

School of Pharmacy

Stakeholders' attitudes towards continued dispensing

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Declaration

To the best of my knowledge and belief this thesis contains no material previously published by any other person except where due acknowledgement has been made. This thesis contains no material which has been accepted for the award of any other degree or diploma or diploma in any university.

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Abstract

Background: Continued Dispensing (CD) is a new mechanism of medication supply in urgent situations for eligible patients. Currently, Statin and Oral Contraceptive (OC) users are the only eligible patients. In all Australian states and territories (except Queensland), pharmacists are allowed to supply, without a valid prescription, one additional supply of a Statin or an OC to patients who were prescribed these medications for a period of six months or more. Pharmacists must ensure that this supply is safe and appropriate. This method was initiated to minimise treatment interruption that may result from patients' inability to obtain a renewed prescription. Patients can utilise the CD once in any 12 months period. While there were mixed announced views about the CD by consumer and health organisations, attitudes of the eligible users, pharmacists and general practitioners (GPs) had not been explored.

Aims and Methods: This research project sought to explore stakeholders' attitudes towards the CD. Three surveys and a case vignette were employed to collect data before and after CD implementation. (a) A nation-wide survey using Computer Assisted Telephone Interviews (CATI) was used to obtain views of patients (i.e. Statin and OC users), with emphasis on their acceptance, and their concerns about the CD. Patient support to include other medications into CD eligible drugs (i.e. CD expansion) and more flexible CD (i.e. CD extension) was also explored. The study also identified how often patients run out of medications and what actions they usually take to obtain their medications. (b) A self-administered questionnaire was posted to a random sample of 1490 community pharmacists in Australia, nation-wide. Data regarding their agreement with CD, its advantages, CD expansion, and CD extension were collected. In addition, the questionnaire asked them to estimate how often and why they usually face medication requests without a valid prescription from their customers (i.e. regular and non-regular customers), and what is their usual practice (i.e. when do they supply and what method do they use, and why they refuse to supply). The participant pharmacists also provided recommendations on how to modify the current urgent medication supply arrangements to improve patients' access to their medications in a timely and cost-effective manner. (c) A case vignette method was used to investigate how appropriately pharmacists would conduct the CD. Six written scenarios were used with 30 pharmacists who attended an annual conference in Perth, Western Australia. This method also allowed for collection of additional and updated data about pharmacists' views of CD post its implementation. (d) The postal survey method was also used to gather GPs' views on CD post implementation. Seventy-five open-ended questionnaires were posted to a random sample of GPs working in Western Australia. This method collected additional information on the GPs' views on how CD could be

improved, CD expansion and CD extension.

Results: Firstly, 151 Statin and 150 OC users were recruited in the patient survey. The majority of them strongly supported the CD. They did not have concerns about CD nor did they perceive CD as a risky method. They also supported CD expansion and CD extension. Statin and OC users trusted their pharmacists to supply when it is safe and refer them to their doctor when it was deemed necessary. Atorvastatin (e.g. Lipitor®) among the Statins and Ethinylestradiol 30 µg + levonorgestrel 150 µg (e.g., Levlen®) among the OCs were the most commonly used drugs. More than one-third of participants had run out of their medication as least on one occasion. Among those who ran out, there were 35.4% and 33.6% who stopped treatment or asked a pharmacist for an urgent supply, respectively. Statin users were less likely to run out of medications than OC users ($P=0.021$). The majority (86%) of the participants had a regular pharmacy, although more so for Statin users (97.4% versus 74.9%, respectively; $P<0.0001$).

Secondly, a total of 385 community pharmacists participated in the postal survey, yielding a response rate of 27.9%. The participants' supported CD for the currently eligible medications. They were more supportive in case of their regular customers than for non-regular customer ($p< 0.0001$). However, they were also in favour of more medications being eligible for supply under CD. Medication type and prescription type affected their support for CD expansion. They were more supportive in the case of drugs without abuse potential and in the case of prescriptions with less administrative burden. They were less supportive of CD extension than the patients. Just over the half of the participants agreed with current CD utilisation frequency (i.e. once in any 12 months). Those who supported more frequent CD cited prescription life span or difficulty to obtain urgent appointments. In this regard, the participants reported being faced continually with requests for medication supply from their regular and non-regular customers when they ran out of medications and were unable to obtain a renewed prescription. Inability to obtain an urgent appointment, interstate traveling without medication, and expired prescriptions were amongst the most common reasons reported for medication requests without a valid prescription. The participants usually were more agreeable to supply the requested medication for their regular customers than non-regular customers. Medication with abuse potential, authority prescriptions, and a second request for the medication were generally associated with 'No supply' practice, particularly if the customer was not a regular pharmacy client. Participants also suggested some modifications to the currently available urgent medication supply arrangements. They suggested increasing the amount of the emergency supply and legalisation to allow fax and email prescriptions. Use of technology to access patients' health records, electronic prescriptions and pharmacist prescribing rights were

highly promoted by the participants as potential solutions to the issue of patient requesting medication without a valid prescription.

Thirdly, pharmacists participated in the case vignettes study. The majority of pharmacists' decisions to use CD with the provided scenarios were appropriate decisions. The pharmacists also reported their reasons for not using CD. Here, the need for a medical review, clinical instability on the medication and absence of the patient's history were the most commonly reported reasons for not using the CD method. The participants reported low use of CD, and cited the presence of other alternatives to supply in urgent cases and CD paperwork as reasons to avoid the CD.

Finally, responses to the GP survey were low with only six GPs working in Perth, Western Australia providing their views and suggestions. The GP participants supported the current CD. However, they suggested CD should be used for more urgent medications than Statins such antihypertensives and antidepressants. They disagreed with CD extension as this may be used to avoid doctor visits. They suggested post-CD patients should visit their GP within a week to ensure they have the necessary medical review.

Conclusions: Whilst the stakeholders (patients, pharmacist and doctors) who participated in this research project supported the current CD as the first step towards improving patient access to medications in urgent situations, they supported CD expansion to include other and more urgently needed drugs. Patients were also supportive to a more flexible CD frequency, whilst pharmacists and GPs supported the current status quo. Participants identified areas in the current CD that need improvement. If their suggested solutions were taken into consideration by health policy makers, they would enhance CD uptake and its ability to improve access to medications for a greater proportion of patients with chronic conditions.

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“In the name of God, the infinitely Compassionate and Merciful. Praise be to God, Lord of all the worlds. The Compassionate, the Merciful. Ruler on the Day of Reckoning. You alone do we worship, and You alone do we ask for help. Guide us on the straight path, the path of those who have received your grace; not the path of those who have brought down wrath, nor of those who wander astray. ” The Noble Qur'an; Chapter 1

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Abbreviations

Australian Bureau of Statistics	ABS	Oral Contraceptive Pill	OCP
Australian Capital Territories	ACT	Over the Counter	OTC
Australian Medical Association	AMA	Owing Prescription	OP
Chronic Obstructive Pulmonary Disease	COPD	Pharmaceutical Benefit Scheme	PBS
Computer Assisted Telephone Interviews	CATI	Pharmaceutical Society of Australia	PSA
Consumers Health Forum of Australia	CHF	Pharmacy Guild of Australia	PGA
Continued Dispensing	CD	Prescription Only Medications	POM
Department of Human Services	DHS	Queensland	QLD
Emergency Contraceptive Pill	ECP	Research Team Evaluations	RTE
Emergency Supply	ES	Services for Australian Rural and Remote Allied Health	SARRAH
Food and Drug Administration	FDA	Short acting beta agonists	SABAs
Gastro-Oesophageal reflux disease	GORD	South Australia	SA
General Practitioner	GP	Statistical Package for the Social Sciences	SPSS
Health Care Consumers' Association	HCCA	Tasmania	TAS
Indirect Citation	IC	Therapeutic Goods Administration	TGA
Information and Communication Technology	ICT	United Kingdom	UK
Medical eligibility criteria	MEC	United States of America	USA
Medication Contenance	MM	Victoria	VIC
Northern Territory	NT	Western Australia	WA
Not Supply	NS	World Health Organisation	WHO
Patient Group Direction	PGD		

Chapter 1: General Introduction

1.1 Overview

As far as we know this is the first research study about stakeholders' (patients, pharmacists and GPs) attitudes towards Continued Dispensing (CD). CD is a recently implemented method to supply medication in urgent situations (commenced September 1, 2013). The eligible patients are Statin and Oral Contraceptive (OC) users who request these medications without a valid prescription because of inability to obtain an appointment with a prescriber to renew their prescription.[1] In this case, CD allows pharmacists to re-dispense one additional supply without a valid prescription. In other words, regular users (i.e. those who have used the medication for six months or more) can obtain one additional monthly supply (i.e. same amount as the last supplied quantity) without the need to see a doctor. Currently, CD has been legalised in all Australian states except Queensland.[2]

The Australian Medical Association (AMA) has condemned CD because it is a medication supply without a medical assessment by a General Practitioner (GP), and it involves only one healthcare professional (i.e. the pharmacist).[3] According to the AMA, this may compromise patient safety, and it involves a conflict of interest for pharmacists. On the other hand, the Pharmacy Guild of Australia (PGA) has supported CD because it is a convenient way to obtain medications in urgent circumstances.[4] In this regard, patient organisations have strongly supported CD and highlighted CD's convenience.[5, 6]

Currently, CD is limited to only two medication classes (i.e. Statins and OCs) and it is only allowable once in any 12 months period for each drug. Consequently, the patient health organization Services for Australian Rural and Remote Allied Health (SARRAH) has criticized these constraints on CD.[5] Moreover, the AMA has stated that Statins are not urgently needed medications and that the patients can safely wait for an appointment if it is not instantly available.[3]

1.2 Research Questions

It is unclear how patients (Statin and OC users), pharmacists and GPs will see CD, to what extent they may agree or disagree with CD, and how CD limitations will affect stakeholders' views. Moreover, what can be done to improve CD, particularly what other medications can be included within CD eligible drugs, and how the presence of other arrangements for urgent medication supply may affect pharmacists' utilisation of this new supply method? Finally, to what extent can pharmacists conduct CD appropriately?

1.3 Focus of dissertation

This project collected data before and after CD implementation. This project explored stakeholders' attitudes towards the current CD method and a modified version (i.e. one that would contain more medications and can be used more frequently).

1.4 Aims

This project had four main aims:

- 1) To explore patients', pharmacists' and doctors' attitudes towards the current CD to identify the pros and cons of CD.
- 2) To identify the disadvantages of current urgent supply mechanisms from the stakeholders' points of view, and how these can be addressed through CD or other suggested systems.
- 3) To evaluate the possibility of expanding CD to other therapeutic classes of medication based on the opinions of patients, pharmacists and doctors (i.e. their views about a modified version of the CD).
- 4) To assess pharmacists' knowledge of the appropriate use of CD using a series of case vignettes.

1.5 Methods

To achieve the project aims four methods were used:

- 1) Computer Assisted Telephone Interviews (CATI) were used to obtain patients' views (nationwide).
- 2) Postal Survey of pharmacists was utilised to obtain their views on CD (nationwide).
- 3) Case vignette study involving pharmacists from Western Australia to assess how appropriately they conduct CD, and also to obtain updated views on CD through a self-administered questionnaire.
- 4) Postal survey and informal interviews with GPs in Western Australia seeking

their views on the current CD and how it might be modified.

1.6 Basis of methods selection

To examine the first three aims a range of questionnaires were used, whilst case vignettes were used to examine the fourth aim. The idea was to use similar (thus comparable) questions with all stakeholder groups. The project approach was to collect qualitative and quantitative data. The method of questionnaire administration was either by trained staff from a telemarketing company, CDM Direct Communication Services in the case of Statin and/or OC users (i.e. Computer Assisted Telephone Interview, [CATI] survey) , or self-administered for pharmacists and GPs using a postal survey. Participants' identities were not collected to ensure the anonymity of the respondents, in the hope that their responses would be more reflective of their actual attitudes.[7, 8] In the case of the questionnaires administered to patients and pharmacists, in addition to questions about demographic information, each questionnaire contained two essential parts; questions about participants' attitudes towards the current CD and additional questions about potential modifications to the CD model. The pharmacists' questionnaire also contained another part about their usual practice when dealing with medication requests without a valid prescription. A literature review and experience from a previous study,[9] assisted in developing the questionnaires. The questionnaires were assessed for face and content validity by staff members within the pharmacy practice group at Curtin University. The questionnaires used with patients and pharmacists contained mainly closed-ended questions. In the case of GPs, the questionnaire contained only open-ended questions, which covered the similar topics as those in the patient and pharmacist surveys.

Participants were selected at random from publicly available resources on the internet in the case of the pharmacists and GPs surveys, and the phone directory for CATI participants. The plan was to obtain a representative sample size for each study: a total of 300 Statin and OC users for the CATI, pharmacists from 20% of the community pharmacies in Australia for the pharmacists' survey (stratified sample), and 24 GPs for doctors' survey.

In order to achieve the fourth aim of the project, a case vignette method was used. This method was considered a reliable method to investigate the appropriateness of community pharmacists conducting the CD method compared to published guidelines. The Pharmaceutical Society of Australia (PSA) published six case scenarios[10] related to CD which were used as the basis to develop the case vignettes for the current study. These scenarios were used to assess pharmacists' ability to identify in which scenarios CD was an appropriate method of supply.

1.7 Research hypotheses

The following hypotheses were tested through this research. The information in brackets identifies in which part of the research project they were tested:

H1 (Patient survey): Patients' concerns regarding CD are affected by their perception of risks.

H2 (Patient survey): Disease sufferers will be more supportive of the inclusion of their medications in an expanded CD than those without the disease.

H3 (Pharmacist postal survey): Pharmacists' decision to supply (regardless of the method of supply) will differ according to customer type (i.e. regular versus non-regular).

H4 (Pharmacist postal survey): Pharmacists' usual practice (before CD) will not be associated with their demographic variables (i.e. age, gender, pharmacy location).

H5 (Pharmacist postal survey): Pharmacists' support for the use CD will differ according to customer type (i.e. regular versus non-regular).

H6 (Pharmacist postal survey): Pharmacists' support to include more medications into eligible CD list will be associated with their demographic variables (i.e. age, gender, pharmacy location).

H7 (Case vignettes): Pharmacists decisions to use CD will differ according to their demographic variables (i.e. age, gender, years of experience).

H8 (GP survey): GP's will not support CD based on the arguments raised by the AMA.

1.8 Research significance

CD was implemented without a trial. Therefore, results of this research study will help health policy makers enhance CD through providing more insight in terms of eligible medications and utilisation frequency. This project provides a perspective on what additional medication classes could be included in an expanded CD system and what might be an appropriate CD utilisation frequency. Further, this project has obtained recommendations from healthcare professionals on what measures should be considered in enhancing CD safety and what modifications could be taken to improve urgent access to medications.

1.9 Thesis outline

This dissertation is divided into eight chapters, starting with a general introduction and ending with overall bibliography. References used for each chapter are presented chronologically at the end of the chapter. All references are displayed again in alphabetical order at the end of the thesis under bibliography section. Since some results of this project have been already published (two papers, and an additional one is under consideration for publication), a decision was made to display Chapters 3,4,5 and 6 using a standardised format (i.e. each has an introduction, aims, methods, results, discussion, conclusions and references). Overall findings are discussed in relation to the overall aims of the project in Chapter 7, whilst general conclusions and research recommendations are presented in Chapter 8. Each abbreviated item is presented in full at its first appearance in each chapter.

1.10 References

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Chapter 2: General Introduction and Literature Review

2.1 General introduction

Continued Dispensing (CD) is a recently implemented method to supply medication in urgent situations, to eligible patients who meet specific criteria. Further, a Pharmaceutical Benefit Scheme (PBS) payment is available for CD supplies that meet the criteria. (Box 2.1).[1]. The PBS is part of the Australian Government's broader National Medicines Policy (Medicare Australia). It provides affordable access to essential medications for all Australian permanent residents, and visitors from selected countries.[2] CD allows pharmacists to claim reimbursement using a "consumer's signed acknowledgement of receipt" instead of a prescription.[1]

Box 2.1 CD Principles for eligibility

- The requested medication is eligible (Statin or OC) .
- They have been using (prescribed) these medications for six months or more.
- They did not utilise CD method to obtain the same medication during the last 12 months.
- Their health condition is stable, and continuation of the medication is supported by a prior clinical review (i.e. the last prescription was provided after consultation).
- There was a recent (less than 12 months) consultation between the consumer and the prescriber.
- They were unable to obtain a prescription.
- The pharmacist judges that there is an immediate and ongoing need for the supply.
- The medicine is safe and appropriate.

Currently, the CD method is restricted to only two classes of medication. Also, it is only usable once in any 12 months period. This method allows community pharmacists to supply one additional supply of Statins (lipid modifying agents) and oral contraceptives (OCs) to the

regular users. Currently, they are the only patients eligible to utilise the CD method when they request these medications without a valid prescription and are unable to obtain an appointment to get a renewed prescription. No additional training is required for pharmacists to conduct the CD method.[3]

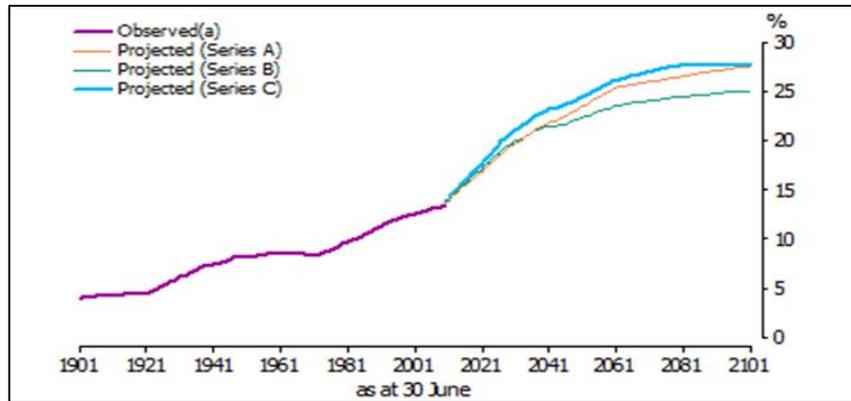
CD provides patients with an additional way to obtain their Prescription Only Medications (POMs) when they do not have a valid prescription.[4] In this research project, the phrase ‘without valid prescription’ means the requested medication has been prescribed by an approved practitioner, however; the consumer (or a carer) requests the medication with an expired prescription (usually after one year of the issued date), with a prescription without any remaining repeats, or the consumer/carer requests the medication from a new pharmacy (no dispensing history) without a paper prescription (in which case the consumer/carer may use an empty pack of the medication as proof of a previous supply). The CD method does not apply to new users of the drug (i.e. those who have been on the medication for less than six months).

CD was considered to be a convenient way to obtain medications in urgent cases because it does not require a valid prescription and urgent access to pharmacists is easier than to doctors. In general, pharmacies are located in most Australian communities.[5] Furthermore, pharmacies opening hours are generally longer than those of doctors’ surgeries.[6] Therefore when patients need medication urgently, it is often more convenient for them to visit a pharmacy than to obtain an immediate appointment with their regular prescriber.

Another factor that makes pharmacies more convenient is the tendency of most patients to visit a specific prescriber (usually their regular doctor).[7, 8] Even though patients particularly with chronic diseases tend to use a regular pharmacy, they may use any pharmacy (or pharmacist). In a previous Australian study, the majority (84·8%) of the respondents had a regular pharmacy.[9] Pharmacy location was the main reason for the selection of the regular pharmacy.[9, 10] Opening hours and accessibility were also reported as important.[11, 12] However, some consumers may obtain their medication from the most accessible pharmacy, particularly if they are travelling, move to a new place of residence, or their regular pharmacy is closed.

Lessening of doctors’ work overload was another reason behind the establishment of CD.[13] There are several factors that led, and continue to lead, to increase doctor workload. General life expectancy has increased (Figure 2.1). Patients tend to be live longer,[14] and be diagnosed with multiple co-morbidities.[15, 16] A recent report by National Health Performance

Authority about public GP attendance stated that there was increase in the average number of GP visits per annum during the last 25 years from 4.5 per person in 1987-88 to 5.6 per person 2012-13, with more than 22% of all Australians having had 6-11 visits (Table 2.1).[17] The report has also described those who had ≥ 20 visits as “high GP attenders” with an average cost of \$3,202 per person. Those attendees represented 3.8% of all Australians.[17]



(a) 1902-10 and 1912-1920 data points have been interpolated. 2009 and 2010 data points were calculated using preliminary population estimates.

Series A assumes high levels of fertility, life expectancy, and overseas migration. Series B assumes medium levels of fertility, life expectancy and overseas migration. Series C assumes medium levels of life expectancy and low levels of fertility and overseas migration.

Source: ABS [Australian Historical Population Statistics 2008](#) (cat. no. 3105.0.65.001); ABS [Australian Demographic Statistics June 2010](#) (cat. no. 3101.0); ABS [Population Projections Australia 2006 to 2101](#) (cat. no. 3222.0)

Figure 2.1 Proportion of the Australian population aged 65 years or older

Source: Australian Bureau of Statistics[14] (No special permission was needed to reproduce)

Table 2.1 Non-Hospital Medicare expenditure by GP attendance; 2012-13

Visits to a GP	GP attendance group [†]		Medicare benefits expenditure [†]		
	Number of Australians	Proportion of the population (%)	Total non-hospital Medicare expenditure [‡] (\$)	Share of non-hospital Medicare expenditure [‡] (%)	Per person non-hospital Medicare expenditure [‡] (\$)
Very high (20+ visits)	882,892	3.8	2.8 billion	17.7	3,202
Frequent (12-19)	2,010,630	8.7	3.7 billion	23.3	1,850
Above average (6-11)	5,268,252	22.8	5.2 billion	32.8	993
Occasional (4-5)	3,650,221	15.8	2.0 billion	12.6	551
Low (1-3)	7,774,432	33.6	2.0 billion	12.5	257
Zero	3,548,854	15.3	0.2 billion	1.0	-
All Australians	23,135,281	100.0	16.0 billion	100.0	690[§]

[†] Non-hospital Medicare Benefits expenditure relates to benefits paid. It excludes services provided to hospital patients, to Department of Veterans' Affairs beneficiaries, some patients under compensation arrangements, through other publicly funded programs and private funding.

[‡] GP attendances were determined using non-referred Medicare benefits-funded patient/doctor encounters.

[§] Calculation includes all non-hospital Medicare expenditure and all Australians.

Note: Columns may not add to totals due to rounding.

Sources: National Health Performance Authority analysis of Department of Human Services Medicare Benefits statistics 2012-13 and Australian Bureau of Statistics Estimated Resident Population 30 June 2013. Data extracted November 2014.

Source: National Health Performance Authority.[17] (No special permission was needed to reproduce)

The increased life expectancy and co-morbidities of the population have resulted in patients potentially requiring more frequent and longer visits with their doctor.[18] Such visits will include some which are solely so patients can obtain new prescriptions for their chronic medications. It was estimated that in 2012-13, there were approximately 4 million visits to GPs just for renewing of prescriptions for ongoing regular medications, which represents 3.2% of the annual visits.[5] This stretches the already busy doctors' schedules. Garth et al. reported that if the patient did not plan in advance to obtain an appointment, it is often difficult or even impossible to obtain one urgently.[19] Also, doctors may squeeze other appointments to see those requesting prescription renewal.[19] Doctor shortages in general, and in rural and remote areas specifically, is another contributing factor,[5] which may increase doctors' workload.

CD may provide better use of pharmacists and efficient use of new pharmacy graduates.[20] Pharmacists are not only medication experts,[5, 21] they also have other skills, which are either unrecognised or unused by patients and/or the health system.[5, 13] Pharmacists are trained in pharmacology and other health related subjects. In practice, these skills have often been focused primarily on dispensing.[22, 23] Doctors are trained and equipped in the areas of

diagnosis and clinical review and prescribing. CD does not undermine the role of doctors.[4] In cases of stable chronic disease, where the diagnosis has already made by a doctor, these patients may be managed by pharmacists. Hoti et al. in their study found pharmacy clients who supported an expanded role for pharmacists (prescribing), supported the form of pharmacist prescribing that does not involve diagnosis (i.e. Supplementary Prescribing).[24] Similarly, in the case of CD when the original prescriber is not available, pharmacists are capable of following up with these patients either by continuing the medication, or referring them to another doctor or emergency departments.[5] Through counselling of patients requesting a repeat supply, pharmacists may identify cases of unnecessary medication use, medication being used incorrectly, and where patients require immediate review by their doctor. For example, Morecroft et al. described how a pharmacist who was counselling a patient for an urgent supply of antidepressant found that the patient was still using a high dose of the drug even though the prescriber had reduced the dose.[6] A respondent in the Morecroft et al. study argued that in some instances of urgent visits to after-hours GP services the regular pharmacist may be in a better position to deal with such requests than an on duty doctor.[6]

Moreover, it has been reported that the inability of doctors in emergency departments to access a patient's regular pharmacy dispensing record may place the patient at increased risk of drug-drug interactions.[25, 26] Not all patients who request a medication (as a repeat supply or a self-medication) from a pharmacist are provided with the medication. Where appropriate the pharmacist may refer the patient to a GP or another appropriate health service. Pharmacist referrals may benefit patients and doctors in different ways. For example, the pharmacist may write a referral letter with all medications used by the patient including Over-the-Counter (OTC) medications. This additional information may expedite the patient seeing the doctor and save time for the doctor in their review.[27] The optimal use of pharmacists' knowledge and skills benefits not only the patients, for whom it was impractical to see their regular doctor, but also the health system.[5, 13]

Another indirect aim of CD is economic savings by the government. This may be achieved through the efficient use of pharmacists' skills, particularly to avoid unnecessary visits to doctors, such for "just" prescription renewal.[20] In 2011-12 over \$140 billion was spent on the health care system in Australia.[28] Suboptimal use of resources, such as the pharmacists, may add avoidable pressure to health expenditure. By removing the prescription requirement for an additional supply of a regular medication, as in the case of the CD, pharmacists are able to continue the medication, if appropriate, without the need for a doctor's visit solely to renew the prescription. In the UK there is a trend to employ pharmacists in GP surgeries, and these

pharmacists (often pharmacist prescribers) are often tasked with prescription renewals.[29, 30] The introduction of pharmacists into GP surgeries was proposed to address GP shortages in the UK. In addition, this step may save some resources by moving unnecessary workload from doctors to pharmacists.[5] Easier access to medications may minimise short and long term treatment interruptions.[30, 31] Treatment discontinuation may lead to more hospitalisation and an associated increase in health expenditure.

2.2 Literature Review

2.2.1 Background

Ensuring timely access to treatment, including medication, is the ultimate goal of any health system. Whilst a medical review and a subsequent prescription from an authorised prescriber are essential to ensure patient safety and the need for the medication, this may result in a delay to obtain the medication if an appointment with the prescriber and thus a prescription cannot be obtained in a timely manner. Patients need a prescription to obtain their POMs. Such prescriptions in Australia are generally valid for 12 months (from the date of writing), after which a new prescription is required. Complicating the issue for patients prescribed multiple chronic medications is the fact that differences in quantity of supply and daily dosages can mean that medications run out at different times, and hence the prescription renewal cycles are often different.[6] In short, there are situations when patients need their medications before the next available appointment with the prescriber.[6, 19] In cases where an urgent appointment with the prescriber and a new valid prescription cannot be achieved, there is a risk of treatment interruption.

Treatment interruption and medication non-adherence are avoidable complications of patients' inability to obtain a new prescription for their ongoing medical care. When patients run out of their medications, they may seek an urgent appointment with the original prescriber to renew their prescription. However, this option is not always available. Consequently, they may request an appointment with another prescriber, or after hour's doctor. However, there are some patients who do not want to change their prescriber, and hence do not avail themselves of these options.[7] Another option is to attend an Emergency Department. The drawbacks of this option are long waiting times, in addition to the delay that such presentations may cause to other more urgent cases.[32] If the patient does not utilise any of the above options, this might result in the patient stopping treatment for a short period. This period may be extended if there is no significant symptoms or acute reaction as a result of medication discontinuance. This may lead to a complete treatment discontinuation (also known as non-persistence).[31]

Treatment regimens may be affected by short or longer period of interruption. For example, unwanted pregnancy from the temporary discontinuation of OCs or complications resulting from a premature discontinuation of antidepressants.[33] Patients' non-adherence to their chronic medications is a significant health issue.[34] Patients who have a tendency not to adhere to their medications may find the inability to obtain a new prescription as an excuse for their actions.

On the other hand, patients who want to adhere to their medication may consider other options to avoid treatment interruptions. For example, some may decrease the daily dose in order to not consume all the medication before the next appointment with the prescriber. Others may borrow the medication from a partner or housemate.[6, 35] All of these options are not recommended and may result in under-treatment, or the potential use of the wrong medication.[35]

A further option which patients may consider, is to request an emergency supply of their medication from their regular pharmacy (or any other pharmacy). Pharmacists regularly face requests for medication supply without a valid prescription from customers who have run out of medication and unable to obtain a new prescription.[6, 36] Patients also may find requesting the urgent supply from their regular pharmacy more convenient and less expensive. For example, in the UK pharmacists may provide their regular customers with a "loan" supply with an anticipated prescription to follow.[6] In this case, the patient will not have to pay any out of pocket expenses.

2.2.2 Urgent medication supply within Australia

In accordance with the Poisons Act, a POM must not be supplied without a prescription. However, pharmacists are legally allowed to supply in the absence of the prescription in the case of an emergency. For example, when patients run out of medications, and it is not practical to obtain a prescription without undue delay, which may affect the patient. When pharmacists face such a situation, it is not always safe to not supply, such as illustrated by a case in America where refusal to supply insulin resulted in a young man's death.[37] However, the pharmacist must be confident that it is safe to supply as well. For example, in cases where the last prescriber had prescribed fewer than usual number of repeats, the patient has been admitted to hospital recently, or the last prescription was made without a consultation with the original prescriber.[38]

Three methods for urgent supply in Australia have been identified from the literature:

- 1) Emergency Supply
- 2) Owing Prescription
- 3) Continued Dispensing

In each method, the pharmacist must be satisfied with the urgency of the request and make the safest decision. All the urgent supply methods share the same set of basic principles as outlined in Box 2.2.[35, 39-44]

Box 2.2 Basic principles of urgent supply methods

- The request for medication is urgent.
- The original prescriber either unavailable or unable to provide a paper prescription.
- The patient is stable on the medication.
- The medication was prescribed by a registered practitioner.
- The urgent supply is safe.

The primary differences between these methods relate to the supply quantity, prescriber involvement, and funding.

2.2.2.1 Emergency Supply (ES)

This method allows pharmacists to supply a three days quantity of the requested medication or the minimum quantity of unbreakable containers such as inhalers. To fulfil this condition pharmacists may need to break an original pack that cannot subsequently be sold; hence this may lead to medication wastage and increased charges by the pharmacy to cover the loss on the broken pack. This method does not require a follow-up prescription (i.e. a prescription after the supply has taken place) or prior contact with the original prescriber.[35] However, this method is not funded by the PBS; the patient must pay the full price for the medication and the dispensing fees.[39] The cost may deter some patients from using this method.

2.2.2.2 Owing Prescription (OP)

This method involves the supply of one additional repeat of the last valid prescription, thus does not require breakage of the original pack. It is also covered by the PBS system, in the case where an owing prescription is presented to the dispensing pharmacy. Therefore, the patient has no additional out of pocket expenses other than the usual co-payments. However, it involves prior contact with the original prescriber. If the original prescriber authorises the supply, then a paper prescription (a follow-up prescription) must be sent by mail within seven days to the supplying pharmacy. The pharmacy will then use this prescription to claim reimbursement from the PBS. Faxed or emailed prescriptions are not accepted.[42] In the case of some Authority items, the prescriber must obtain permission from Medicare, before they can authorise supply over the telephone. Doctors complain about their efforts in writing prescriptions without reimbursement.[2, 45]. In practice, the pharmacist may conduct the OP supply without prior contact with the prescriber.[43] This practice may lead to a financial loss if the doctor decides not to renew the prescription at the patient's next appointment.[39]

2.2.2.3 Continued Dispensing (CD)

This is the most recent method to supply medications in urgent situations. It was implemented in all Australian states and territories from September 1, 2013, except Queensland. It was implemented to complement the ES and OP methods, and to supply certain medication in specific circumstances.[44]

Like the ES method, CD does not involve prior contact with the prescriber. In addition, it shares the OP method regarding the supplied quantity. It is also covered by the PBS system. Pharmacists can claim the cost of the medication and dispensing fees from the PBS. Therefore, there are no additional out of pocket expenses for patients. Whilst this is convenient for patients, it involves extra work for pharmacists to record all the required details to allow claiming from the PBS. Also, the method is restricted to two medication classes only, and it has a limited utilisation frequency. It can be used to supply the same medication (Statin or OC) for the same patient only once in a 12 month period.[46] These restrictions may limit the achievement of CD stated targets.[47] The CD method was originally proposed by Bessell et al. in 2005, under the term "Medication Maintenance" (MM).[35] Bessell et al. conducted a study to propose models to improve Australians' access to their medications. They proposed four models including MM. The MM model was the originally proposed version of the CD method of supply. However, there are some differences between the proposed and the implemented versions. The MM model was not restricted to supply only Statins and OC.

Controlled medications were the only medications excluded from the MM model. However, it was initially proposed to provide medications for patients in Residential Aged Care Facilities. The CD method is useable in the community pharmacy setting, which services a broader range of customers.

The current CD came to fruition after the Fifth Pharmacy Community Agreement between the Australian Government and the Pharmacy Guild of Australia (PGA). The latter represents pharmacy owners in Australia. Other (former) names for CD were Medication Continuance or Repeat Prescribing.[20, 48]

2.2.2.3.1 CD and other PBS arrangements

When CD is used, other existing PBS arrangement will apply such as the Medicare Safety Net and the 20 day rule.[20] The Safety Net reduces the cost of medications when the consumer co-payments reaches the Safety Net threshold.[49] The threshold is \$1453.90 for General consumers and \$366 for Concessional card holders.[50] After consumers co-payments reach the threshold, there is no longer a co-payment for Concessional consumers, and the amount of co-payments for General consumers is reduced to the Concessional co-payment. For example, the usual co-payment (for 2015) by General consumer for Pregabalin Capsule 75 mg is \$ 37.70 before Safety Net threshold, and it is \$6.10 once the threshold is met. Concessional consumers co-payment for the same medication is \$6.10 before the Safety Net threshold, and they are exempted from co-payment when the threshold has been reached.[51]

The 20-day Rule was initiated in 2006 to prevent overuse/misuse of the Medicare Safety Net. According to this rule, any resupply for the same medication within 20 days from the last supply will not be counted towards the safety net. In this case, even though the Safety Net threshold has been reached, the co-payments will be the usual unreduced co-payments. As an example for the medication above, the co-payments (for 2015) would be \$37.70 for General consumers and \$6.10 for Concessional consumers.[52]

2.2.2.3.2 CD eligible medications

Currently, Statins and OCs are the only eligible medications that can be supplied using the CD method. The permitted Statins are atorvastatin, fluvastatin, pravastatin, rosuvastatin, and simvastatin. The allowed OCs are levonorgestrel, levonorgestrel with ethinyloestradiol, norethisterone, norethisterone with ethinyloestradiol, norethisterone with mestranol.[53]

Their relative safety was the reason for selection of these medication classes.[4, 54] It has been suggested that other medications may be added after the complete implementation of e-Health records and electronic prescriptions.[20]

2.2.2.3.3 Statins safety risk ratio

Statins are among the most widely prescribed medication for patients at risk of coronary heart disease and other atherosclerotic vascular disorders. The most commonly reported adverse effects of Statins are the asymptomatic increase in hepatic enzymes and musculoskeletal disorders (myalgia in 5% of users, myopathy in 0.2% or less, and rhabdomyolysis in 0.01% of Statin users).[55] According to Brown, adverse effects are rare, and the benefit to risk ratio is very high.[56] In addition, a large cohort study reported mixed benefits and adverse effects of the Statins, such as a reduction in oesophageal cancer and increase in liver dysfunction and acute renal failure.[57] The relative safety of Statins prompted the availability of low dose preparations without a prescription under pharmacist supervision in the UK.[58] Gotto stated that “After a median of 5.2 years, lovastatin therapy yielded a statistically significant 37% reduction in the rate of first acute major coronary events defined as fatal or nonfatal myocardial infarction, unstable angina, and sudden cardiac death ($P < 0.001$).”[59] According to Therapeutic Goods Administration (TGA) website (last updated 26 October 2015), the most recent concerns about Statin side effects are memory loss and cognitive impairment, which is reversible upon medication withdraw, the risk of type 2 diabetes mellitus, and an increase in liver enzymes. In addition, the TGA mentioned that it “will review the evidence associated with the use of Statins and Protease inhibitors.”[60]

2.2.2.3.4 OCs safety risk ratio

The use of OCs is the most common method of contraception and is used by millions of women around the world. OCs are a safe and effective method of contraception (if properly used). Besides their effect in preventing unwanted pregnancies, they have other health beneficial effects. For example, users of combined OCs have lower death rates overall, and lower death rates from cancer, cardiovascular disorders and other disorders.[61]

The decision to include OCs as an eligible medication class for the CD was based on safety grounds. Their inclusion also supports the recommendations by the World Health Organisation (WHO) to update medication supply policies to allow more convenient access to OCs, and greater consideration of users preferences.[62] According to the WHO, OC users fall into four categories depending on risk: Category A: “A condition for which there is no restriction for

the use of the contraceptive method,” Category B: “A condition where the advantages of using the method generally outweigh the theoretical or proven risks,” Category C: “A condition where the theoretical or proven risks usually, outweigh the advantages of using the method,” and Category D: “A condition which represents an unacceptable health risk.”[63]

Females who fall in Category A and B can use OC without significant clinical review.[62] This suggests that pharmacists would safely be able to supply OCs in such cases.

2.2.2.3.5 Non-adherence to Statins and OCs

Non-adherence to chronic disease medications is a global challenge. Non-adherence is not uncommon in older Australians with chronic diseases. It is estimated that on average only 50% of the users are adherent to their chronic medications.[64, 65]

For Statins, non-adherence is not an uncommon phenomenon.[66] Bates et al. have defined two types of non-adherence. Non-adherence could be primary and result in “the failure to initiate therapy” or secondary where there is “failure to continue the therapy.”[66] According to Bates et al. secondary non-adherence included “premature discontinuation”.[66] It is worth emphasising that secondary non-adherence was defined by Solomon and, Majumdar as “when prescriptions are filled, but the medication is not taken as prescribed.”[67] These authors have used the term lack of persistence to define “self-discontinue therapy by not refilling their prescriptions.”[67] Moreover, non-adherence can be classified as intentional or unintentional. If the patients decided not to use or not to continue a medication, this is intentional non-adherence. However, unintentional non-adherence results from reasons outside the control of the patient such as forgetfulness, traveling without medication, or being unable to access the medication.[34] Therefore, patients who do not have a valid prescription may become unintentionally non-adherent.

In such cases, the discontinuation period may be short until the medication is obtained, or for longer periods. Brookhart et al. reported that 53.8% of new Statin users had a period of Statin discontinuation of 90 days or more, although 60% of patients resumed the treatment within 2 years.[68] Increased patient co-payments are amongst other causes of non-adherence to Statins.[69] Ellis et al. stated that “patients whose average monthly Statin prescription co-payment equalled or exceeded \$20 were more than 4 times as likely to discontinue Statin therapy than those patients who paid less than \$10.”[69] This suggests that cost may be a deterrent factor to patients offered an emergency supply of their Statin which involves full cost recovery from the patient.

Non-adherence to OCs or OC discontinuation may occur when OC users had no access to their medication. The latter may be due to the patient's inability to obtain a new prescription, being away from home and not having the OCP with them, and being unable to obtain a new pack. These were the most cited reasons for OC discontinuation reported by 141 women who participated in a study in North Carolina.[70] The study authors recommend removing barriers to obtain a new pack of OC as this would lead to lower discontinuation rates. This was confirmed by another USA study, which found lower discontinuation rates among women who obtain OC without a prescription in Mexico compared to women who need a prescription to obtain OC from El Paso US clinics.[71] Other factors which may contribute to OC discontinuation include financial difficulty and lack of time for medical visits.[72]

2.2.2.3.6 Statin prescription status

Statins are prescription only medications in Australia. However, in the UK in 2004 a Statin (simvastatin 10 mg) was made available without a prescription, but its supply requires pharmacist supervision; i.e. "Pharmacy P" medication.[73] This ensures convenient access as well as, providing necessary consultation with a health care professional. In Australia, the equivalent term for Pharmacy P medicine is Pharmacist Only Medication.[74] In the USA, there have been several attempts to switch Statins to be available without a prescription. However, the US Food and Drug Administration (FDA) has so far rejected those proposals. The lack of availability of Pharmacist Only Medication provisions in the US may have affected the FDA decision to grant over the counter status to Statins.[75]

Switching medication to non-prescription status in Australia may be followed by their removal from the PBS list of medications. This means that the patients would need to pay in full. The financial burden to the patient may, however, be offset by less expensive generic products driven down by market forces.[76]

2.2.2.3.7 Research about non-prescription Statin

The availability of Statins without a prescription was not supported by GPs in a study conducted in Scotland.[77] Although this study was limited by low response rate, its result was not surprising because of doctors' tendency to oppose down-scheduling medication.[78]

On the other hand, UK pharmacists expressed a strong self-confidence to supply Statins without a prescription.[79] Moreover, pharmacist interventions have proven to be effective in the treatment of patients with lipid disorders.[80]

2.2.2.3.8 OC prescription status

High dose OCs known as the Emergency Contraceptive Pill (ECP) have been available without a prescription since 2004, as a Pharmacist Only Medication in Australia. Given the time-sensitive nature of emergency contraception, access without delay increases the efficacy of ECP.[40]. The PBS does not fund this method.[41] Several countries have made ECP available without prescriptions such as France, the UK and the USA.[81] However, normal OCs are POMs in Australia. In a study by Dixon et al.[82] participants complained about access difficulties and the cost of GP visits, with some reporting these issues had deterred them from taking OCs.

The consequence of not using an OC, or other effective forms of contraception, may be an unintended pregnancy. In Australia, unintended pregnancies are a major issue with approximately half of all pregnancies being unintended (which equates to ~200,000 unplanned pregnancies annually).[83] Unplanned pregnancy is not the only complication of failure to use effective contraception, with one in three cases of unintended pregnancy leading to abortion.[84]

In 2014, a proposal was submitted by Green Cross Health (a New Zealand pharmacy banner group) to the TGA to down schedule OCs to Pharmacist Only Medication (i.e. Schedule S3). This proposal required “patients to fill in a simple questionnaire on any family history of hypertension, heart problems or stroke. The pharmacist would also need to conduct a blood pressure test on the patients to make sure they are suitable for the medication.”[85] The AMA opposed the proposal because of patient-related factors, namely safety and privacy, whilst questioning pharmacists’ ability to interpret patient information.[85] This attempt failed with the TGA in 2015 rejecting the proposal and confirming the need for a prescription to obtain an OC.[86]

Removal of a prescription requirement may increase access to OCs.[87] Grindlay and colleagues,[88] analysed data from 147 countries around the world. They found that, in the majority of these countries, OCs were available without a prescription either legally or informally. The authors concluded that this availability may support the safety of non-prescription OCs. Travelling without OCs or the inability to obtain an OC product when a new menstrual cycle started have been cited as reasons for OCs discontinuation, and the use of a less efficient method or non-use of contraception.[62] Moreover, unintentional pregnancy has health risks on women with other diseases. According to the WHO, there are a 17 medical conditions, such diabetes and epilepsy, where unwanted pregnancy poses a greater risk to the

women.[89]

Easy access to OCs would be preferred by OC users. In a study by Landau and colleagues,[12] exploring women's views about pharmacy access to hormonal contraception in the United States, approximately two-thirds (63%) of the participants supported non-prescription status for OCs under a pharmacist supervision.[62] It is worth emphasising that results of the Landau and colleagues study may be affected by views of women without insurance cover. In Australia, normal supply of OC in the presence of a prescription is covered by the PBS. However, an emergency supply of the OC without a prescription for women who have run out of their regular OCs is not covered by the PBS. Therefore, removing the prescription requirement to obtain the OC, such as in the case of CD, should improve access and minimise treatment interruption. In the case of CD, women can obtain one supply, in any 12 months period, in cases where it is not practical to obtain a new prescription.

