.76	5.00	5.22 ± 0.95	5.00	0.878
Relationship initiation	12	0.358	0.813	0.715	5.17 ± 0.89	5.00	4.96± 0.88	5.00	0.689
	13	0.529	0.675		5.04 ± 1.19	5.00	5.22 ± 0.74	5.00	0.563
	14	0.811	0.333		5.17 ± 0.83	5.00	5.04 ± 0.77	5.00	0.686
Total score				0.912	73.39 ± 8.62	72.00	72.96 ± 9.32	71.00	0.825*

*$ICC_{agreement}$

8.4 Discussion

The PPCI for pharmacists was found to be a valid and reliable instrument to assess the level of collaboration between doctors and pharmacists in Malaysia.

The PPCI for pharmacists had good inter-domain correlations (0.571-0.671) indicating that the three domains were measuring doctor-pharmacist professional exchanges in unison.

The collaborators significantly screened more prescriptions in a day compared to the non-collaborators. This indicates that the collaborators were more actively involved in clinical work compared to the non-collaborators. We also found that the collaborators scored slightly higher than the non-collaborators, but the differences were not significant. However, earlier study by A. J. Zillich et al. (2006) reported that the PPCI for pharmacists was able to differentiate between community pharmacists who were in collaboration with a GP, and those who were not. The small sample size of our study might be the reason why we did not detect a significant difference in scores between collaborators and non-collaborators. In fact, the minimum sample size required for subgroup analysis should be at least 50, but our subgroup analysis only had 9 collaborators and 14 non-collaborators.

The overall Cronbach alpha and the Cronbach alpha for the individual domains of the PPCI for physicians were more than 0.7, indicating good internal consistency. This finding was similar to the values reported by Doucette et al. (2005). Test-retest analysis showed that the PPCI for physicians has achieved stable reliability. All 14 items showed moderate to substantial agreement.

The PPCI for pharmacists was previously used and validated in ambulatory settings, measuring the interaction between GPs and community pharmacists (Doucette et al., 2005; Snyder et al., 2010; A. J. Zillich et al., 2006). Although our participants were hospital pharmacists, we still found that the PPCI for pharmacists was a valid and reliable measure of doctor-pharmacist CWR, suggesting that this tool can be used to measure doctor-pharmacist CWR regardless of the setting.

The strength of our study was that we conducted test-retest analysis in addition to the previous original validation. The response rate in our study was also higher when compared to A. J. Zillich et al. (2006). This could be attributed to the method of data collection; where we approached the participants personally rather than via mails or emails.

The main limitation of this study was the small sample size (n=23). Hence, we were unable to evaluate the discriminative validity of the PPCI for pharmacists. Recruiting pharmacists from multi-centers should overcome this problem.

Future studies should look at ways of correlating the PPCI for pharmacists' scores with patient outcomes. This will help determine the relationship between doctor-pharmacist collaboration with patient outcomes. It will also be useful to map the PPCI for pharmacists scores according to the doctor-pharmacist collaborative stages as proposed by Randal P. McDonough and Doucette (2001). This can be done by administering the PPCI for pharmacists to the same group of participants repeatedly over time, starting from the time they start to collaborate up to the point when they have reached the highest level of collaboration. This would be helpful in identifying at which stage of the CWR that a doctor and a pharmacist are at.

8.5 Conclusion

The PPCI for pharmacists was found to have a good internal consistency and stable test-retest reliability in determining pharmacists' views about CWR with doctors in Malaysia. However, we were not able to determine the discriminative validity of the PPCI for pharmacists due to the small sample size. Future work should be carried out to correlate PPCI for pharmacists scores to patient outcomes, and to determine the PPCI for pharmacists score that correspond to each stage of the doctor-pharmacist CWR.

CHAPTER 9: VALIDATION OF THE PHYSICIAN-PHARMACIST COLLABORATIVE INDEX FOR PHYSICIANS IN MALAYSIA

Following the validation of the PPCI for pharmacists as reported in Chapter 8, this chapter will report on the validation of the PPCI for physicians. These questionnaires were used to assess the professional exchanges between PCPs and pharmacists during the pilot testing of the 4Ps intervention (Chapter 10).

9.1 Introduction

Pharmaceutical care is the provision of drug therapy with the goal of achieving definite therapeutic outcomes towards patients' health and quality of life (Hepler & Strand, 1990). This involves identifying, addressing and preventing medication-related problems by a pharmacist (Hepler & Strand, 1990). The provision of pharmaceutical care has been found to have a positive impact on patient health outcomes in various chronic conditions such as asthma (Abdelhamid, Awad, & Gismallah, 2008), hypertension (Chisholm, Mulloy, Jagadeesan, Martin, & DiPiro, 2002), diabetes (Chung, Chua, Lai, & Chan, 2014) and heart failure (Gattis et al., 1999). It also improves patient safety outcomes such as medication appropriateness (Hanlon et al., 1996; Taylor et al., 2003), and lowers the incidence of ADEs (Schmader et al., 2004; Williams et al., 2004).

For the effective delivery of pharmaceutical care, pharmacists need to build a CWR with doctors (Doucette et al., 2005; Makowsky, Madill, Schindel, & Tsuyuki, 2013; Snyder et al., 2010). According to the generic model proposed by McDonough & Doucette in 2001, the relationship between a doctor and a pharmacist develops in stages: professional awareness (stage 0); professional recognition (stage 1); exploration and trial (stage 2); professional relationship expansion (stage 3); and commitment to a CWR (stage 4) (Randal P. McDonough & Doucette, 2001). This collaboration is driven by individual

characteristics, contextual factors and the interactions between the two healthcare professionals (R. P. McDonough & Doucette, 2003; A. J. Zillich et al., 2004).

The PPCI was developed to capture the exchange characteristics between the two professionals at any stage of the model (Alan J. Zillich et al., 2005). This instrument initially consisted of 27 items, and seven domains: collaborative care, commitment, dependence symmetry, bidirectional communication, trust, initiating behavior and conflict resolution (Alan J. Zillich et al., 2005). Following the initial validation study, the PPCI was reduced to 14 items, comprising of three domains: trustworthiness, role specification and relationship initiation (Alan J. Zillich et al., 2005). The PPCI was then designed in two versions: one for doctors and one for pharmacists (Alan J. Zillich et al., 2005; A. J. Zillich et al., 2006).

Both versions of the PPCI have been validated among primary care practitioners and community pharmacists in the United States (Alan J. Zillich et al., 2005; A. J. Zillich et al., 2006). The PPCI for physicians was found to have good internal consistency and correlated well with other measures of professional interaction and collaboration (Alan J. Zillich et al., 2005; A. J. Zillich et al., 2004). To our knowledge, the PPCI for physicians has not been validated in Malaysia. The aim of our study was to determine the validity and reliability of the PPCI for physicians in assessing the professional exchanges between doctors and pharmacists in Malaysia.

9.2 Methods

9.2.1 Design

This was a prospective validation study.

9.2.2 Setting

This study was conducted at an urban teaching hospital in Kuala Lumpur, Malaysia.

9.2.3 Duration

Data collection was conducted from June to August 2014.

9.2.4 Participants and sampling

We recruited doctors (medical officers, registrars and specialists) from any specialty who were actively involved in clinical work, and prescribed medications for their patients. Medical officers are doctors who have completed their internship, while registrars are doctors undergoing postgraduate training to become specialists. Intern doctors and doctors with less than 12 months of working experience in the hospital under study were excluded.

There were 27 pharmacists in our hospital; out of which nine were clinical pharmacists in the intensive care, infectious disease, geriatric, nephrology, hematology, respiratory, upper gastrointestinal surgery, endocrine and oncology wards. Clinical pharmacists participated in ward rounds, screened prescriptions and handled all medication-related enquiries. If doctors had any medication-related enquiries, they would liaise with their clinical pharmacists. Similarly, if a clinical pharmacist detected any problem, he/she would liaise with the doctor. Doctor-pharmacist interactions occurred approximately 2-5 times per day per pharmacist via the telephone, email or face to face. Medication-related enquiries included questions regarding drug indications, drug dosages, drug-drug interactions, adverse effects, and drug incompatibility.

The remaining 15 pharmacists worked as outpatient, inpatient, production, and store pharmacists. These pharmacists contacted doctors via telephone to clarify any medication-related enquiries at the point of dispensing or preparing medications. Doctors from wards without a clinical pharmacist called the general pharmacy telephone line when they had any medication-related enquiries. The wards that do not have a clinical pharmacist are the rehabilitation medicine, orthopaedics, psychological medicine, ophthalmology, emergency medicine and obstetrics and gynaecology wards. These calls were attended by any random non-clinical pharmacist assigned to answer the telephone for the day. In Malaysia, clinical pharmacists are not required to have postgraduate qualifications or additional specialisation. Hence, no difference exists in terms of the level of education and the years of working experience between clinical and non-clinical pharmacists.

Doctors were grouped into "collaborators" and "non-collaborators" based on the differences in their working pattern with a pharmacist. "Collaborators" were defined as doctors who worked together with a designated clinical pharmacist in their ward; while "non-collaborators" were defined as doctors who interacted with any random pharmacist over the telephone, to solve medication-related problems.

9.2.5 Sample size

Sample size was calculated based on the number of participants required to perform confirmatory factor analysis (CFA), where the participant-to-item ratio should be 5:1 (F. B. Bryant & Yarnold, 1995). Since the total number of items in the PPCI for physicians was 14, the number of doctors required was 14*5=70. Allowing for a loss to follow up of 20%, the total number of doctors required was 84. Adequate number of doctors were recruited in this study (n=116).

9.2.6 Instruments used

9.2.6.1 Demographic form

A demographic form [Appendix F1] was designed to capture individual and contextual characteristics of the doctors including age, gender, years of clinical experience, specialty, post graduate qualifications and average number of patients seen per day.

9.2.6.2 Physician-Pharmacist Collaborative Index for physicians

The original English version of the PPCI for physicians was used in this study [Appendix F2]. It consists of 14 items and three domains: trustworthiness (6 items), role specification (5 items) and relationship initiation (3 items) (Snyder et al., 2010; Alan J. Zillich et al., 2005; A. J. Zillich et al., 2004). Responses were assessed using a seven-point Likert scale from 1 (very strongly disagree) to 7 (very strongly agree) (Snyder et al., 2010; Alan J. Zillich et al., 2005; A. J. Zillich et al., 2004). A higher total score of the PPCI for physicians indicates a higher level of doctor-pharmacist collaboration (Snyder et al., 2010; Alan J. Zillich et al., 2005; A. J. Zillich et al., 2004).

9.2.7 Data collection

We first asked clinical pharmacists to suggest the names of the doctors whom they regularly collaborated with to solve medication-related problems in the ward. These doctors were then invited to participate in the study through email, as it was difficult to locate and approach them personally. In this email, a link to the web version of the PPCI for physicians was provided. Doctors were asked to complete the questionnaire based on his/her relationship with the pharmacist who suggested their names. The survey was answered anonymously as the researcher assigned a unique participant identification number for each participant. After one week, a reminder email was sent to non-respondents.

Non-collaborators were sampled conveniently by approaching them in person as these doctors can be easily sampled from any ward without a clinical pharmacist. Non-collaborators were asked to consider his/her relationship with any pharmacist whom they have interacted previously, and to respond to each item based on their interactions with this particular pharmacist.

Participants were asked to answer the PPCI for physicians at baseline and two weeks later.

9.2.8 Data analysis

IBM SPSS Amos version 21 (IBM Corp., Armonk, New York) was used to perform factor analysis, while IBM SPSS Statistics version 20 (IBM Corp., Armonk, New York) was used to analyse the remaining data. Continuous variables were presented as mean, standard deviation, median and range; whilst categorical variables were presented as frequency and percentage. Normality was assessed using the Shapiro-Wilk test (Ghasemi & Zahediasl, 2012). As data was found to be not normally distributed, Mann-Whitney U test was used to compare continuous variables, whilst chi-square test was used for categorical variables. We assessed the PPCI for physicians' validity (which consists of face and content validity, confirmatory factor analysis and discriminative validity) and reliability (internal consistency and test-retest).

9.2.8.1 Validity

(a) ***Face validity***

The face validity of the PPCI for physicians was assessed by an expert panel consisting of two pharmacists and one family medicine specialist. This involved assessing the layout, language, instructions, response format and clarity of the items in the PPCI for

physicians. In addition, a pilot study was conducted on five registrars at the teaching hospital. Participants were invited to read the questions, to evaluate verbally if the items were difficult for them to comprehend, and to recommend items for deletion or modification.

(b) ***Confirmatory factor analysis***

Each domain within the PPCI for physicians was examined separately. First the Kaiser-Meyer-Oklin (KMO) value and the correlation matrix were computed. A KMO value of >0.6 indicates adequate sample size for factor analysis (Kaiser, 1970). Individual factor loadings (L) of >0.5, average variance extracted (AVE) of >50%, and composite reliability (CR) of >0.7, indicate good structure within the domains (Hair, Tatham, Anderson, & Black, 2005). A good model of fit occurs when the following values are met: chi-square/degrees of freedom (χ^2/df) is <3; the goodness-of-fit indices (GFI), the adjusted-goodness-of-fit index (AGFI), the comparative fit index (CFI) are all >0.9; and the root mean square error approximation index (RMSEA) is <0.08 (Browne & Cudeck, 1992). Modification indices were used to check for cross-loadings between items. The model was adjusted according to the largest modification index value, one change at a time until no further modification was suggested by the analysis. All the individual domains were assessed for normality using the critical ratio for Kurtosis. A value of >5 indicates that the data distribution is not normal. Hence, bootstrap analysis was performed with 1000 samples for each domain. A Bollen-Stine p-value of >0.05 indicates sufficient cross validation and a good model of fit.

Finally, the correlation between the mean scores of the domains was determined using the Spearman's rho; where values of 0.10-0.29 were defined as weak correlation, 0.30-0.49 were moderate correlation and >0.50 were strong correlation (J. Cohen, 1988).

(c) ***Discriminative validity***

We hypothesised that collaborators would have higher scores in the PPCI for physicians compared to non-collaborators, due to the fact that collaborators worked in closer proximity with pharmacists and had more frequent professional interactions with them, than non-collaborators. The scores between the two groups were compared using the Mann-Whitney U test.

9.2.8.2 Reliability

(a) ***Internal consistency***

Internal consistency was calculated for the overall PPCI for physicians and for each domain. Cronbach's alpha values of 0.70-0.79 were considered fair, 0.8-0.89 were good, and >0.90 suggested redundancy in some items (Terwee et al., 2007).

Corrected item-total correlations were then used to identify items which did not agree well with other items in the questionnaire. Corrected item-total correlation values should exceed 0.3 to be considered as acceptable (Tabachnick & Fidell, 2007). The effect of removing a single item on the Cronbach's alpha was also determined.

