New Roles for Health Professionals in Patient-Centred Health Care Services in Rural and Remote Australia:

Community Pharmacists Sharing the Responsibility for Chronic Disease Management

Hana Morrissey
(Student Number: 260392)
1/7/2014
Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table of Contents</td>
<td>2</td>
</tr>
<tr>
<td>List of Figures</td>
<td>6</td>
</tr>
<tr>
<td>List of Tables</td>
<td>10</td>
</tr>
<tr>
<td>List of Electronic Appendices</td>
<td>12</td>
</tr>
<tr>
<td>Thesis Declaration</td>
<td>13</td>
</tr>
<tr>
<td>Acknowledgments</td>
<td>14</td>
</tr>
<tr>
<td>Abstract</td>
<td>16</td>
</tr>
<tr>
<td>Terms and Abbreviations</td>
<td>18</td>
</tr>
<tr>
<td>Chapter I. Introduction</td>
<td>20</td>
</tr>
<tr>
<td>Chapter II. Chronic Diseases, the New Epidemic</td>
<td>25</td>
</tr>
<tr>
<td>Introduction</td>
<td>25</td>
</tr>
<tr>
<td>The Worldwide Community View of Chronic Disease Management and its Relevance to the Australian Health System</td>
<td>29</td>
</tr>
<tr>
<td>The Australian Perspective</td>
<td>39</td>
</tr>
<tr>
<td>Summary</td>
<td>46</td>
</tr>
<tr>
<td>Chapter III. Literature Review</td>
<td>48</td>
</tr>
<tr>
<td>Introduction</td>
<td>48</td>
</tr>
<tr>
<td>Effect of NCDs Medications on the Older Population Quality of Life</td>
<td>51</td>
</tr>
<tr>
<td>Comorbidity of Physical and Mental Conditions</td>
<td>55</td>
</tr>
<tr>
<td>Role of Identification and Early Detection of Modifiable Risk Factors in NCDs Prevention</td>
<td>56</td>
</tr>
<tr>
<td>NCDs Preventative Strategies</td>
<td>58</td>
</tr>
<tr>
<td>Pharmacist Core Activities</td>
<td>59</td>
</tr>
<tr>
<td>Collaboration</td>
<td>62</td>
</tr>
<tr>
<td>Health Workforce</td>
<td>69</td>
</tr>
<tr>
<td>Rural Australia</td>
<td>72</td>
</tr>
<tr>
<td>Adherence to Treatment and Patient Education</td>
<td>74</td>
</tr>
<tr>
<td>Disease Control and Monitoring</td>
<td>78</td>
</tr>
</tbody>
</table>
After study completion ................................................................. 117
Timeline ................................................................................................. 117
Summary ................................................................................................. 118

Chapter V. Demographics and Disease Marker Parameters Results ................................ 120
Introduction ................................................................................................. 120
Age and Gender ................................................................................................. 121
Number of Medications ................................................................................................. 121
Medical Conditions ................................................................................................. 125
Body Mass Index ................................................................................................. 127
Waist Measurements ................................................................................................. 128
Alcohol Consumption ................................................................................................. 130
Smoker Status ................................................................................................. 131
Visual Acuity ................................................................................................. 132
Monofilament Pressure ................................................................................................. 133
Pain Score ................................................................................................. 134
Blood Glucose Level ................................................................................................. 135
Dyslipidaemia ................................................................................................. 138
  Total Cholesterol ................................................................................................. 138
  Triglycerides ................................................................................................. 140
Blood Pressure ................................................................................................. 141
  Systolic blood pressure ................................................................................................. 142
  Diastolic blood pressure ................................................................................................. 144
Heart Rate ................................................................................................ .... 146
International Normalised Ration ................................................................................................. 147

Chapter VI. Survey Results ......................................................................................... 148
Introduction ................................................................................................. 148
Analysis of heiQ™ responses before and after the clinical intervention phase ........ 148
Analysis of heiQ™ follow-up questions 41–50 ............................................................... 156
List of Figures

Figure 1 - Data for life expectancy at birth prior to 1982 (4) ........................................... 26
Figure 2 - Modifiable risk factors, life style and chronic disease relationship (14) ............. 28
Figure 3 - Numbers of risk factors persons with a chronic condition have, 2007-08 (15) ... 29
Figure 4 - Non-communicable Diseases Country Profile: Australia (17) ......................... 34
Figure 5 - Non-communicable Diseases Country Profiles for Australia (17) ..................... 34
Figure 6 - Non-communicable Diseases: Country Profiles for Australia (17) .................... 35
Figure 7 - Association between poverty, NCDs and the Millennium Development Goals (41). ................................................................. 48
Figure 8 - STEPS, the World Health Organization chronic disease surveillance instrument (42) .................................................................................................................. 50
Figure 9 - Number of risk factors by socioeconomic status 2007–2008 (18) .................... 57
Figure 10 - Differential disease burden by geographical region for the ten leading causes of death, 2007 (6) ................................................................. 57
Figure 11 - The concept of collaboration between health providers (70) ......................... 67
Figure 12 - The concept of best practice of patient care (70) ......................................... 68
Figure 13 - The Primary Health Care workforce by remoteness per 100,000 people, 2006 (67) ................................................................................................................. 70
Figure 14 - Clinical information systems and e-Health records quick guide for health care professionals, 2014 (73) .................................................................................. 74
Figure 15 - Diabetes complications at time of hospitalisations with diabetes as principal diagnosis, Australia, 2010 (84). ................................................................. 81
Figure 16 - Rate of hospitalisation for lower-limb amputation among people with diabetes, Australia, 2010 (84) ................................................................. 82
Figure 17 - Study Team Structure ................................................................................. 88
Figure 18 - Cost per 50 tests ......................................................................................... 104
Figure 19 - Age and gender ................................................................................................. 121
Figure 20 - Most frequently prescribed medications by gender........................................ 122
Figure 21 - Medications changes pre- and post-intervention ............................................. 123
Figure 22 - The Shapiro-Wilk tests of normality for total medications pre and post intervention .......................................................................................................................... 124
Figure 23 - Number of patients prescribed medications with Anticholinergic Burden properties in the study sample .......................................................................................................................... 125
Figure 24 - Number of medical conditions per person in the sample population ............ 126
Figure 25 - Body mass index changes pre- and post-intervention ...................................... 127
Figure 26 - The Shapiro-Wilk test of normality for body mass index .................................. 128
Figure 27 - Waist measurement changes pre- and post-intervention ................................. 129
Figure 28 - Waist measurement predicted value males and females comparison .............. 130
Figure 29 - Pain score changes pre and post the intervention ........................................... 135
Figure 30 - Blood glucose level changes pre- and post-intervention ................................. 136
Figure 31 - The Shapiro-Wilk test of normality for blood glucose level ............................ 137
Figure 32 - Total cholesterol level changes pre- and post-intervention ............................... 138
Figure 33 - The Shapiro-Wilk test of normality for total cholesterol level ......................... 139
Figure 34 - Triglycerides level changes pre- and post-intervention ................................. 140
Figure 35 - The Shapiro-Wilk test of normality for triglycerides ...................................... 141
Figure 36 - Systolic blood pressure changes pre- and post-intervention ............................ 143
Figure 37 - The Shapiro-Wilk test of normality for Systolic blood pressure ....................... 143
Figure 38 - Diastolic blood pressure changes pre- and post-intervention .......................... 145
Figure 39 - The Shapiro-Wilk test of normality for diastolic blood pressure ...................... 145
Figure 40 - Heart rate changes pre- and post-intervention .............................................. 146
Figure 41 - The Shapiro-Wilk test of normality for heart rate ........................................... 147
Figure 42 - Total drop-out ................................................................................................. 149
Figure 43 - heiQ™ total scores histogram of the responses ................................................. 150
Figure 44 - The Shapiro-Wilk tests of normality for heiQ™ total scores pre- and post-intervention ................................................................. 150
Figure 45 - Domain 9 heiQ™ FU ................................................................. 157
Figure 46 - Question 3 .................................................................................. 162
Figure 47 - Question 4 .................................................................................. 162
Figure 48 - Question 7 .................................................................................. 164
Figure 49 - Question 8 .................................................................................. 165
Figure 50 - Question 9 .................................................................................. 166
Figure 51 - Question 10 ............................................................................... 167
Figure 52 - Question 11 ............................................................................... 167
Figure 53 - Question 12 ............................................................................... 167
Figure 54 - Question 13 ............................................................................... 168
Figure 55 - Question 14 ............................................................................... 168
Figure 56 - Question 15 ............................................................................... 170
Figure 57 - Question 16 ............................................................................... 170
Figure 58 - Question 17 ............................................................................... 171
Figure 59 - Question 18 ............................................................................... 172
Figure 60 - Question 19 ............................................................................... 173
Figure 61 - Question 20 ............................................................................... 173
Figure 62 - Question 21 ............................................................................... 174
Figure 63 - Question 22 ............................................................................... 175
Figure 64 - Question 23 ............................................................................... 176
Figure 65 - Number of test performed using the Accutrend® Plus and CoaguChek® XS Plus monitors ................................................................................................. 177
Figure 66 - Question 24 ............................................................................... 178
Figure 67 - Question 25 ............................................................................... 178
Figure 68 - Question 26 ............................................................................... 179
Figure 69 - Question 27 ....................................................................................................... 180
Figure 70 - Question 28 ....................................................................................................... 180
Figure 71 - Question 29 ....................................................................................................... 181
Figure 72 - Question 30 ....................................................................................................... 182
Figure 73 - Question 31 ....................................................................................................... 183
Figure 74 - Question 32 ....................................................................................................... 183
Figure 75 - Question 33 ....................................................................................................... 184
Figure 76 - Question 34 ....................................................................................................... 184
Figure 77 - Question 35 ....................................................................................................... 186
Figure 78 - Question 36 ....................................................................................................... 186
Figure 79 - Question 37 ....................................................................................................... 186
Figure 80 - Question 38 ....................................................................................................... 187
Figure 81 - Planning Phase and formulation of study focus ................................................ 190
Figure 82 - Number of patients approached, enrolled and lost to follow up per site ........... 208
Figure 83 – Blood pressure patient records ......................................................................... 211
List of Tables

Table 1 - Study Sample Calculation ................................................................. 92
Table 2 - Forms used in the research ................................................................. 96
Table 3 – Equipment and materials supplied to each site (Appendices 2, 3, 4, 6 and 9).... 102
Table 4 - Consumables cost for Coaguchek® SX Plus and Accutrend® Plus at the time of
the study .............................................................................................................. 103
Table 5 - Monitors running cost ........................................................................ 103
Table 6 - Domains included in the modified heiQ™ baseline and follow-up ............ 112
Table 7 - Number of patients enrolled per site .................................................... 120
Table 8 - Final analysis of variance total medications .......................................... 125
Table 9 - Medical conditions reported in the study sample .................................. 125
Table 10 - The three-way interaction analysis of variance ...................................... 129
Table 11 - Alcohol Consumption analysis of deviance ....................................... 131
Table 12 - Smoker status analysis of deviance .................................................... 132
Table 13 - Visual Acuity analysis of deviance ..................................................... 133
Table 14 - Predicted mean Monofilament Pressure for the pre and post intervention times 134
Table 15 - Pain score final analysis of variance ................................................... 135
Table 16 - Blood glucose level final analysis of variance ...................................... 137
Table 17 - Total cholesterol level final analysis of variance ................................. 139
Table 18 - Relationship between total cholesterol level and time .......................... 139
Table 19 - Triglycerides final analysis of variance .............................................. 141
Table 20 - Systolic blood pressure final analysis of variance ............................... 144
Table 21 - Diastolic blood pressure final analysis of variance ............................. 146
Table 22 - heiQ™ total score ANOVA table ....................................................... 151
Table 23 - Final analysis of variance .................................................................. 151
Table 24 - Predicted mean number of total heiQ™ scores for pre- and post-intervention .. 152
Table 25 - Predicted mean number of total heiQ™ scores for pre- and post-intervention .. 152
Table 26 - heiQ comparison between baseline and follow-up, per question ....................... 152
Table 27 - Communication summary ................................................................................... 209
Table 28 - Paperwork Audit Log ......................................................................................... 214
List of Electronic Appendices

Appendix I. Ethics application and approval
Appendix II. Sites information sheet and consent form
Appendix III. Patient information sheet and consent form
Appendix IV. Chronic Disease Management protocols
Appendix V. Data analysis part A (model selection) and part B (significance)
Appendix VI. Forms and protocol check list
Appendix VII. Equipment specifications and manuals
Appendix VIII. Mid-Study Survey
Appendix IX. Promotion poster
Appendix X. Paper (under review) - New Roles for Community Pharmacists in Patient Centred Health Care Services in Rural and Remote Australia
Appendix XI. Paper (under review) - Is Australia Ready for the International Collaborative Patient Centred Model of Chronic Care Management?
Appendix XII. Paper (accepted) - Use of Chronic Disease Management Algorithms in Australian Community Pharmacies
Appendix XIII. Paper (accepted) - Community Pharmacists’ Intervention: how a 6-episode one-on-one intervention changed patients’ attitudes towards their medication and disease self-management
Appendix XIV. Paper (published) - Anticholinergic Burden Assessed Using Australian General Practice Electronic Records
Thesis Declaration

I hereby declare that the work herein, submitted to Charles Darwin University for the degree of Doctor of Philosophy is the result of my own investigations, and all references to the ideas and work of other researchers have been specifically acknowledged. I hereby certify that the work embodied in this thesis has not already been accepted in substance for any degree and is not being currently submitted in candidature for any other degree.

Candidate: Hana Morrissey

Supervisor: Professor Patrick Ball

Date: 1/7/2014
Acknowledgments

I would like to express my thanks to the following people and organisations:

Professor Patrick Ball, my supervisor, and Professor David Jackson and Professor Louis Pilloto, my co-supervisors, for their professionalism, patience, time, advice and encouragement throughout the project.

All the pharmacists who volunteered to conduct the clinical intervention in their own busy community pharmacies.

Mrs Sharon Nielsen, Qualitative Consulting Unit, Charles Sturt University, for her collaboration in data interpretation and analysis.

Dr Campbell Aitken of Express Editing Writing and Research provided editing services in accordance with the Institute of Professional Editors’ ‘Guidelines for editing research theses’.

Murrumbidgee Medicare Local for endorsing the chronic disease algorithm.

All the organisations that supported my research financially or by donating equipment, information or instruments:

– NSW Pharmacy Guild, which provided a grant for chronic disease research

– Roche Australia Point of Care, for providing eight sets of discounted point of care monitors and training

– Omron Australia, for donating nine digital sphygmomanometers and body composition scales
– The Department of Health and Ageing and the Central Australian Rural Practitioners Association for providing eight CARPA standard treatment manuals
– Algeos Australia, for providing nine monofilament NeuroPens
– EyeCare Plus, for providing nine visual acuity charts
– The World Health Organization, for approving adoption and use of the Chronic Disease Surveillance questionnaire, STEPS™
– Public Health Innovation (Deakin University), for approving use of the heiQ™ baseline and follow-up patient questionnaire
– GuildCare, for providing training on the recording of clinical interventions and monitoring services.

My beautiful daughters Mai, Heidi and Sarah, and their partners, for putting up with my long working hours and for their support and encouragement.

My most sincere thanks to you all.

Hana Morrissey
Abstract

Introduction: Most Australians take at least one prescription medication during their final 30 years and multiple medications during their final 10 years for one or more chronic condition. Chronic disease is increasingly affecting Australians’ quality of life and health expenditure. Medication and healthy lifestyle change are major health interventions, but patient adherence to prescribed therapy is reported to be less than 33%. Patients with chronic disease must collect prescription repeats regularly every month, creating an opportunity for intervention by community pharmacists.

Aim: To investigate if a collaborative community pharmacist and GP model of care in chronic disease management in rural Australia could improve patients’ outcomes through better monitoring of disease markers, increased self-management skills and greater medication adherence.

Design and Methods: This project was a pilot, pre- and post-intervention study designed to support future definitive studies. The clinical intervention phase was designed to support the existing advice patients had been given, was minimally invasive (lancet finger pricks for point of care testing) and did not involve any active medication administration. The study used three tools: a modified Health Education Impact Questionnaire (heiQ™) for patients pre- and post-intervention, mid-study survey for pharmacists and end of study feedback statements from pharmacists and patients. The study was conducted in community pharmacies located in rural and remote Australia in areas with a Pharmacy Access/Remoteness Index of Australia of code 2 to 6. The intervention took place over 12 months, of which three months were promotion, three months enrolment and baseline data collection, and six months
patient monthly monitoring. Data were analysed in ASReml-R™ using linear mixed models and generalised linear mixed models.

**Results:** The patients’ mean modified-heiQ™ score after the intervention was 29.65% higher than at baseline, a statistically significant improvement. The number of medications they took also significantly changed by using alternative medication with fewer side effects, removing duplications and adding medications for previously untreated conditions. During the period of the intervention, all parameters monitored became and remained stable within the patient best target level. Improvement in patients’ body mass index and blood cholesterol were difficult to determine due to the short period of the intervention.

**Conclusion:** Early detection and early intervention improve quality of life and reduce disease burden and medication-related problems. Blood pressure, total cholesterol, blood glucose level and international normalised ratio parameters are possible to monitor in the community pharmacy setting in Australia, but the cost needs to be covered by either Medicare or the community pharmacy and government agreement. Sub-optimal communication between pharmacists and doctors leads to fragmentation in the provision of health services. A national two-way, balanced, collaborative primary care model for chronic disease between general practitioners and other health professionals that includes pharmacists would address disconnections in the continuity of care and improve patients’ outcomes.
Terms and Abbreviations

5th CPA   The Fifth Community Pharmacy Agreement between the Australian Government and the Pharmacy Guild of Australia
ACS-Aus Activity Score Cards – Australia
AIDS       Acquired Immunodeficiency Syndrome
AIHW       Australian Institute of Health and Welfare
CARPA      Central Australian Rural Practitioners Association
CDMA       Chronic Disease Management Australia
CVD        Cardiovascular Diseases
DALY       Disability Adjusted Life Year
DoHA       Department Of Health And Ageing
GORD       Gastro-Oesophageal Reflux Disease
GP         General Practitioner
heiQ™      Health Education Impact Questionnaire
HIV        Human Immunodeficiency Virus
HMR        Home Medication Review
INR        International Normalised Ratio
MJA        Medical Journal Of Australia
MMR        Medication management reviews – for the purpose of this study they can be Home Medication Review (HMR), Residential Medication Management Review (RMMR) or MedsCheck™
MMSE       Mini Mental State Examination
MPR        Medication Position Ratio
NCD        Non-Communicable Diseases
PhARIA     The Pharmacy Access/Remoteness Index of Australia
PoC        Point of Care
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>QALY</td>
<td>Quality Adjusted Life Year</td>
</tr>
<tr>
<td>QCU</td>
<td>Qualitative Consulting Unit at CSU</td>
</tr>
<tr>
<td>QSUM</td>
<td>Quality and Safe Use of Medicine</td>
</tr>
<tr>
<td>RCPAQAP</td>
<td>Quality Assurance Programs Pty Limited</td>
</tr>
<tr>
<td>RN</td>
<td>Registered Nurse</td>
</tr>
<tr>
<td>SHCI</td>
<td>Sharing Health Care Initiatives</td>
</tr>
<tr>
<td>SMS</td>
<td>Short Message Service</td>
</tr>
<tr>
<td>SPSS</td>
<td>IBM SPSS are products that addresses the entire analytical process, from planning to data collection to analysis, reporting and deployment</td>
</tr>
<tr>
<td>STEPS</td>
<td>The STEP wise approach to surveillance is a standardised method for collecting, analysing and disseminating data in World Health Organization member countries</td>
</tr>
<tr>
<td>STM</td>
<td>Standard Treatment Manual</td>
</tr>
<tr>
<td>T2DM</td>
<td>Type 2 Diabetes Mellitus</td>
</tr>
</tbody>
</table>
Chapter I. Introduction

The context for the research described in this thesis is the growing global need to improve management of chronic diseases. Chronic non-communicable diseases have become major health concerns for governments and health care providers. They generate a dual burden consisting of poor health and low quality of life for the patient and escalating costs for health providers. They include diseases arising out of longer survival, and increasingly, a range of diseases arising from diet and lifestyle factors such as chronic obstructive airways disease from smoking tobacco and other substances, type 2 diabetes mellitus (T2DM) from poor diet and sedentary lifestyle, and hypertension associated with excessive salt intake.

Chronic conditions present a new challenge to health services in Australia and around the world, as these services are traditionally designed to manage acute presentations and short-term problems. Typically, non-communicable chronic diseases are diagnosed at one point in the patient’s life, then require ongoing medication, diet and lifestyle advice—and for the patient to adhere to all three.

Each chronic condition has non-modifiable risk factors (e.g., pre-existing conditions, genetic predispositions), and modifiable risk factors (e.g., stopping smoking, losing weight, increasing exercise, taking medication). If addressing modifiable risk factors successfully controls the disease, in most cases the person can expect good quality of life and a relatively ‘normal’ lifespan. If the disease is not controlled, the patient will suffer symptoms, experience complications that will frequently involve hospitalisation, and have poor quality of life and reduced life expectancy. A patient who does not adhere to their prescribed medications costs the health system twice; once for the unused medications and again to treat the health complications when...
they arise. While these situations represent the two extremes, most people with a chronic disease fall somewhere in between, receiving advice and treatment from their doctor but not necessarily taking all of it, all of the time, and controlling their disease to some extent but not well enough to prevent all the possible complications and to optimise their health and quality of life.

As demonstrated in Chapter II, only around one third of patients fully adhere to their treatment. Adherence to treatment is difficult to quantify, and there is limited evidence that extra time spent by health professionals with the patient during each consultation can improve their level of adherence and therefore disease control. This additional time may be perceived as being costly to self-employed general practitioners (GPs) and pharmacists. However, the additional time can be shared between GPs and other primary health care providers, including pharmacists. A model with demonstrated effectiveness in improving patient health knowledge and ability to self-manage their chronic diseases would reduce the financial and time burden on GPs and may be cost effective for health services through prevention of disease complications and hospital admissions.

Medicare data show that patients with a chronic disease will see their GP around four times per year and a specialist around twice per year, but will see their pharmacist 12 times per year. Frequent pharmacy visits represent an obvious opportunity to regularly reinforce disease management messages. However, to avoid message reinforcement sounding ‘like a broken record’ more needs to be provided. For example, taking pertinent measurements at the point of care allows direct feedback, and results can be plotted on graphs to show trends; pharmacists can communicate to patients that ‘this is where you are, and this is where you should be aiming’.
Chapter II presents a literature review of the extent of the chronic disease problem internationally and in Australia, providing justification for further research in the chronic disease management area. It shows that this type of model is consistent with the extant literature relating to how chronic conditions should be managed. Health service providers worldwide are moving away from acute response, single profession models of care towards holistic models focused on regular review of the whole patient, early detection of conditions, and comprehensive management by an interdisciplinary team of health professionals working together.

This new health management approach is of particular importance in rural and remote Australia. The Australian health system (Australian Bureau of Statistics, Demographic Statistics June 2010) acknowledges the differences in access and capability between metropolitan, rural, and remote Australian cities and towns. The health services provided to rural and remote areas are based on the number of health professionals and level of service (tertiary, secondary or primary care) per capita, per postcode. Although vast geographical areas in rural Australia have the same postcode and share low populations, this categorisation seems to take little account of individual challenges such as distance to the nearest town and whether the roads in between are sealed. These factors may prevent timely access to services that are overburdened and insufficient. There is a clear need for better communication between GPs and other health professionals including pharmacists, and these professionals must share the patient care responsibility to allow patients’ easy access and continuity of care from their nearest health care provider when required. This study aimed to examine how well pharmacists can work in collaboration with GPs in the provision of chronic disease management, to overcome the problems posed by
the small number of GPs in rural and remote Australia and provide the patient with additional monitoring between GP visits.

In Chapter III, a literature review examines international models of chronic disease care involving collaboration between health providers. Many of these models have included pharmacists and showed effects (both positive and negative) on patients’ measured outcomes. The literature review supported the development of the concepts underlying this study.

Chapter IV describes the study design and methods, including ethics approval, participant selection criteria, record keeping, and protocols used in the clinical intervention, data collection and analysis methods.

Chapter V presents the results from the clinical intervention. Chapter VI presents the results from the modified-heiQ™ and the mid-study survey.

Chapter VII discusses the findings and their applicability to the Australian health services model, and presents the end of study feedback statement from pharmacists and patients.

Chapter VIII presents the study conclusions.

Although preliminary in nature, this study is significant as it generated evidence that collaboration between GPs and pharmacists is not as effective as it needs to be in an era when chronic diseases are the ‘new epidemic’ driving premature death, major morbidity and escalating health care costs across the world (World Health Organization, 2011).

For the purpose of this study, the terms ‘older’, ‘elderly’ and ‘aged’ will be used for people aged 65 years and older.
The terms ‘patient’, ‘participant’, ‘customer’ and ‘consumer’ are used interchangeably to refer to a person with a non-communicable disease (NCD), who is enrolled in the study.

The term ‘pharmacist’ refers to a pharmacist in a community pharmacy, performing the intervention phase, who has consented to participate in the study and ‘site’ refers to the community pharmacies where the pharmacists delivered the intervention.
Chapter II.  Chronic Diseases, the New Epidemic

Introduction

Older Australians (>65 years of age) comprised 13% (2.8 million) of the total Australian population in 2008, and the number of older Australians is expected to grow to 4.2 million by 2021 (1, 2).

Successful ageing includes health and quality of life, not just living longer (3). However, longevity is usually associated with a level of disability, which varies based on health determinants during the person’s life. Average lifespan differs between males and females and Indigenous Australians (males 67 years and females 73 years) compared to non-Indigenous Australians (79.9 years for males and 84.3 years for females) (Figure 1). According to the Australian Institute of Health and Welfare (AIHW), most Australians live until the age of 65 years without disability or profound activity limitations (2). Non-Indigenous Australian males average 61.6 years without disability, 12.2 years with some disability, and 5.5 years with severe disability. Non-Indigenous Australian females live, on average, 64.3 years without disability, 12.1 years with some disability, and 7.5 years with severe disability.

Around 8% of Indigenous Australian adults are considered to have profound physical disability (2, 4).

By 2020, chronic disease will account for nearly half of all deaths and 80% of disability in Australia (4).
The Department of Health and Ageing (DoHA) chronic diseases webpage defines chronic diseases as illnesses that are rarely completely curable, are not self-limiting, and are present for long times or are life-long. Chronic diseases are complex in nature, aetiology and the extent of their impact on the person, family and community. Some chronic diseases make large contributions to premature death and others contribute more to disability (6).

Chronic diseases have features that make it difficult to precisely define their impact or to derive solutions for them, but as the population ages the impacts of chronic disease will increase (7).

The National Chronic Disease Strategy of the National Health Priority Action Council 2006 (7) has stated:

“Australia’s health system must be able to respond in an appropriate and cost effective way to this challenge. Failure to prevent, detect and treat
chronic disease at an optimal stage in its course impact on affected individuals and their families and carers in terms of pain and suffering, and on the whole Australian community in productivity losses and high health care costs” (7, pg. 3).

The impacts of disease on quality of life and financial and social wellbeing of people are collectively termed the ‘disease burden’ (8). Chronic physical diseases can lead to disability; mental health disorders such as major depression or schizophrenia can cause similar levels of disability to that caused by cancer or dementia (9). Governments and researchers use the disease burden to describe the impact of prolonged illness on disability and premature deaths caused by each disease or injury. The impact usually based on the disability adjusted life year (DALY) measure (9).

Brand et al. (10) argues that Australia’s health system, as it is currently designed (primarily for acute care), is unable to support chronic care management, either through treating exacerbations or maintaining remissions. Consequently, the design of evidence-based, patient-centred, collaborative chronic care services requires exploration (11).

Gross, Leeder and Lewis (12) invited the health community to begin discussion of chronic disease and the burden it places on the health budget and the Australian community (12). A decade later, AIHW indicated that twelve chronic diseases and conditions contributed to 42% of the total DALYs lost in Australia in 1996, out of about 80% of DALYs for all diseases (9).

The AIHW report (2012) demonstrated the severity of chronic disease in Australia, presenting a clear message to the Australian population and primary care health
providers (8, 13). Many Australians live risk factors that later in life can lead to chronic diseases: unhealthy diet, physical inactivity, smoking, high alcohol intake, and obesity (particularly central obesity that is seen around the abdominal area). These risk factors may be mixed with family history of mental illness, cardiovascular disease, respiratory diseases and Type 2 Diabetes Mellitus (T2DM) (8, 13). The authors (8) discussed whether the Australian health system was addressing chronic disease in a holistic way, and questioned whether it is managed as a complex of different individual diseases, or as (often inter-related) single diseases on each occasion that a patient presents with an acute issue. Taking obesity and its effects as an example, and adopting Lopes et al. (2006), Figure 3 presents a model for investigating direct and indirect effects of risk factors, when clinicians investigate single complaints from single diseases at any one visit. Adoption of the holistic approach identified at the United Nations Assembly in 2011 (14) as the best tool for early detection and prevention of progression, allows health providers to use the opportunity of a patient visit to review the patient’s health risks and address all ongoing issues (14).

Figure 2 - Modifiable risk factors, life style and chronic disease relationship (14).
Treating the patient’s most recent presentation, while ignoring other lifestyle risk factors or comorbidities, is not the solution to the patient’s whole problem. Such an approach adversely affects the health system as health care costs increase due to frequent doctor visits or hospital admissions. Patients with one chronic disease may have comorbidities and six or more risk factors (8, 13) (Figure 3). A 2008 AIHW report provided additional data reinforcing the seriousness of chronic disease in Australia, with 45% of people with chronic disease having five or more risk factors (15).

![Figure 3 - Numbers of risk factors persons with a chronic condition have, 2007-08 (15).](image)

**Figure 3** - Numbers of risk factors persons with a chronic condition have, 2007-08 (15).

**Code of the focus risk factors**
- **F**: Insufficient fruit consumption
- **V**: Insufficient vegetable consumption
- **M**: Usual consumption of whole milk
- **PA**: Insufficient physical activity
- **W**: Large waist circumference
- **HBP**: High blood pressure
- **O**: Obesity
- **A**: Risky/high-risk alcohol consumption
- **S**: Daily smoking

Throughout 2000–2005, potentially preventable, chronic disease-related hospitalisations doubled those associated with unpredictable causes (15).

**The Worldwide Community View of Chronic Disease Management and its Relevance to the Australian Health System**

The World Health Organization uses health surveillance data from around the world to lead global health policy, issue directives and recommendations, communicate...
evidence-based standards, support countries in monitoring health issues, and identify
disease trends (14). Most countries base their health strategy on the World Health
Organization Strategic Action Plan adapted to their national requirements. Bench-
marking local health standards to those recommended by the World Health
Organization is considered to be best practice in most developed countries (14).

In 2011, the United Nations announced a change of nomenclature, replacing chronic
disease management with NCD management, and highlighted five key areas of
concern to the international community (14). The declaration listed cardiovascular
disease (CVD), cancer, chronic lung diseases and diabetes as the top four concerns
given they are responsible for three of every five recorded deaths globally. The same
document recognised the need for the engagement of all local sectors to participate in
a global response to prevent and control NCDs by developing effective national-level
plans. The aim of this global response is to enable everyone to enjoy the highest
attainable standards of physical and mental health. For a global response to be
effective, the United Nations requested all countries devote more attention to
modifying chronic disease risk factors such as tobacco smoking, lifestyle, diet,
obesity, physical activity and consumption of alcohol (14).

