The Long Term Conditions service: An examination of the impact of the service on patients' health outcomes and an exploration of pharmacists' views and experiences with the service

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ABSTRACT

Background

International evidence has highlighted the positive contribution community pharmacist-led interventions can have on improving patients' medication adherence and health outcomes. Little evidence to date has been published examining the impact of a New Zealand pharmacist-led service called the Long Term Conditions (LTC) service.

Aims

The present research examined the impact of the LTC service on patients' medication adherence and ambulatory sensitive hospitalisations (ASH). It also sought to understand how community pharmacists provide the LTC service, and to explore community pharmacists' views and experiences with the service and its provision.

Methods

A sequential, explanatory, mixed-method design was employed comprising: 1) a systematic review; 2) a retrospective matched-cohort study (n=102,276) using routinely collected health data; 3) semi-structured interviews with community pharmacists (n=18); 4) observation of community pharmacy sites (n=6).

Results

Enrolment in LTC contributed to improved medication adherence, with patients in the intervention group having 2.99 (95% CI:2.79-3.20) greater odds of being adherent compared to the control group (12 months after start of the intervention). Unexpectedly, enrolment in LTC contributed to greater ASH, with patients in the intervention group having 1.86 (95% CI:1.78-1.96) greater odds of having an ASH compared to the control group (12 months after the start of the intervention).

The present research identified factors that influence LTC service provision, primarily: tensions in the pharmacy, which stem from financial pressures; pharmacists working in isolation; and pharmacists having multiple competing and concurrent roles. Other factors included LTC disrupting pharmacies' 'business-as-usual', as LTC is a time intensive service which ideally requires the integration of the service into pharmacy workflow. For some pharmacists LTC has positively changed the focus of their work, however for the majority of

those interviewed, LTC has not. Pharmacists disclosed they feel there is a lack of value of pharmacy and LTC, and this is reflected in a lack of buy-in to the service by various stakeholders.

Conclusion

The LTC service achieved one of its primary goals of improved medication adherence. However, this was decoupled from improvements in clinical outcomes, as this research found greater ASH amongst LTC enrolled patients. Possible reasons for the greater hospitalisations were proposed, however further research is needed. A range of factors were identified that influence pharmacists' LTC service provision. These factors should be considered when introducing new pharmacy services.

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LIST OF ABBREVIATIONS

ASH	Ambulatory Sensitive Hospitalisations
CI	Confidence Interval
DHB	District Health Board
DHBSS	District Health Board Shared Services
GIA	General Inductive Approach
GP	General Practitioner
LTC	Long Term Conditions Service
MOH	Ministry of Health
MPR	Medication Possession Ratio
NHI	National Health Index
NNPAC	National Non-Admitted Patient Collection
NMDS	National Minimum Dataset
NZ	New Zealand
PDC	Proportion of Days Covered
PhD	Doctor of Philosophy
PHO	Primary Health Organisation Collection
PIS	Participant Information Sheet
PS	Propensity Score
UK	United Kingdom
USA	United States of America

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Please indicate the chapter/section/pages of this thesis that are extracted from a co-authored work and give the title and publication details or details of submission of the co-authored work.	Thesis Chapter 2 Community pharmacist-led interventions and their impact on patients' medication adherence and other health outcomes: a systematic review
Nature of contribution by PhD candidate	Planning the systematic review, developing the search strategy, undertaking the database search, identifying eligible articles, discussing article eligibility, preparing the abstraction forms, data abstraction process, quality appraisal of the articles, interpretation of the data, manuscript writing, and approving the final version of the manuscript.
Extent of contribution by PhD candidate (%)	75%

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Associate Professor Jeff Harrison	Planning the systematic review, developing the search strategy, discussing article eligibility, reviewing the data abstraction form, supervising the data extraction and analysis processes, reviewing the manuscript drafts, and approving the final version of the manuscript.

Certification by Co-Authors

The undersigned hereby certify that:

- the above statement correctly reflects the nature and extent of the PhD candidate's contribution to this work, and the nature of the contribution of each of the co-authors; and
- in cases where the PhD candidate was the lead author of the work that the candidate wrote the text.

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Extent of contribution by PhD candidate (%)	75%

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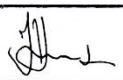
Associate Professor Jeff Harrison		22/06/2020

CHAPTER 1. INTRODUCTION

1.1 Background

New Zealanders are living longer than ever before.[1] As they age, a certain degree of functional decline usually occurs, physical, sensory or cognitive, coupled with an increasing prevalence of acute and chronic health conditions.[1,2] These chronic conditions are particularly concerning for patients and the health care system because they have been shown to contribute to lower quality of life, increased experience of disability and greater use of health resources.[3] This puts an increased burden on the health care system, particularly medical and disability services.[3,4] Many researchers deem chronic conditions as one of the most preventable and costly health issues currently plaguing the health care system.[5]

Medications are the most common health intervention in the developed and developing world.[6] Patients living with chronic conditions are often prescribed several different medications, in several different dosage forms with sometimes complex dosing regimens, requiring dosing throughout the day. Taking these medications appropriately can be made even more difficult due to a range of factors: patient-related, health system-related, social/economic-related, therapy-related, and condition-related.[7-9] Forgetfulness, weak patient-health professional relationships, low socioeconomic status, low literacy, increased treatment complexity, and disease severity are examples of factors that contribute towards sub-optimal medication taking behaviours or what many term medication non-adherence.[9]

The term medication adherence is used to describe how closely patients take their medications as mutually agreed with the prescriber.[9,10] Adherence is often deemed crucial for the success of a patient's treatment[8,11] and the degree to which a patient is adherent can have downstream effects on treatment effectiveness[7,8] and health outcomes, and on the health care system through increased health care costs.[8,12-14]

A growing volume of international evidence has highlighted the positive contribution community pharmacists can have on improving patients' medication adherence, as well as improving health outcomes.[15] Pharmacists predominantly contribute to this through the provision of pharmaceutical care interventions.

Pharmaceutical care has been defined as "the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life".[16] Examples of

pharmaceutical care services have been described internationally: in the United States (USA) as Medication Therapy Management (MTM)[17]; in the United Kingdom (UK) as Medicines Use Review (MUR) and the New Medicine Service (NMS)[18]; in Australia as the Home Medication Review (HMR)[19]; in Canada as MedsCheck[20]; and in New Zealand as MUR and Medicines Therapy Assessment (MTA).[21] Examples of pharmaceutical care activities include identifying medication-related problems, setting goals and working towards solving the patient's medication-related problems, and documenting the pharmaceutical care provided.[22]

In July 2012 a new Community Pharmacy Services Agreement (CPSA) contract was introduced by the New Zealand Government.[23] Under this new contract, a new community pharmacy service was launched, called the Long Term Conditions (LTC) service. The introduction of LTC signalled a change in the organisation and funding of community pharmacy services in New Zealand.[23,24] LTC was intended to help patients with chronic medical conditions who struggle with medication adherence, improve their adherence with the help of their community pharmacist.[23] As well as benefiting patients, controlling pharmacy funding was a strategic driver for implementation of LTC and the new CPSA contract, as previously funding was based on the number of medications dispensed.[24] In recent years this system had become financially unsustainable and also funding had little association to patient outcomes. Revising funding so that it is linked to patient health outcomes and not on dispensing volumes was another key focus of the CPSA contract.[24]

As part of LTC, pharmacists selectively enrol eligible patients into the service and prepare patient-specific management plans to help resolve any adherence issues they have identified. The plan may include, but is not limited to, undertaking medication reconciliation, medication synchronisation, providing more or less frequent dispensings, sending patient reminders for repeat medications, and preparing medication adherence support aids including blister packing.[21] The selection and customisation of these services should be informed by an individual patient's needs, abilities, goals, values and beliefs, in addition to the resources available to the pharmacist in their pharmacy. For patients to be eligible for enrolment into LTC, patients need to reach twenty eligibility points (ten points for medication adherence issues and ten points for co-morbid conditions).[23]

Even though some time has elapsed since the introduction of LTC, little is known about the impact of the service, particularly on patients' medication adherence and health outcomes.[25,26] Understanding the impact of LTC on patients' medication adherence was deemed important by

the researcher, as improving medication adherence is one of the primary goals of LTC. Through this improved adherence, LTC funders hoped that LTC would be able to also improve patients' health outcomes and help reduce hospitalisations.[23] Previous international literature has exemplified that through community pharmacist-led interventions, medication adherence can be improved and hospitalisations reduced.[27,28] To date, the impact of LTC on patients' hospitalisations has been examined by only one earlier study, which showed that enrolment in LTC did not significantly affect acute hospitalisations.[26] The study did not report on the impact of LTC on patients' medication adherence and this was identified as a research gap.[26]

To help explain the health outcomes, it was deemed important to better understand what particular activities or services pharmacists provide as part of LTC, as pharmacists are able to provide a variety of activities to patients under the LTC umbrella. Grasping an understanding of pharmacists' experiences and attitudes towards the LTC service, as well as exploring the factors contributing to their LTC service provision was deemed necessary to paint a more comprehensive picture of LTC service delivery.

1.2 Aims and objectives

Against this background, this thesis aims to:

- Examine the impact of the LTC service on patients' medication adherence and ambulatory sensitive hospitalisations (ASH);
- Understand how New Zealand community pharmacists provide the LTC service;
- Explore community pharmacists' views and experiences with the LTC service and its provision.

The thesis objectives are to:

- Describe patients enrolled in the LTC service in terms of their sociodemographic and clinical characteristics;
- Determine the impact of the LTC service on patients' medication adherence and ASH;
- Determine whether there is evidence of inequalities and inequities in LTC service outcomes, based on the sociodemographic characteristics of age and ethnicity;
- Identify pharmacies for the qualitative phase of this research;

- Understand what activities or services a sample of community pharmacists provide to LTC enrolled patients and how they differ to those provided to patients not enrolled in the LTC service;
- Explore pharmacists' experiences of and attitudes towards the LTC service;
- Explore pharmacists' views on the factors contributing to their LTC service provision.

1.3 Structure of the thesis

The thesis has six chapters. The first chapter provides an overview of the scope and direction of the thesis. It identifies the context for the present research, as well the rationale for undertaking this research. The study aims and objectives which guided the research are stated.

Chapter 2 provides a qualitative synthesis of the pharmacy literature, exploring the impact of community pharmacist-led interventions and services on patients' medication adherence and health outcomes. This review provides a summary of the international literature and sets the scene for the studies described in this thesis. While there is a rich body of research reported about the benefit of community pharmacy services overseas, in New Zealand there are far fewer studies in comparison.

Chapter 3 provides the theoretical basis for the present research. It provides an overview of the deep-rooted assumptions, both epistemological and ontological that are relevant to the present research. How these relate to pharmacy research and more specifically to pharmacoepidemiological research is covered. Specific research methods, particularly the use of both quantitative and qualitative methods, were advantageous in this research, and an explanation of the rationale for their use is described.

Chapter 4 presents the findings gathered from the retrospective, matched-cohort study that involved analysis of routinely collected health data. This matched-cohort study set out to examine the impact of the LTC service on patients' medication adherence and ASH.

Chapter 5 presents the findings gathered from semi-structured interviews with community pharmacists and observation of community pharmacy sites. This qualitative study set out to understand how a sample of New Zealand community pharmacists provide the LTC service and to explore community pharmacists' views and experiences with the LTC service and its provision. The present study also attempted to better explain the matched-cohort study findings.

Chapter 6 presents the final discussion. It provides a summary of the studies undertaken as well as the strengths and limitations of the present research. The implications of the study findings on practice and policy are presented, as are directions for future research.

The final chapter, Chapter 7, provides the conclusion to this thesis, highlighting the take-home messages from the research.

CHAPTER 2. SYSTEMATIC REVIEW

2.1 Chapter overview

This chapter provides a summary of the literature in the area of community pharmacy, specifically examining the impact of community pharmacist-led interventions on patients' medication adherence and other health outcomes. The findings from this systematic review were published in the *International Journal of Pharmacy Practice*.[29] The article is presented in this thesis with permission from the publisher (Appendix 1). An update to this systematic review is presented in Section 2.8.

2.2 Introduction

Medication adherence can be defined as the extent to which one's medication-taking behaviour follows that mutually agreed upon with the prescribing physician.[9] Optimal adherence is often deemed crucial for the success of a patient's treatment,[11] as sub-optimal adherence may lead to treatment failure,[30] and unnecessary medical expenditure.[14] It has been estimated that adherence to chronic disease medications is as low as 50% among the general population in developed countries.[9]

Adherence is a dynamic phenomenon and can vary with time.[7] The interplay of five main factors may influence adherence: disease-related factors (e.g. lack of disease symptoms); medications (e.g. regimen complexity); the health care system (e.g. access to health services); the patient (e.g. disease and medication knowledge); and socio-economic factors (e.g. education level).[7,9] Non-adherence can be subcategorised into intentional or non-intentional,[7,9] with the former being a deliberate action, while the latter results from an individual's inability to take their medications (due to, for example forgetfulness or misunderstanding medication instructions).[9]

An ever-growing volume of international evidence has highlighted the positive contribution community pharmacists can have on improving patients' medication adherence and health outcomes,[15] primarily through the provision of pharmaceutical care interventions.[9] Pharmaceutical care interventions aim to promote a patient's quality of life through the provision of responsible medication therapy services.[9,16]

Community pharmacists have detailed knowledge about medications, disease prevention and management, and this positions them ideally within primary health care system to provide pharmaceutical care interventions.[31,32] Additionally, they are one of the most accessible health care providers to the public,[32,33] and have regular contact with those with chronic health conditions or those in poorer health.[33] Their regular patient contact provides community pharmacists with many opportunities to identify and follow up on patients' adherence issues. This regular contact also enables rapport to be established and a trusting therapeutic relationship to be fostered, between the pharmacist and the patient. Recently, role expansions for community pharmacists have driven a change in their workplace duties, away from predominately dispensing to encompass more patient-centred roles and the provision of pharmaceutical care.[16]

This systematic review summarises the available literature exploring the impact of community pharmacist-led interventions on patients' medication adherence and other health outcomes. To date, pharmacy interventions have been provided in a variety of health care settings, such as primary care clinics, ambulatory centres and community pharmacies. There is reason to believe that the effectiveness of the interventions may differ among the various settings, partially due to different barriers to intervention implementation.[31] In community pharmacy, for example, access to patients' clinical information is limited, and the dispensing process generally drives pharmacy workflow.[31] A review conducted by Blalock et al[31], found that the evidence supporting the positive impact of community pharmacist-led interventions on patient health outcomes and medication adherence is still limited, when compared to other health care settings. The review by Blalock et al[31] was limited to studies published in the United States of America (USA), until December 2011. Consequently, this review is an update, while also encompassing studies published worldwide. The focus will be solely on the community pharmacy setting.

The systematic review will address the following research questions: What disease states and health issues are community pharmacist-led interventions targeting and what is the impact of these interventions on patients' medication adherence and clinical, humanistic, economic and/or other health outcomes? The findings will provide a general overview of the types of interventions that have been implemented in the community pharmacy setting and their effectiveness.

Methods to assess adherence are plentiful in the literature. This review will include studies using objective measures of medication adherence, such as pill counts, pharmacy dispensing records, and electronic monitoring devices, as well as the validated self-report scales, or both. A comparison of the validity of the different adherence measures is beyond the scope of this review.

2.3 Methods

2.3.1 Search strategy

A systematic literature search was conducted to identify articles with information about community pharmacist-led interventions. Refer to Table 1 for the details on the inclusion and exclusion criteria used. Medline, EMBASE, International Pharmaceutical Abstracts, ProQuest Dissertations and Theses, and Google Scholar databases were searched for English, peer-reviewed articles. The search was undertaken in October 2015, and all articles published until October 2015 were included. The literature search strategy was developed in consultation with a subject librarian. Key words for the literature search were informed by the study by Blalock et al.[31] The search terms used for the Medline (Ovid) search were: [Community Pharmacy Services (MeSH) OR community pharmac* OR outpatient pharmac* OR out patient pharmac* OR independent pharmac* OR retail pharmac*] AND [service* or program* or initiative* or intervention*] AND [patient compliance (MeSH) OR medication adherence (MeSH) OR medic* compliance OR medic* adherence OR concordance OR patient adherence OR patient compliance OR persistence] AND [outcome assessment (health care) (MeSH) OR patient outcome assessment (MeSH) OR treatment outcome (MeSH) OR treatment failure (MeSH) OR hospitalization (MeSH) OR "length of stay" (MeSH) OR patient admission (MeSH) OR patient readmission (MeSH) OR outcome* OR hospitali* OR admission*]. The search terms were combined using Boolean operators, and no language or publication date limits were applied to the database searches. In addition, the reference lists of systematic reviews were scanned for potentially relevant articles. Only articles published in English were included in the final review.

2.3.2 Article selection

The titles of all retrieved articles were independently screened for eligibility by two team members (the researcher (AM) and her supervisor (TA)). Abstracts were then screened when the title of the article appeared relevant. This was undertaken by two team members (AM and TA). Full texts were obtained for all the relevant articles published in English. The full texts

were read by two team members (AM and TA). When doubt arose regarding article eligibility, the full text was obtained and discussed amongst all team members (AM, TA and JH). Two of the team members (AM and TA) independently read all the final articles for the systematic review to ensure all articles met the inclusion criteria. The inclusion and exclusion criteria are summarised in Table 1. Duplicate articles were removed using RefWorks® software.

Table 1: Inclusion and exclusion criteria for the systematic review

	Inclusion Criteria	**Exclusion Criteria**
Study designs	Randomised controlled trials, quasi-controlled trials, cluster-controlled trials, before-and-after studies, retrospective and prospective cohort studies.	Studies without a control group.
Participants	All participants, including those with different co-morbidities, sociodemographic characteristics.	No sociodemographic groups were excluded.
Settings	Intervention provided in the community pharmacy setting.	Hospitals or in-patient settings, patient's home, residency sites, nursing homes, ambulatory care clinics, and research or academic sites.
Interventions	Conducted by a community pharmacist or a member of the community pharmacy team, with community pharmacist input.	Other health care professionals involved in implementing the intervention and studies where the contribution of the community pharmacist cannot be isolated from the effects of activities conducted by other health care professionals.
Comparisons	Intervention involved self-comparison or was compared with a control group that received usual care.	Intervention involved neither a self-comparison, nor a control group that received usual care.
Outcomes	Quantitative reporting of behavioural and clinical outcomes: • Behavioural outcome: adherence to prescribed medications. Adherence measured using any of the following: pill counts, clinic, and/or pharmacy records, serum and/or saliva concentrations, biomarkers, direct observation, or using validated self-report tools (e.g. Morisky Medication Adherence Scale, Self-efficacy for Appropriate Medication Use (SEAMS), Hill-Bone Compliance Scale and others). • Clinical outcome: effect of intervention on clinical biomarkers (e.g. blood pressure, glycosylated haemoglobin (HbA1c), low density lipoprotein (LDL)), hospitalisation rates, mortality, emergency room visits, or any other markers of disease progress. The following outcomes were included if reported together with a clinical outcome: • Economic outcome: cost effectiveness analysis, or other relevant analysis. • Humanistic outcome: patient quality of life, knowledge, or satisfaction.	Qualitative behavioural and clinical outcomes (e.g. perceptions without reporting quantifiable outcomes), process outcomes (e.g. number of medication related problems identified, or number of recommendations accepted by prescribers), patient reported clinical outcomes, medication adherence measured using a non-validated tool.

2.3.3 Data extraction

A data extraction form was developed, and relevant data from eligible articles was extracted by the researcher. The data extraction form contained the following fields: study design, setting (e.g. community pharmacy), intervention details (e.g. disease state being targeted, pharmacist training undertaken, type of intervention, frequency of pharmacist-patient visits), outcomes (e.g. behavioural, clinical and/or humanistic and/or economic), participant characteristics (e.g. demographics, participant inclusion and exclusion criteria), and analysis undertaken (e.g. per-protocol).

2.3.4 Quality appraisal and data analysis

A risk of biases assessment was conducted for each of the included articles using Cochrane guidelines.[34] Selection, performance, detection, attrition, and reporting biases were examined. The risks were expressed as 'low risk', 'high risk', and 'unclear risk'. Articles where most of the domains were 'high risk' were discussed amongst the team members to ensure appropriateness of the classification and to justify their inclusion in the final review. Additionally, studies were compared based on their study design, the interventions undertaken and their findings. Pooling of the results to undertake meta-analysis was inappropriate as the study populations, interventions and methods of estimating adherence varied between the studies.

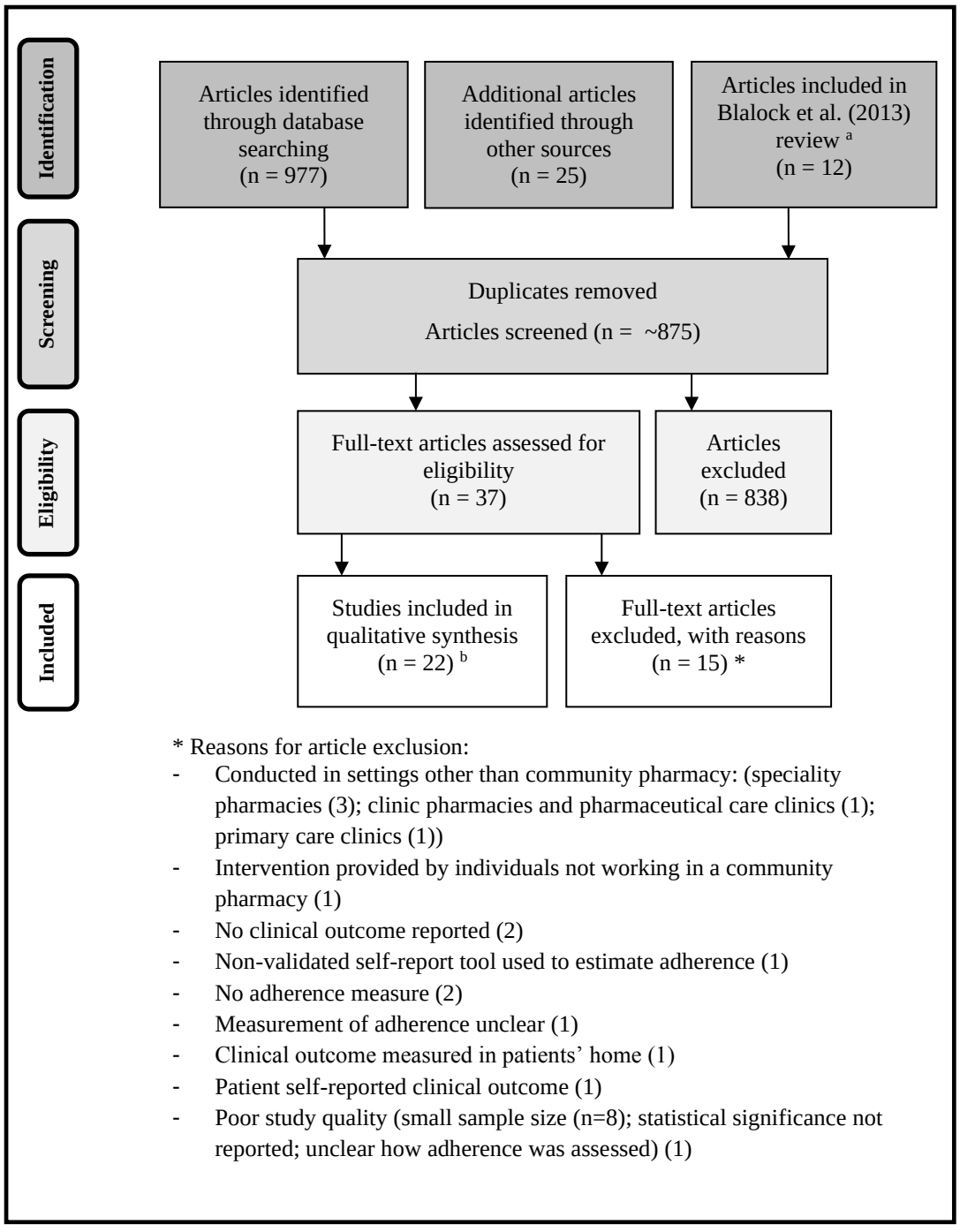


Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) diagram describing article selection procedures for the systematic review

[a] *studies that reported medication adherence as an outcome.*

[b] *some studies were reported in more than one journal article. These additional articles were also included in this review.*

2.4 Results

2.4.1 Overview

The database search yielded 977 articles, with an additional 37 articles being identified from other sources. Duplicate articles were removed, and screening for eligibility was conducted independently by the reseracher and TA, who read the study titles of all 875 articles retrieved. The abstracts were read when eligibility from the title was unclear and after screening, a total of 22 studies remained. After reading the 22 studies, it was found that three of the studies had more than one article published about the study (i.e. different outcomes reported in different journal articles). These articles were also identified from the full text and included in this systematic review. Thus, in this systematic review 22 studies, reported in 26 peer-reviewed journal articles were included in the qualitative synthesis. Refer to Figure 1 for details on the article selection process.

The studies were published from 1973 to 2015, and the majority were randomised controlled trials (n=16). Most of the studies (n=8) were from the USA, followed by Australia, Belgium and the Netherlands (n=3 each). Hypertension was the most frequently targeted health condition (n=9), with diabetes, asthma and depression being discussed equally (n=3). Each study included in the review assessed medication adherence as an outcome, with pharmacy dispensing records (n=9) being the main measure used, and five studies used both pharmacy dispensing records and a self-report tool for their adherence estimates. Table 2 summarises the characteristics of the studies included in the final review.

Table 2. Characteristics of the studies included in the systematic review

Authors	Study design	Country	Conditions targeted	Intervention	Adherence measure	Outcomes
Aguiar et al. (2012) [35]	Cohort study	Brazil	Hypertension	Monthly face-to-face pharmaceutical care visits (40-60minutes) for 10 months. Intervention focused on health education and monitoring for drug related problems (DRPs).	Self-report (4-item Morisky Scale and Haynes et al. Scale)	Medication adherence, BP, drug-related problems (DRPs), BMI, waist circumference.
Armour et al. (2007) [36]	Cluster-RCT	Australia	Asthma	Six month intervention, involving (usually) three visits. Involved education and counselling, review of inhaler technique, adherence assessment, detection of medication problems, goal setting and referral to GP (when necessary).	Self-report (BMQ)	Medication adherence, asthma severity/control, lung function (FEV_1, FEV_1/FVC), medication profile and daily dose, inhaler technique, action plan ownership, asthma-related QOL, perceived control of asthma, asthma knowledge.
Aslani et al. (2010) [37]	RCT	Australia	Dyslipidaemia	Pharmacy visit every three months (approximately), involving non-fasting cholesterol measurement, discussion about adherence and medication related issues, intervention devised, and a multi-part questionnaire.	Self-report (BMQ and MARS)	Medication adherence, non-fasting cholesterol levels.
Blenkinsopp et al. (2000) [38]	Cluster-RCT	UK	Hypertension	Three pharmacist visits over approximately two months (if workload was too high the intervention was conducted over the telephone). Involved the pharmacist asking questions about antihypertensive medications, and according to patients' response pharmacist either gave verbal or written information, contacted or referred patient to doctor.	Dispensing data and self-report (MARS)	Medication adherence, BP.
Bosmans et al. (2007) [39]	RCT	The Netherlands	Depression	Three contacts with community pharmacist for education about medications and	eDEM (electronic	Medication adherence, depression symptoms (Hopkins Symptom

Brook et al. (2003) [40]				coaching, received take-home video and printed material about antidepressants.	pill container)	Checklist (SCL-13)), drug attitude (Drug Attitude Inventory), economic analysis (utilisation of health care resources, costs, cost effectiveness analysis).
Bouvy et al. (2003) [41]	RCT	The Netherlands	Heart failure	Patient-pharmacist interview on the first visit and monthly contact for up to six months thereafter. During the first visit the patient's medication history was used to discuss medication usage and reasons for non-adherence.	MEMS	Medication adherence, hospitalisations, mortality, and disease specific and non-specific QOL.
Jahangard-Rafsanjani et al. (2015) [42]	RCT	Iran	Diabetes	Baseline pharmacy visits and five follow-up visits (one each month) and five phone calls between each visit. Educational intervention about diet management, physical activity, and diabetes complications. Patients received home blood glucose monitoring device, test strips, and a logbook. Referred to their doctor when appropriate.	Self-report (8-item Morisky Scale)	Medication adherence, HbA1c, SBP, DBP, patient satisfaction, willingness to pay for services, self-care activities, BMI, doctor visits.
Lai. (2007) [43]	Quasi-experimental time-series study	USA	Hypertension	Baseline, 1, 3, 6, and 9 month visit with the pharmacist. Involved BP measurement, free BP monitors, focus group at HMO, QOL survey, consultation regarding BP status, medications, non-drug therapy, lifestyle, and self-monitoring. Doctor recommendations if needed.	Dispensing data	Medication adherence, SBP, DBP, frequency of BP monitoring at home, and HRQOL.
McKenney et al. (1973) [44]	Cohort study	USA	Hypertension	Five monthly visits. BP measurement, administration of a true or false test, patient questioning about medications, identification and resolution of medication related issues, patient pamphlets and referral to other health professionals if appropriate.	Pill counts	Medication adherence, BP, patient knowledge and acceptance, suspected ADRs, recommendations to doctor and patient.
Mehuys et al. (2008) [45]	RCT	Belgium	Asthma	Education during visit one and advice on asthma control during visits two and three.	Dispensing data and self-report	Medication adherence, asthma control (ACT), asthma exacerbations, asthma-specific QOL, inhalation technique, asthma knowledge, smoking status.
Mehuys et al. (2011) [46]	RCT	Belgium	Diabetes	Education about type II diabetes and lifestyle, medication adherence counselling,	Dispensing data and self-report	Medication adherence, HbA1c, fasting blood glucose levels, knowledge about

				reminder for annual eye and foot exams, home glucose meter.		diabetes, self-management activities, sustainability of observed effect.
Ottenbros et al. (2014) [47]	Cohort study	The Netherlands	COPD and asthma	Pharmacy care program involving identification of medication-related problems, communicating medication changes to patients and doctors.	Dispensing data	Medication adherence, mean number of HDTs (oral high dosage corticosteroids or antibiotics), 19-item measure of: overuse of short acting betamimetic drugs (SABD), suboptimal maintenance therapy and medication, inappropriate technique or use of inhalation devices, and poor adherence.
Planas et al. (2009) [48]	RCT	USA	Hypertension	Monthly hypertension MTM services: History of medical problems, physical exam and BP measurement, education, medications and adherence discussed, plan developed.	Dispensing data	Medication adherence, SBP, percentage at goal blood pressure (<130/80mmHg).
Rickles et al. (2005) [49]	RCT	USA	Depression	3 monthly phone calls from community pharmacists while providing pharmacist-guided education and monitoring (PGEM).	Dispensing data	Medication adherence (specifically missed doses), patient feedback to pharmacist, depression symptoms (BD-II), antidepressant knowledge, beliefs, and orientation toward treatment progress (OTTP).
Robinson et al. (2010) [50]	Prospective controlled study	USA	Hypertension	History taken, BP measurement, education, monitoring therapy, doctor communication. Follow-up according to pharmacist's discretion (no less than monthly).	Dispensing data	Medication adherence, BP baseline, percentage at goal BP (<140/80mmHg), change in SBP and DBP.
Rubio-Valera et al. (2013) [51,52]	RCT	Spain	Depression	Educational intervention (CPI) when picking up first prescription of the 6-month antidepressant course. A shorter version was used as a reminder when patients refilled their prescriptions.	Dispensing data (MPR)	Medication adherence, depression severity (PHQ-9), HRQOL, satisfaction, quality-adjusted life-year (QALYs), intervention costs, cost-effectiveness analysis.
Spence et al. (2014) [27]	Retrospective cohort study	USA	Diabetes and/or coronary artery disease	Face-to-face B-SMART consult, involving the pharmacist identifying medication adherence barriers, developing solutions for these barriers, recommending adherence aids, motivating patients, and referring patients to other health care professionals if needed.	Dispensing data (MPR and DSR)	Medication adherence, HbA1c, low density lipoprotein (LDL) cholesterol, emergency department visits, hospital admissions, return on investment (ROI).

Stewart et al. (2014) [53,54] Lau et al. (2010) [55]	Cluster-RCT	Australia	Hypertension	Three pharmacy visits (baseline, 3- and 6-months), involving BP measurement, motivational interviewing and education, medication review (MUR), dose administration aid, refill reminders, referral to doctor if needed.	Dispensing data (MPR) and self-report (Morisky Scale* and TABS)	Medication adherence, SBP and DBP.
Sturgess et al. (2003) [56]	Cluster-RCT	Northern Ireland	Older peoples' health	Education on medical conditions, implementation of adherence strategies, rationalising of drug regimens and appropriate monitoring.	Dispensing data and self-report	Medication adherence, number of hospitalisations, sign and symptom control, cost analysis comparison of health care related resource usage, HRQOL (using the SF-36), patient satisfaction (in-house questionnaires), pharmacists' and doctors' perceptions.
Svarstad et al. (2013) [57]	Cluster-RCT	USA	Hypertension	Initial pharmacist consultation then five follow-up visits. Also received: BMQ (modified Brief Medication Questionnaires), wallet card, medication box, leaflets, and pedometer.	Dispensing data (PDC)	Medication adherence, reduction in SBP and DBP, BP control (<140/90mmHg).
Tommelein et al. (2013) [28]	RCT	Belgium	COPD	Two contacts with pharmacist, consisting of education about COPD, medications, adherence, self-management and smoking, as well as inhalation technique demonstration.	Dispensing data (MRA)	Medication adherence, inhalation technique, dyspnoea, COPD disease specific and generic health status, smoking status, exacerbations.
Zillich et al. (2005) [58]	RCT	USA	Hypertension	Pharmacy visits 4 times over 3 months (HI pharmacies) or 3 times over 3 months (LI pharmacies). HI pharmacies: hypertension education, handouts provided, take home BP machine and logbook, and treatment recommendation made to the doctor. LI pharmacies: BP measurement, and informed to see doctor if high BP, no education, BP monitors, nor treatment recommendation to doctor provided.	Self-report (4-item Morisky Scale)	Medication adherence, BP, health resource utilisation (hospitalisations, emergency room visits, physician visits), acceptance of pharmacist recommendations.

ADRs: Adverse Drug Reactions; BMQ: Brief Medication Questionnaire; BP: Blood Pressure; DBP: Diastolic Blood Pressure; DSR: Days Supply Remaining; HRQOL: Health-related Quality of Life; HMO: Health Maintenance Organisation; MARS: Medication Adherence Report Scale; MEMS: Medication Event Monitoring Systems; MPR: Medication Possession Ratio; MRA: Medication Refill Adherence; PDC: Proportion of Days Covered; RCT: Randomised Controlled Trial; SBP: Systolic Blood Pressure; TABS: Tool for Adherence Behaviour Screening; QOL: Quality of Life. *unclear if authors used 4-item or 8-item Morisky Scale.

2.4.2 Risk of bias assessment

The quality of all eligible studies were examined against each of the following criteria: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment for each outcome, incomplete outcome data, and selective reporting. One study identified during the literature search was omitted from this review even though it met the inclusion criteria. It was deemed poor quality by two team members (the researcher and TA), due to the small sample size (n=8), and the limited reporting of the study outcomes, and their statistical significance.[59]

Blinding of participants and personnel was a domain that was frequently identified as being at 'high risk' of bias in the eligible studies. Often the community pharmacist provided the intervention and also assessed the outcome (particularly clinical outcomes such as measurement of blood pressure (BP) and cholesterol levels in the pharmacy, or administering questionnaires to patients, either for self-reported adherence or assessing depression control). This may in part be due to the nature of the interventions conducted by these pharmacists, which were education-based. Patients were often unblinded and aware of their allocation into the intervention or control groups. Since all studies provided patients with information before participating, patients could easily determine this allocation and would have known their adherence and/or clinical outcome were going to be assessed.

2.4.3 Qualitative synthesis of outcomes

The studies included in this review assessed the impact of community pharmacist-led interventions on patients' medication adherence and other health outcomes. The outcomes described in these studies included: behavioural, clinical, humanistic, and economic outcomes. Refer to Appendix 3 for a summary of the study outcomes and their statistical significance.

2.4.3.1 Behavioural outcomes (medication adherence)

Measurement methods

All eligible studies evaluated the impact of a community pharmacist-led intervention on patients' medication adherence (n=22). The tools used to assess adherence varied between the studies. Twelve studies used objective measures to estimate adherence (pharmacy dispensing records, pill counts or electronic pill counters, or MEMS),[27,28,39-41,43,44,47-52,57] while five studies relied solely on validated self-report adherence tools.[35-37,42,58] The Morisky Scale[60] was the most frequently used self-report adherence tool. Five studies used two adherence measures, an objective measure (primarily dispensing records) and a self-report tool.[38,45,46,53-56] Using more

than one adherence method was often done in an attempt to validate the authours' results. Mehuys et al[45] found a significant difference in adherence rates between intervention and control patients using dispensing records yet when assessed using a self-report tool, there was no significant difference in the same cohort. Sturgess et al[56] assessed the change in percentage of patients' adherent to treatment using self-report and dispensing records. Using the self-report tool, they found a significantly higher proportion of intervention patients compared to control patients changed from being non-adherent to adherent by the end of the study. However, when adherence was assessed using the prescription records the difference between the two groups disappeared. These two studies suggest lack of concordance between self-reported and objective adherence measures.

Changes reported

A total of 65 adherence outcomes were reported for the 22 studies, with 61.5% of the outcomes showing a statistically significant results ($p<0.05$), favouring the intervention group. Eleven studies reported the percentage of patients' adherent to treatment as an outcome.[27,28,35,38,42,44,46,53,56-58] In six of these studies, a significantly higher proportion of intervention cohorts were adherent to their medications after the intervention, compared with control groups.[27,28,35,38,56,57] One study found no statistically significant differences,[53] and four other studies did not report on the statistical significance of their results.[42,44,46,58] Of the 11 studies reporting on the percentage of adherent patients, the majority specified a cut-off point that classified adherent and non-adherent patients.[27,28,35,38,42,44,53,57,58] The studies using pharmacy records to estimate adherence primarily used 80% as the cut-off value for defining patients as adherent or non-adherent.[27,28,57]

Twelve studies reported patients' mean adherence rates.[27,28,37-39,43-45,48,50,53,58] Of these, three studies reported a statistically significant difference in the mean adherence rate between the intervention and control groups, favouring the intervention.[28,38,43] Four studies found a non-significant difference in mean adherence rates between the intervention and control groups.[27,39,48,53] One study did not report on the statistical significance of their findings,[44] while another study found no effect of the intervention on the mean adherence rate between intervention and control patients.[37] Two studies reported contradictory findings in their mean adherence rates between the intervention and control groups.[45,50]

2.4.3.2 Clinical outcomes

Blood pressure

Ten studies in the review used blood pressure (BP) measurements as a clinical outcome to assess the effectiveness of their intervention. The BP outcomes from these studies were reported in twelve journal articles.[35,38,42-44,48,50,53-55,57,58]

The proportion of patients reaching their goal BP was assessed in six studies.[38,44,48,50,57,58] Three studies found a significantly greater proportion of patients achieved their goal BP in the intervention group compared with the control group.[38,44,48] Two studies found no significant differences in the proportion of patients reaching their goal BP,[57,58] while one study did not report the significance of the observed differences between the intervention and control groups.[50] Target BPs varied between the studies; Planas et al[48] used a goal BP of <130/80mmHg, while Svarstad et al[57] and Robinson et al[50] used <140/90mmHg. A more lenient goal of <159/89mmHg was used by Blenkinsopp et al.[38]

Five studies assessed the effect of the intervention on patients' systolic BP (SBP), by comparing SBP between the intervention and control patients.[48,50,53,57,58] Four studies found a significantly greater reduction in SBP in the intervention groups compared with the control groups.[48,50,53,57] One study found a non-significant difference between the intervention and control groups.[58]

HbA1c and blood glucose levels

Three studies described the impact of community pharmacist-led interventions on patients' glycated haemoglobin (HbA1c)[27,42,46] and on blood glucose levels.[46] Two studies were randomised controlled trials (RCTs)[42,46] and one was a retrospective cohort study.[27] They were conducted in Belgium,[46] the USA,[27] and Iran.[42] The findings regarding the interventions' impact on mean HbA1c were mixed; with one study reporting a significant difference in mean HbA1c levels, favouring the intervention group,[27] while for the remaining two studies the differences were not statistically significant. Although Jahangard-Rafsanjani et al[42] found no significant difference in their main analysis, they did report a significant reduction in HbA1c in the intervention groups compared to the controls when they undertook subanalysis of patients with a low baseline HbA1c (<7%). Mehuys et al[46] also examined the impact of the intervention on mean fasting blood glucose (FBG) levels and found no significant difference between groups at the end of the study period (six months); however, 18 months after this period the mean FBG level in the intervention group was significantly lower than in the control group.

Blood lipids and cholesterol levels

Two studies reported on the impact of community pharmacist-led interventions on patients' cholesterol levels.[27,37] The first study was an RCT conducted in Australia[37], while the second was a retrospective cohort study and was conducted in the USA.[27] Aslani et al[37] found the intervention group significantly lowered their non-fasting cholesterol levels over the study period, while the control group did not. Spence et al[27] focused on low density lipoprotein cholesterol (LDL-C) and found a significant difference in mean LDL-C levels between the intervention and control groups, favouring the intervention arm.

Respiratory disease control

Four studies described the impact of interventions on either asthma or chronic obstructive pulmonary disease (COPD) control, or both conditions.[28,36,45,47] The outcomes reported in these four studies varied greatly. Ottenbros et al[47] used the prescribing of HDT (oral High Dosage Therapy (corticosteroids or antibiotics)) as a proxy measure of asthma/COPD control, and they did not report the statistical significance of the differences between the intervention and control groups. Mehuys et al[45] and Armour et al[36] explored asthma control, using different outcome assessments. Mehuys et al[45] found improvements in Asthma Control Test score in patients with insufficiently controlled asthma at baseline, as well as a significant reduction in night time awakening in the intervention group compared to the control group. Compared to baseline, intervention patients also showed significantly decreased use of rescue medications during and at the end of the study period.[45] Armour et al[36] found that the proportion of intervention patients with severe asthma significantly declined during the study, while the proportion in the control group did not change significantly. However, no significant changes were found in FEV_1 and FEV_1/FVC from baseline to the end of the study in both groups.[36] Tommelein et al[28] explored COPD control and found a significantly lower frequency of severe exacerbations in the intervention group compared with the control group. The estimated annual rates of severe exacerbations were found to be significantly lower in the intervention group compared to the control group. A non-significant difference was reported between groups for moderate exacerbations.

Symptoms of depression

Depressive symptom control was evaluated in three studies.[39,49,51] Each study used a different assessment tool, the Beck Depression Inventory-II[49], Patient Health Questionnaire (PHQ-9)[51], and the Hopkins Symptom Checklist (SCL-13)[39]. However, none of the studies found a

significant difference in depressive symptom control between the intervention and control groups at the end of the study period.

Other clinical outcomes

Hospital visits: Six studies reported the impact of the intervention on patients' hospitalisation rates.[27,28,41,45,56,58] A total of 13 outcomes were reported. Only three outcomes showed statistically significant differences between the intervention and control groups. In the diabetic cohort, Spence et al[27] found the percentage of patients visiting the emergency department was significantly lower in the intervention group compared with the control group. Similarly, Tommelein et al[28] found a significant reduction in the annual hospitalisation rate (rate ratio: 0.28, p=0.03), as well as the number of hospitalisation days in the intervention group (rate ratio: 0.27, p<0.0001), compared to the control group.

Intensification or change to treatment: Six studies described the impact of community pharmacist-led interventions on patients' treatment regimens.[36,42,46,56-58] The outcome measures varied greatly amongst these studies (see Appendix 3 for more details on study outcomes).

2.4.3.3 Humanistic outcomes

Knowledge about medication and/or illness

Patients' knowledge about their medications and/or their illness was explored in six studies.[36,44-46,49,56] Three studies reported significantly greater patient knowledge in the intervention groups at the end of the study period, when compared with the control groups.[36,44,49]

Patient satisfaction

Six studies reported on the impact of the intervention on patients' satisfaction levels.[38,40,42,51,56,57] All of the six studies reported on patient satisfaction with the particular intervention, while some also incorporated satisfaction with general pharmacy as well.[38,42] In four studies, intervention patients reported being satisfied with community pharmacists' services provided to them.[40,42,56,57] Rubio-Valera et al[51] did not find a difference in terms of patient satisfaction between the intervention and control groups, while Blenkinsopp et al[38] reported a non-significant difference.

Quality of life

Eight studies investigated changes in patients' quality of life as a result of the community pharmacist-led interventions.[28,36,41,43,45,50,51,56] Four studies used generic quality of life assessment tools: SF-36,[50,56] SF-12,[43] EuroQol,[51] while two studies used a generic tool together with a disease specific tool.[28,41] Mehuys et al[45] and Armour et al[36] used a disease-specific tool, the Asthma Quality of Life Questionnaire, to assess the quality of life in those with asthma. The tools used varied greatly between the studies as did the results, making comparisons difficult (see Appendix 3 for more details on the study outcomes).

2.4.3.4 Economic outcomes

Four studies evaluated the impact of the pharmacist-led interventions in terms of their economic benefit.[27,39,52,56] Studies by Rubio-Valera et al[52] and Bosmans et al[39] targeted depression symptom control, and both studies undertook a cost-effectiveness analysis. The first study, an RCT conducted in Spain, found the intervention was unlikely to be cost-effective compared to the control group in terms of improving depression symptoms.[52] Bosmans et al[39] also carried out an RCT and assessed their intervention cost-effectiveness in terms of improving adherence. They reported that the intervention was likely to be cost-effective. [39]

The remaining two studies targeted diabetes control[27] and older people's health.[56] Spence et al[27] found that their intervention had the potential to reduce costs associated with emergency department visits and hospitalisations, while providing a positive return on investment of 5.74 (USD) for every dollar spent on the intervention. Sturgess et al[56] on the other hand found no significant difference in the cost of health care (per patient) between the intervention and control groups, or any significant difference in medication costs.

2.5 Discussion

This systematic review found that community pharmacist-led interventions can improve patients' medication adherence and contribute to better BP control, cholesterol management, COPD and asthma control. However, the findings did not report statistically significant effects of the interventions on glycated haemoglobin (HbA1c) levels, and depression symptom control.

Behavioural outcome (medication adherence)

All the studies in this systematic review evaluated the impact of a community pharmacist-led intervention on patients' medication adherence. A total of 65 outcomes were reported and

nearly two-thirds of the outcomes (61.5%) showed a statistically significant result, favouring the intervention group. This is higher than the overall figure reported by Blalock et al[31] who reported a significant difference in 43.3% of their adherence outcomes. However, the two reviews are different in terms of the types and number of studies, the countries studied, and the outcomes reported.

The tools used to estimate adherence in the present systematic review varied greatly, with objective measures being most frequently used. Fewer studies relied solely on validated self-report adherence tools, and others used both objective measures (primarily pharmacy records) and self-report tools. These authors often used more than one adherence tool in an attempt to validate their results. This is worthwhile, as a review by Van Wijk et al reported differences in adherence rates using the different adherences tools.[61] This was also evidenced in certain studies included in this review, whereby different adherence tools yielded different adherence values.[45,56] It is possible that certain tools are insensitive and thus unable to accurately capture small changes in adherence behaviours in particular study cohorts. Aslani et al[37] suggested that this may have been the case in their study, when they were unable to detect any difference in non-adherence between the intervention and control group using the MARS self-report tool.

Clinical outcomes

Cardiovascular disease is the leading cause of death in many countries, burdening both patients and society. Improving the management of, and targeting the risk factors for, cardiovascular disease are consequently important goals.[62] Diabetes for example, is a major risk factor for kidney failure and stroke, and has been previously described as a contributor to both blindness and lower extremity amputations.[63] The prevalence of diabetes is believed to be between 5%[64] to 6%[65] in New Zealand, 5% in Australia,[62,66], and around 7.8%[67] to 10.5%[68] in the USA. Due the negative consequences and prevalence of this disease, it is somewhat disappointing to see community pharmacist-led interventions, in this systematic review, had little impact on patients' diabetes control. This contradicts other diabetes interventions for example, in a study by Krass et al,[69] who found positive benefits from a pharmacist-led diabetes intervention on patients' HbA1c and blood sugar control. However, the study by Krass and colleagues did not estimate adherence as an outcome and it consequently did not meet the inclusion criteria for this systematic review.[69] Blalock et al[31] also reported positive effects of community pharmacist-led diabetes interventions on patients' diabetes management; however, those diabetes studies in

Blalock's review had generally weak study designs. The present review included three studies exploring diabetes management,[27,42,46] with one being underpowered,[42] thus limiting the researcher's ability to draw fully informed conclusions. Nonetheless, it was interesting to see the importance of patients' baseline characteristics in the diabetes interventions. It was noted that patients with poorer glycaemic control[46] and those deemed non-adherent at baseline[27] had the potential to benefit most from the diabetes interventions.