(b) ***Test-retest reliability***

Test-retest reliability is the extent to which the repeated scores from the same participant remains unchanged over time (Lidwine B Mokkink et al., 2010). The weighted kappa was used to assess the individual items (as these responses were of a Likert scale) (J. Cohen, 1968), whilst the inter-class correlation coefficient ($ICC_{agreement}$) was used to assess the total score at test-retest (Terwee et al., 2007). A weighted kappa or $ICC_{agreement}$ value of 0.7 was considered acceptable (Terwee et al., 2007).

9.2.9 Ethics

Ethics approval was obtained from the UMMC Medical Ethics Committee (approval No: 20144-150) [Appendix E5]. Participants were provided with participant information sheet [Appendix E3], prior to obtaining their written consent [Appendix E4].

9.3 Results

A total of 116 doctors (18 collaborators and 98 non-collaborators) were recruited. Nine clinical pharmacists were approached, out of which seven suggested 23 doctors as collaborators. We sent invitations to these collaborators to participate in our study via email, out of which 18 collaborators responded (response rate =78%). Ninety eight non-collaborators were approached personally, and all of them agreed to participate (response rate=100%).

The demographic characteristics of the participants are presented in Table 9.1. Collaborators were significantly older, and were clinically more experienced than non-collaborators. All collaborators were specialists, out of which internal medicine specialists formed the majority (66.7%). Meanwhile, the majority of non-collaborators were registrars (73.5%) from surgery (45.9%), anesthesiology (21.4) and rehabilitation medicine (12.2%).

Table 9.1: Participant demographic profile grouped according to collaborators and non-collaborators

Characteristics	Collaborators n (%) (n=18)	Non-collaborators n (%) (n=98)	p-value
Mean age ± SD {Median} (range) [years]	39.2 ± 5.0 {39.0} (32-48)	34.0 ± 4.3 {33.0} (27-51)	<0.001[a]*
Male	10 (55.6)	58 (59.2)	0.774[b]
Mean clinical experience ± SD {Median} (range) [years]	14.3 ± 4.6 {14.0} (7-22)	9.0 ± 3.9 {8.0} (3-26)	<0.001[a]*
Designation			<0.001 [b]*
Medical officer	0	5 (5.1)	
Registrar	0	72 (73.5)	
Specialist	18 (100.0)	21 (21.4)	
Department			<0.001 [b]*
Medical	12 (66.7)	4 (4.1)	
Anaesthesiology	2 (11.1)	21 (21.4)	
Surgery	2 (11.1)	45 (45.9)	
Paediatrics	1 (5.6)	2 (2.0)	
Clinical oncology	1 (5.6)	0	
Rehabilitation medicine	0	12 (12.2)	
Orthopaedics surgery	0	5 (5.1)	
Psychological medicine	0	5 (5.1)	
Ophthalmology	0	2 (2.0)	
Emergency medicine	0	1 (1.0)	
Obstetrics & gynaecology	0	1 (1.0)	
Patient load/day			0.588 [b]
<20	5 (27.8)	44 (44.9)	
21-40	10 (55.6)	41 (41.8)	
41-60	3 (16.7)	10 (10.2)	
61-80	0	2 (2.0)	
81-100	0	1 (1.0)	

[a]Mann-Whitney U test; [b]Pearson's chi-square test; *statistically significant at p<0.05

9.3.1 Validity

9.3.1.1 Face validity

All 5 participants from the pilot study did not face any difficulties in understanding and completing the questionnaire. Hence, no changes were made to the original instrument.

9.3.1.2 Confirmatory factor analysis

CFA found that the PPCI for physicians was a 3 factor-model, as it met all the criteria of the goodness of fit indices [Table 9.2].

Table 9.2: The goodness of fit indices of the Physician-Pharmacist Collaborative Index for physicians

	Desired value	Domains		
		Trustworthiness	Role specification	Relationship initiation
KMO	>0.6	0.886	0.792	0.698
Min L	>0.5	0.755	0.664	0.804
Max L		0.849	0.872	0.962
AVE	>0.5	0.665	0.545	0.768
CR	>0.7	0.922	0.856	0.908
χ^2/df	<3	1.594	1.055	2.501
GFI	>0.9	0.971	0.989	0.986
AGFI	>0.9	0.914	0.946	0.915
CFI	>0.9	0.992	0.999	0.993
RMSEA	<0.08	0.072	0.022	0.114*
c.r for Kurtosis	<5	28.154	6.342	3.853
Bollen-Stine p-value	>0.05	0.302	0.545	0.071

KMO=Kaiser-Meyer-Oklin; χ^2/df=chi-square/degrees of freedom; GFI=goodness-of-fit indices; AGFI=adjusted-goodness-of-fit index; CFI=comparative fit index; RMSEA=root mean square error approximation index; c.r for Kurtosis=critical ratio for Kurtosis; L=individual factor loadings; AVE=average variance extracted; CR=composite reliability; *No further modification was suggested by the factor analysis

The correlation of the mean domain scores ranged from 0.711-0.787 [Table 9.3].

Table 9.3: Correlation of the mean scores of the domains in the Physician-Pharmacist Collaborative Index for physicians

Construct	Trustworthiness	Role specification	Relationship initiation
Trustworthiness	1.000	0.787	0.711
Role specification	0.787	1.000	0.711
Relationship initiation	0.711	0.711	1.000

9.3.1.3 Discriminative validity

Collaborators had significantly higher PPCI for physicians scores compared to non-collaborators in all domains as well as the total score [Table 9.4].

Table 9.4: The Physician-Pharmacist Collaborative Index scores of collaborators and non-collaborators

Domains	Range	Collaborators (n=18)		Non-collaborators (n=98)		Mann Whitney U test	
		Median	Mean ± SD	Median	Mean ± SD	z score	p-value
Trustworthiness	6-42	36.0	36.4 ± 4.3	31.0	31.0± 5.2	- 3.886	<0.001*
Role specification	5-35	28.5	28.4 ± 4.6	24.5	23.9 ± 4.8	-3.334	0.001*
Relationship initiation	3-21	16.5	16.5 ± 3.0	15.0	14.4± 3.2	-2.796	0.005*
Total score	14-98	81.5	81.4 ± 10.1	70.0	69.3 ± 12.1	-3.697	<0.001*

*Statistically significant at $p<0.05$

9.3.2 Reliability

9.3.2.1 Internal consistency

The Cronbach alpha for the overall PPCI for physicians was 0.949 while the Cronbach alpha for the individual domains ranged from 0.877-0.926. Corrected item total correlation values were all >0.3 [Table 9.5].

9.3.2.2 Test-retest reliability

Weighted kappa values at test-retest ranged from 0.553-0.752 [Table 9.5]. The $ICC_{agreement}$ of the total PPCI for physicians score was 0.793 at test-retest.

Table 9.5: Internal consistency and test-retest reliability of the Physician-Pharmacist Collaborative Index for physicians

Domain	Item no.	Cronbach alpha	Corrected item-total correlation	Cronbach alpha if item deleted	Test (n=116)		Re-test (n=112)		Kappa with quadratic weighting
					Mean ± SD	Median	Mean ± SD	Median	
Trustworthiness	2	0.926	0.774	0.914	5.22 ± 0.99	5.00	5.28 ± 1.00	5.00	0.631
	3		0.764	0.915	5.33 ± 1.08	5.00	5.14 ± 1.10	5.00	0.579
	4		0.756	0.916	5.33 ± 1.01	5.00	5.09 ± 1.11	5.00	0.611
	9		0.755	0.917	5.34 ± 1.14	5.00	5.33 ± 1.11	5.00	0.672
	10		0.865	0.902	5.34 ± 1.00	5.00	5.34 ± 1.02	5.00	0.752
	11		0.812	0.909	5.29 ± 1.16	5.00	5.24 ± 1.15	5.00	0.634
Role specification	1	0.877	0.662	0.863	4.97 ± 1.28	5.00	5.10 ± 1.12	5.00	0.591
	5		0.675	0.859	4.63 ± 1.23	5.00	4.75 ± 1.23	5.00	0.612
	6		0.736	0.844	4.94 ± 1.27	5.00	5.04 ± 1.10	5.00	0.553
	7		0.745	0.842	4.98 ± 1.28	5.00	5.03 ± 1.20	5.00	0.648
	8		0.732	0.848	5.06 ± 1.09	5.00	5.04 ± 1.09	5.00	0.656
Relationship initiation	12	0.897	0.778	0.874	4.50 ± 1.27	5.00	4.51± 1.22	4.50	0.689
	13		0.750	0.895	5.27 ± 1.09	5.00	5.17 ± 1.18	5.00	0.642
	14		0.876	0.783	4.98 ± 1.20	5.00	4.86 ± 1.15	5.00	0.676

*Statistically significant at $p<0.05$

9.4 Discussion

The PPCI for physicians was a valid and reliable measure in determining doctors' views about CWR with pharmacists, in Malaysia.

The CFA showed that the PPCI for physicians was a 3 factor-model, as it met all the goodness of fit indices. This finding is in agreement with the 3-factor model proposed by Alan J. Zillich et al. (2005) in the original validation study. However, the RMSEA value in the relationship initiation domain was not within the desired range of <0.08. This could be due to the small number of items within this domain (3 items). In addition, the PPCI for physicians had good inter-domain correlations (0.711-0.787); which were slightly higher than the original study (0.52-0.79) (Alan J. Zillich et al., 2005).

The PPCI for physicians had good psychometric properties. The overall Cronbach alpha and the Cronbach alpha for the individual domains of the PPCI for physicians were >0.8, indicating good internal consistency. Our findings concurred with the values reported by Alan J. Zillich et al. (2005). Test-retest analysis showed that the PPCI for physicians has achieved stable reliability. All 14 items showed moderate to substantial agreement.

The PPCI for physicians was able to discriminate the different levels of doctor-pharmacist collaboration between collaborators and non-collaborators. This finding was as expected as collaborators would have more opportunity to establish a CWR as they had more frequent personalised professional interactions with pharmacists than non-collaborators (Randal P. McDonough & Doucette, 2001). Differences in working environment could also contribute to the differences in scores between collaborators and non-collaborators. Non-collaborators (such as doctors from surgery, anesthesiology and

rehabilitation medicine) are expected to prescribe less medicines compared to internal medicine doctors. They would therefore have a lesser need to contact the pharmacist with regards to a drug related enquiry. Collaborators were clinically experienced more than non-collaborators, and this could be another factor contributing to the differences in scores between the two groups of participants.

The PPCI for physicians was initially validated in an ambulatory setting, measuring the interaction between primary care physicians and community pharmacists (Alan J. Zillich et al., 2005). We conducted this study in a hospital setting and found that the PPCI for physicians was a valid and reliable measure of doctor-pharmacist CWR, suggesting that this tool can be used to measure doctor-pharmacist CWR regardless of the setting.

Further work can be conducted to map the PPCI for physicians' scores according to the doctor-pharmacist collaborative stages as proposed by Randal P. McDonough and Doucette (2001). This can be performed by administering the PPCI for physicians to the same group of participants over time, starting from the time they start to collaborate, up to the point when they have reached the highest level of collaboration. This would help researchers and practitioners to identify the CWR stage of a doctor-pharmacist pair based on their respective PPCI for physicians score.

The strength of our study was that we conducted test-retest analysis and discriminative validity in addition to the previous original validation (Alan J. Zillich et al., 2005). We also achieved good response rates in this study, which were higher than the original validation study (34%) (Alan J. Zillich et al., 2005). There was no missing data in our study.

One limitation of our study was the small number of collaborators recruited (n=18). We were not able to recruit any more collaborators, as we had only nine clinical pharmacists in our setting. Despite this, the PPCI for physicians was able to discriminate between collaborators and non-collaborators. Another limitation of our study was that collaborators were identified by the clinical pharmacists. This method of recruitment may be a potential for bias as "bad collaborating doctors" would not have been identified. Non-collaborators were sampled conveniently and this could be regarded as another potential for bias as doctors who had good relationship with pharmacists would be more eager to join the study. In addition, we did not capture the duration of which the doctors and clinical pharmacists have been working together. Non-collaborators were also significantly more junior compared to the collaborators. These two factors could have affected the results, as doctors and clinical pharmacists who have been working together for a longer duration might have achieved a higher level of collaboration (Randal P. McDonough & Doucette, 2001).

9.5 Conclusion

The PPCI for physicians was a valid and reliable measure in determining doctors' views about CWR with pharmacists, in Malaysia. Our findings indicate that doctors who regularly collaborated with a clinical pharmacist assigned to their ward have a higher score than doctors who only collaborated with any random pharmacist over the telephone.

CHAPTER 10: PILOT TESTING OF THE PHYSICIAN-PHARMACIST PARTNERSHIP FOR PATIENT SAFETY INTERVENTION

Following the development of a complex intervention, the UK MRC framework recommends that the intervention undergoes pilot testing. Besides ensuring that the intervention can be delivered as intended, a pilot test can be used to preliminary measure the effectiveness of an intervention. Based on this, we pilot tested the 4Ps with two main aims in mind: (a) to evaluate the effectiveness of the 4Ps intervention in improving doctor-pharmacist CWR (Chapter 10), and (b) to determine the effectiveness of the 4Ps intervention in the identification and resolution of DRPs (Chapter 11).

Each of these aims will be reported in separate chapters as described above. This pilot test is different from the acceptability and feasibility tests reported earlier (Chapter 7, section 7.2.4.5 page 177, and section 7.2.4.8 page 187). The acceptability and feasibility tests were conducted as part of the development process to test out the 4Ps, and to identify any issues with the content and the delivery of the intervention. No outcomes were measured during the acceptability and feasibility tests. This pilot test however will provide some preliminary evidence for the effectiveness of the 4Ps intervention in improving doctor-pharmacist CWR, and resolution of DRPs.

10.1 Introduction

Patients with chronic diseases are often prescribed with complex medication regimen. This puts them at a higher risk for ADEs, thus compromising their safety (Bourgeois et al., 2010; D. C. Chan et al., 2012). Research has shown that pharmacists working together with doctors as part of a multidisciplinary team improves patients' health outcomes such as hypertension (Carter et al., 2009), heart failure (Gattis et al., 1999), and cholesterol reduction (Tsuyuki et al., 2002). In addition, interprofessional collaboration between

doctors and pharmacists have been promising in improving patients' medication safety by improving medication appropriateness (Allard, Hebert, Rioux, Asselin, & Voyer, 2001; Blakey & Hixson-Wallace, 2000; Hanlon et al., 1996; Schmader et al., 2004; Taylor et al., 2003), reducing the occurrence of ADEs (Allard et al., 2001; Blakey & Hixson-Wallace, 2000; Chisholm-Burns et al., 2010; Schmader et al., 2004) and reducing health care utilisation due to medication-related events (Roughead et al., 2005).

Based on this, the 4Ps intervention was developed to improve medication safety for patients with chronic diseases in primary care (Chapter 7, page 163). As part of its development, the 4Ps has been tested for feasibility and acceptability among the stakeholders (Chapter 7, section 7.2.4.5 page 177, and section 7.2.4.8 page 187). It is now necessary to pilot test this intervention to determine its effectiveness in improving doctor-pharmacist CWR, and in the identification and resolution of DRPs. The aim of this chapter was to report the effectiveness of the 4Ps intervention in improving doctor-pharmacist CWR.

