

*The value of pharmacist professional services  
in the community setting*

*A systematic review of the literature October 2002 – March 2005*

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## Executive summary

We were commissioned to update a review of Australian and international literature on professional pharmacist services in the community that covered the literature published between 1990 and October 2002 (Roughead, Semple and Vitry, 2003). Our update covered the literature published between October 2002 and the literature from 2002 to March 2005.

In accordance with our brief, we used the same literature-search methods and inclusion and exclusion criteria as those described in the 2003 report. We concentrated on examining the highest level of evidence, and we therefore confined our attention to reports of randomised controlled trials (RCTs). For those pharmacist professional services that had not been evaluated with RCTs, we only accepted trials that included a control group. However, our report does not provide a comprehensive review of non-randomised studies relating to all pharmacist services.

From our literature search, it appeared that the rate of publication of RCTs had increased markedly. We identified a total of 40 RCTs that had been published in a period of less than two and a half years, up to March 2005, while the previous review identified 70 RCTs over a period of almost 12 years.

Overall, our review indicates that many aspects of professional pharmacy practice in the community are effective in improving treatment processes and outcomes for specific groups of patients, as shown by various measures of morbidity, risk factor levels, treatment compliance, and (in a few situations) mortality. Specific findings for each group of patients (defined by disease conditions or patient characteristics) are given in detail in Chapters 2–15 and are summarised in Table 16.1. In general, the findings from our review reaffirmed the findings of the review by Roughead, Semple and Vitry (2003).

Several of the RCTs that we reviewed incorporated limited economic assessments, or assessed the relative costs of interventions. The following interventions appeared to lead to reduced costs: pharmaceutical care and continuity of care for the elderly (different studies gave different cost outcomes for medication reviews in the elderly); pharmaceutical care for patients with asthma; pharmacist involvement in therapeutic decisions for patients with cardiovascular disease; and medication reviews for patients taking multiple drugs. It should be noted that economic assessments were not undertaken for many of the interventions covered in the RCTs.

The RCTs that we reviewed encompassed a wide range of designs. Many of the RCTs appeared to have been well designed and conducted, with careful attention to the avoidance of observation bias by blinding. Some studies, however, had significant methodological weaknesses. The single most frequent weakness was a lack of information about important aspects of study design, such as calculations of sample size, the method of randomisation, and whether or not observers were blinded to the allocation status of subjects. Other frequent weaknesses were small sample sizes, resulting in insufficient statistical power to

detect any real effects that may have existed; lack of blinding, leading to possible observation biases; and failure to carry out intention-to-treat analyses.

From our experience of conducting this review, we draw the following five corollaries for consideration in the future development and evaluation of pharmacist professional services in the community setting.

First, while the focus on RCTs is desirable for a rigorous evaluation of specific services, it means that informative literature reporting on research that uses other designs is overlooked.

Second, for the development of Australian policy and practice, it is especially important to consider Australian studies of all types. While studies from other countries contribute to the stock of knowledge about the effectiveness of pharmacy interventions, many interventions are highly context-dependent.

Third, in evaluating professional services by pharmacists, it may be preferable to classify interventions according to the type of service provision that they represent, rather than the subdivision of interventions by their purpose or the setting in which they are applied (as was done in the previous review).

Fourth, while we were careful to evaluate effects of interventions that could reasonably be attributed to the specific involvement of pharmacists (as distinct from a multi-disciplinary team), we acknowledge that multi-disciplinary interventions are likely to dominate many aspects of health care in the future. It will therefore become increasingly difficult to isolate the role of pharmacists for the purpose of evaluation. Future evaluations will inevitably consider the effects of multi-disciplinary interventions that involve pharmacists and other professionals working together.

Finally, our experience has highlighted the difficulties of comprehensively assessing a wide range of interventions in a single review. These difficulties relate to the limitations that result from need to use review methods that can be applied to a wide range of types of interventions. We recommend that future reviews concentrate on particular types of pharmacy service provision, as suggested above, and that they include studies using all types of analytical and descriptive designs, not just RCTs. Evidence from any rigorous, well-conducted piece of research warrants consideration.