2.2.2.3.9 Pronounced opinions about CD

2.2.2.3.9.1 The Australia Medical Association (AMA)

The AMA announced in 2011 that it “is strongly opposed to a proposal to allow pharmacists to supply prescription medicine without a valid prescription and without referring to the medical practitioner treating the patient.”[90] According to the AMA, pharmacists are not trained to make decisions to continue or cease the medication. The AMA also claimed that OC are not a chronic disease therapy, and Statins are not urgent medications. The AMA added that the vast majority of GPs can provide immediate prescriptions with or without a consultation if clinically appropriate.[90] Conflict of interest that may arise from pharmacists being a prescriber and dispenser was also cited by the AMA.[91]

2.2.2.3.9.2 Pharmacy Guild of Australia (PGA)

The PGA supported the introduction of CD.[4, 48] The PGA thought CD would benefit the health system through decreasing costs associated with prescription renewal and enhance utilisation of pharmacist skills. The PGA also claimed that CD would benefit patients through minimising treatment interruption that results from running out of medication between appointments, and also offering a financial benefit for consumers through PBS covering of the CD supply. Further, the PGA stated that CD would help minimise the disadvantages of other emergency supply methods such as the administrative burden of the OP and waste production of the ES.[20]

2.2.2.3.9.3 Consumer Organisations

The Consumers Health Forum of Australia (CHF), representing Australian healthcare consumers, supported CD as a method to improve patient adherence to medications and to prevent treatment interruption that may result from inability to renew a prescription.[92] The CHF also emphasised that consumers must be consulted about what medications they believe should be included in the CD method. The CHF also announced its support for consumer satisfaction surveys that would improve the CD method.[92, 93]

The Health Care Consumers' Association (HCCA),[94] also supported the CD through its input on a CD consultation paper in the Australian Capital Territory (ACT), and valued its role to improve access to medications. It also called for CD expansion to include more medications such as diabetes, arthritis and asthma medications. The HCCA also urged the inclusion of opiates and argued that chronic pain has major impacts on consumers. It expressed consumers' concerns about being "forced to pay to visit the doctor every few months to renew their prescription". Furthermore, the HCCA has described this situation as frustrating particularly for consumers who know they have to use these medications continuously for life. It also stated that this may be an expensive and time-consuming process.[94]

The Services for Australian Rural and Remote Allied Health (SARRAH) also supported CD and called for both CD expansion and extension (i.e. more frequent access).[47] SARRAH commented on the CD consultation paper and its response was assisted by Lindy Swain, Pharmacist Academic and a member of SARRAH Advisory Committee. SARRAH provided reasons why CD should be expanded. It claimed that the vast majority of patients prescribed a Statin are using other medication for co-morbidities such as diabetes and hypertension. According to SARRAH, patients and doctors may not understand why a prescription is needed for some medications but not for others. The difficulty in retaining physicians in these areas was also cited as a reason for CD extension, where obtaining an appointment with the doctor is problematic. SARRAH, also valued CD's role in the continuity of care for patients who are travelling without their medication.[47] It is worth mentioning that SARRAH's position on CD may be biased by the assistance they obtained from its pharmacist member.

2.2.2.3.9.4 Public views

Customers' comments about the CD bill (Medication Continuance) showed public support for CD.[95] The reasons provided related to the cost associated with a doctor's visit just to renew a prescription for ongoing medications. Some respondents complained about the need to pay

\$30-60 for a consultation with a doctor that only included writing a prescription.

Further, some consumers acknowledged pharmacists' expertise, and they particularly appreciated the way the pharmacist handled repeat prescriptions. A comment read: "From my experience at least the pharmacist asks questions before giving medication". This comment is probably referring to the difference between prescription renewal (without consultation) by doctors and obtaining a repeat supply from pharmacists.[95]

2.2.3 Urgent medication supply: International Aspects

Worldwide there are urgent medication supply methods. These methods are quite diverse; however, they either involve urgent supply upon request of a prescriber or a patient. Also, they all share fundamental principles with the Australian urgent methods (Box 1.2).

2.2.3.1 Urgent supply in Canada

The Canadian health system allows pharmacists to exercise significant control over medication supply in urgent situations.[96, 97] The quantity of supply may be limited to be enough until the next appointment with the original prescriber or up to one month's supply. In most cases, the prescription must be renewed at the original pharmacy (where a previous normal supply was obtained), however some provinces permit the renewal at any pharmacy.[98] The other general rule is the exclusion of controlled drugs except the use of benzodiazepines in the case of convulsive disorders. Notification of the original prescriber ranged from mandatory to recommended.[98]

In several Canadian Provinces, the pharmacist may adapt the ongoing prescription or even prescribe in the emergency cases when another prescriber is not available and the treatment is needed urgently. For example, in the Province of New Brunswick, pharmacists may legally adjust the dose, or change the dosage form of prescribed medication. They can also renew prescriptions, prescribe independently in case of an emergency, or collaboratively with an authorised practitioner. In the Northwest Territories, pharmacists can continue dispensing for up to 30 days for patients with chronic diseases except for controlled medications. In certain circumstances, pharmacists are also allowed to substitute the prescribed medication with less costly equivalent. It is worth mentioning that in the province of Alberta, pharmacists, who have been acquired an additional prescribing authorisation, have independent prescribing rights.[98]

2.2.3.2 Urgent supply in the United Kingdom (UK)

In the UK, patients who need an urgent supply of their regular medication can request an emergency supply from a pharmacy. The quantity supplied may be up to 30 days' supply, up to five days' supply of permitted controlled medication, a full treatment cycle for OC, and the smallest pack size for special containers such as inhalers. The patient must pay the cost.[99] According to NHS Direct Wales website, most of the pharmacies would refund the patient if a "follow prescription" was obtained.[100] The latter is called "loan" supply in the UK, and it is identical with some forms of OP supply without prior contact with the prescriber in Australia.[35]

On the other side, the request may be made by a prescriber because of the inability to provide an immediate prescription. In this case, the supplied quantity is at the instruction of the prescriber, and it is a funded method, hence incurs no additional cost to the patient. Controlled medications cannot be supplied by this provision except for treatment of epilepsy.[101]

Pharmacists and nurses in the UK can renew prescriptions in urgent cases through Patient Group Direction (PGD). The PGD is defined as "written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for prescribing treatment." [102] This is a funded program, therefore the pharmacist will be remunerated for this service. The quantity supplied usually is the same as for the normal repeat supply or up to one month's supply if that was not known. However, PGD can only be used to supply a limited range of medications such as OCs, emergency contraception, antibiotic and anti-histamines.[33] The supply can be made upon request from a patient, patient representative or a registered prescriber.[103] While, there were no major safety concerns about the PGD, inflexibility of the PGD does not support pharmacists' professional input.[104] For example, the strict inclusion criteria minimises their independent clinical judgment. Therefore, the PGD would be less helpful to experienced pharmacists because it does not add much more experience to skilful practitioners.[104] Similarly, CD restrictions, particularly in terms of its eligible medications, may result in CD avoidance by pharmacists who find difficulty explaining to patients why they can obtain some medication without prescription but still need a prescription for other medications.

In a recently published UK study,[105] Nazar et al. evaluated a new service (NHS Community Pharmacy Emergency Repeat Medication Supply Service (PERMSS)). This service is designed to ensure that patients can access an urgent supply of their regular prescription medicines

where they are unable to obtain a prescription before they need to take their next dose. The authors collected feedback from 1511 patients (response rate 60.8%) and 211 pharmacists (response rate 70%) regards the service. The majority (93%) of the patients found the service was easier or much easier to access than other NHS services. Furthermore, 50% of the patients reported that they would have missed doses of their medication had they had to get a new prescription. Even though 66% of the pharmacists reported the service had increased consultation times and the workload, the majority (92%), were happy or very happy to provide the service. Nazar et al. concluded that community pharmacists were able to manage emergency requests for medication repeats and patients were satisfied with the service.

2.2.3.3 Urgent supply in Ireland

In Ireland, an emergency supply request can be made either by a patient or a prescriber.[106] In both cases, the pharmacists must consider the potential risk of supply or non-supply. The supplied quantity is either as instructed by the prescriber (in the case of request made by a medical practitioner) and no more than five days' supply in the case of requests made by patients, full cycle of OC, or the minimum quantity in case of special containers. Controlled medication cannot be supplied under these provisions.

2.2.3.4 Urgent supply in the United States of America (USA)

There are diverse emergency supply rules in the USA.[107] For example, the quantity of emergency supply varies from no emergency supply to a reasonable amount. The majority of states allow a three days' supply followed by a 30 days' supply. Controlled medication cannot be supplied under these provision.[108]

2.2.3.5 Summary of urgent supply methods

It can be summarised from the above that there are two types of urgent supply in Australia and worldwide. The first type involves a doctor intervention to request or to authorise the urgent supply (e.g. ES under request from a doctor in the UK, and OP in Australia). This type of urgent supply is characterised by a usual amount of the medication (i.e. one month supply or according to the doctor's instruction). This system is usually a funded supply, thus patients pay the standard co-payments without any additional cost.

The second type does not involve a doctor intervention or authorisation (e.g. ES in Australia and ES in the UK upon patient request). The amount of supply often ranges from a three days' supply to one month, according to the country or the state. Moreover, the patient must pay the

full price because this supply is not nationally funded. Consequently, some pharmacists may help the patient through by supplying the medication before a prescription is obtained (such as loan supply in the UK).

It is worth mentioning that regardless of doctors' involvement or not, these urgent methods can be done without the doctor consulting the patient face to face. This may imply that the prescriptions in these cases are only as a legal requirement, not a safety measure. CD has been implemented to ease patients' access to medications through removing this legal requirement for selected medications and specified conditions. However, the stakeholders' views of its value and utility remain largely unknown. For that reason this research was undertaken. Presented below (Section 2.2.5) is a review of the methodologies used in this research for the purpose of ascertaining views of patients, pharmacists and GPs.

2.2.4 Association between pharmacists' demographics and their decisions

The urgent supply of medication involves a decision-making process by the pharmacist to either supply or refuse to supply the medication for the patient requesting a medication without a valid prescription.

The association between healthcare professionals' demographics and their decision-making process has been described in the literature. Weisse et al. studied the effect of physicians' gender and race on pain management using case vignettes.[109] They found that male and female physicians exhibited different treatment patterns. For example, male physicians prescribed higher doses of Hydrocodone to male patients than female patients, while female physicians prescribed higher doses to female patients.[109] Similarly, Hamberg et al. found that male and female physicians managed neck pain differently.[110] Other studies have investigated pharmacy location influences on pharmacies stocks of opioids analgesics.[111, 112] Morrison et al. reported that pharmacies in minority areas were significantly less likely to stock opioids compared with non-white pharmacies: "those in which less than 40 percent of residents were white." [111] Greet et al. has also confirmed the influence of pharmacy location.[112] Moreover, Kahan et al. explored relationships between pharmacist demographics (age and years of practice) and their survey items (number of total daily prescriptions in the pharmacy, number of opioid prescriptions, and number of opioid patients for whom the pharmacist had concerns).[113] In another study about attitudes of pharmacists towards mental illness and providing pharmaceutical care to mentally ill

patients, the authors found numerous associations between pharmacists demographics (gender, age, and years of practice). For example, males had more positive attitudes than female pharmacists, and older and more experienced pharmacists had more positive attitudes than their younger and less experienced counterparts.[114]

2.2.5 Data collection methods

Four techniques of data collection used in this research project. Each method was selected to obtain answers to the study questions.[115] Besides validity and reliability of each method, the method selection criteria were based on two factors: convenient and cost-effectiveness. All techniques used in this project assumed that the participants provided unbiased answers. Certain steps were taken to minimise any potential bias including ethical review and validation processes to detect any biased questions or biased information in the information sheets. Selection of participant samples on a random basis, use of independent interviewers in the patient survey, and all data collected anonymously. Nonetheless, in any study with humans, bias cannot be eliminated completely. Data collection methods are described below:

2.2.5.1 Computer-Assisted Telephone Interviews (CATI)

This method was used to collect data from Statin and OC users from around Australia. This method has several advantages that make it meet the selection criteria for this project. Collecting data from the public must consider that there would be variation in the sample regarding the level of education and thus ability to understand the questions. This method allows the participants to ask questions; it also enables supervision of questionnaire administration by the interviewer.[116] Also, it has been reported that the phone interviews take less time, and are more interesting than the self-administrated method.[117, 118] Participants questioned by telephone are reported to be relaxed and able to talk freely. Also, telephone interviews provide more anonymity than face to face meetings.[119]

In addition, with the geographical expanse of a country like Australia, CATI is a cost-effective method.[24] It would be very difficult, expensive, and time-consuming to obtain a representative sample without using CATI.

In this method, a computer is used to assist the interviewer. The computer enables the interviewer to view the question on the screen, skip irrelevant questions and enter the data instantly.[120]

Disadvantages of this method are related to the technical problems such as disconnected

phones or coverage issues.[121] Some groups of the population are not contactable by this method such as mobile phone only users, persons with hearing difficulties, and individuals who have communication problems including difficulty in understanding the interview language.[122] It also suffers the disadvantage of the absence of visual cues and gestures from the interviewer that may be seen during the face to face interviews. However, such nonverbal data has a risk of misinterpretation.[119] Finally, although “telephone interviews are less vulnerable to interviewer and respondent bias than face to face interviews,”[123] these types of bias are still possible.

2.2.5.2 Self-administered questionnaires

This method was used to collect data from community pharmacists from around Australia. Again, this process meets the selection criteria for this project (convenient and cost-effective). Data collection from workplaces needs to take into consideration how convenient the method is for potential participants.[116] The self-administered method allows the participants to choose the most appropriate time to complete the questionnaire, and it is a less distractive process.[116] Besides, this technique may use both open-ended and/or closed-ended questions. While the open type allows participants to express their opinions, the closed type takes less time.[124]

This method meets the second factor of the selection criteria (cost-effective). Again, the large geographical size of Australia has its effect on data collection process. Sending a questionnaire by mail to a demonstrative sample of Australian community pharmacists (via pharmacies) has the advantage of low cost. In addition, a reminder may be sent according to the response rate without significantly affecting the study budget. It is has been estimated that the cost of the self-administered questionnaire is far less than other methods (50% and 75 % less than telephone and face-face interviews, respectively).[116] Compared to the CATI method, the self-administered questionnaire does not require special training and can be done by one person.[116] This decreases the cost and time.

The self-administered questionnaires can be sent by email. This would be a less costly method, and it may be more convenient for some participants. However, there are technical issues such as the email may be redirected to junk file.[125] Moreover, low response rates may arise due restricted access to computers (other than for usual work) or the internet because of workplace policy.[126]

Self-administered questionnaires are typically administered without the supervision of the

researchers. This allows for greater flexibility, confidentiality and anonymity but researchers have no control on who completed the questionnaire. Moreover, the questionnaire needs to be stand-alone (self-explanatory).[116] Pre-testing the questionnaire through a pilot study will enhance its understandability by the potential respondents.[127]

The response rate is an issue in mailed surveys.[116] However, this can be improved by sending reminders to all those surveyed or the non-respondents.[127]

2.2.5.3 Case vignettes

A case vignette is “a written case history of a fictitious patient based on a realistic clinical situation.”[128] This method can utilise written or video vignettes. In this project, the written type was used because they were convenient and inexpensive to produce and distribute. They were designed so that participants would find it is convenient to read through the case study and then provide their answers.[129]

Regarding the second factor of the selection criteria, the cost-effectiveness, the written vignettes are less expensive than video vignettes. The latter would involve recruiting actors and recording facility. Also, actors’ performance, and the ability of the participants to understand the unspoken gestures may affect the results.[129, 130]

The main disadvantage of case vignettes is the fact that the respondents are aware that they are under evaluation (Hawthorne effect).[131] This may affect their responses.[128]

There are other alternatives to case vignettes. For examples, using mystery shoppers or trained customers. However, they are expensive or may not be applicable.[128] While mystery shoppers may have been used to investigate how the pharmacist deals with non-regular customers, they could not be used to assess how regular customers would be treated.

2.2.5.4 Informal interviews

At one stage of this project, the GPs study, the informal interview was used as a personal communications interview one GP and three pharmacists. This method was used as an additional technique to collect information about concerns by the research team about GP awareness of CD. This method has advantages that may be not fully utilised during this research project. For example, the collection of in-depth data about previous data or to obtain answers to questions that arose during the data collection.[115] This method has some disadvantages, such as it could be less systematic which may affect data analysis, and

audiotaping may not possible.[115]

2.2.6 Questionnaire construction

Appropriate questionnaire construction and design are necessary to maximise the number of participants and to obtain accurate and relevant information. Potential participants must be informed about the study aims and why their participation is important. The questionnaire should be easy to understand. It must contain questions about dependent variables and about independent variables that can be used to explain the dependent variables. It is good practice to include additional questions to detect inconsistency of answers and/or tendency to tick either “agree” or “disagree” to all the questions.[132] Avoiding long and confusing questions is essential for the questionnaire to obtain answers from the respondents.[133] In other words, the question must be about one piece of information. Moreover, terms of different meaning must not be used or clearly defined if used. Time frame references must be used when it is applicable for example, in the past six months. It is also important the question asks the exact level of details.[132]

The response format is another important area in questionnaire construction and designing process. In this regard, open-ended or closed questions may be used. While closed questions are easy and less time to answer they must be carefully constructed to contain all relevant answers.[134] Answer options such as “I do not know” or “not applicable” may be included when it is appropriate.[133] Closed question does not allow participants to express their views. This can be overcome by using additional option “other; please specify”. Open-ended questions allow for the collection of more details and in-depth data. Nevertheless, they take a longer time to answer and more memory efforts than closed question.[132, 133]

The order of the questions is another factor that needs to be considered. According to Ching, there are some general rules to guide in questions arrangement: “Go from general to particular. Go from easy to difficult. Go from factual to abstract. Start with closed format questions. Start with questions relevant to the main subject. Do not start with demographic and personal questions.”[132] It is worth mentioning that demographic questions could be placed at the beginning of the questionnaire, as they are the easiest to answer.[134] In general, there is no right or wrong answer to the question where to put demographic questions? Green et al. studied the effect of place of demographic information at the beginning and at the end of the questionnaire. They could not find any significance differences between the place of demographic questions on the response rate or the missing answers.[135]

Reliability of the questionnaire is important to produce a satisfactory survey. Reliability reflects the extent to which “questions lead to reproducible responses that are internally consistent.”[136] In this regard, questionnaires that contain ambiguous questions or difficult to answer are not reliable. The validity of the questionnaire, or the “extent to which the questions provides a true measure of what they are designed to measure”, [137] is another important factor that must be taken into the account when the questionnaire development process started. According to Hoti,[33] there are four main types of validity: face validity- whether the responses produce accurate information, criterion validity - if questions correlate with the variable, construct validity – if questions present the concept precisely, and content validity – if data is relevant to study aims.” Among the ways to validated a questionnaire are piloting within a small group of the potential respondents, and/ or using a panel of experts. This should be supported by literature review to identify issues which are relevant to study aims and hence provide content validity.[33, 136]

2.2.7 Strategies to increase response rate

Several strategies to increase response rate have been described in the literature.

1) Data collection method:

Using telephone interviews usually yields higher response rates than mail surveys, and they can cover more geographical areas.[138] Nevertheless, mail surveys cost less, and they are more convenient for participants at work-stations, such as pharmacies A mixed approach such telephone plus in-person may improve response rates from hard-to-reach participants such as physicians.[139]

2) Motivations:

Incentives have been proven to increase the response rate.[140] According to Cho et al. even very small incentives, as small as US\$1, are enough to increase the response rate.[141] However, incentives may lead to study bias (some may participate just to obtain the incentives), and untruthful answers if the participant’s identity is collected. Further, in some cases incentives may be not ethically acceptable.[138, 142]

3) Participants’ anonymity:

Assuring anonymity of the respondents is critical to encourage participation and obtaining truthful answers.[139, 143]

4) Questionnaire delivery (how the questionnaires are received and/or returned):

It is important to use stamps on outgoing envelopes and pre-paid stamped addressed return envelopes. In addition to, using a single-sided questionnaire, it is important to have a logo printed on both the information sheet and the questionnaire. According to Edwards et al. "The odds of response were increased by more than a quarter when questionnaires originated from a university rather than an alternative source." [140] Moreover, some questions were shorted to decrease the length of the questionnaire. Shorter questionnaires yield higher response rates than longer ones. However, the shorter ones may put the internal validity of the questionnaire at risk. [142]

5) Follow-up reminders with the potential participants:

A second reminder has been proven an effective tool to enhance response rates. Second mail reminders, particularly those containing another copy of the questionnaire, yield higher response rates. [140, 144] Follow-up phone calls may also be used as they are less expensive. [145] However, according to Brick et al. follow up by mail reminders yield considerably higher response rates than follow up done by telephone. [146]

6) The length of the interviews or the time needed to answer the questionnaire:

Interviews lengths of 15 minutes or less are associated with better response rates. [139] Regarding self-administered questionnaires, every reasonable effort should be made (such as using closed-ended questions rather than open-ended questions) to decrease the time needed to answer. [140] Nevertheless, shorter questionnaires may risk the internal validity of the questionnaire. [142]

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Chapter 3: Patient Attitudes towards Continuing Dispensing and the Role of the Pharmacist

3.1 Overview

This chapter is an amalgam of published papers: the Introduction, Aims, and Methods and the Conclusions have been combined, however the Results (except Demographic data) and Discussion sections have been retained as separate sections.

Paper1: Abukres SH, Hoti K, and Hughes JD. Patient attitudes towards a new role for pharmacists: Continued dispensing. Patient Preference and Adherence. 2014; 8: 1143-1151

DOI: <http://dx.doi.org/10.2147/PPA.S66719>

Paper 2: Abukres SH, Hoti K, and Hughes JD. Continued dispensing: What medications do patients believe should be available? PeerJ. 2015; 3: p.:e924

DOI: <https://dx.doi.org/10.7717/peerj.924>

3.2 Note: Manuscript changes from the submitted papers

The published Papers 1 and 2 have been reproduced in Sections 3.4.1 (Combined Introduction), 3.4.2 (Combined Aims), 3.4.3 (Combined Methods), 3.4.4.1 (Combined Demographic Information and Response Rate), 3.4.4.2- 3.4.4.8 (Other results: Paper 1), 3.4.4.9 (Other results: Paper 2), 3.4.5. (Paper 1 Discussion and Paper 2 Discussion), and 3.4.6 (Combined Conclusions). In the combined sections, some text from both papers was removed to avoid duplication (repeating of same ideas). The Abstracts and Reference lists have been removed, and this is within the terms of the Creative Commons Attribution Non-Commercial 2.0 Generic License,[1], Dove Medical Press Copyright's Notice, [2] and Peer J Copyright's Notice,[3]. Permission from co-authors has been obtained (Appendix 3.1). No significant changes (except spelling) from the original publication have been made regarding content, grammar and headings. While the References used in these published articles are unchanged from the original publication, the References have been renumbered in line with the single reference list in the thesis. The numbers and style of the Appendix, Figure, and Tables have also been aligned with the format of this thesis.

Additional changes requested by thesis examiners

There are two types of changes as result of the examination process:

1. Addition of more data to the thesis; these data are presented between parentheses { }.

Please note that the addition data were not part of the already published papers.

2. Some terms were changed, this include: the term 'affected' replaced with 'associated with', the term 'influence of' replaced with 'associated with' the term 'dispensed' replaced with 'supplied', the term 'asthmatic patients' replaced with 'patients with asthma'.

Important note: Paper 1 was published first and it has been cited in Paper 2. The IC (Indirect Citation) was used after the citation number to specify this type of citation.

3.3 Unpublished data and more details of already published data

Table 3.1 displays demographic information of each group of users separately. These data were not published in any of the papers.

Table 3.1 Comparison between Statin and OC users according to their demographic data

Variables	Variable items	Users	
		Statin	OC
Age (p=0.0001)	18-20	0	14
	21-30	0	43
	31-40	1	51
	41-50	8	38
	51-60	25	1
	61-70	49	2
	71-80	40	1
	>80	28	0
Gender (p=0.001)	Male	60	0
	Female	91	150
State/territory (p=0.0001)	ACT (Australian Capital Territory)	1	3
	QLD (Queensland)	9	13
	NSW (New South Wales)	119	33
	NT (Northern Territory)	0	1
	SA (South Australia)	1	11
	TAS (Tasmania)	3	0
	VIC (Victoria)	15	64
	WA (Western Australia)	3	25
Education level (0.009)#	Primary	9	9
	Secondary	79	65
	University	48	75
	Other	4	0
Employment status (p=0.0001)#	Full time	23	57
	Part time	10	38
	Casual	2	9
	Not currently employed	109	3
	Retired	7	42
	Prefer not to disclose	0	1
Other disease (p=0.0001)	Yes	67	116
	No	82	34
Regular pharmacy (p=0.0001)	Yes	147	112
	No	4	38

p value obtained by Fisher test

Chi-square test or Fisher Exact test (when the expected numbers are small) revealed that both groups differed significantly in addition to age and gender, employment, other diseases and

regular pharmacy (See Table 3.1 for p values), they also differed in terms of :1) state/territory: the majority of Statin users were from NSW, while the majority of OC users were from VIC, and 2) education: OC users were more likely to had higher education status.

Table 3.2 Comparison between Statin and OC users according to other set of variables

Variable	Variable items	Users		Total
		Statin	OC	
Run out of medication (p=0.021)	Never	103	85	188
	Run out	45	65	110
Ask a pharmacist (p=0.0001)	Never	22	32	74
	Yes	25	13	38
CD frequency (p=0.0001)	As planned	53	26	79
	More than once	98	124	222
Concern (p=0.0001)	Not at all concerned	147	112	259
	Fairly concerned	4	38	42
CD risk (p=.06)	Yes	10	5	15
	No	124	140	267
	Neutral	9	5	14
	Prefer not disclose	5	0	5

Table 3.2 provides information about Statin and OC users in terms of: 1) frequency of running out of medication (OC users were more likely to run out of their medication, 2) asking their pharmacist for urgent supply: Statin users were more likely to ask a pharmacist when they run out of their medication,[4], 3) CD frequency: OC users were more likely to agree with more frequent availability of CD, 4) concerns: OC users were more concerned than Statin users about obtaining their medication through CD method, and 5) perceived risks: there was no significant difference between both users in their perceptions of CD risk.

3.4 Published data: paper 1 and paper 2

3.4.1 Introduction

(Combined from Papers 1 and 2)

Medications in Australia are available as: Prescription only medications (Schedule 4, and Schedule 8 for controlled drugs), and non-prescription medications, which include: Pharmacist Only (Schedule 3) which can be provided by a pharmacist, Pharmacy Only (Schedule 2) which can be provided by other pharmacy staff under pharmacists' supervision, and other non-scheduled over the counter medications (OTC) which are available for general sale. Statins and OCs (except for the emergency contraceptive pill) are S4 medications, (i.e. a prescription is required for dispensing).[5] Continued dispensing (CD) is a new medication supply method for certain Prescription only medications in Australia when patients run out of their prescriptions. According to Medicare Australia, the CD initiative "will allow pharmacists to supply eligible PBS [Pharmaceutical Benefit Scheme] medicines to a customer when there is an immediate need for the medicine, but it is not practical for the customer to get a prescription." [6] As part of the Australian government's broader National Medicines Policy, the PBS provides timely, reliable, and affordable access to necessary medicines for Australians. In regards to CD, oral contraceptive (OC) and lipid-modifying agents, namely Statins, are the only medication classes that can be supplied according to current CD guidelines.[4] This system was originally proposed to minimise the risk of patients running out of their medication between doctors' visits.[5, 7]

The usual practice for chronic disease prescribing in Australia is that the doctor writes a prescription for the medication for one month supply and issues up to five repeats to cover up to a 6-month period.[8] For patients meeting specific criteria, up to 11 repeats can be prescribed and therefore cover the patient for one year.[9] However, there are circumstances where patients run out of their medications before the next appointment.[10] As a result, they may need to ask the pharmacist to provide a supply without a prescription.[11, 12] The current system allows pharmacists to dispense under the provisions of Emergency Supply, Owing Prescription, or the recently introduced CD.[13] The Emergency Supply system involves dispensing without a prescription and prior contact with the prescriber; however, its main drawbacks are the limited quantity of medication that may be supplied (namely 3 days' supply), out of pocket expense to the patient, and medication wastage in the pharmacy as a result of broken packs.[7] The Owing Prescription model requires prior authorisation by the prescriber before dispensing and the prescriber should send the new prescription to the

pharmacy within 7 days. The prescription is used to claim reimbursement for the medication from Medicare Australia through the PBS system.[14] This overcomes the above mentioned disadvantages of the Emergency Supply system, but prior contact with the prescriber is not always possible or practical, and it has the potential for unpaid efforts on the part of doctors and pharmacists during the process of following up prescriptions. The CD model has been implemented to provide pharmacists with an additional option to ensure treatment continuation, and in doing so to overcome the practical drawbacks of the Emergency Supply and Owing Prescription systems.[4, 7]

CD does not require prior authorisation by the prescriber or the need to obtain a prescription, and there is no extra {beyond the normal} cost to the patient or medication wastage. In addition, the quantity supplied under the CD method is one standard pack of the medication which is usually enough for one month, allowing adequate time for the patient to obtain an appointment with their doctor, thus avoiding potential non-adherence due to therapy interruption.[4, 7]

CD aims to prevent patient medication non-adherence as it allows continuity of treatment when patients do not have a prescription. Patients would prefer availability of medications without prescription if they were easily accessible, reduced the need to visit their doctors and achieved at a lower cost.[15, 16] Therefore, easier access to medications, without a prescription or an extra cost (which CD provides) are encouraging factors to enhance patient adherence.[4, 17]

On the other hand, patients' lack of awareness and acceptance, pharmacists' unwillingness to participate, and doctors' attitudes towards CD may have negative impacts on CD implementation. Pharmacists have reported low levels of patient awareness of new services provided in community pharmacies.[18, 19] Prior to the implementation of CD in Australia, the Australian Medical Association (AMA),[20] declared that it was "strongly opposed to pharmacists dispensing prescription medication without a valid prescription and without reference to the patient's treating medical practitioner." [4]

The current CD method may provide limited benefit to chronic disease sufferers as they are often on multiple medications.[21] Consequently, they may present to a pharmacy requesting a Statin or an OC, as well as other medications which are currently not eligible for supply under the CD model. In these situations, conducting CD may confuse the patient who can, for instance, obtain their Statin without a prescription but cannot obtain their antihypertensive medication. In this case, CD may not be an appropriate service to offer.[5]

The above suggests that the list of CD eligible medications may need to be expanded to cover a wider range of common diseases, as is the case with pharmacist supplementary prescribing models in other countries. Pharmacist supplementary prescribing is a partnership between doctors and pharmacists where doctors retain their diagnostic role.[22] Patients who experienced supplementary prescribing have shown their support for pharmacists to prescribe a variety of medications such as, but not limited to, medications to treat diabetes, epilepsy, cancer, cardiovascular, respiratory, renal, skin, gastrointestinal, thyroid and blood coagulation diseases.[23] Furthermore, pharmacist interventions with treatment of chronic diseases have been proven to be effective.[24-26] Therefore, applying more responsibility to pharmacists through an expanded version of CD may assist in achieving CD's goals; i.e. a more convenient way for patients to obtain their medication in a timely manner, prevent treatment interruptions, utilise pharmacists' skills and decrease overload on doctors. The AMA has described the current (limited) CD as unsafe and inappropriate.[20] This was in contrast with results of a survey of Statin and oral contraceptive (OC) users, where the majority of the respondents did not perceive CD would pose any risks. They also trusted their pharmacists would conduct CD only when it was safe to do so and that their pharmacist would refer them to their doctor when needed. Furthermore, respondents thought pharmacists are more easily accessible than doctors; that CD would save their and their doctor' time, and that it would help them to not miss any doses of their medications.[4, 5](IC) It is worth mentioning that patients surveyed had no personal experience with CD as the study was conducted before the actual implementation of CD in Australia, so the results represent participants' perceptions rather than their actual experience. Moreover, patients are not necessarily qualified to identify precisely when it's safe or not to obtain a medication without a prescription.[5]

Another limitation of the CD is its restriction to be conducted only once in any 12 month period. This timeframe has been proposed to prevent patients avoiding doctors' visits.[7] It may lead, however, to treatment interruptions in two ways: if the additional supply is not enough until the next available appointment with the doctor,[27, 28] and/or if the patient runs out of valid prescriptions for their medication more than once in a 12 month period. This may occur as a result of 6 months coverage of chronic medication prescriptions.[5, 8]

3.4.2 Aims

(Combined from Papers 1 and 2)

As patient attitudes towards obtaining medication through the CD provisions have not been previously researched, this study aimed to explore their attitudes towards CD, including any perceived concerns and/or risks related to CD.[4]

Another aim of the study was to explore patients' attitudes towards expansion of CD to include a broader range of medications and hence increase the access to the service.

The study was conducted before the actual implementation of CD on September 1, 2013. In doing so, we were able to assess respondents' attitudes before they had experienced the service, and hence without any potential bias of personal experience.[5]

3.4.3 Methods

(Combined from Papers 1 and 2)

This study was approved by the human research ethics committee of Curtin University (approval number PH-06-13; Appendix 3.2). Data were collected by a telemarketing company, CDM Direct Communication Services, using computer-assisted telephone interview (CATI). This method was chosen as it has the advantages of time and cost saving, and is practical when taking into the account the geographical expanse of Australia.[29] It also allows respondents to ask the interviewer questions if clarification is needed. Additionally, the questionnaire usually takes less time and has been reported to be more enjoyable to answer when compared with those that are self-administered.[4, 30, 31]

A telephone number list was generated via a random number generation function based on a broad breakdown of the Australian population as outlined in the June 2013 Australian Bureau of Statistics data,[4] (i.e. New South Wales 32%, Victoria 25%, Queensland 20 %, South Australia 7 %, Western Australia 11%, Australian Capital Territory 2%, Tasmania 2% and Northern Territory 1%).[5, 32] Telephoning was carried out via random digit dialing within each state. The final target list generated had a total of 25,000 records. Telephoning was carried out by staff members of the telemarketing company who were not part of the study, therefore minimising potential bias. This sample {300 participants} allowed for a prevalence estimation of $\pm 5\%$ {and 95% confidence interval}. In addition to being either a Statin user or an OC user,

the respondent had to be 18 years or older and English-speaking. Respondents who used both medications were interviewed as OC users. Eligible candidates were told that the interview would take about 15 minutes and were considered consented if they answered yes to: “Would you like to participate in this interview?” If the person appeared to need assistance, then another household member was allowed to assist the respondent. Respondents were also offered to be called at another time if the first call timing was not convenient, and they could withdraw at any time during the interview.[4] Participation was voluntarily and no incentives were used.[5] The study was conducted in July 2013, before the actual start of the CD supply method in Australia (September 2013). Therefore, respondents’ views were not affected by any positive or negative experience with CD, thus minimising study bias.[4, 33, 34]

3.4.3.1 Questionnaire design

The participants were interviewed using a questionnaire (Appendix 3.3) consisting of 38 closed ended questions, with the option ‘other: please specify’ for some questions. The responses to “Other” option were entered into a database verbatim.[5] A literature review and experience from a previous study,[29] assisted in developing the questionnaire.[4]

The questionnaire contained three parts: Part 1, which collected demographic information; Part 2, which collected basic information about other disease(s) and medication, and Part 3, which focused on patients’ perceptions of concerns and risks associated with CD, their thoughts on maximum number of CD utilisations in a 12-month period, and whether other medications should be included within the CD provisions. A five-point Likert scale was used to measure respondents’ attitudes towards the questions in Part 3 of the questionnaire.[4] The main focus of the questionnaire was to identify areas of CD extension and expansion, particularly what other medications may potentially be included into the CD system. The challenge was to carefully select potential medication classes and medical terms that were easily understandable by the general population. The study tool was assessed for face and content validity by staff members within the pharmacy practice group at Curtin University and by the telemarketing company group CDM Direct Communication Services.[5]

3.4.3.2 Data analysis

From Paper 1: “Patient attitudes towards a new role for pharmacists: Continued dispensing.”[4]

Qualitative data collected through the option “Other please specify” in the questionnaire were translated verbatim and thematically analysed. The statistical analysis for closed-ended

questions was undertaken in three steps using Statistical Package for the Social Sciences (SPSS) version 22. Step 1 was a descriptive analysis and was carried out to describe the distribution of the answers. Step 2 included assessment of respondents' overall support of CD. The study participants were not asked directly if they supported CD; instead they were asked two questions, namely, if they perceived CD as a source of any concerns and risks. For the purpose of analysis, the respondents were divided into three groups: those who perceived CD as a source of either concerns or risks (Group A), those who perceived CD as a source of both concerns and risks (Group B), and those who did not perceive CD as a source of either concerns or risk (Group C, i.e. fully supportive). Step 3 aimed to determine if there were any statistically significant associations between participants' concern and risk perceptions. In contrast with the null hypothesis, the alternative hypothesis assumed that participants' perceptions of concerns were affected by their perception of risks. Therefore, the binary logistic regression test was used to predict the association between perceptions of concern and risk. A P-value <0.05 was considered to be statistically significant.

From Paper 2: "Continued dispensing: What medications do patients believe should be available?" [5]

SPSS version 22 was used for statistical analysis. In this regard, frequency distribution analysis and Chi square test were employed to assess associations between variables. Answers were collected on a 6 point Likert scale (where 1 = Strongly disagree, 2 = Disagree, 3 = Neutral, 4 = Agree, 5 = Strongly agree, and 6 = Prefer not to disclose). For the analysis purposes, the scale was trichotomized as follows: Agreed, which included options 4 and 5, and Disagreed, which included options 1 and 2, and Neutral which included options 3 and 6.

3.4.4 Results

3.4.4.1 Demographic data and response rate

(Combined from Paper 1 and 2)

There were 10,479 attempts to make phone calls. However, there was a large number of failed calls (7,019) due to various reasons, including: number disconnected, answer phones, answering machines, no answer or call busy. This resulted in 3,460 successfully contacted individuals. Among these 2,443 individuals were screened out because of ineligibility (n = 2,146 who were either under 18 years or not taking a Statin or OC, and 297 respondents were deemed incapable of completing the survey because of language or hearing difficulties). In

addition, there were 716 outright refusals, these were the most problematic because they refused to participate at an early stage, before it was clear if they were eligible or not. Since the outright refusals were likely to have a mixed eligibility, the 716 outright refusals were considered to have the same proportion of eligible individuals as the screened sample (i.e. 11% which was calculated by dividing 301 respondents by 2,744). {The 2,744 came from the subtraction of the 716 outright refusals from the total contacted 3,460}. This resulted in an estimated 380 total eligible candidates, giving a response rate of 79% (301 respondents of the total 380 eligible individuals). However, if all the outright refusals were eligible, which is highly improbable, the response rate could have been as low as 30%. Irrespective of the response rate the targeted sample size was successfully obtained.[5]

The respondents were made up of 151 Statin and 150 OC users.[5] The respondents were predominantly female (80%; n=241). Just over half of respondents (51.5%; n=155) were 60 years of age or younger.[4] {Statin users were more likely to be older than OC users, $p=0.0001$ }. The participants were recruited from all Australian states and territories.[5] Almost half of the respondents (50.5%) were from the state of New South Wales (Figure 3.1), and the majority lived in metropolitan areas (84%; n=256).[4]

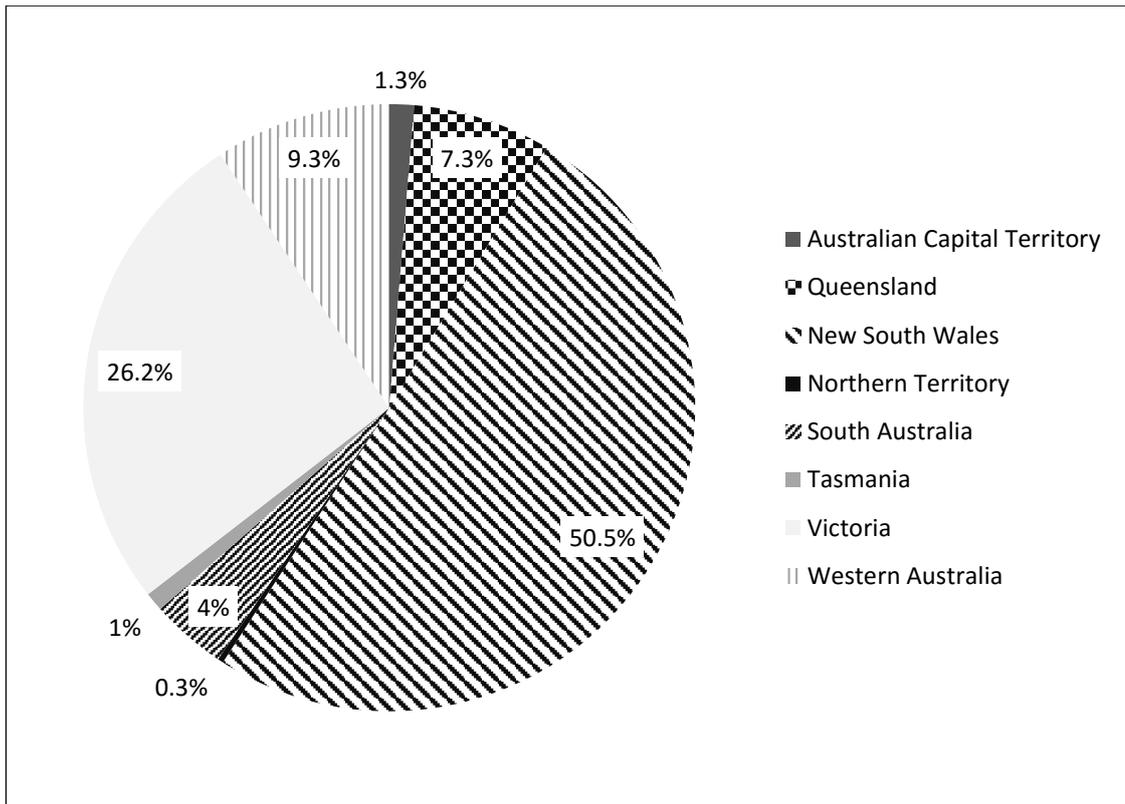


Figure 3.1 Distribution of respondents by their state or territory of residence in Australia

Source paper 1[4]

Paper 1: “Patient attitudes towards a new role for pharmacists: Continued dispensing” [4]

3.4.4.2 Disease and medication data

Atorvastatin (e.g. Lipitor®) was the most commonly used Statin (37.7%; n=57) followed by rosuvastatin (Crestor®); 26.5%; n=40), then simvastatin (e.g. Zocor®); 15.8%; n=24). Ethinylestradiol 30 µg + levonorgestrel 150 µg (e.g., Levlen® or Monofeme®) was the most frequently used contraceptive agent (38.6%; n=58) followed by ethinylestradiol 30/40/30 µg + levonorgestrel 50/75/125 µg (e.g., Trifeme®, Triphasil®, or Triquilar®) which was used by 12.6% (n=19) of OC users. Of the respondents, over a third reported having at least one other disease (38.5%; n=116, see Table 3.3).

Table 3.3 Respondents' Characteristics

Characteristic	Responses	n(%)
Suffer of medical conditions	No	183 (60.8)
	Yes	116 (38.5)
	Prefer not to disclose	2 (0.7)
Approximate number of occasions in past 12 months when respondents reported running out of their medication	0	188 (62.5)
	1	52 (17.3)
	2	33 (11.0)
	> 2	25 (8.3)
	Prefer not to disclose	3 (1.0)
If impractical to see usual doctor action taken by respondents to acquire further medication supply	Nil, stop treatment	40 (35.4)
	Ask pharmacist	37 (33.6)
	See after hours doctor	8 (7.1)
	See another doctor	17 (15.0)
	Borrow	4 (3.5)
	Other	5 (4.4)
Regular customer of a pharmacy	No	42 (14.0)
	Yes	259 (86.0)

Source paper 1[4]

3.4.4.3 Medication supply history

One hundred and ten (36.5%) of the respondents had run out of either their Statin or OC medications in the previous 12 months (Table 3.3). Of these 35.4% reported that they temporarily stopped the medication until they could see their doctor, while 33.6% sought an extra supply from their pharmacists until they could see their doctor. {OC users were more likely to run out of their medication compared with Statin users ($p=0.021$)}.

3.4.4.4 Regular pharmacy

The majority of respondents (86%; $n=259$) reported having a regular pharmacy (Table 3.3). However, this differed amongst OC users and Statin users (74.9% versus 97.4%, respectively; $P<0.0001$).

3.4.4.5 Perceived concerns and risks related to CD

The questionnaire was designed to explore patients' concerns about CD and whether they thought it would be safe to obtain their medication through CD. In order to simplify and explain CD to the participants, CD was presented in the questionnaires as obtaining one additional supply from the pharmacist when the patient ran out of medication and it was not practical to see the doctor.

When patients obtain medication through CD, they need to discuss their health issues with the

pharmacist, and answer a range of questions in order for the pharmacist to determine whether CD is appropriate and safe. The majority of respondents were not concerned with the planned CD initiative (89.4%; n=269), mainly because they trusted their pharmacist's judgment in determining if it would be appropriate for them to obtain medication through this method of supply (72.8%; n=219). Other reasons given in support of CD were "the pharmacist will refer me to the doctor if needed", "pharmacists are easier to access than doctors", "it will save my time", and "it allows me not to miss any doses of my medicine" (Table 3.4).

3.4.4.6 Respondents' perception of concerns and risk

Amongst the 30 respondents who expressed concerns regarding CD, the main issues raised related to consultation privacy and pharmacists' lack of access to their medical records. Some respondents stated they would prefer to see their doctor (n=4), lacked confidence in the pharmacist's capabilities or training (n=4), or saw CD as a way patients might abuse medications (n=1). The majority of respondents (88.7%; n=267) did not see any risk associated with the CD process.