10.2 Methods

10.2.1 Design

This pilot study used mixed methods; both quantitative and qualitative outcomes were obtained. Quantitative data alone was not sufficiently powered to determine the effect of the 4Ps intervention on doctor-pharmacist CWR due to the small number of participants recruited. However, qualitative data collected provided a description of the doctor-pharmacist professional interactions, and was useful in complementing the quantitative findings.

10.2.2 Setting

This study was conducted at the family clinic of the UMMC. The setting has been described previously in Chapter 3, section 3.2.2, page 75.

10.2.3 Duration

This study was conducted from November to December 2014, over a period of three consecutive weeks on Mondays, Wednesdays, Thursdays and Fridays. The family clinic does not attend to follow up patients on Tuesdays.

The initial plan was to conduct the pilot test for four weeks. However, this was not possible as during December, the majority of the PCPs and pharmacists were away on annual leave. It was difficult to get them to commit to the study for four consecutive weeks.

10.2.4 Participants and sampling

Purposive sampling was applied to identify four PCPs: two year 3 clinical masters candidates, one service medical officer and one family medicine specialist. The purpose of selecting PCPs of different designations was to determine the impact of individual participants' characteristics (training, qualification, experience, length of service and familiarity with the system) on the development of CWR between doctors and pharmacists in this study (Randal P. McDonough & Doucette, 2001).

Four most senior outpatient pharmacists were purposely selected as junior pharmacists may lack the experience and training to deliver high quality pharmaceutical care to patients in this study. This might impact on the development of CWR with the PCPs (Randal P. McDonough & Doucette, 2001).

The researcher approached selected PCPs and pharmacists in person and explained the study's aim and procedure, before inviting them to participate. All four PCPs and four pharmacists approached agreed to participate in the study. The PCPs and pharmacists were asked to select their preferred days (Mondays, Wednesdays, Thursdays or Fridays) that they would like to be involved in the study. Based on this, the PCPs and pharmacists were grouped into four PCP-pharmacist pairs [Table 10.1].

Table 10.1: Pairing of the primary care physicians and pharmacists for pilot test

Day	Pair	Pairing
Monday	1	PCP 1
		Pharmacist 1
Wednesday	2	PCP 2
		Pharmacist 2
Thursday	3	PCP 3
		Pharmacist 3
Friday	4	PCP 4
		Pharmacist 4

The primary care clinic team leader of the month was informed of the four PCPs' participation in the study. The team leader was asked to excuse the study PCPs from attending to walk-in patients at the family clinic from 9am-1pm on the respective dates, and to allocate two rooms at the family clinic (one consultation room for the PCP, and another adjacent room for the pharmacist) to be used for the purpose of this study. The consultation room was used for PCP-pharmacist discussion and PCP-patient consultation, while patient assessment by the pharmacist and medication dispensing were performed at the other room.

10.2.5 The intervention

The steps involved in the delivery of the 4Ps intervention are summarised in Figure 10.1.

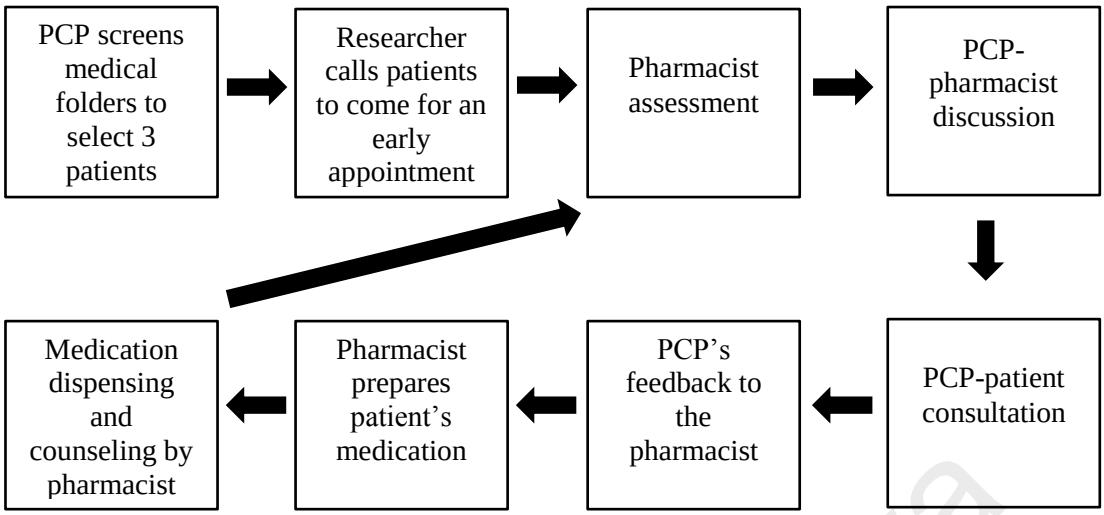


Figure 10.1: The Physician-Pharmacist Partnership for Patient Safety intervention

10.2.5.1 Pharmacists briefing and training

One week prior to the pilot study, the researcher briefed all four pharmacists about the 4Ps. The participants were provided with the 4Ps pharmacist guide [Appendix D13] and were briefed on their roles in the 4Ps. This included their roles in the provision of pharmaceutical care to patients, and their roles in developing a CWR with their respective PCP. The researcher provided patient case examples from previous acceptability and feasibility tests (to illustrate the pharmacists' role in identifying DRPs), as well as examples of good quality recommendations. The pharmacists were also taught how to complete the patient assessment form while delivering the 4Ps based on an example [Appendix G1]. At the end of the two-hour session, a pharmacist representative was selected to introduce the pharmacists' role in the 4Ps to the PCPs.

10.2.5.2 Primary care physicians and pharmacists briefing

This two-hour long briefing session was conducted two days after the pharmacists' briefing. The PCPs and pharmacists were first provided with participant information sheets [Appendix D1 and D2], following which written informed consent was obtained

[Appendix D3]. They were then required to complete a demographic information form [Appendix G2 and G3]. The PCPs were also provided with the 4Ps PCP guide [Appendix D12].

The PCP-pharmacist pairs were introduced to each other, and provided with an overview of the 4Ps. This was followed by the introduction of pharmacists' services offered as part of the 4Ps intervention to the PCPs by a pharmacist representative. The researcher then introduced the PCP's role in supporting the pharmacists' role in providing pharmaceutical care, and developing a CWR with the pharmacist.

10.2.5.3 Patient selection

Patients with chronic diseases who had a follow up appointment at the family clinic were eligible to participate in this study. PCPs selected patients by reviewing the medical folders of their patients who were due for appointment with them the coming week on the allocated days. This was done approximately one week before the intervention on a Tuesday afternoon. Each PCP selected a maximum of three patients based on the predetermined patient selection criteria [Appendix D4] (described in Chapter 7, section 7.2.4.5(e)i, page 179). The PCP completed this checklist and clipped it to the patient's medical folders for the pharmacist's attention.

10.2.5.4 Rescheduling of patients' appointment

The researcher called the selected patients to reschedule their appointment with the PCP from 2pm to 9am (on the same day). Patients were informed that on the day of their appointment, they would be seen by a pharmacist, prior to their doctor's appointment. Patients were told that this was part of a research study, and that the doctor would like

him/her to participate. If the patient agreed to participate, the patient was requested to bring all his/her medications from home so that it can be reviewed by the pharmacist.

10.2.5.5 Patient assessment by the pharmacist for drug related problem

On the day of the appointment, the researcher provided patients with a patient information sheet [Appendix D7 and D8], obtained written informed consent [Appendix D9 and D10], and completed the patient's demographic information form [Appendix G4 and G5]. Patients were then directed to the pharmacist room at the family clinic allocated for the study. Patients scheduled for the particular day were seen by the pharmacist on a first-come-first-serve basis. For each patient, the pharmacist obtained relevant demographic details, medical and medication history. Based on the information obtained, medical records and patient interviews, the pharmacist assessed the patient for any DRP and made recommendations to address each DRP identified. This was done according to the steps outlined in the pharmacist guide provided [Appendix D13], and the process was documented in the patient assessment form v2 [Appendix D11].

10.2.5.6 Primary care physician-pharmacist discussion

Once the pharmacist had finished seeing the first patient, he/she then met with the PCP for a discussion. The pharmacist presented the patient's case, followed by the DRP assessment findings and recommendations. The PCP and pharmacist had a discussion to agree on a management plan for the patient. This was documented on the patient assessment form v2 by the pharmacist. Once finished, the pharmacist returned to the treatment room to see the next patient, while the PCP saw the first patient.

10.2.5.7 Primary care physician-patient consultation

Following the usual PCP-patient consultation, the PCP decided on a suitable management plan for the patient. This was based on the discussion with the pharmacist earlier, and his/her clinical judgment following consultation with the patient. This was documented in the patient's medical folders.

10.2.5.8 Primary care physician's feedback to pharmacist

The PCP updated the pharmacist on the patient's latest medication plan, and conveyed any message to the pharmacist to be reinforced while dispensing medications to the patient. This process was documented by the pharmacist on the patient assessment form.

10.2.5.9 Medication dispensing and counselling by pharmacist

The patients' medications were dispensed by the pharmacist at the treatment room. As PCPs prescribed electronically, the prescriptions were electronically transmitted to the pharmacy and prepared by the pharmacy staff in the outpatient pharmacy. Once ready, the pharmacist went down to collect the medications from the pharmacy, and dispensed it to the patients at the treatment room. The pharmacist then counselled patients on their medications, and reinforced any instructions given by the PCP. This process was also documented in the patient assessment form.

10.2.6 Outcome measures

10.2.6.1 Primary care physician-pharmacist professional exchanges

The professional exchanges between PCP-pharmacist pairs was determined at week 1, 2 and 3 using the validated PPCI for physicians [Appendix F2], and for pharmacists [Appendix E2].

10.2.6.2 Primary care physician-pharmacist collaborative working relationship

The impact of 4Ps on PCP-pharmacist CWR and patient care was explored qualitatively through semi-structured IDIs with each participant at week 1 and week 3.

10.2.7 Instruments used

10.2.7.1 Demographic questionnaire

Demographic questionnaires [Appendix G2 and G3] were designed to capture individual characteristics of the PCPs and pharmacists, including age, gender, years of clinical experience, designation and postgraduate qualifications.

10.2.7.2 Physician-Pharmacist Collaborative Index

The validated original English version of the PPCI for physicians and PPCI for pharmacists were used in this study (Chapter 8 and 9).

10.2.7.3 Topic guide

(a) ***Topic guides for primary care physicians***

Two topic guides were developed for the PCPs; one for IDI at week 1 [Appendix G6] and one for IDI at week 3 [Appendix G7]. These were developed based on the CWR model [Figure 10.2] and the PPCI for physicians (R. P. McDonough & Doucette, 2003; Alan J. Zillich et al., 2005). Each of the drivers of the doctor-pharmacist CWR (individual, contextual and exchange characteristics) were included in the topic guides. For example, the CWR model suggest that co-location of doctors and pharmacists (context characteristics) facilitates the development of CWR between them. This was explored in the topic guide using open-ended questions: What is your comment about the arrangement of having the pharmacist nearby to your room? How does this affect your interaction with the pharmacist? Similarly, items in the PPCI for physicians were further

explored qualitatively in the topic guides using open-ended questions. For example, item 10 of the PPCI for physicians, "I trust this pharmacist's drug expertise" were explored in the topic guide with a series of questions: Do you trust this pharmacist? Why or why not? If yes, how was this trust established? How can this trust maintained?

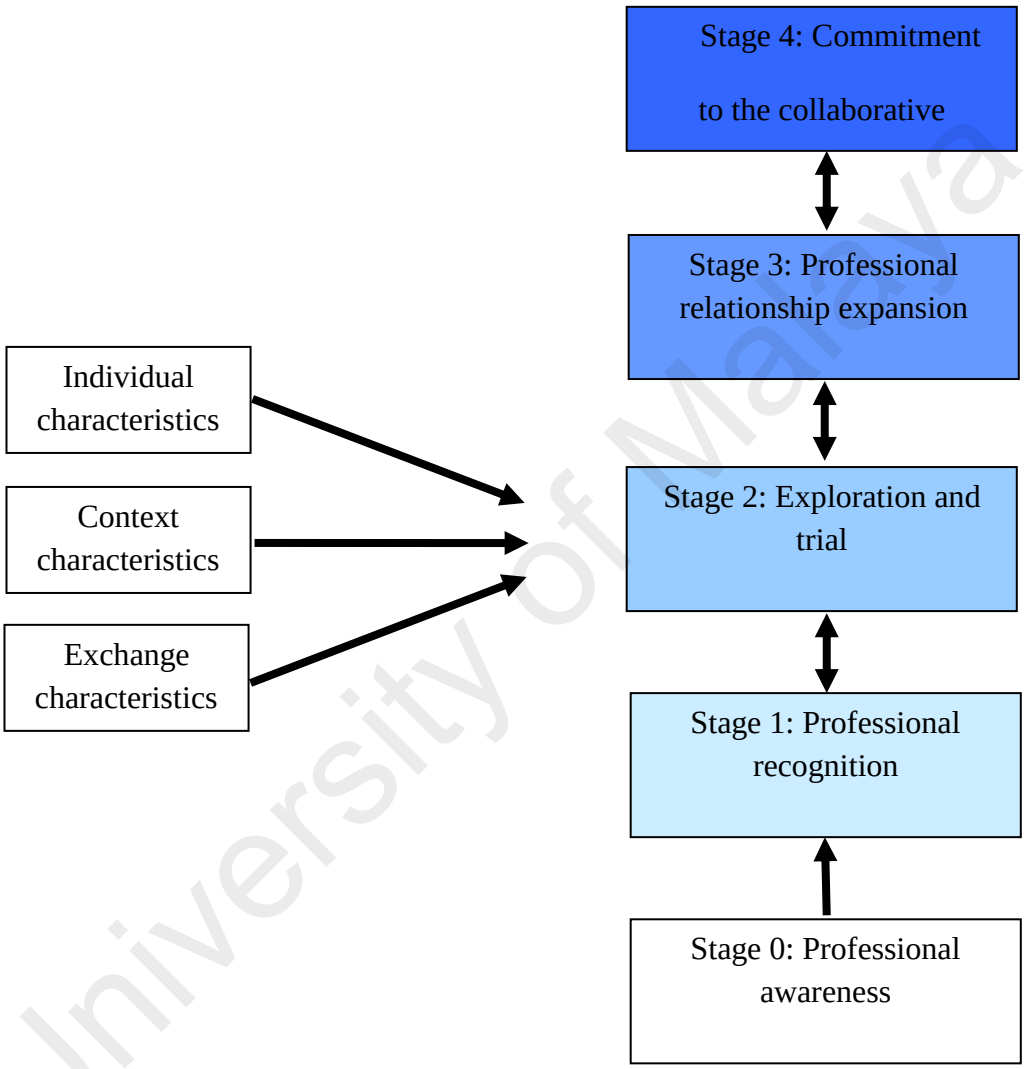


Figure 10.2: Staged approach to developing the physician-pharmacist collaborative working relationship (Randal P. McDonough & Doucette, 2001)

(b) ***Topic guides for pharmacists***

Two topic guides were developed for the pharmacists; one for IDI at week 1 [Appendix G8] and one for IDI at week 3 [Appendix G9]. The CWR model [Figure 10.2] and the PPCI for pharmacists (R. P. McDonough & Doucette, 2003; A. J. Zillich et al., 2006)

were used to develop the topic guides, in a similar manner to the topic guides for PCPs described above.

