Increasing Community Pharmacy Involvement in the Prevention of Cardiovascular Disease

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<td>AQoL</td>
<td>Assessment of Quality of Life</td>
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<td>BP</td>
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<td>BBQ</td>
<td>Beliefs and Behaviour Questionnaire</td>
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<td>CHD</td>
<td>Coronary heart disease</td>
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<td>CMI</td>
<td>Consumer Medicine Information</td>
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<td>CVD</td>
<td>Cardiovascular disease</td>
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<td>DAA</td>
<td>Dose administration aid</td>
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<td>European Health Risk Monitoring</td>
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<td>Expression of interest</td>
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<td>GP</td>
<td>General practitioner</td>
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<td>HBPM</td>
<td>Home blood pressure monitoring</td>
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<td>ICER</td>
<td>Incremental Cost Effectiveness Ratio</td>
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<td>LYa</td>
<td>Life-years</td>
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<td>MPR</td>
<td>Medication-possession ratio</td>
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<td>MUR</td>
<td>Medication use review</td>
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<td>MONICA</td>
<td>MONitoring of trends and determinants in CArdiovascular disease</td>
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<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
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<td>PCG</td>
<td>Pharmacist Care Group</td>
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<td>PhARIA</td>
<td>Pharmacy Access/ Remoteness Index of Australia</td>
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<td>RCT</td>
<td>Randomised controlled trial</td>
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<td>RPSGB</td>
<td>Royal Pharmaceutical Society of Great Britain</td>
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<td>TABS</td>
<td>Tool for Adherence Behaviour Screening</td>
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<td>UCG</td>
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<td>UMORE</td>
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Background

Hypertension in Australia

In 2004-2005, the prevalence of high blood pressure (hypertension) in Australia was 10%\(^1\). In 2003, hypertension accounted for 7.6% of the total burden of disease in Australia\(^2\) and was responsible for the greatest burden in the 65 years and over age group in both males and females\(^3\).

Hypertension is an important risk factor for cardiovascular disease (CVD). Accumulated evidence from several large-scale observational studies demonstrates a progressive positive correlation between increasing BP and death\(^4\). Numerous clinical trials and meta-analyses have concluded that antihypertensive medications substantially reduce the risk of CVD\(^5,6\). Nonadherence is documented as a primary reason for suboptimal management of a wide range of diseases\(^7\). An Australian study\(^8\) has shown that patients who were defined as being adherent using a self-reported measure were significantly less likely to experience a fatal cardiovascular event or first occurrence of stroke. In total, 33% of respondents were nonadherent in some way.

Persistence and adherence with antihypertensive medication

Approaches to improving adherence can be complex, and labour-intensive\(^9\). There are no accepted, fully effective strategies in widespread clinical use. A number of studies found persistence to antihypertensive medication to be less than 50%\(^10-12\). Importantly, day-to-day adherence with therapy and evidence of ‘drug holidays’ for several days were seen to be predictive of persistence with medication use. Multiple medication taking may further reduce adherence. In a retrospective study\(^13\), the adherence rate to both BP and lipid-lowering medications decreased rapidly to 44.7% at the three-month interval, then to 35.9% at six months, and thereafter stabilised in patients newly-initiated on treatment.

Choice of medication is an important factor to take into account when adherence is being considered. Recent literature identifies differential levels of adherence for different antihypertensive drugs\(^14-19\).

The most important personal patient characteristics in terms of their medication-taking behaviour appear to be the patient’s physical and social vulnerability (e.g. being old, suffering a mental illness) and communication failures with the doctor, largely due to the patient’s and doctor’s differing health beliefs\(^20,21\).

The need to improve adherence with antihypertensive medication

Medication adherence is a particularly important factor to consider in hypertension management. Most patients on antihypertensive medicines fail to achieve their recommended target BP\(^19, 20\). It is now clear that poor adherence with medication regimens and a lack of persistence with medication use are two of the major reasons for failure to reach target BP\(^21\). Evidence exists that a more rigorous, evidence-based approach to BP management is the key to controlling hypertension\(^22\).

Most patients taking medication for hypertension require more than one medicine to achieve their target BP\(^23\); therefore, the likely impact of adverse events and medication costs will be greater for this condition than for many others. Elderly patients and young males are especially likely to be nonadherent with blood pressure medication\(^24\). Richardson et al\(^25\) found that concerns about side effects were a major barrier to adherence with antihypertensive therapy by the young and those newly initiated on therapy. This is more likely when the patient poorly understands the benefits of therapy.

The following counselling issues have been identified as interventions to improve BP control, and highlight the importance of using behavioural modification techniques for all adherence interventions\(^26\): assessing patients understanding of hypertension, clarifying misunderstandings and providing education, attending to concerns and questions and emphasising important aspects of management.

Pharmacist promotion of adherence with blood pressure medication

As the medicines experts in the community, pharmacists are in an ideal position to address nonadherence and nonpersistence issues in people with hypertension. Pharmacists have proven their abilities in helping patients to achieve target BP\(^27\). In a US study of 200 community-dwelling elderly patients (92% drug-treated for hypertension), medication adherence increased from 61% to 97% following pharmacist intervention\(^28\), and was associated with improved cardiovascular outcomes. The intervention group also had significantly increased persistence at six months – 96% (intervention) vs. 69% (control). The community pharmacist is uniquely positioned in the Australian health care system to undertake a role in cardiovascular medication management, a role supported by public opinion\(^29\).
In designing an intervention involving pharmacists, it is essential to offer a complex range of strategies – adherence involves a complex set of issues for which homogenous simple interventions applied across the target group will not have an impact\textsuperscript{30}. Examples of strategies that, as part of an overall strategy, can help appropriate patients with their adherence to blood pressure medication and other long-term treatments include medication regimen simplification, motivational interviewing, label reminders to patients, information, counselling, reinforcement, family therapy, psychological therapy, mailed communications, manual telephone follow-up, and other forms of additional supervision or attention (e.g. electronic prompts, SMS reminders)\textsuperscript{30-33}. Blood pressure self-monitoring is another option with some evidence of effectiveness\textsuperscript{34}. Other issues can be addressed through existing pharmacy programs such as medication profiling, home medication reviews and the use of dose administration aids. It is logical to integrate these existing options into new programs, not only to optimise impact for consumers but also to promote uptake by practitioners.

A systematic review of community pharmacist interventions to improve adherence to chronic medication use\textsuperscript{35} noted further research was needed to identify an overall successful adherence-improving strategy.

**Project Phases**

This project had several phases. Phase 1 was a systematic review of published studies of cardiovascular healthcare services. Phase 2 comprised focus group discussions and interviews with stakeholders (consumers, community pharmacists and GPs), to elucidate the desirable features of, and barriers and facilitators to implementing, a best practice adherence/persistence-enhancing service through Australian community pharmacies for people taking antihypertensive medicines. Phase 3 was a randomised controlled trial of a package of intervention strategies undertaken across three States. Phase 4 comprised focus group discussions and interviews with stakeholders (consumers, community pharmacists and GPs) about their experiences with the intervention.

**Phase 1 – Systematic Review**

In order to inform the development of the interventions in Phase 3, a systematic review of published studies describing cardiovascular disease programs was undertaken, with a focus on studies relevant to community pharmacy, the management of hypertension and adherence/persistence.

Although many of the studies identified were randomised controlled trials, a lack of blinding and other suboptimal methodologies meant that the overall quality of the evidence ranged from poor to fair. Previous related reviews\textsuperscript{28,37,38} and meta-analyses\textsuperscript{28,37,38} have drawn similar conclusions. Nonetheless, the review identified that a significant number of relevant studies have been conducted and the findings of some of these helped to inform the proposed intervention. A large proportion of relevant research is from the US, with major contributions also from the UK and Canada. Despite the differences in the healthcare systems between these countries and Australia, some of the findings would appear generalisable and applicable to Australian community pharmacy practice. Although the review focused on hypertension, studies carried out in other chronic medical conditions which are related, either by the nature of the drugs used (e.g. heart failure), or by their generally asymptomatic nature (e.g. dyslipidaemia), were included in the review where they met inclusion criteria. Similarly, even though priority was given to community pharmacy studies, those undertaken in other healthcare environments (e.g. hospital clinics) or by other healthcare professionals (e.g. nurses), were also included in the review where they met inclusion criteria.

The search terms and criteria are provided in Appendix 1. The literature highlights two consistent observations: no single intervention to improve adherence with antihypertensives is consistently effective, and no single community pharmacist intervention to improve adherence with chronic medication is consistently effective.

Interventions for improving adherence with antihypertensives that have some evidence base are simplifying dosing regimens, motivational strategies, unit dose packaging, educational counselling by telephone, treatment in pharmacist- or nurse-operated clinics, mailed refill reminders, self-monitoring, fixed-dose combination drugs, dose-tailoring, rewards, and combinations of the above strategies. Interventions by pharmacists for improving adherence that have some evidence base are counselling, monitoring and education during weekly or monthly appointments. However, it should be noted that some studies suggest these interventions have no effect.

A review and meta-analysis has specifically looked at the sensitivity of patient outcomes to pharmacist interventions in hypertension\textsuperscript{28}. This concluded that systolic BP was sensitive, but that diastolic BP, quality of life and adherence were nonsensitive. A common theme of the research, and concluded by some of the previous reviews, is the need for interventions to be tailored to the needs of the individual patient. Also, interventions that address multiple determinants of hypertension control are advocated\textsuperscript{39}. The interventions proposed for this trial would therefore appear to be appropriate, being supported by the available evidence and meeting the recommendations to be both multi-faceted and individualised.
Phase 2 – Stakeholders focus groups and interviews

From the focus groups and interviews with consumers (10), pharmacists (9) and GPs (6), a number of adherence issues were identified (Focus group guide: Appendix 2). Regimen complexity, denial, lack of knowledge and delayed gratification were all recognised as common barriers. Medication side-effects, cultural barriers, cost of medication and complacency were also mentioned as possible barriers to adherence. These issues are similar to those reported in the adherence literature.

Potential ways suggested to improve adherence included the use of Dose Administration Aids (DAA) and SMS reminders. Any information (not just BP readings) that gives insight into possible adherence problems was considered useful. Patient education focusing on hypertension and its role in cardiovascular disease, its treatment and the importance of adherence were also considered important factors to improve adherence. Studies involving DAAs or patient education have been proven to significantly improve adherence. Repeated and individualised rather than once-off educational sessions appear to be most beneficial.

Blood pressure monitoring between GP visits, either at the pharmacy or at home by the patient, was thought to be beneficial to the success of adherence programs in community pharmacy.

Team work involving consumer, GP and pharmacist was also thought to be essential for the success of a pharmacy-driven adherence program. Consumer consent should be obtained before sharing information between the health professionals. GPs would like patients to be referred back to them for issues that are beyond the pharmacists’ capabilities.

Pharmacist training was seen as especially important, not only to update hypertension knowledge, but also to improve communication skills, including motivational interviewing skills. Published hypertension management guidelines state the need for health professionals to use motivational techniques to encourage adherence.

Lack of adequate space within some pharmacies to conduct private consultations was mentioned as a major barrier to offering any pharmacy service focusing on chronic disease management, and needs to be addressed to ensure patient confidentiality.

All of these issues were addressed in the HAPPY Trial. Components of the trial intervention package to improve adherence in patients on antihypertensive medicines mirror those strategies recommended by the stakeholders. These include education and motivational interviewing, pharmacy and home blood pressure monitoring, medication use reviews, and possibly dose administration aids, medication profiles, home medication reviews, as well as referral to a GP, when needed. Patient prescription reminders were also part of the intervention.

For the successful implementation of the program, the training for pharmacists had a strong focus on education about BP as a risk factor for CVD, protocols for management of BP, and adherence. Theory and practice in motivational interviewing was included to provide pharmacists with the skills to effectively communicate with consumers, be able to educate them, and develop strategies with individuals to address their adherence issues. While training was provided face-to-face, as suggested by the pharmacists interviewed, it was also made available online or by mail for those pharmacists who were unable or chose not to attend, as this has been a barrier to participation by pharmacists in other disease state management program research.

To address the issue of privacy, funding was made available to participating pharmacies to ensure they could provide a private consultation area within their pharmacy, such as acquiring a screen to section off part of the premises.

The main facilitator for successful implementation of a community pharmacy adherence program was seen to be remuneration for pharmacists. Remuneration for pharmacy services has been raised in previous studies. Pharmacists felt that payment should be at least equivalent – if not more substantial – than money they could have earned by dispensing prescriptions during the consultation duration. Possible sources of payment mentioned were service fee payable by consumer, drug company contributions and government funding. Government funding was the preferred option; possible payment strategies included Medicare rebate, bulk billing, bulk grants and increased dispensing service fee. In the randomised controlled trial, pharmacists were remunerated per patient according to the expected time involved.

The findings of the preliminary phase qualitative study are in line with those reported in the literature. This information guided the refinement of the intervention strategies for the randomised controlled trial phase of the project and also assisted in the development of the training program for pharmacists participating in the trial.
Phase 3 – Intervention Phase: Hypertension Adherence Program in PharmacY (HAPPY) Trial

The HAPPY trial was a multi-centre prospective randomised controlled trial (RCT).

Research objective and research questions

The research objective was to test a specific intervention package that could be integrated into the community pharmacy workflow to enable pharmacists to improve patient adherence and/or persistence with antihypertensive medications. Research questions are as follows:

1. Can the proposed intervention package service, compared to usual care:
   a. improve patient adherence and/or persistence with antihypertensive medications?
   b. improve patients' blood pressure control?
   c. change patients' health beliefs and attitudes?
   d. improve patients' quality of life?
   e. generate more benefit at a cost (i.e., the Incremental Cost-Effectiveness Ratio, ICER) that is reasonable and acceptable to the Australian society?

2. Are consumers and other stakeholders (Pharmacists and GPs) satisfied with the service?

3. Can the service be readily implemented within the current community pharmacy structure? What is the consumer’s willingness to pay for the service?

4. Is there an economically viable business case for the service?

Primary outcome measures

The primary outcomes of the HAPPY trial were changes in patient adherence and persistence at the end of six months, measured subjectively using the self-reported Morisky scale\(^44\) and the Tool for Adherence Behaviour Screening (TABS)\(^45\) and objectively using medication refill data (e.g. MedsIndex\(^46\), MPR\(^47\)). The Morisky scale assesses both intentional and unintentional nonadherence and comprises four items. A total score of zero represents good adherence. The TABS is another self-reported adherence measure, which measures both intentional and unintentional deviations from recommended management. It has two subscales – ‘adherence’ and ‘nonadherence’ – each comprising four items. A differential between the two subscales of ≥15 was regarded as good adherence. The MedsIndex is calculated by the dispensing software from prescription refill history. Any score less than 100 suggests suboptimal adherence. The Medication Possession Ratio (MPR) was calculated from the patients’ dispensing history within the pharmacy where they were recruited. A MPR of less than one indicates suboptimal adherence.

Secondary outcome measures

Secondary outcomes included changes in patients’ blood pressure control, changes in health beliefs and attitudes, changes in quality of life, satisfaction with and willingness to pay for the service, and economic benefits.

Methodology

Pharmacy recruitment and training

Pharmacies in each of the Pharmacy Access/Remoteness Index of Australia (PhARIA) categories in three states (Victoria, Western Australia and Tasmania) were contacted by telephone and informed about the project. If they were eligible (Appendix 3) and expressed interest, they were sent an explanatory statement and consent form.