Table 3.4 Respondents' perceptions of concern and risk

Question	Response	n (%)
Do you have any concerns regards CD?	No	269 (89.4)
	Yes	30 (10.0)
	Prefer not to disclose	2 (0.7)
Reasons for lack of concern	Pharmacists know if it is safe or not to take an additional supply when I run out of my medication	219 (72.8)
	The pharmacist will refer me to the doctor if I needed	177 (58.8)
	Pharmacists are easier to access than doctors	171 (57.0)
	Reduce work load of my doctor	141 (47.2)
	It saves my time	167 (55.5)
	It makes me not miss any dose of my medicine	160 (53.2)
	All of the above	147 (48.8)
	Other	19 (6.3)
	Prefer not to disclose	4 (1.3)
Reasons for concern	Lack of privacy in the pharmacy	6 (20.0)
	The pharmacist has no access to my health records	10 (33.3)
	All of the above	6 (20.0)
	Other	8 (26.7)
	Prefer not to disclose	1 (0.3)
Do you believe CD poses any risk?	No	267 (88.7)
	Yes	15 (5.0)
	Prefer not to disclose	19 (6.3)

Source paper 1 [4]

3.4.4.7 Estimation of CD support

As outlined in the Methods section, support for CD was assessed on the basis of the combined responses of respondents to Q16 (Perceived concerns in discussing health issues with the pharmacist as part of CD) and Q20 (Perceived risks from pharmacists providing an additional supply of medication without a valid prescription). Respondents were deemed to be fully supportive of CD if they disagreed about any concerns or risks associated with CD (Figure 3.2).

Two hundred and forty-nine respondents (82.7%) disagreed with both questions (i.e. those in Group C, no concerns and no risk) whilst eight (2.6%) agreed with both questions (i.e. those in Group B, both concern and risk). These results indicated a high level of support for CD by potential users.

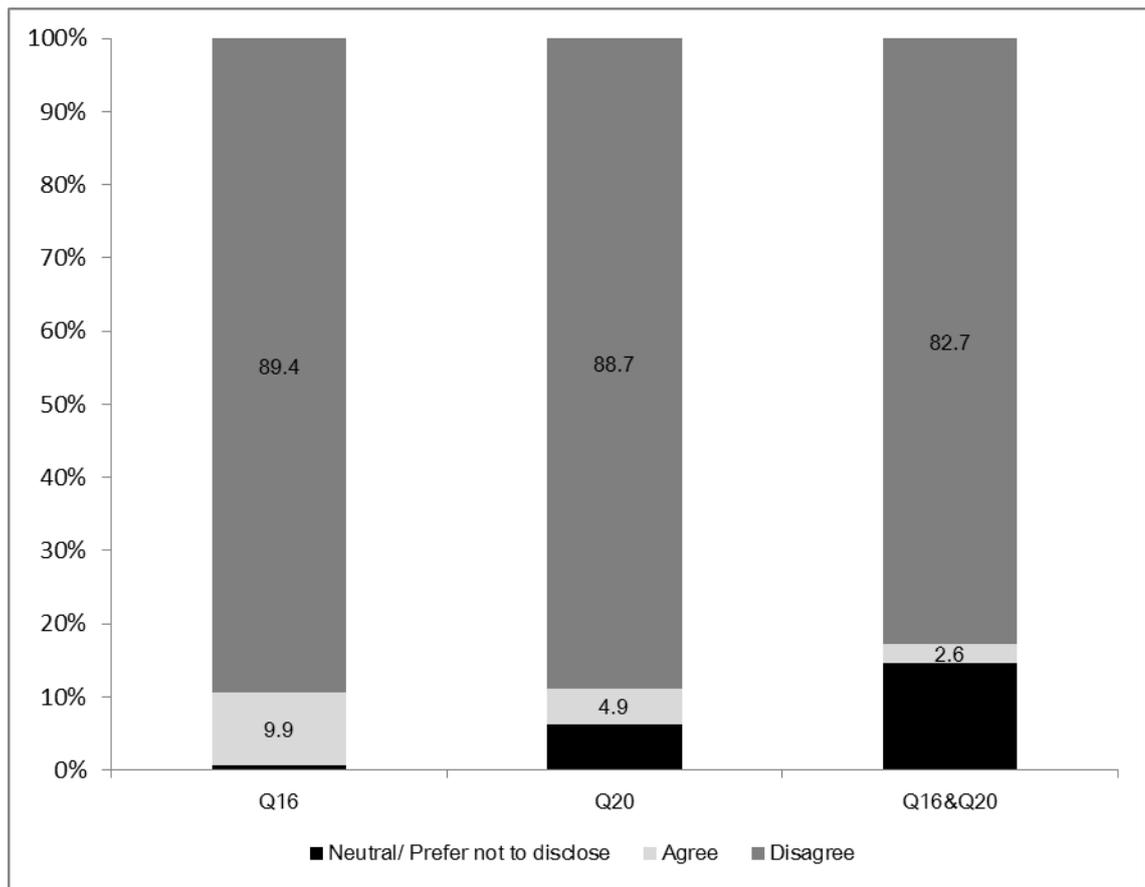


Figure 3.2 Proportion of respondents (n=301) who fully supported CD

(i.e., disagreed with both Q16 & Q20). Where Q16 = Perceived concerns to discuss health issues with the pharmacist when providing an additional supply; and Q20 = Perceived risks for pharmacists providing an additional supply of medication without a valid prescription)

Source paper 1 [4]

3.4.4.8 Relationship between respondents' perceptions of concerns and risks

Binary logistic regression analysis was used to examine if participants' perceptions of concerns were affected by their perception of risks. The null hypothesis assumed no such relationship. This analysis revealed a highly statistically significant association between respondents' perceptions of concerns (independent variable) and perceptions of risks (dependent variable; $P < 0.0001$). "Disagreed" was the reference group. The odds ratio was 16.7, meaning that concerned respondents were 16.7 times more likely than unconcerned respondents to agree that there would be risk associated with CD. This suggests that participants who were concerned may be so because they thought CD is potentially risky.[4]

Paper 2: “Continued dispensing: What medications do patients believe should be available?” [5]

3.4.4.9 Participants’ attitudes towards a modified version of CD

3.4.4.9.1 CD extension: increased access to CD

Participants were asked how many times they thought CD should be allowed within a 12 month period. The majority of participants (73.3%; n = 222) disagreed with the current CD limitation, and selected more than one CD within a 12 month period. Among those who wanted more CD; 16.3% selected ‘twice a year,’ 5.9% selected ‘three times a year,’ and 51.1% of the participants selected ‘any time my repeats run out and I am not able to get an appointment with my doctor.’

3.4.4.9.2 CD expansion: addition of more medications to the current CD list

Participants were asked about their thoughts (i.e. agreement levels) on expanding the current list of CD eligible medications. Table 3.5 shows the proportion of participants who agreed with inclusion of medications for specific diseases/disorders.

Respondents’ support to include particular additional medications into the CD method was associated with the condition to be treated. For example, 78.4% (n = 236) of the participants agreed to the inclusion of asthma medications; however, only 44.2% (n = 133) agreed to the inclusion of antidepressants. The participants’ support for the inclusion of different medications can be divided into three levels based on level of agreement. Level 1: included medications to treat asthma, arthritis, chronic skin problems, indigestion, hypertension, diabetes (oral hypoglycaemic) and chronic bronchitis, where over 60% of the participants supported their inclusion within the CD provision. Level 2: included emphysema medications, chronic pain medications, and anticoagulants where more than 50% (but less than 60%) of the participants agreed to their inclusion, and Level 3: included medications for thyroid disorders, glaucoma, anxiety and depression, which were supported by less than 50% (Table 3.5).

Table 3.5 Respondents' preferences for medications to be covered under CD

Disease/disorder/medication	Neutral/did not disclose n (%)	Disagreed n (%)	Agreed n (%)
Asthma	34 (11.3)	31 (10.3)	236 (78.4)
Arthritis	39 (13.0)	35 (11.6)	227 (75.4)
Chronic skin disorders	40 (13.3)	39 (13.0)	222 (73.8)
Indigestion	42 (14.0)	40 (13.3)	219 (72.8)
Hypertension	40 (13.3)	48 (15.9)	213 (70.8)
Diabetes	62 (20.6)	37 (12.3)	202 (67.1)
Chronic bronchitis	58 (19.3)	55 (18.3)	188 (62.5)
Emphysema	67 (22.3)	59 (19.6)	175 (58.1)
Chronic pain	54 (17.9)	86 (28.6)	161 (53.5)
Blood clotting	62 (20.6)	85 (28.2)	154 (51.2)
Thyroid	84 (27.9)	67 (22.3)	150 (49.8)
Glaucoma	80 (26.6)	71 (23.6)	150 (49.8)
Anxiety	58 (19.3)	98 (32.6)	145 (48.2)
Depression	55 (18.3)	113 (37.5)	133 (44.2)

Source paper 2 [5]

3.4.4.9.3 Views of other disease sufferers

More than one third of participants suffered from other chronic diseases (38.8%; n = 116). The most prevalent co-morbidities were hypertension, type 2 diabetes mellitus, arthritis, depression, asthma, indigestion, and thromboembolic disorders requiring anticoagulation. Table 3.6 compares the views of participants with these particular diseases with those without. Generally, in all diseases except type 2 diabetes and indigestion, the proportion of disease sufferers who agreed with their medication's inclusion into the CD provisions was higher than the proportion of the total study cohort. However, the only statistically significant difference was between participants supporting inclusion of antidepressants, where participants with depression supported inclusion of these medications more than participants without this disorder (92.8 vs 41.8%, p = 0.001).[5]

Table 3.6 Associations of experience with the disease on respondents' attitudes to the inclusion of particular medications in CD

Disease	Agreed participants without the disease n (%)	Agreed participants with the disease n (%)	P value
Hypertension	180 (68.7)	33 (84.6)	0.06
Diabetes mellitus	186 (67.4)	16 (64.0)	0.91
Arthritis	211 (75.1)	16 (80.0)	0.81
Depression	120 (41.8)	13 (92.9)	0.001
Asthma	225 (77.9)	11 (91.7)	0.23
Indigestion	214 (72.8)	5 (71.4)	0.61
Blood clotting	149 (50.5)	5 (83.3)	0.35

Source paper 2 [5]

3.4.5 Discussion

Paper 1: "Patient attitudes towards a new role for pharmacists: Continued dispensing" [4]

This study explored attitudes of Statin and OC users towards the CD method of medication supply. It was conducted almost 2 months before the actual implementation of CD in Australia in September 2013, hence the results represent respondents' attitudes before any positive or negative experiences with CD which may have influenced their views.[34-36]

In the present study, the vast majority of the respondents strongly supported CD, and did not see it as a source of any concerns or risks. The potential explanations for this may be related to consumers' trust in pharmacists assuming additional responsibilities and/or related to the nature of CD itself. Pharmacy consumers' trust of pharmacists assuming new roles has been reported previously in the Australian literature.[29] In the present study, almost three quarters of respondents selected "Pharmacists know if it is safe or not to take an additional supply" option. Further, they thought that their "Pharmacist would refer them to the doctor when it is needed", which is consistent with previous findings.[37, 38] Additionally, CD reserves the diagnosis to doctors, with pharmacists able to continue the treatment until patients can see their doctors. In previous studies,[29, 39] of attitudes towards expanded pharmacists' roles, the majority of respondents (patients and pharmacists) strongly supported expanding the role of pharmacists to prescribe medications for diseases that were previously diagnosed by doctors (supplementary prescribing) rather than pharmacist diagnosing and prescribing (independent pharmacist prescribing). This is in contrast with the negative attitude of doctors towards CD

as reported by the AMA prior to its implementation.[20] The AMA described CD as an unsafe process. Whilst recognising that not all respondents may have been qualified to estimate any risk associated with CD, all were chronic medication users and the majority did not see it as a risky method for obtaining their medications in the short-term. This may be due to their long-term use of medication and prior experience with pharmacists positively influencing their views.

As a method of medication supply, CD was instigated to minimise patient non-adherence with their medications, particularly as a result of treatment interruption, which occurs when patients run out of medication before they are able to obtain a new prescription. Although more than half of the respondents reported never being in this situation, a significant proportion had (~37%), and of these, over a third temporarily stopped treatment until they saw their doctor. Temporary discontinuation of a medication may have negative health outcomes;[17] further, it may lead to permanent treatment cessation.[40] Discontinuation of Statins has been reported as a source of concern to doctors and pharmacists.[38, 41] Significant Statin discontinuation rates have been reported, especially amongst younger patients and asymptomatic cases.[42, 43] In the case of OC users, Rosenberg and Waugh,[44] reported that 80% who stopped using their OCs either adopted another less effective method of contraception or completely discontinued, even though they were still at risk of unwanted pregnancy. In an Australian study,[45] approximately 90% of pregnancies amongst women aged under 18 years were unintended and 80% amongst those aged 18–24 years. In the present study, OC users, who are younger than their Statin counterparts, reported running out of their medication more often than Statin users ($P=0.021$). In the case of Statins, other studies have shown older users report being more adherent than younger users.[42, 43]

Approximately one third of respondents who experienced running out of their medications had requested an additional supply from a pharmacist. Before implementation of CD in Australia, pharmacists had only two options if they were to grant such requests, i.e. Emergency Supply or Owing Prescription. Both options have their disadvantages. Issues with the first include increased out of pocket expense for patients and wastage for pharmacies from open packs. Emmerton et al. reported that the additional medication cost may deter some patients from purchasing medications under Emergency Supply.[16] The other method, Owing Prescription, represents an administrative burden and involves unpaid effort for both doctors and pharmacists. In order to assist patients to obtain their medications at a lower cost, a pharmacist may supply a full pack of the medication and then follow up with their doctor to obtain a new prescription.[7] This “in advance supply”, i.e. before a prescription is issued, is generally

restricted for regular pharmacy customers only, where a dual trust exists between the pharmacist and the patient.

Statin users were less likely to run out of medications than OC users ($P=0.021$). There are a number of possible reasons for this significant difference. Firstly, Statin users were older, being more likely to be aged 60 years or over ($P<0.0001$). It has been reported that those who are older are likely to be more adherent to their medications.[43] Secondly, Statin users are more likely to have other diseases and use more medications ($P<0.0001$), so may have more regular contact with their doctors.[42] Thirdly, Statin users were more likely to have a regular pharmacy than OC users (97% versus 75%, $P<0.0001$), and this would lead Statin users to interact more with their pharmacists and be more likely to ask them for an additional supply if they ran out between doctors' appointments. In addition, pharmacists would empathically dispense when they have the medication history of the patient, which is most likely to be available for regular customers. [44, 46] Finally, OC users were more likely to have full-time jobs ($P<0.0001$) when compared with Statin users, so may have more difficulty in organising a doctor's appointment.[47] {Another reason for the increased likelihood of compliance with Statins could be the risk or fear of myocardial infarction or stroke}. Furthermore, OC users have the option of considering alternative contraceptive methods if they run out of OCs.[44]

Among those who had run out of medication, less than a quarter reported seeing another doctor or an after-hours doctor (~15% and ~7%, respectively). The more common actions were to stop treatment until they saw their regular doctor or ask for an additional supply from the pharmacist (~36% and ~33%, respectively). This indicates that patients are not in favor of changing their doctor to another doctor. This is consistent with a study of patients with asthma that reported patients becoming less adherent to their medications if they received care from colleagues of their doctor {i.e. other doctors working in the same clinic}.[48]

Patient acceptance of any new service is conditioned by how they perceive it. Minimising the risk of treatment interruption, hence non-adherence, is the ultimate goal of CD, which enables more convenient access to medications. Since pharmacists are more accessible than doctors,[35] CD seems to have the capacity to gain client support. This is confirmed by the results of our study, where 57% of respondents agreed with "Pharmacies are easier to access than doctors". Additionally, there were other reasons that were reported by some respondents, including trusting the pharmacist, pharmacy keeping records of dispensing, and being a regular customer and having a personal relationship with the pharmacist. On the other hand, lack of privacy and pharmacists having no access to medical records or both were identified by the

small number of respondents concerned about CD. From a pharmacy perspective, inability to check medication histories for non-regular customers has been cited as a deterrent to more positive interactions,[44] whilst customers' personal experiences and perceptions, positive or negative, about pharmacists may strongly affect their attitudes towards pharmacists' current and future roles.[35]

The limitations of this study are acknowledged. This study was conducted via landline telephone which may limit the representation of individuals who only use mobile phones, especially younger individuals.[49] In addition, some population groups were not included, i.e. those who could not speak English and those aged under 18 years, acknowledging that Australia is a multicultural country,[50] and OCs can be prescribed to teenagers younger than 18 years.[51] Finally, the plan was to obtain a stratified sample of consumers according to the population distribution in Australia, but this was not achieved. The main factors potentially contributing to this were the high number of non-connections, consumers' preference to participate, and project budget and time constraints, which may limit the generalisability of this study.

Future work should explore the attitudes of Statin users and OC users who have experienced CD to find out if their experience with CD has had positive or negative effects on their perceptions of CD. At the same time, the experiences and views of community pharmacists need to be gathered to assess whether they believe CD is an ideal solution to deal with patients who run out of their regular medications. Further areas of research may include the attitudes of patients with other chronic disease diseases regarding inclusion of their medications in the CD provisions.[4]

Paper 2: "Continued dispensing: What medications do patients believe should be available?" [5]

To the best of our knowledge, this is the first study to explore the views of Statin and OC users in regards to potential extension and expansion of the CD system in Australia. More specifically, their support to increase the maximum number of times that CD can be utilised within a 12 month period (i.e. CD extension) and expansion of the range of medications allowed to be dispensed under CD (i.e. CD expansion). Regarding CD extension, the majority of participants disagreed with the current restriction of CD to once in every 12 month period, and preferred the option of using it more frequently. Interestingly, more than half of the participants wanted CD to be available until it was possible for them to see their doctor. This may indicate that patients required more flexibility to avoid unnecessary treatment interruption

if, for any reason, an appointment with their doctor could not be achieved. Previous studies have reported that patients have difficulty in seeing their regular doctor without a prescheduled appointment.[52, 53] Furthermore, it has been reported that patients often do not organise appointments in advance or failed to attend appointments.[54]

On the second question regarding expansion of the medications available through CD, participants generally supported inclusion of more medication classes. However, this support was influenced by the use of those medications. In this regard, the lowest level of support was for medications for the treatment of depression and the highest support was for asthma medications. This profound support for the inclusion of medications to treat a broad range of diseases/disorders may be related to patients' confidence in their self-management and the ability to judge the severity of these diseases. Additionally, this may be related to their confidence that pharmacists can provide monitoring for diseases such as diabetes and hypertension. In a previous study,[55] patients provided reasons for preferring to buy short acting beta agonists (SABAs) without a prescription or with repeats of a previously issued prescription rather than visiting their doctor and obtaining a new prescription after a clinical examination. These reasons included their perception of the worthlessness of visiting their doctor just to obtain a new prescription, their perceptions of medication not requiring such visits and their long experience with the disease, making them feel that they were able to manage and control asthma without the need to see a doctor. This is despite evidence by Braido that "self-reported symptoms poorly correlate with pulmonary function measures".[56] Another study reported that obtaining SABAs without a prescription did not lead to poorer asthma control; instead, it supported the claim that OTC availability of these medications benefits patients with asthma.[57] Moreover, the availability of some medications to treat asthma such as (SABAs) as Pharmacist Only medications in Australia, that do not require a prescription, may have increased participants' confidence to obtain more asthma medications without a valid prescription. On the other hand, other studies reported that OTC asthma medicines have resulted in under-treatment and less consultation with doctors. Furthermore, assessment and counselling provided by pharmacists or other pharmacy staff has been reported to be less than optimal.[58] However, this inadequate counseling may have resulted from unwillingness of patients with long term chronic diseases to discuss with healthcare professionals what they believed they already know. This controversy about effectiveness and benefit of dispensing asthma medications without a doctors' review raises the need to ensure that optimal patient outcomes are being achieved through appropriate monitoring. This suggests that down scheduling of Prescription Only Medication to Pharmacist Only Medication provides better access to those medications.[59] However, appropriate patient

supervision is essential, as is referral to the doctor whenever deemed necessary.[4](IC)]

Disease sufferers were more likely to support inclusion of their medications into CD with the exception of patients with diabetes mellitus and indigestion. This is probably because of low sample size of patients suffering from indigestion. Interestingly, more than 92% of patients with depression supported inclusion of antidepressants in CD, even though the overall support for the inclusion of medication for depression was the lowest. The exact reason for the difference in support for the inclusion of antidepressants is unclear. However, it may reflect a poorer level of mental health literacy amongst the general population without depression, in which diseases like depression still have a social stigma. {Mental health literacy has been defined as “knowledge and beliefs about mental disorders which aid their recognition, management or prevention.”}[60] The lack of support for the availability of anxiolytics may also be explained in the same way, although the potential for abuse of these medications may also be another explanation. On the other side, the fact that most antidepressants are labelled with warnings “do not stop abruptly” may explain why patients with depression were more supportive than the overall participants. In addition, patients on long-term treatment for depression may not see the need for another visit to the doctor, especially if they do not perceive that they receive any new information during their routine appointments.[61] The latter may apply to chronic diseases in general, where patients after several years on the same medication may accept that nothing will be changed and see their doctor’s appointments as adding little value to their management.

Participants’ support to include additional medications under the CD provisions is consistent with practices in Canada, where pharmacists in some provinces are permitted to undertake short-term dispensing to allow patients to avoid interruption of their continuing therapies.[62] It is also consistent with the overall trend to expand pharmacists’ roles through rescheduling more prescription only medicines to non-prescription status that requires additional pharmacist’s intervention (i.e. Pharmacist Only Medications). This includes medications to treat asthma, hypertension and hyperlipidemia.[59, 63, 64] Conversely, doctors have expressed their concerns about safety and appropriateness of CD,[65] as well as any further reclassifying of prescription only to non-prescription status.[66]

Limitations of this study have been reported in detail previously.[4](IC)] These include the respondents’ distribution, with almost half of the participants being from one state (i.e. New South Wales); other factors included the exclusion of those who were under 18 years old, did not speak English, did not use landline phones or were not available at the time of calling. In

regard to this section of the study, participants' support to include more medications in the CD model was not based solely on their personal experience, as no participant had all the listed diseases/disorders. In addition, the number of participants who suffered from other diseases was low; therefore their support to include these medications may not be generalisable. However, participants' responses may reflect, amongst other things, their general awareness of the disease/disorder, the experience of a friend or relative and/or being a health care professional. The fact that the participants were all either Statin or OC users, may bias the results as they may have different views from the general public or patients with the specific diseases, which may limit generalisability of the results of the current study. However, there are factors that contribute towards the study strengths, such as being the first about patients' views on the current CD system and, therefore, it can provide novel insights into how the system may be extended and expanded in the future.

Future research should explore specific diseases in relation to CD, including clinical and economic implications. Further, it is important that research undertaken to assess whether patients' expressed desire to expand and extend CD is in their best health and economic interests. Given the limitations of the current CD method, other medication supply models to patients in cases where there is lack of valid prescription should also be explored.[5]

3.4.6 Conclusions

Presented here are the combined conclusions from Papers 1 and 2.

Australian users of Statin and OC medications showed a high level of support for CD. Given that a significant proportion of patients temporarily stop treatment when they run out of medications and have no valid prescription, CD may alleviate the negative consequences of therapy interruption in Statin users and OC users in the short-term.[4]

Current restrictions on CD may limit its capacity to serve its goals, as suggested by this study with participants highly supporting a more flexible and broader CD system. The currently eligible utilisers of the CD system seem to prefer inclusion of additional medications, and more opportunity to use CD at any time they cannot see their doctor. These findings suggest that ongoing review of CD is essential and changes which do not compromise patient safety or allow the abuse of CD would be welcomed by patients.[5]

Strategies addressing the issue of supply beyond the one month allowable and the currently listed therapeutic groups of medications covered under CD need further exploration.[4]

The overall conclusion of this study can be summarised as; Statin and OC users highly supported the current CD. At the same time, they supported a modified version of CD that enables them to obtain additional supply when they cannot see their doctor, and allows them to obtain other medications (for chronic co-morbidities) not only Statins or OCs. Therefore, the study participants think the current CD is one step towards more convenient access to their medications and seek additional expansion of the scheme to improve this further.

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Chapter 4: Pharmacists attitudes towards continued dispensing

4.1 Overview

This chapter consists of three parts. Part A is entitled: Avoiding treatment interruptions: What role do Australian community pharmacists play? This part consists of a manuscript which has been submitted to the journal PloS One for consideration. Part B is titled: Additional information. This part contains more details about the reasons for patients requesting medications without a valid prescription, as reported by pharmacists. Part C is entitled: Community pharmacists' attitudes towards continued dispensing and its expansion.

4.2 Note: Manuscript changes from the submitted version

The Abstract and Reference list have been removed, and this is within the terms of the Creative Commons Attribution Non-Commercial 2.0 Generic License,[1], and according to PloS One copyright notice.[2] Permission from co-authors has been obtained (Appendix 4.1). No changes (except spelling) from the original publication have been made regarding content, grammar and headings. While the references used in this article are unchanged from the original publication, they have been renumbered in line with the single reference list in the thesis. The numbers and style of the Appendix, Figure, and Tables have also been aligned with the format of this thesis.

4.3 Part A: Avoiding treatment interruptions: What role do Australian community pharmacists play?

4.3.1 Introduction

Pharmacists in community pharmacies worldwide are often faced with customers requesting supply of prescription medication without a prescription or without a current valid prescription.[3-5] In this paper, ‘invalid prescription’ refers to an out of date prescription or a prescription without any remaining repeats. In Australia, except in the case of controlled drugs, prescriptions are valid for one year from the date of issue, or six months for controlled medications.[6] When the prescription expires, the patient must see their regular prescriber or any registered prescriber (e.g. doctor, nurse practitioner) to obtain a new prescription. However, there are situations when obtaining an appointment with the prescriber is not practical and this may result in treatment interruption.[7]

When customers run out of their prescription medicines, they may ask their regular pharmacy (or any other pharmacy) to supply their medication without a valid prescription, based on their last valid prescription. In this situation in Australia, pharmacists have the right to Not Supply (NS), or supply using: (a) Owing Prescription (OP) system, or (b) Emergency Supply (ES) system.[8] In the case of OP, the pharmacist is required to contact the prescriber to approve the OP supply, if the prescriber is not contactable, the pharmacist must not use this method. This method is funded nationally through Pharmaceutical Benefits Scheme (PBS). The PBS is a Government subsidy system for medication costs and professional fees for all Australian residents. Therefore, customers supplied with their one repeat of medication through this system are not charged beyond the usual co-payments. It requires a verbal approval (and a paper prescription within a week) by the original prescriber, and this may not be practical or possible in some situations.[7] Therefore, OP is not always available. The second method of supply (i.e. ES) does not require contact with the original prescriber. However it only enables pharmacists to supply a limited amount of the medication and customers are charged a premium for the cost of medication (i.e. a broken pack fee) and a dispensing fee.[9] Disadvantages of the above systems have led to a new method of supply in the absence of a valid prescription, namely Continued Dispensing (CD). CD has been implemented in the majority of Australian states/territories since September 2013. CD allows the dispensing of one standard pack of the medication. However it is currently only allowable for Statin and Oral Contraceptive users.[7] An expanded version has been supported by its eligible users (i.e. Statins and oral contraceptive users),[10] and health organizations such as the Pharmaceutical

Society of Australia.[11] It is worth mentioning that at the time of conducting the present study, CD was either not implemented (i.e. time of initial survey), or had just implemented (i.e. for less than one month at the time of reminders). Therefore, this study collected information about community pharmacists' practice before (or just shortly after) CD implementation.

Several factors may influence the method that pharmacists use to deal with medication requests without a valid prescription.[12] Firstly, the type of prescription. In Australia there are three types of prescriptions (according to what medications can be prescribed, number of repeats and funding): Standard PBS Prescriptions (Standard), PBS Authority Prescriptions (Authority) and Private Prescriptions. The PBS contains a list of medications (dispensed at a Government-subsidised price) which may be prescribed using Standard Prescriptions or Authority Prescriptions. Standard Prescriptions are the most commonly used for medications on the PBS list because they do not require a third party authorisation. However, the prescriber must abide by the prescribing conditions such as the indication of use and number of repeats for individual Standard PBS items.[13] Authority Prescriptions are used to prescribe PBS listed medications which have restricted supply conditions (e.g. for a particular indication) or are prescribed in greater quantities or with more repeats than usually available through the PBS. For both prescription types, patients' co-payments range from AU \$6.10 to AU \$37.70 (2015 figures) depending on their status of concession. The rest of the medications' costs and pharmacists' fees are paid by the PBS.[14] Private Prescriptions are generally used to prescribe medication not listed in the PBS and/or when supply is not eligible under the PBS rules, in this case patients pay the full cost of the drug and supply.[8] Printed Standard and Authority Prescriptions are required to enable pharmacists to claim reimbursement from the PBS system, The administrative complexity to obtain a new prescription (particularly Authority Prescriptions) to cover medication supply without a valid prescription varies according to prescription type.[9] Consequently, pharmacists are likely to take this factor into their consideration in their decision to supply, and if so using what method of supply.

Secondly, customer type may also influence the method that pharmacists choose in dealing with a medication request in the absence of a valid prescription. Since pharmacies keep records of medication supply for each customer, pharmacists can review the customer's medication dispensing history.[15] In addition, pharmacists may establish a relationship with their regular customers.[7, 16] Therefore, pharmacists may provide different (and potentially more preferable) options for regular compared to non-regular customers.[4] For example supply rather than refusal to supply, or supply with OP rather than ES.

Thirdly, the type of the medication. This factor may have a positive or negative impact on pharmacist's decision.[4] For example requesting an antihypertensive medication is entirely different from seeking a benzodiazepine without a valid prescription. While the motivation for requesting an antihypertensive is likely to be solely for medical reasons, the request for the benzodiazepine may not always be medically motivated.[17]

Fourthly, the frequency of request may also affect pharmacists' decisions.[4] For example, if the customer repeatedly requested the same medication under the guise that they were unable to see their regular prescriber, this would probably reduce the likelihood that the pharmacist would provide an additional supply. However, without a fully implemented electronic health record, pharmacists may not be able to identify if a previous supply without a valid prescription was made in another pharmacy.

Finally, pharmacists' decisions may differ according to their demographic status. Previous studies have shown that pharmacists had different practices according to their age, gender and pharmacy location.[18-20] Therefore, these factors may affected pharmacists' decisions to supply or refuse to supply medications without a valid prescription.

This study investigated: (a) the frequency of requests by different customer types, (b) how would Australian pharmacists deal (supply or not supply and which method of supply they use) if they faced with hypothetical scenarios of customers requesting medications without a valid prescription) and (c) factors which influence their decisions.

4.3.2 Methods

Australia has six states and two territories. They can be arranged according to percent of registered pharmacists as New South Wales (NSW) (31%), Queensland (QLD) (26%), Victoria (VIC) (20%), Western Australia (WA) (11%), South Australia (SA) (7%), Tasmania (TAS) (3%), Australian Capital Territory (ACT) (2%), and Northern Territory (NT) (1%). A self-administered questionnaire was sent to a randomly selected sample of community pharmacies in Australia. All pharmacies in each Australian state or territory (on the Yellow Pages website) were entered into an Excel™ file, and then a random sample (20% of pharmacies) was selected using a simple random technique. A 20% sample was chosen as it allows a representative sample to be drawn from a large number of potential respondents. Therefore, 1490 questionnaires were distributed with an anticipated response rate of approximately 40% (it was anticipated to lead to approximately 600 responses, with 95% confidence level with +/-2.5 confidence interval). The randomization was done by using an

electronic randomizer (<http://www.randomizer.org/>). The Yellow Pages website was the only readily available source to obtain postal and email addresses of Australian pharmacies. Efforts were made to obtain these addresses from licensing bodies, however, these attempts did not succeed. Sample selection depended on a number of pharmacies in each state/ territory. A total of 1490 pharmacies were selected: 464 from NSW, 378 from VIC, 326 from QLD, 135 from WA, 120 from SA, 39 from TAS, 16 from ACT and 12 from NT. The questionnaire was sent during late August 2013 by post. Whilst postal and email reminders [173 emails, (those where email addresses were available)] were sent out a month later (i.e. before and after implementation of the CD system in most Australian States).[21] Therefore, the questionnaire did not contain the option CD as a potential method of supply. In other words, the questionnaire explored the pharmacists' reported practice before CD became an additional option to supply. The questionnaire did not collect information about pharmacies characteristics, such as the number of employees, the number of prescriptions dispensed or ownership of pharmacy. The postal survey was chosen because it is a cost-effective method to contact a relatively large number of pharmacies in Australia given its geographical size.[22] Participants were considered consented if they returned the questionnaire. No incentives were provided for participation.

4.3.2.1 Questionnaire design

Results of a literature review and experience from previous studies were used in the development of the questionnaire.[7, 22] The questionnaire's face and content validity were assessed for by piloting it with five pharmacists and eight pharmacy academic staff members working in the area of pharmacy practice at School of Pharmacy, Curtin University. After incorporation of the suggested changes, such as deletion of some questions (because they were deemed irrelevant), the final questionnaire contained 19 questions. In this manuscript, we report only five questions that cover two areas; (a) frequency of medication requests without a valid prescription by regular and non-regular customers, and (b) the reported practice by pharmacists when dealing with such requests. In addition to these areas we also report participants' demographic information (age, gender of the participant and pharmacy location; urban (population > 100,000) or rural (population < 100,000)).[23] A regular customer was defined as a customer who attended the pharmacy five times or more in the past 12 months, while the a non-regular customer was defined as a customer who: attended the pharmacy fewer than five times in the past 12 months. These definitions were obtained from the Australian Health Department website and were provided within the questionnaire.[24] The first question sought information about the frequency of customers (regular and non-regular) requesting

medication(s) without a valid prescription. The second question looked at what the participants would do (NS, OP, ES or Other) when facing a medication request without a valid prescription. Therefore, they were asked to report what they would normally do when dealing with a request for each of the 19 different medication classes (See Appendix 4.2). In this case the request was made by a regular customer with a stable chronic disease (as judged by the participant after consultation with the customer) and based on a previous supply with: a) Standard Prescription, b) Authority Prescription, or c) Private Prescription. Therefore, three different scenarios were used. We assumed that the pharmacist would not supply when it was not safe to do, would try to contact the original prescriber to supply using OP, or dispense a limited quantity of the requested medication using ES if the communication with the prescriber was not possible (they could also use the “Other” option to report their other actions). The third question was about the reported practice if the same customer requested the same medication (regardless the prescription and medication types) for a second time without seeing the prescriber. The fourth question was the same as the second, whilst the fifth was the same as the third, but both dealt with non-regular customers. Questions 3 and 5 were used to explore only the effect of the frequency of request and customer type on participants’ practice. Therefore they were shortened to include only these factors. This has the advantage of decreasing the time needed to answer the questionnaire (which contained a total of 19 questions), without changing the intended meaning and purpose of the questions. Yet, Questions 3 and 5 provided valuable data particularly comparing participants’ reported practice with regular and non-regular customers. Further details of the questionnaire are provided in the Appendix 4.2.

4.3.2.2 Ethical approval

This study was approved by The Human Research Ethics Committee of Curtin University (Approval number: PH-07-13; See Appendix 4.3).

4.3.2.3 Data analysis

Answers to each question were analysed using SPSS[®] version 22 (<http://www-01.ibm.com/software/au/analytics/spss/>). Responses to questions were entered into an Excel[™] file, and then transferred to an SPSS[®] data file. SPSS[®] was used to summarise data and produce frequency tables and to describe the reported practice according to customer, prescription and medication types. Since the same participant was asked twice (i.e. first, would they supply or refuse to supply for regular customers, and second for non-regular customer), the McNemar test was used to compare the supply practices of medications between regular and non-regular

customers. This test was initially utilised through the Transformed Process in the SPSS® to convert responses into the dichotomous responses of Not Supply (NS) and Supply which included ES, OP and ES&OP responses. Multinomial regression was used to investigate the effect of demographic variables: age, gender, and pharmacy location description (urban or rural) on participants' decisions to supply and what method of supply they used (i.e. ES or OP). Participants were compared according to: age for the purpose of analysis this variable was re-grouped into two groups only (the younger group i.e. ≤ 40 years vs the older group > 40 years of age), gender (male vs female), and pharmacy location (urban vs rural). For all tests a p value of ≤ 0.05 was taken to indicate a statistically significant association. Multinomial regression was used because it is appropriate to model a 3-level categorical outcome variable.[25] According to Tabachnick and Fidell, "regression analysis with over approximately 150 responses are adequate to identify independent variables which exhibit a moderate effect size" [25]. It does not require a large sample and 10 cases in each variables were considered sufficient.[26] Finally, Mann-Whitney test was used to detected differences between those who responded to the initial questionnaire and those who responded to the reminder. This test was used because it is appropriate to compare two independent samples.

4.3.3 Results

4.3.3.1 Response rate

The total questionnaires received were 385 and there were 111 undelivered questionnaires. There were 268 responses from the first mail-out and 117 from the reminder (including six via email). There were only 63 responses from the states where CD was actually implemented. No statistically significant differences (Mann-Whitney test and Wilcoxon test) were detected between those who responded to the initial questionnaire and those who responded to the reminder. The overall response rate was 27.9% of delivered questionnaires. Response rates from states and territories ranged from 0% in Northern Territory to 51.4% in Tasmania.

4.3.3.2 Demographic data

Males were the dominant gender group of the respondents. According to age, the respondents were almost equally divided into two groups (≤ 40 years old and > 40 years old). The distribution of the respondents within states/territories corresponded to the number of pharmacies (hence the sample selected) in each state/territory. The participants' primary place of work was community pharmacy (96.6%). Our demographic data is comparable to data published in a report by Health Workforce Australia 2014.[27] Further demographic details

are shown in Table 4.1.

Table 4.1 Demographic characteristic of the participants (n=385)

Variable	Categories	Survey Data n (%)	Australian Data [#]
Gender	Male	210 (54.5)	8,916 (41.8)
	Female	155 (40.3)	12,415 (58.2)
	Prefer not to disclose	20 (5.2)	*NA
Age	20-30	90 (23.4)	NA
	31-40	98 (25.5)	NA
	41-50	83 (21.6)	NA
	51-60	83 (21.6)	NA
	> 61	26 (1.8)	NA
	Prefer not to disclose	5 (1.3)	NA
State or Territory	ACT (Australian Capital Territory)	5 (1.3)	373 (1.7)
	QLD (Queensland)	92 (23.9)	4,197 (20.0)
	NSW (New South Wales)	90 (23.4)	6,584 (31.0)
	NT (Northern Territory)	0 (0)	157 (0.07)
	SA (South Australia)	31 (8.1)	1,625 (7.6)
	TAS (Tasmania)	18 (4.7)	554 (2.6)
	VIC (Victoria)	92 (23.9)	5,465 (25.6)
	WA (Western Australia)	54 (14.0)	2,367 (11.0)
	Prefer not to disclose	3 (0.8)	NA
Pharmacy location	Urban (Metropolitan)	279 (72.5)	16,225 (76.0)
	Rural (rural, remote and other)	100 (26.0)	5,088 (24.0)
	Prefer not to disclose	6 (1.6)	NA

Source Health Workforce Australia 2014, [24] according to this source the total number of pharmacists in 2012 was 21,331 working in different pharmacy settings (13,454 (63.1%) were working in community pharmacy).*NA: not applicable

4.3.3.3 Weekly requests

The participants were asked to estimate the number of medication requests without a valid prescription that pharmacy received from regular and non-regular customers on weekly basis. Four options were offered to participants to select; zero, one or two, three to four, and five or more. The most reported number of requests per week was five or more made by regular customers reported by 66.8% (n= 257) of the participants, followed by three to four

times reported by 19.5% (n= 75) and one or two times reported by 8.6% (n= 33), while only 2.9% (n=11) reported that they did not face such requests from regular customers and nine participants did not answer this question. Interestingly, one participant reported the number of requests from regular customers as 50 per week. In the case of non-regular customers, one or two requests per week was the most frequent, reported by 48.3% (n= 186) of the participants followed by five or more reported by 21.3% (n=82), three to four times reported by 10.1% (n=39), and zero times was reported by 9.4% (n= 36). There were 42 participants who did not answer this question.

4.3.3.4 Reported practice

The participants were asked about what they would do (Not Supply [NS], Owing Prescription [OP], Emergency Supply [ES] or Other) when dealing with hypothetical scenarios of a patient with a stable chronic disease requesting listed medications without a valid prescription, if this request was based on a previous supply with either a Standard, Authority, or Private Prescription, and was made by: (A) a regular customer or (B) an non-regular customer. The frequency of supply and the reported practice differed according to prescription, customer and medication type is outlined below.

4.3.3.4.1 Total Supply

Figure 4.1 displays the overall supply according to customer, prescription and medication types. Results are summarised below.

According to customer type

Regardless of prescription or medication type, for all listed medications the likelihood of supply for regular customers was greater than for non-regular customers (Figure 4.1).

The McNemar test was used to compare the NS and supply for each medication as dichotomous dependent variables between the two customer types as dichotomous independent variables. In all cases, the difference was statistically significant ($p < 0.0001$), suggesting a higher rate of supply for regular customers in comparison to non-regular customers.

According to prescription type

The lowest rate of supply was for Authority Prescriptions, irrespective of customer or medication type. The highest rate of supply was associated with Standard Prescriptions (for regular customers) or Private Prescriptions (for non-regular customers), depending on medication type (Figure 4.1).

The McNemar test revealed statistically significant differences between the supply, based on Authority Prescriptions and the other prescription types, for all medication types (p value < 0.05) and for each customer type. However, in some cases there were only significant differences between Standard and Private Prescriptions (see Figure 4.1 for more details). Note in the case of psoriasis medication (and similar cases) for regular customers, the percentages of participants who decided to supply in both prescription types were identical (i.e. 68.3%), in these cases the significant differences arose from the differences in the numbers of participants who did not supply. For example, in the case of psoriasis medication for regular customers, there were 111 participants who selected NS in the case of Standard Prescription and 85 participants in the case of Private Prescriptions.

According to medication type

All listed medications, except opioids, were supplied by over 50% of participants' regardless of prescription type if the request for supply was made by a regular customer. If the request was made by a non-regular customer, there were more medications that would not be supplied by pharmacists in the case of Standard or Private Prescriptions (Figure 4.1).

However, if the prescription was an Authority Prescription, the majority of the participants would not supply the listed medications

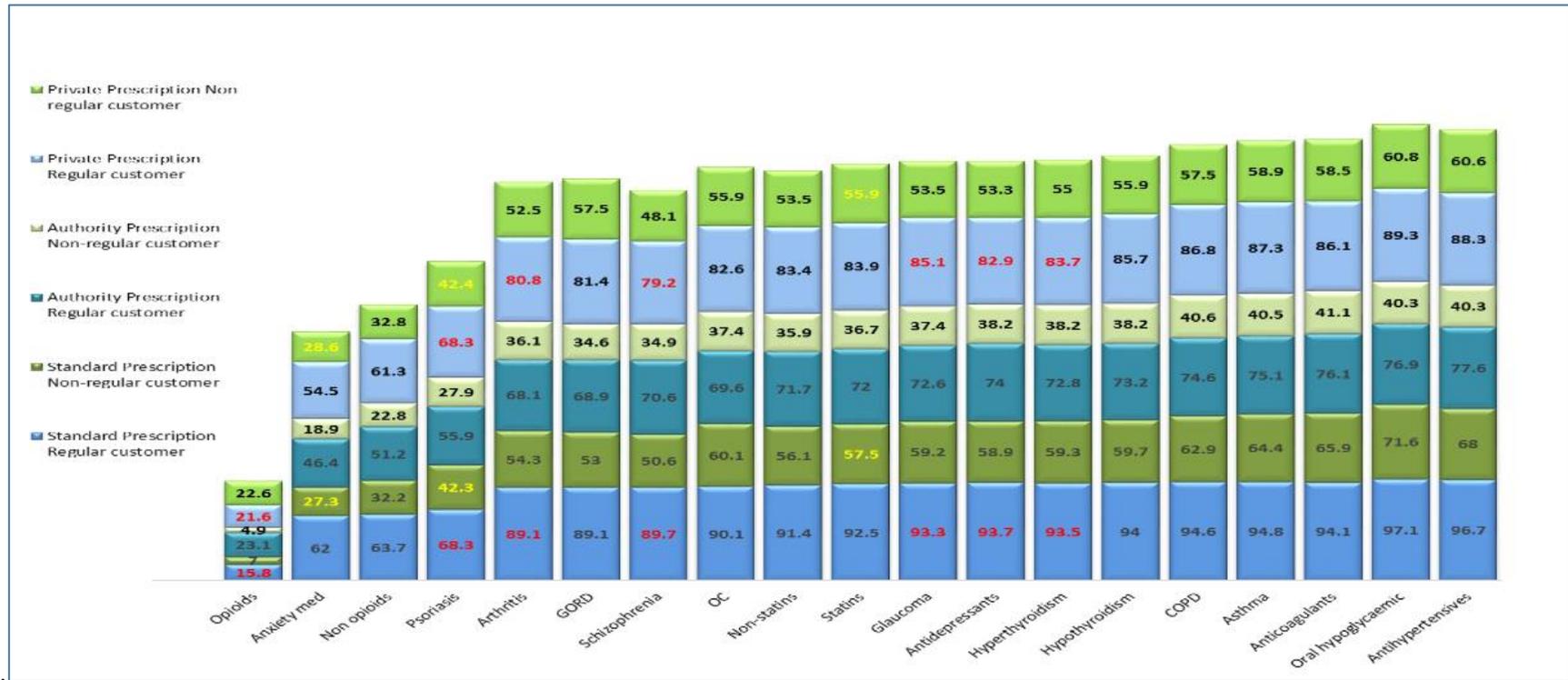


Figure 4.1 Comparison between the supply (%) for regular and non-regular customers according to prescription and medication types

COPD: Chronic Pulmonary Disease, OC: Oral Contraceptives, GORD: Gastroesophageal Reflux Disease

Differences between total supply to regular and non-regular customers were all highly significant ($p < 0.0001$). Significant differences between Standard and Private Prescriptions were only in: a) requests made by regular customers (shown in red); depression ($p = 0.007$), schizophrenia ($p = 0.001$), hyperthyroidism ($p = 0.007$), opioids ($p = 0.013$), arthritis ($p = 0.039$), psoriasis ($p = 0.001$) and glaucoma ($p = 0.039$), and b) requests by non-regular customers (shown in yellow): anxiety ($p = 0.05$), psoriasis ($p = 0.003$), and Statins ($p = 0.035$)

4.3.3.5 The reported practice

Regular customers

The most reported practice of medication supply was OP (Figure 4.2) in the case of either Standard or Private Prescriptions, except in the case of chronic pain non-opioids, antianxiety medications, and opioids. In the case of opioids, the majority of participants reported NS as a usual practice, whereas for non-opioids and antianxiety, there was no clear cut practice as the responses were distributed through NS, ES or OP. In the case of Authority Prescriptions, if participants provided medications they used ES more frequently than OP; however there was a greater level of NS compared to Standard and Private Prescriptions.