10.2.8 Data collection

10.2.8.1 Primary care physician-pharmacist professional exchanges

The PPCI for physicians, and for pharmacists were administered to participants individually at weeks 1, 2 and 3, after each session of the 4Ps. The PPCI was administered consecutively so that the development of CWR between PCPs and pharmacists can be monitored closely. Participants were asked to consider their interaction with their respective PCP/pharmacist pair during the delivery of the 4Ps when completing the PPCI.

10.2.8.2 Primary care physician-pharmacist collaborative working relationship

Semi structured IDIs were conducted at week 1 and week 3 with the PCP and pharmacist individually and separately to explore their opinion and experiences in starting a CWR. Participants were assured that anonymity will be maintained throughout reporting. The researcher (RS) asked open-ended questions and prompted them when important issues were not mentioned. All FGDs were conducted in English, audio-recorded and transcribed verbatim. Checked transcripts were used as data for analysis. RS documented relevant impressions and thoughts after each IDI.

10.2.9 Data analysis

10.2.9.1 Quantitative data

The PPCI scores of participants were reported according to individual dyads instead of combined data due to the small sample size. For each participant, the total score and the total for each domain of the PPCI at week 1, 2 and 3 were calculated. The values were converted to percentage to allow direct comparison between domains and between pairs.

Then, the scores were plotted pairwise, using line graphs to show the score change over three weeks.

10.2.9.2 Qualitative data

Thematic analysis was used to analyse the qualitative data, which was managed using a computer-assisted qualitative data analysis software Nvivo10 (QSR International Pty Ltd, Doncaster, Victoria, Australia). The 16 interview transcripts were grouped into 4 groups according to the PCP-pharmacist pairs. Data was analysed inductively starting with the first transcript, of the first pair. RS familiarised herself with the data by reading the first transcript to identify and index the themes (Pope et al., 2000). All data relevant to each theme were identified and examined through constant comparison (Pope et al., 2000). This process was repeated for the remaining three transcripts from the first pair. These themes obtained from the first four transcripts of Pair 1 were then further refined and reduced in number by grouping them into larger categories (Pope et al., 2000). RS used this coding framework to code the remaining transcripts from Pair 2, 3 and 4. New themes that emerged were added to the list.

10.2.10 Ethics approval

Ethics approval was obtained from the UMMC Medical Ethics Committee prior to the commencement of this study (Ref. No. 890.104).

10.3 Results

Demographic characteristics of the PCPs and pharmacists participated in this study are presented in Table 10.2. The PCPs' age ranged from 30-58 years old with 7-31 years of clinical experiences. Meanwhile, the pharmacists were younger, aged between 26-31 years old, with 4-7 years of working experience.

Table 10.2: Primary care physicians' and pharmacists' demographic profile

Pair		Age	Gender	Years of clinical experience	Designation
1	PCP 1	58	F	31	Service medical officer
	Pharmacist 1	31	F	5	Outpatient pharmacist
2	PCP 2	30	F	7	Clinical masters candidate
	Pharmacist 2	30	M	6	Outpatient pharmacist
3	PCP 3	35	F	8	Clinical masters candidate
	Pharmacist 3	26	F	4	Outpatient pharmacist
4	PCP 4	32	M	8	Family medicine specialist
	Pharmacist 4	29	F	7	Outpatient pharmacist

*Service medical officers, clinical masters candidates and family medicine specialists are doctors working at the primary care clinic, while the outpatient pharmacists work at the outpatient pharmacy.

10.3.1 Primary care physician-pharmacist professional exchanges

The PPCI scores of PCP 1 and pharmacist 1 are presented in Figure 10.3. The PPCI scores of both PCP 1 and pharmacist 1 showed an increasing trend over a three week period. Generally, pharmacist 1 scored higher than PCP 1 in all the individual domains, as well as the total score of the PPCI.

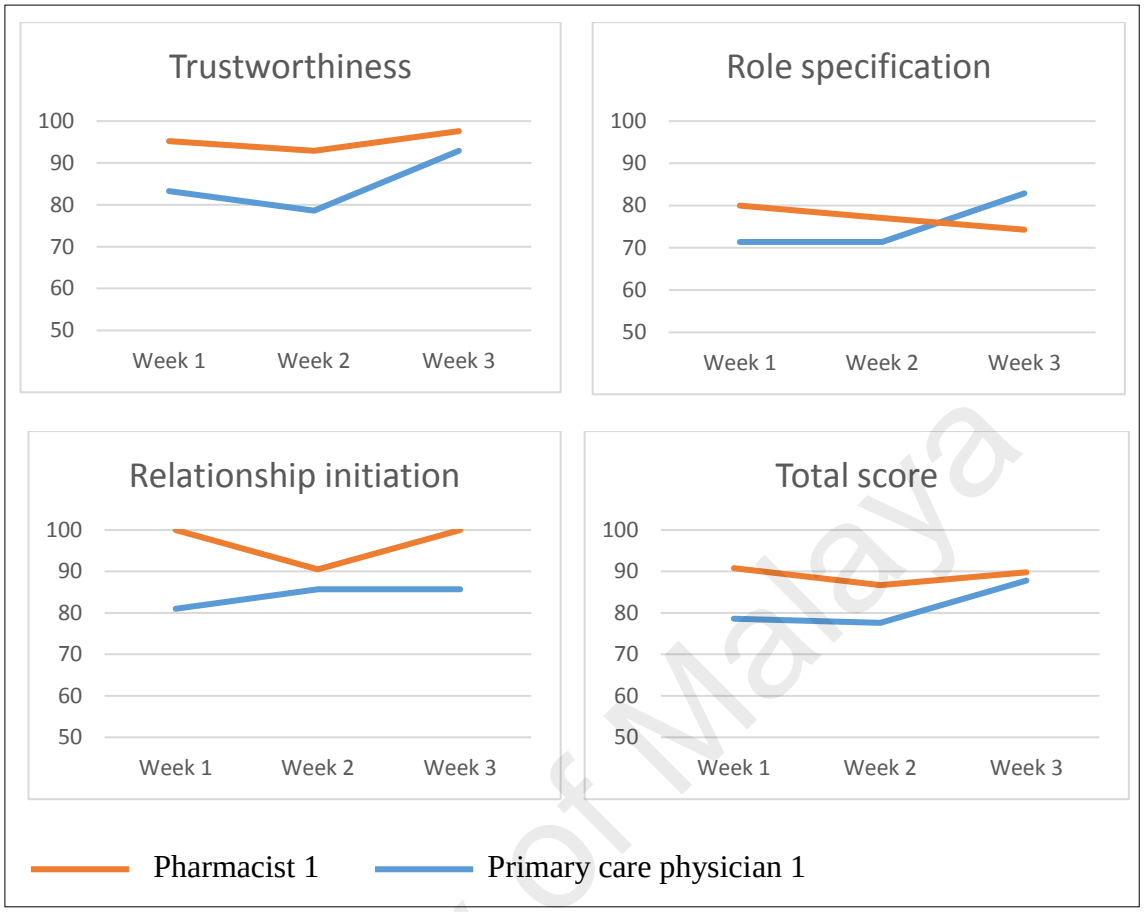


Figure 10.3: Physician-Pharmacist Collaborative Index scores of Pair 1 over three weeks

PPCI scores of pair 2 are presented in Figure 10.4. PCP 2 gave perfect scores for all domains of the PPCI, for all three weeks. This "ceiling effect" does not allow us to further interpret Pair 2's CWR from the PCP's perspective. The PPCI scores of pharmacist 2 however showed a general increasing trend over the period of three weeks for all three domains, and was lower than the PCP 2's scores.

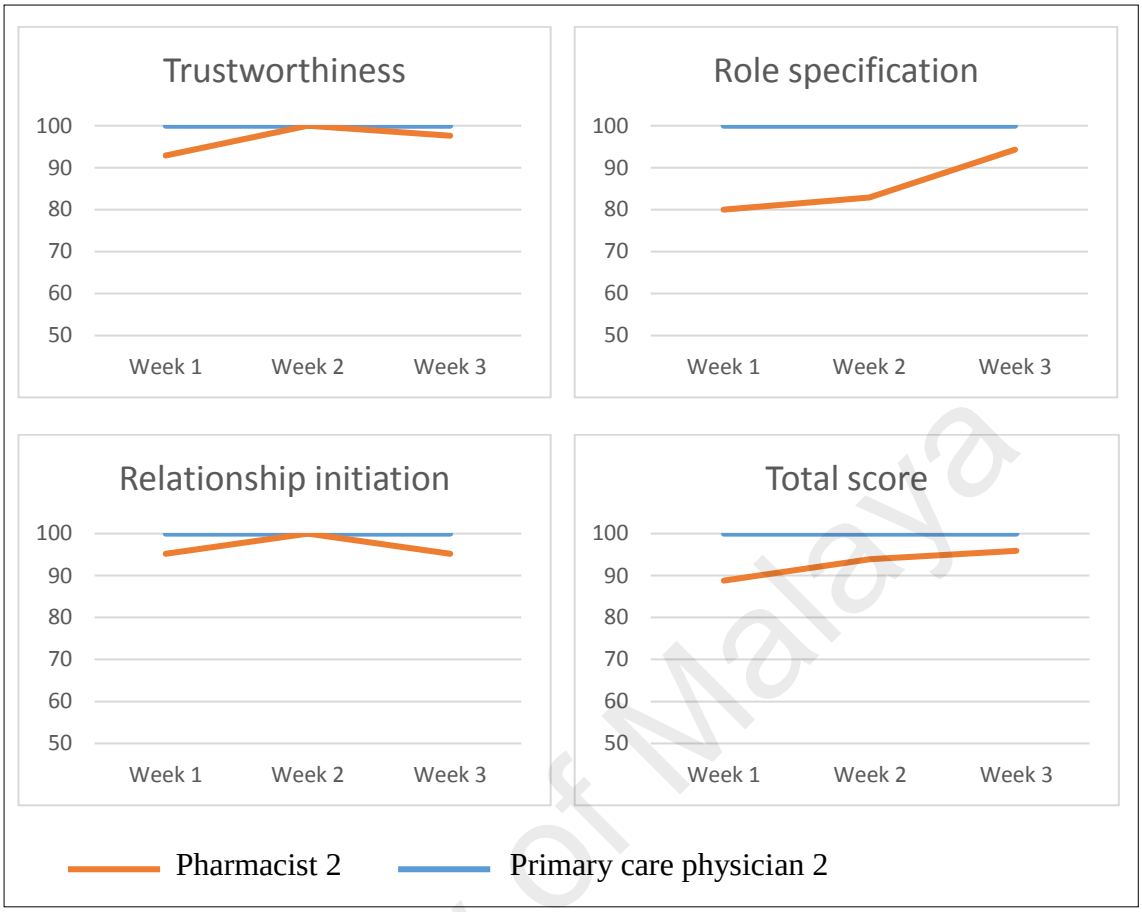


Figure 10.4: Physician-Pharmacist Collaborative Index scores of Pair 2 over three weeks

PPCI scores of Pair 3 [Figure 10.5] showed an increasing trend for all domains over the period of three weeks, with PCP 3 scoring higher than Pharmacist 3.

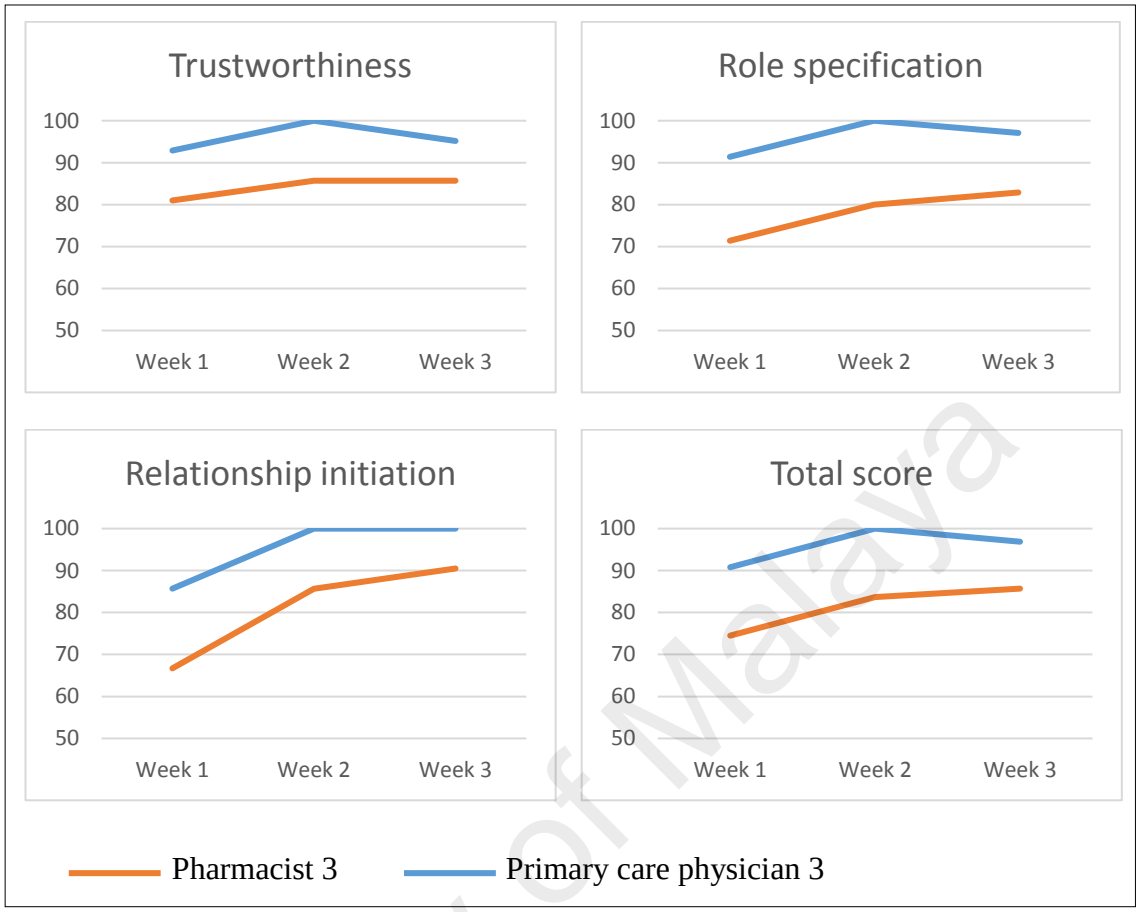


Figure 10.5: Physician-Pharmacist Collaborative Index scores of Pair 3 over three weeks

As for Pair 4, although initially the pharmacist scored higher than the PCP in role specification and relationship initiation domains, this was reversed by the end of three weeks whereby PCP 4 scored higher in all three domains compared to Pharmacist 4 [Figure 10.6]. Generally, the PPCI scores of Pair 4 increased from week 1 to week 3.

