Commonwealth Department of Health

Initial Evaluation of Sixth Community Pharmacy Agreement Medication Management Programs: Home Medication Review

Final Evaluation Report

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Abbreviations

ABS	Australian Bureau of Statistics
ACE	Angiotensin-converting enzyme
ACF	Aged care facility
ADE	Adverse drug events
ADR	Adverse drug reaction
AIHW	Australian Institute of Health and Welfare
AQoL	Assessment of Quality of Life
ATSI	Aboriginal and Torres Strait Islander
BE	Business entity
CABG	Coronary artery bypass graft
CALD	Culturally and linguistically diverse people
CBA	Cost benefit analysis
CE	Cost-effective
CEA	Cost-effectiveness analysis
CHD	Coronary heart disease
CHF	Chronic heart failure
CI	Confidence interval
CIs	Clinical Interventions
CPA	Community Pharmacy Agreement
CRC	Campbell Research and Consulting
CUA	Cost-utility analysis
DAA	Dose Administration Aid
DBI	Drug Burden Index
DoHA	Department of Health and Ageing
DRP	Drug-related problem
DVA	Department of Veterans' Affairs
ED	Emergency department

GBP	Great British Pounds
GP	General practitioner
GPPC	General Practitioner-Pharmacist Collaboration
HMR	Home Medicines Review
HRQoL	Health-related quality of life
HTA	Health technology assessment
ICER	Incremental cost-effectiveness ratio
INR	International normalised ratio
IQR	Interquartile range
IRR	Incidence rate ratio
LYG	Life year gained
MAI	Medication Appropriateness Index
MARS	Medication Adherence Report Scale
MBS	Medicare Benefits Schedule
MMP	Medication Management Program
MSAC	Medical Services Advisory Committee
NR	Not reported
OR	Odds ratio
PBS	Pharmaceutical Benefits Scheme
PCI	Pharmaceutical care issue
PhARIA	Pharmacy Accessibility Remoteness Index of Australia
PIM	Potentially Inappropriate Medicine
PPI	Pharmacy Practice Incentives
PSA	Pharmaceutical Society of Australia
PSG	Programme Specific Guidelines
PwC	Pricewaterhouse Coopers
QALY	Quality-adjusted life year
QoL	Quality of life
QUMAX	Quality Use of Medicines Maximised
RCT	Randomised controlled trial
RMMR	Residential Medication Management Review

RR	Relative risk
SCRIP	Study of Cardiovascular Risk Intervention by Pharmacists
SD	Standard deviation
SS	Statistically significant
TTR	Time (spent) in therapeutic range
UK	United Kingdom
USA	United States of America

Executive Summary

On the 27th October 2016, the Department of Health engaged HealthConsult to undertake an evaluation to determine the clinical/cost-effectiveness of four Medication Management Programs (MMPs) funded under the Sixth Community Pharmacy Agreement (6CPA): Home Medicines Review (HMR); Residential Medication Management Review (RMMR); MedsCheck; and Diabetes MedsCheck. This report presents the initial evaluation of the HMR program, which has involved:

- a literature review to identify evidence to inform the comparative clinical and cost-effectiveness of the HMR program and 'like' programs internationally; and
- an examination of the available Australian utilisation data from the HMR program going back to its commencement under earlier Community Pharmacy Agreements (CPAs).

ES 1 BACKGROUND

The HMR program was designed to enhance the quality use of medicines and reduce the number of adverse medicine events and associated hospital admissions or medical presentations, by assisting consumers to better manage and understand their medicines through a medication review conducted by an accredited pharmacist in the patient's home.

The objectives of HMR are to:

- achieve safe, effective, and appropriate use of medicines by detecting and addressing medicine-related problems that interfere with desired patient outcomes;
- improve the patient's quality of life and health outcomes using a best practice approach that involves cooperation between the GP, pharmacist, other relevant health professionals and the patient (and where appropriate, their carer);
- improve the patient's and health professional's knowledge and understanding of medicines;
- facilitate cooperative working relationships between members of the healthcare team in the interests of patient health and wellbeing; and
- provide medication information to the patient and other healthcare providers involved in the patient's care.

A HMR service is available to an eligible patient whose GP determines that a HMR is clinically necessary to address the patient's needs and optimise the patient's quality use of medicines. Currently, a fee for service is payable to an approved service provider for each HMR conducted after a referral by a GP. The current payment for an HMR service is $213.67.[1] In addition, an accredited pharmacist undertaking a HMR can claim the Rural Loading Allowance ($125 per patient) if the patient receiving the HMR resides in areas categorised as rural or remote, as defined by the Pharmacy Accessibility Remoteness Index of Australia (PhARIA). One HMR service can be conducted per eligible patient on referral from a GP. A subsequent HMR may only be conducted if more than 24 months has elapsed since the date of the most recent service or when the patient's GP specifically deems a subsequent review is clinically necessary.

It is important to note that medical practitioners (e.g. GPs) are able to make an MBS claim (MBS item 900) for participation in an HMR. Different to the HMR service provided by a pharmacist, an item 900 can be claimed every 12 months for a referral issued by a medical practitioner under this MBS item compared to 24 months for subsequent service conducted by a pharmacists.

1-2 Claiming and payment [Internet]. 2015. [cited 2017 Feb 15]. Available from: http://6cpa.com.au/medication-management-programmes/home-medicines-review/

ES 2 METHODOLOGY

This Section summarises the methodology used to identify the published as well as grey literature considered in this initial evaluation of the HMR program.

ES 2.1 Literature search

A systematic literature review was undertaken in December 2016 to identify studies that provide evidence relating to the safety, effectiveness, costs and cost-effectiveness of HMR programs provided by pharmacists to individuals in their homes. The grey literature was also searched, as were the reference lists of included studies. Table ES.1 presents the evidence selection criteria for inclusion in the review.

Table ES.1: Selection criteria for evidence relating to HMR services provided by community pharmacists

Criteria	Description
Population	Patients living in the community (including respite care) who are at risk of experiencing medication misadventure due to multiple chronic conditions; comorbidities; age or social circumstances; the characteristics of their medicine; the complexity of their medication regimen; or a lack of knowledge and skills to use their medicine effectively and safely. Examples of risk criteria include: • taking five or more regular medicines; • taking more than 12 doses of medicine per day; • having three or more concurrent medical conditions; • experiencing significant changes to their medicine regiment (in the past three months); • recently discharged from hospital; • taking medicine with a narrow therapeutic index or requiring therapeutic monitoring; • experiencing symptoms suggestive of an adverse drug reaction or sub-therapeutic response to therapy; • suspected non-compliance or problems with medication-related devices; • self-management of medicines plus literacy or language difficulties or dexterity, vision or cognitive limitations; • attending a number of different doctors, both general practitioners and specialists; or • increasing frailty or changes in health status. *Note: Excludes hospital inpatients, day hospital facility patients or patients in a Residential Care Facility.*
Intervention	A HMR or a similar service consisting of a comprehensive clinical review of a patient's medicines during a single visit to their home by an accredited pharmacist on referral from the patient's general practitioner. *Interventions specifying multiple scheduled visits within a 12-month period will be excluded.*
Comparator	Community patients who did not access to HMR services.
Outcomes	Outcomes include: • changes in adherence/compliance/concordance with prescribed dose schedule (e.g. pill count, self-report); • changes in clinical outcomes (e.g. BP in patients with hypertension, HbA_{1c} in patients with diabetes); • rates of adverse drug event/reactions and medication-related problems; • changes in disability indices; • health care resource use (ED attendance, hospitalisation, GP visits, specialist visits); • patient acceptance/satisfaction; • health-related quality of life; • cost of the service; • cost-effectiveness.
Study design	Comparative studies (randomised or non-randomised controlled trials, comparative cohort studies, case control studies, before/after studies) or systematic reviews of comparative studies. Applicability to the Australian context will be considered.
Publication type	Full English-language publications or reports. Conference abstracts will be excluded.

The literature search identified a number of systematic reviews that did not focus on HMR conducted by a pharmacist in a patient's home, but on medication reviews in any setting or medication review within a multidisciplinary model or a disease management plan, or medication reviews that were delivered by any health professional. Therefore, the findings from these systematic reviews cannot be extrapolated to the HMR service. For this reason, only evidence from studies that evaluated HMR principally delivered by a pharmacist in a patient's home, and independent of any other intervention

aiming at optimising drug regimens and patient outcomes is presented in the systematic literature review.

A total of 16 primary studies were identified that examined pharmacist-led HMR impact on patient outcomes. The studies were mixed in design and included seven randomised controlled trials (RCTs) (Barker et al, 2012; Holland et al 2007; Lenaghan et al, 2007; Holland et al (2005); Krska et al, 2001; Stewart et al, 1998a; Stewart et al, 1998b), three retrospective cohort studies (Bereznicki et al, 2016; Roughead et al, 2011; Roughead et al, 2009), and two retrospective pre- post-design studies (Castelino et al, 2010a; Castelino et al, 2010b). Eight studies were conducted in Australia, and the other four in the UK. Three of the included studies were non-comparative Australian studies based on focus group discussions and investigated patients' perspectives on understanding of the HMR (Ahn et al, 2015; White et al, 2012; Carter et al, 2012). Only one cost-effectiveness study was identified (Pacini et al, 2007).

The studies evaluated HMRs performed by a pharmacist, aimed at checking and optimising the patients' drug regimens (i.e. ability to make recommendations on altering the regimen), and not limited simply to increasing patients' knowledge and/or adherence. Study participants were older people (mean age >65 years) and with a range of diseases (chronic heart failure, congestive heart failure, clinical indications for warfarin use, and other unspecified chronic conditions). The studies included a variety of primary and secondary outcomes, with a focus on hospital admissions, mortality, and quality of life (QoL). Due to the heterogeneity of the included studies, meta-analysis to determine the effect of the HMR on any outcome was not performed.

The search also identified five previous evaluations of the HMR initiative funded under the 3CPA, 4CPA and 5CPA (Urbis Keys Young (2005), Campbell Research and Consulting (2008), Stafford (2009), Stafford (2012) and PwC (2015)). These studies did not meet the inclusion criteria for the systematic review, they were non-comparative and largely took a program evaluation approach. As commented on by some of the authors, the studies provide low level evidence of the impact of HMRs. Nonetheless, given the importance of these studies from a policy perspective and the fact that they specifically address the program being reviewed, they have been summarised in Chapter 4 of this report, and their findings have been included and referenced when drawing conclusions in this Executive Summary.

ES 2.2 Utilisation analysis

The only available data for inclusion in the utilisation analysis were the claims payment data held by the Department of Human Services and the Pharmacy Guild relating to 2011 to 2016. The data have been analysed primarily on longitudinal relationships and also in the context of 'remoteness' inferred from the patient postcode. The analysis sought to assess whether the HMR service providers were implementing the scheme in line with guidance. Key metrics in the analysis are the amount of claims paid, the number of patient HMR services provided, the interval time between dates of service for patients who received more than one service and summary information at patient level about the age and geographic profile of services provided, the reasons for referral and the recommendations from the HMRs.

ES 3 RESULTS OF THE LITERATURE REVIEW

This Section presents a summary of the findings drawn from the systematic literature review and review of the grey literature (which, in a departure from our usual practice for assessment reports prepared for the Medical Services Advisory Committee (MSAC), includes, where relevant, the low level evidence derived from the program evaluations conducted on the HMR program) funded under prior CPAs.

ES 3.1 Hospital admissions

Evidence from a single RCT reported significant benefit in regards to a composite hospitalisation plus out-of-hospital deaths outcome and fewer unplanned readmissions in high-risk patients receiving an HMR post-discharge from an acute care hospital. A detailed analysis of congestive heart failure patient subpopulation of this RCT suggested similar benefits, which lasted for a period of at least 18 months after the HMR. However, results from three other RCTs showed that a pharmacist directed HMR for patients recently discharged from hospital with heart failure had no effect on reducing readmissions.

Only one RCT evaluated the impact of HMRs performed by a pharmacist on reducing hospital admissions in elderly patients prescribed at least four oral daily medicines, and who were not discharged from a hospital. This RCT showed that HMR performed by community pharmacist did not lead to reductions in hospital admissions in this population.

Two of the HMR program evaluations addressed the question of hospital admissions. The Urbis Keys Young (2005) study found a small reduction in hospital admissions following HMR using consumer self-reported data. The VALMER study (Stafford, 2012) also found a small reduction in hospital days in the 12 month period after HMR using consequential analysis (assessment by an pharmacist expert panel) to determine the impact on subsequent health care use of resolution of DRPs by pharmacists.

The RCTs had several limitations that included small sample size, unmatched baseline characteristics with patients receiving the HMR being more symptomatic and thus sicker that patients in the control group. In addition, patients discharged from hospital who have received additional in-hospital service followed by an HMR may present with better outcomes overall. The low level evidence of a small reduction in hospital days in the two program evaluations does not improve the knowledge base. Overall, there is a lack of a clear evidence base demonstrating an effect of HMR on reducing hospital admissions.

ES 3.2 Time to next hospitalisation

Results from two Australian retrospective cohort studies using the Department of Veteran Affairs data provide some evidence for the effectiveness of collaborative HMR in the practice setting in Australia. The studies suggest that HMR can reduce the time to next hospitalisation (thus reducing hospitalisation rates) for older people living in the community at high risk of medication-related hospital admissions, specifically those with heart failure taking heart failure medicines and those taking warfarin. However, retrospective studies are considered of low quality and are subject to bias. Both studies have selection bias, and patients were not well-matched for clinical characteristics. Further, the effect of the HMR appears to have been transitory, with the observed benefits being lost after the 12-month period. Therefore, findings from these studies should be interpreted with caution.

ES 3.3 Care home admissions

Only one RCT reported that at six-month follow-up, there were no difference in care home admissions in patients who received HMR compared to those in the control group.

ES 3.4 Health care resource use or cost

Evidence on the effect of HMR on reducing health care resource use is conflicting. Only one RCT showed significant reduction in prescribed items following an HMR. However, this contradicts findings from another RCT that showed a significant increase in the number of prescription items after HMR. Two of the program evaluations also showed a small reduction in health care resource use (GP and specialist visits, medical investigations, hospital days and medicines), after HMR. The VALMER study further concluded that the costs of the reduced health care resource use were insufficient to

offset the costs of the HMR. Overall, there is a lack of a clear evidence base demonstrating an effect of HMR on reducing health care service use and costs.

ES 3.5 Adherence/compliance/concordance

Only one RCT evaluated the effect of an HMR on improving adherence to medication using two self-administered questionnaires. The study reported very high levels of adherence at all times of follow-up for patients in both groups; with no between-group differences were evident. Final adherence scores were marginally better in those who received the HMR, but the difference was not statistically significant. Additionally, three of the HMR program evaluations reported stakeholder perceptions (consumers and pharmacists) of improved medication adherence based on interview data, but there was no supporting quantitative data. It should be noted that adherence is only a surrogate outcome and improvement in medication adherence does not necessarily translate to improvement in patient health outcomes. Further high quality studies of adequate size and duration, assessing the impact of HMR on adherence to medicines are required to draw firm conclusions.

ES 3.6 Adverse drug events/medication-related problems

None of the included studies specifically reported outcomes relating to adverse drug events or adverse drug reactions. However, three RCTs reported on the number of recommendations made by pharmacist as a result of the HMR. A fourth RCT examined the effect of pharmacist-led HMR coupled with a pharmaceutical care plan on the identification and resolution of pharmaceutical care issues (PCIs). The study reported significantly less PCIs identified in the group that received the HMR compared to the control group. At three-month follow-up, the number of PCIs that were resolved in the intervention group were double that resolved in the control group.

Two of the HMR program evaluations addressed the impact of HMRs on medication-related problems. One study, based on consumer self-reported data, showed fewer medication-related incidents after HMR. The other study summarised stakeholder interview data where the perception was that patients would have fewer medication-related incidents after HMR. This evidence is low level, and taken together with the fact that no RCTs specifically reported outcomes relating to adverse drug events, it is concluded that there is insufficient evidence to draw any robust conclusions.

ES 3.7 Mortality

Evidence from a single RCT reported significant fewer out-of-hospital deaths and fewer total deaths in high-risk patients receiving an HMR post-discharge from an acute care hospital. A detailed analysis of congestive heart failure patient subpopulation of this RCT did not show a similar effect. However, this contradicts findings from three other RCTs where the results suggest that a pharmacist directed HMR for people recently discharged from hospital with heart failure had no significant effect on mortality.

Only one RCT by Lenaghan et al (2007) evaluated the impact of HMRs performed by a pharmacist on mortality in elderly patients aged over 80 years and were prescribed at least four oral daily medicines, and were not discharged from a hospital. This RCT showed that HMR performed by community pharmacist did not lead to reductions in mortality in this population. Overall, there is a lack of a clear evidence base demonstrating an effect of HMR on reducing deaths.

ES 3.8 Health-related quality of life

Evidence from five RCTs indicates that HMRs performed by pharmacists do not appear to improve the patient's quality of life. Two of the HMR program reviews addressed the QoL. The Urbis Keys Young study used the generic EQ-5D questionnaire in a consumer survey (n = 50), and reported a QALY gain of 0.119 per HMR. The VALMER study reported an average gain of 0.003 QALYs after

HMR, i.e. only 2.5% of the gain reported by Urbis Keys Young. Overall, there is no clear evidence to suggest that a HMR performed by a pharmacist results in an improvement in patient QoL.

ES 3.9 Patient acceptance/satisfaction

In the included studies patient satisfaction was marginally reported, with only one study reflecting on this outcome. The three focus group research studies indicate that individuals who experienced the HMR were overall satisfied with the service. Two of the HMR program reviews also reported high levels of patient satisfaction with the HMR service, although one review reported a level of discomfort among Indigenous people with a HMR service conducted in the home. On the whole, there seems to be evidence to suggest a generally high level of patient satisfaction with a HMR service. Future research into HMR should incorporate the opinions of study participants to identify what they would desire in a pharmacist-led service that targets drug regimens and improves patient outcomes.

ES 3.10 Time spent in therapeutic range

One retrospective cohort study assessed whether HMRs are associated with improved international normalised ratio (INR) control in a population of Australian veterans taking warfarin. Results showed that there was no difference in the time spent in therapeutic range (TTR) in the six months following HMR compared with the control group. The authors concluded that pharmacist-led HMRs were not associated with a change in INR control.

ES 3.11 Medication use and appropriateness

One retrospective study examined the effect of HMR on improvement in the use of medicines, measured by a decrease in the Drug Burden Index (DBI) score and the Potentially Inappropriate Medicines (PIMs) score. The study showed that there was a statistically significant reduction in the sum total of DBI scores for all patients observed following pharmacist recommendations during the HMR service. A lower number of medicines contributing to the DBI (medicines with sedative or anticholinergic properties) and low PIMs were identified following pharmacist recommendations during the HMR service compared to prior the HMR service. Therefore, it appears that pharmacists' recommendations during HMR services, if acted upon, may effect changes in the prescribing of sedative and anticholinergic medications, thereby substantially reducing the patient's drug burden. However, this study relied on documentation in the case notes for HMRs, and it is not clear to what extent pharmacist recommendations are acted upon. Therefore, the results may reflect recommended practice rather than actual practice.

One retrospective study evaluated the impact of HMRs on the appropriateness of prescribing, using the Medication Appropriateness Index (MAI) as a tool to categorise pharmacists' recommendations. The study found that almost all (99%) patients had at least one inappropriate rating at baseline and more than 50% of the patients had a cumulative MAI score >15. Pharmacists' recommendations following the HMR and uptake of these recommendations by the GP resulted in a statistically significant decrease in the MAI scores. The authors concluded that HMRs performed by accredited pharmacists can improve the appropriateness of prescribing as measured by a change in the patient's MAI score. However, the clinical importance of the improvement in prescribing appropriateness was not measured, and therefore the effect of improvement in medication or prescribing on improving important health outcomes (such as mortality, quality of life, adverse events) remains unknown.

ES 3.12 Cost-effectiveness

The single included economic evaluation of HMR is a cost-utility analysis based on an RCT conducted in the United Kingdom between 2000 and 2002, involving two home visits by a community pharmacist for medication review at two and eight weeks after hospital discharge versus usual care. The intervention was found to increase hospital admissions by 30%; and a non-statistically significant

difference in life years gained (LYG) and QoL in the intervention group was found. The study reported the HMR cost £124 per patient. The incremental cost per quality-adjusted life year (QALY) gained was £54,454. The authors quote that the threshold for cost-effectiveness in the UK at the time of publication was £25,000–£35,000 per QALY, indicating that HMR was not cost-effective in this population.

Two of the HMR program reviews also included economic evaluations. The economic model in the Urbis Keys Young review suggested a cost saving in year one (2004) of $4.5 million and a gain of 1,435 QALYs. Taken together, these numbers produce a cost per QALY gained of -$3,138, as the benefits are modelled to exceed the costs. The model then suggests that the cost per QALY reduces to -$4,375 in year seven, a figure that is based on sustaining the incremental gain of 0.119 QALYs from one HMR over the seven year period (discounted using life tables).

The economic model in the VALMER study indicated that the HMRs would result in a decrease in healthcare utilisation costs, and an improvement in QoL. However, the authors found that in many HMRs the absolute value of the reductions in health resource utilisation was insufficient to offset the cost of the HMR, and the ICER was $64,939 (95% CI $48,407 to $80,170) per QALY gained, based on an incremental gain of 0.003 QALYs attributed to the intervention.

Thus two of the three identified studies found that HMRs would increase health care costs, and that the cost per QALY gained was higher than normally accepted thresholds. The other study found a very significant net benefit in HMRs and a consequential cost saving per QALY gained. The results of this study seem implausible and are not supported by the other two, more recent studies. Overall, it is concluded that there is insufficient evidence to establish the cost-effectiveness of HMRs.

ES 3.13 Other outcomes

None of the included studies specifically investigated whether the provision of HMR is accompanied by clinically meaningful improvements in clinical outcomes.

ES 4 RESULTS OF THE UTILISATION ANALYSIS

The utilisation analysis found that claims payment policy changes (specifically the introduction of a claims cap of 20 HMRs per provider per month, the effect of enforcing the 'only in the home' ruling, the restriction on the time interval between services, and the 30 day deadline to submit claims) had an apparent and lasting impact upon the volume of HMR claims and participating providers. Before the changes, the uncapped scheme was servicing and increasing number of patients and attracting more providers (both community pharmacies and business entities).

After the payment policy changes, HMR patient and service volumes declined steeply across pharmacy and non-pharmacy providers, but quickly found equilibrium with fewer numbers of patients and providers. The data also suggest changes in behaviour to comply with the claiming frequency guidelines, with a greater proportion of patients receiving only one HMR and longer claiming intervals for patients receiving multiple services. This shift is likely to be due to provider perceptions of more stringent and enforced claims policies, previously suffered non-claimable service provision losses and reductions in access to economies of scale.

ES 5 CONCLUSIONS

Taken together, the systematic literature review and the lower level evidence in reviews funded as part of successive CPAs does not allow a conclusive determination to be made with regard to the clinical and cost-effectiveness of HMRs performed by pharmacists. There is a larger body of evidence for

more comprehensive and multidisciplinary medication review interventions focused on improving clinical outcomes, but findings from these studies cannot be extrapolated to the HMR program.

Drawing conclusions is therefore difficult, as the available studies are patchy and their findings are often conflicting. Very few studies address the ultimate clinical outcomes of a HMR, rather they focus more on interim outcomes (e.g. medication adherence) and patient satisfaction. The impact of HMRs on health care resource use and the associated cost-effectiveness is unclear, with two of the three available studies suggesting that the costs of the HMR service is greater than the value of benefits obtained through changed health care resource use (neither of these studies is considered high quality).

Thus, it is concluded that to make a robust assessment of the clinical and cost-effectiveness of HMRs, further research is required. The nature of that research is difficult to specify, as HMRs have become an accepted part of pharmacy practice. It is considered that some progress could be made by identifying the characteristics of patients that experience adverse medication events and targeting research towards determining whether HMRs by a pharmacist can prevent those problems occurring. The alternative may be to direct research towards developing a multidisciplinary (at the point of care) HMR delivery model.

1 Introduction

On the 27th October 2016, the Department of Health engaged HealthConsult to undertake an evaluation to determine the clinical/cost-effectiveness of four Sixth Community Pharmacy Agreement Medication Management Programs (MMPs): Home Medicines Review (HMR); Residential Medication Management Review (RMMR); MedsCheck; and Diabetes MedsCheck. This report presents the initial evaluation of the HMR program, which has involved:

- a literature review to identify evidence to inform the comparative clinical and cost-effectiveness of the HMR program and 'like' programs internationally; and
- an examination of the available Australian utilisation data from the HMR program going back to its commencement under earlier Community Pharmacy Agreements (CPAs).

1.1 SIXTH COMMUNITY PHARMACY AGREEMENT

In May 2015, the Australian Government and Pharmacy Guild of Australia entered into the 6CPA, which provides around $18.9 billion in remuneration for community pharmacy, as well as support to the pharmaceutical supply chain (with a further $372 million provided for chemotherapy compounding fees). Up to $1.26 billion in funding is available under the 6CPA for evidence-based, patient-focused professional pharmacy programs and services. This consists of:

- $613 million for the continuation of a number of programs and services from 5CPA;
- $50 million for a new pharmacy trial program; and
- up to $600 million for new and expanded community pharmacy programs.

The 6CPA includes three key funding elements:

- community pharmacy remuneration;
- ensuring that all Australians have timely access to the Pharmaceutical Benefits Scheme (PBS) medicines they require regardless of the cost of the medicine or where they live; and
- community pharmacy programs directed at improving consumer management of their medications and delivering primary healthcare services through community pharmacy.

1.2 CONTINUING CPA PROGRAMS

As part of the 6CPA, there are several continuing programs directed at improving medication compliance through community pharmacies in Australia. The continuing programs include:

- Medication Adherence Programs (MAPs):
  - Dose Administration Aids (DAAs);
  - Clinical Interventions (CIs); and
  - Staged Supply (SS).
- Medication Management Programs (MMPs):
  - Home Medicines Reviews (HMR);
  - Residential Medication Management Reviews (RMMR); and
  - MedsCheck and Diabetes MedsCheck.
- Rural Support Programs:

  - Rural Pharmacy Workforce Program; and
  - Rural Pharmacy Maintenance Allowance.
- Aboriginal and Torres Strait Islander (ATSI) Programs:
  - Quality Use of Medicines Maximised for ATSI People (QUMAX);
  - S100 Pharmacy Support Allowance; and
  - ATSI Workforce Program (Pharmacy Assistant Traineeship Scheme and Pharmacy Scholarships Scheme).
- eHealth:
  - Electronic Prescription Fee.

Under 6CPA, all programs and services need to be reviewed by the Medical Services Advisory Committee (MSAC) for clinical and cost-effectiveness and the health benefits they offer to the community. This process is being used to ensure pharmacy programs and services are assessed against the same standards of evidence as for other health professions. It supports a consistent approach to informing investment that delivers the greatest benefit to consumers.

2
Overview of the HMR Program

This Section briefly overviews the HMR program, as described in the Programme Specific Guidelines (PSG), which falls under the MMP within 6CPA.

2.1 HMR INITIATIVE

The HMR program, which is part of the suite of MMPs funded under the 6CPA, was designed to enhance the quality use of medicines and reduce the number of adverse medicine events and associated hospital admissions or medical presentations, by assisting consumers to better manage and understand their medicines through a medication review conducted by an accredited pharmacist in the patient's home.