Non-regular customers

In the case of non-regular customers, there was a greater incidence of NS for all prescription types, and for all types of medication (Figure 4.2). In the case of supply, the preferred method of supply was ES. In contrast to regular customers, the frequency of OP use was more for Private Prescriptions than Standard Prescriptions.

4.3.3.5.1 Frequency of request

The usual practice was NS for both types of customers in cases where a second consecutive request was made before the patient obtained a new prescription. However, the likelihood of obtaining the medication was higher for regular than non-regular customers (26.3% [19.0% ES + 7.3% OP] vs 6.3% [5.5% ES + 0.8% OP], $p < 0.0001$). In addition, 12.9% of the participants in the case of regular customers and 5.1% of participants in the case of non-regular customers reported that they would use another method to supply.

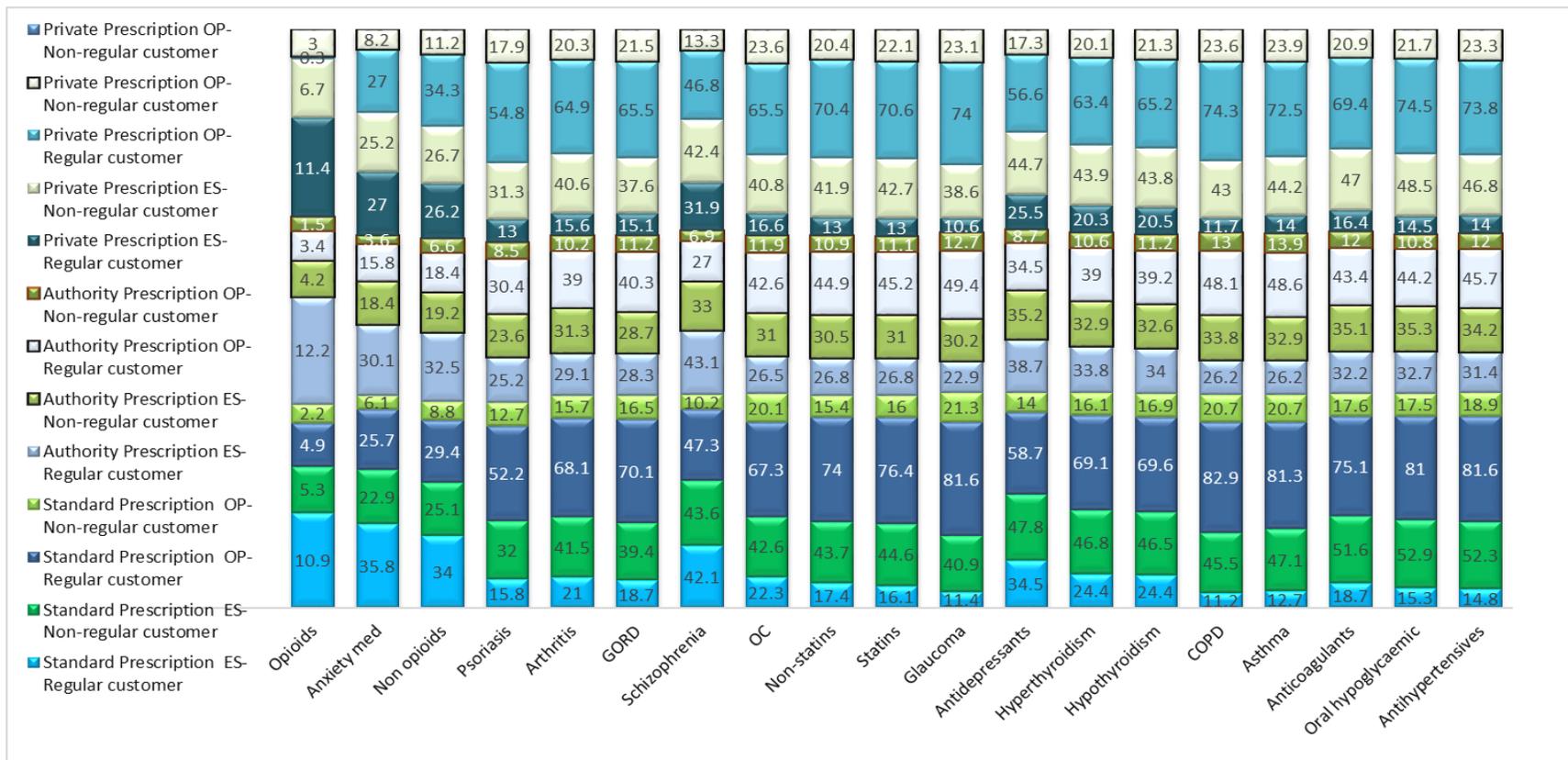


Figure 4.2 Method of supply (%) for regular and regular customers according to prescription and medication types

COPD: Chronic Pulmonary Disease, OC: Oral Contraceptives, GORD: Gastroesophageal Reflux Disease

4.3.3.5.2 Effect of some variables on the usual practice

Multinomial regression analysis revealed that participants' demographic variables (age, gender, and pharmacy location description) had significant effects on the usual practice of how participants dealt with medication supply requests. In general and depending on the prescription and customer type, older participants were more likely than the younger participants to supply the following medications: antianxiety, non-opioids, and opioids. Younger participants, however, were more likely to provide antidepressants, psoriasis medications, Statins, and non-Statins. Participants who worked in urban areas were more likely to supply antianxiety, arthritis, and Gastro-Oesophageal Reflux Disease (GORD) medications than participants worked in rural areas, while male pharmacists were more likely to supply opioids than female pharmacists (See Table 4.2).

4.3.3.6 Alternative model for medication supply

A small number of participants (ranged from 0 to 0.08 %) reported they used a hybrid model of ES and OP for some sub-questions (2-5). In this case, the customer is provided with the minimum applicable quantity of the medication (three days' supply or the full pack [e.g. for an inhaler medication]) and required to pay the full cost (i.e. ES) and then when the customer presents a new valid prescription they are provided with the remaining quantity and either pay or are refunded any difference between ES and PBS co-payments (i.e. OP).

Table 4.2 Effects of demographic variables on participants' decisions to supply (n=385)

Customer type	Medication	Prescription type	More likely to Supply Group	P value
Regular	Antianxiety	Standard	Older (> 40 years)	0.008
	Antianxiety	Authority	Urban	0.044
	Antianxiety	Private	Older (> 40 years)	0.022
	Antidepressants	Standard	Younger \leq 40 years)	0.033
	Antidepressants	Authority	Younger (\leq 40 years)	0.005
	Antidepressants	Private	Younger (\leq 40 years)	0.023
	Non-opioids	Standard	Older (> 40 years)	0.006
	Non-opioids	Authority	Older (> 40 years)	0.023
	Non-opioids	Private	Older (> 40 years)	0.022
	Statins	Standard	Younger (\leq 40 years)	0.007
	Statins	Authority	Younger (\leq 40 years)	0.015
	Statins	Private	Younger (\leq 40 years)	0.022
	Arthritis	Standard	Urban	0.016
	Arthritis	Authority	Urban	0.003
	Arthritis	Private	Rural	0.028
	Opioids	Authority	Older (> 40 years)	0.03
	Opioids	Private	Male	0.027
	Psoriasis	Standard	Male	0.008
	Psoriasis	Private	Female	0.012
	Psoriasis	Private	Younger (\leq 40 years)	0.028
Anticoagulants	Authority	Female	0.028	
GERD	Private	Urban	0.003	
Non-regular	Statins	Standard	Younger (\leq 40 years)	0.03
	Statins	Private	Younger (\leq 40 years)	0.048
	Non-Statins	Standard	Younger (\leq 40 years)	0.046

GORD: Gastro-Oesophageal Reflux Disease

4.3.4 Discussion

To our knowledge, this is the first study to explore thereported practice of Australian community pharmacists when dealing with medication requests in the absence of a valid prescription. Such requests have also been reported in the international literature.[28, 29]

Worldwide there have been a number of changes in legislation to allow pharmacists to supply medication in urgent situations. For example, in some Canadian Provinces, pharmacists may legally adjust the medication dose, or change the dosage form of prescribed medications to ensure treatment continuation when access to the original prescriber is not practical.[29]

Results of the current study showed that Australian community pharmacists face such requests on a weekly, if not daily, basis. Inability of customers to obtain same-day appointments was reported as a cause in both the Australian and international literature.[30, 31] In a recently published Australian study, Garth et al. reported that not all patients requesting same day appointments would be able to be seen by their doctor.[30] In regards to medication requests without a valid prescription, regular customers were more likely to make such requests compared to non-regular customers (5 or more vs. 1-2 times per a week). In a previous study, requesting medication without a valid prescription was also reported by approximately one third of patients who ran out of their medication.[7] In a recently published study from the UK, Morecroft et al. reported that requests for urgent medication supply were more likely around weekends and when other services were not available.[4] In the current study, where possible and appropriate, community pharmacists assist customers by providing an ongoing supply until they can see their doctor. However, they are more likely to provide ongoing supply if the medication requested is not a drug with abuse potential, the customer is a regular and the prescription is either a Standard or Private Prescription, where obtaining a new prescription is less difficult than Authority Prescriptions. The reported practice of pharmacists dealing with medication requests in the absence of a valid prescription emphasises the importance of customers having a regular pharmacy.[12]

Results of this study indicated that there were substantially different practices by pharmacists when dealing with hypothetical scenarios of medication requests without a valid prescription according to the customer, prescription and medication types, and frequency of the request. There were a number of factors associated with lower rates of medication supply and more usage of the ES or NS as the most reported practices. These factors included (1) non-regular customer (probably due to lack of dispensing history), (2) Authority Prescription (this seems a result of potential difficulties in obtaining a new valid prescription, which might result in breach of legal requirements and/or financial loss), and (3) medication type, in particular chronic pain non-opioids, anti-anxiety medications and opioids (probably because of abuse potential). Indeed, as these factors augmented, the medication supply became less frequent, resulting in more NS decisions. While the NS decision is recommended to deal with medications with abuse potential, pharmacists may find themselves in complex situations with

legitimate requests for medical purposes such as patients with cancer.[17]

The ES method was the most commonly reported method of supply, in cases of the presence of one or more of the above factors, presumably because ES does not require contact with the prescriber or a future prescription. However, it is a costly method for the customer and allows only a three days' supply. As a result of the cost,[32, 33] customers may refuse to obtain their medications through ES.[17, 21] Consequently, non-regular customers had a significantly lower overall rate of supply than regular customers ($p < 0.0001$). This is consistent with a previous study, where non-regular customers reported they ran out of their medications more frequently than regular customers.[7] The main reason related to these factors may be a potential lack of trust as reported by Hoti et al. in the pharmacist prescribing context.[34] Pharmacists may not feel confident to supply to customers for whom they do not know their medication supply history, do not trust them to accurately report their health issues and/or bring a new valid prescription back to the pharmacy, particularly in the case of Authority Prescriptions which require a third party approval.

The OP method was the most commonly reported method of supply for requests made by regular customers, based on a previous supply with a Standard or Private Prescription, and when the medication was not a chronic pain non-opioid, anti-anxiety medication or opioid. It is not clear whether participants used the 'Standard OP' procedure (i.e. supply only after the pharmacist communicated with the prescriber) or the "in advance" OP which is conducted without such communication.[7] 'In advance" OP is not strictly a legal method of supply; however it is used when the pharmacist is satisfied a regular customer will bring a valid prescription following their next visit to the prescriber. This is similar to 'loan' supply in the UK, which is used to supply medication for urgent requests without a prescription but with a future prescription anticipation. Morecroft et al. reported that avoiding additional cost to customers was one of the motivations for pharmacists' use of this method.[4] We assume that pharmacists will firstly try to contact the prescriber and if that is not possible (thus the Standard OP is not applicable) then they may refuse to supply, use ES, or use the 'in advance' OP method of supply. In the case of non-regular customers, OP was less frequently used (ranged from 2.1 to 20%). This may reflect difficulty to communicate with the original prescriber of non-regular customers.

Frequency of requests also affected pharmacist's decisions. If the same patient requested a second consecutive supply because of continued inability to see their regular prescriber the most reported practice was NS. Although participants were more flexible with their regular

customers, through providing them an ES supply, compared with non-regular customers for whom the possibility to obtain a second supply was very small ($p < 0.0001$). This may answer the question from a previous research project about “at what point does the pharmacist say, “We will no longer supply until you see the doctor?”[9] This indicates that pharmacists do not endlessly supply medication without a valid prescription and at the same time they appreciate patients’ difficulty in seeing their regular prescribers. In a previous study, repeated requests was also reported as a source of distress for pharmacists, particularly if they perceived them as system abuse by patients to avoid medical review, which they have to pay for or take time off work to have done.[4]

Some demographic variables affected pharmacists’ reported practice. This effect of demographic variables is consistent with previous studies which demonstrated the association between pharmacists’ demographics and their decision making process and/ or their attitudes towards patients.[18-20]. Older, males and/or pharmacists working in rural areas were more likely (than their younger, female and/or urban counterparts) to supply chronic pain non-opioids, anti-anxiety medications and opioids. This may have resulted from the experience of the pharmacist, where male pharmacists tended to be older than females ($p < 0.05$), working more on a full time basis and probably they were more likely to be a pharmacy owner.[27] Thus they may have had longer relationships with their customers and their customers’ doctors. Therefore, they may be more confident that they would obtain the anticipated prescription and/or as owners they were more able to take the financial risk of supplying medication without prescription if the anticipated prescription could not be obtained. Furthermore, pharmacists working in rural areas may have had more regular customers (as a result of fewer pharmacies in rural areas) and/or longer relationships (due to the nature of living in rural areas) with their customers than their counterparts in urban areas.[35]

An alternative method to supply medications was also reported. As far as we know, this method has not been reported in the Australian literature before. It is a combination of both ES and OP methods. This seems to be a practical way to satisfy the customers’ needs for urgent medication supply without strictly breaking the rules, as well as avoiding any financial loss if the anticipated prescription is not obtained. Several steps have been taken by the pharmacy regulatory bodies to improve access to medication when it is impractical to obtain a renewed prescription, such as CD. However, this method is restricted in terms of its frequency and its eligible medications.

Even though the sample of pharmacists was consistent with the number of pharmacies in each

state/ territory the low response rate was the main limitation of this study, which is consistent with the difficulty of obtaining high response rates from healthcare professionals in general, including pharmacists.[36, 37] In addition, there were a number of undelivered questionnaires which may have resulted from outdated addresses on the Yellow Pages website. Access to a more accurate mailing list and greater access to email addresses may have enhanced the response rate. The fact that there were 63 responses from states where CD had been implemented could be seen as a confounding factor. However, there were no statistically significant differences between those who responded to the first mail out and those who responded after the reminder (which was returned less than one month after CD became an available option. Moreover, CD uptake by pharmacists was reported to be very low in the first 10 months of its implementation).[21] No measures were made to identify who participated and who did not, whilst this makes a comparison between respondents and non-respondents not possible, it has the advantage of collecting more truthful data that reflects the actual behaviours of the respondents.[38] There were a large number of pairwise comparisons undertaken, which suggested the existence of a number of significant associations. Because use of the Bonferroni adjustment is not appropriate in this setting (inappropriate null hypothesis), we acknowledge that some p-values may have been less than 0.05 by chance alone (type I error). Furthermore, for statistical purposes we compared participants according to their age as a dichotomous variable, hence decreasing error probability, however, age may not be a valid indicator of pharmacist experience. Finally, results of this study are based on reported behaviours to hypothetical scenarios rather than observation of real practice. Consequently, although the fact that the majority of participants of this study faced similar requests in their practice, minimises the possibility of natural variance between the reports and reality, there is still a possibility that participants may deal differently with actual customers in real practice (i.e. they may have been self-reporting their ideal behaviours rather than their actual practice). Factors which contribute to the strengths of present study, include being the first to explore this area in such detailed way, the sample was selected from all Australian states and territories, and the use of hypothetical scenarios method has been proved to be effective and inexpensive tool to reflect the actual practice by healthcare professionals (doctors) with high content and face validity.[39] Moreover, anonymous reporting by study participants would eliminate “Hawthorne effect” (i.e. participants enhancing their actions under surveillance) that may occur during direct observation studies.[40] According to Evans et al.[41] case vignettes are appropriate to approximate, isolate, manipulate, and measure key aspects of the decision-making processes that individuals use in real world situations, and when “...well designed to test specific questions about judgments and decision-making, they

can be highly generalisable to “real life” behaviour, while overcoming the ethical, practical, and scientific limitations associated with alternative methods (e.g. observation, self-report, standardised patients, archival analysis).”[41] Finally, although study generalisability may be negatively affected by the low response rate, our sample successfully reflected the national figures regarding pharmacists’ demographic information, which supports study representativeness. This study is likely to prompt further investigations of the issues raised by its findings.

Future studies should focus on exploring the use of technology in enhancing the probability of obtaining a medication supply without a valid prescription in cases where contacting the original prescriber is not practical. It should also explore ways to improve communication between healthcare professionals with the view of minimising requests for medication in the absence of valid prescriptions.

4.3.5 Conclusions

Results of the current study showed that pharmacists face requests for medications without a valid prescriptions on a weekly, if not daily basis from both regular and non-regular customers. Our results emphasise the importance of patients having a regular pharmacy to minimise medication interruption when obtaining a new prescription for a chronic medication is not practical. In advance arrangement to obtain a new prescription is highly recommended to avoid such interruptions, particularly for medications with the potential for abuse and for medication that requires authorisation prior to prescribing. Moreover, models of allowing pharmacists to supply without a valid prescription, when it is safe to do, should be explored and implemented especially given that being a regular customer of a pharmacy does not guarantee supply. Future research should investigate reasons for medication requests without a valid prescription, why they are so frequent and what impact might these reasons have on pharmacists’ decisions, particularly taking into account the work by Morecroft et al. who highlighted that a perception of a “genuine mistake” can occur in different responses to a deliberate choice to try to deviate from standard practice.[2] Further, timely and cost-effective ways of communication between healthcare professionals, accessible electronic health records and/or pharmacists prescribing rights as other means of minimising treatment interruptions resulting from the absence of valid prescriptions.

4.4 Part B: Additional data: Reasons for medication request without a valid prescription

4.4.1 Overview

This section contains additional data not reported in the submitted Plos One manuscript (See above). This part details answers obtained from the above study participants about reasons for customers' inability to obtain a new prescription.

4.4.2 Data analysis

There were two types of data: quantitative and qualitative. The quantitative data were obtained through answers to a set of potential reasons (options) that were provided to the participants. These options were: (a) 'Inability to obtain an immediate appointment with their doctors'; (b) 'They realised that they ran out of medication during weekends or public holidays'; (c) 'The prescriber is on leave', and (d) 'All of the above'.

The quantitative data were analysed using the SPSS (Version 22). Data frequencies were analysed to find the most reported reason(s).

The qualitative data were obtained through answers to the option (e) 'Other; please specify'. These answers included two types of reasons: (i) Type 1: Reasons usually cited by the customers to explain why they are not able to obtain a renewed prescription for their regular medication, and (ii) Type 2: Reasons provided by the participants (pharmacists) themselves. These reflected the participants' views about medication requests without a valid prescription.

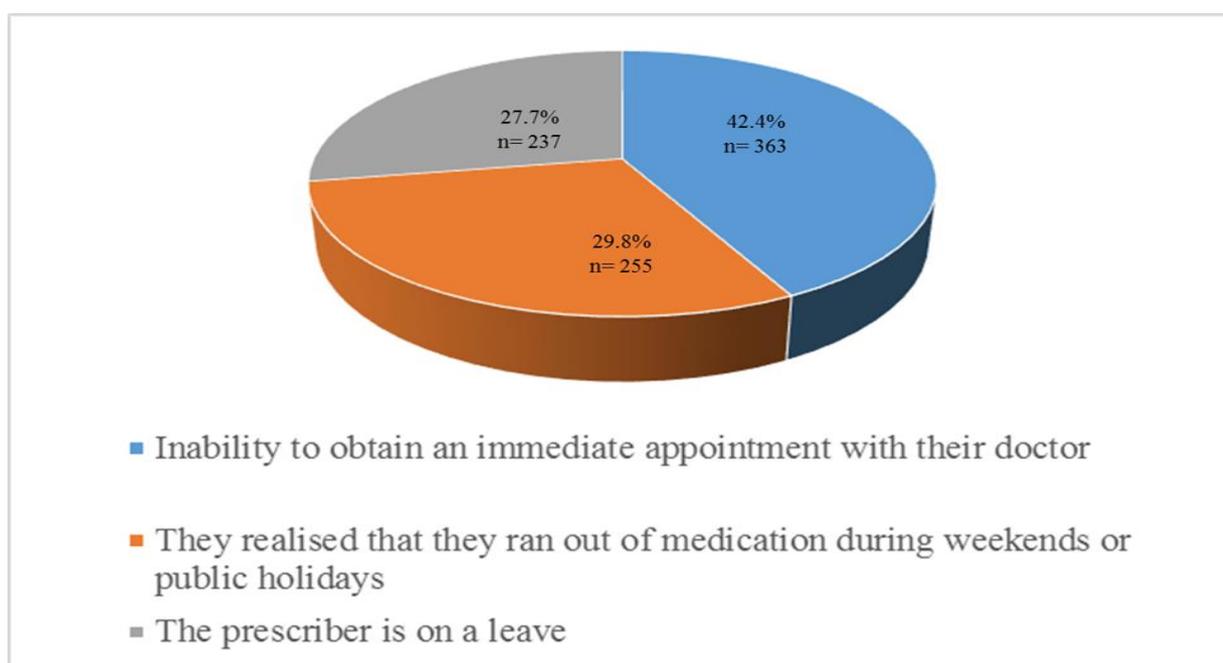
The qualitative data were transcribed verbatim and were analysed thematically using Nvivo (V10 for windows). Content analysis was also used to find out the frequency of each reason (theme). Content analysis was carried out by counting the number of participants who reported each theme. The star sign (*) and the number refer to the number of participants mentioning the theme.

4.4.3 Results

For more details about demographic information please see Section 4.3.3.2 In regard to this question, it was answered by all study participants (385). Some of them chose more than one reason, hence the total is more than 385.

4.4.3.1 Agreement with suggested reasons

Participants were asked to select all applicable reasons from the list of potential reasons (see above Methods). Eleven participants did not answer this question. The other participants (374) either selected one, two, or all the suggested reasons (this means the total number of responses is greater than the actual number of participants). The latter was selected by 203 participants. Figure 4.3 shows distribution of answers according to the suggested reasons. The numbers displayed are those who selected any reason, either a sole reason or with other reasons and including the option 'Other; please specify' (Please see Section 4.4.3.2 below for more details about the option 'Other').



Note: Some participants selected more than one reason, hence the total answers are more than participants who answered the question.

Figure 4.3 Distribution of answers according to the suggested reasons

4.4.3.2 Other reasons for requests of medication without a prescription

Key themes emerging from the 'Other reasons' option (See above) are summarised in Table 4.3 below.

There were eight themes identified from reasons provided by study participants either when they cited their customers (Type 1; see Section 4.4.2) or participants (the pharmacists) reported

what they think are the reasons for this issue (Type 2, see Section 4.4.2):

Theme 1: Travelling without medications (*n= 34)

This was the most frequently reported reason. This resulted from interstate visitors who forget to take their medication and/or prescriptions.

Theme 2: Unaware of last repeat or its requirements (*n= 25)

This theme is about some patients who were unaware of their “last repeat” and they had consumed all the repeats in the prescription during the last dispensing. In addition, some patients may not be able to understand the repeat system requirements. Old patients and those on multiple medications may find it hard to remember to make an appointment after the last supply and to manage their repeats properly.

Theme 3: Appointment difficulty (*n=20)

The participants’ comments provided further insight into this issue, as the majority of the participants had previously ticked options (b) and/or (c) (See above). For example, some patients experienced long waiting times before their appointment ranging from 10 days to one month. Moreover, other participants commented that some patients were unable to see any doctor (including their regular doctor) or they were reluctant to see another doctor at the time of the request, or were not physically able to go and visit a doctor.

Theme 4: Expired prescription (*n= 19)

Patients were unaware that prescriptions may expire (one year after issue date) even though the prescription still has repeats. Examples of expired prescriptions were Thyroxine and OC prescriptions.

Theme 5: Patient lack of responsibility/planning (*n= 17)

These opinions centred on patients’ lack of responsibility and good planning to arrange appointments in advance before they run out of medications. This indicates that while participants accept that there are legitimate reasons for medication request there are patients who try to avoid doctor’s appointments, or those who are pharmacy shoppers for medications with abuse potential.

Theme 6: Lost prescription/ medications (*n= 11)

For various reasons some consumers may lose their prescription or medication. For example, damaged or stolen prescriptions or medication. This theme may reflect that patients, particularly with chronic disease, are confounded with multiple challenges in maintaining adequate supply of their medications. In addition, it may indicate that patients see the pharmacy as the first point of help in such situations.

Theme 7: Time, work or financial constrains (*n= 9)

Patients working on full-time basis may have difficulty in arranging appointments during the normal working hours. Pharmacies have longer opening hours than surgeries. Patients' financial hardship to pay for a doctor visit was also cited.

Theme 8: Doctor related reasons (*n= 4)

This theme emerged from comments that described why some patients may run out of medication as a result of poor or miscommunication with the prescriber regarding what the medication is being used for and how long it needs to be taken. Communication issues between GPs and specialists were also mentioned.

Table 4.3 Themes emerging from reasons reported for urgent medication requests without a valid Prescription

Theme	Comments (examples)
Travelling without medications * n= 34	“Came on holiday with no meds [medications] or not enough meds [medications].”R1 “Interstate visitors without medication and forgot to bring medication.” R23
Unaware of last repeat or its requirements *n= 25	“Did not record the date of last supply which said [the] last repeat.” R69 “Inability to understand archaic repeat system.” R140 “Bring in the duplicate thinking it is a valid script.”R240
Appointment difficulty *n= 20	“Have an appointment within the next 2 weeks.”R186 “Dr is so busy- no available appointment, have a waiting period of about 10 days.” R224 “Our town has a 4-6 weeks wait to see regular GP.”R268
Expired prescription *n= 19	“Medications [repeats] do not run, but prescriptions do e.g. Thyroxine.” R279 “Prescription has expired- usually for OCPs [Oral Contraceptive Pills].” R89
Patient lack of responsibility/planning *n= 17	“Disorganised Lazy, lack of planning.”R81 “Carelessness.” R293
Lost prescription/ medications *n= 11	“Lost their script after taking last dose of a previous supply.” R87 “Broke or lost medication. Lost or report stolen medication.” R304
Time/ work/Financial constrains *n= 9	“Too busy to see [the] doctor. They have not had time to go to [the] doctor.” R282 “Cannot get away from work.” R124 “Financial hardship to visit [the] GP.” R37 “[They] do not want to pay \$ 5 charge Dr`s charge on scripts.” R64
Doctor related reasons *n= 4	“Dr insists unnecessary on not providing repeats.”R267 “[The] Specialist told GP to change meds [medications] but GP not aware of any change.”R227 “They are reluctant to see another doctor if they could not see their doctor.” R139

The * and the number indicate how many times the theme was repeated

4.4.4 Discussion

There were several reasons commonly given by customers when they requested medications without a valid prescription the most frequent being “Inability to obtain an immediate appointment with the doctor”. This is consistent with a previous survey about management of same day appointments in Australia.[30] According to that study, the high demand for immediate appointments affected GPs’ ability to adequately address the issue, in some cases providing a repeat prescription without a face to face consultation. However, more

commonly a prescription could not be obtained without a consultation. This then resulted in a need to “squeeze” the GP’s schedule, thus impacting of their service to other patients.[30]

Some patients may be unable to obtain an appointment not only immediately but also even within several days, particularly those in remote areas. This difficulty in making appointments was also reported by Services for Australian Rural and Remote Allied Health (SARRH).[42] SARRH cited this reason to justify its support for the CD, It is worth mentioning that when the AMA announced its opposition to the CD, the AMA claimed that surgeries have arrangements to address this issue.[43] However, it seems these arrangements are not enough to face the high demand for urgent appointments.[30] This demand may be increased by other factors that were reported by the study participants; lack of responsibility or proper planning by consumers, uncontrolled reasons such as lost prescription/ medication, travel, regular doctor on leave, lack of time, and other constraints such as work or financial hardship. It is worth stating that the reasons we report were obtained from a sample of pharmacists not from patients. Hence, we cannot exclude bias in reporting. However, most of the reasons have been cited in previous publications.[30, 42]

4.4.5 Conclusions

There are several reasons for urgent supply requests for medications without a valid prescription. These reasons are centred around the patient’s inability to obtain a new prescription for the regular medications. Health policymakers must consider implementing solutions that reflect the magnitude of this issue. Expanding the medications available through CD is one possible solution. This could be facilitated by providing pharmacists with access to patients’ health records and having better lines of communication with GPs.

4.5 Part C: Pharmacists attitudes towards CD

4.5.1 Introduction

Continued Dispensing (CD) was implemented in Australia in September 2013,[7] except in the state of Queensland.[21] It aimed to minimise treatment interruption when patients run out of their medications and are unable to obtain a new prescription to replenish their supply.

As a theoretical model “Medication Maintenance” (MM) was the hypothetical version of the current CD. It was initially proposed by Bessel et al. in 2005,[9] to avoid patients running out of medication in Residential Aged Care Facilities (RACF) when all repeats were consumed and there was no valid prescription before the GP’s next regular visit. The proposed solution was to allow pharmacists to “generate a PBS reimbursable form to authorise one month’s supply”. [9] All RACF patients were considered eligible and no particular medication classes were proposed to be eligible pending further consultations; however, there was a suggestion to exclude medication of abuse. There were also some proposed requirements such an ongoing need for the medication, the patient had to have been reviewed by a medical doctor, and the patient’s ‘condition was stable without significant side effects. In addition, the MM model was restricted to one supply. Bessel et al. recommended implementation of the MM model initially within RACF.[9] This model was criticised because it was only a “postponement rather than a solution” and because of concerns about inappropriate continuation of the supply.[44]

The CD model has some basic components of the MM model such as restriction to one supply and the need to inform the prescriber about the supply. However, the key difference is the implementation setting, i.e. community pharmacy rather than only RACFs. Thus the CD method encompasses more potential users, however the eligible medications were restricted to Statins and oral contraceptives (OCs). Under the CD model, medication supply can only be done once in any 12 months period. Patients must be at least six months on the same medication. In addition, CD guidelines also involve documentation of CD activity by the pharmacist.[45]

The CD method was implemented to complement other urgent medication supply methods that can be conducted without a valid prescription (i.e. Emergency Supply [ES]) or without an official paper prescription, only a verbal or faxed prescription (i.e. Owing Prescription [OP]). [46] The Owing Prescription (OP) system which is a legal way to supply one additional repeat without a hard copy of the prescription, however the pharmacist must contact the original prescriber to obtain a verbal or faxed prescription. The Emergency Supply (ES) supply does

not require a valid prescription, written or verbal. However, only limited amount of the medication can be supplied.

The OP method requires a verbal authorisation by the prescriber and a follow up prescription and because of this it may be refused to be utilised by pharmacists. On the other hand, patients may refuse the ES method as a result of cost involved.[32] In addition, non-regular customers may not be supplied due to their inability to provide enough information to allow safe dispensing.[7] These factors may cause treatment interruption and increase the risk of patient's non-adherence to their medications. Moreover, the requirement that the prescriber should send a follow-up prescription, to allow pharmacists to apply for reimbursement from the PBS system, has the potential to increase the work load on prescribers without any income.[7]

The CD model of medication supply was designed to address these drawbacks and increase patient adherence.[47] Also, providing patients with a timely and convenient way to obtain their medications when obtaining an appointment with the prescriber was impractical.[7] Even though some surgeries have their arrangements for urgent appointments, this system may not be adequately effective.[30] While the AMA has announced its opposition,[43] the Consumers Health Forum of Australia (CHF), [48] other organisations,[42, 49, 50] members of the community,[51] and users of Statins and OCs,[7, 10] have already shown their support for CD. In addition, CD supporters recommend more chronic disease medications be included and more frequent utilisation opportunities to cover patients' needs.[10, 42, 52]

4.5.2 Aims

Community pharmacists' attitudes towards the current CD, its expansion (to include more eligible medication) and extension (to be used more frequently) have not been researched thus far. Therefore, the aim of this study was to explore these attitudes.

4.5.3 Methods

More details on the methodology employed are reported above in Section 4.3.2. In brief, a self-administered questionnaire (Appendix 4.2) was sent to 1490 randomly selected pharmacies within Australia. A 20% sample was chosen as it allows a representative sample to be drawn from a large number of potential respondents. 1490 questionnaires were distributed with an anticipated response rate of approximately 40% (it was anticipated to lead to approximately 600 responses, with 95% confidence level with +/-2.5 confidence interval. The questions directly related to this part of the study were about pharmacists' support for the

currently eligible CD medications (Statins and OCs), and for the possible inclusion of more medications under the CD system. Participants were asked to indicate from list of 17 medication classes (developed from a literature review) which they believed could be included. This list was similar to the list of medications used in our previous survey of Statin and OCs users.[10] Further, there were additional questions that focussed on participants' support of CD extension (i.e. to be utilised more frequently). Finally, participants were asked about their level of agreement with statements about: (a) CD increasing patient adherence to medications, (b) CD decreasing waste production, (c) the prescriber annotating the prescription to allow or disallow CD, and (d) their support for pharmacists' access to patients' electronic health records. This study was conducted less than one month before CD implementation in Australia, and a reminder was sent one month later. Therefore, although pharmacists were aware of CD, it is unlikely that their responses were affected by any experience with the CD. This should minimise potential bias arising from actual experience with CD.

4.5.3.1 Ethics approval

This study was approved by The Human Research Ethics Committee of Curtin University (Approval number: PH-07-13). (See Section 4.3.2.2 and Appendix 4.3)

4.5.3.2 Data Analysis

The data analysis process in part has already described in Section 4.3.2.3. A 5 point Likert scale was used to assess participants' agreement levels. For the purpose of statistical analysis responses were collapsed to: Agreed (strongly agree and agree), Disagreed (strongly disagree, disagree), Neutral/ Preferred not to disclose, and missing answers. The option 'Other; please specify' was also used to provide additional qualitative data. The analysis of quantitative data was conducted by using SPSS (version 22). The participants were divided into groups of two. Firstly, according to the age they were (≤ 40 years old, and >40 years old,). Secondly, according to gender (male participants and female participants). Finally, according to pharmacy location, into participants working in urban areas and participants working in rural areas. The Mann-Whitney test was used to find any difference between these groups. Wilcoxon test was used to find the difference between participants' decisions according to customer type for the same medication class (e.g. compare responses about asthma medications for regular customers vs. non-regular customers). Chi-square and nominal logistic regression tests were used to identify any significant relationships between independent variables (gender, age, pharmacy location) and dependent variables (e.g. response to the question about inclusion of

oral hypoglycaemic medications).

The qualitative data were obtained through participants' answers to open-ended questions and their comments on the option 'Other; please specify'. This type of data was thematically analysed. Answers and comments were analysed to identify themes and subthemes, using Nvivo (V10 for Windows®). The study team agreed on the concluded themes and subthemes. The content analysis was done by counting how many times a theme or subtheme was repeated. A star sign and a number (e.g. *n=10) was used to indicate the number of repetitions of the theme (or the subtheme). If a comment was made by only one participant, then the term 'additional note' was used to describe such comments.

4.5.4 Results

4.5.4.1 Demographic data

See section 4.3.3.2 for more details. Briefly, there were 385 participants (54.5% were males). The response rate 37.9% and 48.8% of participants were ≥ 40 years old. The majority of the participants were working in urban areas with only 26% working in rural areas. None of the participants was from the NT (Northern Territory).

4.5.4.2 Participants' support for the current CD

Study participants highly supported dispensing of Statins and OC using the CD method for regular customers. Statins were supported by 89.1% (343) and OC by 87.8% (338) of the participants. The support for supply of these medications through the CD method was far less (p values were < 0.0001) in the case of non-regular customers. Only 51.4% (198) of the participants supported Statins, and 52.7% (203) supported OC.

4.5.4.3 Additional comments about CD

Participants provided further comments about CD. These commentaries reflected their attitudes towards the current CD and what modifications they thought should be made to the current CD. These comments can be divided into negative, conditional (modification required), or positive views. These comments were reported in different parts of the participants' response mainly to Question 19 of the questionnaire about what solutions they could suggest for the issue of patients requesting medications without a valid prescription. Below is a thematic analysis from the verbatim transcription of their responses (any comment provided by only one participant is presented as an additional note).

Theme 1: Negative views: Identified disadvantages of the CD (*n=8)

Negative views were expressed by participants who were concerned about the disadvantages of CD. The following disadvantages were identified by study participants.

Subtheme 1.1: CD is a bad idea (*n=5)

Some participants were concerned about: a) how patients would receive the CD especially participants who do not understand why they need a prescription for non-eligible medications or why they cannot obtain another supply within a 12 months period, b) CD makes patients reliant on pharmacists and therefore they do not take responsibility to arrange appointments to obtain prescriptions and c) concerns about GPs' acceptance of CD. This is illustrated by the comments below:

“Continued supply is a very bad idea, customer will not understand its limitation and further make life hell for pharmacist.” R231

“A pharmacist is not in the position to decide if therapy with any agent should continue. We have no access to any medical results (e.g. blood tests).” R386

“It is [the CD] further making the patient not take responsibility for their own health.” R180

“The GPs I work with will not agree with continued dispensing.” R286

“I do not agree with continued dispensing.” R170

Subtheme 1.2: Abuse potential (*n=3)

Participants were also concerned about CD abuse by patients who may avoid visiting their doctor or obtain medication of abuse potential. Concerns were also raised about CD abuse by some pharmacy owners or particular pharmacy groups, as illustrated by the comments below:

“Patients' abuse of CD.” R13

“Continued dispensing will be a program that will be exploited by pharmacy owners.” R286

“I have serious concerns about certain pharmacy groups trying to abuse this system.” R323

Theme 2: Conditional views: Modifications required (*n= 6)

Some participants suggested that the current CD needs modification.

Subtheme 2.1: CD expansion (*n=2)

Participants thought the current CD does not provide enough solutions for patients prescribed multiple medications. Thus, they suggested addition of more medications. This is illustrated by the comments below:

“CD should not be restricted to Statin & OC. We should be able to supply a wider range of medication to actually improve the compliance of the patient e.g. Antihypertensive, Antidepressants etc.” R294

“Increase the scope of medicines that can be issued under CD, not just 2 currently.” R270

Subtheme 2.3: Pharmacists remuneration (*n= 3)

Some participants complained that they usually do not obtain payment that reflects the amount of work they do. See comments below:

“Pharmacists already do more than we are remunerated for.” R286

“They need to pay a fee – so we can continue providing their service as I have no doubt that they will take more of the pharmacist time i.e Talking to the patient , reviewing their history, making sure of the correct dosing + strength. If you are going to push for their CD` service, then you must push for reimbursement to the pharmacist/ pharmacy for providing it from the beginning. We are sick of doing this For Free. Our service becomes de-valued by consumer!!” R206

“Consider the time and effort needed by the pharmacist when facing this situation.” R54

Additionally, one participant thought the currently eligible medications (Statins) might not require an urgent supply, and they suggested that more urgently needed drugs should be available.

“Depending on the medication and whether regular, daily therapy is essential for safety, e.g. cardiovascular therapy as opposed to say a Statin whereby missed doses/ time is not so critical.” R216

Theme 3: Positive views: Identified CD advantages (*n= 6)

On the other hand, there were positive attitudes towards CD as shown below.

Subtheme 3.1: Less administrative burden (*n= 5)

Some participants thought the CD has the advantage of “no prescription need”, hence posed less of an administrative burden. This would enable patients to be more adherent, and encourage pharmacist supply. This is illustrated from the comments below:

“I worry about customers having OP scripts [Owing Prescriptions] for say Seretide®, never dispensed wanting an owing. But generally a great idea less waste + less chasing up owing scripts!! & better patient outcomes due to continued supply. I work with some pharmacists that would not even give an emergency supply for an antidepressant if they have not been to us before & that causes worse patient outcomes.” R240

R145“Continued dispensing is the way to go! [for emergency supply of medication without a valid prescription].” R258

In addition one participant suggested CD provided an opportunity for medication review as CD involves consultation with patients, and hence a good opportunity to identify any medication-related issues, such as side effects or drug interactions.

“Good opportunity to assess treatment and it is progress.” R301

4.5.4.4 Participants’ support of CD expansion

Participants were asked to show their support to include more medications into the CD method (i.e. CD expansion). They were presented with a list of 17 medication classes plus those already eligible under the current CD method (i.e. Statins and OCs). Their responses are summarised in Table 4.4.

The first finding of this study was that the already eligible medications for CD were supported by ~ 87-89% of participants for regular customers and by ~ 51-52% for non-regular customers. However, these medications were not the most supported medications to be available through CD by participants. The most supported medications were antihypertensives for regular customers (90% agreed) and asthma medication for non-regular customers (53% agreed). Customer type significantly influenced participants’ support for inclusion in the CD method.

For any medication class, participants showed more support for dispensing it under CD

provisions for regular rather than non-regular customers ($p < 0.0001$, using Wilcoxon test).

Participants' support to include particular medications within CD provisions differed according to customer type. All medications, but four, were supported by the majority (i.e. more than 50%) of participants in the case of regular customers. This was in contrast to non-regular customers for whom there were only four medications supported by the majority of participants including the two already available under the current CD (i.e. Statins and OCs). The support was stronger (61-90%) in the case of regular than non-regular customers (51-53%). The support to include opioids, in particular, and medications such as anti-anxiety, non-opioid analgesics and medications to treat schizophrenia was very low for both customer type.

The participants were more likely to choose "Neutral" than "Disagreed" in the case of the regular customers. However, in the case of non-regular customers they tended to select "Disagreed" more than "Neutral".

Table 4.4 Participants' agreement and disagreement to include the selected medications under the CD provisions

Medication/ disease	Regular customer			Non-regular customer		
	Agree (%)	Neutral (%)	Disagree (%)	Agree (%)	Neutral (%)	Disagree (%)
Antihypertensives	347 (90.1)	13 (3.4)	18 (4.7)	191 (49.6)	67 (17.4)	95 (24.7)
Asthma	343 (89.1)	18 (4.7)	18 (4.7)	204 (53.0)	63 (16.4)	86 (22.3)
Statins	343 (89.1)	15 (3.9)	21 (5.5)	198 (51.4)	65 (16.9)	90 (23.3)
COPD	339 (87.8)	23 (6.0)	16 (4.0)	197 (52.7)	69 (17.9)	87 (22.6)
OC	338 (88.1)	20 (5.2)	18 (4.7)	203 (51.2)	64 (16.6)	86 (22.3)
Non-Statins	323 (83.4)	27 (7.0)	26 (6.0)	189 (47.0)	72 (18.7)	92 (23.9)
Hypoglycaemic	321 (83.1)	22 (5.7)	30 (7.8)	181 (49.1)	67 (17.4)	104 (27.0)
GORD	314 (81.6)	30 (7.8)	32 (8.3)	184 (47.8)	64 (16.6)	105 (27.3)
Glaucoma	294 (76.4)	38 (9.9)	40 (10.4)	178 (46.2)	71 (18.4)	103 (26.8)
Hypothyroidism	284 (73.8)	53 (13.8)	39 (10.1)	149 (38.7)	92 (23.9)	111 (28.8)
Arthritis	284 (73.8)	60 (15.6)	32 (8.3)	158 (41.0)	85 (22.1)	110 (28.6)
Hyperthyroidism	263 (68.3)	64 (16.6)	48 (12.5)	140 (36.4)	89 (23.1)	123 (32.0)
Anticoagulants	256 (66.5)	53 (13.8)	61 (15.8)	143 (37.1)	62 (16.1)	144 (37.4)
Psoriasis	241 (62.6)	76 (19.7)	61 (15.8)	139 (36.1)	81 (21.0)	133 (34.5)
Antidepressants	235 (61)	58 (15.1)	82 (21.3)	124 (32.2)	72 (18.7)	156 (40.5)
Schizophrenia	175 (45.5)	71 (18.4)	127 (33.0)	94 (24.4)	80 (20.1)	178 (46.2)
Non opioids	153 (39.7)	66 (17.1)	155 (40.2)	74 (19.2)	74 (19.2)	204 (53.9)
Anxiety med	105 (27.3)	86 (22.3)	183 (47.5)	47 (12.2)	68 (17.7)	236 (61.3)
Opioids	37 (9.1)	41 (10.6)	298 (77.4)	15 (3.9)	37 (9.6)	300 (77.9)

4.5.4.5 Effect of demographics

Gender, age and pharmacy location significantly affected participants' support to include the listed medication (Table 4.5 displays more details). Significant differences were detected for the gender variable in 12 cases out of 38 (31.6%), in four cases (10.5%) for the age variable, and in one case (2.6%) for the location variable. Males and /or older participants were more likely to show stronger support than females and/or younger participants. Except for antidepressants for non-regular customers, in which case stronger support was indicated by the younger participants.