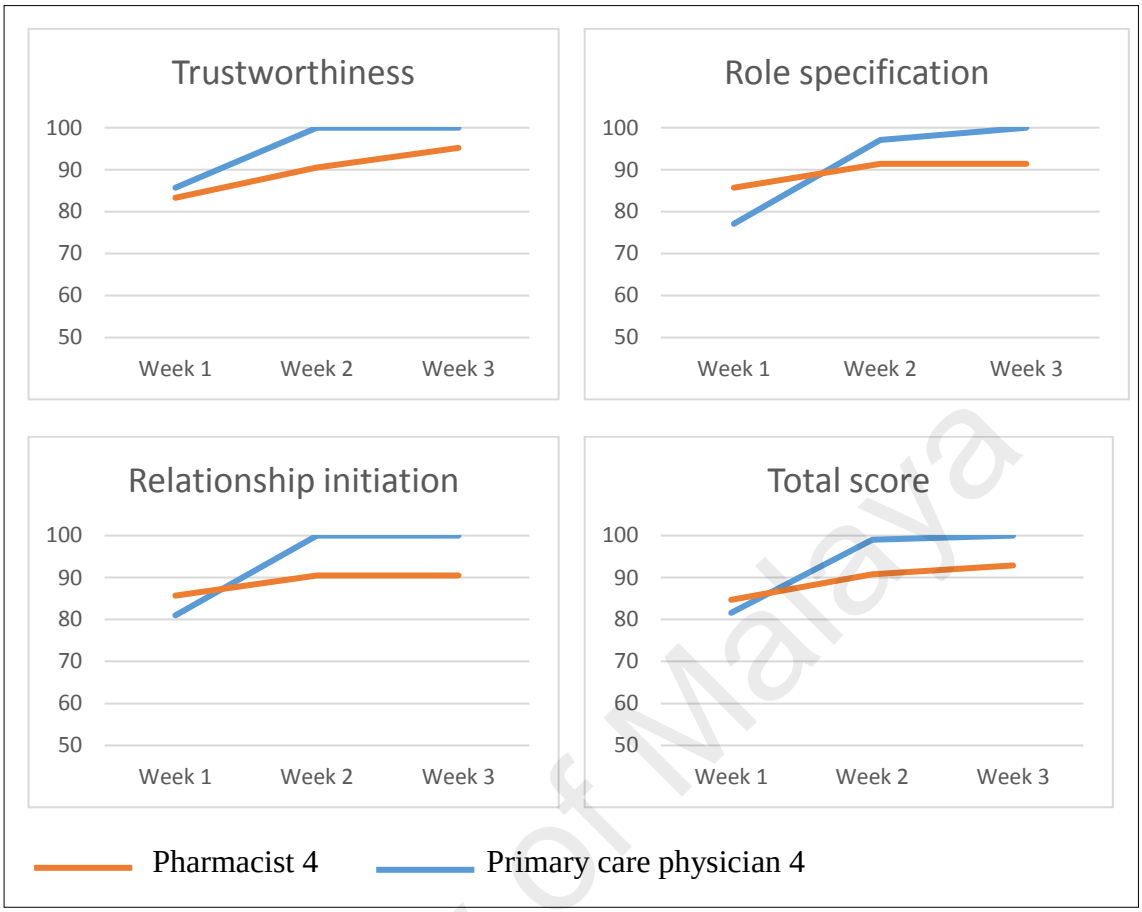


Figure 10.6: Physician-Pharmacist Collaborative Index scores of Pair 4 over three weeks

10.3.2 Primary care physician-pharmacist collaborative working relationship

A total of 16 IDIs were conducted, each lasted for 13-25 minutes. Three main themes emerged from the analysis, which were impact on PCP-pharmacist CWR, impact on self and impact on patient care. These are summarised in Table 10.3.

Table 10.3: Impact of the Physician-Pharmacist for Patient Safety intervention on primary care physician-pharmacist collaborative working relationship, self and patient care

Impact on PCP-pharmacist CWR
Trust
Communication
Sharing of patient care roles
Conflict resolution
Challenges
Effort to improve the CWR
Impact on self
Learning experience
Job satisfaction
Impact on patient care
Consultation
Medication safety

10.3.2.1 Impact on primary care physician-pharmacist collaborative working relationship

(a) ***Trust***

At week 1, most PCPs and pharmacists trusted each other based on their respective professional credentials. Pharmacists were regarded as the medication experts and PCPs as the clinical experts to make patient care decisions. However, in some instances trust was also based on the knowledge and performance of the individual: PCPs reported that they trusted the pharmacist as the pharmacist was knowledgeable, while pharmacists trusted the PCP because the PCP was confident when dealing with patients. After three weeks, participants reported that the 4Ps facilitated the building of trust between PCPs and pharmacists, but was limited by the short duration of the pilot test.

"I trust that you know pharmacists are experts in medication. They should know the medication in and out. So when Pharmacist 2 give a recommendation I would trust his judgment."

PCP 2, IDI at week 3

"It is more of what she decides is the best treatment for the patient. So in that way I trust her because I know that she is making decisions based on her findings with the patient and not based on what the patient has said or what was written in the medical history."

Pharmacist 1, IDI at week 3

"I think I trust her [Pharmacist 4] because she straight away met my expectation. During the first discussion, she straight away told me, "OK, this patient is on these medications, and what are the issues with the medications". She sort of answered all the questions in my mind without me actually asking her. And straight away I just trusted her because I thought "OK, this pharmacist is actually quite good".

PCP 4, IDI at week 1

"Initially, the first week, we just got to know each other and you know to try to build up the trust. It takes time but at the second and third week, because I know how she manages and how she does things, I feel comfortable, more confident and like you know I can trust her more. But of course three weeks is too short. Maybe if we work together longer, then it will be even better."

PCP 3, IDI at week 3

(b) ***Communication***

PCPs had no problems communicating with the pharmacists but the pharmacists were more reserved initially, which improved by the end of the third week. The main reason behind this was unfamiliarity with each other at the first week. By the third week, all participants felt that they could voice out their individual opinions freely and make a decision together. The main facilitator reported was co-location of the pharmacist (having the pharmacist at the family clinic together with the PCP). This overcame the previous barrier whereby PCPs had to contact pharmacists through a very busy telephone line at the pharmacy. The 4Ps therefore created a platform for PCP and pharmacist to communicate more effective and efficiently. Participants individual characteristics such as being friendly, approachable, easy to work with and open to receiving opinion from another health care professional were the other facilitators mentioned.

"At first I was a little bit nervous because I don't know what will the doctor feel when I tell something about her patients. But as time progresses, I feel more confident in voicing out my opinion and any information that I got from the patients."

Pharmacist 2, IDI at week 3

"The good thing is I know that the pharmacist is around, and who is the pharmacist. Rather than the pharmacist is at the pharmacy and I don't know them, whether they are busy or not, whether they have a lot of patients, or so many medications to dispense or whatsoever. But here I have an easy access to the pharmacist and when I have a problem I can just catch the pharmacist and say, "OK I have a problem with this patient. Why don't you help me to tackle this patient?" So I think it is really fantastic to have a pharmacist around."

PCP 4, IDI at week 3

"Over the course of three weeks er… I find Pharmacist 2 to be very friendly. He is very approachable. Initially he seems very shy and you know even from the way he talks as if he is not sure of what to say. But as the weeks go by, I think he is more comfortable, and it is easier to talk to him."

PCP 2, IDI at week 3

"She [Pharmacist 1] is easy going and you know, easy to communicate mainly. Pharmacist 1 is an easy person to get along with"

PCP 1, IDI at week 3

The communication between Pair 1 was slightly different from the rest. Familiarity with each other was not an issue with this pair, but rather the differences in knowledge and experience between PCP 1 and Pharmacist 1 was a barrier. In the first session, Pharmacist 1 felt that the PCP-pharmacist discussions were dominated by PCP 1 as she did not have anything to offer to the PCP. She however felt confident to talk about issues that she was familiar with such as medication storage and preparation. Nevertheless, the pharmacist acknowledged that PCP 1 was approachable, and made efforts to maintain a two way communication between them. PCP 1 often stopped and asked for the pharmacist's opinion, which helped the pharmacist in voicing out her opinion.

"It (the communication) was interactive. Although at first I think it was more she [PCP 1] was telling me a lot of things. Then... slowly I managed to tell, to talk to her [PCP 1] also. Slowly I got comfortable to her."

Pharmacist 1, IDI at week 1

"For me to let her know the type of medications and whether it should be out of the foil or in the foil. That I felt very confident because that one I knew best. I was a bit confident in that certain parts. Also certain creams. What I was so sure of I was confident."

Pharmacist 1, IDI at week 1

"But I think she [PCP 1] said, OK Pharmacist 1, what do you think? And then, when I told her what I think she said, actually this is what I think. But she [PCP 1] kept asking me in between what do you think, and that was easy for me to let her know."

Pharmacist 1, IDI at week 3

(c) ***Sharing of patient care roles***

PCPs and pharmacists denied any "clashes" in patient care roles during the delivery of the 4Ps, as they felt that they utilised their professional expertise to complement each other. However, initially PCP 2 was surprised that pharmacist 2 explored patient's lifestyle issues during initial patient assessment, while PCP 4 was surprised that pharmacist 4 could advise patients on adjusting insulin dosage according to blood glucose levels. This happened because PCPs were initially unfamiliar with the professional expertise of a pharmacist, and it was the first time they collaborated with a pharmacist. This improved in subsequent sessions, whereby PCPs were glad that the pharmacist could take up these roles while they concentrated on other issues during patient consultation.

"I didn't feel any clash of roles with her [Pharmacist 1] because she [Pharmacist 1] asked everything about medications from the patients, and informed me. After the patients see me, I just tell them to get the medication from her [Pharmacist 1]. And patients were

happy. So I don't think there was a clash role between me and her because I'm doing my part as a doctor, she was doing her part as a pharmacist."

PCP 3, IDI at week 3

"I was actually really surprised he [Pharmacist 2] went into diet and exercise because I thought that was what I was going to do. I thought he [Pharmacist 2] was going to just talk about the medication. Then I knew, he [Pharmacist 2] does not just talk about the medication. He [Pharmacist 2] also sees whether there are any other factors erm… especially the environment in which she (patient) is working. He [Pharmacist 2] was delving more into that to try to see why patient is not compliant. So I think that is good as well."

PCP 2, IDI at week 1

"Uhm... I have no idea what the pharmacist can do actually. I'm worried if the pharmacist miss it or... if I don't do it ... can the pharmacist do it? For example, uhm… adjusting insulin. I know that it is my responsibility to tell the patient how to adjust his insulin dose, but later on I found out that the pharmacist can do it also. So... after knowing this, I said OK, I can just uhm... inform the pharmacist to explain about it to patients rather than I have to tell everything during my consultation."

PCP 4, IDI at week 1

The interaction between Pair 1 was again slightly different than the rest of the pairs. Although PCP 1 felt that no one was superior in the relationship and they complemented each other's role, pharmacist 1 felt that PCP 1 contributed more than her to the collaboration. This was because PCP 1's many years of working experience gave her an upper hand in terms of knowledge and experience.

"To me at the end of the day, whether I achieved my target, which is good control and patient is compliant. And on her (pharmacist 1) side, it is the way whether the patient is taking correctly, or the patient is collecting the medicine but not taking it. So finally it is her effort and my effort put together, and the end result is patient is well and taken care of. So I think at the end of the day we don't see who is the main person. I mean if we can do something out of the consultation and benefit the patient, then fine!"

PCP 1, IDI at week 3

"I actually enjoyed working with her [PCP 1] because she is so specialised in what she does. I think if it was a newer doctor, probably there can be a lot more things I can tell, but she [PCP 1] knew a lot. In fact, she [PCP 1] told me a lot more than I did. I think what she [PCP 1] got from me is mostly the charging (of medication) or the administration side of the pharmacy, but I learned a lot. In fact, I asked her [PCP 1] certain questions as I wanted to know why or how to pick up certain things."

Pharmacist 1, IDI at week 1

(d) ***Conflict resolution***

Participants denied any major disagreement between the pairs during their participation in the 4Ps. PCPs were regarded as the main decision maker and any recommendations by pharmacists were given due consideration. PCPs provided explanation to the pharmacists for each decision made and this was well received by the pharmacists.

"Whatever suggestion that Pharmacist 2 gave, I kind of accepted it as a possible option for the patient. Erm… let say for example adding fenofibrate to simvastatin. "Oh you know the triglycerides are still the same even with simvastatin 20 milligram. Maybe

we can add on fenofibrate as an option". So that was his [Pharmacist 2's] suggestion, and my suggestion was, well we can also increase the simvastatin dose itself to 40 milligrams and see. I think either one is OK, and he [Pharmacist 2] agreed. So there was no disagreement, we just discussed about it."

PCP 2, IDI at week 3

"Basically PCP 2 explained the rationale of her decision each time and I respected her views. Even though I suggested something else and she disagreed, she respected my suggestion, and took into consideration. At the end she made the decision after her patient consultation, and she will feedback to me."

Pharmacist 2, IDI at week 3

(e) ***Challenges***

PCPs did not identify any challenges to start collaborating with the pharmacists, but most pharmacists admitted to being 'out of touch' with their clinical knowledge as they have not been actively involved with direct patient care for a while. In addition, the pharmacists were not familiar with the primary care clinic setting and patient characteristics. All these led to a lack of confidence in providing recommendations and communicating with the PCPs. In addition, Pharmacist 1 found it challenging to work with PCP 1 as PCP 1 was a senior PCP with many years of working experience. She felt intimidated by the PCP's experience and knowledge.

"The first patient was injecting 18 units of insulin twice a day. And when I told the doctor [PCP 4] this, the next question that the doctor asked was, "Oh did you check his injection technique?" Which I didn't! It didn't really like strike me. So maybe what the doctor needs for the pharmacist to do is to be more patient-oriented. Like when this

doesn't seem right, the next step is…? Like for me, maybe I have lost that since I was working in outpatient all the time and you don't really go and probe the patient, "Oh how are you injecting it? Are you doing it correctly? So yeah, it didn't really like strike me at that point."

Pharmacist 4, IDI at week 1

"Today is a very good experience actually [referring to collaborating with PCP 3]. To be honest I'm not very familiar with primary care patients. So I am still trying to learn and getting used to this. But because it is her [PCP 3] patients, she is quite familiar with her patients. I am just helping by informing her [PCP 3] the additional stuff that patients tell me, which I think indirectly helped the doctor to review the patient. In terms of medication, I try to put in as much as I can."