## Abbreviations

AD	Anti-depressants
ADE	Adverse drug event
ADL	Activity of daily living
AHCPR	Agency for Health Care Policy and Research
ARHQ	Agency for Healthcare Research and Quality
BMI	Body mass index
BP	Blood pressure
CHD	Coronary artery disease
CI	Confidence Interval
COOP/WONCA	Cooperative Information Project/World Organization of National Colleges
DBP	Diastolic blood pressure
DCP	Diabetes care plan
DRP	Drug related problems
EC	Enhanced care
ED	Emergency Department
GMI	Group mean imputation
GP	General Practitioner
HAART	HIV patients' adherence to active antiretroviral therapy
HBA <sub>1c</sub>	Haemoglobin A <sub>1c</sub>
HIV	Human immunodeficiency virus
HMO	Health maintenance organisation
HMR	Home medicines reviews
INR	International normalised ratio
ITT	Intention-to-treat
KP	Kaiser Permanente Medical Care
LDL	Low density lipoprotein
LOCF	Last observation carried forward
MAI	Medication Appropriateness Index
MHFQ	Minnesota living with heart failure questionnaire
MMP	Medication management plan
MR	Medication review
NH	Nursing Home
NSAID	Non-steroidal anti-inflammatory drugs
OTC	Over-the-counter (medicine sales)
OR	Odds ratio
PAQLQ	Paediatric asthma quality of life questionnaire
PCP	Primary care practitioner
PEFR	Peak expiratory flow rate
PMR	Patient Medication Records
PPCM	Physician pharmacist co-management
QOL	Quality of life
RCT	Randomised controlled trial

RNA	Ribose nucleic acid
RR	Relative risk
RT-CPR	Reverse-transcription polymerase chain reaction
SBP	Systolic blood pressure
SF-12	Short Form 12-Health Survey
SF-36	Short Form 36-Health Survey
SIGN	Scottish Intercollegiate Guidelines Network
UC	Usual care
UNCCH	University of North Carolina, Chapel Hill

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# 1 Introduction

## 1.1 Background and objectives

In 1998, Emerson, Whitehead and Benrimoj reported on a review of Australian and international literature on professional pharmacist services in the community. It was entitled *Value of Professional Pharmacist Services* (Emerson, Whitehead et al, 1998), and covered the literature from 1990 to June 1998. In 2003, Roughead, Semple and Vitry produced a further report that built on the Emerson report. It evaluated evidence for the effectiveness of professional pharmacy services with reference to patient outcomes and economic benefit, and covered the literature published up to October 2002.

We were commissioned to update the review that was done by Roughead, Semple and Vitry (2003). We covered the English-language literature published between October 2002 to March 2005.

## 1.2 Methods

### 1.2.1 Overall approach

In accordance with our brief, we used the same literature-search methods and inclusion criteria as those described in the 2003 report. Like Roughead, Semple and Vitry (2003), we broadly defined the term *pharmacist services* 'to include any pharmacist activity that was aimed at promoting the quality use of medicines and improving patient outcomes.'

We concentrated on examining the highest level of evidence, and we therefore confined our attention to reports of randomised controlled trials (RCTs) that were conducted between 2002 and March 2005. For those pharmacist professional services which had not been evaluated with RCTs, we only accepted trials that included a control group. However, our report does not provide a comprehensive review of non-randomised studies relating to all pharmacist services.

Roughead, Semple and Vitry (2003) developed a classification system to group studies evaluating similar types of community pharmacist services into categories. As far as possible, we followed their classification system, which is described in detail below (section 1.3). Like them, we have written a separate chapter for each group. Their categories and our adaptation of their approach is described in section 1.3 below.

## 1.2.2 Literature search methods

### *Electronic literature databases*

The following databases were searched to identify Australian and international literature that was published between 2002 and March 2005 and that assessed the value and effectiveness of professional pharmacy services:

- MEDLINE (via Ovid);
- International Pharmaceutical Abstracts;
- Current Contents;
- Australasian Medical Index (via Meditext);
- EMBASE.com; and
- The Cochrane Library.

The search terms that we used were the same as those used by Roughead, Semple and Vitry (2003). They are listed in Appendix I.

### *Inclusion and exclusion criteria*

We included research papers and reports that:

- were written in English;
- were published between 2002 and March 2005;
- were not included in the review by Roughead, Semple and Vitry (2003);
- used one of the following designs – RCT, non-randomised controlled study, or pre-post comparison study with a control group; and
- were undertaken in a community, ambulatory care, aged care or long-term care setting, or were undertaken in a hospital setting but had relevance to community pharmacy.