Pharmacies were eligible to participate in the trial if they met all the following criteria:

- use the pharmacy dispensing program ‘FRED Dispense®’;
- agree to install a software application (MedeMineCVD) to identify patients who are using or have used antihypertensive medicines in the previous six months;
- had at least 40 patients who currently used or had used antihypertensive medicines in the previous six months;
- had a private counselling area within the pharmacy;
- were willing and able to undertake project training either face-to-face or online;
- had time within the working week to allocate about one uninterrupted hour per patient to collect the baseline data; and
- were able to follow-up participants for at least six months from baseline.
Training was organised for participating pharmacists in two modes, face-to-face and online. Materials and resources were made available as hard copy, online and on CD-ROM, to provide flexible learning opportunities. Knowledge was assessed afterwards (Appendices 4-5).

**Cluster randomisation**

In each state, pharmacies were stratified according to PhARIA and then randomised within strata to either Pharmacist Care Group (PCG) or Usual Care Group (UCG). Randomisation was carried out at the pharmacy level to avoid any contamination likely to result from the same pharmacy recruiting and following up both intervention and control group patients.

To check for any 'Hawthorne effect' in the UCG due to the effect of pharmacist contact with patients in the UCG, a third group of patients (Hidden Control Group - HCG) who were taking or had taken antihypertensive medicines in the previous six months (but not included in the UCG) were also identified from the UCG pharmacies.

**Intervention package**

The PCG participants received a package of interventions from the pharmacist for enhancing their antihypertensive medication adherence, which included:

- a home BP monitor (Omron®HEM-790IT) with the capacity to store and download BP readings to be used for discussion at three- and six-month follow-ups;
- training by the pharmacist on self-monitoring of BP;
- motivational interviewing and education by the pharmacist to help patients improve their medication adherence and achieve target BP;
- medication use review (MUR) where necessary to identify and resolve possible medication-related hypertension (e.g. due to non-steroidal anti-inflammatory drugs, cold preparations, complementary medicines, etc.);
- pharmacist-initiated dose administration aid (DAA), home medicines review (HMR), and/or patient medication profile (PMP), where necessary;
- referral to a GP when needed (e.g. very high blood pressure); and
- refill reminders, if they so chose, (by SMS, telephone or mail) from their pharmacist three days before their antihypertensive medication was due to run out.

**Promotion of project to general practitioners**

GPs were not directly involved in the conduct of the project but it was acknowledged that their awareness was essential for an optimal multidisciplinary approach to patient care. Local General Practice Networks and Divisions were informed of the project to raise awareness among their members. Individual GPs nominated by the patients were sent more detailed project information (Appendix 6) at the beginning of the trial, including a request for confirmation of a participating patient’s hypertension diagnosis and their target blood pressure.

**Sample size**

Australian, European and North American studies have estimated that around 50% of patients initiating an antihypertensive medication discontinue their medication (become nonpersistent) within twelve months. To demonstrate a 15% difference in adherence between the control and intervention groups at six months (e.g. 50% in the UCG versus 65% in the PCG) with 80% power and a two-sided p-value of 0.05, 182 patients are required per study group. To allow for potential drop-outs (approximately 25% over six months) the intent was to recruit 225 patients per group; i.e. a total of 450 patients at baseline.

**Patient recruitment**

A software application, MedeMineCVD was installed on the dispensing computer of participating pharmacies. MedeMineCVD extracted data from the widely used pharmacy dispensing software system in Australia (FRED Dispense®) and preferentially identified patients who had last had their antihypertensive medications dispensed more than 59 days ago and those with suboptimal refill adherence.

Through MedeMineCVD, Expression of Interest invitation letters (EOI) were sent to potential participants (Appendix 7). Patients were asked to complete the EOI and return it to the pharmacy.
Inclusion criteria

- using, or having used in the last six months, at least one antihypertensive medication belonging to four common classes of antihypertensives in Australia – angiotensin converting enzyme inhibitors, angiotensin-II receptor antagonists, calcium channel blockers, beta blockers – (www.aihw.gov.au/publications/cvd/mfchatua/mfchatua.pdf) or fixed combinations of antihypertensive medications belonging to the above classes with other antihypertensives (e.g. diuretics);
- a diagnosis of primary hypertension;
- aged 18 years or above; and
- available for follow-up for at least six months from baseline.

Exclusion criteria

- participation in other adherence promotion programs;
- having had a pharmacist-conducted HMR service in the last 12 months;
- unable to communicate in English; and
- not self-administering antihypertensive medicines.

Data collection

Baseline visit

During the baseline visit to the pharmacy, the pharmacist measured the patient’s BP using a digital BP monitor (Omron®HEM-790IT) (average of two readings as per WHO MONICA and EHRM protocols – if these differed by more than 10 mmHg for systolic or 5 mmHg for diastolic, a third reading was taken and the average of the two closest readings recorded). Adherence was measured using the Morisky scale, TABS and the MedsIndex score for each antihypertensive medicine. The eight-item short Assessment of Quality of Life (AQoL) was used to measure health-related quality of life. The pharmacist also collected information on the patient’s medications and their understanding of and ability to use these medications. Patients in the PCG then received the intervention described earlier. The baseline data collection form is attached as Appendix 8.

Three-month visit – Pharmacist Care Group (PCG) Only

During the patient’s visit to the pharmacy at three months, the pharmacist administered the Morisky scale and TABS and measured the patient’s BP. Patients then received the intervention based on the downloaded home BP measures. The three-month data collection form is attached as Appendix 9.

Six-month (final) visit

Measures performed at baseline were repeated for both UCG and PCG patients at their six-month visit to the pharmacy. The six-month data collection form is attached as Appendix 10.

Usual Care Group (UCG) Only

Following final measurements, each UCG participant was eligible to receive the same package of interventions offered to the PCG at baseline, apart from the option to receive prescription refill reminders.

Hidden Control Group

At six months, the patients’ lowest MedsIndex scores for their antihypertensive medicines were used to assess differences in adherence between the UCG and HCG patients. Further, the lowest, highest and average MPRs for antihypertensive medicines were compared between baseline and six-month follow-up to also assess difference in adherence between the UCG and HCG. MPRs were calculated for the six months prior to the trial and the six months of the trial.

Statistical analysis

Analysis was performed using SAS version 9.2 (SAS Institute Cary, NC, USA). Paired t-tests (or Wilcoxon Sign Rank) were used to determine within group changes, whilst unpaired t-tests (or Wilcoxon Rank Sum) were used to compare between group differences.

Ethical issues

This project was approved by the Human Research Ethics Committees of Monash University, Curtin University of Technology and The University of Melbourne, and the Human Research Ethics Network of Tasmania. All pharmacists and patient participants provided written informed consent at the time of enrolment. The researchers had access only to de-identified patient data.
Economic Evaluation and Business Case

Economic Evaluation

A full economic evaluation was performed in which both effectiveness and cost were examined and compared between the PCG and the UCG.

Measurement of Effectiveness

Effectiveness in this study is measured in terms of the Quality Adjusted Life Years (QALYs) gained, where quality of life was measured using AQoL8\textsuperscript{53,54} at the patient level. The patient’s utility score produced by AQoL8 is scored on a life-death scale between 1 and -0.04, (1.00 equals perfect health; 0 equals death and negative values represent states worse than death).

Measurement of Costs

According to the rule of importance\textsuperscript{55}, all related major cost items were included.

There are two major service provider costs: (1) fixed cost (the initial investment to set up the service and training for pharmacists) and (2) variable cost (labour input for provision of service).

There are three major patient costs: (1) BP monitor; (2) medical costs (CVD medications, CVD-related GP visits, Emergency Department visits, and hospital stay); and (3) out-of-pocket costs (e.g. co-payments, travel expenses).

The measurement of each cost item, unit price and sources of information on cost and how such data were collected are reported in the Results section.

Cost-effectiveness analysis

Cost-effectiveness analysis was performed using Incremental Cost-Effectiveness Ratio (ICER) Analysis\textsuperscript{55,56}. The denominator in the ICER equation is the difference in QALYs gained between the PCG and the UCG. The numerator is the difference in the total major costs between the two groups.

As participants were only followed-up for six months, the ten year cost-effectiveness of the service was modelled using the Markov process\textsuperscript{57-59}. Discounting rate was 5% in the ten-year model of the base case. Sensitivity analysis included 0% and 10% discount rates for the ten-year model and addressed variations in the quality of life utility scores; variation in costs of the pharmacist’s time for delivering the new service; and the patient’s emergency department visits and hospital stays in the ten-year model on the ICER.

Analyses were performed using SPSS version 18.0 and Microsoft Excel 2003. The level of significance for all tests was set at the conventional level of 5% (i.e., p<0.05).

Business Case

The business case evaluation was addressed in an economic evaluation section of the six-month data collection form (Appendix 10), the Business Case questionnaire (Appendix 11) for PCG participants at baseline and six-month follow-up and the stakeholders’ focus groups and interviews in Phase 2 and 4. Measurements included willingness to pay (WTP), shopping frequency, spending per visit and satisfaction.

Results – Randomised Control Trial

Pharmacies

Pharmacy recruitment

A total of 55 pharmacies were recruited into the project; 29 were randomised into the Pharmacist Care Group (PCG) and 26 into the Usual Care Group (UCG). Of these, 40 were from Victoria (20 in PCG; 20 in UCG), nine from Western Australia (5 PCG; 4 UCG) and six from Tasmania (4 PCG; 2 UCG). Thirty-seven (67.3%) pharmacies were located in PhARIA 1, five (9.1%) in each of PhARIA 2 and 3, four (7.3%) in PhARIA 4 and two (3.6%) in each of PhARIA 5 and 6. Independent pharmacies accounted for 56.4%. Eight different pharmacy banners were represented. The majority of pharmacies (52.7%) were located along shopping strips.
Training of pharmacists

A total of 18 pharmacists (from 17 pharmacies) attended face-to-face training and 39 pharmacists (from 38 pharmacies) did the training either online or using the CD provided.

Assessment of knowledge of pharmacists

Of the 31 PCG pharmacists who undertook the training, 24 (77.4%) completed the knowledge assessment after the training. Sixteen (66.7%) completed it on paper and 8 (33.3%) online. Each question for the PCG assessment was answered correctly by between 70.8% and 100% of pharmacists.

Patients

Baseline characteristics of recruited patients

207 patients were enrolled in the PCG, 188 in the UCG. Baseline characteristics are shown in Table 1.

In the PCG, 52.2% were women. The average age was 67.0 ± 12.1 years. Seventy-three (35.3%) reported having CVD, 40 (19.3%) having diabetes, and 35 (16.9%) suffered depression. The median Charleson Index score was 2 (range 0 - 8). Overall, patients reported modest quality of life (0.71 ± 0.24). The Morisky scale showed the proportion of patients nonadherent to their antihypertensive to be 43.1% (85/197), the TABS differential 88.5% (177/200), and MedsIndex score 58.9% (122/207).

In the UCG, 45.4% of participants were women. The average age was 67.0 ± 11.8 years. Seventy-four (39.4%) reported having CVD, 31 (16.5%) having diabetes and 34 (18.1%) depression. The median Charleson Index score was 2 (range 0 - 9). Overall, patients reported modest quality of life (0.71 ± 0.24). With regard to adherence measures, the Morisky scale showed 42.5% (79/186), TABS differential 84.9% (158/186), and MedsIndex score 55.9% (105/188) of patients to be nonadherent to their antihypertensive medicines. Overall, there were no statistically significant differences between the characteristics of the two groups at baseline.

Baseline Blood Pressure measurement

In the PCG, the reported mean systolic blood pressure was 141.9 ± 20.0 mmHg and the mean diastolic BP was 84.3 ± 11.0 mmHg. The mean systolic blood pressure in UCG patients was 140.1 ± 20.2 mmHg and the mean diastolic BP was 83.2 ± 11.6 mmHg. There were no statistically significant differences between the two groups in these measurements.

Changes to key parameters at three months (PCG only)

At the three-month visit, data were collected for 190 PCG patients.

There was a statistically significant difference between the baseline and three-month Morisky scores (p=0.006) indicating increased overall adherence to antihypertensive medications; however, not all patients demonstrated increased adherence. One hundred and fifteen (115/181, 63.5%) patients showed no change in their Morisky score between baseline and three months; 89 (49.2%) remained adherent and 26 (14.4%) remained nonadherent. Forty-four (24.3%) showed a trend towards adherence and 22 (12.2%) towards nonadherence.

Twenty-seven (27/173, 15.6%) patients showed no change in the TABS between baseline and three months; 10 (5.8%) remained adherent and 17 (9.8%) remained nonadherent. Eighty-five (49.1%) showed a trend towards adherence and 61 (61/173, 35.3%) towards nonadherence. There was no statistically significant difference between the baseline and three-month figures (p=0.148).

There was a statistically significant reduction in patients’ recorded BP measurements from baseline to three-months: 8 mm Hg for systolic (p<0.001) and 4 mm Hg for diastolic (p<0.001).

Changes to key parameters at six months

At the six-month visit, data were collected for 354 consumers, 176 in the UCG and 178 in the PCG.

Changes in adherence

Of the 173 UCG and 170 PCG participants for whom Morisky scores were calculated at baseline and six months, the proportion judged to be adherent by this measure increased from 57.2% to 63.5% in the UCG and 60.0% to
73.5% in the PCG. Thus, a crude difference of 15% between the groups, which the trial was powered to detect, was not demonstrated.

In addition, not all participants improved their adherence over the time period (Figure 1). No significant difference was observed between the groups (p>0.1).

**Figure 1: Change in adherence rate according to Morisky scale from baseline to six months**

The proportions identified as adherent using TABS and MedsIndex remained consistent from baseline to six months (<5% change).

Adherence scores in the PCG improved significantly on various measures of adherence (Morisky, MedsIndex and MPR) at six-months, but no statistically significant differences were detected between groups. Changes in patient adherence over the six-month period in UCG and PCG are illustrated in Table 2.