2.2 OBJECTIVES OF THE HMR PROGRAM

The objectives of HMR are to:

- achieve safe, effective, and appropriate use of medicines by detecting and addressing medicine-related problems that interfere with desired patient outcomes;
- improve the patient's quality of life and health outcomes using a best practice approach that involves cooperation between the GP, pharmacist, other relevant health professionals and the patient (and where appropriate, their carer);
- improve the patient's and health professional's knowledge and understanding of medicines;
- facilitate cooperative working relationships between members of the healthcare team in the interests of patient health and wellbeing; and
- provide medication information to the patient and other healthcare providers involved in the patient's care.

A HMR service is available to an eligible patient whose GP determines that a HMR is clinically necessary to address the patient's needs and optimise the patient's quality use of medicines.

A complete HMR service includes the service provided by the GP, the HMR Service Provider and the patient's choice of usual community pharmacy from the time the patient is identified through to the implementation and ongoing monitoring of the medication management plan.

2.3 PARTICIPATION IN THE HMR INITIATIVE

To be eligible to participate in the HMR program a service provider must:

(1) Abide by the 6CPA General Terms and Conditions;

(2) Undertake to provide the HMR service in accordance with the PSG;

(3) Be able to certify that the same Accredited Pharmacist (who is approved to conduct HMR services) will conduct the patient interview, the clinical assessment and report writing steps of the HMR service;

(4) Understand that no more than twenty (20) HMR services per HMR Service Provider per calendar month will be remunerated;

(5) Understand that an Accredited Pharmacist can conduct no more than a total of twenty (20) HMR services per calendar month, irrespective of the number of HMR Service Providers they provide HMR services on behalf of.

(6) Provide the HMR interview in the patient's home, unless prior approval is granted.

The patient must satisfy the following mandatory HMR service eligibility criteria:

- the patient is a current Medicare/Department of Veterans' Affairs (DVA) cardholder;
- the patient is living in a community setting;
- the patient is at risk of or experiencing medication misadventure; and
- the GP confirms that there is an identifiable clinical need and the patient will benefit from a HMR service.

HMR services are not available to inpatients of public or private hospitals, day hospital facilities, transition care facilities or to residents of an aged care facility (ACF).

Currently services are payable to approved service providers for each HMR conducted after a referral by a GP. The current payment rate for an HMR service is $213.67.[2]

The current MBS fee for participation by a medical practitioner (including a GP, but not including a specialist or consultant physician) in a Domiciliary Medication Management Review (DMMR) for patients living in a community setting is $154.80.

2.4 FREQUENCY OF SERVICE

One HMR service can be conducted per eligible patient on referral from a GP. A subsequent HMR may only be claimed if more than 24 months has elapsed since the date of the most recent service or when the patient's GP specifically deems a subsequent review is clinically necessary such as when there has been significant change to the patient's condition or medication regimen.

Reasons why an additional review may be requested include:

- discharge from hospital after an unplanned admission in the previous four weeks;
- significant change to medication regimen in the past three months;
- change in medical condition or abilities (including falls, cognition, physical function);
- prescription of a medicine with a narrow therapeutic index or requiring therapeutic monitoring;
- presentation of symptoms suggestive of an adverse drug reaction;
- sub-therapeutic response to therapy; or
- suspected non-compliance or problems with managing medication-related devices; or
- risk of or inability to continue managing own medicines due to changes in dexterity, confusion or impaired vision.

Provision of a subsequent HMR must not be triggered solely by an 'anniversary' date. The HMR service is not intended to be an ongoing review cycle.

It is important to note that medical practitioners (e.g. GPs) are able to make an MBS claim under MBS item 900, for participation in a HMR. Different to the HMR service provided by a pharmacist, an MBS item 900 can be claimed every 12 months for an HMR conducted by a medical practitioner compared to 24 months if conducted by a pharmacists.

2-2 Claiming and payment [Internet]. 2015. [cited 2017 Feb 15]. Available from: http://6cpa.com.au/medication-management-programmes/home-medicines-review/

2.5 IDENTIFYING A PATIENT

A HMR could benefit a patient for whom quality use of medicines may be an issue or; patients who are at risk of medication misadventure because of factors such as their comorbidities, age or social circumstances, the characteristics of their medicines, or the complexity of their medication treatment regimen. If the patient has not been identified by the GP, a recommendation based on the patient's current clinical need should be provided to the GP. The recommendation may be provided by a Registered Pharmacist, the patient/carer or another health care professional. However, the GP is required to provide the initial referral

2.6 REFERRAL

The patient's GP will assess eligibility and outline the HMR service to the patient. If the patient agrees that a HMR service is necessary and is willing to have the interview conducted in their home, the GP will obtain patient consent to participate in the HMR service. Following a discussion between the GP and patient, the patient may choose to be referred to the patient's choice of/usual community pharmacy or to an Accredited Pharmacist who meets the patient's needs. The HMR referral should include reason for referral and all relevant prescribing and clinical history. The patient interview must take place within ninety (90) days of the date of the referral to be remunerated under the HMR programme.

2.7 HMR RURAL LOADING ALLOWANCE

HMR Rural Loading is an initiative of the HMR Programme which was established to provide financial support to pharmacies to enable patients living in rural and remote areas to access the HMR service.

In rural areas, funding of up to $125 is available to contribute towards travel costs incurred (i.e. not necessarily cover all costs incurred) by the accredited pharmacist to conduct the interview at the patient's home under the HMR Rural Loading Allowance[3]. The allowance is based on the location of the patient receiving the HMR service. A patient is deemed to be a rural patient if they live in categories 2–6 as defined by the Pharmacy Accessibility Remoteness Index of Australia (PhARIA)[4].

[3] http://6cpa.com.au/medication-management-programmes/home-medicines-review/
4 The PhARIA index can be accessed at http://www.adelaide.edu.au/apmrc/research/projects/pharia/ The current PhARIA data will be applied to determine eligibility.

3
Review Methodology

This Chapter describes the methodology used to identify and assess the evidence relating to HMR, or similar pharmacist-led programs. The evaluation encompasses a systematic literature review of Australian and international evidence for the effectiveness and cost-effectiveness of pharmacist-delivered services such as those provided by HMR to residents in the community, and an analysis of available data on the utilisation of the service provided.

3.1 SYSTEMATIC LITERATURE REVIEW

This Section presents the selection criteria, the search strategy used to identify the relevant evidence, and a summary of the process used to include and/or exclude identified evidence to assess the safety, effectiveness and cost-effectiveness of HMR services.

3.1.1 PICO criteria

Table 3.1 presents the selection criteria for evidence assessing the safety, effectiveness and cost-effectiveness of HMR services.

Table 3.1: Selection criteria for evidence relating to HMR services provided by community pharmacists

Criteria	Description
Population	Patients living in the community (including respite care) who are at risk of experiencing medication misadventure due to multiple chronic conditions; comorbidities; age or social circumstances; the characteristics of their medicine; the complexity of their medication regimen; or a lack of knowledge and skills to use their medicine effectively and safely. Examples of risk criteria include: • taking five or more regular medicines; • taking more than 12 doses of medicine per day; • having three or more concurrent medical conditions; • experiencing significant changes to their medicine regiment (in the past three months); • recently discharged from hospital; • taking medicine with a narrow therapeutic index or requiring therapeutic monitoring; • experiencing symptoms suggestive of an adverse drug reaction or sub-therapeutic response to therapy; • suspected non-compliance or problems with medication-related devices; • self-management of medicines plus literacy or language difficulties or dexterity, vision or cognitive limitations; • attending a number of different doctors, both general practitioners and specialists; or • increasing frailty or changes in health status. *Note: Excludes hospital inpatients, day hospital facility patients or patients in a Residential Care Facility.*
Intervention	A HMR or a similar service consisting of a comprehensive clinical review of a patient's medicines during a single visit to their home by an accredited pharmacist on referral from the patient's general practitioner. *Interventions specifying multiple scheduled visits within a 12-month period will be excluded.*
Comparator	Patients living in the community who did not access HMR services.
Outcomes	Outcomes include: • changes in adherence/compliance/concordance with prescribed dose schedule (e.g. pill count, self-report); • changes in clinical outcomes (e.g. BP in patients with hypertension, HbA_{1c} in patients with diabetes); • rates of adverse drug event/reactions and medication-related problems; • changes in disability indices; • health care resource use (ED attendance, hospitalisation, GP visits, specialist visits); • patient acceptance/satisfaction; • health-related quality of life; • cost of the service; • cost-effectiveness.

Criteria	Description
Study design	Comparative studies (randomised or non-randomised controlled trials, comparative cohort studies, case control studies, before/after studies) or systematic reviews of comparative studies. Applicability to the Australian context will be considered.
Publication type	Full English-language publications or reports. Conference abstracts will be excluded.

3.1.2 Search strategy

A comprehensive search of peer-reviewed scientific literature was conducted in December 2016 to identify studies that provide evidence relating to the effectiveness and cost-effectiveness of HMR or similar programs provided by pharmacists to individuals living in the community.

Three electronic databases were searched for original research papers describing relevant systematic reviews, meta-analyses or comparative studies; Embase (OVID), Medline (OVID) and the Cochrane Library of Systematic Reviews (Cochrane Database of Systematic Reviews; Database of Abstracts of Reviews of Effects; Cochrane Central Register of Controlled Trials; Health Technology Assessments Database; NHS Economic Evaluation Database). The search was conducted on 19th December 2016, and the publication date was unrestricted. A search of the Health Systems Evidence database, and the websites of HTA agencies was also conducted.

The specific search terms used to identify relevant literature are outlined in 0. The search strategy was designed to identify articles relevant to the evaluation of HMR, RMMR and also the MedsCheck and Diabetes MedsCheck programs. While the screening for evidence pertinent to each of these programs was conducted simultaneously, the evaluation of HMR, RMMR, MedsCheck and Diabetes MedsCheck is reported separately.

3.1.3 Selection of relevant evidence

The literature search outlined above identified 5,282 records from Embase, Medline and the Cochrane Library (3,670 unique citations; Table 3.2) and 373 records in the Health Systems Evidence database. The following exclusion criteria were applied:

- wrong publication or study type– excludes narrative reviews, conference abstracts and editorials, and non-comparative studies (i.e. single arm, descriptive studies);
- wrong population – excludes services for patients not living at home (e.g. hospital inpatients, residential aged care facilities, patients attending GP clinics);
- wrong intervention – excludes studies of interventions that do not align with HMR services as described in Appendix C (e.g. provided by a health professional other than a pharmacist, multidisciplinary models, or interventions that involve other services in addition to medicines review);
- wrong comparator – excludes studies that do not include a comparator group of patients for whom the service was not provided;
- wrong outcomes – excludes studies that do not assess one of the outcomes outlined in Section 0 (studies that assessed intermediate outcomes such as medication appropriateness and use were included); and
- not in English – excludes studies not published in English language or those that do not include at least some information (e.g. a summary) in English.

The exclusion of citations during screening of these records is presented in Table 3.2. The Health Systems Evidence search yielded an additional 32 systematic reviews or economic analyses, of which six were eligible for inclusion and 26 did not meet the exclusion criteria (e.g. focus of review too broad, including out-of-scope studies), but were checked for included studies that did meet our inclusion

criteria. A further 17 citations were identified by hand searching reference lists of these and other studies, and two records were identified in targeted HTA website searches and the grey literature.

Table 3.2: Summary of the process used to identify studies and reports relevant to the evaluation of HMR service

Description	Embase	Medline	Cochrane Library
Records retrieved	3,131	1,507	644
Total number of citations	5,282		
Duplicates within and across sets removed	1,612		
Total number of citations screened	3,670		
Excluded at title/abstract review:			
Wrong publication type	238		
Wrong population	360		
Wrong intervention	2,144		
Wrong comparator	10		
Wrong outcome	81		
Not English	90		
Total citations excluded at title/abstract review	*2,923*		
Citations screened at full text review	747		
Excluded at full text review:			
Wrong publication type	26		
Wrong population	37		
Wrong intervention	656		
Wrong comparator	3		
Wrong outcome	11		
Total citations excluded at full text review	*733*		
Total included studies or reports from Embase/Medline/Cochrane	14		
Included from Health Systems Evidence database	0		
Included from HTA websites	0		
Included from hand searching reference lists	2		
Total included studies or reports: Relevant to HMR	16		

Abbreviations; HMR, Home Medicines Review

3.1.4 Previous program evaluations of the HMR program

The targeted search of the websites of relevant pharmacy organisations and the Commonwealth Department of Health identified five evaluations of the HMR program that were funded under prior CPAs. The citations are provided in Table 3.3. A summary of the findings and conclusions of these prior evaluations, including economic evaluations, where they were conducted is provided in Chapter 4.

Table 3.3: Citation details of program evaluations of the HMR program

Study ID	Citation
UKY (2005)	Urbis Keys Young – Evaluation of the Home Medicines Review Program: Pharmacy component; 2005.
CRC (2008)	Campbell Research and Consulting – Home Medicines Review Program Qualitative Research Report: Final Report; 2008.
Stafford (2009)	Stafford A, Tenni P, Peterson G, Doran C, Kelly W. VALMER (The Economic Value of Home Medicines Reviews); 2009.
Stafford (2012)	Stafford C. A clinical and economic evaluation of medication reviews conducted by pharmacists for community dwelling Australians; 2012
PwC (2015)	PwC – Combined Review of Fifth Community Pharmacy Agreement Medication Management Programmes: Final Report; 2015.

Note: A report commissioned under the 5CPA to undertake a project called 'HMR: Refining Patient Eligibility Criteria' included a systematic review undertaken by Monash University. This report and systematic review (although some of the primary studies have been included) were excluded as they were focused on broader HMR models including multidisciplinary models or multifaceted pharmacy-led interventions, or medication reviews delivered by combinations of health professionals (e.g. physician, nurses) where the pharmacist was only partly involved. Therefore, the findings from these systematic reviews (including the Monash systematic review) cannot be extrapolated (in whole) to this evaluation of the HMR service.

3.1.5 Systematic reviews

The literature search identified a number of systematic reviews and narrative reviews that did not focus on HMR conducted by a pharmacist but on medication reviews in any setting, or medication review within a multidisciplinary model or a disease management plan, or medication reviews that were delivered by any health professional. Systematic reviews that presented analysis (or meta-analysis) from pharmacy interventions that included services other than the HMR specifically performed by a pharmacist were excluded. A list of these reviews is presented in Appendix C. The reference lists of each of the excluded systematic reviews were hand-searched to identify any relevant studies not found elsewhere.

3.1.6 Primary studies

The systematic literature search for primary studies identified 16 eligible publications that investigated the effect of HMR on a number of patient outcomes. Table 3.4 presents the list of included studies.

Table 3.4: Citation details for included studies of HMR

Study ID	Citation
Effectiveness	
Bereznicki (2016)	Bereznicki, L. R. E., E. C. van Tienen, et al. (2016). Home medicines reviews in Australian war veterans taking warfarin do not influence international normalised ratio control. Internal Medicine Journal; 46(3): 288-294.
Barker (2012)	Barker A, Barlis P, Berlowitz D, Page K, Jackson B, Lim WK (2012). Pharmacist directed home medication reviews in patients with chronic heart failure: a randomised clinical trial. Int J Cardiol; 159:139–143.
Castelino (2010a)	Castelino RL, Hilmer SN, Bajorek BV, Nishtala P, Chen TF. (2010a). Drug Burden Index and Potentially Inappropriate Medications in Community-Dwelling Older People: The Impact of Home Medicines Review. Drugs and Aging 2010;27(2):135-35.
Castelino (2010b)	Castelino RL, Bajorek BV, Chen TF. (2010b). Retrospective evaluation of home medicines review by pharmacists in older Australian patients using the medication appropriateness index. Ann Pharmacother; 44: 1922–9.
Roughead (2011)	Roughead EE, Barratt JD, Ramsay E, Pratt N, Ryan P, Peck R et al. (2011). Collaborative home medicines review delays time to next hospitalization for warfarin associated bleeding in Australian war veterans. J Clin Pharm Ther; 36: 27–32.
Roughead (2009)	Roughead EE, Barratt JD, Ramsay E, Pratt N, Ryan P, Peck R et al. (2009). The effectiveness of collaborative medicine reviews in delaying time to next hospitalization for patients with heart failure in the practice setting: results of a cohort study. Circ Heart Fail; 2: 424–8.
Lenaghan (2007)	Lenaghan, E., R. Holland, et al. (2007). Home-based medication review in a high risk elderly population in primary care - The POLYMED randomised controlled trial. Age and Ageing; 36(3): 292-297.
Holland (2007)	Holland, R., I. Brooksby, et al. (2007). Effectiveness of visits from community pharmacists for patients with heart failure: HeartMed randomised controlled trial. British Medical Journal 334(7603): 1098-1101.
Holland (2005)	Holland R, Lenaghan E, Harvey I, Smith R, Shepstone L, Lipp A, Christou M, Evans D, Hand C. (2005). Does home based medication review keep older people out of hospital? The HOMER randomised controlled trial. BMJ; 330: 293.

Study ID	Citation
Krska (2001)	Krska J, Cromarty JA, Arris F, Jamieson D, Hansford D, Duffus PR, et al. (2001). Pharmacist-led medication review in patients over 65: a randomized, controlled trial in primary care. Age Ageing; 30: 205-11.
Stewart (1998a, 1998b)	Stewart S, Pearson S, Luke CG, Horowitz JD (1998a). Effects of home-based intervention on unplanned readmissions and out-of-hospital deaths. J Am Geriatr Soc; 46:174-80. Subpopulation analysis (congestive heart failure patients): Stewart S, Pearson S, Horowitz JD (1998b). Effects of a home-based intervention among patients with congestive heart failure discharged from acute hospital care. Arch Intern Med; 158: 1067–72.
Patient satisfaction	
Ahn(2015)	Ahn, J., Park, J. E., Anthony, C. and Burke, M. (2015). Understanding, benefits and difficulties of home medicines review - patients' perspectives. Australian family physician 44(4): 249-253.
Carter (2012)	Carter, S. R., T. F. Chen, et al. (2012). Home medicines reviews: A quantitative study of the views of recipients and eligible non-recipients. International Journal of Pharmacy Practice 20(4): 209-217.
White (2012)	White, L., C. Klinner, et al. (2012). Consumer perspectives of the Australian Home Medicines Review Program: Benefits and barriers. Research in Social and Administrative Pharmacy 8(1): 4-16.
Cost-effectiveness	
Pacini (2007)	Pacini, M., R. D. Smith, et al. (2007). Home-based medication review in older people: Is it cost effective? PharmacoEconomics 25(2): 171-180.

Appendix C presents a list of other primary studies of medication reviews identified through the literature search and the reasons for their exclusion. Studies that examined HMR as part of a more comprehensive pharmacy care program or were part of a multidisciplinary model were excluded. Studies that evaluated HMR performed by a healthcare professional other than a pharmacist were also excluded. Other exclusions were applied to studies that assessed HMRs in a hospital setting or general practitioner setting.

3.2 UTILISATION ANALYSIS

Utilisation of HMR services was analysed using the claims payment data extracted from DHS systems for years 2011/12, 2012/13 and 2013/14 and Pharmacy Guild claims systems extracts for years 2014/15 and 2015/16. The analysis is restricted to claims paid for date of service between 1st July, 2011 and 30th June, 2016 (records that do not have valid dates or have unrealistic dates were excluded from the datasets). The encryption of some key identifying fields in the DHS datasets placed some limitations on the analysis, which have been noted, where relevant.

HMR de-identified claims payment data have been analysed with the emphasis on longitudinal relationships within the claims system extracts, especially with regard to the frequency of service stipulations (outlined in Section 2.4). The data have also been analysed to assess 'remoteness'[5], as inferred from the postcode of each patient's residence (where that information was available). Postcodes were mapped to remoteness area using the Australian Bureau of Statistics (ABS) mapping table.

[5] ABS postcode to remoteness.xls available from http://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/1270.0.55.006July%202011?OpenDocument (accessed 5th October, 2016)

4
Previous evaluations of the HMR Program

This Chapter summarises the findings of evaluations of the HMR program funded under prior CPAs. Five program evaluations were identified by Urbis Keys Young, Campbell Research and Consulting, Stafford et al., Stafford (VALMER), and PricewaterhouseCoopers (PwC). These summaries are offered to provide MSAC with an understanding of the approaches taken to evaluate the HMR program in Australia, as well as present the evaluation findings in relation to the clinical and cost-effectiveness of the HMR service. Please note that the views reported here are those of the evaluators who undertook the original evaluations and not HealthConsult's.

4.1 EVALUATION OF THE HMR PROGRAM – PHARMACY COMPONENT (URBIS)

In October 2004, Urbis Keys Young was commissioned by the Pharmacy Guild of Australia (the Guild) to conduct the evaluation of the pharmacy component of the HMR (funded under 3CPA, and the MBS through Item 900 for GP services). This work incorporated two broad components:

- consideration of the costs associated with the HMR program (for consumers, pharmacy and the health system), compared with the possible costs of not addressing medication-related problems; and
- an assessment of the cost-effectiveness of the program by way of a cost-utility analysis.

The objective of the evaluation was to determine how effective the HMR program, including the supporting MMR Facilitator Program, was in achieving its objectives from a pharmacy perspective. The evaluation was intended to help inform Guild and Government decisions about the future objectives and funding of the program including: the continuation of the program, whether the program was meeting its stated aims and objectives, and whether it was still appropriate and fulfilling a community need.

The evaluation used a mixed methods approach comprising of collection and analysis of data relating to the HMR program; a systematic review of relevant literature, with a focus on available information on patient outcomes from medication reviews; consultations with representatives of a broad range of stakeholder organisations; four focus groups with pharmacists in metropolitan and regional locations; a national pharmacy survey (n=1,702); in-depth telephone interviews with pharmacists (n=25) in diverse locations; telephone interviews with consumers (n=50) who had had an HMR in the previous three to twelve months; case studies (n=9) conducted in metropolitan and regional locations, each involving an HMR consumer, his or her GP and the accredited pharmacist who conducted the consumer's HMR interview; in-depth telephone interviews with MMR Facilitators (n=260); and an economic cost benefit analysis of the HMR program.

This Section presents the high level program evaluation findings, with emphasis on those specifically relating to the PICO criteria (Section 3.1.1) where they exist (including a cost-effectiveness analysis), followed by discussion of the limitations of the study and its overall conclusions.

4.1.1 General findings of the evaluation

The evaluation found that between October 2001 and April 2005, 72,458 HMRs were claimed. The great majority of HMR consumers were people aged 65 or over, with a clear preponderance of women over men (even after allowing for the higher numbers of women in older age groups).

The evaluators found that the number of reviews conducted was below the levels budgeted for, and that only a minority of GPs had made HMR referrals. However results of the evaluation identified that there were numbers of GPs who saw the HMR as a highly desirable and effective program.

The evaluation found that community groups that experienced HMR under-servicing were people of CALD backgrounds, Indigenous communities and people living in isolated or sparsely populated areas. Specific groups identified as likely to benefit from improved access to HMRs included older men, and younger people with chronic disease or other serious health problems.

Table 4.1 summarises the main findings, in relation to program areas not covered by the PICO criteria, of the evaluation in relation to the HMR program.

Table 4.1: Main findings of the 2005 Urbis Keys Young HMR Program Evaluation

Program areas	Key findings
Collaboration	In providing a structured basis for collaboration between GPs and pharmacists in patient care, the Australian Government's introduction of the HMR represents an important and innovative step in developing and improving primary health care services.
MMR Facilitator role	Services designed to promote and support the delivery of HMRs have been provided, on a part-time basis, by MMR Facilitators based in some 97% of Divisions of General Practice. In many cases it is reported that the Facilitator's role has led to wider benefits such as involvement by pharmacists in a range of Division activities.
HMR Referrals	HMR referrals were considered lower than was estimated in 2001, with the result that the budget for pharmacy services to June 2005 being underspent.
Workplace issues	The evaluation identified workplace issues relating to relatively low number of MMR-accredited pharmacists, and in rural areas inadequate numbers of health professionals in general; and the time and cost involved in the process of MMR accreditation and re-accreditation. Some pharmacists saw it as desirable for accreditation training to include a stronger emphasis on the practical issues likely to arise in the conduct of HMRs, including effective communication with GPs.
Conduct of HMRs	Information gathered during the evaluation suggested that the conduct of HMRs was generally in accordance with business rules and guidelines disseminated by the HIC and the then Department of Health and Ageing. The exception to this finding was that there was apparently a variable level of contact between GPs and the consumer's chosen community pharmacy after the HMR report was delivered; it also appeared that the pharmacy does not consistently receive from the GP a copy of a Medication Management Plan.
HMR effectiveness	A review of existing literature on home-based medication reviews, and in particular of relevant RCTs, showed that there was a lack of clear clinical evidence supporting the effectiveness of the HMR model. Given the nature of the intervention and the fact that its impact may take a long time to become clear, building up this evidence is likely to be a relatively complex and costly process. However they concluded that relevant data collection and analysis be part of any ongoing implementation of the HMR.

Source: Evaluation of the HMR Program by Urbis Keys Young 2005
Abbreviations: GPs, General Practitioners; HMR, Home Medication Review; MMR, Medication Management Review; HIC, Health Insurance Commission; DoHA, Department of Health and Ageing.

4.1.2 Changes in adherence/compliance/concordance with prescribed dose schedule

The evaluation found that HMR services provided opportunity for identification of potential compliance issues. These finding included:

- Analysis of **stakeholder perspectives** on the HMR found that where the HMR was used, anecdotal information suggests patients benefited in terms of education, improved compliance and improved quality of life. It was noted that recommendations for changes in medication were not necessarily typical outcomes of the HMR; patient education and efforts to improve compliance were important aspects of the review, along with informing the GP of the full range of medication being used.

- **Pharmacy perspectives** on the HMR, ascertained via focus groups, identified a number of perceived benefits of HMR including:
  - assisting the consumer to use medication aids and devices effectively;
  - providing the GP with an accurate list of the medications being used, including herbal medicines and over-the-counter drugs;
  - better consumer understanding of the medications (prescribed and other) which they are using;
  - identifying options for changes in medications or in dosages;[6]
  - identification of undesirable side effects or interactions that may be reduced through use of different medications;
  - identifying and disposing of out-of-date medications;
  - identifying issues around storage of medications;
  - identifying compliance issues and providing relevant information/education (for example, suggesting use of a Dosette box or similar);
  - proposing simpler dosage arrangements that may assist with compliance (e.g. once daily dosage in place of two or three separate doses);
  - identifying cases where duplicate medications are being used (for example through confusion about brand names);
  - identifying excessive or inappropriate use of over-the-counter products such as aspirin;
  - providing information and advice on significant 'lifestyle' issues such as diet and exercise; and
  - identifying other health or welfare issues, such as a need for meals-on-wheels or home help, or a referral to some other health professional – for example, a physiotherapist.
- Reported perceived benefits for the health system generally included:
  - better consumer understanding and compliance, and thus improved impact of medications[7];
  - reduced risk of harm or misadventure; and
  - direct provision of lifestyle information and education for consumers, to complement use of medications.
- Analysis of the pharmacy survey, found that each of the following was included in just over half their reports:
  - suggestions on how/when medications should be taken;
  - comments on potential side effects or interactions;
  - suggested changes to the medications prescribed; and
  - notes on compliance issues.
- Around 30%of HMR reports were said to include:
  - suggested changes in dosages; and
  - suggestions for use of a dose administration aid.
- **Consumers' experience** of HMR, as ascertained via telephone interview and case studies, provided insight as to perceptions about compliance with prescribed dose schedule[8], with 7% of respondents identifying that their HMR improved their understanding of the importance of compliance.