Reductions in BP have been associated with lower cardiovascular morbidity and death rates, as well as lower number of strokes and coronary events.[70] It is promising to see the large number of community pharmacist-led interventions targeting hypertension, and the significant contribution pharmacists can have in managing this condition. This is possibly because hypertension can be easily monitored in the community pharmacy setting by measuring a patient's BP.[38] Most hypertension interventions aimed for patients to reach a target BP; however, these targets varied often by country, by comorbid disease states and the year that the studies were undertaken. For example, Blenkinsopp et al[38] used targets applicable to the 1998 setting, which described controlled BP as <159 mmHg systolic and/or <89 mmHg diastolic readings. In more recent studies, the targets are stricter with many reporting target BPs as 130/80 or 140/90 mmHg. Six studies assessed the proportion of patients reaching their goal BP,[38,44,48,50,57,58] and in half the studies, a significantly greater proportion of intervention patients achieved their goal BP, compared with control patients.[38,44,48]

The interventions

The most effective interventions to improve adherence are multifaceted,[71] targeted and personalised.[72] They usually have a combination of components including education, simplification of treatment regimens, communication between patients and their health care professionals, follow-up and monitoring.[71] Most of the interventions assessed in this review focussed on patient education and/or counselling, as well as other components; thus they were multifaceted. This finding is in line with another study.[73] Thoopputra et al[73] classified interventions into patient-orientated and professional interventions (including medication review and referral), and they identified more than half (53%) as patient orientated focussing on patient education, counselling, monitoring, and risk screening. They found fewer studies involved both patient and professional interventions (44%). In the present systematic review, most studies involved a component of patient education or counselling. The focus was primarily on patients' medications, medical conditions and demonstration of effective

technique (for example inhaler technique). Educational interventions are easy to implement in the community pharmacy setting, while being relatively low cost, and effective among different participant groups.[32] They can also positively influence patient satisfaction and knowledge,[74] because patients generally desire greater information about their therapies.[38] The findings from this systematic review align with this notion, as the pharmacist-led interventions positively influenced patients' satisfaction and knowledge.

Most of the reviewed studies were randomised controlled trials, and the randomisation process was mostly done at the pharmacy level. This could be due to authors attempting to minimise contamination (by control patients accidentally receiving the intervention), practicality issues associated with altering consultations between patients or due to potential ethical issues.[38]

Some studies selectively recruited patients, and this may have contributed to selection biases. Blenkinsopp et al[38] reported that a small number of pharmacists intentionally excluded certain patients from participation, with the reasons for this selective recruitment not being specified; perhaps recruiting regular patients more frequently, and avoiding those with whom they lacked rapport.

Barriers to implementation of community pharmacist-led interventions has been described previously and they include but are not limited to, lack of time, training, resources, inter-professional relationships and collaboration and lack of public awareness of available services.[33] The timing of the intervention can also play an important role in its success. Eussen et al[32] suggested that patients newly starting statin treatment may be most likely to benefit from pharmaceutical care interventions during the initial months, as adherence levels usually decline several months after beginning treatment.[32] Although this example pertains to statin initiation, similar findings have been found for hypertension medications too, with 50% of patients stopping antihypertensive treatment one year after commencement.[75] Another time component to consider is duration of the intervention itself, as a review conducted by van Dalem et al[76] found intervention duration can impact adherence intervention effectiveness in patients with cardiovascular disease.[76]

Furthermore, pharmacists have been reported as being their own barrier to successful pharmaceutical care, with many finding extended pharmacy interventions too overwhelming to implement.[38] Zillich et al[58] found that not all pharmacists are equally assertive, and certain pharmacists did not recommend changes to patient therapy, possibly as a result of this assertiveness. A potential solution is further pharmacist training, policy development as

described by Mossialos et al[77] and providing remuneration for services provided. This would help ensure pharmacists are sufficiently skilled, motivated and confident in providing new services, and are appropriately rewarded for their work.[77]

Another barrier which is important to consider is the transferability of interventions to other community pharmacy settings. Zillich et al[58] reported that their high intensity intervention may be unsuitable for all community pharmacies to implement due to high workload, and the time intensive nature of their intervention. Chabot et al[78] also raised this concern. Zillich et al[58] found that for their high intensity interventions pharmacists spent approximately 100 minutes per patient, compared to the low intensity interventions where pharmacists spent less than 15 minutes per patient. It is possible that patient consultations by appointment are needed for successful implementation of certain interventions.[78]

Quality of included articles

The risk of bias assessment indicated that many of the reviewed studies were biased in the performance bias domain, whereby blinding of either participants or pharmacists did not occur. The community pharmacist often delivered the intervention and also assessed the outcomes. However, often the outcome was assessed using an objective measurement tool, which may have minimised the potential effects of this bias on the outcome (e.g. a blood test to assess cholesterol, dispensing records to assess adherence or BP readings to assess hypertension control). Some studies involved personnel other than the pharmacist to measure the clinical outcomes.[39,40,45,49,51,52,56] This may help mitigate bias related to lack of blinding and may be worthwhile adopting in future similar studies.

Another domain often assessed as 'high risk' in the studies included in this review was selection bias, as concealment of patient allocation was rarely undertaken. This could have given rise to the Hawthorne effect which sees patients' behaviours change as a result of knowing they are being observed or assessed, leading to them behaving in a socially desirable manner.[46,79-81] This is particularly an issue for patients in the control group, as improvements in their outcomes may occur by them merely participating in the study. This has potential to mask the full effect of the intervention.[46]

2.6 Limitations

When interpreting the results from this review, several caveats need to be considered. Only studies published in English were reviewed, and it is possible that there were more studies published in other languages that have not been reported. Only one team member (the researcher) was involved data extraction, and this is a possible limitation of this review. Some of the reviewed studies were observational studies; Roebuck et al[14] noted that observational studies can be at risk of biases, as an unobserved confounder can influence both the groups being compared and the outcome that is being assessed. However, since this review aimed to provide a general overview of all the studies available in this area, exclusion of these observational studies would have been inappropriate. Furthermore, this review only analysed community pharmacist-led interventions and interventions often had several components, and this made it difficult to ascertain which particular component of the interventions contributed to the improvements observed.[27,46,58] Future studies should attempt to identify which aspects of the intervention have the greatest impact on their desired health outcomes, in their particular cohort. This may include, but should not be limited to, the contribution of multicompartment adherence aids and refill reminders, in improving patient health outcomes.

Most of the reviewed studies were unblinded, and usually both patients and pharmacists volunteered to participate in the studies. There may be systematic differences between patients and pharmacies who voluntarily participate compared to those who do not. Additionally, some of the reviewed studies lacked details about the intervention procedures, such as the nature of the intervention and the individuals involved in data collection. For example, one study explored the impact of a one-month pharmacist-led intervention on heart failure control; however, details on how the intervention was delivered was not provided (e.g. face-to-face intervention or through telephone).[41] This makes comparisons across studies challenging. Attempts to contact authours did not occur, and only the information provided in the journal articles was used in the analysis.

2.7 Conclusion

Community pharmacist-led interventions have contributed to improved patient medication adherence and better disease control. Particularly, they have contributed to better BP control, cholesterol management, COPD and asthma control. The studies in this review, however, did not find an effect of the interventions on glycated haemoglobin (HbA1c) levels or depressive symptom control. Most of the interventions were delivered face-to-face and involved an

educational component, to improve patients' understanding of their medications or illnesses. While literature is already available to support the use of educational interventions in the community setting, understanding the contribution of the other intervention components is also important. Future research should attempt to better understand which components make the greatest contribution towards improving adherence and health outcomes, for patients with different medical conditions.

2.8 Update on the literature

An updated review of the literature was undertaken in July 2020. An updated search of the same databases as those described earlier in this chapter, were searched once again to identify any newly published work in this area. The following databases were searched - Medline, EMBASE, Google Scholar, International Pharmaceutical Abstracts, and ProQuest Theses and Dissertations. The same key words were used for the database searches as were used in the initial systematic review search. The search was limited to those articles published from 1 October 2015 until 1 July 2020.

The search yielded just two new articles that met the systematic review inclusion and exclusion criteria. The characteristics of each of the studies are included in Table 3. These two studies are each summarised below.

The first study, by Akinbosoye et al,[82] assessed the impact of a community pharmacist-led intervention on patients newly starting a medication for a chronic condition. The authors identified 16 medication classes that are most frequently dispensed for chronic conditions and patients had to be newly starting one of these 16 medications in order to be included in the study. Patients included in the study received two counselling sessions with the community pharmacist face-to-face or via telephone. During the first session, the pharmacist used motivational interviewing to understand patients' motivations and level of eagerness to follow the prescribed medication regimen, as well as addressing any medication concerns and suggesting how taking medications could be scheduled into their day. During the second session, the pharmacist checked in with the patient to see how they were managing the new medications and attempted to identify if there were any medication adherence barriers. Adherence was also encouraged using refill reminders to inform patients when their refills were due (proactive) and over-due (reactive). The study consisted of a retrospective cohort analysis (n=72,410 in the intervention group and n=72,410 in the control). The authors assessed

medication adherence using the proportion of days covered (PDC). PDC ≥80% was used to classify patients as adherent (≥80%) or non-adherent (<80%). The authors reported their results in terms of an unadjusted model and adjusted model, the latter model adjusting for covariate imbalances that persisted after propensity score matching.

The authors reported that the pharmacist-led intervention contributed to significantly higher medication adherence in the intervention group, compared to the control group at the end of the study period (difference of 3% in the unadjusted model and 1.8% difference in the adjusted model). The proportion of patients who were adherent (PDC ≥80%) at the end of the study period, using the unadjusted model, was also significantly greater in the intervention group (n=24,830 (34.3%)) compared to the control group (n=23,402 (32.3%)) (difference = 2%, p<0.0001). In the adjusted model, the statistically significant difference remained. One of the limitations of the present study was that, while the authors commented on the statistical significance of their findings, they did not comment on their clinical significance. It is questionable whether the number of patients who became adherent (24,830-23,402=1,428 patients) out of the study population (n=144,820) would contribute to much of a clinically significant change.

The proportion of patients, in the unadjusted model with one or more hospitalisations was significantly lower in the intervention group (n=3,591 (5%)) than the control group (n=4,907 (6.8%)). For the adjusted model the proportion of patients with one or more hospitalisations was not reported. In terms of health costs and health utilisation, the intervention group had significantly lower health costs and health utilisation than the control group in both the adjusted and unadjusted models (except for inpatient costs (in both the adjusted and unadjusted models), as well as pharmacy costs (in the unadjusted model)).

The study involved retrospective analysis of routinely collected health data, therefore biases which often affected other studies in the foregoing systematic review, such as lack of blinding of participants, was not an issue for this study.

The second study, by Kovačević et al,[83] aimed to improve asthma patients' self-management through a community pharmacist-led education and inhaler technique intervention. A total of 128 patients from ten different pharmacies across Serbia were recruited and 90 patients (70.3%) completed the study.

During the first session, patients were administered questionnaires (the Asthma Control Test (ACT), 8-item Morisky Scale, Knowledge of Asthma and Asthma Medicines (KAM) and Beliefs about Medicines Questionnaire (BMQ)) by pharmacists. Detailed education and counselling was provided, focusing on: disease characteristics, symptoms, medication mechanism of action, difference between preventer and reliever medication, dosage regimen, peak flow meter use, recognising and acting on asthma attack symptoms, adverse reactions and ways to mitigate them, and asthma triggers. Pharmacists also provided a demonstration of inhaler technique and provided patients with a written asthma action plan.

Three months after the education and counselling session, another session occurred that only involved the pharmacist administering questionnaires to patients. If patients returned to the pharmacy before this, patients were able to ask pharmacists any questions and raise any concerns about their asthma medications.

It was found that after the intervention, patients had significantly improved asthma disease control, through improvements in their ACT scores. The proportion of patients with poorly controlled asthma reduced significantly (from n=49, 54% at baseline to n=33, 37% at the end of the study). At the end of the study, patients also had significantly improved inhaler adherence, assessed with the Morisky Scale, with the proportion of patients with low adherence significantly reduced (from n=54, 60% at baseline to n=42, 47% at the end of the study). The authors also reported patients had greater knowledge, improved beliefs about asthma medications and their condition, reduced concerns about asthma medications, and improved perceived benefits of asthma medications. The authors suggested that the improved disease control may be the result of greater disease and medication knowledge, as well as the pharmacist demonstrating the inhaler technique and supporting patients' adherence. The authors attributed the improvements in asthma management to improved patient knowledge and improved attitudes, which empowered patients to take charge of their health condition.

One of the limitations of the study by Kovačević et al is the lack of blinding. Pharmacists were involved in delivering the intervention and for administering the questionnaires, meaning that the outcome assessment was unblinded, leading to potential bias. It is possible that patients answered more favourably post-intervention due to the improved relationship and rapport developed with the pharmacist through the study. While the study met the systematic review inclusion criteria due to the presence of before- and after- analysis, the study did lack a control group. To fully understand the impact of the intervention, it would have been beneficial to have

a control group who received usual care, to enable comparisons in outcomes between intervention and control patients.

Table 3. Characteristics of the studies included into the systematic review update

Authors	Study design	Country	Conditions targeted	Intervention	Adherence measure	Outcomes
Akinbosoye et al.[82]	Retrospective cohort study	USA	Patients newly starting medications for chronic diseases	Two counselling sessions either face-to-face or via telephone. Session one: the pharmacist used motivational interviewing to understand the patients' motivations and eagerness to follow the prescribed medication regimen, as well as addressing any medication concerns and suggesting how medication taking could be scheduled into their day. Session two: The pharmacist checked in with the patient to see how they were managing the new medications and attempted to identify if there were any medication adherence barriers. Adherence was also encouraged using refill reminders, to inform patients when their refills were due (proactive) and over-due (reactive).	Dispensing data (PDC)	Medication adherence, hospital admissions, emergency department visits, outpatient visits, health care costs
Kovačević et al.[83]	Prospective cohort study	Serbia	Asthma	A face-to-face counselling and education session. Session one: Patients administered questionnaires by pharmacists. Detailed education and counselling covering disease characteristics, symptoms, medication mechanism of action, difference between preventer and reliver medication, dosage regimen, peak flow meter use, recognizing and acting on asthma attack symptoms, ADRs and ways to mitigate them, asthma triggers. Pharmacists also provided a demonstration of inhaler technique and provided patients with a written asthma action plan. Session two (not compulsory): if patients returned to pharmacy before session three, then the pharmacist provided extra counselling upon patients' request. Session three: Occurred three months after first session. Patients administered questionnaires by pharmacists.	Self-report (8-item Morisky Scale)	Medication adherence, BMQ, KAM, ACT

ACT: Asthma Control Test, ADRs: Adverse Drug Reactions, BMQ: Beliefs about Medicines Questionnaire, KAM: Knowledge of asthma and asthma medicines, PDC: Proportion of Days Covered.

2.9 What the updated literature adds

The two new studies support the earlier systematic review findings, showing that community pharmacist-led interventions can improve patients' medication adherence and contribute to improved clinical outcomes.

The first study, by Akinbosoye et al,[82] reported positive effects of the intervention on patients newly starting chronic disease medications and found the intervention significantly reduced patients' admissions into hospital and reduced health care costs. The second study, by Kovačević et al,[83] reported positive effects of their asthma intervention on patients' disease control, finding significant improvement in Asthma Control Test (ACT) scores, as well improved humanistic outcomes.

CHAPTER 3. METHODOLOGY

3.1 Chapter overview

This chapter provides an overview of the research paradigms, methodology and methods underpinning the present research. The research is comprised of two studies: a quantitative retrospective matched-cohort study; and a qualitative study, consisting of semi-structured interviews and observations. The matched-cohort study aimed to examine the impact of LTC on patients' medication adherence and ambulatory sensitive hospitalisations (ASH). Semi-structured interviews with community pharmacists who provide LTC, as well as observation of pharmacy sites, were undertaken to explore pharmacists' experiences of and attitudes towards the LTC service, explore the factors that contribute to their LTC service provision, and understand what activities or services community pharmacists provide to LTC enrolled patients. This chapter explores the rationale for each research method and describes the analysis techniques used.

3.2 Research paradigms

Research paradigms have been defined as "the basic belief system or worldview that guides the investigator, not only in choices of method but in ontologically and epistemologically fundamental ways".[84] The concept of research paradigms is often attributed to the works of Thomas Kuhn[85]; however, Kuhn himself used more than twenty different definitions for the term. Paradigms play an important role in influencing the research process,[86] in the research aims, motivations and research expectations.[87] The research paradigm or worldview provides a lens for viewing and interpreting the study material at hand.[86,88]

There are three basic elements of research paradigms - ontology, epistemology, and methodology.[84,89] Ontology focuses on reality, and what reality is. Epistemology and methodology are driven by ontological beliefs. Epistemology covers how researchers come to know reality. The relationship between the researcher and what can be known is underpinned by epistemology. Methodology refers to how the research is undertaken and how new knowledge is obtained.

For the present research, the researcher used an explanatory sequential design, undertaking a quantitative matched-cohort study which then informed the subsequent qualitative interviews and observations. There are certain worldviews that inform mixed methods research. These are

described by Creswell as post-positivism, constructivism, participatory paradigm, and pragmatism.[90]

Positivism is a paradigm of enquiry that seeks to find the truth,[84] so it is based on the rules of logic, measurement, truth, prediction, and absolute prediction.[86] Although positivism is not normally one of the worldviews adopted for mixed methods research, it is explained here to provide comparison with the other paradigms. Positivism dominated the world of physical and social science for more than four hundred years.[84] Positivist researchers believe one 'reality' exists and it is their job to discover this reality using specifically quantitative methods.[91] These quantitative methods are influenced by the positivist methodology, which is experimental in nature.[91] Positivist researchers endeavour to control confounding variables to prevent the outcome being influenced. Their epistemology is that of objectivity and, therefore, positivist researchers distance themselves from the research processes.[84] Doing so, prevents the researcher influencing the matter under study, as well as the study matter influencing the researcher.[84]

Post-positivism is an alternative paradigm that emerged through the realisation that reality can never be completely known to the researcher.[86] The ontological beliefs of post-positivism are a development of critical realism, where researchers believe a 'truth' exists, but this truth is unable to be easily found or identified.[84,88] Using post-positivism, a theory or hypothesis cannot be 'proven'; rather, evidence can be collated disproving alternative explanations (falsifying hypotheses).[84,88] The post-positivist epistemology values objectivity, but understands that one is unable to be truly objective. For this reason, post-positivists try to control for the potential influence the researcher can have on the findings. Furthermore, they believe in experimental study designs, particularly quasi-experimental study designs. However, qualitative methods may also be used to answer certain research questions.[84]

Similar to post-positivist researchers who adopt both qualitative and quantitative study methods, pragmatic researchers use both study methods to answer their research questions. Through the pragmatism lens, the focus is on answering the research question, using whichever study design works best to do so.[92] This research paradigm, which was first described by Pierce in 1905, is focused on the outcome.[93] The study methods, particularly the data collection and data analysis, are tailored around how best to answer the study questions at hand.[87,94] This flexibility means that the researcher is not limited to using one system of philosophy or reality.[87]

Unlike post-positivist researchers, who begin with a theory, constructivists inductively create a theory through their research.[88] The interpretivist/constructivist paradigm focuses on understanding human experiences.[91] These researchers do not begin with theory; rather, they generate it through their research. They start "from the bottom up", as Creswell described, meaning they use individuals' own experiences and perspectives to develop broader patterns and gain an understanding of the phenomenon under study.[90] They rely primarily on qualitative data collection methods.[87,88] The research relies heavily on subjects' views[88] and thus is conducted through the eyes of those people who have lived through relevant situations.[86] Through the interpretivist/constructivist lens, researchers deem reality to be socially constructed.

The participatory paradigm is issue-focused and attempts to collaborate with and involve certain participant groups in order to bring about a change in practices.[88] Participants are actively involved in the research from conception, study design, data collection, and data interpretation, through to actually seeing the research bringing about change. Historically this paradigm has been used for qualitative research but more recently it has been incorporated into quantitative study methods too.[88]

The aims of this thesis are to examine the impact of the LTC service on patients' medication adherence and ASH, understand how New Zealand community pharmacists provide the LTC service, and explore community pharmacists' views and experiences with the LTC service and its provision. It would be difficult to address these research aims using either quantitative or qualitative methods alone, so a mixed methods approach was adopted. The mixed method design precludes the exclusive use of quantitative and qualitative methods, and thus the adoption of positivism and interpretivism paradigms. Rather the post-positivism and pragmatism lenses are more appropriate when undertaking mixed methods research. The pragmatism paradigm lends itself well to the present research, due to its flexibility and 'what works best approach', allowing the researcher to adopt any study methods that best address the research aims.

3.3 Research methodology

The use of both quantitative and qualitative methods lends itself well to the adoption of mixed methods research. A major advantage of such an approach is that it facilitates a more complete understanding of a phenomenon, compared with using only one method.[88]

Mixed methods research involves the collection and analysis of both quantitative and qualitative data.[95,96] Mixed methods research allows the strengths from quantitative and qualitative data to be joined, enabling the researcher to better answer the research question at hand.[92] Data can be collected concurrently, whereby both quantitative and qualitative data are collected at once, or sequentially, when either the quantitative or qualitative data are collected prior to the other.[97]

There are three main ways of integrating quantitative and qualitative data in mixed methods research - merging, connecting, and embedding.[92] Merging involves combining quantitative data together with qualitative data, while connecting involves either using quantitative findings to inform a subsequent qualitative study, or vice versa. Embedding involves integrating a smaller set of data into another larger data set.[92]

In the past, an incompatibility thesis was proposed with mixed methods research. Certain philosophers and researchers argued that the differences in ontological and epistemological assumptions that underpin each method, quantitative and qualitative, are too large, therefore precluding them from being used together in a single piece of work.[96,98] However, due to the efforts of many scientists, the use of the pragmatist paradigm for mixed methods research has been well accepted as valid and deemed useful for answering certain research questions.[96,98] When answering the research questions at hand, the idea of using 'what works' is appropriate. Therefore, reality is thought to be that which works best at a particular time point.[88]

There are different types of mixed methods research designs, each with their own data collection and data analysis steps and timelines.[90] They include: convergent designs, whereby quantitative and qualitative data are collected concurrently; explanatory designs, where quantitative data are collected and analysed first to inform the qualitative study; and exploratory designs, which require qualitative data to be collected initially, the findings from which are used to inform the quantitative phase.[90]

For mixed methods, pragmatism enables various study designs, data collection methods, data analyses, worldviews and assumptions to be used.[88] The pragmatism worldview was adopted for the present research as it appeared to be most appropriate for addressing the research aims and objectives. Furthermore, an explanatory sequential, mixed method design was adopted that involved using the findings from the quantitative phase to inform the subsequent qualitative phase.[90] The first study, which was quantitative in nature, was used to answer the first research aim, relating to the impact of the LTC service on patients' medication adherence and ASH. The

data set and findings from the quantitative study helped identify pharmacist participants for the qualitative study, which comprised the second study of this thesis. The qualitative study aimed to understand how New Zealand community pharmacists provide the LTC service and to explore pharmacists' views and experiences with the LTC service and its provision.

3.4 Research methods

The quantitative study involved retrospective analysis of routinely collected health data sets. It used a deductive approach to synthesise numeric evidence about LTC effectiveness from thousands of patients. The study method also allowed generalisability of the study findings to the wider LTC population.[92,99]

The qualitative study involved semi-structured interviews with community pharmacists, who provide the LTC service and observation of community pharmacy sites where LTC is provided. While the quantitative study involved data manipulation, the qualitative study involved naturalistic inquiry and provided a real-world perspective using pharmacists' own voices.[92,99,100] Such rich information could not have been captured via quantitative methods.[92] As part of the qualitative study, there was a small component that was quantitative, specifically, the collection of information about pharmacy characteristics and details about the LTC activities or services provided in the pharmacy.

The next two sections discuss each study separately.

3.5 Phase I (Quantitative study)

The first study aimed to examine the impact of the LTC service on patients' medication adherence and ASH. Details on the choice of quantitative approach and data analysis techniques used and the analyses undertaken are summarised below.

3.5.1 Choice of quantitative study design

To assess the effectiveness of services, the use of experimental study designs such as randomised controlled trials (RCTs) is generally considered the gold standard approach.[34,101-104] In an RCT patients are randomly allocated to either the intervention group or the control group, thereby theoretically balancing background characteristics (covariates) between the two groups. Therefore, this ensures treatment effect will not be confounded by the background characteristics of participants.[101,104] Thus, in a well-designed RCT, the only systematic

difference between patients in the treatment and control groups should be the exposure to the treatment.[104,105] This helps to eliminate the issue of selection bias.

Patients enrolled in the LTC service are systematically different to patients not enrolled. Enrolled patients generally have more chronic conditions, are prescribed a greater number of medications and have poorer medication adherence compared with those individuals not enrolled.[106] These differences between enrolled and not enrolled patients, therefore precludes the use of RCT study designs comparing those enrolled with those not enrolled, because the impact of the intervention may be biased due to differences in background characteristics between the two groups.

It is also important to consider the fact that the LTC service is a nationwide, community pharmacy service, which has enrolled patients continuously since July 2012. The delivery of the LTC service is thought to vary between pharmacies.[26] Thus, undertaking a well-designed and well-executed RCT would be difficult, as randomising patients into the intervention and control groups would need to occur at the pharmacy level (i.e. randomise some patients in a pharmacy to the intervention group and some patients into the control group). This would put patients at risk of contamination as pharmacists would need to provide the LTC service to intervention patients and standard service to control patients. Furthermore, patients come into the pharmacies at unscheduled times, making it difficult for the pharmacists to know which group (the intervention or control) each patient belongs to. It would also be challenging for pharmacists to ensure that other patients in the pharmacy do not overhear the intervention. These challenges are particularly important, as a large component of the LTC service is education and counselling,[21] which usually occurs at the pharmacy counter when patients come to collect their medications. Such complexity is one of the innate limitations to using a RCT study design for this research.[107]

Consequently, the researcher had to consider alternative quantitative study approaches, such as observational study designs.

Observational studies involve the researcher studying the association between variables.[102] Patient assignment into the intervention or control group is not under the researcher's control, unlike in a RCT where the researcher deliberately imposes a treatment onto patients.[101] A major advantage of using observational study designs is that it allows the researcher to examine an intervention without disturbing the natural setting.[102] This was deemed an important advantage

for assessing the LTC service, as the researcher did not want the disrupt the natural LTC processes for the data analysis.

Observational studies have been used in the past when RCTs have been unfeasible, too costly or ethically inappropriate.[102]

There are also certain methodological challenges in observational research that need to be considered, primarily, the issues of selection bias and confounding, which can contribute to underestimates or overestimates of the actual effect of an intervention.[102,108] Selection bias can arise due to the way study participants are selected. As mentioned above, in an observational study, assignment of individuals into the intervention or control group is not under the researcher's control. Therefore, there are possibly important differences in confounding variables between individuals in the intervention and control groups. Patients with certain variables or characteristics may be more likely to be in the intervention group compared with other patients. This is often referred to as selection bias. Selection bias was a particular issue for the present research because baseline characteristics (or covariates) of LTC enrolled individuals differ from those not enrolled. If these covariates also affect the outcome, they can produce biased conclusions. Thus, any differences in outcome may be caused by the intervention itself or by differences in measured and unmeasured confounders. The issue of imbalance in confounders is due to the lack of randomisation.[101]

Fortunately, the bias caused by measured confounders can be minimised using standard statistical methods techniques, such as regression[109] and propensity score analysis.[110] For the present study, both regression and propensity score analysis were used to balance patients' covariates and minimise bias. Further details on each of these techniques are presented in subsequent sections in this chapter.

Another reason that observational study designs were particularly attractive for the present research was the extensive, and reliable health data routinely collected by the New Zealand Ministry of Health (MOH). For each New Zealander, every encounter with the health care system is recorded in the MOH national collections and includes information on patient demographics, hospitalisations, pharmacy medication dispensings, and mortality.[111] Each individual has a unique national health identifier number (NHI), and this NHI enables researchers to link data stored within all the data sets. It is believed that information about virtually all public hospitalisations experienced and subsidised medications received are held within these national collections.[111] Since these data are routinely collected and thus readily

available for all health care system users, the quantitative approach was particularly appealing. The vast coverage of the national collections ensures that patients across the entire country can be included in the analysis without excluding those in more difficult-to-reach or rural communities. This approach is different to an RCT, where analysis would be limited to individuals randomised into the study and capturing patients from across the nation would be more difficult due to resource constraints and recruitment practicalities. As the LTC service is offered nationwide, capturing information from patients enrolled across the entire country was deemed vital, thereby supporting the use of observational study methods and the analysis of data from the MOH national collections.

The aim of the first phase of the research was to examine the impact of LTC on patients' medication adherence and ambulatory sensitive hospitalisations. To address this aim, a quantitative, retrospective, observational study was undertaken using data collated from the MOH national collections. The different national collections data sets were linked to individuals using their encrypted NHI number. Details on the analyses undertaken are presented below.

3.5.2 Data analysis techniques

3.5.2.1 Propensity score analysis

In the present study propensity score (PS) analysis was used to estimate the impact of LTC enrolment on patients' medication adherence and ambulatory sensitive hospitalisations. The PS in the study reflects the conditional probability of a patient becoming enrolled in LTC, having controlled for potential confounders.[104,112] To undertake propensity score analysis two steps were followed: firstly a propensity model was generated; and secondly a treatment effect model was generated. For the propensity model, a logistic regression model was used to generate the PS using LTC enrolment as the treatment outcome (dependent variable) and all potential confounders (variables affecting enrolment) as explanatory or independent variables.[112,113] All these potential confounders were collapsed into a single variable, termed the PS.[114]

After generating a PS for each patient, the score can be used in one of four ways: PS matching; stratification on the PS; inverse probability of treatment weighting (IPTW); and adjustment of covariates.[101]

Propensity score matching involves matching sets of enrolled patients to those not enrolled in LTC, but who share a similar PS.[101] Most commonly, pairs of patients are formed using 1:1 matching; however 'many:1' (M:1) matching can also be undertaken.[101,115] Matching can be limited when there are no exact PS matches between enrolled patients and those not enrolled, causing certain patients to be omitted from the analysis, potentially underestimating the effect of the treatment.[113] Matching may lead to analysis of a non-representative sample of patients with similar observed characteristics, all of whom are potential candidates for treatment.[107] This can also occur in stratification.[115] In stratification, patients are separated into strata, and matching of patients within the same strata is undertaken.[115] In inverse probability of treatment weighting (IPTW), the method does not remove any patients from the analysis, but it can result in extreme PS that can bias treatment effects.[115] Adjustment is another PS method and involves using the PS as a covariate in the final regression model.[101] As it currently stands, there is no consensus among statisticians as to which PS method is the best, as each method carries its own strengths and limitations.[105] For the present research, 1:1 nearest neighbour matching was undertaken, matching a single intervention (LTC enrolled) patient with a single control (not enrolled) patient.[116] Using this method, no intervention patients were discarded for the analysis. It was also easy to assess the degree of covariate overlap between the intervention and control group using this method.

This research method allows large-scale quantitative research to be undertaken, which would not have been possible via other data collection methods. Previous research has exemplified that PS methods can be used to obtain estimates of treatment effects that are of a similar metric to those obtained from RCTs.[105] An advantage of using PS analysis is that it allows the researcher to determine the degree to which the confounders have been balanced between the treated and control individuals. A study by Austin and Mamdani[105] was undertaken to compare the four different PS methods. The researchers undertook a retrospective analysis exploring the effect of statin lipid-lowering treatment on reducing all-cause mortality for patients discharged from hospital after acute myocardial infarction. The researchers undertook their analysis using the four commonly used PS techniques. They also estimated residual confounding and found that those receiving the treatment (that is, statin therapy post-MI), were younger and healthier than those individuals in the control, thus leading to potential confounding to treatment assignment and prognosis. The researchers found that greater balancing of covariates was achieved using the matching method than by using stratification, as the stratification used a smaller sample size. The reduced sample size was the result of many treated patients not having

an appropriate control to match with and thus being discarded. The authors also measured residual imbalance between treated and control patients using quantile-quantile (Q-Q) plots and box plots. It was reported that using Q-Q plots was sensitive enough for detecting residual imbalances between treated and control groups.[105]

The present research involved several steps. Firstly, preliminary analysis was undertaken followed by estimation of PS, PS matching, outcome analysis, sensitivity analysis, and finally sub-analysis.[117] Chapter 4 of this thesis presents the findings from this PS matched-cohort analysis that followed these steps. To undertake the PS matching, the methods outlined by Randolph et al[116] were followed and developed upon. Analysis was undertaken in R Studio® software.

3.5.2.2 Regression

Like propensity score analysis, regression is another statistical analytical technique that can be used to estimate treatment effect while controlling for potential confounding variables.[118] Regression analysis involves describing the relationship between a dependent variable and one or more independent variables.[109,119] In regression the researcher fits a model to the data and uses the model to predict values of the dependent (outcome) variable from one or more independent variables. This is termed simple regression if predicting an outcome variable from one independent variable, or multiple regression if predicting from several independent variables.[120] During regression, the impact of a given independent variable on the dependent (outcome) variable is concomitantly adjusted for the contributions of all the other independent variables present in the predictive model. Researchers use the technique called method of least squares to fit a line that best describes the data collected. The residuals are then summed up and the squared differences are produced. From this one can understand how well a particular line fits the data, with a large squared difference suggesting a line non-representative of the data, while a small squared difference suggests the line is representative of the data.[120]

Different types of regression models exist for example, linear regression, which is used to analyse continuous relationships. Simple linear regression describes the relationship between one independent variable and one dependent (outcome) variable.[121] When there is more than one independent variable this is called multiple linear regression. In both of these linear regression models the data need to adhere to certain assumptions, such as ensuring that the data are normally distributed.[121] Other types of regression models include logistic regression, which describes the relationship between a binary dependent (outcome) variable and one or more

independent variables (covariates), or cox regression, which is used for time-to-event analysis.[122] Poisson regression predicts the probability of a given number of events occurring in a specific time period.[122]

3.5.2.3 Propensity score analysis versus regression

Research to date has shown that PS analysis produces comparable results to regression models.[114,123] Researchers have found that the two techniques did not differ in the strength or statistical significance of the association between the independent variables and outcomes.[123] An advantage of using PS analysis is that the degree of overlap for each confounder between the intervention and control groups is much easier to assess. PS analysis is also favourable when the number of events is low and there are multiple confounders. In such situations, PS analysis leads to more precise and robust estimates than regression.[114] PS analysis can be used with models that incorporate interactions and nonlinear terms. With respect to controlling for unobserved confounders, neither PS analysis nor regression is more superior than the other.

3.6 Phase II (Qualitative study)

3.6.1 Choice of qualitative study design

There is no single accepted method for undertaking qualitative research,[124] rather, the methods adopted depend on the researcher's ontological and epistemological beliefs, the research aims, the characteristics of the participants, and intended audiences.[125] Qualitative research methods answer research questions by analysing textual, non-numeric data, such as transcripts of interviews, focus groups, field notes, images, and documents.[124]

Approaches for gathering qualitative data are often categorised into two groups: naturally occurring data; and researcher-generated data.[125,126] Naturally occurring data are collected from the enactment of social behaviours, while generated data involve the recounting and reconstructing of specific behaviours. Observation, documentary analysis, discourse and conversation analysis focus on naturally occurring data, and these are ideal when studying subconscious or instinctive behaviours, or when the researcher is concerned about the participants' representation of what has occurred.[125] Therefore, these data collection methods allow for delicate or complex manifestations to be studied, and allow examination of new cultures and communities to identify factors or rules that govern them. On the other hand, generated data usually involves a process of re-telling or re-processing attitudes, beliefs or behaviours. These methods typically involve biographical methods (narrative, life stories),

interviews with individuals, and focus groups. These generated data collection methods give the researcher insights into the participants' perspectives, interpretations and meanings of the phenomena being studied. They can also provide an understanding of participants' motivations and decision processes, which allows them to reflect on their behaviours or the beliefs under study.[125]

From the range of qualitative data collection methods that could have been adopted, the researcher chose to use data generated from semi-structured interviews together with naturally occurring data from observations, as it was believed these would best address the study aims and objectives in a timely fashion. The aims were to understand how New Zealand community pharmacists provide the LTC service and to explore community pharmacists' views and experiences with the LTC service and its provision. To address these aims various qualitative methods were considered such as focus groups. Focus groups are a type of group interview where participants can interact with and develop ideas from one another.[127-130] For the present research this was deemed inappropriate as the researcher did not want participant responses to influence those of others. Moreover, during focus groups participants may be less inclined of openly discuss and present ideas due fear of being judged by other participants. The researcher also deemed that more in-depth discussion would be achieved through individual interviews with each participant rather than via focus groups.

After consideration of the various qualitative methods, it was decided to use semi-structured interviews with community pharmacists to gather views and experiences, followed by observation of community pharmacy sites to see if those views held true in pharmacists' behaviours and to see first-hand the delivery of the LTC service.

3.6.1.1 Semi-structured interviews

Individual interviews are the most commonly used data collection method in qualitative research.[124,125] There are three main types of interviews - unstructured, semi-structured, and structured interviews.[131] The choice of interview type is greatly dependent on the research questions at hand. Unstructured interviews, as the name suggests, are the least structured interview method and interview questions evolve during the interview process. Structured interviews are on the opposite end of the spectrum as they ensure all participants are asked the same questions. Unfortunately, its inflexibility limits the researcher's ability to explore new ideas as they arise during the interview. Semi-structured interviews lie in the middle of the

continuum and take advantage of certain aspects from both interview methods. Semi-structured interviews enable the researcher to gather in-depth responses while adapting their questioning according to participants' responses.[131] This type of interview is the most commonly used interview technique in health and social sciences research.[132] They are worthwhile as they can result in an in-depth investigation of individual participants' personal perspectives.[133] They allow the participant the opportunity to clarify details and provide more context to the answers.[125]

For the present research, the researcher used semi-structured interviews to understand community pharmacists' perspectives on LTC service provision. In order to capture the views of pharmacists working all over New Zealand, including rural and more difficult-to-access pharmacists, the interviews were undertaken over the telephone. Often semi-structured interviews are undertaken face-to-face; however due to cost constraints this would have limited the research to the Auckland area, where the researcher lives. Restricting the research to only the Auckland region, thus narrowing down the possible participants to only those pharmacists working in Auckland, would have been inappropriate, as LTC is a nationwide service and the first study in the present research involved a nationwide analysis. The researcher was particularly interested in understanding pharmacists' views and experiences on the service and its delivery, and it was possible there might be differences in LTC service delivery based on factors such as geographic location, pharmacy ownership, and staffing levels.

Alternative modalities for undertaking interviews have also been discussed, such as using FaceTime and video-assisted technology.[134] One major disadvantage of them is the fact the participant needs internet connection for the interview and poor internet connections may interrupt the interview.[134] Telephone interviews were therefore chosen as all pharmacist participants should have access to a phone either at their workplace or at their home. Historically telephone interviews were discouraged, as the researcher cannot pick up on visual and non-verbal cues.[131,135] However more recent research has reported no major differences in reporting between using telephone or face-to-face interviews.[135]

3.6.1.2 Observation

Observation is a data collection technique that involves the researcher being present at a study site, in order to observe and document data about behaviours and the environment, and to

examine first-hand the activities occurring at the site.[124,125,128,136,137] It attempts to document what actually goes on rather than what participants say goes on.[128] The purpose of observation is to confirm what one knows or what one thinks or to discover unanticipated behaviours. Thus, it is an exercise of discovery.[137] The researcher decided to add observation as a second layer to the qualitative research in order to gather first-hand data on how LTC is delivered. The first layer, the pharmacist interviews, was to provide an understanding of pharmacists' views and experiences on the LTC service and its provision. However as with any type of self-report, participants may not disclose everything as they may deem the behaviour or activity to be irrelevant, common or incorrect.[136] Thus, observation overcomes some of the limitations of interviews. As Smith[128] explained, combining observation with other study methods provides additional data from a different perspective. Several pharmacy practice researchers have used interviews together with observation to generate a more in-depth picture of their research phenomena.[138] In pharmacy practice, covert observation has also been used through mystery shopping to examine pharmacists' behaviour without their knowledge.[139,140] Observation has also been adopted in the hospital pharmacy research sector.[141] When using observation to supplement participant interviews, the observation can be used as the basis for the interviews, or the interview questions and responses may be used to dictate what one later observes.[136] For the present research, the latter strategy was adopted, where the interviews were used to determine the observation schedule for analysis during the observation phase. The interviews highlighted the areas that needed greater focus in the observation phase.

In the pharmacy setting, both quantitative and qualitative observational studies have been conducted; the former involves collecting numeric frequencies about activities or interactions, while the latter focuses more on the behaviours of individuals in their natural environment.[128] In quantitative observational studies, structured systematic observations occur, and in qualitative methodology a more descriptive approach is taken, where field notes are jotted down and the researcher looks into understanding the events or behaviours.[136] The qualitive observational methodology moves beyond just merely counting to explore the meaning of the events and provides in-depth insights into the entire environment, such as the barriers and facilitators of behaviours, interactions between individuals, and the environmental constraints.[128,136] For the observational component of the present study, a qualitative methodology was used, in order to grasp how pharmacists deliver the LTC service and to explore the reasons for this delivery. This approach moves beyond just counting how many times a pharmacist interacts with an LTC enrolled patient for example, or how long a

pharmacist spends with an LTC enrolled patient, compared with a not enrolled patient. However these are important, and will be captured in some sense in the observation phase, the focus of the observation was intended to be more holistic, looking at how pharmacy staff interact with each other, how patients are approached in general, how LTC patients are approached by staff, how interactions occur, what kinds of LTC activities or services staff provide to LTC enrolled patients, and whether there are differences between the services provided to enrolled versus not enrolled patients. These questions were important areas of focus for the observational phase; while some of this information would be provided by pharmacists during the interviews giving the pharmacist's perspectives, observations would provide this information from another source and facet. This is termed triangulation. To undertake this type of qualitative observation, often an observation schedule is developed to help the researcher focus their thoughts and observations. An observation schedule (Appendix 14) was used in this work and was developed and adapted from that described by Mack et al.[137] Field notes were made about observations that were not listed in the observation schedule and this helped add depth to the data collection. Also schematic drawings of the pharmacy sites were done to understand the pharmacy layout.[136]

Observation can also be categorised into non-participant and participant observation.[124,128] During non-participant observation the researcher is a discrete, outside observer who documents behaviours without influencing individuals' normal behaviours. This is different to participant observation where the researcher is grossly immersed in the environment and acts and interacts just like a member of the team. To improve the validity of findings, it is important that the individuals being observed continue working as they normally do.[128] For the present research it was decided to undertake non-participant observation, as the researcher wanted to be fully engrossed in the observation, rather than working in the pharmacy while concomitantly observing other staff and patients.

One important limitation to consider is the fact that individuals' behaviours may change when they know they are being observed. This is termed the Hawthorne effect.[46,79-81,128] As researchers spend more time at the study sites, it has been reported that this can make the participants more comfortable and accustomed and the less the researcher's presence will influence their behaviours.[136] Consequently, for the present study, the researcher, also known as the observer, spent a whole day at each observation site to enable sufficient time for the pharmacy staff to become accustomed and relaxed with being observed. In addition, prior to

the observations starting, the researcher spent substantial time speaking to all pharmacy staff and helping them feel comfortable. This approach has been reported to be an effective way to build rapport with study participants and put them at ease.[128]

To ensure the observation schedule was capturing the relevant behaviours and activities, and was practical to use, the observation schedule was piloted with two community pharmacists. These pharmacists also commented on the acceptability of the proposed data collection process.[128]

3.6.2 Participant selection

Semi-structured interviews with community pharmacists

For this part of the research, the researcher wanted to gather community pharmacists' perspectives and personal opinions of LTC service provision. Therefore, gathering data via qualitative methods was considered to be most appropriate. Interviews with pharmacists providing the service were considered worthwhile as it was believed pharmacists may be less likely to divulge certain activities or convey their truthful opinions in focus groups when surrounded by other pharmacists who also provide LTC (whether it be at their own pharmacy or from other pharmacies). The LTC service is a pharmacist-led intervention, however other team members such as other technicians or intern pharmacists may possibly be involved in providing the service. However, ultimately pharmacists are the individuals who are responsible for their patients. As defined in the Pharmacy Council of New Zealand's 2018 Code of Ethics clause 7.1, they are responsible and accountable for all the services provided under their supervision.[142] Thus all aspects of LTC provided to patients, even if they are conducted by other pharmacy staff, must be under the supervision and knowledge of the pharmacist in charge.[142]

To identify pharmacists for the interviews, the pharmacies were sampled from the matched-cohort study. Stratified random sampling was undertaken with the goal of recruiting a range of pharmacies. Further details on why this sampling technique was chosen is presented in Section 3.6.2.1.

Community pharmacy observation

The second part of the qualitative phase involved observation at community pharmacy sites. All interviewed community pharmacists were invited to take part in the observation phase.

Only those community pharmacies, where the manager or owner consented, were observed. There is an obvious limitation to using this recruitment method, as it may be that only those pharmacists with more positive views of LTC or who believe that they deliver a high quality LTC service agreed to be observed. While those with more negative views and experiences may decline to participate. Ethical considerations meant that this possibility could not be avoided, as the researcher could not go and observe practice at the pharmacies without the approval from the pharmacy manager or owner.

3.6.2.1 Sampling strategy

Semi-structured pharmacist interviews

Sampling strategies in qualitative research do not focus on generating a statistically representative sample[143]; rather, sampling aims to recruit information rich participants who are more likely to provide worthwhile insights and provide the researcher with a deeper understanding of a phenomenon under study.[144]

There are three main types of sampling in qualitative research: convenience, theoretical and purposive sampling.[128,144] Convenience sampling involves recruiting easily accessible participants. While this sampling technique can be quick and low cost, it can also result in poor quality data with limited credibility. Theoretical sampling has a focus on theory development from the data and selectively samples to further build on the theory being developed in the study. Purposive sampling, which is the most commonly used sampling technique, involves the researcher selectively recruiting individuals who can best address the research questions.[128,144] A sampling framework can be adopted to help the researcher recruit a balanced sample of appropriate participants.[125] The framework categories are often based on findings from published literature and the researchers' background knowledge of the topic.

For the present study, the researcher used stratified random sampling to recruit a sample of diverse participants.[145] Stratified random sampling is rarely used to sample for qualitative research,[144] however in the present research it was deemed appropriate as the researcher wanted to use the quantitative, matched-cohort to recruit participants for the subsequent qualitative phase. The researcher wanted to delve deeper and better understand the reasons for the study findings from the quantitative study, so it was appropriate to recruit the exact pharmacists who were delivering the LTC service and who contributed to the findings from the quantitative,

matched-cohort study. The researcher also hypothesised that pharmacists may deliver LTC in different ways, based on their location, their dispensing load, and the number of LTC enrolled patients, for example, thus there was a desire to capture this variation if it were to exist. A sampling framework was generated which used three dichotomised variables: geographical location (urban or rural); percentage of patients in the pharmacy who are adherent to their medications (low or high); and percentage of patients in the pharmacy who are enrolled in LTC (low or high). A sampling framework with eight groups was generated from these variables. Attempts were made to recruit 30 pharmacies from each subgroup and then use random sampling to select participants from each subgroup. Four pharmacies from each of subgroup were selected, however only two pharmacists were recruited from one group, as there were insufficient pharmacies in this group who were willing to take part. Likewise, for three other groups there were no pharmacies meeting the criteria. Further details on sampling are presented in Section 5.5.1.

Community pharmacy observation

Due to the small number of interviewed pharmacists willing to have practice at their pharmacy observed, sampling was not necessary, as all who were willing to participate were observed. Pharmacists were free to decline participation in this phase of the research at any time prior to the observation without providing reasons.

3.6.2.2 Sample size

Semi-structured pharmacist interviews

Unlike quantitative studies, in qualitative studies there is no calculation available to estimate the required sample size. Rather the optimal sample size is dependent on how many participants are needed to reach data saturation.[127,143,144,146,147] This is heavily dependent upon the research question, the richness and quality of the data collected, and the study methods used.[146] The number of participants required often becomes more evident as the study progresses, as new ideas stop emerging during successive interviews.[144] This is often termed data saturation and reflects the point where data collection is deemed sufficient and further data collection stops. It has been suggested that 12 participants are needed to reach data saturation,[147] while others researchers have suggested higher numbers such as 30 to 60 participants for semi-structured interviews.[146] Due to the variability of opinions with respect to the sample size needed to reach

data saturation, the researcher decided to continue undertaking interviews until no new ideas had emerged in four successive interviews.

Pharmacy observation

Observation is a time consuming research method, so the choice of study sites and sample size is important to consider, particularly when the sites are dispersed over a wide geographical area.[128] Generally in qualitative research, small samples are used to provide more in-depth analysis and understanding; however small sample sizes reduce the utility of random sampling. Rather, stratifying pharmacies based on certain characteristics is recommended to ensure that the sample observed is diverse and captures the activities of diverse participants.[128] In pharmacy research observation, sample size has generally ranged from four to 64 sites and observation duration has ranged from two hours to four days.[128] As mentioned earlier, sampling was not appropriate for this phase as the researcher recruited all pharmacies into the observation phase, that were willing to take part in the research.

3.6.3 Rapport development with participants during the interviews and observations

Ensuring participants feel comfortable to behave normally while being observed and to speak honestly when being interviewed is vital for obtaining accurate reflections and for producing robust findings.[128] This was particularly important in this phase of the research, which consisted of semi-structured telephone interviews and observation of pharmacy sites. Developing rapport with pharmacists during the telephone interviews was perhaps more difficult, as the participants were not able to see the researcher nor non-verbal communication features (such as changes in facial expression or hand gestures). Consequently, at the start of the interviews, the interviewer started by having an informal conversation with each participant. The purpose of this informal conversation was to put the participant at ease and make them feel comfortable. The researcher also spoke with the participants over the telephone during the recruitment phase also, so the interview was not the first time they had spoken.