The declaration reports 57 million deaths per year globally from diseases with 36
million deaths from NCDs. Nine million of these deaths occurred among people aged
less than 60 years. It also recognised that the increase in uncontrolled NCDs had
doubled the risk of death from communicable diseases. This is particularly evident
in developing countries, such as in parts of Africa where HIV/AIDS are endemic and
people become more prone to infection or further complications, which might have
some similarity to the Australian Indigenous population, who are suffering from
chronic kidney diseases and diabetes. In addition, some chronic diseases such as tuberculosis, malaria and HIV/AIDS, and the medications used in their treatment, can cause chronic conditions such as anaemia and respiratory complications and therefore contribute to the global NCD burden (14).

The United Nations noted that identifying risk factors and implementing preventative measures, in addition to screening, monitoring, treating and caring interventions are essential in the effort to control the four major NCDs. The 2011 report also noted the importance of mental health disorders and neurological diseases as contributors to the overall NCD burden. Other contributing factors were kidney disease, oral and eye diseases; tobacco, illicit drugs and alcohol use; sedentary lifestyle; inadequate or unhealthy diet; ageing population and illiteracy; poverty and socioeconomic global deterioration; political and environmental changes. All of these must be considered in plans for the prevention and control of NCDs (14).

Point 28 of the United Nations declaration, headed ‘challenges facing the world’, addresses inequality of access to immediate and effective health care. This is relevant to the Australian context, where access to care is relatively poor among rural and remote indigenous and non-indigenous communities, due to the vast geographical spread of these populations and their varying needs.

The United Nations emphasised early detection and disease prevention as effective measures for reducing risk exposure. It noted that the health system could be strengthened by a coordinated effort between all stakeholders, to reduce the impact of NCDs on the population and the health system. The report noted the need to establish plans for improving access to, and ensuring continuity of supply of, medications, and the monitoring of NCDs to keep them controlled (14).
The United Nations declaration elaborated on how countries can strengthen their health systems, (point number 45). The integration of services, a sustainable primary health care sector and coordination between health care providers were seen to be appropriate approaches (14). It states:

“According to national priorities, give greater priority to surveillance, early detection, screening, diagnosis and treatment of non-communicable diseases and prevention and control, and to improving the accessibility to the safe, affordable, effective and quality medicines and technologies to diagnose and to treat them; provide sustainable access to medicines and technologies, including through the development and use of evidence-based guidelines for the treatment of non-communicable diseases, and efficient procurement and distribution of medicines in countries; and strengthen viable financing options and promote the use of affordable medicines, including generics, as well as improved access to preventive, curative, palliative and rehabilitative services, particularly at the community level” (14, pgs. 9–10).

The World Health Organization conducted a world-wide country capacity survey to examine the health capability countries allocated for the management of NCDs, to allow a better understanding of the required resources to effectively manage NCDs globally. Of the countries who responded to the survey, 89% indicated that they had a unit responsible for NCD management (16). In Australia, DoHA has programs, guidelines and a webpage on the management of NCDs, but not a devoted department. Twelve percent of responding countries indicated that they do not have a fund for NCDs management (16). In Australia, the top five NCDs of the United Nations are included in the national health priority areas. The challenge is how best
to adapt existing platforms into models able to respond efficiently and effectively to any population health issue and provide continuity of care, access to health providers and medications. For example when infants are due for vaccination, a complete health check is usually performed. With respect to adults, catch up or travel vaccinations could provide good opportunity to address smoking cessation or obesity.

The World Health Organization also identified NCD burden by country, including estimates of countries’ abilities to cope with the identified burden, and noted whether policies or guidelines were in place (17). Figures 4, 5 and 6 show the total death of NCDs in Australia as 63% of total deaths, and the prevalence of risk factors that are impacting the quality of life of Australians with NDSs and causing burdens to the health system.
**Australia**

2010 total population: 22,268,384  
Income group: High

<table>
<thead>
<tr>
<th>NCD mortality</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2008 estimates</td>
<td>males</td>
</tr>
<tr>
<td>Total NCD deaths (000s)</td>
<td>63.4</td>
</tr>
<tr>
<td>NCD deaths under age 60 (percent of all NCD deaths)</td>
<td>13.4</td>
</tr>
<tr>
<td>Age-standardized death rate per 100,000</td>
<td></td>
</tr>
<tr>
<td>All NCDs</td>
<td>364.8</td>
</tr>
<tr>
<td>Cancers</td>
<td>140.8</td>
</tr>
<tr>
<td>Chronic respiratory diseases</td>
<td>25.6</td>
</tr>
<tr>
<td>Cardiovascular diseases and diabetes</td>
<td>136.3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Behavioural risk factors</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2008 estimated prevalence (%)</td>
<td>males</td>
</tr>
<tr>
<td>Current daily tobacco smoking</td>
<td>18.3</td>
</tr>
<tr>
<td>Physical inactivity</td>
<td>38.0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Metabolic risk factors</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2008 estimated prevalence (%)</td>
<td>males</td>
</tr>
<tr>
<td>Raised blood pressure</td>
<td>41.1</td>
</tr>
<tr>
<td>Raised blood glucose</td>
<td>10.8</td>
</tr>
<tr>
<td>Overweight</td>
<td>68.2</td>
</tr>
<tr>
<td>Obesity</td>
<td>26.4</td>
</tr>
<tr>
<td>Raised cholesterol</td>
<td>55.9</td>
</tr>
</tbody>
</table>

Figure 4 - Non-communicable Diseases Country Profile: Australia (17).

Figure 5 - Non-communicable Diseases Country Profiles for Australia (17).
Between 2006 and 2008, the World Health Organization ran a series of regional workshops to map the epidemiology of NCDs and their modifiable risk factors, while developing standards and guidelines for reducing the affected population’s exposure to the identified risk factors.

This resulted in the World Health Organization 5-year Action Plan (2008-2013) (18, 19) for a global strategy for the prevention and control on NCDs which aims to:

- Raise the priority accorded to NCDs in development work at global and national levels
- Integrate prevention and control of NCDs into policies across all government departments
- Establish and strengthen national policies and plans for the prevention and control of NCDs
- Promote interventions to reduce the main shared modifiable risk factors for NCDs: tobacco use, unhealthy diets, physical inactivity and harmful use of alcohol
- Promote research for the prevention and control of NCDs
– Promote partnerships for the prevention and control of NCDs

– Monitor NCDs and their determinants and evaluate progress at the national, regional and global levels (18, 19).

The document also stated three main objectives:

– To map the emerging epidemics of NCDs to inform policies and financial allocation

– To reduce the local population NCDs risk factors

– To develop cost-effective interventions for CVDs, cancer, diabetes and chronic respiratory diseases.

The plan acknowledges that improvements in disease management can reduce morbidity, disability and death and contribute to better health outcomes (19).

The World Health Organization Action Plan (19) states prevention of NCDs is possible and that early detection of risk factors and application of appropriate interventions can prevent their consequences. The consequences are intensified as a result of inequity in the environmental, economic and social circumstances into which people are born, grow, live, work and age, including their access to health care. The plan emphasises the need for more attention focused on managing people at moderate risk, as early intervention can prevent progression to high risk and resultant high costs (19). Consequently, a comprehensive prevention strategy needs to blend an approach reducing risk factors in the population as a whole, with a strategy specifically directed to high-risk individuals. Finally, the report indicates that for community-based interventions to succeed, community participation, supportive policy decisions, inter-sectoral action, appropriate legislation, health care
reforms, and collaboration with non-governmental organisations, industry and the private sector must be involved (19).

The following are the goals listed in the report to provide countries with comprehensive, realistic strategy (19, pg. 39) with comment on their relevance to Australia:

– *Generate local information through surveillances to inform policy development and evaluation of the efficiency of current ones.* In Australia, the Australian Bureau of Statistics and the AIHW are responsible for the conduct and analysis of the national health surveys, which cover all areas recommended by the World Health Organization (population causes of death, risk factors and their determinants).

– *Establish NCDs health promotion and preventative health programs.* In Australia, two government levels are responsible: Commonwealth and local government. In addition to the official government websites, sites such as HealthInfoNet™, BetterHealth™, HealthInsite™ and MedicineWise™ provide the Australian population and health professionals with access to those programs.

– *Assess the impact of social and economic development on the burden of the major NCDs with a view to conducting comprehensive, multidisciplinary analysis.* Australia reviews the top areas of health priorities periodically; for example injuries, cancer, CVDs and mental health were the top priorities in 1996, and diabetes was added in 1997, followed by asthma in 1999, arthritis in 2002, obesity in 2008 and dementia in 2012.

– *Transform the role of health professionals to promote and maintain the health of a defined population.* In Australia, a number of changes occurred in the past
decade such as prescribing by dentists, nurse practitioners, podiatrists, optometrists and physiotherapists, and GP’s chronic disease management plans which include referrals to allied health professionals covered by Medicare; however, none of these changes included pharmacists.

At the Commonwealth Pharmacists’ Association (CPA) conference held in 2011, pharmacists from 22 Commonwealth countries met to discuss the contribution that pharmacists can make to participate in programs to control NCDs. They agreed that pharmacists have many opportunities to interact with patients, in both the public and private sectors, and to supply medicines and provide access to health promotion information to assist consumers to control their risk factors (20).

The CPA issued a declaration on the commitment of pharmacists to combating the NCDs identified in the 2011 United Nations declaration throughout the Commonwealth. However, the president of the Association also stated that evidence shows that access to appropriate and affordable health services and medicine are essential to the management of NCDs (21). He emphasised that achieving the global goal requires that pharmacists establish their new place in the health care team (21).

In countries such as United States of America, United Kingdom, Canada and New Zealand pharmacists are more included in all levels of health settings (e.g., participating in immunisation, prescribing and anticoagulation oral therapy management). In Australia, pharmacists are not yet participating in any of these activities.

The CPA called on the Commonwealth’s Ministers of Health to engage with pharmacy professional bodies (22) to ensure their contribution to combating NCDs is maximised. This is an opportunity for Australia.
The Australian Perspective

In Australia, there is insufficient data available to support (or decry) the benefit of frequent complete screening by any of the health care providers in any setting, in managing chronic diseases with multiple risk factors. The national average health care cost per person is $6,230 per year; primary health care visits cost 36% of total health expenditure, not including dental, medicines and research. Hospital admissions cost 39.8% of the total health budget (23). On an average day in 2009, there were 342,000 visits to GPs, 742,000 medicines dispensed by pharmacists, 23,000 hospital admissions and 17,000 visits to emergency departments (23). Some of the GP and pharmacy visits for dispensing were for acute causes, but many others were for ongoing routine reviews. It is these review visits which should be better utilised for holistic patient checks, given their potential to produce cost savings later through reducing disease complications and hospital admissions (23).

Around 1.33% of people had to wait to see the GP due to no appointment being available (49%), or no available service (25%). In the same year (2009), 23% of Australians (aged 15 years and over) consulted pharmacists on health-related questions. The advice they received met their need completely in 79% of cases and partially in 18% (24). The Australian health care system is now encouraging self-management of NCDs for all patients (25).

Involving patients in the self-management of their NCD encourages them to:

- Engage in health-promoting activities that build physiological reserve and prevent adverse events
- Interact with health care providers and adhere to agreed and recommended treatment and interventions
Monitor their physical and emotional status and make appropriate self-management decisions based on these assessments

Manage the effects of their illness on their day-to-day functioning, emotions, behaviour, self-esteem and relationships with others.

To achieve effective self-management of chronic conditions, health professionals must conduct regular multidisciplinary case management, and utilise pharmacy MMR and regular scheduled chronic care monitoring (26, 27). Consideration should be also given to developing networks between pharmacists, GPs and allied health practitioners and to make available both electronic and hard copy resources for patients regarding patient education and chronic disease self-management strategies in several languages and for a range of literacy levels (26, 27). Point of care monitoring (PoC) will become more useful if performed at all levels of primary care provision, such as pathology laboratories on patient request without referral, by registered nurses in doctor clinics or by district nurses at patients’ homes and in the GPs offices by a GP, a nurse practitioner or a registered nurse, funded by Medicare. However, within the current health model, pharmacists are not considered as a PoC outlet, nor are they funded to operate such services (26, 27).

A large proportion of medical emergencies and subsequent hospital admissions are precipitated by exacerbations or complications of NCDs (9). To manage these patients effectively, periodic, systematic assessment and review should be conducted to detect early the signs of deterioration and facilitate timely intervention.

Assessment of NCD patients using a systematic, multidisciplinary framework has potential to assist in minimising acute exacerbations and long-term complications (7). Prescribing software systems such as Medical Director™ (Health
Communication Network, St Leonard’s NSW) Medical Observer™ (Medical Observer, Chatswood, NSW) and reference manuals such as the Central Australian Rural Practitioners Association - Standard Treatment Manual (28), contain evidence-based chronic care clinical pathways, which guide a range of health professionals to achieve best outcomes.

The Australian Health Ministers (2005) stated that the goals of chronic disease management in Australia are that (29):

- Health care provision is patient focused
- Patients are involved in decisions and choices about their disease management
- Treatment aims to satisfy the patient’s desired outcome
- Care is individualised to the patient's needs as a collaborative concordance, not rigid instructions
- There is recognition of the patient's rights and abilities to self-manage with education, support and advice after inclusive risk assessment and consent
- A therapeutic relationship exists with the patient
- Recognition is given to a patient's experience in managing their own chronic disease and what has worked for them in the past
- Education and advice are provided on prevention and health promotion strategies.

The Primary Health Care Reform Report of 2006 (25) was the first in Australia to highlight pharmacist involvement. It also discussed patient input and the need for multidisciplinary team care. Their recommendations were:

- Identification of the health care needs of individual patients
- Provision of high quality, appropriate services, informed by best practice
- Facilitation of continuity of care
- Full utilisation of an interdisciplinary health care team
- Timely access to health services
- Effective clinical governance
- Improved quality of life for patients
- Improved quality of life for carers
- Reductions in hospital admissions, from complications of the disease process
- Decreased total health service presentations for avoidable complications and comorbidities from NCD.

DoHA (26) states that prevention across the continuum enables a holistic approach towards better NCD control, with intervention at multiple points. They group the proposed interventions into three categories (26):

- Primary prevention to prevent movement of the ‘well’ to the ‘at risk’ population
- Secondary prevention to prevent progression from ‘at risk’ to ‘established’ disease state
- Tertiary prevention to prevent and/or delay progression to complications from the disease.

Their NCD webpage (9) discusses early detection and appropriate treatment as another important element. (13). The Australia, Healthiest Country report (30) listed potential activities as enablers to conquer the NCD epidemic and achieve better health for all Australians by year 2020. Those activities are listed below:

- Health promotion and risk reduction
- Improving health literacy
- Monitoring and surveillance of risks
– Interventions to raise awareness of risk factors and follow up
– Facilitating best practice
– Improving the safety and quality of care
– Collaborative and multidisciplinary models of care
– Capacity building and infrastructure support to enhance integration.

The Pharmacy Guild of Australia identified potential activities to be undertaken by community pharmacists to address NCD in Australia; however, those activities are neither comprehensive nor fully funded. Their recommendations are listed below (31, 32):

– Rural Programs: Strengthening and supporting the rural pharmacy workforce and providing increased access to quality pharmacy services in rural and remote regions of Australia.

– Research on maintaining and improving the health outcomes of Australians through evidence-based best practice on issues related to pharmacy and the provision of quality pharmaceutical services to patients.

– Medication continuance to ensure ongoing access for patients to current medications until they can see their treating clinician.

– Clinical interventions to support pharmacists to provide clinical interventions for patients related to their medication. This would be an enhanced service over and above that associated with dispensing to (31, 33):
  
  o Improve the provision of clinical interventions
  o Improve communication with patients and prescribers
  o Provide integrated care from the pharmacy to the treating doctor
Complement other services such as in-pharmacy medication-use reviews, home medicine reviews and provision of dose administration aids.

The DoHA HealthInsitex™ page explains NCD to patients and provides information for prescribers regarding the Medicare NCD management plans, the General Practitioner Management Plan and the Team Care Arrangement (34, 35). These plans have been the subject of some controversy (36, 37). Since they were recently introduced in 2005, insufficient data exist to support their benefit to patients. The ability of GPs in small practices to complete them for all patients and their ability to improve the referral system or communication between providers are similarly untested.

The General Practitioner Management Plan (MediCare item 721) is an initiative designed to overcome the shortage of medical practitioners, by allowing some management activities to be shared or delegated to other health practitioners. This plan also involves coordination of Team Care Arrangements (MediCare item 732) (36, 38). MediCare pays for the GP’s time and effort in preparing the General Practitioner Management Plan and:

- Coordination of the General Practitioner Management Plan for patients with chronic or terminal medical condition who require ongoing care from a multidisciplinary team of at least three health or care providers.
- Preparation of the collaborating agreement with the other participating providers on required treatment/services, and with the patient, documenting the arrangements and review dates in the patients’ Team Care Arrangement, and providing copies of the relevant document to the collaborating providers.
Patients who have both a General Practitioner Management Plan and Team Care Arrangement are able to access a maximum of five funded allied health services per calendar year. The General Practitioner Management Plan should include the GP plus at least two other health practitioners who provide ongoing treatment/care for the patient. The Team Care Arrangement collaboration was described by Medicare as two-way communication (telephone, face-to-face or via an exchange of emails or faxes) (40). The AIHW indicated that 2,155,376 Medicare subsidised General Practitioner Management Plan and Team Care Arrangement services were conducted in 2007–2008 (40). There were 115,819 referrals to Aboriginal Health Workers, totalling 364 services per 1000 population. The program is well-funded and GPs are encouraged to conduct more General Practitioner Management Plan and Team Care Arrangement (38). Over the same period, 75,590 GP referrals were received by pharmacists for HMRs. This represents 14 services per 1000 population. The entire HMR program came under threat in 2013 due to a budgetary overspend (32).

The *Australian Prescriber* has published several articles on health team composition and levels of collaboration. Rigby (2010) stated that:

“The traditional relationship between the doctor as prescriber, and pharmacist as dispenser, is no longer appropriate to ensure safety, effectiveness and adherence to therapy” (33, pg. 191).

This concept, in part, is based on lessons learned from the experiences of other developed countries and on Australia’s national need to share patient care responsibilities to fill gaps in health professional supply. Barber (2009) discussed United Kingdom initiatives for non-medical prescribing which included pharmacists, an initiative that is still far from reality in Australia (39). The United Kingdom
moved to non-medical prescribing as their health system acknowledged that pharmacological regimes became too complex for the current model of care whereby only the GPs have the leadership and referral power (39). Barber (2009) suggested that doctors should move to new roles that set direction, strategy and priorities, and work with teams of colleagues, including non-medical prescribers and allied health professionals (39).

Additionally, from January 2012, Medicare introduced the Practice Nurse Incentive Program (PNIP) which subsidised the cost of recruiting or retaining a registered nurse, enrolled nurse or Aboriginal Health Worker. It also covered the employment of an allied health professional instead of, or in addition to, a practice nurse and/or Aboriginal Health Worker in eligible registered rural practices. The list of eligible allied health professionals covers 14 different specialities; however, as occurred in the case of General Practitioner Management Plan and Team Care Arrangement, pharmacists were not included in the PNIP.

Expanding the list to include the employment of pharmacists could be justified through the provision of a quality and safe use of medicines (QSUM) service (32).

**Summary**

NCDs are causing more deaths than communicable diseases. Without modification of the contributing risk factors, the problem will continue to worsen; the burden of NCDs on the health system is unsustainable. Services designed to respond to acute disease presentations, which are driven by GPs only, are not coping and are poorly suited to NCD management. Most developed countries have moved to a multidisciplinary model of care that includes the pharmacist as part of the health care team and have revised health professionals’ responsibilities to complement the
increased demand and the gaps in the supply of practitioners in particular situations, especially in rural and remote locations.

The health system in Australia introduced a number of new initiatives in the past decade, but all are GP-centred and only one involves pharmacists. Consequently, Australia appears to be falling behind international best practice.
Chapter III. Literature Review

Introduction

Beaglehole et al. (41) identified priority actions for the NCDs global crisis, labelling NCDs as one of the major barriers to world development. The authors proposed a list of issues to discuss in the 2011 United Nations Assembly, as summarised in Figure 7.

![Figure 7 - Association between poverty, NCDs and the Millennium Development Goals (41).](image)

Considering the extent of the NCD problem in Australia, the Australian health system’s capability, the core function of health professionals, and how they relate to each other are key issues for research in the field of NCDs management.

The following features are common to many chronic conditions (7, 15):
– Multiple risk factors
– Long latency periods
– Prolonged course of illness
– Functional impairment or disability.

Three categories of NCDs are distinguished by their impact on individuals and families, as well as their demand on health services (15):

– Fatal, such as cardiac events or stroke
– Non-fatal but requiring lifelong management, such as arthritis
– Serious and eventually fatal, such as diabetes.

Health surveillance is one of the main functions of the World Health Organization. For data reported from various countries to be useful and applicable, a standardised tool is required. The World Health Organization’s STEPwise approach (STEPS™) is one such system for standardised NCD data collection and reporting (42). The intention of STEPS™ is to make the surveillance of NCDs sustainable and more valuable, since high-quality data that is comparable between locations has great utility in guiding international policy and direction (19, 42).

The STEPS™ approach includes collecting comprehensive demographic data, and is based upon two sets of items: core and expanded. They cover the same topics, but the expanded items consider additional information that supports the data collected under core items. Step-1 (collection from patient charts or patient interviews) includes smoking status, alcohol intake, diet, and physical activity, history of hypertension and history of diabetes. Step-2 (physical measuring) includes body mass index, waist circumference, hip circumference, blood pressure, heart rate, blood glucose level and total lipids. Step-3 is blood sample collection for laboratory
assessment (19, 42). Figure 8 further explain the definition of each category under each step.

Figure 8 - STEPS, the World Health Organization chronic disease surveillance instrument (42).

Thirteen of the top twenty (67.2%) causes of death in Australia are NCDs (4, 43). Despite all efforts and allocated funds applied since 2000 using the current Australian model of primary health care, by 2009 only seven diseases improved in ranking (lung cancer, colon cancer, lower respiratory diseases, leukaemia, heart failure, influenza and pneumonia, and land accidents); four did not change at all (Ischaemic heart disease, stroke, prostate cancer and suicide) and nine became worse (dementia and Alzheimer’s, diabetes, kidney diseases, breast cancer, pancreatic cancer, hypertension, skin cancer, cardiac arrhythmias and liver diseases) (43).

To reinforce the importance of disease ranking, in 2000 the National Health Performance Committee introduced a new Australian Health Performance framework. This framework consists of three tiers, including health status,
determinants of health and health system performance. Within each tier are a number of dimensions. For example, tier one consist of four dimensions: health conditions, human function, life expectancy and wellbeing, and deaths. The life expectancy and wellbeing dimension is used to measure disease burden and quality of life, or DALY. The DALY is the sum of years of life lost due to premature mortality (YLL) and years of life lost due to disability (YLD). The quality adjusted life years (QALY) is the other parameter used to measure the improvement in quality of life and reduction in disease burden by modifying the risk factors of chronic diseases (44). The DALY and QALY performance indicators and dimensions are reviewed every three years.

**Effect of NCDs Medications on the Older Population Quality of Life**

Older people are at greatest risk of NCDs, and their number and proportion in the Australian population will increase substantially in the years ahead. The ageing population exhibits negative trends in diet, exercise levels, obesity, binge drinking and other risk factors, suggesting that prevalence of chronic disease will increase even further (45). In 2004, the 12 leading causes of death in the older population included CVD, diabetes, respiratory diseases, cancers and dementia. Dementia accounts for 15% of total disease burden and ranked ninth for men and fourth for women. CVDs were the leading cause of death for both men and women (45).

With the increase in chronic conditions among the older population, the number of medications they require also increases, with 25% of older population taking medication (sleeping tablets, antidepressants and mood stabilisers) for mental wellbeing (45). Medications contribute to cognitive impairment in the older population. For example, a systematic review of 27 studies (46) found a correlation
between medications with anticholinergic activity and reduced cognitive function leading to confusion or delirium. Most people with mild cognitive impairment will develop dementia within five to ten years (47). Drugs such as antiemetics, antispasmodics, bronchodilators, corticosteroids are used increasingly in the elderly. Additionally, the ageing body exhibits increased permeability of the blood-brain barrier, together with slower metabolism and inadequate elimination of many medications, leading to accumulation in the body and toxicity (48). Campbell et al. (46) estimated that between 20–50% of the ≥65 year old population in America, including four million diagnosed with dementia, took at least one medication with known anticholinergic activity (38). McNeel (48) suggests that older populations are at greater risk of suffering anticholinergic side effects of drugs than are the younger population. The authors speculated that this was due not only to the age-related changes in metabolism, elimination, and blood-brain barrier permeability, but also to the increase in the number and type of medications used (e.g., insomnia, pain and incontinence therapies) (48).

Ersek et al. (2004) studied the association between delirium and opioid use in patients with cancer and in patients with acute or chronic pain not associated with malignancy (49). This study was important, considering that cancers and arthritis constituted five out of the leading causes of death in the older population, and require pain treatment for extended periods (45). The authors concluded that the cognitive effects of opioids influenced the success or failure of opioid therapy. Stable opioid therapy was found to be associated with minimal cognitive changes, where the administration of parenteral opioids was most likely to cause cognitive impairment. It was noted that in some patients, chronic oral opioid therapy did not affect or enhanced cognitive functioning.
Bruce et al. (2008) studied predictors of cognitive decline in older individuals with diabetes (50). He used a multiple logistic regression, investigating factors such as age, education, presence of cognitive impairment without dementia, insulin treatment, and antihypertensive medications such as angiotensin converting enzyme inhibitors or angiotensin II receptor antagonists and blockers. The findings of Bruce et al. (50) were contradictory to all other similar published studies in concluding that 1.6 years after diagnosis, almost 16% of older patients with T2DM experienced a clinically relevant decline in cognitive function (50). After controlling for a number of factors (age, education, cognitive function, and the use of either angiotensin converting enzyme inhibitors or angiotensin II receptor antagonists and blockers), the authors found that some beneficial effects occur independently of lowered blood pressure, possibly by reducing inflammation in diabetic patients with microalbuminuria. These findings are of potential clinical importance but require confirmation.

With the increase in NCDs in the population, the comorbidity resulting from disease complications also increases (e.g., due to the relationship between CVD and renal diseases, between diabetes and eye diseases, and between most chronic diseases and mental health). Consequently pharmacological interventions become more common. This may contribute to an additional physical, mental or cognitive burden; Mintzer (51) found that nearly 60% of older people in nursing homes were prescribed drugs with anticholinergic effect compared to only 23% of the same age group in the community. Peters (52) listed 22 drug categories that have significant anticholinergic effects.
Mintzer (51) recognised that the number of over-the-counter preparations that possess anticholinergic properties is increasing (e.g., antihistamine and cold and flu treatments), making the monitoring of anticholinergic effects a more difficult task. He also identified the need to be able to recognise central anticholinergic effects (memory deficit, confusion, disorientation, agitation, hallucination and delirium) as clearly as the peripheral effects (dry and stick lips, urinary disorder, falls, and increased anxiety) (52).

Fox et al. (53) conducted a longitudinal study in five centres in the United Kingdom to investigate the relationship between anticholinergic medications and mortality and patient deterioration. The authors randomly selected 2500 people aged >65 years per centre (N=13,004) and administered the Mini Mental State Examination (MMSE™) at baseline and at two-year follow up. Information about medications and daily activities were collected through structured interviews. Medication review was then conducted for each patient and the anticholinergic burden was calculated using the Anticholinergic Cognitive Burden Scale. The result of the MMSE was then reviewed against the individual total Anticholinergic Burden Scale score to identify whether there was a correlation between the cognitive impairment and the Anticholinergic Burden Scale score. The Fox Anticholinergic Burden Scale was developed by inclusion or exclusion of drugs following review by a multidisciplinary panel of geriatricians, pharmacists, geriatric psychiatrists, general physicians, specialist geriatric nurses and researchers of the ageing brain (53).

Medication duplication, side effects, appropriateness of dose, appropriate use and adherence are issues addressed by pharmacists as part of daily practice prior to dispensing any prescription or pharmacist only medication. MMR can be conducted
comprehensively on hospital admission and discharge, and during home or residential medication reviews. Comprehensive medication review in the community requires GP referral. Only 14 services per 1000 population were completed in the period of 2007–2008. This means only 1.4% of medication reviews were conducted, which when compared to the prevalence of chronic disease in Australia, is insignificant. Only 2 medication reviews per 1000 population were conducted in remote and very remote Australia where a large number of older Australian reside (40). This shows that there are missed opportunities for Australians to be offered advice around safe and quality use of medication, caused by lack of referral from GPs and inadequate funding by government.

**Comorbidity of Physical and Mental Conditions**

According to the International Classification of Diseases and Diagnostic and Statistical Manual of Mental Disorders, there are strong links between mental and chronic disease in people with chronic diseases. One in every nine Australians (aged 16–85 years) experiences comorbid mental and physical conditions (54). This group of people have a higher rate of hospitalisation, days out of work and days unable to function. They have also been shown to have higher prevalence of smoking and alcohol intake. Chronic conditions such as CVDs, chronic obstructive pulmonary disease, early dementia, arthritis, cancers, diabetes, renal failure and chronic pain have been shown to have a higher incidence of major depression as comorbidity than in individuals without chronic diseases (48). These are among the most common chronic conditions and lead to substantial disability among Australians (4, 43). In addition to influencing the health and wellbeing of individuals, these conditions represent a large economic burden for Australia, accounting for a substantial
proportion of health care resources currently committed and for future health budgets (55). Additionally, there are strong relationships between severe mental health disorders and poor housing, poor education, poor diet or alcohol abuse.

**Role of Identification and Early Detection of Modifiable Risk Factors in NCDs Prevention**

Modifiable risk factors for chronic diseases include smoking, physical inactivity, risky alcohol consumption, inadequate vegetable and fruit intake and obesity. Many leading health organisations such as the AIHW, Centres for Disease Control and Prevention, World Health Organization and the Partnership to Fight Chronic Disease, have agreed that without access to health care providers, the identification and early detection of those modifiable risk factors is impossible, even if there is a policy of managing them in place. The barriers to accessing medical care complicate patient monitoring and the continuity of treatment. Minority and at-risk groups, such as low-income populations, are less likely to access and receive the preventive services necessary compared with those who can afford the cost of services, so it is important to detect conditions at an early stage.

It is estimated that 80% of all CVD and T2DM, and 40% of all cancers could be avoided if the major risk factors were fully addressed using existing interventions. The burden of three or more chronic diseases, and the lifestyle factors that contribute to them, have been shown to rest more heavily in lower socioeconomic groups (18) (Figure 9) and higher diseases burden rural Australia (6) (Figure 10).
Tobacco is a known major contributor to chronic disease. The harmful use of alcohol is another key contributor, particularly for younger people among whom binge drinking and overall consumption is rising (18).
Additional risk factors such as complexity of the medication regime, reduced dexterity, failing eyesight and short-term memory loss can result in medication administration errors or non-adherence with medication regimens among the elderly.

**NCDs Preventative Strategies**

A growing body of evidence shows that preventative strategies can be effective in reducing the effect of chronic conditions, and in particular, that early detection results in less severe outcomes (6, 11). Clinical preventive services include screening for the existence of the disease or predisposition to its development, and counselling and immunisations against infectious agents (19). Despite their effectiveness, funding for, and the utilisation of, preventive services are typically lower than occurs for regular medical services. In contrast to their apparent cost in time and money, the benefits of preventive services are not directly perceived by patients because their effects are felt only in the long-term, or are greater for society as a whole than for the individual (18).