6 In the absence of direct feedback (e.g. in the form of an MMP), pharmacists might nevertheless see some changes in prescribing in the weeks following an HMR.

7 The point was made that, perhaps for legal reasons, printed consumer medication information could be quite 'off-putting', possibly leading the consumer to under-use a particular medication or to avoid it altogether.

8-The evaluators state that the consumers whose responses are discussed were in no sense a random sample, and that therefore caution is necessary in drawing general conclusions from the information they provided.

4.1.3 Rates of adverse drug event/reactions and medication-related problems

Of the 57 consumers consulted, one in four said that in the past two years they had had an illness or significant health problem that they recalled was related to, or caused by, their medications. These respondents had generally experienced either a single incident or problems that were ongoing over a period of several weeks.

Table 4.2 shows that 12 of the 14 respondents who reported medication-related health problems had experienced one or more occurrences of this before the HMR; however, only three reported experiencing such problems after the review. The evaluation found that, for all other indicators (e.g. hospital admissions), consumers reported fewer occurrences following the HMR.

Table 4.2: Medication-related health problems experienced before and after the HMR

Indicator report	Total reports	Pre-HMR occurrences	Post-HMR occurrences
Any incidents	14	12	2
Hospital admission	4	4	0
Stay in hospital (one or more days)	3	3	0
Visit to an Emergency Department	3	3	0
Visit to a GP (medications-related)	7	5	2
Visit to a specialist (medications-related)	3	3	0
Days off work (one or more)	0	0	0
Unable to do usual tasks around the home (one or more days)	6	6	0
Days taken off work by somebody else to help or look after respondent (one or more)	1	1	0

Source: Evaluation of the HMR Program by Urbis Keys Young 2005
Abbreviation: HMR, Home Medication Review

4.1.4 Health care resource use

Consumers were asked, via the consumer survey, whether in the past two years they had experienced illness or significant health problems related to their medications and, if so, the extent to which various events had occurred before and after their HMR. The evaluators reported that although the consumer survey faced issues of low statistical power, as well as selection and measurement bias, a number of the responses given were in line with expectations based on the published literature. These changes in the number of events are summarised in Table 4.3.

Table 4.3: Number of Events before and after the HMR

Medication-related event	Frequency of events	
	Pre-HMR	Post-HMR
Medication incidents	11%	2%
Hospital admissions	5%	0%
Days in hospital	33	0
Visits to an emergency department	5%	0%
GP visits	9%	5%
Specialist visits	5%	0%
Number of days off work	0	0
Days unable to do usual tasks at home	7%[sic]	0%[sic]
Days off work by someone else to care for respondent	2%[sic]	0%[sic]

Source: Evaluation of the HMR Program by Urbis Keys Young 2005 – Consumer survey, Question 14 N =57
Abbreviation: HMR, Home Medication Review

There were no days off work recorded in the survey pre- or post-HMR, which probably reflects the fact that only 5% of the sample was employed.[9] There was, however, a fall in the number of days on which

9-Consumer survey, Question 17b1.

the patient was unable to do usual tasks post-HMR and a fall in days off work by someone else to care for the respondent.[10]

Fifty of these 57 consumers (88%) said they had gone back to the GP following the pharmacist's review – typically some seven to 14 days later[11]. A number of the respondents mentioned that they had appointments with their GP at regular intervals and that the appointment after the HMR was one of these. Of those who reported going back to the GP after their HMR interview, just over half (58%) stated they did not discuss with their GP changing or improving anything in the light of the review. Among the 19 respondents who did report discussing changes or improvements, the most common changes recalled by the consumer related to dosages. The responses suggest that where changes were discussed with the GP, this resulted in a number of alterations to the consumer's medication and health regimen.

Relatively few respondents (15 out of the 50 who reported visiting their GP after the review) recalled the GP developing a Medication Management Plan with them. Almost all who did recall a plan being prepared, however, said they had received a copy and felt that they had been able to keep to the plan.

4.1.5 Patient acceptance/satisfaction

Consumers' experience of and attitudes to the HMR were explored through telephone interviews with 50 people who had participated in an HMR at some time in the previous 3-12 months, and from the first seven of the nine case studies conducted in various urban and regional locations.[12]

Overall satisfaction with the HMR was very high: 75% of respondents being very satisfied and 23% satisfied. No respondents reported being dissatisfied with the HMR. Similarly positive attitudes were indicated by respondents' level of agreement with various statements about the HMR. Only two respondents identified any negatives associated with the HMR. One respondent said that the HMR had tended to make her feel 'paranoid' about medication side effects; the other had been asked, unexpectedly, to pay for the follow-up visit to her GP.

4.1.6 Health-related quality of life

A cost-utility analysis (CUA) was used to consider the cost-effectiveness of the HMR program, allowing a range of clinical outcomes to be incorporated into a single unit of measure, the cost per quality-adjusted life year (QALY) ratio. Information from the consumer survey, combined with data from previous reports and published literature, was used to derive utility values for patients around the time of their HMR. Data were extracted from the literature to estimate utility values beyond the initial intervention period. The final result was expressed as a cost per QALY gained.

The consumer survey used the generic EQ-5D questionnaire to capture five quality of life attributes. The evaluators used the questionnaire, a standardised instrument, to support validation of the utility scores and allow for comparisons across different disease states and populations. The survey revealed, among other things, that a substantial number of patients felt better following the review. This is reflected in 44% of respondents indicating that they were reassured and felt more confident regarding their medications post-HMR[13].

The results of the EQ-5D questionnaire showed an improvement in the mean utility score from 0.562 to 0.681 post-HMR[14], equating to a gain of 0.119 QALYs per HMR. This result was tested using the Wilcoxon signed-ranks test, and the resulting p value ($p = 0.0001$) indicates a highly significant

10-Consumer survey, Question 14.
11-Five respondents said that they did *not* go back to their GP, while two could not remember what had occurred.
12-There were 34 responses from consumers living in capital cities and 23 from consumers in non-metropolitan areas.
13-Consumer survey, question 9b2.
14-Scores range from 1.0 (indicating perfect health) to 0 (indicating death).

difference, with post-HMR scores having the higher average values[15]. The results revealed that the most responsive attribute was anxiety and depression, providing an important measure of the qualitative outcome, where patients indicated they felt better post-HMR. The HMR made no difference to the person's capacity for self-care, but this is not surprising given the nature of the intervention.

4.1.7 Cost of the service

Funding provided by the Government for implementation of the HMR between 2000-01 and 2004-05 included $18.1 million for services provided by GPs, $25.3 million for pharmacist services, and $19.5 million for the role of MMR Facilitators based in Divisions of General Practice across Australia[16,17].

Thematic analysis of the focus group data found that the payment received by an accredited pharmacist for conducting the medications review and preparing the HMR report was typically in the $110-$120 range. This left some $20-$30 for a community pharmacy which contracted out its HMRs – seen by some as 'hardly worth the trouble' in purely financial terms[18].

While there were some focus group participants who regarded the level of HMR remuneration to accredited pharmacists as adequate, the more common view was that payments were low relative to the amount of work involved. Varying estimates were given of the total time required to conduct an HMR. Estimates of average time, including travel, interview and report preparation, ranged from an hour or less in some cases, up to 4 or 5 hours, with something like 2 to 3 hours as the norm[19]. Some said that a fee of $120 for this task compared poorly with the Item 900 fee (currently $128) that GPs could claim for what was thought to be considerably less work. It was said that some accredited pharmacists had given up HMR work because of the low remuneration.

There were some suggestions for a sliding payment scale depending on the complexity of the HMR.

4.1.8 Cost-effectiveness analysis

An economic assessment was conducted as part of the evaluation. Objectives of the analysis were to evaluate the cost-effectiveness of the HMR program from the perspective of consumers, pharmacists and the health system, and to compare this with the potential costs of not addressing medication-related problems.

The results indicate cost-effectiveness of the HMR program, once the establishment costs of the MMR Facilitator Program have been absorbed. There are large potential future cost-savings, especially if the number of accredited pharmacists and HMRs delivered can be increased.

The sensitivity analyses confirmed that the key findings, including QALY gains and increasing cost-savings into the future, were robust. The evaluators state that this was further supported by the conservative approach taken in estimating the projected growth in HMRs and new accreditations.

The HMR model was developed using two scenarios. First, the HMRs delivered in 2004 were viewed separately to evaluate the intervention and calculate the cost-effectiveness of an HMR as the cost per

15-The Wilcoxon test was used as the distribution of the utilities and, more importantly, the distribution of the differences, between pre- and post-HMR values are not normally distributed. This is the non-parametric equivalent of a paired t-test (for normal data).
16-Introduction of the HMR has been supported by a national MMR Facilitator Program. This involves a Facilitator working in most Divisions of General Practice to provide GPs, pharmacists and other relevant parties with information, advice and practical support in relation to the HMR. Each State/Territory branch of the Guild also employs a State Facilitator to oversee and coordinate the Facilitator Program in their respective jurisdictions.
17-The MMR Facilitator Program is overseen by a National Management Group (NMG), consisting of representatives from the Guild and the ADGP. Each State/Territory Guild Branch has also been funded to employ an MMR Facilitator to support the HMR at State/Territory level. In addition, the Guild provides funds to State Based Organisations (SBOs) to provide further administrative and other support.
18-Negotiating fees between community pharmacies and accredited pharmacists 'can be very difficult', it was said.
19-See also sections 5.2.5 and 5.2.11. Pharmacists reported that it was often 'hard to get away' from home visits because consumers were keen to chat or to treat the visit as a social occasion – especially if they knew the pharmacist fairly well.

QALY. Second, HMR data were extrapolated to provide national figures in order to offer a health system perspective and to evaluate the total program in the context of initial start-up costs. The results are net benefits compared with the alternative of no HMR program.

The evaluators stated that the modelling approach was conservative with post-2004 figures for number of pharmacist accreditations assumed to remain constant at 2004 levels. The conservative case was used because growth in the number of accreditations slowed in 2004. Growth in the number of HMRs delivered was assumed to increase at 10% per annum, which was considered modest in comparison to the average growth of 26% per annum over the period 2002–04. HMR figures for April 2005 indicated a significant increase of approximately 20% per month over March and April 2005[20] which, even if viewed as a temporary event, the evaluators reported demonstrated the potential for further increases in HMR volumes.[21] Any increase in HMR growth above the assumed level of 10% would increase both costs and benefits. Overall, this would generate additional net benefits from the program. The base case which formed the basis of the sensitivity analysis incorporated a 10% annual growth rate in the number of HMR services provided.

4.1.9 Cost-utility analysis

Based on the utility scores from the EQ-5D questionnaire, a gain of 0.119 QALYs per HMR was derived. This value was halved in year one to reflect the spread of benefits across the year prior to the interview (i.e. the fact that benefits resulted after the HMR, which was taken to be half-way through the year on average). Analysis inputs (costs) were: accreditation costs, accreditation training, maintain accreditation, training to maintain accreditation, HMR (interview and administration), GP Item 900 (MBS). Outputs (benefits) were medication saving and adverse events avoided.

The initial costs of accreditation and the costs of maintaining accreditation were taken from the pharmacist survey for the number of new accreditations in 2004. Training time was based on a two-day HMR Stage 1 Workshop (AACP accredited course) for new accreditations, plus two days for maintenance based on attending discussion groups or courses. Time attending the courses was costed at reported pharmacist award rates of pay.[22] The evaluators stated that the additional time used for private study was difficult to quantify accurately and often seen by pharmacists as an unpaid personal investment in professional development. For this reason, private study and reading time was not included in the costs of gaining accreditation.

The benefits were reviewed in relation to two key areas. First, medication savings were calculated as average savings per HMR from the St George Report (2000) based on the total number of HMRs delivered in 2004 and the reported HIC figures.[23] Second, total costs avoided were estimated from results of the Quality Use of Medicines in the Community Implementation Trial (2000), which incorporates cost-savings due to events avoided and associated costs for hospitalisation, GP and specialist visits.[24] All costs and benefits were discounted at 5% per annum, based on Australian guidelines. Additionally, QALYs have been adjusted for life expectancy using Australian Bureau of Statistics life tables.[25]

20-This increase may be related to the commencement in February 2005 of the Department of Veterans' Affairs' MATES program, which has involved promoting the HMR to Veterans likely to benefit from an HMR along with their GPs.
21-Source: Home Medicines Review Statistics, April 2005. An initiative of the Pharmacy Guild of Australia and the Australian Divisions of General Practice Limited.
22-Effectiveness and cost-effectiveness of dose administration aids (DAAs), Final Report, 5 November 2004, page 202. Project conducted by Quality Medication Care Pty Ltd in conjunction with the Therapeutics Research Unit, University of Queensland, Princess Alexandra Hospital. ttp://www.guild.org.au/public/researchdocs/daa_finalreport.pdf
23-Bennett A, Smith C, Chen T et al. 2000. A comparative study of two collaborative models for the provision of domiciliary medication review. St George Canterbury Medico/Pharmacy project. Executive Report.
24-Gilbert A and Beilby J. (2000). Quality Use of Medicines in the Community Implementation Trial. Report to the Department of Health and Aged Care, July.
25-Australian Bureau of Statistics. 2003. Deaths, Australia 2002. ABS Cat. No. 3302.0. Canberra: Australian Bureau of Statistics.

The model suggested a cost saving in year one (2004) of $4.5 million and a gain of 1,435 QALYs. Taken together, these numbers produce a cost per QALY gained of -$3,138, as the benefits are modelled to exceed the costs. The model goes on to suggest that the cost per QALY gained reduces to -$4,375 in year seven, a figure which appears to be based on sustaining the incremental gain of 0.119 QALYs from one HMR over the seven year period (discounted using life tables).

4.1.10 Cost benefit analysis

The model was extended using figures extrapolated forward to provide net discounted costs per year and to evaluate the initial investment in the MMR Facilitator Program. Using the same cost and benefit inputs as the CUA, the HMR program was projected to recover remaining start-up costs over 2005−06, and deliver a cumulative gain of $2.1 million in 2009. Total costs were expected to fall substantially in 2005, based on decreasing (assumed) future funding for the MMR Facilitator Program. If funding for the Facilitator Program or some other system for promoting and supporting HMRs remains higher, then the cost recovery period will extend accordingly. From 2005, total HMR benefits remained significantly above total costs and produced increasing cumulative cost-savings beyond 2007.

At the time of the evaluation, it was not known what the future costs of the MMR Facilitator Program would be in relation to HMRs. For the purposes of the analysis, it was assumed that HMR-related funding would continue at a diminishing rate from the current average level of $4.9 million per year.[26] The pattern of reduced HMR-related funding was assumed to be $4 million in 2005, decreasing by $1 million a year until 2008, to remain at $1 million per year as an ongoing administrative support function.

4.1.11 Limitations

The evaluators reported that while the pharmacist survey was distributed widely and of a substantial sample size, the small size and non-random nature of the consumer survey raises issues of low statistical power, skewed distributions, and selection and measurement bias; these limitations restrict the generalisability of some results. However, the evaluators found that the results were consistent with previous studies showing cost-effectiveness of the HMR program.

A major limitation relating to the economic evaluation reported by the evaluators was the lack of systematic national data on HMR patients' health outcomes, thus conclusions about the success of the HMR program relative to its stated objectives could not be made. Instead, information from secondary sources, including information available from existing literature and information gathered from survey research with pharmacists and consumers, was used to develop estimates of costs and outcomes associated with the HMR program.

4.1.12 Conclusion

Consultations with stakeholders revealed that they generally saw the HMR program as addressing genuine and ongoing community needs, and as delivering benefits for consumer health and wellbeing. Consumers with HMR experience have generally been pleased and well satisfied with the services provided. While pharmacists expressed reservations about the adequacy of HMR remuneration, many regarded participation in the program as a stimulating and satisfying way of using their professional skills and of strengthening their customer and community relationships.

The evaluators concluded that the Australian Government should continue to fund the pharmacy component of the HMR program, and that the program will prove cost-effective within relatively few

26-This figure is an average of the current MMR Facilitator Grant of $19.5 million over 4 years.

years, especially if HMR numbers increase and if MMR Facilitator Program costs that are attributable specifically to HMRs decline in the future.

4.2 HMR PROGRAM QUALITATIVE RESEARCH PROJECT – CRC 2008

From late 2007 until mid-2008, Campbell Research & Consulting conducted a multi-staged research project on behalf of the then Department of Health and Ageing, canvassing and analysing a wide range of views and experiences of the HMR program[27].

The objectives of the research project were to:

- identify gaps in access to the program and the reasons for these gaps in access; and
- determine what drives participation in the program, including identifying barriers and enablers relative to different target groups.

The research project used a multifaceted methods approach based on a series of qualitative interviews with representatives from peak bodies and stakeholder organisations (n=31); a review of available literature on MMPs (n=75); review of submissions received via a public call for submissions (n=84); a series of in-depth interviews with health professionals (n=109); together with focus groups (n=100 total participants) and in-depth interviews with consumers (n=28).

This Section presents the high level project findings, with emphasis on those specifically relating to the PICO criteria (Section 3.1.1) where they exist (including a cost-effectiveness analysis), followed by limitations of the study and their overall conclusions.

4.2.1 General findings of the evaluation

Based on the views of GPs, accredited pharmacists, consumers and information gathered through the stakeholder and call for submissions phases, as well as observations made during the course of this research, most of those receiving HMRs present as:

- unlikely to misuse their medication;
- using their medications in a safe and appropriate way;
- requiring few if any changes to their medication regimen as a result of the HMR; and/or
- experiencing no substantial change in their quality of life or health outcomes as a result of the HMR.

Table 4.4 summarises the main findings, outside the PICO criteria, of the evaluation in relation to the HMR program.

27-It is important to note that this qualitative research project was not designed as an evaluation, although the findings provide a number of important questions to be addressed in a formal evaluation of the HMR Program.

Table 4.4: Main findings of the 2008 CRC HMR Program Research Project

Program areas	Key findings
Consumer perspectives	Consumers receiving HMRs demonstrated an improved knowledge and understanding of their medication as a result of the HMR.
Stakeholder perspectives	Health professionals did not report an improvement in their understanding of medications as a result of HMRs. Members of the healthcare team did not appear to have increased cooperation as a result of HMRs, even though where these existed they made the path for HMRs much smoother.
Medication misadventure	HMRs did not appear to be effective in reaching people most at risk of medication misadventure.
GP and pharmacist perspectives	Many GPs and pharmacists, including those participating in the program, consider HMRs to often be ineffective, used inappropriately and implemented inefficiently. Regardless of the actions that can be taken to address program uptake, it will remain low without a change in the level of support for the program by GPs. While there are a number of strategies that could be employed to achieve incremental improvements in GP response, a substantial change in their level of interest is unlikely to occur until they can see clear evidence that it is producing significant benefits for patients. Participation and interest at the pharmacy level is mixed. Some are enthusiastic. Most are ambivalent. Some are quite negative.
Participation in the HMR program.	Increasing participation by health professionals and access for consumers requires change to the Program rules to enable flexibility and direct referral, evidence of effectiveness and maintaining the participation of the community pharmacy, GP and accredited pharmacist.
Suggested changes to the HMR model	Keeping the current model but making adjustments, potentially leading to greater uptake. Changing to a more effective model with a clear focus on consumers who are most in need of a HMR. This would potentially lead to substantial uptake of a more effective service.

Source: HMR Program Qualitative Research Project Final Report by Campbell Research & Consulting 2008
Abbreviations: CRC, Campbell Research & Consulting; HMR, Home Medicines Review; GP, General practitioner.

4.2.2 Changes in adherence/compliance/concordance with prescribed dose schedule

Health professionals from Aboriginal Health Services reported, as per the *health professionals' perceptions of the effectiveness of HMRs* section of the evaluation, that non-adherence to medication regimes was a chronic and ongoing problem among the communities that they service. They reported that the medication issues included imminent and current risk of adverse events, including hospitalisation, arising from inappropriate medicine use. While clear steps forward had been made in relation to screening for diseases, there was often a lack of understanding in taking the prescribed medication for the diagnosed disease. *The hospitalisations are high … and are related to <non-adherence with medications leading to> complications from diabetes and hypertension*[28]*;* and *the comorbidities because of the lack of adherence to medications are very significant. We see high rates of infection and the patients don't want to go to hospital or discharge themselves from hospital.*"[29]

The researchers found that some respondents expressed strong opinions that it was not appropriate to refer non-compliant patients for HMRs, because a HMR was unlikely to make a difference for this type of patient. Some respondents (including some Facilitators) tended to actively support measures designed to focus on long-term prevention and younger, less complex patients rather than those seen as '*too far gone'*. Others felt the opposite was true – that non-compliant patients were precisely the type of patients who should be targeted by a more intensive and deliberate approach to the HMR program. These respondents emphasised that even small adjustments to medication for patients with highly complex illnesses could make a real difference to their quality of life and survival.

4.2.3 Changes in clinical outcomes

The research project found that GPs, as gatekeepers of the Program, are critical to participation and access. Most GPs were ambivalent about HMRs and considered them ineffective in producing substantial improvements in a patient's health. GPs generally favoured a highly selective approach with

28-Remote AHS Manager
29-Regional Non-HMR GP working in an AHS

a focus on high-risk patients. Their ambivalence appeared difficult to overcome, although evidence of clinical outcomes may assist.

Many stakeholders and submission authors noted that HMR competes for the GP's attention and prioritisation against much more established programs with well proven clinical outcomes: HMR must reach this level if it is to be a serious contender for GP attention.

Most health professionals stated that the HMR program influenced prevention and education rather than producing immediate clinical outcomes.

4.2.4 Rates of adverse drug event/reactions and medication-related problems

Health professionals identified a number of areas where a HMR could be effective but at present these consumers are not typically receiving a HMR. The consumers identified by respondents as having the greatest gaps in their access to HMRs were those patients at highest risk of medication misadventure, including:

- patients post-hospital discharge;
- Indigenous consumers;
- consumers in remote locations;
- CALD consumers;
- palliative care patients;
- non-compliant consumers; and
- consumers who are transient or homeless.

The overwhelming issues identified for Indigenous Australians related to adverse events arising from not adhering to medication regimes. Patient education provided in culturally appropriate ways was seen as essential.

Both eligible and HMR consumers reported potential for confusion about changes in the name and appearance of medications when generic medication was prescribed; the likelihood of confusion about changes to their medication after a stay in hospital and some reported adverse reactions from prescription medication where the brand had been changed.

No consumers who had received a HMR suggested that their HMR referral had arisen as a result of an experience with an adverse drug reaction. Often the adverse reaction had occurred some years earlier.

4.2.5 Health care resource use

Some consumers reported that they had not been back to see their GP for a follow-up appointment after receiving a HMR. Others reported that they believed the follow-up had simply taken place within a regular check-up appointment. Other respondents reported that they did not know if they needed to see the GP, but would follow this up with their pharmacy. A small number of consumers were aware that the follow-up visit to the GP after the HMR was part of the process.

4.2.6 Limitations

No limitations of the research project were presented by the researchers.

4.2.7 Conclusion

The research revealed in principle support for the concept of the HMR program but very little support for the current approach to implementation. This was particularly the case for GPs and owners and managers of community pharmacies. Consultant accredited pharmacists were supportive of the program but considered the current business model is preventing them from being able to respond effectively. Participation of GPs is essential. Without GP involvement, consumers are highly unlikely to consider participating. This study confirmed that GPs are ultimately trusted over other health professionals when it comes to medication advice, so it was deemed appropriate to retain their role as the primary source of referrals.

While the current model of HMRs was widely criticised, nearly all stakeholders identified strategies for improvement. These strategies included major structural changes based around referrals, with the most critical of these: referral directly from hospital upon a patient's discharge; and the inclusion of an option for direct referral to a consultant accredited pharmacist (either from a GP or a hospital medical officer or hospital pharmacist). Another key area requiring urgent consideration is the introduction of a far more appropriate model for Indigenous Australians, in both remote areas and major regional cities.

The evaluators concluded that without substantial changes in the way the Program is delivered, the HMR program is unlikely to meet its objectives.

4.3 VALMER -THE ECONOMIC VALUE OF HOME MEDICINES REVIEWS

The VALMER study, the Economic Value of Home Medicines Reviews (also published by Stafford in 2012)[30], was conceived to clarify the benefits of HMRs by investigating the drug-related problems (DRPs) identified in them and evaluating the potential economic outcomes of resolving these issues. The study was an 18-month project conducted by the Unit for Medication Outcomes Research and Education, School of Pharmacy, University of Tasmania, with collaborators from the Australian Association of Consultant Pharmacy and the University of New South Wales.

The fundamental aim of the VALMER study was to assess the economic effects of HMRs. To achieve this aim, two broad objectives for the study were formulated:

- **To quantify the following aspects of HMRs:**
  - the number and type of DRPs identified;
  - the drug groups often associated with DRPs;
  - the recommendations made by the pharmacists to resolve the DRPs; and
  - the rate of uptake of the recommendations.
- **To evaluate the potential outcomes of HMRs in terms of:**
  - the number of days of "poor health" saved;
  - days in hospital prevented;
  - consultations with GP and/or specialists prevented;
  - investigations prevented; and
  - total financial costs to the health system.

The economic modelling technique that was used in the study relied upon the DRPs that were identified in the HMR being classified according to a standardised system. The D.O.C.U.M.E.N.T classification system was developed in conjunction with the economic model, so was utilised in the study to classify the interventions made in the HMR (Peterson, 2004).

[30] Stafford C. A clinical and economic evaluation of medication reviews conducted by pharmacists for community dwelling Australians; 2012.

A combination of empirical and modelled data was used to perform the economic analysis. The net position associated with conducting each HMR was defined according to:

Net position = Cost of HMR + (Medication cost after HMR – Medication cost before HMR) + (Healthcare costs after HMR – Healthcare costs before HMR)

The cost of each HMR was $323.80 which included both payment to the accredited pharmacy ($183.60) and GP (MBS Item 900, value $140.20). Calculating the change in medication costs in the study was performed by costing the changes to each patient's medication regimen (PBS listed items only) that occurred as a result of the HMR.

The assessment of the HMRs by the expert panel was performed between March and July 2009. Fourteen of the 16 assessors completed their assigned cases. The assessors were permitted to select and assign probabilities to as many, or as few, potential consequences they felt appropriate for each DRP. Agreement between the assessors regarding probable outcomes was poor. There was agreement between at least two of the assessors in 257 (53%) of the 487 DRPs assessed in 139 of the 180 HMR assessed.

For each DRP assessed, the study used the mean probabilities assigned by the panellists of the consequence (or no consequence) occurring before and after the HMR. Cost estimates assigned to each consequence were used to generate an estimate of the health care utilisation and quality of life (utility, largely derived from the literature) for each DRP with and without the HMR occurring. The outcome data were used to determine an average resolution rate and this was applied to the each DRP according to subtype. The cost and median length of hospital admission was derived from the 2006/07 AR-DRG version 5.1 values for public hospitals Australia wide. The MBS was used to cost any pathology items, GP and specialist visits.