Pharmacist 3, IDI at week 1

"PCP 1... is a specialist. She seemed to have known everything under the sun. It was difficult for me because at that point when you have so many things to think about, and then you go and sit in front of her it was a bit… scary... like ... kind of forgot everything. But then... she said it, she said everything. Like you know I wanted to suggest. I think at one point said wait, wait! Let me suggest first [laughed]. Because I know she was going to suggest exactly the same thing and I wanted to do it so that it was like, OK, yeah, I did manage to suggest something you know? So yeah I was a little bit intimidated. But she did not make me feel intimidated. She was very... she was very warm. She is more like a ... like a teacher, like a really good teacher."

Pharmacist 1, IDI at week 1

(f) ***Efforts to improve the collaborative working relationship***

As the pharmacists were aware that they were lacking in terms of clinical knowledge, they took the effort to read up and prepare prior to their respective sessions. Also they made conscious effort to identify and meet PCP's patient care needs.

"I did some homework before I come so that I am more confident. When you [referring to the researcher] handed to me the patient assessment form with patient's registration number earlier, I get to actually check through the patient's medication profile. Based on that I can roughly guess their co-morbid and read up a bit so that I am more prepared."

Pharmacist 3, IDI at week 3

"Each patient I try to think what best way I could help. I could see what the doctor wanted. So I did try and figure out. In today's visit there were a lot of things that I could bring to her at the table rather than going and you know empty handed. So I felt that this visit I did give quite a bit of information to her."

Pharmacist 1, IDI at week 3

"Initially, she told me what are the [medication] issues and gave me some options. After I see the patients, she asked me whether there is anything else that I want her to do. So I can tell her to emphasise on this that while dispensing, and she is doing that for me, which is very helpful actually."

PCP 3, IDI at week 1

10.3.2.2 Impact on self

(a) ***Learning experience***

Participating in the 4Ps was an enriching experience for both the PCPs and the pharmacists. PCPs gained information on side effects of medication, proper administration methods and medication availability at the hospital pharmacy. In addition, PCP 3 realised that she should look beyond adherence to medications in her future patient consultations, to obtain a complete picture on patients' medication-taking behaviour. As for the pharmacists, the 4Ps created an opportunity to improve their clinical knowledge and apply their knowledge about medications on real patient scenarios. Also the pharmacists felt that they got to understand patients' medication-taking behaviour better through their interactions with patients in the 4Ps, which they do not get to do while dispensing at the outpatient pharmacy.

"I learned a lot of things actually, because to be honest I can't remember all the medications' drug-drug interactions, side effects, to take it before meals, after meals. Maybe the common ones, yes I know. I also don't know what is available at the pharmacy. For example, just now the single pill [combination pill], I rarely prescribe patients on single pills. So I just ask the pharmacist what is available in our pharmacy and then she suggested few things."

PCP 4, IDI at week 3

"For me, I think there are certain things I learned from the pharmacist. Like side effects of some medications and what are the other medication issues that I can concentrate when I see patients. Not just compliance, but I need to explore more on

problems that patients have with their medications. Also if they are taking any other medications from outside or supplements that may affect my management.'

PCP 3, IDI at week 1

"I think in this three weeks time, it actually teaches me a lot. Basically in terms of a clinical practice, I think I get a lot more information regarding how to alter the patient's drug therapy from the doctor. So it is a very valuable experience to work together with this doctor."

Pharmacist 2, IDI at week 3

"I got to know more about the patient. Yeah! Because if we were to dispense at the outpatient pharmacy, we just dispense and see on the surface what medication the patient is taking. But now when we are involved in this [4Ps], we get to see the whole picture. We get to see their lifestyle, we get to see what kind of food they are taking, diet and also their family background. All these helps in understanding their problems [with medications] and finding a solution to it."

Pharmacist 3, IDI at week 3

(b) ***Job satisfaction***

Besides knowledge gain, the pharmacists felt a sense of achievement and professional satisfaction with this collaborative role in improving patient care.

"One is job satisfaction. Feel like a pharmacist. You don't feel like someone who pushes out medicines only. The other one is uhm...achievement. Some sort of achievement when someone is willing to accept your point of view ... achievement, yeah."

Pharmacist 2, IDI at week 3

10.3.2.3 Impact on patient care

(a) ***Consultation***

PCP-pharmacist collaboration in the 4Ps had an impact on PCP-patient consultation. Mainly PCPs felt that the consultations were shorter and more consideration were given to medications as the pharmacist has already informed them of patients' medication-related problems. In fact, patients were also more prepared and PCPs had to spend less time to probe for patients' problems. With the pharmacist taking up the role to assess patients for medication-related issues and to provide medication education, PCPs felt that their workload had been reduced and they could focus on other matters during patient consultation. However, PCPs felt that the assessment by the pharmacist may sometimes be incomplete or inappropriate. The PCP needs to use his/her clinical judgement to make a decision rather than to rely completely on the pharmacist.

"Today my consultation was a little bit different because I went more in detail about medications. Like, "OK this medication, how do you take it? Any problem with this medication? Do you know what for you take for this medication? I rarely ask these. I usually assume that the patient knows because patient has been taking the medication for many many years. Surprisingly, one of the patients just now, has no idea what is the medication for and thought it is actually for diabetes. I don't think that I would explore that if the pharmacist didn't tell me earlier."

PCP 4, IDI at week 1

"The moment she [patient] was here, she said, "Yeah, I know I have to work on my diet. I know I have to exercise". She already like has that attitude that, "OK I'm going to work harder to manage myself" and I think that is important. On a normal clinic day when they come in, after all the pleasantries and then I have to tell them about the results

and then they get, "Oh!" shocked and then drag on, "erm… oh… maybe it is my diet". But here it is like, once you come in they already have established that these are the problems that is contributing to my poor control. So they already have the mind set when I see the doctor, OK this is what we are going to do. They already have that lets get going kind of attitude which is remarkable change in this patient. For this patient especially, every time I see her I have to talk about that and she says that all the time. "Oh I'm going to work harder". But this time, this is the first time she so determined, "OK I'm going to work harder! Yeah."

PCP 2, IDI at week 1

"It [referring to collaborating with Pharmacist 4] shortens my consultations (laughs). Or else I need to break up my consultations. For example, one of the patients asked me how to adjust the insulin dose and I already spend a lot of time with him on other things. So I told the patient, "OK, let's discuss in the next consultation." But I forgot that the pharmacist that I work with can actually advise the patient on that. So all I need to do is collaborate with the pharmacist, discuss with her, "OK I will concentrate on this, and then you talk about this with the patient."

PCP 4, IDI at week 1

"During the discussion with the pharmacist, the pharmacist might suggest certain things that might influence my management. I give you an example. One of my patients was on four antihypertensive and the patient complained of having dizziness because of this four medications. The pharmacist made a conclusion that, OK maybe we need to reduce the number of antihypertensives. So, when she suggested that, erm… initially I might be influenced. But when I look at the patient, the dizziness may not be due to the antihypertensives, and we cannot reduce the antihypertensives because the BP is still not

well controlled. At the end, we made a decision to change the antihypertensives to single pill [combination pill] to cut down the numbers of pills taken by the patient. So the point that I want to bring up here is the suggestions might influence my management if I don't really think properly while I'm consulting the patients. So I need to be aware that any suggestion is just a suggestion."

PCP 4, IDI at week 3

(b) ***Medication safety***

PCP-pharmacist collaboration in the 4Ps managed to identify and solve many of patients' DRPs, which would have been missed by the PCPs during normal consultations. Patients were also more open and comfortable in discussing their medications with the pharmacists. Most of the DRPs identified were solved almost immediately as PCPs and pharmacists were working closely at the family clinic. PCPs acknowledged that it was a great help to collaborate with the pharmacists, as the pharmacists helped them to explore patients' medication-related issues in great detail, provide medication education to patients and reinforce PCPs' instructions regarding the use of medications.

"More than anything I think it is the relationship that we have developed and we realise that there are things that can be picked up with two people working together. Two different people from two different departments, rather than we just prescribe and they (pharmacists) just dispense blindly.

PCP 1, IDI at week 3

"Even the patient was happy that we are working together and everything can be sorted immediately. You don't have to like, "Oh, aunty, you wait here ah, I will go and call the doctor." Then, you feel that the patient thinks that you don't know anything, and

you have to confirm with the doctor. Like over here I felt that, the patient was a bit more confident towards our advice or how we were teaching them to take their medications. So I felt that actually patient got the benefit of us trying to work together, instead of separately upstairs [referring to the family clinic] and downstairs [referring to the outpatient pharmacy]."

Pharmacist 4, IDI at week 1

"I think it is good you see. She [Pharmacist 1] has picked up that he [patient] has taken out the telmisartan out of the blister and placed it in the (medication) box. Everything is now sticking to each other in the box. I wouldn't have picked it up, he [patient] wouldn't have shown it to me. I wouldn't have had the time also if it is in my follow up clinic. To ask him [patient] to show me his medicine, show me how you keep it, or how you take it. Isn't it? So this is important because then we will think that why is his BP not controlled? And we will go on increasing the medicine and then he comes in with hypotension. So I think it's good to look at their containers, their storage, and spend some time. I think it's a good two-way."

PCP 1, IDI at week 1

"When the pharmacist take history from patients, she gets a lot more history on the medications, compared to when the doctor asks the patients. I will not get the same information, even though that I ask the same questions. I need to prompt and prompt and prompt. For example, just now, the patient is taking supplements. When I asked her, initially the patient said she is not taking any other medication. I would have just believed her, if the pharmacist hasn't told me that the patient is taking other supplement. So I prompted her, "Any other medication that you are taking? What about the glucosamine?

Then she said "Oh, right, yeah! I've been taking glucosamine". So I might miss this kind of information"

PCP 4, IDI at week 3

"When I changed the patients' medication, increased or decreased the dose, she [Pharmacist 3] helped me to explain to patients. In the sense I have already explained to patients, but when she is dispensing the medication, she helped to emphasis more on what I wanted. So it is very convenient."

PCP 3, IDI at week 1

10.4 Discussion

The PPCI scores of PCPs and pharmacists participated in the 4Ps increased gradually over the period of three weeks, indicating increased professional exchanges and collaboration between pairs. Results from the IDIs showed that the 4Ps created a platform for interdisciplinary collaboration between PCPs and pharmacists. Together, PCPs and pharmacists were able to identify and resolve patients' DRPs and provide medication education to patients in a coordinated manner. In addition, the 4Ps allowed knowledge exchange between PCPs and pharmacists, and provided the pharmacists with a sense of professional satisfaction through their active contribution in improving patient care.

Our findings suggest that overall, the 4Ps improved PCP-pharmacist collaboration gradually over three weeks. However, there were differences in the way PCPs and pharmacists rated their professional exchanges; PCPs scored higher than pharmacists in all domains and total score of the PPCI. A similar trend was reported in earlier studies which explored the professional exchanges between GPs and community pharmacists (Snyder et al., 2010). Looking at the qualitative interviews in our study, the most possible

reason for this is the lack of confidence among pharmacists which makes them feel less strongly about their CWR with the PCPs (R. P. McDonough & Doucette, 2003; A. J. Zillich et al., 2006). Literature also suggest that there is an unspoken hierarchy that exists between doctors and pharmacists, where doctors questioned the role and skills of pharmacists and felt that greater involvement in prescribing would not be particularly appropriate (Hughes & McCann, 2003). The pharmacists in this study may be conscious of this hierarchical system and therefore scored lesser in the PPCI as compared to the PCPs.

There were also marked differences in professional interactions between pairs, especially Pair 1. While other PCPs scored higher than their pharmacist pair, PCP 1 scored lower than Pharmacist 1 in all domains of the PPCI. This was most probably due to the marked differences in years of clinical experience of PCP 1 as compared to the rest of the PCPs; PCP 1 is a service medical officer with 30 years of clinical experience while the other PCPs had 7-8 years of clinical experience. PCP 1 therefore might have felt that she gained less from the CWR with Pharmacist 1, as compared to the rest of the PCPs. This was supported by qualitative interviews in which Pharmacist 1 felt that she learnt most from the relationship and felt intimidated by the PCP 1's knowledge and experience. Despite this huge difference in experience between the pair, the 4Ps intervention was able to facilitate the development of CWR between them. This is demonstrated by the increasing PPCI scores over three weeks, and IDIs in which PCP 1 and pharmacist 1 admitted that they were getting comfortable with each other, and were working more efficiently as a team.

In addition, while PPCI scores of the rest of PCPs and pharmacists improved from week 1 to week 3, role specification scores of Pharmacist 1 worsen. This was most

probably due to items 5 and 6 of the PPCI for pharmacist, which were "This doctor depends on me as much as I depend on him/her" and "This doctor and I are mutually dependent on each other for caring for patients". Based on the qualitative interviews, Pharmacist 1 felt that she could not contribute much to the collaboration as PCP 1 was more experienced and knowledgeable. Pharmacist 1 would have therefore scored poorly in this domain as she did not feel that PCP 1 had to depend on her in caring for patients. The differences in interaction between Pair 1 as compared to the rest of the pairs supports that individual characteristics (participants' knowledge and experience) may influence the development of CWR between doctors and pharmacists (Randal P. McDonough & Doucette, 2001).

Similar to previous findings, our participants associated trust based on knowledge and contribution to patient care (Snyder et al., 2010). In addition, we also found that participants initially trusted their respective pairs based on their professional credentials. This suggests that trust builds over time based on individual's performance and contributions (Randal P. McDonough & Doucette, 2001; Snyder et al., 2010). However, at the initial stages trust is based on professional credentials i.e. pharmacists as the medication expert and doctors as the clinical expert.

Our findings on face-to-face contact being an important determinant of successful communication and collaboration is in agreement with previous findings (Brock & Doucette, 2004; Dey et al., 2011; Snyder et al., 2010; E. C. Tan, Stewart, Elliott, & George, 2013). We however did not find any significant input on the relationship initiating behaviour of either group of participant. A possible explanation is, this was an intervention study that was coordinated by the researcher. Therefore it is essentially different from previous studies in which GPs and community pharmacists in collaborative

relationship were studied (Brock & Doucette, 2004; Dey et al., 2011; Snyder et al., 2010). However, the pharmacists involved in the 4Ps did make an effort to improve their contribution to patient care, by reading up patients' notes before attending the clinic, and also identifying ways to complement PCP's role in patient care.

Two PCPs commented that the pharmacist's recommendations might influence their patient management. When patient complained of dizziness after taking antihypertensive medications to the pharmacist, the pharmacist was quick to suggest to reduce the number of medications, when the symptom could be due to a new medical problem. This needs to be highlighted to PCPs and pharmacists in future, should the 4Ps intervention is implemented in actual practice. The pharmacist should be careful not to frame their recommendations in a very leading manner, and any new presenting complaint should be conveyed to the PCP for further assessment (Snyder et al., 2010). The PCPs on the other hand, should not be obliged to follow the pharmacist's recommendations without proper patient assessment. Nevertheless, as PCP 4 mentioned, this was not so much of a problem by the third week once he got comfortable working with Pharmacist 4.