Public health programs have an important role in educating the public, promoting healthy lifestyles and raising general awareness about chronic diseases. While such programs can be funded by state or federal governments or private sources, their implementation occurs primarily through local agencies and community-based organisations (9).

Pharmacists are experts in medication management. Quality and safe use of medications is a core activity in the pharmacy profession to ensure appropriate use of medicines and reduce the risk of medication misadventure (30, 56). As pharmacists do not currently have access to patient health information from other health providers, pharmacists and GPs should encourage patients to use only one pharmacy
and one GP to assist in achieving safe and optimal therapeutic outcomes for patients (57).

**Pharmacist Core Activities**

Pharmacy practice in Australia encompasses management and supply of medicines, counselling on prescribed medications and over-the-counter medications and their related medical complaints, providing drug information, and monitoring drug therapy and patient adherence. Monitoring drug therapy includes the provision of medication reviews, smoking cessation advice and services, weight control advice, diabetes and asthma management plans, and patient medication profiles. Pharmacists are also involved in health promotion programs (58, 59).

The Medication Management Plan implemented in a number of hospitals in 2011 has not been adopted by all hospitals in Australia. The plan includes a medication history and reconciliation conducted during the patient’s admission and concludes with a discharge summary, with copies forwarded to both the patient’s GP and community pharmacy. The plan is intended to trigger a Home Medication Review (HMR) referral, within 24 hours after discharge (60). However, with the limited pharmacist workforce employed in the Australian hospitals, the Medication Management Plan is seen by many hospital managers as not being a priority and labour intensive. Only a few hospitals, particularly in metropolitan areas, have been able to fully implement it and even then it is implemented only in a few selected wards or departments. For example, large district hospitals in capital cities, and other similarly sized hospitals or more advanced tertiary hospitals across Australia, have teams such as a cardiac team (comprised of physicians, surgeons, educators and pharmacists), which gives them the capability to complete the medication
management plan. Many small rural town hospitals do not have even one pharmacist.

A comprehensive medication management plan includes:

− The current medication profile, education on medication indication, how they work, what they do, side effects, storage and disposal
− Education on devices technique for use and maintenance (e.g., spacers or inhaling devices)
− Education on personal equipment use, calibration and cleaning (e.g., blood glucose meters or blood pressure monitors)
− Detailed noting and recording of patient medical history, allergies, and contraindicated medications
− Communication to the patient of their role in sharing the responsibility for self-management of their condition through adherence, monitoring and life style modification.

The development of the Medication Management Plan also assists the doctor in the prescribing process, when the pharmacist has reviewed the patient’s medications during admission. It makes it easier for the prescriber to determine the most appropriate treatment. Support for self-management could be enhanced by incorporating it into these care plans through linked referrals to other health professionals, such as district nurses, health workers, diabetes educators and community pharmacists for HMR (61).

The 5th CPA between the Australian Government and the Pharmacy Guild of Australia include the costs of the professional pharmaceutical services previously supported under the 4th CPA plus additional programs to support and deliver clinical
services (31, 32). These include new medication management services, MedsCheck™ and Diabetes MedsCheck™, which involve an in-pharmacy review aiming to improve the patients’ quality and safe use of their medication and reduce the likelihood of adverse events. These services are intended to support patients with chronic diseases such as diabetes, when no other service provider is available or if the available services are inadequate.

Additionally, the Pharmacy Practice Incentive, PPI™, a new service funded under the 5th CPA (32), is intended to help meet local population needs. This is a payment based on the number of services the community pharmacy provides for their local population, such as monitoring patient adherence to long-term medication and preventive health campaigns (31). Under the PPI™ initiatives, more weight was given to clinical interventions intended to encourage pharmacists to integrate their services with those provided by the prescribers, and through better communications with GPs to improve the quality use of medications. This might be through in-pharmacy medication reviews, the provision of dose administration aids, and utilisation of long-stay national inpatient medication charts in residential care, and electronic recording of controlled drugs (31).

In addition to medication supply, the pharmacist is qualified to provide medication counselling services, medication management reviews, patient education and ongoing monitoring of disease-specific indicators to improve patient outcomes and quality of life (32).

Poor medication adherence by patients can be due to poor knowledge about their condition, prognosis and the reason behind the need for the prescribed medication. It can also be due to inability to pay for those medications, and the complexity of the
regimen or medication supplied in multiple formulations that require special
techniques to administer and produce therapeutic effect. Additionally, problems may
occur with access to a continuous supply of medication and services due to distance
between patient and nearest medical provider (62).

As a minimum requirement at each dispensing of a new prescription, pharmacists
should address the patient’s quality of life. This is a multidimensional concept that
includes physical, psychological and social domains. They need to assist in the
management of ongoing pain and suffering and be aware of possible associated
anxiety, depression, loss of independence and interference of disease with work and
relationships. Pharmacists are trained to undertake systematic and comprehensive
assessments for the purposes of understanding a client’s physical, psychological and
social functioning (63). Pharmacists can effectively engage in conversation with
patients and make them feel sufficiently comfortable to disclose their relevant
medical history. They also have excellent communication skills to establish rapport
with the patient (57), to ensure they understand the importance of adhering to their
medicines, and commit to regular consultations with the same pharmacist at the same
pharmacy.

However, there is still a need to have a body of research that investigates whether a
pharmacist-led intervention to optimising medication use can be effective in reducing
hospital admissions due to medication misadventures.

**Collaboration**

Anderson, *et al.* (64) measured the collaboration between health providers to support
the provision of Multi-Purpose Services, which were introduced in 1991 to address
the shortage in health professionals willing to work in rural Australia, and to improve
the rural community’s poor health outcomes in comparison to city dwellers (64). The Multi-Purpose Services required the creation of a new model of service provision and the merging of some existing facilities, such as hospitals and nursing homes.

“The merging provided an insight into the perceptions of community members, staff members and managers involved in the process of developing a multi-purpose service. It revealed that the anticipation of risk was intrinsic to a process of changing from a traditional hospital service to collaborating in a new model of health care provided at a multi-purpose service” (65, pgs. 52–53).

The authors described the management of perceived risk as being a matter of trust in the ability of others, and the suspension of preconceptions. Collaboration was more successful when participating services trusted each other (64).

One pilot study has ignored all the current concepts of innovative case management, multidisciplinary approaches and collaboration models (65). Its approach looked back to the era where the health system did not trust anyone other than doctors to provide health care and clinical interventions. The study enrolled four general practices, 154 patients and collected data from one pharmacy. The authors acknowledged the input of pharmacists ‘trying’ over the years to understand how they can improve patients’ compliance to prescribed medications, but then questioned whether pharmacists had adequate patient communication skills. This was followed by a statement, presented without supporting evidence, that “physicians, who usually possess great proficiency in communication and/or medical management will achieve better medication adherence among their patients, but that this has not been examined definitively” (65, pg. 98).
The authors then added that no matter what the patient believed about their illness or medications, if they believe in their doctor, they would obey the instructions. This study is an indication that there are some GPs who, despite the global trends in NCDs, are still resistant to the idea of sharing patient direct disease management with any other professionals.

As previously discussed, the Team Care Arrangement can provide patients with access to allied health professionals, through referrals from their GPs. Increased levels of collaboration between general practice and private and public allied health services would help to promote the multidisciplinary team care concept (33, 58, 59). However, the multidisciplinary team included in the eligibility list for the Team Care Arrangement referrals does not include the pharmacist or the dentist and many others. Additionally it is not two-way driven. It is initiated, controlled and its main benefits are directed to the GP and those to whom the individual GP elects to refer.

Although the GP and general medical practice are and will remain the crucial point for diagnosis and coordination of the management of NCDs, evidence clearly shows that other health professionals add value in terms of adherence to therapy and lifestyle changes and that their interventions can be cost effective (66). In Australia, at the time of writing this thesis, government policy dictates that everyone with NCDs must visit their pharmacist at least once a month to collect prescription repeats; this is currently an under-utilised resource (58, 59).

It has been suggested that a model for monitoring of patients with comorbidities that integrates other health professionals would form best practice (14, 16).

For the purpose of continuity of care, and to overcome shortages in health care professionals, nurse practitioners, optometrists, dentists and physiotherapists are able
to prescribe medications within protocol. However, the extension of the same privileges for Australian pharmacists is still under discussion (59).

The traditional relationship between the doctor as prescriber, and pharmacist as dispenser, without allowances for any crossover, based on community geographical location and health practitioner availability, is no longer sustainable in the context of the current shortage in the rural health professional workforce (67). A health professional’s duty of care is not only to provide health services when possible but to ensure continuity of this care, including monitoring of the clinical response and continuity of supply of medications, adherence to and the effectiveness of therapy.

A collaborative approach is considered an appropriate way to address these issues (68). Although it would be beneficial in metropolitan areas, this collaboration is essential to boost the health system in regional, rural and remote Australia. For this to occur, the role of the pharmacist needs to be redefined to reflect the activities that can be performed by the pharmacist beyond dispensing prescriptions and supplying medications. Current Australian primary health care is fragmented and communication between pharmacists and GPs ineffective (69). If the recommended changes listed in the Grattan report could be achieved, especially in regional, rural and remote Australian, fragmentation would be reduced. These recommended activities are: vaccination, prescriptions re-write for NCDs and NCDs management (69).

Traditionally, the Australian health system applies total separation between functions such as diagnosis and prescribing, and between dispensing and administration. Recently, crossover and multi-functional accreditations have started to change the face of traditional practice. Today, health workers in very remote Aboriginal
communities manage patients and provide them with medications within approved protocols. After appropriate training, nurse practitioners and physicians’ assistants can also prescribe within approved formularies (6). Registered nurses with advanced training diagnose and administer medications in emergency rooms under standing orders with and without prior telephone contact with the doctor (58).

In the ‘Caring Together’ review published in 2009 (27), it was found that the shortages and high workloads mean that medical professionals in New South Wales do not have the time to teach patients about disease self-management. However, almost all the national health professional practice standards recognise and expect that all health providers (across medical, allied health and nursing) have a responsibility to actively empower the patient, and regularly reinforce to them and their carers the need to take part in the management of their conditions (27). This involves discussion of the prognosis, goal-setting, identification of barriers to reaching those goals and strategies to overcome those barriers (9).

Pharmacists are in a position to see patients with NCDs on monthly basis for repeat prescription dispensing. According to the Pharmacy Guild of Australia (32), diseases such as chronic pain, gout, osteoarthritis, rheumatoid arthritis, CVD, asthma, chronic obstructive pulmonary disease, Parkinson’s disease, epilepsy, depression, bipolar disorders, schizophrenia, degenerative neurological conditions, thyroid gland conditions, diabetes, gastro-oesophageal reflux disease, inflammatory bowel diseases, osteoporosis, psoriasis, eczema and glaucoma are the most common chronic conditions that pharmacist see in the community.

At the 2010 Chronic Disease Management Australia conference, Georgeff (70) suggested that, for a chronic disease model of care to be workable, it needs to be
performed in collaboration with the entire care team including the patient, with regular follow-up and review (Figure 11) (70).

In a survey by the e-Health developers (70) Medical Management Review (MMR) services were found to increase by 498% after the General Practitioner Management Plan component of the chronic disease management system had commenced (70).

The CDMNet™ is the foundation of this service; it allows GPs to extract patient data from their desktop computer, create an electronic personalised care plan, and share this with the health care team and the patient. This collaborative, web-based service allows the GP to monitor and update the plan and health records with automated short message services (SMS) for follow-ups and review (70).

Figure 11 - The concept of collaboration between health providers (70).
Figure 12 shows GP responses to Georgeff’s survey. Barriers to best practice included: too much paperwork, collaboration is too time-consuming, tracking adherence is too hard and communication does not happen (70). The results of the survey (70) are of particular importance to this study as the investigator faced the same situation and attitude towards collaboration between GPs and the community pharmacists.

**Figure 12 - The concept of best practice of patient care (70).**

Rigby (2011) called for better collaboration between GPs and pharmacists and the extension of the pharmacist’s role beyond medication supply; however, she finished her short report with a number of questions which require further investigation (58, 59), such as:
If pharmacy services were extended to close the loop and provide continuity of chronic disease management in collaboration with GPs (funded by Medicare),

- How would the effects be measured?
- What would be the extent of public funding for those services?

These questions seem reasonable considering that almost all current chronic disease programs are GP-led, and there has been resistance from GPs to sharing leadership with any others involved in patient primary care (69).

**Health Workforce**

The shortage of rural GPs is very well documented in most of the recent Australian health care reviews. Some towns in Australia still do not have a doctor or a pharmacist, because low population densities will not sustain health professionals financially or allow them to maintain their skills (71, 72). Managing ambulatory chronic patients in rural communities therefore presents unique challenges, including vast distances between patients and health facilities, limited access to health professionals and shortages in the health workforce (25).

The Australian Bureau of Statistics 2006 census of population and housing indicated that only 25% of the combined health professional workforce was employed in primary health care in general medical practice (26,900) or community-based dental practice, community-based allied health and pharmacy (12,400) and 59% of Australians experiencing health work force shortage (25). Most (84.8%) pharmacists are employed in a community setting and only 11.2% in the hospital setting, with an average of 74 pharmacists per 100,000 population and 24% in regional, rural and remote Australia (25). In contrast, there are 112.2 GPs per 100,000 population with an estimated 33% GPs working in primary care occupations in regional, rural and
remote areas (25). However, the non-metropolitan workforce is largely located in major regional centres and only half of those are accessible by people living in remote areas (71). While 68% of Australians live in major cities, 85% of specialists, 77% of GPs and 76% of pharmacists practice there (67). This suggests an imbalance between need and service provision (Figure 13).

![The Primary Health Care workforce by remoteness per 100,000 people, 2006 (67).](image)

The Primary Health Care Reform in Australia Report (67), which was based on analysis of stake holder submissions, contains the following statement:

“A number of common themes were present in submissions received from groups with an interest in pharmacy. Overwhelmingly, these submissions indicated the need for improvements to be made in managing patients as they transition from one care setting to another (e.g. pre/post-admission to hospital) and for pharmacy to play a role in this process. Other key issues included the role that e-Health can play in reducing adverse reactions to medications and prescribing behaviours, the importance of improved data
collection and the need for pharmacists to be included as part of the primary health care team” (67, pg. 25).

This statement (67) clearly describes pharmacists’ expectations that their role will change from simple dispensing and medication supply, expanding into active participation as part of the primary care multidisciplinary approach to link together services ensuring continuity of care.

The report stated that 80% of Australians visit a GP at least once a year, with their visits subsidised by Medicare, however, other service providers, such as specialists, nurses and pharmacists, are under-utilised (67). In relation to Medicare, there are initiatives to introduce a $6 payment when visiting GPs or hospitals. This is a professionally fair approach, which will allow the Australian public to understand why they pay when they get their medicine, but not when visit the doctor. It may also change false beliefs of some the GPs and members of the public that pharmacists earn more money than GPs, when the actual reason of the payment is to cover the gap between subsidy and the actual cost of goods and services (http://www.abc.net.au/news/2013-12-29/ama-criticises-proposals-for-new-gp-fee/5177522).

The report (67) also identified that patients with NCDs usually start their care in the GP clinic; however, in the long run and for the continuity of care, they need to access other services. For example, a typical diabetic patient will require access to a GP, a pharmacist, a nurse, specialists (a cardiologist, neurologist, ophthalmologist, nephrologists, urologist, and endocrinologist), a diabetes educator, a podiatrist and a dietician. However, many health professionals, patients and carers are unaware of the full range of services available in Australia or how to access them (67).
Rural Australia

The inequity in service provision between metropolitan areas, regional areas and rural areas can be at least partially overcome with new and collaborative models of care that include currently under-utilised health professionals. As noted in the DoHA report,

“With its network of over 5,000 pharmacies in urban, regional and rural communities throughout Australia and its highly trained workforce, community pharmacy is the most accessible of all health services, and is well placed to play a constructive and dynamic role in the provision of effective primary health care”. (67, pg. 38)

The workforce implications of the above statement identified in the report are the potential of pharmacists to provide (67, 73):

- Supporting services for GPs in areas such as continuity of care and preventive health care
- Continuity of targeting risk factor modification and lifestyle-related programs
- Continuity of medication supply regardless of the patient’s location, be it in the immediate proximity, a remote location or while the patient is in secondary or residential care.

The AIHW’s Health and Community Services Labour Force survey (2009) identified that several preventive health care programs are currently delivered through community pharmacies in the United Kingdom, such as men’s health checks, targeted public health campaigns, vascular checks, diabetes testing, and lifestyle risk
assessment testing, but in Australia there is limited government funding for these (73).

To allow the continuity of care to be effective, a protected information flow, or sharing facility, between the members of the entire health care team is essential. The Pharmacy Guild of Australia acknowledged this aspect in their submission to government as part of the e-health concept development (73).

Pharmacy services are completely computerised and include resources that support almost all the functions they provide, including clinical services and finance. Around 96% of pharmacies also possess business-grade broadband internet connections (73).

The DoHA primary health care workforce survey recognised that within the scope of practice for primary care, GPs and pharmacists need each other to sustain practice and provide meaningful services (25). The introduction of e-Health should allow sharing of patient information in a timely manner without experiencing delays due to communication barriers between health professionals. Information such as allergies, adverse drug reactions or drug-drug interaction should not wait for phone or email communications. Using e-Health, this information will be in the system for viewing by practitioners before prescribing, dispensing or administering of treatment (74). Figure 14 shows the structure of the secured repositories of personally controlled e-Health record files.
An Australian Pharmacy Council report on the remote and rural pharmacists’ scope of practice project found that state and national legislation caused remote pharmacists a great deal of confusion (75). Currently pharmacists are prevented by legislation from dispensing and providing pharmaceutical services outside registered pharmacy premises, which is considered a significant barrier to the provision of PoC testing for the NCD management during Health Management Review.

**Adherence to Treatment and Patient Education**

In a number of small observational studies, the association between medication non-adherence and adverse outcomes is deemed as common but not the only cause (76, 61):

- Intentional or active non-adherence: where the patient made a rational decision after weighing the medication side effects verses the cost or the benefits of treatment (as it perceived by them)
– Unintentional or passive non-adherence: where the patient may be experiencing barriers to adherence due to illiteracy, forgetfulness or the treatment complexity.

Measurement of Adherence as a behaviour is very difficult; however, the evidence of adherence can be sometimes measured through: (76, 61)

– Patient self-reported diaries, interviews
– Laboratory drug therapeutic monitoring of their levels in body
– Through repeat prescription dispensing records, pill counts, point of care monitoring of certain parameters or indirect.

Interventions to improve medication adherence can be (76, 61):

– Uni-modal: Conducted by a single practitioner or number of practitioners but individually, however, these are generally less successful because the reasons are often multifactorial

– Multi-modal: Conducted by a multidisciplinary team, where authors found that the intervention improved both adherence and outcomes.

However, larger, rigorous intervention studies are now needed to evaluate whether the increasing body of understanding of the causes of medication non-adherence can be translated into meaningful improvements in patient outcomes (33, 58).

Appropriate use of and adherence to medication regimens yields cost-effective therapy and improves health outcomes and quality of life, avoiding the costs of further medical treatment and hospital admission. Pharmacists are seen nationally and internationally as the most appropriate health professionals to improve management of medication safe usage and adherence but are underutilised (77), as the following quote from Australian Pharmacy Council remote pharmacist project illustrates:
“Pharmacy services play an integral role in minimising the risks of medication misadventure. A safe and effective medication supply process that involves both prescription review and counselling of the patient is vital in maintaining a high quality and safe health-care system. Although pharmacists add value by professional counselling in dispensing and supplying of all scheduled products, pharmacy is frequently overlooked in planning activities aimed at improving the health care system. This may partly be a result of the hybrid nature of funding and regulation – the Commonwealth providing funding through the PBS, while regulation about pharmacy ownership and scheduling of medicines is incorporated in state and territory legislation” (65, pg. 19).

In 2005, Wakerman et al. (78) examined the Sharing Health Care Initiative (SHCI), which aims to improve health service management and quality of life for people with chronic disease through patient education and self-management. The study was based on six in-depth interviews with five key informants, which were thematically analysed. The study five themes were: context, community engagement, system flexibility and adaptability, information systems and the human nature of health care and policy. They found that behavioural change in participants only became effective when the person was empowered with knowledge of their condition and medication, and then became, in their own time, ready to change (78). Wakerman et al. (2005) also indicated that in a rural setting, the success of the SHCI might depend on the provider, as personality issues between provider and patient may prevent the achievement of behavioural change (78). There may also be additional factors such as high staff turnover, staff resistance to change, individual behaviours, and key individuals being overcommitted and unable to focus sufficiently on projects.
Stone and Packer (79), evaluated a rural chronic disease self-management program using the Health Education Impact Questionnaire (heiQ™) (79). The concept of their study was based on the five key strategies of the federal government program Better Health Initiative (http://www.healthnetworks.health.wa.gov.au/abhi/home/). The Better Health Initiative five-priority areas for action are (79):

- Promoting healthy lifestyles
- Supporting early detection of risk factors and chronic disease
- Supporting lifestyle and risk modification
- Encouraging active patient self-management of chronic conditions
- Improving the communication and coordination between care services.

The study methodology involved enrolling ten leaders (in the context of train the trainers), seven health professionals from any speciality and three others with an office administration background (79). The 10 leaders were trained on the proposed program over three courses. Thirty-three participants were enrolled, and the heiQ™ was administered to test their baseline health, lifestyle and healthy behaviour knowledge. The leaders then delivered the health education course they had previously received to the participants, then administered a structured interview and heiQ™ follow-up to the 33 participants to measure the level of knowledge improvement, if any, on their health, lifestyle and healthy behaviour. The results were evaluated according to the heiQ™ scoring guidelines for both the baseline and follow-up heiQ™ (80).

This instrument provided a consistent measure of the impact of the chronic disease self-management program (CDSMP) the authors were offering (79).
Doney and Packer (3) examined activity levels in elderly Australians and validated the Activity Card Sort – Australia (ACS-Aus) against the Adelaide Activity Profile. Only 50% of the 70–74 years age group, 20% of the 80–84 years age group and 6% of participants older than 85 years were categorised as having a high activity level, an important component in modifying CVD risk.

In a study conducted in Western Australia to evaluate the introduction of the standard CDSMP into rural health services, the heiQ™ and the ACS were utilised to measure participants’ outcomes (79). Seven health professionals (GPs and area health service staff, not including pharmacists) and three others were enrolled and trained to deliver the CDSMP. One of the study recommendations was to integrate the CDSMP into everyday practice:

“A whole-of-system approach that includes system redesign to focus on continuity of care among service providers and establishing and maintaining group leadership skills and responsibilities; self-management is characterised by a genuine partnership between clients and clinicians, a paradigm shift that is not well understood or embraced by health professionals” (79, pg. 8).

**Disease Control and Monitoring**

As previously mentioned, one of the methods to measure adherence to therapy is direct testing the drug serum level or their effect on disease specific parameters such as pain score, blood pressure, blood glucose level, total cholesterol, triglycerides or international normalised ratio (INR).

Organisations such as CARPA recognise the need to monitor NCD markers (evidence of adherence, improvement or deterioration) in the primary health care setting. The CARPA Standard Treatment Manual (STM) (28) is a treatment guide
for local practitioners that covers most of the chronic conditions that are common in remote practice. It looks at conditions that have different presentations and management issues that are life threatening, dangerous or frightening for practitioners, have public health implications and management that needs to be coordinated and standardised. The manual covers life support protocols and procedures for diseases such as mental health issues (e.g., depression, dementia, anxiety and psychosis), NCDs and lifestyle problems that have become population health issues (e.g., obesity and smoking). The CARPA STM protocols include differential diagnosis, condition management (targets and monitoring), medication choices and lifestyle advice (28).

Krass et al. (81), in a collaboration of researchers from Sydney University, Curtin University, The University of Tasmania and Monash University on diabetes management in primary care settings in Australia, estimated that there will be 366 million people worldwide (7.3% of the world population) with T2DM by 2030 (81). The authors’ aim was to investigate prescribing habits, how to improve them, and the effect of adherence to medication on blood pressure, blood glucose level, total cholesterol, triglycerides and INR. The study was conducted between 2007 and 2008 in a community pharmacy setting and was part of the 4th CPA, funded by the DoHA. A total of 430 patients participated. Smoking status, height, weight, HbA1c, blood pressure, total cholesterol, triglycerides and renal function baseline data were collected from patients’ GPs. Pharmacists then reviewed the patients’ current regimens and calculated adherence using the medication position ratio, which is based on the ratio of daily doses supplied to frequency of dispensing (e.g., 90 tablets of medication for daily doses, should be sufficient for 90 days). If the patient collected their repeat prescription after 90 days, their adherence was calculated as
one (1), if they collected the prescription after 120 days, the adherence fraction dropped to 0.75. The study concluded that post-intervention, 70% of patients were ≥0.9 adherent to their therapy and 4% had an adherence ratio of <0.6. Krass et al. (2011) also concluded that diabetic patients need innovative methods to help them manage their blood glucose level to achieve their target and accordingly reduce diabetes complications (81).

A similar study was conducted in Belgium (82) in 66 community pharmacies, selecting five patients from each. Mehuys et al. (2011) intervention was based on five activities: disease education, medication education, medication adherence, lifestyle education and reminders to arrange foot examinations and annual eye checks. The GPs of the enrolled patients were informed by letter. The sustainability of the intervention was also evaluated; an 18-week follow up was conducted to determine whether patients maintained their blood glucose level at the level achieved during the study (82). The study concluded that there was significant improvement in the intervention group at the beginning of the study after the medications were changed and there was improvement in patient knowledge after the delivery of education session on diabetes self-management (82). However, after 18 month, the follow-up results did not show significant difference between the intervention and the control group (82). This suggests the importance of ongoing monitoring, refreshing education on the condition, and enforcing the importance of self-management more frequently than every 18 months. Pharmacists see patients more often than any other health professionals (74) for dispensing of prescription medications or over-the-counter medication supply, so this opportunity can be used for similar interventions.
An AIHW 2010 analysis of the National Hospital Morbidity Database noted that 4% of the total reported, and 7.1% of hospital admissions considered preventable, were due to diabetes complications (83, 84). Examples of T2DM complications were poor diabetes control, hypoglycaemia, circulatory complications, eye complications, kidney complications, acidosis and multiple complications (Figure 15).

In an editorial by Bergin et al. (2012) published in the Medical Journal of Australia (85), the prevalence of potentially preventable diabetes-related hospital admissions published in the AIHW Australian hospital statistics (2010) report was discussed, noting that in 2007–2008 one amputation was performed every three hours in Australia. This editorial recognised the importance of diabetes control in the prevention of peripheral circulation impairment leading to diabetes complications (83, 84, 85) (Figure 16).
The Fremantle diabetes study is a longitudinal observational study of community-based people with diabetes from an urban postcode-defined population in Fremantle, Western Australia. At the time of writing, the Fremantle study had generated 49 articles and four letters in peer-reviewed journals. Many of these publications are relevant to CDM. Chubb et al. (2011) investigated the benefit of diabetes education provided to T2DM patients during their encounters with health professionals, concluding that while education programs improved patients’ knowledge, specialised programs are still required for the elderly and minority groups (86).

Davis et al. (2007) found that patients’ risk of retinopathy after five years of blood glucose level self-monitoring was reduced by 48% (87).

Chubb et al. (2011) and Davis et al. (2006) (88) found that neither health care provider management nor self-monitoring without adherence improved patients’ glycaemic control.

**Anticoagulants**

Warfarin is a narrow therapeutic index medication that requires close monitoring. In a study to investigate the impact of pharmacists’ warfarin management (89), the
authors acknowledged the difficulty of controlling INR due to factors such as adherence to therapy, dosage and side effects. In the United States of America, United Kingdom and now in New Zealand, pharmacists perform INR testing for patients taking warfarin; these clinics have been proven to contribute to patients reaching and staying at their INR target, to medical staff satisfaction of the process and the outcome and to reduction in INR monitoring costs (89). In Australia, pharmacists do not participate formally in INR management or warfarin dose adjustment recommendations, but provide professionally integrated advice on warfarin to patients.

Another study conducted by Glover et al. (90) identified that to ensure that there is a future role for the PoC testing in warfarin management, the user must demonstrate competency all times and ensure that PoC monitors are well maintained and used in a controlled environment (90). In Australia, independent laboratories not related to the manufacture of the INR monitor perform quality assurance surveys, testing the operator process and results compared to all other users. This to ensure that the results are reproducible and comparable to INR measurements performed in pathology laboratories.

In an evaluation of pharmacists’ perceptions of service benefits to older people in New Zealand, among 20 pharmacists who responded, 35% provided screening (blood pressure and total cholesterol), 28% provided HMR, 90% delivered medications to the elderly homes, 27% sent prescription repeats reminders and 32% provided education on medication use to the community. Tordoff et al. (2011) found that pharmacists believed patients benefit more when they combine medication
management reviews (MMR) with other services such as INR monitoring, PoC testing or education (91).

**Summary**

In this chapter, through a review of the literature, it became clear that there are a number of gaps in the Australian primary health care system that potentially can be filled, at least in part, by extending the current pharmacist role to one of more clinical focus. It was become clear that professional barriers prevent their inclusion as member of the NCD patient management team. NCD programs that do not have the GP as the leading force receive insufficient funds; however, the reasons for this are unclear. It was also found that there is insufficient research into pharmacist-GP collaboration or the effectiveness of interventions involving professionals other than GPs in provision of patient education; across follow-up or PoC testing. Accordingly, this study will add value to this field of research.
Chapter IV. Study Outlines, Methods and Design

Introduction

As noted in the Introduction, the broad aim of this project was to assess how well pharmacists can work in collaboration with GPs in the provision of chronic disease management. Its ultimate purpose was to determine whether such a model could overcome the problems posed by the small number of GPs in rural and remote Australia and provide patients with additional monitoring between doctors’ visits.

In selecting the study question, there were several options to be considered:

– To measure the quality of the intervention itself, the method of delivery and pharmacists competency in delivering it. However, this would have only addressed the pharmacy profession’s need to extend the pharmacist role to new activities and not the patient’s need, or the collaboration with other health practitioners’ aspects of multidisciplinary case management.

– To concentrate on the patient outcomes; however, this approach would not elucidate whether the pharmacist intervention was the only new variable that caused the improvement or if it the close collaboration with the local health practitioners.

– To combine both first and second options:
  
  o A patient-centred component through improving patient knowledge and understanding of their condition and medication, and measuring disease state markers as evidence of treatment adherence
  
  o A professional development component recording the additional time that pharmacists spent with patients, measuring the quality of the pharmacist-GP collaboration and the quality and cost of the intervention.
The resultant research question was: Can a model of care based on a chronic disease management collaboration (between rural Australia community pharmacists, GPS, allied health professionals and the patient) improve treatment adherence and overall health outcomes, and be sustainable within those practitioners’ workloads?

**Specific aims**

This study aimed to investigate:

1. If the collaborative community pharmacist and GP model of care in chronic disease management, applied to patients in rural Australia, could improve the treatment adherence and health outcomes of chronic disease patients through better self-management skills, medication knowledge and additional face-to-face availability of health professionals.

2. The sustainability of an effective pharmacist intervention, which is time and labour efficient, consistent with protocols, and in collaboration with GPs and other allied health professionals, in rural Australian towns.