4.3.1 Results of VALMER study

The general characteristics of the patients reviewed in the HMR included: female patients contributed a majority of the study population (57.9%); there was a broad range of patient's ages, although patients aged 65 years or older accounted for over 85% of the patient group; over half the patients had between five and ten diagnosed medical conditions. The HMR referrals documented 5,846 medical conditions. The most common diagnoses were cardiovascular conditions such as hypertension, ischaemic heart disease and atrial fibrillation.

The patient sample was documented as taking a total of 7,790 medications. Over two thirds of patients were taking a lipid modifying agent, an angiotensin-converting enzyme (ACE) inhibitor or angiotensin-II receptor antagonist and/or an antiplatelet agent. The authors noted this was not surprising given the high prevalence of cardiovascular disease.

The HMR reports documented 2,323 actual or potential DRPs, equating to 3.5 (±1.8, range 0-13) DRPs per HMR. No DRPs were identified in 18 (2.7%) HMRs. The most frequently identified type of problem involved 'untreated indications'. 'Drug selection' issues, were also frequently identified. The pharmacists made 2,610 recommendations to resolve the DRPs, equating to approximately one recommendation per DRP. No recommendation was made to resolve 117 (5%) of the DRPs.

Outcome data were available for 560 (84.7%) of the HMRs that were submitted for the study, equating to 1,769 (68%) of the total number of recommendations made in the HMRs, and 1,565 (67%) of the DRPs identified. The outcomes data were grouped into two classes according to whether or not any action was taken by the GP to address the DRPs identified. The data indicate that over 80% of the DRPs identified in the HMRs would potentially have been resolved in some way. 'Education and information', and 'compliance and concordance' DRPs had a high rate of potential resolution. DRPs

relating to too-high doses and medications without indications had relatively low rates of potential resolution compared to the remaining DRP types.

A sample of 180 reviews was selected from the 661 VALMER HMRs for analysis by medication therapy experts to determine the probable clinical outcomes. For the 18 HMR where there was no DRP reported, these were excluded from the analysis dataset leaving 643 HMRs. Then 180 HMRs were randomly selected from the 643 HMRs according to proportions in a pre-defined stratification (i.e. amount of detail in HMR). When comparing the sampled HMRs to the VALMER dataset, the authors concluded they varied little in terms of gender, age and medical conditions, although the sample was taking a statistically significant different number of medications (approximately one more medication than the VALMER dataset). Also the difference in the mean number of DRPs per HMR was most likely due to the exclusion of the 18 HMRs that did not identify a DRP.

Table 4.5 present the results of the analysis of the baseline scenario. The assessment indicated that the HMRs would result in a significant decrease in healthcare utilisation costs, and an improvement in QoL. However, in many HMRs the absolute value of these reductions in health resource utilisation was insufficient to offset the cost of the HMR, and the ICER was $64,939 (95% CI $48 407 to $80 170) per QALY gained. Fifty five HMRs (31%) were highly cost-effective at a cost-effectiveness threshold of $50,000 per QALY gained. Using a threshold of $150,000 per QALY gained, 75 HMRs (42%) would be considered cost-effective.

Table 4.5: Analysis of costs and QoL differences for baseline assumptions

Parameter	Median predicted value (IQR) per HMR		Median change (IQR) Wilcoxon signed rank test	Median change (IQR) Upper quartile* (n=45)	Total saving (180 HMRs)
	Before HMR	After HMR			
Number of GP visits	1.88 (3.20)	1.42 (2.47)	0.27 (0.83) z=-8.00 P<0.001	1.18 (1.31)	112.6
Cost of GP visits	$63.00 ($107.20)	$47.51 ($82.76)	$9.16 ($28.01) z=-8.00 P<0.001	$39.52 ($43.92)	$3,778
Number of specialist visits	0.46 (0.79)	0.31 (0.61)	0.07 (0.19) z=-7.61 P<0.001	0.35 (0.44)	29.69
Cost of specialist visits	$29.63 ($49.86)	$19.61 ($37.65)	$4.64 ($13.93) z=-7.76 P<0.001	$20.90 ($27.97)	$1,892
Cost of investigations	$35.78 ($61.25)	$27.79 ($44.79)	$4.02 ($15.34) z=-7.59 P<0.001	$22.95 ($31.82)	$2,061
Days in hospital	0.16 (0.40)	0.13 (0.31)	0.02 (0.07) z=-5.15 P<0.001	0.03 (0.07)	11.7
Cost of hospitalisation	$148.68 ($382.44)	$134.09 ($350.67)	$15.73 ($69.06) z=-5.10 P<0.001	$161.01 ($212.08)	$11,747
Annual medication costs	Not reported			$104.64 ($369.00)	Not reported
Total health resource costs	$299.83 ($570.48)	$251.23 ($496.57)	$44.05 ($211.24) z=-6.79 P<0.001	$418.95 ($535.22)	$23,086
Disability	0.011 (0.025)	0.008 (0.019)	0.001 (0.0045) z=-5.22 P<0.001	0.006 (0.015)	0.54
ICER (including cost of HMR and changes in drug costs)			**$64,939**	-$22,811	

Source: VALMER (the Economic Value of Home Medicines Reviews); 2009. Note: positive values indicate costs savings or improvements in QoL.
* Based on savings

In summary, in the 12 months following each HMR, on average, the savings per HMR were:

- 0.63 GP visits, saving $20.99;
- 0.16 specialist visits, saving $10.51;
- $11.45 in reduced medical investigations;
- 0.065 days in hospital, saving $65.26; and
- $20.04 in drug costs.

Additionally, the average gain in QoL was 0.003 QALYs.

The total of these savings ($128.25) was insufficient to offset the cost of the HMR ($323.80).

The evaluators stated that the baseline scenario was highly conservative estimate of the economic benefits of HMRs as the estimate was substantially discounted by two separate factors (uptake and attribution). To investigate the degree of influence of these factors a scenario was undertaken whereby both discount values were removed.

An increase in the probability of HMRs being highly cost-effective at a threshold of $50,000 per QALY was identified in both the attributed potential value and absolute potential value scenarios. As the outcomes data indicated a relatively high rate of resolution of most types of DRPs, increasing the resolution rate in the attributed potential value did not result in a substantial reduction in the ICER. However removing the attribution discount factor, and hence assuming that all of the potential savings were due solely to the HMR (as opposed to another health professional) resulted in a substantial increase in health system saving and improved quality of life. Consequently in this scenario the ICER was substantially reduced with a 100% probability of cost-effectiveness threshold of 50,000 per QALY.

4.3.2 Limitations

The authors reported that the first limitation results from the study's design and the use of expert opinion to model the outcomes of the HMRs. By utilising expert opinion rather than a controlled study design, the level of evidence provided by the study is comparatively low. The following factors were considered to minimise confounding due to this limitation in the study:

- Each expert was an active practitioner and had extensive experience in managing patients similar to those reviewed in the HMRs. Most experts were involved in managing such patients on a regular basis in their usual practice.
- Experts were asked to utilise primarily their knowledge of relevant medical evidence relating to the HMRs when they assessed them. Several experts also possessed experience as academics and educators and were very familiar with the medical literature relevant to the HMRs.
- The values assigned to each of the consequences (e.g. hospitalisation costs, utilities etc.) were obtained from reference sources wherever possible.

Implicit in the expert assessment process is that assumption that each assessor was able to accurately predict the potential outcomes of the DRPs identified in the HMRs given the information made available to them.

A further limitation resulting from the modelling is that any follow-up other than the data collected by the reviewing pharmacist was not performed. It was assumed that any changes to a patient's drug therapy resulting from the HMR would be sustained for the subsequent 12 months, which may not be the case.

The lack of complete data for each patient resulted in a third limitation to the study. The majority of information provided in HMR reports (and hence the focus of the economic analysis) related to clinical aspects of patient therapy. Advice or counselling provided by the pharmacist in the HMR interview was documented minimally if at all.

A fourth limitation resulted from the pharmacists who performed the HMRs being responsible for submitting them for the study.

Further limitations involve aspects of the economic modelling technique we used for the study. The consequence of death was not available for the experts to select and assign probabilities to as a potential outcome of the HMRs.

A final limitation results from the perspective chosen to perform the economic analysis. The study estimated the economic outcomes of HMRs from the perspective of the Australian Government as a third party payer. Consequently, out-of-pocket costs to consumers were not considered, and may have limited the extent of both drug cost-savings and healthcare utilisation costs resulting from the HMRs. Conversely, a cost which was not accounted for in the model was the expense of additional monitoring which may have occurred subsequent to the HMR.

4.3.3 Conclusion

The evaluators state that the study demonstrated that HMRs continue to provide an opportunity for pharmacists to identify and manage DRPs in patients likely to be at high risk of adverse drug events. The study demonstrated that HMRs would most likely result in a statistically significant reduction in health resource utilisation and improve QoL in most patients. Despite the statistical significance of these findings, in many HMRs the economic value of these improvements is limited in the 12 months following the HMR, and insufficient to offset the cost of the HMR.

4.4 5CPA PROGRAM COMBINED REVIEW BY PRICEWATERHOUSECOOPERS 2015

The HMR program was evaluated as part of the 5CPA Review of the MMPs performed by PwC in 2015[31]. The overall aim of the evaluation was to better inform how the 5CPA MMPs contribute to improving consumer health outcomes, in order to better inform future investment by the Australian Government in pharmacy programs and services.

PwC evaluated the three programs: HMR, RMMR and MedsCheck/Diabetes MedsCheck. The evaluation methodology involved an analysis of the program data in order to assess the uptake and volume of services delivered over the duration of the 5CPA (between 2011 and 2014), stakeholder consultations, consumer focus groups, practitioner focus groups, a practitioner survey and a consumer survey.

This Section presents the program evaluation findings against the PICO criteria (Section 3.1.1), where they exist, followed by thematic analysis of practitioner views and the evaluators views on the limitations of the study and the gathered data.

4.4.1 Changes in adherence/compliance/concordance with prescribed dose schedule

All stakeholders consulted[32] commented that the perceived benefits of the MMPs included educating consumers about correct medication adherence; and improving consumers' confidence/compliance in taking medicines. HMR program specific feedback was not included in the evaluation report.

4.4.2 Changes in clinical outcomes

All stakeholders consulted commented that MMPs were contributing to improving consumer health outcomes. The benefits that were cited included improving consumer health and reducing hospital admissions due to medication misadventures. However, the majority of stakeholders also commented that impacts and outcomes of the services needed to be reviewed regularly to ensure that the budget was being well spent and cost-effective. "Due to the programs and reviews being undertaken in isolation to other initiatives within primary health care, it is often difficult to attribute health outcomes to having received a MMP". HMR program specific feedback was not included in the evaluation report.

31-PricewaterhouseCoopers. Combined Review of Fifth Community Pharmacy Agreement Medication Management Programmes: Final Report; 2015.
32 41 stakeholder consultations with over 50 individuals driven by insights from sector experience

4.4.3 Health care resource use

Utilisation analysis showed that there were 8,159 service providers that participated in delivering HMR services between 1st July 2010 and 28th February 2014. For this period, a total of 406,041 HMR services were conducted, with a median number of 16 HMR services conducted per service provider, with 50% of pharmacists conducting between 5 and 47 HMRs each.

Approximately 16,016 GPs referred 278,835 different consumers to receive HMRs. 55 consumers received a combination of HMR, RMMR and MedsCheck services in the evaluation period. The average age of consumers who received HMR services was 72.9 years.

A total of 43,347 of claims for HMR services were rejected. Common reasons for rejection included: missing data (47%), accredited pharmacist not known to Medicare (23%), HMR service claim received after the specified time frame (3%), and other reasons not stated (27%).

4.4.4 Patient acceptance / satisfaction

The evaluators found, as ascertained via the consumer focus group, that:

- "…HMRs were seen as highly valuable by all consumers who had received them, through preventing medicine-related adverse events and providing consumers with education and comfort that their medicines are being managed effectively";
- "… No Aboriginal and Torres Strait Islander consumers who participated in the focus group had received an HMR and participants noted that they would not feel comfortable having a pharmacist come into their home to review their medicines"; and
- "…Consumers who had received HMR services noted that they were a key part of maintaining their health and "keeping on top of their medicines". HMRs were viewed to be a core part of the preventative healthcare strategy, and should be available as a yearly service".

The evaluators stated that more consumers could benefit from HMR if they were appropriately advertised, and awareness was raised.

4.4.5 Pharmacist views about the RMMR program

Table 4.6 summarises the thematic analysis of data gathered from the practitioners' focus groups and survey. Briefly, a total of 767 primary health care practitioners, with the majority being pharmacists (94%), responded to the practitioner survey. Most of them (80%) were involved in the HMR program.

Table 4.6: Main findings of the 2015 5CPA combined review, 2011-2014

Measure/domain	Key findings
Practitioner focus group themes raised	
Addressing consumer need	All participants commented that, when performed well, HMR provided the most value/benefit to the consumer in achieving positive health outcomes and providing education on medication safety and adherence, as well as providing costs savings to the health system through de-prescribing and preventing hospital admissions due to medication misadventure.
Program implementation	Many participants felt that a multidisciplinary, collaborative approach to programs/services would aid in the implementation of the programs and benefit the impacts and outcomes for consumers. It was suggested that funding should be allocated to support implementation to prevent inconsistencies in the way that the programs are delivered. It was generally noted that there was potential for investment in implementation activities to yield faster and more complete uptake of Programmes, as well as more consistency in the quality of delivery of Programmes. This could be interpreted to mean more resourcing, better targeted resourcing, or both. The targets might be improvement to the payment and claiming system, other administrative systems or targeting awareness of the Programmes. It was suggested that the focus should be optimising uptake of various programmes and services.
Policy and strategy	Participants agreed that generally the 5CPA programs/services added value and should be part of the overall preventative strategy for consumers. Some stakeholders indicted there is opportunity for the

Measure/domain	Key findings
	MMPs to better support primary care services by being more widely accessible to consumers.
Unintended consequences	The majority of participants commented that MMPs, unintentionally foster business models that rely on quantity rather than quality.
Interaction between programs	The majority of participants commented that there was little interaction and that there was not a clear flow between MMPs, each program/service was seen as fulfilling a specific purpose and do not necessarily form part of a continuum..
Areas for improvement – funding arrangements	Funding arrangements could readjust to better facilitate programme objectives: funding could be moved out of CPA into MBS, enabling similar audit procedures; appropriate funding should be allocated to each health professional to incentivise collaboration for the benefit of the consumer.
Practitioners/providers survey results	
Interaction between programs	Less than half of survey respondents agreed or strongly agreed that the linkages/pathways between the programs/services were clearly identified. More than half agreed there were gaps in the services provided, resulting in unmet needs of the consumer.
Factors influencing clinical decision making (asked of pharmacists and GPs)	Among Accredited Pharmacists, the most common aspects of consumers' needs influencing clinical judgement to provide HMR were: to better assess the medicines that the consumer is taking; enabling a more in-depth discussion with the consumer; and better understand other factors that may impact on the consumers' health.
Provider satisfaction	Just over half of those involved in HMR reported being satisfied or very satisfied. The majority of those who noted being dissatisfied or very dissatisfied with their involvement attributed this to regular policy changes, particularly the recent capping, and expressed discontent at the limited peak body representation. The majority reported being satisfied with the benefit their consumers received through the HMR program.
Collaboration	GPs reported communicating with pharmacists after the service somewhat more commonly than pharmacists reported communicating with the GP. A breakdown was not available by specific program.

Source: PricewaterhouseCoopers Combined Review of 5CPA Medication Management Programmes (2015)
Abbreviations: 5CPA, Fifth Community Pharmacy Agreement; CPA, Community Pharmacy Agreement; GP, general practitioner; MBS, Medicare Benefits Scheme; MMP, Medication Management Programmes; RMMR, Residential Medication Management Review.

Overall, practitioners reported being reasonably satisfied with their involvement in the MMP. They also reported being satisfied with the benefit their consumers received through MMPs and services, and they saw clear benefit in the suite of MMPs and services as contributing towards improving the health outcomes of consumers.

However, stakeholders and practitioners indicated that 5CPA programs were difficult to access for consumers due to low consumer awareness, information on programs not being readily available to consumers, and low GP engagement and awareness to refer consumers to the relevant programs, particularly for Indigenous and culturally and linguistically diverse (CALD) peoples.

4.4.6 Limitations of the evaluation

The evaluators reported that a "CBA was not performed in this Review, thus direct and indirect benefits resulting from delivering MMPs, such as the HMR program, could not be inferred". The evaluators recommended that a baseline benefits analysis be conducted in a future review to inform the health, social and economic benefits that result from programs implemented as part of the 6CPA and evaluate the cost-benefits as a result of the 6CPA investment. "A reliable CBA would require a more sophisticated approach towards collection of data, linking program data (multiple datasets, including at consumer level) combined with regular auditing and reporting requirements to enable consumer health outcomes to be more effectively monitored and measured over time".

There were also a number of limitations reported in relation to program data analysis:

- Data collected as part of the claims process provided limited insight on uptake and volume of programs and services since multiple services could be submitted under one claim. The evaluators presented service level data where possible, merging accepted, rejected and claims datasets to conduct more accurate analyses.

- Consumer level data was de-identified and not linked to other data sources (e.g. Medicare or hospital data); therefore, it was not possible to determine the impact of participating in specific programs on consumer outcomes, outside of that particular episode of care.
- Consumer demographic data, such as age and gender, were only available for HMR, RMMR and MedsCheck/Diabetes MedsCheck, therefore data were not able to be linked across all six datasets (i.e. including DAAs, CIs and SS services). Postcode was not captured at the consumer level within any program/service dataset, therefore analysis of the data could not be performed for socioeconomic indicator (SEIFA) or remoteness (ARIA).
- The number of medicines and health conditions of consumers was not captured in the PPI Program dataset, resulting in the inability to analyse trends over time and potential investment value, including impact, for other programs and services.
- Analysis of program data beyond 28th February 2014 was not performed, resulting in failure to capture the effects of administrative changes to programs and services implemented on 1st March 2014 on the uptake and volume of programs and services.

5
Evidence for the effectiveness of the HMR program

This Chapter presents evidence of the effectiveness and safety from primary studies (both Australian and international) that evaluated HMR principally delivered by a pharmacist, and independent of any other intervention aiming at optimising drug regimens and patient outcomes. The evidence is presented in relation to the PICO criteria outlined in Section 3.1.1. This Chapter dos not repeat the evidence reported from previous evaluations of the MMP Program HMR initiative, which was summarised in Chapter 4.

In reviewing this Chapter, it should be noted that 22 systematic reviews were assessed using the eligibility criteria for studies to be included in this review against the characteristics of each previous review. It appeared that the identified systematic reviews included studies (RCT- and non-RCT evidence) that evaluated the effects of medication reviews in any setting, including the home, residential aged care facility, community pharmacy, as well as hospital, outpatient clinic, and medical centre. Further, the systematic reviews included studies that evaluated medication reviews as part of a multidisciplinary model or multifaceted pharmacy-led intervention, or medication reviews delivered by combinations of health professionals (e.g. physician, nurses) where the pharmacist was only partly involved. Therefore, findings from these systematic reviews cannot be extrapolated to the evaluation of the HMR service, and thus will not be discussed further.

5.1 EVIDENCE FROM PRIMARY STUDIES

The systematic literature review identified 12 studies with mixed design, and included seven RCTs, three retrospective cohort studies, and two retrospective pre- post-design. Eight studies were conducted in Australia, and the other four in the UK.

The studies evaluated HMRs performed by a pharmacist, aimed at checking and optimising the patients' drug regimens (i.e. ability to make recommendations on altering the regimen), and not limited simply to increasing patients' knowledge and/or adherence. Study participants were older people (mean age > 65 years) and with a range of diseases (chronic heart failure, congestive heart failure, clinical indications for warfarin use, and other unspecified chronic conditions). The studies included a variety of primary and secondary outcomes, with a focus on hospitalisation, mortality, and quality of life (QoL). Due to the heterogeneity of the included studies, meta-analysis to determine the effect of the HMR on any outcome was not performed.

The characteristics and results of the 12 identified studies are presented in Table 5.1 and Table 5.2, respectively. The majority of studies assessed the HMR in people taking multiple medications (polypharmacy).

Table 5.1: Characteristics of the included studies-HMR performed by a pharmacist

Study ID Country	Study design/ follow-up duration	Mean age	Population	Intervention	Control	Outcomes
Bereznicki (2016) Australia	Retrospective cohort study (N=818) *6 months*	83.0	Veterans (received an HMR vs who did not receive an HMR), and had at least 2 dispensings of warfarin in the 6 months prior to the HMR	HMR[a]	Veterans who did not receive an HMR	• international normalised ratio (INR) control • time (spent) in therapeutic range (TTR) (%)[b]
Barker (2012) Australia	RCT (N=120) *6 months*	73.0	Discharged patients with chronic heart failure, and were on 4 or more medications (n=64 intervention/56 control)	Patients received in-hospital care followed by an HMR performed by a pharmacist post-hospital discharge, and a follow-up at 1 and 6 months. The pharmacist discussed the participant's medication regime to ensure medication use was as prescribed, provided education, checked that the patient had a follow-up appointment with their GP, and disposed of expired medications.	Patients received the same in-hospital care as the intervention group, and also received a visit from the pharmacist but no HMR was performed, and no pharmacy advice was provided unless requested	Primary outcomes • hospitalisation • death • quality of life (AQoL, SF-36[d])
Castelino (2010a) Australia	Retrospective pre-post-design (N=372) *44 months*	75.3	Community patients aged > 65 years; taking ≥5 regular medications; taking >12 doses of medication/day; significant changes made to the medication regimen in the last 3 months; taking a medication with a narrow therapeutic index; and recent (within the last 4 weeks) discharge from a facility/hospital (N=372)	HMR	Baseline (pre-HMR) vs post-HMR	Intermediate outcome • improvement in Drug Burden Index score (measured by DBI) • improvement in Potentially Inappropriate Medicines score (PIM)
Castelino (2010b) Australia	Retrospective pre-post-design (N=270) *44 months*	76.1	Same criteria as above (N=270)	HMR	Baseline (pre-HMR) vs post-HMR	Intermediate outcome • improvement in medication appropriateness (measured by MAI tool)[c]
Roughead (2011) Australia	Retrospective cohort study (N=17,136) *30 months*	81.5	War veterans ≥65 years receiving warfarin treatment; and who received an HMR (n =816 exposed to HMR/16,320 no HMR exposure)	HMR[a]	Dispensed warfarin but without an HMR	• rate of hospitalisation (time to next hospitalisation for bleeding)

Study ID Country	Study design/ follow-up duration	Mean age	Population	Intervention	Control	Outcomes
Roughead (2009) Australia	Retrospective cohort study (N=5,717) *30 months*	81.6	War veterans ≥65 years receiving treatment for heart failure (β-blocker 6 months before the HMR); and who received an HMR (n= 273 exposed to HMR/5,444 no HMR exposure)	HMR[a]	No HMR	• rate of hospitalisation (time to next hospitalisation for heart failure)
Lenaghan (2007) POLYMED trial UK	RCT *6 months*	Not available	Community patients >80 years of age, living at home, taking ≥4 medicines, and had at least one additional medicines-related risk factor (n=69 intervention/67 control)	HMR performed by a community pharmacist who visited the patient, educated the patient/carer about their medicines, noted any pharmaceutical care issues, assessed need for an adherence aid, and met with the lead GP to agree on actions.	Standard care	Primary outcome • total non-elective hospital admissions within 6 months Secondary outcomes • mortality • care home admissions • quality of life (EQ-5D) • impact on number of medicines prescribed
Holland (HeartMed RCT, 2007) UK	RCT, after discharge from hospitals (N=293) *6 months*	77.6	Patients >18 years, admitted as an emergency in which heart failure was an ongoing clinical condition, and prescribed 2 or more drugs (from any drug class) on discharge. (n=149 intervention/ 144 control	Home visit by pharmacist with one follow-up visit (within 2 and 8 weeks post-discharge) to review drugs, check adherence, ability to self-medicate, educate patient/carer about heart failure, removed discontinued drugs, feedback recommendations to GP, and assessed need for a drug compliance aid	Usual care	Primary outcome • total hospital admissions Secondary outcomes • mortality • quality of life (Minnesota living with heart failure questionnaire, EQ-5D) • adherence (MARS, European heart failure self-care behaviour scale) • health care resource use • patient satisfaction
Holland (HOMER RCT, 2005) UK	RCT, (N=872) *26 months*	85.4	Post-hospital discharge patients >80 years, (patients admitted to hospital as an emergency, and prescribed >2 drugs on discharge; n = 437 intervention/ 435 control)	Home visit by pharmacist with one follow-up visit (over 6 months) to check adherence, ability to self-medicate, evaluate patients and carer, remove out-of-date drugs, report ADRs to GP, and need for interventions such as compliance aid	Usual care	Primary outcomes: • total emergency readmissions to hospital at six months Secondary outcomes • mortality • quality of life (EQ-5D)

Study ID Country	Study design/ follow-up duration	Mean age	Population	Intervention	Control	Outcomes
Krska (2001) UK	RCT (N=332) *3 months*	74.8	Patients ≥65 years with 2 or more chronic diseases and a minimum of 4 regularly prescribed medicines from general practices (n=168 intervention/ 164 control)	Patients received a HMR coupled with a pharmaceutical care plan	Normal care	• pharmaceutical care issues (PCIs) • use of health and social services • medication cost • quality of life (SF-36)
Stewart (1998a) Australia	RCT (N=762) *6 months*	66.0	Post-hospital discharge patients ≥60 years, treated for a chronic condition with 2 or more prescribed medications, and are considered to be at high risk of readmission; n=381 intervention/ 381 control)	Discharged patients received a single visit from the study nurse (not involved in the HMR) and the pharmacist in order to determine levels of compliance and medication knowledge, identify early clinical deterioration, and intensify follow-up where appropriate	Usual care	Primary outcome • number of unplanned readmissions plus out-of-hospital deaths (combined mortality and hospitalisation outcome) Secondary outcome • unplanned readmissions • total days of readmission (elective and unplanned) • emergency service attendances • out-of-hospital mortality • overall mortality • total cost of hospital-based health care • quality of life (SF-36)
Stewart (1998b) Australia	RCT (N=97) *6 months*	76	Patients ≥60 years, discharged from acute hospital care, have congestive heart failure, with 2 or more prescribed medications, and are considered to be at high risk of readmission; n=49 intervention/48 control)	Discharged patients received a single visit from the study nurse (not involved in the HMR) and the pharmacist in order to determine levels of compliance and medication knowledge, identify early clinical deterioration, and intensify follow-up where appropriate	Usual care	Primary outcome • combined hospitalisation-morbidity outcome Secondary outcome • unplanned readmissions • out-of-hospital deaths • total deaths • emergency department attendance • total days of hospitalisation

Abbreviations: ADR, adverse drug reactions; AQoL, Assessment of Quality of Life; DBI, Drug Burden Index; EQ-5D, EuroQOL-5 dimension; GP, general practitioner; HMR, home medicine review; INR, international normalised ratio; MAI, Medication Appropriateness Index; MARS, Medication Adherence Report Scale; PCI, pharmaceutical care issue; PIM, Potentially Inappropriate Medicines; RCT, randomised controlled trial; TTR, time in therapeutic range; UK, United Kingdom.

a Australian HMR is a collaborative model, where GPs refer patients to an accredited pharmacist who undertakes a home visit. The pharmacist identifies any medication-related problems, including potential underuse, overuse, adverse events, compliance and knowledge problems, or hoarding. The pharmacist provides a report, which is discussed with the physician. The physician is responsible for developing the medication management plan, communicating this with the patient and has responsibility for follow-up with the patient. The service can only be provided be a pharmacist who is accredited.

b The time spent in therapeutic range (TTR) was calculated using Rosendaal's linear interpolation method for the 6 months prior to the HMR or index date, compared to the 6 months following the HMR or index date. An INR target range of 2.0–3.0 was considered to be appropriate for most elderly patients.

c Medication Appropriateness Index (MAI) is a tool for measuring potentially inappropriate prescribing in older adults.

d SF-36 questionnaire provides information about patients' perceptions of health-related quality of life in eight different domains.