With regard to the last point, we included hospital studies involving an outpatient clinic setting, studies evaluating services to improve continuity of care between hospital and community settings, and studies evaluating discharge services and drug information services.

Studies were excluded from our review if:

- the interventions assessed were performed by a group of health professionals, and the role of the pharmacist could not be isolated;
- the only outcomes measured were patient or physician satisfaction with the service.

To correspond with the methods used by Roughead, Semple and Vitry (2003), we invoked specific inclusion and exclusion criteria for each type of pharmacy service (described in section 1.3). These specific criteria are outlined at the beginning of each of Chapters 2–15.

Studies were additionally classified by their study design and outcome measure. The classification used to allocate studies are detailed below.

### 1.2.3 Methodological categorisation

#### *Level of evidence or study design*

Studies were rated according to a hierarchy of study designs based on those used by the Scottish Intercollegiate Guidelines Network (SIGN) (Scottish Intercollegiate Guidelines Network (SIGN) 2001) (Table 1.1). We adopted the same hierarchy as that used by Roughead, Semple and Vitry.

**Table 1.1:** Hierarchy of study designs (based on SIGN, 2001) (Scottish Intercollegiate Guidelines Network (SIGN) 2001)

1++	High quality meta analyses, systematic reviews of randomised controlled trials (RCTs), or RCT with very low risk of bias
1+	Well conducted meta analyses, systematic reviews of RCTs or RCTs with a low risk of bias
1-	Meta analyses, systematic reviews of RCTs or RCTs with a high risk of bias
2*	Case-control or cohort studies*
3	Non-analytic studies e.g. case reports, case series
4	Expert opinion

\*Level 2 studies were not classified into 2++, 2+ and 2-, as this review included only level 1 studies, unless no RCTs were available.

#### *Outcome measures*

Studies were included if they assessed:

- clinical outcomes, including mortality, morbidity (including disease progression, symptoms, adverse events and quality of life), and adverse drug events;
- surrogate or intermediate outcomes (including laboratory or other tests) with well-established connections to the clinical outcome(s) of interest;
- other measurable variables with indirect or unestablished connections to the clinical outcome(s) of interest (including medication concordance, knowledge of medications, use of medication devices, or smoking cessation); or
- quality of prescribing or quality of medication use.

Outcome measures were rated based on the system used previously by the Agency for Healthcare Research and Quality (ARHQ) (Agency for Healthcare Research and Quality (AHRQ) 2001) (Table 1.2).

**Table 1.2:** Hierarchy of outcome measures (adapted from AHRQ, 2001) (Agency for Healthcare Research and Quality (AHRQ) 2001)

Level 1	Clinical outcomes – morbidity, mortality, adverse events
Level 2	Surrogate outcomes – intermediate outcomes, e.g. laboratory results with well-established connections to the clinical outcome of interest
Level 3	Other measurable variables with an indirect or unestablished connection to the target outcome e.g. pre-test/post-test after educational intervention
Level 4	Other relevant variables, but not direct outcomes, e.g. patient or medical practitioner satisfaction

### *Economic analysis*

Economic assessments of community pharmacy services were only included if the studies also examined patient outcomes and were conducted in RCTs. Studies that included economic assessments were categorised using the following classification system, based on the method used for papers submitted to the British Medical Journal (Jefferson, Demicheli et al. 1995) (Table 1.3). In this system, the direction of numbering is the opposite to that used in evaluating the strength of evidence (Table 1.1); level 3 studies provide the best economic evidence.

**Table 1.3:** Hierarchy of economic outcome measures (adapted from BMJ, 1995) (Jefferson, Demicheli et al. 1995)

Level 1	Studies with minimal economic input: studies that have included medication cost as an outcome without considering any other costs.
Level 2	Descriptive economic studies: studies that have measured and compared the costs of the intervention group versus the control group without attempting to assess the cost-effectiveness of the intervention.
Level 3	Full economic evaluation studies: studies in which analytical methods have been used to assess the cost-effectiveness of the intervention.

## 1.3 Content classification: types of pharmacist services

As mentioned in section 1.2.1, Roughead, Semple and Vitry (2003) developed a method of classification to group the numerous services provided by pharmacists into categories, so that they could analyse the result of comparable studies. Studies were classified into types of services, with reference to the interventions used by the pharmacist. Interventions usually consisted of one or more activities, including but not limited to:

- Provision of information;
- Provision of education;
- Medication chart review
- Review of medical case notes;
- Patient interviews;
- Development of care plans;

- Liaison or collaboration with other health care professionals;
- Monitoring signs and symptoms;
- Monitoring laboratory results;
- Device education and monitoring; and
- Follow-up.