The only effect of pharmacy location (i.e. Metropolitan vs. Rural) was for the inclusion of opioids for regular customers which was supported more by participants working in rural areas ($p < 0.05$).

Table 4.5 Statistically significant effects of demographic variables on participants' support of the CD

Customer	Drug class/ disease	Groups*	Did not agree n (%)	Agreed n (%)	P value
Regular	Oral hypoglycaemic	Male* (n=210)	22 (10.5)	188 (89.5)	0.0001
		Female (n=155)	40 (25.8)	115 (74.2)	
	Non-opioids	Male*	111 (52.9)	99 (47.1)	0.0001
		Female	112 (72.3)	43 (27.7)	
	COPD	Male*	19 (09.0)	191 (91.0)	0.042
		Female	25 (16.1)	130 (83.9)	
	Arthritis	Male*	45 (21.4)	165 (78.6)	Male
		Female	53 (34.2)	102 (65.8)	
	Glaucoma	Male*	41 (19.5)	169 (80.5)	0.018
		Female	47 (30.3)	108 (69.7)	
Non-Statins	Male*	25 (11.9)	185 (88.1)	0.007	
	Female	35 (22.6)	120 (77.4)		
Non-regular	Oral hypoglycaemic	Male*	99 (47.4)	111 (52.9)	0.011
		Female	94 (60.6)	61 (39.4)	
	Antihypertensives	Male*	91 (43.3)	119 (56.7)	0.004
		Female	91 (58.7)	64 (41.3)	
	COPD**	Male*	92 (43.8)	118 (56.2)	0.038
		Female	85 (54.8)	70 (45.2)	
	Glaucoma	Male*	102 (48.6)	108 (51.4)	0.031
		Female	93 (60.0)	62 (40.0)	
	Statins	Male*	91 (43.3)	119 (56.7)	0.030
		Female	85 (54.8)	70 (45.2)	
Non-Statins	Male*	95 (45.2)	115 (54.8)	0.022	
	Female	89 (57.4)	66 (42.6)		
Regular	Anxiety	≤ 40 (188)	148 (78.7)	40 (21.3)	0.012
		> 40* (192)	129 (67.2)	63 (32.8)	
	Hypothyroidism	≤ 40	60 (31.9)	128 (68.1)	0.015
		> 40*	40 (20.8)	152 (79.2)	
Hyperthyroidism	≤ 40	69 (36.7)	119 (63.3)	0.045	
	>40*	52 (27.1)	140 (72.9)		
Non-regular	Antidepressants	≤ 40*	117 (62.2)	71 (37.8)	0.027
		> 40	140 (72.9)	52 (27.1)	
Regular	Opioids	Metropolitan (n=279)	257 (92.1)	22 (7.9)	0.043
		Rural* (n=100)	85 (85.0)	15 (15.0)	

* More supportive group, #Did not agree: disagreed, Neutral and missing answers; **COPD; Chronic Obstructive Pulmonary disease

4.5.4.6 CD extension

Participants were asked (Q15) to report their views on the current frequency of CD utilisation (i.e. once in any 12 months period) and their support to increase the frequency of utilisation (i.e. an extended version of CD).

Just over half of the participants (51.4%; n=198) agreed with the current utilisation frequency of CD. The remainder did not agree with the current restriction and suggested more frequent CD. This included 116 (30.1%) who supported twice in any 12 months CD, 53 (13.8%) who supported utilising the CD three times in any 12 months, and 17 (4.4%) who supported CD availability until it is possible for the patient to obtain a renewed prescription. One participant (0.3%) did not answer the question.

4.5.4.7 Participants' comments about CD extension

Participants were asked to give reason(s) for their answers to the Q15. A thematic analysis of these comments was then undertaken and the results of which are provided below.

Analysis of the comments, provided to explain why the participants selected a particular frequency of CD, revealed that there were three main themes that emerged from these comments: 1) Why the frequency must not be increased, 2) Why a particular frequency is needed, and 3) The CD frequency should be left at the pharmacist discretion (See Table 4.6).

Theme 1: Why the frequency must not be increased (Safety must always be priority)

This theme has been repeated 216 times, which is far more than the other two themes. This theme emerged from participants who were trying to explain that the CD frequency, which they had selected, must not be increased otherwise there would be negative consequences. For example, decrease in medical reviews by doctors and/or abuse of the system. Therefore, the theme was generally related to justifying maintaining the status quo (i.e. one CD/ 12 months). More details are given below.

a. The need for medical review

The need for the medical review was the most cited reason to limit the frequency of CD utilisation, because any increase potentially decreases the chance for a review by the doctor. This reason was cited a total of 101 times. By 78 (77%) participants to defend why CD must be no more than once in any 12 months period and by 18 (18%) to justify why CD should be

limited to twice in 12 months. The following examples illustrate the participants' reasons for the need for medical reviews:

“Patient’s condition may change and needs to be checked/assessed by a medical practitioner.”
R111

Patient need to have follow up/ check-up regularly to ensure that their condition is under-control.” R84

“Community pharmacy setting does not allow for proper monitoring on long-term basis. Changes may not be picked up and differences in therapy cannot be detected.” R147

b. Patient must take more responsibility

This subtheme was repeated 41 times, to justify why frequency of CD utilisation must not exceed once (29; 71%) or twice (7; 17%), in any 12 month period. Participants thought some patients did not make enough effort to arrange for appointments before they ran out of medications. Therefore, they were concerned that more frequent CD may encourage patients' dependence on pharmacists. This subtheme is illustrated by the following examples:

“Patients must take responsibility for their own medication management. More frequently CD encourages laziness/ apathy / irresponsibility.” R180

“Increased frequency will reduce customers' incentive to take responsibility for their own health.” R195

c. Potential abuse of CD by patients

This subtheme was repeated 38 times. It was mainly used to justify why CD must not be more than once in any 12 months in the majority of cases (84%). Participants who cited this reason to limit CD were concerned that any increase in CD frequency will increase the probability of patient abuse of the system to obtain medications without visiting their doctors. This can be illustrated by the following examples:

“To avoid the customer choosing not to see their primary healthcare provider.” R279

“Some patients may take advantage of this to avoid seeing the doctor. Also, chronic conditions still need to be monitored by doctors regularly.” R89

d. The selected frequency provides enough time

This was assigned as a low relevance subtheme. It was repeated 24 times and was only used to defend why CD must not be no more than once (83%) or twice (17%) in any 12 months period. As illustrated by the following example:

“Once is enough, people need to make arrangement & also see their doctor at least annually.”
R287

e. CD must be emergency only

This theme was assigned very low relevance as it was repeated only 12 times. It was mentioned only to justify why the CD must be limited to once in any 12 month period. The following is an example of such comments:

“Since it is an emergency supply and should be enough.” R148

Theme 2: Why a particular frequency is needed (Improve access to medications)

This theme emerged from those who were defending the number they selected (regardless of the number). For example, some of participants who selected once in any 12 months and others who selected twice stated that the nominated frequency provides enough time to obtain an appointment with the doctor. This theme was more commonly used to defend an increase to twice in any 12 months. This theme has three subthemes:

a. Appointment difficulty/Doctors availability

This subtheme was repeated in comments 51 times, and it was used to explain why the participant chose a specific frequency of CD. For example, this theme was used 28 times (55%) to defend that CD must be twice in any 12 months period. Participants stressed the difficulty and delays in obtaining an appointment because of high demand which resulted from doctors' shortages. As illustrated by the following examples:

“Shortage of GP's, many times – Dr only writes Rx- no consultation – increase load to [the] Medicare for no extra service – will free our Drs time.” R37

“It is very hard to get appointment with Drs these days, px [patients] cannot get in at their right times and need their meds [medications] urgently.” R86

b. Allow continuity of treatment and regular medical review

This subtheme was repeated 48 times mainly to justify the use of CD once in any 12 months by 44% of the participants and twice by 35%. Here participants thought that these CD frequencies were reasonable, because while easing access to medications they still ensure medical review by doctors at least once annually. As illustrated by these comments:

“To provide continuity of medication, but still need to see Doctor every 6 months.” R346

“Patient who has co-morbidities should regularly checked to prevent progression of disease. Occasional supply without script under certain circumstances provided patient is stable should be acceptable.” R303

c. Prescription life span

Forty-eight participants reported the above reason to justify their selection of the CD frequency. Since the majority of participants (82%) mentioned a six months life span for chronic disease prescriptions, this subtheme was mainly used to explain why the frequency of CD utilisation should be increased to twice in any 12 months. An example of these comments is:

“Each Rx [prescription] is only for 6 months, so 1 extra supply per Rx [prescription] is considered acceptable.” R23

Theme 3: CD frequency should be left to the pharmacist’s discretion (Pharmacist skills)

This theme has emerged from participants who, although they selected a frequency of CD, they thought the CD frequency should be decided by the pharmacist who faced the request for urgent supply. Here the pharmacist would consider all influencing factors such as the medication type and the probability to obtain an urgent appointment. This theme was generally used to justify a greater frequency of CD. There were two subthemes emerged from this theme:

a. Pharmacists are able to manage

This subtheme emerged from 16 comments used to justify more frequent CD, particularly three times in any 12 months (in 8 cases; 50%). As illustrated by this example: “A pharmacist can easily use their professional discretion to determine where there is a genuine need for continuing supply. Continued dispensing already occurs via the “owing “mechanism and has

done for many years – CD will formalise and legalise this practice.” R208.

b. According to the situation

This subtheme was also mentioned 16 times. Interestingly, this subtheme was used by approximately 25% of participants to justify each selected frequency (See Table 4.6). This example illustrates this subtheme: “It is dependent on circumstances & no hard & soft rule should apply. Professional judgment should be applied.” R51

Table 4.6 Reasons for participants’ selection of a particular CD frequency number

Main theme (N)	Sub-subthemes (n)	CD frequency (/12 months)	n (%)
Theme 1 (216) Why the frequency must not be increased	The need for medical review (101)	0 (no CD)	1 (0.9)
		1	78 (77.0)
		2	18 (18.0)
		3	4 (4.0)
		Anytime [#]	1 (1.0)
	Patient must take more responsibility (41)	1	29 (71.0)
		2	7 (17.0)
		3	3 (7.0)
		Anytime	1 (2.0)
	Potential abuse of CD by patients (38)	1	32 (84.0)
		2	4 (11.0)
		3	2 (5.0)
	The selected frequency provides enough time (24)	1	20 (83.0)
CD must be emergency only (12)	1	12 (100.0)	
Theme 2 (145) Why a particular frequency is needed	Appointment difficulty/Doctors availability (51)	1	8 (16.0)
		2	28 (55.0)
		3	13 (25.0)
		Anytime	2 (0.04)
	Allow continuity of treatment and regular medical review (48)	1	21 (44.0)
		2	17(35.0)
		3	8 (17.0)
		Anytime	1(0.2)
	Prescription life span (46)	1	3 (7.0)
		2	38 (82.0)
3		3 (7.0)	
Anytime		2 (4.0)	
Theme 3 (32) CD frequency should be left to the pharmacist’s discretion	Pharmacists are able to manage (16)	1	2 (12.0)
		2	4 (25.0)
		3	8 (50.0)
		Anytime	2 (12.0)
	According to situation (16)	1	4 (25.0)
		2	4 (25.0)
		3	3 (19.0)
		Anytime	4 (25.0)
		Other	1 (6.0)

[#]: anytime until it is possible for the patient to obtain a renewed prescription, N: number of repetition,

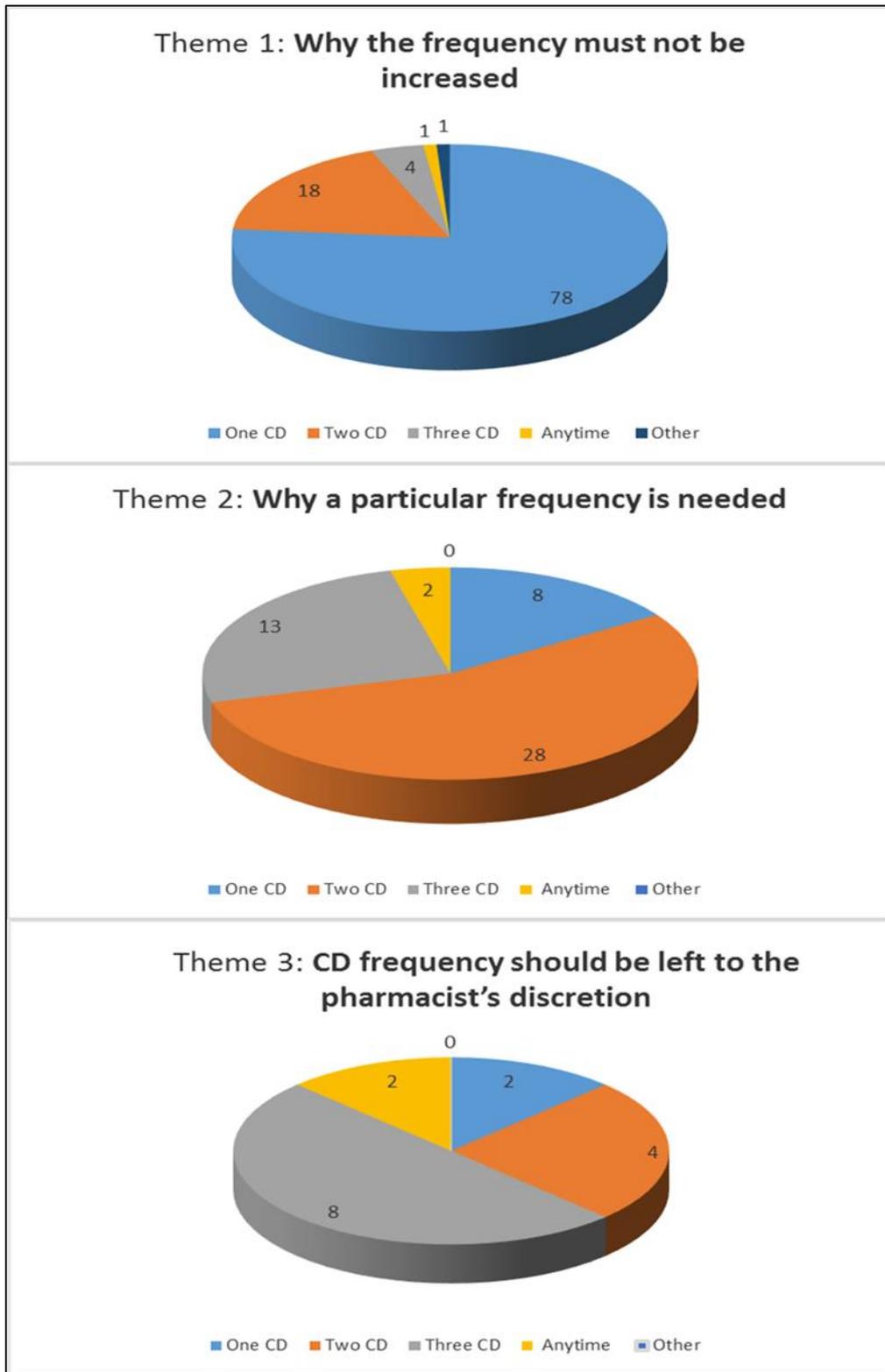


Figure 4.4 Comparison of the main themes according to CD frequency

Figure 4.4 displays where each theme was cited most. Theme 1 was mainly used to justify one CD, Theme 2, was mostly used to justify two CD, Theme 3 was mostly used to justify three CD. It can be concluded that participants who were concerned about negative consequences of more frequent CD were more likely to cite Theme 1 (Safety always must be priority) which included five subthemes: The need for medical review, Patients must take more responsibility, Potential abuse of CD by patients, The selected number provides enough time and, CD must be for emergency only. Participants who were more concerned about urgent access to medication in urgent situations were more likely to cite Theme 2 (Improve access to medications), which included: Appointment difficulty/Doctors availability, Allow continuity of treatment and regular medical review, and Prescription life span. Participants who wanted more flexible CD cited Theme 3 (Pharmacist skills), which included Pharmacist able to manage, and According to the situation.

4.5.4.8 CD advantages, annotation and health record

Participants indicated their level of agreement/disagreement with the statements presented in Questions 17(17.1-17.4) and 18. The first three statements were about potential advantages of CD (i.e. CD advantages question). The fourth statement was about a suggestion to allow doctors to annotate the prescription to make it clear that the medication is not to be continued without review by the treating medical practitioner (i.e. doctor' annotation question). Question 18 was about pharmacists being able to supply according to the Patient Controlled Electronic Health Record without the need for a hardcopy prescription (i.e. Health Record question). Table 4.7 displays responses to these questions.

Table 4.7 Participants' agreement with CD advantages, annotation and health record

Question	Statement	Agreed n (%)	Neutral n (%)	Disagreed n (%)
Q17.1	CD is likely to increase patients' medication adherence	311 (80.8)	31 (8.1)	41 (10.6)
Q17.2	CD is likely to lessen the administrative burden of having to chase OP [#]	322 (83.6)	23 (6.0)	38 (9.9)
Q17.3	CD will decrease the wastage that occurs when an original pack of medication has to be broken to adhere to the Emergency Supply provisions under the current State/Territory legislation.	327 (84.9)	30 (7.8)	27 (7.0)
Q17.4	The prescriber should be able to annotate the prescription to make it clear that the medication is not to be continued without review by the treating medical practitioner.	327 (84.9)	21 (5.5)	36 (9.4)
Q18	Pharmacists being able to supply according to Patient Controlled Electronic Health Record without the need for a hardcopy prescription	264 (68.6)	64 (16.6)	56 (14.5)

'OP': OWING PRESCRIPTION

In general, the majority (80.8-84.9%) of participants agreed with all the proposed advantages of CD, and 84.9% agreed with suggestion to allow doctors to annotate patients not suitable for CD. However, only 68.6% of participants agreed with the Health Record question (i.e. pharmacists should be able to supply according to Patient Controlled Electronic Health Record without the need for a hardcopy prescription). Multinomial regression analysis revealed that male participants agreed more that 'CD may increase patient adherence' ($p = 0.002$), and younger ($p= 0.026$) and male participants (0.024) agreed more that 'CD may alleviate the administrative burden of the OP compared to older and/or female participants.

4.5.4.9 Comments about Doctor Prescription Annotation

While the majority agreed with doctor annotation, there were some participants who voluntary reported additional comments about the Q17.4. See below:

Additional note 1: Overuse of annotation: some doctors may use this authority to prevent CD:

"Note @ question 17.4 above- some medications would only be appropriate for supply after review by doctor, if patient is unstable, however some doctors will ' tick the box' block supply all the time to prop up their visits therefore income." R246

Additional note 2: Annotation may be impractical

Pharmacists may not be able to know doctor's decision (doctor annotation) if the customer did not present the previous paper prescription. The comment below by one of the participants illustrates this issue:

“Agree [with doctor annotation] but how do we know if we do not see the script at the time of continued supply.” R211

4.5.4.10 Suggested solutions to address urgent medication requests

The study participants were asked to suggest solutions for urgent medication requests without a valid prescription. Thematic analysis of these comments produced 6 themes and 18 subthemes (Figure 4.5). The star sign and the number, for example, *n=46, indicates that there were 46 participants who suggested the theme “better use of technology”, and *n=9 indicates that there were nine participants who suggested the subtheme “Pharmacist prescribing”.

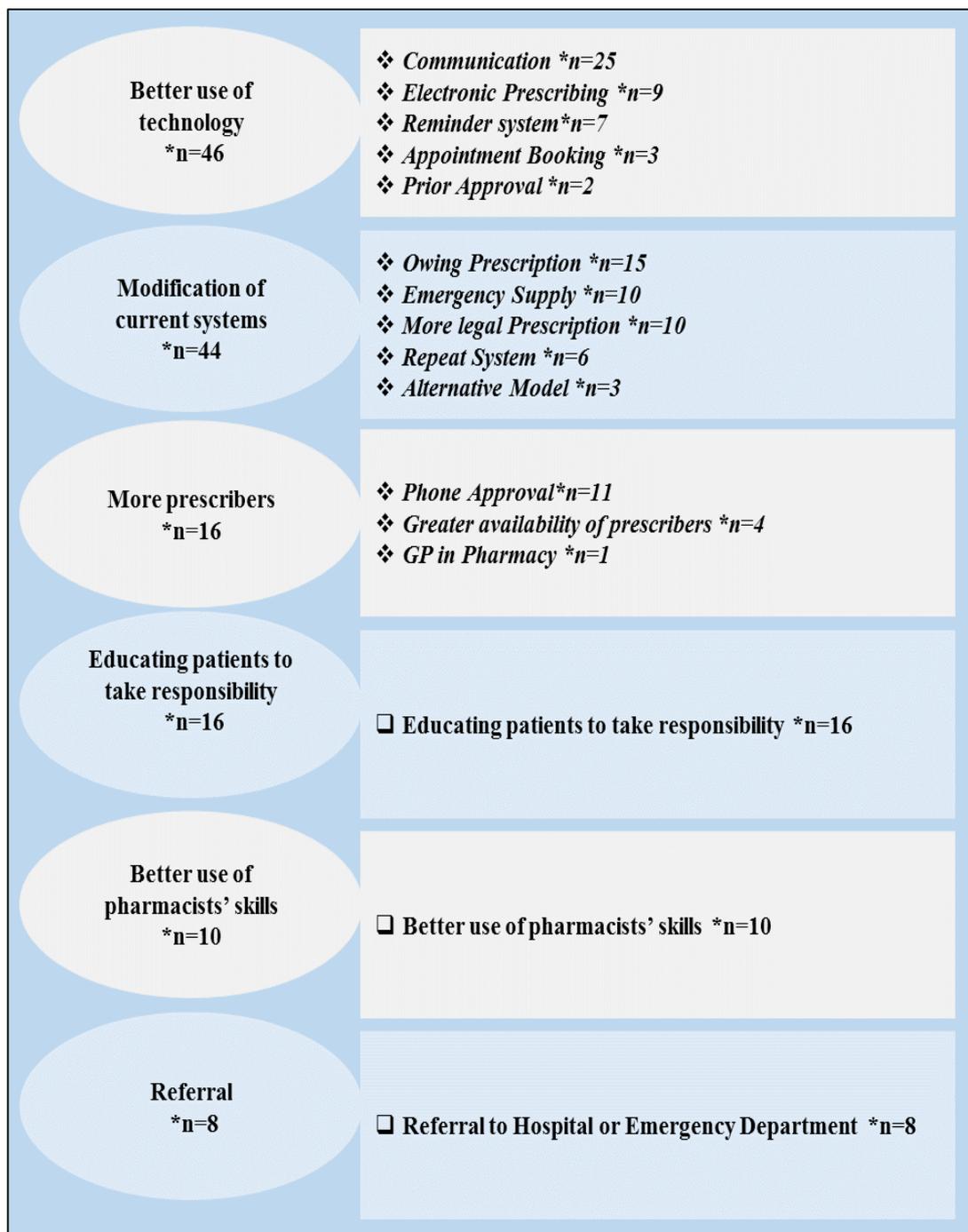


Figure 4.5 Themes and subthemes of suggested solutions for medication request without a valid prescription

Theme 1: Better use of technology (*n=46)

Five subthemes emerged from this theme. The participants thought that technology could provide the following benefits:

Subtheme 1.1: Communication with the prescribers and access to health record (*n=25)

Participants suggested more communication with the prescribers and access to health record. The following examples illustrate this:

“Better Electronic communication between doctor & pharmacist.” R28

“Being able to access health record of non-regular customers.” R222

Subtheme 1.2: Electronic prescription system (*n=9)

Electronic prescription system was also suggested. The following examples illustrate this:

“Access to ERx [Electronic Prescription] data?” R11

“Rx [prescription] request and response system.” R75

“Better interaction in our dispensing software & DR [doctor] s` software to request new Rxs [Prescriptions].” R28

Subtheme 1.3: Reminder system (*n=7)

A reminder system was also suggested:

“SMS reminder service – notifies if last repeat.” R66

Subtheme 1.4: Appointment booking (*n=3)

Appointment booking was also suggested:

“Medical practice could forward book appointment & use SMS messaging to request patients to refuse or book appointment.” R224

Subtheme 1.5: Prior approval (*n=2)

Prior approval was also suggested:

“Prior Dr approval for continued supply via electronic record & approval” R37

Theme 2: Modification of the current system (*n=44)

Participants suggested modifying the current medication supply systems, and five subthemes emerged in this regard:

Subtheme 2.1: Owing Prescription (OP) modification (*n=15)

Participants mentioned the following modifications to the OP system:

A. To avoid issues of obtaining a prescription

“Pharmacist should be able write a once off Rx after confirmation with Dr [doctor] that will minimise the paperwork and also gives time (28-30 days) for Pt [Patient] to seek regular GP for check-up/ Rxs [prescriptions].” R158

“Penalties on doctors not supplying Rx`s [prescriptions] after faxed requests from pharmacists after writing up treatment charts for nursing home patients. Pharmacists left holding the bag legally.” R328

B. Stop patients abuse of OP

“The inclusion of PBS legislated owing script fee paid by the patient may encourage patients to be more aware of how many repeats they have left.” R65

“Owing Rx`s should be outlawed; if you run out of medication then you must see your Dr [doctor] or pay a private price for one month continuation of supply. This would save on all the administrative work as well as forcing the patient to see the Dr [doctor].” R163

Subtheme 2.2: Emergency supply (ES) modifications (*n=10)

Most suggestions were about increasing the quantity available through ES. The comments below illustrate this:

“Emergency supply should allow for one original pack to be supplied rather than just 3 days.”
R162

“The sample size packs (normally 1 week) that drug companies give to GP (doctors) to start the patients on – should be made available, even if is at cost, to pharmacies to on sell to patients if they need them.” R7

“The legal supply is for 3 days only as emergency supply. 3 days’ supply is not sufficient when most patients cannot get an apt [appointment] within 3 days. 3 days should be extended to one week.” R212

“I think 3 days ES is not enough time for a lot of people – 7 days would be better and could keep the same arrangements intact as present for everything else.” R227

Subtheme 2.3: More legal prescriptions (*n=10)

Allowing faxed and emailed prescription was also suggested to address issues of delays in obtaining a new prescription from the doctor. The following examples illustrate this:

“Law can allow faxed prescriptions to be valid as long as the original is posted to the pharmacy.” R207

“Email your GP who emails script to pharmacy.” R8

Subtheme 2.4: Repeat system modifications (*n=6)

The repeat system was also another area of suggested modifications:

Allow non-medical control over repeat system

“Regular nurses supplying repeat script at surgeries as long as monitoring is completed annually.” R269

“Using repeat authorisation in your pharmacy and request direct to Dr [doctor] if more repeat are needed.” R101

“If the Dr [doctor] placed an electronic note in the patient’ file as to whether or not they would be ok with an emergency / owing supply then we could ring up with the clinic and the receptionist would be able to tell us without wasting the Dr`s time” R202

Extend time frame of the repeat system

“Longer repeats e.g. why not make Oral contraceptive last for 2 years of 11 rpts [repeats] for Antihypertensives.” R16

“Increase the expiry date and number of repeats on the prescription.” R151

Subtheme 2.5: Use an alternative model (*n=3)

Some participants suggested the use of an “alternative model” (See Section 4.3.3.6). The following comments explain this:

“What about "pharmacy prescriptions" - the pharmacist fill the script and paid by Medicare Dispense as owing, however, only supply 3 days' worth and when patient brings in prescription from their doctor, give balance of tablets.” R147

“Emergency supply, patients to pay full price then do a refund when scripts have been received.” R84

“Px [patient] pays full private price for 1 week`s supply for a whole pack (like a bond) – then gets refund if Rx [prescription] returned.” R227

Theme 3: More prescribers (doctors/nurse practitioners) are needed (*n=16)

This comments related to this theme produced two subthemes:

Subtheme 3.1: More doctors for phone calls in clinics (*n=11)

This was suggested to increase cooperation by doctor with the OP system. This comment explains this subtheme:

“Dr`s being more contactable for verbal prescription & write late or just allowing pharmacist to supply a box to continue.” R169

Subtheme 3.2: Greater availability of prescribers (*n=4)

The need for greater availability of prescribers in rural areas and during weekends/public

holiday was identified as an issue. The following comments illustrate this subtheme:

“Quicker access to rural GPs!” R268

“On call general practitioner or nurse practitioner available in town or by phone.” R131

“A doctor being available on weekends and public holidays.” R235

Additionally one participant suggested; “.....[having] a GP in every pharmacy.” R194

Theme 4: Educating patients to take responsibility (*n=16)

Comments supporting this theme related to educating patients to take more responsibility for their own medication supply, as illustrated below:

“Patient education, it is not rocket science to count the number of tablet you have left in the pack.” R64

“More patient education about compliance to increase patient understanding responsibility.” R275

Theme 5: Better use of pharmacists' skills (*n=10)

Some participants argued that allowing pharmacists to prescribe would address the issue of urgent medication requests without a prescription. The participants did not specify whether they meant collaborative or independent prescribing rights.

“Pharmacist consultation and pharmacist- issued prescription if clinically safe and responsible per any prescription issued.” R267

“pharmacist is able to prescribe once only for regular medication, if he follows the disease state management of his patient.” R220

Theme 6: Referral to hospitals or emergency department (*n=8)

Referral to hospitals or emergency department also emerged as solutions. The following examples illustrate this theme.

“Refer to public hospital.” R180

“In our town we send the patient to the hospital to get supplied with medications.” R136

“We often refuse emergency supply due to accumulation of unsellable stock & instead refer customers to the hospital ED [Emergency Department] for scripts.” R195

4.5.5 Discussion

This study aimed to explore the Australian community pharmacists’ attitudes towards CD, to estimate their support for an expanded CD version (include more medications), and an extended CD version (more frequent utilisation). As far as we know, it is the first study in Australia to explore community pharmacists’ attitudes towards CD.

Results of this study confirmed the relevance for the patient being a regular pharmacy customer.[7] Participants supported medication supply using the CD method more strongly for regular customers than non-regular customers (p values < 0.0001) across a range of medication classes. This indicates that participants of this study do not supply unless they have the essential patient information they need. This is consistent with CD guidelines which recommend that the pharmacist must contact the original prescriber or the regular pharmacy of the non-regular customer to verify any information obtained from non-regular customers.[45] Moreover, this difference between participants regarding their support of the CD according to customer type may be affected by the difficulty to refuse a request from regular customers.[4] This may be confirmed by the fact that participants of the current study were more likely to select the option ‘Neutral’ if they did not agree rather than the options ‘Disagree/ Strongly Disagree’ in the case of regular customers. However, in the case of non-regular customer the participants tended to selected “Disagree/Strongly Disagree”.

The currently eligible medications for CD (Statins and OCs), were supported by the majority of participants, with stronger support for using CD to supply medication to regular customers more than non-regular customers. However, other medications (e.g. asthma medication) were supported more by participants. The fact that Statins and OCs are already eligible CD medications may have affected their support by the participants. This support for antihypertensives was explained by participants who commented that antihypertensives are more urgently needed than Statins. This is consistent with the AMA, which stated that Statin users can safely break their Statin treatment for one or two weeks.[43] However, there are studies which have reported harmful effects of short-term Statin discontinuation.[53-55]

Some participants provided additional comments about CD. These comments reflected their

views about the CD and they could be divided into negative, conditional (modification required) and positive views. Firstly, the negative views came from participants who thought CD may confuse patients prescribed multiple medications because they cannot obtain all medications through the CD. This confirms previously reported concerns by Services for Australian Rural and Remote Allied Health (SARRAH).[42] It is worth mentioning that according to PSA, the pharmacist must not use CD if there is a risk of patient confusion.[45] Other participants were concerned about potential abuse of CD by the patients or some pharmacy groups, and others thought CD would not be accepted by doctors.[56, 57] Secondly, participants with conditional views thought CD must be expanded to include other urgently needed medications.[42] Finally, positive views reflected that CD may alleviate other supply systems drawbacks, such as issues with prescription follow up for OP system or quantities available through ES.[7, 9] Some participants believed that CD is capable of encouraging continuity of care and patient adherence to their medications. Therefore, those participants supported the primary driver for CD implementation.[45]

The study participants supported CD expansion to include more eligible medications from a list of medications. This support differed according to customer and medication type. In the case of regular customers, all the medications were supported by the majority of participants except opioids, anti-anxiety, non-opioids analgesics and schizophrenia. However in the case of non-regular customers, only four medication classes (asthma, Statins, OCs, and COPD) were supported by the majority of participants. Medication type also affected the level of support. For example, opioids were supported by less than 10%. However, antihypertensives and antidepressants for regular customers were supported by more than 90% and 60% of the participants, respectively.

In a previous study, about down scheduling selected prescription-only medications (POM) to Pharmacists only Medication, 37.7% of respondent pharmacists supported supplying selected antihypertensives medications without a prescription, 42.3% for selected Statins, and 51% for selected birth control drugs.[58] This level of support is far less than the results of the current study, probably because of the differences between CD and POM provisions, where the CD does not include diagnosis and establishment of the therapy as in the case in the POM system.

In another study 85% of respondent pharmacists supported initiating and supplying OCs without a prescription.[59] This is consistent with our results, and it potentially reflects that patients think they are safe and the pharmacist can provide them without a prescription.[60]

For the majority of answers asked about the listed medication, there were no significant

differences as a result of participants' demographics. However, in some cases males were more likely than females to support CD expansion. This may be explained by the same factors that were used to explain why male participants were more supportive to supply medications in urgent cases (See Section 4.3.4). In brief, more work experience (gained from working longer hours and on a full-time basis) and being pharmacy owners are probably contributing factors towards stronger support by males. Also, males were significantly (p values < 0.05) more likely than females to see more CD advantage in increasing patient adherence and decreasing the administrative burden of OP system. In a previous, study pharmacy owners were more supportive to expanding pharmacist roles.[44] Other variables (age and pharmacy location) affected only a limited number of responses where older, and participants working in rural areas were often more supportive.

Regarding CD extension, the participants were almost equally divided into two attitudes; 51.4% of participants were satisfied with the current utilisation frequency of CD (i.e. once in any 12 months), the rest of the participants supported more frequent CD. The thematic analysis of comments provided by participants to explain why they selected a particular frequency for CD revealed that whatever the selected frequency was the participants had tried to balance patient safety and improving urgent access to medications. Therefore, there were some comments to allow the pharmacist who faced a medication request to decide to use or not use the CD depending on circumstances and the clinical status of the requester rather than having a fixed frequency as explained by this comment: "As pharmacists we have a strong understanding of pharmacotherapy and the considerations based on questioning and history if it is appropriate. A set number cannot help define the so many reasons that can arise."

Regarding participants' agreement/disagreement with some statements about the CD, the majority of the participants agreed that CD may improve patient medication adherence, [7, 9] and overcomes some of other supply system disadvantages.[7]

Irrespective of concerns expressed by some participants about potential use of this feature to prevent appropriate CD supply by some doctors, the majority of the participants agreed that the original prescriber should be able to annotate the prescription to make it clear that the medication is not to be continued without review by the treating medical practitioner. This indicates that the participants are supportive of the AMA's suggestion to include prescription annotation by doctors,[61] and more cooperative communications with prescribers to ensure patient safety.[62] This may explain participants' support of the pharmacist being able to view the patient's electronic health record. Information exchange between health professionals was

also demanded by participants of a previous study that sought pharmacists' (and others) attitudes towards the hypothesised version of CD (i.e. MM).[9] In this regard, pharmacists may inform doctors about all the medication the patient uses including OTC medication.[63]

Participants were asked to suggest other solutions to medication requests without a valid prescription. Three themes emerged from their responses. Firstly, Theme 1: "Solutions to decrease the need for urgent supply". This included solutions using technology to remind the patients to book appointments, more prescribers available in rural areas and during weekends/public holidays (or at community pharmacies), and patient education. This is consistent with a previous report about GP shortages in rural areas in Australia, where "The number of services per person in the lowest-access rural areas is less than half that of the major cities". [64] It is also consistent with a previous study in the UK where requests for urgent supply tends to be more common during weekends/public holidays.[4] The surprise call for "a GP in every pharmacy" is not consistent with doctors shortage in Australia.[42, 65] Moreover, in the UK pharmacists are assisting in the relief of the doctors' shortage through work in GP surgeries.[66] Secondly, Theme 2: "Solutions to decrease the need for an urgent prescription". This theme included suggestions by participants about electronic prescribing, better communication, and modification of the current urgent supply systems. All of these suggestions have been reported in earlier studies [9, 44, 67]. Thus, our results confirm the need to review the current systems and implement changes to make them more efficient and effective. Participants of the current study also suggested prior approval, more doctors to approve the OP, and pharmacist prescribing. Pharmacist prescribing rights was deemed by the study participants as other non-medical prescribing in Australia. In Australia nurse practitioners, midwives and optometrists have prescribing rights under the PBS.[52] Thirdly, Theme 3: "Solution to refer patients who need urgent care by a doctor", such as referral to hospital or emergency departments. Although this is a valuable safety measure, it has the disadvantage of applying more pressure on already crowded emergency departments and it also may affect access to medical services for more urgent patients.[68]

Study limitations have been reported in Section 4.3.4. The low response rate was an issue in this study. Although participants had similar views regarding their support of CD, CD expansion and CD extension, it may be that the non-responders had different opinions. Also, non-responders may not have been interested in the CD method due to a lack of experience with it, and their satisfaction with the currently available supply methods. This study was conducted before CD implementation in Australia. Therefore, future research needs to explore the Australian community pharmacists' views on CD after CD implementation.

4.5.6 Conclusions

The study participants (i.e. Australian community pharmacists), whilst supporting the current version of CD, also highly supported CD expansion for regular customers and to a lesser CD extension. While some participants reported concerns about the CD method, regarding its limitation and potential abuse, others thought CD would overcome disadvantages of other urgent supply methods.

Study participants also suggested other proposed solutions to address or minimise urgent requests for medication. Pharmacists' access to health records and more communications with other health care providers may assist the pharmacists to conduct safe and appropriate CD with all customers, including non-regular customers. Health policy makers may use results of this study to evaluate the current CD system and it may provide scope for enhancements. Other suggested solutions to address urgent access to medication should also be further explored.

4.5.7 Summary of findings

Given there are three parts in this chapter, below is a summary of the main findings:

Part A of this chapter showed that pharmacists have different practices in regards urgency supply according to type of the customer. They were more likely to supply medications urgently, without a valid prescription, to their regular customers than non-regular clients. This confirms the need for patients to have a regular pharmacy to minimise treatment interruption when obtaining a new prescription is not practical. Prescription-type and medication type also affected pharmacists' decisions to supply. The participants were less likely to supply medication in urgent situations if the patient was not regular, the medication had an abuse potential, and/or the prescription was an authority prescription.

Part B of this chapter described the reasons usually cited for urgent requests of medications. All the reported reasons were centred around the difficulty to obtain a new prescription. These included, doctors/ appointment unavailability. Traveling without medications, patients' unaware of last repeat or its requirements, expired prescription, and patients' lack of responsibility/planning were also reported among other reasons. Health policymakers must consider implementing solutions that reflect the magnitude of this issue.

Part C examined pharmacists' attitudes toward the current CD and modifications of the CD system. Participants supported the current CD, but also supported CD modifications to allow

it to be a more practical solution for urgent supply of medication. In particular these included the inclusion of more eligible medications, and appropriate pharmacist remuneration. Participants also suggested other solutions such as better use of technology and modification of current methods to supply medication in urgent situations.

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Chapter 5: Case vignettes with pharmacists

5.1 Introduction

Continued Dispensing (CD), is a medication supply method which does not require a valid prescription. Only one health professional conducts the CD, namely pharmacists. Therefore, there is no “second check” of the process.[1] The pharmacist reviews the patient’s history and supplies the medication according to last supply with a valid prescription. While this eases access to medication, it has the potential to be used inappropriately.[2]

In order to optimise CD conduct and minimise the inappropriate use of CD, the Pharmaceutical Society of Australia (PSA) has developed guidelines for pharmacists who supply medication using the CD method.[3] According to the PSA guidelines, a pharmacist who faces a request for an urgent supply of a Statin and/or Oral Contraceptive Pill (OCP) must establish that there is an urgent need for the medication to be continued and a prescription could not be obtained for practical reason(s). Besides, the patient’s therapy has to be stable on the requested medication, and the medication needs to have been prescribed after a clinical review by the prescriber. Therefore, medication supply via CD outside these requirements is not appropriate. In addition, if the customer is not a regular customer of the pharmacy, the pharmacy where the medication was last supplied and the customer’s regular pharmacy (if they have one) must be contacted to verify information obtained from the patient.[4] Hence, it is implied that supply to non-regular customer without prior contact with their regular pharmacy is not appropriate.

To illustrate how the CD guidelines should be applied, the PSA has published six case scenarios (Available from: <https://www.psa.org.au/download/guidelines/medication-management/continued-dispensing-scenarios.pdf>) involving medication provision through the CD model.[4] Each scenario portrays a customer requesting an eligible medication (i.e. a Statin or OCP) without a valid prescription as it was not practical for them to obtain an appointment with the prescriber. In each scenario, the PSA discusses why CD supply is or is not appropriate. For example, in the PSA’s Scenario 2 the customer was not a regular, however, the use of CD was listed as “May be appropriate”. This “may be” indicating that CD could be appropriate if the information provided by the customer has been validated from the customer’s regular pharmacy. In Scenarios 3, 5 and 6, CD was not appropriate according to the PSA. The reasons provided to justify the inappropriateness of the use of CD for these scenarios were: the customer was not stabilised on the treatment, no prior clinical review by a prescriber or because of information provided by the customer was insufficient to make a decision to supply.[4]

Pharmacists may differ in their interpretation of some parts of the guidelines.[5] For example, opinion may differ on the urgency of request. In this regard, while some pharmacists may consider a request from a customer, who had only a few tablets left an urgent request, others may think that there is still time to obtain a prescription. Timing of the request may also affect the degree of urgency, particularly with requests occurring during weekends or public holidays.[6] Pharmacists may also differ in their assessment of treatment interruption; is one or two days without a medication long enough to consider that the treatment has been really interrupted? OC users are still considered adherent to therapy after two days of missing pills.[7] Similarly, a customer may request eligible and non-eligible medications (e.g. Statin and antihypertensive) at the same time and for the same reasons. In this case pharmacists' decisions may vary; some may use CD for the Statin and another method for the antihypertensive, whilst other pharmacists may consider patient confusion that may result from using different methods, and supply both medications via an alternative method.[4]

Pharmacists' adherence to PSA guidelines may be measured by various methods. For example, it may be measured by direct observation. However, this method has disadvantages of high cost, being time-consuming to conduct and obtain a suitable number of cases, and potential bias as a result of the Hawthorne effect (i.e. participants enhancing their actions under surveillance).[8] Adherence to guidelines needs to be measured using lower cost valid and reliable methods.[9] Written case vignettes meet these requirements.[10] Compared to video case vignettes the pencil and paper vignettes save research time and resources.[8]

5.2 Aims and objectives

This study aimed to explore:

1. The appropriateness of pharmacists' application of the CD guidelines across a range of clinical scenarios.
2. Pharmacist general views about CD after eight months of its implementation in Western Australia.

5.3 Methods

Purposeful sampling was used to collect the data in this study. Purposeful sampling is "a technique used for the identification and selection of information-rich cases for the most effective use of limited resources. Such as identifying and selecting individuals or

groups of individuals that are especially knowledgeable about or experienced with a phenomenon of interest.”[11] A questionnaire containing six case vignettes was distributed to pharmacists who attended the PSA Western Australian Branch seminar, Perth Western Australia, May 2014, along with a participant information sheet. Respondents were also given a ticket to go into a draw for a \$100 Gift Voucher. Participants were considered consented if they returned the completed questionnaire.

5.3.1 Questionnaire development

The scenarios used in case vignettes were adopted from the “Continued Dispensing Scenarios for Pharmacists” which were developed by the PSA to guide pharmacists conducting the CD (Available from: <https://www.psa.org.au/download/guidelines/medication-management/continued-dispensing-scenarios.pdf>).[4] Amendments made were to the original scenarios to provide more details such as inclusion of consumer age, changing the medicine type from statin to OC, or vice versa, changing hospitalisation time from 3 weeks to 12 days. The questionnaire also had a section to collect demographic information about the respondents (Appendix 5.1). The participants were also asked to comment on their experience with the CD method. The questionnaire was reviewed for face and content validity by staff members from the pharmacy practice team, School of Pharmacy, Curtin University. The study was approved by the Human Research Ethics Committee of Curtin University. (Approval number: PH-15-14) (See Appendix 5.2)

5.3.2 Development of a checklist

As a result of the amendments that were made by the research team (the PhD candidate and the supervisors) to the PSA scenarios, a checklist was developed to determine scenarios in which medication supply through CD was or was not appropriate according to CD requirements (See Section 2.1; Box 2.).