Table 5.2: Summary of results of the included studies

Study ID Country	Study design/ duration	Population	Relevant comparison	Effect	Authors' conclusions
Bereznicki (2016) Australia	Retrospective cohort study (N=818) 6 months	Veterans (received an HMR vs who did not receive an HMR), and had at least 2 dispensings of warfarin in the 6 months prior to the HMR	HMR vs no HMR	*TTR* • TTR for the veteran cohort during the study period was 64.0% • no significant difference following HMR compared with the control group (63.0% vs 67.0%; p=0.27) • with the TTR in patients with INR data available in the 6 months prior to, and the 6 months following HMR, remaining high (67.9% vs 69.6% p=0.63) • one-third of veterans had a percentage TTR below 60%	HMRs were not associated with a change in INR control (as estimated by TTR) in a veteran population taking warfarin.
Barker (2012) Australia	RCT (N=120) 6 months	Discharged patients with chronic heart failure, and were on 4 or more medications (n=64 intervention/ 56 control)	HMR vs no HMR	*Mortality* • no significant difference between groups (9 vs 6; HR=1.41, 95% CI 0.50-3.97; p=0.514) *CHF hospitalisations* • no significant difference between groups (IRR=1.74, 95% CI 0.85–3.60; p=0.131) *Days of hospital stay for CHF* • exacerbations in the 6-month follow-up were significantly greater in the intervention group (IRR=2.34, 95% CI 1.80–3.05; p=0.000) *QoL* • no significant difference in the QoL utility domains between the intervention and control groups at any time. • the intervention group had significantly greater improvements than controls on the physical functioning and mental health domains	Post-discharge pharmacy directed HMR appeared to have no effect on mortality and health care utilisation above that achieved with standard care. According to the authors, "The post-acute management of chronic heart failure must be a collaborative multidisciplinary effort by the health care team as it is the additive effect of interventions that are most effective."
Castelino (2010a) Australia	Retrospective pre-post-design *44 months*	Community patients aged > 65 years; taking ≥5 regular medications; taking >12 doses of medication/day; significant changes made to the medication regimen in the last 3 months; taking a medication with a narrow therapeutic index; and recent (within the last 4 weeks) discharge from a facility/hospital (N=372)	Baseline (pre-HMR) vs post-HMR	*Improvement in the use of medication* • total DBI score: 206.9 pre-HMR vs 157.3 post-HMR; p<0.001 • medicines contributing to the DBI (medicines with sedative or anticholinergic properties) were identified in 60.5% of patients (225/372) prior to the HMR, and 51.6% (192/372) of the patients following pharmacist recommendations during the HMR service • PIMs were identified in 39.8% (148/372) of the patients prior to the HMR, and 28.2% (105/372) of the patients following pharmacist recommendations during the HMR service	Pharmacists' recommendations during HMR services, if acted upon, may effect changes in the prescribing of sedative and anticholinergic medications, thereby substantially reducing the patient's drug burden. However, the effect on improved health outcomes was not determined. The study also showed a positive influence of HMR services on the prescribing of PIMs.

Study ID Country	Study design/ duration	Population	Relevant comparison	Effect	Authors' conclusions
Castelino (2010b) Australia	Retrospective pre-post-design *44 months*	Same criteria as above (N=270)	Baseline (pre-HMR) vs post-HMR	*Improvement in medication appropriateness* • mean MAI score at baseline was 18.6 ± 11.3 vs 9.3 ± 7.5 after HMR *Number of patients with a cumulative MAI score ≤15* • 116 at baselines vs 216 after the HMR service	The provision of HMRs by accredited pharmacists can improve the appropriateness of prescribing as demonstrated by the change in MAI score and. hence, has the potential to improve patient outcomes. However, the effect on improved health outcomes was not determined.
Roughead (2009) Australia	Retrospective cohort study (N=17,136) *30 months*	War veterans ≥65 years old dispensed with warfarin (n = 816 exposed to HMR/16,320 no HMR exposure)	HMR vs no intervention	*Rate of hospitalisation* • 79% reduction in likelihood of hospitalisation for bleeding between 2 and 6 months (HR 0.21; 95% CI 0.05–0.87)	HMR delays time to next hospitalisation for bleeding in those treated with warfarin in the period 2 to 6 months after the review, but is not sustained over time. Six monthly MRs may be required for patients on warfarin who are considered at high risk of bleeding.
Roughead (2009) Australia	Retrospective cohort study (N=5,717) *30 months*	War veterans ≥65 years old dispensed with heart failure medicines (n = 273 exposed to HMR/5,444 no HMR exposure)	HMR vs no intervention	*Rate of hospitalisation* • 45% reduction (HR 0.55; 95% CI, 0.39–0.77)	HMR is effective in delaying time to next hospitalisation for heart failure in those treated with heart failure medicines.
Lenaghan (2007) POLYMED trial UK	RCT *6 months*	Community patients >80 years of age, living at home, taking ≥4 medicines, and had at least one additional medicines-related risk factor (n=69 intervention/ 67 control)	HMR vs standard care	*Hospital admissions* • 21 HMR group vs 20 control; p=0.80 *QoL* • small (non-significant) decrease in QoL in the HMR group *Prescribed medication* • statistically significant reduction in the mean number of medicines prescribed (−0.87 items in favour of the intervention group, 95% CI −1.66 to −0.08, p=0.03)	HMR did not demonstrate a positive impact on clinical outcomes or quality of life, however, it did appear to reduce prescribing.

Study ID Country	Study design/ duration	Population	Relevant comparison	Effect	Authors' conclusions
Holland (HeartMed RCT, 2007) UK	RCT, after discharge from hospitals (N=293) 6 months	Patients >18 years, admitted as an emergency in which heart failure was an ongoing clinical condition, and prescribed 2 or more drugs (from any drug class) on discharge. (n = 149 intervention/ 144 control	HMR vs usual care	*Hospital admissions* • 134 vs 112 (rate ratio=1.15, 95% CI 0.89–1.48; p=0.28) *Death* • 30 vs 24 (HR 1.18, 95% CI 0.69–2.03; p=0.54). *QoL* • Although EQ-5D scores favoured the intervention group, Minnesota living with heart failure questionnaire scores favoured controls; neither difference was statistically significant	HMR performed by community pharmacist did not lead to reductions in hospital admissions in contrast to those found in trials of specialist nurse led interventions in heart failure.
Holland (HOMER RCT, 2005) UK	RCT, after discharge from acute or community hospitals (N=872) *26 months*	Patients >80 years, admitted to hospital as an emergency, and prescribed >2 drugs on discharge (n = 437 intervention/ 435 control)	HMR vs usual care	*Readmissions* • 234 vs 178 (rate ratio = 1.30, 95% CI 1.07–1.58; p=0.009) *Deaths* • 49 vs 63 (HR = 0.75, 95% CI 0.52–1.10; p=0.14) *QoL* • EQ-5D scores decreased by a mean of 0.13 in the intervention group and 0.14 in the control group (difference = 0.01, 95% CI − 0.05 to 0.06; p=0.84)	HMRs were associated with a significantly higher rate of unplanned hospital admissions and did not significantly improve quality of life or reduce deaths. The authors noted that further research is needed to explain this counterintuitive finding and to identify more effective methods of medication review.
Krska (2001) UK	RCT 3 months	Patients ≥65 years with 2 or more chronic diseases and a minimum of 4 regularly prescribed medicines from general practices (n=168 intervention/ 164 control)	HMR vs normal care	• all patients had at least 2 PCIs • at 3-month follow-up, more PCIs were likely to be resolved in the intervention group (79%, 950/1206) compared with the control group (39%, 542/1380) • there were no statistically significant differences in the average monthly costs of prescribed medication per patient between groups • there were no statistically significant differences in hospital clinic attendance or admissions post the intervention • there were no significant differences in the HRQoL between the two groups	HMR followed by a pharmaceutical care plan (recommendations) resulted in a significant reduction in PCIs. However, the HMR did not result in any reductions in medicine costs, hospital admissions, or HRQoL.

Study ID Country	Study design/ duration	Population	Relevant comparison	Effect	Authors' conclusions
Stewart (1998a) Australia	RCT (N=762) 6 months	Patients ≥60 years, discharged from acute hospital care, and treated for a chronic condition with 2 or more prescribed medications, and are considered to be at high risk of readmission; n = 381 intervention/ 381 control)	HMR vs usual care	*Combined hospitalisation-morbidity outcome* • 155 vs 217 episodes (p<0.001) *Unplanned readmissions* • 154 vs 197 (p=0.022) *Out-of-hospital deaths* • 1 vs 20 (p<0.001) *Total deaths* • 12 vs 29 (p=0.006) *Emergency department attendance* • 236 vs 314 (p<0.001) *Total days of hospitalisation* • 1452 vs 1766 (p<0.001) *Hospital-based costs of health care during study follow-up* • $A2190 vs $A2680 per patient: P = 0.102) • mean cost of HMR (HBI) was $A190 per patient visited • no difference in other community-based health care costs between the groups	HMR (also referred to as HBI) is beneficial in limiting unplanned readmissions and reducing risk of out-of-hospital death in high-risk patients discharged from acute hospital care. It may be particularly cost-effective if applied selectively to patients with a history of frequent unplanned hospital admission.
Stewart (1998b, subpopulation of the 1998a study) Australia	RCT (N=97) 6 months	Patients ≥60 years, discharged from acute hospital care, have congestive heart failure, with 2 or more prescribed medications, and are considered to be at high risk of readmission; n = 49 intervention/48 control)	HMR vs usual care	*Combined hospitalisation-morbidity outcome incidence* • 0.8 vs 1.4 per patient (p=0.03) *Unplanned readmissions* • 36 vs 63 (p=0.03) *Out-of-hospital deaths* • 1 vs 5 (p=0.11) *Total deaths* • 6 vs 12 (p=0.11) *Emergency department attendance* • 48 vs 87 (p=0.05) *Total days of hospitalisation* • 261 vs 452 (p=0.05)	HMR (also referred to as HBI) is beneficial in reducing the frequency of unplanned readmissions plus out-of-hospital deaths (combined hospitalisation-mortality outcome) in high-risk patients with congestive heart failure discharged from acute hospital care.

Abbreviations: CHF, chronic heart failure; CI, confidence interval; DBI, Drug Burden Index HBI, home-based intervention; HMR, home medication review; HR, hazard ratio; HRQoL, health-related quality of life; INR, international normalised ratio; IRR, incidence rate ratio; MAI, Medication Appropriateness Index; PCI, pharmaceutical care issue; RCT, randomised controlled trial; TTR, time in therapeutic range; vs, versus.

5.1.1 Hospital admissions

Four RCTs (five publications) reported on the effects of HMR performed by pharmacists on hospitalisation in high-risk patients that were discharged from hospital and were at high risk of readmission: Barker et al (2012), Holland et al (2007), Holland et al (2005), and Stewart et al (1998a, 1998b). The Polymed RCT by Lenaghan et al (2007) evaluated the effect of HMR by pharmacists on hospitalisation in older community patients prescribed at least four oral daily medicines (polypharmacy), and who were not recently discharged from hospital.

Post-hospital discharge patients

The Australian study by Barker et al (2012) evaluated the impact of HMR on chronic heart failure (CHF) patient outcomes. It included 120 patients hospitalised for CHF that were randomised to receive a pharmacist directed post-discharge HMR (n=64) or standard care (n=56). Participants were followed for six months. Both groups received conventional in-hospital care, which included: pre-discharge medication counselling, provision of a medication list and copies of discharge medications for their local medical officers and community pharmacist. Participants in both groups were visited by a pharmacist within four days of hospital discharge, and at one and six months after discharge. For the intervention group the pharmacist discussed the participant's medication regime to ensure medication use was as prescribed, provided education, checked that the patient had a follow-up appointment with their local doctor, and disposed of expired medication. The pharmacist also informed the community pharmacist of the medication regime to ensure continuity. For those in the usual care group, discussions with the pharmacist were very generic around how they were feeling, with no direct pharmacy advice was given unless requested. Primary outcomes were CHF hospitalisation, length of hospital stay, and mortality. Quality of life was a secondary outcome. The study found no significant difference between the intervention and control groups for the number of people who represented to hospital (or hospital representation rates). However, there was a significant increase in all-cause (IRR=1.25, 95% CI 1.06–1.48; p=0.009) and heart failure related (IRR=2.34, 95%CI 1.80–3.05; p=0.000) hospital in-patient days in the intervention group compared with the control group. For conditions other than heart failure, there were significantly fewer hospital in-patient days in the intervention group compared with the control group (IRR=0.72, 95% CI: 0.57–0.90; p=0.005).

The HeartMed RCT by Holland et al (2007) evaluated the effect of HMR by community pharmacists on reducing hospital admissions in heart failure patients. It included 293 patients aged over 18 years, admitted as an emergency in which heart failure was an important ongoing clinical condition, and prescribed two or more drugs (from any drug class) on discharge. Patients living in a residential or nursing home, awaiting surgery for ischaemic or valvular heart disease or heart transplantation, or had terminal malignancy were excluded. Patients in the intervention group (n=149) received an HMR within two and eight weeks of discharge, where the pharmacists reviewed drugs and gave symptom self-management and lifestyle advice. Patients in the control group (n=144) received usual care. The primary outcome was total hospital readmissions at six months. Secondary outcomes included mortality and quality of life (measured using the Minnesota living with heart failure questionnaire and EQ-5D). The study found that by six months, there were more readmissions in the intervention group compared to the control groups (134 versus 112 readmissions, respectively; RR=1.15, 95% CI 0.89–1.48; p = 0.28).

The HOMER RCT by Holland et al (2005) was a large pragmatic RCT[33] of a medication review intervention delivered by pharmacists at the patient's home. It targeted a group at high risk of hospital admission patients aged >80 years, discharged home after an emergency admission. The study included 872 patients aged over 80 recruited during an emergency admission (any cause) if returning to own

[33] A pragmatic RCTs test effectiveness in everyday practice with relatively unselected participants and under flexible conditions.

home or warden controlled accommodation and taking two or more drugs daily on discharge. Patients were randomised to either receiving a home medication review by a "review pharmacist" (n=429) or usual care (n=426). The intervention consisted of two home visits within two weeks and eight weeks of discharge and aimed to educate patients and carers about their drugs, remove out-of-date drugs, inform GPs of drug reactions or interactions, and inform the local pharmacist if a compliance aid is needed. On average the first visits lasted a mean (SD) of 61 (23) minutes, whereas second visits were shorter lasting at a mean (SD) of 42 (19) minutes. The primary outcome was total emergency readmissions to hospital at six months. Secondary outcomes included mortality (all-cause) and quality of life measured with the EQ-5D. Only 3% of participants withdrew or were lost to follow-up. The study found that by six months, there were more readmissions in the intervention group compared to the control groups (234 versus 178 readmissions, respectively; RR 1.30, 95% CI 1.07-1.58; P = 0.009).

The Australian study by Stewart et al (1998a) evaluated the effect of HMR by pharmacist on patient outcomes one week post-hospital discharge. Patients (N=762) discharged after admission with a number of chronic conditions (with 28% primarily cardiac) were randomised to receiving a home-based intervention (n=381) where a pharmacist and study nurse determine the levels of compliance and medication knowledge, identify early clinical deterioration, and improve liaison with community-based health services. Patients in the control group (n=381) received usual care, which included a follow-up with their GP or cardiologist two weeks post-discharge, and unrestricted visits by community nurse. The primary outcome was a composite of unplanned readmissions plus out-of-hospital deaths over a 6-month follow-up period, and mortality (out-of-hospital and total deaths), hospitalisation (unplanned readmissions, emergency department admissions, and days of hospitalisation), and costs served as secondary outcomes. The authors also published a detailed analysis of a congestive heart failure patient subpopulation of this RCT (Stewart et al, 1998b) with findings presented in Table 5.2 above.

The study found that the intervention group demonstrated fewer unplanned readmissions compared to the control group (154 versus 197, respectively; p=0.022), with the composite hospitalisation-morbidity outcome occurring less commonly in the intervention group compared to the control group (155 versus 217 episodes; p<0.001). Compared with the control group, the intervention group experienced significantly fewer emergency department attendances (236 versus 314, respectively; p <0.001) and significantly fewer total days of hospitalisation (1,452 versus 1,766, respectively; p < 0.001).

Community patients with polypharmacy

The Polymed RCT by Lenaghan et al (2007) evaluated the impact of HMRs performed by a pharmacist on reducing hospital admissions in "non-high-risk patients". The study included patients aged over 80 years, living in their own homes who were prescribed at least four oral daily medicines. Care home residents or patients already using an adherence aid were excluded. The study included 136 patients randomised to either receiving a HMR performed by a pharmacist (n=69) or standard care (n=67). Patients in the HMR group received their first visit by a review pharmacist referred by a GP, and who performed an HMR aimed at identifying possible drug interactions, adverse effects or storage issues, educating the patient, and assessing the need for an adherence aid. The review pharmacist then met with the referring GP where possible changes to the patient's prescribed medication were discussed, agreed, and acted upon by the referring GP. A follow-up visit occurred 6 to 8 weeks later to reinforce the original advice made by the pharmacist, and assess whether there were any further pharmaceutical care issues to address with the GP. The primary outcome was the total number of non-elective hospital admissions at six months' follow-up. Secondary outcomes were deaths, admission to care homes, number of drug items prescribed and self-assessed quality of life (EQ-5D). Results were analysed according to the intention-to-treat principle. The study found that at 6-month follow-up, there were no difference in hospital admissions in patients who received HMR versus those in the control group (21 versus 20, respectively; p = 0.80).

Findings: *Evidence from a single RCT by Stewart et al (1998a, 1998b) reported significant benefit in regards to a composite hospitalisation plus out-of-hospital deaths outcome and fewer unplanned readmissions in high-risk patients receiving an HMR post-discharge from an acute care hospital. A detailed analysis of congestive heart failure patient subpopulation of this RCT suggested similar benefits and which lasted for a period of at least 18 months after the HMR (Stewart et al, 1998b, 2002). However, this is in contradiction with the results of three other RCTs (Barker et al, 2012; Holland et al, 2007; Holland et al, 2005), which suggest that a pharmacist directed HMR for people recently discharged from hospital with heart failure had no effect on reducing hospital readmissions. The RCTs had some limitations particularly the Barker et al (2012) study, where baseline characteristics were not closely matched between the two groups, with patients in the intervention group being more symptomatic with their heart failure (and generally sicker) than the control group, thus requiring interventions for their symptoms. The RCT by Stewart et al (1998) included a large proportion of high-risk patients in the intervention group, who received in-hospital care and an HMR. It therefore remains uncertain whether the in-hospital component of the intervention (counselling by a pharmacist and/or study nurse) contributed to the overall beneficial effect of the HMR. Negative results from these RCTs may also suggest that the management of heart failure is more effective with a multidisciplinary collaborative intervention by the health care teams.*

Only one RCT by Lenaghan et al (2007) evaluated the impact of HMRs performed by a pharmacist on reducing hospital admissions in elderly patients aged over 80 who were prescribed at least four oral daily medicines (and were not discharged from a hospital). This RCT showed that HMR performed by community pharmacist did not lead to reductions in hospital admissions in this population. A major limitation of this study is its relatively small sample size.

5.1.2 Time to rehospitalisation

Two retrospective cohort studies published since 2008 examined the effectiveness of the HMR in groups at high risk of medication-related hospital admissions; those with heart failure and those taking warfarin (Roughead et al 2009, 2011). They were conducted using administrative claims data for Australian war veterans and war widows, which included prescription medicines data, medical and allied health services use (including HMR) and hospitalisations.

The study by Roughead et al (2009) examined the impact of HMR on altering the time to next hospitalisation for heart failure in the Australian war veteran and war widows population with heart failure. It included 273 veterans that were exposed to a HMR and 5,444 that were not exposed to the HMR (unexposed group). Notably, the exposed group presented with more comorbidities, more prescriptions, more changes in their medications before the HMR, more prescribers, and more hospitalisations.

The study showed that the time to hospitalisation for heart failure is significantly delayed in the group that had received an HMR. The adjusted results showed that for those who received an HMR there was a 45% reduction in the rate of hospitalisation (HR=0.55; 95% CI 0.39–0.77). Unadjusted results showed a 37% reduction in rate of hospitalisation for heart failure at any time (HR= 0.63; 95% CI 0.44–0.89). The authors concluded that HMR performed in the population with heart failure was effective in delaying time to hospitalisation for heart failure. The study has several limitations including selection bias, where the cohort receiving a HMR had a higher burden of illness than those who did not, potentially indicating the exposed group were more likely to receive the service because of more severe diseases. Another limitation was that only a small proportion of veterans received the HMR (5%), and was limited to only those who were dispensed β-blockers for heart failure.

Roughead et al also published a similar study in 2011 that examined the impact of HMR on altering the time to next hospitalisation for bleeding in the Australian war veteran and war widows population dispensed warfarin. There were 816 veterans exposed to the HMR and 16,320 unexposed patients. Notably, the exposed group had more comorbidities, more prescriptions, more prior hospitalisations, and more occupational therapy visits.

The results showed that in the 2 to 6 months after an HMR, there was 79% reduction in likelihood of hospitalisation for bleeding between 2 and 6 months (HR=0.21, 95% CI 0.05–0.87). This effect was not apparent in the first two months post-HMR, nor after 6 months post-HMR. However, the HMR exposed group were at increased risk of being hospitalised for bleeding more than 12 months post-HMR. This may be due to the HMR educational effects being lost and changes to the patient's health status or patterns of care were likely to have occurred.

Findings: *Results from two Australian retrospective cohort studies using the Department of Veteran Affairs data provide some evidence for the effectiveness of collaborative HMR in the practice setting in Australia. The studies suggest that HMR can reduce the time to next hospitalisation (thus temporarily reducing hospitalisation rates) for older people living in the community at high risk of medication-related hospital admissions, specifically those with heart failure taking heart failure medicines and those taking warfarin. However, retrospective studies are considered of low quality and are subject to bias. Both studies have selection bias, and patients were not well-matched for clinical characteristics. Further, the effect of the HMR appears to have been transitory, with the observed benefits being lost after the 12-month period. Therefore, findings from these studies should be interpreted with caution.*

5.1.3 Care home admissions

Only one RCT reported on the whether HMR has an impact on care home admissions. The Polymed RCT by Lenaghan et al (2007) found that at 6-month follow-up, there was no difference in care home admissions in patients who received HMR compared to those in the control group (1 versus 3, p = 0.30, respectively).

5.1.4 Health care resource use or cost

Four RCTs (Holland et al, 2007; Lenaghan et al, 2007; Krska et al, 2001; Stewart et al, 1998a) reported on HMR impact on various health care resource use and costs.

The HeartMed RCT by Holland et al (2007) reported that the provision of the HMR seemed to increase primary care activity both in the home and in the general practice surgery; GP practice attendance increased in the intervention group compared to the control group, however this increase was not significant (373 versus 316, respectively; RR=1.13, 95% CI 0.96–1.33; p=0.13). Of note, there was a significant increase in the number of prescription items in the HMR group compared to the control group (47 versus 41, respectively; RR=1.12, 95% CI 1.06–1.18); p<0.001).

The Polymed RCT by Lenaghan et al (2007) examined the effect of HMR on reducing the number of prescribed medications. Results from this RCT showed a statistically significant reduction in the mean number of medicines prescribed (−0.87 items in favour of the intervention group, 95% CI −1.66 to −0.08; p = 0.03).

The RCT by Krska et al (2001) evaluated the effect of HMR coupled with a pharmaceutical care plan on medicine costs and the use of health care services. This RCT recruited patients (n=332), aged at least 65 years old with two or more chronic diseases and a minimum of four regularly prescribed medicines, from general medical practices in Scotland. Patients in the intervention group (n=168) received a HMR performed by a clinically trained pharmacist who had prior access to the patient's drug and medical history. Following the review, a pharmaceutical care plan was drawn up listing all potential and actual pharmaceutical care issues (PCIs) along with recommendations for action. Patients in the control group (n=164) were also interviewed and pharmaceutical care issues were identified but no pharmaceutical care plan was implemented. Results from this study found no significant differences in the average monthly costs of prescribed medication per patient between groups, either at the initial interview or after the HMR. Further, there were no differences in hospital clinic attendance or use of social services.

The Australian RCT by Stewart et al (1998a) evaluated the effect of HMR one week post-hospital discharge in patients with a number of chronic conditions on costs. It reported that hospital-based costs of health care during study follow-up tended to be lower in the intervention group, however this was not significant ($A2,190 versus $A2,680 per patient; p =0.102). Mean cost of the HMR was $A190 per patient visited, whereas other community-based health care costs (e.g. community health nurse visiting the patient regularly) were similar in both groups.

Findings: *Evidence on the effect of HMR on reducing health care resource use is conflicting. Only the Polymed RCT (Lenaghan et al, 2007) showed significant reduction in prescribed items following the provision of an HMR. However, the HeartMed RCT (Holland et al, 2007) showed that there was a significant increase in the number of prescription items after HMR. This may be attributed to the different patient populations recruited in each study. Studies reporting the impact of HMR on health care costs (prescription, physician, and hospital) are presented in Section 6. Overall, there is a lack of a clear evidence base demonstrating an effect of HMR on reducing health care service use and costs.*

5.1.5 Mortality

Five RCTs (Barker et al, 2012; Holland et al, 2007; Holland et al, 2005; Lenaghan et al 2007; Stewart et al, 1998a) examined the effects of HMR on mortality.

Post-hospital discharge patients

The RCT by Barker et al (2012) found no significant difference in deaths between the intervention and the control groups (9 versus 6 respectively; HR=1.41, 95% CI 0.50–3.97; p=0.514).

The HeartMed RCT by Holland et al (2007) found no statistically significant difference between groups for mortality, but favoured the control group (30 versus 24 deaths, respectively, HR=1.18, 95% CI 0.69–2.03; p=0.54).

The HOMER RCT by Holland et al (2005) found that the difference in the numbers of deaths was not statistically significant between groups, but favoured the intervention group (49 versus 63 deaths, respectively; HR=0.75, 95% CI 0.52-1.10; p=0.14).

The RCT by Stewart et al (1998a) found that the intervention group demonstrated significantly fewer out-of-hospital deaths compared with the control group (1 versus 20, respectively; OR=0.04, 95% CI 0-0.4; p <0.001), and fewer total deaths (12 versus 29, respectively; OR=0.4, 95% CI 0.2-0.8; p=0.006).

Community patients with polypharmacy

The Polymed RCT by Lenaghan et al (2007) found no significant difference in the number of deaths in patients who received HMR versus those in the control group (7 versus 6, respectively; p=0.81).