The first question in the interview schedule was “I can see from your pharmacy managers or owner’s responses on the brief questionnaire that your pharmacy provides the LTC service. In your pharmacy what services do you provide to enrolled patients as part of LTC?”. This question was used to ease both parties into the interview and provide the participant with an easy question to start off with. This question also enabled the interviewer to clarify and confirm

anything written in the brief questionnaire about the services the pharmacy provides for LTC patients.

To further develop rapport, throughout the interview the interviewer used minimal encouragers, such as "yes", "aha", "I see" to demonstrate active listening. Likewise, the interviewer would summarise and paraphrase some of the points the participant presented to ensure the interviewer fully understood the response and allow the participant to clarify any points.

Developing rapport when undertaking observational research is vital, to ensure that the researcher gains all the important information about their activities and to gain more honest information.[136] As the relationship between the researcher and the observers develops the researcher can begin to feel more like an 'insider' to participants and those being observed may begin to act more freely and comfortably in front of the researcher. This is essential for undertaking rigorous observational research. To develop this rapport in observational research, five main skills or attributes need to be demonstrated by the researcher: honesty, effective listening, approachability, unobtrusiveness and being unassuming.[136] For the observation phase of the research, the researcher (the observer) applied these five skills at each pharmacy site.

3.6.4 Data analysis

3.6.4.1 Interview data preparation and analysis approach

Each telephone interview (n=18) included in the present research was audio-recorded, with permission from the participants. Once each interview was completed, the interview was transcribed verbatim. The researcher transcribed the first two interviews and a professional transcriber transcribed the remaining interviews. Previous research has suggested it is worthwhile for a researcher to complete at least one transcription themselves, while transcribing further interviews does not add value to the analysis process.[134] After transcribing was completed, the researcher read through each interview transcript, while listening to the audio-recorded interviews. This was done to ensure the accuracy of the transcriptions and to identify and amend any discrepancies. This was an important step as the transcriber did not come from a health or pharmacy background and she may have misinterpreted certain terms or phrases used during the interviews.

There are two main approaches to analysing qualitative and quantitative data: the deductive or inductive approach.[143,148] Using the inductive approach, theories are derived from the data through the analysis stages,[143] while using the deductive approach one starts with theories, develops hypotheses and uses the data to prove or disprove the hypotheses.[125] Deductive analysis is less common in qualitative research, but in recent times it is increasing in popularity with qualitative researchers.[143] The deductive approach is more structured, and it starts from pre-set aims and a pre-determined framework for analysis.[143] The deductive approach is time efficient, but is limited due to inflexibility and potential bias during the analysis stages, as the coding framework is pre-determined and limits the emergence of new themes and theory development.[148] For the present research, while there was literature available about pharmacists' views and experiences with delivering pharmacy services overseas, little was known about New Zealand pharmacists' perspectives on LTC service provision. Through consultation with other researchers and searching the literature, it was decided to adopt the general inductive approach (GIA) for the analysis of the semi-structured interviews.[149-151] GIA was chosen due to its methodological flexibility,[150] having both deductive and inductive features.[151] In GIA data analysis is guided by the research objectives, as well as the raw data - with study findings emerging from the objectives (deductive) and from the interpretation of the raw data (inductive).[151] GIA involves the development and presentation of emergent themes.[149-151]

3.6.4.2 Coding and identification of themes from interview data

Coding has been defined as a process of "examining and organising the information contained in each interview".[133] Open coding was used in the study, where each interview transcript was read several times and notes were made by the researcher, summarising what was being communicated by the participant. The text was examined line by line and a single phrase or word was then used for the open coding of all text that related to the aims and objectives of the research.[148,152] In accordance with the GIA, after the initial coding, categories were generated and later themes identified.[133,153,154] Themes are the outcome of coding[152] and were generated by reviewing categories and identifying links between them.[153]

Data can be coded either by one researcher or by more than one researcher.[152] If more than one researcher is involved in coding, it is important that all coders understand the coding process and undertake coding independently.[133,149] The codes and emergent themes are then discussed amongst the research team, to check for overlap. If overlap is low, then further discussions

between team members is needed to discuss the topic and subsequent analysis and to develop more consistent categories. In the present study, the researcher coded all the interviews. However, a second team member (TA) undertook parallel blinded coding, so that both researchers independently coded two of the interviews. This was done to strengthen the integrity of the work. After the coding was completed, the two team members compared their coding and discussed any discrepancies. The third research team member (JH) was also present during these discussions. These discussions helped the researcher generate a coding framework.

After completing the coding, the researcher generated categories from the codes. These categories attempted to bring together similar points that described or supported a view point.[133] Once the categories were identified, they were analysed in more detail to facilitate the emergence of themes from the interview data.[133] The themes moved beyond pure description of codes and categories and they aimed to explain and interpret the phenomena under study.[133,152,153] This was done by linking theory or previous research into the study. Illustrative quotes from the transcripts were identified that supported the emergent themes and these were interwoven into the thesis.[143,148] NVivo® (version 12) software was used to facilitate the data analysis process. The software helped sort, manage and organise the data-heavy interviews.

3.6.4.3 Pharmacy observations

When undertaking observational research, there are three main components to consider: the location, the people, and the activity.[136] Understanding these components is vital as they help the researcher to learn what the day-to-day life is like in the pharmacy for an 'insider'.[137] During each observation the researcher, herself a pharmacist, spent one day during business working hours, at the community pharmacy, as this the setting where the LTC service is delivered and where the staff work and interact.[137] When at the pharmacy, the researcher introduced herself to each of the staff members and provided a brief summary of the study aims and objectives. The researcher aimed to be friendly, honest and responsive in order to develop good rapport with staff members. Establishing good rapport with staff is vital for participants to behave naturally, as mentioned earlier. After the introductions were completed, the researcher made notes in her field book about the setting and layout of pharmacy premises and sketched a diagram of the pharmacy layout. The researcher took note of staff, patient and pharmacy appearances, verbal and physical behaviours, the interactions and space between these individuals, the activities undertaken by pharmacy staff, as well as patient traffic, and

patients who stood out for various reasons. An observation schedule (Appendix 14) was developed and adapted from that described by Mack et al[137] and from using expert opinion. During the observations, conversations occurred between the researcher and the staff to clarify aspects of the data collected and to aid rapport development. These informal conversations are important in observational research and were recorded in the field notes.[137]

At the end of each observation, the researcher wrote up a detailed summary of all the field notes and details from the observation schedule for each pharmacy. The researcher imported this summary into NVivo® and used the themes identified from the interviews to thematically analyse the observations. This analysis was done to find similarities and differences in views and experiences expressed during the interviews versus behaviours observed during the observations.

3.6.4.4 Verification

Verification of study findings is important in qualitative research to ensure the findings are valid and reliable.[155] Guba and Lincoln described four components that should be considered to ensure research rigor: credibility, transferability, dependability, and confirmability.[156] These four components were considered for this research. The procedures followed to ensure this research was valid and reliable are described below.

Providing a sample of participants with their transcriptions and the coding framework their quotes were coded under, has been suggested as a possible way to verify study findings.[148,157] This can be time consuming for participants and may add to the burden of participation. Some participants may have changed their views or perspectives after some time has elapsed, and may wish to change their responses to more socially desirable responses.[148] Due to these factors, this exact method was not adopted for this research. Rather after each interview, each participant was given the opportunity to clarify anything that they had said and amend their responses if they so desired. They were also given the opportunity to review their transcripts and correct any inaccuracies.

An alternative method for verification is to provide interview transcripts and emerging themes to an independent reviewer.[148,151,157] Doing this can help to minimise some types of biases (i.e. lone researcher bias) and provide insight into theme and theory development.[148,157] This method was adopted for this research, whereby a team member (TA) was given a random sample of

two interview transcripts and independently coded these interviews, away from the researcher. Upon completion, TA met with the researcher and both team members discussed their own, individual coding. Similarities and differences between the two were discussed, until unison was reached and a detailed coding framework was agreed upon.

Triangulation of data is another strategy adopted in this research to help verify study findings and improve the research trustworthiness.[151,158] Triangulation was used in two ways in this research. Firstly, data were triangulated between the quantitative study and qualitative study; with the qualitative study being used to explore, at least in part, the findings from the quantitative study. Secondly, triangulation was used in the qualitative phase, where views expressed by participants during the interviews were compared and contrasted with the behaviours observed during the pharmacy observations.

3.6.4.5 Reflexivity

In qualitative studies the researchers' background, previous experiences, personal biases and beliefs are understood to influence how qualitative data are analysed, interpreted and discussed.[124,159-161] Clearly outlining and presenting the researchers' background is an important part of qualitative research. Below is a summary of the researcher's background and the possible impact this might have had on the qualitative study.

The researcher is a young, New Zealand trained and registered pharmacist who has experience working in both the hospital setting and community pharmacy setting. Being a registered pharmacist enabled her to establish rapport easily with pharmacist participants during the qualitative study. Having worked in community pharmacy and having delivered LTC herself, she was able to empathise with and understand the genuine challenges and rewards faced by pharmacists when delivering the service. It is possible that if an alternative individual who perhaps was not a pharmacist undertook the same qualitative research, different views and experiences may have emerged from the thematic analysis of interviews and the observations. When analysing the qualitative data, the researcher jotted down her personal views in her field book during the interviews and observations, to make it clear what her thoughts were separate from the thoughts expressed by participants. The researcher discussed her own biases with other members of the research team prior to undertaking each phase of the qualitative study.

The views and previous experiences of the other team members might also have influenced the analysis and interpretation of the qualitative research too. These team members (JH and TA) were the doctoral supervisors, both of whom are primarily academics. One supervisor has a hospital pharmacy background, with strong involvement in the New Zealand Pharmacy Council, while the second supervisor comes from a community pharmacy background. Since all three team members come from very different backgrounds and have vastly different experiences, this team composition contributed valuable diverse perspectives, particularly with respect to interpretation of study findings.

3.7 Ethical considerations

Prior to commencing the research, ethical approval was sought from the appropriate ethics committees. For the quantitative study, ethical approval was sought from the Health and Disability Ethics Committee, as the research involved using New Zealand wide routinely collected health data. The research involved analysis of anonymised health data, meaning that the identity of patients remained unknown to the research team through the study period. Consequently, the Health and Disability Ethics Committee deemed the study to be exempt from requiring ethical approval (reference number: 16/NTA114).

For the qualitative phase of this research, ethical approval was obtained from the University of Auckland Human Participants Ethics Committee (reference number: 018178). The interview and observation participants were provided with Participant Information Sheets detailing the study purpose, method, and possible benefits and risks associated with taking part. It was explained that participation in the research was completely voluntary, and that withdrawal of their responses was possible within a specified time frame without needing to provide a reason to the researcher. In terms of the risks, loss of privacy and confidentiality of participants' material was a potential risk. To mitigate this, the telephone interviews were conducted in a private office at the university, which allowed for open communication, without the possibility of people overhearing the interview from the researcher's end. All recordings, electronic documents and notes from the interviews, as well as electronic documents and notes from the observation phase were stored on a password protected computer. The signed consent forms were stored in a locked filing cabinet at the university. The only individuals who had access to these documents were the researcher and her supervisors (JH and TA). Upon completion of the interviews, the audio recordings were deleted from the recorders. Participants were provided

with a $20 (NZD) supermarket voucher to acknowledge their contribution to the research. The pharmacies observed were each provided with a morning tea for staff, to acknowledge their involvement.

3.8 Chapter summary

This chapter presents the research methodology, outlining the theoretical framework underpinning this research and the methods adopted. The theoretical framework adopted for this thesis was the pragmatic paradigm. This research adopted a mixed methods approach, exploiting the strengths of both quantitative and qualitative study methods. Quantitative data arising from the linkage of routinely collected health information were analysed using propensity score analysis. Qualitative data were collected from semi-structured interviews with community pharmacists and observations of pharmacy sites. The interviews were analysed using the general inductive approach (GIA), while observations were used to supplement and add further depth and understanding to interview responses and the quantitative study findings.

CHAPTER 4. THE IMPACT OF THE LONG TERM CONDITIONS SERVICE ON PATIENTS' HEALTH OUTCOMES

4.1 Chapter overview

This chapter provides an overview of the findings from the quantitative matched-cohort study. The first three sections of this chapter cover the study background, aims and objectives. The study methods are then described, specifically the design, data procurement and data preparation. The analysis undertaken is explained in detail, including the underlying principles of the analytical approach taken. The final sections present the study findings, discussion and an overview of the study's limitations. Finally, conclusions are presented, together with some questions for further research.

This chapter formed the basis of an article published in the journal *Research in Social and Administrative Pharmacy*.[162] The article contents are reproduced with permission from the publisher (Appendix 2).

4.2 Introduction

During the systematic review process, presented in Chapter 2, a plethora of evidence was identified exemplifying the positive contribution community pharmacist-led interventions can have on improving patients' medication adherence and disease control.[29] Pharmacists primarily contributed to these health improvements through the provision of multi-faceted or multi-component interventions. Most of the interventions were education or counselling focused, whereby community pharmacists educated or counselled patients about their medications and chronic medical conditions. These studies were primarily published in the USA, with a few being published in the UK, Western Europe and Australia. No published studies, that met the systematic review inclusion criteria, were from New Zealand.

Consequently, this systematic review identified an important research gap. There was a need to understand the impact of community pharmacist-led services in New Zealand, in light of major community pharmacy restructuring that had taken place in July 2012.[24] The restructure saw the introduction of the LTC service in July 2012. The LTC service was introduced to help those patients who are living with chronic medical conditions and adherence issues, to improve

their adherence with the help of their community pharmacist. As part of the service, community pharmacists identify and attempt to resolve any adherence-related issues identified.[23]

Though some time had elapsed since the introduction of the LTC service, little was known about the impact of the service, particularly its impact on patients' health outcomes. To address this gap in the literature, the present study was designed to examine the impact of the LTC service on patients' medication adherence and ambulatory sensitive hospitalisations (ASH).

4.3 Aim and hypothesis

The study aim was to examine the impact of the LTC service patients' medication adherence and ASH.

The hypothesis was that enrolment in the LTC service improves patients' medication adherence and reduces ASH.

4.4 Objectives

The study objectives were as follows:

- To describe patients enrolled in the LTC service in terms of their sociodemographic and clinical characteristics;
- To determine the impact of the LTC service on patients' medication adherence and ASH;
- To determine whether there is evidence of inequalities and inequities in LTC service outcomes, based on the sociodemographic characteristics of age and ethnicity;
- To identify pharmacies for the qualitative phase of this research.

4.5 Methods

4.5.1 Study design and study population

This was a retrospective matched-cohort study, involving the analysis of routinely collected health data. The study population comprised all individuals enrolled in LTC at any time from July 2013 until December 2014, as well as control individuals who had never previously received the LTC service. This time period was chosen to give sufficient time for the LTC service to have become established in community pharmacies.

4.5.2 Data sources

Data for the present study came from two sources; the national collections data were obtained from the New Zealand Ministry of Health (MOH) and LTC enrolment data were obtained from the District Health Board Shared Services (DHBSS).

Information contained within the LTC enrolment data was linked to five national collections data sets: The National Health Index; the Primary Health Organisation Collection; Pharmaceutical Collection; National Minimum Dataset; and Non-Admitted Patient Collection. The information contained within each data set is described below.

National Health Index

Contains demographic information for majority of the New Zealand population (~98% coverage).[163] Data from 2012 to 2016 were extracted.

Primary Health Organisation (PHO) Collection

Contains demographic information on all patients enrolled within a Primary Health Organisation in New Zealand.[164] Data from 2012 to 2016 were extracted.

Pharmaceutical (Pharms) Collection

Contains information on all the subsidised medications dispensed from community pharmacies in New Zealand.[165] Data from July 2012 to April 2016 were extracted.

National Minimum Dataset (NMDS)

Contains information on all hospital admissions in New Zealand.[166] Reasons for admission were coded using ICD-10AM. Data from July 2012 to December 2015 were extracted.

National Non-Admitted Patient Collection (NNPAC)

Contains information on all non-admitted public hospital visits in New Zealand, including emergency department visits and out-patient clinic visits.[167] Data from July 2012 to December 2015 were extracted.

4.5.3 Data linkage

Patients' encrypted NHI numbers were used for the data linkage process, to link all the different data sets from the MOH and DHBSS together. The NHI number is a unique identifier allocated to each individual that has ever had contact with the New Zealand health care system.[163]

4.5.4 Data preparation

Once the data were sourced from the MOH and DHBSS and were linked together, certain variables were extracted (e.g. age) and constructed (e.g. Charlson comorbidity index) to produce a single, final data set. The final data set consisted of all the independent variables listed in Table 4.

Table 4. Independent variables present in the final data set

Independent variables used in the logistic regression model to generate the propensity scores	Independent variables used for descriptive statistics
Age	Duration of time patient has been enrolled in the LTC service
Care Plus status (Y/N response)	Duration of time patient was previously enrolled in the LTC service
Charlson comorbidity index	Encrypted pharmacy claimant number
Community Services Card holder status (Y/N response)	Funding DHB
Count of high risk medications	Previous LTC enrolment (Y/N response)
Count of hospitalisations one-year prior to enrolment (all hospitalisations - acute admissions, emergency department visits, and ASH)	Urban/rural indicator
Deprivation quintile	
Gender	
High User Health Card holder status (Y/N response)	
LTC enrolment status - enrolled in the LTC service during July 2013 to December 2014 - Y/N response	
Medication adherence one-year prior to enrolment	
Prioritised ethnicity	

All of the independent variables listed in Table 4 left hand column were included in the logistic regression model to estimate the propensity score (PS), modelling the impact of these independent variables on LTC service enrolment. The independent variables in Table 4 right hand column were not used in the generation of the propensity score, but rather for descriptive statistics (e.g. funding DHB) or for identifying participants for the qualitative phase of this research (e.g. encrypted pharmacy claimant number and urban/rural indicator). Further details on how these independent variables were defined and constructed is presented in Section 4.5.4.1.

Table 5 lists the dependent variables (outcome data) that were present in the final data set.

Table 5. Dependent variables present in the final data set

ASH	Medication adherence
Count of ASH at 6 months post-enrolment	Medication adherence at 12 months post-enrolment
Count of ASH at 12 months post-enrolment	Medication adherence at 12 months post-end (after the end of the enrolment period)
Count of ASH at 3 months post-end (after the end of the enrolment period)	
Count of ASH at 6 months post-end (after the end of the enrolment period)	

Further details on how each of these outcome variables was defined and constructed is presented in Section 4.5.4.2.

4.5.4.1 Independent variable (covariate) selection

Independent variables were identified that were believed to influence patient enrolment into the LTC service. The list of variables was developed using the LTC eligibility criteria,[106] as well as previously published work that commented on the relationship between LTC enrolment and patient-related factors.[26]

These independent variables, often termed covariates, were used in the first logistic regression model to generate the PS. The PS is the conditional probability of being enrolled in LTC given a set of covariates.[104,112]

Each of the independent variables (covariates) used in the logistic regression model to generate the PS are described below. The rationale for their inclusion and how they were calculated are also summarised here.

Age

The incidence and prevalence of disease and mortality are strongly age-related.[168] Reasons for this may be cumulative exposure or biological causes.[168] Consequently, controlling for age was believed to be important in this research. It is also known that patients enrolled in LTC may belong to any age range, as there is no minimum or maximum age for enrolling patients into the intervention.

The researcher initially adopted the six age categories used by the MOH. The categories were: 1 (0-4 years); 2 (5-14 years); 3 (15-24 years); 4 (25-44 years); 5 (45-64 years); and 6 (65+ years). The age categories 1, 2 and 3 were later collapsed together as there were relatively few individuals newly enrolled in LTC in these age categories (0-4 years n=17; 5-14 years n=106; 15-24 years n=893). Consequently, four age categories were later used: 0-24 years, 25-44 years, 45-64 years, and 65+ years.

The age variable is present in the PHO collection, as well as the NHI data set. For the present research, age was extracted from the NHI data set, as this data set is regularly updated, while the PHO collection is not updated.

Care Plus status

Patients are enrolled into Care Plus by their general practitioner (GP) or nurse to help support patients with chronic medical conditions, or those with acute medical, mental health or terminal conditions.[169] It is intended that Care Plus will replace the High Use Health Card (HUHC) in the future. HUHC focuses solely on reducing the cost of GP visits, while Care Plus, is a step above and beyond that, as it aims to improve outcomes for patients living with chronic medical conditions. After enrolment in Care Plus patients receive an assessment of their health needs, goals are set, and regular follow-ups scheduled with their GP. The provision of Care Plus varies with each PHO and government funding for the PHO increases as more patients are enrolled in Care Plus.[169]

Charlson comorbidity index

Comorbidity scores provide an aggregate of patients' comorbid conditions into a single variable.[170] The variable can then be used in the regression model to control for the patient's degree of ill health. There is currently no gold standard comorbidity score, as each scoring method carries its own advantages and limitations.

The Charlson comorbidity index[171] is the most frequently used comorbidity score[172] and it is considered to be a valid prognostic indicator for mortality.[173] The score is calculated by summing the presence and absence of 19 conditions, each one receiving a weighting from 1 to 6, with greater weight suggesting greater disease severity.[171] The Charlson comorbidity index has been shown to correlate with overall and disease-specific survival, and with treatment-related complications[174] and burden of disease.[173] Thus, it predicts one-year mortality in

patients with a range of medical conditions. The Charlson comorbidity index has well-defined comorbidity indices and is easy to calculate from routinely collected health data.[174]

Other comorbidity scores considered were the Chronic Disease Score (CDS), Elixhauser, Co-Existent Disease (ICED), Cumulative Illness Rating Scale (CIRS), and Kaplan-Feinstein Index (KFI).

The Chronic Disease Score (CDS) is another comorbidity score that generates a score by summing the use of medications from several different classes.[175] The score is based on the presence of medication use, and not on the number of times a medication is dispensed.[175] For this research CDS was not adopted, as patients' medication use patterns would have been accounted for in the 'medication adherence one-year prior to enrolment' variable (which was included in the propensity score model).

Another comorbidity score is the Elixhauser. The Elixhauser has not been widely validated and consequently its use is not widespread.[172] The Elixhauser is considered to be a superior predictor of mortality, compared to the Charlson comorbidity index, in patients with myocardial infarction,[172] cancer,[176] respiratory illnesses, and osteoarthritis.[176] Since patients in the present research were multi-morbid, with many medical conditions, it was deemed inappropriate to use the Elixhauser score.

Other measurements of comorbidity are available as well, such as the Index of Co-Existent Disease (ICED), Cumulative Illness Rating Scale (CIRS), Kaplan-Feinstein Index (KFI), which in certain situations have shown greater prognostic power than the Charlson comorbidity index. However, these other measurements have limitations; the KFI was initially designed for use on diabetic patients only, while the ICED and CIRS require training courses and coding manuals in order to be used accurately.[174] The complexity of the latter comorbidity measures limited their use in the present research, while the fact that the KFI is used for diabetic patients negated its use in the diverse, multi-morbid LTC cohort.

Therefore, after thorough consideration of all the co-morbidity score options, an adaptation of the Charlson comorbidity index was used in the present study. The Charlson comorbidity index weightings reported by the original researchers were not used,[171] and rather more recent and validated weights were adopted.[173] The rationale was that the original weightings date back to

1987, and nowadays patients live longer and the healthcare system has drastically improved over the ensuing decades.[173]

Most of the codes available in the literature for calculating comorbidity indices in R Studio® software use ICD-9; however, the data held within the MOH data sets is coded using ICD-10AM. The ICD-10AM weightings published by Quan et al[173] were used in this research. These Charlson weightings have been validated with New Zealand data.[173] The maximum score an individual can have using the newly validated weightings is 24, and there are only 12 conditions compared to 17 conditions in the original score.[173] Table 6 summarises the comorbidities and their associated weightings that were used in the present research. New Zealand and Australia use ICD-AM, which is a modification of the ICD-10. The modification still allows for 'international compatibility' with ICD-10.[177]

Table 6. Disease categories and their weightings used to generate the Charlson comorbidity index (adapted from Quan and colleagues)[173]

Comorbidities	**Weighting**
Myocardial infarction	0
Congestive heart failure	2
Peripheral vascular disease	0
Cerebrovascular disease	0
Dementia	2
Chronic pulmonary disease	1
Rheumatic disease	1
Peptic ulcer disease	0
Mild liver disease	2
Diabetes without chronic complications	0
Diabetes with chronic complications	1
Hemiplegia and paraplegia	2
Renal disease	1
Any malignancy, including leukaemia and lymphoma	2
Moderate or severe liver disease	4
Metastatic solid tumour	6
AIDS/HIV	4

The last hospitalisation prior to enrolment was used to generate the Charlson comorbidity index in the present study. If the patient was not hospitalised, then the latest recorded hospitalisation was used to generate the Charlson comorbidity index.

Community Services Card holder

Similar to the HUHC, the Community Services Card (CSC) is provided to patients to reduce the cost of prescriptions, visits to afterhours general practices, visits to general practices that they are not enrolled with, home assistance, travel costs and accommodation when a patient requires treatment at a hospital far away their home, emergency dental care, and vision-enhancing glasses for children.[178] A CSC is provided to individuals who have low to middle income and the CSC can be used by all family members who are less than 18 years of age.[178]

The level of subsidy is the same for both the CSC and HUHC for prescription fees and general practice visits.[178] The main difference between the two cards is that CSC can be issued for all dependent family members, while HUHC is issued for only a single patient.

Count of high-risk medications prior to enrolment and count of hospitalisations prior to enrolment

These variables were created using the Pharmaceutical Collection (for the high risk medications) and the National Minimum Dataset (for the hospitalisations). Both covariates were calculated in the one-year period preceding enrolment. They were vital covariates in this research, as they are both variables pharmacists consider when deciding whether to enrol patients into the LTC service (as per the LTC eligibility criteria).[106]

Deprivation

The New Zealand Deprivation Index (NZDep) classifies patients into deciles of deprivation based on census data collected about the socioeconomic characteristics of their residence area.[179] It is constructed using the following patient characteristics: income; owning a home; support; employment; qualifications; living conditions; access to telephone and transport.[179] For the present research NZDep2013 was used. The NZDep is frequently used as a proxy measure for patients' socioeconomic status.[180] Using the method described by Milne et al[181] the researcher formed five quintiles by joining adjacent deciles: deciles 1-2, 3-4, 5-6, 7-8, and 9-10, were joined to prepare quintiles 1 to 5. Quintile 1 represents the least deprived and quintile 5 represents the most deprived.[181]

Duration of time patient has been enrolled in LTC

A condition of the LTC service is that patients can only be enrolled at one pharmacy at a time.[182] The LTC enrolment data received from DHBSS is also a monthly payment file, detailing the patients' encrypted NHI numbers for whom each community pharmacy has received a payment for each month. The researcher identified gaps in this LTC enrolment data of one or two months where pharmacies did not receive payment for certain patients. However, the researcher could see that the patient was still enrolled in the LTC service in the same pharmacy in the months after the gap. Consequently, when analysing LTC enrolment data the researcher used a three-month period as a buffer; thereby the variables 'Time in LTC' and 'Duration previously enrolled' allowed a 3-month gap in payment before considering the patient as no longer enrolled in LTC at that particular pharmacy. Put simply, if a patient had a gap of ≤3 months, then the gap was ignored, and continuous enrolment was assumed.

It is also worthwhile to note, if an LTC enrolled patient has not picked up their medications in three months, the pharmacist (from the pharmacy where they are enrolled), would need to contact them to clarify why they have not come back to the pharmacy. If the patient stops returning to the pharmacy for more than 120 days (four months) the pharmacy will not receive further LTC payment for that patient.[182] Thus, when more than 120 days elapses without LTC patient dispensing, then the patient is exited from the service and LTC payments stop.[182]

Encrypted pharmacy claimant number

The pharmacy claimant number is an encrypted code used to identify each pharmacy in New Zealand. The researcher assigned a single pharmacy claimant number to each patient. This corresponded to the pharmacy where the patient had had the most medications dispensed during the study period (July 2013-December 2014). This included all medications, not just those used to manage chronic conditions.

Funding District Health Board (DHB)

There are 20 District Health Boards (DHBs) in New Zealand and this variable denotes which DHB the patient belongs to. Each DHB is responsible for funding and providing health services to patients in their district.[183]

Gender

This variable denotes whether the patient identifies as male or female.

High Use Health Card holder

A High Use Health Card (HUHC) is given to a patient who has visited their regular GP at least twelve times within a one-year period.[178] Once a patient has a HUHC, the cost of GP visits and cost of certain prescriptions is decreased. The HUHC is issued to a single patient.

LTC enrolment status and previous LTC enrolment

LTC enrolment status is a bivariate variable and denotes whether the patient was enrolled in the LTC service during the study period (July 2013 to December 2014) (Y) or not enrolled during the study period (N). The previous LTC enrolment variable is also a bivariate and denotes whether the patient was enrolled in LTC prior to the study period (Y or N). If the patient was previously enrolled in LTC, then this meant they could not be included in the control group (as the control group never received LTC).

Medication adherence one-year prior to enrolment

Patients' medication adherence in the one-year preceding LTC enrolment was calculated using the method described by Kerr et al.[111] Patients were classified as being adherent at baseline if they picked up their medications in three out of four quarters of the year preceding LTC enrolment (≥75%). Those patients who picked up medications <75% of the year were deemed non-adherent.

Prioritised ethnicity

Ethnicity was constructed using a prioritised definition, meaning each patient was assigned a single ethnic group using a priority system.[184] This prioritised ethnicity is most often used in MOH statistics, as it easy to work with and prevents smaller sized ethnic groups, as well as those with policy importance, being swamped by the majority, which is the NZ European ethnic group. The ethnic priorities in descending order are: Māori; Pacific; Asian; other groups except NZ European; and NZ European. Naturally this approach has several limitations, the first being that it goes against the principles of self-identification, and it also over-represents certain ethnic groups at the expense of others, for example, Māori gain at the expense of Pacific individuals.[184] In addition to being used in MOH reports, analysis using such prioritised ethnicity has been used in earlier studies in New Zealand.[185,186]

Urban/rural indicator

The researcher generated a variable to classify whether the pharmacy, which the patient received most of their medication dispensings and consequently received LTC, was in an urban or rural location. A count of mesh blocks was used to assign patients' pharmacies as either rural or urban. This variable was not used for PS matching procedures. Rather it was used for identifying pharmacies for the qualitative phase of this thesis.

4.5.4.2 Dependent variable (outcome variable) creation

Two main outcomes were examined in the present study - ambulatory sensitive hospitalisations (ASH), and medication adherence. These outcomes were assessed during the intervention and post-intervention. Ambulatory sensitive hospitalisations were assessed over four different time periods: at 6 and 12 months post-enrolment, as well as at 3 and 6 months after the end of enrolment period (post-end). Medication adherence was assessed over two different periods: at 12 months post-enrolment and 12 months after end of the enrolment period (post-end).

A brief description of each study outcome, rationale for their use and how they were calculated is presented below.

Ambulatory Sensitive Hospitalisations (ASH)

Ambulatory Sensitive Hospitalisations (ASH) are defined as those hospitalisations that can be prevented through appropriate prophylactic interventions delivered in the primary care setting.[187,188] ASH are a type of 'potentially avoidable hospitalisations'.[187]

There are also other types of hospitalisations that are 'potentially avoidable hospitalisations', specifically: preventable hospitalisations (PH) and hospitalisation avoidable through injury prevention (IP). These hospitalisations were not analysed as part of this research, as their focus is beyond what could be expected to be improved through a community pharmacy based intervention. PH focus on hospitalisations that can be prevented through population-based health strategies, such as taxation on cigarettes, while IP focus on hospitalisations that can be minimised by reducing injury risk (e.g. wearing seat belts while driving).[187]

Several strategies have been suggested for preventing ASH, particularly ensuring effective management of chronic medical conditions, timely access to primary care as well as, strengthening continuity of care.[189,190] Being able to target these ambulatory care sensitive

conditions (ACSC) has potential to minimise patient harm and suffering and save substantial health care costs for the New Zealand government.[189] The cost of avoidable hospitalisations in one hospital alone was reported to be $96.6 million NZD in 2003, and ASH comprised 31% of all hospitalisations.[191] For the present research, the ACSC were adopted from authors Hutchinson et al.[188] The authors defined the following as ACSC conditions: (i) vaccine preventable (influenza, pneumonia, and other vaccine preventable conditions); (ii) chronic (diabetes complications, nutritional deficiencies, iron deficiency anaemia, hypertension, congestive heart failure, angina, chronic obstructive pulmonary disease, asthma); (iii) acute (dehydration and gastroenteritis, convulsions and epilepsy, ear, nose, throat infections, dental conditions, perforated/bleeding ulcer, ruptured appendix, pyelonephritis, pelvic inflammatory disease, cellulitis, and gangrene).

For the present research ASH were calculated using the National Minimum Dataset, which as described in Section 4.5.2, holds all the information about patients' hospitalisations. The reason for hospital admission was coded in ICD-10-AM. Propensity score (PS) matching, using logistic regression models, was used to estimate and compare the prevalence of ASH in the LTC enrolled cohort (intervention group), versus the control group, during and after the intervention period. ASH was a bivariate outcome, with two categories: zero, and one or more ASH, and a range of covariates were used as independent variables. The independent variables used to generate the PS were described in Section 4.5.4.1 of this chapter.

Medication adherence

Adherence has been defined as the degree to which a person takes their medications as mutually agreed upon with the prescriber.[9] Ensuring patients are adherent to their medications is pivotal for the success of their treatment.[11] Since a major goal of LTC is to improve patients' medication adherence, it is reasonable and even vital to evaluate medication adherence during and after enrolment in the service.

In the last few years, research focusing on adherence to a few specific medications has been undertaken in New Zealand using dispensing data contained in the Pharmaceutical Collection.[111,180,192-195] In New Zealand, GPs can prescribe up to three months of medications at one time to their patients (this does not apply to contraceptives and controlled drugs, where they can prescribe up to six months and one month, respectively). Certain medications,

particularly those used for chronic conditions, can be dispensed as three months' supply all at once from community pharmacies. This is termed 'stat' dispensing.

Estimating adherence in the present study is made difficult due LTC enrolled patients taking several different medications for their chronic conditions. Since LTC focuses on patients' medication adherence holistically, and the service aims to improve adherence to all medications used to manage their chronic conditions, in this case it would be inappropriate to estimate adherence to just a few medications, as previous studies have done. Thus, generating a composite adherence score that incorporates and captures their adherence to all medications taken for their chronic diseases was necessary.

Medication adherence was calculated using a count of 'stat' of dispensing (or dispensing quarters), using the method reported by Kerr et al.[111] This method categorised patients as being adherent when they filled a prescription for the medication in three out of four quarters. This method was used in the final data analysis.

For exploratory purposes, the researcher also calculated a second adherence score. This second score involved using the 'days supply' variable from the Pharmaceutical Collection and estimating the days covered by the medication supply during the 12-month period. This is referred to as the fixed medication possession ratio (FMPR).[196] The use of FMPR is believed to be appropriate for medications for chronic conditions. Two variables were used for this particular adherence calculation: 'days supply' and the 'date dispensed'.[196] Unfortunately, due to the large amount of missing data in the 'days supply' variable the reliability of this adherence outcome was poor.

Both of these medication adherence scores produced a cumulative adherence score, for all the chronic disease medications that the patients were prescribed. The medications used in the calculation were those that were also being dispensed at the point of enrolment (and thus used in the adherence calculation in the year preceding LTC enrolment). Medications for acute conditions, topical preparations, nasal preparations, and 'prn/when required' medications were not included in the medication adherence calculation, as the focus of the LTC service is on managing patients' chronic conditions. Appendix 5 has the full list of the medications used for the adherence calculation. The list was generated using the chronic conditions listed in the LTC

eligibility criteria and by identifying all the medications used to manage these chronic conditions from the New Zealand Pharmaceutical Schedule.

4.5.5 Data completeness

The Pharmaceutical Collection contains a number of variables, including the 'days supply' variable. This variable specifies how much medication was supplied to the patient at a pharmacy visit.[165] When used with the 'date dispensed' variable, one can then estimate the amount of medication the patient had in their possession during that time period, thus giving an adherence estimate. Unfortunately, the 'days supply' variable had ~20% missingness in the study data set.

To deal with the missing data the researcher, upon discussion with a data analyst, attempted to impute the missing 'days supply'. For a medication dispensing where the 'days supply' variable was missing, the 'days supply' from another dispensing on the same day that had a 'days supply' was used and the value carried forward to fill the missing variable. If there were no other dispensings on that day, then the 'dates dispensed' were used as proxies (i.e. if the gap between the two dates is 90 days or less, assume 'stat' dispensing and sufficient medication possession during that whole time period).

Even with the best effort, this adherence produced very unusual odds ratios in the outcome analysis. Therefore, following research team discussions and discussions with a data analyst, the adherence values obtained from using the quarters method, described by Kerr et al,[111] was used instead for the analysis.

4.5.6 Data manipulation

The original data set had 4,272,801 individuals, with 88 variables associated with each individual. Figures 2 and 3 provide a summary of the data manipulation steps undertaken. Just over 200 individuals had duplicate NHIs, and these duplicates were removed. This left 4,272,584 individuals. For 559 individuals, the majority of the demographic data was missing (specifically: age, gender, prioritised ethnicity, Community Services Card status, Care Plus status, HUHC status, and DHB). These 559 individuals were removed from the analysis, leaving 4,272,025 individuals. Descriptive statistics were collated for these 4,272,025 individuals (see Section 4.6.1).

Missing values, which were denoted as NA in R Studio® software, were present extensively in the adherence variables, and these NAs were associated with individuals who did not have any chronic disease medications dispensed to them before and during the study period. Appendix 5 gives the full list of chronic disease medications included in the adherence calculation. This is different to an adherence value of zero, which means the patient had a medication from the specified chronic medication list dispensed to them before the study period but not during the study period. It is thus assumed those patients with an adherence value of zero were non-adherent. To manage the missing adherence values, those individuals with NAs in their adherence variable were removed from the data set. The rationale was that, if a patient has NAs, then they are unlikely to be eligible for enrolment into LTC, as LTC enrolled patients need to have adherence issues and often take several medications for their chronic conditions. Furthermore, these patients would not be suitable as control patients either, as they did not take chronic medications, and therefore matching and comparing them to enrolled patients would be inappropriate. Thus, any individuals with NAs in the adherence variables, that is one year prior to enrolment, post-enrolment and post-end of enrolment, were excluded and removed from the analysis. This left 1,129,936 individuals.

From these, individuals with a missing deprivation quintile were also removed. Deprivation quintile is an important variable in this research, as it is the only variable that provides information about sociodemographic characteristics. The variable was constructed using the following patient characteristics: income; owning a home; support; employment; qualifications; living conditions; access to telephone and transport.[179] No other variable available in the routinely collected MOH data sets contains this information. Thus, there were no alternative variables available to use in this research other than deprivation quintile. After removing those with a missing deprivation quintile, 1,069,534 individuals remained.

Five hundred and sixty-nine individuals did not have a pharmacy claimant number recorded in the MOH Pharmaceutical Collection. This claimant number was used for identifying community pharmacies for the qualitative phase of this research. Thus, for those individuals with no claimant number the researcher could not be certain if or where they were receiving any pharmacy services. For this reason, these individuals were also removed. This left 1,068,965 individuals in the data set.

Next only individuals who were newly enrolled in the LTC service (intervention group) and those who had never received the LTC service (control group) were extracted and used for the

final analysis. The intervention group consisted of individuals who were enrolled in LTC any time from July 2013 to December 2014 (n=51,138), while those in the control group, who never received LTC (during the study period, as well as before the study period) (n=903,159). This left a total of 954,297 individuals.

From these 954,297 individuals, propensity score matching of the intervention group with the control group was undertaken using the MatchIt® package in R Studio® developed by Ho et al.[197] One-to-one nearest neighbor matching yielded the final matched cohort with 102,276 individuals (51,138 in the intervention group and 51,138 in the control group).

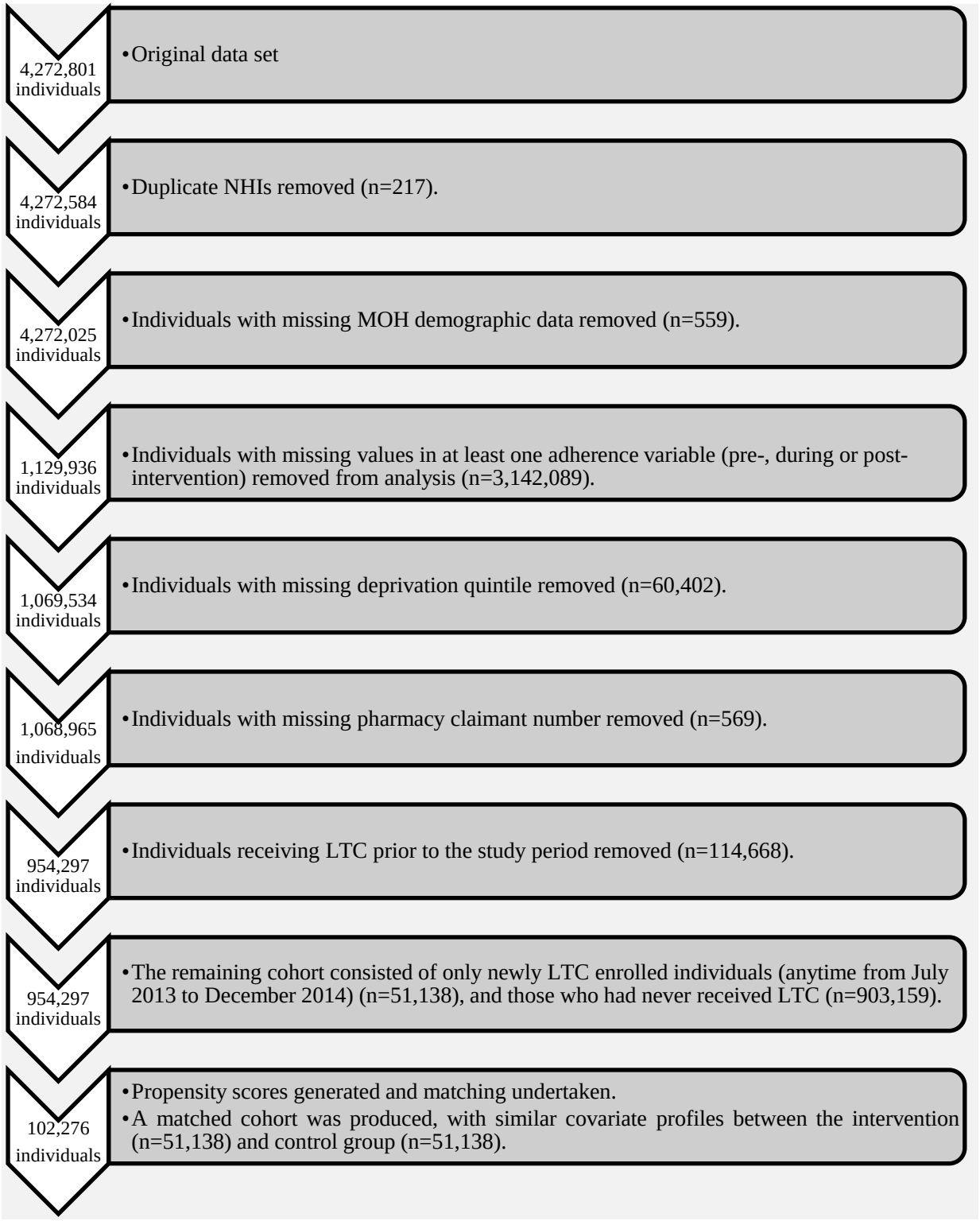


Figure 2. Flow chart of the data preparation and data manipulation steps undertaken to prepare the matched-cohort data set for analysis

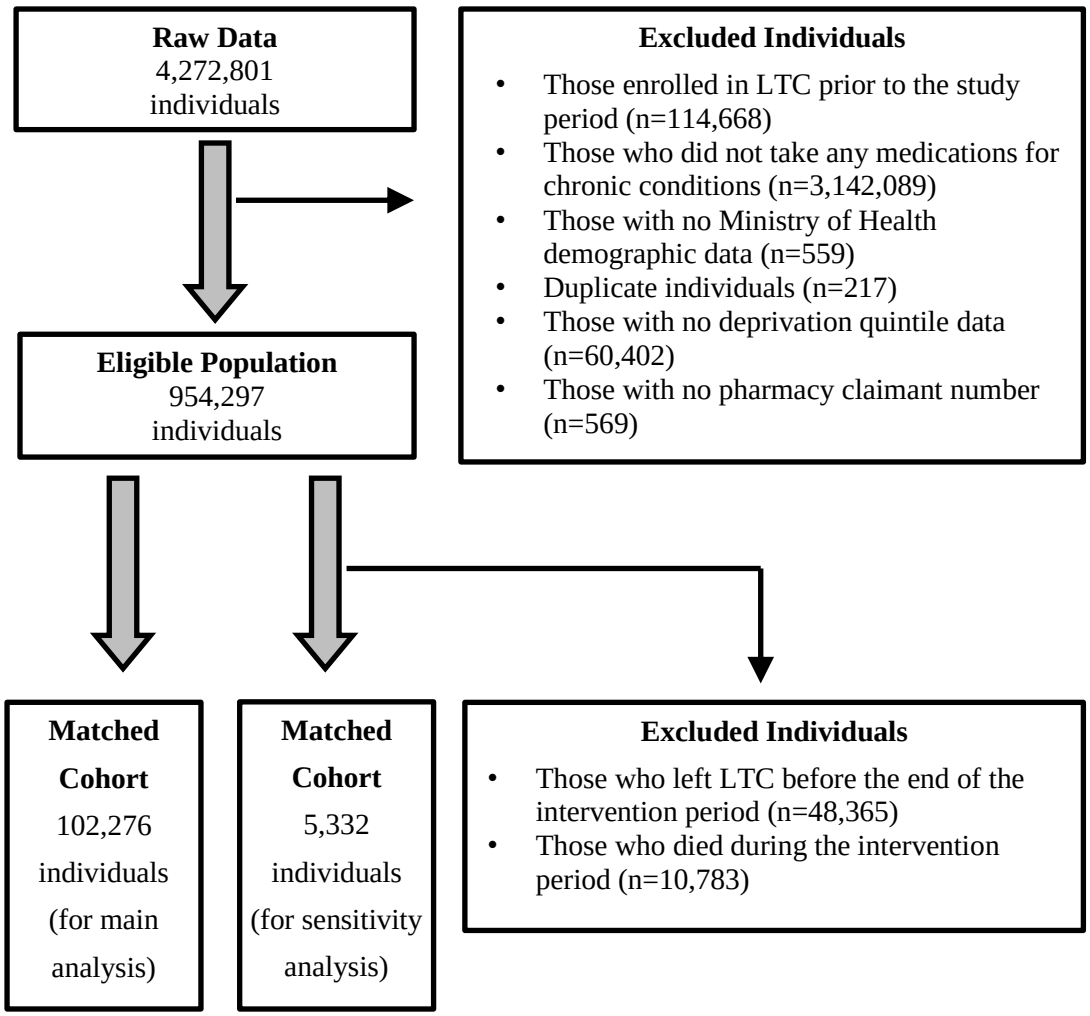


Figure 3. Flow chart of the data manipulation steps undertaken to prepare the matched-cohort data set for analysis

Conversion of outcome (dependent) variables from counts into bivariate variables

To undertake matching procedures and the outcome analysis, both of which use logistic regression models, the outcomes (medication adherence and ASH) were changed to bivariate outcomes.

For medication adherence, the methodology described by Kerr et al[111] was used. Kerr et al classified patients as adherent or non-adherent (bivariate), depending on whether they picked up their medications in three out of four quarters over a one-year period. Thus, for the present study an adherence cut off of 75% was used.[111]

For ASH, a bivariate variable was generated. The categories were zero hospitalisations and one or more hospitalisations. In the data, for the individuals who had an ASH, the majority of them had only one ASH in the follow-up periods. Examination of the spread of ASH in the follow up periods showed that the outcome was not a continuous variable and did not produce a bell-shaped curve, and this prevented the use of linear regression. Consequently, the hospitalisation variable was collapsed into a bivariate, which has been previously done by other researchers.[198]

The conversion of the outcome variables into bivariate variables enabled the use of logistic regression in the present study.

Conversion of independent variables from counts into categorical variables for generating the propensity score model

For logistic regression, all independent variables (covariates) used in the propensity score model were changed from count variables to categorical variables. The reason for this is, that often count variables are not continuous variables and one cannot assume normal distribution, thereby discouraging their use for logistic regression models. Using count variables in logistic regression models can make interpretations of odds ratios difficult.[109] Consequently, all count variables were converted to categorical variables (including: 'count of high risk medications'; 'count of hospitalisations one-year prior to enrolment'; 'Charlson comorbidity index'; and 'medication adherence one-year prior to enrolment'). The conversion of count variables into categorical variables is usually undertaken in one of three ways: categorising based on meaningful cut-offs (using previous literature to guide the cut-offs); categorising based on

percentiles quintiles or quantiles (i.e. upper, lower quantiles and median); or categorising based on clustering.[199] For the present research the first two methods were primarily used. Further details on how count variables were categorised is summarised below.