The following questions formed the checklist:

Is the requested medication eligible?

Is the patient a regular customer?

Has the patient been on the same medication for six months or more?

Is a medical review by a GP needed as soon as possible?

For medication supply using the CD method to be considered appropriate, the first three questions had to be answered by YES, and the fourth question had to be answered by NO.

5.3.3 Research Team Evaluations (RTE)

The research team made assumptions about appropriateness of CD utilisation in various scenarios provided. These assumptions were based on CD guidelines established by the PSA. These scenarios were then piloted with the pharmacy practice team in the School of Pharmacy. Following this process, a final decision was made that CD was appropriate for Scenarios 1, 3 and 4 and it was inappropriate for scenarios 2 (not a regular customer), 5 (New medication [i.e. less than six months]), and Scenario 6 (Not stable –Recent hospitalization- GP review is needed).

Example of vignettes

Scenario 5: An 18 year old female consumer comes into the pharmacy with an empty box of the oral contraceptive. She says it is not practicable for her to go to her GP. The pharmacist reads on the label that her GP has given her a three months' supply with no repeats. On further questioning, she says her GP changed her onto a new oral contraceptive three months ago.

RTE: CD is not appropriate for this scenario because the medication was new (i.e. patient using it for less than six months).

5.3.4 Data Analysis

The data were initially entered in an Excel® (2010) spreadsheet, then imported into SPSS® Version (22) for analysis. SPSS® was used to produce frequency tables and examine the effects of independent variables (age, gender, and years of practice) on the dependent variable, (i.e. participants' decisions). A P value of ≤ 0.05 was considered statistically significant using 95% confidence interval. Open-ended questions were transcribed verbatim and thematically analysed.

The relevance of each theme was ranked according to their prevalence in participants' comments. For example the theme that appeared four times was assigned an *n=4 and so on. The purpose of ranking themes was to estimate which theme was more important from the participant's perception. Also, this was done to avoid unnecessary repetition of similar comments.

5.4 Results

5.4.1 Response rate

Thirty questionnaires were returned from an estimated 50 pharmacist attendees which equates to an approximate response rate of 60%.

5.4.2 Demographic data

The participants were mainly female (73.3%). The dominant age group and years of experience were 25-34 years and 11-20 years, respectively. Community pharmacy was the dominant primary area of work for 73.3% of study participants. Table 5.1 provides a summary of participant's demographics.

Table 5.1 Demographic data

Variable	Item	n (%)
Gender	Male	8 (26.7)
	Female	22 (73.3)
Age	<25	3 (10.0)
	25-34	13 (43.3)
	35-44	5 (16.7)
	45-54	5 (16.7)
	55-64	2 (6.7)
	65 or older	1 (3.3)
	Prefer not to disclose	1 (3.3)
Experience as registered pharmacist	< 5 years	7 (23.3)
	5-10 years	9 (30.0)
	11-20 years	13 (43.3)
	> 20 years	1 (3.3)
Primary Area of Pharmacy Practice	Community Pharmacy	22 (73.3)
	Hospital Pharmacy	4 (13.3)
	Other	4 (13.3)

5.4.3 Inconsistency with the Research Team Evaluations (RTE)

According to data provided in each scenario, the research team used the checklist to decide in which cases medication supply through CD would be an appropriate decision. These evaluations were not provided to the participants.

Participant decisions that differed from the **RTE** were considered inconsistent with the **RTE** research team assumptions (Table 5.2).

Overall, 53 (29.4%) of the 180 recommendations made were inconsistent with **RTE**. Inconsistent decisions were either a decision to not use CD when it was appropriate (incorrect refusal: 26 decisions in 53; 49%) or a decision to use CD when it was not appropriate (incorrect supply : 27; 51%).

Table 5.2 Participants' inconsistent decisions with research team evaluations

Scenario No	RTE	RTE' reason(s) for inappropriateness	*Inconsistent responses n (%)
1	Appropriate	None	4 (13.3)
2	Inappropriate	Not a regular customer	16 (53.3)
3	Appropriate	None	5 (16.7)
4	Appropriate	None	17 (56.7)
5	Inappropriate	New medication- less than 6 months	3 (10.0)
6	Inappropriate	Not stable –Recent hospitalisation- GP review needed	8 (26.7)

*Inconsistent responses with the research team's evaluations (RTE)

Incorrect refusal decisions

There were 26 incorrect refusal that occurred in relation to Scenarios 1, 3 and 4. The majority (65.4%) of these decisions were in Scenario 4. This scenario contained a request for two medications: a Statin (CD eligible) and an antihypertensive medication (not eligible for CD).

Incorrect supply decisions

There were 27 (15%) incorrect supply (or inappropriate use of the CD) which occurred in Scenarios 2, 5, and 6. The majority (59.3%) of these decisions were in Scenario 2. This case was considered by the research team as an inappropriate case for CD because the customer was not a regular customer. However, 16 out of 30 participants (i.e. 53.3%) decided that the supply through the CD method was appropriate. In other words, the majority of participants did not think CD was inappropriate for a non-regular customer in this scenario.

5.4.4 Effect of demographic variables on participants' decisions

Table 5.3 displays effects of demographic variables on participants' decisions. These decisions were categorised as: Consistent (with **RTE**) or Not Consistent, then they were tested to see if there was any effect of demographic variables on these decision. These decisions did not differ significantly ($p > 0.05$) according to participants' demographic data (gender: males vs females; age: < 45 vs ≥ 45 , Years of practice: <10 vs ≥ 10) as indicated by Chi-square and Mann-Whitney tests.

Table 5.3 Effects of demographic variables on participants' decisions

Variables	Scenarios (P value)					
	Scenario1	Scenario 2	Scenario 3	Scenario 4	Scenario5	Scenario 6
Gender	0.937	0.828	0.717	0.662	0.787	0.903
Age groups	0.359	0.736	0.520	0.439	0.631	0.158
Years of practice	0.359	0.290	0.748	0.961	0.631	0.828

5.4.5 Participants' beliefs when CD must not be used

Respondents who nominated a case as inappropriate for the CD were asked to give their reason(s) for their answer. In general, participants thought that CD method of supply was inappropriate if there was a need for medical review, no dispensing history, and if the patient condition was not stable. The provided reasons were ranked according to the number of repetitions (Table 5.4).

Table 5.4 Themes emerging from the reasons cited for not supplying the medication via CD

Themes (Reasons)	N	Scenarios	Subthemes
The need for a medical review	40	1,2,3,4,5 and 6	The need for a medical review (n=40)
The patient was not stable	20	1,2,4,5 and 6	The request was for a new medication (n=11) Recent hospitalisation(n=5) Prescription has changed (n=2) For safety reasons (n=2)
No history	14	1,2 and 6	The customer was not regular and/or Absence of medication history (n=14)
Absence of urgency	7	2,3 and 4	Absence of urgency (n=7)
Treatment was already interrupted	4	2 and 3	Treatment was already interrupted (n=4)

The Table 5.4 shows which reasons were more commonly cited by respondents when they thought CD was inappropriate. Key reasons cited for non-supply were as follows: **The need for a medical review (*n=40)** was cited as a reason for not supplying in every scenario, followed by: **The patient was not stable (*n=20)**, **No history (*n=14)**, **Absence of urgency (*n=7)**, and **Treatment was already interrupted (*n=4)**.

5.4.6 Most reported reasons for CD inappropriateness

The above reasons can be combined to produce two main themes: **A) It was not safe to supply.** Medical view was required (The patient was not stable; and No history), and **B) It was not an urgent situation** (Absence of urgency; and Treatment was already interrupted).

More details and examples are provided below about why the participants thought CD was not

appropriate for each scenario.

Scenario 1: A 26 year old female regular customer of the pharmacy requests repeat prescription of her oral contraceptive pill. Although there are still repeats, the prescription has expired and it is impractical for her to see her GP to renew the prescription because she is leaving the next day (Sunday) for a couple of week's holiday.

RTE: CD in this scenario is appropriate.

Four (13.3%) decisions which were inconsistent with RTE. The reported reason(s) for not using CD were:

The need for a medical review (*n=2):

This reason was reported twice. The following examples illustrate this:

“She has not seen GP for a long period of time.” ph4

“Can get Rx [prescription] during the month- Should see a doctor for BP [blood pressure] check .etc.” ph27

The customer was not regular and/or Absence of medication history (*n=2):

This reason was cited by two participants. The following examples illustrate this:

“May not be using (the medication) regularly.” ph10

“Unknown time of last doctor` visit- time delay between commencing treatment& it beginning to be effective.” ph14

Scenario 2: The wife of a 48 year old male comes into the pharmacy. She and her husband are visiting from another state and she says her husband has run out of his Statin a week ago. He would prefer not to see another GP, however they are staying for another 3 weeks, and she is concerned about the interruption to his treatment.

RTE: CD in this scenario is not appropriate because the customer was not regular.

The number of respondents whose decisions were consistent with **RTE** was 14 (46.7%). Their reasons for this decision were mostly associated with cases where the customer and the

medication history were unknown to the pharmacist (i.e. customer was not regular).

The customer was not regular and/or Absence of medication history (*n=6):

These reasons were cited by six participants. The following examples illustrate this:

“No dispensing history for the patient.” ph9

“Not regular customer with no history of compliance.” ph29

“No history on stability of condition.” ph4

Treatment was already interrupted (*n=2):

This reason was cited by two participants. The following examples illustrate this:

“Interruption of therapy.” ph18

“Treatment is not continuous (week break).” ph23

The need for a medical review (*n=1):

This reason was cited by one participant. The following example illustrates this:

“Need to check-up.” ph15

Absence of urgency (*n=2):

This reason was reported twice. The following examples illustrate this:

“..... time enough to organise Dr [doctor] appointment.” ph7

“Just phone Dr [doctor] and get a Rx [prescription] faxed.” ph6

The request was for a new medication (*n=1):

This reason was cited by one participant. The following example illustrates this:

“New medication.” ph1

Pharmacist preferred direct consultation with the patient (*n=1):

This reason was cited by one participant. The following example illustrates this:

“Ask to speak to patient himself.” ph3

Note: one participant did not provide a reason.

Scenario 3: A 61 year old male regular consumer tells the pharmacist that he urgently needs some of his cholesterol medicine. He mentions that he ran out two days ago. The pharmacist reviews the consumer’s medication history and until this break on therapy, the consumer had been stable on Statin therapy for five years.

RTE: CD is appropriate.

Five (16.7%) decisions were inconsistent with **RTE**. The cited reasons for this decision were:

Treatment was already interrupted (*n=2):

This reason was reported twice. The following examples illustrate this:

“Not adherent.” ph13

“Interruption of therapy.” ph18

Absence of urgency (*n=2):

Absence of urgency was cited by two participants. The following examples illustrate this:

“2/7 not sufficient risk.” ph24

“Will get Rx [prescription] during month.” ph27

The need for a medical review (*n=1):

This reason was cited by one participant. The following example illustrates this:

“Need to check up if strength of the drug still appropriate.” ph15

Scenario 4: A 48 year old regular female customer tells the pharmacist that she is unable to obtain an appointment with her doctor for new prescriptions for her Statin and blood pressure medicines and prefers not to see another GP. She has been taking them for about 6 months and now only has a few tablets left.

RTE: CD is appropriate

Seventeen (56.7%) decisions were inconsistent with **RTE**. The key reported reason(s) for this decision were:

The need for a medical review (*n=10):

This reason was cited by 10 participants. The following examples illustrate this:

“She needs a clinical assessment of her BP [blood pressure].” ph3

“12 months Rx [prescription].” ph13

“Should see another GP.” ph8

“Can see any doctor.” ph17

The request was for a new medication (*n=2):

This reason was cited by two participants. The following examples illustrate this:

“New med [medication].” ph10

“Review for a new medication is important.” ph21

The patient also requested ineligible medication (*n=2):

This reason was cited by two participants. The following examples illustrate this:

“BP [blood pressure] medicine cannot be supplied. So Rx [prescription] needed to see a GP.”
ph14

“Cannot do CD for BP [blood pressure] meds [medications].” ph18

Absence of urgency (*n=3):

This reason was cited by three participants. The following examples illustrate this:

“She may still be able to contact her GP before medications runs out.” ph20

“Will get appointment within a month.” ph27

“She still have supply, it has been 6 months, so need to be reviewed.” ph28

Scenario 5: An 18 year old female consumer comes into the pharmacy with an empty box of the oral contraceptive. She says it is not practicable for her to go to her GP. The pharmacist reads on the label that her GP has given her a three months’ supply with no repeats. On further questioning, she says her GP changed her onto a new oral contraceptive three months ago.

RTE: CD is not appropriate for this scenario because the medication was new (i.e. patient using it for less than six months).

Twenty-seven (90%) of respondents indicated CD was not appropriate (i.e. consistent with **RTE**). Their reasons for this decision were related to the need for a medical review and to the medication used being new and instability of the treatment.

The need for a medical review (*n=19):

The need for a medical review was cited by 19 participants. The following examples illustrate this:

“Refer back to GP to assess whether the new pill is suitable for her.” ph11

“GP may change the pill she is on.” ph20

“GP may want a review on her new pill.” ph21

“Needs GP review.” ph23

The request was for a new medication (*n=8):

This reason was cited by eight participants. The following examples illustrate this:

“New medication & has only had one supply.” ph9

“Duration less than 12 months.” ph18

For safety reasons (*n=2):

These reasons were cited by two participants. The following examples illustrate this:

“Safety. Suitability.” ph22

“Risk out?” ph24

Scenario 6: A 36 year old female comes to the pharmacy after being in hospital for 14 days. Last week she ran out of the supply provided by the hospital and has not been able to visit her GP since leaving hospital. She would like a supply of her usual Statin.

RTE: CD is not appropriate for this scenario because the customer was not stable on the medication, she had recent hospitalisation, and a medical review is needed.

Participants who thought CD was not appropriate (22; 73.3 %) cited the following reasons:

The need for a medical review (*n=8):

This reason was cited by eight participants. The following examples illustrate this:

“Needs to see GP.” ph16

“Refer to the regular doctor.” ph19

The customer was not regular and/or Absence of medication history (*n=6):

These reasons were cited by six participants. The following examples illustrate this:

“Unknown history of Statin.” ph4

“Unknown if treatment is stable.” ph14

“Maybe new- See GP.” ph17

Recent hospitalisation (*n=6):

This reason was cited by six participants. The following examples illustrate this:

“May have had changes in hospital.” ph12

“Hospitalisation in last 12 months.” ph18

Prescription has changed (*n=2):

This reason was cited by two participants. The following example illustrates this:

“Not same Rx [prescription].” ph7

5.4.7 What was the suitable action?

After the question about the appropriateness of the each scenario for CD supply, participants were asked what would be their preferred course of action among the following four options: Continued Dispensing (CD), Owing Prescription (OP), Emergency Supply (ES), Not supply (NS), Refer to an After-Hours GP, or Other.

The results (Table 5.5) showed that CD was preferred by at least one half of the respondents for Scenarios 1 and 3. Nearly a quarter of respondents preferred the CD method for Scenario 4 where OP was the most preferred option. The least preferred option was referring patients to after-hours GPs in Scenarios 5 and 6. The ‘Other’ option included referring patient to a GP, the original prescriber, a clinic or a hospital.

Table 5.5 Respondents' preferred course of action

Scenario No	CD n (%)	OP n (%)	ES n (%)	NS n (%)	^Other n (%)	Missing n (%)
1	16 (53.3)	10 (33.3)	0	1(3.3)	2 (6.7)	1 (3.3)
2	13 (43.3)	1(3.3)	3 (10.0)	0	11 (36.7)	2 (6.7)
3	15 (50.0)	10 (33.3)	1(3.3)	0	0	4 (13.3)
4	8 (26.7)	10 (33.3)	1 (3.3)	4 (13.3)	4 (13.3)	3 (10.0)
5*	1 (3.3)	1 (3.3)	1 (3.3)	5 (16.7)	12 (40.0)	9 (30.0)
6*	3 (10.0)	1 (3.3)	6 (20)	2 (6.7)	11 (36.7)	6 (20.0)

CD: Continued Dispensing, OP: Owing Prescription, ES: Emergency Supply, NS: Not Supply^ Other: ‘refer to a GP’ *One respondent reported ‘Refer to after-hours GP’

5.4.8 Respondents' views about CD

Respondents were asked to comment on their experience with CD particularly with a focus on whether they believed it is an efficient process. Only two respondents expressed positive views regarding the CD system while 17 respondents either identified some of CD disadvantages such as paperwork, and/or expressed lack of knowledge and /or experience and/or use of CD. The main theme emerging from these comments is low uptake of the CD by study respondents. More details are provided below:

a. Positive views (*n=2)

Two respondents (one working in community and the other in hospital) showed positive attitudes towards CD. Although the community pharmacist did comment that its narrow focus limited its useability.

“I think it is a good idea, however as it is limited to only Statin and Oral contraceptive tablets I have not used it a lot at my community pharmacy.” Ph9

“I work in hospital pharmacy so I do not have much experience with continued dispensing but I believe it is a good idea.” ph11

b. Negative views (*n=5)

Five respondents expressed their concerns about the complexity of conducting CD. They were also satisfied with other current medication supply methods such as OP and ES. One respondent mentioned the need to contact the prescriber as an extra workload even though prior contact with the prescriber is not a condition to conduct the CD method, as in case of the OP system to obtain the prescriber's authorisation. However, CD requirements stipulate that the pharmacist must inform the last prescriber. This communication may be perceived as an extra workload even though it is an imperative to minimise treatment duplication and fragmentation of care. Being time consuming and onerous paperwork were also mentioned. These are needed to record and claim the reimbursements and to ensure the appropriateness of medication supply by using the CD method. All respondents with negative views had chosen not to use CD in practice. More details and examples are provided below.

“...script owing [OP] is easier and effective.”ph6

“Do not feel the need as owing Rx [owing prescription] is easier and less time consuming.”
ph25

“....extra workload to contact prescriber- better alternatives available/ not unhappy with current alternatives.” Ph8

“...., too much paperwork, patient needs to go to Dr [doctor] eventually anyway.” ph27

“I agree that pharmacists are capable and competent to do CD, but I do not really see the need for it- Emergency or owing are enough.” ph23

c. Lack of knowledge and/or experience and/or use of CD (*n=11)

Seven respondents stated that they have not used CD in practice at the time of the survey. In addition four respondents reported their lack of understanding of CD/ experience with this method of medication supply. See examples below:

“As yet, not used.” ph7

“Have not done any continued dispensing-....” Ph8

“Minimal experience duo to lack of knowledge of regulations.” ph10

“No experience.” ph17

“Do not quite understand the process.” ph20

“I know very little if anything about it!” ph30

5.4.9 Effect of CD knowledge on participants decisions

A comparison was conducted between Group A (the 11 participants who stated Lack of knowledge and/or experience and/or use of CD) and Group B (those who did not report this [one participant], did not answer the question [17 participants], and the one participant who reported: I have not used it a lot). Both groups had a similar consistency with RTE. 71.2% of Group A decisions and 71.0% of Group B decisions were consistent with the RTE. In other words, the accuracy of both groups to identify when CD was appropriate or not was not significantly different.

5.5 Discussion

This study aimed to identify how pharmacists act when faced with theoretical scenarios of patients requesting Statins, OC or other medications without a valid prescription and were unable to see their doctors. In particular it sought to determine pharmacists' understanding of and experience with CD (i.e. how appropriately they conduct the CD).

The majority of participants would only conduct CD when it was appropriate. Irrespective of the fact that the majority of respondents who commented about their experience with CD, did not use CD (hence they had no real-life experience), only a small percentage (15%) of their overall decisions were incorrect supply (i.e. inappropriate use of the CD). However, these pharmacists may have had different views if they were dealing with real cases in practice,[12] as risk-taking behaviour would be less in the case scenarios as opposed to a real patient. It is critical to mention that the estimation of appropriateness was based on CD guidelines, which according to the PSA are "not definitive statements of correct procedure" rather they are a kind of advice about the best practice.[3, 13] Therefore, the fact that the incorrect supply decisions were not consistent with guidelines does not imply that these decisions were necessarily not clinically inappropriate. Besides, the current respondents proved that they were considering patient safety as a priority and would only supply when it is safe to do so. This was an emerging theme from respondents' views about why CD was not appropriate in some scenarios (see above). Although some pharmacists may require training about CD, the fact that the vast majority of pharmacists' decisions were appropriate suggests that not all pharmacists would require additional training to conduct CD.[14] This was confirmed by the absence of any significant differences between accuracy of participants' decisions according to their level of CD knowledge. Moreover, the majority of the incorrect supply decisions resulted from the decision of 53.3% (n=16) of respondents to use CD in case of a non-regular customer. In such cases, if the previous dispensing pharmacist can be contacted and can confirm the customer's history, CD can be used.

According to CD guidelines,[15] the pharmacists should contact the regular pharmacy of non-regular customers before using CD supply. This detail was not included in the scenario. Respondents who decided CD was appropriate for this scenario may have been affected by their experience in which they have no difficulty in contacting the regular pharmacy of non-regular customers. Furthermore, less preferred supply options available to supply for non-regular customers may affect respondents' decisions. For example, pharmacists who have a relationship with their customers may use OP system; however OP is unlikely to be usable

with non-regular customers.[16] Therefore, pharmacists may see CD as a potential solution for those customers. It is worth mentioning that Consumers Health Forum of Australia (CHF) recommended that there should be no “ambiguity” to identify the legitimate requests from non-regular customers.[17]

The incorrect refusals were the decisions to not use CD when it was deemed appropriate to do so. The majority of these decisions were in relation to Scenario 4. This scenario contained medication supply requests for two medications; one was eligible (Statin) according to current CD guidelines, and another one was not eligible (i.e. an antihypertensive). While CD was appropriate for the eligible medication, 17 in 30 respondents (56.7%) decided that the CD was not appropriate. This decision may indicate that pharmacists may not use the CD method with customers who are concurrently requesting eligible and illegible medications. This is likely to be the case for patients prescribed multiple medications, particularly with Statin users who usually diagnosed with other co-morbidities and use other medication.[18] This avoidance of the CD could negatively affect the circumstances under which to utilise CD in practice. It is worth mentioning that the PSA recommends not using CD if there is a risk of patient confusion as a result of using more than one method to supply the requested medications.[15] This could contribute to the low uptake of CD, particularly with Statin users who have comorbidities.[19]

This study provides insights into circumstances where pharmacists thought CD was not appropriate. The respondents thought CD was not appropriate if there was a need for a medical review, particularly if the patient had not seen the GP for a long period, or patient status was not stable on the same medication. This confirms the previous reports by Statin and OC users that their pharmacists would refer them to their GP when it was needed.[16] Furthermore, they thought CD was inappropriate if they did not know the patient or did not have a dispensing history, or the medication was new (i.e. prescribed less than six months ago). Patients who were recently hospitalised were also deemed unsuitable to utilise CD. This indicates that pharmacists are practising according to CD guidelines,[4] and they know their practice limitations and refer patients to doctors when that is deemed necessary. These results may alleviate the AMA’s concerns about the CD. Communication and cooperation between healthcare professionals results in optimisation of patient care and treatment outcomes.[20]

Another reason for not using CD that was cited in three scenarios was the absence of urgency. It is worth mentioning that the AMA has stated that Statins are not urgently needed medications.[2] Respondents reported that there was a possibility to obtain a prescription, or the medication had not run out yet. CD is only usable when it is impractical for the patient to

see the doctor. However, according to the study results this may be a grey area and would be subject to variation in the interpretation of urgency of the request among the pharmacists. Moreover, some respondents cited “treatment already interrupted” after one week without the medication. In the guidelines, there is no determination of the duration without treatment after which the medication must not be supplied. Hence, there is a need for more clarification of CD guidelines by authorities.

Results of this study also showed that the vast majority of respondents did not conduct CD. This was despite the fact that it had been implemented in Western Australia for more than eight months (from September 2013 to May 2014). This is supported by reports of low CD uptake by community pharmacists.[21] Study respondents also reported negative views about the CD. The key reason for these negative views included that they do not see the need for CD. This supported the AMA claim that CD is a solution for a problem that does not exist.[2] Respondents also think that the OP is much easier, and CD involves significant paperwork. These factors may be contributing to low uptake of CD by pharmacists,[21] particularly those who are still confused by the CD process.[22] Low uptake of new pharmacy services has been reported in the literature.[23, 24] For example in Canada, only one-third of pharmacies participated in the Ontario Pharmacy Smoking Cessation Program after more than 25 months of the program implementation.[23] Moreover, respondents also reported a lack of knowledge or understanding of the CD process despite the fact that a copy of guidelines was “distributed to each registered pharmacist in Australia during August 2013”.[25] This is consistent with previous studies, which reported low knowledge of guidelines.[10, 13]

This study has a number of limitations and strengths. The research tool was not piloted with the actual respondents. Although for the fact that majority of the participants primary place of work was the community pharmacy setting improves study representativeness. However, the respondents were the attendees at an annual seminar; therefore those who did not attend were not represented. Further, respondents’ responses to hypothetical scenarios may differ from actions in clinical practice, which is a general disadvantage of case vignettes studies. Case vignettes may not provide the full context, do not provide opportunity for questions and simplify the request. Moreover, inconsistency between some respondents’ decisions and **RTE** should not suggest that these decisions were clinically inappropriate rather they represent be different clinical evaluations of the presented scenarios. Public availability of the original scenarios on which the study vignettes were based, on the PSA website, may have biased participants’ responses. Finally, the sample size was small. These limitations may have negatively affected the generalisability of the results. However, despite the above limitations,

there are some strengths such as being the first to use case vignettes to study the CD model of medication supply. The study also explored pharmacists' limited experience with CD after its implementation. As a method of measurement, case vignettes reflect the actual practice by doctors with high content and face validity.[9] Therefore, this method is likely to reflect the actual practice by pharmacists when they are dealing with medication requests without a valid prescription. This reflection of the actual behaviours may have been improved by the fact that participants were not observed when they completed the survey tool.

Further research should be undertaken to explore how CD could be improved to enhance its utilisation by community pharmacists.

5.6 Conclusions

The majority of the respondents correctly identified the inappropriate cases for CD based supply, even though they had little or no personal experience with the CD. They rarely used the CD and preferred other options to supply medications in urgent cases without a valid prescription. The need for a medical review, absence of dispensing history, health or medication instability, and non-urgency were the main reasons that may cause pharmacists to avoid CD on clinical grounds. Other practical reasons such as patient confusion, co-morbidities, CD paperwork, time-consumption and the presence of other more convenient alternatives may have also contributed to low CD uptake. Irrespective of CD guidelines, it seems that the respondents considered that CD is still safe with non-regular customers if they were stable on their medication, no medical review was needed, and the request was urgent. Other regulations to ease non-regular customers' difficulty to obtain their medications should be explored. An expanded version of the CD (i.e. adding more eligible medication classes) may gain more acceptance and utilisation by the pharmacists.

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Chapter 6: Views of a small sample of General Practitioners on Continued Dispensing

6.1 Background

A prescription is required to obtain a supply of a Schedule 4 “Prescription Only Medication (POM)” in Australia. Legally accepted prescriptions may come from medical practitioners or other authorised healthcare providers (i.e. Nurse Practitioners, Dentists, Optometrists, or Midwives).[1] However, Continued Dispensing (CD) involves the supply of POMs without a valid prescription to eligible patients. Currently, the only eligible patients are Statin and Oral Contraceptive (OC) users. To be eligible, patients must: (a) have been prescribed these medications before from a registered prescriber (e.g. GP, nurse practitioner or midwife);[2] (b) have been stable on these medications for at least 6 months; and (c) have not utilised CD in the past 12 months.[3] The Australian Medical Association (AMA) has voiced its opposition to CD. According to the AMA, there are two main reasons for this pronouncement, namely concerns about the safety of dispensing without a clinical review and obscurity of the emergency.[4]

The AMA concerns about the safety of the CD supply may have risen from the absence of medical assessment before supply. Ideally, doctors would not renew the prescription without appropriate medical checks to ensure that the medication is still needed and it is safe to be used.[4] However, in practice there would be cases where the GPs may renew a prescription without seeing the patient. For example with the Owing Prescription (OP) system (i.e. prescription issued based on a phone call between the pharmacist and the GP).[5] Further, if the GP was unable to see the patient, the GP might renew the prescription, if appropriate, based on the patient’s medical record.[4, 6] This indicates that there are situations where prescription renewal may be made safely without a medical review. In other words, not all renewed supply without GP – patient face to face consultation is unsafe. Furthermore, CD supply is only possible if the patient cannot see the GP.[3] Therefore, pharmacists must balance the risks of supplying including delays in medical review with the risk of treatment interruption.

The other concern by the AMA is the absence of emergency for CD supply in case of Statin therapy. According to the AMA, “a patient’s medical condition was unlikely to deteriorate without lipid modifying agents for one or two weeks”. This opinion is consistent with the conclusion made by McGowan that a short period of Statin washout does not lead to significant clinical risk for patients with stable cardiac disease.[7, 8] However, there is evidence of rapid adverse effects on healthy volunteers and patients with different types of chronic diseases as a result of Statin short-term discontinuation.[9] Statins’ pharmacological actions are not limited to lipids. Statins also increase Nitric Oxide (NO) production. Therefore, the short-

term consequences of Statin discontinuation on healthy students were related to lower NO bioavailability.[9] Heeschen et al.[9] researched the effect of Statin short-term interruption on three patient groups. A “Statin Discontinued” Group, those who stopped Statin on or shortly after hospital admission, “Statin Continued” Group, those who did not stop Statin and “No Statin” Group for those who never used Statin. After one week of Statin discontinuation by the “Statin Discontinued” group, the cardiac risks increased compared to the other two groups, even though the baseline characteristics did not differ significantly between “Statin Discontinued” and “Statin Continued” groups. The study authors concluded that Statin discontinuation had demolished previous benefits of Statin therapy. An additional benefit seen in those who continued Statin therapy compared with those who did not was their hospital admission period was shorter. The drawbacks of the Heeschen et al. [9] study were that its results were based on retrospective data, and the results may have been affected by the lower sample size of the Statin Discontinued Group (86 patients).[9]

It is important to appreciate that the short treatment interruptions may result in a complete discontinuation. Particularly, if patients are asymptomatic and/or do not notice any difference after stopping the medication. [10-13] In a previous study, 13% of those who stopped statins reported “no longer needed” as a reason.[14] Medication use only if there were symptoms was previously reported by 62% of patients with asthma, despite the fact they were prescribed it as a continued therapy irrespective of symptoms.[15]

Another concern for the AMA was pharmacists’ conflict of interest related the CD. The AMA claimed that CD enables the pharmacist to become prescribers and dispensers.[16] This was also reported by participants in a previous study about a theoretical model of CD (i.e. Medication Maintenance).[17] However, the Pharmacy Guild of Australia (PGA) has stated that “the issue of conflict of interest with the pharmacist being both the prescriber and dispenser is addressed by the proposed expansion of the existing continued dispensing provisions, rather than proposing full independent pharmacist prescribing.”[18] However, the potential for conflict of interest may not have been completely eliminated.[19]

GPs’ attitudes towards the CD have not been explored before. It is not clear whether GPs have similar or different views from those of the AMA. It is not essential that an organisation’s view represents its members’ views. For example, in an article in Health IT Outcomes, September 7, 2011 [20] it was reported that 77% of American doctors disagree with the American Medical Association views on a new health policy (i.e. Health reform).

GPs may have mixed views on CD. It has been reported that GPs are frustrated by patients requesting urgent appointments for prescription renewals.[6] In such cases, they may need to squeeze other appointments or they may not be able to see the patient.[6] GPs have also complained about writing owing prescriptions.[21] Further, communication with the pharmacist seeking authorisation to supply an OP may also place more pressure on the GP's schedule. Therefore, GPs may see some benefit for themselves and/or their patients from the CD. Conversely, GPs may see CD as a source of financial concern as it enables patients to obtain an additional supply without the need to visit the doctor.[17, 22] It is worth emphasising that this financial concern seems very limited as the current CD is restricted in terms of its eligible medications and frequency. In addition, GPs may be concerned that CD may delay medical reviews.[17, 22] Provision of an additional supply may result in delays in patients seeking medical reviews. However, when reviewing the safety of supplying through the CD the pharmacist should take into consideration the patient's clinical status and all other medications.[23] In doing so, the pharmacist can identify any significant patient issues that would necessitate referral to a GP or emergency department.[24]

GPs attitudes towards the CD are critical for CD utilisation by their patients. Patients generally see that doctors have a higher authority over their healthcare than pharmacists.[25-28] Therefore, if the doctor advised the patients to not use the CD, it is likely that the patient will take that advice. GPs may not accept the expanded role of pharmacists, particularly those who perceive pharmacists as shopkeepers rather than healthcare professionals, or if they think the new role may adversely affect their authority on patient treatment.[29, 30] They may see pharmacists as competitors and/or be concerned about CD's effect on their relationship with the patient.[17, 31] According to Ernieda et al. [31] GP acceptance of new services by pharmacists depends on the service significance, its benefit to their patients and their practice, and their awareness of pharmacists skills. A low level of CD uptake by community pharmacists has been reported. There were only 2390 CD transactions (0.0016%) among all Pharmaceutical Benefit Scheme (PBS) transactions in the 10 months from 1 September 2013 to 30 June 2014.[32, 33] GPs may improve CD uptake through instructing their patients to use their regular pharmacy to obtain additional supply if they run out of medication before the next scheduled appointment. Therefore, it is important that new services by pharmacists gain GP support.

6.2 Aims

The primary aim of this study was to explore GPs' views about the current CD model of medication supply. Other aims were to obtain GPs' views on CD expansion (to include more medication), and CD extension (more frequent usage) including how CD may be improved.

6.3 Methods

6.3.1 Investigation of GP's attitudes/perceptions towards CD

A self-administered questionnaire was used to collect the data (see Appendix 6.1). The questionnaire contained seven open-ended questions. It was validated for face and content by staff members of pharmacy practice department at School of Pharmacy, Curtin University. The estimated time to complete the questionnaire was 10 minutes. A \$50 gift voucher was offered as an incentive for participation. The target was to obtain approximately 24 respondents, a number that would normally allow the achievement of data saturation.[34] The questionnaire was mailed to a sample of GPs in Western Australia. Phone calls were used as reminders. Receptionists were contacted and asked if they would remind the GP in their practice who received the questionnaire to complete and return it. Participants were considered consented if they returned the questionnaire.

6.3.2 Questionnaire development

Results of previous research on patients' and pharmacists' attitudes to CD informed the development of the questionnaire.[5, 35] The questionnaire contained seven questions. All questions were open ended to allow participants more freedom to express their opinions. The challenge with the questionnaire development was to ask sufficient and appropriate questions to cover the study topic, whilst, at the same time, considering GPs' time constraints. Some similarity with previous questionnaires used in the patient and pharmacist surveys was essential to obtain comparable views from stakeholders. In contrast to the previous surveys, the GP questionnaire did not contain a list of medication to be added to CD eligible medications. Instead, they were asked to suggest any potential medications. This was to keep question number to the lowest possible, and better utilise GP's time, in an attempt to attain a good response rate and avoid potential bias.

6.3.3 Reason for use the mail questionnaire method

Whilst it was initially planned to conduct face-to-face interviews, difficulties in identifying GPs willing to participate in these led to the use of a mail survey instead. The mail questionnaire method has a number of advantages compared to face-to face interviews, namely there is no interviewer bias, it allows the participants to choose a convenient time to respond and is less costly than face to face interviews to conduct.[36-38] In addition, according to Van Geest et al. postal questionnaires had a better response rate compared to other methods such as email or the Internet-based surveys.[39] In the literature, there are a mixed reports regarding the difference in response rates and quality of data obtained from self-administered mail surveys and face-to-face interviews.[40] The more accepted opinion among researchers is that face-face interviews yield better response rates and more detailed answers, particularly with a presence of well trained and motivated interviewer.[41] However, some authors reported comparable results between mail questionnaires and face-face interviews.[40, 42]

6.3.4 Variation in methods

Due to the poor response rate to the initial questionnaire sent out, two additional strategies were used in an attempt to enhance the response rate, (See Figure 6.1).

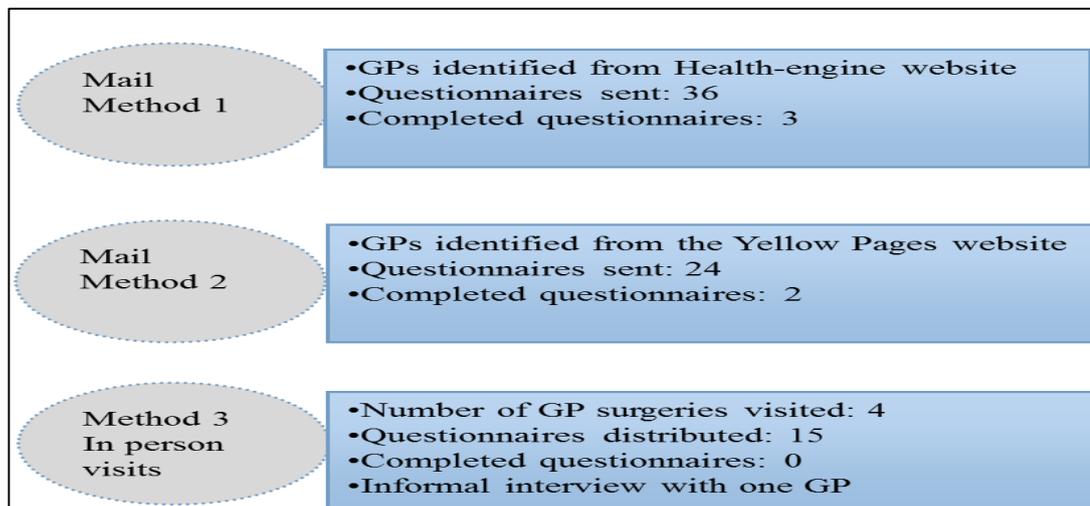


Figure 6.1 Methods diagram

Method 1: GPs identified from Health-engine website

The questionnaire was sent to a sample of 36 GPs practising in Perth, Western Australia. It was sent in late November 2014. The sample pool was identified from all recorded doctors' postal addresses available on the Health Engine website in November 2014 (<https://healthengine.com.au/>). Two lists of 36 doctors were randomly selected using an electronic randomiser (<http://www.randomizer.org/>). The first list was the key one whereas the second list was used as a back-up to replace any ineligible doctors from the first list (because the doctor was a specialist rather than a GP, or more than one GP from the same practice).

Method 2: GPs identified from the Yellow Pages website

As a result of the low response rate using Method 1 and the significant number of undelivered questionnaires returned with a note "the GP has left the address" from the sample list generated from Health Engine, another sample was randomly selected (by the same procedure as the above) from the Yellow Pages website (<https://www.yellowpages.com.au/>). This time an additional step was employed. A phone call was made to ensure that the address was still valid for each doctor and to confirm he/she was a GP, not a specialist. Through this process 20 of the selected doctors were deemed to be ineligible for the survey for the following reasons: the GP had left the practice, had retired or was on leave, the landline phone was disconnected at the time of calling, or in one case the doctor was a specialist, not a GP. Therefore, the substitute list was used to replace the non-eligible doctors. Phone calls were again made to confirm the doctor's eligibility (i.e. a GP not a specialist) and address. Through this process a final list of 24 GPs was compiled. The questionnaire was sent out during February 2015. This was followed by a phone call to confirm that the questionnaire had been received and also to ask the receptionist to remind the GP to complete it if they were willing to do so.

Method 3: In person visits to GP surgeries

Given the disappointing response rate achieved through Method 2 another attempt was made to improve the response rate through in-person visits made by the primary researcher (SA). Four surgeries were visited; one each in Cannington, Bentley, St James, and at Curtin University Bentley campus. Fifteen questionnaires were distributed to the receptionists corresponding to the number of GPs in each surgery. On one occasion, the investigator was invited to see the GP at which time an informal interview was carried out. The visited surgeries were selected through a convenience sampling technique; however all the GPs in these surgeries were targeted.

6.3.5 Ethical approval

This study was approved by The Human Research Ethics Committee of Curtin University (Approval number: PH-17-14 ; See Appendix 6.2).

6.3.6 Data analysis

Answers to the open-ended question were transcribed verbatim and thematically analysed. Answers to each question were coded according to the themes which emerged. Discussion between the study team (PhD candidate and the supervisors) resolved any doubts about the analysis.

6.4 Results

6.4.1 Response rate and demographic information

In addition to one GP recruited through Method 3 (the informal interview), only five questionnaires were returned from the mail surveys, despite reminder phone calls in an attempt to enhance the response rate. There were three respondents from the Method 1, and two from Method 2. There were a total of 11 undelivered surveys from Method 1. In these cases, the questionnaires were resent to other GPs. This meant that a total of 75 questionnaires distributed through the three methods.

The overall response rate was disappointing at just 6.6% (or 8% if the interviewed GP was included). Out of the five questionnaires returned, two respondents did not fill the demographic part. The three GP participants who provided their demographic information were female, aged 45 years or more and had more than 20 years practice experience. The interviewed GP was also female.

6.4.2 GP perceptions of CD based on survey responses

Results are presented under three main categories: attitudes towards current CD, attitudes towards CD expansion, and attitudes towards CD extension. Themes are bold and subthemes are italic and bold.

Since only five GPs participated in this study there were some comments that were made by one participant only. Therefore they cannot be considered as a theme or subtheme. These comments are presented under 'Additional note'.

6.4.2.1 Category A: GPs attitudes towards current CD

Theme A.1: GPs had positive attitudes towards the current CD method

GPs described their experience with CD as a positive experience, and they had not had any issue with CD. However, they also mentioned little awareness of CD by its eligible users. The following examples illustrate this:

“I have had no problem.” GP1

“Very positive.” GP2

“Quite good. I have been aware of patients who have been supplied with both medicine groups. Most patients, especially contraceptive patients, are not aware.” GP3

“.....I have not encountered any problems to date....” GP4

Theme A.2: CD has advantages (Reasons behind positive attitudes)

Subtheme A.2.1: Continuity of treatment

CD would minimise treatment interruption and the resultant consequences. The comments below illustrate this:

“Continuity.” GP2

“Prevent patient from running out.” GP1

“Prevention of cessation of contraception (and risk of pregnancy) if pharmacy can supply urgently.” GP5

Subtheme A.2.2: CD is convenient for patients

It is easier and faster for patients to obtain their medication through CD when they run out of their medication and are unable to see their doctor. See comments below:

“The main benefit for patients is convenience if they forget to book an appointment before script [prescription] runs out.” GP4

”Ease of continuing medication.” GP2

Subtheme A.2.3: CD would minimise GPs being interrupted

This subtheme is further divided to a sub-subtheme and an additional note. As below:

Sub-subtheme A.2.3.1: CD may minimise GP interruption through patients (unnecessary) demand for urgent appointment

Patients who ran out of medications may request an immediate appointment with their doctor. It is not always possible to find time for these patients if the doctor is fully booked. Requests for urgent appointments may interrupt doctors (and other patients) as they have to decrease the time available for the already booked appointments.

“Cannot always fit extras in.” GP1

“It saves having to squeeze patients in for let in appointments and making you run out behind schedule.” GP4

Theme A.3: CD disadvantages

Subtheme A.3.1: Lack of clinical review and/or diagnosis of new disease

Delays in medical review as a result of CD supply were also reported (CD involves supply of a additional supply which may be enough for one month). This subtheme is illustrated below:

“Lack of chance to undertake prevention care if pill patients not reviewed. It’s usually the time for a Pap smear and BP [blood pressure] check. 2. Similar for Statins, monitoring of levels, liver function + CK [Creatine kinase] gets delayed/ missed.” GP3

“...Many people taking Statins have co-morbidities which make medical review with a script very important.....” GP5

“Obviously, if a patient is not seeing a doctor that could be risks such as uncontrolled cholesterol levels and failure to do regular Pap smear. I have not encountered any problem personally.” GP4

“Reviews is being missed...” GP3

“.....Risk of delays in medical review.....” GP5

“...Delays in identification of new health problems (e.g. angina).....” GP5

Subtheme A.3.2: CD may help patients to avoid the doctor’ visit

Some patients may use CD to avoid visiting their doctors to decrease the cost. Pharmacists’ ability to detect such misuse was also cited. See the comments below:

“I am not certain whether patients could use multiple pharmacies to get continuing supplies of medication without clinical review....” GP5

“.....Do pharmacists know if any pharmacy has dispensed? Not sure. Can the patient do this at several places?” GP3

“If patients able to get enough for some time may not attend review appointments particularly if they have to pay Dr’ [doctor] bill.” GP1

Subtheme A.3.3: Lack of patient history

Pharmacists’ ability to verify information obtained from non-regular customers and lack of awareness of other medication or appropriateness of the medication were seen as disadvantages of the current CD. (However, these concerns are addressed through the Pharmaceutical Society of Australia (PSA) guidelines and CD conditions. For example, the need to contact the regular pharmacy in case of non-regular customers, and not supplying patients who were prescribed the medication for less than 6 months are considered). The following comments explain this subtheme:

“Pharmacists may have difficulties assessing the accuracy of information provided by patients (e.g. not for regular pharmacist and last dispensing pharmacy not contactable/ or GP not contactable).....” GP5

“...Lack of awareness of polypharmacy. Lack of awareness of appropriateness of ongoing prescription.” GP5

Subtheme A.3.4: CD does not reflect enough urgency through supply of non-urgent medication such as Statins

Statins were not seen as urgently needed medications. Patients who run out of Statins may stop their Statins until they can see their doctor.