**Table 2: Changes in adherence between baseline and six months**

<table>
<thead>
<tr>
<th>Measure of adherence</th>
<th>Baseline</th>
<th>Six months</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morisky total score [median (IQR)]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UCG (n = 173)</td>
<td>0 (0 – 1)</td>
<td>0 (0 – 1)</td>
<td><strong>0.030</strong> (Sign Rank)</td>
</tr>
<tr>
<td>PCG (n = 170)</td>
<td>0 (0 – 1)</td>
<td>0 (0 – 1)</td>
<td><strong>0.019</strong> (Sign Rank)</td>
</tr>
<tr>
<td>Difference between UCG and PCG</td>
<td></td>
<td>0.31</td>
<td>(Wilcoxon Rank)</td>
</tr>
<tr>
<td>TABS adherence score (mean ± SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UCG (n = 170)</td>
<td>19.12 ± 1.93</td>
<td>19.07 ± 1.65</td>
<td>0.852 (Paired t-test)</td>
</tr>
<tr>
<td>PCG (n = 170)</td>
<td>18.35 ± 2.73</td>
<td>18.83 ± 2.15</td>
<td>0.179 (Paired t-test)</td>
</tr>
<tr>
<td>Difference between UCG and PCG</td>
<td></td>
<td>0.234</td>
<td>(t-test)</td>
</tr>
<tr>
<td>TABS nonadherence score (mean ±SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UCG (n = 170)</td>
<td>8.20 ± 2.89</td>
<td>7.52 ± 2.60</td>
<td><strong>0.021</strong> (Paired t-test)</td>
</tr>
<tr>
<td>PCG (n = 168)</td>
<td>8.10 ± 2.71</td>
<td>7.74 ± 2.98</td>
<td>0.154 (Paired t-test)</td>
</tr>
<tr>
<td>Measure of adherence</td>
<td>Baseline</td>
<td>Six months</td>
<td>p</td>
</tr>
<tr>
<td>--------------------------------------------</td>
<td>--------------</td>
<td>---------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Difference between UCG and PCG</td>
<td></td>
<td></td>
<td>0.580 (t-test)</td>
</tr>
<tr>
<td><strong>TABS differential (mean ±SD)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UCG (n = 165)</td>
<td>10.92 ± 3.67</td>
<td>11.59 ± 3.33</td>
<td>0.063 (Paired t-test)</td>
</tr>
<tr>
<td>PCG (n = 164)</td>
<td>10.25 ± 3.77</td>
<td>11.10 ± 3.83</td>
<td>0.111 (Paired t-test)</td>
</tr>
<tr>
<td>Difference between UCG and PCG</td>
<td></td>
<td></td>
<td>0.856 (t-test)</td>
</tr>
<tr>
<td><strong>MedsIndex score for BP medicines (mean ± SD)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UCG (n = 142)</td>
<td>80.42 ± 20.23</td>
<td>82.86 ± 19.42</td>
<td>0.229 (Paired t-test)</td>
</tr>
<tr>
<td>PCG (n = 133)</td>
<td>80.15 ± 18.36</td>
<td>84.75 ± 17.13</td>
<td>0.002 (Paired t-test)</td>
</tr>
<tr>
<td>Difference between UCG and PCG</td>
<td></td>
<td></td>
<td>0.228 (t-test)</td>
</tr>
<tr>
<td><strong>Medication Possession Ratio</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>[median (range)]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UCG (n = 151)</td>
<td>0.76 (0.22 – 1.88)</td>
<td>0.93 (0.19 – 1.50)</td>
<td>&lt; 0.001 (Sign Rank)</td>
</tr>
<tr>
<td>PCG (n = 174)</td>
<td>0.77 (0.27 – 2.00)</td>
<td>0.95 (0.26 – 4.29)</td>
<td>&lt; 0.001 (Sign Rank)</td>
</tr>
<tr>
<td>Difference between UCG and PCG</td>
<td></td>
<td></td>
<td>0.496 (Wilcoxon Rank)</td>
</tr>
</tbody>
</table>

**Changes in BP**

Both systolic and diastolic BP decreased significantly over the study period in both groups. The change in mean systolic BP was significantly greater in the PCG than the UCG. The decrease in systolic BP was 5.37 mmHg ± 2.33 greater in the PCG. The changes in BP over the six-month period are illustrated in Table 3.

**Table 3: Changes in blood pressure between baseline and six months**

<table>
<thead>
<tr>
<th>BP readings</th>
<th>Baseline</th>
<th>Six months</th>
<th>Reduction</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Systolic BP (mean ± SD)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UCG (n = 176)</td>
<td>140.07 ± 20.19</td>
<td>135.27 ± 20.66</td>
<td>4.61 ± 23.05</td>
<td>0.009 (Paired t-test)</td>
</tr>
<tr>
<td>PCG (n = 176)</td>
<td>141.87 ± 19.96</td>
<td>131.77 ± 16.75</td>
<td>9.97 ± 20.61</td>
<td>&lt; 0.001 (Paired t-test)</td>
</tr>
<tr>
<td>Difference between UCG and PCG</td>
<td></td>
<td></td>
<td>5.37 ± 2.33</td>
<td>0.022 (t-test)</td>
</tr>
<tr>
<td><strong>Diastolic BP (mean ± SD)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UCG (n = 176)</td>
<td>83.22 ± 11.60</td>
<td>78.84 ± 11.24</td>
<td>4.22 ± 12.83</td>
<td>&lt; 0.001 (Paired t-test)</td>
</tr>
<tr>
<td>PCG (n = 176)</td>
<td>84.31 ± 11.04</td>
<td>80.21 ± 10.81</td>
<td>4.48 ± 12.38</td>
<td>&lt; 0.001 (Paired t-test)</td>
</tr>
<tr>
<td>Difference between UCG and PCG</td>
<td></td>
<td></td>
<td>0.27 ± 1.34</td>
<td>0.843 (t-test)</td>
</tr>
</tbody>
</table>
Changes in Health Beliefs and Attitudes

Although the ‘confidence’ of PCG participants increased more than that of UCG participants; the difference between groups was just short of reaching significance (Table 4). The changes in scores on the other domains of the BBQ (‘concern’, ‘satisfaction’ and ‘disappointment’) were not significant.

Table 4: Changes to health beliefs and attitudes between baseline and six months.

<table>
<thead>
<tr>
<th>BBQ domain</th>
<th>Baseline</th>
<th>6 months</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confidence median (IQR); mean ± SD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UCG (n = 161)</td>
<td>38.5 (34.0 – 42.0)</td>
<td>39.5 (35.25 – 43.0)</td>
<td>0.045 (Signed Rank)</td>
</tr>
<tr>
<td></td>
<td>38.0 ± 4.91</td>
<td>38.79 ± 4.80</td>
<td></td>
</tr>
<tr>
<td>PCG (n = 143)</td>
<td>37.0 (34.25 - 41)</td>
<td>40 (36.0 – 42.0)</td>
<td>&lt;0.001 (Paired t-test)</td>
</tr>
<tr>
<td></td>
<td>37.14 ± 5.10</td>
<td>38.87 ± 4.41</td>
<td></td>
</tr>
<tr>
<td>Difference between UCG and PCG</td>
<td></td>
<td></td>
<td>0.053 (Wilcoxon Rank)</td>
</tr>
</tbody>
</table>

Subgroup Analyses

A number of subgroup analyses were performed on patients:

I. who self-reported nonadherence on the Morisky scale (total score>0) at baseline;
II. whose BP (systolic and/or diastolic) was above the GP target at baseline; and
III. who self-reported nonadherence on the Morisky scale (total score >0) and whose BP (systolic and/or diastolic) was above GP target at baseline.

Changes in adherence rates

For subgroup analyses I and III (where all patients were nonadherent at baseline according to the Morisky scale), the percentage of participants who became adherent at six months was greater in the PCG than the UCG (Figure 2). A significant difference was detected between the groups in subgroup I ($\chi^2 = 7.22, p=0.007$) and subgroup III ($\chi^2 = 4.27, p = 0.039$).

Figure 2: Subgroups I & III: Change in adherence rate according to Morisky scale from baseline to six months

<table>
<thead>
<tr>
<th>Sub-group I (nonadherent by Morisky)</th>
<th>PCG: n=68; UCG: n=74</th>
</tr>
</thead>
<tbody>
<tr>
<td>Became adherent</td>
<td>61.8</td>
</tr>
<tr>
<td>No change</td>
<td>39.2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Subgroup III (nonadherent by Morisky &amp; above target BP)</th>
<th>PCG: n=44; UCG: n=53</th>
</tr>
</thead>
<tbody>
<tr>
<td>Became adherent</td>
<td>56.8</td>
</tr>
<tr>
<td>No change</td>
<td>43.2</td>
</tr>
</tbody>
</table>
Morisky total score
In all three subgroups, as was also the case for the whole group, the total Morisky scores in the PCG showed significant improvements towards adherence from baseline to six months (Figure 3); however the differences in the UCG did not reach statistical significance.

Figure 3: Changes in mean total Morisky score from baseline to six months

TABS scores
In subgroup I (nonadherent according to Morisky), the TABS adherence subscale scores showed significant improvements in the PCG from baseline to six months (p=0.027, Sign Rank) which was significantly greater than in the UCG (p=0.046, Wilcoxon Rank).

In subgroup II (above target BP), no significant improvements in TABS adherence scores were found either within PCG or when compared to UCG.

While the TABS adherence scores significantly improved from baseline to six months in the PCG of subgroup III (nonadherent to Morisky and above target BP) (p=0.043, Sign Rank), when compared to UCG, the difference fell short of significance (p=0.063, Wilcoxon Rank).

The TABS nonadherence subscale and TABS differential did not show any significant improvements in all three subgroup analyses.
MedsIndex score for BP medicines

The PCG demonstrated significant improvements in the lowest MedsIndex score from all antihypertensive medicines at six months in all three subgroups (Figure 4), but the differences with UCG did not reach statistical significance.

Figure 4: Changes in mean lowest MedsIndex score from baseline to six months

![Graph showing changes in lowest MedsIndex score from baseline to six months](image)

* significant improvements in lowest MedsIndex score (p < 0.05)

Changes in Blood Pressure

In all three subgroups, systolic and diastolic BP decreased over the study period in both the PCG and UCG (Table 5).

Table 5: Subgroup I, II & III: Changes in systolic and diastolic BP from baseline and six months

<table>
<thead>
<tr>
<th>Systolic BP readings</th>
<th>Subgroup I (mmHg)</th>
<th>Subgroup II (mmHg)</th>
<th>Subgroup III (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCG baseline (mean ± SD)</td>
<td>141.8 ± 20.4</td>
<td>150.0 ± 17.7</td>
<td>150.2 ± 18.4</td>
</tr>
<tr>
<td>PCG six months (mean ± SD)</td>
<td>128.7 ± 15.3</td>
<td>133.4 ± 16.1</td>
<td>129.9 ± 15.6</td>
</tr>
<tr>
<td>UCG baseline (mean ± SD)</td>
<td>138.2 ± 20.2</td>
<td>147.6 ± 17.7</td>
<td>144.8 ± 17.3</td>
</tr>
<tr>
<td>UCG six months (mean ± SD)</td>
<td>134.2 ± 21.2</td>
<td>138.1 ± 20.5</td>
<td>137.4 ± 17.8</td>
</tr>
</tbody>
</table>
In the PCG, the reduction in systolic BP over the study period was statistically significant (Figure 5).

**Table 6: Subgroup I, II & III: Mean difference in systolic BP reduction between PCG and UCG**

<table>
<thead>
<tr>
<th>Subgroups</th>
<th>Mean difference in systolic BP reduction between PCG and UCG</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Subgroup I</strong> (Adherent to Morisky at baseline)</td>
<td>- 9.37 mmHg</td>
<td><strong>0.01</strong> (Paired t-test)</td>
</tr>
<tr>
<td><strong>Subgroup II</strong> (above target BP at baseline)</td>
<td>- 7.14 mmHg</td>
<td><strong>0.01</strong> (Paired t-test)</td>
</tr>
<tr>
<td><strong>Subgroup III</strong> (adherent to Morisky and above target BP at baseline)</td>
<td>- 12.95 mmHg</td>
<td><strong>0.003</strong> (Paired t-test)</td>
</tr>
</tbody>
</table>

While the reduction in diastolic BP from baseline to six months was significant in the PCG, there was no statistical significance when compared to UCG in all three subgroups.
Hidden Control Group

At the end of the six-month follow-up there was no statistically significant difference in the lowest MedsIndex scores (as calculated for all antihypertensive medicines the patients were taking) between the UCG (82.32 ± 19.59) and HCG (80.97 ± 19.45).

There was also no statistically significant difference in the mean change of the MPR from baseline to the end of the six-month follow-up, using the lowest, highest or average values, between the UCG and the HCG.

Discussion

The aim of the study was to test an intervention to assist community pharmacists to improve patient adherence and/or persistence with antihypertensive medications (primary outcome measure). The expectation was that improving adherence would lead to improved blood pressure control (secondary outcome).

Haynes et al. (2008) highlighted the need for examining the effectiveness of adherence interventions involving allied health professionals in regard not only to adherence, but also to their clinical benefit, as improving medication adherence will not necessarily translate into clinical benefits for the patient. Hence, interventions should also be assessed in terms of their effects on clinically important outcomes and feasibility in usual practice settings.

Effects on adherence

The proportion of participants in each group who were identified to be adherent by the Morisky score increased in both groups from baseline to six months; however, while some individuals achieved improved adherence, others became nonadherent and this observation did not differ significantly between the groups. It is unclear why adherence scores became worse for some people, particularly in the PCG. Although the proportion of patients who became adherent over the course of the study was not significantly different between groups overall, significant differences in favour of the PCG were detected for both the subgroups in which all participants were nonadherent according to the Morisky score at baseline.

Significant improvements in adherence were seen in the PCG over the six months of the trial in several measures of adherence – the Morisky score, MedsIndex, and the MPR. Improvements in the Morisky score and the MPR were also seen in the UCG, but to a lesser extent. The UCG demonstrated a significant reduction in the TABS nonadherence score, which was not shown by the PCG. Being part of the trial may, in itself, have influenced the adherent behaviour of the UCG patients, either through the Hawthorne effect or simply by raising their awareness of the importance of blood pressure control. It is likely that participants may have answered questions in the Morisky scale and TABS in a socially acceptable manner, especially at the six-month visit. Comparisons were made with the HCG to check for any Hawthorne effect using MedsIndex scores and MPRs, both of which have inherent limitations as adherence measures. These were, however, the only measures for which data were available given the nature of the HCG. While no differences were found between the between the HCG and UCG on MedsIndex or MPR, indicating that there was minimal ‘Hawthorne effect’ on persistence/adherence per se, pharmacist contact might have had influences on other factors (e.g. medication knowledge, knowledge about BP) in the UCG.

No significant differences between the groups were demonstrated for any of the adherence measures. This is consistent with the results of a review and meta-analysis looking at the sensitivity of patient outcomes to pharmacist interventions in hypertension, which concluded that adherence was a nonsensitive measure. This may reflect inadequacy of the adherence measures for the purpose.

Another possibility for seeing improvement in both groups is that an external influence may have impacted upon adherence during the course of the trial (e.g. the Mirixa program or adult education conducted by consumer groups). This cannot be confirmed, as no data about other potential confounders were collected. This possibility is supported, however, by the fact that no statistically significant differences in the MedsIndex scores or MPRs were detected between the UCG and HCG patients, even though the MPR increased in the both groupsover the trial period.

Given that a high proportion of participants were adherent at baseline (according to the various adherence measures and anecdotal feedback from pharmacists) a subgroup analysis was performed on those participants who were nonadherent according to the Morisky score, in order to explore whether this was a likely explanation. The Morisky score was chosen over the other measures as it is the most widely recognised self-reported adherence measure and may be suitable to use as an additional screen for eligible participants to receive the service if it were to be implemented in the future. This analysis showed a significant improvement in the PCG over the UCG in the TABS adherence score. The PCG demonstrated significant improvements in the Morisky score and MedsIndex
score at six months and the UCG demonstrated significant improvement on the Morisky score only. Differences between the groups were not significant for MedsIndex or Morisky score at the predetermined \( p < 0.05 \) level, although the difference in Morisky score was significant at the \( p < 0.1 \) level, suggesting that a larger sample size may demonstrate significance, given that the subgroup contained around 70 per group rather than the calculated 182.

A second subgroup analysis was undertaken on patients who were above their target blood pressure at baseline to determine if this could potentially be a useful eligibility criterion for receiving the service. Again, the PCG group demonstrated significant improvement in Morisky score and the MedsIndex score at six months, but the differences were not significant when compared to the UCG. (Sample size for this subgroup was 90-120.)

Analysis of the group who were both nonadherent according to the Morisky score and above target BP at baseline (sample size around 50 per group) showed a significant difference between groups in regard to the proportion of participants who became adherent over the course of the trial, with a higher proportion of the PCG group becoming adherent. In addition, the PCG demonstrated significant improvements in Morisky score, TABS adherence and MedsIndex score at six months, the difference in MedsIndex score being significant \( (p = 0.046) \) when compared to the UCG. (Sample size for this subgroup was 36-53).

**Effects on blood pressure**

Both systolic and diastolic BP decreased significantly over the study period in both groups. The change in mean systolic blood pressure was significantly greater in PCG than UCG patients. Difference in diastolic blood pressure between PCG and UCG patients was not statistically significant. This is consistent with other studies; a review and meta-analysis of patient outcomes resulting from pharmacist interventions in hypertension concluded that systolic blood pressure was sensitive to intervention, but that diastolic blood pressure was not\(^1\).

The fact that systolic blood pressure was significantly reduced suggests that the intervention is valuable in terms of health outcomes, as a decrease in systolic blood pressure of 10 mmHg was achieved in the PCG.