To categorise 'count of high risk medications' the researcher used polypharmacy cut-offs described in the literature, as well as the LTC eligibility criteria. Polypharmacy definitions vary with time and between studies,[200,201] however most frequently five or more medications are used to define polypharmacy.[200] Similarly, the LTC eligibility criteria define polypharmacy as five or more medications (with patients receiving five eligibility points) and if they take nine or more medications (ten points).[106] For this reason, three categories were used for 'count of high risk medications': ≤5, 6-8, ≥9.

The 'count of hospitalisations one-year prior to enrolment' variable existed as a count variable. Most individuals had zero hospitalisations in the one-year preceding LTC enrolment (n=714,676, 74.89% (of 954,297 individuals)). There is no agreed upon method for categorising hospitalisation data. Consequently, the researcher reviewed several different papers to inform the decision on how to categorise the hospitalisation variable. Some authors categorised 'frequent hospitalisations' as three or more hospitalisations in a one-year period,[202] while others have used five or more hospitalisations in one-year period to define 'frequent hospitalisation'.[203] Another group of researchers used the term 'frequent hospitalisations' for three hospitalisations in a one-year period and 'very frequent hospitalisations' for four or more hospitalisations in a one-year period.[204] With respect to the data in the present study and how it is dispersed, very few individuals had four or more hospitalisations in the one-year preceding LTC enrolment (four hospitalisations: n=15,701; 1.65%; five hospitalisations: n=8,170; 0.86% (of 954,297 individuals)). Due to the relatively small numbers of individuals with 'very frequent hospitalisations' per year compared to the rest of the raw population, the following categories for hospitalisations one-year preceding enrolment were used: 0, 1, 2, ≥3.

To categorise the 'Charlson comorbidity index', the following categories were generated, as used by other researchers[204,205]: 0, 1-2, ≥3.

For 'medication adherence one-year prior to enrolment' variable, the same categories were used as those described by New Zealand-based researchers Kerr et al.[111] Patients were classified as adherent if they picked up their medications in three out of four quarters (≥75%) and non-adherent if they picked up their medications <75%. Thus, two categories were generated: adherent, and non-adherent. Overseas literature usually uses a cut off of 80% to

define patients as adherent or non-adherent.[11,27,28,57] However the lack of availability of the 'days supply' variable in the New Zealand MOH Pharmaceutical Collection prevented the researcher calculating adherence using medication possession ratio (MPR) or proportion of days covered (PDC), which international researchers have frequently used to calculate adherence using dispensing data.[11]

4.5.7 Data analysis

Univariate analysis

Descriptive statistics were generated to describe patient demographics, clinical characteristics and medication usage patterns. Percentages and counts were calculated for categorical variables, and mean and standard deviations were calculated for continuous variables.

Bivariate analysis

Bivariate analysis was undertaken, using logistic regression, to examine the association between each outcome (ASH or medication adherence) and each of the independent variables (covariates). The odds ratios were calculated, as well as two-sided P-values and 95% confidence intervals.

Multivariate analysis

Propensity score (PS) analysis and logistic regression were used to estimate the impact of LTC enrolment on patients' medication adherence and ASH rates. A PS in the present study is the conditional probability of a patient becoming enrolled in LTC, having controlled for potential confounders.[104,112] The generation of PS involved a two-step analysis process. Firstly, a propensity model was generated and secondly a treatment effect model. For the propensity model, a logistic regression model was used to generate a PS using enrolment as the treatment outcome (dependent variable) and all potential confounders (variables potentially affecting enrolment) were included as independent variables.[112,113] All potential confounders were collapsed into a single variable, termed the PS.[114] After generating the PS for each patient, the score was able to be used in one of four ways: PS matching, stratification on the PS, inverse probability of treatment weighting (IPTW) using the PS, and adjustment of covariates using the PS.[101]

For the present study, PS matching was used. Matching is preferred as it involves comparing like with like, that is, comparing a single enrolled individual to a single unenrolled individual,

with the same balance of covariates. The ability to examine the distribution of covariates/confounders between the intervention and control groups is a major advantage of using PS matching.[114] This ensures that the intervention and control groups are balanced in their covariate profile and thus are able to be compared. In a systematic review by Shah et al[123] it was found that only 44% of papers included in their review checked that the confounders were balanced between the intervention and control groups. Testing the degree of fit of the model with the data of a PS model does not rely on goodness-of-fit estimates, but rather on whether the PS sufficiently balances covariates.[123] The balance of the covariates was assessed after matching was undertaken, using standardised mean difference (SMD). Rosenbaum and Rubin[110] have suggested that if the difference is 20% or less than the average standard deviation of the intervention and control groups, the groups can be assumed to be well balanced, with minimal residual covariate imbalance. More recent literature has used either more lenient cut-offs of 25% [206] or stricter cut-offs of 10%.[207] Quantile-Quantile (Q-Q plots) were also generated to assess balance, as they compare the distribution of variables in the population and the matched cohort.[208] Histograms were also generated in the present research to visualise the distribution of PS between the intervention and control groups. Historically researchers have used t-tests of the difference in means to assess balance, but it is now thought to produce misleading information and thus should not be used.[208] Consequently, for the present research only standardardised mean difference, Q-Q plots and histograms were used.

Once an acceptable level of balance is achieved after matching, the literature is mixed about whether there is a need to use all the covariates used to generate the PS in the outcome regression model.[123] This is often termed ‘double-adjustment’. Conceptually if acceptable balance is achieved, as identified by having SMD <10%, and there is considerable overlap in covariates in the Q-Q plots and histograms, then it is unnecessary to adjust for these covariates once again. This reasoning was discussed with a biostatistician at the University of Auckland, who concurred. His recommendation was to use double-adjustment only when there is imbalance remaining after the matching procedures. This would be the case if SMD >10% and there was little overlap in the Q-Q plots and histograms. For completeness, in the final outcome analysis no covariates were used in the logistic regression model, only for modelling the effect of LTC enrolment on the outcomes (medication adherence and ASH). For the sensitivity analysis double-adjustment was used, by adding all the covariates used to generate the PS into the outcome logistic regression model. This was undertaken to improve the validity of the findings.

There are different types of PS matching, including matching with a caliper and greedy matching.[117] For the present research nearest neighbour matching was used as it involves the selection of the best control individual for each intervention individual by matching those with the closest PS to each other.[197] A recent study compared 12 matching algorithms and did not find substantial differences in balancing by nearest neighbour matching and other algorithms such as optimal matching.[209]

The MatchIt® package available in R Studio® software was used for the matching procedures, as well as for assessing balance in the covariate profile. The 'mean Diff' function was used for calculating the standardised mean difference, and 'plot()' function was used to generate the Q-Q plots and histograms.

Intention-to-treat and per-protocol analysis

Intention-to-treat (ITT) and per-protocol (PP) are terms frequently used in the analysis of RCTs. However, some researchers have also adopted these terms for use in observational studies.[210] Undertaking only PP analysis has been suggested as biased.[210] Therefore both ITT and PP analysis were undertaken in the present research.[210] The ITT method involved analysing all individuals in the intervention and control groups, including those who died and those who were lost to follow-up. The PP method excluded from the analysis those individuals who died and those who did not remain enrolled in LTC until the end of the study period (December 2014). As recommended by Danaei et al[211] the ITT analysis was undertaken prior to the PP analysis.

Sub-analysis

Two different sub-analyses were undertaken. The first sub-analysis was based on patient age, to examine whether the outcomes, medication adherence and ASH differed between older LTC enrolled individuals (those 65 years and older) compared to younger LTC enrolled individuals (those 64 years and younger). After matching procedures, the data were separated into two groups those aged 65 years and older, and those 64 years and younger. Logistic regression modeling of the outcomes, ASH and medication adherence was then undertaken for each of these two age groups.

The second sub-analysis undertaken was based on patient ethnicity, to examine whether the outcomes, medication adherence and ASH differed between LTC enrolled Māori individuals compared to LTC enrolled NZ European individuals. After matching procedures, the data were separated according to ethnicity into two groups, those identifying as Māori and those identifying as NZ European. Logistic regression modeling of the outcomes, ASH and medication adherence was then undertaken for each of these groups.

4.5.8 Ethics approval

Ethics approval was sought from the New Zealand Health and Disability Ethics Committees. The committee deemed the study out of scope (reference number: 16/NTA114 (Appendix 4)).

4.6 Results

4.6.1 Descriptive statistics

The New Zealand census population (n=4,272,025)

Characteristics on this New Zealand census population are summarised in Table 7. As presented in Table 7, four LTC cohorts existed:

- Individuals who were never enrolled in the LTC service (n=4,077,044, 95.44%);
- Individuals who were newly enrolled in the LTC service during the study period (July 2013-December 2014) and who never received LTC previously (n=58,612, 1.37%);
- Individuals who were enrolled in the LTC service during the study period (July 2013-December 2014) and who had received LTC previously (n=131,647, 3.08%);
- Individuals who were not enrolled in the LTC service during the study period (July 2013-December 2014) but enrolled previously (n=4,722, 0.11%)

In this population of 4,272,025 individuals, nearly two-thirds of individuals identified as NZ European (66.10%) and less than a sixth identified as Māori (14.28%). Most individuals were aged 25-44 years and 45-64 years (25.54% and 25.76%, respectively), and fewest were aged 0-4 years (7.05%). In terms of gender, there was a nearly equal split between males and females, with 48.31% identifying as male. Individuals lived in a range of areas, ranging from least deprived (deprivation quintile 1) to most deprived (deprivation quintile 5). There was a nearly equal split of individuals living in the five different deprivation quintiles. Most individuals were not HUHC holders (99.41%), Care Plus members (96.22%), or CSC holders (79.03%).

Table 7. Characteristics of the New Zealand census population (n=4,272,025)

Variables	n	%
Study cohorts		
Never enrolled in LTC	4,077,044	95.44
Enrolled in LTC anytime from July 2013 to Dec 2014	58,612	1.37
Enrolled in LTC during July 2013-Dec 2014 and received LTC previously	131,647	3.08
Not enrolled in LTC July 2013-Dec 2014 but enrolled previously	4,722	0.11
Age (in years)		
0 - 4	301,146	7.05
5 - 14	588,391	13.77
15 - 24	576,272	13.49
25 - 44	1,090,889	25.54
45 - 64	1,100,482	25.76
65 or older	614,845	14.39
Prioritised ethnicity		
NZ European	2,823,972	66.10
Māori	610,037	14.28
Pacific	312,165	7.31
Asian	401,152	9.39
Other	124,699	2.92
Gender		
Female	2,208,009	51.69
Male	2,064,016	48.31
Deprivation quintile*		
1 (least deprived)	770,690	18.04
2	752,376	17.61
3	775,312	18.15
4	836,776	19.59
5 (most deprived)	907,974	21.25
Care Plus status		
Yes	161,392	3.78
No	4,110,633	96.22
Community Services Card (CSC) holder		
Yes	895,936	20.97
No	3,376,089	79.03
High Use Health Card (HUHC) holder		
Yes	25,286	0.59
No	4,246,739	99.41

* 229,456 (5.36%) missing values for deprivation quintile

Eligible population (n=954,297) and matched cohort (n=102,276)

After several data manipulation steps, as described in Section 4.5.6, the NZ census population data set (n=4,272,025) was manipulated, leaving 954,297 individuals. Figures 2 and 3 summarise the data manipulation steps followed to produce the data set with 954,297 individuals.

From these 954,297 individuals, a matched cohort was generated consisting of 102,276 individuals (n=51,138 in the intervention group and n=51,138 in the control group). A comparison of the characteristics of individuals in the eligible population (n=954,297) versus the matched cohort (n=102,276) is presented in Table 8.

As can be seen in Table 8, the individuals who were ‘never enrolled in LTC’ from the eligible population were all used to generate the matched cohort, so no intervention individuals were lost during the matching procedures. In other words, a match for each individual in the intervention group was found from the control group.

As presented in Table 8, the eligible population (n=954,297) consisted of 51,138 individuals enrolled in LTC (5.36%) and the remaining individuals (n=903,159) were not enrolled in LTC (94.64%).

The LTC cohort (n=51,138)

More than half of the individuals in the LTC cohort were aged 65 years and older (57.47%) and were mostly NZ European ethnicity (70.17%). Māori individuals made up nearly 14% of the LTC enrolled cohort. Just under half of individuals were male (47.25%). Nearly a third of individuals resided in the most deprived areas of the country (27.88%). Almost a quarter of individuals were members of Care Plus (23.52%), and just under half were CSC holders (47.09%). Only 2.93% of individuals were holders of a HUHC. Nearly a quarter of individuals had had three or more hospitalisations in the year preceding enrolment (22.57%), while 50.87% did not have even a single hospitalisation. Most individuals had a Charlson comorbidity index score of zero (77.28%), while nearly a fifth of individuals had a Charlson comorbidity index of 1 to 2 (19.42%). The majority used five or fewer high risk medications (71.85%). Nearly a quarter used six to eight high risk medications in the year preceding enrolment (24.82%). Preceding enrolment, 5.51% of individuals had been non-adherent to their medications.

Table 8. Comparison of baseline characteristics between intervention and control individuals in the eligible population and in the propensity score matched cohort

	Eligible Population (n=954,297)		Matched Cohort (n=102,276)	
Variables	LTC Enrolled (51,138)	Never Enrolled (903,159)	LTC Enrolled (51,138)	Never Enrolled (51,138)
Age (years)				
0 - 24	1016 (1.99%)	55227 (6.11%)	1016 (1.99%)	1049 (2.05%)
25 - 44	4572 (8.94%)	144873 (16.04%)	4572 (8.94%)	4578 (8.95%)
45 - 64	16160 (31.60%)	378623 (41.92%)	16160 (31.60%)	15956 (31.20%)
65 or older	29390 (57.47%)	324436 (35.92%)	29390 (57.47%)	29555 (57.79%)
Prioritised ethnicity				
NZ European	35885 (70.17%)	714058 (79.06%)	35885 (70.17%)	36046 (70.49%)
Māori	7098 (13.88%)	76665 (8.49%)	7098 (13.88%)	7009 (13.71%)
Pacific	3911 (7.65%)	35057 (3.88%)	3911 (7.65%)	3763 (7.36%)
Asian	3413 (6.67%)	59626 (6.60%)	3413 (6.67%)	3470 (6.79%)
Other	832 (1.63%)	17753(1.97%)	832 (1.63%)	850 (1.66%)
Gender				
Female	26975 (52.75%)	486852 (53.91%)	26975 (52.75%)	27013 (52.826%)
Male	24163 (47.25%)	416307 (46.09%)	24163 (47.25%)	24125 (47.18%)
Deprivation quintile				
1 (least deprived)	6984 (13.66%)	177996 (19.71%)	6984 (13.66%)	6990 (13.67%)
2	7820 (15.29%)	173759 (19.24%)	7820 (15.29%)	7890 (15.43%)
3	9618 (18.81%)	186148 (20.61%)	9618 (18.81%)	9622 (18.82%)
4	12457 (24.36%)	193810 (21.46%)	12457 (24.36%)	12562 (24.56%)
5 (most deprived)	14259 (27.88%)	171446 (18.98%)	14259 (27.88%)	14074 (27.52%)
Care Plus status				
Yes	12026 (23.52%)	81649 (9.04%)	12026 (23.52%)	12160 (23.78%)
No	39112 (76.48%)	821510 (90.96%)	39112 (76.48%)	38978 (76.22%)
CSC holder status				
Yes	24079 (47.09%)	233135 (25.81%)	24079 (47.09%)	24247 (47.41%)
No	27059 (52.91%)	670024 (74.19%)	27059 (52.91%)	26891 (52.59%)
HUHC holder status				
Yes	1496 (2.93%)	8848 (0.98%)	1496 (2.93%)	1666 (3.26%)
No	49642 (97.07%)	894311 (99.02%)	49642 (97.07%)	49472 (96.74%)
Count of hospitalisations before enrolment				
0	26012 (50.87%)	688664 (76.25%)	26012 (50.87%)	25228 (49.33%)
1	6747 (13.19%)	102087 (11.30%)	6747 (13.19%)	7046 (13.78%)
2	6836 (13.37%)	58560 (6.48%)	6836 (13.37%)	7101 (13.89%)
≥3	11543 (22.57%)	53848 (5.96%)	11543 (22.57%)	11763 (23.00%)
Charlson comorbidity index before enrolment				
0	39517 (77.28%)	869430 (96.27%)	39517 (77.28%)	40125 (78.46%)
1-2	9929 (19.42%)	30083 (3.33%)	9929 (19.42%)	9529 (18.63%)
≥3	1692 (3.31%)	3646 (0.40%)	1692 (3.31%)	1484 (2.90%)
Count of high risk medications before enrolment				
≤5	36743 (71.85%)	859775 (95.20%)	36743 (71.85%)	37013 (72.38%)
6-8	12694 (24.82%)	40500 (4.48%)	12694 (24.82%)	12593 (24.63%)
≥9	1701 (3.33%)	2884 (0.32%)	1701 (3.33%)	1532 (3.00%)
% patients adherent to their medications before enrolment				
Non-adherent	2819 (5.51%)	152356 (16.87%)	2819 (5.51%)	2622 (5.13%)
Adherent	48319 (94.49%)	750803 (83.13%)	48319 (94.49%)	48516 (94.87%)

4.6.2 Preliminary analysis

To identify which particular independent variables (covariates) had a statistically significant effect on the study outcomes (medication adherence and ASH), a logistic regression model was constructed for each of the outcomes at the various study periods. The logistic regression models examined the impact of LTC enrolment and all the independent variables (covariates) on the outcomes: ASH at 6 months post-enrolment, ASH at 12 months post-enrolment, ASH at 3 months post-end of enrolment and ASH at 6 months post-end of enrolment, as well as medication adherence at 12 months post-enrolment and at 12 months post-end of enrolment.

The outputs from each of these six logistic regression models are presented in Appendix 6.

4.6.3 Estimation of the propensity scores and matching procedures

The MatchIt package in R Studio® was used to generate the propensity scores for each individual and to undertake nearest neighbour, 1:1 matching procedures. Matched procedures yielded the matched-cohort cohort (n=102,276).

Covariate balance after matching

After undertaking matching procedures using MatchIt in R Studio®, an output was produced that summarised the balance of independent variables (covariates) between the intervention and control groups, before and after matching, using the standardised mean difference (SMD). As described in the earlier section of this chapter, if the SMD is 10% or less, then the intervention and control groups are assumed to be well balanced, with minimal residual covariate imbalance.[207] The output, presented in Table 9, shows that before matching procedures (column one) several covariates (shown in bold in the table) were imbalanced between the intervention and control groups, due to the SMD being ≥ 10%. However as can be seen in column two of Table 9, after matching procedures, an appropriate level of covariate balance was achieved between the intervention group and control group (as none of the covariates had a SMD ≥ 10%).

A quantile-quantile (Q-Q) plot and histogram of the distribution of propensity scores are presented in Figures 4 and 5, respectively. As can be seen in the plots, no individuals in the intervention group were discarded from the analysis. There appears to be good overlap in the propensity scores between the matched intervention and control groups, suggesting covariates are well balanced between the two groups. In Table 8, the characteristics of the matched cohort

are summarised. In this table it is evident that each of the covariates is well balanced between the intervention and control groups, in the matched cohort.

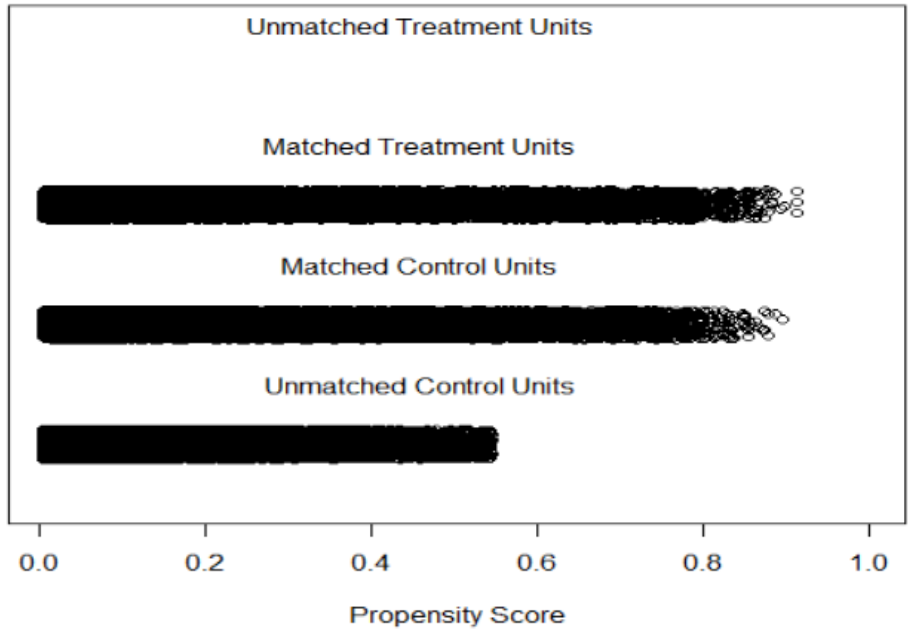


Figure 4. Quantile-quantile plot with the distribution of propensity scores after matching procedures

As can be seen in Figure 4, the distribution of propensity scores for matched individuals in the intervention group (‘matched treatment units’) and the control group (‘matched control units’) are similar. This suggests that the balance of covariates is similar between the intervention and control groups. Figure 4 also highlights that no intervention patients were discarded from the analysis (‘unmatched treatment units’).

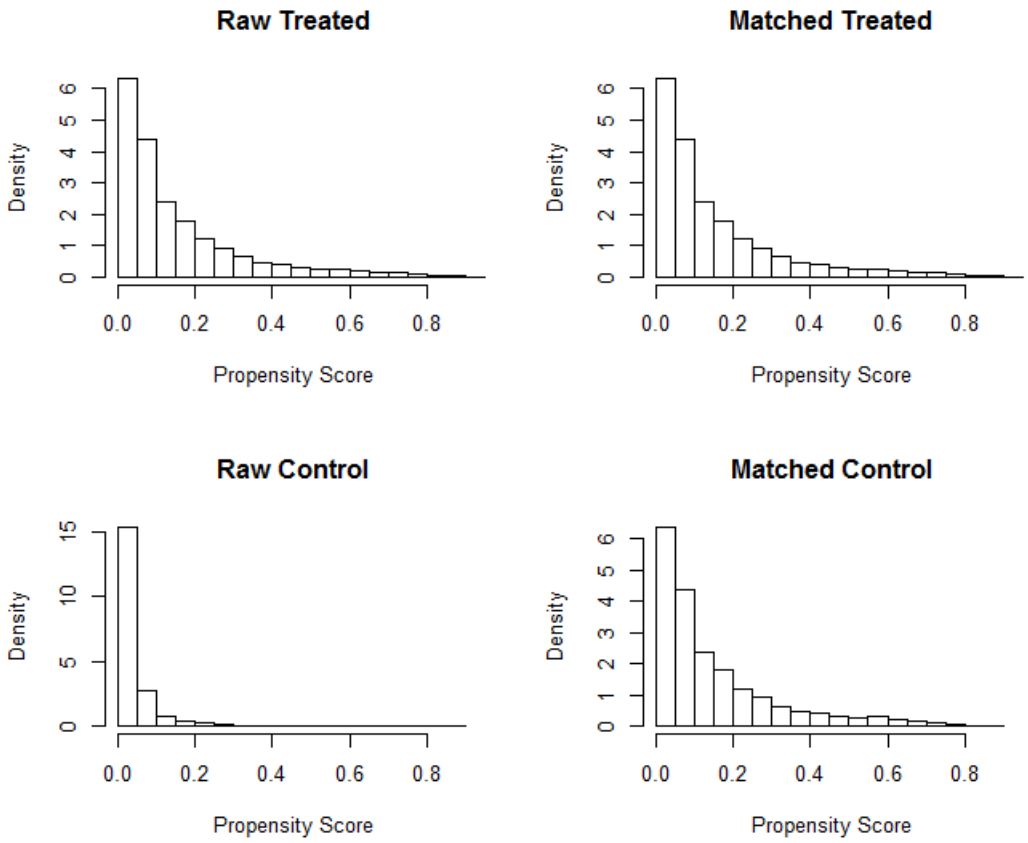


Figure 5. Histograms with the distribution of propensity scores before and after matching procedures

As seen in Figure 5, the distribution of propensity scores between the intervention group (‘matched treated’) is similar to the control group (‘matched control’). This suggests that the balance of covariates is similar between the intervention and control groups.

Table 9. Standardised mean difference (SMD) comparing covariate balance between the intervention and control groups before and after matching

Variables	SMD before matching (n=954,297)	SMD after matching (n=102,276)
Age (years)		
0 - 24	-	-
25 - 44	**-0.2488**	-0.0004
45 - 64	**-0.2220**	0.0086
65 or older	**0.4359**	-0.0065
Prioritised ethnicity		
NZ European	-	-
Māori	**0.1559**	0.0050
Pacific	**0.1417**	0.0109
Asian	-0.0029	-0.0045
Other	-0.0269	-0.0029
Gender		
Female	-	-
Male	0.0232	0.0015
Deprivation quintile		
1 (least deprived)	**-0.1762**	-0.0003
2	**-0.1097**	-0.0038
3	-0.0461	-0.0002
4	0.0676	-0.0048
5 (most deprived)	**0.1985**	0.0081
Care Plus status		
No	-	-
Yes	**0.3413**	-0.0062
CSC holder		
No	-	-
Yes	**0.4262**	-0.0066
HUHC holder		
No	-	-
Yes	**0.1155**	-0.0197
Count of hospitalisations before enrolment		
0	-0.5078	0.0307
1	0.0559	-0.0173
2	**0.2023**	-0.0152
≥3	**0.3973**	-0.0103
Charlson comorbidity index before enrolment		
0	-	-
1-2	**0.4066**	0.0198
≥3	**0.1624**	0.0227
Count of high risk meds before enrolment		
≤5	-	-
6-8	**0.4708**	0.0046
≥9	**0.1677**	0.0184
% patients adherent before enrolment		
Non-adherent	-	-
Adherent	**0.4976**	-0.0169

* Reference category indicated using "-"
* Values in bold have a SMD ≥ 0.1 (10%)

4.6.4 Outcomes analysis

The final logistic regression model was generated examining the impact of LTC enrolment (Y/N) on patients' outcomes (ASH and medication adherence) at different time periods. No independent variables (covariates) were used in this model other than LTC enrolment (Y/N). As seen in Section 4.6.3 the independent variables (covariates) were well balanced after matching between the intervention and the control groups, and there was no SMD > 10% after matching. Therefore, it was unnecessary to regress once again all the covariates used in the matching step (called double-adjustment). As mentioned in the methods section of this chapter, the literature is mixed with regard to using the covariates in the final regression model when balance is achieved, with some arguing that if balance is achieved through matching, then there is no need to put these covariates back into the final regression model again.[207] Consequently, for the outcome analysis, double-adjustment was not undertaken, but it was completed as part of the sensitivity analysis.

Tables 10 and 11 present the outputs from the final logistic regression models, for ASH and medication adherence, respectively. As can be seen from the odds ratios (ORs), enrolment in LTC had a significant impact on both ASH and medication adherence. Individuals enrolled in LTC (the intervention group) had significantly greater odds of having an ASH, compared to not enrolled individuals (the control group). Likewise, individuals enrolled in LTC had significantly greater odds of being adherent to their medications, compared to not enrolled individuals. Further details on each outcome are presented below.

Ambulatory Sensitive Hospitalisations (ASH)

Enrolment in LTC contributed to significantly greater ASH, with patients in the intervention group having 1.73 (95% CI: 1.63-1.84) greater odds of having an ASH compared to the control group at 6 months after the start of the intervention (post-enrolment). At 12 months after the start of the intervention, patients in the intervention group had 1.86 (95% CI: 1.78-1.96) greater odds of having an ASH, compared to the control group.

After completion of the intervention, at 3 months post-end, the intervention group still had significantly greater odds of ASH compared to the control (OR: 1.70, 95% CI: 1.56-1.84). At 6 months post-end, this significant difference remained, as patients in the intervention had 1.58 (95% CI: 1.49-1.68) greater odds of having an ASH, compared to the control group.

Medication adherence

Enrolment in LTC contributed to improved medication adherence, with patients in the intervention group having 2.99 (95% CI: 2.79-3.20) greater odds of being adherent to their medications compared to the control group at 12 months after the start of the intervention (post-enrolment).

After completion of the intervention, at 12 months post-end, the intervention group still had significantly greater odds of being adherent compared to the control group (OR: 1.51 95% CI: 1.44-1.58).

Table 10. The odds of having an ambulatory sensitive hospitalisation in the intervention group compared to the control group using the matched-cohort (n=102,276)

LTC Enrolled	**Post-enrolment** Odds Ratios (95% CI)		**Post-end** Odds Ratios (95% CI)	
	6 months	12 months	3 months	6 months
No (control)	1.00	1.00	1.00	1.00
Yes (intervention)	**1.73 (1.63-1.84)**	**1.86 (1.78-1.96)**	**1.70 (1.56-1.84)**	**1.58 (1.49-1.68)**

Table 11. The odds of being adherent to medications in the intervention group compared to the control group using the matched-cohort (n=102,276)

LTC Enrolled	**Post-enrolment** Odds Ratios (95% CI) 12 months	**Post-end** Odds Ratios (95% CI) 12 months
No (control)	1.00	1.00
Yes (intervention)	**2.99 (2.79-3.20)**	**1.51 (1.44-1.58)**

A summary of the counts and percentages of patients hospitalised are presented in Table 12, and counts and percentages of patients adherent to their medications are presented in Table 13.

To be able to fully interpret these findings, the researcher deemed it vital to present ASH as well as all hospitalisations data too. The following section summarises the outcome analysis when all hospitalisations were analysed, rather than only ASH.

All Hospitalisations – comparison with control group

Twelve months after the start of the intervention, enrolment in LTC was associated with significantly greater odds of hospitalisation, with patients in the intervention group having 1.50 (95% CI 1.46-1.54) greater odds of having a hospitalisation compared to the control group.

All Hospitalisations – comparison with baseline

At baseline before matching, there was a greater percentage of patients with one or more hospitalisations in the intervention group compared to the control group (49.13% in the intervention group and 23.74% in the control). After matching procedures, these hospitalisations were balanced between the intervention and control group (49.13% in the intervention group and 50.67% in the control group). At 12 months post-enrolment, the percentage of patients in the intervention group with one or more hospitalisations was reduced to 45.36% (reduction of 3.77% over the 12 month period).

Table 12. Count of patients hospitalised before and after LTC enrolment

	Count of patients hospitalised (all hospitalisations)						**Count of patients hospitalised (ASH hospitalisations)**							
	1 year before enrolment *From Table 8 (before matching)		**1 year before enrolment** *From Table 8 (after matching)		**1 year (12months) post-enrolment** *ORs presented in the thesis		**1 year (12months) post-enrolment** *ORs presented in the thesis		**6 months post-enrolment** *ORs presented in the thesis		**6 months post-end** *ORs presented in the thesis		**3 months post-end** *ORs presented in the thesis	
	Enrolled (n=51138)	Non-Enrolled (n=903159)	Enrolled (n=51138)	Non-Enrolled (n=51138)	Enrolled (n=51138)	Non-Enrolled (n=51138)	Enrolled (n=51138)	Non-Enrolled (n=51138)	Enrolled (n=51138)	Non-Enrolled (n=51138)	Enrolled (n=51138)	Non-Enrolled (n=51138)	Enrolled (n=51138)	Non-Enrolled (n=51138)
0	26012 (50.87%)	688664 (76.25%)	26012 (50.87%)	25228 (49.33%)	27944 (54.64%)	32930 (64.39%)	46229 (90.40%)	48381 (94.61%)	48368 (94.58%)	49500 (96.80%)	48233 (94.32%)	49261 (96.33%)	49521 (96.84%)	50172 (98.11%)
1 or more	25126 (49.13%)	214495 (23.74%)	25126 (49.13%)	25910 (50.67%)	23194 (45.36%)	18208 (35.61%)	4909 (9.60%)	2757 (5.39%)	2770 (5.42%)	1638 (3.20%)	2905 (5.68%)	1877 (3.67%)	1617 (3.16%)	966 (1.95%)

Abbreviations: ORs - Odds Ratios

Table 13. Count of patients adherent to their medications before and after LTC enrolment

	1 year before enrolment *From Table 8 (before matching)		**1 year before enrolment** *From Table 8 (after matching)		**1 year (12months) post-enrolment** *ORs presented in the thesis		**1 year (12months) post-end** *****ORs presented in the thesis	
	Enrolled (n=51138)	Non-Enrolled (n=903159)	Enrolled (n=51138)	Non-Enrolled (n=51138)	Enrolled (n=51138)	Non-Enrolled (n=51138)	Enrolled (n=51138)	Non-Enrolled (n=51138)
Non-adherent	2819 (5.51%)	152356 (16.87%)	2819 (5.51%)	2622 (5.13%)	1166 (2.28%)	3331 (6.51%)	2802 (5.48%)	4111 (8.04%)
Adherent	48319 (94.49%)	750803 (83.13%)	48319 (94.49%)	48516 (94.87%)	49972 (97.72%)	47807 (93.49%)	48336 (94.52%)	47027 (91.96%)

Abbreviations: ORs - Odds Ratios

4.6.5 Sensitivity analysis

4.6.5.1 Per-protocol analysis

Per-protocol (PP) analysis was undertaken, whereby analysis was limited to those individuals who remained enrolled in LTC during the entire intervention period (July 2013 to December 2014), as well as those who did not die during the intervention period. After removing these individuals from the study population, propensity score matching was undertaken. Matching procedures produced a matched cohort of 5,332 individuals, with 2,666 individuals in the intervention group and 2,666 in the control group. Logistic regression analysis, modeling each of the outcomes (ASH and medication adherence), was undertaken for this matched cohort. Tables 14 and 15 present the results from the PP analysis.

Ambulatory Sensitive Hospitalisations (ASH)

As presented in Table 14, LTC enrolment contributed to significantly greater ASH, with patients in the intervention group having 1.77 (95% CI: 1.37-2.30) greater odds of having an ASH compared to the control group at 6 months after the start of the intervention (post-enrolment). At 12 months after the start of the intervention, patients in the intervention had very similar odds of having an ASH compared to 6 months (OR: 1.77, 95% CI: 1.44-2.19), however the confidence interval was narrower. From the commencement of the intervention until the very end of the intervention (at 18 months post-enrolment), patients in the intervention had 1.86 (95% CI: 1.56-2.23) greater odds of having as ASH compared to control patients.

After completion of the intervention, at 3 months post-end, the intervention group still had significantly greater odds of ASH compared to the control 1.61 (95% CI: 1.13-2.30). At 6 months post-end, this significant difference remained, as patients in the intervention had 1.59 (95% CI: 1.22-2.08) greater odds of having an ASH compared to the control group.

Medication adherence

LTC enrolment contributed to greater adherence, with patients in the intervention group having 6.30 (95% CI: 4.19-9.88) greater odds of being adherent to their medications compared to the control group at 12 months after the start of the intervention (post-enrolment).

After completion of the intervention, at 12 months post-end, the intervention group still had significantly greater odds of being adherent compared to the control group (OR: 2.59, 95% CI: 1.92-3.53).

Table 14. The odds of having an ambulatory sensitive hospitalisation in the intervention group compared to the control group (per-protocol analysis, n=5,332)

LTC Enrolled	Post-enrolment Odds Ratios (95% CI)			Post-end Odds Ratios (95% CI)	
	6 months	12 months	18 months	3 months	6 months
No (control)	1.00	1.00	1.00	1.00	1.00
Yes (intervention)	**1.77 (1.37-2.30)**	**1.77 (1.44-2.19)**	**1.86 (1.56-2.23)**	**1.61 (1.13-2.30)**	**1.59 (1.22-2.08)**

Table 15. The odds of being adherent to medications in the intervention group compared to the control group (per-protocol analysis, n=5,332)

LTC Enrolled	Post-enrolment Odds Ratios (95% CI)	Post-end Odds Ratios (95% CI)
	12 months	12 months
No (control)	1.00	1.00
Yes (intervention)	**6.30 (4.19-9.88)**	**2.59 (1.92-3.53)**

4.6.5.2 Analysis using double-adjustment

As mentioned earlier in this chapter, previous research has suggested that if covariates after matching are well balanced, then it is not necessary to undertake double adjustment. However, to ensure the robustness of the results and to support the main research findings, PS analysis was undertaken using double adjustment. All the variables used to generate the PS were subsequently used in the outcome logistic regression models to assess the impact of LTC enrolment on the outcomes, medication adherence and ASH. Tables 16 and 17 present the odds ratios from PS matching using double adjustment.

Ambulatory Sensitive Hospitalisations (ASH)

LTC enrolment contributed to significantly greater ASH, with patients in the intervention group having 1.76 (95% CI: 1.65-1.87) greater odds of having an ASH compared to the control group at 6 months after the start of the intervention (post-enrolment). At 12 months after the start of the intervention, patients in the intervention had 1.92 (95% CI: 1.83-2.02) greater odds of having an ASH.

After completion of the intervention, at 3 months post-end, the intervention group still had significantly greater odds of ASH compared to the control 1.69 (95% CI:1.56-1.83). At 6 months post-end, this significant difference remained, as patients in the intervention having 1.58 (95% CI: 1.49-1.68) greater odds of having an ASH compared to the control group.

Medication adherence

LTC enrolment contributed to greater adherence, with patients in the intervention group having 3.28 (95% CI: 3.06-3.52) greater odds of being adherent to their medications compared to the control group at 12 months after the start of the intervention (post-enrolment).

After completion of the intervention, at 12 months post-end, the intervention group still had significantly greater odds of being adherent compared to the control group (OR: 1.55, 95% CI: 1.48-1.64).

Table 16. The odds of having an ambulatory sensitive hospitalisation in the intervention group compared to the control group (double-adjustment analysis, n=102,276)

LTC Enrolled	**Post-enrolment** Odds Ratios (95% CI)		**Post-end** Odds Ratios (95% CI)	
	6 months	12 months	3 months	6 months
No (control)	1.00	1.00	1.00	1.00
Yes (intervention)	**1.76 (1.65-1.87)**	**1.92 (1.83-2.02)**	**1.69 (1.56-1.83)**	**1.58 (1.49-1.68)**

Table 17. The odds of being adherent to medications in the intervention group compared to the control group (double-adjustment analysis, n=102,276)

LTC Enrolled	**Post-enrolment** Odds Ratios (95% CI)	**Post-end** Odds Ratios (95% CI)
	12 months	12 months
No (control)	1.00	1.00
Yes (intervention)	**3.28 (3.06-3.52)**	**1.55 (1.48-1.64)**

4.6.5 Sub-analysis

4.6.5.1 Comparison of outcomes between individuals aged ≥ 64 years and ≤ 65 years

Sub-analysis was undertaken of PS matched individuals based on age. The data were separated into two groups after matching, those aged 64 years or younger, and those aged 65 years or older. Logistic regression models were generated to examine the impact of age on the outcomes (ASH and medication adherence) for each age group.

Ambulatory Sensitive Hospitalisations (ASH)

During the sub-analysis it was found that regardless of patients' age, individuals in the intervention group had significantly greater odds of having an ASH compared to the control group. Also, it was found that individuals aged 65 years and older had consistently greater odds of having an ASH compared to individuals aged 64 years and younger, during the intervention period (post-enrolment) and after completion of the intervention (post-end). Tables 18 and 19 summarise the odds ratios.

Table 18. The odds of having an ambulatory sensitive hospitalisation in the intervention group compared to the control group amongst individuals aged ≤ 64 years

LTC Enrolled	Post-enrolment Odds Ratios (95% CI)		Post-end Odds Ratios (95% CI)	
	6 months	12 months	3 months	6 months
No (control)	1.00	1.00	1.00	1.00
Yes (intervention)	**1.57 (1.42-1.75)**	**1.70 (1.57-1.85)**	**1.57 (1.37-1.80)**	**1.48 (1.33-1.64)**

Table 19. The odds of having an ambulatory sensitive hospitalisation in the intervention group compared to the control group amongst individuals aged ≥ 65 years

LTC Enrolled	Post-enrolment Odds Ratios (95% CI)		Post-end Odds Ratios (95% CI)	
	6 months	12 months	3 months	6 months
No (control)	1.00	1.00	1.00	1.00
Yes (intervention)	**1.87 (1.73-2.03)**	**2.06 (1.94-2.19)**	**1.76 (1.59-1.95)**	**1.65 (1.53-1.78)**

Medication adherence

During the sub-analysis it was found that regardless of patients' age, those individuals in the intervention group had significantly greater odds of being adherent to their medications compared to the control group.

Furthermore, individuals aged 65 years and older had consistently lower odds of being adherent, compared to individuals aged 64 years and younger, during the intervention period (post-enrolment) and after completion of the intervention (post-end). Tables 20 and 21 summarise the odds ratios.

Table 20. The odds of being adherent to medications in the intervention group compared to the control group amongst individuals aged ≤ 64 years

LTC Enrolled	Post-enrolment Odds Ratios (95% CI)	Post-end Odds Ratios (95% CI)
	12 months	12 months
No (control)	1.00	1.00
Yes (intervention)	**3.88 (3.55-4.24)**	**1.97 (1.84-2.12)**

Table 21. The odds of being adherent to medications in the intervention group compared to the control group amongst individuals aged ≥ 65 years

LTC Enrolled	Post-enrolment Odds Ratios (95% CI)	Post-end Odds Ratios (95% CI)
	12 months	12 months
No (control)	1.00	1.00
Yes (intervention)	**2.29 (2.04-2.58)**	**1.21 (1.12-1.30)**

4.6.5.2 Comparison of outcomes between Māori and NZ European individuals

Sub-analysis was undertaken of PS matched individuals based on ethnicity. The data were separated into two groups after matching, those who identify as Māori and those who identify as NZ European. Logistic regression models examining the impact of ethnicity on the outcomes, ASH and medication adherence were undertaken for each age group.

Ambulatory Sensitive Hospitalisations (ASH)

Regardless of ethnicity, individuals enrolled in LTC had significantly greater odds of having an ASH compared to the control group. NZ European individuals had greater odds of having an ASH during the intervention period (post-enrolment) and after completion of the intervention (post-end), compared to Māori individuals. Tables 22 and 23 summarise the odds ratios.

Table 22. The odds of having an ambulatory sensitive hospitalisation in the intervention group compared to the control group amongst Māori individuals

LTC Enrolled	**Post-enrolment** Odds Ratios (95% CI)		**Post-end** Odds Ratios (95% CI)	
	6 months	12 months	3 months	6 months
No (control)	1.00	1.00	1.00	1.00
Yes (intervention)	**1.64 (1.42-1.91)**	**1.79 (1.59-2.02)**	**1.54 (1.28-1.85)**	**1.40 (1.21-1.61)**

Table 23. The odds of having an ambulatory sensitive hospitalisation in the intervention group compared to the control group amongst NZ European individuals

LTC Enrolled	**Post-enrolment** Odds Ratios (95% CI)		**Post-end** Odds Ratios (95% CI)	
	6 months	12 months	3 months	6 months
No (control)	1.00	1.00	1.00	1.00
Yes (intervention)	**1.87 (1.73-2.03)**	**2.02 (1.90-2.15)**	**1.72 (1.56-1.91)**	**1.64 (1.52-1.77)**

Medication adherence

Regardless of ethnicity, individuals enrolled in LTC had significantly greater odds of being adherent to their medications compared to the control group.

Individuals identifying as Māori and NZ European had very similar odds for being adherent at 12 months post-enrolment (Māori OR: 3.24 (95% CI 2.79-3.76), NZ European OR: 3.36 (95% CI: 3.04-3.72)). At 12 months post-end, the LTC enrolled Māori individuals had greater adherence (Māori OR: 1.61 (95% CI 1.43-1.81), compared to NZ European individuals (NZ European OR: 1.47 (95% CI 1.37-1.56). Tables 24 and 25 summarise the odds ratios.

Table 24. The odds of being adherent to medications in the intervention group compared to the control group amongst Māori individuals

LTC Enrolled	Post-enrolment Odds Ratios (95% CI) 12 months	Post-end Odds Ratios (95% CI) 12 months
No (control)	1.00	1.00
Yes (intervention)	**3.24 (2.79-3.76)**	**1.61 (1.43-1.81)**

Table 25. The odds of being adherent to medications in the intervention group compared to the control group amongst NZ European individuals

LTC Enrolled	Post-enrolment Odds Ratios (95% CI) 12 months	Post-end Odds Ratios (95% CI) 12 months
No (control)	1.00	1.00
Yes (intervention)	**3.36 (3.04-3.72)**	**1.47 (1.37-1.56)**

4.6.5.3 Alternative methods tested for sub-analysis

To ensure the robustness of the sub-analysis the researcher also attempted sub-analysis using two alternative methods. The sub-analysis presented in this chapter involved sub-setting the data set, based on age and ethnicity, after matching procedures were undertaken. The alternative methods tried were:

- Undertaking matching procedures, excluding age or ethnicity. Then the data were separated based on age (≤64 years and ≥65 years) or ethnicity (NZ European and Māori). Then outcomes analysis was undertaken on each group.
- The data were separated based on age (≤64 years and ≥65 years) or ethnicity (NZ European and Māori). Then matching procedures were undertaken on each group. Finally, outcome analysis was undertaken on each group.

These alternative methods of sub-analysis yielded very similar results to those determined during the sub-analysis presented in Sections 4.6.5.1 and 4.6.5.2.

4.7 Discussion

This retrospective, matched-cohort study examined the impact of the LTC service on patients' health outcomes, specifically medication adherence and ASH. Enrolment in the LTC service was associated with greater odds of patients being adherent to their medications, and unexpectedly greater odds of having an ASH.

Improving medication adherence is one of the major goals of the LTC service,[182] so it is encouraging to find that the service is able to effectively improve medication adherence amongst enrolled patients. This finding is consistent with earlier work, both primary research and systematic reviews, examining the effectiveness of community pharmacist-led interventions in improving patients' medication adherence in other countries, showing that community pharmacist-led interventions like LTC can contribute to improved patient adherence.[27-29,38]

The LTC service is focussed on medication adherence and is delivered to enrolled patients at the time their medications are picked up and at annual scheduled appointments between the pharmacist and the patient.[182] It is primarily delivered face-to-face, however, pharmacists may use other means of communication such as phone calls and text messages to deliver elements of the service to their patients.[182] A systematic review by Cutrona et al[212] examined the effectiveness of different modes of delivering adherence interventions for those with cardiovascular conditions, and their findings support the provision of face-to-face pharmacist-led interventions at the time of medication pick-up. The authors suggested this enables counselling to occur concurrently with medication dispensing and thus is a beneficial mode and time for delivering adherence interventions. This is how LTC is primarily delivered, which provides the opportunity for pharmacists to follow up with patients at every visit. This can help with the prompt identification and mitigation of adherence and health issues.

Another pharmacy intervention targeting community dwelling patients older than 65 years sought to improve medication adherence and certain clinical outcomes (blood pressure (BP) and low density lipoprotein cholesterol (LDL-C)).[213] This intervention included pharmacist-patient education, tailored medication provision and blister packing. The authors Lee et al[213] reported a positive effect of the intervention on patients' adherence, leading to an increase in adherence rates from 61.2% to 96.9%, along with significant reductions in systolic BP and LDL-C. Upon cessation of the intervention, there was decreased medication adherence and persistence. This supports the notion that in order for improvements in adherence to continue, multifactorial interventions need to be continued. Similar results were seen in the present LTC study, whereby adherence rates were higher during the intervention period yet after the end of the study period the values dropped. Furthermore, like the intervention by Lee et al[213] which consisted of education and blister packing components, the LTC service usually involves these two components being provided to enrolled patients.[182]

In terms of hospitalisations, the present study found several things; that compared to baseline, the percentage of LTC patients having one or more hospitalisation was reduced during the study period (from 49.13% to 45.36%). However, in terms of the odds of hospitalisation between the intervention and control group, for all hospitalisations as well as ASH, patients in the intervention group had significantly greater odds of hospitalisation during and after the study period, compared to the control group.

Interestingly, at baseline, before matching procedures, the percentage of patients with one or more hospitalisations was greater in the LTC intervention group compared to the control group (49.13% and 23.74% respectively). This suggests that at baseline patients in the intervention are already more pre-disposed to being hospitalised than those patients not receiving the service. This is perhaps expected as patients in the LTC service are generally more co-morbid patients, with polypharmacy and adherence issues. However, after propensity score matching these baseline hospitalisations were balanced out between the intervention and control groups. Yet even after the matching, during the outcome analysis it was found that patients in LTC still had greater odds of being hospitalised. Why this the case, is unclear from the data. One can however speculate that it may be that even though LTC can somewhat reduce hospitalisations from baseline, this group of LTC patients are still more likely to be hospitalised than control patients.