3. The parameters (body mass index, waist measurement, heart rate, pain score, blood pressure, total cholesterol level, triglycerides, blood glucose level, visual acuity and monofilament pressure) that can be practically monitored in community pharmacies to guide the patient self-management and treatment process.

4. The effect of the intervention on enforcing lifestyle messages on smoking, alcohol consumption, physical inactivity and obesity on patient health outcomes.

**Ethics**

The Charles Sturt University Human Research Ethics Committee approved this study on 15 May 2012 (Appendix I). The participating community pharmacies (sites)
consented to perform the intervention within the study protocol (12 months from 1 June 2012 – 1 July 2013, Appendix II) and patients consented to participate for the duration of the study (12 months from 1 June 2012 – 1 July 2013, Appendix III).

**Design**

As shown in the literature review (Chapter III), few studies of clinical pharmacy practice have been undertaken to date in Australia. One reason for this is that rigorous, comprehensive studies require very large budgets and large teams of investigators. Smaller-scale, pilot studies improve the research base, and generate preliminary evidence to support the development and funding of larger studies in the future. Few pharmacy-focused studies have received small grants from DoHA or the National Health and Medical Research Council. All other known relevant government-funded Australian studies, such as the Fremantle Diabetes Study have a pharmacy intervention component but no previous studies have a sole focus on a pharmacy intervention.

This project was a pilot, pre- and post-intervention study designed to support future definitive studies. The clinical intervention phase was designed to (as far as possible) support the existing advice patients had received from their doctors, was minimally invasive (lancet finger pricks for point of care testing) and did not involve any active medication administration. The study used three tools: a modified Health Education Impact Questionnaire (heiQ™) for patients pre- and post-intervention, mid-study survey for pharmacists and end of study feedback statements from pharmacists and patients. The study was conducted in community pharmacies located in rural and remote Australia in areas with Pharmacy Access/Remoteness Index of Australia codes of 2 to 6. The intervention took place over 12 months, of
which three months were promotion, three months enrolment and baseline data collection and six months patient monthly monitoring. Data were analysed in ASReml-R™ using linear mixed models and generalised linear mixed models.

**Team Structure**

The project team was designed to cover all necessary areas of expertise: pharmacy, medicine, pathology and statistics (Figure 17). The structure took into account that the study intervention sites are privately owned and constitute the only income source for participating pharmacists. This dictated that the intervention had to be of a manageable workload that could be absorbed into the sites’ daily activities within their current workforce ability and had to incorporate low project running costs as the participation was not paid in time or consumables used in testing.

*Figure 17 - Study Team Structure*

*X* indicates no communication between the two participants
* <————> indicates governance communications
* — — — — indicates communication with patients is limited to local GPs and pharmacists
Responsibilities

This study was designed and coordinated by the investigator. The local pharmacists performed the intervention phase within the study protocol (Project Site information sheet and consent form are presented in Appendix II).

Investigator role:

– Develop the disease-management protocols and all other required forms
– Write all required information sheets and consent forms
– Provide training to the pharmacists participating in the study
– Provide the required equipment, information and consent forms, and heiQ™ forms
– Coordinate all study activities
– Conduct the two quality-control audits
– Collate the data
– Analyse the data
– Discuss and report findings
– Write the final papers.

Participating pharmacists’ role:

– Enrol patients into the study
– De-identify patient-specific information sent on from the pharmacy using the site unique code
– Collect baseline data
– Perform the study intervention

– Collect the control data (12 months medication history before 1 July 2012 and 12 months medication history from 1 July 2012)

– Communicate all collected, de-identified data to the investigator.

Qualitative Consulting Unit (QCU) role:

– Data analysis in collaboration with investigator.

Study supervisors ensured that:

– The investigator followed the study design

– The local pharmacists and GPs were appropriately briefed on all aspects of the study.

Sample, Control and Randomisation

Randomisation to treatment and control groups was considered, but was deemed to be impractical for several reasons. In rural communities in NSW, where few health practitioners are effectively shared by almost all the town’s population, any control population would be expected to become contaminated rapidly. Moreover, as entire communities are often served by only one general practice and one community pharmacy, the participating health professionals were united in the opinion that it would be unfair and possibly unethical to exclude any of their patients from opportunities for additional care. In addition, local pharmacists and GPs advised that the communities would not support randomisation to treatment and control groups, as this would be seen as selective denial of service access. Additionally, randomisation within the small populations in many rural towns could leave the study with a very small sample.
The possibility of selecting one town as an intervention site and another in the same geographical area as a control site was considered. However, it would be very hard to identify two very similar rural Australian towns, considering that the type of industry or farming in each town shapes their community in a unique way including the common infestations, communicable diseases and NCDs (92). Dynamics, industry and demographic characteristics often differ markedly from one community to another, limiting their capacity to act as true experimental controls.

Given the problem associated with randomisation and control group selection outlined above, this study used the enrolled patients’ own previous 12 month medical and medication history as the study control and the enrolment-day medication list and onsite measured parameters as the baseline data. For this pilot study, the target sample was approximately 600 individuals from nine community pharmacies located in the nine towns. The sample was purposively selected.

The inclusion criteria were:

- Adults (aged >44yrs) with one or more chronic disease
- Ability to provide written consent
- Ongoing customer, not transit or traveller
- Living independently and able to collect their medications.

Potential participants who did not meet these criteria, as well as pregnant or breastfeeding women, were excluded from the study.

**Sample Calculation**

Due to the distances involved in the area where the study was conducted in rural NSW and the available funds, only eight towns with one or two pharmacies were
identified as being on one route from Wagga Wagga to Orange NSW. This was a journey the investigator had to make frequently for other reasons. The selected towns have nursing and/or residential homes where residents are not living independently as per the study selection criteria. Accordingly, the sample was calculated from the total population between the ages of 44 and 80 years (n=588) (Table 1).

Table 1 - Study Sample Calculation

<table>
<thead>
<tr>
<th>Town</th>
<th>Total Population</th>
<th>44 years and under</th>
<th>&gt;44 years</th>
<th>&gt;80 years</th>
<th>Between the ages of 45-80 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>GD</td>
<td>1926</td>
<td>977</td>
<td>949</td>
<td>132</td>
<td></td>
</tr>
<tr>
<td>JJ</td>
<td>4400</td>
<td>2635</td>
<td>1765</td>
<td>171</td>
<td></td>
</tr>
<tr>
<td>TF</td>
<td>3874</td>
<td>1826</td>
<td>2021</td>
<td>310</td>
<td></td>
</tr>
<tr>
<td>PE &amp; PR</td>
<td>10026</td>
<td>4725</td>
<td>5301</td>
<td>606</td>
<td></td>
</tr>
<tr>
<td>HA</td>
<td>1925</td>
<td>739</td>
<td>1186</td>
<td>127</td>
<td></td>
</tr>
<tr>
<td>LOC</td>
<td>800</td>
<td>261</td>
<td>539</td>
<td>104</td>
<td></td>
</tr>
<tr>
<td>CV</td>
<td>1424</td>
<td>538</td>
<td>886</td>
<td>86</td>
<td></td>
</tr>
<tr>
<td>BS</td>
<td>1211</td>
<td>468</td>
<td>743</td>
<td>95</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>25586</td>
<td>12172</td>
<td>13390</td>
<td>1631</td>
<td>11759</td>
</tr>
<tr>
<td>Sample (5%)</td>
<td></td>
<td>1280</td>
<td>670</td>
<td>588</td>
<td></td>
</tr>
</tbody>
</table>

The intention was to enrol all eligible patients if they would consent to participate, which could be up to 588 participants (up to 50 per small town [<1500 population] and 100 per larger towns). However, during the enrolment phase this was impossible as pharmacists in the nine pharmacies proved unable to contribute the time and effort to which they had initially committed. This was due to them adopting other income generating projects under the 5th CPA, which was announced after data collection had commenced. It was decided that a total of 100 patients would be a manageable workload for the sites and it would provide data sufficient for a pilot study to detect trends and significance. Accordingly, an ethics variation application was submitted (Appendix I) and approved in March 2013.
Method

The effect of pharmacist intervention on patient knowledge of their medications, medical conditions and self-management of both medications and medical conditions using the disease parameters that can be measured to indicate patient adherence to treatment was investigated.

Data source

The following summarises the source of this study’s data:

- The control was the 12 month medication history dated back to 1 July 2011, medical history taken from the patient or diagnostic results if the GP collaborated or if the patient had copies.

- The baseline included the parameters measured in the community pharmacy on the day of enrolment into the study. The follow-up was the monthly intervention to coincide with the individual patient’s repeat prescription dispensing.

- The effect was measured by comparing the baseline results to the final testing results.

Limitations and Constraints

The study was conceived and built around a group of motivated local community pharmacists, taking into account the small population size, familial connection between residents, and financial hardship of small retail business, and opening hour limitations of community pharmacies in small towns.

Sixteen months elapsed between the initial communication with those sites and their signing of the formal consent to participate. Ethical approval was delayed because at first submission an error occurred that resulted in a significant part of the submitted
paperwork not reaching the committee members. This delay became relevant because during this time, the 5th CPA introduced several government-remunerated services, which had similarities to this study initiative. In addition, several other DoHA-funded studies were competing for pharmacists’ time at the same intervention sites (the ‘Know your numbers’ stroke study, and again under the 5th CPA MedsCheck™ and Diabetes MedsCheck™).

Seven out of the nine data collection sites were in single-pharmacy small towns, the other two data collection sites were the only two pharmacies in a slightly larger town with a transient mining population. They were in NSW located in the Murrumbidgee and Western Central Medicare Local areas between the cities of Wagga Wagga and Orange.

**Communication plan and implementation**

During June 2011, all GPs in the local medical practices, whose patients were likely to be enrolled in the study, were visited by the investigator and principal supervisor to explain the study in person. Forty-eight GPs were visited, representing 100% of all GP practices in the selected towns. It was made clear that a key feature of the proposed intervention was that the patient would be asked what advice they had already been given by their GP, and that pharmacists would aim to reinforce and build from this, and that if it was felt appropriate to challenge any previous advice, the doctor would be consulted first.

The investigator and all participating pharmacists met three times at a central location to ensure a full understanding of the study’s aim, objectives and protocols (February, April, June 2011 and May, June, July 2012). After 30 July 2012, the investigator visited sites individually every two weeks until 31 January 2013, then
monthly for six months (1 July 2013) to collect data, address any problems and provide support, and as requested by the sites.

All sites were provided with prepaid envelopes and USB drives to allow them to send data to the investigator every month throughout the intervention.

Each site had 24-hour telephone access to the investigator and principle supervisor.

**Training**

Between 15 May 2012 and 30 June 2012, the investigator personally trained the participating pharmacists to use the study protocol and forms. Pharmacists also received one-on-one, hands-on training on the use of the Roche Diagnostics™ equipment from two Roche-employed specialist trainers on 15 May 2012 and 30 June 2012. Additionally, a workshop was conducted on 25 of May 2012 where three additional up-skilling sessions were presented. The training sessions were registered as education workshops through the Australian Pharmacy Council (registration number CNP120048). Eighteen pharmacists attended the training. Sessions included:

- The investigator provided hands-on training for the blood pressure monitor, body fat composition scales and the visual acuity charts
- The investigator and supervisor delivered a session on the use of the monofilament Neuro-pen™
- A Guildcare™ trainer delivered another on the Guildcare™ software suite
- Dr Paul Harper delivered a videoconference session (live from New Zealand) on INR monitoring and its importance in warfarin dose recommendation
- Roche Diagnostics™ specialist trainers delivered one-on-one training on the use, calibration, quality control and cleaning of PoC monitors.
**Forms**

The forms were developed to ensure that all sites would collect the same type and quality of information and data. Additionally, using the same algorithms and reference textbook would ensure that the delivery of information on medication, disease and the parameters monitored was standardised. Several of these forms are intrinsic to the pharmacy GuildCare™ pharmacy management and dispensing support software. All participating pharmacists were requested to use paper copies of form 20 (Table 2) or use the form in their dispensing software, depending on whether they could provide electronic copies of the required information to the investigator (Appendix VI).

<table>
<thead>
<tr>
<th>Form Number</th>
<th>Form Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Training timesheet for continuous professional development (CPD) and equipment receipt</td>
</tr>
<tr>
<td>2</td>
<td>Consent forms (signed by site head pharmacist, to be kept by the investigator - paper copy)</td>
</tr>
<tr>
<td>3</td>
<td>Staff in-house training checklist</td>
</tr>
<tr>
<td>4</td>
<td>Number of patients offered to participate, number of patients agreed to participate and participants withdrew</td>
</tr>
<tr>
<td>5</td>
<td>Initial intervention time count</td>
</tr>
<tr>
<td>6 A</td>
<td>Consent forms (signed by the patients, to be kept by the site - paper copy)</td>
</tr>
<tr>
<td>6 B</td>
<td>Patient de-identification / Identification form (to be kept by the site - paper copy)</td>
</tr>
<tr>
<td>7</td>
<td>heiQ™ BL (completed by the patients, to be kept by the investigator - paper copy)</td>
</tr>
<tr>
<td>8</td>
<td>World Health Organization Chronic Disease surveillance questionnaire</td>
</tr>
<tr>
<td>9</td>
<td>Withdrawal (paper copy)</td>
</tr>
<tr>
<td>10</td>
<td>Process Improvement (fill in and print paper copy for CPD)</td>
</tr>
<tr>
<td>11</td>
<td>Pharmacists communication with GP vs. GP returned communication AND Referral form</td>
</tr>
<tr>
<td>12</td>
<td>Quality Audit</td>
</tr>
<tr>
<td>13</td>
<td>Ongoing intervention time count</td>
</tr>
<tr>
<td>14</td>
<td>Equipment calibration</td>
</tr>
<tr>
<td>15</td>
<td>Number of patients’ recruited vs. number of medication management reviews (MMR) performed, previously or based on after the study referral</td>
</tr>
<tr>
<td>16</td>
<td>Other interventions (e.g. smoke cessation, weight management, etc.)</td>
</tr>
<tr>
<td>17</td>
<td>Medication management review template</td>
</tr>
<tr>
<td>18</td>
<td>Quality Audit</td>
</tr>
<tr>
<td>19</td>
<td>heiQ™ follow-up (completed by the patients, to be kept by the investigator - paper copy)</td>
</tr>
<tr>
<td>20</td>
<td>Protocols - Conditions management pathways</td>
</tr>
</tbody>
</table>
Form-1: For the purpose of maintaining records of training as accredited professional continuing development for the attendees and also as evidence that all sites received the same training. Regarding the equipment receipt form, this was to ensure that the pharmacists were aware that these equipment items were the only equipment to be used, to ensure reproducibility of results at the individual site and to make the result comparable between sites (Appendix VII). The forms were signed at the end of the training workshop (May 2012) and kept by the investigator.

Form 2: The pharmacist’s consent form, which constituted part of the formal study site information sheet. This was provided to pharmacists at the beginning of the training workshop (May 2012). All aspects included in the information sheet were explained followed by a discussion session; consent to deliver the clinical intervention forms were signed by the sites’ lead pharmacists, and kept by the investigator.

Form 3: Staff in-house training check list, at least one or two other pharmacists or pharmacist interns were trained after the May workshop; this form was used to make sure that no aspect of the initial training was overlooked. In-house training was delivered to the local staff by their pharmacists, who were trained in the May workshop. Knowledge and techniques were tested and corrected by the investigator at the first following visit.

Forms 4 and 9: Recording the number of patients invited to participate, the number of patients who agreed to participate and number who withdrew. These forms are essential to provide data for future studies, especially if the participant elected to share the reason for not participating or withdrawal.
Forms 5 and 13: These were used for determining the initial and ongoing intervention time spent with the patient, as one of the study professional dimensions, which could shape the future of possible consideration by DoHA of ‘pharmacy NCD management plans’ similar to the General Practitioner Management Plan. Additionally, this information is needed by bodies such as Medicare and the Pharmacy Guild of Australia, if the service is to be considered for funding in the future. It is also essential to determine workload and staffing issues.

Form 6 A and B: The patient consent form constituted part of the formal study’s patient information sheet. The information sheet was the first form handed to potential participants by the site pharmacists. Potential participants were asked to either discuss it the same day they received it or to take it home and make an appointment to come later at a more convenient time. When the patient was ready, the site pharmacist explained everything in the sheet, explained how the data would be collected, how it would be stored and for what purpose. Site pharmacists also clearly disclosed that neither the investigator nor themselves would gain financial benefit from the intervention and that they had the freedom to withdraw at any time without providing reason for their withdrawal. They also explained the type of data that would be collected: including demographics, knowledge, specific medication and disease history, as well as the PoC testing and other testing (e.g., blood pressure, heart rate, body mass index, waist measurement, visual acuity and monofilament pressure). The Patient de-identification / identification form was for the site to keep; this allowed them to allocate an identification code for the patient when communicating data with the investigator and to match records when they were communicating with the patient. This form was not intended to be seen by the investigator.
Form 7 and 19: Modified heiQ™ baseline and modified heiQ™ follow-up printed questionnaires could be either completed by the participant alone or supported (explained, without input) by the pharmacist during enrolment and during the end of the study. The 12 questions in the heiQ™ baseline were repeated again in the heiQ™ follow-up with four new questions. The completed questionnaires were then labelled with the patient ID and returned to the investigator where the scores were allocated and calculated. The heiQ™ measures patient knowledge over eight domains with an additional domain (nine) in the heiQ™ follow-up to evaluate the study and the way it was delivered. The nine domains are: health directed behaviour, positive and active engagement in life, emotional well-being, self-monitoring and insight, constructive attitudes and approaches, skill and technique acquisition, social integration and support, health services navigation and intervention evaluation.

Written approval was obtained from Deakin University for use of the heiQ™ BL and heiQ™ FU tools and for their modification (by omitting some questions and adding additional questions from their selection, without changing the content of any questions). This was conditional on acknowledging the use of the heiQ™ Ltd in the final published papers.

Form 8: The World Health Organization modified STEPS™, chronic disease surveillance questionnaire or the master sheet were intended to be used electronically by sites and the investigator; however, this did not occur, due to time constraints at the sites and shortage of computers available for roles other than Point of Sale terminals and dispensing. Pharmacy computers are generally dedicated to dispensing/point of sale software; many do not have Microsoft applications and the machines are in constant demand. The pharmacists preferred to use hard copies, which were then transcribed by the investigator onto the master sheet. Written
approval was obtained from the World Health Organization for their STEPS™ chronic disease surveillance questionnaire, and for their modification (by omitting some questions and adding additional questions, without changing the content of any questions) (Appendix IV). This was conditional on acknowledging the use of the World Health Organization STEPS™ in the final published papers.

Form 10: the Process Improvement form was designed to be used at the end of the study if the site decided to continue to provide the intervention. This allowed them to receive extra continuous professional development points, and in a higher category, towards their annual registration requirements, but also provided end of study feedback for the investigator.

Form 11: The pharmacists’ communications with GPs was the second aspect of the study professional dimensions, which could shape the future possibility of inclusion of pharmacists more effectively and actively in the primary care health team. This form counted the number of times the pharmacist initiated communication with the GP regarding patient information and number of times the patient was referred back to the GP for additional investigations. It also counted the number of times the GP responded to the pharmacist communication and referral, or number of times the GP initiated communication or referral to the pharmacist.

Form 12: Quality Audit, this was to ensure that the enrolment process was completed, the required data and forms were accurate and the equipment was used according to manufacturer recommendations.

Form 14: Recording equipment calibration, which is essential for the accurate reproducibility of results. Required calibrations were test strip batch chip calibration, quality control and the INR monitor quality assurance samples. Pharmacists were
trained to perform these calibrations during the May 2012 training session. The importance of the activities were elaborated on by the manufacturer and included in the site information sheet.

**Form 15, 16 and 17:** A medication management electronic template was provided only as an additional resource. The MMRs of any type (HMR, MedsCheck™ or Diabetes MedsCheck™), is part of the pharmacist core activities in the quality and safe use of medications, however require the pharmacist to be proactive and identify those patients who will benefit from receiving MMR. It was essential for the study to be able to report on the number of clinical interventions performed by the sites during the study period and the reasons for the interventions including MMR. They also recorded other interventions (e.g. smoking cessation, weight management).

**Form 18:** The final quality audit form was to ensure that all completed patient data and the final feedback statements were returned to the investigator, archived or disposed of.

**Form 20 (multiple sections):** These electronic forms were provided as guides or checklists to ensure that patients with the same condition over the nine sites received the same intervention (Appendix IV).

**Equipment and Materials**

Table 3 lists the equipment supplied to the sites for the purpose of standardisation. The table also includes all other materials provided to sites to support the delivery of the intervention. The PoC monitors used were selected as they are Therapeutic Goods Administration registered and commonly used in Australian GPs clinics, by district nurses and in pathology laboratories.
All other equipment was also Therapeutic Goods Administration registered and widely used.

The CARPA STM was used as the supporting reference for disease state and treatment, and is used widely in the rural health facilities.

Posters and patient information sheets were designed to communicate the study purpose and method with patients, in plain English to meet all levels of literacy.

Table 3 – Equipment and materials supplied to each site (Appendices 2, 3, 4, 6 and 9)

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Quantity</th>
<th>Test to be performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accutrend® Plus (Product number 05050499023, ARTG 197926 Class 1) + manual + starter kit (ARTG 201876)</td>
<td>1</td>
<td>Total cholesterol, Triglycerides and blood glucose level</td>
</tr>
<tr>
<td>CoaguChek™ XS Plus (Product number 04800842190, ARTG 197926 Class 1) + manual + starter kit (ARTG 198119)</td>
<td>1</td>
<td>INR</td>
</tr>
<tr>
<td>Neuropen™ (Product number LA4891)</td>
<td>1</td>
<td>Monofilament Pressure</td>
</tr>
<tr>
<td>Body Composite Scale (Product Number HBF-202, ARTG 136767)</td>
<td>1</td>
<td>Body Mass Index</td>
</tr>
<tr>
<td>Digital Sphygmomanometer (Product number HEM-721, ARTG 138588)</td>
<td>1</td>
<td>Blood Pressure</td>
</tr>
<tr>
<td>Vision Chart (Hanks adults near point vision chart)</td>
<td>1</td>
<td>Visual Acuity</td>
</tr>
<tr>
<td>CARPA STM</td>
<td>1</td>
<td>Reference</td>
</tr>
<tr>
<td>Pre-addressed envelopes and stamps</td>
<td>12</td>
<td>Communication</td>
</tr>
<tr>
<td>USB</td>
<td>1</td>
<td>Forms</td>
</tr>
<tr>
<td>Poster (Appendix IX)</td>
<td>2</td>
<td>Communication</td>
</tr>
<tr>
<td>Pre-printed materials</td>
<td>30 of each</td>
<td>heiQ™ BL, heiQ™ FU, Patient information sheets and consent forms</td>
</tr>
</tbody>
</table>

**Consumable Cost Considerations**

The monitors were subsidised by the manufacturer, but the running costs were paid by the participating sites. This was purposefully planned within the protocol since, if
the cost was not bearable during 12 months of the study, it is likely to be unsustainable after the intervention without Medicare support (Tables 4 and 5 and Figure 18).

Table 4 - Consumables cost for Coagucheck® SX Plus and Accutrend® Plus at the time of the study

<table>
<thead>
<tr>
<th>Test Strips</th>
<th>Running Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>CoaguChek® XS PT 04625315019</td>
<td>48 Tests $202.00</td>
</tr>
<tr>
<td>CoaguChek® XS PT 04625358019</td>
<td>24 Tests $120.00</td>
</tr>
<tr>
<td>Accutrend® Plus Cholesterol 11418262171</td>
<td>25 Test $71.88</td>
</tr>
<tr>
<td>Accutrend® Plus Glucose 11443054187</td>
<td>25 Test $11.02</td>
</tr>
<tr>
<td>Accutrend® Plus Triglycerides 11538144016</td>
<td>25 Test $72.18</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quality Control</th>
<th>Running Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>CoaguChek® XS Controls 04696522190 2 x 4ml</td>
<td>$40.47</td>
</tr>
<tr>
<td>Accutrend® Plus Cholesterol Control 11418289190 1 x 1.5mL</td>
<td>$19.97</td>
</tr>
<tr>
<td>Accutrend® Plus Control G 11284878190 2 x 4mL</td>
<td>$14.18</td>
</tr>
<tr>
<td>Accutrend® Plus triglycerides Control 11538152190 1 x 1.5mL</td>
<td>$20.08</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Consumables</th>
<th>Running Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accu-Chek® Safe-T-Pro Lancets 03603539200</td>
<td>200 lancets $55.38</td>
</tr>
</tbody>
</table>

Table 5 - Monitors running cost

<table>
<thead>
<tr>
<th>Monitor (Test strips, Control, Lancet)</th>
<th>Running Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>CoaguChek® XS Plus PT running cost for 48 tests</td>
<td>$297.85</td>
</tr>
<tr>
<td>Accutrend® Plus Glucose running cost for 25 tests</td>
<td>$80.58</td>
</tr>
<tr>
<td>Accutrend® Plus Triglycerides running cost for 25 tests</td>
<td>$147.53</td>
</tr>
<tr>
<td>Accutrend® Plus Cholesterol running cost for 25 tests</td>
<td>$147.23</td>
</tr>
<tr>
<td>Accutrend® Plus Cholesterol, triglycerides and blood glucose level 25 test</td>
<td>$375.34</td>
</tr>
</tbody>
</table>
Benefit to Sites and Patients

No monetary incentive was provided to sites or patients. However, the pharmacy sites received nationally accredited continuous professional development points for the time spent in training, and the equipment listed in Table 3 was provided to each site free of charge.

Patients benefited from free of charge patient education, printed information on medications and their medical conditions, a medication management review, weight loss management (any products used were purchased by the participant when applicable and if they requested), smoking cessation management (products were purchased by the participant when applicable and if they requested), visual acuity testing, monofilament pressure testing, blood pressure monitoring, total cholesterol, triglycerides, blood glucose level and INR monitoring.

The Intervention Process

Posters were displayed in sites from 1 July 2012 after all GPs were visited.

Pharmacists invited all patients who met the selection criteria to participate until the
required number of subjects per pharmacy was reached, or they no longer had pharmacy workforce capacity to enrol more. Patient information sheets (Appendix III) were made available for interested consumers who inquired about the study when they viewed the poster or when invited by the pharmacist. Patients were given the option to enrol at that visit if they had time, or come back later on the same day or take the information sheet home and make an appointment to complete the enrolment at a mutually convenient time. The number of patients approached and number of those who returned for the interview were recorded. The patients were informed that the process might take up to an hour and PoC testing would be required. Patients were given the option to undertake this process at the same visit or over two visits.

On receipt of a completed and signed consent form from the patients (also at Appendix III) to participate in the study, (first record, kept at the research site, with patient’s identity concealed from the investigator), the patient’s details were entered onto a patient de-identification form 6B (Table 2) and patient ID was allocated and recorded. The ID consisted of the first letter of the town’s name, the first letter of the pharmacist’s name and a two-digit serial number (second record, site to keep). The patient ID was planned to avoid mixing data from different patients and to ensure that the data for each patient was accurately collated throughout the study. The first participant was enrolled on 1 September 2012 and the last on 31 December 2012. Pharmacists kept master lists of their patients and their IDs and used them to label subsequent measurements.

Demographic data were collected as listed in form 8 (modified World Health Organization STEPS™) to create the patient file. Pharmacists then printed the patient’s past 12 month medication history, either obtained directly from the patient or requested from the patient’s GP (with patient consent) to create the control data
for that patient. As part of the medical history taken, pharmacists also established what the participants were told by their GPs about their conditions and how to manage them. This was to avoid providing conflicting advice and confusing the patient. At this point, pharmacists were to ensure that patient was aware of the relationship between adherence to their medication and disease complications and prognosis. Considering that the CARPA STM was also used by all local medical facilities, it was adopted as a supporting reference for patient education and monitoring. CARPA provided written approval to use the manual.

The next step was to complete the heiQ™ BL, which was administered by pharmacists at the data collection sites to measure patient’s medication adherence characteristics before the intervention. It consists of 12 questions, each with four possible answers: strongly disagree, disagree, agree and strongly agree. Patients were asked to circle the most applicable answer that described their level of knowledge. The questionnaire was estimated to take one minute per question and maximum of 15 minutes to complete. The heiQ™ BL was de-identified before being received by the investigator (third record – posted to investigator to keep).

Site pharmacists then applied the chronic disease management protocols (Appendix IV). The chronic disease management protocols developed for the study were adapted from established Australian evidence-based guidelines, and modified to concentrate on items that could be effectively delivered in a community pharmacy environment. They were reviewed and approved by the Quality Use of Medicine Committee, Riverina Division of General Practice, Wagga Wagga. The protocols guided the pharmacists on which parameters needed to be monitored by them for each condition.
The next step was to measure the baseline parameters. Monitoring was performed using Roche Diagnostics (Sydney, Australia) PoC monitors. The selected PoC monitors are registered with the Therapeutics Goods Administration, and if used appropriately, have sufficient accuracy and reproducibility for trend-monitoring of chronic disease (85, 86, 87); GP clinics around Australia use the same monitors for this purpose. Roche Diagnostic staff trained the pharmacists in the use and care of the devices. A quality assurance program was employed to ensure pharmacists were applying the correct user protocols. The quality assurance testing for the CoaguChek® XS Plus monitors was provided by RCPA Quality Assurance Programs Pty Limited (RCPA QAP) (St Leonards, Australia) (National Association of Testing Authorities), which is an accredited proficiency testing scheme operated by an independent laboratory. The required tests were performed by the pharmacists based on a provided schedule. The quality assurance process involved five surveys per site to assure accurate operation. The quality assurance surveys were scheduled to ensure that the operator (the pharmacists) used the correct process when performing the tests using the CoaguChek® XS Plus. The parameters monitored by the PoC monitors were blood glucose level, total cholesterol level, triglycerides using the Accutrend plus and the INR using the Coagucheck XS plus. When patients are adherent to their pharmacological therapy and lifestyle modification the disease will be controlled, and they will achieve the target for their disease parameters (e.g., when diabetes is controlled, blood glucose level should fall under 6.5 mmol/L). Patients were reminded that these tests were additional to their normal monitoring regime, and that they should continue to have periodic tests performed by their GP or accredited laboratories as directed by their GPs.
All the following screenings were performed at baseline: blood pressure, heart rate, body mass index, waist measurement, visual acuity screening, pain score and the monofilament pressure screening.

The follow-up parameters measured were specific to the condition (e.g., blood pressure, heart rate, body mass index and waist measurement for patients who had only hypertension) adding other tests as applicable (e.g., blood glucose level, waist measurement, visual acuity screening, pain score and the monofilament pressure screening, total cholesterol level and triglycerides for diabetic patients or INR for a patient taking warfarin). However, all parameters measured at baseline were re-tested in the final reading. It was intended that the data would primarily be collected directly onto electronic forms supplied on the USB drive to all sites; however, due to the computer availability issues referred to above, many sites decided they preferred to print these forms and record on paper. This created an additional transcription step that was mostly performed by the investigator from the de-identified paper forms supplied by the pharmacists. (Fourth record – copy retained by both site and investigator.)

Patient adherence to medication was measured through repeat dispensing records, leftover pill counts on the day of the repeat dispensing and patient reporting, plus indirectly through the monitoring of disease markers. The disease markers selected, were limited to those that are usually modifiable and responsive to the prescribed medication, modified diet and lifestyle, and the adherence to all three components of therapy. During this period, other interventions were offered to the patient, such as medication management review, smoking cessation and weight management.
The mid-study survey was delivered to the sites’ pharmacists by the investigator to review any issues that had arisen during enrolment (only 84 were enrolled out of initial commitment of 500) and any issues regarding study equipment and communication with GPs. The survey consisted of 38 questions (Appendix VIII).