Subgroup analysis of the group who were nonadherent at baseline also showed a decrease in systolic blood pressure in the PCG group of the order of 13 mmHg, which was significantly greater than the drop in the UCG. A reduction of 12 to 13 mmHg over four years of follow-up has been shown to reduce the incidence of heart attacks, strokes and deaths from cardiovascular disease\(^2\).

Subgroup analysis of participants who were above target blood pressure at baseline showed a decrease in systolic blood pressure in the PCG group of the order of 16 mmHg, and 20mmHg for the group who were also nonadherent according to Morisky scale. These reductions were significantly greater than the drop in the UCG and suggest that patients with blood pressure above target may achieve even greater long-term health benefits from the intervention.

Even though improvement in adherence was not demonstrated, the intervention has shown potential to reduce cardiovascular risk. As mentioned before, it may be that the adherence measures are not sensitive enough to detect change. Regardless of that, the intervention has resulted in behaviour change that has improved blood pressure control. Feedback from consumers and pharmacists during Phase 4 focus groups and interviews was that the two most important components of the intervention were monitoring their own BP regularly and the education from the pharmacists, which empowered them to have greater understanding of and input into their BP control.

**Results – Economic Evaluation**

**Analysis of cost**

Cost analysis of the Pharmacy Care Group (PCG) vs the Usual Care Group (UCG) over six months is illustrated in Table 7.

**Table 7: Cost analysis of PCG and UCG for six months (Australian dollars, 2009)**

<table>
<thead>
<tr>
<th></th>
<th>PCG</th>
<th>UCG</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N  Visit</td>
<td>Mean SD</td>
<td>N  Visit</td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Setup Cost(^1)</td>
<td>$38.89</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Training cost(^2)</td>
<td>$13.67</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacist time cost(^3)</td>
<td>190</td>
<td>$60.10</td>
<td>$21.62</td>
</tr>
<tr>
<td></td>
<td>Subtotal</td>
<td>Patient cost</td>
<td></td>
</tr>
<tr>
<td>----------------------</td>
<td>------------</td>
<td>--------------</td>
<td>-----</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td>$112.66</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td><strong>Patient cost</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BP Monitor</td>
<td>$19.17</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Medication</td>
<td>$202.76</td>
<td>$106.54</td>
<td>188</td>
</tr>
<tr>
<td>GP visit</td>
<td>$121.62</td>
<td>$172.41</td>
<td>188</td>
</tr>
<tr>
<td>ED visit</td>
<td>$28.17</td>
<td>$142.15</td>
<td>188</td>
</tr>
<tr>
<td>Inpatient stay</td>
<td>$260.39</td>
<td>$1279.3</td>
<td>188</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td>$632.11</td>
<td>$705.37</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>$744.76</td>
<td>$705.37</td>
<td></td>
</tr>
</tbody>
</table>

Notes:
1. Setup cost is estimated as $1400 for one pharmacy, divided by 6 patients (i.e., average number of patients per PCG pharmacy), and amortised to 3 years. Setup cost is the initial investment to provide a specific service, based on assumption of well-equipped pharmacies.

Components of the setup cost include:

   i. ‘FRED Dispense®’, pharmacy dispensing program (a pre-requisite for MedeMineCVD; assume shared cost of $100).
   ii. MedeMineCVD, software to identify patients who are using or have used antihypertensive medicines in the past (provided for free in the research, assume licence fee $100 per site).
   iii. Cost for setting up or modifying a private counselling area within the pharmacy. (This was included in the $500 paid to each pharmacy in the project, but may vary from $0 to $500 e.g., a table/desk, two chairs, one screen, signage, a power point –assume $100) NOTE: Most community pharmacies have QCPP accreditation, which requires a private counselling area, which would be used for multiple services.
   iv. Pharmacists training time either face-to-face or online. Assume 1 (or 2) pharmacist(s) for one half-day training.
   Time cost to the participating pharmacist is estimated to be $250 (or $500), including salary and travel expense.
   v. Administrative overheads associated with participating in the project and preparing for and organising related activities. Assume pharmacy manager/pharmacist spent 14 hours (two working days) in total. Cost is estimated to be $700 (i.e., $50*14)
   vi. BP monitor for pharmacy. Cost is $115
   vii. Other small items and fees: IT related costs, communications, meetings…etc, assume $100 in total.

With reference to other Pharmacy Guild projects like PMP, the set-up cost is estimated as around $1, 400 per pharmacy.

2. Training program setup and delivery cost was estimated to be AU$17,000, divided by total 207 patients in PCG and amortised to 3 years.
3. Pharmacist service time cost for the intervention was based on time spent for the intervention (mean 22.9 ±12.4 minutes, i.e., time for collecting research data has been excluded); salary information used was that published by APESMA together with 40% on-cost. Average hourly rate was $52.53 (including on-cost). It was assumed that pharmacists provided service every three months. For the first appointment, pharmacists spent more time on educating patients, which would cost $60.10 on average in the first six-month period, and $40.10 for any other period of six months.
4. BP monitor cost was not retail cost and was GST exempt. Model number is Omron HEM-790IT. Price was $115, amortised to 3 years with annual cost of $38.30. For six months, the cost was $19.17.
5. Unit costs of medicines were from PBS website: www.pbs.gov.au. MedsIndex was used to adjust the amount of medicine dispensed to each patient.
6. GP cost was the sum of the patient’s out-of-pocket expenses and provider cost. The average provider cost was $34.30, according to the Medicare Benefits Schedule.
7. ED visit cost was the sum of the patient’s out-of-pocket expenses and provider cost. The average provider cost was $407, according to National Hospital Cost Data Collection round 12.
8. Inpatient stay cost was the sum of patient’s out-of-pocket expenses and provider cost. The average provider cost was $5,356 according to National Hospital Cost Data Collection round 12.
**Analysis of effectiveness**

The changes in utility scores for patient quality of life, as measured by AQoL8 over the six-month period, are illustrated in Table 8.

**Table 8: AQoL8 utility scores generated from Pharmacy Care Group (PCG) and Usual Care Group (UCG)**

<table>
<thead>
<tr>
<th></th>
<th>PCG</th>
<th>UCG</th>
<th>Total</th>
<th>p (t-Test)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean</td>
<td>SD</td>
<td>N</td>
</tr>
<tr>
<td>Baseline</td>
<td>192</td>
<td>0.71</td>
<td>0.24</td>
<td>180</td>
</tr>
<tr>
<td>Six Months</td>
<td>176</td>
<td>0.70</td>
<td>0.28</td>
<td>171</td>
</tr>
<tr>
<td>Total</td>
<td>368</td>
<td>0.70</td>
<td>0.26</td>
<td>351</td>
</tr>
<tr>
<td>t-test</td>
<td></td>
<td>p=0.725</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The quality of life utility scores were identical in the PCG and UCG at baseline. At the six-month follow-up, the utility score of the PCG had decreased by 0.1 and the utility score of the UCG had increased by 0.1. The differences were not statistically significant either within or between groups. Therefore, the average score (0.71) of the four scores was used for adjusting the life-years (LYs) gained in the economic model.

The economic model in this study is built on the findings of Sesso et al. The estimations of life-year gain and related cost in the 10-year period between the PCG and the UCG are illustrated in Table 9.

**Table 9: Results of cost-effectiveness analysis for PCG and UCG (Australian dollars, 2009)**

**1 Year scenario**

<table>
<thead>
<tr>
<th></th>
<th>PCG</th>
<th>UCG</th>
<th>Incremental</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discounted total cost</td>
<td>$1469.54</td>
<td>$1410.74</td>
<td>$58.80</td>
</tr>
<tr>
<td>Discounted QALYs</td>
<td>0.0549</td>
<td>0.0456</td>
<td>0.0093</td>
</tr>
<tr>
<td>Incremental cost per QALY</td>
<td>-</td>
<td>-</td>
<td>$6,322.58</td>
</tr>
</tbody>
</table>

**10 years scenario**

<table>
<thead>
<tr>
<th></th>
<th>PCG</th>
<th>UCG</th>
<th>Incremental</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discounted total cost</td>
<td>$13,333.99</td>
<td>$12,957.61</td>
<td>$376.38</td>
</tr>
<tr>
<td>Discounted QALYs</td>
<td>0.5491</td>
<td>0.4556</td>
<td>0.0935</td>
</tr>
<tr>
<td>Incremental cost per QALY</td>
<td>-</td>
<td>-</td>
<td>$4,025.45</td>
</tr>
</tbody>
</table>

Note: 1. Discount rate is 5%
2. Inflation rate is 3%

**Analysis of cost-effectiveness**

The expected life-year gain for each patient in the PCG and the UCG was calculated based on age of the patient, gender, baseline systolic BP, six-month systolic BP and whether the patient had diabetes. The life-year gain was then adjusted by the utility score of 0.71 to become QALYs gained. The QALYs gained each year is assumed to be equal in each year during the 10-year period. It is further discounted by 5% to the baseline year and added to become total life-years gained over the 10-year period. The results of QALYs gained for one year and 10 years are reported in Table 9. The costs for the PCG and the UCG were calculated and compared using a similar process, but with 3% inflation each year forward. As shown in Table 9, the incremental cost per QALY gained is AU$6,322.58 for one year and AU$4,025.45 for the 10-year period.

The sensitivity analysis (Table 10) performed for each of the key parameters has shown the robustness of the cost-effectiveness of this intervention. The range of cost per QALY gained is from AU$524.80 to AU$7,527.29.

**Table 10: Sensitivity analysis of cost-effectiveness between PCG and UCG (Australian dollars, 2009)**
The threshold analysis (11) provides information on the maximum setup cost that the intervention can still be considered as cost-effective based on threshold A ($50,000) and threshold B ($70,000). For threshold of $50,000, the setup cost must not exceed $9,823 and for threshold of $70,000 the setup cost cannot exceed $13,487 if the intervention is considered to be cost-effective.

<table>
<thead>
<tr>
<th>Table 11: Threshold Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Set up cost</td>
</tr>
<tr>
<td>$500</td>
</tr>
<tr>
<td>$1,400</td>
</tr>
<tr>
<td>$9,822.60</td>
</tr>
<tr>
<td><strong>Threshold</strong></td>
</tr>
</tbody>
</table>

**Economic Evaluation Summary**

The economic evaluation in this trial has estimated and compared both cost and QALYs gained due to the intervention between the PCG and the comparator (UCG). The ICER has demonstrated that the intervention is highly cost-effective compared to usual care. In this trial, the cost is AU$6,322.58 per QALY for the one-year scenario and AU$4,025.45 per QALY for the ten-year scenario, which is considered highly cost-effective when compared to the gold standard of AU$70,000 per QALY gained. Due to the fact that setup cost can impact on the cost-effectiveness of this intervention if it is to be rolled out nationally, a further threshold analysis shows the maximum setup cost should be kept under $9,823 (at threshold of $50,000) or $13,487 (at threshold $70,000).

**Results – Business Case Evaluation**

**Part I: Evaluation based on quantitative data**

1. *Are the trial intervention services performed by community pharmacists cost-effective in hypertension management?*

The Economic Evaluation provides a sound foundation that community a pharmacist-led service can be an important intervention for at-risk patients to gain a better understanding of their BP management and to reduce BP.

2. *What is the cost to the pharmacy for setting up this service?*
Set-up cost is the initial investment to provide a specific service; the setup cost includes: (1) shared cost for ‘FRED Dispense®’; (2) MedeMineCVD, software to identify patients who are using or have used antihypertensive medicines in the past; (3) Cost for setting up a private counselling area within the pharmacy; (4) Pharmacists’ training time cost either face-to-face or online; (5) Administrative overheads associated with participating in the project and preparing for and organising related activities; (6) BP monitor for pharmacy; (7) other small items and fees; IT related costs, communications, meetings…etc. The set-up cost is estimated at around $1,400 per pharmacy. (See Notes to Table 7 for details)

3. What is the cost to the pharmacy for providing this service?

The cost of providing the service is mainly the time spent by the pharmacist to deliver the service to the patient. The service on average takes 45 minutes for the initial visit and 23 minutes for the follow-up visits. Thus, the cost per visit is around $25 to the pharmacy.

There was no statistically significant difference in WTP by PCG participants between baseline and six months. However, the median and mode values changed dramatically. The changes in willingness to pay and other business case statistics are presented in Table 12.

Table 12: Results of business case evaluation

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Baseline Data</th>
<th>6 Months Follow-up</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mean ± SD; median; mode</td>
<td>mean ± SD; median; mode</td>
<td>(paired t-test)</td>
</tr>
<tr>
<td>WTP (n = 142)</td>
<td>$17.40 ± $16.98 ($10: $0)</td>
<td>$18.89 ± $17.39 ($20: $20)</td>
<td>0.108</td>
</tr>
<tr>
<td>Satisfaction (1~7) (n = 184)</td>
<td>6.7 ± 0.6 (7:7)</td>
<td>6.8 ± 0.5 (7:7)</td>
<td>0.170</td>
</tr>
<tr>
<td>Shopping frequency (in six months) (n = 188)</td>
<td>13.0 ± 6.9 (13:13)</td>
<td>12.6 ± 6.8 (8.7:8.7)</td>
<td>0.292</td>
</tr>
<tr>
<td>Spending per visit (n = 172)</td>
<td>$80.42 ± $110.67($36.25:$20)</td>
<td>$87.11 ± $129.72 ($32.50:$20)</td>
<td>0.187</td>
</tr>
</tbody>
</table>

After experiencing the service, the consumers’ most often reported willingness to pay was AU$20; however, the total cost of providing this service is higher. Consumers’ willingness to pay for this service can recover the variable cost. The fixed cost of providing this service remains to be covered via other sources of funding, presumably by the individual pharmacy. The satisfaction of PCG patients at the six-month follow-up visit increased slightly from 6.7 to 6.8. Since satisfaction at baseline was already high, the room for increase in satisfaction was very limited.

The service had not resulted in significantly more business to the pharmacy in the six-month period. The frequencies of shopping and spending at the pharmacy each time are very similar between the baseline and the six-month follow-up. The mean spending per visit seems somewhat inflated when compared to usual spending habits of consumers. A likely explanation may be misinterpretation of the question by the consumers. However, as the two figures at baseline and six-month follow-up are very similar, it can be assumed that the misinterpretation occurred at both stages and therefore, the difference between the two points in time, which is not statistically significant, is still valid.

4. Who should pay for the service and how should it be financed?

WTP normally reflects the benefits the consumer believes they could receive. In addition, this new pharmacist service could be expected to produce “positive externality” to the market of which the consumer may not be aware.

Part 2: Evaluation based on qualitative data

The HAPPY Trial was perceived as being able to increase a pharmacy’s competitive advantage by attracting patients who value this new service, as well as increasing pharmacist’s dignity and satisfaction with their work. GPs perceived that this new service would assist GPs to better manage patients’ BP.

There were other perceived benefits to the wider society by increased workforce productivity and reduced cost to the Australian health care system.

Some pharmacists perceived that the funding of this service should not rely only on the patient’s willingness pay, but that the government also has a role in this respect. Further, attracting patients at risk who do not seek health professional care was also raised.
**Business Case Summary**

The business case investigated the set-up costs of well-equipped pharmacies and patients’ willingness to pay. The set-up cost should be considered carefully if the new service is to be rolled out for less-equipped pharmacies in the future. Patients are willing to pay around AU$20 for the new service and the remaining cost is appropriate to be subsidised by the government on the grounds of positive externality to the wider society in Australia.

**Phase 4**

**Stakeholders Post-trial Focus Groups and Interviews**

Twelve pharmacists, 13 consumers and three GPs participated in focus groups or telephone interviews. The pharmacists and consumers were drawn from across the PhARIA distribution. Further, a spread of pharmacies in the HAPPY Trial service was targeted to ensure consumer experiences were from a broader base. Focus guides were used for each stakeholder group (Appendices 12-14).