A possible reason for the greater hospitalisations amongst the LTC intervention group, is closer monitoring. One may speculate that individuals enrolled in the LTC service are more closely monitored by their pharmacists as they are high needs patients (non-adherent, co-morbid and have polypharmacy). They may also have developed stronger relationships with their pharmacists as part of the LTC service, enabling them to seek greater advice and assistance about their medications and illnesses from their pharmacist. Therefore, these patients may seek medical help or be referred for hospital treatment more frequently than those not enrolled in LTC. In the present study it was not possible to determine and match for patients' health literacy, health beliefs and autonomy, as such information is not available in routinely collected health data in New Zealand. Thus, it may be that patients enrolled in LTC are more autonomous and proactive with maintaining their health, they may also become more health literate and familiar with the health system through the intervention and thus may recognise and act on warning signs more readily than those who are not enrolled. They may therefore also seek hospital treatment more readily than non-enrolled patients. Such an explanation was suggested some years ago by Holland et al,[214] while examining the impact of a pharmacist-led home-

based medication review on hospital readmission rates in elderly patients. Their findings showed that patients randomised to receive the pharmacist's medication review had 30% higher rates of hospital admission than patients receiving standard care from their GPs. Medication adherence was not assessed in the study, but the authors did hypothesise that adherence may have improved during the intervention and this may have led to greater medication adverse effects and medication interactions and thus resulted in greater hospital admissions. Furthermore, the researchers postulated that the home-based medication review may have resulted in greater patient confusion, fear and increased medication complexity, compared to patients receiving standard care.[214] The present study examined medication adherence together with hospitalisations. One of the major goals of the LTC service is to make medication taking easier and simpler for the patients, and the choice of interventions that pharmacists provide to enrolled patients is flexible and based on individual patient needs and capabilities. Thus unlike that proposed in the study by Holland et al,[214] the researcher does not propose that patient confusion, fear and increased medication complexity are causes of increased hospitalisations in the present study. Gaining a better understanding of why ASH are greater amongst LTC enrolled patients was explored further in the qualitative study (see Chapter 5).

A more comprehensive understanding of the interventions that are being delivered as part of the LTC service is crucial for understanding the reasons for the increased number of ASH. For example, in the study described above by Holland et al,[214] the authors referred to their intervention as 'a medication review', however a short review written by other researchers, suggested that this was not a clinical medication review, which involves accessing patients notes and prescription history; but rather the pharmacists were conducting a simpler technical review of a patient's medication list.[215] It may be argued that for the LTC service this detailed understanding of what is actually being done for patients is lacking, since pharmacists can provide an array of activities or services under the LTC umbrella.

It is also important to mention that pharmacies are paid for providing LTC on a patient-by-patient basis and only if an individual remains enrolled in the LTC service in that specific pharmacy. One crucial way of staying enrolled is ensuring that patients get prescription medications dispensed at least every four months.[182] It would be worthwhile to investigate if adherence would be different if alternative adherence measures were used (e.g. self-report, pill counts). This, as discussed later in the limitations section of this chapter, is an innate limitation of using secondary databases to estimate adherence. While in the present study it appears that LTC enrolled patients are picking up medications from their pharmacies more regularly, one

cannot be sure if this reflects more regular consumption of their medications. Perhaps if greater picking up as well as greater consumption of medications was occurring a decline in hospitalisations would follow. Previous research has suggested such a pattern; whereby improvements in medication adherence resulted in fewer hospitalisations.[14,82,216-221] Other researchers have contradicted this, showing that even when adherence was improved, it did not result in a decline in hospitalisations.[27] Such inconsistencies may be associated with different pharmacy interventions being delivered, as well as different patient characteristics, medical conditions or medications being studied. It may also be possible that taking medications regularly as a result of LTC might result in too much medication being taken, especially if doses have been titrated due to poor disease control. Thus, hyper-adherence could occur. Once the patient becomes adherent this may result in adverse drug effects and admission into hospital.

Furthermore, it is also important to consider whether the greater hospitalisations are a result of natural disease progression. However, if this were the case, due to propensity score matching such disease progression should be occurring in both the matched intervention and control groups.

Ongoing research examining the LTC service in more depth is vital to fully understand the reasons for these apparent greater hospitalisations amongst LTC enrolled individuals.

4.8 Strengths and limitations

4.8.1 Strengths

One of the major advantages of the study design is that it enables one to undertake population-based research using large population groups, which would be unfeasible using other methodologies, such as RCTs.[222] This methodology mitigates the Hawthorne effect, whereby patients change their behaviours when they know they are being studied.[79-81,222] Therefore, this observational study design allowed for more naturalistic estimates of medication-taking behaviours.[220,222] This form of database research is termed ‘real-world research’ for this very reason.[11]

Another major advantage of the study design was that all subsidised dispensed medications from all prescribers were included.[112] Furthermore, in contrast to self-reports, dispensing data is thought to be less susceptible to deception and recall bias (patients being unable to accurately

remember information).[7,220] Due to the completeness and accuracy of the data, this method is thought to be superior to that obtained from self-report.[112] Additionally, it is a more cost-effective method of obtaining data, compared to undertaking primary data collection.[112]

Looking at the present research more specifically, a major strength of the present study is that the researcher undertook several different sensitivity analyses to support the research findings. The researcher used logistic regression, 1:1 matching with no covariates, 1:1 matching using covariates, 1:1 matching using a caliper, and finally analysis of only those who completed the intervention and did not die during the intervention period. Throughout the sensitivity analyses, minor differences in odds ratios existed; however, the conclusions were still the same and they all supported the main study findings.

4.8.2 Limitations

Despite the many assumptions underpinning secondary data analysis, this methodology has previously been shown to provide a valid estimate of adherence for large populations. Although a dispensed medication does not mean a medication has been consumed by the patient, only that it has been acquired, it has nonetheless been shown to be a valid estimate of a patients' adherence.[7,11,27,223,224] This is perhaps one of the most important limitations to consider for this research, as one cannot be certain that patients actually take their medications even if they have been picked up.[7,11,27] There is also the possibility that patients obtain medications from other sources such as from family and friends[225] or during a hospital admission.[7,224] Unfortunately accounting for medication sharing between patients and family or friends is not feasible using this study method. Acquiring medications during hospitalisation was not an issue for the present research, due to the crude adherence measure used. Furthermore, this secondary data analysis method does not take into account those medications that may have been purchased over-the-counter (e.g. aspirin, omeprazole).[226] Another limitation is the fact that using the adherence method described in the present study, patients in both the intervention and control groups had relatively high adherence at baseline. Using an alternative method to assess adherence may have produced more conservative baseline adherence.

When undertaking this analysis, one is limited to using only the information available in the data sets and unmeasured or residual confounding cannot be excluded.[27,227,228] The regression models can be biased due to incompleteness of the model, particularly as certain unmeasurable variables may also influence patient enrolment into LTC (for example, patients' poor health

literacy, lack of self-efficacy, negative beliefs about their medications or medical conditions, lack of disease acceptance, unhealthy lifestyles). This limitation is a possibility in any research using secondary databases and to be able to control for a variable, such as health literacy would be very difficult using routinely collected health data.

Furthermore, from the secondary databases we cannot ascertain if patients were receiving other New Zealand community pharmacy services such as the Community Pharmacy Anti-Coagulation Management Service (CPAMS),[21] Medicines Use Review (MUR), Medicines Therapy Assessment (MTA), Comprehensive Medicines Management (CMM)[21] on top of the LTC service, as this information is not stored in the MOH databases. Some published research has exemplified the positive contribution these extended pharmacy services can have on patients' medication knowledge and perception on their medications, as well as adherence (for MUR).[229] It is possible that receiving or not receiving these extended pharmacy services may have had some impact on the study outcomes. Furthermore, there are also additional services offered to high-needs patients in other health settings outsides of community pharmacy, for example in general practice and through organisations such as Diabetes NZ where more in-depth help, support and education are provided to these patients. It is possible that patients enrolled in LTC would also be receiving these extended services as well.

Nonetheless, the researcher is confident that she has used all the relevant variables which were available in the MOH data sets for generating the propensity scores.

4.9 Conclusion

The present study found that enrolment in the LTC service achieved one of the service's primary goals of improved patient medication adherence. However, counter-intuitively it also appeared to contribute to increased ASH rates, which is an unexpected finding. Possible reasons for this result were explored in the second phase of this PhD research through qualitative interviews with community pharmacists and observation of pharmacy sites.

CHAPTER 5. AN EXPLORATION OF COMMUNITY PHARMACISTS' PERSPECTIVES WITH RESPECT TO LONG TERM CONDITIONS SERVICE PROVISION

5.1 Chapter overview

This chapter describes a qualitative study which explored community pharmacists' perspectives on LTC service provision. The first sections detail the study background, aims and objectives. The methods then follow, and include study design, sampling, recruitment, data collection, analysis, and ethical considerations. Then, an overview of the results is provided, as well as discussion of the findings, their interpretation and the limitations.

5.2 Introduction

The preceding chapter presented the impact of the LTC service on patients' health outcomes using a retrospective, matched-cohort study. It was found that enrolment in the LTC service was associated with an expected greater medication adherence and counter-intuitively greater ambulatory sensitive hospitalisations (ASH). The goal of the LTC service is to improve patients' medication adherence,[23,182] thus it is encouraging to see improved adherence amongst LTC enrolled patients. It was also found that LTC enrolled patients have greater ASH, which was an unexpected finding. Gaining a more in-depth understanding of the reasons for these outcomes was deemed vital to draw more informed conclusions about the LTC service.

This chapter builds on the quantitative study and considers the LTC service from two different perspectives - the perspective of pharmacists providing this service, and researcher observation of pharmacies where the service is provided. Exploring pharmacists' views and experiences with the LTC service and its provision was deemed important to give context to the quantitative study. It was also deemed vital to better understand what particular activities or services are provided as part of LTC.

While work by other researchers has already examined elements of the LTC service,[25,26] the present research considers LTC from an as yet unexplored facet.

5.3 Aims

The aim of this qualitative phase was to understand how New Zealand community pharmacists provide the LTC service and to explore their views and experiences with the service and its provision.

The data was collected to provide a richer, more nuanced understanding of LTC in practice and assist in explaining some of the findings from the earlier quantitative study described in Chapter 4.

5.4 Objectives

- To understand what activities or services a sample of community pharmacists provide to LTC enrolled patients and how they differ to those provided to patients not enrolled in LTC;
- To explore pharmacists' experiences and attitudes towards the LTC service;
- To explore pharmacists' views on the factors contributing to their LTC service provision.

5.5 Methods

5.5.1 Design, sampling and recruitment

A qualitative study, which was explorative in nature was undertaken. The study involved two phases - semi-structured interviews with community pharmacists, followed by observation of some of the community pharmacies where these pharmacists provide LTC to patients.

Semi-structured interviews with community pharmacists

The semi-structured interviews were undertaken to explore pharmacists' views and experiences with the LTC service and its provision. Through the interviews the researcher tried to elicit pharmacists' views on the possible reasons for the findings from the earlier quantitative, matched-cohort study. Semi-structured interviews were chosen as the most appropriate qualitative study design as they enable the collection of in-depth responses, and allow subsequent questioning to be adapted based on earlier responses, and earlier interviews.[125,132] This flexibility allowed pharmacists to clarify any details and provide more context to their responses.[125] Other types of qualitative data collection methods such as focus groups were not

undertaken, as the researcher wanted to ensure that pharmacists could openly express their attitudes, views and experiences without being influenced by other participants' answers.[127,128]

Eligible participants were registered community pharmacists working in New Zealand community pharmacies and providing the LTC service during the study period. These pharmacists were ideal study participants, as they are information rich individuals, having detailed personal experiences with the LTC service and its provision. Although other pharmacy staff, such as pharmacy technicians and pharmacy interns, may provide aspects of the LTC service, pharmacists have overall responsibility for the provision of the service.[142] Consequently only pharmacists were included in the interviews, but all pharmacy staff were included in the observations.

To identify participants for interviews, the quantitative matched-cohort data set was used for sampling. The matched-cohort, which consisted of 102,276 patients, was used to examine the impact of LTC on patients' medication adherence and ASH. In the matched-cohort data set, there was a single encrypted pharmacy claimant number associated with each patient. This encrypted claimant number is unique for each community pharmacy in New Zealand.[165] For this research it was used for identifying which pharmacy a patient had most of their medications dispensed from and this pharmacy was then taken to be the pharmacy they received LTC from. As part of LTC patients can only be enrolled into a single pharmacy and thus should receive most of their dispensed medication from there.[182] Consequently each patient was assigned a single claimant number, representing that pharmacy where they receive most of their prescription dispensings and where they receive the LTC service. This claimant number was used to assist with sampling for the interviews.

A sampling framework was developed to identifying community pharmacies for the qualitative study. The sampling framework, which is presented in Table 26, had the following dichotomised variables: geographical location (urban or rural); percentage of patients in the pharmacy who are adherent (high or low), and percentage of patients in the pharmacy who are enrolled in LTC (high or low). This produced a total of eight sampling categories in the sampling framework. The sampling framework presents the number of pharmacies within each category, and the values in brackets outline the number of pharmacies that were extracted from each category (to undertake stratified random sampling).

Table 26. Sampling framework for the qualitative study using the matched-cohort data set

Sampling framework			
Rural	Number of pharmacies	**Urban**	Number of pharmacies
(Group 1) Low % adherent Low % enrolled	0	(Group 2) Low % adherent Low % enrolled	9 (all)
(Group 3) High % adherent Low % enrolled	14 (all)	(Group 4) High % adherent Low % enrolled	560 (a random sample of 30 pharmacies)
(Group 5) Low % adherent High % enrolled	0	(Group 6) Low % adherent High % enrolled	0
(Group 7) High % adherent High % enrolled	26 (all)	(Group 8) High % adherent High % enrolled	401 (a random sample of 30 pharmacies)

There were three categories that had no pharmacies meeting the criteria: Group 1 (rural, low percentage of patients who are adherent and low percentage of patients enrolled in LTC); Group 5 (rural, low percentage adherent and high percentage of patients enrolled in LTC); and Group 6 (urban, low percentage adherent and high percentage of patients enrolled in LTC). For the remaining five categories, the encrypted claimant numbers from these pharmacies were aggregated into a single list.

This list with encrypted claimant numbers, was then sent to the Ministry of Health (MOH) data analytics team. The analytics team returned unencrypted details for the selected pharmacies to the researcher. The unencrypted details provided were: pharmacy name, contact phone number, and address. The analytics team returned the unencrypted data as a random list, so the researcher was unable to determine which encrypted claimant number belonged to which pharmacy. However, from this list the researcher was able to determine which category each pharmacy belonged to.

Using this list, the researcher then sequentially contacted the pharmacies one-by-one by telephone. The researcher ensured that she was contacting pharmacies within each of the five categories, to ensure a variety of pharmacies were being contacted. During the telephone call the researcher spoke to the pharmacist on duty and informed them of the study details. If the pharmacist was interested in participating, they were asked for their email address and they were emailed five documents: 1) the Participant Information Sheet (PIS) for the pharmacy manager or owner; 2) the PIS for the pharmacist (who will take part in the interview); 3) the

Consent Form (CF) for the pharmacy manager or owner; 4) the CF for the pharmacist; and 5) the brief pharmacy questionnaire (Appendices 8 to 12). If the pharmacist on the telephone was also the pharmacy manager or owner, they were asked to complete all the documents themselves. While those pharmacists who were employees were asked to get their pharmacy manager or owner to read the PIS and consent to participation, by completing the CF. If during the initial telephone call the pharmacist was not interested in participating, they were not contacted again.

During the recruitment telephone call, the researcher also informed the pharmacist of the subsequent phase of the qualitative study, the observation and asked if they would like to be involved. On the CF the pharmacist was asked to indicate their interest by answering yes or no to the observation question. Those pharmacists who returned the signed CFs to the researcher were included in the semi-structured interviews. Once a signed CF was received, the researcher contacted the pharmacist via email or telephone to organise an appropriate time for the telephone interview to occur. Pharmacists were asked to complete the brief questionnaire and return it before the interview date. The questionnaire (Appendix 12), contained the following questions: the number of patients enrolled in the LTC service in the pharmacy; the District Health Board (DHB) that the pharmacy belongs to; the services or activities provided as part of LTC; the pharmacy staff that provide the LTC service; the roles of the pharmacy staff providing the service; and pharmacy characteristics (location, ownership, average daily prescription count, and the number of staff working during an average day).

As LTC is a nationwide service, it was deemed vital to recruit pharmacists all over New Zealand. Stratified random sampling of pharmacies and the use of telephone interviews enabled the researcher to capture the views of pharmacists working across New Zealand; in both urban and rural settings; large and small pharmacies; independent and franchise pharmacies. A total of 18 community pharmacists who provide the LTC service were interviewed until data saturation was deemed to have occurred. Each of the pharmacists worked in a different community pharmacy. To achieve 18 interviews, 53 pharmacies were contacted with 35 pharmacists declining to participate. The most frequent reason for declining participation was due to being too busy and not having enough time to take part in the research. Rarely pharmacists responded that they were not interested in the study topic.

Observation of community pharmacy sites

From the 18 pharmacists who took part in the interviews, a total of six agreed to take part in the observation phase. By recruiting from the interview participants, this ensured that the observations would help add depth and further explain the interview findings. The pharmacy manager or owner, as well as the pharmacist interviewed (if they were not the same person), were both required to complete the CFs before the pharmacy observation could occur. Contact was made with the pharmacy manager or owner to identify a suitable day for the observation.

5.5.2 Data collection

Semi-structured interviews with community pharmacists

The semi-structured interviews were conducted via telephone by the researcher between November 2018 and February 2019. The interviews were undertaken at the University of Auckland in a quiet, private office space to ensure participants' confidentiality was maintained.

Before commencing each interview, the researcher explained her role, the purpose of the interview and clarified any questions the participant had. Participants were informed that they could withdraw from the study at any point, without needing to provide any explanation to the researcher, up to one week after interview completion. They were also informed that they did not need to answer all of the interview questions and at the end of the interview they would be given an opportunity to change or clarify anything they had said. Each participant received a $20 (NZD) supermarket voucher for taking part in the research.

The interviews were audio recorded and each participant was informed of this before commencing the interview. Each participant was informed that the study findings would be reported in a PhD thesis and could be published in journal articles and presented at conferences. The reporting of any study findings would be done in a manner that prevents the participants, their colleagues, their pharmacies and their patients from being identified.

To guide the interviews, the researcher followed an interview schedule (Appendix 13). During the interview the researcher added and adapted subsequent questions according to participant responses. The researcher used responses from the brief pharmacy questionnaire to begin the interview and made notes throughout the interview.

Interviews were undertaken until data saturation[127,143,144,146,147,150] was deemed to have occurred – that is, when the last four interviews did not produce any new ideas. In the present study this

was deemed to have occurred after 18 interviews. The average duration of the interviews was 51 minutes (ranging from: 37 to 77 minutes).

Observation of community pharmacy sites

The researcher undertook all the observations and organised her own transport to each site. She spent an entire business day observing pharmacy staff behaviour, listening to conversations and gaining an in-depth understanding of how LTC was delivered in each pharmacy.

Upon arrival at the pharmacy sites the researcher introduced herself to all the pharmacy staff, explaining her role and the purpose of her visit. She used this opportunity to try build rapport, put staff members at ease and try to reduce (as much as possible) the Hawthorne effect.[79-81,222] She also brought morning tea for all pharmacy staff as a sign of appreciation for their contribution to this research.

A large poster was printed and pasted in several places in each pharmacy site during the observation period, to inform patients that observation was under way. The poster explained that if patients did not want their conversation to be observed to inform the pharmacist on duty.

An observation schedule was developed and adapted from one presented by Mack et al[137] and from using expert opinion. This observation schedule was used to record what was seen and heard by the researcher. The observation schedule (Appendix 14) was used only as a guide and additional field notes were made throughout the observation. The observation schedule underwent a process of piloting with two community pharmacists before the final version was finalised. The observation schedule was discussed with these community pharmacists, who were not involved in the research to identify any issues with the schedule.

Upon completion of each observation the researcher wrote a detailed reflection of the day's observations, along with preliminary ideas and findings.

5.5.3 Data analysis

Semi-structured interviews with community pharmacists

In-depth analysis of the interviews occurred once all the interviews had been completed. The following procedures were followed.

To start, the researcher transcribed the first two interviews. The remaining interviews were transcribed by a professional transcriber. Once transcription was completed, the researcher read each transcript and listened to the voice recording to check for any discrepancies between the transcripts and recordings.

An ID number was assigned to each interview and its transcript. The ID numbers were used instead of participants' names to maintain confidentiality. This was also done when saving the interview recordings and transcripts on the computer, whereby the ID numbers, rather than participants' names were used. All computer files were password protected for added security.

The interview transcripts were imported into NVivo® version 12. The researcher used the general inductive approach to analyse the interviews,[149-151] and this involved reading the interview transcripts and the field notes several times and moving backwards and forwards between the data and the study objectives. The researcher began identifying preliminary codes from the data. This coding process was undertaken by the researcher independently. During this beginning stage, another member of the research team (TA) also coded two randomly selected transcripts independently from the researcher. TA completed the coding in Microsoft Word using the comments boxes in the review function. This was done at the beginning of the coding phase as part of the verification process and to help ensure consistencies with coding,[230] and to minimise the risk of lone researcher bias.[148,157] Once both the researcher and TA had completed the coding of the same two interviews, the two researchers met and discussed their respective codes over several meetings. During these meetings similarities and differences between the coding were identified and resolved. The third member of the research team (JA) was present during these discussions and helped reach a consensus with the coding. Once consensus was reached, the researcher went on to complete coding of all the interviews. The codes were ongoingly reviewed and reworked. During the coding process, the researcher developed her own codebook, listing all the codes, their definitions, and examples. As the researcher continued to code the interviews this codebook was frequently modified. These codes were then written onto post-it notes and collapsed together to identify common categories. From these categories emergent themes and sub-themes were identified. These themes and sub-themes were visually presented to the other research members (TA and JH) and they provided insight into appropriateness of the theme development from the codes and categories. A concept map was drawn to help conceptualise and understand how the themes and sub-themes related to one another.

Observation of community pharmacy sites

At the end of each observation, the researcher wrote up a detailed summary of all the field notes and details from the observation schedule for each pharmacy. The researcher imported this summary into NVivo® version 12 and used the themes and sub-themes identified from the interviews to thematically analyse the observations. This was done to find similarities and differences in views and experiences expressed during the interviews alongside the behaviour observed during the observations.

5.5.4 Ethics approval

Ethics approval was sought from and granted by the University of Auckland Human Participants Ethics Committee for undertaking the semi-structured interviews and pharmacy observations (reference number: 018178 (Appendix 7)).

5.6 Results

5.6.1 Characteristics of the community pharmacists and their pharmacies

A total of 18 community pharmacists working in 18 different community pharmacies across New Zealand were interviewed in the study. Of these participants, there was a nearly equal split in terms of gender (males, n=10, 55.6%). The majority of participants were the manager or owner of the pharmacy (n=13, 72.2%) and the remaining participants were employed pharmacists. All of the male participants were pharmacy managers or owners.

The community pharmacies were located in a range of DHBs across New Zealand. Just over half of the pharmacies were located adjacent to, or near to, a medical centre (n=10, 55.6%). In terms of pharmacy ownership, more than half were independently owned (n=10, 55.6%) and the remaining pharmacies were owned by a group or franchise.

The number of LTC enrolled patients varied greatly across the pharmacies, from 26 patients to 419 patients (mean = 216 patients). In terms of the volume of prescriptions dispensed, the greatest proportion of pharmacies dispensed on average more than 300 prescription medications per day (n=8, 44.4%), with fewer dispensing 200-300 prescriptions daily (n=4, 22.2%) or 100-200 prescriptions (n=5, 27.8%).

Other characteristics of the community pharmacies recruited for the interviews are presented in Table 27. From these pharmacies, six sites were willing and were recruited for observation. The characteristics of the community pharmacy sites (n=6) recruited for observation are presented in Table 28.

Table 27. Characteristics of the community pharmacy sites where the interviewed pharmacists work

Site	Region	Location*	Ownership*	No. of enrolled LTC patients*	No. of scripts dispensed daily*	LTC activities/ services provided*	Staff that provide LTC*	Staff working on average day*
1	Canterbury	Adjacent/near to medical centre	Group/ franchise	205	>300	BPk, C+E, Dis, Rem, YC	CP, Tech, Shop	CP (x3), Tech (x2), Shop M, Shop (x2), Shop (x2 p/t)
2	Auckland (East)	Adjacent/near to medical centre	Independent	150	200-300	BPk, C+E, Rem, Syn	CP, Tech	CP, Tech, Shop, Trainee Tech
3	Northland	Other: Mainstreet	Independent	340	>300	BPk, Del, Rem, Syn	CP, Tech, Trainee Tech	CP (x2), Trainee Tech (x2), Shop (x4), Shop M
4	Wellington	Adjacent/near to medical centre	Group/ franchise	177	>300	BPk; MR, Rem	CP	CP (x3), Shop (x3)
5	Auckland (West)	Adjacent/near to medical centre	Group/ franchise	298	No response provided	BPk, Del, Dis, MR, Rem, Syn, YC	CP, Intern,	CP, CP (x4 p/t), Intern, Tech
6	Gisborne	Adjacent/near to medical centre	Independent	300	>300	BPk, C+E, Del, MR, Syn	CP, Intern	CP (x4), Tech (x5), Shop (x2), p/t (x3)
7	Taranaki	Other: Mainstreet	Independent	177	>300	BPk, C+E, Rem, Syn	CP, Tech	CP, CP (p/t x2), Tech, Tech (p/t x2), Shop (x4)
8	Auckland (East)	Other: Mainstreet	Group/ franchise	310	200-300	BPk, Rem	CP, Intern	No response provided
9	Otago	Other: Rural township	Independent	70	100-200	BPk, Rem, Syn, YC	CP, Tech	CP, Tech, Shop (p/t)
10	South Canterbury	Adjacent/near to medical centre	Independent	259	>300	BPk, C+E, Rem, Syn, YC	CP, Tech	CP (x3), Tech (x5), Shop (x2)
11	Tasman	Adjacent/near to medical centre	Independent	200	100-200	BPk; C+E, Dis, Syn, YC	CP, Tech	CP, Tech (x2)
12	Canterbury	In a shopping mall	Independent	238	>300	BPk, Del, Rem	CP	CP (x3), Tech (x3), Shop (x5), Shop M
13	Northland	Adjacent/near to medical centre	Group/ franchise	168	100-200	BPk, Del, MR, Rem, Syn	CP, Tech	CP, Tech, Shop (x2 or x3)
14	Auckland (North)	Adjacent/near to medical centre	Group/ franchise	26	200-300	BPk, Dis, Rem, Syn	CP, Tech	CP, Tech (x3), Trainee Tech
15	Waikato	Other: Mainstreet	Independent	419	100-200	BPk, C+E, New Rx, Rem, Syn,	CP	CP, Tech, Shop
16	Southland	Adjacent/near to medical centre	Independent	108	100-200	BPk, Del, Rem, Trans	CP, Intern, Tech	CP, Intern, Tech
17	Auckland (South)	Other: Mainstreet	Group/ franchise	260	>300	BPk, C+E, Del, New Rx, MR, Rem, Syn	CP, Tech	CP (x3), Tech (x3), Shop (x5)
18	Tasman	Other: Mainstreet	Group/ franchise	182	200-300	BPk, MR, Rem, Syn	CP, Tech	CP, CP (p/t), Tech (x2), Shop (x2), Shop (p/t)

* Information from pharmacy questionnaire; ^ Information from StatsNZ (based on pharmacy location)

Abbreviations: BPk – Blister pack; Rem – Reminders; C+E – Counselling and education; Syn – Medication synchronization; New Rx – Organizing new prescriptions; CP – Community pharmacists; Tech – Pharmacy technician; Shop – Shop or pharmacy assistant; YC – Yellow card or medication card; p/t – Part-time; Intern – Intern pharmacist;; Dis – Dispose of unused medications; MR – Medication reconciliation; Del – Medication deliveries; Shop M – Shop manager; Trans – Translation

Table 28. Characteristics of the observed pharmacy sites

Site	Region	Location*	Ownership*	Group (A-E)^	Rural / Urban^	No. of enrolled LTC patients*	No. of scripts dispensed daily*
1	Tasman	Adjacent/near to medical centre	Independent	E	Rural	200	100-200
2	Auckland (East)	Adjacent/near to medical centre	Independent	A	Urban	150	200-300
3	Wellington	Adjacent/near to medical centre	Group/ franchise	C	Urban	177	>300
4	Auckland (East)	Other: Mainstreet	Group/ franchise	B	Urban	310	200-300
5	Otago	Other: Rural township	Independent	E	Rural	70	100-200
6	Waikato	Other: Mainstreet	Independent	B	Urban	419	100-200

* Information from pharmacy questionnaire; ^ Information from StatsNZ (based on pharmacy location)

The findings generated from the analysis of the interviews and observations fell within four overarching themes: pharmacists' perceptions of the benefits of LTC; tensions in the community pharmacy environment; LTC disrupting community pharmacies' 'business-as-usual'; and perceived lack of value of community pharmacy and LTC, and subsequent lack of buy-in to the service. How these themes and their sub-themes fit within the study aims and objectives are presented in Figure 6.

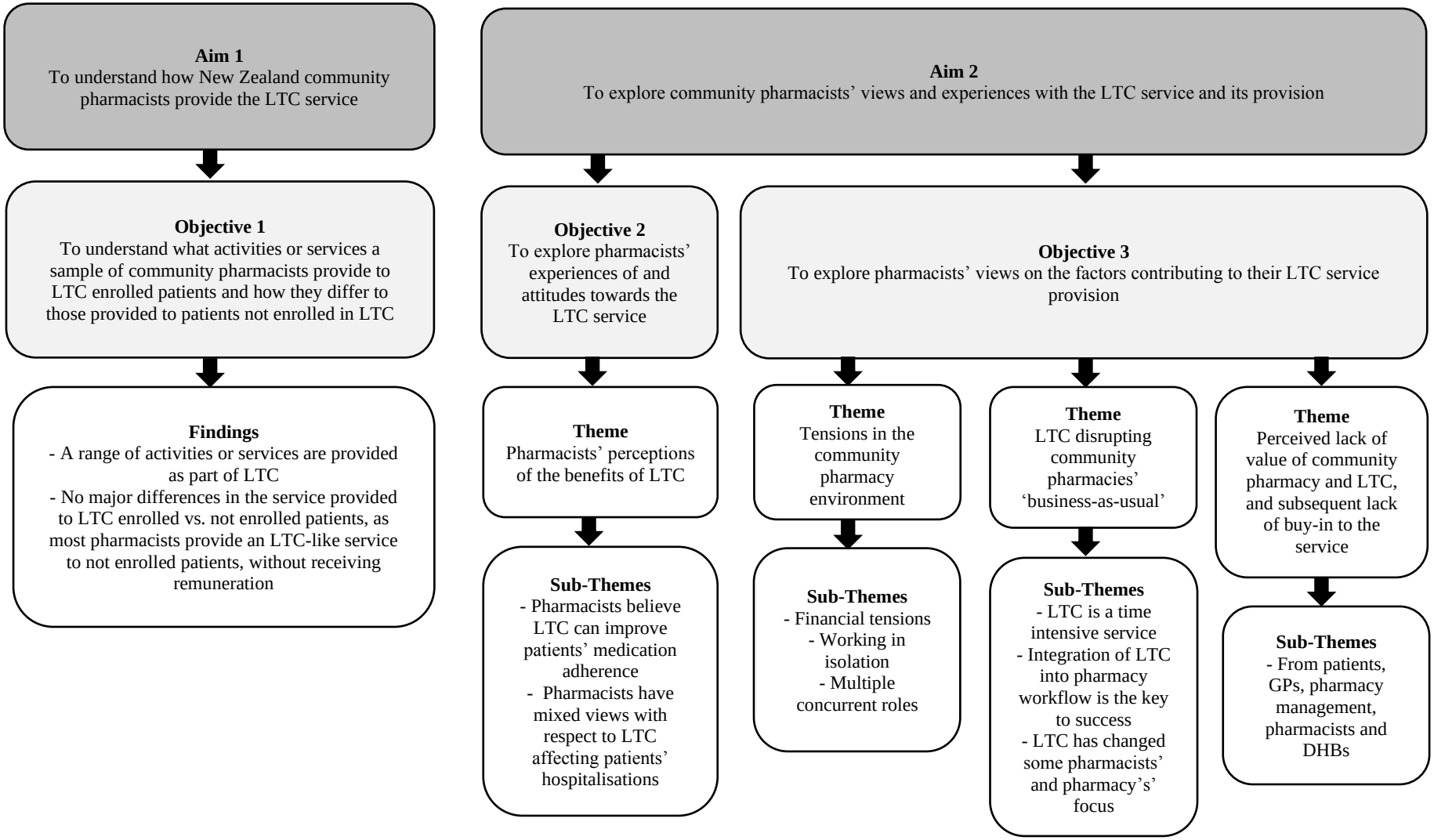


Figure 6. Flow chart of the qualitative study aims and objectives, and the emergent themes

5.6.2 Pharmacy activities or services provided to patients as part of LTC

The community pharmacists interviewed all provide a variety of activities as part of the LTC service. The particular activities reported during the interviews as being provided were: preparation of medication adherence aids, most often blister packing; undertaking medication reconciliation and medication synchronisation; sending text and/or phone reminders to patients to pick up their repeat medications; providing education, counselling and medicines information to patients; providing written information and yellow cards (which list all of the patient's medications, their indications and doses); and delivering medications to patients' homes. The delivery of these activities in the community pharmacies was seen first-hand during the observation phase.

Many pharmacist participants believed that it is a combination of the LTC activities together that has the most benefit for a patient's health; not just one activity in isolation. A few participants explained that different activities are more worthwhile for different patients, so some suggested it is important that pharmacists know their patients; what they want or need help with, their preferences and expectations, and why they are struggling to take their medications. Participants reported several reasons why their patients struggle to take their medications, for example: forgetfulness; confusion; not understanding medication labels; misunderstanding GPs' instructions; poor English; poor health literacy; and difficulty opening medication packets. Once the reasons are determined, then pharmacists can tailor LTC accordingly. Some pharmacists mentioned that building a clear picture of patients' reasons for non-adherence is an important first step in tailoring the LTC service.

> *We sit with them [patients] at the start and we go through their meds and we just tell them what these medications are for, [we ask] "How are you taking them?" and we ask them all sorts of questions… Just to build that picture, to see what services we can provide. And once we come up with an overall picture, then we can decide what the plan is. (P16, male, owner/manager)*

The difference between services provided to LTC enrolled patients and not enrolled patients

Many pharmacist participants believed that there is no major difference in terms of the pharmacy services provided to LTC enrolled patients, versus those patients not enrolled in the service. Some participants explained that they frequently identify patients who need extra pharmacist help and would benefit from LTC, but do not qualify for the service. These patients are then provided with an LTC-like service without the pharmacy receiving the monthly LTC

payment. Some pharmacists said they do not withhold a service for patients just because they do not get paid for it. They believe it is their ethical and professional obligation to provide a high-standard service to everyone regardless of whether they are in LTC or not and regardless of whether they are paid for those services or not.

> *Even though we have LTC patients, we actually provide the same service to everybody. It's hard but it's almost like if someone's in need of a blister pack or their family believes that they need blister packing, then why withhold a level of service just because I don't get $20 from that person a month?…I think that's probably something a lot of pharmacists struggle with. (P15, female, owner/manager)*

Certain pharmacists did however, highlight differences in the activities or services provided to LTC enrolled and not enrolled patients, specifically: less documentation and paperwork, as the pharmacists do not complete the LTC management plans and annual reviews for not enrolled patients, less frequent contact and less checking-in with patients who are not enrolled. Some pharmacists explained that LTC enrolled patients receive closer monitoring; whereby pharmacists frequently check-in with patients about their medications and their medical conditions and address any issues they may have. A few pharmacists admitted that it can be harder to keep track of not enrolled patients as often they visit the pharmacy less frequently and use more than one pharmacy, therefore the pharmacist cannot monitor their adherence and medication management as closely.

The LTC activities or services described during the interviews were consistent with those seen during the observations. During the observation the researcher could not see any obvious differences in the services provided to LTC versus not enrolled patients, as all patients appeared to receive a high-standard of service and the service they received appeared to be based on the patients' needs, rather whether the patient was enrolled in LTC or not. Such a view was also stated by one pharmacist during the observation saying that the level of service that she provides is dependent upon her patients' needs not whether they are in LTC, and therefore whether she receives remuneration for providing the service. This was also reported during the interviews. A couple of the observation sites were not able to enrol any new patients into LTC as their region's quota for LTC patients had been exceeded. The pharmacists referred to this as LTC capping and they highlighted that despite being unable to enrol new patients into LTC, they still provide an LTC-like service to them.

5.6.3 Pharmacists' perceptions on the benefits of the LTC service

Most pharmacists believed LTC is beneficial for enrolled patients, with improved medication adherence being one of the service benefits. In terms of whether LTC can influence hospitalisations, pharmacist responses were mixed, with some believing that LTC can reduce hospitalisations while others did not think LTC can do so.

Some however, acknowledged that it is difficult to isolate the specific benefits of LTC as patients also often receive other health services from other health professionals, and sometimes receive other extended pharmacy services (e.g. Medicines Use Review (MUR) or Medicines Therapy Assessment (MTA)).

5.6.3.1 Pharmacists believe LTC can improve patients' medication adherence

In terms of LTC improving adherence, the majority of pharmacists believed that LTC improves patients' medication adherence. Therefore, many were unsurprised by the research finding of greater adherence amongst LTC enrolled patients. When probed about how they know that patients are improving their adherence, responses included their LTC patients pick their medications up on time, they run out of supply at the appropriate times, and their medication repeats expire less often. Certain pharmacists also have patients coming back into the pharmacy and verbally updating them on how much medication they have left at home. Some participants highlighted that dispensing medications on a monthly basis ('non-stat') makes it easier to monitor patients' adherence, compared to dispensing three months at a time ('stat'), which often occurred prior to LTC introduction.

A few pharmacists however sounded a warning that it is not that easy to tell if LTC has improved adherence, as even though patients pick up their medications and verbally tell them that they take their medications, this does not necessarily mean that they are actually consuming them.

Most pharmacists believe a combination of LTC activities together can improve adherence more effectively rather than solely one activity or service. Others believe that certain activities play a bigger role than others in terms of improving adherence. Certain participants explained blister packing for example, is particularly helpful for improving adherence, as it makes

medication taking much simpler and easier for patients to follow. Yellow cards were also suggested by some participants as being worthwhile for improving patients' medication adherence as they increase patients' understanding of what medications they take; highlighting any dose changes or new medications started, or those that have been stopped. Yellow cards usually contain a list of patients' medications, their indication, dose and possible side effects.[182] While pharmacists acknowledged that yellow cards improve patients' understanding of what their medications are for, several participants believed that the verbal education and counselling provided by the pharmacist is pivotal for improving adherence amongst patients. Those participant pharmacists believe that education and counselling help patients to understand the importance of their medications and helps to identify any medication issues or myths that may be preventing patients from taking their medications appropriately. During the interviews some pharmacists highlighted that patients becoming more educated about their medications improves their health literacy, which in turn they believe can help to improve medication adherence. A few participants suggested that greater education can also help improve patient self-efficacy, allowing patients to become empowered and motivated to take charge of their own health.

Some pharmacists believed that the education and counselling provided as part of LTC makes patients feel important and that their pharmacist cares about them, their health and this ultimately encourages patients to be adherent. Some participants suggested that when patients realise that their pharmacist will check-in on them to see how they are managing their medications this encourages patients to be adherent. One participant wondered whether the greater adherence amongst LTC patients was the result of pharmacists "pampering and conditioning" them.

While most participants had positive views with respect to LTC improving medication adherence, some participants suggested that there may be negative health implications for patients who suddenly become adherent, such as precipitating adverse effects.

> *If they [patients] are non-compliant to one blood pressure medication, they go back to the doctor and the doctor says "Oh your blood pressure is still too high" and puts them on another medication without bothering to ask "Are you taking your medication?". And then they have some postural hypotension and take a fall - if they suddenly start becoming adherent to both*

medications. By having that extra service [LTC] where we're able to ask those questions, we can sort of intervene before it gets to that point in quite a few cases. (P12, female, pharmacist)

5.6.3.2 Pharmacists have mixed views with respect to LTC affecting patients' hospitalisations

When pharmacist participants were asked about the impact of LTC on hospitalisations, very few pharmacists believed that LTC can reduce hospitalisations. Others believed otherwise - that LTC is unable to affect patients' hospitalisations. When presented with the study finding of greater hospitalisations amongst the LTC enrolled patients, some participants suggested this may be the result of closer monitoring of patients by their pharmacist. A few suggested that perhaps pharmacists are picking up health or medication issues more quickly and referring patients in a timelier manner for medical attention, because the LTC enrolled individuals are more closely monitored and more frequently checked-in on than not enrolled individuals.

We're picking up on things faster or we're letting them [patients] know, this is quite serious. Because the communication opens up drastically… these customers are coming in much more often, and they're elderly... and we might be doing a blood pressure and it is really high… We're probably getting people to the doctors or to the hospital more often. (P3, male, owner/manager)

Another reason for the greater hospitalisations amongst LTC patients, suggested by some participants, was increased patient knowledge. Some participants explained that for LTC patients, pharmacists often explain what signs, symptoms or medication adverse effects to look out for and what to do if they occur. Through this education and counselling patients gain important knowledge about their health and medications and begin to understand when to seek help, thereby making them to some extent more self-efficacious. A few pharmacist participants even suggested that those who agree to be enrolled in LTC in the first place may in actual fact be more likely to seek help and more willing to be helped compared to those individuals who decline enrolment in LTC.

Possibly the LTC enrolled ones are the ones more likely to sort of seek help or be willing to be helped by the system. Whereas the people that decline the service potentially are the ones that are not happy about having to take medication in the first place, not happy that they're sick, they don't want anything to do with it… it could also be that people that are agreeable to join LTC are more likely to access help services and be more comfortable taking medications. (P12,

female, pharmacist)

During the interviews, some pharmacists conceptualised patient health knowledge as health literacy and suggested that health literacy may have an impact on patients' hospitalisations. Some postulated that differences in health literacy between LTC enrolled and not enrolled individuals may have contributed to differences in their hospitalisations. One participant suggested a link between poorer health literacy and more unhealthy lifestyles. He suggested that unhealthy lifestyles may impact on patients' hospitalisations to some extent.

Certain participants suggested that hospitalisations may be occurring for reasons which may not be affected by their medications and their adherence. Some pharmacist participants believe some hospitalisations occur regardless of whether patients are adherent to their medications and thus cannot be prevented. They acknowledged that sometimes absolute adherence will not prevent all adverse health care events from occurring.

> *I've seen patients that are totally compliant and totally adherent and they ask me the question: "I have been taking my medications at all the right times and right doses, why then did I get a heart attack? Do you have an answer for that?" ... In certain cases where the hospitalisation is happening more due to non-adherence or non-compliance and their medical conditions are not controlled as they're not taking their medications at the right time or the right way - in those case it [good adherence] can reduce the hospitalisations. (P13, male, owner/manager)*

As described in this section, a range of possible reasons were presented by pharmacist participants in terms of the rationale for the greater hospitalisations amongst LTC patients. Consequently it is unsurprising that during the interviews several pharmacists believed that in order to explain this finding, more details about the hospitalisations are required; specifically to determine whether the greater hospitalisations are: due to LTC patients' getting diagnosed with new medical conditions; existing medical conditions being poorly controlled; due to population aging and natural disease progression; due to polypharmacy; due to non-adherence or too high adherence. These points are further discussed in the final discussion chapter of this thesis.

During the observations, certain staff spoke of the benefits of LTC. For the most part, staff had similar views as those expressed by pharmacists during the interviews in terms of improved

adherence and mixed views on hospitalisations. At one pharmacy observation site however, the entire pharmacy team had relatively negative views about LTC and during their communication with the researcher/observer, they explained that LTC has had no added benefit to patients compared to the standard service they provide to not enrolled patients. While observing this pharmacy, the researcher also could not see any obvious difference in service provided to enrolled versus not enrolled patients. For the most part the pharmacists were seen dispensing medications, with minimal patient interaction, education or counselling - which at other pharmacy sites are the crux of LTC. At this particular site, the pharmacy owner admitted that to this day he still does not fully understand LTC and what is expected of him and his staff.

5.6.4 Factors contributing to pharmacists' LTC service provision

Pharmacists reported several factors that contribute to or influence their LTC service provision. These have been categorised into three themes: tensions in the community pharmacy environment, LTC disrupting community pharmacies' 'business-as-usual', perceived lack of value of community pharmacy and LTC, and subsequent lack of buy-in to the service.

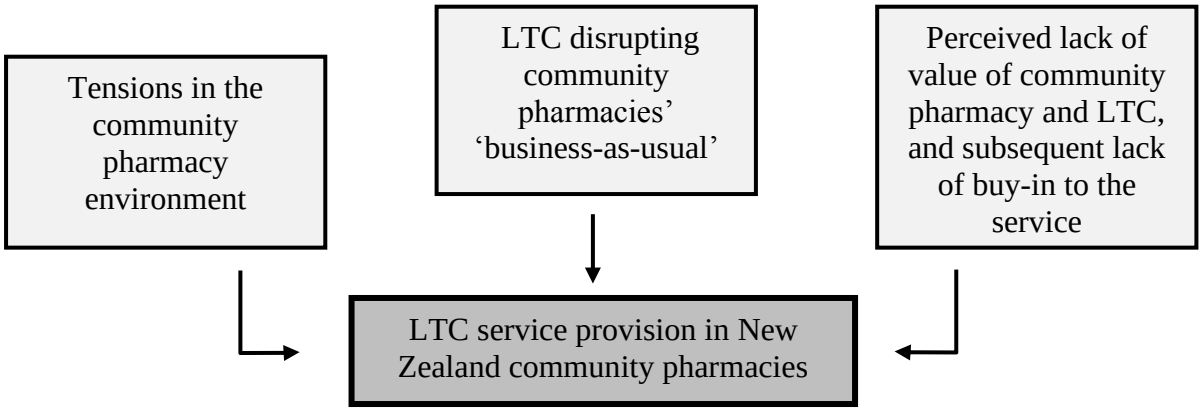


Figure 7. Pharmacists' views on the factors contributing to their LTC service provision

5.6.4.1 Tensions in the community pharmacy environment

During the interviews, pharmacists described a range of tensions in the community pharmacy environment that influence how they deliver the LTC service to patients. Some of these tensions were also observed during observation of pharmacy sites.

5.6.4.1.1 Financial tensions

Financial tensions relating to LTC service provision were frequently described by pharmacists. Many reported that the current LTC remuneration is too low considering the work associated

with delivering the service. Some participants highlighted that considerable pharmacist time is needed to undertake the various LTC activities. The actual time depends on the patient needs and sometimes involves an in-depth medication review, for which pharmacists are not paid for as part of LTC. Some participants suggested to facilitate the delivery of LTC there is a need to free up pharmacist time and to employ additional pharmacy staff, however, the LTC remuneration is too low to justify this.

> *Pharmacists are what, like, $30 to $40 an hour? And if you spend two hours with a patient going through their medications, that's like $40 you're paying for the patient, plus your time, plus all the resources. And you're only getting paid $20 a month for that [as part of LTC]. And it's not even just that, afterwards you come back to the pharmacy, you fill out forms, you go through their medications and you blister pack them for them. That's a lot of time and I don't think you're being paid enough for the services that you do. (P2, female, owner/manager)*

Furthermore, some pharmacists highlighted there is a perverse financial disincentive to deliver a high-standard LTC service. When patients meet the LTC goal of good adherence, pharmacist participants say these patients must then be unenrolled from the service, as they no longer meet the LTC eligibility criteria. By helping patients achieve the goal of improved adherence, pharmacies are essentially financially disadvantaged as they unenroll these patients and lose the monthly LTC remuneration for them. Some pharmacists questioned whether it is appropriate for pharmacists to be financially disadvantaged for helping their patients meet the goal of LTC of improved adherence. Ultimately some participants feel there is no incentive for them to deliver a good service for their patients, other than a moral and ethical obligation and personal satisfaction that only they feel.

> *Do we get rewarded [for helping patients to become adherent]? It's like that old adage, if you pee your pants in a dark suit, it's a nice warm feeling, but no one else notices (laughter). So no, not really, we get rewarded by having less income… What is the incentive, other than the moral, ethical obligation to our patients? Yeah, you're right, not a lot. (P9, male, owner/manager)*

One participant suggested introducing incentives for pharmacists to deliver a high-standard LTC service would help. For example, he proposed providing pharmacists with continuing professional development (CPD) points for delivering the LTC service and for patients reaching their health goals.

During the observations, seeing financial tensions first-hand was challenging. During the observations staff themselves expressed two issues that have contributed to financial tensions for their pharmacies specifically, the introduction of LTC capping, and the emergence of nearby discount pharmacies.

At two pharmacy observation sites, staff explained to the researcher that the introduction of capping caused financial tension for their pharmacies. The capping they explained meant they could not enrol any new patients into LTC and actually had to unenroll some existing LTC patients from the service. As a result, these pharmacies stopped receiving LTC payments for these patients. However, the pharmacists still continued to provide the same level of service as when the patients were in the LTC service, as they believed it was unethical to change the quality of their patients' service based on the remuneration the pharmacy receives.