The comments below illustrate this.

“..... I do not think that supply of Statins is an urgent issue which could not wait for a doctor’s appointment....” GP5

“Antihypertensives are more immediate than Statins.” GP2

Theme A.4: Areas for improvement

GPs thought CD could be improved through patients having to visit their doctor within a week of CD supply. They also recommended that the regular doctor must be informed. GPs also suggested the inclusion of more medications under CD. They also recommended limiting the CD supply to just enough until the next available appointment, to ensure patients must visit their doctor.

The following subthemes emerged from GPs comments.

Subtheme A.4.1: Patients must have GP follow-up post CD

This subtheme was reported twice by the same GP while answering two questions:

“I have not encountered any problems with the continued dispensing so am not sure it will be improved, but I think generally the patient should attend the doctor within a week after dispensing of the script in order to make sure they are up to date with blood tests etc.” GP4

“.....patient attends the doctor within the following week for a blood check.” GP4

Subtheme A. 4.2: Informing the GP of medication supply is essential

This subtheme is illustrated by the following comments:

“Better communication with dr’s [doctor’s] surgery as to what has been done.” GP2

“Notify GP if given?” GP3

It should be noted this is already among the CD requirements.

Subtheme A.4.3: Include more medications

CD expansion through including more medications emerged from the following comments.

“Expanded.” GP1

“Antihypertensives (even 7 days as they can get appointment. Heart failure meds [medications]. Insulin. Not huge quantities – enough to get by.” GP1

Additional notes

Additional note 1: There is a need for CD

A GP was aware of situations where patients may run out of their medication and unable to see their doctor. See the following comment:

“...We often have patients who ran out of medications (e.g. antidepressants and antihypertensives who cannot get an appointment to get a script [prescription] at the time...”
GP4

Additional note 2: The regular pharmacist

A GP had already recommended the use of the regular pharmacy to obtain additional supply in urgent situations. See the following comment:

“... I often tell them if they have a regular pharmacist they can get the medication then book an appointment for the script [prescription] within the following week.” GP4

Additional note 3: GPs interruption through Owing Prescription system.

GPs may also be interrupted by pharmacists who call them to authorise supply for the Owing Prescription (OP) system. This usually occurs if patients who ran out of their medications requested a supply from pharmacists without a valid prescription. In this case, the pharmacists may phone the prescriber of the last prescription to obtain a verbal prescription that must be followed by a paper prescription. This is another source of interruption for GPs. See the comment below:

“Not being rang for urgent scripts.” GP3

Additional note 4: system abuse

Potential to obtain medication of abuse. (However, the current CD is not for this type of medications.)

“[Dispensing] drugs of addiction...” GP2

Additional note 5: Conflict of interest

Pharmacists may have financial interest from the CD supply if they independently authorise the supply and dispensing of the medication.

“Pharmacist becomes a prescriber and dispenser – a conflict of interest.” GP5

6.4.2.2 Category B: Attitudes towards CD expansion

These were generally positive with GPs supportive of expanding the medications available under CD.

Theme B.1: CD can be expanded to include more important medications

GPs thought CD may be expanded to include more urgently needed medications and/or medications that cannot be safely stopped. The examples provided were: antihypertensives, diabetes medications, antidepressants and heart failure drugs, however; they suggested supply of small quantities that were only enough until the next appointment with their doctor.

“..... I believe it could be extended to antihypertensive with proves that the patient attends the doctor within the following week for a blood check.” GP4

“Anticonvulsants, medications for control of diabetes. The dispensing should only be for emergency short term supply, not for longer term management.” GP5

“..... SSRIs [Selective Serotonin Reuptake Inhibitors] for short supply.” GP3

6.4.2.3 Category C: Attitudes towards CD extension

GPs thought current CD restriction regarding the frequency of CD use (once/ 12 months) is appropriate. Thus they disagreed with CD extension because of need for the medical review. The following theme emerged from their responses.

Theme C.1: Patients required clinical review before prescription renewal

The participants stressed the importance of clinical assessment before prescription renewal. Therefore, they thought one CD in every 12 months is enough. The comments below illustrate this.

“No, I think it works well.” GP2

“No. Patients need review and doses perhaps need changing.” GP3

“No- the idea of presenting to a GP for script is so that a medical assessment/ review is done to ensure treatment is appropriate and that tests and management of co-morbidities is arranged.” GP5

Additionally, one GP mentioned that availability of CD frequency could be dependent on the amount supplied under CD:

“If it’s only a small quantities twice a year.” GP1

6.4.3 Interview with the GP

One informal interview was undertaken with a GP during one of the primary investigator’s in-person visits to GP surgeries. The GP invited the primary investigator to have a conversation about the study topic (i.e. CD). The GP stated that she was not aware of CD, and to her knowledge none of her patients had been supplied by this method.

6.5 Discussion

Although every reasonable effort was made to improve the response rate (see methods section), this study is disadvantaged by a very low number of respondents. To the best of our knowledge, this study was the first to explore GPs attitudes towards CD. As a method of medication supply, CD does not require a valid prescription. Whilst, the AMA has announced its opposition to CD,[16] it is not clear whether GPs in general have similar or different views about the CD. Results of this study showed that the participants have positive attitudes towards the CD. They were aware that some patients may urgently need medication supply without a valid prescription. They thought CD may prevent treatment interruption when patients were unable to obtain an urgent appointment with their doctor. This is in contrast with the claim that CD is a solution for a “problem that does not exist”.[16] In addition, the participants thought CD may benefit doctors through minimising urgent requests for appointments, and phone calls by pharmacists for prescriptions associated with OP supply. In a previous study, doctors expressed concerns about urgent requests for appointments that can lead to ‘squeezing’ of other appointment times.[6]

The main CD related concerns expressed by GP respondents were potential delays in medical

review and in detection of newly emerging medical issues. This particularly applied if the patient was able to utilise CD from different pharmacies without visiting the GP. Therefore, they highlighted that the patient must see the doctor after CD supply, preferably within the next week.

It is worth emphasising that according to the current model, patients are not allowed to use CD more than once in every 12 months. Therefore if a patient requested supply of a medication from their regular pharmacy more than once in that period, the pharmacist would refuse to supply based on their dispensing history. Moreover, applying the PSA recommendations regarding how to deal with non-regular customers should prevent CD abuse by patients. The PSA recommends that “When the consumer is not a regular customer of the pharmacy, the pharmacy that has dispensed the medicine most recently and regularly should be consulted for the most recent prescriber, an accurate dispensing history and to validate information obtained from the consumer.”[43] The latter addresses in part the concern expressed by GPs regarding pharmacists’ ability to accurately obtain a patient’s medical history. An incentive for pharmacists to ensure patients do not abuse the CD provisions is to avoid claims for reimbursement being declined by the Department of Human Services (DHS). “The DHS-Medicare systems will reject payment for attempted CD supplies made within this 12-month period, provided past CD records are held by DHS-Medicare”.[44]

There was concern by one respondent about conflict of interest that may result from the pharmacist being the prescriber and the dispenser. However, the potential for conflict of interest is less with CD than other forms of pharmacist prescribing. The PGA stated “ the issue of conflict of interest with the pharmacist being both the prescriber and dispenser is addressed by the proposed expansion of the existing continued dispensing provisions, rather than proposing full independent pharmacist prescribing.”[18]

GPs thought that there are potential areas for CD improvement. The respondent GPs suggested more communication with the prescriber, and that the patient should be reviewed by their doctor within a week after CD supply as other ways to improve CD. It seems that if the last recommendation was added to the CD requirements, this would address the GPs’ and AMA’s major concerns related to the CD system. This may lead to more usage of the CD. For example, patients who need their medication and request an urgent appointment with their doctor may be instructed, by their doctors, to obtain their regular medications through CD then book an appointment within a week.

GPs had mixed views about CD expansion and CD extension. GP participants thought CD

may be improved through expanding to other medication classes such as antihypertensive medications, diabetic medications, anticonvulsants and antidepressants, such as SSRIs. This supports the calls of patients for CD to be expanded to include more medication classes.[35, 45] However, the respondent GPs did not support CD extension to be used more than once in a 12 months period. This was in contrast to Statin and OC users who supported a more flexible CD system that can be used whenever it is not possible to see the doctor.[35]

After the informal interview with the GP, the research team suspected that GPs may be unaware of the CD potentially due to low uptake of CD by pharmacists. This was confirmed by the available publications.[32, 33] Therefore to investigate the low uptake of CD by pharmacists the primary investigator conducted informal interviews with pharmacists working in three different community pharmacies in the Cannington area. Outcomes of these interviews are reported as personal communications below. (See Appendix 6.3 for more details)

According to one pharmacist, the “optimistic idea of CD was not so practical”. (Personal communications). The very limited criteria of CD eligibility has been worsened by the fact that many users of Statins and OC (the only CD eligible medication classes) are not eligible to use CD unless they were on a concession status (i.e. have a reduced co-payment for medications). Moreover, OC users who request a supply with an expired prescription (after a year of issue date) “must see their doctor anyway after a year”. (Personal communications) Furthermore, the time-consuming nature and paperwork required for CD make other forms of urgent supply more appealing and convenient. The pharmacists reported not being faced with complaints from GPs about CD after they became aware that CD was a legal process. Whilst, all the pharmacists interviewed thought CD expansion is vital to increasing its usability. (Personal communications)

As with any study, this study was not without its limitations. The crucial limitation was the low response rate, and the respondents were recruited from only one Australian state (Western Australia) which means the study results may not be generalised. We acknowledge that if the questionnaire was distributed to a larger sample this would have helped obtaining a richer data and probability different views. However, this was not practical due to study budget and time constrains. Further, those who did not participate may have had different views to study participants, and the fact that low levels of exposure to CD by GPs are likely to have influenced the respondents’ comments. In addition, in some cases convenience sampling was used, which has its own limitations as a sampling technique (however; this technique did not produce any response). Finally, respondent bias (willing to complete the questionnaire) may suggest a

strong positive bias towards pharmacy, however; the responses showed balanced views. In the study's defence, low response rates are not uncommon in surveys involving healthcare professionals.[46]

In regards to the informal interviews which were not recorded, these were of short duration and notes were made immediately after the interview, to minimise any memory bias.

Future research may focus on the practical and financial aspects of adding new requirements to CD, such as making it essential to see the GP within a certain time interval after CD supply. In other words, how practical they would be to implement will be explored.

6.6 Conclusions

GP participants' views about the CD were generally supportive. There were concerns about CD being used by patients to avoid doctors' appointments and the fact that supply is undertaken without clinical review. However, the CD restriction which does not allow patients to use CD more than once in every 12 months in part addresses these concerns. They thought pharmacists, particularly the patient's regular pharmacist is capable of providing treatment continuity, and that CD offered benefits to GPs in reducing requests for medication-related urgent appointments. They also thought that CD could be improved through patients seeing their doctor within a week after the CD supply for review. The interviewed pharmacists suggested the need for expansion of CD to a broader range of medication to make it more practical and accessible.

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Chapter 7: General Discussion

7.1 Overview

Each of the Chapters 3, 4, 5 and 6 contain their own discussion. Below is a general discussion which covers the overall results of this research project.

7.2 Stakeholders' attitudes towards the Current CD

7.2.1 Patients' attitudes

This research project involved a telephone survey of Statin and/or OC users (See Chapter 3). They indicated strong support for being able to obtain one additional supply of their medications through CD when they are unable to see their doctor to obtain a new prescription. The majority of the respondents did not have any concerns about CD or thought CD presented any undue risk.[1] This support is consistent with consumers' health organisations, and public support for CD.[2-4] CD supporters put a high value on CD convenience for patients, who are unable to obtain a prescription. It also reflects the obvious need for CD.

Fifty-seven percent of the participants selected 'that access to pharmacists is easier than to doctors' as a reason why they were not concerned about CD, in addition to 55.5% of participants who selected 'it (i.e. CD) saves my time.'[1] In contrast to the difficulty to obtain an urgent appointment with doctors, pharmacists are available without an appointment.[5] Interestingly, the participants of pharmacist postal survey and the participants in the GPs survey both agreed with the convenience of CD and acknowledged the difficulty that may be encountered in patients seeing their regular prescriber. As an indication of how patients value the convenience of community pharmacy, in the UK patients at risk of the flu paid for vaccination at pharmacies even though they were eligible for free vaccination at GPs surgeries because that was easier for them.[6] Similarly in Australia, "in many cases, consumers decided to have their vaccination [Queensland Pharmacist Immunization Pilot] in the pharmacy despite the fact they were eligible under the National Immunisation Program and could have returned to their doctor and received the vaccination for free." [7]

The majority of Statin and OC users did not see any risk from obtaining their medication through the CD. They trusted their pharmacist to supply when it is safe and refer to the doctor when it was deemed necessary.[1] Obtaining medication from the regular pharmacist was also supported from a participant in the GPs survey, who said "... I often tell them if they have a regular pharmacist they can get the medication then book an appointment for the script [prescription] within the following week." (GP4). Pharmacists in the postal survey highly

supported CD in the case of regular customers for a range of medication classes. This support indicated that they did not see any risk to supply chronic medications without a valid prescription.

On the other hand, there were a few participants (patient survey) who did not support CD. Those who were concerned about pharmacists' lack of access to health records, privacy issues and/or they thought CD was not safe without doctors' supervision.[1] It is worth mentioning that some pharmacists in the pharmacist postal survey and the participant GPs were also concerned about the lack of access to basic health information such as blood test results. These findings are consistent with the previous studies about barriers to expanding pharmacists' roles.[8, 9] The need for pharmacist access to patients' health records was confirmed by the postal survey results where there were clear and significant differences between pharmacist practices with regular vs. non-regular customers. The participant pharmacists cited the lack of patient history as a reason for not supplying to non-regular customers. According to Services for Australian Rural and Remote Allied Health (SARRAH) "The pharmacist needs to be able to access patient medical records via E-health." [3]

7.2.2 Pharmacists' attitudes (Postal, Vignettes and Informal Interviews)

Results of this project suggested that there were differences between pharmacists' attitudes towards CD before (at the time of the postal survey) and after implementation (when the case vignettes and informal interviews were conducted).

Pre-implementation, the participant pharmacists were highly supportive of the current CD model to supply Statins and OCs to regular customers and, to a lesser extent, non-regular customers. This may be explained by the mutual trust between the pharmacists and their regular customers,[1, 10-12] and pharmacists access to dispensing history of the regular customers.

The pharmacists also specified that CD may alleviate difficulties with the current urgent supply methods. For example, the need to contact the prescriber and obtain a new prescription in case of OP supply and the insufficient amount available through ES. This supports previous calls to enhance the current urgent supply methods.[13, 14]

While pharmacists saw CD as one step forward, they also identified some drawbacks of the current CD. These disadvantages may affect the uptake of CD by community pharmacists. There were signs that the current CD may not strongly appeal to the pharmacists. For example,

they supported the inclusion of other medication classes in place of the currently eligible medications. They believed that other medication classes are more urgently needed than Statins. They also articulated some concerns about potential abuse of CD by patients who may use the CD to avoid doctors' appointments.[11, 14] Further, they also expressed concerns about the lack of access to patients' health records,[15] and about patients confusion regarding CD limitations. In the case of the latter, pharmacists may need to explain to patients why they are able to obtain some of their medications without a prescription while they still need a prescription for other medications.[3] Moreover, pharmacists who participated in this study were concerned about doctors' disapproval of CD. This may depend on how doctors see the CD, they may be concerned about shared patient responsibility that may result from CD.[16] They may also see it as a financial threat.[14]

Another factor that may affect pharmacists' acceptance and use of the CD is the other adopted methods of supply, particularly "in advance supply" and the "alternative method". The "in advance supply" is a modified version of the OP system.[1] The standard OP system requires that the pharmacist must contact the original prescriber to obtain a verbal authorisation or faxed prescription to supply and a follow-up paper prescription that must be posted to the pharmacy within a week of supply. However, using "advanced supply", the pharmacist would supply without contacting the GP and trust the patient to bring a prescription from the prescriber at a later date. It is more likely that this service is available for selected regular customers. For example, those who after several years of interaction with their doctor and their pharmacist, obtained the trust of the pharmacist and the ability to bring a new prescription from the prescriber. In this case, the "in advance supply" may be more convenient for the pharmacist than CD. A similar system of supply was reported by the UK pharmacists (i.e. Loan emergency supply).[11, 17] This system is widely used with regular customers.

The "alternative method" is a two-step method to supply medication, to less trusted customers when the pharmacist thinks that the "in advance supply" is a risky practice because of the significant probability of not obtaining the anticipated prescription (a follow-up prescription).[18] The first step is supplying a limited quantity of the medication as per ES; the patient is charged as if it was a private supply. The second step involves supplying the remaining amount and refunding the patient who has returned with the follow-up prescription. Therefore, pharmacists will choose the most convenient method from five methods: ED, OP, "in advance supply", "alternative model", or CD. In this regard, it seems that the probability of using CD may be low in the following circumstances: (a) for the long-term regular customers in whom "in advance supply" is possible, (b) for customers whose regular prescriber

was contactable at the time of the request for the OP supply, (c) customers who request other Statins/ or OC in addition to other CD ineligible medications (to avoid patient confusion),[19] (d) for patients who themselves are concerned about the CD, (e) to non-regular customers whom their regular prescriber or regular pharmacy are uncontactable,[19] and (f) for medication requests that are considered not urgent by the pharmacist (Statins ,in particular, were mentioned by the pharmacists and the GPs as being less urgent than other chronic medications). It is worth mentioning that the AMA also cited the absence of urgency of Statins when it announced its opposition to CD.[20]

All of the above factors may contribute to the low uptake of the CD. This was confirmed by informal interviews with a small number of community pharmacists who mentioned that currently CD is available to a limited number of eligible patients in practice; principally those on concession status. They also said that CD is not an option in cases where the cost of the medication falls below the standard co-payment of \$37.50, i.e. for non-concessional patients. Moreover, pharmacists who participated in the case vignettes study reported lack of experience and knowledge about the CD. They also expressed concerns about the amount of paperwork to conduct the CD, and in some cases even questioned the need for the CD, according to one participant, “I avoid it, too much paperwork, patient needs to go to Dr [doctor] eventually anyway.” The perception of lack of the need for CD is consistent with AMA claims that CD is a solution for a non-existing problem,[21] although this is not consistent with consumer sentiments captured through the patients survey.[1]

Therefore, it can be concluded that while pharmacists initially welcomed CD prior to implementation, as did consumers, its uptake by pharmacists has been less enthusiastic. This was confirmed by reports of low CD uptake by community pharmacists. According to two reports CD was only used for 0.0016% of all medications supplied under PBS during 10 months (from 1 September 2013 to 30 June 2014). [22, 23]

7.2.3 General Practitioners’ Attitudes to CD

Even though the GP survey had a very low response rate, participant GPs were not against CD. They acknowledged that there are situations where patients are unable to obtain appointments when they run out of medications. One GP reported that she usually advises patients to obtain a supply from their regular pharmacy then book an appointment. This supports a finding of a previous study by Garth et al.[24] where requests for same day appointments were seen as a frustrating issue. According to Garth et al. “One practice manager (Clinic C) sometimes

suggested patients ask the chemist [pharmacist] for an ‘owing-script’ [Owing Prescription OP] and then make the next available appointment with the GP.” [24] However as mentioned by Garth et al.[24], this is in contrast with the AMA claim “The Bill [Continued Dispensing] is effectively fixing a problem that does not exist. GPs currently have arrangements in place to see patients who urgently need a consultation to renew prescriptions or get new prescriptions.”[21] In addition, the participant GPs reported some potential benefits from the CD, for example; CD would minimise the requests for urgent appointments and phone calls by pharmacists for the OP supply. This confirms the reported frustrations of GPs regarding unpaid efforts to write owing prescriptions and delays resulting from phone calls. [13, 25, 26]

7.2.4 Summary of stakeholders’ attitudes

Overall, based on the results of this research it can be concluded that generally the stakeholders supported the introduction of the current CD supply mechanism. This is in agreement with the key driver for the CD implementation, i.e. a convenient way to obtain medication when getting an appointment with the prescriber is not practical. However, all stakeholders who participated in this project emphasised the need to modify CD in order to achieve its goals. A discussion of these views is presented below.

7.3 Stakeholders’ attitudes towards a modified version of the CD

7.3.1 CD extension (Increased availability)

Mixed views were expressed on CD extensions. Whilst the Statin and OC users reported the strongest support for CD extension (i.e. to be available more frequently), [27] the limited GPs who participated in this study generally disagreed with any change in CD utilisation frequency and supported the status quo (i.e. once in any 12 months period). These differences need to be interpreted with caution given lower number (and hence representation) of GPs. More than half (51.1%) of the CD eligible users supported CD availability until it is possible to see the doctor.[27] This may reflect the difficulty of obtaining an urgent appointment with their doctors. It may also indicate the high frequency of running out of medications. This is confirmed by pharmacist postal survey results, where the participants reported facing urgent medication requests on a weekly, if not daily basis. However, only 4.4% of pharmacists supported CD availability until it is possible for the patient to obtain a renewed prescription. This may be because pharmacists were concerned about CD abuse by patients to avoid doctor visits. This is consistent with GPs survey results. The GPs thought that more CD may not be

safe and may affect the regular check-ups or could lead to patient abuse of the CD, to avoid appointments with their doctors. Continued use of CD was cited as a source of concern for GPs in a previous study which evaluated a theoretical model of CD (i.e. Medication Maintenance).[14]

The participant pharmacists were divided in their views about CD extension. Supporters of the current CD utilisation number cited the need for medical review and the potential abuse by patients to avoid the regular check-ups, which is consistent with GP views. On the other hand, pharmacists who supported more frequent utilisation of the CD model quoted the usual six months prescription lifespan allows the probability of running out twice a year. Therefore, it seems more appropriate and practical to allow pharmacists to decide on the number of CD utilisations on a case by case basis.

7.3.2 CD expansion (Increased medication coverage)

All stakeholders agreed on the need to increase CD eligible medications. This reflected the main disadvantage of the current CD. In addition to being restricted to only two medication classes, the many theoretically eligible customers were not eligible in practice, as explained by pharmacists. This finding is consistent with previous calls to expand the CD.[28] This is because of concerns about patients' confusion if they requested both CD eligible and ineligible medications.[19] Therefore, patients,[27] pharmacist and GPs agreed with CD expansion to include more medications.

Patients (Statin and OC users) supported, to varying degrees, the inclusion of all medications from a list of 14 medication classes presented to them (See Table 3.5). Nonetheless they were more supportive for medications without abuse potential.[27] The support to include medications with abuse potential was comparable in both patient and pharmacist surveys. While a GP was concerned that CD may be used to supply this type of medications, very few pharmacists supported the inclusion of these medications. It is worth noting that 48% of patients supported dispensing of anti-anxiety medications through the CD. This may reflect an awareness that this type of medication has legitimate uses and/or should not be stopped abruptly.[27]

Pharmacists also supported CD expansion through agreement to include the majority of medications included in a list of 17 medication classes for regular customers (see Table 4.4). However, they supported a narrower range of medications in case of non-regular customers. According to the pharmacists, asthma and antihypertensive medications were more suitable

medications for supply under CD than the Statins and OCs. Pharmacies are the most and easiest accessible point of healthcare to many patients with chronic disease(s). Patients see the pharmacist every time they need their regular medication. Previous studies highlighted the central role of pharmacists in chronic disease management. Pharmacists' involvement enhances patient adherence and assists patients in achieving better treatment outcomes.[29-31] Naik-Panvelkar et al.[32] studied Pharmacy Asthma Management Service, which is a "comprehensive patient-focused specialised model of asthma management in primary health care" in Australia. Even though that study was limited by recruiting patients who have utilised the service which may have biased the results, participants strongly supported the pharmacist role and reported increased awareness of their asthma and its medications. They also reported that the service had increased their asthma self-management ability.

Comparing patients with pharmacist attitudes indicated that their support was comparable for some medications and different for others. For example, 75.4% of the patients and 73.8% of the pharmacists supported inclusion of arthritis medications while 48.2% of the patients and 27.3% of the pharmacists supported the inclusion of anti-anxiety medications.[27] These results suggest that whilst patients were motivated by their need for convenient access to medications, pharmacists may be affected by concerns about overuse or abuse of such medications. This has been confirmed by pharmacists' support for dispensing antidepressants through the CD method to regular customers, which was less than that of patients with depression. It is worth mentioning that this support by pharmacists was stronger than the support by patients without depression. This may be explained in part by their awareness of clinical advice to avoid premature discontinuation of antidepressants.[27, 33] This recommendation may also explain why some GPs suggested SSRI (used as antidepressants) could be included within the CD eligible medications. Hoti reported that patients may experience behavioural difficulties if they run out of their medication.[13]

The participant GPs also supported inclusion of more medications that usually need an urgent supply such as antihypertensive and diabetic medications. This indicated that doctors are supportive of continuity of care for critical treatment, and they were also concerned about patient non-adherence to their chronic disease medications.[34]

7.3.3 Disadvantages of other methods of medication supply

Identifying drawbacks of the currently available methods of supply namely ES and OP methods was among the aims of this project. This was indirectly achieved through

pharmacists' responses to suggested solutions to address the issue of urgent medication requests. In these responses, they suggested modifications to the ES and OP methods in addition to the repeat system. These modifications, in fact, reflected the disadvantages of these methods. The waste production and the very limited quantity of the ES, and difficulty to obtain follow-up prescriptions for the OP system were the most commonly reported disadvantages of the current urgent supply methods. The participant GPs reported phone calls to authorise OP supply as a source of interruption. The commonly reported disadvantages from this study have been previously described in the Australian literature.[13, 14] This indicates that these issues still need solutions. In this regard, the comments from the pharmacist postal survey suggested some areas in the current urgent supply systems that needed to be modified to address the issue of medication requests without a valid prescription. The amount of supply available through ES was deemed insufficient, and the pharmacists called to increase this amount to one month supply or at least until the next available appointment. A call for such a change has been reported previously.[13] For the OP system, there were calls for legalisation changes to allow the use of faxed or emailed prescriptions. In addition to more cooperation by doctors with the OP system, or allowing nurses to renew the prescription based on previous instructions by the GP. It is worth mentioning that doctors have shown their frustration with the OP system.[13, 25, 35] Moreover, more trust in pharmacists through prescribing rights to legally prescribe, dependently or independently, when access to the original prescriber or a new prescription were impractical. Despite the similarity in basic pharmacy education curriculum between Australia and the UK, the Australian pharmacists have not been granted independent prescribing rights as have their counterparts in the UK.[36]

7.4 Case vignette study – Appropriate use of CD

The fourth aim of this project was to assess pharmacists' ability to identify the cases where CD is not appropriate. To achieve this goal, a case vignette method was used. A group of 30 pharmacists responded to case vignettes scenarios. In general, the majority of the participants identified the inappropriate situations. Surprisingly for one scenario involving a non-regular customer, 53.3% of the respondents did not identify that the CD was not appropriate without contacting the regular pharmacy (or pharmacy of last dispensing) in the case of non-regular customers. This was consistent with the pharmacist postal survey results where 51.4% of the respondents agreed to use CD to supply Statins to non-regular customers. It is worth mentioning that the PSA guidelines recommended contacting the regular pharmacy of the non-regular customer to verify any information obtained from the customer.[37] Therefore, the fact that over the half of the participants in each study would supply Statins and/or OCs to non-

regular customers may be explained by pharmacists wanting to supply medications through a less costly method. For this customer type, the OP is not possible (the original prescriber is uncontactable), the “in advance supply” poses a high risk of not obtaining a follow-up prescription,[1, 14] and the ES method is costly and it provides insufficient quantity,[13] (ES was the least preferred option to supply by case vignettes respondents). In these instances there is a higher probability of the pharmacist using the CD method, particularly, if the pharmacist is able to contact the regular pharmacy of the consumer. Other factors may affect pharmacists’ decision to supply to non-regular customers, such as the customer age and health status, and the ability of the consumer to provide sufficient information about their medical and medication histories.[38] Pharmacists should only supply if it is safe to do so, and they have the skills to identify those cases where a referral to a doctor is necessary.[1]

Participants in the case vignettes study reported the circumstances where they thought CD is inappropriate. These included situations where there was a need for a medical review, if the patient was not stable on the medication or in case of recent hospitalisation. This is consistent with pharmacist and GP surveys, where participants cited similar concerns about the CD. The fear of system abuse by patients was mentioned in every survey in this project. It is worth mentioning that pharmacists reported ‘not supply’, as a usual practice when a second request for the medication without a prescription was made before any medical review. Additionally, the Department of Human Services Medicare systems may help to identify overuse of CD (more than once in any 12 months) through refusing of reimbursement claims by pharmacists.[19] Nevertheless, abuse of the system, to avoid doctor visits, requires a more comprehensive solution that involves both patient education,[39] and full implementation of electronic health record.[40]

The case vignettes study also collected additional pharmacists’ views about the CD. These views were collected eight months after CD implementation. Therefore, they provide more updated insights about the CD than those of the pharmacist postal survey that was carried out before the actual implementation. The majority of case vignette participants who commented about their experience with CD said they did not use it, and/or were not aware of CD process “Have not done any continued dispensing- extra workload to contact prescriber- better alternatives available/ not unhappy with current alternatives” and “Do not quite understand the process”. It is worth emphasising that while these views may not represent those who did not comment on their experience with CD, it could be concluded that low awareness was not a barrier for the majority of pharmacists to identify when CD was appropriate and when it was not. This confirms that pharmacists can conduct CD without any training.[41] However,

training may be required for those who still do not understand the process. Participants also thought CD is an unnecessary method, and they preferred other alternatives. The amount of paperwork needed to conduct CD and its limitation may have influenced these views. This was reflected by participant's answers about what would be their preferred course of action. On average, only 43.3% of the participants selected the CD method of medication supply as their preferred course of action even though CD was appropriate for Scenarios 1, 3 and 4. In the pharmacist postal survey, the average support to use CD was 88.5% (89.1 % for Statins and 87.8% for OCs). Therefore, the decline in CD support between the postal and the case vignettes surveys may be explained that the high expectations of CD before implementation had been negatively affected by CD requirements and/or its limitation and/or presence of other available supply methods. It has been reported that there has been a low uptake of the CD by the community pharmacists.[23] While emphasising that this low uptake may be simply a result of the low number of eligible cases to utilise the CD, it could be a result of pharmacists' unwillingness to use the CD method, as a consequence of the reasons mentioned above.

7.5 Overarching discussion

Patients, GPs and pharmacists have justified CD implementation. Collectively, they believe that CD is a convenient way to obtain medications if urgently needed and no GP appointment is available or practical. The patients' survey results confirmed previous literature findings that access to pharmacists is easier as no appointment is required to see a pharmacist in contrast to a doctor. Patients reported that they would stop taking their medication until they can see their doctor. In this regard, one GP, who was unable to provide an urgent appointment, has advised patients to obtain a supply from the regular pharmacist. The pharmacists reported that they frequently receive requests to supply without a valid prescription, mostly because it is impractical for patients to see the original prescriber. Patients, pharmacists and GPs thought CD will prevent treatment interruptions. Whilst pharmacists thought CD will minimise the administrative burden to obtain a follow-up prescription after they use 'in-advance' supply, doctors suggested that CD would remove the need to squeeze their schedule to allow for urgent appointments for prescription renewals or being interrupted by phone calls from pharmacists seeking OP supply authorisation.

Participants expressed some concerns about the current CD scheme. Firstly, CD abuse by patients to avoid GP visits was the most frequently reported concern by all three stakeholder groups. However, the current CD system is only usable once in any 12 months period, which makes such abuse of limited significance. Secondly, all stakeholder groups had concerns about

pharmacists' inability to view patients' medical records and lack of information about patients' history. It seems that lack of patient history would result in more decision to not supply by pharmacists to non-regular customers. Thirdly, the current CD system does not include medications which require emergency supply and does not cover an appropriate range of medications. Pharmacists and GPs thought that Statins do not represent medications with urgent need. Those healthcare professionals and the patients thought the current CD is too restricted regarding its eligible medications. Finally, pharmacists completing the case vignettes study were concerned about CD paperwork and perceived CD as time consuming process. Based on these concerns, the stakeholders suggested a number of areas for improvement in the current CD.

The most agreed area of improvement amongst participants was CD expansion to include other medication classes. Medications to treat hypertension, asthma, diabetes mellitus (oral hypoglycaemics), depression and other drugs were supported for inclusions by patients and pharmacists. GPs suggested antihypertensives, anticonvulsants and antidepressants. The other area of improvement was CD extension. While the majority of pharmacists and GPs did not support a more frequent use of CD rather than the currently allowable frequency of once a year (12 months), the patients demanded more frequent CD. It is worth emphasising that while patients' motivation of this support was CD convenience, the healthcare professionals were concerned about CD abuse or need for medical review. In this regard, the GPs suggested a post CD visit to the prescriber to ensure patient safety. However, it seems that this visit may not be necessary because patients' safety was a priority for pharmacists in both postal and case vignettes studies. Safety of the patient or the need for medical review were the most cited reasons for non-supply of medication by pharmacists in the case vignettes study.

7.6 Limitations of this research project

Limitations of each survey were included in the Discussion sections of Chapters 3, 4, 5 and 6.

This project has the advantages of being first in this field, and it involved patients and pharmacists from across Australia, as well as GPs from Western Australia. It could have been strengthened by better response rates to both the pharmacist and GP surveys. However, common themes captured through triangulation of data from the four components of the research, suggest that it has been successful in identifying stakeholders' views on the current CD system, and provides evidence for the need for its review and potential modification. Representativeness may have also been improved through conducting the study in other

Australian states (for case vignettes and GP surveys). However, similar attitudes are reasonable to expect given the similarities in training, roles and overall professional practice of Australian pharmacists.

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Chapter 8: Conclusions and Recommendations

8.1 Conclusions

Results of this project have shown a general support for the current CD model of medication supply by the majority of respondents from all the three groups of stakeholders. Patients, in particular, followed by the pharmacists supported the current and an expanded versions of the CD. We could not reject research hypotheses (H1 and H2) which stated that patients' concern regarding CD are affected by their perception of risk and disease sufferers will be more supportive of the inclusion of their medication, respectively. We also could not reject research hypotheses (H3, H5 and H6) because we found significance difference between pharmacists' decisions to supply according to customer type (H3), and their support for the use of CD according customer type (H5) and pharmacists' support to include more medication according to their demographic variables (H6). However, we could reject hypothesis (H4) which stated that pharmacists' reported practice will not be associated with their demographic variables. The participating GPs reported the need for CD when an appointment with the GP is not practical. This rejects hypothesis (H8), which stated that GPs will not support CD based on the argument raised by the AMA. However, this should be perceived with caution due to the very low response rate. All stakeholders agreed that CD has some benefits for patients, pharmacists and doctors. The main advantages seen for CD were: it is a convenience method to obtain medications when an appointment with a doctor is not feasible, it removes the administrative burden to obtain a prescription, and it decreases the demand for urgent appointments.

Based on the results of case vignette study it appeared that pharmacists generally conducted CD in accordance with the PSA guidelines. Importantly, they did not use CD method if there was a need for a medical review. Pharmacists decisions to use CD were not associated with their demographic information (age, gender, years of practice). Thus, hypothesis (H7), which stated that these decisions will differ according to pharmacists' demographic variables, could not be rejected. Nevertheless, this could have resulted from sample size (30 pharmacists).

All stakeholders supported CD expansion to include more medications. Among pharmacists and patients there was general agreement to support most of the medications suggested by the research team with the exception of medications with abuse potential such as opioids. GPs also suggested the addition medications that were more urgently need or cannot be abruptly stopped such as antihypertensive and antidepressants.

Regarding CD extension to be more frequently usable, this was highly supported by patients,

less supported by pharmacists, and it was not supported by GPs. Based on the reasons cited to support/ oppose CD extension, it seems that CD frequency would be more practical if it was left to pharmacists' discretion.

Pharmacists had different practices of urgent supply according to customer, medication and prescription type. While pharmacists reported facing requests for urgent supply on a daily basis from regular and non-regular customers, they were partial to supplying medications to their regular customers. They also reported that they would be less likely to use CD in the case of non-regular compared to regular customers. It is worth mentioning that patients who did not have a regular pharmacy reported running out of their medications more frequently than those who had a regular pharmacy. Therefore, it seems CD may not be used to supply medication to those without a regular pharmacy as much as those with a regular pharmacy. This is a significant issue, bearing in mind that interstate travel without medication was among the most reported reasons for requests for urgent supply medication.

The results of this research suggest that the current CD is not a practical method. It does not have enough eligible medications and is restricted in its utility, and it is more complex to undertake compared with other alternative methods for urgent supply. Therefore, whilst CD is safe as long as safeguarded guidelines and medical reviews were maintained, the current CD needs to be amended in order to achieve its main goal of allowing medication continuity when a new prescription/appointment are unavailable.

Better communication between doctors, doctors and patients, and doctors and pharmacist were all suggested as means of enhancing patients' adherence to their medications. As an example, pharmacists were highly supportive of 'prescriber annotation' of prescriptions which would allow them to exclude unsuitable patients from CD. Therefore, results of this project indicate that many pharmacists support CD as a means to improve access to medications and ensure a safe continuation of the treatment when patients are unable to obtain an appointment with their doctor. Result also confirm that pharmacists are aware that not all patients are suitable for the CD, and they support better communications with doctors to exclude those patients.

At the same time, the results of this project suggest that not all pharmacists share the same enthusiasm for CD and this may influence the uptake of CD by the pharmacists. In particular, those who felt that they are already providing services for which they are not appropriately remunerated or who did not see a need for CD. Pharmacists who were satisfied with other methods of medication supply were less likely to use it, particularly those who do not see the need for the CD, or those who have concerns about the amount of paperwork associated with

CD. Pharmacists who do not see an urgency for Statin requests may not use it. Pharmacists concerned about patients' confusion of CD may use alternatives to supply Statins and OCs, specifically when the patient requests another medication with their Statin or OC.

While findings of this research may be limited by low response rates in the pharmacist and (in particular) GP surveys, it did achieve its aims. The research explored patients' and pharmacists' attitudes on the CD pre-implementation, and then it explored pharmacists' and GPs' attitudes post-implementation. In doing so, this research project has identified a change in pharmacists' attitudes as a result CD introduction. The research also has identified issues with current CD that need to be addressed in order to make CD a rationale solution to improve urgent access to medication.

This research project has also identified some disadvantages of and improvement areas for other currently available methods to supply, namely OP, ES and the repeat system. The issues with OP system were stopping patients' abuse of this system, through applying dispensing fees, and allowing the use faxed or emailed prescriptions. The amount of supply with ES system is not enough even to allow patients time to see their doctor where the demand for appointments is higher than the available service. Hence, there were calls by the pharmacists to increase this quantity to be enough for at least one week. Regarding the repeat system, the pharmacists have called for non-medical control of the repeat system through allowing nurse practitioners to write repeat prescriptions. There were also suggestions to prolong the lifespan of the prescription and increase the number of repeats.

While pharmacists are waiting for changes in the currently available systems, some are using an alternative way to satisfy their customers without breaking the law (See Section 4.3.3.6). In this alternative method the customer is provided with the minimum applicable quantity of the medication and required to pay the full cost (i.e. ES) and then when the customer presents a new valid prescription they are provided with the remaining quantity and either pay or are refunded any difference between ES and PBS co-payments (i.e. OP).

As a main conclusion of this project, whilst CD is seen, by stakeholders, as a forward step for more convenient urgent access to medications, it has several areas that could be improved. These are addressed in the recommendations below.

8.2 Recommendations

Based on the findings of this research the following recommendations are made:

Recommendation 1: Current CD requires a revision

(See sections: 3.7.9.1, 3.7.9.2, 4.5.4.4, 4.5.4.6, 5.5 and 6.4.2.2)

Findings from this project suggest that a revision of the current CD model is required to enhance its uptake. This revision would need to include eligible medications under CD, frequency of CD use, greater pharmacist autonomy, improved communication between pharmacists and GPs, and reduced administrative burden.

Recommendation 2: CD should contain more eligible medications

(See sections: 3.7.9.1, 3.7.9.2, 4.5.4.4, 4.5.4.6, 5.5 and 6.4.2.2)

The most appealing modification to the current CD model is the addition of more eligible medications. The majority of stakeholders who participated in this project supported CD expansion. The high level of stakeholder support for certain chronic medications requires a critical review aimed at improving access to these medications. Expansion of CD may be achieved by providing regular pharmacists with greater flexibility to continue a broader range of medication, whilst referring patients for a medical review when it is deemed necessary based on their clinical status. As such, the CD list of eligible medications needs to reflect patients' needs, whilst enabling patients to utilise CD for all their medications, except for a limited few. This would minimise pharmacist avoidance of CD for patients who run out of multiple medications. Which medications may be included requires further research, however the medications supported by this project's participants may be used as a starting point.

Recommendation 3: Pharmacists should be given control over the CD utilisation frequency

(See section: 4.5.4.7)

The CD restriction of one supply in any 12 month period is another area for potential modification. According to different and mixed opinions collected from stakeholders in this study, it seems that one additional supply after the completion of each set of repeats may be more suitable. In this case, patients who have five repeats would potentially be able to use CD twice a year and patients with 11 repeats would have only one potential CD provision per a year. However, this should be used as a guide and pharmacists should be allowed to use/ refuse CD based on their clinical discretion.

Recommendation 4: The original prescriber should be able to exclude unsuitable patients
(See section: 4.5.4.9)

It is also suggested that provision be made to allow doctors to exclude patients for whom they believe CD is not clinically appropriate. This could be achieved through adding an additional checkbox on the prescription to notify the pharmacist that the patient is “Not Eligible” for CD on clinical grounds.

Recommendation 5: Post CD supply visit to the GP
(See section: 6.4.2.1)

Another amendment, suggested by the participating GPs, was CD utilisers must see their doctor within a week of CD supply. This suggestion would allow continuation of treatment and would ensure a convenient medical review. It is also an appropriate recommendation for patients who had five or more repeats as they are likely not to have visited their doctor for six months or more. It is worth mentioning that a visit within one week post CD supply may be not practical because of long waiting times as reported in pharmacists’ postal survey.

Recommendation 6: Current CD requires more clarifications
(See sections: 4.4.3.1, 4.4.3.2, 4.5.4.7, 5.4.5 and 6.4.2)

Other areas that need improvement are the potential ‘grey’ areas of current CD model. For example, CD may only be used when there is an “urgent” need for the medication, and it is “impractical” to obtain a prescription. The possible differences between the pharmacist’s estimation of what is “urgent” and what is “impractical” need clarification in the guidelines. Some pharmacist and GP participants did not think Statins require urgent supply. Moreover, in the postal survey, pharmacists reported reasons why patients requested medication supply without a valid prescription. There were reasons that needed to be clarified as to whether they fitted within “impractical” or not. For example, if the patient is busy at work or has a financial reason. Another example if the patient refused to see another doctor to obtain a prescription because they prefer to visit their regular doctor. In this case, while it is impractical to obtain a prescription from the original doctor, the prescription could be obtained from another medical practitioner. In other words, there are situations where patients may make requests based on their preference (not to visit the GP to get a new prescription) rather than it being impractical to do so. It is worth stating, as previously mentioned in the literature review section, that patients with chronic diseases prefer to see their regular doctor.

Recommendation 7: Pharmacists should be remunerated for the service

(See section: 4.5.4.3)

Pharmacist remuneration for CD should be considered. CD is reported to take more time and effort than the normal dispensing of original and repeat prescriptions. This is due to the fact that in evaluating the appropriateness of CD the pharmacist is required to undertake a comprehensive medication review. Therefore, pharmacists should be remunerated for their time whether they decide to use CD or refer to a GP. This would remove any conflict of interest that may be associated with CD supply. Moreover, pharmacist's remuneration may be justified by the potential role of CD in minimising unnecessary visits to GPs, emergency departments, or after-hours clinics.

Recommendation 8: Better use of community pharmacists' skills

(See section: 4.5.4.10)

As indicated by results of this project, pharmacists are the first option for patients to obtain medications when they run out and are unable to see their doctor. The pharmacist is being trusted by patients and doctors to continue medication supply in urgent cases. Thus, better use of the pharmacists may allow avoidance of unnecessary visits to doctors or the use of other health services. In this regard, pharmacists may be able to identify the urgency of the medical review after CD supply.

Recommendation 9: Better use of Technology

(See section: 4.5.4.10)

Additional use of information and communication technology (ICT) may help improve timely access to medication for all patients regardless of whether they are regular or not regular customers of the pharmacy. For example, email technology through smart mobile phones would make communication between pharmacists and doctors easier and less interruptive process. Although not all GPs and pharmacists would be interested in this service, it would make the communication possible even after-hours or if the doctor was away. Communication through the internet would allow pharmacists to access medical records and update the records. The technology of SMS (Short Message Service) from dispensing computers may be used to remind patients to book an appointment to renew their medication (This service is currently used by some pharmacies in Australia). Full implementation of electronic transfer of prescriptions is another field where use of technology could improve urgent access to medication. Currently in cases where electronic transfer of prescription is not enabled, if a

pharmacist contacts the original prescriber about a patient requesting a medication without a valid prescription, the prescriber needs to write a prescription, and then send it by mail. However in case of secure electronic transfer of prescriptions, the prescription would be instantly available. This would enable the pharmacist to supply and claim reimbursement from the PBS without the frustration of the current OP system. Optimum utilisation of the electronic health record would address various stakeholder concerns about information availability to pharmacists.