Overall, the HAPPY Trial was positively received by all stakeholder groups. Distance education was a well-accepted tool for training pharmacists. Motivational interviewing was an area which pharmacists believed needed to be covered more extensively. This is backed up by the training assessment where one of the motivational interviewing questions was only answered correctly by 50% of participants. Therefore, future training courses will need to dedicate more time and practical exercises to motivational interviewing.

MedeMineCVD can be a useful tool to identify nonadherent or nonpersistent consumers. However, using dispensing data from only one pharmacy may lead to inaccurate identification of nonadherence or nonpersistence. Difficulty arises from privacy laws, which preclude sharing of dispensing data among pharmacies. To select consumers most at need of this service, additional ways to assess nonadherence or patient suitability may need to be used in conjunction with MedeMineCVD. This may involve greater input from pharmacists at the selection stage or GPs referring patients to the pharmacy.

The HAPPY Trial was positively received by all stakeholder groups. Pharmacist and consumer satisfaction with the service was high. In fact, every component was so highly regarded that most could not think of any ways to improve the service. The length of the data collection instruments was seen as the only negative impact on the service, as the instruments prolonged the interview time, and some questions were considered overly personal. In future implementation of this service, many of the questions which have only been included for research purposes and do not impact upon the service should be omitted from the forms to reduce the consultation time.

Ideally, it was thought that pharmacists should provide the HAPPY service. It was commonly recognised that GP resources were stretched and extension of their current services may be not be possible. Pharmacies were seen as a relaxing environment, and pharmacists seen as approachable. For the same reason, expecting substantial pharmacist–GP collaboration in delivering such an intervention is probably not feasible.

While GPs believed that a pharmacist-led educational program would be beneficial to the patient, the issue of information sharing between the two professionals was once again raised, as in the pre-trial focus groups. While all GPs had received some information either at the beginning of the trial from pharmacies or by feedback from the patient, more formalised and personalised communication is required. In future rollout of the HAPPY service, pharmacists should be supplied with formal referral slips to share relevant information with GPs.

It was evident from the qualitative information that, while pharmacists and consumers believed patients were mostly adherent, the HAPPY Trial has been instrumental in helping patients to gain better understanding to manage their BP and resulted in medication or lifestyle changes that enabled better control. The most important components were identified as consumers monitoring their own BP regularly and the education they received from the pharmacists. Most consumers felt they had been given the tools to have a greater input into their BP management.

Unfortunately, not all consumers had the same beneficial interactions with their pharmacist or received the interventions as intended. As is the case with any service, there will be variability among service providers. However, for those patients, it shows that BP monitor supply alone may be insufficient to give them the same understanding and BP control as when monitor supply is coupled with pharmacist education. Therefore, the pharmacist–consumer interaction is an important component of the intervention package. Accreditation of pharmacists to supply the service should address this issue of varying standards in any future rollout of the service.

The future supply of free BP monitors was questioned, and while they are an important component of this service, most believed that monitors should not be supplied free of charge, as the service value may be diminished by consumers participating solely to receive a free monitor.
Overall Summary

The research objective was to test a specific intervention package that could be integrated into the community pharmacy workflow to enable pharmacists to improve patient adherence and/or persistence with antihypertensive medications. A number of specific research questions were posed.

Can the proposed intervention package service, compared to usual care, improve patient adherence and/or persistence with antihypertensive medications?

The proportion of participants who were judged to be adherent by the Morisky score increased in both groups from baseline to six months, but there was no significant difference in adherence rates between the groups. It was observed in both groups that, while some individuals achieved improved adherence, others became nonadherent, meaning that a connection between the intervention and improved adherence cannot be made.

Similarly, while significant improvements in adherence occurred in the PCG on a number of measures of adherence, no significant differences between the groups were demonstrated. It cannot, therefore, be concluded that the intervention resulted in improved adherence in comparison to usual care.

Subgroup analysis of participants who were identified as nonadherent (by Morisky score) at baseline showed a significant improvement for the PCG over the UCG in the TABS adherence score. In the subgroup of nonadherent consumers (by Morisky score) who also had above target BP, the difference in the TABS adherence scores between PCG and UCG fell just short of significance. While the PCG in both subgroups demonstrated significant improvements in the Morisky score and MedsIndex score from baseline to six months, differences between the groups were only significant for the subgroup of participants who were nonadherent and above target BP.

Subgroup analysis of participants who were above their target blood pressure at baseline showed significant improvements in Morisky score and the MedsIndex score for the PCG group at six months, but the differences compared to the UCG were not significant at the 5% level.

Can the proposed intervention package service, compared to usual care, improve patients’ blood pressure control?

While significant decreases in both diastolic and systolic BP were observed in both groups, the intervention was associated with a significantly greater reduction in mean systolic blood pressure in comparison to usual care. The change in the PCG was -10 mm Hg.

Subgroup analysis of the participants who were nonadherent at baseline showed a decrease in systolic blood pressure in the PCG group of the order of 13 mm Hg, which was significantly greater than the drop in the UCG. The literature indicates that this degree of change in systolic blood pressure could be associated with reduced cardiovascular risk if it were able to be sustained.

Subgroup analysis of participants who were above target blood pressure at baseline showed a decrease in systolic blood pressure in the PCG group of the order of 16 mm Hg and 20mmHg in those who were also nonadherent according to Morisky score at baseline. These reductions were significantly greater than the drop in the UCG and suggest that patients with blood pressure above target may achieve even greater long-term health benefits from the intervention.

Even though improvement in adherence was not demonstrated, the intervention has shown potential to reduce cardiovascular risk. Whether or not the self-reported adherence measures were sensitive enough to measure a change in adherence, the intervention has resulted in behaviour change that has improved blood pressure control.

Can the proposed intervention package service, compared to usual care, change patients’ health beliefs and attitudes?

There were no significant changes in the health beliefs and attitudes of participants between groups at baseline or six months, as measured by the subsections of the BBQ, although there was a tendency towards greater increase in ‘confidence’ following the intervention than after usual care.

This is supported by comments from focus group discussions and interviews with consumers following the trial, most of whom were very pleased with the service and also with the personal results they achieved. They reported that the service had facilitated better understanding and helped them achieve better control of their blood pressure.

Can the proposed intervention package service, compared to usual care, improve patients’ quality of life?
The changes in utility scores for patient quality of life, as measured by AQoL8, were not significantly different within or between groups over the period of the trial. The AQoL8 is a measure of general quality of life. While it is preferable to use disease-state specific QoL measures, it is not surprising that none exists for hypertension, as it is a largely symptomless condition with minimal expected impact on QoL.

Can the proposed intervention package service, compared to usual care, generate more benefit at a cost (i.e., the Incremental Cost-Effectiveness Ratio, ICER) that is reasonable and acceptable to the Australian society?

According to the results shown by the ICER, the intervention is highly cost-effective, because the cost per Quality-Adjusted Life-Year (QALY) gain of AU$6,322.58 is far less than the benchmark AU$70,000 accepted by the Australian government.

Are consumers and other stakeholders (Pharmacists and GPs) satisfied with the service?

Since consumer satisfaction with the pharmacies was already high at baseline, there was little room to demonstrate improvement quantitatively. This is often the case in research of this nature, as consumers may be satisfied with what they are receiving without realising what they could potentially receive.

The qualitative focus groups and interviews revealed that the HAPPY Trial was positively received by all stakeholder groups. Pharmacist and consumer satisfaction with the service was high. Every component was so highly regarded that most could not think of any ways to improve the service. Some criticism was made of the time taken for data collection, but this could be reduced when implementing a program, as some data were collected for research purposes only. Consumers thought it appropriate and convenient that the service be offered through community pharmacies.

The HAPPY Trial was seen to have been instrumental in helping patients to gain better understanding of their BP and to manage it better through medication and/or lifestyle changes. Most consumers felt they had been given the tools to have a greater input into their BP management.

Can the service be readily implemented within the current community pharmacy structure?

The focus group discussions and interviews with consumers, pharmacists and GPs prior to the trial indicated that consumers viewed community pharmacies as a comfortable and convenient place for the service to occur. Pharmacists felt that, with appropriate training, they were capable of delivering the service. GPs emphasised the need for a teamwork approach to ensure patients were referred back to them for more complex issues.

Lack of adequate space within some pharmacies to conduct private consultations was mentioned by stakeholders as a barrier to offering any pharmacy service focusing on chronic disease management because of risks to patient confidentiality. Pharmacies accredited under the Quality Care Pharmacy Program (QCPP) – a high proportion of community pharmacies – are required to have such an area; however, in some cases this may not have been considered adequate by consumers. An initial investment may need to be made to set the pharmacy up appropriately. This was addressed in the trial by giving pharmacies a small allowance for the purpose.

The main facilitator for successful implementation of a community pharmacy adherence program was seen to be remuneration for pharmacists at a level at least equivalent to what could be earned by the pharmacy for dispensing prescriptions in the same time period. In the trial, pharmacists were remunerated per patient according to the expected time involved.

Pharmacists believed that the MedeMineCVD software was a useful organisational tool during the trial, assisting them to follow the trial protocol and helping with the printing of recruitment letters and data collection forms. If the service were to be implemented, MedeMineCVD will be a useful tool to identify potential participants and preferably should be embedded into dispensing software programs to allow seamless integration of the intervention package into the community pharmacy workflow. MedeMineCVD would also need to be adapted to suit the delivery of the service rather than the requirements of the research, which is its current purpose, i.e. not all the forms that are currently generated would be required.

Some difficulties with recruitment were described, however, in that a higher proportion of patients were reported being adherent at baseline than expected. Considering the highly effective reduction in systolic BP in subgroup analyses, screening for eligibility using Morisky score and/or control of blood pressure relative to target, after identification by MedeMineCVD (or an adaptation) may be useful strategies with which to better target potential recipients of the service.

The time taken for appointments was seen as a barrier, particularly in relation to the length and nature of some of the questionnaires. While most pharmacists did not need to make changes to day-to-day operation of the pharmacy in order to participate in the trial, they aware that the time involved posed a strain on other pharmacy staff. Some
pharmacists had to organise patient appointments only when extra assistance was available, or after hours. The duration of appointments should readily be able to be reduced for service implementation, by omitting questions required for research purposes only e.g. some of the demographic information, quality of life and business case questions should be removed. For implementation of the service, pharmacists should also record a patient’s BP, adherence issues, risk factors and pharmacist plan of management.

What is the consumer’s willingness to pay for the service?
Consumers indicated that, on average, they would be willing to pay $20 per month for the service.

Is there an economically viable business case for the service?
The service did not demonstrate any tangible financial benefit to the pharmacy. Pharmacists, however, commented on the value such services have in building customer loyalty.

Strengths

In designing the HAPPY trial, several innovative strategies were included:

- use of MedeMineCVD to identify potential participants;
- use of MedeMineCVD to simplify the administrative load of the pharmacists;
- provision of pharmacist education in face-to-face, print and online modes;
- provision of home BP monitor to usual care patients at the conclusion of the trial; and
- an offer for usual care patients to receive the intervention service from the pharmacist at the conclusion of the trial.

The intent of these strategies was to optimise recruitment and retention of both pharmacists and patients in the trial. Sixty pharmacies were recruited, but five withdrew prior to commencement. Another pharmacy withdrew after baseline data collection due to change of ownership. Retention rate was 98.2% (54/55). Retention of patients was 86.0% in the PCG and 93.6% in the UCG at six months.

In addition, a hidden control group was identified in the UCG pharmacies to allow comparison of measures of adherence (MedsIndex and MPR) available from dispensing histories within the pharmacy where the patient was recruited. This feature of the methodology is not usually feasible and represents an innovative approach. While insignificant differences between the groups do not guarantee that a Hawthorne effect has not occurred, it provides at least some measure of comparison between usual care and a true control.

Limitations

Although MedeMineCVD identified patients apparently experiencing problems with adherence or persistence to their medications, high proportions reported adherence at baseline. This may be due, in part, to the incomplete data available from one pharmacy. Given the large number of potential participants who were sent invitations to participate and the small numbers responding, the sample may be biased towards those who were already interested in managing their medicines to best advantage.

The calculated sample size of 182 participants in each group was not quite achieved. Assumptions made in the sample size calculation were not observed in the study i.e. the adherence at baseline was greater than 50%, adherence in the intervention group did not increase by 15% and adherence also increased in the usual care group. Experience from this trial will inform calculation of sample size for future studies.

As with all studies of adherence, there is no gold standard for measurement. Self-reported measures are subject to the Hawthorne affect and to recall bias. Calculations from refill data are limited by incomplete information, given that records are not linked between pharmacies, and by the assumption that if the patient has collected the medicine they have actually taken it as prescribed.

Conclusions

As no significant differences between the groups were demonstrated for any of the adherence measures, it cannot be concluded that the intervention was responsible for improved adherence in the PCG in comparison with the UCG. However, the intervention must have resulted in a change of behaviour in consumers, as a change in mean systolic blood pressure that was significantly greater in PCG than UCG patients was achieved. The magnitude of the mean change appears capable, if sustained, of reducing longer-term cardiovascular risk. In a clinical sense, this is a more important outcome than improving adherence alone. The intervention was evaluated as highly cost-effective.
Future Implications

For potential future implementation of the HAPPY service, the main focus may need to shift from improving medication adherence to reduction of BP. In order to optimise the effect of the intervention, it would be useful to test the effect of a two-stage identification and screening process for assessing eligibility to participate in the program. A software application such as MedeMineCVD, adapted to suit the service rather than the research, could be used to flag patients who are likely to benefit from an intervention. Further screening could be performed using Morisky scale and BP measurement. If nonadherence is evident and/or BP is above target, the patient would be eligible to enrol in the program. However, this may need to be tested in large RCTs before wider implementation through community pharmacies.

Further, for successful implementation of the service:

– Pharmacists require appropriate and accredited training to deliver the service;
– Pharmacies will be expected to have the space to conduct private consultations;
– Pharmacists require appropriate remuneration to provide the service;
– MedeMineCVD is a useful tool to identify potential participants and to assist pharmacists with administrative tasks; however it would need to be amended to be suitable for service provision as opposed to research purposes and preferably should be integrated into the dispensing software.
– Data collection will need to be reduced to focus on service aspects and not research.
References


54. Hawthorne G, Choosing between the different versions of the AQoL(Assessment of Quality of Life) instruments. (Unpublished manuscript). Dr. Arthur Hsueh personal communication with the author on 24th April 2009


Appendix 1:
Phase 1 – Systematic Review Search Terms and Criteria

A systematic review of published studies describing cardiovascular disease programs, with a focus on those studies that are relevant to the following, has been undertaken:
- community pharmacy
- management of hypertension
- adherence / persistence

The review has used the following sources:
- MEDLINE
- International Pharmaceutical Abstracts (IPA)
- Cochrane library
- EMBASE
- INFORMIT
- CINAHL
- Kinetica search strategy

All studies identified as relevant have been entered into an Access database and these have then been reviewed independently by two researchers, with the evidence graded according to standard NHMRC criteria.

Meta-analysis of the studies was not considered appropriate due to the diversity of methods and outcomes used.

Following the review and grading of evidence, any discrepancies were resolved through consensus and where necessary with the involvement of a third researcher. The final product is an electronic, searchable database of relevant articles, including an assessment of the quality of studies.

The literature search was partly developed from previous work done by the UMORE team as part of the Pharmacy Cardiovascular Health Care Model 2005. The broad terms of this previous work meant that any literature published prior to 2005 and relevant to the current study would already be available to the research team.

Consequently, the new searches were carried out with the publication date range limited to 2005 to 2008. In addition, a robust review of the reference lists of all papers identified through the database searches, was conducted to provide further re-assurance that all relevant material was identified.