Due to the wide range of definitions and interpretations of terms such as ‘pharmaceutical care’, ‘clinical pharmacy services’, ‘medication management’, and ‘medication review’, Roughead, Semple and Vitry (2003) classified the studies by the activity or activities implemented in the intervention, rather than the author’s own classification. For example, any intervention that included a patient interview by a pharmacist to identify and resolve medication problems or manage a specific condition, as well as the development of a care plan and follow-up, was categorised as *pharmaceutical care*. Interventions that included the review of medication charts without the involvement of the patient were categorised as *medication review*.

Although the interventions in the majority of studies were targeted at particular populations (for example, patients in a specific age group, with a specific condition, or on specific medicines or number of medicines), studies were classified by the type of intervention rather than the target population. The reason given was that similar activities were included in the intervention regardless of the target population. Two exceptions are *smoking cessation* and *immunisation*.

Roughead, Semple, and Vitry (2003) identified 19 categories of professional pharmacist services. They reviewed 73 RCTs. We reviewed 40 RCTs that met the inclusion criteria and were reviewed. Table 1.4 outlines the categories and the number of studies reviewed in each.

**Table 1.4:** Summary of studies assessed for each professional service

Professional service	Number of level 1 studies, 2002 – March 2005	Number of level 1 studies reviewed by Roughead et al, 2003
Pharmaceutical care services	9	20
Continuity of care services	6	9
Pharmacist clinic services	2	2
Pre-admission clinics	0	0
Medication review for repeat prescriptions	3	2
Medication review in aged-care facilities	0	3
Medication review in the outpatient setting	1	2
Pharmacist services providing education to patients or consumers	7	16
Education services for health care professionals	2	9

Drug information services	0	0
Pharmacist participation in therapeutic decision making	5 (includes 1 with no results)	2
Pharmacist involvement in non-prescription medicine use	0	1
Smoking cessation services	2	3
Pharmacist advocacy for immunisation services	0	2
Pharmacist administration of vaccines	0	0
Clinical interventions	0	0
Hospital in the home	0	0
Screening	0	0
Monitoring services	3	2
Pharmacist prescribing	0	0
<b>Total</b>	<b>40</b>	<b>73</b>

We searched the following websites in order to identify RCTs in unpublished (grey) literature:

- Canadian Pharmacists Association
- Irish Pharmaceutical Union
- National Community Pharmacists Association
- National Pharmaceutical Association
- Pharmacy Guild of Australia
- Pharmacy Guild of New Zealand
- Royal Pharmaceutical Society of Great Britain

However, unlike the previous review, we did not contact individual pharmacy schools in Australia to identify unpublished studies assessing pharmacist services in Australia.

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## 2 Pharmaceutical care services

### 2.1 The service

Roughead, Semple and Vitry (2003) cite the following definition of 'pharmaceutical care' as

'... the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes are (i) cure of a disease; (ii) elimination or reduction of a patient's symptomatology; (iii) arresting or slowing of a disease process; or (iv) preventing a disease or symptomatology.'(1).

They also cite the patient care process in pharmaceutical care as

'...including:

- 'Establishment of a therapeutic relationship
- Assessment, including identification of medication-related problems
- Development of a care plan
- Evaluation
- Continuous follow-up.' (2)

### 2.2 Studies included

The terms 'pharmaceutical care', 'clinical pharmacy services', 'medication management' and 'medication review' are used in the literature to describe a variety of practices. Sometimes they are used interchangeably, while at other times they describe different types of practice. For the purposes of this review, an intervention was considered to be a pharmaceutical care intervention if it included, as a minimum, the following:

- A one-to-one consultation between a patient and a pharmacist with a focus on managing health or resolving drug-related problems;
- Development of a care-plan;
- Follow-up.

Pharmaceutical care is a patient-focused service, very often for people considered at high-risk of medication-related problems. The service is also offered to people suffering from specific conditions or with specific risk factors for diseases. For the purposes of this review, studies that focused on any of these target groups could be included.

We included studies that were conducted in any of the following settings:

- Community
- Hospital outpatient clinics; or
- Ambulatory care clinics.