During observation at another site, the pharmacy received an advertising pamphlet from a nearby discount pharmacy advertising free prescription dispensings. This led to the revelation by the pharmacist that several patients are refusing to visit her pharmacy lately as they do not provide free prescriptions. She thought by providing high-standard pharmacy services including LTC, she would be able to keep patients satisfied and thus keep them coming back to her pharmacy. However, the pharmacist revealed that it appears for many patients cost is the overriding driver of behaviour and if patients can get free prescriptions, they would rather drive out of their way to get a free prescription compared to paying $5 per medication at their local pharmacy. This develops further on the issue of pharmacy financial tensions and raises the question of how this can be mitigated? The issue here, as described the pharmacist, is that many pharmacies simply do not have the financial backing to absorb the cost of free prescriptions. This has led to them losing both LTC enrolled and not enrolled patients.

5.6.4.1.2 Working in isolation

Certain pharmacists explained that working and delivering LTC in isolation is a major source of tension and stress for them. Several pharmacists highlighted that they work in isolation in their own pharmacy, as it is often the pharmacist who oversees the delivery of LTC and ensures that all the necessary LTC documentation is completed. Doing this alone was described by some participants as increasing their workload and causing greater work stress.

> *In our pharmacy it's only the pharmacist who takes responsibility for LTC, even though it should be everyone's responsibility, it feels as though it's only falling onto the pharmacist. (P14, female, pharmacist)*

Furthermore, this isolation spans other areas too. For example, certain pharmacists explained that they do not share information and actually do not know what other pharmacies do as part of LTC, particularly how they deliver the activities or services, and the procedures they have put in place for managing LTC. Sharing ideas between pharmacies on a mutually accessible platform would be beneficial according to some participants to gain tips and tricks on their own LTC delivery. Interestingly enough during the observation some pharmacies were seen working together with their neighbouring pharmacies, even if they are not owned by the same individuals and are not part of the same franchise. During observation at one particular pharmacy, the pharmacist on several occasions telephoned the nearby pharmacy to ask to borrow medication stock for patients, both LTC enrolled patients and those not enrolled. During their communications it became apparent that they have a good relationship; however, it was not clear if this relationship spans other aspects of pharmacy, for example the sharing of LTC ideas between pharmacies.

Some participants also described feeling isolated from GPs, as GPs often do not know about LTC and do not refer patients to the service. Most interviewed pharmacists did not have access to GPs' clinical records, and thus provide LTC without fully understanding the goal of patients' therapy or what the patient is using their medications for. However, a few pharmacists believed that having access to GP clinical records is not necessary for delivering an adherence service like LTC, but that access is important for more comprehensive services like MUR and MTA. Certain participants did however highlight having access to these clinical records would save pharmacists substantial time when delivering LTC and would encourage collaboration between GPs and pharmacists. None of the pharmacies during the observation were seen to have access to clinical records. At one pharmacy, during the observation, the pharmacist made countless calls to the GP and hospital to clarify a medication prescribing error for an LTC patient, to be told that the GP is on holiday and to call back the following day. One may postulate that having access to patients' clinical records may have helped address this issue in a timelier fashion.

Developing on from that, some participants believed that working in isolation from GPs is made worse by the fact that participants believe it is hard to communicate with GPs. From the interviews it is unclear which comes first the isolation or the difficulty in communication – as it is all linked together. Certain medication issues are not serious enough to interrupt a GP's appointment, but are still worthwhile to inform the GP of. Having an easier method to communicate confidential messages to GPs was suggested by one participant as a way to encourage and develop the communication and collaboration between GPs and pharmacists.

Furthermore, some pharmacists reported tensions arising from working in isolation from the District Health Boards (DHBs) and not fully understanding the DHB's expectations of them in terms of LTC service delivery. One of these pharmacists during the observation, addressed the same issue to the researcher/observer, saying he does not understand the LTC service, particularly what the DHB expectations are.

> *I still think to this day a lot of pharmacies would still find it quite grey as to what is the actual LTC. (P17, male, owner/manager)*

5.6.4.1.3 Multiple concurrent and competing roles

Another tension raised by some participants was that community pharmacists generally have a heavy workload and are often required to fulfil multiple concurrent roles in the pharmacy. This was particularly felt by pharmacists who work sole-charge and struggle to balance and cope with all the pharmacy activities occurring in parallel. They feel stretched in multiple directions, with being both a retailer and a health professional. Having a high prescription load to dispense was highlighted as impacting on the ability of pharmacists to get out of the dispensary and speak to patients. Some participants highlighted that this negatively impacts LTC delivery. To manage this, participants believed having adequate staffing levels is vital, to ensure pharmacists are free to deliver LTC. It was suggested by some pharmacists that providing LTC as a team, involving all pharmacy staff, is the key to success (versus LTC being provided by a single pharmacist).

> *The things that would prevent me from providing the [LTC] service is staff…you need to have their workload right, so they have time to be able to let you go away to provide these services. (P11, male, owner/manager)*

During the observations, pharmacists having multiple concurrent roles was clearly seen. The struggles in managing various pharmacy concurrent tasks was evident. Pharmacists appeared particularly burdened with dispensing prescriptions at all the pharmacy sites observed, with them spending substantial parts of their day dispensing medications. This reduced the time available for them to provide other pharmacy service, like LTC. For many of the sites, they explained that they are becoming increasingly busy with dispensing prescriptions and a couple sites have introduced double checking steps, to help reduce the chances of medication dispensing errors occurring due to increased busyness.

One site introduced two robots into the pharmacy to help reduce the pressure of dispensing and the team were seen heavily relying on them for dispensing and for the preparation of blister packs. From the observations it appeared that these pharmacists spent less time dispensing medications, compared to other sites which did not have the robotics. At another site, one pharmacist owner explained another way that reduces the pressure of heavy prescription load, is by using and encouraging staff to work to the top of their scopes. He provided an example of pharmacies having qualified technicians to carry out most of the dispensing tasks and the pharmacist being involved in the final check and counselling stages. This approach was evident in a couple pharmacies. In another pharmacy this was strikingly absent. This particular site had no technicians and no intern pharmacists employed, and one staff member explained it is because the pharmacy is very busy. There were four pharmacists in the dispensary for most of the day, dispensing medications, packing them up, with minimal patient education and counselling being seen.

5.6.4.2 LTC disrupting community pharmacies' 'business-as-usual'

5.6.4.2.1 LTC is a time intensive service

Some pharmacists believe LTC is time-consuming, and felt they lacked sufficient time to provide LTC and complete the necessary LTC documentation and paperwork, including the annual reviews and management plans. Some pharmacists revealed that in the past they never used to document patient interactions, however since the introduction of LTC this has become an integral part of the service. Because of time constraints a few pharmacists struggled with maintaining the monthly contact that is stipulated in the LTC contract.

> *Definitely LTC takes a bit of time, it is quite time-consuming. It's something that I have to factor into my work week, which I never had to think about beforehand. (P5, female, pharmacist)*

During the observation certain pharmacists reiterated that LTC is a time-intensive service, with a pharmacist at one site explaining that the documentation and paperwork is particularly time intensive. She however acknowledged that this documentation and paperwork is important to consistency in care (particularly for another pharmacist to know what he/she did) and for DHB audit procedures. During the observation, it was evident that pharmacists spent time completing LTC documentation, particularly after face-to-face interaction or after a telephone call with an LTC patient.

At another site, the pharmacist had similar views with respect to the time-intensive nature of the service. This pharmacist suggested pharmacists need to find ways to free up pharmacists' time to enable them greater time to do services, like LTC. He suggested one possible way of freeing up pharmacist time was during the dispensing process, where pharmacists could dispense whole unit dose packs, whereby whole boxes of medications would be dispensed to patients rather than repacking them. He explained such a dispensing method is used overseas, but rarely done in New Zealand community pharmacies.

5.6.4.2.2 Integration of LTC into pharmacy workflow is the key to success

Certain pharmacists explained that providing the LTC service effectively requires it to be integrated into the pharmacy workflow. Some participants reported investing substantial time and money into putting procedures in place for delivering LTC and keeping track of their LTC patients. Doing so was believed to be important due to LTC being time-intensive. They explained that without having clear procedures in place for managing LTC, their pharmacy would be unable to keep track and would instead provide an *ad hoc* service, only when they have some free time.

> *It has made us develop systems... LTC has said "Hey, there's more funding here, rather than just dispensing. Develop systems for looking after medicines." (P11, male, owner/manager)*

During the observation it appeared that certain pharmacies have developed their own procedures for managing LTC patients. It also appeared that those pharmacy owners that deem

LTC to be beneficial to patients had invested time and money into setting up good systems for managing LTC patients.

5.6.4.2.3 LTC has changed some pharmacies' and pharmacists' focus

For very few pharmacists interviewed, the introduction of LTC has changed the focus of their pharmacy operations from medication supply and dispensing, to a more patient centred focus. One pharmacy owner explained that providing the LTC service has helped him change his own attitudes and focus to be more holistic, encompassing patients' care as a whole, not just their medications. Another pharmacist explained that this has given him a new sense of appreciation of his job and greater job satisfaction.

> *I feel this is what pharmacists should be involved in, more than the classic dispensing of medication and giving some advice and off you go. With LTC you feel you're more involved. It benefits you as a pharmacist as well, because you've been working for years, and the routine gets boring as well. And it actually makes your job more interesting and you feel you're more beneficial to the public…And you feel it's more rewarding. (P16, male, owner/manager)*

One participant suggested that for some pharmacies LTC caused a dramatic change in the focus of their pharmacy, whereas for other pharmacies it was not such a substantial change, as they were already providing a patient centred, LTC-like service prior to the LTC roll out in 2012. Another participant suggested that the focus of the pharmacy is still none-the-less dictated based on what pays the pharmacy bills.

> *A lot of their focus goes to the part of the business that pays the bills.*
> *(P11, male, owner/manager)*

During the observation, it was difficult to observe and consequently comment on the change in pharmacists' and pharmacies' focus resulting from the introduction of LTC.

5.6.4.3 Perceived lack of value of community pharmacy and LTC, and subsequent lack of buy-in to the service

Certain pharmacist participants believe that there is a lack of buy-in to LTC by patients, GPs, pharmacy management, community pharmacists themselves, and DHBs.

5.6.4.3.1 Patients valuing pharmacy and their buy-in to LTC

Some pharmacists believe that certain patients lack buy-in to LTC and other pharmacy services. A couple of participants suggested this was the result of patients not fully understanding pharmacy services, what services are offered, the role of the pharmacist and how they can help them. A few participants explained that certain patients just want and expect to come into the pharmacy and get their medications as quickly as possible, with very little interaction with pharmacy staff. Another participant expressed her frustration that patients also appear to expect to have all pharmacy services provided to them for free, without needing to pay. She said this was disappointing as it is a stark contrast to that seen with GPs, where she believes patients pay for many extra GP services. She alluded to the fact this may be due to patients not valuing pharmacy and the services they provide.

> *A lot of the time they [patients] expect to come into the pharmacy and some of them are in a hurry and just want their medication. They don't expect to have a huge conversation about their medications... I guess it's a different mindset for them for coming into the pharmacy than what it would be if you go to the doctor and have more of a discussion about things. (P1, female, pharmacist)*

These participants suggested there is a need to boost patients' understanding and expectations of the pharmacists' role and their services, in order to help improve patients' perceptions of community pharmacists and their services, particularly LTC, as this may influence patients' subsequent buy-in to LTC. It was suggested that educational material may help to achieve this. However, one participant noted that it would be best if this was provided from the Ministry of Health or an alternate neutral body, rather than the pharmacy sector, as this may be seen as self-promotion. Material informing patients of new pharmacy services was believed to be lacking, and one participant explained that the public were never informed about LTC before its introduction in 2012.

> *When it [LTC] was first brought out, there was nothing put out by the Ministry to say this is going to be happening. It was basically just left to us… Which I thought was quite disappointing actually. (P10, male, owner/manager)*

Some participants alluded to the fact that pharmacists are the invisible profession, which lacks public recognition. Some pharmacists are going 'above and beyond' for their LTC patients, with very little appreciation from patients.

> *I've just heard from so many people that you do all this work for LTC, and you don't really get appreciated that much for it. (P2, female, owner/manager)*

> *There are so many things which happen in the background other than just paperwork…The pharmacist spends a lot of time outside of that paperwork to sort out a lot of stuff for that patient. But no one realizes how much effort the pharmacist is putting in [as part of LTC] and they're not getting paid for any of that. (P13, male, owner/manager)*

Other participants contradicted this and said that their patients do value pharmacists. A pharmacist who works rurally, explained her entire community greatly values her and her staff as patients, both in LTC and not in LTC, rely on them to get help and health advice. She said her patients also see her pharmacy as a comfortable place to socialise with staff and other members of their small community. During the observation this is exactly what was seen, with extended family members running into each other at the pharmacy and hanging around talking for long periods of time to each other and to staff. It was interesting to observe how the pharmacy staff had developed themselves to be integral parts of the community; the pharmacy itself but also the staff. It was obvious during this observation that the pharmacy staff had a very strong relationship with their community and patients within it. Patients valuing their services, staff being approachable and caring towards patients, is what the staff and owner believe has contributed to this close relationship with the community. This develops on the notion, that having a strong relationship and good rapport with patients, as suggested by some participants facilitates providing the LTC service.

> *They [patients] have got to trust you and they've got to like you. It's bit like teachers. If kids don't like a teacher, it doesn't matter what they say… They won't take it and they won't want to know… it's about the rapport you have with them. (P9, male, owner/manager)*

Some participants developed further on patients' LTC buy-in. They suggested that a lack of patient buy-in into LTC may not in actual fact be due to their lack of valuing their pharmacist,

rather they may decline enrolment into LTC as they are in denial about their health and medical conditions.

> *They [patients] think they don't need it [LTC] that's probably the main thing, because they think they're coping fine without it until something happens and then, off they go to hospital.* (*P10, male, owner/manager)*

5.6.4.3.2 GPs valuing pharmacy and their LTC buy-in

A couple of pharmacists suggested that GPs lack buy-in to LTC and other pharmacy services. Despite explaining the LTC service to their GP colleagues, some pharmacists reported that their nearby GPs very rarely refer patients to LTC. Instead GPs sometimes inform pharmacists of patients who need pharmacists' help e.g. patients who need a blister pack. Some participants wondered whether this apparent lack of interest in LTC and other pharmacy services was the result of GPs not valuing pharmacists or whether it was due to them being too busy and being burdened with their own workload.

> *We do inform them [GPs], like every now and again. We'll be like "This is our LTC patient." I don't think they know about it and I don't think they really care about it. (P2, female, owner/manager)*

During the observations face-to-face interactions between GPs and pharmacists were not seen. However, some pharmacists commented on their relationship with GPs; for example, a pharmacist at one site explained he is actively involved in collaborating with nearby GPs as part of the multidisciplinary team (MDT). The MDT frequently meet in his pharmacy office to undertake patient medication reviews together. At another site, the owner said they regularly have a training doctor (registrar) work at their pharmacy as part of an induction programme run by a nearby GP, to showcase the pharmacists' role and the services they offer.

The researcher believes these situations highlighted above exemplify the positive relationships these pharmacists have with their colleague GPs. They also exemplify that certain GPs do in fact value their pharmacist colleagues' input and work.

5.6.4.3.3 Pharmacy management valuing pharmacy and their LTC buy-in

Some pharmacists said there is a lack of buy-in from pharmacy management towards LTC. A couple of pharmacists suggested that the degree of management's buy-in into LTC and pharmacy in general affects how much staffing they provide to their pharmacy, the focus of the pharmacy as well as their investment into the pharmacy premises and into developing pharmacy procedures.

> *Whoever is at the top sets the example and sets the tone. So if they dismiss it [LTC] and poo-poo it and say it's just all about money, I think you would find that the rest of the staff haven't bought into it as well as someone who really think it's important, and says, no, we're going to do this, and we're going to do it right. (P6, male, owner/manager)*

During the observation this was particularly obvious at one observation site, where the owner expressed negative views about LTC. He did not believe that LTC had any benefit to patients and did not buy into the idea of LTC. During the observation pharmacists at this site were mainly focused on dispensing medications, rather than on LTC delivery. Furthermore, at this site there appeared to be minimal investment by the owner and the team into developing procedures for managing LTC patients.

This was in stark contrast to other observation sites, where management had positive views on LTC. These pharmacies had clear procedures in place on how to manage LTC patients, i.e. what services to provide, who provides them, and what to document after each interaction.

A few pharmacist participants believed that those in management are unaware of pharmacists' stresses and have unrealistic expectations of their pharmacists about LTC, particularly when management expects higher LTC enrolment numbers.

> *Our boss doesn't work in the pharmacy, so it's just the manager and whenever the boss comes in, they will comment on the fact we don't have much LTC [patients]. But until that day, it's not really a focus in our pharmacy. Maybe other pharmacies do have people dealing with LTC specifically and dedicate their time to that, whereas we don't have time dedicated solely to LTC, it's like when you have time, do this. (P14, female, pharmacist)*

All the observation sites had the owners working alongside staff and were seen being active team members. Therefore, this misalignment in expectations between the owners and

pharmacist staff was not observed in the observation sites at all. Rather, the owners observed appeared to be very supportive of their staff.

5.6.4.3.4 Pharmacists valuing pharmacy and their LTC buy-in

Some pharmacists themselves do not see the value in LTC. Certain participants believed that some pharmacists and pharmacy staff still do not fully understand LTC, what is expected of them, and do not see the value of the service.

> *I just don't think there's - or in my staff - that there's buy-in to LTC. It's kind of the thing in the background, they'd [pharmacists] rather it just went away, and they didn't have to deal with it. (P4, male, owner/manager)*

One participant believed that the degree of a pharmacist's buy-in influences the effort they put into providing the service. This was clear during observation of pharmacy sites, whereby those pharmacists who expressed their support for LTC put substantial effort in delivering the service, while the opposite was true for those pharmacists who see LTC in a negative light.

> *It's probably to do with how much effort they [pharmacists] put into it. I mean, let's be honest, if you're making a genuine effort, and you buy into the process, then you're going to do a better job, and one would expect you'd get better results. (P6, male, owner/manager)*

5.6.4.3.5 DHBs valuing of pharmacy and their LTC buy-in

Some pharmacists explained that they believe there is lack of trust and valuing of community pharmacists from the DHBs. These participants explained they feel DHBs have not fully brought into LTC and rather they believe DHBs are more interested in ensuring pharmacists complete all the necessary LTC paperwork and documentation, rather than about the quality of the service they provide. For this reason, some participants reported providing a comprehensive paper trial more for auditing purposes and for satisfying DHBs, rather than those procedures actually being helpful to patients or the service delivery. This apparent lack of buy-in to LTC from DHBs was suggested by certain pharmacy staff during the observations also.

> *They [the DHB] seem to be looking for boxes to tick. Like one of the most important things they seem to have on their audit list is, do we have a signed consent form from the patient? That seems to be their biggest audit concern, or, is the patient getting, you know, regular contact? That's about it. They're not auditing the quality of the service. (P4, male, owner/manager)*

5.7 Discussion

The present study aimed to understand how New Zealand community pharmacists provide the LTC service and to explore their views and experiences with the LTC service and its provision. To address these, semi-structured interviews with community pharmacists, who provide LTC were undertaken, as well as observation of pharmacy sites, where LTC is provided. To ease interpretation, the discussion is framed to reflect the order in which the themes were presented in the previous section of this chapter, that is: pharmacy activities or services provided to patients as part of LTC; pharmacists' perceptions of the benefits of LTC; and factors contributing to their LTC service provision.

Pharmacy activities or services provided to patients as part of LTC

Pharmacists in the present study provided a range of activities or services as part of LTC, such as preparation of medication adherence aids, undertaking medication reconciliation and medication synchronisation, sending text and/or phone reminders, providing education, counselling and medicines information to patients, providing written information and yellow cards, and delivering medications to patients' homes. When choosing what activities or services to provide for LTC enrolled patients, certain participants highlighted they first ascertain the reason for their medication non-adherence and tailor LTC accordingly. Understanding the reasons for non-adherence is a vital step for tailoring an adherence service for patients and identifying appropriate solutions.[231,232] It is encouraging to see certain pharmacist participants undertake this important step.

Community pharmacists in this study provided the same services as part of LTC as that stipulated in the service guidelines.[23] The extent to which they provided the service varied between pharmacies, with some pharmacies going above and beyond for their patients and even doing activities such as medication reviews, which are not part of LTC and for which they are not paid. Participants justify this by explaining they provide their pharmacy services based on patients' needs, not based on the remuneration that they will or will not receive.

Pharmacists' perceptions on the benefits of the LTC service

Medication adherence – is it a true reflection of patients' medication consumption?

The majority of pharmacist participants believed that LTC can improve patients' medication adherence. Thus, many were unsurprised by the earlier study finding that LTC enrolled patients

had greater odds of being adherent, compared to patients not enrolled in the service. Pharmacist participants suggested this greater adherence was evidenced amongst their LTC patients through patients picking up their medications on time, running out of supply at the appropriate time, and their medication repeats expiring less often. Some patients also verbally feedback to their pharmacist about how much medication they have left at home. This suggests unison between our earlier study finding and that reported in this qualitative study. However, this apparent validation of the quantitative results needs to be considered in the context of an important limitation in both studies - that patients' collection of their medications on time does not necessarily reflect their consumption patterns. This was highlighted by certain participants in the present qualitative study and raises an important question – would greater adherence amongst LTC enrolled patients have been observed if an alternative adherence method was used? This limitation is explored in more depth in the final discussion chapter (Section 6.4.1).

After interviewing pharmacists and observing them first hand, there appeared to be certain actions that can be undertaken to possibly help pharmacists ensure patients medication consumption is correctly reflected through their medication acquisitions. A key factor may be having a good relationship between the pharmacists and patients, so patients feel comfortable disclosing their true medication usage. Also educating and counselling patients about the importance of good adherence, so they are aware of the benefits of taking their medications as prescribed. Some may consider asking patients to return used medication bottles and blister packs to the pharmacy when they come to pick up their next supply of medications. This would help pharmacists ascertain what proportion of their medications were consumed.

Activities or services that are particularly beneficial for improving medication adherence

Pharmacists participants believed a combination of LTC activities together can improve adherence more effectively, rather than solely one activity or service. This notion has been supported by others who have found that multifactorial adherence interventions are more effective than mono-factorial interventions.[71,233,234]

Others pharmacist participants believed that certain activities play a bigger role in terms of improving adherence. For example, certain pharmacists explained that blister packs are particularly helpful for improving patients' adherence as they make medication taking simpler for patients. Published literature supports this notion with a Cochrane review showing that adherence aids improved patients' medication adherence and certain clinical outcomes.[235]

While there is evidence highlighting the advantages of blister packing, one obvious downside is the time intensiveness of preparing the packs. One pharmacy site observed during the study mitigated this issue by introducing robots to prepare the blister packs. The pharmacy owner made substantial financial investment into robotics, allowing the robots to do most of the blister packing and medication dispensing. Such a move appeared to greatly free up pharmacists' time to undertake other pharmacy activities, including providing LTC.

Participants also highlighted that education and counselling, as well as yellow cards play important roles in improving medication adherence. These verbal and written forms of information aim to improve patients' understanding of their medications. Some participants highlighted that increasing patients' understanding about their medications and medical conditions may improve their health literacy, which in turn they believe can improve medication adherence. Overseas literature has supported this notion of greater health literacy contributing to improved adherence.[236-238]

Hospitalisations

According to LTC service guidelines,[23] in addition to improving medication adherence amongst patients, LTC was also introduced to minimise patients' hospital admissions. Very few pharmacists in the present study believed that LTC can reduce patients' hospitalisations. Others, the majority, believed the LTC service was unable to affect patients' hospitalisations.

When presented with our earlier study finding of greater hospitalisations amongst the LTC enrolled patients, pharmacists attempted to explain why that may be the case. Various reasons were suggested for the greater hospitalisations including: closer pharmacist monitoring of patients, with pharmacists picking up health or medication issues quickly and referring patients in a timelier manner for medical attention; pharmacist education and counselling contributing to improve patient health knowledge, which some participants conceptualised as health literacy, and this may contribute to patients becoming more aware and empowered on when to seek help. Some also suggested there may be possible differences in individuals who agree to be enrolled in LTC versus those that decline enrolment and these factors may have some influence on hospitalisations (e.g. unhealthy lifestyles, willingness to accept help, disease acceptance etc). Others postulated whether greater hospitalisation are related to medication adherence. Further details on these greater hospitalisations is discussed in the final discussion chapter.

Factors contributing to pharmacists' LTC service provision

Tensions in the community pharmacy environment

A range of factors were identified that influence how pharmacists deliver LTC to their patients, namely financial tensions, working in isolation and pharmacists having concurrent and competing roles in the pharmacy.

Financial tensions in community pharmacy are well described in the literature, with various authors citing insufficient remuneration as a significant barrier to community pharmacy service provision.[25,239-242] Thus, it is then not surprising that this was a tension identified during the present study; whereby participants felt that LTC remuneration was insufficient for the work associated with providing the service. The participants further explained there is even a financial disincentive to providing an LTC service of a high standard, as once LTC patients are adherent and thus meet the goal of LTC, they must be exited from the service, thereby forfeiting further LTC payments. This disincentive for delivering an effective service was suggested as having a negative impact on LTC service provision.

These financial tensions are made worse with the introduction of LTC capping and through the emergence of discount pharmacies, which provide prescription medication dispensings free of charge to patients. Free prescriptions are a relatively recent development in New Zealand community pharmacies thus the full impact of free prescriptions is yet unknown. Some pharmacists in the present study suggested these discount pharmacies pose significant competition for them, with one participant suggesting that even if she provides the highest standard of pharmacy service to patients, including LTC, patients still switch to discount pharmacies, taking their prescriptions and consequently LTC enrolment with them, even if it is out of their way. While providing prescription medicines free of charge to patients was seen in a negative light by pharmacists in the present study, due to their business competition, some overseas literature has suggested free prescriptions may contribute to improved patient health, reduce health inequalities between patients,[243] and even contribute to improved medication adherence.[244] Certain researchers did sound a warning, however, that this benefit is somewhat offset by the risk of medication stockpiling and medication wastage.[243]

Developing on from that participants also highlighted that working in isolation is another tension affecting the delivery of LTC, specifically isolation from the rest of the pharmacy team; from other pharmacies; GPs and DHBs. This working in isolation has been described in the

literature[245-247] and appears to be an ongoing issue internationally. It is saddening to see in the present study that pharmacists feel isolated, particularly from GPs, as one of goals of the LTC service was to strengthen the working relationship between pharmacists and GPs and enhance collaboration between the two professions.[23] From the present research it appears this has not been achieved. An earlier LTC study by Moore et al[26] reported a similar finding, with the authors suggesting the working relationship between pharmacists and GPs did not improve as a result of the LTC service.

Having multiple roles in the pharmacy and trying to juggle the roles of being a health care professional and retailer, concomitantly, was described as causing tension. This dichotomy in community pharmacy puts pressure on pharmacists to juggle wanting to maintain a successful business, yet also maintaining their professional morals and ethics.[240,248] In the present study, many participants explained that they based their LTC services on patients' needs, not based on whether they are being remunerated for the services. Such thinking has led to some pharmacists providing an LTC-like service to patients, even upon them exiting the service and when LTC payments had cessed.

LTC disrupting community pharmacies' 'business-as-usual'

Certain pharmacist participants explained that providing the LTC service effectively requires it to be integrated into the usual pharmacy workflow. Some participants have invested substantial time and money into putting procedures in place for delivering LTC and keeping track of their LTC patients. Doing so was believed to be important by some participants due to LTC being time-intensive. This is not the first time LTC has been described as time-intensive, with New Zealand based researchers finding a similar result a few years ago.[249] A study by Roberts et al[250] suggested that in order for new pharmacy services to be implemented successfully there is a need for restructuring of the pharmacy day-to-day pharmacy business. The authors suggested this may include reallocating activities between staff members, employing new staff, changing the layout of the pharmacy, to name a few.[250]

Furthermore, for a few pharmacist participants the introduction of LTC has changed the focus of their pharmacy operations from medication supply and dispensing, to a more patient-centred focus. One pharmacy owner explained that providing the LTC service has helped him change his own attitudes and focus to be more holistic, encompassing patients' care as a whole, without

thinking only about medication supply. However, unfortunately for most participants, LTC did not elicit such a change in focus or behaviour.

Perceived value of community pharmacy and LTC, and the subsequent buy-in to the service

Some pharmacists believed that certain patients lacked buy-in to LTC and other pharmacy services. A couple of participants suggested this was the result of patients not fully understanding the services, what services are offered, the role of the pharmacist and how they can help them. It is perhaps then not surprising that overseas literature has suggested this also, with authors citing that patients are sometimes unaware of the pharmacists' role and their responsibilities.[251-253] In the present study, a few participants explained that certain patients just want and expect to come into the pharmacy and get their medications as quickly as possible, with very little interaction with pharmacists. In the past it has been suggested that patients' expectations are low of community pharmacists, however upon exposure to more extended pharmacy services, patient expectations do increase.[254]

Certain pharmacists highlighted this lack of buy-in spanned other areas too. Some believed GPs have not brought into LTC and other community pharmacy services. This thinking is not a first, with other researchers reporting that GPs are not always supportive of extended pharmacists services for various reasons including: GPs perceiving pharmacists as lacking appropriate skills, GPs being unaware of pharmacists' qualifications, and GPs fearing competition between pharmacists and GPs.[255] Other research has suggested GPs also perceive some pharmacy services as a threat to their autonomy and control.[256] This research, together with the present study findings, suggest that perhaps further work is still needed to exemplify to GPs about community pharmacists' skills, and the value their services can have on patients' health. The Pharmacy Action Plan, which sets out the goals for the profession from 2016 to 2020, outlined a need for pharmacists to work as part of a collaborative team with GPs.[257] A few participants in the present study are on board with this and are active members of the multidisciplinary team with GPs, while for other participants this appears to not be the case.

This apparent lack of valuing and buy-in to LTC was believed to affect other stakeholders also, not just patients and GPs, but also pharmacists themselves, pharmacy management and DHBs.

5.8 Limitations

The research findings need to be considered in the context of certain limitations.

Firstly, participants recruited for the present qualitative study are not a representative sample of all community pharmacists in New Zealand, therefore the views and experiences presented in the study are not generalisable.[124,258] This limits the transferability of the study findings to the broader New Zealand community pharmacy setting. However, great care was taken during the study, to sample and recruit community pharmacists working in a range of community pharmacies, using a detailed sampling framework.

The transferability of findings is also limited by the fact that the LTC service is a New Zealand based community pharmacy service, with no other countries internationally providing the exact same service. Thus, the views and experiences in the present study may not be the same as those held by other community pharmacists overseas who provide alternative services.

Another limitation to consider is the small sample size for the observation phase. Only six community pharmacy sites were observed, yet 18 pharmacists working in 18 community pharmacies were interviewed. While all 18 pharmacist participants were contacted and invited to participate in the observations, only six consented to be observed. This is a limitation of the study.

Finally, the views presented in this study are those held by the community pharmacists interviewed and observed, and the pharmacist participants frequently commented on their patients' behaviours and beliefs. These views, which belong to these pharmacists, may not necessarily represent patients' true actions and beliefs.

5.9 Conclusion

This chapter presented the findings from semi-structured interviews with community pharmacists and observation of pharmacy sites. Interviewed pharmacists provided a variety of activities or services as part of LTC and many believe that it is the combination of all these together that helps to improve patients' medication adherence. LTC is a time intensive service which requires ideally the integration of the service into pharmacy workflow. Factors were

identified that influence LTC provision in community pharmacies, primarily: tensions in the pharmacy, which stem from financial pressures, pharmacists working in isolation, and having multiple and competing roles. Other factors included LTC disrupting pharmacies' 'business-as-usual'. For a few the introduction of this service has positively changed the focus of their work, from that focused on medication supply to patient centred care, however for the majority of participants, LTC has not. Certain pharmacists disclosed they feel there is a lack of valuing of pharmacy and LTC, that is reflected in a lack of buy-in to the service by patients, GPs, pharmacy management, DHBs and even by pharmacists themselves.

CHAPTER 6. FINAL DISCUSSION

6.1 Chapter overview

This chapter summarises the key findings from the present research, as well as its strengths and limitations. It details the implications of the study findings for practice and policy, as well as directions for future research.

6.2 Key findings from the thesis

This research was undertaken to better understand the LTC service - a New Zealand community pharmacy-based service. Against this background this research aimed to:

- Examine the impact of the Long Term Conditions (LTC) service on patients' medication adherence and ambulatory sensitive hospitalisations (ASH);
- Understand how New Zealand community pharmacists provide the LTC service;
- Explore community pharmacists' views and experiences with the LTC service and its provision.

The research objectives were to:

- Describe patients enrolled in the LTC service in terms of their sociodemographic and clinical characteristics;
- Determine the impact of the LTC service on patients' medication adherence and ASH;
- Determine whether there is evidence of inequalities and inequities in LTC service outcomes, based on the sociodemographic characteristics of age and ethnicity;
- Identify pharmacies for the qualitative phase of this research;
- Understand what activities or services a sample of community pharmacists provide to LTC enrolled patients and how they differ from those provided to patients not enrolled in the LTC service;
- Explore pharmacists' experiences and attitudes about the LTC service;
- Explore pharmacists' views on the factors contributing to their LTC service provision.

6.2.1 Summary and triangulation

An early section in this thesis, the systematic review, demonstrated the positive contribution community pharmacist-led interventions or services can have on improving patients'

medication adherence and certain clinical outcomes.[27,28,31,38] It reviewed studies from the USA, UK, Western Europe, and Australia. However, there were no research articles published in New Zealand in this field that met the review inclusion criteria. This was identified as a significant research gap, particularly in light of significant changes to community pharmacy funding and delivery in New Zealand with the introduction of the LTC service. The LTC service was introduced in July 2012 to help community dwelling patients improve their medication adherence through the help of their community pharmacist.[182] The service also sought to improve patients' clinical outcomes and reduce patients' admissions into hospital.[23]

Even though some time has elapsed since LTC introduction, no research had been published examining the impact of this new service on patients' medication adherence, and only one study had been published examining the impact of LTC on patients' health outcomes, specifically hospitalisations.[26] Understanding the impact of the service on patients' medication adherence and hospitalisations was deemed vital. The researcher understood that not all hospitalisations are preventable through health care, and thus set out to assess the impact of LTC on ASH, which are hospitalisations that can be prevented through effective primary healthcare interventions and services.[187,188]

Against this background, the researcher sought to examine the impact of the LTC service on patients' medication adherence and ASH. A matched-cohort study was undertaken using routinely collected Ministry of Health (MOH) data. The study found that LTC achieved its primary goal of improved medication adherence amongst enrolled patients. However, LTC enrolment was also associated with greater ASH. These greater hospitalisations were an unexpected finding, particularly as there is an abundance of research showing that improved adherence has been associated with reduced hospitalisations.[14,82,216-221] Other research has contradicted this, showing that even when medication adherence was improved, reductions in hospitalisations did not always follow.[27]

Through semi-structured interviews with community pharmacists who provide LTC and observation of pharmacy sites where LTC is delivered, the research sought to better understand LTC delivery and explore potential reasons for the quantitative results, particularly the greater hospitalisations. The research also sought to explore pharmacists' views and experiences with LTC and its provision, as well as understand the activities that pharmacists provide as part of the service. The data from the quantitative, matched-cohort study informed the subsequent

qualitative study. Randomised stratified sampling from the matched-cohort study was used to identify and recruit pharmacists for the interviews (n=18). All interview participants were invited to take part in the pharmacy observation, and those who consented were included in the observation phase (n=6).

Upon completion of the interviews and observations, the researcher gained insights from participants about the possible reasons for the greater hospitalisations seen amongst LTC enrolled patients. These perceived reasons, presented in Figure 8, included patients receiving greater pharmacist education and counselling, contributing to increased patient knowledge about their medications and medical conditions. Participants theorised that as a result of increased health knowledge, patients may become more self-reliant and know which symptoms to act upon and to seek medical help for, as well as hospital treatment. Such an explanation has previously been proposed by other researchers.[214,259]

Another reason proposed for the greater hospitalisations may be closer pharmacist monitoring, as pharmacists may pick up on health or medication issues more quickly and refer patients for medical attention in a timelier manner. In the systematic review presented in Chapter 2, most of the interventions consisted of pharmacist education and counselling coupled with pharmacist monitoring. Thus, the idea that pharmacists may be picking up patients issues more readily through LTC is a possibility.

Certain participants suggested that the hospitalisations may be affected by medication adherence; that is, greater medication adherence may cause adverse effects, such as hospitalisations, as pharmacists do not assess medication appropriateness as part of LTC. Patients may be taking inappropriate medications or inappropriately dosed medications and that may contribute to hospitalisations. For example, prescribers may even inadvertently increase medication doses as they may interpret lack of disease control as treatment failure without realising the patient is non-adherent.[260] This may lead to adverse effects and lead to hospitalisation. A similar example was presented by one of the participants in the present study.

Others questioned whether the greater adherence identified in the matched-cohort study was a true reflection of patients' true medication taking behaviour and suggested that patients possibly may not consume medications appropriately even though they pick them up. This is an important limitation of the matched-cohort study and is discussed further in Section 6.4.1.

Lastly, some pharmacists thought it is possible that patients who agree to be enrolled in LTC are different from those patients who decline enrolment. Some participants alluded to the fact there may be uncontrolled confounding between patients who agree to be enrolled in LTC versus those patients who decline enrolment. Through the interviews and observations, it emerged that some patients who agree to be enrolled embrace the fact their pharmacist wants to help, and they agree to be enrolled in LTC. Some participants suggested that the patients who decline LTC enrolment may not want that control to be taken from them, possibly due to fear of losing their own autonomy, independence and self-efficacy, or due to not accepting their illnesses. The present research showed most LTC patients were elderly, with several co-morbidities, so this may be a possible explanation. Some participants also suggested that patients may also differ in terms of their lifestyles, as well as health literacy. These proposed differences in characteristics between LTC enrolled and not enrolled patients perhaps could be important to take into consideration when analysing differences in outcomes between the two groups.

These proposed explanations for greater hospitalisations amongst LTC enrolled patients are speculative only, and further investigations are needed to prove or disprove these theories. Section 6.7 in this chapter, details future research that could be undertaken to further explore these ideas.

Through the qualitative study, the researcher also sought to understand what activities or services pharmacists provide to LTC enrolled patients and how they differ from those provided to patients not enrolled in LTC. Pharmacists were found to undertake a variety of activities as part of LTC. While there is consistency in the services provided with respect to the LTC guidelines,[23,182] there is also variation in the way these services are delivered between the pharmacies.

The LTC activities are tailored to patients' needs and abilities and certain pharmacists try to understand the reasons for patients' non-adherence and tailor LTC accordingly. Pharmacists deliver a comprehensive service to all patients, regardless of LTC enrolment status. They do not withhold a service even if a patient is not enrolled in the service and they do not receive LTC remuneration.

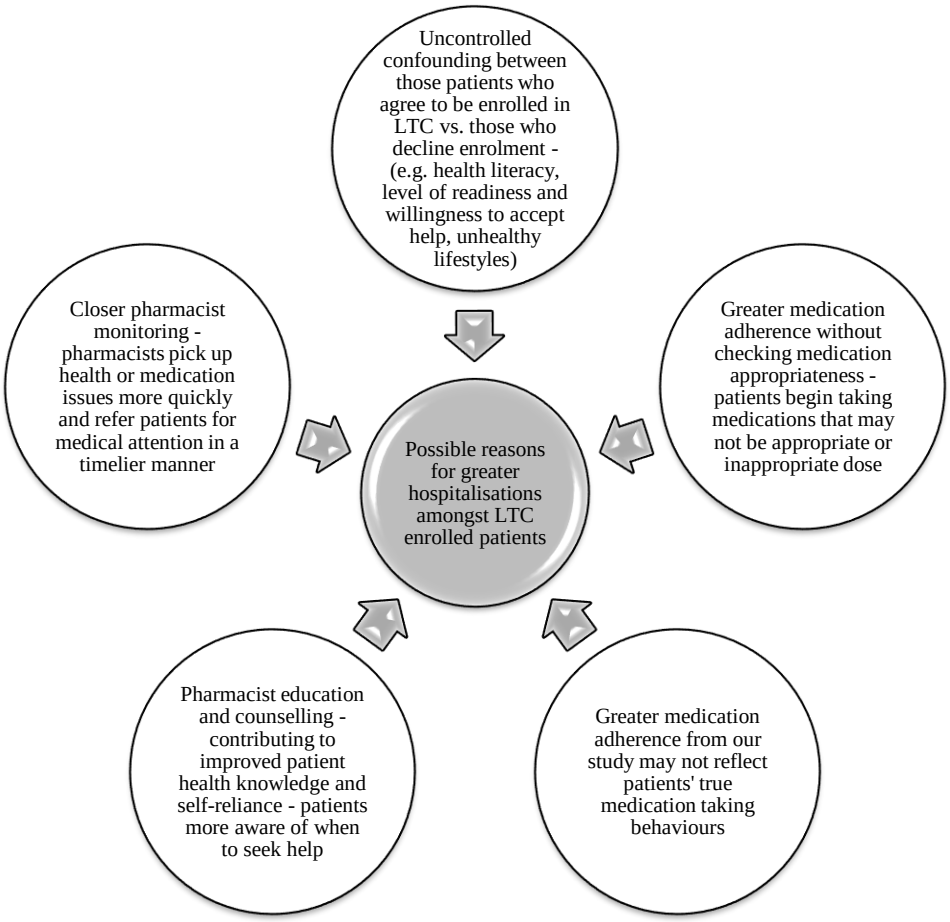


Figure 8. Possible reasons for greater hospitalisations amongst LTC enrolled patients (compared to not enrolled patients)

Furthermore, the researcher explored community pharmacists' views on the factors contributing to their LTC service provision. Three main themes emerged that influence LTC service provision. The first was tensions in the community pharmacy environment (caused by financial tensions; pharmacists working in isolation; and pharmacists having multiple and competing roles). The second theme related to LTC disrupting pharmacies' 'business-as-usual' (due to LTC being a time intensive service; which ideally requires it to be integrated into pharmacy workflow; and for a few, the introduction of this service has contributed to a change in work focus, from that focused on medication supply to more patient centred care). The last theme was related to the valuing of community pharmacy and LTC, and subsequent buy-in to the service. Certain pharmacists identified a lack of perceived value in community pharmacy

and LTC, and lack of subsequent buy-in to the LTC service from various stakeholders - patients, GPs, pharmacy management, pharmacists themselves, and DHBs

6.3 Research strengths

This research adopted a sequential, explanatory mixed method design,[88,92] which involved a quantitative study and a subsequent qualitative study. Findings from the quantitative phase informed the qualitative phase in several ways. The quantitative findings informed the development of the interview schedule and the observation schedule. Furthermore, using the study cohort from the quantitative phase, the researcher was able to develop a sampling framework and subsequently undertake stratified random sampling at a pharmacy level to recruit pharmacists for the interviews. These interviews were then used to recruit for the observation phase, recruiting those pharmacies who agreed to take part. Upon completion of the qualitative phase, the interview responses and observations helped to explain the results from the quantitative phase. This mixed method design allowed strengths from the quantitative and qualitative data to be synergised and minimised some of their respective weaknesses.[92] The triangulation of the quantitative and qualitative data also helped maximise the confidence in the research, and improved the validity and trustworthiness of the findings.[261-263]

6.4 Research limitations

The main limitations to of the present research are related to the measurement of medication adherence and its definition, and the transferability of the research findings.

6.4.1 Measurement of medication adherence and its definition

For the quantitative study, medication adherence was calculated using routinely collected health data. This method was chosen due to the completeness of the data,[112] which encompassed the whole country, the absence of deception potential and recall bias,[7,220] and the ease of accessing and analysing the data. A plethora of literature internationally has exemplified that estimating adherence using routinely collected health data is an acceptable measure of patients' true adherence.[48,51,57,223]

From the matched-cohort study, it was found that LTC enrolment contributed to greater medication adherence. Such a finding needs to be considered in the context of a limitation, that is, one cannot be entirely sure that this a perfect reflection of patients' medication consumption.

It is possible that patients pick up their medications from their pharmacy, but do not consume them as prescribed.[7,11,27] This however is an innate, widely known and accepted limitation of estimating adherence using routinely collected health data.[7,11,27,223,224] In light of this limitation, the researcher explored this adherence finding with pharmacist participants during the interviews and observations. Most participants affirmed and supported the study findings and believed that the LTC service has contributed to improved adherence among their patients.

Another limitation related to the medication adherence for the present research, is related to the adherence definition used. When calculating medication adherence using routinely collected health data, researchers internationally often use medication possession ratio (MPR) or proportion of days covered (PDC) or alike measurements. MPR and PDC describe how much medication a patient has in their possession and both are commonly used[11,264] and accepted estimates of medication adherence.[265] MPR is calculated using the sum of the number of 'days supply' of the medication during a specified time period divided by the number of days in that time period.[227] Thus this calculation requires the availability of the 'days supply' variable in the data set. When preparing the quantitative data set for analysis, it became apparent that this 'days supply' variable was frequently missing (~20%) from the MOH Pharmaceutical Collection. The MOH highlighted this data incompleteness in their Pharmaceutical Collection data dictionary for this particular variable.[165]

Alternative methods of assessing medication adherence were then considered. Looking at the New Zealand literature, adherence using a count of stat dispensings had previously been undertaken.[111,266] This method involves estimating adherence using quarter year periods of supply, without relying on the 'days supply' variable. Using this less sensitive method of stat dispensings, the matched-cohort had higher than expected baseline adherence (enrolled patients who are adherent 94.49% and control patients who are adherent 83.13%). According to international literature, it is expected that patients' adherence to chronic medications is ~50%.[9] The researcher does not foresee this to have a large impact on the data analysis, as the analysis involved comparison between the intervention and control groups, and the method of estimating adherence in the two groups was identical.

Using this method of stat dispensings to estimate adherence, the researcher was unable to estimate changes in patient's individual adherence during enrolment in the LTC service. Changes in patients' medication adherence during or after the intervention is often reported in

other studies.[27,43,53] This would have been possible if MPR or PDC were calculated, but was not possible with the stat dispensing method used.

Even though this adherence method has some innate limitations, these nonetheless do not affect the conclusions generated from the data.

6.4.2 Transferability of the research findings

For the second study, an important limitation to consider is the limited transferability of the study findings. Stratified random sampling was used to recruit pharmacists working in a variety of pharmacies across New Zealand. Even though every effort was taken to sample pharmacists working in a range of pharmacies, nonetheless the findings and views expressed by participants are limited to only those who participated in this research. Thus, one cannot generalise the findings to all other pharmacists and pharmacies working in New Zealand. However, this is an innate limitation of qualitative research and is not a usual goal of this research method.[124,258]

The transferability of the qualitative study findings to other community pharmacy services internationally is also limited due to the unique service that LTC is, the difference in the patient demographics, and difference in the health systems and medication funding between different countries. For example, in New Zealand patients receive an exemption card after they have paid for 20 medication dispensings for them or their dependent family members. After this they get free prescription dispensings for the rest of the year.[267] Such a strategy reduces the financial burden that prescription dispensing can be for patients with polypharmacy and many comorbidities. Such a scheme is unique to New Zealand and may have some impact on patients' medication adherence. However, many of the concepts presented in the thesis, particularly about medication adherence, hospitalisations, factors influencing pharmacy service provision, may be relevant to other community pharmacy services in New Zealand and overseas.

6.5 Implications for practice and policy

Pharmacy services should focus on improving clinical outcomes together with medication adherence – rather than adherence alone

The present research found that enrolment in the LTC service contributed to greater patient medication adherence, as well as, unexpectedly, greater ASH. This suggests that improvements in patients' medication adherence are decoupled from reductions in ASH. While it appears LTC has achieved one of its main goals of improved adherence, it does raise the question if

this gain is the extent of the service benefits? While LTC may improve adherence, it may not be able to improve clinical outcomes amongst enrolled patients. It was a reasonable goal that LTC developers proposed, that by improving adherence, LTC would also improve clinical outcomes, particularly hospitalisations,[23] as there is substantial research suggesting such a relationship (that improved adherence contributes to reduced hospitalisations).[14,216-218,220,221] As mentioned, one of the LTC service objectives was to improve patients' clinical outcomes and to reduce hospitalisations,[23] however, from the present research it appears that LTC has been unable to achieve this reduction in hospitalisations. The present research highlights a need for future pharmacy services to be focused on improving patients' clinical outcomes, rather than solely focusing on improving an intermediate outcome, like medication adherence, which may or may not have downstream effects on clinical outcomes.

The future - consider medication optimisation services in the future

There is major learning that has come from the present research. It has identified a need for future pharmacy services to have a greater focus on medication optimisation, where community pharmacists are involved in determining medication appropriateness, together with improving patients' medication adherence.[268] An interesting point was raised by a participant during the qualitative phase of this research, which resonated with the researcher and that is - is it appropriate for community pharmacists to be encouraging greater adherence amongst LTC enrolled patients' when pharmacists are unaware of the appropriateness of patients' treatment? This question is important to consider, as many pharmacists in the present research explained they lack access to patients' clinical records, and thus lack context and awareness of patients' medical history. Thus, for medication optimisation services to be possible in the future, there are certain requirements, that as a minimum, should be in place, such as community pharmacists having access to patients' clinical records[242,249] and having strong collaboration and information sharing between community pharmacists and GPs.[249] Other requirements include: adequate incentives and remuneration[242,269]; detailed service guidelines[269]; clear goals of the service[253]; adequate training[253]; in-depth consultation, engagement and piloting[253] with various stakeholders such as pharmacists, pharmacy management, GPs, patients and DHBs. Each of these requirements was raised by participants either during the interviews or during the observation, as being facilitators to enhanced pharmacist services.