It had been planned to include the Community Pharmacy Research Database in this literature review, however this database has consistently been out of service during the time this review has been undertaken.

**Medline**
via PubMed

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Kinnetica
Incorporated in National Library of Australia

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Appendix 2:  
Phase 2 - Focus Group Guide  
Introduction to topic:

Cardiovascular disease (CVD) is a major cause of illness, disability and death in the Australian community.

High blood pressure (BP) is known to be an important risk factor for development of CVD.

High blood pressure can be controlled by attention to diet and exercise and by taking medicine.

One of the biggest hurdles is that most people do not take their medicines in the best way all the time. Who might be able to help them? e.g. with practical hints, education, motivation

Leads into community pharmacists having the drug knowledge

Other advantages of running a service through community pharmacies e.g. readily accessible, seen frequently, previous successful examples of disease state management models run by community pharmacists.

What could community pharmacists provide? e.g. (prompt if not forthcoming)

- Education on importance of controlling BP
- Working with the patient to understand reasons behind nonadherence and developing strategies to improve adherence
- Monitoring adherence
- Education and support for patients to monitor their blood pressure at home

What would make it easy for a service to be provided from this source? (Facilitators)

- Pharmacists remuneration, sufficient trained staff, collaboration with doctor and patient as a team
- Doctors remuneration
- Patients convenient location, low cost, privacy

What would make it difficult? (Barriers) e.g. (from previous experience)

- Pharmacists lack of time, money, expertise
- Doctors my job, not pharmacists, patient could get mixed messages
- Patients may not recognise the need, time, cost, lack of privacy

How could these barriers be overcome?

- Training, remuneration, partnerships, load sharing,

How could a useful, practical service through community pharmacies be achieved? e.g.

- Recommendations for meeting these challenges
- Ideas for wider implementation of the service
- Strategies for improving acceptance of the service by patients and health professionals, especially GPs.
Appendix 3:
Phase 3 - Pharmacy Eligibility Form

COMMUNITY PHARMACY INVOLVEMENT IN PREVENTION OF CARDIOVASCULAR DISEASE
Pharmacy Screening Questionnaire

Pharmacy Name: __________________________________________
Pharmacist’s Name: _______________________________________
Date: __________________________

1. Do you use ‘FRED Dispense’ OR ‘Fred Health’ in your pharmacy?
   □ Yes  □ No  (ineligible to participate in the study)

2. Are you happy to install a software application (MedeMine) on your dispensing computer to identify patients who are using or have used antihypertensive medicines in the previous six months?
   (NOTE: This software is used in different states without any problems in speed or compatibility)
   □ Yes  □ No  (ineligible to participate in the study)

3. Do you have AT LEAST 40 patients who are currently using or have used ANY ONE OR MORE of the following antihypertensive medicines in the last 6 months?
   • Angiotensin Converting Enzyme Inhibitors
   • Angiotensin-II Receptor Antagonists
   • Calcium Channel Blockers
   • Beta Blockers
   • Thiazide Diuretics
   □ Yes  □ No  (ineligible to participate in the study)

4. Do you have private counselling area within your pharmacy where one-on-one consultation with a patient will be shielded from public eye and ear?
   □ Yes  □ No  (There is $500 allocated to each pharmacy to help in securing a private area)

5. As the initial consultation with each patient may take up to one hour, do you have time within your working week to allocate this amount of uninterrupted time to the patients?
   □ Yes  □ No  (ineligible to participate in the study)

6. The end of this project will approximately be in February 2010. Are you aware of any possible changes in the pharmacy which may affect your ability to participate in this study for this duration?
   □ Yes (not ineligible, however cautious to include)  □ No

8. Do you have access to MedsIndex? (This can either be already installed on the computer or in disk format. Eligibility of participation is not depended on pharmacies having their own copy of MedsIndex.)
   □ Yes  □ No

9. Will your pharmacy likely participate in the MIRIXA project which will be rolled out by the Pharmacy Guild?
   □ Yes  □ No

10. Does your pharmacy use a SMS reminder for prescriptions service?
    □ Yes  □ No
Appendix 4:  
Phase 3 – Assessment of Knowledge form (PCG)

INCREASING COMMUNITY PHARMACY INVOLVEMENT IN THE PREVENTION OF CARDIOVASCULAR DISEASE

ASSESSMENT QUESTIONNAIRE (PCG):

Name: _______________________________________________

Pharmacy Name: ______________________________________

1. Hypertension is defined as blood pressure measurements which are consistently:
   a. 120mmHg or greater systolic or 80 mmHg or greater diastolic
   b. 120mmHg or greater systolic and 80 mmHg or greater diastolic
   c. 140mmHg or greater systolic or 90 mmHg or greater diastolic
   d. 140mmHg or greater systolic and 90 mmHg or greater diastolic

2. Which of the following is NOT recommended when measuring a patient’s blood pressure:
   a. Making sure the patient is sitting quietly for a few minutes
   b. Advising the patient to skip their blood pressure medications on the day of assessment
   c. Advising the patient to wait until 2-4 hours after taking antihypertensive medicines before taking BP at home
   d. Raising the patient’s arm so the cuff is at the same height as the heart

3. Patients are considered at high risk of cardiovascular disease if their five year risk of fatal or nonfatal cardiovascular risk exceeds:
   a. 5%
   b. 10%
   c. 15%
   d. 20%

4. Which of the following drug classes is not considered a preferred antihypertensive agent for patients over 65 years and with no co-morbidities:
   a. Thiazide diuretics
   b. Beta blockers
   c. ACE inhibitors
   d. Calcium channel blockers
5. If a patient is unresponsive to monotherapy initiated with a single antihypertensive agent, what course of action should be taken:
   a. Add a second agent
   b. Increase the dose
   c. Increase the dose and add a second agent
   d. Withdraw the first drug and initiate an alternative antihypertensive drug

6. Which of the following combinations of drugs is considered safest and most effective in the absence of complicating factors:
   a. ACE inhibitor plus calcium channel blocker
   b. ACE inhibitor plus Angiotensin II receptor antagonist
   c. ACEI/AlIIRA plus K-sparing diuretic
   d. Verapamil plus beta-blocker

Mr Smith is a 67 year old retiree who lives alone. He takes some over the counter (OTC) medications for his arthritis. He has a history of depression, but is currently not on any medications for this. He takes Cozaar (losartan) 50 mg in the morning for his high blood pressure (BP). Mr Smith usually takes Cozaar after breakfast, but he has no set routine. He occasionally misses the dose, but he thinks it is not a 'big deal'. He does not have a home blood pressure monitor.

Mr Smith's GP is always busy and he sees Mr Smith for barely 10 min every 3 months. The GP is not aware of Mr Smith's noncompliance and his use of OTC medicines. Mr Smith's BP has lately been uncontrolled and his GP is considering an increase in the dose of Cozaar. Mr Smith usually gets his prescriptions dispensed at the Getwell pharmacy where you are the pharmacist in-charge.

(Question 7 & 8 refer to this case study)

7. Which of the following is NOT a risk factor by itself for noncompliance in Mr Smith?
   a. He is 67 years old
   b. He has no set routine for taking his medication
   c. His GP is very busy and has little time for discussing compliance issues
   d. He has a history of depression, but is currently not on any medications for this
   e. He gets no regular feedback about his BP control

8. Which of the following compliance interventions is NOT ideal in Mr Smith?
   a. Reminders (SMS or telephone) when refills are due
   b. Home blood pressure monitoring
   c. Dose administration aid
   d. Medication use review
   e. Routinisation
9. Please tell us whether each of the following statements are TRUE OR FALSE
   a. Non-persistence refers to the discontinuation of treatment by a patient earlier than intended by their health professional
   b. Adherence (compliance) improves consistently with the severity of the disease
   c. Electronic monitoring is the ‘gold standard’ for measuring adherence

10. Motivational Interviewing is
    a. Changes imposed on a passive client by an expert
    b. Manipulative didactic arguments that maintain control
    c. The use of behavioural penalties to elicit changes
    d. Achieving change by encouraging intrinsic cognitive-emotional problem-solving
    e. None of the above

11. The OARS Model utilises
    a. Reflective listening
    b. Reflective listening and summarising
    c. Open-ended questioning and affirming support
    d. Addresses resistance and ambivalence
    e. All of the above

12. In the recruitment of patients, after patients have been identified by MedeMine what is the next step?
    a. Look at identified patients and exclude those that you know would not be eligible
    b. Print individual Expression of Interest (ESI) forms
    c. Mark patient as “EOI” returned
    d. Print a batch of EOI forms

13. Before you can begin collecting data at baseline, what things must be completed?
    a. Indicate in MedeMine that Consent form has been signed
    b. Patient Consent form signed by patient
    c. Data collection forms printed
    d. GP Faxback form returned from GP
    e. All of the above

14. Regarding patient prescription reminders, please tell us if each of the statements are TRUE or FALSE
    a. Patient can have any combination of reminders (SMS, letter or phone)
    b. SMS reminders will be automatically sent by MedeMine
    c. MedeMine will automatically ring patients who have chosen phone reminders
Appendix 5:
Phase 3 – Assessment of Knowledge form (UCG)

INCREASING COMMUNITY PHARMACY INVOLVEMENT IN THE PREVENTION OF CARDIOVASCULAR DISEASE

ASSESSMENT QUESTIONNAIRE (UCG):

Name: _______________________________________________

Pharmacy Name: ______________________________________

15. In the recruitment of patients, after patients have been identified by MedeMine what is the next step?
   a. Look at identified patients and exclude those that you know would not be eligible
   b. Print individual Expression of Interest (EOI) forms
   c. Mark patient as “EOI” returned
   d. Print a batch of EOI forms

16. Before you can begin collecting data at baseline, what things must be completed?
   a. Indicate in MedeMine that Consent form has been signed
   b. Patient Consent form signed by patient
   c. Data collection forms printed
   d. GP Faxback form returned from GP
   e. All of the above

17. Please indicate whether each of the following statements is TRUE or FALSE
   a. After the baseline appointment if you have identified adherence issues you should not take any action to improve adherence.
   b. Despite being in a control group, if the patient has uncontrolled high blood pressure you should refer them to the GP.
   c. All recruited patients in the Usual Care Group will receive the project interventions after the 6-month trial
Appendix 6:
Phase 3 - General Practitioner Letter and Faxback Form

<proprietor name>
<pharmacy name>
<pharmacy address>
<pharmacy suburb>
<pharmacy state>   < postcode>
Ph: <ph num>  fax: <fax num>

COMMUNITY PHARMACY INVOLVEMENT IN PREVENTION OF CARDIOVASCULAR DISEASE —
INTERVENTION TRIAL

Today’s date

Dear Doctor

<Pharmacy Name> is participating in a research project with the Faculty of Pharmacy and Pharmaceutical Sciences, Monash University. The aim of this project is to develop and test specific intervention strategies to enable pharmacists to support consumers to improve their adherence and/or persistence with antihypertensive medications and thus improve their blood pressure control.

Pharmacies have been randomly allocated to one of two groups. One group will undertake consultations with participants at baseline, three months and six months after the initial consultation. The second group will undertake consultations at baseline and again six months later. Participants will be provided with a blood pressure monitor either at the start of the project or towards the end of the project (depending on which group they are allocated to) and asked to check their blood pressure at home between visits. The project is supported by the Victorian Divisions of General Practice and has received ethical approval from Monash University’s Standing Committee on Ethics in Research Involving Humans.

To be eligible to participate in the research project, consumers must have a diagnosis of primary hypertension and be on prescribed medication for its treatment. Pharmacists will refer patients to you if problems are detected, such as poorly controlled blood pressure despite good adherence with medications.

One of your patients <Patient Name>, <Patient address> is interested in participating in the research project. Please see attached a copy of the signed consent form from <Patient Name> expressing their interest in participating in the study and giving their permission for you to provide this information to the pharmacist (i.e. confirmation of a diagnosis of primary hypertension; target blood pressure).

I kindly ask that you provide us the requested details (see next page) about <Patient Name>.

If you would like further information about any aspect of the project, please contact me at the pharmacy or Assoc Prof Kay Stewart at the Faculty of Pharmacy and Pharmaceutical Sciences, Monash University on telephone 9903 9618 or email Kay.Stewart@pharm.monash.edu.au.

Yours Sincerely

<Pharmacist name>
GP Faxback Form

Please tick (✓) the box and fill the spaces provided

☐ I confirm that <Patient Name> has primary hypertension

The target blood pressure for <Patient Name> is _________ / _________ mmHg

Name of Doctor:  ________________________________

Signature:   ________________________________

Please fax this form to <pharmacy name>, <fax num> or send by post to <pharmacy name>, <pharmacy address>, <pharmacy suburb>, <pharmacy postcode>.
Our pharmacy is carrying out a research project in collaboration with University of Tasmania and Curtin University. This project aims to develop and test pharmacy services to assist and support consumers to achieve the best results from their blood pressure medicines.

We would like to invite you to participate in this project. This project will require you to meet with your pharmacist two or three times within a 6 month period. As part of the project you will also be provided with a blood pressure monitor for self-monitoring of blood pressure at home. The monitor will be yours to keep after the study provided you meet the project requirements. You will receive it either at the beginning or at the end of the 6 months project, depending on the project group to which you will be allocated.

To help us assess your eligibility to participate in the project, please answer the following:

Have you ever been diagnosed with high blood pressure?  □ Yes  □ No  □ Don’t know
I consent to the pharmacist contacting my General Practitioner to confirm my diagnosis of high blood pressure and to find and to find out my target blood pressure.

Name: ______________________________________________
Signature:________________________________________ __
Date : ________________________________

If you want any further information about this project, please provide your contact details:

Name ________________________________________________
Address ________________________________________________

Tel: _____________________  Mobile (optional): ___________________
Best time(s) to contact you: _____________________

NOTE: We will contact you to provide more project details. Please be assured that requesting more information does not commit you to taking part in the project.

Please return this form within the week to the pharmacy in the stamped envelope provided, regardless of whether you are interested in participating or not.
Appendix 8:  
Phase 3 - Baseline Collection Data Form  
Baseline Visit  
Time start:______

Section A: General demographics

1. What is your age? ________ years

2. Are you male or female?  □ Male  □ Female

3. Where were you born?  Country  ________________________

4. What language do you speak mostly to your family?  ________________________

5. Was your father born in Australia?  □ Yes  □ No, specify country  ______________

6. Was your mother born in Australia?  □ Yes  □ No, specify country  ______________

7. Are you of Aboriginal or Torres Strait Islander origin?  
☐ Yes, Aboriginal  ☐ Yes, Torres Strait Islander  ☐ No

8. What is your highest level of education?  
☐ No formal schooling  
☐ Primary school  
☐ High school  
☐ Secondary school  
☐ Technical or further educational institution (including TAFE Colleges)  
☐ University education

9. What is your marital status?  
☐ Married  ☐ Widowed  ☐ Cohabiting/Partnered/Defacto  
☐ Single  ☐ Separated  ☐ Divorced

10. What is your average annual household gross income before tax in Australian dollars?  
☐ less than $50,000  ☐ $50,000 – $75,000  ☐ $75,001 – $100,000  
☐ $100,001 – $125,000  ☐ $125,001 – $150,000  ☐ more than $150,000

11. Do you have an Australian healthcare concession card?  
☐ No concession card  
☐ Healthcare card  
☐ Pensioner concession card  
☐ Commonwealth Seniors Health card  
☐ Repatriation Health Card  specify colour:  ☐ Gold  ☐ White  ☐ Yellow
Section B: Health

12. Have you ever been told by a doctor that you have the following health conditions? (Tick one or more boxes)

- □ Arthritis
- □ Liver disease
- □ Eye disease such as glaucoma
- □ Cancer
- □ Heart condition such as heart attack, angina or blocked arteries
- □ Dementia
- □ Kidney problem
- □ Lung condition or asthma
- □ Diabetes
- □ Stomach ulcer
- □ Depression or mental health condition
- □ Stroke
- □ Osteoporosis, or weak or brittle bones
- □ HIV or AIDS

Section C: Clinical Measurements

13. How has your blood pressure been recently?

- □ Too low
- □ Normal/target
- □ Too High
- □ Not sure/don’t know

14. Self-reported BP ______ / ______ mm Hg

15. Do you know what your target blood pressure is?

- □ Yes, specify ______ / ______mmHg
- □ No

16. Measured blood pressure:

   Date:______________(dd/mm/yy)

   Time:______________(am/pm)

Arm Circumference: _ _ . _ cm

Pulse: □ Regular □ Irregular

BP 1: ___ ___/____ ___mmHg  Pulse 1: ___ ___ / min

BP 2: ___ ___/____ ___ mmHg  Pulse 2: ___ ___ / min

Note: A third BP measure is necessary if the first two readings differ by 10mmHg (systolic) or ≥ 5mmHg (diastolic). Maximum three measurements

BP 3: (if necessary) ___ ___/____ ___ mmHg  Pulse 3: ___ ___ / min
Section D: Your use of medicines

Please list ALL of the medicines you use – including prescription, over the counter, herbal or other supplements.