Two further inclusion criteria were:

the existence of a control or comparison group

the use of endpoints that included at least one patient outcome, which could include any of the following: hospital admissions or re-admissions; adverse events; mortality; quality of life; symptoms; surrogate health endpoint (e.g. BP control, cholesterol, blood glucose); knowledge or compliance (level 1, 2 or 3 outcomes).

Medication review services, which involved a medication chart review but did not involve one-to-one consultation with patients, are discussed elsewhere in this report.

Continuity of care services, which often incorporate the intervention detailed above, but occur across the hospital to community interface and specifically aim to improve communication about medicines between hospital and community care providers, are also reviewed elsewhere in this report.

Studies only assessing level 4 outcomes, such as changes in satisfaction with or opinion of the service were excluded.

## 2.3 Study design

We found nine randomised controlled trials (RCTs) (level 1 evidence) that evaluated the effectiveness of pharmaceutical care services (Bouvy, Heerdink et al. 2003; McLean, Gillis et al. 2003; Sturgess, McElnay et al. 2003; Taylor, Byrd et al. 2003; Peterson, Fitzmaurice et al. 2004; Simpson, Johnson et al. 2004; Clifford, Davis et al. 2005; Odegard, Goo et al. 2005; Rothman, Malone et al. 2005). The majority of these trials were conducted in North America – three in the USA and two in Canada. Two studies were conducted in Europe – one in the Netherlands and one in Northern Ireland. The remaining two studies were conducted in Australia – one in Western Australia and one in Tasmania.

Six studies directly compared pharmaceutical care with usual or standard care (Bouvy, Heerdink et al. 2003; Sturgess, McElnay et al. 2003; Taylor, Byrd et al. 2003; Peterson, Fitzmaurice et al. 2004; Clifford, Davis et al. 2005; Odegard, Goo et al. 2005). The other three studies also compared pharmaceutical care with usual or standard care but added either an educational session or follow-up interviews by the pharmacist for the group receiving usual care (McLean, Gillis et al. 2003; Simpson, Johnson et al. 2004; Rothman, Malone et al. 2005).

Pharmacist interventions in all nine studies included a combination of face-to-face and telephone consultations with the patient. Seven studies had set follow-up periods, ranging from every two to three weeks, to monthly, to every three months until the end of the study period. In another study, the pharmacist only came in contact with the patient during a regular appointment with the GP (Taylor, Byrd et al. 2003). One other study involved a consultation with the pharmacist, but the frequency and timing of any follow-up with the patient was difficult to determine from the article (Sturgess, McElnay et al. 2003).

Implementation of pharmaceutical care was directed at several different target groups. Six studies had disease-specific target groups which included patients with diabetes (4 studies), heart failure (1 study), and asthma (1 study). Three of the four studies targeted only adult patients with diabetes ( $\geq 18$  years). The fourth study did not mention any age restrictions. The two studies which dealt with heart failure and asthma also did not mention any age restrictions. One study assessed pharmaceutical care for the management of a risk factor, i.e. dyslipidaemia in the adult population only. Finally, two studies targeted populations considered to be at risk of drug-related problems, specifically adults on multiple medications with concurrent disease and the elderly ( $\geq 65$  years).

Implementation of interventions was carried out in single or multiple sites. Six studies were conducted in multiple sites, three of which did not require further training for the pharmacists, two studies included further training for the intervention pharmacists in the study design and one study required previously trained pharmacists. Only three studies were conducted in one location. Two of these studies did not require further training for the pharmacists and one study required previously trained pharmacists. The units of randomisation in the RCTs were either pharmacies, or pharmacists, or individual patients.

Follow-up periods in the studies were: four months (1 study), six months (two studies), 12 months (five studies) and 18 months (1 study).

Patient sample sizes ranged from 81 to 675. Three studies had less than 100 participants, three had between 100 and 200 participants and three had over 200 participants at the start of the study period. Of the nine RCTs, five provided sample size calculations.