One may postulate, that if a medication optimisation service was implemented, as described above, rather than solely an adherence service like LTC, then the notion that increased

hospitalisations seen amongst LTC patients, being the result of patients taking inappropriate medications, would not have occurred.

Now - the LTC service now - what areas of change did participants identify?

During the qualitative phase of this research, certain key areas of change for the LTC service were identified. These are described below.

Financial tensions

Many participants in the present research felt that the LTC remuneration is insufficient and thus identified a need for adequate remuneration and incentives for pharmacists to provide LTC of a high standard. Historically insufficient renumeration and incentives have been cited as barriers to effective community pharmacy service delivery.[25,239-242] To mitigate this, pharmacists could be offered incentives, even if they are not financial ones, for when LTC patients reach their goal of being adherent. For example, offering continuing professional development (CPD) points to pharmacists, was suggested by a participant, as a possible incentive to enhance LTC service provision.

Working in isolation

Certain participants explained that delivering LTC in isolation is a source of tension and stress for them. This is not unique to only LTC and spans other pharmacy services overseas too.[245-247] To help with the delivery of the LTC service, collaboration within the pharmacy team should be encouraged and all staff should try to be involved in delivering aspects of the service.

Furthermore, pharmacists should be encouraged to share information between different pharmacies, for example, through a mutual communication platform. Currently there is a community pharmacy group on Facebook and pharmacists should be encouraged to continue to engage and use such platforms to share ideas, problems and problem-solve together, about LTC.

Additionally, collaboration and information sharing should be encouraged between pharmacists and GPs. This could be encouraged through the use confidential communication platforms where pharmacists and GPs send messages to each other about patients' care. Currently MedTech[270] is available which enables communication between pharmacists and GPs and enables pharmacists to look up patients' clinical records, discharge summaries and

laboratory results. Unfortunately, many participants in the present research did not have access to this platform and thus did not have access to any of this clinical information about their patients. Enabling pharmacists' access to clinical records, discharge summaries and laboratory would provide pharmacists with greater insight into their patients' treatment and help them provide LTC.

Multiple concurrent and competing roles

Certain participants acknowledged that having multiple concurrent and competing roles in the pharmacy affects their LTC provision. Thus, it was suggested that delivering LTC as a team, involving all pharmacy staff could reduce pharmacists' workload and give them more time to deliver LTC. Having adequate staffing is important for this to be feasible. Some participants have introduced robots to help streamline the dispensing and blister packing processes.

Integration of LTC of into pharmacy workflow key to success

Pharmacists should be encouraged to develop their own ways of incorporating LTC into their pharmacy workflow, which is tailored to their pharmacy, their staff and their patients' needs. The importance of piloting of new pharmacy services is illuminated from the present research, to ensure that implementing new services is practical and feasible in the existing pharmacy environment.

Change of pharmacy and pharmacist focus

For a few participants, LTC contributed to a change in their work focus, from that focused on medication supply to more patient-centred care. Some found this change increased their job satisfaction. For others, the majority, LTC did not contribute to much of a change in focus, or practice. This highlights the notion suggested by other researchers, that introducing a new service will not necessarily mean that pharmacists' practice, focus, or behaviours will change.[253] There is a need to consider how future services can encourage changes in pharmacist focus and behaviour. When introducing new services, there needs to be a fundamental change in mindset or focus, as well change in behaviour.

Perceived lack of value of community pharmacy and LTC, and subsequent lack of buy-in to the service from various stakeholders

There is a need to boost patients' understanding and expectations of the pharmacist's role and their services, particularly for LTC. Campaigns would be valuable to highlight the pharmacists' role and the services offered, using various channels such as television, radio or medical centres.

There is a need to ensure patients and GPs are involved in the development of new pharmacy services, to ensure stakeholders see the value and benefit of pharmacy services.

6.7 Directions for future research

As with any research this piece of work has answered some research questions, but also raised new questions about the LTC service. The researcher proposes several areas of research to better understand the LTC service and help develop the service further.

There is a need to examine the greater hospitalisations seen amongst LTC enrolled patients in more detail. Possible research questions that could be addressed to better explain this finding are outlined here.

- Were the greater hospitalisations due to patients' medications?
    - Are the hospitalisations occurring as a result of pharmacists correcting patients' non-adherence and inadvertently precipitating adverse effects?
    - Are the hospitalisations occurring as a result of inappropriate medications being prescribed and taken?
- What is the impact of pharmacist monitoring, education and counselling on patients' health knowledge?
    - Does the change in patients' health knowledge (which some participants in the present study conceptualised as health literacy) have an impact on patients' hospitalisations? Certain overseas literature has suggested an association between health literacy and hospitalisations.[237]
- What is the impact of uncontrolled confounding variables on the hospitalisation findings?
    - Are there differences at baseline between patients who agree to be enrolled in LTC versus those who decline enrolment, based on health literacy, self-efficacy, disease acceptance, willingness to accept help or lifestyles?

These questions cannot be answered using retrospective analysis, rather the use prospective methods, such as patient surveys or patient interviews may be beneficial. It may also be

worthwhile to do before- and after- analysis to address certain questions, for example examining the impact of LTC enrolment on patients' health literacy. A researcher may consider comparing patients' health literacy at baseline and after enrolment in LTC.

Furthermore, future research may consider investigating the impact of newly introduced discount pharmacies on patients' engagement with pharmacy services. Pharmacist participants identified that the emergence of discount pharmacies has affected their patients' use of pharmacy services, including the LTC service. It would be valuable to examine whether there are differences in patient engagement with pharmacies who offer free prescription costs versus those who do not.

From the present research, it was apparent that there is a perceived need to highlight the community pharmacists' role and the services offered. There is a need to introduce campaigns highlighting community pharmacists' roles, the services on offer, and the possible benefits of these services for patients. That information could be introduced through various channels such as health centres, television or radio. This could contribute to improved patients' awareness of pharmacists' services and improve patients' buy-in to their services.

Future community pharmacy research should also actively engage and involve GPs. This is vital - to identify what community pharmacy services GPs view as being valuable to them and their patients; to explore GPs' views on the future of community pharmacy in New Zealand; and to explore GPs' views on possible approaches to strengthen collaboration between them and community pharmacists.

CHAPTER 7. CONCLUSIONS

This research was undertaken to address an important gap in the literature, specifically the impact of the New Zealand Long Term Conditions service on patients' medication adherence and ambulatory sensitive hospitalisations. A retrospective, matched-cohort study was undertaken, and it was found that LTC enrolment was associated with improved medication adherence. Such a finding is encouraging as improving adherence is one of the main goals of the service. Improved adherence was not associated with improvements in clinical outcome measures, which in the present research, were estimated using ambulatory sensitive hospitalisations. Counter-intuitively, it was found that LTC enrolment was associated with greater ambulatory sensitive hospitalisations. While the present research attempted to shed light on this, more research is still needed to understand the rationale for this finding.

This research identified factors that influence LTC provision in community pharmacies and they include: tensions in the pharmacy environment, which stem from financial pressures; pharmacists working in isolation; and pharmacists having multiple and competing roles. Other factors that influence LTC provision include: LTC disrupting pharmacies' 'business-as-usual', due to LTC being a time intensive service, which ideally requires integration into pharmacy workflow. For a few participants, the introduction of the service has positively changed the focus of their work, from that focused on medication supply to patient centred care, however, for the majority of participants, LTC has not. Certain pharmacists disclosed they feel there is a lack of value of community pharmacy and LTC, and this is reflected in a lack of buy-in to the service by patients, general practitioners, pharmacy management, District Health Boards and even by pharmacists themselves.

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APPENDICES

Appendix 1 - Copyright permission for the systematic review from the International Journal of Pharmacy Practice

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Appendix 2 - Copyright permission for the matched-cohort study publication from the Research in Social and Administrative Pharmacy journal

Dear Aleksandra,

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Appendix 3 - Summary of systematic review study outcomes

Author	Measure	Time assessed following baseline	Comparator	Outcomes
Medication adherence				
Planas at al. (2009)	Mean adherence rate (Rx records)	9 months	Control group	NS
Svarstad et al. (2013)	% of patients with PDC >0.8 (Rx records)	6 months	Control group	Intervention: 60% Comparator: 34% P<0.001
Svarstad et al. (2013)	% of patients with PDC >0.8 (Rx records)	12 months (6 months after intervention discontinuation)	Control group	Intervention: 62% Comparator: 44% P<0.001
Robinson et al. (2010)	Mean adherence rate	1-6 months (during study period)	Control group	Intervention: 0.91±0.15 Comparator: 0.78±0.30 P=0.02
Robinson et al. (2010)	Mean adherence rate	7-12 months (end of study period)	Control group	NS
Lai. (2007)	Adherence rate (Rx records)	9 months	Baseline	Intervention: 95.8% Comparator: 70.6% P=0.02
Spence et al. (2014)	% of patients adherent (Rx records) [a]	1 year after index data	Control group	Intervention:53.5% Comparator: 37.4% P=0.001
Spence et al. (2014)	Mean adherence rate (MPR-Rx records) [a]	1 year after index data	Control group	NS
Spence et al. (2014)	Change in adherence rates (MPR-Rx records) [a]	1 year after index data	Baseline	Intervention: +0.19 Comparator: +0.15 P=0.024
Spence et al. (2014)	% of patients discontinuing medicines [a]	Post-index date	Control group	Intervention: 11.7% Comparator: 35.5% P<0.001
Spence et al. (2014)	Timely refill [a]	Post-index date	Control group	Intervention: 34.8% Comparator: 12.9% P<0.001
Spence et al. (2014)	Mean number of days to first prescription fill [a]	Post-index date	Control group	Intervention: 79.3 days Comparator: 156.3 days P<0.001

Spence et al. (2014)	% of patients adherent (Rx records) [b]	1 year after index data	Control group	NS
Spence et al. (2014)	Mean adherence (MPR-Rx records) [b]	1 year after index data	Control group	Intervention: 0.7 Comparator: 0.74 P=0.003
Spence et al. (2014)	Change in adherence rates (MPR-Rx records) [b]	1 year after index data	Baseline	NS
Spence et al. (2014)	% of patients discontinuing medicines [b]	Post-index date	Control group	Intervention: 21.1% Comparator: 35.4% P<0.001
Spence et al. (2014)	Timely refill [b]	Post-index date	Control group	Intervention: 28.3% Comparator: 15.2% P<0.001
Spence et al. (2014)	Mean number of days to first prescription fill [a]	Post-index date	Control group	Intervention: 106.9 days Comparator: 162.6 days P<0.001
Mehuys et al. (2011)	Median adherence rate (Rx records)	6 months	Control group	NR
Mehuys et al. (2011)	% adherent (self-report)	6 months	Control group	NR
Mehuys et al. (2008)	Mean adherence rate (Rx records)	6 months	Control group	Intervention: 90.3% Comparator: 74.6% P=0.016
Mehuys et al. (2008)	Mean adherence (self-reported)	6 months	Control group	NS
McKenney et al. (1973)	% of patients adherent (90-110% of prescribed dose) (Pill counts)	~5 months	Control group	NR
McKenney et al. (1973)	Average adherence rate (Pill counts)	~5 months	Control group	NR
Rickles et al. (2005)	% omitted antidepressant doses (Rx records)	3 months	Control group	NS
Rickles et al. (2005)	% omitted antidepressant doses (Rx records)	6 months	Control group	Intervention: 30.3±36.4 Control: 48.6±39.2 P≤0.05
Tommelein et al. (2013)	Mean Medication Refill Adherence (MRA) score	3 months	Control group	Intervention: 93.9% Comparator: 85.7% P<0.0001
Tommelein et al. (2013)	Patients with Medication Refill Adherence (MRA) ≥80%	3 months	Control group	Intervention: 78.1% Comparator: 62.5% Odds Ratio: 2.15 (p<0.0001)

Ottenbros et al. (2014)	Days covered of LABD <80 or >120%	10 months	Control group	Intervention: Odds Ratio: 0.66 (p<0.05)
Ottenbros et al. (2014)	LABD probably stopped	10 months	Control group	NS
Ottenbros et al. (2014)	Days covered of ICS <80%	10 months	Control group	Intervention: Odds Ratio: 0.69 P<0.05
Ottenbros et al. (2014)	Days covered of ICS >120%	10 months	Control group	Intervention: Odds Ratio: 0.81 P<0.05
Armour et al. (2007)	Change in adherence to preventer medication (80-120%)	6 months	Control group	Intervention: 16.6% Comparator: -1.7% Odds ratio: 1.89 (p=0.03)
Armour et al. (2007)	Risk of non-adherence using BMQ	6 months	Control group	Intervention: -0.64 Comparator: -0.2 Mean difference: -0.44 (p=0.04)
Armour et al. (2007)	Mean daily dose of salbutamol (microgram)	6 months	Control group	Intervention: -145.4 Comparator: 3.8 Mean difference: -149.1 (p= 0.03)
Armour et al. (2007)	% of patients using combination of reliever and preventer medications, with or without a LABA, as opposed to reliever only	6 months	Control group	Intervention: -5.7% Comparator: 7.5% Odds Ratio: 3.8
Bouvy et al. (2003)	Days without dosing (MEMs)	-	Control group	Intervention: 140/7656 Comparator: 337/6196 Relative risk: 0.33 (CI 95% 0.24-0.38)
Bouvy et al. (2003)	≥2 days without dosing (MEMs)	-	Control group	Intervention: 18/7656 Comparator: 46/6196 Relative risk: 0.32 (CI 95% 0.19-0.55)
Bouvy et al. (2003)	< 80% adherence (MEMs)	6 months	Control group	Intervention: 0% Comparator: 14% Relative risk: 0.5
Bouvy et al. (2003)	< 95% adherence (MEMs)	6 months	Control group	Intervention: 13% Comparator: 37% Relative risk: 0.3
Jahangard-Rafsanjani et al. (2015)	Low adherence rate (Morisky score <6)	5 months	Control group	Intervention: 24% Comparator: 49% P=0.02
Jahangard-Rafsanjani et al. (2015)	Moderate/high adherence rate (Morisky score 6-8)	5 months	Control group	NR

Sturgess et al. (2003)	% of patients adherent (self-reported)	12 months	Control group	Intervention: 40.4% Comparator: 24.4% P<0.05
Sturgess et al. (2003)	% of patients adherent (self-reported)	18 months	Control group	Intervention: 47.3% Comparator: 14.7% P<0.05
Sturgess et al. (2003)	Change in adherence from non-adherent to adherent (self-reported)	18 months	Control group	Intervention:13.4% Comparator: 9.1% Authors stated statistically significant difference (no p-value reported)
Sturgess et al. (2003)	% of patients adherent (Rx records)	6 months	Control group	Intervention: 46.2% Comparator: 19.1% P=0.02
Sturgess et al. (2003)	Change in adherence from non-adherent to adherent (Rx records)	18 months	Control group	Intervention: No difference.
Rubio-Valera et al. (2013) [x]	Probability of patients remaining adherent	3 and 6 months	Control group	NS
Stewart et al. (2014)*	Morisky total score	6 months	Control group	NS
Stewart et al. (2014)*	Change in proportion of patients adherent (self-reported)	6 months	Baseline	Intervention: +13.5% (p=0.003) Control: +6.4% (p=0.1)
Stewart et al. (2014)*	% of patients adherent (self-reported)	6 months	Control group	NS
Stewart et al. (2014)*	Change in TABS score (self-reported)	6 months	Control group	NS
Stewart et al. (2014)*	MPR (Rx records)	6 months	Baseline	Intervention: 0.81±0.24 to 0.94±0.35 (p<0.001) Control: 0.81±0.25 to 0.89±0.21 (p<0.001)
Stewart et al. (2014)*	MPR (Rx records)	6 months	Control group	NS
Stewart et al. (2014)*	% of non-adherent patients that became adherent (self-reported)	6 months	Control group	Intervention: +22.6% (p=0.007)
Stewart et al. (2014)*	MedsIndex score for blood pressure medicines	6 months	Control group	NS
Zillich et al. (2005)	Medication adherence (self-reported)	3 months	Baseline	Intervention (HI group): no values provided (p=0.004) Control (LO group): NS
Zillich et al. (2005)	% of patients with high medication adherence (self-reported)	3 months	Baseline	Intervention (HI group): NR Control (LO group): NR

Blenkinsopp et al. (2000)	% of patients adherent (MARS)	6 months	Control group	Intervention: 62.9% Comparator: 50% P<0.05
Blenkinsopp et al. (2000)	Mean collection rate (Rx records) for consenting patients	6 months	Control group	Intervention: 5.38 Comparator: 4.99 Authors stated statistically significant (no p-value reported)
Blenkinsopp et al. (2000)	Mean collection rate (Rx records) for non-consenting patients	6 months	Control group	NS
Bosmans et al. (2007)	Mean adherence rate (electronic pill counter)	6 months	Control group	NS
Aslani et al. (2010)	Adherence rate (MARS)	9 months	Control group	No difference between control and intervention.
Aslani et al. (2010)	Likelihood of patients taking less than their prescribed dose	3 months	Control group	Intervention: less likely to take less than the prescribed dose ($F_{2,178}$ = 4.3, p<0.05)
Aguiar et al. (2012)	% of patients adherent (Morisky and Haynes et al.)	10 months	Baseline	Intervention: 68.6% Comparator: 17.1% P=0.0000
Blood pressure				
Planas et al. (2009)	Mean SBP	9 months	Control group	Intervention: -17.32 mmHg Comparator: +2.73 mmHg Difference: 20.05 mm Hg (p=0.003)
Planas et al. (2009)	Percentage reaching goal BP (<130/80mmHg)	9 months	Control group	Intervention: 48% Comparator: 6.67% P=0.007
Planas et al. (2009)	Odds of reaching goal BP (<130/80mmHg)	9 months	Control group	Odds ratio: 12.92 (P=0.021).
Svarstad et al. (2013)	Net reduction in SBP	6 months	Baseline	Intervention: -7.31 mmHg (p<0.001)
Svarstad et al. (2013)	Net reduction in DBP	6 months	Baseline	Intervention: -2.95 mmHg (p=0.01)
Svarstad et al. (2013)	BP control (<140/90mmHg)	6 months	Baseline	Intervention: +14% (p=0.01)
Svarstad et al. (2013)	Mean SBP	12 months(6 months after intervention discontinuation)	Control group	Intervention: 137.46 mmHg Comparator: 143.37mmHg P<0.001
Svarstad et al. (2013)	Reduction in SBP	12 months (6 months after intervention discontinuation)	Control group	Intervention: -13.64mmHg Comparator: -8.3 mmHg P=0.004
Svarstad et al. (2013)	Changes in DBP	12 months (6 months after intervention discontinuation)	Control group	NS

Svarstad et al. (2013)	BP control (<140/90mmHg)	12 months (6 months after intervention discontinuation)	Control group	NS
Robinson et al. (2010)	Proportion reaching goal BP (<140/90mmHg)	12 months	Control group	NR
Robinson et al. (2010)	Reduction in SBP	12 months	Control group	Intervention: -9.9 mmHg Comparator: -2.8 mmHg P<0.05
Robinson et al. (2010)	Reduction in DBP	12 months	Control group	NS
Lai. (2007)	Reduction in SBP	1 month	Baseline	Intervention: 133.8 ±13.7 mmHg Comparator: 150.5±16.5 mmHg P=0.02
Lai. (2007)	Reduction in SBP	3, 6, & 9 months	Baseline	NR
Lai. (2007)	Reduction in DBP	3 months	Baseline	Intervention: 83.3±8.8mmHg Comparator: 95.5±8.4mmHg P=0.04
Lai. (2007)	Reduction in DBP	1, 6, & 9 months	Baseline	NR
McKenney et al. (1973)	% of patients normotensive (DBP <90mmHg)	~5 months	Control group	Intervention: 79% Comparator: 20% P<0.001
Jahangard-Rafsanjani et al. (2015)	Change in SBP and DBP	5 months	Control group	NS
Stewart et al. (2014)*	Change in SBP	6 months	Control group	Intervention: -5.3mmHg (p=0.05)
Stewart et al. (2014)*	Change in DBP	6 months	Control group	NS
Zillich et al. (2005)	Change in SBP	3 months	Control group	NS
Zillich et al. (2005)	Change in DBP	3 months	Control group	Intervention: -3.2 mmHg (p=0.03)
Zillich et al. (2005)	% of patients achieving controlled BP	3 months	Control group	NS
Blenkinsopp et al. (2000)	Patients achieving controlled BP (<159mmHg SBP and/or <89mmHg DBP)	Unclear; authours used retrospectively collected BP	Control group	Intervention: 35.7% Comparator: 17.1% P<0.05
Aguiar et al. (2012)	% of patients with controlled BP	10 months	Baseline	Baseline: 0% End of study period: 57.2% P=0.000
Aguiar et al. (2012)	Change in SBP, DBP and pulse pressure	10 months	Baseline	SBP: -26.6mmHg (p<0.0001) DBP: -10.4mmHg (p<0.0001) Pulse pressure: -15.7mmHg (p<0.0001)
Cholesterol				
Spence et al. (2014)	Mean LDL-C	-	Control group	Intervention: 105.1 (no units specified)

				Comparator: 110.4(no units specified) P=0.001
Spence et al. (2014)	Change in LDL-C	-	Baseline	Intervention: -30.51 Comparator: -22.44 P=0.001
Aslani et al. (2010)	Mean non-fasting cholesterol levels	Across study period (9 months)	Control group	NS
Aslani et al. (2010)	Change in non-fasting cholesterol levels	Across study period (9 months)	Control group	Intervention: $F_{2, 190} = 4.89$ P<0.05
Blood glucose				
Mehuys et al. (2011)	Reduction in FBG	6 months	Baseline	Intervention: -0.45 mmol/L (p=0.004) Control: -0.78 mmol/L (p<0.001)
Mehuys et al. (2011)	Mean difference in FBG	6 months	Control group	NS
Mehuys et al. (2011)	Reduction in FBG in patients with baseline FBG >10.6 mmol/L	6 months	Control group	Intervention: -2.17 mmol⁄L P=0.010
Mehuys et al. (2011)	Proportion reaching target FBG (5-7.2 mmol/L)	6 months	Control group	Intervention: +19.8% Comparator: +5.3% P=0.002
Mehuys et al. (2011)	Sustainability of reduced FBG	6-12 weeks	Baseline	No values (p=0.002)
Mehuys et al. (2011)	Sustainability of reduced FBG	18 weeks	Baseline	No values (p<0.001)
Mehuys et al. (2011)	Mean FBG	18 months post intervention	Control group	Intervention: 7.26 ± 1.63 mmol⁄L Comparator: 8. 30 ± 3.43 mmol⁄L P=0.046
Mehuys et al. (2011)	Proportion reaching target BG (5-7.2 mmol/L)	18 months post intervention	Control group	Intervention: 60.3% Comparator: 50.0%
Mehuys et al. (2011)	Decrease in FBG (after the end of the intervention)	18 months post intervention	Control group	NS
HbA1c				
Mehuys et al. (2011)	Change in HbA1c	6 months	Baseline	Intervention: -0.6% (p<0.001) Control group: NS
Mehuys et al. (2011)	% of patients with target HbA1c (<7%)	6 months	Control group	NS
Mehuys et al. (2011)	Mean HbA1c	18 months post intervention	Control group	NS
Mehuys et al. (2011)	% of patients with target HbA1c	18 months post intervention	Control group	NS
Spence et al. (2014)	Mean HbA1c	-	Control group	Intervention: 8.48 Comparator: 8.8 P=0.024

Spence et al. (2014)	Change in HbA1c	-	Baseline	Intervention: -1.25 (units not specified) Comparator: -0.75 (units not specified) P=0.001
Jahangard-Rafsanjani et al. (2015)	HbA1c	5 months	Control group	NS
Jahangard-Rafsanjani et al. (2015)	HbA1c (sub-group analysis of patients with baseline HbA1c <7%)	5 months	Control group	Intervention: 5.8±0.8 Comparator: 6.7±1.4 P=0.02
Hospital visits				
Spence et al. (2014)	Percentage of patients with ED visit [a]	-	Control group	Intervention: 1.67% Comparator: 4.21% P=0.04
Spence et al. (2014)	Percentage of patients admitted into hospital [a+b]	-	Control group	NS
Spence et al. (2014)	Percentage of patients with ED visit [b]	-	Control group	NS
Tommelein et al. (2013)	Annual hospitalisation rate	-	Control group	Intervention: 0.1 Comparator: 0.4 Rate Ratio: 0.28 (p=0.003)
Tommelein et al. (2013)	Duration of hospital stays	3 months	Control group	NS
Tommelein et al. (2013)	Emergency room visits	3 months	Control group	NS
Tommelein et al. (2013)	Rate of hospitalisation days	3 months	Control group	Intervention: 0.87 Control: 3.51 Rate Ratio: 0.27 (p< 0.0001)
Bouvy et al. (2003)	Total number of hospitalisations, planned admissions, and other hospital admissions	6 months	Control group	NS
Bouvy et al. (2003)	Number of patients with either hospitalisation or death for heart failure	6 months	Control group	NS
Sturgess et al. (2003)	Number of hospitalisations	18 months	Baseline	NS
Sturgess et al. (2003)	At least one hospitalisation	18 months	Control group	NS
Zillich et al. (2005)	Number of hospitalisations or ED visits	3 months	Control group (LO group)	NS
Mehuys et al. (2008)	Number of emergency room visits or hospitalisations (total events)	6 months	Control group	Intervention: 1 Control: 7 Incidence too low to compare statistically

Contact with doctors				
Sturgess et al. (2003)	Number of GP visits	12 months	Control group	P<0.05. During the months 1-12 intervention patients reported higher number of contacts with their GP.
Sturgess et al. (2003)	Number of specialist visits	Months 7-18	Control group	P<0.05. During the months 7-18 intervention patients reported higher number of contacts with their specialists.
Jahangard-Rafsanjani et al. (2015)	At least 1 doctor visit	5 months	Control group	Intervention: 71.7% Comparator: 32.5% P=0.0001
Zillich et al. (2005)	Number of doctor visits	3 months	Control group (LO group)	Intervention (HI group): 20 Comparator (LO group): 56 P=0.007
Asthma and COPD control				
Ottenbros et al. (2014)	Change in mean number of HDTs prescribed from start to end of study	10 months	Control group	NR
Ottenbros et al. (2014)	Change in mean number of HDTs prescribed from start to end of study in patients also using ICS	10 months	Control group	NR
Asthma control				
Mehuys et al. (2008)	Mean ACT score	6 months	Baseline	Intervention: No change
Mehuys et al. (2008)	Mean ACT score change in patients with insufficiently controlled asthma at baseline	6 months	Control group	Intervention: +2.3 Comparator: +0.3 P=0.038
Mehuys et al. (2008)	Need for rescue medication (per day)	3 months	Baseline	Intervention: -0.56 Comparator: -0.03 P=0.012
Mehuys et al. (2008)	Need for rescue medication (per day)	6 months	Baseline	Intervention: -0.57 Control group: -0.43 P=0.012
Mehuys et al. (2008)	Night time awakening	6 months	Control group	Intervention: 10.7±19.3 Comparator: 3.9±9.1 P=0.044
Mehuys et al. (2008)	Peak Expiratory Flow (PEF) morning and evening % predicted	6 months	Control group	NS

Mehuys et al. (2008)	Number of severe asthma exacerbations (total events)	6 months	Control group	NS
Armour et al. (2007)	Proportion of patients classified as having severe asthma	6 months	Baseline	Intervention: 87.9% to 52.7% (p<0.001) Control: 71.2% to 67.9% (p=0.11) Odds ratio: 5.68 (CI 95% 1.64-4.37)
Armour et al. (2007)	FEV_1 and FEV_1/FVC (% predicted)	6 months	Baseline	Intervention: NS Control: NS
COPD control				
Tommelein et al. (2013)	Estimated annual rates of moderate exacerbations	•	Control group	NS
Tommelein et al. (2013)	Estimated annual rates of severe exacerbations	•	Control group	Intervention:0.27 Comparator: 0.61 Rate ratio: 0.45 (p<0.007)
Tommelein et al. (2013)	Frequency of severe exacerbations	3 months	Control group	Intervention:19 Comparator: 33 OR: 0.55 (p<0.038)
Inhaler technique				
Mehuys et al. (2008)	Correct inhalation technique (correct steps)	6 months	Control group	Intervention: 83.7±22.5 Comparator: 93.2±10.7 P=0.004
Tommelein et al. (2013)	Correct inhalation technique (correct steps)	3 months	Control group	Intervention: 93.4% Comparator: 79% Difference: 13.5% (p<0.0001)
Tommelein et al. (2013)	% patients scoring 100% on correct inhalation technique	3 months	Control group	Intervention: 68.5% Comparator: 32.9% OR: 3.03 (p<0.0001)
Armour et al. (2007)	Correct inhaler technique	6 months	Baseline	Intervention: 48.6% (p<0.001)
Depression symptom control				
Rickles et al. (2005)	≥ 50% improvement in Beck Depression Inventory (BDI) -II score	3 months	Baseline	Intervention:75% Control group: 65.6% P≤0.001 for each group.
Rickles et al. (2005)	<50% improvement in Beck Depression Inventory (BDI) -II score	3 months	Control group	NS
Rubio-Valera et al. (2013)	Patient Health Questionnaire (PHQ-9)	6 months	Control group	Intervention: No difference.
Bosmans et al. (2007)	Hopkins Symptom Checklist (SCL-13)	6 months	Control group	NS (also for per-protocol analysis)
Intensification or change of treatment				

Svarstad et al. (2013)	Increased daily dosage or number of BP medicines	6 months	Control group	Intervention: 33% (n=72) Comparator: 25% (n=75) P=0.045
Mehuys et al. (2011)	Changes to hypoglycaemic treatment	6 months	Control group	Intervention: 41.4% Comparator: 24.8% P=0.004
Armour et al. (2007)	Patients with asthma action plan	6 months	Baseline	Intervention: 40.4% (p<0.001)
Jahangard-Rafsanjani et al. (2015)	Drug therapy modifications	5 months	Control group	Intervention: 21.3% Comparator: 7.5% P=0.07
Sturgess et al. (2003)	Number of prescribed medicines	18 months	Baseline	Intervention patients were taking significantly more prescribed medicines during the study compared to baseline, while control patients remained constant (p<0.05).
Zillich et al. (2005)	Number of patients with antihypertensive medications added or increased	3 months	Control group (LO group)	Intervention: 38 patients Comparator: 16 patients
Zillich et al. (2005)	Number of antihypertensive medications added	3 months	Control group (LO group)	Intervention: 29 medications Comparator: 14 medications
Zillich et al. (2005)	Number of antihypertensive medication doses increased or discontinued	3 months	Control group (LO group)	Dose increases: Intervention: 29 and Comparator: 14 Discontinuation: Intervention: 9 and Comparator: 3
Patient satisfaction				
Svarstad et al. (2013)	To adherence monitoring and support by their pharmacists than control	6 months	Control group	Intervention: Higher level of monitoring and support compared to control group.
Jahangard-Rafsanjani et al. (2015)	Patient satisfaction	5 months	-	Intervention: Very high satisfaction scores.
Sturgess et al. (2003)	Patient satisfaction	18 months	Baseline	Intervention: 84.7% thought the service was better than the service received prior to the study. Furthermore, all patients in both the intervention and control rated the services they received as excellent or good.
Rubio-Valera et al. (2013)	Patient satisfaction	3 and 6 months	Control group	Intervention: No difference.
Blenkinsopp et al. (2000)	Patient satisfaction	6 months	Control group	NS

Brook et al. (2003)	Patient satisfaction	3 months	Control group	Intervention: patients were significantly more positive of their experience than control patients ($p<0.001$)
Quality of life				
Robinson et al. (2010)	SF-36 (self-reported)	12 months	Control group	Intervention: larger improvement in physical and social function ($p<0.05$)
Lai. (2007)	SF-12 (self-reported)	9 months	Baseline	NS
Mehuys et al. (2008)	Asthma related Quality of Life Questionnaire (AQLQ)	6 months	Control group	NS
Tommelein et al. (2013)	Modified Medical Research Council (mMRC) dyspnoea scale (COPD disease specific)	3 months	Control group	Intervention: No difference.
Tommelein et al. (2013)	COPD Assessment Test (CAT)	3 months	Control group	NS
Tommelein et al. (2013)	Generic quality of life (EuroQol (EQ-5D utility score) and (EQ-VAS score))	3 months	Control group	NS
Armour et al. (2007)	Asthma related Quality of Life Questionnaire (AQLQ)	6 months	Control group	Intervention: -0.64 Comparator: -0.41 Mean difference: -0.23 ($p=0.05$)
Bouvy et al. (2003)	Minnesota Heart Failure Questionnaire (MHFQ)	6 months	Control group	NS
Bouvy et al. (2003)	Generic quality of life (COOP/WONCA)	6 months	Control group	Intervention: 0.5±3.9 Comparator: -2.5±6.4 P=0.03
Sturgess et al. (2003)	SF-36	Baseline	Control group	At baseline intervention patients reported better quality of life than control patients in all dimensions, significant differences in mental health, physical functioning and vitality dimensions ($p<0.05$)
Sturgess et al. (2003)	SF-36	18 months	Control group	During the study intervention patients QOL declined and control patients QOL improved (significantly for physical functioning and vitality domains ($p<0.05$)).
Rubio-Valera et al. (2013)[x]	EuroQol-5D (EQ-5D)	6 months	Control group	Intervention: 0.25 Comparator: 0.14 A significant time and group interaction was found in EQ-5D tariffs in favour of the intervention group.
Rubio-Valera et al. (2013)	EuroQol-5D (EQ-5D)	6 months	Control group	NS

Patient knowledge				
Mehuys et al. (2011)	Diabetes (Brief Diabetes Knowledge Test)	6 months	Baseline	Intervention: +12.7% ($p<0.001$) Control group: NS
Mehuys et al. (2008)	Asthma	6 months	Baseline	Intervention: No difference.
McKenney et al. (1973)	Hypertension	5 months	Control group	Difference in knowledge between the intervention and control group. $p<0.001$
Rickles et al. (2005)	Depression	3 months	Control group	Intervention:2.54±0.744 Comparator: 2.06±0.929 $P\leq0.05$
Armour et al. (2007)	Consumer Asthma Knowledge score (CQ)	6 months	Control group	Intervention: 1.11 Comparator: -0.07 Mean difference: 1.18 ($p<0.01$)
Sturgess et al. (2003)	Knowledge about medicines	18 months	Baseline	Intervention: NS Control: NS
Economic analysis				
Spence et al. (2014)	Estimated cost avoidance for hospitalisations	-	-	$11,367,548 (USD)
Spence et al. (2014)	Estimated cost avoidance for ED visits	-	-	$272,748 (USD)
Spence et al. (2014)	ROI	-	-	$5.79 (USD) could be saved for every dollar spent on the program.
Sturgess et al. (2003)	Average cost of health care per patient	Baseline, 6, 12, and 18 months	Control group	NS. The average costs of health care per patient compared between the intervention and control group was not statistically significant.
Sturgess et al. (2003)	Average cost of health care per patient	18 months	Baseline	NS. Despite costs for control patients being less during the study compared to before the study, these differences were not significant ($p>0.05$).
Sturgess et al. (2003)	Drug costs	Baseline	Control group	NS. Intervention patients had lower drugs costs compared to control patients however the difference was not statistically significant ($p>0.05$).
Sturgess et al. (2003)	Drug costs	12 months	Control group	NS. Intervention patients incurred lower costs associated with their prescribed medicines compared to control patients, approached statistical significance ($p=0.06$)

Rubio-Valera et al. (2013)	Total costs (indirect and direct costs)	6 months	Control group	NS. Overall costs tended to be higher in the intervention group than the control group, however not significantly so. The largest part of the cost difference (>90%) was due to the difference in indirect costs (productivity loss).
Rubio-Valera et al. (2013)	Intervention costs	6 months	Control group	The intervention costs were significantly higher in the intervention group compared to the control group.
Rubio-Valera et al. (2013)	Cost-effectiveness analysis	6 months	Control group	NS. No statistically significant differences between intervention and control groups in costs or clinical outcomes.
Rubio-Valera et al. (2013)	Incremental cost-effectiveness ratio (ICER)	6 months	Control group	1866 € needs to be invested per extra adherent patient. The intervention group showed higher costs and a small increase in terms of QALYs compared to the control group. Even though costs were higher, the intervention group showed a negative improvement in the remission of depression symptoms; resulting in a negative ICER. ICER is 962 € per extra adherent patient for the intervention group compared to the control group. The ICER was smaller in terms of QALYS (3592 € per one extra remission).
Rubio-Valera et al. (2013)	Cost for remission of symptoms	6 months	Control group	The control group dominated the intervention group (-3946 € per one extra remission).
Rubio-Valera et al. (2013)	Probability of intervention being cost-effective	6 months	Control group	The intervention had a probability of 0.71 (in terms of improving adherence) and 0.75 (in terms of improving QALYs) of being cost-effective when compared to the control group. The intervention is unlikely to be cost-effective in comparison to the control group in terms of symptom remission.
Bosmans et al. (2003)	Utilisation of health care resources	6 months	Control group	NS
Bosmans et al. (2003)	Direct, indirect and/or total costs	6 months	Control group	NS (also for per-protocol analysis)
Bosmans et al. (2003)	Cost-effectiveness	6 months	Control group	Incremental cost-effectiveness ratio for the intervention compared to control was €149 per 1% improvement in adherence and €2550 per

				point improvement in SCL depression score. Authors believe that the intervention is cost-effective as a means of increasing adherence compared to the control. For per-protocol analysis the intervention was found not to be cost-effective compared to control.
Perceived control				
Armour et al. (2007)	Perceived Control of Asthma score (PCAQ)	6 months	Control group	Intervention: -2.53 Comparator: -1.14 Mean difference: -1.39 (-2.44 to -0.35) ($p<0.01$) The improvement in perceived asthma control is significantly greater in the intervention group compared to the control group.
Sturgess et al. (2003)	Sign and symptom control	18 months	Baseline	Intervention: 83.1% (no p-value reported) A significant proportion of intervention patients stated they controlled their medical conditions better than before participation.

NS: observed difference is not statistically significant. NR: statistical significance of observed differences not reported. Rx: pharmacy. PDC: proportion of days covered. MPR: medication possession ratio. DBP: diastolic blood pressure. SBP: systolic blood pressure. LABA: long-acting b2 agonist. LABD: long acting beta-mimetic drug. HDT: oral high dosage corticosteroids or antibiotics. COOP/WONCA: Dartmouth Primary Care Cooperative Information Project/World Organization of National Colleges, Academies and Academic Associations of General Practice /Family Physicians. GP: general practitioner. x: values reported in text of article and table are different (those written in text used). * outcomes reported from two articles by Stewart et al., 2014, and one article from Lau et al., 2010. TABS: Tool for Adherence Behaviour Screening. The study by Spence et al had two intervention groups - a: the diabetes cohort. b: the dyslipidaemia cohort.

Appendix 4 - Ethics approval for matched-cohort study

Health and Disability Ethics Committees

Health and Disability Ethics Committees
Ministry of Health
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28 July 2016

Dr Jeff Harrison
University of Auckland
Level 3
Building 505
85 Park Road
Grafton, Auckland 1142

Dear Dr Harrison

Re:	**HDEC ref:**	**16/NTA/114**
	Study title:	The effect of the Long-Term Conditions (LTC) service on patients' medication adherence and avoidable hospitalisation rates.

Thank you for submitting your application for HDEC review on 25 July 2016. The Secretariat has assessed the information provided in your application and supporting documents against the Standard Operating Procedures.

This application has not been validated, as on the basis of the information you have submitted, it does not appear to be within the scope of HDEC review. This scope is described in section three of the *Standard Operating Procedures for Health and Disability Ethics Committees*.

This study aims to evaluate the effectiveness of the Long-Term Conditions Service. This service was intended for patients with chronic medical conditions who have difficulty adhering to their complex medicine regimens. This research will assess the effectiveness of this service in improving patients' medication adherence and reducing avoidable hospitalisation rates.

As your study is an Audit or related activity it does not require HDEC review as it does not involve the use, collection, or storage of human tissue without consent (paragraph 33 of the Standard Operating Procedures for Health and Disability Ethics Committees).

If you consider that our decision not to validate this application is in error please contact us as soon as possible giving reasons for this.

This letter does not constitute ethical approval or endorsement for the activity described in your application, but may be used as evidence that HDEC review is not required for it.

Please don't hesitate to contact us for further information.

Yours sincerely,

Fox Swindells
Advisor
Health and Disability Ethics Committees
hdecs@moh.govt.nz

Appendix 5 - List of chronic disease medications used for calculating medication adherence for the matched-cohort study

Therapeutic Group 3 (TG3) Name	Generic Medication Name
H_2 antagonists	Cimetidine, Rantidine
Proton pump inhibitors	Lansoprazole, Pantoprazole, Omeprazole
Alpha Glucosidase Inhibitors	Acarbose
Oral Hypoglycaemic Agents	Glibenclamide, Gliclazide, Glipizide, Metformin hydrochloride, Tolbutamide, Pioglitazone
Vitamin D	Alfacalcidol, Cholecalciferol, Calcitriol
Antiplatelet Agents	Aspirin, Clopidogrel, Dipyridamole, Prasugrel
Oral anticoagulants	Warfarin sodium, Rivaroxaban, Dabigatran
Fibrates	Bezafibrate, Gemfibrozil
HMG CoA Reductase Inhibitors (Statins)	Atorvastatin, Simvastatin, Pravastatin
Selective Cholesterol Absorption Inhibitors	Ezetimibe, Ezetimibe with simvastatin
Alpha Adrenoceptor Blockers	Prazosin hydrochloride, Doxazosin mesylate, Terazosin hydrochloride
ACE Inhibitors	Enalapril, Cilazapril, Quinapril, Lisinopril, Perindopril
ACE Inhibitors with Diuretics	Cilazapril with hydrochlorothiazide, Enalapril with hydrochlorothiazide, Lisinopril with hydrochlorothiazide, Quinapril with hydrochlorothiazide
Angiotension II Antagonists	Losartan, Candesartan, Losartan with hydrochlorothiazide
Antiarrhythmics	Amiodarone hydrochloride, Digoxin, Disopyramide phosphate, Flecainide acetate
Antihypotensives	Midodrine
Beta Adrenoceptor Blockers	Atenolol, Labetalol, Metoprolol succinate, Metoprolol tartrate, Nadolol, Pindolol, Propranolol, Sotalol, Timolol maleate, Timolol, Celiprolol, Carvedilol, Bisoprolol fumarate
Dihydropyridine Calcium Channel Blockers (DHP CCBs)	Nifedipine, Felodipine, Isradipine, Amlodipine
Other Calcium Channel Blockers	Perhexiline maleate, Verapamil hydrochloride, Diltiazem hydrochloride
Centrally Acting Agents	Clonidine, Clonidine hydrochloride, Methyldopa
Loop Diuretics	Bumetanide, Furosemide
Potassium Sparing Diuretics	Amiloride, Spironolactone
Potassium Sparing Combination Diuretics	Amiloride with frusemide, Amiloride with hydrochlorothiazide
Thiazide and Related Diuretics	Bendrofluazide, Chlorthalidone, Indapamide
Nitrates	Nicorandil, Isosorbide mononitrate
Vasodilators	Minoxidil, Oxypentifylline
5-Alpha Reductase Inhibitors	Terazosin hydrochloride, Finasteride

Alpha-1A Adrenoreceptor Blockers	Tamsulosin hydrochloride
Other urinary agents	Oxybutynin, Tolterodine L-tartrate, Solifenacin succinate
Thyroid and Antithyroid Agents	Levothyroxine
Hepatitis B Treatment	Lamivudine, Adefovir dipivoxil, Entecavir
Hepatitis B/ HIV/AIDS Treatment	Tenofovir disoproxil fumarate
Non-nucleosides Reverse Transcriptase Inhibitors	Nevirapine, Efavirenz, Etravirine
Nucleosides Reverse Transcriptase Inhibitors	Stavudine [d4T], Zidovudine [AZT] with lamivudine, Zidovudine [AZT], Didanosine (ddI), Didanosine [DDI], Zalcitabine [DDC], Lamivudine, Abacavir sulphate, Abacavir sulphate with lamivudine, Emtricitabine
Protease Inhibitors	Saquinavir, Ritonavir, Indinavir, Nelfinavir, Didanosine (ddI), Lopinavir with ritonavir, Atazanavir sulphate, Darunavir
Strand Transfer Inhibitors	Raltegravir potassium
HIV Fusion Inhibitors	Enfuvirtide
Anticholinesterases	Neostigmine, Pyridostigmine bromide
Antirheumatoid Agents	Penicillamine, Leflunomide
Alendronate for Osteoporosis	Alendronate sodium, Alendronate sodium with cholecalciferol
Alendronate for Paget's disease	Alendronate sodium
Other treatments	Raloxifene hydrochloride
Hyperuricaemia and Antigout	Allopurinol, Probenecid
Dopamine Agonists and Related Agents	Amantadine hydrochloride, Tolcapone, Bromocriptine mesylate, Levodopa with benserazide, Levodopa with carbidopa, Entacapone, Ropinirole hydrochloride, Pramipexole hydrochloride
Anticholinergics	Benztropine mesylate, Procyclidine hydrochloride
Agents for Essential Tremor, Chorea and Related Disorder	Tetrabenazine
Cyclic and Related Agents	Amitriptyline, Clomipramine hydrochloride, Dothiepin hydrochloride, Doxepin hydrochloride, Imipramine hydrochloride, Maprotiline hydrochloride, Nortriptyline hydrochloride, Trimipramine maleate
Monoamine-Oxidase Inhibitors (MAOIs) – Non-Selective	Phenelzine sulphate, Tranylcypromine sulphate
Monoamine-Oxidase Type A Inhibitors	Moclobemide
Selective Serotonin Reuptake Inhibitors	Citalopram hydrobromide, Fluoxetine hydrochloride, Escitalopram, Sertraline, Paroxetine hydrochloride
Other Antidepressants	Venlafaxine, Mirtazapine
Agents for Control of Status Epilepticus	Phenobarbitone sodium, Phenytoin sodium
Control of Epilepsy	Lamotrigine, Vigabatrin, Gabapentin, Topiramate, Oxcarbazepine,

	Carbamazepine, Clobazam, Ethosuximide, Phenytoin sodium, Primidone, Sodium valproate, Phenobarbitone, Levetiracetam, Lacosamide
Antipsychotics – General	Risperidone, Clozapine, Olanzapine, Quetiapine, Quetiapine Fumarate, Zuclopenthixol dihydrochloride, Pericyazine, Lithium carbonate, Ziprasidone, Aripiprazole, Amisulpride, Zuclopenthixol hydrochloride
Orodispersible Antipsychotics	Risperidone, Olanzapine
Stimulants/ADHD treatments	Dexamphetamine sulphate, Methylphenidate hydrochloride, Rivastigmine, Methylphenidate hydrochloride extended-release, Atomoxetine, Modafinil
Treatments for dementia	Donepezil hydrochloride
Treatments for Substance Dependence	Disulfiram, Naltrexone hydrochloride, Bupropion hydrochloride
Cytotoxic Immunosuppressants	Mycophenolate mofetil, Azathioprine
Immunosuppressants	Tacrolimus, Sirolimus
Other Immunosuppressants	Cyclosporin

Appendix 6 - Preliminary analysis for the matched-cohort study

Logistic regression model examining the effect of LTC enrolment and covariates on ASH 6 months after the start of enrolment (n=954,297) (six months post enrolment)

	B	Wald z-statistic	p-value	Adjusted odds ratio (95% CI)
LTC enrolled				
No				1.00
Yes	**0.594**	**23.66**	**$2x10^{-16}$**	**1.812 (1.724-1.903)**
Age (years)				
0 - 24				1.00
25 - 44	**-0.979**	**-25.475**	**$2x10^{-16}$**	**0.376 (0.348-0.405)**
45 - 64	**-0.934**	**-28.780**	**$2x10^{-16}$**	**0.393 (0.369-0.419)**
65 or older	**-0.638**	**-19.641**	**$2x10^{-16}$**	**0.529 (0.496-0.563)**
Prioritised ethnicity				
NZ European				1.00
Māori	**0.455**	**17.022**	**$2x10^{-16}$**	**1.576 (1.495-1.661)**
Pacific	**0.516**	**14.458**	**$2x10^{-16}$**	**1.671 (1.558-1.791)**
Asian	0.015	0.375	0.707	1.015 (0.938-1.097)
Other	-0.009	-0.131	0.896	0.991 (0.862-1.133)
Gender				
Female				1.00
Male	**0.058**	**3.208**	**$1.34x10^{-3}$**	**1.059 (1.023-1.097)**
Deprivation quintile				
1 (least deprived)				1.00
2	0.0366	1.082	0.279	1.037 (0.971-1.108)
3	0.121	3.768	$1.64x10^{-4}$	1.129 (1.060-1.202
4	**0.169**	**5.437**	**$5.41x10^{-8}$**	**1.184 (1.114-1.259)**
5 (most deprived)	**0.261**	**8.298**	**$2x10^{-16}$**	**1.298 (1.221-1.381)**
Care Plus status				
No				1.00
Yes	**0.325**	**13.781**	**$2x10^{-16}$**	**1.384 (1.321-1.449)**
CSC holder				
No				1.00
Yes	**0.425**	**22.265**	**$2x10^{-16}$**	**1.529 (1.473-1.587)**
HUHC status				
No				1.00
Yes	**0.431**	**8.091**	**$5.91x10^{-16}$**	**1.540 (1.385-1.707)**
Count of hospitalisations before enrolment				
0				1.00
1	**0.472**	**16.745**	**$2x10^{-16}$**	**1.603 (1.517-1.694)**
2	**0.762**	**25.828**	**$2x10^{-16}$**	**2.143 (2.022-2.271)**
≥3	**1.265**	**48.015**	**$2x10^{-16}$**	**3.544 (3.365-3.731)**
Charlson comorbidity index before enrolment				
0				1.00
1-2	**1.100**	**42.479**	**$2x10^{-16}$**	**3.004 (2.856-3.161)**
≥3	**1.141**	**22.476**	**$2x10^{-16}$**	**3.131 (2.832-3.456)**
Count of high risk meds before enrolment				
≤5				1.00
6-8	**0.338**	**11.932**	**$2x10^{-16}$**	**1.402 (1.326-1.481)**
≥9	**0.647**	**10.434**	**$2x10^{-16}$**	**1.911 (1.689-2.154)**
% patients adherent before enrolment				
Non-adherent				1.00
Adherent	**0.123**	**4.383**	**$1.17x10^{-5}$**	**1.130 (1.070-1.194)**