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<th>Why are you using this medicine?</th>
<th>How long have you been using this medicine?</th>
<th>Meds Index score</th>
<th>Do you think this medicine is working?</th>
<th>Do you experience any problems or side effects with using this medicine?</th>
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**Section D: Your use of medicines**

Please list ALL of the medicines you use – including prescription, over the counter, herbal or other supplements.

<table>
<thead>
<tr>
<th>Medicine name, strength and dose</th>
<th>Why are you using this medicine?</th>
<th>How long have you been using this medicine?</th>
<th>Meds Index score</th>
<th>Do you think this medicine is working?</th>
<th>Do you experience any problems or side effects with using this medicine?</th>
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</table>

**WELL**

**OKAY**

**NOT WELL**

**DON'T KNOW**

**YES (SPECIFY)**

**NO**
Section D: Your use of medicines (continued)

17. Have you ever had any problems (such as side effects) with any of your medicines?
   □ Yes, specify ________________________________    □ No

18. How would you rate the complexity/difficulty in using/taking ALL your medicines as prescribed on a scale of 1 (very simple) to 5 (very complex)?
   (Very simple) 1---------2---------3---------4---------5 (Very complex)

19. Which of the following would you be willing to try if further reduction in your BP becomes necessary? (Tick one or more boxes)
   □ Additional medicine    □ Change of medicine
   □ Higher dose of current medicine(s)    □ Change in lifestyle (e.g. salt or fluid restriction)

20. Do you have any of the following difficulties or problems with your medicines? I have difficulty: (Tick one or more boxes)
   □ Opening containers    □ Swallowing my medicines
   □ Getting to the doctor or pharmacy when my medicines run out
   □ Understanding different brands of the same medicines such as using generics
   □ Reading and understanding labels
   □ Other (please specify _______________________________________________

21. Do you use any of the following to help you remember to use/take your medicines? (Tick one or more boxes)
   □ Alarm beeper    □ Calendar    □ Diary    □ Medicine box (Dosette, Webster)
   □ Medicine list    □ Relative/carer    □ Other _________________________

22. Have you had a Medication Profiling service from a pharmacy in the last 12 months?
   □ Yes, specify when ________________    □ No

Section E: About your high blood pressure and its management

23. Do you ever forget to take your medicines?    □ Yes    □ No

24. Are you always careful in taking your medicines?    □ Yes    □ No

25. When you feel better do you sometimes stop taking your medicines?    □ Yes    □ No

26. Sometimes, if you feel worse when you take your medicines do you stop taking it?    □ Yes    □ No
27. For each of the following statements, please tick (✓) the box that best corresponds to your beliefs and experiences.

Management means all the things that your doctor has recommended that you do to control your high blood pressure, like taking medicines, losing weight, exercising etc.

<table>
<thead>
<tr>
<th>Statements</th>
<th>Definitely True</th>
<th>Mostly True</th>
<th>Don't Know</th>
<th>Mostly False</th>
<th>Definitely False</th>
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<td>I have a say in the way my high BP is managed</td>
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<td>I have sufficient understanding about the options for managing my high BP</td>
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<td>My doctors are very knowledgeable</td>
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<thead>
<tr>
<th>Statements</th>
<th>Extremely</th>
<th>Quite a bit</th>
<th>Moderately</th>
<th>Slightly</th>
<th>Not at all</th>
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<tr>
<td>I am concerned about the side effects from my medicines</td>
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<td>It is unpleasant (e.g. taste, smell) to use some of my medicines</td>
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<td>It is physically difficult to handle some of my medicines</td>
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<td>I am satisfied with the information my doctors share with me</td>
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<td>My doctors are compassionate</td>
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</table>
Section F: About your general wellbeing

For each of the following statements, please tick (✓) the alternative that best describes you during the last week.

28. When doing household tasks: *(For example, preparing food, gardening, using the video recorder, radio, telephone or washing the car)*

- [ ] I need no help at all.
- [ ] Occasionally I need some help with household tasks.
- [ ] I need help with the more difficult household tasks.
- [ ] I need daily help with most or all household tasks.

29. Thinking about how easily I can get around my home and community:

- [ ] I get around my home and community by myself without any difficulty.
- [ ] I find it difficult to get around my home and community by myself.
- [ ] I cannot get around the community by myself, but I can get around my home with some difficulty.
- [ ] I cannot get around either the community or my home by myself.
SOCIAL RELATIONSHIPS

30. Thinking about my relationship with other people:
   - I have plenty of friends, and am never lonely.
   - Although I have friends, I am occasionally lonely.
   - I have some friends, but am often lonely for company.
   - I am socially isolated and feel lonely.

31. Thinking about my health and my relationship with my family:
   - My role in the family is unaffected by my health.
   - There are some parts of my family role I cannot carry out.
   - There are many parts of my family role I cannot carry out.
   - I cannot carry out any part of my family role.

PHYSICAL SENSES

32. Thinking about my hearing, including using my hearing aid if needed:
   - I hear normally.
   - I have some difficulty hearing or I do not hear clearly.
     (For example: I ask people to speak up, or turn up the TV or radio volume.)
   - I have difficulty hearing things clearly.
     (For example: Often I do not understand what is said. I usually do not take part in conversations because I cannot hear what is said.)
   - I hear very little indeed.
     (For example: I cannot fully understand loud voices speaking directly to me.)

33. When I communicate with others: (For example: by talking, listening, writing or signing)
   - I have no trouble speaking to them or understanding what they are saying.
   - I have some difficulty being understood by people who do not know me. I have no trouble understanding what others are saying to me.
   - I am only understood by people who know me well. I have great trouble understanding what others are saying to me.
   - I cannot adequately communicate with others.
PSYCHOLOGICAL WELL-BEING

34. Thinking about how I generally feel:
   □ I do not feel anxious, worried or depressed.
   □ I am slightly anxious, worried or depressed.
   □ I feel moderately anxious, worried or depressed.
   □ I am extremely anxious, worried or depressed.

35. How much pain or discomfort do I experience?
   □ None at all.
   □ I have moderate pain.
   □ I suffer from severe pain.
   □ I suffer unbearable pain.

Section G: OVERALL QUALITY OF LIFE with hypertension/heart disease

36. We would like to know the extent to which hypertension/heart disease has affected your quality of your daily life. Using the score of 0 (death) to 100 (perfect health), what is your current quality of life?
   Score:_________________
Section I: Pharmacist Notes page (PCG only)

Issues Identified (e.g. poor adherence, side effects from medicines, concerns about medicines, poor BP measurement technique, lack of routine):

Recommendations (e.g. Medication Profiling, Home Medicines Review, Referral to GP, Dose Administration Aids, etc):

Goals set after discussion with the participant (e.g. develop a routine for medicine use, monitor BP daily):

Review date and time:

Checklist
- [ ] BP measurement technique taught
- [ ] Discussed adherence issues (if any)
- [ ] Discussed target blood pressure (if relevant)
- [ ] Referred patient to GP (if needed)
Appendix 9:
Phase 3 - Three-month Collection Data Form (PCG)
Follow-up Visit (3 months)

Section A: Clinical Measurements

How has your blood pressure been recently?

☐ Too low  ☐ Normal/target  ☐ Too High  ☐ Not sure/don’t know

Do you know what your target blood pressure is?

☐ Yes, specify ______ / ______ mmHg  ☐ No

Measured blood pressure:

Arm Circumference: _ _ . _ cm

Pulse: ☐ Regular  ☐ Irregular

BP 1: ___ ___/___ ___ mmHg  Pulse 1: ___ ___ / min

BP 2: ___ ___/___ ___ mmHg  Pulse 2: ___ ___ / min

Note: A third BP measure is necessary if the first two readings differ by 10 mmHg (systolic) or ≥ 5 mmHg (diastolic).
Maximum three measurements

BP 3: (if necessary) ___ ___/___ ___ mmHg  Pulse 3: ___ ___ / min

Download home BP recordings from patient’s home BP monitor and discuss
Section B: About your high blood pressure and its management.

Do you ever forget to take your medicines? □ Yes □ No

Are you always careful in taking your medicines? □ Yes □ No

When you feel better do you sometimes stop taking your medicines? □ Yes □ No

Sometimes, if you feel worse when you take your medicines, do you stop taking it? □ Yes □ No

8. For each of the following statements, please tick (✓) the box that best corresponds to your beliefs and experiences.

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<thead>
<tr>
<th>Statements</th>
<th>Always</th>
<th>Often</th>
<th>Sometimes</th>
<th>Rarely</th>
<th>Never</th>
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<tbody>
<tr>
<td>I get confused about my medicines</td>
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<td>I have strict routines for using my regular medicines</td>
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<td>I keep my medicines close to where I need to use them</td>
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<td>I ensure I have enough medicines so that I don’t run out</td>
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<td>I strive to follow the instructions of my doctors</td>
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<td>I make changes in the recommended management to suit my lifestyle</td>
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<td>I vary my recommended management based on how I am feeling</td>
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<tr>
<td>I put up with my medical problems before taking any action</td>
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</table>
Section C: Pharmacist Notes page

Issues Identified (e.g. poor adherence, side effects from medicines, concerns about medicines, poor BP measurement technique, lack of routine):

Recommendations (e.g. Medication Profiling, Home Medicines Review, Referral to GP, Dosette):

Goals set after discussion with the participant (e.g. develop a routine for medicine use, monitor BP daily):

Review date and time:

Checklist

☐ Downloaded home BP recordings
☐ Discussed home BP recordings
☐ Discussed target blood pressure (if relevant)
☐ Reviewed BP measurement techniques
☐ Discussed adherence issues (if any)
☐ Referred patient to GP (if needed)
Appendix 10:
Phase 3 - Six-month Collection Data Form

Final Visit (6 months)

Time start:________

Section A: Clinical Measurements

1. How has your blood pressure been recently?
   - [ ] Too low
   - [ ] Normal/target
   - [ ] Too High
   - [ ] Not sure/don’t know

2. Do you know what your target blood pressure is?
   - [ ] Yes, specify ______ / ______mmHg
   - [ ] No

3. Measured blood pressure:

   Arm Circumference: _ _ . _ cm

   Date:______________(dd/mm/yy)
   Time:______________(am/pm)

   Pulse: [ ] Regular
   [ ] Irregular

   BP 1: ___ ___/___ ___mmHg  Pulse 1: ___ ___ / min

   BP 2: ___ ___/___ ___ mmHg  Pulse 2: ___ ___ / min

Note: A third BP measure is necessary if the first two readings differ by 10mmHg (systolic) or ≥ 5mmHg (diastolic). Maximum three measurements

   BP 3: (if necessary) ___ ___/___ ___ mmHg  Pulse 3: ___ ___ / min

Download home BP recordings from patient’s home BP monitor and discuss
(Pharmacist Care group ONLY)
Section B: Your use of medicines

Please list ALL of the medicines you use – including prescription, over the counter, herbal or other supplements.

<table>
<thead>
<tr>
<th>Medicine name, strength and dose</th>
<th>Why are you using this medicine?</th>
<th>How long have you been using this medicine?</th>
<th>MedsIndex score</th>
<th>Do you think this medicine is working?</th>
<th>Do you experience any problems or side effects with using this medicine?</th>
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</table>
Section B: Your use of medicines

4. Please list ALL of the medicines you use – including prescription, over the counter, herbal or other supplements.

<table>
<thead>
<tr>
<th>Medicine name, strength and dose</th>
<th>Why are you using this medicine?</th>
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</table>
Section C: About your high blood pressure and its management.

4. Do you ever forget to take your medicines? □ Yes    □ No
5. Are you always careful in taking your medicines? □ Yes    □ No
6. When you feel better do you sometimes stop taking your medicines? □ Yes    □ No
7. Sometimes, if you feel worse when you take your medicines, do you stop taking it? □ Yes    □ No

8. For each of the following statements, please tick (✓) the box that best corresponds to your beliefs and experiences.

Management means all the things that your doctor has recommended that you do to control your high blood pressure, like taking medicines, losing weight, exercising etc.

<table>
<thead>
<tr>
<th>Statements</th>
<th>Definitely True</th>
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<th>Don’t Know</th>
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<tbody>
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<tr>
<td>I have sufficient understanding about the options for managing my high BP</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>My doctors are very knowledgeable</td>
<td></td>
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</tr>
<tr>
<td>Statements</td>
<td>Extremely</td>
<td>Quite a bit</td>
<td>Moderately</td>
<td>Slightly</td>
<td>Not at all</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>I am concerned about the side effects from my medicines</td>
<td></td>
<td></td>
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<tr>
<td>It is unpleasant (e.g. taste, smell) to use some of my medicines</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>It is physically difficult to handle some of my medicines</td>
<td></td>
<td></td>
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<tr>
<td>I am satisfied with the information my doctors share with me</td>
<td></td>
<td></td>
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<tr>
<td>My doctors are compassionate</td>
<td></td>
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<tr>
<td>Financial difficulties limit my access to the best healthcare</td>
<td></td>
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<tr>
<td>My doctors spend adequate time with me</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The management of my high BP disrupts my life</td>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Statements</th>
<th>Always</th>
<th>Often</th>
<th>Sometimes</th>
<th>Rarely</th>
<th>Never</th>
</tr>
</thead>
<tbody>
<tr>
<td>I get confused about my medicines</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>I have strict routines for using my regular medicines</td>
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<tr>
<td>I keep my medicines close to where I need to use them</td>
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<tr>
<td>I ensure I have enough medicines so that I don’t run out</td>
<td></td>
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<tr>
<td>I strive to follow the instructions of my doctors</td>
<td></td>
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<tr>
<td>I make changes in the recommended management to suit my lifestyle</td>
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<tr>
<td>I vary my recommended management based on how I am feeling</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>I put up with my medical problems before taking any action</td>
<td></td>
<td></td>
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</tbody>
</table>
Section D: About your general wellbeing

For each of the following statements, please tick (√) the alternative that best describes you during the last week.

INDEPENDENT LIVING

9. When doing household tasks: *(For example, preparing food, gardening, using the video recorder, radio, telephone or washing the car)*

- [ ] I need no help at all.
- [ ] Occasionally I need some help with household tasks.
- [ ] I need help with the more difficult household tasks.
- [ ] I need daily help with most or all household tasks.