While this pilot study provided evidence suggesting that the 4Ps intervention facilitated the development of CWR between PCPs and pharmacists, there was still room for improvement. There is a need to address the challenges faced by pharmacists to collaborate with PCPs, mainly the lack of training and knowledge in delivering pharmaceutical care (Jorgenson, Laubscher, et al., 2013). The two hours briefing session provided as part of the 4Ps intervention might be insufficient, and a more comprehensive training may be required by the pharmacists. This should include an introduction to the primary care clinic setting and patients, training in identifying DRPs, providing recommendations to address DRPs and communication skills to improve PCP-pharmacist

communication (Dolovich et al., 2008). These would probably help to boost the pharmacists' knowledge and confidence in providing patient care in collaboration with the PCPs.

Besides creating a platform for PCP-pharmacist CWR development, the 4Ps had a positive impact on patient care. With the pharmacists assessing patients for DRPs, PCPs felt that their patient consultation was shorter and their workload reduced. The 4Ps could therefore be a solution to the increasing burden of chronic diseases on primary care, especially in managing "high risk" patients. In addition, findings from the IDIs also suggested that PCP-pharmacist collaboration was successful in identifying and resolving many of patients' DRPs almost immediately, which would have been missed during standard consultations. The PCPs also appreciated having the pharmacist at the clinic to reinforce medication instructions and to provide medication education to patients. With the PCPs and pharmacists working together, PCPs were assured that the information conveyed by pharmacists would not contradict theirs, and patients' adherence would improve. Our findings have highlighted the potential of the 4Ps in improving medication use and the safety of patients with chronic diseases in primary care. However, this pilot study only provides preliminary evidence on the impact of the 4Ps on patient care. More definitive evaluation using RCT with objective outcomes such as MEs, ADEs, hospitalisations and mortality, would be required to determine the effectiveness of the 4Ps in improving medication safety in primary care.

10.4.1 Strength

The strength of our study was that we explored doctor-pharmacist CWR using mixed methods (qualitative and quantitative), from both the doctors' and the pharmacists' perspective. In addition, our study was conducted prospectively, to explore early stages

of CWR development between the PCP-pharmacist pairs; whilst other studies mainly explored CWR among doctors and pharmacists who are already in high level of collaboration (Dey et al., 2011; Snyder et al., 2010; C. Van et al., 2011). Findings from our study may then be useful as different variables might influence doctor-pharmacist CWR at different stages of a CWR (Liu, Doucette, & Farris, 2010). We also interviewed participants immediately after each session, eliminating recall bias. With the current emphasis on multidisciplinary approach to primary care, we believe our findings would be of use to pharmacists integrating into such teams; providing some insight into what to expect during the early stages of collaboration and how to overcome the challenges. In addition, we included doctors with various background (age, years of clinical experience and post graduate qualifications) but pharmacists with more or less similar characteristics. This helped to highlight that knowledge and experience of PCPs could be one challenge that the pharmacists would face when starting to collaborate with different doctors.

10.4.2 Limitation

The main limitation of our study was the small sample size. Hence, we were unable to determine the effectiveness of the 4Ps intervention in improving doctor-pharmacist CWR and medication safety. The short study duration was another limitation. Ideally, the PCP-pharmacist pairs should be followed up for a longer duration to see how their CWR develops, and how this affects patient care. A RCT should be conducted to determine the effectiveness of the 4Ps intervention in improving these two outcomes. In addition, it is also worth exploring patients' perspective on the impact of PCP-pharmacist collaboration on the care received by them.

It can also be argued that this intervention was conducted in an 'ideal' setting which may not be transferable to the 'real world'. For example, senior pharmacists were

purposely selected so that they will be more experienced, and able to deliver high quality pharmaceutical care to patients in this study. In addition, as part of the 4Ps intervention, the pharmacist collected patient's medications from the pharmacy and dispensed the medications at the family clinic. While this step was necessary for the pharmacist to counsel patients on their medications, this might not be feasible to be implemented in actual practice. Pharmacy assistants might be required to help the pharmacist to collect patients' medications from the pharmacy.

10.5 Conclusion

The 4Ps created a platform for PCP-pharmacist collaboration in caring for patients with chronic diseases in primary care. The interdisciplinary collaboration between PCPs and pharmacists was able to identify and resolve many of patients' DRP in a timely and efficient manner. More definitive evaluation is needed to establish the effectiveness of the 4Ps in improving PCP-pharmacist collaboration and medication safety.

CHAPTER 11: DRUG RELATED PROBLEMS IDENTIFIED AND RESOLVED BY DOCTORS AND PHARMACISTS INVOLVED IN THE PHYSICIAN-PHARMACIST PARTNERSHIP FOR PATIENT SAFETY INTERVENTION: A PILOT TEST

This chapter will describe the DRPs identified and resolved by the PCPs and pharmacists during the pilot testing of the 4Ps intervention. This will include the types and causes of DRPs that were identified, types of recommendations proposed by the pharmacists, and the outcome of the DRPs.

11.1 Introduction

Complex medical problems and the use of multiple long-term medications places patients with chronic diseases at a higher risk for DRPs (Gurwitz et al., 2003; Howard et al., 2008). DRPs are a major burden on health care as it often results in ED visits, outpatient clinic visits and hospital admissions (Budnitz et al., 2006; Koh, Fatimah, & Li, 2003; Zhan et al., 2005).

The provision of pharmaceutical care by pharmacists has been shown to reduce the occurrence of DRPs (Hanlon et al., 2004). Pharmaceutical care refers to the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life (Hepler & Strand, 1990). It is a process in which a pharmacist designs, implements and monitors a therapeutic plan for a patient, with aim to identify, resolve and prevent DRPs (Hepler & Strand, 1990). This is a complex process that requires a collaborative effort from the prescriber, pharmacist and patient themselves (Hepler & Strand, 1990).

The 4Ps is a doctor-pharmacist collaboration intervention that was developed to improve medication safety of patients with chronic diseases in primary care (Chapter 7). This article aims to describe the DRPs identified and resolved by the PCP-pharmacist pairs during pilot testing of the 4Ps intervention.

11.2 Methods

This was part of the previous prospective, observational study described in Chapter 10, section 10.2 page 233. Therefore, only additional information will be reported in this section.

11.2.1 Sample size

As this was a pilot study, no sample size calculation was performed. A maximum of three patients per day were asked to come to see the pharmacist and PCP. This was based on the number of patients that could be seen by both the doctor and pharmacist over a 4-hour period (9am-1pm).

11.2.2 Instruments used

11.2.2.1 Demographic form

A demographic form [Appendix G4 and G5] was used to capture patient characteristics including age, gender, ethnicity, education, type and number of chronic diseases, and number of medications.

11.2.2.2 Patient assessment form

This form was used by the pharmacists to document patient's medication history, DRPs identified, recommendations proposed to the PCP, feedback from PCP on patient's management plan, and medication counselling points [Appendix D11].

11.2.3 Data collection

DRPs identified and recommendations proposed by the pharmacists were extracted from the patient assessment form by RS. The outcomes of the DRPs were determined by reviewing medical folders of the study patients six months after the intervention.

11.2.4 Data analysis

Based on the information provided in the help section of the PCNE Classification V 6.2 [Appendix D6], RS classified each DRP documented in the patient assessment form. Each DRP was classified as a problem, cause(s), intervention(s) proposed by the pharmacist and outcome. One DRP may be attributed to more than one cause and intervention. The classification of the DRPs was checked by PSML and any discrepancies were discussed until a consensus was reached between the two researchers (RS and PSML).

Patients' demographic details were entered into the IBM SPSS Statistics version 20 (IBM Corp., Armonk, New York). Continuous data was expressed as median and range. Categorical data was expressed as absolute numbers and relative frequencies (percentage).

11.3 Results

Over the period of three weeks, a total of 34 patients were contacted by the researcher. Two patients refused participation as it was inconvenient for them to attend the clinic in the morning, while three patients did not turn up for the appointment. This led to a final sample size of n=29 (response rate=90.6%). The recruitment process is summarised in Figure 11.1.

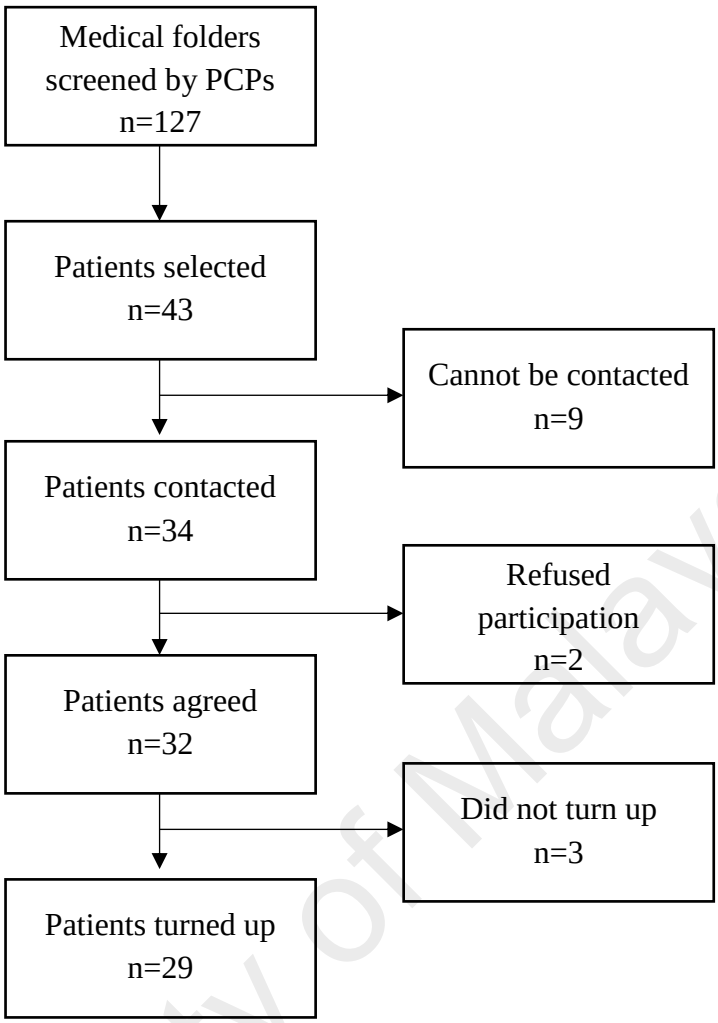


Figure 11.1: Patient recruitment for the pilot testing of the Physician-Pharmacist Partnership for Patient Safety intervention

11.3.1 Demographic information of patients

The majority of the patients were male (55.2%) with a median age of 70 years, had an average of three co-morbidities per person, and were on average five medications per person [Table 11.1]. More than 50% of patients selected were elderly, and were on ≥5 medications [Table 11.2].

Table 11.1: Patients' demographic characteristics

Characteristics	n (%)
N	29
Median age (years) [range]	70 [29-90]
Gender	
Male	16 (55.2)
Female	13 (44.8)
Ethnicity	
Chinese	12 (41.4)
Indian	10 (34.5)
Malay	7 (24.1)
Highest level of education	
None	1 (3.4)
Primary school	18 (62.1)
Secondary school	15 (51.7)
Certificate/diploma	4 (13.8)
Bachelor degree	1 (3.4)
Median no. of comorbidities [range]	3 [1-6]
Dyslipidaemia	27 (93.1)
Hypertension	25 (86.2)
Diabetes	21 (72.4)
Median no. of medications [range]	5 [1-10]

Table 11.2: Primary care physicians' reasons for selecting the patients for the Physician-Pharmacist Partnership for Patient Safety intervention

Reasons*	n (%) [n=29]
Elderly (≥65 years old)	17 (58.6)
Polypharmacy (≥5 medications)	15 (51.7)
Uncontrolled diabetes	11 (37.9)
Uncontrolled hypertension	7 (24.1)
Uncontrolled dyslipidaemia	7 (24.1)
Non-adherence to treatment	3 (10.3)

*more than one reason can be provided when selecting patients

11.3.2 Drug related problems

A total of 77 DRPs were identified. The mean number of DRPs identified per patient was 2.7 [Table 11.3]. The majority of the DRPs identified were effect of drug treatment not optimal (39.0%). Three additional DRPs were added into the "Others" domain as

there were no other suitable category in the PCNE classification V 6.2 that matched the DRP identified (poor medication knowledge, complex medication regimen and lack of treatment monitoring). There were 79 causes of DRPs, the majority was due to drug selection (30.4%) and drug use process by the patient (34.2%) [Table 11.4]. Among the causes classified under drug selection include new indication for drug treatment presented (15.2%) and inappropriate/contraindicated drug prescribed (7.6%). Meanwhile, under the drug use process by the patient, 12.7% of DRPS were due to patients deliberately under-using their prescribed medications. In addition, 8.9% of DRPs were related to patients lack of medication knowledge.

Table 11.3: Drug related problems classified according to Pharmaceutical Care Network Europe Classification V 6.2

Primary domain	Code	Detailed classification	n (%)	Total [n(%)]
Treatment effectiveness	P1.1	No effect of drug treatment/therapy failure	6 (7.8)	51 (66.2)
	P1.2	Effect of drug treatment not optimal	30 (39.0)	
	P1.4	Untreated indication	15 (19.5)	
Adverse reactions	P2.1	Adverse drug event (non-allergic)	6 (7.8)	6 (7.8)
Treatment costs	P3.2	Unnecessary treatment	8 (10.4)	8 (10.4)
Others	*P4.3	Poor medication knowledge	7 (9.1)	12 (15.6)
	*P4.4	Complex medication regimen	4 (5.2)	
	*P4.5	Lack of treatment monitoring	1 (1.3)	
Total				77 (100.0)

*added items to the original classification

Table 11.4: Causes of the drug related problems classified according to the Pharmaceutical Care Network Europe Classification V 6.2

Primary domain	Code	Detailed classification	N (%)	Total [n(%)]
Drug selection	C1.1	Inappropriate drug (incl. contra-indicated)	6 (7.6)	24 (30.4)
	C1.2	No indication for drug	3 (3.8)	
	C1.6	Too many drugs prescribed for indication	3 (3.8)	
	C1.9	New indication for drug treatment presented	12 (15.2)	
Dose selection	C3.1	Drug dose too low	2 (2.5)	7 (8.9)
	C3.2	Drug dose too high	1 (1.3)	
	C3.3	Dosage regimen not frequent enough	1 (1.3)	
	C3.4	Dosage regimen too frequent	2 (2.5)	
	C3.7	Deterioration/improvement of disease state requiring dose adjustment	1 (1.3)	
Drug use process	C5.1	Inappropriate timing of administration and/or dosing intervals	7 (8.9)	27 (34.2)
	C5.2	Drug underused/ under-administered (deliberately)	10 (12.7)	
	C5.3	Drug overused/ over-administered (deliberately)	2 (2.5)	
	C5.4	Drug not taken/administered at all	5 (6.3)	
	C5.5	Wrong drug taken/administered	1 (1.3)	
	C5.7	Patient unable to use drug/form as directed	2 (2.5)	
Patient	C7.1	Patient forgets to use/take drug	4 (5.1)	9 (11.4)
	C7.2	Patient uses unnecessary drug	4 (5.1)	
	C7.4	Patient stored drug inappropriately	1 (1.3)	
Other	C8.1	Other cause; please specify		12 (15.2)
		Patient lack of medication knowledge	7 (8.9)	
		Patient refuse to start on medication	2 (2.5)	
		Patient not practicing lifestyle modification	1 (1.3)	
		Lack of treatment monitoring	1 (1.3)	
	C8.2	No obvious cause	1 (1.3)	
Total				79 (100.0)

A total of 174 interventions (on average 6 interventions per patient) were made by the pharmacists during the study period [Table 11.5]. The majority of intervention proposed was patient counselling (37.9%). This include counselling patients on the indication and direction of use for each of their medication. Patients were also counselled on appropriate lifestyle changes such as regular exercise, and low sugar and cholesterol diet. Forty-two out of 57 (73.7%) intervention proposed to the prescriber were approved. A doctor complained regarding the substitution of original alfuzosin with generic alfuzosin, which failed to provide the patient with adequate therapeutic outcome.