The intervention was concluded on 30 June 2013, when a current medication list was printed, the final measurement of all parameters was performed and the heiQ™ follow-up completed. All results were then returned to the investigator in addition to the pharmacists’ final feedback on the study.

Data Analysis

Series of meetings took place between the investigator and the Charles Sturt University Qualitative Consulting Unit (QCU) from April 2011 to April 2012 to ensure that meaningful data would be collected, would be suitable for analysis and that the most appropriate analytical techniques would be applied to the data. The CSU QCU involvement was planned to continue throughout the data analysis phase.

Mid-study survey and study final patients and pharmacists’ feedback

Mid-study survey and study final patients and pharmacists’ feedback were trended by a simple Excel™ (Microsoft, Seattle, United States of America) data sort and then thematically analysed.

Disease markers parameters analysis

The patients’ data collected at the end of the intervention period was compared to the baseline data and control to determine the effect and influence of the pharmacist interventions and monitoring on patient outcomes.
The patient’s 12 month medication history (control) and baseline parameter measures (control) were compared to their final medication list and final readings, to measure the change in the same individuals over time. A time-dependent analysis was used to assess the probability that change was a consequence of the pharmacist intervention.

The data were analysed in ASReml-R™ using linear mixed models or generalised linear mixed models (http://www.r-project.org/) (depending on the data type). The model used to analyse disease markers parameters (body mass index, waist measurement, visual acuity, monofilament pressure, heart rate, pain score, total cholesterol, triglycerides, blood glucose levels and INR), change in medication (numbers only, not type of medication) and heiQ™ total score (number only, not psychometrically) to compare the pre- and post- intervention results to determine if there was an effect of the intervention. This can be written as:

\[
\text{Response} \sim \text{Time} + \text{Age} + \text{Sex} + \text{Time:Age} + \text{Time:Sex} + \text{Sex:Age} + \text{Time:Age:Sex} + \text{Patient} + \text{Site}.
\]

– Terms fitted in the model as random are italicised; all other terms were fitted as fixed terms

– The predicted values were assigned a rank based on the Tukey family of pairwise differences with a family confidence level of 5%. Therefore, no overall standard error or difference or least significant difference were generated.

Medical conditions and types of medications presented in the study sample were trended by simple Excel™ data sort.
Alcohol consumption status, smoker status and visual acuity test results are binomial variables; they were analysed using a generalised linear model, which can be symbolically written as:

\[ \text{Smoke} = \text{mean} + \text{Time} + \text{Age} + \text{Sex} + \text{Pharmacy} \]
\[ \text{Alcohol} = \text{mean} + \text{Time} + \text{Age} + \text{Sex} + \text{Pharmacy} \]
\[ \text{VA} = \text{mean} + \text{Time} + \text{Age} + \text{Sex} + \text{Pharmacy} \]

**Health Education Impact Questionnaires (heiQ™)**

The heiQ™ is a generic instrument for evaluating patient training and self-management programs. It was developed in 2005 and has been validated and proved to be psychometrically robust in many studies across Australia, Germany, France, Japan and many others, and translated to 20 languages and administered to over 50,000 people (80).

The original heiQ™ covers nine domains, which are only known to the researcher; the questions in each domain are not consecutive but rather can be placed anywhere between one and 50; the participant will only see questions listed without a domain subtitle so they do not reveal what the researcher will be measuring (Table 6). This allows participants to answer the individual questions based on their own perspective rather than the domain title, while allowing the analyst to measure answers within each domain.

The heiQ™ has a scoring system for each domain and, once applied, the domain mean score achieved in the project site is then compared to the national mean score to determine if the participants’ knowledge has improved after the delivery of the relevant patient disease education. However, the full questionnaire was considered
too long to administer in a community pharmacy environment. Accordingly, as a result of removing (with approval from heiQ™ Professor Richard H Osborne PhD) some questions considered irrelevant to the current study, the complete scoring system was not used. The score for the modified domains 1, 4, 5, 6, 7 and 8 (Table 6), before and after the intervention were compared for each patient and used as an indicator of knowledge level improvement. The modified domain 9 was used to provide patient feedback on the intervention phase conducted by local community pharmacies.

Table 6 - Domains included in the modified heiQ™ baseline and follow-up

<table>
<thead>
<tr>
<th>Domains*: All domains are baseline and follow-up except domain 9 only included in follow-up</th>
<th>Actual questions</th>
<th>Modified questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 - Health-directed behaviour (Keywords: healthful behaviours including prevention, diet, exercise, relaxation; tangible change). This construct is similar to the first in that it relates to a change in lifestyle; however this change is tangible and specifically related to healthful behaviours. Activities may include changes in diet, exercise and relaxation routines. These activities may be aimed at either disease prevention and/or health promotion.</td>
<td>1, 9, 13, 19</td>
<td>9</td>
</tr>
<tr>
<td>2 - Positive and active engagement in life (Keywords: getting engaged in life, intent for actions, indicators of now being engaged and involved in life). This construct covers motivation to be active and embodies the notion of participants in self-management/health education programs engaging or re-engaging in life-fulfilling activities as a result of program involvement. Items in this construct aim to measure the individuals’ activities to convert intention into positive outcomes, and imply a change of lifestyle and life activities. –positive and active engagement in life</td>
<td>2, 5, 8, 10, 15</td>
<td>Nil</td>
</tr>
<tr>
<td>3 - Emotional well-being (Keywords: overall health-related negative affect; attitude to life; anxiety, stress, anger and depression). This construct measures overall negative affective responses to illness, including anxiety, anger and depression (which are attributed to the illness). These indicators give a sense of individuals’ general emotional well-being and satisfaction with life.</td>
<td>4, 7, 12, 14, 18, 21</td>
<td>Nil</td>
</tr>
<tr>
<td>4 - Self-monitoring and insight (Keywords: self-monitoring of (sub) clinical indicators, self-management, setting reasonable limits or targets, and insight into living with a health problem). This construct captures the individuals’ ability to monitor their condition, and their physical and/or emotional responses that lead to insight and appropriate actions to self-manage. An important</td>
<td>3, 6, 11, 16, 17, 20</td>
<td>3, 6, 11, 16, 20</td>
</tr>
</tbody>
</table>
Domains*: All domains are baseline and follow-up except domain 9 only included in follow-up

Component of this construct is the individuals’ acknowledgment of realistic disease-related limitations, and the ability and confidence to adhere to these limits. This may also relate to the monitoring of specific subclinical indicators of disease status.

5 - Constructive attitudes and approaches (Keywords: minimising the illness “I am not going to let this disease control my life”). This construct is embodied by the statement “I am not going to let this disease control my life” and includes a shift in how individuals view the impact of their condition(s) on their life.

6 - Skill and technique acquisition (Keywords: symptom relief skills, skills and techniques to manage own health). This construct aims to capture the knowledge-based skills and techniques (including the use of aids) that participants acquire or re-learn to help them manage and cope with disease-related symptoms and health problems.

7 - Social integration and support (Keywords: social interaction, feelings of social isolation as a result of the illness, “kinship” in group leading to sense of support, seeking support from others). This construct aims to capture the positive impact of social engagement and support that evolves through interaction with others. This impact may arise from interaction with others sharing similar health-related life experiences. This ‘shift’ also involves the confidence to seek support from interpersonal relationships as well as from community-based organizations.

8 - Health service navigation (Keywords: communication, decision processes, relationships, understanding; interaction with and negotiation of the health care system, including the confidence to talk with health care professionals; the understanding of ways to access health care to get needs met). This construct is concerned with an individual’s understanding of and ability to confidently interact with a range of health organizations and health professionals. Further, it measures the confidence and ability to communicate and negotiate with health care providers to get needs met.

9 - Study Evaluation

The guidelines for administering the heiQ™ were provided to patients to improve their understanding of the purpose of administering the questionnaire before the education intervention. Pharmacists were asked to read and explain the following
statement (adapted from the questionnaire developers’ template) to participants before administering the baseline heiQ™.

*Good morning/ afternoon. Welcome to the Sharing the Responsibility for Chronic Disease Management’ study*

*Before we start I’ll just spend a few minutes talking about how we will be gauging the success or otherwise of this intervention.*

*I am going to ask you to fill in a questionnaire asking you about some of the improvements or changes we would hope you make as a result of the course. This is the Baseline questionnaire (measuring your characteristics before you start the intervention).*

*At the end of the study you will be asked to complete a Follow-Up questionnaire (measuring how your characteristics have changed following completion of the intervention). The results of the two questionnaires are compared to see how you have changed as a result of the study.*

*The information collected on the questionnaire will be confidential and data will be de-identified so you will not be known by name, only your ID number. The reason for information being collected is to ensure that the Baseline questionnaire, demographic data and parameter readings can be matched up with the Follow-Up questionnaire for each participant at the completion of the study.*

*This information will assist us in providing better community pharmacy clinical interventions well-tailored to the needs of our consumers. Though the questions may look similar they are subtly different and by answering all*
questions together you provide an accurate picture of how the study has helped you.

Four Likert scale points were offered as response options for all questions; a score of 1 was allocated to strongly disagree, 2 to disagree, 3 to agree and 4 to strongly agree.

Due to the limited time that community pharmacists could allocate to the intervention and that participants were willing to spent in the pharmacy, some questions were omitted: only 12 of 40 heiQ™ questions were used at BL and 15 of 50 for FU. As a result, the conventional interpretation of heiQ™ results could not be used. The complete heiQ™ does not recommend the use of total score as a measure; this is easily explained by the fact the individual question scores refer only to the degree of agreement and disagreement. The user guidelines for heiQ™ interpretation require each domain mean score for the sample to be compared within the sample (BL and FU) then to the national mean score (the confirmatory factor analysis) for that question. The national mean score for domains are updated regularly to include new study results. The national mean score could not be used for interpreting the result of the study, as not all questions in each domain were used, and the partially agree or partially disagree and not sure options were excluded. The total score for the 12 questions was used in both the heiQ™ baseline and heiQ™ follow-up as indication of the number of questions answered as agree or strongly agree.

It was accepted that this methodology would mean that the study results would not be included in the national database or mean score, however, they are useful for the future development by heiQ™ of a model of the questionnaire that suits different settings such as community pharmacies.
The modification and the proposed analysis was discussed and approved by heiQ™ prior to signing the agreement to allow the use of the modified heiQ™ in the study.

**Cost effectiveness**

Participants did not pay for the clinical intervention services; the investigator’s budget carried the cost of equipment and materials and sites carried the cost of consumables (test strips and lancets) and labour. The cost of the intervention was not the focus of this study; however, was identified by the site as a limitation for its future implementation.

**Record Keeping and Disposal**

**During the study**

Site pharmacists and GPs held all identified data. Their practice recording systems complied with requirements for the safe storage of confidential medical information.

De-identified data generated for the purposes of the study were managed by the investigator in accordance with the *Privacy Act 1988, Health Records and Information Privacy Act 2002 and NSW Department of Health Directive number PD2005_593, Privacy Manual (Version 2).*

Only de-identified data were supplied to the investigator, and shared with supervisors for advice or QCU for data analysis advice as required. A portable USB drive was used to transfer data at face-to-face meetings with supervisors or QCU. Files were password protected, and the supervisors’ and QCU’s copies were deleted once consultations were completed.
After study completion

All identified data remained at the sites, and were stored and archived as part of their ongoing patient records system, tagged with the study name. The storage systems used complied with requirements for the safe storage of confidential medical information.

All other de-identified data generated for the purposes of the study were managed by the investigator as follows:

– All hard and e-copies securely archived for five to seven years, then will be destroyed


Timeline

The study timeline was as follows:

<table>
<thead>
<tr>
<th>Date</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/03/2011</td>
<td>Literature review and developing the study question</td>
</tr>
<tr>
<td>1/06/2011</td>
<td></td>
</tr>
<tr>
<td>1/09/2011</td>
<td></td>
</tr>
<tr>
<td>1/01/2012</td>
<td></td>
</tr>
<tr>
<td>1/03/2012</td>
<td>Developing study materials</td>
</tr>
<tr>
<td>1/06/2012</td>
<td></td>
</tr>
<tr>
<td>1/09/2012</td>
<td></td>
</tr>
<tr>
<td>1/01/2013</td>
<td></td>
</tr>
<tr>
<td>1/03/2013</td>
<td>Training and implementaion</td>
</tr>
<tr>
<td>1/06/2013</td>
<td></td>
</tr>
<tr>
<td>1/09/2013</td>
<td>Clinical intervention</td>
</tr>
<tr>
<td>1/01/2014</td>
<td></td>
</tr>
<tr>
<td>1/02/2014</td>
<td>Data analysis and examination</td>
</tr>
<tr>
<td>1/03/2014</td>
<td></td>
</tr>
<tr>
<td>1/06/2014</td>
<td></td>
</tr>
</tbody>
</table>
Summary

The following is a summary of the sites’ study protocol; participated sites pharmacists performed the following steps:

− Display Posters in the pharmacy to attract patients’ attention and to trigger patients’ request for more information

− Facilitate patient enrolment

− Assist the patient to complete the heiQ™ BL

− Collect and record demographics

− Perform PoC testing and other measurements:
  - Body mass index (using Omron body composition scale)
  - Blood pressure (Omron digital sphygmomanometer)
  - Total cholesterol level (Accutrend® Plus)
  - Triglycerides (Accutrend® Plus)
  - Blood glucose level (Accutrend® Plus)
  - INR, if required (CoaguChek® XS Plus)
  - Eye sight, (Hanks™ near vision chart)
  - Monofilament test, (NeuroPen™ provided kit)
  - Pain (CARPA STM pain score chart).

− Allocate the patient an ID and enter it into patient de-identification/re-identification form. The patient de-identification/re-identification form was not to be shared with the investigator and was kept in the folder with ethics approval and consent forms

− Record the time spent with the patient, HMR/RMMR/ MedsCheck™ status and the plan to conduct one if required
– Print the patient’s previous 12 month medication history
– Enter the patient’s current medical conditions and medications into the master sheet.

Disease specific parameters were to be monitored from January 2013 to 1 July 2013. All parameters measured at baseline were to be measured during June but not later than 1 July and the heiQ™ follow-up completed. Pharmacists sent heiQ™, the 12 month medication history, and the data collection sheets to the investigator and filed all other collected data.
Chapter V. Demographics and Disease Marker Parameters

Results

Introduction

The complete analysis report for this section is at Appendix V. It contains an assessment of the effect of the intervention on monitored patient parameters, comparing patient data pre- and post-intervention.

Table 7 shows the number of participants recruited per site. Fewer patients were recruited than initially anticipated. Five patients later withdrew; reasons for withdrawal were investigated in a mid-study survey, which is presented in Chapter VI.

<table>
<thead>
<tr>
<th>Site ID</th>
<th>Number of patients enrolled</th>
</tr>
</thead>
<tbody>
<tr>
<td>BS</td>
<td>27</td>
</tr>
<tr>
<td>CV</td>
<td>15</td>
</tr>
<tr>
<td>GD</td>
<td>6</td>
</tr>
<tr>
<td>HA</td>
<td>4</td>
</tr>
<tr>
<td>JJ</td>
<td>8</td>
</tr>
<tr>
<td>LOC</td>
<td>5</td>
</tr>
<tr>
<td>PE</td>
<td>4</td>
</tr>
<tr>
<td>PR</td>
<td>17</td>
</tr>
</tbody>
</table>

The study protocol called for: (1) all parameters to be measured at baseline; (2) all parameters indicated as disease markers for the individual patients to be monitored during the intervention phase; and (3) all parameters to be measured again regardless of patient condition at the end of the clinical intervention date. However, when the baseline data were collected in January, the investigator found that only six sites completed all baseline collection and measurement. Two sites tested and measured only parameters related to patient condition and they were asked to rectify and perform the intervention at the earliest possible date before the end of January. One
site did not perform any testing or measuring and later on withdrew from the study at the end of January due to lack of time for participation.

**Age and Gender**

The 84 participants were divided into five age groups: <49 years, 50–59 years, 60–69 years, 70–79 years and >80 years. Eighty-six percent of the participants were aged between 50 and 79 years (50% women). Figure 19 displays the age distribution of the participants.

![Figure 19 - Age and gender](image)

**Number of Medications**

Men averaged 7.8 daily medications and women 8.5 medications. Thirty women (70%) and 27 men (60%) were taking five or more prescribed medications.

Prescribed medications were mostly for CVD (hypertension, heart disease, dyslipidaemia and others), T2DM, Chronic Pain Syndrome and mental health disorders. The most commonly prescribed medication group was the HMGCoA reductase inhibitors (statins) (Figure 20). Some medications were grouped due to the large number of available generics and the fact that the prescribing choice was based
on patient response rather than the difference in the drug action (e.g., statins, NSAIDs and PPIs).

Figure 20 - Most frequently prescribed medications by gender
Changes in the number of medications are significant to the patient’s therapeutic outcomes, side effects and adherence behaviour to their therapy (regardless of whether they increase or decrease in number). An increase in the number of medications as a result of the study MMR may mean that the previously prescribed medications were not sufficient for certain condition (e.g., only diabetes medications where the patient can benefit from other medications such as angiotensin converting enzyme inhibitors, statin and aspirin) or untreated condition such as hypertension or pain.

During the intervention period, 54 patients had their medication changed by removal of duplicate or unwanted medications (67%) or addition of a medication to treat previously untreated conditions based on the pharmacist’s recommendations (33%).

The boxplots below suggest that the post-intervention total number of medications were fewer than the pre-intervention number of medications for the entire sample population (but not per patient). It also appears that males had fewer medications than females (Figure 21).

Figure 21 - Medications changes pre- and post-intervention
The model assumptions were that the residuals are normally distributed (i.e., they have a constant variance and are independent) and that the factor-level variances are equal for the treatments. The Shapiro-Wilk test of normality was used to determine if the residuals are normally distributed. In this case, it was concluded that the residuals are derived from a population that is normally distributed ($p=0.062$) (Figure 22).

![Residual Plots](image)

Figure 22 - The Shapiro-Wilk tests of normality for total medications pre and post intervention

A log-likelihood ratio test was required to determine if a significant amount of variability was associated with the different sites and the individual patients. This provides an indication of whether there are differences in the response for the different sites and patients. The variability associated with patient was significant at the 5% level (Table 8). The changes in medication number per patient can be interpreted as being a result of the MMR conducted during the intervention period.

The analysis shown in Table 8 demonstrates that a significant change in the number of medications prescribed per patient occurred across the intervention period.
Table 8 - Final analysis of variance total medications

<table>
<thead>
<tr>
<th></th>
<th>Df</th>
<th>denDF</th>
<th>F.inc</th>
<th>Pr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>1</td>
<td>77.0</td>
<td>19.50</td>
<td>0.000</td>
</tr>
<tr>
<td>Time</td>
<td>1</td>
<td>79.5</td>
<td>4.15</td>
<td>0.045</td>
</tr>
<tr>
<td>Sex</td>
<td>1</td>
<td>76.1</td>
<td>2.29</td>
<td>0.134</td>
</tr>
</tbody>
</table>

Analysis of the type of medications used, based on Fox et al. (53), revealed a high anticholinergic burden score of ≥4 for 21 of 73 patients (29%) prescribed a medication. However, the scores were based solely on prescription items, so are probably underestimates. Sixty percent of participants had scores between 1 and 3, and 11% took no medication containing Anticholinergic Burden Scale score (Figure 23).

Figure 23 - Number of patients prescribed medications with Anticholinergic Burden properties in the study sample

Medical Conditions

Table 9 presents the frequencies of the most commonly reported medical conditions.

Table 9 - Medical conditions reported in the study sample

<table>
<thead>
<tr>
<th>Chronic Medical Condition</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>39</td>
</tr>
<tr>
<td>Hypertension</td>
<td>65</td>
</tr>
<tr>
<td>Other CVD</td>
<td>29</td>
</tr>
<tr>
<td>Dyslipidaemia (Increase in lipids levels)</td>
<td>61</td>
</tr>
<tr>
<td>Asthma</td>
<td>14</td>
</tr>
<tr>
<td>chronic obstructive pulmonary disease</td>
<td>6</td>
</tr>
<tr>
<td>GORD</td>
<td>45</td>
</tr>
<tr>
<td>Other gastrointestinal tract conditions</td>
<td>13</td>
</tr>
<tr>
<td>MH</td>
<td>20</td>
</tr>
<tr>
<td>Chronic Medical Condition</td>
<td>Number of Patients</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>Chronic pain</td>
<td>55</td>
</tr>
<tr>
<td>Cancer</td>
<td>3</td>
</tr>
<tr>
<td>Glaucoma</td>
<td>6</td>
</tr>
<tr>
<td>Thyroid disorder</td>
<td>7</td>
</tr>
<tr>
<td>Gout</td>
<td>9</td>
</tr>
<tr>
<td>Migraine</td>
<td>7</td>
</tr>
<tr>
<td>Arthritis</td>
<td>21</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>5</td>
</tr>
<tr>
<td>Urinary tract</td>
<td>8</td>
</tr>
<tr>
<td>Rhinitis</td>
<td>3</td>
</tr>
<tr>
<td>Skin disorders e.g. psoriasis</td>
<td>6</td>
</tr>
<tr>
<td>Neuromuscular e.g. Parkinson’s disease</td>
<td>5</td>
</tr>
</tbody>
</table>

Figure 24 shows the distribution of chronic comorbidities per patient; this explains the large number of medications per person (mean = 8.2 medication per person).

The possibility of a relationship between body mass index >25 and number of medical conditions—and accordingly number of medications—was also investigated. There was a linear relationship between these two variables \(p\)-value = 0.092); a simple linear regression model was fitted to define this relationship. The increase in the patient body mass index explains 5.1% of the increase in number of medical conditions.
Body Mass Index

Body mass index is a modifiable lifestyle factor. It is one of the parameters that the study was aiming to improve through patient education and increased awareness of obesity on the prognosis of most chronic diseases.

In males, the highest body mass index was for a 52 year-old male (48.8 pre-intervention and 48.5 post-intervention). In females, the highest body mass index was for a 44 year-old female (47.4 pre-intervention and 47 post-intervention).

The boxplots show that the post-intervention body mass index appears to be less than the pre-intervention for the entire sample population and that males had lower body mass index than did females (Figure 25).

Figure 25 - Body mass index changes pre- and post-intervention

The Shapiro-Wilk test of normality was used, and in this case the residuals were not normally distributed ($p$-value = 0) (Figure 26).
A log-likelihood ratio test was performed, and showed that there was a significant amount of variability associated only with patient at the 5% significance level. None of the main effects were found significant at the 5% level.

**Waist Measurements**

In males, the highest waist measurement was in an 85 year-old (116.63 cm pre-intervention and 133.82 cm post-intervention). In females, the highest waist measurement was in an 85 year-old (109.15 cm pre-intervention and 107.64 cm post-intervention).

The boxplots show that waist measurement was reduced after the intervention; the effect was less pronounced in men than women and in older participants than in younger participants (Figure 27).
The analysis of waist measurement showed a heterogeneous relationship with the observed value and the variance; accordingly, data were transformed. A log-likelihood ratio test of variability associated with the different pharmacies and the individual patients showed significant variability associated with patient at the 5% significance level, but no significant variability associated with pharmacy. All the interaction terms were checked for significance, time:age:sex relationship were significant at the 5% level (\(p\)-value = 0.041) (Table 10).

Table 10 - The three-way interaction analysis of variance

<table>
<thead>
<tr>
<th></th>
<th>Df</th>
<th>denDF</th>
<th>F.inc</th>
<th>Pr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>1</td>
<td>27.0</td>
<td>0.42</td>
<td>0.523</td>
</tr>
<tr>
<td>Age</td>
<td>1</td>
<td>41.0</td>
<td>2.12</td>
<td>0.153</td>
</tr>
<tr>
<td>Sex</td>
<td>1</td>
<td>45.7</td>
<td>6.00</td>
<td>0.018</td>
</tr>
<tr>
<td>Time : Age</td>
<td>1</td>
<td>27.0</td>
<td>1.88</td>
<td>0.182</td>
</tr>
<tr>
<td>Time : Sex</td>
<td>1</td>
<td>27.1</td>
<td>8.48</td>
<td>0.007</td>
</tr>
<tr>
<td>Sex : Age</td>
<td>1</td>
<td>45.0</td>
<td>0.11</td>
<td>0.747</td>
</tr>
<tr>
<td>Time : Age : Sex</td>
<td>1</td>
<td>27.1</td>
<td>4.62</td>
<td>0.041</td>
</tr>
</tbody>
</table>
In Figure 28, the red lines represent the females before intervention, and the green lines represent females after intervention. The blue lines represent the males before intervention, and the orange lines represent males after intervention.

Figure 28 - Waist measurement predicted value males and females comparison

A simple linear regression model shows a significant linear relationship between body mass index and waist measurement \((p\text{-value} < 0.001)\). The variability in the waist measurement explains 65% of the variability in body mass index.

**Alcohol Consumption**

Alcohol consumption is one of the modifiable risk factors for many conditions such as CVD and T2DM. Alcohol consumption can also interact with medications, making them either ineffective or toxic due to its effect on the liver and competition for the metabolising enzymes.

Alcohol consumption is a count variable, defined as the number of standard drinks per week recorded. In males, the highest consumption was among a 68 year-old
male (112 drinks per week pre-intervention and 63 drinks per week post-intervention). In females, the highest consumption was among an 88 year-old female (20 drinks per week pre-intervention and 14 drinks per week post-intervention).

It was decided to classify the response as binomial (drinks alcohol or does not drink alcohol).

Alcohol = mean + Time + Age + Sex + Pharmacy

From the analysis of deviance presented in Table 11, alcohol consumption was affected by sex only ($p$-value < 0.001). In a binomial generalised linear model, it is a requirement that the deviance/error degree of freedom is not significantly different from 1. In this analysis, it was found that the deviance/error degrees of freedom was 1.236 ($p$-value = 0.266).

<table>
<thead>
<tr>
<th>Table 11 - Alcohol Consumption analysis of deviance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Df</strong></td>
</tr>
<tr>
<td>NULL</td>
</tr>
<tr>
<td>Time</td>
</tr>
<tr>
<td>Sex</td>
</tr>
<tr>
<td>Age</td>
</tr>
<tr>
<td>Pharmacy</td>
</tr>
</tbody>
</table>

This indicates that the changes were not significant in most patients; only seven patients reported changes in their alcohol consumption by the end of the clinical intervention. However, this is considered to be significant health and wellbeing improvement for those seven patients.

**Smoker Status**

Smoking is another of the modifiable risk factors for many conditions such as CVD and T2DM. Smoking can also interact with medications making them either
ineffective or toxic due to its effect on the liver and competition on the metabolising enzymes.

Smoker status was a binomial variable (yes/no). A generalised linear model was used for analysis according to the model:

\[
\text{Smoke} \sim \text{mean} + \text{Time} + \text{Age} + \text{Sex} + \text{Pharmacy}
\]

Smoker status was affected by pharmacy only (\(p\)-value = 0.004). In this analysis the deviance/error degrees of freedom was 0.5 (\(p\)-value = 0.48) (Table 12).

<table>
<thead>
<tr>
<th></th>
<th>Df</th>
<th>Deviance (Residual Df)</th>
<th>Resid. Df</th>
<th>Resid. Dev</th>
<th>Pr(&gt;Chi)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NULL</td>
<td></td>
<td></td>
<td>155</td>
<td>96.19</td>
<td></td>
</tr>
<tr>
<td>Time</td>
<td>1</td>
<td>0.00</td>
<td>154</td>
<td>96.19</td>
<td>1.0000</td>
</tr>
<tr>
<td>Sex</td>
<td>1</td>
<td>0.80</td>
<td>153</td>
<td>95.39</td>
<td>0.3720</td>
</tr>
<tr>
<td>Age</td>
<td>1</td>
<td>2.32</td>
<td>152</td>
<td>93.07</td>
<td>0.1277</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>7</td>
<td>20.61</td>
<td>145</td>
<td>72.46</td>
<td>0.0044</td>
</tr>
</tbody>
</table>

This suggests that smoking cessation programs are more effective in some towns compared to others.

**Visual Acuity**

Retinopathy is one of the known complications of T2DM (39 patients), which can only be detected by visual field measurements and retina photography; however, the outcome can be detected by changes in a person’s visual acuity. Other conditions may also affect the person vision such as CVD (65 patients), cataracts, and glaucoma (6 patients). Vision also can be affected by age.

Visual acuity was measured by asking patients to read passages from a validated handheld visual acuity chart (EyeCare™ plus, Port Macquarie, NSW) made up of different font sizes. The smallest font size that could be read was recorded, such that
a smaller value corresponded to better eyesight. It was analysed using a generalised linear model with a Poisson family link function:

\[
\text{Visual Acuity} \sim \text{mean} + \text{Time} + \text{Age} + \text{Sex} + \text{Pharmacy}
\]

The analysis of deviance tabled demonstrates that visual acuity was affected by age \((p = 0.009)\) and there were differences between the pharmacies \((p < 0.001)\). In this case (Table 13), the deviance/error degrees of freedom was 1 \((p = 0.287)\).

<table>
<thead>
<tr>
<th></th>
<th>Df</th>
<th>Deviance</th>
<th>Resid. Df</th>
<th>Resid. Dev</th>
<th>Pr(&gt;Chi)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NULL</td>
<td></td>
<td></td>
<td>129</td>
<td>230.58</td>
<td></td>
</tr>
<tr>
<td>Time</td>
<td>1</td>
<td>0.18</td>
<td>128</td>
<td>230.39</td>
<td>0.6688</td>
</tr>
<tr>
<td>Sex</td>
<td>1</td>
<td>0.03</td>
<td>127</td>
<td>230.36</td>
<td>0.8537</td>
</tr>
<tr>
<td>Age</td>
<td>1</td>
<td>6.74</td>
<td>126</td>
<td>223.62</td>
<td>0.0094</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>7</td>
<td>88.67</td>
<td>119</td>
<td>134.95</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

All participants in the study sample population had chronic diseases and 86% were aged above 50 years. The possibility for improving vision after deterioration is very slim, but appropriate corrective lenses may improve functioning. Deterioration was detected in one patient who was referred to GP for professional follow-up.

**Monofilament Pressure**

Poor peripheral circulation and neuropathy are two known complications of T2DM, which can lead to diabetic foot and amputations (93). The outcome of the changes can be detected by changes in the person’s feeling in a number of identified pressure points on the foot. However, other conditions may also affect the person’s peripheral circulation, such as CVD. It is also evident in old age. The fewer pressure points that can be felt by the person on applying a 10 g pressure, the higher the possibility of the person experiencing peripheral circulation and neuropathy complications. Noting changes allows early investigation and intervention.
The residual plot in Appendix V shows the residuals have a constant variance, are independent and the variances are the same (Hartley’s $p = 0.146$). A log-likelihood ratio test shows a significant amount of variability associated with Patient at the 5% significance level.

None of the main effects were significant at the 5% significance level but the analysis implies that the intervention had some effect on Monofilament Pressure at the 10% significance level (Table 14).

<table>
<thead>
<tr>
<th>Time</th>
<th>Predicted Value</th>
<th>Standard Error</th>
<th>Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>After</td>
<td>2.7</td>
<td>0.1</td>
<td>a</td>
</tr>
<tr>
<td>Before</td>
<td>2.8</td>
<td>0.1</td>
<td>a</td>
</tr>
</tbody>
</table>

When monofilament pressure was checked at three points, patients who lacked sensation at $\geq 1$ point were referred to a podiatrist or their GP for review.