Logistic regression model examining the effect of LTC enrolment and covariates on ASH 12 months after the start of enrolment (n=954,297) (12 months post enrolment)

	B	Wald z-statistic	p-value	Adjusted odds ratio (95% CI)
LTC enrolled				
No				1.00
Yes	**0.682**	**35.348**	**$2x10^{-16}$**	**1.978 (1.905-2.054)**
Age (years)				
0 - 24				1.00
25 - 44	**-0.917**	**-31.073**	**$2x10^{-16}$**	**0.400 (0.377-0.423)**
45 - 64	**-0.899**	**-35.579**	**$2x10^{-16}$**	**0.407 (0.387-0.428)**
65 or older	**-0.553**	**-21.901**	**$2x10^{-16}$**	**0.575 (0.548-0.605)**
Prioritised ethnicity				
NZ European				1.00
Māori	**0.472**	**22.957**	**$2x10^{-16}$**	**1.603 (1.540-1.669)**
Pacific	**0.529**	**19.252**	**$2x10^{-16}$**	**1.697 (1.607-1.790)**
Asian	0.017	0.565	0.572	1.017 (0.958-1.079)
Other	0.079	1.560	0.119	1.083 (0.978-1.195)
Gender				
Female				1.00
Male	**0.074**	**5.440**	**$5.33x10^{-8}$**	**1.077 (1.049-1.106)**
Deprivation quintile				
1 (least deprived)				1.00
2	0.059	2.318	**$2.04x10^{-2}$**	1.061 (1.009-1.115)
3	0.154	6.337	$2.34x10^{-10}$	1.167 (1.112-1.224)
4	**0.203**	**8.608**	**$2x10^{-16}$**	**1.225 (1.170-1.283)**
5 (most deprived)	**0.306**	**12.798**	**$2x10^{-16}$**	**1.357 (1.295-1.423)**
Care Plus status				
No				1.00
Yes	**0.356**	**19.730**	**$2x10^{-16}$**	**1.427 (1.377-1.478)**
CSC holder				
No				1.00
Yes	**0.423**	**29.171**	**$2x10^{-16}$**	**1.526 (1.483-1.570)**
HUHC status				
No				1.00
Yes	**0.491**	**11.869**	**$2x10^{-16}$**	**1.633 (1.505-1.770)**
Count of hospitalisations before enrolment				
0				1.00
1	**0.435**	**20.759**	**$2x10^{-16}$**	**1.545 (1.483-1.610)**
2	**0.697**	**31.081**	**$2x10^{-16}$**	**2.007 (1.920-2.097)**
≥3	**1.158**	**57.343**	**$2x10^{-16}$**	**3.184 (3.060-3.313)**
Charlson comorbidity index before enrolment				
0				1.00
1-2	**1.021**	**50.106**	**$2x10^{-16}$**	**2.777 (2.668-2.890)**
≥3	**1.044**	**24.987**	**$2x10^{-16}$**	**2.841 (2.616-3.082)**
Count of high risk meds before enrolment				
≤5				1.00
6-8	**0.377**	**17.415**	**$2x10^{-16}$**	**1.458 (1.398-1.521)**
≥9	**0.834**	**17.338**	**$2x10^{-16}$**	**2.303 (2.094-2.528)**
% patients adherent before enrolment				
Non-adherent				1.00
Adherent	**0.151**	**7.064**	**$1.61x10^{-12}$**	**1.163 (1.116-1.213)**

Logistic regression model examining the effect of LTC enrolment and covariates on ASH three months after the end of enrolment (n=954,297) (three months post-end)

	B	Wald z-statistic	p-value	Adjusted odds ratio (95% CI)
LTC enrolled				
No				1.00
Yes	**0.532**	**16.51**	**$2x10^{-16}$**	**1.703 (1.599-1.814)**
Age (years)				
0 - 24				1.00
25 - 44	**-0.739**	**-13.652**	**$2x10^{-16}$**	**0.478 (0.430-0.531)**
45 - 64	**-0.663**	**-14.331**	**$2x10^{-16}$**	**0.515 (0.471-0.565)**
65 or older	**-0.240**	**-5.236**	**$1.64x10^{-7}$**	**0.786 (0.719-0.861)**
Prioritised ethnicity				
NZ European				1.00
Māori	**0.556**	**16.344**	**$2x10^{-16}$**	**1.743 (1.630-1.863)**
Pacific	**0.579**	**12.838**	**$2x10^{-16}$**	**1.784 (1.632-1.948)**
Asian	0.020	0.390	0.697	1.020 (0.921-1.127)
Other	0.059	0.651	0.515	1.060 (0.885-1.260)
Gender				
Female				1.00
Male	**0.153**	**6.652**	**$2.89x10^{-11}$**	**1.165 (1.114-1.219)**
Deprivation quintile				
1 (least deprived)				1.00
2	0.013	0.306	0.760	1.013 (0.931-1.104)
3	0.138	3.361	$7.77x10^{-4}$	1.148 (1.059-1.244)
4	**0.165**	**4.135**	**$3.55x10^{-5}$**	**1.180 (1.091-1.276)**
5 (most deprived)	**0.257**	**6.360**	**$2.02x10^{-10}$**	**1.293 (1.195-1.399)**
Care Plus status				
No				1.00
Yes	**0.426**	**14.653**	**$2x10^{-16}$**	**1.531 (1.446-1.620)**
CSC holder				
No				1.00
Yes	**0.418**	**17.075**	**$2x10^{-16}$**	**1.519 (1.448-1.594)**
HUHC status				
No				1.00
Yes	**0.447**	**6.521**	**$7x10^{-11}$**	**1.564 (1.364-1.784)**
Count of hospitalisations before enrolment				
0				1.00
1	**0.319**	**8.764**	**$2x10^{-16}$**	**1.376 (1.281-1.478)**
2	**0.509**	**12.962**	**$2x10^{-16}$**	**1.663 (1.539-1.796)**
≥3	**1.002**	**28.807**	**$2x10^{-16}$**	**2.723 (2.543-2.915)**
Charlson comorbidity index before enrolment				
0				1.00
1-2	**1.041**	**29.348**	**$2x10^{-16}$**	**2.757 (2.576-2.950)**
≥3	**1.095**	**16.785**	**$2x10^{-16}$**	**2.989 (2.626-3.391)**
Count of high risk meds before enrolment				
≤5				1.00
6-8	**0.393**	**11.285**	**$2x10^{-16}$**	**1.481 (1.383-1.585)**
≥9	**0.703**	**9.389**	**$2x10^{-16}$**	**2.020 (1.740-2.334)**
% patients adherent before enrolment				
Non-adherent				1.00
Adherent	**0.206**	**5.409**	**$6.34x10^{-8}$**	**1.228 (1.141-1.324)**

Logistic regression model examining the effect of LTC enrolment and covariates on ASH Six months after the end of enrolment (n=954,297) (six months post-end)

	B	Wald z-statistic	p-value	Adjusted odds ratio (95% CI)
LTC enrolled				
No				1.00
Yes	**0.495**	**20.517**	**$2x10^{-16}$**	**1.641 (1.565-1.720)**
Age (years)				
0 - 24				1.00
25 - 44	**-0.732**	**-18.328**	**$2x10^{-16}$**	**0.481 (0.445-0.520)**
45 - 64	**-0.643**	**-18.796**	**$2x10^{-16}$**	**0.526 (0.492-0.562)**
65 or older	**-0.176**	**-5.186**	**$2.15x10^{-7}$**	**0.839 (0.785-0.897)**
Prioritised ethnicity				
NZ European				1.00
Māori	**0.535**	**21.264**	**$2x10^{-16}$**	**1.708 (1.626-1.794)**
Pacific	**0.539**	**15.913**	**$2x10^{-16}$**	**1.714 (1.603-1.831)**
Asian	0.020	0.528	0.597	1.020 (0.947-1.097)
Other	0.050	0.768	0.443	1.052 (0.923-1.193)
Gender				
Female				1.00
Male	**0.119**	**7.127**	**$1.02x10^{-12}$**	**1.127 (1.090-1.165)**
Deprivation quintile				
1 (least deprived)				1.00
2	-0.015	-0.462	0.644	0.986 (0.927-1.048)
3	0.114	3.833	$1.27x10^{-4}$	1.121 (1.057-1.188)
4	**0.171**	**5.930**	**$3.02x10^{-9}$**	**1.186 (1.121-1.255)**
5 (most deprived)	**0.270**	**9.276**	**$2x10^{-16}$**	**1.310 (1.238-1.388)**
Care Plus status				
No				1.00
Yes	**0.399**	**18.515**	**$2x10^{-16}$**	**1.490 (1.428-1.554)**
CSC holder				
No				1.00
Yes	**0.429**	**24.064**	**$2x10^{-16}$**	**1.536 (1.483-1.590)**
HUHC status				
No				1.00
Yes	**0.469**	**9.268**	**$2x10^{-16}$**	**1.598 (1.445-1.763)**
Count of hospitalisations before enrolment				
0				1.00
1	**0.3328**	**12.764**	**$2x10^{-16}$**	**1.395 (1.325-1.468)**
2	**0.5104**	**17.939**	**$2x10^{-16}$**	**1.666 (1.575-1.761)**
≥3	**0.9616**	**37.637**	**$2x10^{-16}$**	**2.616 (2.488-2.750)**
Charlson comorbidity index before enrolment				
0				1.00
1-2	**0.997**	**38.935**	**$2x10^{-16}$**	**2.710 (2.577-2.849)**
≥3	**1.028**	**20.270**	**$2x10^{-16}$**	**2.795 (2.529-3.085)**
Count of high risk meds before enrolment				
≤5				1.00
6-8	**0.419**	**16.358**	**$2x10^{-16}$**	**1.521 (1.446-1.599)**
≥9	**0.766**	**13.457**	**$2x10^{-16}$**	**2.151 (1.922-2.402)**
% patients adherent before enrolment				
Non-adherent				1.00
Adherent	**0.246**	**8.773**	**$2x10^{-16}$**	**1.278 (1.210-1.351)**

Logistic regression model examining the effect of LTC enrolment and covariates on medication adherence 12 months after enrolment (n=954,297) (12 months post enrolment)

	B	Wald z-statistic	p-value	Adjusted odds ratio (95% CI)
LTC enrolled				
No				1.00
Yes	**1.192**	**38.343**	**$2x10^{-16}$**	**3.294 (3.101-3.503)**
Age (years)				
0 - 24				1.00
25 - 44	**0.251**	**20.213**	**$2x10^{-16}$**	**1.285 (1.255-1.317)**
45 - 64	**0.689**	**58.964**	**$2x10^{-16}$**	**1.992 (1.947-2.039**
65 or older	**1.257**	**94.275**	**$2x10^{-16}$**	**3.156 (3.425-3.609)**
Prioritised ethnicity				
NZ European				1.00
Māori	**-0.313**	**-27.037**	**$2x10^{-16}$**	**0.731 (0.715-0.748)**
Pacific	**-0.539**	**-34.978**	**$2x10^{-16}$**	**0.583 (0.566-0.601)**
Asian	-0.428	-35.024	**$2x10^{-16}$**	0.652 (0.637-0.668)
Other	-0.223	-10.185	**$2x10^{-16}$**	0.800 (0.766-0.835)
Gender				
Female				1.00
Male	**-0.011**	**-1.546**	**0.122**	**0.989 (0.976-1.003)**
Deprivation quintile				
1 (least deprived)				1.00
2	0.012	1.078	0.281	1.012 (0.990-1.034)
3	0.052	4.757	**$1.96x10^{-6}$**	1.054 (1.031-1.077)
4	**0.071**	**6.460**	**$1.05x10^{-10}$**	**1.074 (1.051-1.097)**
5 (most deprived)	**0.013**	**1.143**	**0.253**	**1.013 (0.991-1.036)**
Care Plus status				
No				1.00
Yes	**0.328**	**21.359**	**$2x10^{-16}$**	**1.388 (1.347-1.431)**
CSC holder				
No				1.00
Yes	**0.109**	**12.401**	**$2x10^{-16}$**	**1.115 (1.096-1.134)**
HUHC status				
No				1.00
Yes	**0.530**	**10.594**	**$2x10^{-16}$**	**1.699 (1.542-1.876)**
Count of hospitalisations before enrolment				
0				1.00
1	**-0.005**	**-0.432**	**0.666**	**0.995 (0.974-1.017)**
2	**0.038**	**2.571**	**0.010**	**1.039 (1.009-1.069)**
≥3	**0.048**	**3.044**	**$2.33x10^{-3}$**	**1.050 (1.017-1.083)**
Charlson comorbidity index before enrolment				
0				1.00
1-2	**0.255**	**10.492**	**$2x10^{-16}$**	**1.291 (1.231-1.354)**
≥3	**0.089**	**1.405**	**0.160**	**1.093 (0.967-1.240)**
Count of high risk meds before enrolment				
≤5				1.00
6-8	**0.887**	**28.697**	**$2x10^{-16}$**	**2.428 (2.287-2.581)**
≥9	**1.112**	**8.347**	**$2x10^{-16}$**	**3.040 (2.365-3.994)**
% patients adherent before enrolment				
Non-adherent				1.00
Adherent	**1.897**	**266.211**	**$2x10^{-16}$**	**6.664 (6.572-6.758)**

Logistic regression model examining the effect of LTC enrolment and covariates on medication adherence 12 months after the end of enrolment (n=954,297) (12 months post end)

	B	Wald z-statistic	p-value	Adjusted odds ratio (95% CI)
LTC enrolled				
No				1.00
Yes	**0.433**	**20.615**	**$2x10^{-16}$**	**1.541 (1.480-1.606)**
Age (years)				
0 - 24				1.00
25 - 44	**0.381**	**31.873**	**$2x10^{-16}$**	**1.463 (1.429-1.498)**
45 - 64	**0.920**	**81.432**	**$2x10^{-16}$**	**2.509 (2.454-2.565)**
65 or older	**1.301**	**103.218**	**$2x10^{-16}$**	**3.674 (3.585-3.766)**
Prioritised ethnicity				
NZ European				1.00
Māori	**-0.236**	**-20.781**	**$2x10^{-16}$**	**0.790 (0.772-0.808)**
Pacific	**-0.413**	**-27.131**	**$2x10^{-16}$**	**0.662 (0.642-0.682)**
Asian	-0.364	-30.244	**$2x10^{-16}$**	0.695 (0.678-0.711)
Other	-0.271	-12.873	**$2x10^{-16}$**	0.762 (0.731-0.795)
Gender				
Female				1.00
Male	**-0.009**	**-1.327**	**0.184**	**0.991 (0.978-1.004)**
Deprivation quintile				
1 (least deprived)				1.00
2	0.053	4.895	**$9.81x10^{-7}$**	1.054 (1.032-1.077)
3	0.082	7.660	**$1.85x10^{-14}$**	1.085 (1.063-1.109)
4	**0.095**	**8.875**	**$2x10^{-16}$**	**1.099 (1.077-1.123)**
5 (most deprived)	**0.069**	**6.173**	**$6.69x10^{-10}$**	**1.072 (1.048-1.096)**
Care Plus status				
No				1.00
Yes	**0.232**	**16.563**	**$2x10^{-16}$**	**1.261 (1.227-1.296)**
CSC holder				
No				1.00
Yes	**0.041**	**4.952**	**$7.35x10^{-7}$**	**1.042 (1.025-1.059)**
HUHC status				
No				1.00
Yes	**0.012**	**0.309**	**0.757**	**1.012 (0.940-1.090)**
Count of hospitalisations before enrolment				
0				1.00
1	**0.021**	**1.969**	**0.049**	**1.021 (1.000-1.043)**
2	**0.061**	**4.272**	**$1.94x10^{-5}$**	**1.063 (1.033-1.093)**
≥3	**-0.037**	**-2.528**	**0.012**	**0.964 (0.936-0.992)**
Charlson comorbidity index before enrolment				
0				1.00
1-2	**-0.109**	**-5.392**	**$6.97x10^{-8}$**	**0.896 (0.861-0.933)**
≥3	**-0.775**	**-18.086**	**$2x10^{-16}$**	**0.461 (0.424-0.501)**
Count of high risk meds before enrolment				
≤5				1.00
6-8	**0.450**	**19.737**	**$2x10^{-16}$**	**1.569 (1.501-1.641)**
≥9	**0.134**	**1.951**	**0.051**	**1.143 (1.002-1.312)**
% patients adherent before enrolment				
Non-adherent				1.00
Adherent	**1.461**	**203.630**	**$2x10^{-16}$**	**4.310 (4.250-4.371)**

Appendix 7 - Ethics approval for pharmacist interviews and pharmacy observations

Research Office
Post–Award Support Services

The University of Auckland
Private Bag 92019
Auckland, New Zealand

Level 10, 49 Symonds Street
Telephone: 64 9 373 7599
Extension: 83711
Facsimile: 64 9 373 7432
ro-ethics@auckland.ac.nz

UNIVERSITY OF AUCKLAND HUMAN PARTICIPANTS ETHICS COMMITTEE (UAHPEC)

17-Aug-2018

MEMORANDUM TO:

Dr Jeffrey Harrison
Pharmacy

Re: Request for change of Ethics Approval (Our Ref. 018178): Amendments Approved

The Committee considered your request for change for your study entitled **An exploration of community pharmacies with respect to Long-Term Conditions (LTC) service delivery.** and approval was granted for the following amendments on 17-Aug-2018.

The Committee approved the following amendments:

1. Changing the study title from: "An exploration of community pharmacies with respect to Long-Term Conditions (LTC) service delivery", to: "An exploration into the delivery of the Long Term Conditions (LTC) service in New Zealand community pharmacies".

2. Amending the interview schedule.

3. Undertaking telephone interviews with pharmacists instead of face-to-face interviews.

4. Using the interviews to identify community pharmacies for observation.

5. Observing the pharmacies to see how they use the management plans in real-life instead of requesting pharmacists to provide 30 LTC management plans.

6. Changing the study protocol to include telephone interviews with pharmacists until data saturation occurs (~20-30 interviews) instead of using 6 case studies as approved in the initial application. Certain pharmacies whose pharmacists have conveyed interesting or unusual findings will be asked for consent for observing their pharmacy for one day. Approximately 6 pharmacies in different parts of New Zealand will be included in the observation aspect of the study.

The expiry date for this approval is 06-Dec-2019.

If the project changes significantly you are required to resubmit a new application to the Committee for further consideration.

In order that an up-to-date record can be maintained, it would be appreciated if you could notify the Committee once your study is completed.

The Chair and the members of the Committee would be happy to discuss general matters relating to ethics approvals. If you wish to do so, please contact the UAHPEC Ethics Administrators at ro-ethics@auckland.ac.nz in the first instance.

Please quote reference number **018178** on all communications with the UAHPEC regarding this application.

(This is a computer generated letter. No signature required.)

UAHPEC Administrators
University of Auckland Human Participants Ethics Committee

c.c. Head of Department / School, Pharmacy
Dr Trudi Aspden
Miss Aleksandra Milosavljevic

Appendix 8 - Consent form for pharmacy managers or pharmacy owners

THIS FORM WILL BE HELD FOR A PERIOD OF 6 YEARS

An exploration into the delivery of the Long Term Conditions (LTC) service in New Zealand community pharmacies

Research team:
Principle investigator: Associate Professor Jeff Harrison, Head of School, School of Pharmacy, jeff.harrison@auckland.ac.nz
Co-investigators: Dr Trudi Aspden, Lecturer, School of Pharmacy, t.aspden@auckland.ac.nz
PhD student: Miss Aleksandra Milosavljevic, School of Pharmacy, a.milosavljevic@auckland.ac.nz

……

I have read the Participant Information Sheet, have understood the nature of the research, and why I have been selected. I have had the opportunity to ask questions and have had them answered to my satisfaction.

- I agree to take part in this research. Participation in this study involves:
  - A pharmacist undertaking a telephone interview about LTC service provision with a member of the research team (Aleksandra Milosavljevic).
  - Pharmacy owner/manager completing a brief questionnaire about the pharmacy characteristics.
- I give permission to be approached for the observation phase: **YES / NO** Pharmacist activities, interactions and conversations taking place in the pharmacy will be observed. Please note if you decline the observation, this does not prevent a pharmacist at your pharmacy providing an interview.
- I understand that I am free to withdraw my pharmacy from participation at any time, and to withdraw any data traceable to me, my pharmacy and staff no later than one week after the interview has taken place (for interview data) and one week after observation has taken place (for observation data)
- I **wish** to receive the summary of findings: **YES / NO**
- I understand that data will be kept for 6 years, after which they will be destroyed.
- I understand that the identity of the pharmacies, pharmacy owners/managers, pharmacists and patients will remain confidential in all publications and presentations arising from this project.
- I give my assurance that participation or non-participation of employees will not affect their employment or relationship with the organisation.

Name: …… [Please print]

Signature: ……

Date: ……

Email: ……

Please return the completed Consent Form to a.milosavljevic@auckland.ac.nz

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Approved by the University of Auckland Human Participants Ethics Committee on 6th December 2016 for three years. Reference number 018178

Appendix 9 - Consent form for community pharmacists

THIS FORM WILL BE HELD FOR A PERIOD OF 6 YEARS
An exploration into the delivery of the Long Term Conditions (LTC) service in New Zealand community pharmacies

Research team:
Principle investigator: Associate Professor Jeff Harrison, Head of School, School of Pharmacy, jeff.harrison@auckland.ac.nz
Co-investigators: Dr Trudi Aspden, Lecturer, School of Pharmacy, t.aspden@auckland.ac.nz
PhD student: Miss Aleksandra Milosavljevic, School of Pharmacy, a.milosavljevic@auckland.ac.nz

……

I have read the Participant Information Sheet, have understood the nature of the research, and why I have been selected. I have had the opportunity to ask questions and have had them answered to my satisfaction.

- I agree to take part in this research. Participation in this study involves:
  - A pharmacist undertaking a telephone interview about LTC service provision with a member of the research team (Aleksandra Milosavljevic).
  - Pharmacy owner/manager completing a brief questionnaire about the pharmacy characteristics.
- I understand a member of the research team (Aleksandra) will observe a sample of pharmacies after the interviews and this may or may not be your pharmacy. Pharmacist activities, interactions and conversations taking place in the pharmacy will be observed. I understand that I can take part in the interviews even if my owner/manager does not consent to the observation phase.
- I understand that I am free to withdraw at any time, and to withdraw any data traceable to me no later than a week after the interview has taken place
- I **wish** to receive the summary of findings: **YES / NO**
- I understand that data will be kept for 6 years, after which they will be destroyed.
- I understand that the identity of the pharmacies, pharmacy owners/managers, pharmacists and patients will remain confidential in all publications and presentations arising from this project.
- I understand that the owner/manager has given an assurance that participation or non-participation of employees will not affect their employment or relationship with the organisation.

Name: ……..…… [Please print]

Signature: ……

Date: ……..……

Email: ……

Please return the completed Consent Form to a.milosavljevic@auckland.ac.nz

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Approved by the University of Auckland Human Participants Ethics Committee on 6th December 2016 for three years. Reference number 018178

Appendix 10 - Participant information sheet for pharmacy managers or pharmacy owners

An exploration into the delivery of the Long Term Conditions (LTC) service in New Zealand community pharmacies

The University of Auckland
Private Bag 92019
Auckland
New Zealand

School of Pharmacy
Faculty of Medical and Health Sciences
Associate Professor Jeff Harrison
Telephone: +64 9 923 2144
Facsimile: +64 9 367 7192
Email: jeff.harrison@auckland.ac.nz
www.fmhs.auckland.ac.nz

This Participant Information Sheet (PIS) aims to help you decide whether to agree to your pharmacy participating in this study.

Research team:
Principle investigator: Associate Professor Jeff Harrison, Head of School, School of Pharmacy.
Co-investigators: Dr Trudi Aspden, Lecturer, School of Pharmacy.
PhD student: Miss Aleksandra Milosavljevic, School of Pharmacy.

Researcher Introduction:
I am Aleksandra Milosavljevic and I am a PhD student at the University of Auckland, School of Pharmacy. My supervisor is Associate Professor Jeff Harrison, Head of School, School of Pharmacy.

Background Information:
As the pharmacy manager/owner you are invited to participate in a study which is happening from August to December 2018.

The study will describe community pharmacists' perspectives, with respect to the Long Term Conditions (LTC) service delivery. We will explore pharmacists' views and experiences with LTC service provision and explore the factors that contribute to their LTC service provision. We also want to understand what services are provided to patients as part of LTC.

Participation in the study:
Participation in this study would involve a pharmacist, who is most involved in providing LTC in your pharmacy, undertaking a telephone interview with a member of the research team (Aleksandra). Consenting pharmacists will be asked to read the Patient Information Sheet (PIS) and to complete the Consent Form (CF).

As the pharmacy owner/manager you will be asked to complete a brief questionnaire about your pharmacy characteristics. This should be emailed back to the research team at a.milosavljevic@auckland.ac.nz, together with the signed CFs. This may be shown to your pharmacist participant if they wish to see the responses during the interview.

One pharmacist, who is most involved in LTC service provision (this could be you), will be asked to participate in a 30 to 60 minute telephone interview with Aleksandra, who will ask them questions about LTC service delivery. The interviews will take place at a time which suits the pharmacist. Pharmacists will receive a $20 supermarket voucher for their contribution to this study. After completion of the interviews, the pharmacist will be given the opportunity to review and edit their transcripts.

After the analysis of the interviews is complete the second phase of this research involves a day long observation of a sample of community pharmacies, to see first-hand how LTC is delivered. A member of the research team (Aleksandra) will unobtrusively visit and spend time observing LTC activities in a sample of pharmacies to gain greater insight into the delivery of LTC. During the observation, which may last up to a day, pharmacists' activities and patient interactions will be observed. This will happen in consultation with the pharmacy manager to ensure that Aleksandra's presence is discrete and does not distract staff or customers or hinder usual pharmacy business. The observation will also take place on a day that suits you and your team. Participation in the observation phase is completely voluntary as indicated on the consent form. Even if you do not give permission for the observation your pharmacy can still participate in the first phase (interviews).

Participation in this research is entirely voluntary. You can withdraw your participation at any time without giving a reason, no later than one week after the interview has taken place (for interview data) and one week after observation has taken place (for observation data).

We seek your assurance that participation or non-participation of employees will not affect their employment or relationship with the organisation.

Risk and benefits:
There are no direct risks or benefits to you, your pharmacy, staff or patients for participating in this study. By participating in this research pharmacists will be able to express their views and experiences about LTC service delivery. They will provide valuable insight for the researchers and contribute to improving community pharmacy services in New Zealand. The researchers will be able to provide feedback to pharmacies about this. If any incidental findings emerge from the study, the pharmacist and pharmacy manager/owner will be informed.

Anonymity and confidentiality:
If you decide to participate, the research processes will provide confidentiality for you, your pharmacy and pharmacists. Your participation will only be known to the research team. The results from this research will be used in the write up of a PhD thesis. The results may also be presented at conferences and/or published in peer-reviewed journals. This will be done in a way that does not identify your pharmacy nor your pharmacists or patients.

Data storage and retention:
Study data will be stored securely on a password protected computer at the University of Auckland and paper-based data will be stored in a locked cabinet. All data will be stored for six years, then securely destroyed by deletion (electronic documents) and shredding (paper documents). Interviews will be recorded using a digital recorder and transcribed by a member of the research team and/or a professional transcriber. The professional transcriber will not be provided with any identifiable information about participants. The recordings will be deleted after transcription. Each pharmacist will be assigned a unique identifier. A document will be securely stored which links the pharmacists' unique identifier and their interview recording and transcription.

Right to withdraw from participation:
You may withdraw from this study at any time up to one week after the interview has taken place (for interview data) and one week after observation has taken place (for observation data). If you wish to withdraw, you may do so by contacting and informing the principal investigator Associate Professor Jeff Harrison (Email: jeff.harrison@auckland.ac.nz, Phone: +64 9 923 2144).

Study results:
If you participate in the study and wish to receive a summary of the results, please indicate this on the Consent Form. A summary will be emailed to you once the results are available.

Project funding:
The research is funded by the Postgraduate Research Student Support (PReSS) at the University of Auckland. Funding for Aleksandra's PhD has been provided by Vernon Tews Educational Trust.

Contact details:
If you have any queries about the study or would like a summary of the results upon completion of the data analysis stage, please contact the principal investigator Associate Professor Jeff Harrison, who is Head of Pharmacy School, Email: jeff.harrison@auckland.ac.nz, Phone: +64 9 923 2144. Alternatively, you can contact Professor John Fraser, Dean at the Faculty and Medical Health Sciences at The University of Auckland, Email: j.fraser@auckland.ac.nz, Phone: +64 9 923 6036.
Co-investigators: Dr Trudi Aspden (t.aspden@auckland.ac.nz), Miss Aleksandra Milosavljevic (a.milosavljevic@auckland.ac.nz).

Support and advocacy:
For any questions regarding ethical concerns please contact the Chair, The University of Auckland Human Participants Ethics Committee, The University of Auckland, Research Office, Private Bag 92019, Auckland 1142. Phone: 09 3737599 ext 83711. Email: ro-ethics@auckland.ac.nz

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Approved by the University of Auckland Human Participants Ethics Committee on 6th December 2016 for three years. Reference number 018178

Appendix 11 - Participant information sheet for community pharmacists

An exploration into the delivery of the Long Term Conditions (LTC) service in New Zealand community pharmacies

The University of Auckland
Private Bag 92019
Auckland
New Zealand

School of Pharmacy
Faculty of Medical and Health Sciences
Associate Professor Jeff Harrison
Telephone: +64 9 923 2144
Facsimile: +64 9 367 7192
Email: jeff.harrison@auckland.ac.nz
www.fmhs.auckland.ac.nz

This Participant Information Sheet (PIS) aims to help you decide whether to agree to participate in this study.

Research team:
Principle investigator: Dr Jeff Harrison, Head of School, School of Pharmacy.
Co-investigators: Dr Trudi Aspden, Lecturer, School of Pharmacy.
PhD student: Miss Aleksandra Milosavljevic, School of Pharmacy.

Researcher Introduction:
I am Aleksandra Milosavljevic and I am a PhD student at the University of Auckland, School of Pharmacy. My supervisor is Associate Professor Jeff Harrison, Head of School, School of Pharmacy.

Background Information:
As a community pharmacist working with patients enrolled in the Long Term Conditions (LTC) service, you are invited to participate in a study which is happening from August to December 2018.

The study will describe community pharmacists' perspectives, with respect to the Long Term Conditions (LTC) service delivery. We will explore pharmacists' views and experiences with LTC service provision and explore the factors that contribute to their LTC service provision. We also want to understand what services are provided to patients as part of LTC.

Participation in the study:
Participation in this study would involve you undertaking a telephone interview with Aleksandra, a member of the research team. Consenting pharmacists will be asked to read the Patient Information Sheet (PIS) and to complete the Consent Form (CF).

If you agree to participate you will have a 30 to 60 minute telephone interview with Aleksandra, who will ask you questions about LTC service delivery. The telephone interview will take place at a time that suits you. You will receive a $20 supermarket voucher for your contribution to this study. After completion of the interviews, you will be given the opportunity to review and edit your transcript.

Your pharmacy owner/manager has completed a brief questionnaire about your pharmacy characteristics. You will be able to see this if you wish.

We will also be undertaking a day long observation in a sample of community pharmacies, to see first-hand how LTC is delivered. This may or may not be your pharmacy, as the sample of pharmacies will be identified after the interviews. Your owner/manager will need to consent to observation to be considered for this sample. You will still be able to participate in the interviews even if your owner/manager does not consent to observation.

Participation in this research is entirely voluntary. You can withdraw your participation at any time without giving a reason, no later than one week after the interview has taken place.

We have assurance from your owner/manager that your participation or non-participation will not affect your employment or relationship with the organisation.

Risk and benefits:
There are no direct risks or benefits to you, your pharmacy, pharmacy colleagues or patients for participating in this study. By participating in this research pharmacists will be able to express their views and experiences about LTC service delivery. They will provide valuable insight for the researchers and contribute to improving community pharmacy services in New Zealand. The researchers will be able to provide feedback to pharmacies about this. If any incidental findings emerge from the study, the pharmacist and pharmacy manager/owner will be informed.

Anonymity and confidentiality:
If you decide to participate, the research processes will provide confidentiality for you, your pharmacy and pharmacy colleagues. Your participation will only be known to the research team. The results from this research will be used in the write up of a PhD thesis. The results may also be presented at conferences and/or published in peer-reviewed journals. This will be done in a way that does not identify you, your pharmacy nor your pharmacy colleagues or patients.

Data storage and retention:
Study data will be stored securely on a password protected computer at the University of Auckland and paper-based data will be stored in a locked cabinet. All data will be stored for six years, then securely destroyed by deletion (electronic documents) and shredding (paper documents). Interviews will be recorded using a digital recorder and transcribed by a member of the research team and/or a professional transcriber. The professional transcriber will not be provided with any identifiable information about participants. The recordings will be deleted after transcription. Each pharmacist will be assigned a unique identifier. A document will be securely stored which links the pharmacists' unique identifier and their interview recording and transcription.

Right to withdraw from participation:
You may withdraw from this study at any time up to one week after the interview has taken place. If you wish to withdraw, you may do so by contacting and informing the principal investigator Associate Professor Jeff Harrison (Email: jeff.harrison@auckland.ac.nz, Phone: +64 9 923 2144).

Study results:
If you participate in the study and wish to receive a summary of the results, please indicate this on the Consent Form. A summary will be sent to you once the results are available.

Project funding:
The research is funded by the Postgraduate Research Student Support (PReSS) at the University of Auckland. Funding for Aleksandra's PhD has been provided by Vernon Tews Educational Trust.

Contact details:
If you have any queries about the study or would like a summary of the results upon completion of the data analysis stage, please contact the principal investigator Associate Professor Jeff Harrison, who is Head of Pharmacy School, Email: jeff.harrison@auckland.ac.nz, Phone: +64 9 923 2144. Alternatively, you can contact Professor John Fraser, Dean at the Faculty and Medical Health Sciences at The University of Auckland, Email: j.fraser@auckland.ac.nz, Phone: +64 9 923 6036.
Co-investigators: Dr Trudi Aspden (t.aspden@auckland.ac.nz), Miss Aleksandra Milosavljevic (a.milosavljevic@auckland.ac.nz).

Support and advocacy:
For any questions regarding ethical concerns please contact the Chair, The University of Auckland Human Participants Ethics Committee, The University of Auckland, Research Office, Private Bag 92019, Auckland 1142. Phone: 09 3737599 ext 83711. Email: ro-ethics@auckland.ac.nz

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Approved by the University of Auckland Human Participants Ethics Committee on 6th December 2016 for three years. Reference number 018178

Appendix 12 - Brief pharmacy questionnaire

ID No: __ __ __

An exploration into the delivery of the Long Term Conditions (LTC) service in New Zealand community pharmacies

If you wish for your pharmacy to participate in this study, please sign the consent form and complete the following brief questionnaire:

Q1. How many patients are currently enrolled in LTC in your pharmacy? ……..……

Q2. Which District Health Board (DHB) is your pharmacy located in? .....

Q3. Please describe the services that your pharmacy provides to LTC enrolled patients:

……
……
……
……

Q4. Please describe the pharmacy staff members that provide LTC in your pharmacy *(e.g. 1x pharmacist and 1x technician provide LTC, or all pharmacists provide LTC etc.):*

.....
.....
.....
.....
.....

Q5. What are the roles of the pharmacy staff members that provide LTC *(eg. 1x pharmacist is dedicated to sending text reminders and preparing blister packs to LTC enrolled patients etc.):*

……...…
……...…
……...
……...
……...……
……...

Q6. Pharmacy characteristics:

- Location: Adjacent to or in a medical centre ☐ In a shopping mall ☐

Other (please specify): ……..……

- Ownership: Group/franchise pharmacy ☐ Independent pharmacy ☐

Other (please specify): ……..

- Prescriptions:
  How many prescriptions does your pharmacy dispense during an average week day?
  <100 ☐ 100 to 200 ☐ 200 to 300 ☐ >300 ☐

- Staff:

Please briefly describe how many staff members work during an average week and their job title/role:
……
……
……..……..
……
……..……..

Thank you for your participation in this study.

Please return this questionnaire (with the Consent Form) via email to:
Aleksandra Milosavljevic, email: a.milosavljevic@auckland.ac.nz

---

Approved by the University of Auckland Human Participants Ethics Committee on 6th December 2016 for three years. Reference number 018178.

Appendix 13 - Community pharmacist interview schedule

An exploration into the delivery of the Long Term Conditions (LTC) service in New Zealand community pharmacies

Introduction

Hello. My name is Aleksandra and I am PhD student at the University of Auckland. I will be conducting the interviews exploring your views on the delivery of the Long-Term Conditions (LTC) service. Your pharmacy manager/owner has completed a brief questionnaire about LTC service delivery in your pharmacy; [provide the pharmacist with a copy of the completed questionnaire, if they wish]. The interviews will be recorded and the findings will be included in a PhD thesis and may be published and/or presented at conferences. The reporting of this material will be done in a way that does not identify you as the source. This means your name will not be published and you will not be identified in any way. The same is true for your pharmacy, which will not be identified during publication. If you do not wish to answer some of the questions, that is completely fine. At the end of the interview I will give you a chance to change or clarify anything that you have said. If you wish to withdraw your data after the interview, you need to inform myself or my supervisor (Associate Professor Jeff Harrison) no later than one week after your interview.

I will switch on the voice recorder now. This is interviewee number _____. This interview is starting at *[[time]]* on *[[date]]*.

1. <u>Warm up</u>

a) I can see from your pharmacy managers/owner's responses on the brief questionnaire that your pharmacy provides the LTC service. In your pharmacy what services do you provide to enrolled patients, as part of LTC?

Probes:

What activities or tasks do you provide for patients enrolled in LTC? [e.g. medication reconciliation, medication synchronisation, returning unused medications, changing dispensing frequency, blister packing, reminder services, medication records, counselling, education etc]

Do LTC enrolled patients pay for these services? [e.g. blister packing fee etc]

How does this compare to the services you provide to non-LTC enrolled patients?

b) How do you decide what services to offer an individual?

Probes:

Are there certain patient characteristics that guide you in your decisions about what services to provide? [e.g. poor English, arthritis in hands, no transportation etc]

Do you tend to have a range of services that you offer to certain categories/groups of LTC enrolled patients?

c) How do the services you provide to LTC enrolled patients differ to those services you provide to non-LTC enrolled patients who are non-adherent, co-morbid (have several chronic medical conditions) or have polypharmacy (take several medications)?

Probes:

Is there a difference in the services that you provide to enrolled versus not enrolled patients?

How are they different? [e.g. type of service, extent of service, cost etc]

d) Each enrolled patient usually has a LTC management plan. Can you please tell me if you use these plans when providing care to LTC enrolled patients, and if so, how are they used?

Probes:

In your opinion, do you think the management plans thoroughly document all the tasks you undertake for LTC enrolled patients? Why?

In your opinion, is the LTC management plan a worthwhile/valuable document?

Is the management plan easy to use and to complete in a timely manner?

What do you think makes up a good management plan?

What goes into these management plans in your pharmacy?

In your pharmacy, how often would a typical plan be reviewed and updated? What prompts you to do this review?

2. Views on LTC delivery in the pharmacy

e) How do you think patients enrolled in LTC have benefitted from the service provided in your pharmacy?

Probes:

Have you received feedback from enrolled patients about LTC and how the service has helped or hindered their health?

How do you know if they have benefited?

Are there any conditions or patient groups that you think may be more likely to benefit from LTC? Why?

f) How do you think the LTC service has impacted on your patients' medication adherence?

Probes:

Medication adherence can be defined as the extent to which an individual takes their medication as mutually agreed upon with their doctor.

Thinking about adherence, have you seen patients picking up their medications more frequently and on time since being enrolled in LTC? Why?

g) Since the introduction of LTC how has your practice of pharmacy changed?

Probes:

Has there been a change in your relationship with general practitioners (GPs)?

Has it been a positive or negative change?

Do you think you have started working to a higher scope as a result of LTC?

What changes have occurred within the pharmacy to accommodate LTC?

3. Findings from the first study

h) As part of our research, we explored the effectiveness of LTC in improving patients' medication adherence and reducing hospitalisations. Do you think LTC is able to improve adherence and reduce hospitalisations? Why?

Probe:

Have you seen any improvements in your patients' health since being in LTC?

i) **We found that LTC enrolled patients had a higher number of hospitalisations compared to non-enrolled patients. Why do you think this might be?**
Probes:
Are you surprised by this finding? Why?
Do you agree with this finding? Why?
Do you think this might be the case in your pharmacy?

j) **We also found that LTC enrolled patients had better medication adherence compared to non-enrolled patients. Why do you think this might be?**
Probes:
Are you surprised by this finding? Why?
Do you agree with this finding? Why?
What else do you think should be considered when assessing the effectiveness of the LTC service?

k) **Previous research has suggested that certain pharmacies perform better than others in terms of LTC service provision. Why do you think this is?**
Probes:
What are your thoughts on this?
Do you think that your pharmacy is a high or low LTC performing pharmacy? Why?
What do you think your pharmacy does well?
What makes certain pharmacies perform better than others?

l) **What pharmacist services do you think are especially worthwhile to LTC enrolled patients?**
Probes:
In your opinion, what activities or tasks undertaken as part of LTC contribute to improved patient care? [e.g. medication reconciliation, medication synchronisation, returning unused medications, changing dispensing frequency, blister packing, reminder services, medication records, counselling, education etc]
Do you undertake all these activities in your pharmacy? If no, why not?

m) **What pharmacist services do you think are <u>not</u> worthwhile to LTC enrolled patients?**
Probes:
In your opinion, what activities or tasks undertaken as part of LTC do <u>not</u> contribute to improved patient care? [e.g. medication reconciliation (are they used for LTC provision), medication synchronisation, returning unused medications, changing dispensing frequency, blister packing, reminder services, medication records, counselling, education, note-taking (do you use the notes and refer to them later)]
Do you undertake these activities in your pharmacy? If yes, why?

n) **If you could design a new LTC service for pharmacy, which focuses on improving patient medication adherence, what would the new service look like?**
Probes:
What activities would you provide as part of your LTC service? Why would you provide them?
Would there be certain patient groups who would be targeted?

o) **Following on from that, if you could recommend a change to how LTC is delivered now, what would that change be? This can be for pharmacy in general or your pharmacy specifically**
Probes:

Is there anything that policy makers can do to help improve the provision of LTC?
Is there anything that your manager or owner can do to help improve the provision of LTC?

4. Barriers and facilitators

p) There has been research published exploring some of the barriers and facilitators to the provision of community pharmacy services. In your opinion, what are some barriers and facilitators to LTC provision in your pharmacy?

Probes:

Do you think these barriers and facilitators apply to all community pharmacy services or only LTC?

Are there any specific to LTC?

Do you think these are specific to just your pharmacy or other pharmacies too?

[e.g. co-operation with GPs, documentation, reimbursement, patient and staff attitudes, involvement of pharmacy owner/manager, recruitment of patients etc]

q) What could be done to remove, or at least reduce some of these barriers?

Probes**:**

What could be done to help pharmacists provide LTC to their patients?

[e.g. employing more dispensary staff (such as: checking technicians)**,** increase monthly payments for LTC enrolled patients etc]

r) What are your thoughts about the LTC eligibility/assessment tool. Does the tool recruit the appropriate patients?

Probes:

Do you think the assessment tool is easy to use?

In your opinion, do you think there are patients who would benefit from LTC who do not qualify for enrolment? Can you please describe the characteristics of these patients?

5. Final questions/comments

s) Is there anything you would like to add to your responses, or are there any issues that you would like to comment on?

Probe:

If Yes, please discuss.

t) Is there anything you wish to clarify about what you have said?

6. Conclusion

Thank you for your time and effort today. If you requested a summary of the results on your consent form, this will be sent to you.

Approved by the University of Auckland Human Participants Ethics Committee on 6th December 2016 for three years. Reference number 018178.

Appendix 14 - Pharmacy observation schedule

Observation Schedule

Observation will take place at the pharmacy premises for one day. During the observation period a member of the research team, Aleksandra Milosavljevic, will observe and document several aspects of the pharmacy environment, pharmacy staff and patients. There will be a particular focus on the pharmacist-patient interaction and the delivery of the Long Term Conditions (LTC) service.

The following categories will be observed:

Category	**Includes**	**Researcher should note**
Appearance	Age, gender, physical appearance of: - Pharmacists - Other pharmacy staff - Patients - Others visiting the pharmacy (e.g. healthcare professionals (HCP), drug company representatives (drug reps))	- Appearance of pharmacists, patients, pharmacy staff, and others visiting the pharmacy. May include their clothing (e.g. white lab coat).
Verbal behaviour and interactions	Patient-pharmacist; patient-staff; pharmacist-staff and pharmacist-other HCP verbal communication: - Who initiates the interaction? - Language and tone used; - Any written information provided to supplement verbal communication; - Time spent talking to patients (time spent talking with patients and staff will not be measured); - Do pharmacists communicate with other HCPs (particularly general practitioners (GPs))? Reasons for their interaction?; Do pharmacists spend more time liaising with GPs about LTC enrolled patients (than non-enrolled patients)?; - Do LTC enrolled patients receive different verbal information than those not enrolled in the service? Can we tell if they are enrolled in LTC from the patient-pharmacist interaction?	- Gender, age, and profession of those speaking; - Dynamics of the interaction; - Who communicates with whom; - What has been discussed (particularly between the pharmacist-patient and pharmacist-other HCP)

Physical behaviour and gestures	- Pharmacist activities/tasks (what do they do and not do?); - Time pharmacists spend doing different activities (time spent undertaking activities will not be measured, rather rough estimates will be noted); - Do patients enrolled in LTC spend more time with the pharmacist? - Are there certain tasks that the pharmacist undertakes that other staff do not? - Who does the pharmacist interact with and who does the pharmacist not interact with?; - Activities of other pharmacy staff; - Who do other staff interact with? - Who do patients interact with? - Who makes the initial contact with patients? - Non-verbal communication used during the interactions	- The activities undertaken by the pharmacist (e.g. dispensing medicines, checking the final dispensed product etc.); - Pharmacist, staff and patient body language; - Utilisation of specialised staff (e.g. checking technician – to free up pharmacist time).
Services provided	- What services are offered at the pharmacy (e.g. LTC, MUR, ECP, vaccination etc.)? - What services are provided to LTC enrolled patients (e.g. medication synchronisation, reconciliation, text reminders, blister packing, counselling, education etc.)? - The role of the management plans in caring for LTC enrolled patients (are they used during the patient interaction? which staff member uses them?) - Do the services provided differ between LTC enrolled and non-enrolled patients? - Which staff member provides these different services? - Do patients pay for these services? (do LTC enrolled patients receive services at a lower price?)	- The pharmacy services provided to patients; - Who provides the services?; - Is there a difference in the services provided to LTC enrolled patients compared to non-enrolled patients?
Space	- How close do people stand when interacting with each other? - Presence of a private consultation area (is this area used? what is it used for? do LTC enrolled patients get counselling in this area?)	- What do individuals' preferences concerning personal space suggest about their relationship?

	- Use of pharmacy counter (do staff come around the counter to speak with patients?) - Is the pharmacist always behind the counter in the dispensary?	
Setting	- The pharmacy premises (the dispensary and the shop); - Pharmacy location (e.g. adjacent to medical centre or in a shopping mall).	- Appearance of pharmacy premises (tidiness, layout, and presence of private consultation rooms). - A drawing of the pharmacy layout - Utilisation of private consultation rooms; - Presence of robotics (to free up pharmacist time).
Human traffic	- Where do patients come in from (e.g. adjacent medical centre)? - Who do the patients primarily interact with? (Does it depend on their reason for coming into the pharmacy? Do LTC enrolled patients preferentially interact with the pharmacist?); - Who are the people coming into the pharmacy? (Patients, caregivers, drug reps, other HCPs); Are they accompanied by others?	- People who enter the pharmacy and leave the pharmacy.
People who stand out	- Identification of patients or staff members that receive a lot of attention from others (e.g. particular pharmacists that patients specifically request to see) - Do LTC enrolled patients stand out from non-enrolled patients?	- The characteristics of these individuals; - What differentiates them from others?