10. Thinking about how easily I can get around my home and community:

- [ ] I get around my home and community by myself without any difficulty.
- [ ] I find it difficult to get around my home and community by myself.
- [ ] I cannot get around the community by myself, but I can get around my home with some difficulty.
- [ ] I cannot get around either the community or my home by myself.

SOCIAL RELATIONSHIPS

11. Thinking about my relationship with other people:

- [ ] I have plenty of friends, and am never lonely.
- [ ] Although I have friends, I am occasionally lonely.
- [ ] I have some friends, but am often lonely for company.
- [ ] I am socially isolated and feel lonely.

12. Thinking about my health and my relationship with my family:

- [ ] My role in the family is unaffected by my health.
- [ ] There are some parts of my family role I cannot carry out.
- [ ] There are many parts of my family role I cannot carry out.
- [ ] I cannot carry out any part of my family role.
PHYSICAL SENSES

13. Thinking about my hearing, including using my hearing aid if needed:
   - I hear normally.
   - I have some difficulty hearing or I do not hear clearly.
     *(For example: I ask people to speak up, or turn up the TV or radio volume.)*
   - I have difficulty hearing things clearly. *(For example: Often I do not understand what is said. I usually do not take part in conversations because I cannot hear what is said.)*
   - I hear very little indeed.
     *(For example: I cannot fully understand loud voices speaking directly to me.)*

14. When I communicate with others: *(For example: by talking, listening, writing or signing)*
   - I have no trouble speaking to them or understanding what they are saying.
   - I have some difficulty being understood by people who do not know me. I have no trouble understanding what others are saying to me.
   - I am only understood by people who know me well. I have great trouble understanding what others are saying to me.
   - I cannot adequately communicate with others.

PSYCHOLOGICAL WELL-BEING

15. Thinking about how I generally feel:
   - I do not feel anxious, worried or depressed.
   - I am slightly anxious, worried or depressed.
   - I feel moderately anxious, worried or depressed.
   - I am extremely anxious, worried or depressed.

16. How much pain or discomfort do I experience?
   - None at all.
   - I have moderate pain.
   - I suffer from severe pain.
   - I suffer unbearable pain.
Section E: OVERALL QUALITY OF LIFE with hypertension/heart disease

We would like to know the extent to which hypertension/heart disease has affected your quality of your daily life. Using the score of 0 (death) to 100 (perfect health), what is your current quality of life?
Score:_________________

Section F: Medicine use and expenses in the past 6 months

17. How many times did you visit your family doctor for hypertension/heart condition in the past 6 months?
   1. None
   2. Yes
   If Yes, how many times:_____________

18. Following question 17, on average, how much did you pay out of pocket each time for visiting your family doctor (including baby sitting, travel, medical and other related cost for the visit)?
   AU$ ______________ (Average)

19. Have you made any emergency visit to the hospital for hypertension/heart condition during the past 6 month?
   1. None
   2. Yes
   If Yes, how many times? _________

20. Following question 19, on average how much did you pay out of pocket for the emergency visit each time (including baby sitting, travel, medical and other related cost for the visit)?
   AU$ _________________ (Average)

21. Have you had any inpatient stay due to hypertension/heart condition during the past 6 months?
   1. None
   2. Yes
   If Yes, how many times? __________

22. Following question 21, on average how much did you pay out of pocket for the inpatient stay each time (including baby sitting, travel, medical and other related cost for the visit)?
   AU$ _________________ (Average)
Section G: Pharmacist Notes page (PCG only)

Issues Identified (e.g. poor adherence, side effects from medicines, concerns about medicines, poor BP measurement technique, lack of routine):

Recommendations (e.g. Medication Profiling, Home Medicines Review, Referral to GP, Dose Administration Aids, etc):

Goals set after discussion with the participant (e.g. develop a routine for medicine use, monitor BP daily):

Checklist

☐ Downloaded home BP recordings
☐ Discussed home BP recordings
☐ Discussed target blood pressure (if relevant)
☐ Reviewed BP measurement techniques
☐ Discussed adherence issues (if any)
☐ Referred patient to GP (if needed)

Time end:_________
Appendix 11:  
Phase 3 - Business Case Evaluation Form (PCG)

Final Visit (6 months)  
ID ________

Business Case Questionnaire

1. If there is a new service package available, say, the pharmacist can help you to better manage hypertension/heart disease by monitoring blood pressure and providing consultation regularly, how much are you willing to pay (maximum dollar) for this additional service per month (one to two visits to the pharmacist)?  
   AU$: __________ per month.

2. How often did you shop at this pharmacy during the past 6 months:
   ____: Once a week
   ____: Once in every two weeks
   ____: Once in every three weeks
   ____: Once a month or more

3. During the past 6 months, how much did you spend at this pharmacy during each visit (including medicine and other goods)?
   AU$: ______________ (average)

4. What is your overall satisfaction with this pharmacy? (1: very unsatisfied to 7: very satisfied)

   Level of satisfaction; ______________

5. Please tell us the first thing that comes to your mind about the service of this pharmacy?

   ____________________________________________
Appendix 12:  
Phase 4 - Consumer Focus Group/Interview Guide

HAPPY Trial Patient Feedback – Focus Group / Interview Guide (post RCT)  
After the 6 month Service has been completed

Starting the focus group/interview

Your participation is entirely voluntary and you will not be able to be identified by your response, which will remain strictly confidential. As was outlined to you in the information and consent forms that you signed this conversation will be recorded. Is it OK if I turn the recorder on now?

The purpose of this focus group/interview is to explore your opinions and experiences with the HAPPY Trial.

Patient experience after they have finished the service:

What was your overall experience with HAPPY?
Prompts
• What went well?
• What could be improved?
• Which aspects of the service have been most/least useful?
Prompts
• Adherence assessment
• BP monitoring service from the pharmacy
• Home BP monitor
• Discussion of specific blood pressure issues
• Goal setting
• Prescription reminder service
• What aspects of the service have you most/least appreciated?

How and why did you get involved in the Service?
Prompts
• Approached by Pharmacists or Pharmacy Assistant
• BP monitors an incentive?
• Believe that they had a problem taking their BP medications?

What have you learnt about your BP since participating in the Service?
Prompts
• How to take my medications
• About my BP control and target BP
• Blood pressure – the disease
• Lifestyle factors
In general, how do you feel about receiving this Service **from your Pharmacist**?

**Prompts**
- How were your interactions/communications with your Pharmacists e.g:
  - Their understanding of your situation
  - Availability
  - Easy to understand
  - Friendliness
  - Promptness
  - Environment

Has your relationship with your GP changed due to the Service and how?

Who would you prefer to receive this service from?
- Pharmacist, GP or another Health Care Professional?

Over the 6 month service you had 3 visits. Do you feel that this was enough visits with your Pharmacist? Would you have preferred more or less visits over this time period?

**Business Case**

Community pharmacists’ involvement in enhancing patient compliance may generate other positive effects on the society, meaning extra benefits to the society as a whole in addition to the patient. I would like to discuss that further and perhaps try to estimate or measure it.

**Other than the benefits to the patients, what extra benefits do you believe that this service can generate?**

**Prompts:**
- To the health sector in Australia?
  e.g. release medical workforce and capital for other medical treatment…etc.
- To other sectors in Australia?
  e.g. reduce the resource burden to non-health part of the society such as transportation, education, legal and housing…etc.
- To the primary physicians?
  e.g. increase income by team care arrangements between GP & pharmacists
- To the pharmacists?
  e.g. increase in job satisfaction and reduce in job turn over…etc.
- To the pharmacy?
  e.g. increase in other business revenue to the pharmacy, …etc.
- To others?

**Which of the above benefits is/are likely to be the largest?**
The Future

In the future, if this Service was offered to many more people with high blood pressure, how do you think they should be recruited?

Prompts
- Exclusion or inclusion of BP monitor, possibly buying own monitor

How much demand do you think there is for a Service like this in community pharmacy?

How important do you think this Service is for people with high blood pressure in the community?

Should this Service be available to patients on a regular basis?

Would you continue to use this Service if it was available long term?

Prompts
- How often do you think you would need to visit the pharmacy?
- How long should the Service run for? Would it be a short term Service or indefinite?
- By appointment or drop in?

How do you think the Service could be improved for patients in the future?

Before we wrap up, is there anything else you would like to add?

THANK YOU FOR YOUR PARTICIPATION
Appendix 13:
Phase 4 Pharmacist Focus Group/Interview Guide

HAPPY Pharmacist Feedback – Focus Group / Interview Guide (Post RCT)

After the 6 month Service has been completed

Starting the focus group/interview

The purpose of this focus group/interview is to explore your opinions and experiences with the HAPPY Trial.

Pharmacist experience

What has been your overall experience with the HAPPY trial?

Prompts

• What went well?
• What could be improved?

How well did the training equip you to deliver the service? What worked particularly well/helped to prepare you? Were there any gaps in the training? What did not work well?

Prompts

• Online vs face to face training
• Knowledge – disease, management, adherence, motivational interviewing
• Knowledge of interventions
• Skills – BP monitor
• Confidence
• Motivation
• Recruitment - MedeMine

What has been your experience in recruiting patients?

Prompts

• Easy or difficult (including use of Medemine compared to other modes)
• What barriers, if any did you experience?
• Time involved in recruitment & preparation
• Number of patients – right or too many or too few
• BP monitor to patients an incentive?
• Enthusiasm of patients?

How easy or difficult has it been to implement the HAPPY service in your pharmacy?

Prompts

• What made it easy to implement? (facilitators)
• What difficulties did you experience? (barriers)
• Have there been any issues with competing priorities within the pharmacy?
• Have you made any changes to your pharmacy operations?
  • Roster
  • Staff
  • Routine
  • Layout

What did you think of the service protocol now that you have tried it?
Prompts
• What worked well/not so well?
• Time involvement in recruiting, preparation and appts
• Any suggestions for improvement?

What was the average time you spent with a patient during a HAPPY visit?
Prompts
• Baseline c.f. 3 and 6 month follow-ups
• Amount of additional time spent c.f. usual hypertensive patients (in quantity)

What did you think of having 3 visits in 6 month?
Prompts
• Enough time to get patients to understand?
• Would you have preferred more or less visits?
• Interference with workflow?

Pharmacist’s perspective of patient’s experience
Thinking about the service from your patient’s perspective, how do you think the service has been received by your patients so far?
Prompts
• Which aspects of the service have been most/least useful from the patient’s perspective?
• What aspects of the service have been most/least appreciated by patients?
• Have you had any issues with patients being unwilling to return for further visits?

What have been the most and least useful parts of the service for your patients?
Prompts
• Adherence assessment
• BP monitoring service through pharmacies
• Home BP monitor & technique of taking BP
• Discussion of specific blood pressure and medication issues
• Prescription reminder service
• Interaction with pharmacist

How do you think the Service could be improved for patients in the future?

GP/Specialist interaction with the Service
Have you had contact with GPs as a direct result of your involvement with HAPPY? If so, in what ways?
Prompts
• Initial contact at the beginning
  o Fax, phonecall
    o Further correspondence afterwards
Practice Manager
Referral of patients to GP
Written Feedback to GPs

Are you aware if any GPs initiated blood pressure services for your HAPPY patients during the service?
Prompts
• Change of medication treatment
• GP management plan
• HMR

What, if any, impact has your involvement with HAPPY had on your professional relationship with local GPs?

Overall, what do you think that GPs thought of the HAPPY service?

Business Case

Community pharmacists’ involvement in enhancing patient compliance may generate other positive effects on the society, meaning extra benefits to the society as a whole in addition to the patient. I would like to discuss that further and perhaps try to estimate or measure it.

Other than the benefits to the patients, what extra benefits do you believe that this service can generate?

Prompts:
• To the health sector in Australia?
e.g. release medical workforce and capital for other medical treatment…etc.
• To other sectors in Australia?
e.g. reduce the resource burden to non-health part of the society such as transportation, education, legal and housing…etc.
• To the primary physicians?
e.g. increase income by team care arrangements between GP & pharmacists
• To the pharmacists?
e.g. increase in job satisfaction and reduce in job turnover…etc.
• To the pharmacy?
e.g. increase in other business revenue to the pharmacy, …etc.
• To others?

Which of the above benefits is/are likely to be the largest?

Other impacts

What other spinoffs, if any, have you experienced so far as a result of offering the service?

Prompts
• Business (covered above too)
• Demands for other services
• Invitation to participate in other professional activities e.g. seminars, committees etc.

The Future

How much demand do you think there is for a service like this in community pharmacy?

How do you think this service could be improved in the future?

Prompts:
• Duration of service (number of services and length of service)

How important do you think this service is for people with high blood pressure in the community?
Would you continue to provide this service if it was ongoing?

Before we wrap up, is there anything else you would like to add?

THANK YOU FOR YOUR PARTICIPATION
Appendix 14: 
Phase 4 - General Practitioners Focus Group/Interview Guide

HAPPY Trial General Practitioner Feedback – Focus Group / Interview Guide (Post RCT)

After the 6 month Service has been completed

Starting the focus group/interview

The purpose of this focus group/interview is to explore your opinions and experiences with the HAPPY Trial.

GP experience

How were you notified about your local community Pharmacist’s participation in the HAPPY trial?

Prompts
- Division of General Practice
- Letter/Fax from Pharmacist
- Phone call / visit from Pharmacist
- Your patient was referred to you as part of HAPPY

What would be your preferred method of notification about such a Service?

What has been your overall experience with the HAPPY trial?

Prompts
- What went well?
- What could be improved?
- Context: Did they know about it?

What follow-up occurred after the initial contact between you and the Pharmacist, if anything?

Prompts
- Personal communication between yourself and the Pharmacist
- Written communication between yourself and the Pharmacist
- Referral of patients without contact by pharmacist

Did you initiate any services for hypertension for your HAPPY patients?

Prompts
- Change in medication
- GP management plan
- HMR

What, if any, impact has it had on your professional relationship with your local community Pharmacist(s)?

Prompts
- Enhanced communication
- More direct contact
- Onflowing effect to other patients not involved in this trial
- Any negative outcomes?

How do you think HAPPY can assist you or compliment your management of the patient with hypertension? How can it impact on your practice in practical terms?
Prompts
• Is adherence a priority issue?
• Do they feel GPs can deal with it themselves?

**GP’s perspective of patient’s experience**

*Thinking about the service from your patient’s perspective, how do you think the service has been received by your patients so far?*

**Prompts**
• Which aspects of the service have been most/least useful from the patient’s perspective?
• What aspects of the service have been most/least appreciated by patients?

**Business Case**

Community pharmacists’ involvement in enhancing patient compliance may generate other positive effects on the society, meaning extra benefits to the society as a whole in addition to the patient. I would like to discuss that further and perhaps try to estimate or measure it.

*Other than the benefits to the patients, what extra benefits do you believe that this service can generate?*

**Prompts:**
• To the health sector in Australia?
e.g. release medical workforce and capital for other medical treatment…etc.
• To other sectors in Australia?
e.g. reduce the resource burden to non-health part of the society such as transportation, education, legal and housing…etc.
• To the primary physicians?
e.g. increase income by team care arrangements between GP & pharmacists
• To the pharmacists?
e.g. increase in job satisfaction and reduce in job turn over…etc.
• To the pharmacy?
e.g. increase in other business revenue to the pharmacy, …etc.
• To others?

*Which of the above benefits is/are likely to be the largest?*

**The Future**

*How do you think the Service could be improved for patients in the future?*

*How much demand do you think there is for a service like this in community pharmacy?*

*Before we wrap up, is there anything else you would like to add?*

THANK YOU FOR YOUR PARTICIPATION
HAPPY_trial

MONASH University
Pharmacy and Pharmaceutical Sciences

UTAS

Curtin University of Technology

GREATER GREEN TRIANGLE
University Dept. of Rural Health

THE UNIVERSITY OF MELBOURNE