All participants had chronic diseases, and 39 had comorbidity of diabetes, CVD and dyslipidaemia. Deterioration was detected in two patients who were referred to a GP for professional follow-up.

**Pain Score**

Chronic pain was reported by 31 patients (21 females and 10 males). Chronic pain syndrome can be disabling, affecting the person’s quality of life. Patient education about self-management of pain plays a big part of improving quality of life. Pain was measured on a scale of 10, using CARPA STM; 17 patients reported moderate-severe to very severe pain (scored 5–10).

The boxplots show that pain scores were slightly reduced in the total sample population after the intervention; the effect was more pronounced in males than females and in older participants than in younger participants (Figure 29).
The analysis of pain scores showed that the residuals did not conform to the assumptions; as a result, pain score was transformed using a log-likelihood ratio test, showing significant variability associated with patient at the 5% level (Table 15).

Table 15 - Pain score final analysis of variance

<table>
<thead>
<tr>
<th></th>
<th>Df</th>
<th>denDF</th>
<th>F.inc</th>
<th>Pr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>1</td>
<td>60.2</td>
<td>0.60</td>
<td>0.441</td>
</tr>
<tr>
<td>Age</td>
<td>1</td>
<td>65.5</td>
<td>0.00</td>
<td>0.959</td>
</tr>
<tr>
<td>Sex</td>
<td>1</td>
<td>66.2</td>
<td>1.24</td>
<td>0.269</td>
</tr>
</tbody>
</table>

At the end of the intervention, there was improvement in eight patients (six females and two males) and the pain was worse in three females who were referred to their GP for professional investigations.

**Blood Glucose Level**

It is essential that diabetic patients effectively participate in their diabetes control through self-management and ongoing monitoring. Every T2DM patient has their own blood glucose level target; however, all must remain >7 mmol/L fasting blood glucose level. Blood glucose level is sensitive to meals eaten and the interval of
testing after eating. Consequently, measuring blood glucose level once a month might not truly indicate good or poor control. Daily monitoring produces better results; however, it was not feasible in this study. Regular, monthly monitoring can indicate trends in control.

The boxplots show that blood glucose level was slightly reduced in the total sample population after the intervention. The effect was more pronounced in females than males (Figure 30).

Figure 30 - Blood glucose level changes pre- and post-intervention

Heterogeneity was detected in the residual plot and it was assumed that the residuals were independent (Figure 31).
The log-likelihood ratio test showed there was not a significant amount of variability associated with patient or pharmacy at the 5% significance level (Table 16).

Table 16 - Blood glucose level final analysis of variance

<table>
<thead>
<tr>
<th></th>
<th>Df</th>
<th>denDF</th>
<th>F.inc</th>
<th>Pr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>1</td>
<td>52.4</td>
<td>0.03</td>
<td>0.870</td>
</tr>
<tr>
<td>Age</td>
<td>1</td>
<td>60.3</td>
<td>0.16</td>
<td>0.693</td>
</tr>
<tr>
<td>Sex</td>
<td>1</td>
<td>64.1</td>
<td>0.00</td>
<td>0.987</td>
</tr>
</tbody>
</table>

None of the main effects were significant at the 5% level. Among the 39 patients who had T2DM, 27 started the study with blood glucose level $>7$ mmol/L. At the end of the intervention, 17 patients had their blood glucose level $>7$ mmol/L. When reviewing the 17 patients, six had a slight increase (between 7–7.5 mmol/L) and started the study with blood glucose level $<7$ mmol/L. The other 11 patients did not reach their target ($<7$ mmol/L); however, two patients dropped their blood glucose level from $>10$ mmol/L to $<9$ mmol/L and all others from $>12$ mmol/L to $<10$ mmol/L. Considering the complications caused by uncontrolled high blood glucose level, these changes are considered clinically significant.
**Dyslipidaemia**

Dyslipidaemia is an underlying cause of many CVDs, such as stroke and myocardial infarction. When familial or secondary to other diseases, medications and lifestyle modifications are required lifelong. When caused by a lifestyle stressor such as obesity or smoking, lifestyle changes are essential, supported by medications until targets are achieved or lifelong if the patient is from a high risk group such as a diabetic or someone who has experienced a cardiovascular event (e.g., stroke or myocardial infarction). Good total cholesterol control requires the patient to maintain a target of <4mmol/L and triglycerides <2.0 mmol/L.

**Total Cholesterol**

The boxplots show that total cholesterol was slightly reduced in the total sample population after the intervention. The effect was more pronounced in males than females (Figure 32). Fifty-three patients started the study with total cholesterol level >4 mmol/L (21 males and 32 females).

![Figure 32 - Total cholesterol level changes pre- and post-intervention](image-url)
The residuals were derived from a population that is normally distributed (Shapiro-Wilk \( p = 0.001 \)) showing heterogeneity was present, which required the data to be transformed (Figure 33).

![Residual Plots](image)

Figure 33 - The Shapiro-Wilk test of normality for total cholesterol level

The log-likelihood ratio test showed no significant variability associated with patient or pharmacy at the 5% significance level. Table 17 shows a significant effect on total cholesterol level due to time (\( p = 0.046 \)).

<table>
<thead>
<tr>
<th></th>
<th>Df</th>
<th>denDF</th>
<th>F.inc</th>
<th>Pr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>1</td>
<td>56.6</td>
<td>4.16</td>
<td>0.046</td>
</tr>
<tr>
<td>Age</td>
<td>1</td>
<td>58.0</td>
<td>2.84</td>
<td>0.097</td>
</tr>
<tr>
<td>Sex</td>
<td>1</td>
<td>55.1</td>
<td>2.74</td>
<td>0.104</td>
</tr>
</tbody>
</table>

Also, results suggest that both age and sex have an association with total cholesterol level as the \( p \)-values are around 10% (Table 18).

<table>
<thead>
<tr>
<th></th>
<th>Predicted Value</th>
<th>Standard Error</th>
<th>Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>After</td>
<td>1.491</td>
<td>0.035</td>
<td>a</td>
</tr>
<tr>
<td>Before</td>
<td>1.552</td>
<td>0.035</td>
<td>b</td>
</tr>
</tbody>
</table>
At the end of the study, among the 53 patients who had a high total cholesterol level at the start of the study, 15 patients’ total cholesterol level was reduced by an average of 1.4 mmol/L (4 males and 11 females). Four males had their total cholesterol level raised when compared to the baseline level (0.3 mmol/L), while none of the other patients showed any change between pre- and post-intervention readings.

**Triglycerides**

The boxplots show that triglycerides were slightly reduced in the total sample population after the intervention. The effect was more pronounced in females than males (Figure 34). Sixteen patients started the study with triglycerides >2 mmol/L (8 males and 8 females).

![Figure 34 - Triglycerides level changes pre- and post-intervention](image)

The residuals were derived from a population that is normally distributed (Shapiro-Wilk $p = 0.102$) showing heterogeneity was present, which required the data to be transformed (Figure 35).
The log-likelihood ratio test shows no significant variability associated with patient or pharmacy at the 5% significance level. All the interaction terms were checked for significance and dropped if the $p$-values were $> 0.05$. None of the interaction terms were statistically significant (Table 18).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Df</th>
<th>denDF</th>
<th>F.inc</th>
<th>Pr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>1</td>
<td>25.0</td>
<td>0.10</td>
<td>0.750</td>
</tr>
<tr>
<td>Age</td>
<td>1</td>
<td>26.9</td>
<td>1.85</td>
<td>0.185</td>
</tr>
<tr>
<td>Sex</td>
<td>1</td>
<td>26.2</td>
<td>0.35</td>
<td>0.561</td>
</tr>
</tbody>
</table>

Any change towards the healthy target of triglycerides is considered clinically significant. Five females had their triglycerides readings reduced by an average of 0.6 mmol/L and three males by an average of 1.5 mmol/L.

**Blood Pressure**

Death risk from ischaemic heart disease or stroke increases progressively as blood pressure increases. Systolic blood pressure indicates the pressure on the artery walls.
that occurs when the heart contracts and pushes the blood to the rest of the body. Diastolic blood pressure indicates the pressure in the arteries when the heart rests between beats.

For every 20 mm Hg systolic or 10 mm Hg diastolic increase in blood pressure above 115/75 mm Hg, the mortality rate for both ischaemic heart disease and stroke doubles. One in every 11 deaths is prevented in patients with CVD risk when a sustained reduction of 12 mm Hg in systolic blood pressure over 10 years is achieved.

Controlling blood pressure within normal daytime readings (around 120/80 mmHg) or at the target, when a patient has other comorbidities, is essential in preventing further CVD complications and renal failure.

Sixty-five patients were reported to have hypertension at the start of the study. Twenty six females had systolic blood pressure >135 mmHg and 13 had diastolic blood pressure >85 mmHg. Twenty six males had systolic blood pressure >135 mmHg and 19 had diastolic blood pressure >85 mmHg.

This parameter consists of two readings, systolic and diastolic blood pressure, and the analysis of the combined reading was not feasible. Accordingly, they were analysed separately.

**Systolic blood pressure**

Sixty-five patients were reported to have hypertension at the start of the study. Of these 52 had a systolic blood pressure >135 mmHg (26 females, 26 males).

The boxplots show that systolic blood pressure was slightly reduced in the total sample population after the intervention. The effect was equal in the number of
patients but a greater overall pressure reduction was seen in males than females (Figure 36).

The residuals are derived from a population that is normally distributed (Shapiro-Wilk $p = 0.386$) showing heterogeneity was present, which required the data to be transformed (Figure 37).

Figure 36 - Systolic blood pressure changes pre- and post-intervention

Figure 37 - The Shapiro-Wilk test of normality for Systolic blood pressure
The log-likelihood ratio test shows a significant amount of variability associated with patient at the 5% significance level (Table 20).

<table>
<thead>
<tr>
<th></th>
<th>Df</th>
<th>denDF</th>
<th>F.inc</th>
<th>Pr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>1</td>
<td>61.3</td>
<td>3.00</td>
<td>0.089</td>
</tr>
<tr>
<td>Age</td>
<td>1</td>
<td>77.0</td>
<td>1.12</td>
<td>0.294</td>
</tr>
<tr>
<td>Sex</td>
<td>1</td>
<td>79.3</td>
<td>1.51</td>
<td>0.223</td>
</tr>
</tbody>
</table>

None of the main effects were significant at the 5% significance level but the findings suggested that there might be some effect on systolic blood pressure at the 10% significance level.

At the end of the study, only 13 females and 13 males had systolic blood pressure >135 mmHg, which is believed clinically significant.

**Diastolic blood pressure**

Sixty-five patients reported hypertension at the start of the study. Thirteen females and 19 males had diastolic blood pressure >85 mmHg.

The boxplots show that systolic blood pressure was slightly reduced in the total sample population after the intervention. The effect was equal among all patients, but there was greater overall pressure reduction in males than in females (Figure 38).
The residuals were derived from a population that is normally distributed (Shapiro-Wilk $p = 0.805$) showing heterogeneity was present, which required the data to be transformed (Figure 48).

Figure 38 - Diastolic blood pressure changes pre- and post-intervention

Figure 39 - The Shapiro-Wilk test of normality for diastolic blood pressure
The log-likelihood ratio test shows a significant amount of variability associated with the patient at the 5% significance level. Diastolic blood pressure was affected by age ($p$-value = 0.001) but is not affected by any of the other main effects (Table 21).

### Table 21 - Diastolic blood pressure final analysis of variance

<table>
<thead>
<tr>
<th></th>
<th>Df</th>
<th>denDF</th>
<th>F.inc</th>
<th>Pr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>1</td>
<td>74.6</td>
<td>10.97</td>
<td>0.001</td>
</tr>
<tr>
<td>Time</td>
<td>1</td>
<td>61.0</td>
<td>2.09</td>
<td>0.153</td>
</tr>
<tr>
<td>Sex</td>
<td>1</td>
<td>78.9</td>
<td>1.18</td>
<td>0.281</td>
</tr>
</tbody>
</table>

At the end of the study, nine females and ten males had diastolic blood pressure >85 mmHg, which, again, is clinically significant.

### Heart Rate

Although in the protocol, not all sites measured heart rate; only 36 patients had their heart rate recorded. At the start of the study two females and three males had their heart rate above normal.

The boxplots show that heart rate was slightly reduced in the total sample population after the intervention. The effect was equal in males and females (Figure 40).

**Figure 40 - Heart rate changes pre- and post-intervention**
The residuals are derived from a population that is normally distributed (Shapiro-Wilk $p = 0.65$) showing heterogeneity was present, which required the data to be transformed (Figure 41).

Figure 41 - The Shapiro-Wilk test of normality for heart rate

The log-likelihood ratio test shows there was not a significant amount of variability associated with patient or pharmacy at the 5% significance level. None of the interaction terms were significant.

At the end of the study, out of the five patients who had elevated heart rate, three (one female and two male) returned to normal and only two remained high. The elevation might have been caused by anxiety rather than cardiovascular abnormality.

**International Normalised Ration**

Out of seven patients monitored for INR, five became within target (2–3 for all and 2.5–3.5 in two patients), while one patient remained poorly controlled.
Chapter VI. Survey Results

Introduction

The study protocol required pharmacists to measure all parameters (body mass index, waist measurement, heart rate, blood pressure, total cholesterol level, triglycerides, blood glucose level, visual acuity, monofilament pressure, pain score and INR, if applicable) at baseline, between 1 September and 30 December 2012, depending on the date the patient was enrolled. Only the parameters designated as disease markers in the diseases algorithms (Form 20, Table 2) were to be monitored from 1 January to 30 June 2013, but all parameters were to be measured again at the end of the clinical intervention (no later than 1 July 2013). HeiQ™ questionnaires were required to be completed; one at baseline, the other at follow-up, for all patients. The pharmacists were also requested to complete the mid-study survey to comment on the positive and negative aspects of the study and its effect on their practice improvement.

The next two sections describe the results of analysis of HeiQ™ baseline and follow-up data and data from the mid-study survey.

Analysis of HeiQ™ responses before and after the clinical intervention phase

Eighty-four HeiQ™ BL forms were completed at baseline, but at the end of the intervention phase only 65 (77.4%) forms were completed. Of those who were lost to attrition, three were patients enrolled at a site that had withdrawn in the middle of the study due to the pharmacist’s other commitments. Three more patients formally withdrew from the study due to diagnosis of new conditions or worsening of existing conditions (cancer, arthritis and chronic obstructive pulmonary disease) that rendered them housebound and prevented continued participation. The remaining 13 patients
(15%) lost to follow up failed to keep or were not given their final appointments (Figure 42).

Figure 42 - Total Drop-out

The model assumptions are that the residuals are normally distributed, they have a constant variance and are independent, and the factor level variances are equal for the treatments.

Figure 43 is a histogram of responses, which identifies any outliers and possible treatment effects. The boxplots show that post-intervention heiQ™ total scores were higher than the pre-intervention heiQ™ total scores for the entire sample population, but not per question or per person. It also appears that females had higher heiQ™ total scores than males.
Figure 43 - heiQ™ total scores histogram of the responses

Figure 44 presents the Shapiro-Wilk test of normality used to determine if the residuals were normally distributed. It was concluded that the residuals were derived from a population that was normally distributed (as the Shapiro-Wilk \( p \)-value = 0.06).

![Residual Plots](image)

Figure 44 - The Shapiro-Wilk tests of normality for heiQ™ total scores pre- and post-intervention
From the residual plot, it can be seen that the residuals had a constant variance and the assumption that the residuals are independent could be made. For the factor level treatment variances, it can be seen that the variances were the same (Hartley’s $p$-value = 0.325). The analysis of variance was performed using the one-way ANOVA table (Table 22).

Table 22 - heiQ™ total score ANOVA table

<table>
<thead>
<tr>
<th></th>
<th>Df</th>
<th>denDF</th>
<th>F.inc</th>
<th>Pr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>1</td>
<td>70.6</td>
<td>12.42</td>
<td>0.001</td>
</tr>
<tr>
<td>Age</td>
<td>1</td>
<td>72.9</td>
<td>0.27</td>
<td>0.607</td>
</tr>
<tr>
<td>Sex</td>
<td>1</td>
<td>74.1</td>
<td>3.96</td>
<td>0.050</td>
</tr>
<tr>
<td>Time : Age</td>
<td>1</td>
<td>68.5</td>
<td>1.91</td>
<td>0.172</td>
</tr>
<tr>
<td>Time : Sex</td>
<td>1</td>
<td>71.3</td>
<td>0.67</td>
<td>0.416</td>
</tr>
<tr>
<td>Sex : Age</td>
<td>1</td>
<td>71.2</td>
<td>2.33</td>
<td>0.131</td>
</tr>
<tr>
<td>Time : Age : Sex</td>
<td>1</td>
<td>69.6</td>
<td>4.74</td>
<td>0.033</td>
</tr>
</tbody>
</table>

A log-likelihood ratio test was required to determine whether there was a significant amount of variability associated with the different pharmacies and the individual patients. There was not a significant amount of variability associated with patient or pharmacy at the 5% significance level. All the interaction terms were checked for significance and dropped if the $p$-values $>0.05$. None of the interaction terms were significant. The final analysis of variance is presented in Table 23.

Table 23 - Final analysis of variance

<table>
<thead>
<tr>
<th></th>
<th>Df</th>
<th>denDF</th>
<th>F.inc</th>
<th>Pr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>1</td>
<td>74.0</td>
<td>11.70</td>
<td>0.001</td>
</tr>
<tr>
<td>Sex</td>
<td>1</td>
<td>74.5</td>
<td>4.10</td>
<td>0.046</td>
</tr>
<tr>
<td>Age</td>
<td>1</td>
<td>73.1</td>
<td>0.19</td>
<td>0.661</td>
</tr>
</tbody>
</table>

The sex variable showed that there was an effect on the number of heiQ™ total scores, as it had a $p$-value = 0.046. The predicted mean number of the total scores for the pre- and post-intervention times is shown in Table 24.
The intervention showed that there was an effect on the heiQ™ total scores, as it had a $p$-value $\leq 0.001$. The predicted mean of total score for the pre- and post-intervention times are shown in Table 25.

<table>
<thead>
<tr>
<th>Time</th>
<th>Predicted Value</th>
<th>Standard Error</th>
<th>Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before</td>
<td>37.2</td>
<td>0.7</td>
<td>A</td>
</tr>
<tr>
<td>After</td>
<td>39.4</td>
<td>0.7</td>
<td>B</td>
</tr>
</tbody>
</table>

There were significant improvements seen in all domains, with the highest improvement in health services navigation (33.25%). Table 26 shows a comparison between the individual questions and the responses by all patients, pre- and post-intervention.

Table 26 - heiQ comparison between baseline and follow-up, per question

<table>
<thead>
<tr>
<th>Question</th>
<th>knowledge (increased)</th>
<th>Changes from before the clinical intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q3 - Domain 4 - <em>Self monitoring and insight</em> - As well as seeing my doctor, I regularly monitor changes in my health</td>
<td>34.8%</td>
<td></td>
</tr>
<tr>
<td>Question</td>
<td>knowledge (increased)</td>
<td>Changes from before the clinical intervention</td>
</tr>
<tr>
<td>----------</td>
<td>-----------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Q6 - Domain 4 - <strong>Self monitoring and insight</strong> - I know what things can trigger my health problems and make them worse</td>
<td>26%</td>
<td><img src="Graph1.png" alt="Graph" /></td>
</tr>
<tr>
<td>Q9 - Domain 1 - <strong>Health directed behaviour</strong> - I do at least one type of physical activity every day for at least 30 minutes (e.g., walking, gardening, housework, golf, bowls, dancing, Tai Chi, swimming)</td>
<td>24.6%</td>
<td><img src="Graph2.png" alt="Graph" /></td>
</tr>
<tr>
<td>Q11 - Domain 4 - <strong>Self monitoring and insight</strong> - I have a very good understanding of when and why I am supposed to take my medication</td>
<td>31.9%</td>
<td><img src="Graph3.png" alt="Graph" /></td>
</tr>
<tr>
<td>Q16 - Domain 4 - <strong>Self monitoring and insight</strong> - When I have health problems, I have a clear understanding of what I need to do to control them</td>
<td>30.4%</td>
<td><img src="Graph4.png" alt="Graph" /></td>
</tr>
<tr>
<td>Question</td>
<td>knowledge (increased)</td>
<td>Changes from before the clinical intervention</td>
</tr>
<tr>
<td>----------</td>
<td>----------------------</td>
<td>-----------------------------------------------</td>
</tr>
</tbody>
</table>
| Q20 - Domain 4 - **Self monitoring and insight** - With my health in mind, I have realistic expectations of what I can and cannot do | 23.2%  
| Q24 - Domain 8 - **Health services navigation** - I have very positive relationships with my health care professionals | 33.4%  
| Q30 - Domain 6 - **Skill and technique acquisition** - I have a good understanding of equipment that could make my life Easier | 30.4%  
| Q31 - Domain 7 - **Social integration and support** - When I feel ill, my family and carers really understand what I am going through | 26.1%  
| Q32 - Domain 8 - **Health services navigation** - I confidently give health care professionals the information they need to help me | 27.5%  

![Responses before and after comparison](chart1)  
![Responses before and after comparison](chart2)  
![Responses before and after comparison](chart3)  
![Responses before and after comparison](chart4)
Appendix VI shows the changes (pre- and post-intervention) in responses per patient; 58% of participants responses changed to agree and strongly agree options, 29% remained the same, and 13% changed to disagree and strongly disagree or omitted some questions. The reason for changes towards strongly disagree were unclear, but
could represent either intentional change or misunderstanding of the questions as the baseline and follow-up questionnaires were the same.

**Analysis of heiQ™ follow-up questions 41–50**

These questions were only asked in the heiQ™ follow-up; they concern the participants’ opinions regarding the project and whether they considered it feasible to continue with the intervention, or believed another approach might work better. Question 50A had the highest mean satisfaction score, followed by 50B and 50C. Question 42 returned the lowest mean score (Figure 45). Scores above three can be interpreted as representing *agree* and *strongly agree*, where 4 is represents *strongly agree.*
Patients’ Comments

Question 50D heiQ™ asked whether patients had any other comments or suggestions or other things they would like to see in future studies, or if the intervention were implemented in their local community pharmacy what they would include and omit. The key themes arising out of this question were as follows:

- Positive (17 comments): it was worth participating and receiving additional services
- Negative (one comment): equipment did not work every time (Accutrend® Plus)

*JJ01 – Some equipment was not reliable every time.*
CV03 – If I will benefit from my participation I believe it is worthwhile.

CV09 – Very worthwhile, I am thankful.

CV13 – Great to know everyone is working towards my wellbeing.

BS01 – It was very worthwhile doing it.

BS12 – It was great to know where to get expert advice when I need it.

BS26 – Very well set up and informative, thanks.

PR02 – Told the Dr what I had been doing, i.e. keeping an eye on blood pressure.
The doctor is pleased, eating habits have changed and I increased exercise.

PR05 – My irregular heartbeat was discovered in the pharmacy and I was advised to consult my GP. Have had an echocardiogram and have an appointment with cardiologist next week.

PR10 – Very useful, got me off Pergout® as suggested but months later got mild gout which is disappointing, so started it again, will discuss with the GP about regular lower dose.

PR11 – Helpful as I am on many medications. It is useful to know if they will interact with anything new.

PR12 – Staff always very helpful with ideas and knowledge.

GD05 – I get to spend plenty of one on one time with pharmacist.

LOC01 – I get to spend plenty of one on one time with pharmacist.

LOC02 – It’s free and easy to speak to my local chemist.

LOC03 – I found that pharmacist and staff are friendly and trustworthy.
LOC04 – Local GP is working part time due to truck accident, is easy to ask for help and questions at pharmacy, I don’t like the new Dr.

LOC05 – The pharmacist speaks clearly and slowly.

Mid-Study Survey Results

The nine participating sites were sent a 38-item questionnaire on 30 December 2012 with a return date of 30 January 2013. Completed questionnaires were returned by eight sites (88.9%); three sites had two responses each, one from each of the involved pharmacists and one site did not respond and later withdrew from the study, citing personal reasons. Consequently, 11 completed questionnaires were received.

The mid-study survey was delivered to the sites’ pharmacists by the investigator to review any issues that had arisen during enrolment (only 84 were enrolled out of an initial commitment of 500) and any issues relating to study equipment and communication with GPs (Appendix VIII).

Question 1: Does your GP support the study concept?

This question aimed to determine if there had been additional communication between the pharmacist and local GPs other than that conducted by the investigator in June 2012 (Figure 36). During the training session in May 2012, site pharmacists were told that the investigator would meet with local GPs to inform them about the study, clarify whether they were happy for their patients to participate, and if they had any reservations about their local pharmacists participating. The second step was for the pharmacists to have communication with their GPs to discuss how they would communicate and share information about the enrolled patients (investigated in Q3) during the study. Five of the 11 survey respondents (46%) agreed that their local GPs were supporting the study, and a further 27% (3) agreed with the concept
of the study but did not want to be involved. The rest (three responses) were either the GP did not communicate at all (18%) or opposed the study (9%).

One of the stated objectives for this study was to improve communication between pharmacists and local practitioners. However, it appears that the GPs changed their opinion about the intervention between the investigator’s visit and the commencement of the project (a maximum interval of 30 days), as in most cases the communication was ineffective.

Not all of the pharmacists included comments at the end of this question. One pharmacist indicated that the word ‘oppose’ used in the question was a strong word and ‘passive’ might be better. The pharmacists said that regardless of whether they supported the study, GPs did not want to open their database to the study. Pharmacists also indicated that GPs did not want any extra work but do not care what the local pharmacy is doing as long as it is not taking business away from their clinics.

**Question 2: Does your GP support the study PoC testing?**

The intention of this question was to understand which PoC testing parameters the GPs agreed to have performed between patient visits, and why others were not considered acceptable. The question was developed to understand why most sites did not measure INR as part of BL data.

This was to elucidate whether lack of measurement was because:

- The pharmacists decided for themselves not to monitor INR
- The patients did not want their INR monitored in the pharmacy
- There were no appropriate patients signed up in that pharmacy
- The GP objected to in-pharmacy monitoring.
Fewer than half (46%) of pharmacists agreed that their local GP supported all the study parameters; the rest (54%) indicated that the GP either agreed, without contribution or did not communicate their opinion at all.

**Question 3: Did you discuss with your GP how you will share the participating patient medication and medical history based on the patient consent, and what was the GP’s position?**

This question aimed to determine whether the pharmacist took the second step to make contact with their GPs to discuss how they would share information during the study (Figure 46). During the investigator’s visits to GPs in June 2012, all in the eight towns (of which one two has two sites) indicated that they were happy to participate and collaborate. However, as illustrated in Figure 38, in practice only one GP practice agreed to two-way information sharing (from pharmacy to GP practice and from GP practice to pharmacy, even if no GP action was required); at five sites the local GPs agreed to one-way sharing (from pharmacy to GP practice only, if urgent and required GP action) accepting the study in principle without active collaboration with the pharmacy; and at four sites local GPs expressed no interest in participation with pharmacy research activities. One site indicated the local GPs opposed any collaboration.
Question 4: Regarding pharmacist referral request to GP, which statement is correct?

This question aimed to determine if the GPs responded to the pharmacists’ recommendations, such as for the referral of patients for HMR, specialist appointment requests, diabetes educator appointments and allied health appointments (Figure 47). Three sites indicated the local GPs referred patients for MMR based on a message from their patient without the pharmacist’s referral. Three sites indicated that the local GPs responded to the pharmacist’s referral requests, and four sites indicated the local GPs did not respond to the pharmacist repeated requests for referral.
**Question 5: If the GP is supporting your participation, did you receive any instruction or direction? Which statement is most correct?**

This question aimed to determine the method the GPs used to provide their response to the pharmacists’ communication regarding support for the study and collaboration plan. Pharmacists could not produce evidence of GPs’ written communication, but one pharmacist indicated that written communication was received from the local GP. Two pharmacists indicated that they received direct verbal communication and three indicated that the GPs only implied their support without directly saying they were supportive. Only two pharmacists indicated no communication was received from their GPs.

**Question 6: If the GP opposes your participation, did you receive any instruction or direction? Which statement is most correct?**

This question aimed to determine the method the GPs used to provide their response to the pharmacist communication regarding their opposition to the study and collaboration plan. Five sites received no communication from their local GPs to support or oppose their participation in the study. Four sites received a form of instruction or directions opposing their participation.

Pharmacists indicated that in most cases, GPs responded verbally and were very passive, which may imply non-support indicating that they have no time to respond in writing.

**Question 7: Regarding the time taken per patient on the initial visit, which statement is correct?**

This question aimed to quantify the time taken by pharmacists to inform a patient about the study concept and outlines (Figure 48). This would inform the final
recommendations on the feasibility of continuing the study concept as a future component of pharmacy practice.

Contrary to what was reported at baseline, when the average initial intervention time reported was 30 minutes, all the mid-study survey responses indicated that at least 40 to 60 minutes were needed to complete the initial interview. It transpired that most sites completed the baseline parameter measures over two visits, and few sites added the time spent in the second visit to that recorded in the enrolment visit and counted a second stand-alone visit. Future studies will need to measure in more detail the time spent during the intervention.

![Figure 48 - Question 7](image)

**Question 8: Regarding time taken per patient for a subsequent visit, which statement is correct?**

This question was intended to quantify the time taken for pharmacists to perform the monthly follow-up with patients (Figure 49), and relates to the sustainability of the concept.

All the pharmacists selected five minutes per test and per activity for the follow-up, but not all pharmacists monitored all PoC parameters. Pharmacists cited problems with performing the measurements, notably:
– Inability to achieve readings (especially error messages on the monitor in cold weather)
– Blood flow from finger pricks were insufficient to allow a sample to be collected and tested in less than 30 seconds.
– The test should be conducted only every three months (e.g., triglycerides and cholesterol)
– The pharmacist and/or the patient were unwilling to spare the time for testing.

These responses provide some explanation for the amount of missing data over the period of three months of recruitment.

Figure 49 - Question 8

Pharmacists indicated that the PoC monitors sometimes need to warm up in cold weather and usually take up to five minutes; if not warm enough the meter fails to read, and patients and pharmacists rarely have this time to spare.

**Question 9: Regarding your and your staff’s availability to perform the intervention, which statement is correct?**

This question focused on site ability to sustain the services. No site indicated that staffing level was a barrier to recruiting sufficient patients (Figure 50). Two pharmacists indicated that sometimes they have to ask participants to come back when the pharmacy is busy.
Only two pharmacists entered comment at the end of this question indicating that they were able to complete the monthly intervention in about 70% of time but they found it too hard to do when only one pharmacist was on duty. The other comment indicated that the shortfall in staff was due to a pharmacist who had gone on maternity leave who they were unable to replace.

**Question 10: Regarding your and your staff’s ability to apply the study protocol, which statement is correct?**

This question was intended to determine site ability to deliver the study intervention, including one-on-one communication (initial and ongoing) and performing the PoC monitoring of the disease markers (Figure 51). No specific complaint was received from any of the participating site pharmacists. One site (BS) developed its hard-copy data collection sheet based on the electronic forms provided by the study. This form was then adopted by all sites to allow unified mean of the data collection to be calculated. The majority of pharmacists indicated that they were able (with minor difficulty) to apply the protocol.
Questions 11 to 14:

Regarding your ability to conduct HMR, which statement is correct?