Findings: *Evidence from a single RCT by Stewart et al (1998a, 1998b) reported significant fewer outer of hospital deaths and fewer total deaths in high-risk patients receiving an HMR post-discharge from an acute care hospital. A detailed analysis of congestive heart failure patient subpopulation of this RCT did not show a similar effect (Stewart et al, 1998b). However, this is in contradiction with the results of three other RCTs (Barker et al, 2012; Holland et al, 2007; Holland et al, 2005) whose results suggest that a pharmacist directed HMR for people recently discharged from hospital with heart failure had no significant effect on reducing deaths.*

Only one RCT by Lenaghan et al (2007) evaluated the impact of HMRs performed by a pharmacist on mortality in elderly patients aged over 80 years who were prescribed at least four oral daily medicines (and were not discharged from a hospital). This RCT showed that HMR performed by community pharmacist did not lead to reductions in mortality in this population.

5.1.6 Adverse drug reactions/medication-related problems

None of the included studies specifically reported outcomes relating to adverse drug events, adverse drug reactions or medication-related problems. However, three RCTs reported on the number of recommendations made by pharmacist as a result of the HMR (with one RCT reporting a single case of an adverse drug event identified by the pharmacist). One RCT by Krska et al (2001) reported on the identification of pharmaceutical care issues (PCIs) through the HMR and the resolution of these issues at 3-month follow-up.

The HeartMed RCT by Holland et al (2007) reported that HMR generated a total of 384 recommendations to GPs (at a rate of 2.8/visited patient), with approximately one-third of recommendations related to heart failure drugs or monitoring; the remainder generally referred to other drug advice or monitoring by the GP.

The RCT by Lenaghan et al (2007) reported that HMR generated a total of 220 recommendations to GPs, with 71 (32%) recommendations related to other drug advice and monitoring by the GP. Only one case of possible adverse drug event was identified by the pharmacist.

The HOMER RCT by Holland et al (2005) reported a total of 933 recommendations or comments forwarded to GPs by the review pharmacists (at a rate of 2.58/visited patient); 120 of these referred to possible drug reactions or interactions in 81 patients (22% of visited patients).

The RCT by Krska et al (2001) examined the effect of pharmacist-led medication review coupled with a pharmaceutical care plan on resolution of PCIs. The study was powered to detect a 25% reduction in the number of patients with PCIs. The study reported a total of 2,586 PCIs, with significantly less PCIs identified in the group that received the HMR compared to the control group (1,206 versus 1,380, respectively), and a median of eight PCIs per patient, with each patient having at least two issues. The number of PCIs was positively correlated with both the number of medicines being taken and with the number of chronic diseases. Overall, PCIs were associated most frequently with cardiovascular drugs, in particular diuretics (26%), nitrates, calcium channel blockers and potassium channel activators (10.9%). At three-month follow-up, 79% (950/1206) PCIs were resolved in the intervention group compared with 39% (542/1380) in the control.

5.1.7 Quality of life

Five RCTs (Barker et al, 2012; Holland et al, 2007; Holland et al, 2005; Lenaghan et al 2007; Krska et al, 2001) examined the effects of HMR on quality of life.

The RCT by Barker et al (2012) reported no significant difference in the AQoL utility domains or total change scores between the intervention and control groups at one- and six-month follow-up. Compared to baseline scores, the role-physical, bodily pain, vitality, social functioning and role-emotional domains of the SF-36 utility all improved over time in both groups, however the between-group differences were not statistically significant. Of note, the intervention group had significantly greater improvements than controls on the physical functioning (at 1-month and 6-month follow-up) and mental health (at 6 months) domains.

The HeartMed RCT by Holland et al (2007) reported that EQ-5D scores decreased (i.e. worsened) by 10% for the intervention group at 6-month follow-up, however the difference between groups was not significant (adjusted mean difference= 0.07, 95% CI−0.01 to 0.14; p=0.08). In relation to the Minnesota Living with Heart Failure Questionnaires, patients' scores in the intervention group increased (worsened) slightly, whereas scores for the control patients decreased (improved) slightly. However, this difference was not significant (adjusted mean difference=3.73, 95% CI −3.67 to 11.13; p=0.32).

The HOMER RCT by Holland et al (2005) reported that EQ-5D scores decreased (worsened) by a mean of 0.13 in the intervention group and 0.14 in the control group (difference = 0.01, 95% CI − 0.05 to 0.06; p = 0.84).

The Polymed RCT by Lenaghan et al (2007) reported a small decrease in the EQ-5D utility score over 6-month follow-up in both groups. There was a small difference in the change in utility scores over 6 months in favour of the control group, but this was not statistically significant (0.09 in favour of the control, 95% CI -0.19–0.02, p=0.10)

The RCT by Krska et al (2001) examined the effect of pharmacist-led medication review coupled with a pharmaceutical care plan on health-related quality of life (HRQoL). The SF-36 questionnaire was administered at baseline and at three-month follow-up. The RCT found no significant differences in any of the scores at baseline between the intervention and control groups, with none of the SF-36 domains showed any significant changes in either group at 3-month follow-up.

Findings: *Evidence from five RCTs indicates that HMRs by pharmacists do not appear to improve the quality of life. It should be stressed that none of the included trials is of a sufficient size to identify a small but important gain in quality of life. Further, the inability to demonstrate benefits to the quality of life may stem from the wide variations in the delivery of care and patient selection in the included trials.*

5.1.8 Adherence

Only one RCT evaluated the effect of an HMR on improving adherence to medication. The HeartMed RCT by Holland et al (2007) assessed dug adherence using two self-administered questionnaires: The Medication Adherence Report Scale (MARS) and the European heart failure self-care behaviour scale. The study reported very high levels of adherence at all times of follow-up for patients in both groups; with no between-group differences evident. Final adherence scores were marginally higher (better) in those who received the HMR (adjusted mean difference=0.12 units, 95% CI −0.48 to 0.73 units; p=0.68). It should be noted that adherence is only a surrogate outcome and improvement in medication adherence does not necessarily translate to improvement in patient health outcomes.

5.1.9 Patient satisfaction

Only one RCT reported on patient satisfaction in patients who received an HMR. The remaining 11 studies provided no information on patients' satisfaction, harms or barriers to the HMR service. Due to the paucity of high level evidence reporting on patient satisfaction, findings from three non-comparative Australian studies that investigated patients' perspectives on understanding of the HMR, and its perceived benefits and difficulties are presented in this Section.

The HeartMed RCT by Holland et al (2007) reported that 82% (102/124) of those surviving patients who received HMR responded to the satisfaction questionnaire at three-month follow-up, of whom 74% (75/102) patients considered the pharmacy visits to have been extremely or very useful.

Table 5.3 presents the main findings from three Australian studies that investigated patients' perceived benefits and barriers regarding the HMR. Patients' perceptions were collected using semi-structured focus group interviews held throughout Australia.

Table 5.3: Summary of patient perspectives on HMRs from three Australian studies

Study ID Country	Study design/ study objective	Number of participants	Intervention	Key findings/conclusions

Study ID Country	Study design/ study objective	Number of participants	Intervention	Key findings/conclusions
Ahn (2015) Australia	Semi-structured interviews, thematic analysis To investigate patients' perspectives on understanding, and perceived benefits and difficulties of HMRs	N=64	HMR	Understanding and expectations of HMR: • The participants varied in how well they understood the HMR. They ranged from not having received any explanation or a very brief explanation, to having a specific purpose for their participation. • The majority of participants had a general understanding that there would be a discussion of medications with a pharmacist. Perceived patients' benefits: • The majority of participants reported positive outcomes from their HMR experience: increased knowledge, a holistic review, medication improvement, increased health seeking behaviour, strengthened self-management and interest of participants in encouraging others to seek out an HMR. • Participants reported positive outcomes in acquisition of knowledge. Perceived patients' difficulties • inadequate introduction, follow-up and support for the program by the GP, and inadequate time spent and poor attitude from the pharmacist. • lack of deliberate follow-up with the GP, receiving their results incidentally as they made visits for other purposes.
Carter (2012) Australia	Semi-structured focus group interviews To investigate psychosocial factors (e.g. worry) which may motivate patients who are at risk of experiencing medication-related problems to participate in the HMR	N=88	Participants who had experienced an HMR or would be eligible to participate in the program because they were at risk of experiencing medicine-related problems	• Participants' expectancies of HMR were that: it was a medication-information source which would assist them to manage their medicines. • HMR recipients held overall positive outcome expectancies, whereas non-recipients' expectancies varied widely. • The majority of HMR recipients expressed that they wanted another one. They often described pleasant feelings about their experience, such as feeling respected and cared for. • Participants who expressed some worry about their medicines, generally held positive outcome expectancies and were willing to participate in HMR. • Compared with younger participants, older participants (those aged [74 years) tended to engage less in their thoughts about being at risk, and consequently did not experience worry.

Study ID Country	Study design/ study objective	Number of participants	Intervention	Key findings/conclusions
White (2012) Australia	Semi-structured focus group discussions Investigates patients' perceived benefits and barriers regarding the HMR service in those who have used the service and those who are eligible for it but have never used it	N=87	Participants who had experienced an HMR and those who are eligible for it but have never used it	HMR benefits from patients' perspectives: • acquisition of medicine information, • reassurance, • feeling valued and cared for, and • willingness to advocate medication changes to the general practitioner Patients' perceived barriers for receiving an HMR: • concerns regarding upsetting the general practitioner, • pride and independence, • confidence issues with an unknown pharmacist, • privacy and safety concerns regarding the home visit, and • lack of information about the program Participants agreed that the potential benefits of the HMR service outweighed its potential barriers

Abbreviations: GP, general practitioner; HMR, home medicines review

Findings from the three Australian focus group studies indicate that individuals who experienced the HMR were overall highly satisfied with the service. A number of barriers to the use of the HMR program were identified, mostly related to participants' knowledge and awareness of the HMR service. It appears that the majority of participants had a limited understanding that the HMR provides an opportunity to have their medication regime evaluated and improved if necessary. Another issue was that patients did not often follow-up the HMR with the doctor because they were unaware that the HMR was an ongoing process with subsequent follow-up by the GP to monitor the progress of the recommendations made by the pharmacist.

It should be noted that the three studies were based on focus group research and thus are limited by the social contexts in which they are conducted, potentially causing problematic silences and/or exaggerated speech. In the study by White et al (2012), patients who were offered but refused to have an HMR were not specifically recruited for this study and neither did the study include patients who are house-bound due to their physical inability to attend a focus group. Focus groups by nature will appeal to those participants who are willing to discuss issues in a public forum. Therefore, it is possible that the views of persons who do not wish to discuss medication-related problems on an interpersonal level may be underrepresented. Therefore, attention has to be given not to exclude the perceptions of patients who refused an HMR or carers of HMR eligible patients from the medication review process. Further, focus group research with larger patient samples and quantitative research would be beneficial to verify correlations, for example between patients' attitudes towards HMRs and their relationships with doctors and pharmacists.

Findings: *There is insufficient evidence to assess patient acceptance or satisfaction with pharmacist-led HMR. Patient satisfaction was marginally reported, with only one of the included studies reflecting on this outcome. Three focus group research studies indicate that individuals who experienced the HMR were overall satisfied with the service, however these studies are subject to limitations and bias. Future research into HMR should incorporate the opinions of study participants to identify what they would desire in a pharmacist-led service that targets drug regimens and improves patient outcomes.*

5.2 EFFECT OF HMR ON CERTAIN INTERMEDIATE OUTCOMES

5.2.1 Time spent in therapeutic range

The retrospective cohort study by Bereznicki et al (2016) assessed whether HMRs are associated with improved international normalised ratio (INR) control in a population of Australian veterans taking warfarin. Eligible veterans were initially identified and selected by the Department of Veteran Affairs (DVA) based on data from their patient database. A cohort of veterans who were dispensed warfarin, residing at home, and who received an HMR (HMR group, n=281) were compared to a matched cohort of veterans who had the same inclusion criteria but had not been exposed to an HMR in the study period (control group, n=537). The groups were well-matched with respect to gender, prior hospitalisations, prior bleeding and thrombotic events and region. However, the median number of comorbidities was statistically significantly higher in the HMR group. Eligible veterans in the control group were randomly allocated to an index month in the study period to match the time of the HMR in the HMR group. Control group veterans were only matched once in the study period. The primary outcome was the percentage time spent in therapeutic range (TTR)[34] for the six months prior to the HMR or index date, compared to the six months following the HMR or index date. At least two INR results were required to allow calculation of the TTR.

In the overall study cohort, the mean TTR was 64.0 ± 27.3% (n = 321). The proportion of veterans whose percentage TTR was >60% and >70% were 64.5% and 49.2% respectively. The mean percentage TTR following HMR and index date was 63.0 ± 30.1% (n = 98) and 67.0 ± 27.7% (n = 181); respectively (p=0.27). The authors concluded that there was no significant change in the TTR in either of the groups or the overall veteran cohort in the period following the HMR or index date from the six-month baseline period. The authors also reported that there was no change in the combined number of bleeding and thrombotic events leading to hospitalisation (4/281 in the HMR group versus 6/537 compared with the control group; p = 0.74). However, the study was underpowered to detect differences in hospitalisation for major bleeding and thrombosis.

5.2.2 Medication use and appropriateness (use of medicines and medication appropriateness)

The study by Castelino et al (2010a) used a pre- and post-intervention design to examine whether HMR services by pharmacists for community-dwelling older people would lead to an improvement in the use of medicines, measured by a decrease in the Drug Burden Index (DBI) score and the Potentially Inappropriate Medicines (PIMs) score. This study was based on a retrospective review of HMR reports submitted to the Australian Association of Consultant Pharmacy pertaining to 372 community patients aged 65 years or older. Patients were referred to the HMR service on the basis of standard criteria, such as taking ≥5 regular medications; taking >12 doses of medication/day; significant changes made to the medication regimen in the last three months; taking a medication with a narrow therapeutic index; and recent (within the last four weeks) discharge from a facility/hospital. The scores for DBI and PIMs were calculated pre- and post-HMR. The PIMs score was calculated using the published Beers criteria[35].

Medicines contributing to the DBI (medicines with sedative or anticholinergic properties) were identified in 60.5% of patients (225/372) prior to the HMR, and 51.6% (192/372) of the patients following pharmacist recommendations during the HMR service. With respect to the primary outcome measure of total DBI score, there was a statistically significant reduction in the sum total of DBI scores for all patients observed following pharmacist recommendations during the HMR service (206.9 pre-

[34] The percentage TTR is strongly associated with bleeding and thromboembolism in people taking warfarin, however TTR is considered a surrogate measure of these clinical outcomes

[35] The Beers criteria are the most widely used criteria for identifying drugs that potentially increase the likelihood of adverse drug events (ADEs) in elderly patients (Chang et al, 2005).

intervention versus 157.3 post-intervention; $p<0.001$). Further, PIMs were identified in 39.8% (148/372) of the patients prior to the HMR, and 28.2% (105/372) of the patients following pharmacist's recommendations during the HMR service.

The authors concluded that pharmacists' recommendations during HMR services, if acted upon, may effect changes in the prescribing of sedative and anticholinergic medications, thereby substantially reducing the patient's drug burden. This study relied on documentation in the case notes for HMRs, and it is not clear to what extent pharmacist recommendations are acted upon. Therefore, the results may reflect recommended practice rather than actual practice.

Castelino and colleagues also retrospectively evaluated the impact of HMRs on the appropriateness of prescribing, using the Medication Appropriateness Index (MAI) as a tool to categorise pharmacists' recommendations (Castelino et al, 2010b). HMR cases and reports submitted to the Australian Association of Consultant Pharmacy pertaining to 270 community patients aged 65 years or older were analysed. Patients were referred to the HMR service on the basis of standard criteria, such as taking ≥5 regular medications; taking >12 doses of medication/day; significant changes made to the medication regimen in the last three months; taking a medication with a narrow therapeutic index; and recent (within the last four weeks) discharge from a facility/hospital. The MAI was measured at baseline (i.e. prior to the HMR service), after the HMR service (i.e. based on pharmacist recommendations to the GP) and following GP uptake of pharmacist recommendations.

The study found that almost all (99%) patients had at least one inappropriate rating at baseline and more than 50% of the patients had a cumulative MAI score >15. The mean MAI score at baseline was 18.6 ± 11.3, which decreased to 9.3 ± 7.5 after HMR. The number of patients with a cumulative MAI score ≤15 increased to 216 after the HMR service, compared to 116 at baseline. Pharmacists' recommendations documented in the HMR reports and uptake of these recommendations by the GP resulted in a statistically significant decrease in the MAI scores (both $p < 0.001$). The authors concluded that HMRs performed by accredited pharmacists can improve the appropriateness of prescribing as demonstrated by a change in the patient's MAI score and therefore have the potential to improve patient health outcomes.

The studies by Castelino et al (2010a, 2010b) have several limitations being retrospective observation studies and no blinding of outcome assessment. Importantly, the clinical importance of the improvement in prescribing appropriateness was not measured, and no attempts have been made to measure the effect of improvement in medication or prescribing on improving important health outcomes (e.g. mortality, quality of life, adverse events).

6
Evidence relating to cost and cost-effectiveness

This Chapter presents the evidence identified in the systematic literature review relating to the cost and cost-effectiveness of HMR services with reference to the PICO criteria outlined in Section 3.1.1. It does not include evidence relating to cost and cost-effectiveness that has been reported in previous evaluations of the HMR program, which was summarised in Chapter 4.

A review of existing published economic evaluations of HMR has been performed to provide a local and international economic context against which HMR should be considered for use in Australia. Literature searches in Medline, Embase, Cochrane and Health Systems Evidence databases were conducted in Dec/Jan 2016/17 using the search strategy shown in Appendix C. References were included if they assessed the cost-effectiveness of HMR, either in Australia or overseas. If no cost-effectiveness studies were identified, cost studies were included for discussion. Table 6.1 shows the single cost-effectiveness study identified for inclusion in this review.

Table 6.1: Publication of the economic evaluation in HMR identified in the literature search

Ref ID	Citation
Pacini (2007)	Pacini, M., R. D. Smith, et al. (2007). Home-based medication review in older people: Is it cost effective? PharmacoEconomics 25(2): 171-180.

The included economic evaluation of HMR (Pacini et al, 2007) is a cost-utility analysis, the characteristics of which are shown in Table 6.2. The RCT upon which the economic evaluation was based (HOMER: HOME-based medication Review) was conducted in the United Kingdom between 2000 and 2002. This study has been discussed in the clinical review (Section 5.1) of this report. The intervention involved two home visits by a pharmacist for medication review within two and eight weeks following hospital discharge versus usual care. Patients had to be over 80 years, admitted to hospital and then returning home taking two or more medicines per day. The primary outcome was the number of emergency hospital admissions over six months of follow-up.

As summarised by Pacini et al, the home-based, face-to-face medicines review by community pharmacists was found to increase hospital admissions by 30% (234 admissions in the intervention group, and 178 admissions in the control group); and a non-statistically significant difference in life years gained (LYG) and QoL in favour of the intervention group was found. These results contrast with the expected effect of HMR, that the intervention could achieve a reduction in hospital admissions of 20%.

Table 6.2: Summary of the included HMR study that examined cost-effectiveness

Study ID Country Evaluation type Setting	Derivation of effectiveness Intervention Population N Follow-up Outcomes	Currency Price year Perspective Model type Time horizon Cycle length	Derivation of costs Discount rate Outcome of interest Source of utilities	Findings Conclusions	Assumptions
Pacini (2007) UK CUA	• Study: HOMER RCT. • Intervention: 2 home visits by a pharmacist within 2 and 8 weeks of hospital discharge vs usual care. • Population: >80 years, admitted to hospital and then returning home, ≥2 medicines per day. • N = 829; 415 in the intervention group and 414 in the control group. • Follow-up: 6 months. • Outcomes: Number of emergency hospital admissions over 6 months, mortality, QoL.	• Currency: GBP. • Price year: 2000. • Perspective: UK NHS. • Model type: NA. • Time horizon: no extrapolation in terms of life expectancy was made beyond the 6 month follow-up period. • Cycle length: NA.	• Intervention costs; resource use data collected from hospital episode statistics and from a sample of GP records of trial participants. • Discounting: none. • Outcome: QALY. • Utilities: EQ-5D.	• Authors' findings: The intervention did not reduce hospital admissions. The average cost per intervention group patient was £1695 compared with £1424 for control patients. The incremental cost per LYG through the intervention was £33,541. The incremental cost per QALY gained in the intervention was £54,454. Sensitivity analysis suggested a 25% probability that home-based medication review is cost-effective using a threshold of £30,000 per QALY. • Authors' conclusion: The current policy imperative for implementing medicines review needs to be reconsidered in the light of the findings of this study: a small, non-significant gain in QoL, no reduction in hospital admissions and a low probability of cost-effectiveness.	Authors assumed that the change in QALY observed accrued evenly over the 6 month follow-up; it is possible that the difference appeared earlier, potentially improving the CE of the intervention.

Abbreviations: CE, cost-effectiveness; CUA, cost-utility analysis; EQ-5D, EuroQol five dimensions questionnaire; HMR, home medicines review; HOMER, HOME-based medication Review; NA, not applicable; NHS, National Health Service; GBP, Great British pounds; LYG, life year gained; QALY, quality-adjusted life year; QoL, quality of life; RCT, randomised controlled trial; UK, United Kingdom.

The economic evaluation found that the HMR intervention cost £124 per patient. The average cost per intervention group patient was £1,695 compared with £1,424 for control patients. The incremental cost per LYG was £33,541; the incremental cost per QALY gained was £54,454. The authors quote that the threshold for cost-effectiveness in the UK at the time of publication was £25,000–£35,000 per QALY, indicating that HMR was not cost-effective in this population. Sensitivity analysis suggested a 25% probability that home-based medication review is cost-effective using a threshold of £30,000 per QALY.

The increase in hospital admissions was the basis for the large incremental cost-effectiveness ratio (ICER) that was observed for this evaluation. The authors speculate that a favourable interpretation of this is that HMR did help patients understand their conditions, leading to help-seeking behaviour, which in turn led to increased hospital admissions. Less favourable interpretations included HMR precipitating iatrogenic illness, and/or an increase in anxiety, confusion or dependence. The authors concluded that the current policy imperative for implementing medicines review needs to be reconsidered in the light of the findings of this study: a small, non-significant gain in QoL, no reduction in hospital admissions and a low probability of cost-effectiveness.

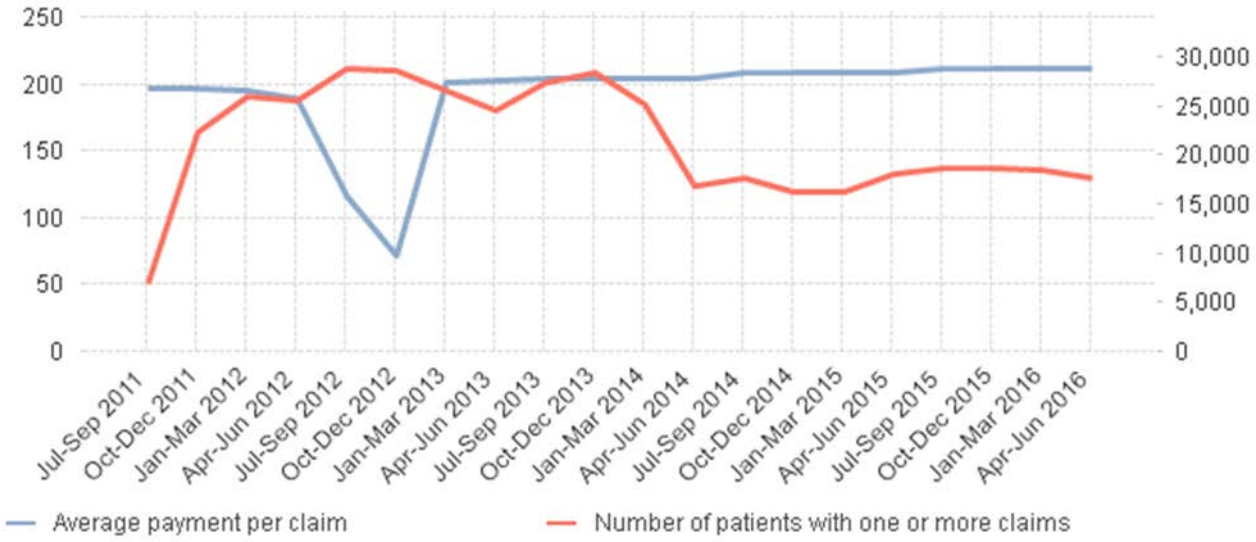
7
Utilisation Analysis

This Chapter examines the claims payment data held by the Department of Human Services and the Pharmacy Guild relating to 2011 to 2016. The data have been analysed primarily on inter-record and longitudinal relationships and also in the context of 'remoteness' inferred from the patient postcode. The analysis seeks to assess whether the HMR service providers were implementing the scheme in line with guidance. Key metrics in the analysis are the amount of claims paid, the number of patient HMR services provided, the interval time between dates of service for patients who received more than one service and summary information at patient level about the reasons for referral and recommendations from their HMRs. In reviewing the analysis, please note that claims relating to the HMR Rural Loading Allowance funding of up to $125 to contribute towards travel costs are not included in the analysis.

7.1 CLAIMS MADE AND AMOUNT PER CLAIM

Figure 7.1 shows the average payment per claim (between July 2011 and June 2016 based upon the date of service) compared with the number of unique patients receiving HMRs over the same period. It demonstrates that the average payment per claim remained stable (between $196 and $211) with the exception of significantly reduced payment for claims made for services performed in Quarter 3 and Quarter 4 2012. This transient dip in payment per claim is due to stricter enforcement of the policy ruling that HMRs must take place in the home and not elsewhere. Since HMR claims are submitted in a batch for payment, unpaid claims within a batch reduce the average payment per claim for that batch.

Figure 7.1: Average payment per HMR claim and number of patients for whom claims are made, 2011 to 2016



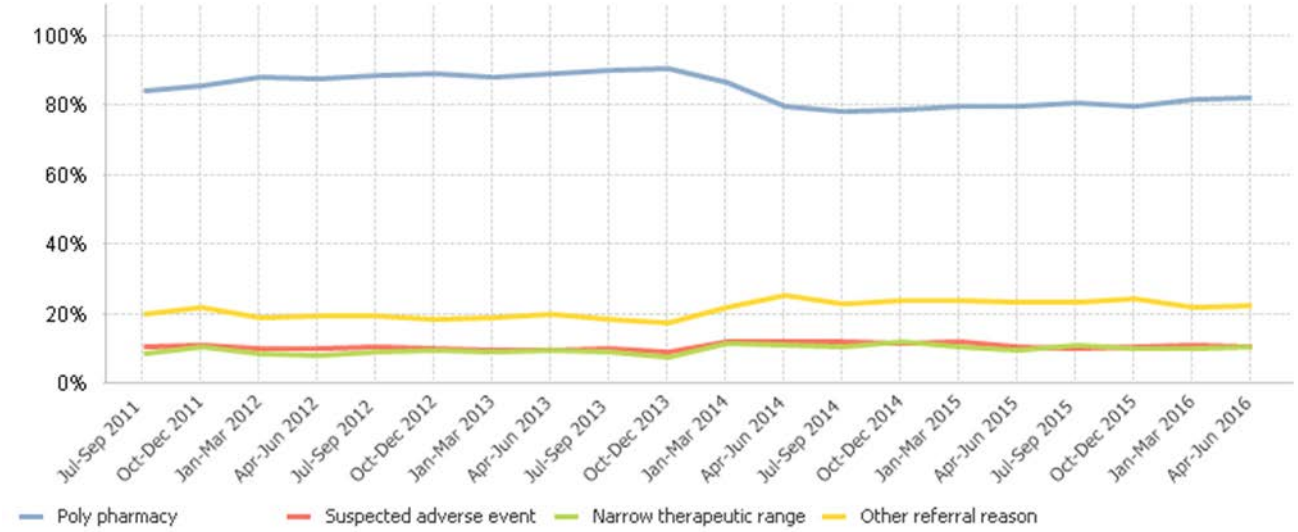
Source: DHS claims systems extracts for years 2011/12, 2012/13 and 2013/14, Pharmacy Guild claims systems extracts for years 2014/15 and 2015/16.