## 2.4 Study outcomes

Outcome measures used in the randomised controlled trials included:

- Adverse drug events (level 1)
- Quality of life (QoL): Juniper Questionnaire; Medical Outcomes Study 36-item Short-Form Health Survey (SF-36); Dartmouth Primary Care Cooperative Information Project/World Organization of National Colleges, Academies, and Academic Associations of General Practice/Family Physicians (COOP/WONCA); Disease-specific quality of life: Minnesota Living With Heart Failure Questionnaire (MHFQ) (level 1)
- Mortality (level 1)
- Hospital admissions (level 1)
- Emergency department admissions (level 1)
- Disease symptom severity, symptom control (level 1)
- Body mass index (BMI) ( $\text{kg}/\text{m}^2$ ) (level 2)
- Glycaemic control: glycated haemoglobin  $\text{HbA}_{1c}$  (%) (level 2)
- Fasting plasma glucose (level 2)
- Blood pressure (level 2)
- Serum lipids (level 2)

- Urinary albumin-to-creatinine ratio (level 2)
- Peak expiratory flow rate (PEFR) (level 2)
- International Normalized Ratio (INR) (level 2)
- Disease-specific risk: coronary heart disease (CHD), stroke; 10-yr risk for cardiovascular events using Framingham equation (level 3)
- Medication use (level 3)
- Medication appropriateness: Medication Appropriateness Index (MAI) (level 3)
- Medication compliance (level 3)
- Medication or disease-state knowledge (level 3)
- Medication problems (level 3)
- Health or clinical services use and costs (level 3)
- Primary outcome measure – a composite measure of GP performing a fasting lipid profile, adding a cholesterol-lowering drug, or increasing dosage of a cholesterol-lowering drug (level 3)
- Days off from work or school (level 3)
- Patient satisfaction survey (level 4)
- GP satisfaction survey (level 4)

## 2.5 Evidence for effectiveness of practice

Evidence from the RCTs published between 2002 and March 2005 generally supports the findings from the review by Roughead, Semple and Vitry (2003) that pharmaceutical care is effective in improving patient outcomes.

The benefits of pharmaceutical care were apparent for all of the target groups of the nine RCTs that we reviewed. Benefits were greatest for patients with diabetes and heart failure, for elderly patients, and those with increased risk of drug-related problems.

The benefits were not reflected in all of the various study outcomes. For example, the four studies targeting patients with diabetes and the one study targeting patients requiring cholesterol risk management used only level 2, 3 and 4 outcome measures. The benefits of pharmaceutical care for patients with diabetes were therefore confined to surrogate clinical measures such as fasting blood glucose levels and glycated haemoglobin levels, as well as outcomes such as adherence to medication. The one study that targeted heart failure patients covered level 1 and 3 outcomes, which included mortality and quality of life (QOL). The one study that targeted asthma patients included outcomes of all four levels, such as symptom severity, hospital admissions, and respiratory function test measurements such as peak expiratory flow rates.

### *Evidence of effectiveness with respect to morbidity and mortality outcomes (level 1)*

#### *Mortality and hospital admissions*

In the RCTs that targeted patients with heart failure and asthma and those that targeted the elderly, no significant difference was found between intervention and control groups in

mortality rates (where assessed) (Bouvy, Heerdink et al. 2003) and hospital admissions (Bouvy, Heerdink et al. 2003; McLean, Gillis et al. 2003; Sturgess, McElnay et al. 2003).

On the other hand, in the RCT that targeted patients at high risk of drug-related problems (Taylor et al, 2003), the patients who received pharmaceutical care had significantly fewer hospital admissions than those who received usual care ( $p=0.003$ ).

#### *Emergency department (ED) admissions*

Significant reductions in the number of ED visits were recorded only for intervention patients receiving pharmaceutical care in the two studies that respectively targeted patients with asthma and those at risk of drug-related problems (McLean, 2003 #244; Taylor, 2003 #238).

#### *Quality of life*

Four studies assessed the effect of pharmaceutical care on patients' QOL. Three different types of questionnaires were used. Taylor et al (2003) targeted patients at risk of drug-related problems, used the SF-36, and did not find any significant difference on the QOL scores of intervention patients who received pharmaceutical care compared to control patients. McLean et al (2003) found a significant increase in the QOL scores of intervention patients compared to control patients with asthma, using the Juniper Questionnaire.

In contrast, control patients had significant improvements in their QOL scores compared to intervention patients in two studies targeting the elderly and patients with heart failure (Bouvy, Heerdink et al. 2003; Sturgess, McElnay et al. 2003). Questionnaires used were the COOP/WONCA and SF-36.