- HMR was previously conducted in the past 12 months: 4 responses
- Conducted HMR for the purpose of the study: 2 responses
- Awaiting GP referral to conduct HMR for the purpose of the study: 4 responses
- Scheduled HMR for the purpose of the study: 1 response

Figure 52 - Question 11

Regarding your inability to conduct HMR, which statement is correct?

- Patient not eligible for HMR: 6 responses
- GP refused to forward a HMR referral: 1 response
- Patient refused to have a HMR: 1 response
- Not accredited to conduct HMR: 3 responses

Figure 53 - Question 12
Questions 11 to 14 (Figures 52 to 55) aimed to investigate site ability to conduct medication reviews under either the HMR or MedsCheck™ scheme (which would enable the pharmacist to be remunerated) and to understand why some sites were unable to do so.

All participating pharmacists expressed that they prefer MedsCheck™ over HMR due to their experience of having to wait long times for the referral to arrive from the GP clinic to be able to initiate an HMR. Pharmacists can initiate the MedsCheck™
without GP referral and it provides the patient with the same benefit. However, at the time of the audit, MedsCheck™ was a new process and not all of the nine sites had the process established with Medicare. The pharmacists did not indicate the number of patients who had received any kind of medication review or who had never undergone a medication review, or the time since last medication review or when the next review was due. There was no indication of what action the pharmacist intended to take if there was no history of a medication review. Some indicated that they considered individual patients ineligible; however, all the enrolled patients had chronic conditions and were receiving multiple medications that require therapeutic monitoring, so met the eligibility criteria for both HMR and MedsCheck™.

Four pharmacists entered comments after questions 11 to 14. Two pharmacists indicated that doing MedsCheck™ is easier than waiting for the GP to make a referral as they rarely reply. They also indicated that only one pharmacist per site is accredited to do HMR. One pharmacist indicated that they are not yet accredited to do HMR or MedsCheck™. One pharmacist indicated that some patients had HMR less than 12 months ago and are not yet eligible for another one, but some patients refused to have any medication review of any type due to time constraints.

**Question 15: Regarding the availability of a private consultation area or room, which statement is correct?**

This question was directed at the ability to deliver one-on-one communication (initial and ongoing) while maintaining patient confidentiality and convenience (Figure 56). All pharmacists indicated that they had a private room available to use when communicating with patients. However, during site visits it was clear that four of the
nine sites had a dedicated desk in a quiet end of the dispensary, rather than a separate room as indicated.

**Figure 56 - Question 15**

**Question 16: Regarding the usability of Accutrend® Plus, which statement is correct?**

This question investigated pharmacists’ ability to use the PoC monitors to perform measurement of disease-state markers (Figure 57); almost all regarded themselves as competent.

**Figure 57 - Question 16**
Pharmacist’s quote:

*I decided not to perform the cholesterol and triglycerides monitoring and use Accucheck® to monitor blood glucose level instead because of difficulty in bleeding the patient and getting the machine to read results.*

**Question 17: Regarding the useability of Coagucheck® XS Plus, which statement is correct?**

This question collected information about the use of the Coagucheck® XS Plus device for monitoring (Figure 58). As described in the methods chapter, all efforts were made to equip pharmacists with the information and training required for the operation and maintenance of PoC monitors. However, only two sites out of the nine were involved in INR monitoring prior to study commencement.

![Figure 58 - Question 17](image)

During the training prior to the commencement of the study, all pharmacists indicated that the Coagucheck® XS Plus is easy to use; however, when they entered comments at the end of this question one pharmacist indicated that the monitor is too complicated. Another comment was interesting as one pharmacist indicated that the testing process did not start due to a GP verbally communicating that they had a
problem agreeing to a pharmacist performing the test and accordingly did not enrol any patients who required INR monitoring.

**Question 18: Regarding the useability of digital blood pressure monitors, which statement is correct?**

This question concerned the useability of the Omron digital blood pressure monitors chosen for this study (Figure 59). Most pharmacists indicated that had experienced no problems with the instrument.

![Figure 59 - Question 18](image)

**Question 19: Regarding the useability of the body composition scale, which statement is correct?**

Health practitioners frequently calculate body mass index manually using the patient’s height and weight (Figure 60). The study provided the sites with body Omron composition scales to eliminate this manual calculation and prevent interpretation errors. They also saved time as only a single measurement was needed. Only one out of the eleven pharmacists indicated a minor level of difficulty with these scales.
Pharmacist’s quote:

*Needed to refresh knowledge when we did not use it for a while*

**Question 20: Regarding the useability of the monofilament testing kit, which statement is correct?**

With regards to the 10 g pressure monofilament testing device, most participants indicated that they were competent (Figure 61). However, sites considered this parameter as being not required for all patients, which was inconsistent with the protocol. The monofilament pressure test is intended for early detection of sensation changes that have not previously been identified in diabetic patients, in addition to the monitoring of recognised disease markers.
Question 21: Regarding the useability of the Hanks visual acuity chart, which statement is correct?

Most participants indicated that they were competent in the use of the visual acuity chart (Figure 62). Sites considered this parameter as being not required for all patients, which again is inconsistent with the protocol, as it is an important screening tool for a range of conditions and complications.

![Figure 62 - Question 21](chart.png)

Pharmacist’s quote:

*Need to refresh knowledge when we do not use it for a while.*

Question 22: Regarding the application of training in practice, which statement is correct?

This question targeted the perceived effectiveness of the training provided to pharmacists as part of the study. As shown in Figure 63, pharmacists attended the face-to-face and hands-on training provided about the study protocol, the forms, the CARPA STM, the PoC monitoring equipment, GuildCare software and other devices. Three of those who attended the training did not take part in the study and withdrew from the study in June 2012. Two replacement sites were recruited and their training was delivered by the investigator and the field trainers (for the PoC devices).
Additional training on the protocol was requested at three sites and additional training on the monitors in four sites between July and September 2012. The investigator provided protocol training and manufacturers’ field educators provided device training. An additional training session on the monitors was provided to one site by teleconference during November 2012. Most participants indicated they were competent or had only minor difficulties.

![Bar chart showing competence levels](image)

**Figure 63 - Question 22**

**Question 23: Regarding your willingness to use the Accutrend® Plus and Coaguchek® XS Plus, which statement is correct?**

This question was aimed to gain understanding about why some sites did not use the PoC monitors to their maximum functionality (Accutrend® Plus for total cholesterol level, triglycerides and blood glucose level) or at all (Coaguchek® XS Plus) (Figure 64).
Most participating pharmacists reported their willingness to use the Accutrend and Coaguchek® XS Plus monitors with no reservations, while two were hesitant due to personal difficulty using the equipment. However, only three sites used all the PoC monitors to their maximum functionality. Figure 65 shows the large gap between the number of testing of each parameter, theoretically and based on the study protocols, blood pressure and blood glucose level should be measured monthly in diabetic patients, INR in patient taking warfarin and blood pressure should be measured monthly and total cholesterol and triglycerides should be measured every three months. However, this was not the case as the pharmacists omitted some testing based on time availability and if they did not achieve to have reading from first time due to process errors. Also all parameters except INR were to be measured for all patients regardless of condition at baseline and at the end of the study, but at the end of the study not all patients had all parameters measures.
Only two sites used the Coaguchek® XS Plus (with 7 of 84 patients (8%)). Only five sites measured total cholesterol level (74 of 84 patients (74%)); six sites triglycerides (41 of 84 patients (49%)); and eight sites blood glucose level (73 of 84 patients (87%)). Sites considered those parameters as being not required for all patients, which again was inconsistent with the study protocol; early detection of changes is important.

**Question 24: Regarding the cost of consumables used in PoC testing, which statement is correct?**

This question assessed whether pharmacists were willing to absorb the cost of ongoing testing (not including the cost of the PoC monitors) (Figure 66). Most were willing to accept the cost ($1000) during the study, but not ongoing costs without Medicare subsidy.
Question 25: Regarding the average time taken to perform a test that requires a finger prick, which statement is correct?

This question related to barriers to testing and using the PoC monitors experienced by the pharmacists, indicated by the length of time taken to complete PoC testing (Figure 67). The aim was to determine whether (1) pharmacists are anxious about pricking skin, seeing blood, or failing to perform the test correctly; (2) they dislike feeling pressured by being watched by others in the pharmacy, or are worried about hurting patients; and (3) it took longer to administer the test than it would if performed by a GP or registered nurse. Seven respondents indicated they took five minutes per test and three indicated 15 minutes. However, it was felt this question was open to interpretation and that the latter meant 5 minutes per three tests (equallling 15 minutes) not 15 minutes per test.
**Question 26: Regarding patient agreement to be tested, which statement is correct?**

This question was intended to elucidate if patient-related issues were a barrier to testing and using the PoC monitors (Figure 68). Most respondents indicated that all patients enrolled had agreed to the study’s PoC monitoring. Two sites indicated that a few patients (a total of five for both sites) did not return to sign the consent and enrol after verbally agreeing to participate, which may or may not relate to testing.

![Figure 68 - Question 26](image)

One pharmacist’s commented that one or two patients declined giving time constraints as the reason.

**Question 27: Regarding the cleaning of PoC monitors, which statement is correct?**

This question was asked to determine whether the pharmacists undertook the required infection control precautions and performed the manufacturer-recommended cleaning (after each use, per patient) of the PoC monitors (Figure 69). Few pharmacists indicated that they were competent in cleaning the equipment as recommended, and most others pharmacists indicated they were able to perform
cleaning but with some minor issues. Infection control was evident at all sites during the investigator visits.

![Figure 69 - Question 27](image)

**Question 28: Regarding PoC monitor calibration, which statement is correct?**

Calibration, which should be undertaken whenever a new batch of reagent strips is received, is essential for ensuring that a PoC monitor is performing optimally and its results are reliable (Figure 70). Most respondents indicated that they were competent at calibrating their machines.

![Figure 70 - Question 28](image)

**Question 29: Regarding quality control, which statement is correct?**

This question determined whether the pharmacists were able to perform the manufacturer-recommended quality control procedures which ensure that the PoC are working to the standards they are designed for. Quality control tests involve
using a quality control reagent. Pharmacists indicated they felt capable with a level of difficulties ranging from manageable for all to being difficult to manage (one site) (Figure 71).

![Bar chart showing the number of responses for different levels of difficulty with quality control reagent management.]

**Figure 71 - Question 29**

**Question 30: Regarding quality control cost, which statement is correct?**

This question relates to pharmacists’ perceptions of the sustainability of providing PoC testing (Figure 72). Neither of the controls for the Coaguchek® XS Plus and Accutrend® Plus are stocked by the local pharmaceutical wholesalers and can only be purchased on special order, so can take up to two weeks to arrive. Consequently, they often arrive at the pharmacy short-dated. They also require refrigeration. Each control test costs $20 and the test must be carried out either monthly or with every new batch of strips, whichever occurs first.

Most responders expressed willingness to accept the quality control cost during the study. Based on verbal communication, one of the three pharmacists performed only the blood glucose level test, and the other two performed blood glucose level and total cholesterol level only. The pharmacist who was unwilling to carry the cost withdrew from the study and did not perform any testing.
Question 31: Regarding quality assurance (Coaguchek® XS Plus only), which statement is correct?

This question was asked to determine if the pharmacists performed the manufacturer-recommended quality assurance (Figure 73). The quality assurance testing reagents and RCPA QAP subscription were funded from the project budget, ($500 per site, $4500 total) and supplied at the beginning of the testing period. The recommended quality assurance program comprised five bi-monthly surveys.

Only the Coaguchek® XS Plus has standardised, commercially independent quality assurance testing (Accutrend® Plus does not). Most pharmacists indicated that they were either competent or ‘able’ to perform the quality assurance tests. Two sites requested a second delivery as they had not read the instructions and failed to keep the reagents refrigerated. Only one site performed the five quality assurance surveys, five performed the first quality assurance survey only and three did not perform any quality assurance.
Two pharmacists entered comments at the end of this question indicating that the quality assurance test for Coaguchek® XS Plus was difficult and accordingly they did not do it and the other said that their site did only one out of the five surveys because they did not enrol any patients require INR monitoring.

**Questions 32 to 34**

Regarding suitable patients’ availability for enrolment and consultation, which statement is correct?
These three questions were intended to explore the cause for low patient recruitment numbers, which may have been due to a lack of suitable patients (see selection criteria, Chapter III), or due to the pharmacist being unwilling to carry the additional study workload they signed up for when they consented to participate (Figures 75 to 76). Some pharmacists stated that they made the choice to complete enrolment over two visits, as it made the patient more comfortable and the interview less time consuming. They provided the information session, collected demographics and completed the heiQ™ baseline survey on the first visit. On the second visit they
performed the monitoring tests and MedsCheck™ if required. Some pharmacists also indicated that the MMR (MedsCheck™ or HMR) was conducted at the third visit. Five patients did not enrol after being approached as a result of being unwilling to commit to the monthly monitoring, but all pharmacists also indicated that it had frequently been necessary to ask participants to return because the pharmacy was busy, and some patients did not return and missed that month’s monitoring and follow-up.

Six sites indicated that they underestimated the workload when they signed up for the study, and that when they enrolled the first few patients they found that they took longer than they estimated they would; accordingly, they decided that they would not be able to commit to the number agreed per site (15–20 patients).

Three pharmacists’ commented that some patients did not come back for testing due to time constraints and that they found that the follow-up testing was harder than enrolment testing. One pharmacist indicated that the rapport established during recent HMR made it easier to communicate with patients and do the testing.

Questions 35 to 38

Question 35: Are you currently participating in any other unpaid (i.e., you are not receiving financial or incentive support from the project investigator or organisation) projects commenced before you verbally consented (15/6/2011) to participate in this study?
Question 35: Are you currently participating in other paid (i.e., you are receiving financial or incentive support from the project investigator or organisation) projects commenced before you verbally consented (15/6/2011) to participate in this study?

Question 37: Are you currently participating in other unpaid (i.e., you are not receiving financial or incentive support from the project investigator or organisation) projects commenced after you verbally consented (15/6/2011) to participate in this study?
Question 38: Are you currently participating in other paid (i.e., you are receiving financial or incentive support from the project investigator or organisation) projects commenced after you verbally consented (15/6/2011) to participate in this study?

![Bar chart showing number of responses]

Figure 80 - Question 38

Questions 35 to 38 were designed to explore pharmacies pre-existing or post-commencement research commitments. Before the commencement of the study, only one site disclosed participating in another project, but when the questionnaire was completed mid-study, two respondents reported that their sites had, at commencement, been involved in other paid projects.

As Figures 90–93 show, after the commencement of the study, most respondents were participating in one to three other projects, some of them paid. The new paid and unpaid projects were all one-off interventions without follow-up and all required some form of testing intervention—blood pressure monitoring, clinical intervention or MedsCheck™. Based on verbal communications, all 11 respondents were involved in blood pressure monitoring and MedsCheck™ in other paid or unpaid projects.
Chapter VII. Discussion

Introduction

A search in PubMed was performed using the following terms: chronic, aged, elderly, health, conditions, cognitive, pharmacist, General Practitioner, non-communicable, disease, health professional, monitor, adherence, health service, self-management and communication.

This search yielded few papers that specifically targeted the relationship between pharmacists and GPs, patient medication adherence and self-management, pharmacists’ collaboration with GPs in patient chronic disease management, or pharmacists’ contribution to patient chronic disease management. However, the papers found were sufficient to support the development of the concept for a better-funded, larger chronic disease management community pharmacy-focused study.

NCDs are epidemic and causing more deaths globally than communicable diseases (14). Without modifying the contributing risk factors, the problem will continue to worsen; organisations such as the World Health Organization warn that the burden of NCDs on the health system cannot be sustained. The current Australian GP-centric, acute response model of health is neither coping with current national needs nor suitable for chronic disease management (11, 13). Countries such as United States of America, United Kingdom, Canada and New Zealand have already moved to multidisciplinary models of care that include the pharmacist as part of the health care team, and have revised health professional responsibilities to complement the increased demand and the shortage of practitioners, especially in rural and remote locations (10, 11, 12). The health system in Australia has introduced a number of new initiatives in the past decade, but all are GP-focussed, and only HMR includes
pharmacists. This is inconsistent with international best practice (94). The following section examines the professional barriers and system faults that affected this study, and compares these issues with what is happening in other developed countries and the wider international health care context.

The Journey

Planning Phase and formulation of study focus

The progress of this project was disrupted by a number of external factors that arose during the data collection phase. This section explains how these factors affected the project. The planning phase took 15 months: The first 12 months examined and selected the best model of pharmacist–GP collaboration from those used around the world. It was important to find the most practical pharmacist role to suit the Australian rural community pharmacy setting, the Australian Health Professional Regulatory Agency and the various professional board standards and regulations. It was also important to investigate which services pharmacists can perform while remaining covered under the current Australian professional indemnity insurances. This required investigation of the current issues that concern NCD patients living in regional and remote Australia.

Addressing NCDs with a multidisciplinary team rather than a single provider has the potential to achieve continuity of care in regional and remote Australia, where the supply of health practitioners is limited and an older population exists (1, 2, 67). A large number of services are currently provided by community pharmacists, which are government or health-provider funded in countries such as United Kingdom, United States of America, New Zealand, Canada, South Africa and many others in Europe (Figure 8194).
Community pharmacies in the local area were visited during January and February 2011 to invite the local pharmacists to indicate their interest in participating in research projects. A group of 12 pharmacists approached the investigator offering their support and expressing a wish to participate in research projects, as they wished to be more involved in NCD management and saw the pharmacy setting as a natural contributor. A first focus group meeting was held on 23 February 2011 with the 12 pharmacists...
local community pharmacists, to understand what rural community pharmacists could and could not do to effectively participate in the management of patients with NCDs living in their communities.

During the meeting, the pharmacists indicated a willingness to commit to research for up to 24 months, without financial benefit. They were prepared to commit their time and also their own resources. They welcomed the concept of establishing a communication channel and collaboration with other health professionals, particularly GPs, and to having a similar level of involvement in NCD patient care as that of their hospital-based colleagues. The attending pharmacists believed that recruiting 30–60 patients per site, who were above the age of 40 years, with one or more chronic conditions (CVD, T2DM, respiratory conditions such as chronic obstructive pulmonary disease or asthma, mental health and chronic pain) would represent an achievable task. If they were to enrol one to two patients per day for 30 days it would not create an excessive workload. The pharmacists were interested in participating in PoC monitoring (total cholesterol level, triglycerides, blood glucose level and INR), and ongoing monitoring of blood pressure, body mass index, visual acuity and monofilament pressure testing for peripheral neuropathy.

However, during the running of this project, community pharmacies had their basic remuneration for supply reduced, and became the target of a number of health promotion short programs that carried some remuneration. Facing financial hardships associated with small businesses, many participating pharmacists found it necessary to participate in those short projects carrying payments up to $5000 for conducting simple one-off interventions such as measuring the blood pressure for 500 people.
From June to October 2011, the investigator developed 10 protocols for the evidence-based management of NCDs by community pharmacists in collaboration with their local GPs and allied health professionals. These protocols were adapted from existing Australian guidelines, to cover the recommended components of care that could practically be delivered in a pharmacy setting. They were submitted to the Quality Use of Medicines Committee of The Riverina Division of General Practice (which subsequently became a committee of Murrumbidgee Medicare Local Ltd) in November 2011 for peer review and endorsement, which was granted in March 2012. At the same time, the approval from the World Health Organization to use the World Health Organisation STEPS™ chronic disease surveillance tool, modified for the Australian rural environment, was gained. Agreement was also signed with heiQ™ developer, Professor Richard Osborn, for use of a modified form of their baseline and follow-up surveys. A letter of endorsement was received from CARPA to use their STM (which is based on the same Australian guidelines) as the reference textbook for the community pharmacists during the study. This is the first time that the World Health Organization STEPS™, heiQ™ and CARPA STM have been used in a community pharmacy setting in Australia.

**Governance and Professional Benchmark for PoC Testing**

Before the application for ethics approval was submitted, it was essential to explore which PoC monitors and other equipment could be used in a community pharmacy environment. The aim was to identify PoC monitors that were registered devices with the Therapeutic Goods Administration, and, if used according to the manufacturer guidelines and specifications, would provide reproducible results of sufficient precision to compare with the results produced by (1) GPs using PoC
monitors and (2) pathology laboratories, to enable trend monitoring without misleading patients.

It was also essential to explore the required infection control, quality control and quality assurance procedures to ensure the safety of patients enrolled in the study and the quality of the results produced.

To control variables, it was decided that all sites would use the same equipment, receive the same training provided by the same trainers, and apply the same usage and maintenance protocols. One monitor was selected for combined blood glucose level, total cholesterol level and triglycerides; the Accutrend® Plus (Roche Diagnostics, Sydney) allowed the use of two monitors rather than three and substantially reduced costs and time spent on user maintenance. CoaguChek® XS Plus (Roche Diagnostics, Sydney) was selected for the INR testing.

These were crucial decisions, because the literature showed that some of the main arguments used by doctors against wider services in pharmacies concerned the suitability of the pharmacy setting and pharmacists as providers to deliver any clinical intervention that required any invasive procedure, mastering the use of PoC monitors and record-keeping of invasive procedures (69). After thorough planning and ensuring that pharmacists were appropriately skilled and trained to undertake the task, Roche Diagnostics Australia Pty Limited was approached in March 2012 and agreed to provide an education package for the pharmacists, which included directions on use, cleaning, infection control, quality control and for the CoaguChek® XS Plus only, external quality assurance. The only aspect not included in their training was the external quality assurance using the RCPA QAP reagents, as they were supplied directly to sites after enrolment. However, their use did not differ
from the technique of testing a blood sample. The manufacturer’s quality control process is designed to ensure that the monitor is functioning optimally, while the quality assurance process aims to validate the user process rather than the machine functionality. Both quality checks are essential to the validity of the study’s results.

The manufacturer’s staff provided on-site, one-on-one training to teach all aspects of monitor use. Williams et al. (2007), Plesch et al. (2009) and Bereznicki et al. (2007) investigated the accuracy and reproducibility of results from tests performed using the CoaguChek® XS Plus. The authors concluded that the readings obtained, regardless of whether the machine was used by health professionals or patients, were comparable with commercial laboratory readings (95, 96, 97). The investigator took the decision to undertake quality assurance testing for this study to ensure that community pharmacists in Australia have the same ability as their counterparts and other health professionals who participated in overseas studies (95, 96, 97). The quality assurance for the INR machines operated through the RCPA QAP and Haematology Laboratory Pty Limited is the only program that conducts the quality assurance nationally. The quality assurance consists of five tests, every second month to ensure that the user is applying correct technique and process.

In addition to the initial training workshop, the investigator organised on-site visits during July to August 2012, by Roche Diagnostics™ trainers to allow checking of the knowledge and skill retention by the pharmacists before the participants enrolment commenced on 1 September 2012. The on-site session also allowed additional training and evaluation for any other additional pharmacists who would be supporting the PoC testing at the site, but had not been at the workshop.
Training on PoC monitors took longer than planned; the initial training was in-person face-to-face, and hands-on, with attendees practicing on each other using their own monitor. The session did not end until all attendees had been declared competent by the professional trainers, in all aspects of using the monitor. After the manufacturer’s on-site training, six out of the nine sites required additional training, which was provided by the investigator during July and August site visits, with a teleconference connection with the manufacturer’s trainer for additional remote support. Additional one-on-one training was provided at the beginning of September 2012. The first training session was for a site where their trained pharmacist was unable to train other staff, and the pharmacy owner made a request to allow the involvement for an additional pharmacist as backup when the trained pharmacist was not on site. The second session was for site where the trained pharmacists had left employment at the site, and the third case was for training an additional pharmacist who was filling in as a locum for the trained pharmacist who had taken maternity leave. The fourth site requested further training because the pharmacist was still having trouble obtaining an adequate blood sample to achieve a successful reading. The manufacturer provided the training remotely with the investigator in attendance at the site. The pharmacist practiced on the investigator, and the session continued until the pharmacist achieved two correct readings.

In the mid-study survey, three of the participating pharmacists reported that they were unable to obtain a sufficient blood sample for the monitors to read and this required them to repeatedly prick the patient, which they found embarrassing. The agents for the monitors and the investigator again provided additional training, but these three pharmacists continued to be unable to perform the required monitoring, claiming the problem was with the complexity of the monitor’s operation, not their
skill. The manufacturer of the monitor claims that bleeding patients several times should not be necessary if the operator follows correct procedure. The Accutrend® Plus and CoaguChek® XS Plus monitors are in daily use across Australia and around the world and by a range of health professionals including overseas pharmacists. The manufacturer added that, some users experienced some initial problems on their first few tests, but with ongoing use they become competent. The pharmacists enrolled in this study had only small numbers of patients (some only had three patients), accordingly they used the Accutrend® Plus once every three months, which did not give them sufficient practice or confidence. Accordingly, they did not achieve the skill improvement their peers in nursing or medical profession achieve in a short time and had to read the manuals while the patient was attending, to ensure they followed the correct steps. Ongoing training and guidance (by telephone) continued throughout the intervention period to attempt to resolve this problem. One site later decided not to perform most of the required monitoring tests, and continued to identify the monitors as being the only barrier.

The manufacturer admitted that doing blood glucose levels on their AccuChek® rather than their Accutrend® Plus is easier, cheaper and requires a smaller blood sample. However, when comparing the Accutrend® Plus to the Accutrend®, which does lipids only, the Accutrend® Plus has better performance records. Also, if the sites are required to perform blood glucose level, total cholesterol level and triglycerides, the cost of the Accutrend® and AccuChek® plus their consumables is greater than the Accutrend® Plus and its consumables.

Considering that PoC monitoring was a new process for the pharmacists at seven out of the nine sites, they had to practice daily and adhere to the manufacturer’s manual.
In particular, they had to ensure immediate access to the correct consumables in the testing area, proper testing time allocation, appropriate preparation of the patient bleeding site before testing and a focus on the task. These aspects were relayed to the pharmacists; however, only five sites that had a private consultation room were able to demonstrate that they had these arrangements in place.

On inspection of monitors by the investigator during site visits, eight out of the nine sets of monitors looked clean (no blood stains or dust) and well maintained, the nine testing areas were clean and tidy, and a hand wash basin and detergent were accessible in the testing area. The issue of a monitor set that was found with blood stains was addressed with the pharmacist and corrected.

The three-in-one Accutrend® Plus monitor, even if cheaper to run, proved to have limitations as a PoC monitor for the pharmacy environment. The reasons indicated by pharmacists were:

1. The monitor required 25°C room temperature to work; if the temperature significantly deviated from this, the device gives an error message and will not initiate testing. In the community pharmacy setting, where the shop door opens and closes many times, the temperature in the pharmacy is usually between 25–30°C especially during suer. This meant that pharmacists had to ask the patient to wait or return later when the machine could be used. Some patients did not return and missed out the PoC testing for that month.

2. The testing strips batch calibration chips lose sensitivity after a few uses. Since the monitor was used for three different tests for every patient, it required testing strip calibration for each of the three tests. Considering that the test strips calibration takes the same time for testing, the use of the
Accutrend® Plus meant doubling up the testing time for each patient. Some pharmacists found it was easier to use an AccuChek® device for blood glucose level and Accutrend® Plus for total cholesterol level, and omit triglycerides to save time. Other pharmacists decided not to perform three tests every month or put the PoC off for the month or asked the patient to come back later, particularly in situations where staffing was short.

Unexpected shoppers are a common situation in community pharmacies in rural Australia. Demand can suddenly and unexpectedly peak when a tourist bus arrives. Another problem reported for rural pharmacies was when retired Australians towing caravans or in motorhomes, arrive in town, frequently in groups. They place considerable demands on rural pharmacies as they frequently wish to pick up prescription repeats of medications little used in the local town but favoured by out-of-state prescribers, which therefore have to be ordered.

3. The monitor proved very sensitive to the amount of blood and the process time (30 seconds). If the blood amount was insufficient, or took too long to collect, an error message would appear that could only be cleared by re-initiating the whole process. This proved frustrating for both the pharmacists and the patients. The pharmacists felt that the patients would lose confidence in them, especially when comparing their testing to that done in the GP clinic by, for example, a registered nurse who may undertake the PoC testing numerous times every day. The consensus between the nine sites was that they did not want to perform the tests more than once per visit, so when the Accutrend® Plus did not work, the test was omitted for that month regardless
of the study protocols and the emphasis by the investigator on the need of PoC testing frequencies.

4. The consumables shelf-life was short (the starter pack has a 30-day shelf life, and the batches the pharmacists purchased arrived with only three months of shelf life). The low throughput in these pharmacies meant that an opened product frequently became time-expired before it was used. This made the process more expensive than was forecasted and costly to sustain. Some pharmacists decided not to buy more triglycerides strips after they ran out or disposed of the pack was included in the starter kit.

5. The control solution was available only on direct order from the Roche Diagnostics warehouse (product and delivery costs from the Melbourne warehouse, involving special paperwork) or from a wholesaler as a ‘buy-on-order’ (i.e., they do not hold stock but they buy the exact quantity ordered from Roche Diagnostics when a customer places an order). This has a two to four weeks’ lead-time (between the order and supply date). The control solutions are essential to maintain the integrity of testing; however, it was not considered sustainable for a community pharmacy that normally holds only a few days’ stock and operates on a just-in-time process of daily ordering to reduce running cost and waste.

These problems were discussed with the manufacturer, who responded that they had not previously been reported, and they suggested the pharmacists might just need additional training. For some of the problems raised this would seem reasonable, based on overseas experience where these monitors are used in pharmacies regularly. However, it was noted that the manufacturer’s online Accutrend® Plus education slides 102–110 discuss the above complaints noted by the pharmacists; test strip is
usable (discard strip and use new one), temperature (18–35°C), internal error 142 (turn power off and on again or contact agent), of which all are time consuming to fix and costly to maintain.


For future studies, separate PoC monitors would be a quicker and potentially lower-cost option, if the amount of strips disposed of and the labour time spent to try to achieve readings from the Accutrend® Plus is fully accounted for. However, if the PoC lipid testing was implemented as a pharmacy service, larger patient numbers would be tested leading to more continuous use and greater user familiarity. Greater throughput appears to be the key to more efficient use of the Accutrend® Plus device.

The CoaguChek® XS Plus monitor was easier to use than the Accutrend® Plus. However, the running cost was more expensive, it took a longer time to get consumables and control solution supplies and, because it was rarely used, the wastage was more than that for the Accutrend® Plus. The GPs in six of the study sites were resistant to the concept of INR testing in the community pharmacy by a pharmacist; more so than for total cholesterol level and triglycerides. PoC tests have Medicare-funded GP procedure numbers, similar to that for the GP consultation, paid to the GP for every test, or shared between the GP and the registered nurse performed the testing from the GP practice. All nine sites’ GPs, including the three sites where the GPs had agreed to the pharmacists INR testing, refused to accept the INR reading performed by the pharmacist, or to adjust the warfarin dose if indicated. As a result, within this study, it was pointless for the pharmacist to continue to do the
test. Furthermore, patients found it burdensome to have the test repeated in the GP clinic just to confirm the pharmacy reading before having their medication adjusted. Many of these problems would be addressed by a formal national system that used the resources of pharmacy and increased throughput. This would bring Australia in line with other international experiences, where pharmacy testing is seen as important and valuable.

The CoaguChek® XS Plus use in Australia did not have many problems; however, on 16 May 2013 the Therapeutic Goods Administration issued a product recall (http://www.tga.gov.au/safety/alerts-device-coaguchek-inr-monitors-130516.htm) for all the CoaguChek® XS Plus models distributed in 2013 due to a conflicting error message. The error message was similar to that for unusable test strip, but occurred when the patient had a dangerously high INR and the error was dismissed and the patient was sent home as being fine. This was considered a medical emergency that could be fatal. This shows that problems may present in any setting, including the patient’s home, and the problems experienced in this study should not be used as barriers for pharmacist intervention. The CoaguChek® XS Plus recall did not include the monitors used in the study.