Figure 7.1 also shows that there is also an obvious and significant drop in the number of unique patients receiving HMRs between Quarter 4, 2013 and Quarter 2, 2014, patients reduced from 24,685 to 16,736 (a reduction of 7,949 patients or 32.2%). This drop likely reflects reduced provider activity as a result of the introduction of a cap per provider of 20 HMR claims per month. Figure 7.1 shows that patient volumes appear to have re-established at a stable baseline of around 17,500 unique patients receiving a HMR service in a quarter, with no strong growth (or decline) trends in evidence.

7.2 REFERRAL REASONS AND RECOMMENDATIONS MADE

Figure 7.2 examines the referral reasons for HMRs that are captured in the claims data. The pattern across all years has been remarkably consistent with the possible exception of Quarter 1 and Quarter 2, 2014, where polypharmacy is cited less often as a reason for referral, dropping from being cited in 90.3% of referrals in Quarter 4, 2013 to 78.1% of referrals in Quarter 3, 2014. There is a near equal and opposite change in 'other referral reason' in the same period but further drill-down into other referral reasons is not feasible from the dataset. Please note that more than one referral reason can be provided per HMR.

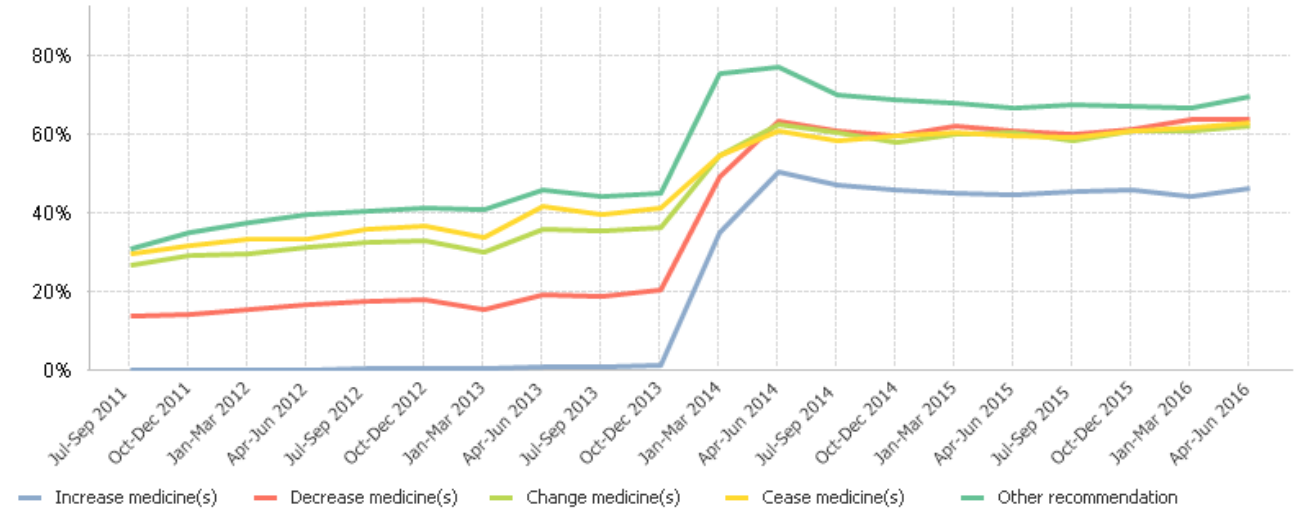
Figure 7.2: Proportion of HMR claims with cited referral reason, July 2011 to June 2016



Source: DHS claims systems extracts for years 2011/12, 2012/13 and 2013/14, Pharmacy Guild claims systems extracts for years 2014/15 and 2015/16.

Figure 7.3 examines the recommendations made from HMRs that are captured in the claims data. The relative use of the different types of recommendations is quite consistent across all years, with the exception of the recommendation of an 'increase in one or more medicines', which is cited in a negligible 1% of claims until Quarter 4 2013 and then quickly rises to 50% of claims by Quarter 2, 2014. The timing of this increase coincides with a notable increase in the inclusion of recommendation information in claims generally. Again, please note that more than one recommendation can be provided per HMR.

Figure 7.3: Proportion of HMR claims with cited recommendations, July 2011 to June 2016



Source: DHS claims systems extracts for years 2011/12, 2012/13 and 2013/14, Pharmacy Guild claims systems extracts for years 2014/15 and 2015/16.

7.3 NUMBER OF CLAIMS BY PATIENT AGE

Figure 7.4 profiles patients according to how many HMR services they have received over 10 continuous quarters before the claims cap (i.e. a date of service between July 2011 and Dec 2013). Please note that patients who have had an HMR service in both the pre- and post-cap periods are counted post-cap, and that patients have been classified according to their age at the time of receiving their most recent HMR.

Figure 7.4: Patient age by number of HMRs received, July 2011 and December 2013

Patient Age	Number of HMR services performed							Age dist
	1	2	3	4	5	6	7	
0-4	51	2	-	-	-	-	-	0%
5-9	74	8	-	-	-	-	-	0%
10-14	85	2	-	-	-	-	-	0%
15-19	141	19	-	-	-	-	-	0%
20-24	284	36	3	-	-	-	-	0%
25-29	454	73	4	-	-	-	-	0%
30-34	826	115	6	-	-	-	-	1%
35-39	1280	194	15	-	-	-	-	1%
40-44	2385	333	25	2	-	-	-	1%
45-49	3901	569	47	3	-	-	-	2%
50-54	6313	952	104	6	-	-	-	4%
55-59	8848	1470	131	6	2	-	-	6%
60-64	13613	2299	220	11	-	-	-	9%
65-69	19057	3420	321	17	-	1	-	12%
70-74	21873	4061	401	18	1	1	-	14%
75-79	25816	4968	541	34	1	-	1	17%
80-84	24987	5010	573	26	4	-	-	16%
85-89	17807	3599	405	29	4	-	-	12%
90-94	6244	1274	149	4	1	-	-	4%
95-99	908	196	22	3	-	-	-	1%
100-104	59	4	-	-	-	-	-	0%
105-109	6	-	-	-	-	-	-	0%
110-114	15	1	-	-	-	-	-	0%
% Distribution	83%	15%	2%	0%	0%	0%	0%	

Source: DHS claims systems extracts for years 2011/12, 2012/13 and 2013/14, Pharmacy Guild claims systems extracts for years 2014/15 and 2015/16.

The data show that an overwhelming majority (83%) of patients received just a single HMR service in the two and-a-half year period, only around 2% of patients received three or more HMR services. Interestingly one patient received seven services in the 30 month period (i.e. on average, at least one every six months). However, only 17% of patients received repeat HMRs, where the between HMR interval becomes relevant when considering adherence to guidelines (see Figure 7.6). Figure 7.4 (far right column) also shows that 75% of the patients receiving an HMR were aged 65 years or more, and that there was at least one patient in every age cohort from 0-4 years through to 100-114 years who received an HMR.

Figure 7.5 profiles patients according to how many HMR services they have received over 10 continuous quarters 'mostly' after the introduction of the claims cap (i.e. a date of most recent service between January 2014 and June 2016). Please note again that patients who have had an HMR service in both the pre- and post-cap periods are counted post-cap, and that patients have been classified according to their age at the time of receiving their most recent HMR. Figure 7.5 (far right column) shows that post-cap 75% of the patients receiving an HMR were aged 65 years or more (same as pre-cap), and that there was at least one patient in every age cohort from 0-4 years through to 100-114 years who received an HMR (again same as pre-cap).

Figure 7.5: Patient age by number of HMRs received, January 2014 and June 2016

Patient Age	Number of HMR services performed							Age dist
	1	2	3	4	5	6	7	
0-4	125	2	-	-	-			0%
5-9	37	1	-	-	-			0%
10-14	58	-	-	-	-			0%
15-19	122	2	1	-	-			0%
20-24	306	8	2	-	-			0%
25-29	523	34	1	-	-			0%
30-34	878	30	4	-	-			1%
35-39	1443	66	8	-	-			1%
40-44	2674	125	16	-	-			2%
45-49	4227	228	11	1	-			3%
50-54	6692	347	26	1	-			4%
55-59	9277	520	31	2	-			6%
60-64	13388	786	64	6	-			8%
65-69	19717	1198	95	5	1			12%
70-74	23097	1565	97	5	1			14%
75-79	27248	2011	131	10	-			17%
80-84	25429	2049	129	15	-			16%
85-89	18174	1433	100	9	1			11%
90-94	6781	550	43	3	1			4%
95-99	1003	95	7	1	-			1%
100-104	130	2	-	-	-			0%
105-109	9	-	-	-	-			0%
110-114	10	-	-	-	-			0%
% Distribution	93%	6%	0%	0%	0%	0%	0%	

Source: DHS claims systems extracts for years 2011/12, 2012/13 and 2013/14, Pharmacy Guild claims systems extracts for years 2014/15 and 2015/16.

However, Figure 7.5 shows that, after the payment policy change, the proportion of patients receiving a single HMR service grew by 10% to 93%, with less than 1% of patients receiving three or more HMR services (compared to 2% pre-cap). Also, the maximum number of HMRs received was five, compared to seven pre-cap. Corresponding to the increase on once only HMRs, the proportion of patients that received repeat HMRs dropped from 17% to 7%. These data suggest that following the introduction of the service cap, an even smaller proportion of patients were deemed to be in need of repeat HMRs, thereby improving compliance with the policy around the required interval between services (see Figure 7.7). The data also suggest that the introduction of the service cap policy changed the propensity of service providers to determine that a repeat HMR was required.

7.4 ADHERENCE TO PROGRAM CLAIMING GUIDELINES

Figure 7.6 profiles the 17% of patients who received two or more HMR services over 10 continuous quarters in the pre-claim-cap period (i.e. with a date of service between July 2011 and Dec 2013). The patients have been classified according to their age at the time of receiving their most recent HMR. The data show that 79% of patients receiving more than a single service, are aged 65 years or more, compared to 75% of patients receiving one or more HMRs (i.e. patients receiving repeat HMRs are on average older than patients receiving any HMR).

Figure 7.6 also clearly shows that most repeat patients received a follow-up HMRs within 0-6 months (37%) or 12-18 months (45%) of their previous HMR (note that the frequency of service guidelines mandating that HMR services should be no more frequent than every two years (except where GPs are satisfied that the patient meets give clinical criteria (see Section 2.4) were only introduced in March, 2014). In fact, in the period, to December, 2013, only 1% of patients who had two or more HMRs had an interval of 24 months or greater.

Figure 7.6: Patient age by HMR interval, patients with two or more HMRs, July 2011 to December 2013

Patient Age	HMR interval						Age dist
	0-6 Mths	6-12 Mths	12-18 Mths	18-24 Mths	24-30 Mths	30-36 Mths	
0-4	2	-	-	-	-		0%
5-9	6	1	-	-	-		0%
10-14	1	-	1	1	-		0%
15-19	13	-	4	2	-		0%
20-24	19	3	10	1	-		0%
25-29	35	3	30	1	-		0%
30-34	46	14	44	4	-		0%
35-39	75	21	81	14	2		1%
40-44	142	35	133	23	2		1%
45-49	229	75	210	35	4		2%
50-54	396	89	416	71	7		3%
55-59	578	143	624	86	7		5%
60-64	912	238	971	141	15		8%
65-69	1239	337	1534	245	24		12%
70-74	1511	419	1846	224	24		14%
75-79	1775	539	2322	283	32		17%
80-84	1756	565	2303	333	31		17%
85-89	1316	403	1697	277	32		13%
90-94	408	159	659	105	14		5%
95-99	65	27	88	11	6		1%
100-104	2	1	4	1	-		0%
110-114	-	-	1	-	-		0%
% Distribution	37%	11%	45%	6%	1%	0%	

Source: DHS claims systems extracts for years 2011/12, 2012/13 and 2013/14, Pharmacy Guild claims systems extracts for years 2014/15 and 2015/16.

Figure 7.7 profiles the 7% of patients who received two or more HMR services over 10 continuous quarters in the post-claim-cap period (i.e. with a date of service between January 2014 and June 2016). As before, the patients have been classified according to their age at the time of receiving their most recent HMR. The data show that the patient's age distribution is very similar with, post-cap, 79% of patients receiving more than a single service being aged 65 years or more (same as pre-cap).

Figure 7.7: Patient age by HMR interval, patients with two or more HMRs, January 2014 and June 2016

Patient Age	HMR interval						Age dist
	0-6 Mths	6-12 Mths	12-18 Mths	18-24 Mths	24-30 Mths	30-36 Mths	
0-4	3	4	4	1	-		0%
5-9	-	-	-	1	-		0%
15-19	2	-	-	1	-		0%
20-24	3	2	2	1	1		0%
25-29	4	6	11	2	6		0%
30-34	10	4	10	3	-		0%
35-39	17	12	19	9	4		1%
40-44	35	25	50	12	10		1%
45-49	47	37	86	31	15		2%
50-54	90	79	95	38	28		3%
55-59	133	85	182	56	40		5%
60-64	209	121	259	87	58		7%
65-69	325	161	398	149	89		11%
70-74	427	219	488	194	116		14%
75-79	567	299	626	242	153		18%
80-84	568	304	635	214	148		18%
85-89	337	211	461	150	88		12%
90-94	116	85	206	59	41		5%
95-99	14	10	37	15	7		
100-104	1	-	2	-	-		
% Distribution	28%	16%	35%	12%	8%	0%	

Source: DHS claims systems extracts for years 2011/12, 2012/13 and 2013/14, Pharmacy Guild claims systems extracts for years 2014/15 and 2015/16.

Figure 7.7 shows a different picture with regard to the HMR service intervals in this period. Again, most patients received their follow-up HMRs within 0-6 months (28%) or 12-18 months (35%) of their previous HMR, that is a reduction of 19% (in aggregate) in those two interval brackets. The proportion of patients have an HMR service interval 24 months or greater has grown to 8% (compared to 1% pre-cap). The data suggest that the introduction of the claiming frequency guidelines has had an impact on provider practices. The more stringent claims policies and a general emphasis by the Department and Pharmacy Guild on the need for compliance with program guidelines have probably also contributed to a shift in provider behaviour around the frequency of HMRs.

7.5 CLAIMS BY PROVIDER TYPE

Table 7.1 summarises the key utilisation metrics with regard to patient, provider and HMR service volumes and average payment per claim for each half financial year, further sub-divided by the type of provider. Please note that 'Unknown Org Type' arises due to encrypted provider identifiers, where we could not flag the provider unambiguously as a Business Entity (BE). But, in some of those instances, as S90 registered pharmacies have a separate identifying column, we have used that to infer S90 status.

Table 7.1: Key utilisation metrics by provider type, July 2011 to June 2016

Year	Half	Provider type	Average payment/claim	Patient volumes	Claims volume	Provider volume	Provider type split
2011-2012	H1 2011-2012	BE	$199	7,638	7,677	347	13%
		S90 Pharmacy	$201	18,880	19,081	2,372	87%
		Total	**$201**	**26,499**	**26,758**	**2,719**	**100%**
	H2 2011-2012	BE	$232	23,674	23,810	529	18%
		S90 Pharmacy	$224	23,183	23,368	2,394	82%
		Total	**$228**	**46,812**	**47,178**	**2,923**	**100%**
2012-2013	H1 2012-2013	BE	$91	28,702	28,777	599	21%
		S90 Pharmacy	$93	21,456	21,507	2,215	79%
		Total	**$92**	**50,134**	**50,284**	**2,814**	**100%**
	H2 2012-2013	BE	$202	22,597	22,656	645	26%
		S90 Pharmacy	$202	12,369	12,393	1,806	74%
		Total	**$202**	**34,945**	**35,049**	**2,451**	**100%**
2013-2014	H1 2013-2014	BE	$205	31,927	32,011	708	28%
		S90 Pharmacy	$205	16,617	16,646	1,840	72%
		Unknown Org Type	$204	4	4	1	0%
		Total	**$205**	**48,527**	**48,661**	**2,549**	**100%**
	H2 2013-2014	BE	$208	26,973	27,238	1,213	36%
		S90 Pharmacy	$208	12,711	12,826	2,091	63%
		Unknown Org Type	$206	151	151	29	1%
		Total	**$208**	**39,797**	**40,215**	**3,333**	**100%**
2014-2015	H1 2014-2015	BE	$211	22,280	22,469	848	35%
		S90 Pharmacy	$211	11,417	11,528	1,546	64%
		Unknown Org Type	$208	48	48	13	1%
		Total	**$211**	**33,707**	**34,045**	**2,407**	**100%**
	H2 2014-2015	BE	$211	22,515	22,645	855	36%
		S90 Pharmacy	$210	11,719	11,771	1,544	64%
		Unknown Org Type	$208	21	21	5	0%
		Total	**$211**	**34,233**	**34,437**	**2,404**	**100%**
2015-2016	H1 2015-2016	BE	$213	24,880	24,997	908	38%
		S90 Pharmacy	$213	12,110	12,151	1,478	62%
		Unknown Org Type	$211	158	158	45	2%
		Total	**$213**	**37,126**	**37,306**	**2,397**	**100%**
	H2 2015-2016	BE	$213	23,794	23,919	859	38%
		S90 Pharmacy	$213	10,108	10,138	1,260	56%
		Unknown Org Type	$213	1,974	1,987	153	7%
		Total	**$213**	**35,847**	**36,044**	**2,243**	**100%**

Source: DHS claims systems extracts for years 2011/12, 2012/13 and 2013/14, Pharmacy Guild claims systems extracts for years 2014/15 and 2015/16.
Abbreviations: BE, Business Entity (includes sole traders)
Note: Provider identifiers in years 2011/12, 2012/13 and 2013/14 were supplied in encrypted form. They have been categorised in cases where the encrypted identifier was also used in the 2014/15 or in 2015/16 datasets and in cases where the S90 Pharmacy identifier was supplied.

The data show that in the first half of 2011-2012, there were 2,719 participating providers peaking in the second half of 2013-2014 at 3,333 providers, an increase of 614 providers or 22.6%. Of these providers, S90 registered pharmacies accounted for 87% in the first half of 2011-2012, with a count of 2,372 individual pharmacies. Over the period to second half of 2013-2014 the pharmacy participation retreated by 281 to 2,091 pharmacies accounting for 63% of providers. From the first half of 2014-2015 and onwards participation by both S90 pharmacies and business entities has declined, coinciding with the introduction of the claims cap of 20 per month. These data suggest that some providers chose to exit the market perhaps driven in part by more stringent claims policies, an increase in claims processing rigour and guideline enforcement, and reduced economies of scale.

7.6 CLAIMS BY GEPOGRAPHIC LOCATION

Table 7.2 summarises the patient, provider and HMR service volumes, sub-divided by the ABS remoteness area of patient homes in which the HMR services were provided.

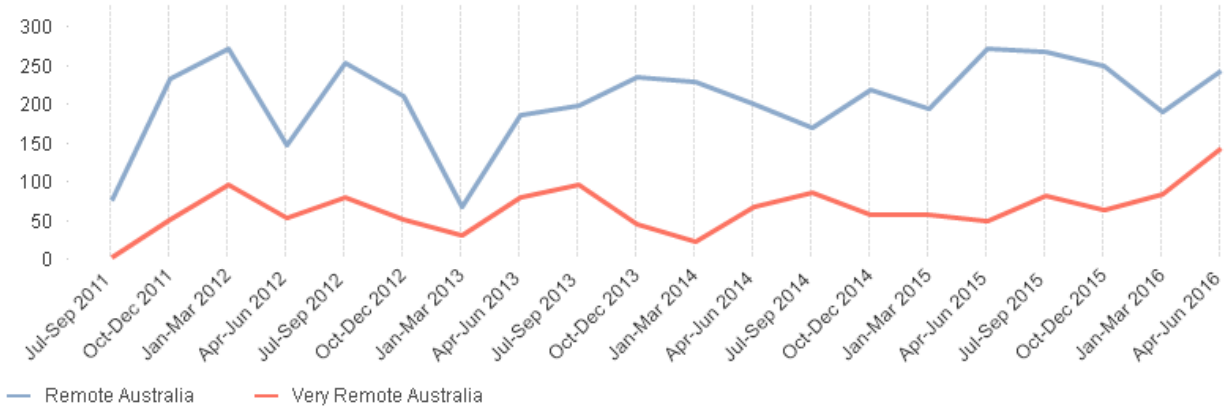
Table 7.2: Key utilisation metrics by geographic location of service, July 2011 to June 2016

Period	ABS remoteness	Patient volume	HMR service volume	Provider volume
2011-2012	Inner Regional Australia	18,001	18,260	959
	Major Cities of Australia	47,030	47,599	2,533
	Outer Regional Australia	6,476	6,549	417
	Remote Australia	724	743	57
	Very Remote Australia	202	203	18
	Location unknown	578	581	281
	Total	**72,978**	**73,935**	**3,535**
2012-2013	Inner Regional Australia	20,066	20,262	928
	Major Cities of Australia	55,822	56,258	2,419
	Outer Regional Australia	7,396	7,473	414
	Remote Australia	716	719	61
	Very Remote Australia	241	241	22
	Location unknown	379	379	208
	Total	**84,591**	**85,332**	**3,324**
2013-2014	Inner Regional Australia	20,780	20,922	1,421
	Major Cities of Australia	58,427	58,855	3,446
	Outer Regional Australia	7,457	7,486	588
	Remote Australia	864	864	77
	Very Remote Australia	232	232	27
	Location unknown	519	519	257
	Total	**88,258**	**88,875**	**4,882**
2014-2015	Inner Regional Australia	16,797	16,999	871
	Major Cities of Australia	43,219	43,807	2,105
	Outer Regional Australia	6,261	6,360	356
	Remote Australia	849	859	43
	Very Remote Australia	247	248	21
	Location unknown	203	209	92
	Total	**67,566**	**68,482**	**2,941**
2015-2016	Inner Regional Australia	16,755	16,900	852
	Major Cities of Australia	47,274	47,814	2,004
	Outer Regional Australia	7,121	7,199	374
	Remote Australia	941	951	50
	Very Remote Australia	368	373	21
	Location unknown	111	113	80
	Total	**72,560**	**73,350**	**2,819**

Source: DHS claims systems extracts for years 2011/12, 2012/13 and 2013/14, Pharmacy Guild claims systems extracts for years 2014/15 and 2015/16, used with ABS postcode to remoteness.xls available from http://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/1270.0.55.006July%202011?OpenDocument (accessed 5th October, 2016)
Abbreviations: BE, Business Entity (includes sole traders). ABS, Australian Bureau of Statistics
Note: Provider identifiers in years 2011/12, 2012/13 and 2013/14 were supplied in encrypted form. They have been categorised in cases where the encrypted identifier was also used in the 2014/15 or in 2015/16 datasets and in cases where the S90 Pharmacy identifier was supplied; and that 'Location Unknown' arises due to missing or unrecognised patient postcodes in the DHS and Pharmacy Guild datasets.

Table 7.2 shows that overall the volume of services, patients and providers have all declined in the period (July 2011 to June 2016) from 73,935 HMRs provided in 2011-2012 to 73,350 HMRs provided in 2015-2016. This trend is not reflected for remote and very remote areas of Australia, which have fluctuated in the period but generally trended towards growth with 946 HMRs provided in remote or very remote locations in 2011-2012 and 1,324 HMRs provided in 2015-2016 (see Figure 7.8).

Figure 7.8: HMR changes in patient volume in remote and very remote areas between July 2011 and June 2016



Source: DHS claims systems extracts for years 2011/12, 2012/13 and 2013/14, Pharmacy Guild claims systems extracts for years 2014/15 and 2015/16, used with ABS postcode to remoteness.xls available from http://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/1270.0.55.006July%202011?OpenDocument (accessed 5th October, 2016)
Abbreviations: BE, Business Entity (includes sole traders). ABS, Australian Bureau of Statistics
Note: Provider identifiers in years 2011/12, 2012/13 and 2013/14 were supplied in encrypted form. They have been categorised in cases where the encrypted identifier was also used in the 2014/15 or in 2015/16 datasets and in cases where the S90 Pharmacy identifier was supplied.

7.7 SUMMARY OF UTILSATION ANALYSIS FINDINGS

In summary, we found that claims payment policy changes (specifically the introduction of a claims cap of 20 HMRs per provider per month, the effect of enforcing the 'only in the home' ruling, the restriction on the time interval between services, and the 30 day deadline to submit claims) has had an apparent and lasting impact upon the volume of HMR claims and participating providers. Before the changes, the uncapped scheme was servicing and increasing number of patients and attracting more providers (both community pharmacies and business entities).

After the payment policy changes, HMR patient and service volumes declined steeply across pharmacy and non-pharmacy providers, but quickly found equilibrium with fewer numbers of patients and providers. The data also suggest changes in behaviour to comply with the claiming frequency guidelines, with a greater proportion of patients receiving only one HMR and longer claiming intervals for patients receiving multiple services. This shift is likely to be due to provider perceptions of more stringent and enforced claims policies, previously suffered non-claimable service provision losses and reductions in access to economies of scale.

APPENDIX A REFERENCES

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Lenaghan, E., R. Holland, et al. (2007). Home-based medication review in a high risk elderly population in primary care - The POLYMED randomised controlled trial. Age and Ageing; 36(3): 292-297.

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APPENDIX B SEARCH STRATEGY

The literature searches in Embase, Medline, Cochrane library, and the Health Systems Evidence database that were performed as part of this evaluation are presented in Table A-B.1, Table A-B.2, Table A-B.3, and Table A-B.4 respectively.