Recommendation10: Pharmacist training

(See section: 5.5)

Currently, pharmacists are not required to undergo training to conduct CD. However, in light of the results of the case vignette study, it does appear that some pharmacists may require training in the provisions and the mechanics of the current CD system.

8.3 Recommendations for future research

There is a need to assess whether, in fact, CD has impacted on medication adherence and persistence, unplanned hospital admission due to discontinuation of therapy, requests for urgent appointments and number of visits to emergency departments (just to obtain a prescription for the ongoing medications). CD's impact on access to medication in remote and rural areas is another area for future research.

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Note: Thesis bibliography contains all the reference used in alphabetic order, please see Reference Section at end of Chapters 1-7 for a numbered list.

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I would be pleased to hear from any copyright owner who has been omitted or incorrectly acknowledged.

Appendices

Please note the first number is the Chapter number, the second number is the Appendix number

Appendix 3.1 Permission from Co-authors for paper one and two

1. Permission form Professor Jeffery Hughes

Curtin University
School of Pharmacy

I, Professor Jeffery David Hughes, as a co-author of the articles below, I give permission to Salem Hasn Abukres (a PhD candidate, under my supervision) to re-produce the articles in his PhD Thesis, providing that the articles are fully and correctly cited, and obtain other needed permissions. I understand and do not object to him depositing his thesis in espace@Curtin.

1. Abukres SH, Hoti K, and Hughes JD. Patient attitudes towards a new role for pharmacists: Continued dispensing. *Patient Preference and Adherence*, 2014. 8, 1143-1151 DOI: <http://dx.doi.org/10.2147/PPA.S66719>
2. Abukres SH, Hoti K, and Hughes JD. Continued dispensing: What medications do patients believe should be available? *PeerJ*. 2015; 3: p.:e924 DOI: <https://dx.doi.org/10.7717/peerj.924>

Name: Prof Jeffery David Hughes

Signature:



Date: 21st June 2015

2. Permission from Dr Kreshnik Hoti

Curtin University
School of Pharmacy

I, Dr Kreshnik Hoti, as a co-author of the articles below, I give permission to Salem Hasn Abukres (a PhD candidate, under my co-supervision) to re-produce the articles in his PhD Thesis, providing that the articles are fully and correctly cited, and obtain other needed permissions. I understand and do not do not object to him depositing his thesis in espace@Curtin.

1. Abukres SH, Hoti K, and Hughes JD. Patient attitudes towards a new role for pharmacists: Continued dispensing. Patient Preference and Adherence, 2014. 8, 1143-1151 DOI: <http://dx.doi.org/10.2147/PPA.S66719>
2. Abukres SH, Hoti K, and Hughes JD. Continued dispensing: What medications do patients believe should be available? PeerJ. 2015; 3: p.:e924 DOI: <https://dx.doi.org/10.7717/peerj.924>

Name: Dr Kreshnik Hoti

Signature: 

Date: 21st June 2015

Appendix 3.2 Ethics approval for Patients Survey



Memorandum

To	Salem Abukres
From	Alison Smith, Form C Coordinator
Subject	Protocol Approval PH-06-13
Date	13 June 2013
Copy	Jeff Hughes, Kreshnik Hoti

Office of Research and Development
Human Research Ethics Committee
Telephone 9266 2784
Facsimile 9266 3793
Email hrec@curtin.edu.au

Thank you for your "Form C Application for Approval of Research with Low Risk (Ethical Requirements)" for the project titled "Stakeholders' attitudes (patients) towards continued dispensing". On behalf of the Human Research Ethics Committee, I am authorised to inform you that the project is approved.

Approval of this project is for a period of 4 years **13/06/2013 to 13/06/2017**.

Your approval has the following conditions:

- (i) Annual progress reports on the project must be submitted to the Ethics Office.
- (ii) It is your responsibility, as the researcher, to meet the conditions outlined above and to retain the necessary records demonstrating that these have been completed.**

The approval number for your project is **PH-06-13**. Please quote this number in any future correspondence. If at any time during the approval term changes/amendments occur, or if a serious or unexpected adverse event occurs, please advise me immediately.

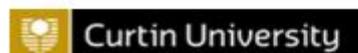
Sincerely,

Alison Smith
Research & Development Support Coordinator
School of Pharmacy

Please Note: The following standard statement must be included in the information sheet to participants:
This study has been approved under Curtin University's process for lower-risk Studies (Approval Number PH-06-13). This process complies with the National Statement on Ethical Conduct in Human Research (Chapter 5.1.7 and Chapters 5.1.18-5.1.21). For further information on this study contact the researchers named above or the Curtin University Human Research Ethics Committee. c/- Office of Research and Development, Curtin University, GPO Box U1987, Perth 6845 or by telephoning 9266 9223 or by emailing hrec@curtin.edu.au.

CRICOS Provider Code 00301J

Appendix 3.3 Information sheet and Questionnaire for Patients Survey



QUESTIONNAIRE FOR CUSTOMERS VIEW ABOUT CONTINUED DISPENSING

Hi, my name is () and I am calling on behalf of School of Pharmacy at Curtin University, Perth, Western Australia. Can I speak to an adult, please? *(If the answer is Yes, continue if No please ask: Is there anyone 18 years or older that I can speak to). If the answer No to both: Thank you and Goodbye.*

You were selected randomly from the public phone directory.

If needed please introduce yourself again and who you represent (as above)

The reason for this call is to obtain your opinion about a new policy that would allow pharmacists to dispense one additional supply of medication without the need for a new prescription. To be entitled to this additional supply, patients need to have been using their medicine for 6 months or more. This process is called **continued dispensing**.

Your opinion about this policy would be much appreciated, so we can transfer the public voice to policy makers. In order to get your opinion we need to ask you a few questions. This project has been approved by Curtin University Human Research Ethics Committee. *The Human Research Ethics Committee (Secretary) may be contacted should you wish to make a complaint on ethical grounds (if the respondent wishes to contact the ethics committee please provide the phone number (08) 9266 2784 and ask them to quote the reference number PH-06-13). A written information sheet is available on request. Would you like a written information sheet be sent to you? YES (log into respondents requiring additional information sheet register) NO (please continue)*

There will be no right or wrong answers and all your answers will be treated with strict confidence. Further, no personal or identifiable details will be collected during the interview.

To be eligible to participate in this survey, you need to be **18 years or older** and to be currently using a prescription medicine (**STATIN**) to *lower your cholesterol/lipids* and /or an *oral contraceptive* medicine for *6 months or more*.

Eligibility: YES (please continue); if **NO** (not eligible): Is there anyone in the household that I can speak to who regularly takes a medication to lower cholesterol or an oral contraceptive?
If No: Thank you for your time. Unfortunately you do not classify for this study. Goodbye.)

It is estimated that this interview will take about **15 minutes**. **Would you like to participate in this interview?**

Yes Remind the participant that he/she can choose NOT to proceed at any time during the interview. Double check the eligibility and go to question **number 1**

No (Please go to **question A**)

A. Would you prefer we call you at another time that is more convenient to you?

If Yes; please write what time (Log into convenient call register) and call at that time.

If No: thank you and goodbye.

Note for the interviewer: If the person appears to need assistance, ask if he/she would like discuss participation with someone who could assist them in answering the interview questions. If the person who could assist him/her is not there, ask about a convenient time you could call back. Record convenient time and log into convenient call register: _____)

Now, I will ask you some general questions. If you feel uncomfortable answering any of the questions, please decline to do so.

Q1: Which age group do you fall into? (please tick the appropriate box)

18-20	21-30	31-40	41-50	51-60	61-70	71-80	> 80

Q2: Gender Male Female

Q3 In which state/territory do you live?

ACT QLD NSW NT SA TAS VIC WA

Q4: What best describes where you live?

- Capital city
- Major regional centre
- Country town
- Rural
- Remote
- Others; please specify.....

Q5: Were you born in Australia?

- YES (*Go to Question 7*)
- NO; please specify the country you came from: _____ (*Go to Question 6*)
- Prefer not to disclose

Q6: When did you come to Australia?

- 0-5 years
- 6-10 years
- More than 10 years
- Prefer not to disclose

Q7: Highest Level of Education completed:

- Primary
- Secondary
- University
- Other: please specify:.....
- Prefer not to disclose

Q8: Employment status

- Full-time
- Part-time
- Casual
- Retired
- Not currently employed
- Prefer not to disclose

Q9: What is (was) your primary occupation?..... Prefer not to disclose

Now I will ask you some questions about your medications

Important notes for the interviewer:

- A. To obtain the correct name of medication, please ask the participant to spell the name if possible. If this is not possible, please write the name, as you understand it when the participant speaks. In both instances, please match the response against the supplied list (1) for lipid lowering medicines and supply list (2) for oral contraceptive medicines to identify the correct medication name.
- B. The strength of the lipid (i.e. statin) medications means how many milligrams per tablet (for example 10 mg).
- C. How long the participant has been taking the medication is the period from first usage of medication until the current time.
- D. In some cases, the patient may use both types of medications (i.e. lipid lowering drug and an oral contraceptive). In this case, please inform the participant that the subsequent questions only relate to the use of her oral contraceptive and NOT the lipid lowering medicine.

10: What is the name of the medication you are currently taking?

<p>1. To lower your cholesterol or lipids?</p>	<p>2. As an oral contraceptive? NOTE TO THE INTERVIEWER: Oral contraceptives would only apply to female respondents</p>
<p> <input type="radio"/> Atorvastatin <input type="radio"/> Fluvastatin <input type="radio"/> Pravastatin <input type="radio"/> Rosuvastatin <input type="radio"/> Simvastatin <input type="radio"/> Other, List name <input type="radio"/> I am not sure </p>	<p> <input type="radio"/> Microgynon 20 <input type="radio"/> Yasmin <input type="radio"/> Nordette <input type="radio"/> Micronor <input type="radio"/> Juliet-35 <input type="radio"/> Diane <input type="radio"/> Brenda <input type="radio"/> Other, List name <input type="radio"/> I am not sure </p>
<p>a) What is the strength of the medication?</p> <p> <input type="radio"/> I am not sure <input type="radio"/> 5 milligrams <input type="radio"/> 10 milligrams <input type="radio"/> 20 milligrams <input type="radio"/> 40 milligrams <input type="radio"/> 80 milligrams <input type="radio"/> Other: please specify:_____ milligrams </p>	<p>a) How you are taking this medicine?</p> <p> <input type="radio"/> One tablet for 21 days <input type="radio"/> One tablet every day <input type="radio"/> other :please specify..... </p>
<p>b) How many times per day you are taking this medicine (the dose)?</p> <p> <input type="radio"/> I am not sure <input type="radio"/> 1 tablet / day <input type="radio"/> 2 tablet/ day <input type="radio"/> Others please specify..... </p>	<p>b) How long have you been using this medication?</p> <p> <input type="radio"/> Less than 6 months <input type="radio"/> From 6 months to 1 year <input type="radio"/> For more than 1 year <input type="radio"/> For more than 2 years <input type="radio"/> I am not sure </p>
<p>c) How long have you been using this medication?</p> <p> <input type="radio"/> Less than 6 months <input type="radio"/> From 6 months to 1 year <input type="radio"/> For more than 1 year <input type="radio"/> For more than 2 years <input type="radio"/> I am not sure </p> <p>d) Have you been using any other medication(s) for your cholesterol or lipids during this time?</p> <p> <input type="radio"/> I am not sure <input type="radio"/> NO <input type="radio"/> YES Please list:..... </p>	<p>b) How long have you been using this medication?</p> <p> <input type="radio"/> Less than 6 months <input type="radio"/> From 6 months to 1 year <input type="radio"/> For more than 1 year <input type="radio"/> For more than 2 years <input type="radio"/> I am not sure </p>

NOTE TO THE INTERVIEWER: If the respondent is taking both a lipid lowering drug and an oral contraceptive, please let the respondent know that the following questions only relate to the use of her oral contraceptive.

Q11: Do you suffer from any other chronic disease for which you have used a medicine for more than 6 months?

- NO** (Please go straight to Question 13) **YES** (Please ask him/ her question 12)

Q12: Could you please name your current chronic disease/ diseases? (Please tick the answer from the following list, if the disease/ disease is/ are not included please tick other)

- Diabetes
- High Blood pressure (Hypertension)
- Blood clotting problem
- Anxiety
- Depression
- Thyroid disorders
- Chronic pain
- Asthma
- Emphysema
- Chronic bronchitis
- Arthritis
- Skin chronic problems for example (Eczema Psoriasis)
- Reflux and ingestion
- Other** (please tick other if the disease is not included above)

Q13: In the past 12 months how many times have you run out of your prescription medicine and not had a repeat prescription to have it filled (approximately)?

- Never** (Please go to Question 15) **Once** **Twice** **More**

Q14: What do you usually do when you run out of your prescription medicine when you do not have a repeat prescription and you are not able to get an appointment with your doctor?

- Stop treatment until you see the doctor
- Ask your pharmacist to get an extra supply until you can see your doctor
- See an after-hours doctors to get a new prescription
- Buy through the internet
- See another doctor
- Borrow from a friend or house mate
- Other please specify:.....

Q15: Do you have a regular pharmacy? **YES** **NO**

Q16: How concerned would you be about discussing your health issues with the pharmacist in order that he/she could provide you with one additional supply of my regular medication when your repeats have run out and you cannot see your doctor?

- Not at all concerned Fairly concerned Moderately concerned Very concerned Extremely concerned

If the answer is Not at all concerned, please ask the participant question 17

If the answer is **Fairly concerned/ Moderately concerned / Very concerned/ Extremely concerned**, please ask the participant question 18

If the answer is **Not at all concerned**, please ask the participant the following questions 17

Q17: Why you are not concerned, is that because: (please tick as much as applicable).

- Pharmacists know if it is safe or not to take an additional supply when I run out of my medication
- The pharmacist will refer me to the doctor if I needed
- Pharmacists are easier to access than doctors
- Reduce work load of my doctor
- It saves my time
- It makes me not miss any dose of my medicine
- All of the above
- Other (please specify:.....)

If the answer is **Fairly concerned/ Moderately concerned / Very concerned/ Extremely concerned**, please ask the participant Q 18

Q18: What would you be concerned about? (Please tick as much as applicable).

- Lack of privacy in the pharmacy
- The pharmacist has no access to my health records
- Others please specify
-
-
-

Q19: How many times per year would you prefer to be able to get additional supply of your regular medicine from your pharmacist if you are not able to obtain a new prescription from your doctor before you ran out?

- Once every 12 months
- Twice in every 12 months
- Three times in every 12 months
- Any time my repeats run out and I am not able to get an appointment with my doctor

For the following question please indicate your level of agreement or disagreement to the given statement by answering:

Strongly Disagree; Disagree; Neutral; Agree; Strongly Agree

Q20: There is no risk to my health if my pharmacist was to provide me with one additional supply of my regular medicine without a new prescription when I run out of repeats to allow me time to see my doctor

- Strongly Disagree Disagree Neutral Agree Strongly Agree

Now I will ask the last question which is about your level of agreement with the ability of pharmacists to re-dispense certain prescription medications in the absence of a valid repeat prescription from the doctor.

Q 21: Pharmacists should be able to provide an additional supply for which of the following prescription medications in the case where it is not convenient to obtain a new prescription from your doctor when all your repeats have run out? (Please indicate your level of agreement or disagreement)

Therapeutic area (medicines which are used for the following diseases)	Level of Agreement						
	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Prefer not to disclose	
Oral diabetes medicine	<input type="radio"/>						
Medicines to treat high blood pressure	<input type="radio"/>						
Medicines to treat blood clotting	<input type="radio"/>						
Medicines to treat anxiety	<input type="radio"/>						
Medicines to treat depression	<input type="radio"/>						
Medicines to treat thyroid disorders	<input type="radio"/>						
Medicines to treat chronic pain	<input type="radio"/>						
Medicines to treat asthma	<input type="radio"/>						
Medicines to treat emphysema	<input type="radio"/>						
Medicines to treat chronic bronchitis	<input type="radio"/>						
Medicines to treat arthritis	<input type="radio"/>						
Medicines to treat chronic skin problems	<input type="radio"/>						
Medicines to treat indigestion	<input type="radio"/>						
Medicines to treat glaucoma	<input type="radio"/>						
Others please specify							
1.							
2.							
3.							

That was the last question, thank you for your time; we appreciate your participation and wish you happy long life

Appendix 4.1 Permission from Co-authors for paper three (under-consideration)

1. Permission form Professor Jeffery Hughes

Curtin University
School of Pharmacy

I, Professor Jeffery David Hughes, as a co-author of the article under consideration for publication in PloS One below, hereby give permission to Salem Hasn Abukres (a PhD candidate, under my supervision) to re-produce the article in his PhD Thesis, providing that the article is fully and correctly cited, and obtain other needed permissions. I understand and do not object to him depositing his thesis in espace@Curtin.

Abukres SH, Hoti K, and Hughes JD. Avoiding treatment interruptions: What role do Australian community pharmacists play? PloS One (Under review)

Name: Prof Jeffery David Hughes

Signature:



Date: 7th October 2015

2. Permission from Dr Kreshnik Hoti

Curtin University
School of Pharmacy

I, Dr Kreshnik Hoti, as a co-author of the articles under consideration for publication by PloS One journal below, below, I give permission to Salem Hasn Abukres (a PhD candidate, under my co-supervision) to re-produce the articles in his PhD Thesis, providing that the article is fully and correctly cited, and obtain other needed permissions. I understand and do not do not object to him depositing his thesis in espace@Curtin.

Abukres SH, Hoti K, and Hughes JD. Avoiding treatment interruptions:
What role do Australian community pharmacists play?

Name: Dr Kreshnik Hoti

Signature:



Date: 7th October 2015

Appendix 4.2 Information sheet and Questionnaire for Pharmacists Postal Survey



Stakeholders' attitudes (Pharmacists) towards Continued Dispensing

INFORMATION SHEET

Dear pharmacist,

Continued Dispensing (CD) is a new initiative planned to be implemented under the Fifth community Pharmacy Agreements in Australia during 2013. As funded under the Fifth Agreement, CD refers to the provision of a standard PBS supply of a chronic therapy medicine to a patient by a community pharmacy, under specific circumstances, on the basis of a previous prescription, where a valid prescription is unavailable. Initially, CD supply will be limited to oral hormonal contraceptives and lipid modifying agents (i.e. statins).

The main aims of this project are:

- 1) To explore pharmacists attitudes towards CD
- 2) To identify potential improvements and expanded therapeutic areas for CD
- 3) To investigate other possible solutions for situations when patients require one of their regular medications however they do not have a valid prescription

You are invited to participate in this project by answering the attached questionnaire, which should take approximately 10-15 minutes of your time to complete. Your participation in this project would be very valuable.

Participation is completely voluntary. All information is to be provided anonymously, thus identification of individual respondents will not be possible. The research results will be grouped for the purpose of data analysis and publication.

If you wish to participate in this study please complete the questionnaire and return it using the enclosed prepaid envelope.

If you have any questions/concerns in regards to the study, please feel free to contact me, Salem Abukres, PhD Candidate at the School of Pharmacy, Curtin University (salamhasn.abukres@postgrad.curtin.edu.au) or one of my supervisors, Prof Jeff Hughes and Dr Kreshnik Hoti (J.D.Hughes@curtin.edu.au; Kreshnik.Hoti@curtin.edu.au).

The research is being conducted in strict accordance with Curtin University ethical protocols and the Australian Code for the Responsible Conduct of Research. As a participant, you will be free at any time to withdraw consent to further participation without prejudice in any way. This project has been approved by the Curtin University Human Research Ethics Committee (Approval Number: PH-07-13). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. Its main role is to protect participants. The Human Research Ethics Committee (Secretary) may be contacted should participants wish to make a complaint on ethical grounds. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth, 6845 or by telephoning (08) 9266 2784 or by emailing hrec@curtin.edu.au.

Thank you for taking time

Yours sincerely

Abukres Salem

Study of Continued Dispensing: Pharmacist Survey

Part 1: DEMOGRAPHIC INFORMATION (Please tick the appropriate answer)

Q1: Age group 20-30 31-40 41-50 51-60
 61 or more years

Q2: Gender Male Female

Q3 Work History (Please tick all applicable)

	Community Pharmacy	Hospital Pharmacy	Academia	Medication Management Review	Other (please specify)
Primary Place of Work					
Average work hours per week					
Total number of years in the primary place of work					
Secondary Place of Work					
Average work hours per week					
Total number of years in the Secondary place of work					
Years of practice as a registered pharmacist	<input type="radio"/> >2 year <input type="radio"/> 2- 5 years <input type="radio"/> 6- 10 years <input type="radio"/> 11-20 years <input type="radio"/> >20				

Q4: If you are a consultant pharmacist, which of the following accreditations do you hold?

AACP SHPA Not accredited

Q5: In which state/territory do you primarily work?

ACT QLD NSW NT SA TAS VIC WA

Q6: What best describes where you work?

- Capital city (State or Territory)
- Major regional centre
- Country town
- Rural
- Remote
- Others; please specify.....

Q7: Which of the following qualification(s) do you hold? (You may tick more than ONE)

- BPharm MPharm (Graduate Entry) PGradDipPharm MClinPharm
- Masters PhD Other; please specify.....

Part 2: QUESTIONS ABOUT CONTINUED DISPENSING AND OTHER FORMS OF MEDICATION SUPPLY

If you are a practising community pharmacist please answers Questions 8 and 9 if not please go straight to Q10

Q8: In the past 6 months approximately how many times per week have you faced the situation where a patient with a chronic disease requests a medication supply without a valid prescription because he/she is unable to obtain an appointment with their doctor? (Please tick ONE answer for each)

	Requests from regular customers*	Requests from	Non-regular customers*
Zero	<input type="radio"/>		<input type="radio"/>
One or two	<input type="radio"/>		<input type="radio"/>
Three to four	<input type="radio"/>		<input type="radio"/>
Five or more	<input type="radio"/>		<input type="radio"/>

As guided by the final Continued Dispensing of Medicines consult paper:

*Regular customers: Attends the pharmacy 5 times or more in the past 12 months,

* Non-regular customers: Attended the pharmacy fewer than 5 times in the past 12 months. (<http://www.health.gov.au>)

If your answer is zero, please skip to Q10.

Q9: What are the reasons that patients commonly report to you regarding their inability to obtain a new prescription? (Please tick as many answers as applicable)

- Inability to obtain an immediate appointment with their doctor
- Ran out of their medication over the weekend or on a public holiday
- Their doctor is on a leave
- Other; (please specify)

Q10: If a REGULAR CUSTOMER* with a stable chronic disease requested medication without a prescription because he or she reported an inability to obtain an appointment with the prescriber what would you normally do for the following medications?

Medicine type	Prescription type								
	PBS prescription medicines			Authority prescription			Private prescription		
	Not supply	Emergency supply	Owing prescription	Not supply	Emergency supply	Owing prescription	Not supply	Emergency supply	Owing prescription
Oral hypoglycaemics	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Antihypertensives	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Anticoagulants	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Anxiety medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Antidepressants	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Schizophrenia medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hypothyroidism medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hyperthyroidism medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Chronic pain: opioids	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Chronic pain: non-opioids	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Asthma medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
COPD medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Arthritis medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Psoriasis/eczema medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
GORD medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Glaucoma medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Statins	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Non-Statin lipid lowering agents	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Oral contraceptives	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

As guided by the final Continued Dispensing of Medicines consult paper. Regular customer: Attended the pharmacy 5 times or more in the past 12 months. (<http://www.health.gov.au>)*

Q11: If the same REGULAR CUSTOMER were to return for a second time asking the same medication without seeing the prescriber what would you do?

Not supply Emergency Supply Owing Prescription Other: please specify:.....

Q12 If a NON-REGULAR CUSTOMER* with a stable chronic disease requested medication without a prescription because he or she reported an inability to obtain an appointment with the prescriber what would you normally do for the following medications?

Medicine type	Prescription type								
	PBS prescription medicines			Authority prescription			Private prescription		
	Not supply	Emergency supply	Owing prescription	Not supply	Emergency supply	Owing prescription	Not supply	Emergency supply	Owing prescription
Oral hypoglycaemics	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Antihypertensives	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Anticoagulants	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Anxiety medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Antidepressants	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Schizophrenia medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hypothyroidism medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hyperthyroidism medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Chronic pain: opioids	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Chronic pain: non-opioids	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Asthma medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
COPD medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Arthritis medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Psoriasis/eczema medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
GORD medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Glaucoma medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Statins	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Non-Statins lipid lowering agents	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Oral contraceptives	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

As guided by the final Continued Dispensing of Medicines consult paper; *Non-regular customer: Attended the pharmacy fewer than 5 times in the past 12 months. (<http://www.health.gov.au>)

Q13: If the same patient above (i.e. NON-REGULAR CUSTOMER) were to return for a second time asking the same medication without seeing the prescriber what would you do?

Not supply Emergency Supply Owing Prescription Other: please specify:.....

Q14: For which of the following MEDICATIONS do you think that pharmacists should have CONTINUED DISPENSING RIGHTS in cases where the patient is unable to obtain an appointment with the original prescriber and provided that the patient has used the medicine for 6 months or more?

Medications	Level of Agreement									
	For a REGULAR CUSTOMER* * Attended 5 times or more in the past 12 months					For an NON-REGULAR CUSTOMER* * Attended fewer than 5 times in the past 12 months.				
	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Oral hypoglycaemics	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Antihypertensives	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Anticoagulants	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Anxiety medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Antidepressants	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Schizophrenia medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hypothyroidism medicines	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hyperthyroidism medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Chronic pain: opioids	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Chronic pain: non-opioids	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Asthma medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
COPD medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Arthritis medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Psoriasis/eczema medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
GORD medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Glaucoma medications	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Statins	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Non-Statins lipid lowering agents	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Oral contraceptives	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other: Please specify.....										
.....										
.....										

Q15: How many times within a 12-month period should Continued Dispensing be allowed to occur for the same medication?

- One (as currently proposed)
 Two
 Three
 Other, please state

Q16: Please provide the rationale for your choice to Question 15?

.....
.....

Q17: Please indicate your level of agreement with following statements:

17.1 Continued Dispensing is likely to increase patients' medication adherence.

- Strongly disagree Disagree Neutral Agree Strongly agree

17.2 Continued Dispensing is likely to lessen the administrative burden of having to chase 'owing' prescriptions.

- Strongly disagree Disagree Neutral Agree Strongly agree

17.3 Continued Dispensing is likely to decrease the wastage that occurs when an original pack of medication has to be broken to adhere to the Emergency Supply provisions under the current State/Territory legislation.

- Strongly disagree Disagree Neutral Agree Strongly agree

17.4 Prescribers should be able to annotate the original prescription to make it clear that the medication is not to be continued without review by a medical practitioner.

- Strongly disagree Disagree Neutral Agree Strongly agree

Q18: Please indicate your level of support for pharmacists being able to dispense according to the medication list within THE PATIENT CONTROLLED ELECTRONIC HEALTH RECORD without the need for a hardcopy prescription.

- Strongly disagree Disagree Neutral Agree Strongly agree

Q19: What other possible solutions could you suggest to deal with the issue of a patient requesting supply of one of his/her regular medications without having a valid prescription?

.....
.....
.....

THANK YOU FOR YOUR TIME.

PLEASE RETURN THE QUESTIONNAIRE USING THE ENCLOSED PREPAID ENVELOPE.

Appendix 4.3 Ethics approval for Pharmacists Postal Survey



Memorandum

To	Salem Abukres
From	Alison Smith, Form C Coordinator
Subject	Protocol Approval PH-07-13
Date	23 July 2013
Copy	Jeff Hughes, Kreshnik Hoti

Office of Research and Development
Human Research Ethics Committee
Telephone 9266 2784
Facsimile 9266 3793
Email hrec@curtin.edu.au

Thank you for your "Form C Application for Approval of Research with Low Risk (Ethical Requirements)" for the project titled "*Stakeholders' attitudes (pharmacists) towards continued dispensing*". On behalf of the Human Research Ethics Committee, I am authorised to inform you that the project is approved.

Approval of this project is for a period of 4 years **23/07/2013 to 23/07/2017**.

Your approval has the following conditions:

- (i) Please review question 18 as there appears to be unnecessary CAPITAL TEXT.
- (ii) Annual progress reports on the project must be submitted to the Ethics Office.
- (iii) It is your responsibility, as the researcher, to meet the conditions outlined above and to retain the necessary records demonstrating that these have been completed.

The approval number for your project is **PH-07-13**. Please quote this number in any future correspondence. If at any time during the approval term changes/amendments occur, or if a serious or unexpected adverse event occurs, please advise me immediately.

Sincerely,

Alison Smith
Research & Development Support Coordinator
School of Pharmacy

Please Note: The following standard statement must be included in the information sheet to participants:
This study has been approved under Curtin University's process for lower-risk Studies (Approval Number PH-07-13). This process complies with the National Statement on Ethical Conduct in Human Research (Chapter 5.1.7 and Chapters 5.1.18-5.1.21).
For further information on this study contact the researchers named above or the Curtin University Human Research Ethics Committee. c/- Office of Research and Development, Curtin University, GPO Box U1587, Perth 6845 or by telephoning 9266 9223 or by emailing hrec@curtin.edu.au.

CRICOS Provider Code 00301J

Appendix 5.1 Information sheet and Questionnaire for Case Vignettes Study



Study on Continued Dispensing by Pharmacists

Information sheet

Dear Pharmacist,

My name is Salem Abukres, and I am a PhD Candidate at the School of Pharmacy, Curtin University, Western Australia. My research focuses on the new Continuing Dispensing initiative, which has been progressively implemented nationally from 1st of September 2013. In this part of my research I am seeking to explore circumstances in which pharmacists believe Continued Dispensing is appropriate using a number of case scenarios.

Therefore, I am seeking your assistance in completing the questionnaire and providing the demographic information listed below. This will take approximately 10 minutes of your time. Your participation in this survey is completely voluntary. All information is to be provided anonymously, thus identification of individual respondents will not be possible. All information will be treated with the strictest confidence and presented as grouped data.

The project has received ethical approval from the Curtin University, Human Research Ethics Committee. If you have any questions/concerns in regards to the study, you are free to contact me, Salem Abukres, (salamhasn.abukres@postgrad.curtin.edu.au) or my supervisors, Prof Jeff Hughes and Dr Kreshnik Hoti (J.D.Hughes@curtin.edu.au; Kreshnik.Hoti@curtin.edu.au).

Respondents will be given a ticket to go into the draw for a \$100 Myers Gift voucher.

Thanking you for your participation.

Kind regards

Salem Hasn Abukres, PhD Candidate

The research is being conducted in strict accordance with Curtin University ethical protocols and the Australian Code for the Responsible Conduct of Research. As a participant, you will be free at any time to withdraw consent to further participation without prejudice in any way. This project has been approved by the Curtin University Human Research Ethics Committee (Approval Number: PH-15-14). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. Its main role is to protect participants. The Human Research Ethics Committee (Secretary) may be contacted should participants wish to make a complaint on ethical grounds. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth, 6845 or by telephoning (08) 9266 2784 or by emailing hrec@curtin.edu.au.

Part: 1: Appropriateness of Continued Dispensing (Please read each scenario and tick the appropriate answer)

Scenario 1

A 26 years old female regular customer of the pharmacy requests repeat prescription of her oral contraceptive pill. Although there are still repeats, the prescription has expired and it is impractical for her to see her GP to renew the prescription because she is leaving the next day (Sunday) for a couple of weeks holiday.

Q1: Is continued dispensing appropriate in this case?

A. Yes

B. No Why:

Q2: In this case what would be your preferred course of action? (Please answer below)

A. Continued Dispensing B. Owing Prescription C. Emergency Supply D. Not supply

E. Refer to an After Hours GP F. Other Please specify: _____

Scenario 2

The wife of a 48 year old male comes into the pharmacy. She and her husband are visiting from another state and says her husband has run out of his statin a week ago. He would prefer not to see another GP, however they are staying for another 3 weeks, and she is concerned about the interruption to his treatment.

Q1: Is continued dispensing appropriate in this case?

A. Yes

B. No Why:

Q2: In this case what would be your preferred course of action? (Please answer below)

A. Continued Dispensing B. Owing Prescription C. Emergency Supply D. Not supply

E. Refer to an After Hours GP F. Other Please specify: _____

Scenario 3

A 61 year old male regular consumer tells the pharmacist that he urgently needs some of his cholesterol medicine. He mentions that he ran out two days ago. The pharmacist reviews the consumer's medication history and until this break on therapy, the consumer had been stable on statin therapy for five years.

Q1: Is continued dispensing appropriate in this case?

A. Yes

B. No Why:

Q2: In this case what would be your preferred course of action? (Please answer below)

A. Continued Dispensing B. Owing Prescription C. Emergency Supply D. Not supply

E. Refer to an After Hours GP F. Other Please specify: _____

Scenario 4

An 48 year old regular female customer tells the pharmacist that she is unable to obtain an appointment with her doctor for new prescriptions for her statin and blood pressure medicines and prefers not to see another GP. She has been taking them for about 6 months and now only has a few tablets left.

Q1: Is continued dispensing appropriate in this case?

A. Yes

B. No Why:

Q2: In this case what would be your preferred course of action? (Please answer below)

A. Continued Dispensing B. Owing Prescription C. Emergency Supply D. Not supply

E. Refer to an After Hours GP F. Other Please specify: _____

Scenario 5

A 18 year old female consumer comes into the pharmacy with an empty box of the oral contraceptive. She says it is not practicable for her to go to her GP. The pharmacist reads on the label that her GP has given her a three months' supply with no repeats. On further questioning, she says her GP changed her onto a new oral contraceptive three months ago.

Q1: Is continued dispensing appropriate in this case?

A. Yes

B. No **Why:**

Q2: In this case what would be your preferred course of action? (Please answer below)

A. Continued Dispensing **B. Owing Prescription** **C. Emergency Supply** **D. Not supply**

E. Refer to an After Hours GP **F. Other** **Please specify:** _____

Scenario 6

A 36 year old female comes to the pharmacy after being in hospital for 14 days. Last week she ran out of the supply provided by the hospital and has not been able to visit her GP since leaving hospital. She would like a supply of her usual statin.

Q1: Is continued dispensing appropriate in this case?

A. Yes

B. No **Why:**

Q2: In this case what would be your preferred course of action? (Please answer below)

A. Continued Dispensing **B. Owing Prescription** **C. Emergency Supply** **D. Not supply**

E. Refer to an After Hours GP **F. Other** **Please specify:** _____

Part 2: Demographic Information (Please tick the appropriate answer)

Q1. Gender

- A. Female B. Male

Q2. Age

- A. < 25 years B. 25-34 years C. 35-44 years D. 45-54 years E. 55-64 years
F. 65 year or older

Q3. Years of Practise

- A. < 5 years B. 5-10 years C. 11-20 years D. > 20 years

Q4. Primary Area of Pharmacy Practice

- A. Community Pharmacy
B. Hospital Pharmacy
C. Consultant Pharmacy
D. Other

Q5. Please provide any comments about your experience with Continued Dispensing to date; do you feel that is an effective process?

Please return the questionnaire to the Curtin University stand at the seminar

THANK YOU FOR YOUR TIME. YOUR ANSWERS WILL BE OF GREAT VALUE TO THIS RESEARCH

Appendix 5.2 Ethics approval for Case Vignettes Study



Memorandum

To	Salem Abukres
From	Alison Smith
Subject	Protocol Extension Approval PH-15-14
Date	14 May 2014
Copy	Jeff Hughes

Office of Research and Development
Human Research Ethics Committee

TELEPHONE 9266 2784
FACSIMILE 9266 3793
EMAIL hrec@curtin.edu.au

Thank you for keeping us informed of the progress of your research. The Human Research Ethics Committee acknowledges receipt of your indication of modifications for the project "*Stakeholders' attitudes (doctors) towards continued dispensing*". Your application has been **approved**.

The Committee notes the following amendments have been approved:

1. **Project title changed** from "*Stakeholders' attitudes (doctors) towards continued dispensing*" to "*Stakeholders' attitudes (pharmacists – case vignettes) towards continued dispensing*"

Approval for this project remains as **14/05/2018**, being 4 years from approval date.

Your approval has the following conditions:

- (i) Annual Progress Reports on the project must be submitted to the Ethics Office.

Your approval number remains **PH-15-14**. Please quote this number in any further correspondence regarding this project.

Sincerely,

Alison Smith
Research & Development Support Coordinator
School of Pharmacy

Appendix 6.1 Information sheet, Questionnaire, and Gift Voucher for General Practitioners Survey



General Practitioners' attitudes towards Continued Dispensing

INFORMATION SHEET

Dear Doctor,

By way of introduction my name is Salem Abukres, and I am a PhD Candidate in the School of Pharmacy, Curtin University. My PhD studies include the exploration of doctors' attitudes towards Continued Dispensing, therefore I am writing to you seeking participation in this study.

The study involves answering **seven** questions; the estimated time to answer all questions is around **10 minutes**. I understand your time is a valuable and I would like to provide you with a \$ 50 gift voucher in appreciation of your participation. Your answers will be transcribed verbatim and thematically analysed in order to be used in my thesis and publications. All responses will be anonymous. If you would like a copy of research results, please tick the appropriate box on the enclosed Gift Voucher Form. The data will be stored as **non-identifiable data** at the School of Pharmacy, Curtin University. There is no **direct benefit or risk from** this study to you. However, **your responses will add valuable information** to the existing knowledge about the Continued Dispensing system as described below.

The **Continued Dispensing** initiative was introduced in September 2013 and allows pharmacists to supply eligible PBS medicines to a customer when there is an immediate need for the medicine, but it is not practical for the customer to get a prescription. (<http://www.medicareaustralia.gov.au/provider/pbs/fifth-agreement/medication-continuance.jsp>)

Supply under Continued Dispensing is currently limited to two therapeutic categories, namely Oral Hormonal Contraceptives for systemic use, and Lipid Modifying Agents, specifically the HMG CoA reductase inhibitors ('statins') as listed in the Schedule of Pharmaceutical Benefits.

Pharmacists may supply medicine under this initiative when:

- the medicine requested is listed in the relevant legislation as eligible for supply under continued dispensing
- there is an immediate need for the medicine and the customer can't get to a prescriber
- the medicine has been prescribed before
- the customer's therapy is stable
- there has been prior clinical review by the prescriber that supports continuation of the medicine
- there is an ongoing need for the medicine, and the medicine is safe and appropriate for the customer.

If you have any questions/concerns in regards to the study, please contact me, Salem Abukres, salamhasn.abukres@postgrad.curtin.edu.au) or my supervisors, Prof Jeff Hughes and Dr Kreshnik Hoti (J.D.Hughes@curtin.edu.au; Kreshnik.Hoti@curtin.edu.au).

Yours sincerely,
Salem Abukres

The research is being conducted in strict accordance with Curtin University ethical protocols and the Australian Code for the Responsible Conduct of Research. As a participant, you will be free at any time to withdraw consent to further participation without prejudice in any way. This project has been approved by the Curtin University Human Research Ethics Committee (Approval Number: PH-17-14). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. Its main role is to protect participants. The Human Research Ethics Committee (Secretary) may be contacted should participants wish to make a complaint on ethical grounds. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth, 6845 or by telephoning (08) 9266 2784 or by emailing hrec@curtin.edu.au.

General Practitioner's attitudes towards Continued Dispensing

Please answer the following questions; please provide as much information as you can, if you need more space please use the blank page provided at the end of the questionnaire.

Q1: What has been your experience with Continued Dispensing to date?

Demographic information

Demographic information will be used for analysis purposes so please provide us with following information:

Please tick the appropriate answer

Gender

A. Female B. Male

Age

A. < 25 years B. 25-34 years C. 35-44 years D. 45-54 years E. 55-64 years
F. 65 year or older

Years of Practise

A. < 5 years B. 5-10 years C. 11-20 years D. > 20 years

THANK YOU FOR YOUR TIME. YOUR ANSWERS WILL BE OF GREAT VALUE TO THIS RESEARCH.

Please return the questionnaire using the enclosed pre-paid envelope

General Practitioners' attitudes towards Continued Dispensing

\$ 50 Gift Voucher Form

Dear Doctor,

Thank you for taking time to complete the questionnaire. Please return the questionnaire and this slip using the enclosed pre-paid envelope. This slip will not be stored with the questionnaire and will be sent back to you.

Please provide the following information to receive the \$ 50 gift voucher

Name _____

Postal address

Please tick the box if you would like to be sent a copy of the results of the project

Yours sincerely,

Salem Abukres

PhD Candidate

Appendix 6.2 Ethics approval for General Practitioners Survey



Memorandum

To	Abukres Salen
From	Ausana Naidoo, Form C Coordinator
Subject	Protocol Approval PH-17-14
Date	1 September 2014
Copy	Prof Jeff Hughes, Dr Kreshnik Hoti

Faculty of Health Sciences

School of Pharmacy

TELEPHONE 9266 7418
FACSIMILE 9266 3793
EMAIL Ausana.Naidoo@curtin.edu.au

Thank you for your "Form C Application for Approval of Research with Low Risk (Ethical Requirements)" for the project titled "Doctors' attitudes towards Continuing Dispensing". On behalf of the Human Research Ethics Committee, I am authorised to inform you that the project is **approved**.

Approval of this project is for a period of 4 years **01/09/2014 to 01/09/2018**.

Your approval has the following conditions:

- (i) **Annual Progress Reports** on the project must be submitted to the Ethics Office.
- (ii) It is your responsibility, as the researcher, to **meet the conditions** outlined and to retain the necessary **records** demonstrating that these have been completed.
- (iii) It is the investigator's responsibility to complete **Risk Assessments** as appropriate to the research activities, prior to commencement of this research. The Curtin University Risk Assessment form is [available here](#).

The approval number for your project is **PH-17-14**. Please quote this number in any future correspondence. If at any time during the approval term changes/amendments occur, or if a serious or unexpected adverse event occurs, please advise me immediately.

Sincerely,

Ausana Naidoo
Research & Development Support Coordinator
School of Pharmacy

Please Note: The following standard statement must be included in the information sheet to participants:
This study has been approved under Curtin University's process for lower-risk Studies (Approval Number PH-17-14). This process complies with the National Statement on Ethical Conduct in Human Research (Chapter 5.1.7 and Chapters 5.1.18-5.1.21). For further information on this study contact the researchers named above or the Curtin University Human Research Ethics Committee. c/o- Office of Research and Development, Curtin University, GPO Box U1987, Perth 6845 or by telephoning 9266 9223 or by emailing hrec@curtin.edu.au.

CRICOS Provider Code 00301J

Appendix 6.3 Pharmacists' perceptions of CD based on informal interviews

After the informal interview with the GP, the research team suspected that GPs may be unaware of the CD potentially due to low uptake of CD by pharmacists.[1, 2] Therefore to investigate this the primary investigator conducted informal interviews with three pharmacists working in three different community pharmacies in Cannington area.

Pharmacist 1 was aware of CD and some of his oral contraceptives customers used it. He provided a number of reasons why there was low utilisation of the CD. Firstly, there is a more convenient way to deal with customers seeking medications without a valid prescription, namely supplying a small quantity of OC enough for three days or nearest appointment with the GP (i.e. ES), then when the customer brings a new prescription they take the rest of the pack and obtain a refund (In this model, the patient will obtain one additional repeat without out of pocket expense and the pharmacist will avoid the time-consuming CD). However, this model may not be used in the case of non-regular customers such as interstate visitors. Secondly, OC prescriptions expire one year after the date of issue, which means it is time to see the GP before starting a new course. The pharmacist also said if CD was expanded to more medication classes then it would be more practical and usable. Asked if GPs ever complained about CD, the pharmacist said they had never experienced that.

Pharmacist 2 was aware of CD, but never used it. The pharmacist thought it required too much paper work, and there are other easier alternatives. The pharmacist felt that if CD was expanded it would be more practical. The pharmacist was unaware if GPs ever complained about CD.

Pharmacist 3 provided the most comprehensive review of CD. The pharmacist said CD is good in theory but not in practice, because most Statin users usually use generic Statins. The pharmacist mentioned that these generic Statins are cheaper than the usual co-payment for a consumer who is not on a concession (i.e. \$37.70). The pharmacist also added for OC users they must be a concession card holder to be supplied using the CD method; otherwise CD is not practical for them and costs more. The pharmacist said if the customer was a regular customer, she usually used the OP method, if not and the patient was CD eligible then she may use the CD method. The pharmacist said only a few Statin and OC medications users are aware i.e.: "We need to tell them that they are eligible". The pharmacist said she used CD less than five times since it started in September 2013. She said GPs had complained about CD

before they were aware that it was a legal method of supply. She expressed her opinion that CD needs to be expanded to include more medications to be usable but now it restricted to two types of medications and in practice only a small number of patients may benefit from the CD method.

References cited in this appendix

1 Department of Health. Report to Parliament on the Operation of S 89a of the National Health Act 1953 ('Continued Dispensing') 2014. Available from: <http://www.pbs.gov.au/info/publication/reports/continued-dispensing/report-to-parliament>. Accessed: 2015-05-12. (Archived by WebCite® at <http://www.webcitation.org/6YrL6IWkr>).

2 Australian Medical Association. Continued Dispensing Has Started- but You Would Not Know It 2015. Available from: <https://ama.com.au/ausmed/continued-dispensing-has-started-%E2%80%93-you-wouldn%E2%80%99t-know-it>. Accessed: 2015-08-18. (Archived by WebCite® at <http://www.webcitation.org/6as6EOYfj>).