INR testing with warfarin dose adjustment by the pharmacist is currently in place in New Zealand, United States of America, Canada, many European countries and the United Kingdom. Timely communication and dose adjustment by GPs need to be addressed; it is inefficient for a pharmacist to perform a test, only for a GP to insist on retesting the same or next day in the GP practice before adjusting the dose.

Seven patients had their INR monitored in three sites; the pharmacists’ intervention kept the patient within target during the period of the study. However with no other
data available in Australia, it is difficult to accept this result as being an affect of the intervention or due to better patient education. Warfarin patient education in Australia has always been provided by the pharmacist, in hospital or the community. The matter of rigid GPs’ professional boundaries appears exceptionally strong in the Australian health system, which appears to always favour the GPs over all other health professionals. This is an obstacle to achieving a robust, national multidisciplinary primary health care approach that will require government intervention to address.

Collaborative Primary Health Care

After the training workshop on the 26 May 2012, all the sites’ local GP practices (41 GPs) were visited by the investigator and primary supervisor.

The visits were arranged in advance by telephone and in most practices involved a group of GPs. The project was explained verbally and reinforced with an individual personalised letter to each GP in the practice, requesting their support or at least their acceptance of the project proceeding. The support requested from GPs was to allow the extraction of the historical data for the enrolled patients (only for those parameters monitored by pharmacists during the study), and an equivalent sample (control) of data for other patients not enrolled in the study. It was suggested a third party, Murrumbidgee Medicare Local Ltd, extract this data electronically to avoid additional workload for clinic staff.

Although almost all of these practices had previously supplied data for pharmacy-led research purposes under a similar arrangement, run under the auspices of the Riverina Division of General Practice, no GP practice would agree to this option now that it came under the (at the time, very new) Murrumbidgee Medicare Local Ltd.
This was surprising because in this case it was exactly the same people, operating from exactly the same offices as before, just under a new organisational name. However, some GPs agreed in principle to extract the data themselves. Others refused to provide such information, citing it as an unacceptable additional workload, but they were happy for the pharmacists to be involved in the study. Most GPs indicated that as long as nothing was required from them, they did not mind the study proceeding. The practical result was that all the GP practices indicated that the control data would not be provided out of their practice records. This was totally unexpected and disappointing as the project planning for this step had been based on the extensive and productive cooperation previously experienced.

As noted above, the start of this study coincided with the introduction of Medicare locals, and matters unrelated to this study (discussed below) influenced these decisions. Some GPs agreed to support patient selection or recommend patients whom they believed would benefit from the additional care, but by the end of the enrolment phase, no recommendations were received by any site from local GPs.

As a result of GPs’ unwillingness, the collection of control data had to occur via the participating sites. This was achieved by using patients’ own baseline data and the previous 12 months medication history (12 months prior to the patient enrolment date) from the pharmacy, as the pre-intervention control. This was far less effective than the previously planned method of using an automated tool to extract 12 months of control data including recent investigations, from the GP computer systems. The pharmacies’ 12 months medication history included only medications dispensed from that pharmacy and did not include indications or laboratory results. On the other hand, the data mining from the GP system, used in previous studies could have
extracted all medications prescribed including indications (and items that might be prescribed by a specialist and dispensed from another town), diagnostic and laboratory results. If the community pharmacists had access to this data it would have been a much better starting point and would have saved the pharmacists and the patients’ considerable time trying to get an accurate picture of their conditions from the GP to complete the demographic data. Additional baseline data from GP records, which were factored into the study plan but not available as a result of the GPs refusing to share their records with the pharmacists, included HbA1c, FEV1 or serum levels for medications such as digoxin, theophylline or valproate. These parameters would have been useful to determine any improvement in patient adherence because of the pharmacist intervention.

One of the GPs visited reported that a pharmacy in another town (and unrelated to this study) had been telling some (he stated ‘many’) of his patients, that the pharmacy could do all their monitoring and that they did not need to go to the doctor. The pharmacy referred to was in a nearby city, likely to be visited by clients from at least five of the study towns on fairly regular basis and this may have negatively impacted upon the GP’s perceptions of what this study aimed to do. This pharmacy was indeed strongly promoting their own PoC monitoring without any consultation or discussion with the local GPs.

Written communications were received from two GPs in different towns in the last week of June 2012. One opposed the study; the other questioned its chances of success. The first led to the entire town (three planned sites) withdrawing their consent to participate. The two GP practices in that town (one GP wrote on behalf of all 12 GPs even though there were no negative comments offered face-to-face when
the sites were visited) notified the three sites’ pharmacists and the investigator of their decision to oppose the conduct of the study.

The first GP wrote (June 2012) that he regretted to inform the investigator that the entire district medical centres and community pharmacies declined to be involved. He added that they do not believe that this study is suitable to run in the real world of busy general practice and community pharmacies. He suggested that pharmacists should stick to projects involving the use of domiciliary reviews and that pharmacists working out of general practice would have more value than the proposed activities.

The second communication was received from a single-GP practice (June 2012), relating to a pharmacy that remained in the study; this GP did not oppose or support the study, but argued that the intervention was out of the pharmacists’ scope of practice. The main concern for this GP was GPs losing income to community pharmacies if pharmacists were to participate in PoC testing, which currently carries a Medicare procedure number for GPs, nurse practitioners and pathology laboratories. The GP also argued that if the practice participated there may have been an increase in unpaid workload; if there would be reimbursement the practice position may have been different. The GP remained sceptical and suspicious that the study was a further assault on the ‘envied domains of general practice’.

The responses were poorly informed about current pharmacy practice or the national priorities for collaborative NCD management. To address the first response, it is important to accept that all different types of medication reviews, RMMR, HMR or MedsCheck™, work to improve patients’ outcomes, but they are one-off interventions every 12 months, and do not provide ongoing reinforcement of adherence and knowledge. In addition, they are based on GP referral (HMR) which
is income-generating for GPs and pharmacists. Under the 5th CPA, the RMMR requirement for GP referral changed and the MedsCheck™ initiative was introduced (12, 97, 99).

To address the second charge that the model would increase GPs’ workload, the project proposed only to fill in the gaps, not to replace patients’ GP appointments, and pharmacists were willing and offering, to share the results with GPs rather than duplicating workload. Considering the long waiting times in most of the GP clinics concerned and the shortage of health professionals in rural, remote and very remote Australia, where pharmacists are among very few permanent health practitioners, broadening community pharmacists’ area of responsibility can only benefit the health of the community.

Verbal communication with the second GP gave the impression that the GP believed pharmacists ‘earn sufficient income from dispensing prescriptions’ and that they were only aiming for more prescriptions to dispense. This is not supported by the evidence.

From the Australian Bureau of Statistics Household Expenditure on Health: A Snapshot, 2004–05 expenditure on GP's fees was comparatively less than other types of doctor's fees. Out of all people who indicated that they had seen a health practitioner in the last two weeks, a fifth had seen a general practitioner (20%) (76).

The $2 per week for GP fees which is the average out-of-pocket Australian pays is actually a reflection of the higher level of the government subsidy of GP services; the rest of the GPs’ income comes from the Medicare levy paid by all Australians, but this is not directly felt as it is part of direct taxation (76). The $11.50 per week that the average Australian spends on medications and therapeutic goods is a reflection of
the lower level of government subsidy for pharmaceutical services, and patients carrying this gap. This impacts directly on the patient at the cash register and is perceived as pharmacists earning more, but the public are largely unaware that every time their Medicare card is used in the GP clinic the government pays the GP a fee for service (76).

The lack of collaboration from GPs was one of the main barriers to the success of this project. In seven out of the eight towns (seven sites), the participating pharmacy was the only pharmacy in the town. Three out of the eight towns (four sites), had only one GP practice. One town had only two pharmacies with two different owners; three towns had two GP practices with different owners. One town had two GP practices with one owner and one town had five GP practices with different owners.

The town with five GP practices and two pharmacies (PR and PE) did all testing but only one did the INR tests. They performed most MMRs and most of the clinical interventions, reporting good communication (two-way) with all the local GPs in all matters, stating the GPs either verbally agreed to or did not interfere with the pharmacies participation. The population of this town was >10,000. The sites had three to five pharmacists at all times but enrolled only 21 patients in total as a result of high workload and large number of daily prescriptions (Figure 82 and Table 27).

Two towns were in closer proximity to larger regional cities; the sites’ pharmacists (JJ and CV) had reasonable relationships with the GPs in all matters, who either verbally agreed or did not interfere with the pharmacies participation. They had populations between 1500–4500. They were busy community pharmacies—not as busy as PR and PE—but they had fewer staff (two to three pharmacists at all times).
They enrolled two additional patients (23 patients combined) and performed most testing, but both omitted TGs and only one did the INR test.

The opposite was seen in smaller towns with one to two pharmacists and one or two GP practices owned by the same GP. It appears that the GPs at this site felt threatened with loss of income from pharmacies engaging in PoC monitoring; as described above, it appears to have been perceived as a way to justify pharmacists taking over all monitoring.

Figure 82 - Number of patients approached, enrolled and lost to follow up per site
Accordingly, the GPs’ reaction were either openly opposing or non-communicative. Ultimately, no GP practices effectively supported the concept. Several pharmacists indicated that they had support from local GPs, but in all verbal communications they clearly indicated that they could not compromise their relationship and risk loss of income as a result of the GP sending patients to the pharmacy in the next town as implied by GPs.

Other Equipment and Forms

There was a wide range of digital blood pressure monitors and body composition scales to choose from; however, in addition to quality, the cost had to be considered. There was very limited range of all other equipment; those selected were mid-range in price but were Therapeutic Goods Administration registered, used by GPs, podiatrists (monofilament pressure sensitivity kits) and optometrists (visual acuity near vision reading charts), and of high quality.
To standardise data collection, a set of documents was developed for use by all sites. This material had to cover all possible situations and scenarios that could arise during the study and, at the same time, needed to be practical and unambiguous. It was designed to be used either in electronic (filled in directly on a computer to avoid later transcription and transcription error) or paper format, if more feasible to the site.

Training

The initial training session was run on 26 May 2012 (See chapter 3). It appeared broadly successful, as pharmacists were engaged, asked questions, took notes and individually demonstrated the techniques successfully in the presence of the trainers. However, since the pharmacists had to undertake this additional training after working hours in the evening or on a Sunday, and/or employ locum pharmacists to enable attendance, additional group sessions would have been difficult to arrange and costly. Accordingly from this point, education was conducted on sites individually by the investigator.

Although everyone had agreed initially to use electronic forms, during the enrolment period, eight sites reported that they had found it easier to print the data collection form, and only one site continued to directly enter information into the electronic forms with supporting paper documentation. This was manageable since all the forms had been designed ‘dual purpose’, but was undesirable as it created an additional unintended transcription step. A revised, simpler data collection sheet was developed by one site, consisting of copying the baseline and intervention columns only instead of printing the entire master sheet. This hard copy sheet was adopted by all sites within the same week. This avoided creating different data quality between sites. At the end of the study, additional two sites used the electronic forms;
however, they could not provide any other supporting documentation, and the other six sites provided paper documentation only.

Pharmacists were able to adopt the GuildCare™ software quickly as it also provided them with facilities to record all clinical interventions including MedsCheck™. The software also provides printable materials, which the pharmacists used as visual aids to demonstrate to patients how they were progressing with their self-management (blood pressure and lipids recording chart) similar to that presented in Figure 83.


The investigator clarified to each site that as the study aimed to improve the health outcomes of patients, sites needed to test all parameters, which would:

- Allow the early detection of conditions not addressed by current medications leading then to GP referral by the pharmacist.
- Allow the detection of a medication used by the patient without current indication leading then to GP referral by the pharmacist.
Regarding the follow-up data collection, the investigator asked all sites to test the parameters indicated in each disease protocol on a monthly basis (except the total cholesterol level and triglycerides which were indicated every three months); the following directions were communicated by email to all sites:

- **T2DM**: monitor blood pressure, body mass index INR (if applicable), blood glucose level, visual acuity and monofilaments with every repeat prescription dispensing. Total cholesterol level and triglycerides monitored every third repeat prescription dispensing.

- **CVD**: monitor blood pressure, body mass index and INR (if applicable) with every repeat prescription dispensing; total cholesterol level and triglycerides every third repeat prescription dispensing, unless comorbidity exist, then apply the other diseases protocols.

- **Hyperlipidaemia**: total cholesterol level and triglycerides monitored every third repeat prescription dispensing, unless comorbidity exist, then apply the all CVD or all diabetes protocols.

- **MH (patient using antidepressants or antipsychotics)**: all parameters as in baseline less visual acuity and monofilaments unless comorbidity exist, then apply the all the other diseases protocols.

- **Respiratory**: adherence + others as applicable based on comorbidity.

- **Pain**: pain score + others as applicable based on comorbidity.

All sites were competent and confident in using the CARPA STM as a reference source without any further training requests. This reference was used to answer patients’ additional questions, provide the patient with information about self-help
websites and also for measurement of pain score (100). Pharmacists indicated that 
they will continue to use the manual regularly.

Data Quality Audits

The data sets received were incomplete in many respects. Some patients did not 
have their baseline survey; some did not have the testing completed for all 
parameters, but rather only those related to their specific conditions. Consequently 
only 69 out of the 84 patients’ data was analysed for the heiQ™ and 53 for all other 
data at the end of the study.

Taking into consideration that all the patients enrolled had confirmed diagnosis of 
one or more NCD, without accurate record of the patients’ demographics, the 
analysis of all other measured parameters became difficult to trend. The intention 
was to correlate to personal, lifestyle modifiable (weight, smoking and alcohol 
intake) or non-modifiable (age and gender) factors. The omissions might have 
occurred due to pharmacists’ workloads or, since the patients were familiar to them, 
they have the patient file in their dispensing database, so they omitted recording 
these details intending to add them later, but not doing so. The lack of experience of 
many of the pharmacists in terms of taking part in formal research projects and not 
appreciating the significance of every field specified in the study protocol may also 
have contributed.

In December 2012, the investigator visited all sites and conducted audits to ensure 
that:

– All participating sites were well informed of the study protocol and had obtained 
signatures on all participation consent forms.
– All enrolled patients were well informed about the study protocol, the testing processes and the use of the data, and that all had enrolled voluntarily and signed participation consent forms.

– All enrolled patients had completed the heiQ™ baseline questionnaire.

– All patients had their baseline parameters measured and recorded.

– All participating sites were recording data in accordance with the study protocol.

– All patient information and collected data were stored in accordance with the requirements of confidentiality and the Privacy Act.

– All monitoring devices usage, cleaning, calibration, quality control and quality assurance processes were correctly conducted and met infection control standards and the manufacturer’s user maintenance requirements.

– Capture any shortfalls; such as inadequate training, inability to use monitor instruments or insufficient number of patients.

The following areas were audited by the investigator during December 2012 visit to the nine participating sites (Table 28).

<table>
<thead>
<tr>
<th>Item</th>
<th>Completed</th>
<th>Appropriately Stored</th>
<th>Custodian of Records</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sites participation consent forms</td>
<td>Nine forms completed and signed</td>
<td>Yes</td>
<td>Investigator</td>
</tr>
<tr>
<td>Patients’ consent forms</td>
<td>84 forms completed and signed</td>
<td>Yes</td>
<td>Sites (blinded to the investigator)</td>
</tr>
<tr>
<td>HeiQ™ Baseline</td>
<td>84 surveys completed and signed</td>
<td>Yes</td>
<td>Investigator</td>
</tr>
<tr>
<td>De-identification records</td>
<td>84 records over nine sites</td>
<td>Yes</td>
<td>Sites (blinded to the investigator)</td>
</tr>
<tr>
<td>Baseline electronic and paper based parameters data</td>
<td>81 de-identified recorded vary e-copy and paper copy records</td>
<td>Yes</td>
<td>Investigator and sites</td>
</tr>
<tr>
<td>Baseline 12 months medication history</td>
<td>81 de-identified paper copy records</td>
<td>Yes</td>
<td>Investigator</td>
</tr>
<tr>
<td>Mid-study survey</td>
<td>11 questionnaires completed</td>
<td>Yes</td>
<td>Investigator</td>
</tr>
</tbody>
</table>
Only five of the nine sites were able to produce evidence for ongoing monitoring and clinical intervention.

The sites who recruited fewer than 10 patients were the ones who answered all questions positively in the mid-study survey. However, the three sites that enrolled the most patients provided more comprehensive data and were actively involved. They demonstrated a better understanding of the importance of governance in research. Their failure to recruit greater numbers is difficult to explain, although anecdotal evidence suggests that research was given secondary importance to the daily activities of running the business.

Verbal communication with all sites about reasons for not being able to enrol the numbers they initially indicated, demonstrated that they were participating in the newly introduced GuildCare ‘Know your numbers’ study, MedsCheck™ and others. All of these programs post-dated the planning of this study. All of these projects were all based on one-off interventions, rather than ongoing interventions. Some attracted remuneration. These may more easily fit within current community pharmacy practice, but models such as the one evaluated here have worked well in community pharmacies in New Zealand (INR management), Canada (blood pressure) and the United Kingdom.

Other Limitations and Shortfalls

During the period of data collection, two major Australian political changes influenced the health system landscape nationally and may have seriously affected GP attitudes to participation in the study. When the data collection commenced in July 2011, the Federal Government announced the formation of Medicare Locals to replace Divisions of General Practice. As data collection continued, two of the
Divisions of General Practice from which participating pharmacists and GPs were located merged into one Medicare Local. Participating GPs exhibited marked differences of opinion concerning the structure of the new Medicare Local and deep suspicion as to the political aims and motivations behind the change. GP practices that had previously collaborated in pharmacist-led research under the previous Division to General Practice structure declined to be involved in any way with the Medicare Local. Many of these suspicions later settled down, but at the time of data collection, they appear to have negatively contributed to the GPs position of refusing to take part of the study.

Also during the data collection period, the Federal Government and the Pharmacy Guild of Australia signed the 5th CPA and implemented its provisions. This Agreement introduced MedsCheck™ as a remunerated service, which the Pharmacy Guild was advocating to replace the HMR. In the researcher’s opinion, this and other new programs for which pharmacists could claim income, seriously reduced the pharmacists desire to continue their effective participation in this unremunerated research study, and they either withdrew or recruited fewer patients than that they initially committed to.

Nevertheless, the findings from this study add knowledge to future larger studies as it tested a model of service, which is consistent with the recommendations of the major international bodies such as the World Health Organization.

**End of the Study Comments**

In addition to the town that withdrew prior to the commencement of the study intervention, one site (TF) withdrew in March 2013. The same site enrolled three patients and completed the heiQ™ BL only. However, the pharmacist did not
perform any PoC monitoring, complete the mid-study survey or provide the patients’ 12 month medication history control.

At the end of the study, only two sites were ready to provide the final data on time. All the others received reminders and visits before they provided the required data.

Data was entered into an Excel™ spread-sheet and cleaned of typographical errors and abbreviations, in preparation for the final data analysis. Data analysis took place using the available data. Any data that arrived after 5 July 2013 were not included as it was past the cut-off date for testing. Only 53 patients out of 84 had complete data and accordingly were fully analysed.

Several problems were identified by investigators, participating pharmacists, GPs and patients during the study, some of which could be rectified in future studies. Some of the problems arose because of external changes in the health care environment during the gestation of the project. This was a complicated project with many parts, and it took many months to bring all the components together and be ready to commence data collection. The project gestation was further extended by more than six months total owing to procedural delays within the university under which the investigator was initially registered. The proposal was initially sent to inappropriate referees (laboratory scientists) with no experience of clinical research. They blocked the project from proceeding and called for extensive changes. Following an internal appeal, the project was eventually submitted to appropriate reviewers, who approved it without modification.

There was also a delay in receiving ethics approval because paperwork that had been submitted was omitted from that circulated to committee members. These are things that can happen in any large organisation, but in the context of the shifting political
landscape at the time, the extra six-month delay meant that the project was rolled out under the support of the newly formed Murrumbidgee Medicare Local Ltd., not the Riverina Division of General Practice with which the GPs and the university already had a positive working relationship.

This was further complicated because the new Murrumbidgee Medicare Local was being formed through the merging of two Divisions of General Practice with a realignment of boundaries. At the time the project was commencing, there was an ongoing process to select the board for the new Murrumbidgee Medicare Local, and it was clear that there were strong and opposing views across the project footprint about who should hold the positions.

When the GPs were approached to inform them of the project, it was clear that, at that time, most GPs were not at all happy with, and deeply suspicious of, the concept of the Medicare Locals, the revised boundaries and in particular, some of the people they believed were likely to be appointed to the board. As this project was endorsed by the new Murrumbidgee Medicare Local Ltd, these perceptions of the organisation were extensively transferred to this project. This was clear from the GP comments that under no circumstances would they allow the Medicare Local to access data from their computers, despite having previously allowed the same people, from the same office, to do it under a different organisational title.

It was a challenge to maintain commitment among the community pharmacists for a research project of this length without financial incentive. As small businesses with financial imperatives, the eight sites who continued to the end of the study should be commended on their achievement.
Those sites that did not have a closed consultation room found it difficult to conduct testing, especially to convince patients to accept the monofilament pressure test. Many patients declined as they did not wish to take their shoes and socks off in the pharmacy, although some pharmacists reported that in a previous study, they had not experienced this reaction.

The visual acuity chart is based on asking the patient to read a passage; this allows measurement of their sight and provides the pharmacist with some information on the patient’s level of literacy. This could assist in targeting adherence aids and information at an appropriate level. The visual acuity chart was described by two pharmacists (CV and BS), as being difficult for many of their older patients. As it was based on reading a passage, some patients with English as a second language, or poor reading skills might experience problems. In a future study it might be better to have available an alternative chart using letters, shapes or numbers to account for people with language or literacy difficulties.

The blood pressure digital sphygmomanometer proved to be practical and it was used by all sites. It is also equipped to measure heart rate; however four sites omitted measuring patients’ heart rates, discounting its importance. This indicates a gap in knowledge that requires to be addressed through professional development. One site indicated verbally, and provided de-identified written evidence, that they referred one patient for further investigation after measuring their heart rate. This was subsequently identified as a previously untreated serious clinical problem.

The body composition scale was used by all sites and proved to be useful and less time consuming than manual body mass index calculations. However, three sites indicated that they had to refer to the manual every time, to interpret the readings.
Also, not all sites measured waist circumference, which is important in confirming central obesity, because patients refused to be measured, discounting its importance. This indicates a further gap in knowledge that could be addressed through professional development.

The length of the World Health Organization STEPS™ instrument (106 questions, including PoC testing data) prevented the use of the complete tool in a community pharmacy setting. It is believed that is a study design could be developed that would allow its use in a community pharmacy setting; it has the potential to be a comprehensive instrument for this type of intervention in the future. Out of the 84 patients enrolled, all completed the modified heiQ™ baseline (100%), but only 69 (82%) modified heiQ™ follow-up were completed. The drop-out rate was 16 participants (18%). The unmodified heiQ™ consists of 45 questions for the baseline and 50 question for the follow-up. They are comprehensive and informative; however, they are designed to test the effect of structured patient education programs. The education provided by the pharmacists is directed to what needs to be covered, and is tailored to meet each patient’s medical conditions and medications. Again, it was considered too long for a community pharmacy setting and for unstructured patient education. The developer of the heiQ™ conducted a new study, published in 2013 (90), further refining a tool that suits a population level health survey; the Health Literacy Questionnaire, to meet the current need for measuring patients’ health literacy to allow for better targeted health educations interventions. This is considered a potentially more appropriate tool for future studies. It was clear that an incentive for pharmacists was a paramount issue in the decision to continue to participate and at what level. It was clear also that to GPs, incentive was a paramount issue in any decision relating to their participation. This is
understandable given that participants were taking part in their own time and
utilising their own private practices, which are their only source of income. Several
GPs indicated that they would have supported the study if they could have received
either financial or credentialing compensation. Some pharmacists did not perform
the required interventions to reduce their costs and/or to use their time to gain
financial benefit from other activities that had recently become available. The
participating pharmacists also questioned the next step; if the study showed benefit
for patients, how would the services be covered in the future? It would have to be
funded through Medicare or under a future 6th Community Pharmacy Agreement.
However, they understood that the reason for undertaking the study was both to
measure improvement in patient health outcomes after pharmacist intervention, and
to generate data that might convince governments to support this.

This study strongly suggests that in a community pharmacy setting, research needs to
be for a shorter period if not remunerated, or longer projects need to secure sufficient
funding to remunerate time and effort. The data from this study will provide support
and valuable information for future definitive studies.

The initial plan was to enrol a minimum of 20 patients per site; however, the
following issues interrupted this plan:

– Unplanned changes in sites’ staffing levels (maternity leave, completion of
  internship year, sale of the pharmacy).

– The commencement of other paid and unpaid Pharmacy Guild of Australia
driven projects or research projects.

– Pharmacists’ concerns about damaging relationships with their local GPs.
The project design and methods were discussed in detail over 12 months during the focus groups meeting, and again during the May 2012 workshop. When the intervention phase commenced on 1 July 2012, more questions regarding the study methods arose, which is an indication that these issues had not been adequately clarified. To address the issue, the investigator wrote a checklist extract from the study protocol for the pharmacists to use from enrolment to final testing (Appendix VI)

**End of Study Pharmacist Comments**

The following are all the comments received from the sites pharmacists regarding their experience during the study and how they would like to see the services implemented. The feedback covers the difficulties they faced and suggestions on how similar interventions could be established in the future

**BS comment**

“Main barriers to conduct more MedsCheck™ were patient time and patient belief that they know enough about their medications.”

**PR comment**

We thought it was good to get to know the customers and their health conditions better. We were pleasantly surprised by some of our good patient outcomes attributed to the study. It was also good to connect with the customers on a more personalised level and to feel the trust that these people put in our profession.”

**JJ comment**

“Things that the pharmacists believe we can remain involved with; triglycerides, total cholesterol level, blood glucose level, INR, blood pressure, body mass index,
review of current medications and conditions and optimum outcomes and referral to
doctors and other health professionals. Patients were probably less likely to perform
foot testing and eye charts. Time was an issue within our pharmacy and having
enough staff to organise and run appointments. The issue could be overcome if a set
date or day was put aside for the appointments. Pharmacists believe extra
equipment e.g. blood glucose meter, Coaguchek® XS Plus, Accutrend® Plus are
valuable to a pharmacy and will be used for patients, pharmacy promotion days (e.g.
heart week, diabetes week) and can be used during HMR visits. Some customers
would ask about when their next appointment was and got very involved.
Unfortunately due to unforeseeable circumstances other patients could not make
monthly visits.”

CV comment

“We had discussion with a patient and feedback to the GP when a patient required
ongoing support and referral to the DoHA ‘get healthy’ webpage.”

TF comment:

“Unfortunately, I have decided to withdraw our Pharmacy from the project as I
cannot seem to enthuse patients to become involved. I have found that the ones who
should, won't and the ones who will are already compliant and don't really need the
time. My struggle is in having several different locums throughout the week, they are
not involved in this, and in fact my commitment this year is to record interventions
properly as a way of proving our worth to those concerned. I also want to do some
serious continuing education this year for myself, so it is necessary for me to
prioritise my time. I have found my time is so precious, and it's difficult to meet
every commitment. After my short involvement and failed attempts to increase the
numbers participating in the program I have thought to use ‘community engagement strategies in health’ as an area that I would like to consider in my Rural Pharmacy Learning plan.”

GD and PE comment

“We will implement all study aspects in our every-day practice.”

HA and LOC

The two sites did not provide any further comments.

Future Research

Proposed future research will seek adequate funding at the start to target one disease at a time and the related parameters, with a longer intervention period. This will reduce omission of activities, and provide more comprehensive data and robust findings.
Chapter VIII. Conclusion and Recommendations

The purpose of this study was to address the under-utilised capacity of pharmacists in Australia, which could be transformed to fill the gap in ongoing monitoring and long-term management of patients with NCDs. These patients do not see their GP on a monthly basis, but see their pharmacist to dispense their prescription repeats.

Considering the growing global effort to use all available resources to provide continuity of care in NCD patients, it is puzzling that the DoHA chronic disease management guidelines do not mention pharmacists as part of recent projects. Three years after the United Nations declaration on NCDs, the Australian Medical Association is still debating collaboration, and the health system is not yet fully utilising pharmacists’ clinical capacity even when there is little alternative care available. The Australian Pharmacy Council (2012) recommended that pharmacist-based clinical services need to be examined, particularly in remote settings; however, to date this has not occurred.

The results of this study suggest that pharmacists and GPs in rural NSW are not yet prepared for the level of collaboration planned. A paradigm shift is needed; Australia is currently lagging far behind international best practice. To be successfully adopted, this model of care must be (1) supported by research that clearly demonstrates that the chosen models work in the community pharmacy setting and (2) driven by national professional bodies and through regulation.

The present fee-for-service funding models result in a culture where Australian health practitioners are not prepared to put time into clinical activities that do not generate income.
For PoC monitoring to be successful in community pharmacy, it needs to be accepted by others in the team and be made a routine practice so that pharmacists are familiar with the machines, and the devices have appropriate levels of throughput. For this to be achieved services need to be remunerated. For the ongoing monitoring of stable NCDs this would represent a smaller funding burden than monthly clinic visits.

PoC monitoring is currently not considered to be a core pharmacy activity in Australia. Visible feedback is integral to the reinforcement of adherence, so PoC monitoring should be considered an extended scope of practice that can be undertaken in community pharmacies after the pharmacists completes appropriate training and achieves competency.

Community pharmacies engaging in these activities will require private consulting rooms and must maintain adequate infection control and quality assurance. In addition, if pharmacists are to become substantial providers of testing, they must be prepared to accept all monitoring requests and give them the same priority as their other commitments, including dispensing.

Blood pressure, total cholesterol and blood glucose level proved feasible to manage in the community pharmacy setting. In contrast, triglycerides monitoring currently carries costs that community pharmacy cannot absorb. To ensure good governance and auditable practice, monitoring tests for these parameters should be performed, as part of a General Practitioner Management Plan referral to a pharmacist or at the pharmacist’s recommendation if the patient meets certain criteria, similar to the decision process for Medicheck™. INR is easy to measure accurately; many patients perform this activity at home. However, before this becomes an accepted practice, it needs to be adopted in the United States of America, United Kingdom and New
Zealand, where pharmacists have direct communication with GPs and warfarin dose adjustment can occur in real time. Without a robust DoHA-approved protocol that recognises pharmacists and GPs as co-providers who are properly funded (similar to the HMR process) these parameters will be impossible to monitor in a practical, ongoing, disease management context.

The study revealed much about the communication culture existing between pharmacist and GPs in Australia, and highlighted a major disconnect that affects continuity of care. Pharmacists are a highly qualified professional resource that, if fully utilised, could fill some of the gaps in health service provision, especially in rural and remote Australia.
References


Access date 27/1/2014.


Medical Journal of Australia. 2011; 194 (5): 236-239. From:


75. Australian Pharmacy Council. Remote Rural Pharmacists Project 2012. Available from:


92. Allan, J., Crockett, J., Ball, P., Alston, M. 'You have to face your mistakes in the street': The contextual keys that shape health service access and workforce retention in rural areas. Rural and Remote Health 8 (online), 2008: 835. SSN 1445-6354 Available from: http://www.rrh.org.au.