Table A-B.1 Embase search strategy for studies relevant to Medication Management Review services

#	Search strategy for EMBASE OVID (19 Dec 2016)	Records
1	MedsCheck.mp.	20
2	home medic$ review.mp.	130
3	residential medic$ management.mp.	14
4	(residential adj2 medic$ adj2 (review or management)).ti,ab.	14
5	(home adj2 medic$ adj2 (review or management)).ti,ab.	183
6	or/1-5	245
7	(pharmacist-led or pharmacist-run).ti,ab.	1,055
8	(review$ or assess$ or management).ti,ab.	5,483,928
9	7 and 8	840
10	((medication$ or medicine$ or drug or pharmac$) adj2 (management or review)).ti,ab,kw.	27,309
11	(pharmacy or pharmacies or pharmacist$).ti,ab,kw.	104,037
12	10 and 11	6,738
13	(home or domiciliary or community).ti,ab.	648,137
14	12 and 13	2,209
15	residential.ti,ab.	30,024
16	((aged or geriatric or elderly) adj2 (care or home$ or facility or facilities or residential)).ti,ab.	13,701
17	((care or convalescent) adj (home$ or center$ or centre$ or facility or facilities)).ti,ab.	57,085
18	home$ for the aged.ti,ab.	1,623
19	home for the aged/	11,273
20	exp nursing homes/	49,989
21	or/15-20	142,931
22	12 and 21	440
23	6 or 9 or 14 or 22	3,214
24	((medication or medicine$) adj review).ti.	565
25	((medication or medicine$) adj management review).ti.	8
26	or/23-25	3,559
27	editorial/ or erratum/ or letter/ or note/ or short survey/ or abstract report/ or letter/ or case study/ or (editorial or erratum or letter or note or short survey or conference abstract or abstract report or case study or case report).tw.	3,474,064
28	26 not 27	3,241
29	remove duplicates from 28	3,131

Table A-B.2 Medline search strategy for studies relevant to Medication Management Review services

#	Search strategy for Medline OVID (19 Dec 2016) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, OVID MEDLINE(R) Daily and OVID MEDLINE(R) 1946 to Present	Records
1	MedsCheck.mp.	9
2	home medic$ review.mp.	63
3	residential medic$ management.mp.	8
4	(residential adj2 medic$ adj2 (review or management)).ti,ab.	10
5	(home adj2 medic$ adj2 (review or management)).ti,ab.	118
6	or/1-5	137
7	(pharmacist-led or pharmacist-run).ti,ab.	481
8	(review$ or assess$ or management).ti,ab.	4,491,449
9	7 and 8	374
10	((medication$ or medicine$ or drug or pharmac$) adj2 (management or review)).ti,ab,kw.	19,306
11	(pharmacy or pharmacies or pharmacist$).ti,ab,kw.	55,772
12	10 and 11	3,402

#	Search strategy for Medline OVID (19 Dec 2016) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, OVID MEDLINE(R) Daily and OVID MEDLINE(R) 1946 to Present	Records
13	(home or domiciliary or community).ti,ab.	571,338
14	12 and 13	1,015
15	residential.ti,ab.	26,722
16	((aged or geriatric or elderly) adj2 (care or home$ or facility or facilities or residential)).ti,ab.	11,685
17	((care or convalescent) adj (home$ or center$ or centre$ or facility or facilities)).ti,ab.	44,622
18	home$ for the aged.ti,ab.	1,469
19	homes for the aged/	12,927
20	exp nursing homes/	36,659
21	or/15-20	113,285
22	12 and 21	231
23	6 or 9 or 14 or 22	1,509
24	((medication or medicine$) adj review).ti.	300
25	((medication or medicine$) adj management review).ti.	8
26	or/23-25	1,709
27	editorial/ or erratum/ or letter/ or note/ or case study/ or (editorial or erratum or letter or note or short survey or conference abstract or abstract report or case study or case report).tw.	3,362,429
28	26 not 27	1,632
29	remove duplicates from 28	1,507

Table A-B.3 Cochrane Library search strategy for studies relevant to Medication Management Review services

#	Search strategy for Cochrane Library (19 December 2016)	Records
#1	MedsCheck (Word variations have been searched)	1
#2	"home medication review" or "home medicine* review"	15
#3	(home near/2 medic* near/2 (review or management))	36
#4	"residential medication management" or "residential medicine* management"	0
#5	residential and ((medication or medicine*) near/2 (review or management))	71
#6	(pharmacist-led or pharmacist-run):ti,ab,kw	151
#7	(review* or assess* or management):ti,ab,kw	341,261
#8	#6 and #7	129
#9	((medication* or medicine* or drug or pharmac*) near/2 (management or review)):ti,ab,kw	1,947
#10	(pharmacy or pharmacies or pharmacist*):ti,ab,kw	3,434
#11	#9 and #10	472
#12	MeSH descriptor: [Medication Therapy Management] explode all trees	72
#13	MeSH descriptor: [Medication Reconciliation] explode all trees	41
#14	(#12 or #13) and #10	61
#15	(medication* next management or medication* next therapy next management or medication* next strategy or medication* next strategies or (medication* near/2 review*)):ti,ab,kw	844
#16	#15 and #10	312
#17	#1 or #2 or #3 or #4 or #5 or #8 or #11 or #14 or #16	644
	By database:	
	Cochrane Database of Systematic Reviews	67
	Database of Abstracts of Reviews of Effects (Other reviews)	19
	Cochrane Central Register of Controlled Trials	525
	Methods studies	5
	Health Technology Assessments Database	3
	NHS Economic Evaluation Database	25

Table A-B.4 Health Systems Evidence search strategy for studies relevant to Medication Management Review services

Item	Search strategy for Health Systems Evidence database (3 January 2017)	
Search terms	'medicine review' OR 'medicines review' OR 'medication review' OR 'medication management'	2116
Filter	Provider = pharmacist	373

APPENDIX C EXCLUDED SYSTEMATIC REVIEWS AND PRIMARY STUDIES

The list of excluded systematic reviews and list of excluded primary studies are presented in Table A-C.1, and Table A-C.2 respectively.

Table A-C.1 List of excluded systematic reviews

Citations
Alldred David, P., M.-C. Kennedy, et al. (2016) Interventions to optimise prescribing for older people in care homes. Cochrane Database of Systematic Reviews.
Cheema, E., P. Sutcliffe, et al. (2014). The impact of interventions by pharmacists in community pharmacies on control of hypertension: A systematic review and meta-analysis of randomized controlled trials. British Journal of Clinical Pharmacology 78(6): 1238-1247.
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Hinchliffe A (2010). Pharmacist-led medication review for older people in the community setting. Available from https://www2.nphs.wales.nhs.uk/PharmaceuticalPHTDocs.nsf/
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Loganathan, M., S. Singh, et al. (2011). Interventions to optimise prescribing in care homes: Systematic review." Age and Ageing 40(2): 150-162.
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Nieuwlaat, R., N. Wilczynski, et al. (2014) Interventions for enhancing medication adherence. Cochrane Database of Systematic Reviews DOI: 10.1002/14651858.CD000011.pub4
Nkansah N, Mostovetsky O, Yu C, Chheng T, Beney J, Bond CM, Bero L. Effect of outpatient pharmacists' non-dispensing roles on patient outcomes and prescribing patterns. Cochrane Database of Systematic Reviews 2010, Issue 7. Art. No.: CD000336.
Riordan, D. O., K. A. Walsh, et al. (2016). The effect of pharmacist-led interventions in optimising prescribing in older adults in primary care: A systematic review. SAGE Open Medicine 4: 2050312116652568.
Rollason V, Vogt N. Reduction of polypharmacy in the elderly. A systematic review of the role of the pharmacist. Drugs Aging 2003; 20: 817-32.
Royal, S., L. Smeaton, et al. (2006). "Interventions in primary care to reduce medication related adverse events and hospital admissions: Systematic review and meta-analysis." Quality and Safety in Health Care 15(1): 23-31.
Patterson Susan, M., A. Cadogan Cathal, et al. (2014) Interventions to improve the appropriate use of polypharmacy for older people. Cochrane Database of Systematic Reviews DOI: 10.1002/14651858.CD008165.pub3
Smith Susan, M., E. Wallace, et al. (2016) Interventions for improving outcomes in patients with multimorbidity in primary care and community settings. Cochrane Database of Systematic Reviews.
Viswanathan, M., L. C. Kahwati, et al. (2014) Medication therapy management interventions in outpatient settings (Provisional abstract). Database of Abstracts of Reviews of Effects 1
Wallerstedt, S. M., J. M. Kindblom, et al. (2014). "Medication reviews for nursing home residents to reduce mortality and hospitalization: Systematic review and meta-analysis." British Journal of Clinical Pharmacology 78(3): 488-497.

Table A-C.2 List of excluded primary studies

Citations	Reason for exclusion
Akinbosoye, O. E., M. S. Taitel, et al. (2016). Improving Medication Adherence and Health Care Outcomes in a Commercial Population through a Community Pharmacy. Population Health Management 19(6): 454-461.	Intervention comprises 2 counselling sessions, first 3-5 min, and second counselling session 1-2 min.
Begley S, Livingstone C, Hodges N, Williamson V. Impact of domiciliary pharmacy visits on medication management in an elderly population. Int J Pharm Pract 1997; 5: 111–21.	Home visits and counselling by a research pharmacist after hospital discharge. Comprises 3 groups: an intervention group (receiving counselling on the correct use and storage of their drugs during 5 domiciliary visits), a control (V) group (receiving visits but no counselling), or a control (NV) group (having no contact between an initial visit and the end of the study). (all groups received at least one home visit by the pharmacist)
Bernsten C, Björkman I, et al. Improving the well-being of elderly patients via community pharmacy-based provision of pharmaceutical care: a multicentre study in seven European countries. Drugs Aging 2001; 18: 63–77.	This study does not specify who performed the medication review.
Bond C, Matheson C, Williams S, Williams P, Donnan P. Repeat prescribing: A role for community pharmacists in controlling and monitoring repeat prescriptions. British Journal of General Practice 2000;50(453):271–5.	Wrong outcome
Borenstein JE, Graber G, Saltiel E,Wallace J, Ryu S, Archi J, et al. Physician-pharmacist co management of hypertension: A randomised, comparative trial. Pharmacotherapy 2003;23 (2):209–16.	Clinic setting/physician-pharmacist multidisciplinary intervention
Brulhart, M. I. and J. P. Wermeille (2011). Multidisciplinary medication review: Evaluation of a pharmaceutical care model for nursing homes. International Journal of Clinical Pharmacy 33(3): 549-557.	Hospital pharmacists were conducting MR however, within a multidisciplinary team that includes a GP and a nurse.
Brummel, A. R., A. M. Soliman, et al. (2013). Optimal diabetes care outcomes following face-to-face medication therapy management services. Population Health Management 16(1): 28-34.	Wrong setting-patients attended Fairview Health System Clinics staffed by medication therapy management pharmacists
Bryant, L. J. M., G. Coster, et al. (2011). The General Practitioner-Pharmacist Collaboration (GPPC) study: a randomised controlled trial of clinical medication reviews in community pharmacy. International Journal of Pharmacy Practice 19(2): 94-105.	Mixed setting: HMR and MedsCheck-however, not clear what the proportion of patients received one or the other-collaborative with GP but there was high pharmacist withdrawal in the study.
Bucci C, Jackevicius C, McFarlane K, Liu P. Pharmacist's contribution in a heart function clinic: patient perception and medication appropriateness. Canadian Journal of Cardiology 2003;19(4):391–6.	Hospital clinic setting/intervention not performed solely by pharmacist - patients followed by a multidisciplinary team including a pharmacist
Cabezas CL, Salvador CF, QuadradaDC et al. Randomized clinical trial of a postdischarge pharmaceutical care program vs. regular follow-up in patients with heart failure. Farm Hosp, 2006;30:328–342.	Mixed setting (patients in hospital and followed up post-discharge). A multifaceted intervention focusing on education
Castelino RL, Bajorek BV, Chen TF. Are interventions recommended by pharmacists during Home Medicines Review evidence-based? J Eval Clin Pract 2011; 17: 104–10.	Non-comparative design and wrong outcome
Cavalieri TA, Chopra A, Gray-Miceli D, Shreve S, Waxman H, Forman LJ. Geriatric assessment teams in nursing homes: do they work? J Am Osteopath Assoc 1993; 93: 1269–72.	Intervention not performed by a pharmacist
Clifford RM, Davis WA, Batty KT, Davis TM. Effect of a pharmaceutical care program on vascular risk factors in type 2 diabetes: The Fremantle Diabetes Study. Diabetes Care 2005;28(4):771–6. Clifford RM, Batty KT, Davis TME, et al. A randomised controlled trial of a pharmaceutical care programme in high-risk diabetic patients in an outpatient clinic. Int J Pharm Pract. 2002;10(2):85- 89.	A comprehensive pharmaceutical care program that addresses all aspects of diabetes care

Citations	Reason for exclusion
Crotty M, Halbert J, Rowett D, Giles L, Birks R, Williams H, Whitehead C. An outreach geriatric medication advisory service in residential aged care: a randomised controlled trial of case conferencing. Age Ageing 2004; 33: 612–7.	Multidisciplinary case conferences (GP, geriatrician, pharmacist, residential care staff and representative of the Alzheimer's Association of South Australia); responsible physician involved vs standard care
Dalleur O, Boland B, Losseau C, Henrard S, Wouters D, Speybroeck N, et al. Reduction of potentially inappropriate medications using the STOPP criteria in frail older inpatients: a randomised controlled study. Drugs & Aging 2014;31(4):291–8.	Hospital setting
Davis RG, Hepfinger CA, Sauer KA, Wilhardt MS. Retrospective evaluation of medication appropriateness and clinical pharmacist drug therapy recommendations for home-based primary care veterans. American Journal Geriatric Pharmacotherapy 2007;5(1):40-47.	Wrong intervention
Dolovich L, Gagnon A, McAiney CA, Sparrow L, Burns S. Initial pharmacist experience with the Ontario-based MedsCheck program. Can Pharm J Rev Pharm Can. 2008;141(6):339e345.e1.	Pharmacists views about MedsCheck
Dolovich L, Pottie K, Kaczorowski J, Farrell B, Austin Z, Rodriguez C et al. Integrating family medicine and pharmacy to advance primary care therapeutics. Clin Pharmacol Ther 2008; 83: 913–7.	Wrong study design, large-scale demonstration project; with pharmacists integrated within interdisciplinary healthcare team
Doucette WR, Witry MJ, Farris KB, McDonough RP. Community pharmacist-provided extended diabetes care. Ann Pharmacother 2009; 43:882–9.	Diabetes care plan-5 step process, assessment of clinical parameters
Faulkner MA, Wadibia EC, Lucas BD, Hilleman DE. Impact of pharmacy counselling on compliance and effectiveness of combination lipid-lowering therapy in patients undergoing coronary artery revascularization: a randomized, controlled trial. Pharmacotherapy 2000; 20:410–6.	A pharmacist telephoned patients at their home every week for 12 weeks.
Fornos JA, Andre´s NF, Andre´s JC, Guerra MM, Egea B. A pharmacotherapy follow-up program in patients with type-2 diabetes in community pharmacies in Spain. Pharm World Sci 2006; 28:65–72.	Pharmacotherapy follow-up/no medication review
Gallagher PF, O'Connor MN, O'Mahony D. Prevention of potentially inappropriate prescribing for elderly patients: a randomized controlled trial using STOPP/START criteria. Clinical Pharmacology and Therapeutics 2011;89(6):845–54.	Hospital setting
Garfinkel D, Zur-Gil S, Ben-Israel J. The war against polypharmacy: a new cost-effective geriatric-palliative approach for improving drug therapy in disabled elderly people. Isr Med Assoc J 2007; 9: 430–4.	Medication review performed by a physician/ unsuitable study design
Gilbert AL, Roughead EE, Beilby J,Mott K, Barratt JD. Collaborative medication management services: improving patient care.Med J Aust 2002; 177: 189–92.	Intervention includes a preliminary case conference component between the pharmacist and GP, and a post-visit case conference-this is non-comparative -Excluded
Graffen M, Kennedy D, Simpson M. Quality use of medicines in the rural ambulant elderly: a pilot study. Rural Remote Health 2004; 4: 184.	No patient interviews were performed by the pharmacist
Hogg W, Lemelin J, Dahrouge S, Liddy C, Armstrong CD, Legault F, et al. Randomized controlled trial of Anticipatory and Preventive multidisciplinary Team Care. Canadian Family Physician December 2009;55(12):e76–85.	Home-based multidisciplinary team approach and includes a medication review.
Jameson J, Van Noord G, Vanderwoud K. The impact of pharmacotherapy consultation on the cost and outcome of medical therapy. J Fam Pract 1995; 41: 469–72.	Pharmacist performed the MR in the primary care clinic and with the attending GP present.
Kassam R, Farris KB, Burback L, Volume CI, Cox CE, Cave A. Pharmaceutical care research and education project: pharmacists' interventions. J Am Pharm Assoc (Wash) 2001; 41: 401–10.	Non-comparative/unsuitable study design
King MA, Roberts MS. Multidisciplinary case conference reviews: improving outcomes for nursing home residents, carers and health professionals. Pharm World Sci 2001; 23: 41–5	Multidisciplinary case conference by GPs, GP project officer, pharmacist, nurses and other health professionals

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Lapane KL, Hughes CM, Daiello LA, Cameron KA, Feinberg J. Effect of a pharmacist-led multicomponent intervention focusing on the medication monitoring phase to prevent potential adverse drug events in nursing homes. J Am Geriatr Soc 2011; 59: 1238–45.	Multicomponent intervention
Lapane KL, Hughes CM, Christian JB, Daiello LA, Cameron KA, Feinberg J. Evaluation of the fleetwood model of long-term care pharmacy. J Am Med Dir Assoc 2011; 12: 355–63.	Comparing medication review by pharmacists according to the Fleetwood Model of Long-Term Care Pharmacy (responsible physician not involved) with medication review by pharmacists
Lim WS, Low HN, Chan SP, Chen HN, Ding YY, Tan TL. Impact of a pharmacist consult clinic on a hospital-based geriatric outpatient clinic in Singapore. Ann Acad Med Singapore 2004; 33: 220–7.	Relevant and interpretable data not reported for primary outcome
Lipton HL, Bero LA, Bird JA,McPhee SJ. The impact of clinical pharmacists' consultations on physicians' geriatric drug prescribing. A randomized controlled trial.Med Care 1992; 30: 646–58	Hospital setting
Lowe CJ, Raynor DK, Purvis J, Farrin A,Hudson J. Effects of a medicine review and education programme for older people in general practice. Br J Clin Pharmacol 2000; 50: 172–5.	General practice setting/also 3 home visits (1 questionnaire, 2 education, and 3 repeat questionnaire)
Mackie CA, Lawson DH,Maclaren AG, Kaczorowski J, Sellors J. A randomised controlled trial of medication review in patients receiving polypharmacy in general practice. Pharm J 1999; 263 (Suppl.): R7.	General practice setting
McMullin ST, Hennenfent JA, Ritchie DJ, Huey WY, Lonergan TP, Schaiff RA, Tonn ME, Bailey TC. A prospective, randomized trial to assess the cost impact of pharmacist-initiated interventions. Arch Intern Med 1999; 159: 2306–9.	Hospital setting
Mehuys, E., D. L. Dupon, et al. (2012). Medication management among home-dwelling older patients with chronic diseases: Possible roles for community pharmacists. Journal of Nutrition, Health and Aging 16(8): 721-726.	Non-comparative observational study (MedsCheck: Medication management included patient drug knowledge and practical drug management capacity)
Meredith S, Feldman P, Frey D, Giammarco L, Hall K, Arnold K, et al. Improving medication use in newly admitted home healthcare patients: a randomized controlled trial. Journal of the American Geriatrics Society 2002;50(9): 1484–91.	Home health agency, collaboration between pharmacist and the agency nurse
Milos, V., E. Rekman, et al. (2013). Improving the quality of pharmacotherapy in elderly primary care patients through medication reviews: A randomised controlled study. Drugs and Aging 30(4): 235-246.	RMMR and community pts-mixed population referred to as the intervention group-proportions of which received a HMR or RMMR unknown
Naunton M, Peterson GM. Evaluation of home-based follow-up of high-risk elderly patients discharged from hospital. J Pharm Prac Res 2003; 33: 176–82.	Both intervention and control groups received MR but at different time points (control group received MR 90 days post-hospital discharge vs 5 days in the intervention group)
Nazareth I, Burton A, Shulman S, Smith P, Haines A, Timberal H. Pharmacy discharge plan for hospitalized elderly patients – a randomized controlled trial. Age Ageing 2001; 30: 33–40. (development of discharge plan by hospital pharmacist. Home visit by community pharmacist between 7 and 14 days after discharge, pts taking 4 or more medications)"	A cordinated hospital-community pharmacy discharge plan
Nola KM, Gourley DR, Portner TS, et al. Clinical and humanistic outcomes of a lipid management program in the community pharmacy setting. J Am Pharm Assoc (Wash) 2000;40:166–73.	Collaborative-led intervention
Peterson GM, Fitzmaurice KD, Naunton M, Vial JH, Stewart K, Krum H. Impact of pharmacist-conducted home visits on the outcomes of lipid-lowering drug therapy. Journal of Clinical Pharmacy and Therapeutics 2004;29(1): 23–30.	Total blood cholesterol measurement was determined/ home visits were repeated on monthly bases over a 6 month period

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Patterson SM, Hughes CM, Crealey G, Cardwell C, Lapane KL An evaluation of an adapted U.S. model of pharmaceutical care to improve psychoactive prescribing for nursing home residents in Northern Ireland (Fleetwood Northern Ireland study). J Am Geriatr Soc 2010; 58: 44–53. Patterson SM, Hughes CM, Cardwell C, Lapane KL, Murray AM, Crealey GE. A cluster randomized controlled trial of an adapted U.S. model of pharmaceutical care for nursing home residents in Northern Ireland (Fleetwood Northern Ireland study): a cost-effectiveness analysis. J Am Geriatr Soc 2011; 59: 586–93.	Not polypharmacy focus. Approriateness of psychoactive drugs only "pharmacists visited nursing homes monthly for 12 months and reviewed residents' clinical and prescribing information, applied an algorithm that guided them in assessing the appropriateness of psychoactive medication"
Phelan M, Blenkinsopp A, Foster NE, Thomas E, Hay EM. Pharmacist-led medication review for knee pain in older adults: Content, process and outcomes. Int J Pharm Pract 2008; 16: 347–55.	General practice setting
Pit SW, Byles JE, Henry DA, Holt L, Hansen V, Bowman DA. A Quality Use of Medicines program for general practitioners and older people: a cluster randomised controlled trial. Medical Journal of Australia 2007;187(1): 23–30.	General practice setting
Pope G, Wall N, Peters CM, O'Connor M, Saunders J, O'Sullivan C, Donnelly TM, Walsh T, Jackson S, Lyons D, Clinch D. Specialist medication review does not benefit short-term outcomes and net costs in continuing-care patients. Age Ageing 2011; 40: 307–12.	Medication review not performed by a pharmacist. Medical assessment performed by a geriatrician and medication review by a multidisciplinary expert panel including geriatricians, pharmacists and nurses
Raynor DK, Nicolson M, Nunney J, Petty D, Vail A, Davies L. The development and evaluation of an extended adherence support programme by community pharmacists for elderly patients at home. Int J Pharm Pract 2000; 8: 157–64.	Setting not clear; pharmacist-GP collaborative approach/shared-care model
Rhodes, S. A., A. E. Reynolds, et al. (2013). Evaluating the economic impact of a targeted medication intervention program. Journal of Pharmacy Practice 26(6): 562-573.	Wrong outcome-return on investment from a pharmacy perspective
Roberts MS, Stokes JA, King MA, Lynne TA, Purdie DM, Glasziou PP, Wilson DA, McCarthy ST, Brooks GE, de Looze FJ, Del Mar CB. Outcomes of a randomized controlled trial of a clinical pharmacy intervention in 52 nursing homes. Br J Clin Pharmacol 2001; 51: 257–65.	HMR: multifaceted intervention (confounded study): Three-phase intervention: introducing a new professional role to stakeholders with relationship- building; nurse education; and medication review by pharmacist
Rubio-Valera M, Bosmans J, Fernández A, et al. Cost-effectiveness of a community pharmacist intervention in patients with depression: a randomized controlled trial (PRODEFAR Study). PLoS One. 2013;8: e70588.	No MR performed, an educational intervention by the pharmacist
Schneider J, Barber N. Provision of a domiciliary service by community pharmacists. Int J Pharm Pract 1996; 4: 19–24.	Non-comparative
Sorensen L, Stokes JA, Purdie DM, Woodward M, Elliott R, Roberts MS. Medication reviews in the community: results of a randomized, controlled effectiveness trial. Br J Clin Pharmacol 2004; 58: 648–64.	RMMR: multifaceted intervention
Stafford L, Stafford A, Hughes J, Angley M, Bereznicki L, Peterson G. Drug-related problems identified in post-discharge medication reviews for patients taking warfarin. Int J Clin Pharm 2011; 33: 621–6. Stafford L, Peterson GM, Bereznicki LR, Jackson SL, van Tienen EC, Angley MT et al. Clinical outcomes of a collaborative, home-based postdischarge warfarin management service. Ann Pharmacother 2011; 45: 325–34.	Post-discharge pts were visited by the pharmacist 2-3 times in their homes within 10 days post-discharge for the management of warfarin.
Stell, R., Bonollo, M., Fiddes, K. and Dooley, M. J. (2008). Successful integration of a clinical pharmacist into a disease management unit. Journal of Pharmacy Practice and Research 38(2): 132-136.	Non-comparative
Sturgess IK, McElnay JC, Hughes CM, Crealey G. Community pharmacy based provision of pharmaceutical care to older patients. Pharm World Sci, 2003;25:218–226.	Mixed setting (patients were firstly seen by the pharmacist then visited at home by the pharmacist)
Taylor CT, Byrd DC, Krueger K. Improving primary care in rural Alabama with a pharmacy initiative. American Journal of Health-System Pharmacy 2003;60(11):1123–9.	Family medicine clinic setting

Citations	Reason for exclusion
Trygstad TK, Christensen DB, Wegner SE, Sullivan R, Garmise JM. Analysis of the North Carolina long-term care polypharmacy initiative: a multiple-cohort approach using propensity-score matching for both evaluation and targeting. Clin Ther 2009; 31: 2018–37.	This study compares medication review with medication therapy management program plus medication review
Tsuyuki RT, Johnson JA, Teo KK, et al. A randomized trial of the effect of community pharmacist intervention on cholesterol risk management: the Study of Cardiovascular Risk Intervention by Pharmacists (SCRIP). Arch Intern Med 2002;162:1149–55.	Laboratory tests ordered
Weber V, White A, McIlvried R. An electronic medical record (EMR)-based intervention to reduce polypharmacy and falls in an ambulatory rural elderly population. Journal of General Internal Medicine 2008;23(4):399–404.	Medication review by pharmacist or geriatrician using electronic medical record system focusing on psychoactive medications, polypharmacy, and inappropriate dosages. Recommendations sent to primary physician via EMR. Control, usual care and no EMR
Welch EK, Delate T, Chester EA, Stubbings T. Assessment of the impact of medication therapy management delivered to home-based Medicare beneficiaries. Ann Pharmacother 2009;43(4):603-10.	MR performed through a telephone consultation with the pharmacist for people living at home
Williams ME, Pulliam CC, Hunter R, Johnson TM, Owens JE, Kincaid J, Porter C, Koch G. The short-term effect of interdisciplinary medication review on function and cost in ambulatory elderly people. J Am Geriatr Soc 2004; 52: 93–8.	Health centre ambulatory clinic setting, and medication review performed by a specialised team
Zermansky AG et al. Randomised controlled trial of clinical medication review by a pharmacist of elderly patients receiving repeat prescriptions in general practice. BMJ 2001; 323: 1340-3	General practice setting-clinic based
Taylor, S. J., Milanova, T., Hourihan, F., Krass, I., Coleman, C., & Armour, C. L. (2005). A cost-effectiveness analysis of a community pharmacist-initiated disease state management service for type 2 diabetes mellitus. International Journal of Pharmacy Practice, 13, 33–40."	CEA-exclude mixed setting and includes hospital diabetes clinics/confounding (more pts in the control group attended the diabetes clinic)

Abbreviations: CEA, cost-effectiveness analysis; EMR, electronic medical record; MR, medication review; RMMR, residential medication management review; GP, general practitioner