Table 11.5: Interventions proposed by pharmacists during pilot testing of the Physician-Pharmacist Partnership for Patient Safety intervention

Primary domain	Code	Detailed classification	N (%)	Total
At prescriber level	I1.1	Prescriber informed only	18 (10.3)	75 (43.1)
	I1.3	Intervention proposed, approved by prescriber	42 (24.1)	
	I1.4	Intervention proposed, not approved by prescriber	15 (8.6)	
At patient/carer level	I2.1	Patient (medication) counselling	66 (37.9)	67 (38.5)
	I2.3	Patient referred to prescriber	1 (0.6)	
At drug level	I3.1	Drug changed to…	4 (2.3)	31 (17.8)
	I3.2	Dosage changed to…	10 (5.7)	
	I3.4	Instructions for use changed to…	1 (0.6)	
	I3.5	Drug stopped	9 (5.2)	
	I3.6	New drug started	7 (4.0)	
Other intervention or activity	I4.1	Other intervention (specify)		1 (0.6)
		Product complain made	1 (0.6)	
Total				174 (100.0)

Sixty-six out of 77 (85.7%) DRPs identified by the PCPs and pharmacists were resolved [Table 11.6]. The outcome of one DRP was not known as there was no entry in the patient's medical folder at the time of review which was six months later.

Table 11.6: Outcome of the drug related problems classified according to Pharmaceutical Care Network Europe Classification V 6.2

Primary domain	Code	Detailed classification	n (%)	Total [n(%)]
Not known	O0.0	Outcome intervention not known	1 (1.3)	1 (1.3)
Solved	O1.0	Problem totally solved	66 (85.7)	66 (85.7)
Partially solved	O2.0	Problem partially solved	2 (2.6)	2 (2.6)
Not solved	O3.1	Problem not solved, lack of cooperation of patient	1 (1.3)	8 (10.4)
	O3.2	Problem not solved, lack of cooperation of prescriber	1 (1.3)	
	O3.3	Problem not solved, intervention not effective	2 (2.6)	
	O3.4	No need or possibility to solve problem	4 (5.2)	
Total				77 (100.0)

11.4 Discussion

PCP-pharmacist collaboration through the 4Ps intervention identified approximately two DRPs per patient. On average six interventions per patient were proposed by the pharmacists. The most common DRP was problems related to treatment effectiveness, while the most common causes of the DRPs were new indication for drug treatment presented and drug underused deliberately by patients. The majority of the intervention proposed by pharmacists was medication counselling for patients. By the end of six months, 85.7% of the DRPs identified were resolved.

The number of DRPs identified in this study was fewer compared to previous studies. This may be because previous studies recruited patients who were much older, had more medical conditions and were prescribed with more medications (Ellis et al., 2000; Grymonpre et al., 2001; Krska et al., 2001; Zermansky et al., 2001), which puts them at higher risk for DRPs (Bourgeois et al., 2010; D. C. Chan et al., 2012). Our relatively short

study duration and small number of PCPs and pharmacists involved in this study could be another reason. In addition, the outpatient pharmacists involved in our study reported of being 'out of touch' with their clinical knowledge (Chapter 10, section 10.3.2.1(e), page 256). Besides, the PCP-pharmacist collaboration in our study was still in the early stages. This could have affected the number of DRPs identified and resolved. Another possible explanation for the differences in DRP detection rates between studies could be due to the different DRP classification systems used. While, there is currently no gold standard to classify DRPs, we have classified our DRPs according to the PCNE classification V 6.2, as it has been used widely. Furthermore, the PCNE classification V 6.2 has been revised several times based on user feedback to increase its usability (Eichenberger, Lampert, Kahmann, van Mil, & Hersberger, 2010; Pharmaceutical Care Network Europe Foundation, 2010).

The PCNE classification V 6.2 however did not consider poor medication knowledge as a DRP. Many of the patients participated in this study were not aware of the indication of their medications, and some were not aware of the correct dose and/or frequency of their medication. This was an important problem to be documented because poor medication knowledge may affect patients' adherence to treatment and their safety (Alm-Roijer et al., 2004; Gee et al., 2012; E. Lau & Dolovich, 2005); patients' medication knowledge determines whether they take the right medication at the right time at the right dosage. We therefore used "others" to record this by adding an additional category to problems and causes in the PCNE classification V 6.2. Similarly, there was no suitable category to document complex medication regimen as a DRP. We considered this as a potential DRP as complex medication regimen has been associated with poor adherence and a higher risk for ADEs (Bourgeois et al., 2010; Vik, Maxwell, & Hogan, 2004). There was also no category for documenting lack of treatment monitoring; one patient was on

hypoglycaemic agent but there was no recent HbA1c reading for the past one year. These suggests that the PCNE classification V 6.2 can be further improved to be more comprehensive.

In our study, 85.7% of DRPs identified were resolved by the end of the study period. This may be because of the face-to-face communication between PCPs and pharmacists that allowed the DRPs to be resolved in a timely an efficient manner (Ellis et al., 2000). This was in contrary to previous studies where pharmacists' recommendations were usually written and attached to patient notes, emailed or faxed to prescriber (Grymonpre et al., 2001; Krska et al., 2001; Zermansky et al., 2001). However, face-to-face communication as practiced in the 4Ps intervention might be more time consuming and PCPs might feel obliged to follow pharmacist's recommendations (Chapter 10, section 10.3.2.3(a), page 261). PCPs and pharmacists should be alerted of this potential problem during the initial briefing sessions of the intervention, which is said to improve over time as they learn each other's strengths and limitations and how to work together towards patients' safety (Chapter 10, section 10.3.2.3, page 261).

11.4.1 Strength

The strength of our study was that we determined the impact of the CWR between PCPs and pharmacists in identifying and revolving patients' DRP. Some of the DRPs were not identified by the pharmacists alone, but rather by the PCP-pharmacist pairs during their initial discussion, and both professionals decided on an intervention together. This collaborative approach was important given the complexity of medication management for chronic diseases in primary care (Bajcar et al., 2005).

11.4.2 Limitation

A limitation of our study was that we were unable to determine the effectiveness of the 4Ps intervention in reducing DRPs. This was due to the design of the study, and the limited time we had to conduct the study. In addition, the accuracy of the DRPs identified and resolved could be affected by under- or over-reporting between pharmacists. Ideally, a RCT with outcomes more directly reflecting medication safety such as ADEs, hospitalisation rate and mortality will be needed to establish the effectiveness of the 4Ps doctor-pharmacist collaboration in improving medication safety for patients with chronic diseases in primary care. Finally, the DRPs identified by the pharmacist were classified according to the PCNE classification V 6.2 by only one researcher, and this could be a source of bias.

Future studies should also attempt to correlate the different levels of doctor-pharmacist collaboration and its impact on medication safety to support the hypothesis that higher doctor-pharmacist collaboration will lead to improved medication safety for patients with chronic diseases in primary care.

11.5 Conclusion

This study provided preliminary evidence that PCP-pharmacist collaboration through the 4Ps intervention was able to identify and resolve patients' DRPs in a timely and efficient manner. A randomised controlled trial will be needed to establish the effectiveness of the 4Ps in improving medication safety for patients with chronic diseases in primary care.

CHAPTER 12: CONCLUSION AND RECOMMENDATIONS

12.1 Correlation between chapters

The aim of this study was to develop a doctor-pharmacist collaboration intervention to improve medication safety for patients with chronic diseases in primary care. Based on the UK MRC framework for developing and evaluating complex intervention, this project was divided into three phases; needs assessment (Chapters 3-6), development of intervention and validation of tools (Chapters 7-9) and pilot testing (Chapters 10-11).

The needs assessment was conducted using qualitative methods to explore the problems faced by PCPs in prescribing medications for chronic diseases (Chapter 3), pharmacist in dispensing medications (Chapter 5) and patients in taking medications for their chronic diseases (Chapter 4). Meanwhile, Chapter 6 qualitatively explored PCPs', pharmacists' and patients' views on the implementation of an ACPS in the primary care clinic of UMMC.

Chapter 7 of this thesis aimed to provide a detailed information on the development of the 4Ps intervention based on information gathered from needs assessment (Chapters 3, 4, 5 and 6), literature review (Chapter 2) and a conceptual framework. The first draft of the 4Ps intervention was reviewed, tested and revised iteratively to improve acceptability and feasibility as proposed by the UK MRC framework. Details on the conduct and findings of this iterative review-testing-revision process were also reported in Chapter 7. Next, Chapters 8 and 9, reported the validation of the PPCI for pharmacists, and the PPCI for physicians in measuring doctor-pharmacist professional inetractions in Malaysia.

Lastly, the 4Ps intervention was pilot tested among four PCP-pharmacist pairs for a period of three weeks. Chapter 10 reported the effectiveness of the 4Ps intervention in

improving doctor-pharmacist CWR, while Chapter 11 reported the effectiveness of the 4Ps intervention in identification and resolution of patients' DRPs.

12.2 Conclusion and recommendations

In the needs assessment, we found that a combination of patient, health care professional and health care system factors influenced medication safety outcomes in primary care. Patient factors include lack of knowledge about their medications, their belief and concern about medications, and their medication taking behaviours. Health care professional-related factors include failure to advice patients on proper use of medications due to the lack of time during consultation and dispensing. Poor communication among health care providers and the lack of time due to high workload were the two main health care system factors that contributed to MEs in primary care

However, it was not possible to address all these areas of concern. In this study, we focused on improving the interprofessional collaboration between PCPs and pharmacists, which was the 4Ps intervention. Hence, there is a need to address the other problems identified in this study such as the poor communication among different specialties within the hospital regarding patient's therapeutic management. In addition, there is a need to train and support PCPs in addressing the complexity of drug therapy for chronic diseases. PCPs should also be encouraged to maintain proper documentation on patients' therapeutic plan in medical records, despite the use of e-prescribing. Particular attention need to be given on preventing the medication stock problems, and educating patients on the use of generic medications. These actions are necessary to prevent MEs and improve medication safety of patients with chronic diseases in primary care.

The UK MRC framework was useful in guiding the systematic development and evaluation of a doctor-pharmacist collaboration intervention in this study. Information gathered from needs assessment was used to determine the target for intervention, while evidence from literature provided information on the types and effectiveness of available interventions in improving medication safety in primary care. On the other hand, the theoretical framework was useful in guiding and explaining the development CWR between PCPs and pharmacists involved in the 4Ps intervention. Next, the iterative review-testing-revision process proposed by the UK MRC helped to identify several issues related to the implementation of the 4Ps intervention. These issues were subsequently addressed and incorporated into the final intervention. This was found to be an important step in ensuring the acceptability and feasibility of the final intervention.

Findings from the pilot test of the 4Ps intervention suggest that the 4Ps intervention facilitated the development of CWR between PCPs and pharmacists. This collaboration resulted in the identification and resolution of patients' DRPs in a timely and efficient manner. These findings can be used to convince and engage policy makers to implement the 4Ps intervention in actual practice. However, several issues need to be ironed out prior to implementation. For example, there is a need to train the outpatient pharmacists to refresh their clinical knowledge in delivering pharmaceutical care. Pharmacy assistants should be provided as support staff for the pharmacists to conduct medication dispensing at the family clinic. There is need to orientate and introduce the 4Ps to new PCPs and pharmacists to ensure the sustainability of the service. The intervention should also be regularly assessed through feedback sessions with stakeholders to identify and resolve any problems encountered. These measures may however incur extra health care cost and need to be justified in terms of health care savings achieved through resolution of DRPs and prevention of ADEs.

Lastly, a RCT with a longer duration of follow up is required to establish the effectiveness of the 4Ps intervention in improving medication safety outcomes such as ADEs, MEs, health care utilisation and mortality. A single centre RCT might not be feasible due to potential contamination between the control and the intervention group. Therefore, a cluster RCT might be a more appropriate study design. In addition, there is a need to explore patients' perspective on the care received by them as a result of the doctor-pharmacist collaboration.

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LIST OF PUBLICATIONS AND PAPERS PRESENTED

Articles in academic journals

1. Sellappans, R., Ng, C. J., & Lai, P. S. (2015). Validation of the Physician-Pharmacist Collaborative Index for physicians in Malaysia. Int J Clin Pharm, 37(6), 1242-1249. *(ISI-Cited publication)* [Appendix H1]

2. Sellappans, R., Lai, P. S., & Ng, C. J. (2015). Challenges faced by primary care physicians when prescribing for patients with chronic diseases in a teaching hospital in Malaysia: a qualitative study. *BMJ Open, 5*(8), e007817. *(ISI-Cited publication)* [Appendix H2]

Oral presentations

1. Sellappans, R., Ng, C. J., & Lai, P. S. M. (2014). What are the medication experiences of older people with chronic diseases? A qualitative study. WONCA Asia Pacific Regional Conference 2014, Kuching, Sarawak, 21-24 May 2014. *(International)*

2. Sellappans, R., Ng, C. J., & Lai, P. S. M. (2013). Prescribing problems faced by primary care doctors in chronic disease management. The 13th Asian Conference on Clinical Pharmacy, HaiPhong, Vietnam, 13-15 September 2015. *(International)*

Poster presentations

1. Lai, P.S.M., Sellappans, R. & Ng, C. J. (2015). Validation of the Physician-Pharmacist Collaborative Index for physicians in Malaysia. The 15th Asian Conference on Clinical Pharmacy, Bangkok, Thailand, 23-26 June 2015. *(International)*

2. Sellappans, R., Ng, C. J., & Lai, P. S. M. (2013). Primary care doctors' views on the implementation of an Ambulatory Care Pharmacist Service. The 13th Asian Conference on Clinical Pharmacy, HaiPhong, Vietnam, 13-15 September 2013. *(International)*

Awards received

1. Second place winner at faculty level of the University of Malaya Three Minute Thesis (UM3MT) Competition 2014. *(University)*

2. Oral merit award, WONCA Asia Pacific Regional Conference 2014, Kuching, Sarawak, 21-24 May 2014. *(International)*