#### *Disease-specific quality of life*

The Minnesota Heart Failure Questionnaire (MHFQ) was used by Bouvy et al (2003) to assess the disease-specific quality of life of patients with heart failure. Both intervention and control groups improved their scores, with a slightly higher score in the control group. However, results were not significant.

#### *Adverse drug events (ADEs)*

Two studies assessed ADEs through patient self-report (Taylor, Byrd et al. 2003; Rothman, Malone et al. 2005). Target groups included patients with diabetes and patients considered at risk of drug-related problems. No significant differences were found in the two studies between the rates of ADEs in the intervention groups and the control groups.

#### *Disease symptom severity and symptom control*

A study targeting patients with asthma assessed changes in the severity of symptoms when comparing patients who received pharmaceutical care to those who received usual care (McLean, Gillis et al. 2003). Some of the symptoms assessed included dyspnea, cough, wheeze, and chest tightness. For all individual symptoms and the total score, improvements were significantly greater in the intervention group. In the RCT targeting elderly patients (Sturgess, McElnay et al. 2003), a large proportion of intervention patients (83.1% at 18

months) agreed that they controlled their condition better during the study than before their participation.

### ***Evidence for effectiveness with respect to surrogate endpoints (level 2 outcomes)***

#### ***Body mass index (BMI)***

In one study targeting patients with diabetes (Clifford, Davis et al. 2005) reductions in BMI were significantly greater for the intervention group than reductions in the control group ( $p=0.005$ ).

#### ***Glycaemic control: glycated haemoglobin (HbA<sub>1c</sub>) (%)***

Three studies, two targeting patients with diabetes and one targeting patients at risk of drug-related problems, found that patients who received pharmaceutical care had a significantly greater reduction in HbA<sub>1c</sub> compared to patients who received usual care (Taylor, Byrd et al. 2003; Clifford, Davis et al. 2005; Rothman, Malone et al. 2005). In one study, significant reductions in HbA<sub>1c</sub> levels occurred in both the intervention and the control groups, but the difference between them was not significant (Odegard, Goo et al. 2005).

#### ***Fasting plasma glucose***

In one study targeting patients with diabetes (Clifford, Davis et al. 2005), significantly greater reductions in fasting plasma glucose levels occurred in the intervention group than the control group ( $p<0.001$ ).

#### ***Blood pressure (BP)***

Three studies targeting patients with diabetes used blood pressure as a surrogate endpoint (Simpson, Johnson et al. 2004; Clifford, Davis et al. 2005; Rothman, Malone et al. 2005). Clifford et al (2005) and Rothman et al (2005) found significant reductions in the systolic (SBP) and diastolic blood pressures (DBP) of patients in the intervention group who received pharmaceutical care compared to controls who received usual care. The third study by Simpson et al (2004) measured SBP only in the intervention group and found no significant difference between patients with and without diabetes at follow-up.

In a fourth study, targeting individuals at risk of drug-related problems, which also used BP as a surrogate endpoint, intervention patients who received pharmaceutical care were significantly more likely to have reached the target BP at 12 months follow-up than control patients ( $p=0.001$ ) (Taylor, Byrd et al. 2003).

#### ***Serum lipids***

Three studies targeting patients with diabetes used serum lipids as a surrogate endpoint. In two studies, improvements in serum lipid levels did not differ between intervention and control groups (Clifford, Davis et al. 2005; Rothman, Malone et al. 2005). In one study serum lipid levels were measured only in the intervention group (Simpson, Johnson et al. 2004). A significant reduction occurred in patients with diabetes ( $p<0.01$ ), but no change in patients without diabetes, also in the intervention group.

Significant improvements in serum lipid levels in intervention patients were seen in two studies, one assessing pharmaceutical care for the management of cholesterol and the other targeting patients at risk of drug-related problems (Taylor, Byrd et al. 2003; Peterson, Fitzmaurice et al. 2004).

#### *Urinary albumin-to-creatinine ratio*

No significant improvements were seen in this measure when tested by Clifford et al (2005) on patients with diabetes who received either usual care or pharmaceutical care for 12 months.

#### *Peak expiratory flow rate (PEFR)*

McLean et al (2003) targeted patients with asthma. PEFrs improved significantly in the intervention group, andh virtually no change seen in the control group. The difference between the two groups was approximately 11% and was highly significant.

#### *International Normalised Ratio (INR)*

The study by Taylor et al (2003) targeted the adult population considered to be at risk of drug-related problems. Coagulation status was measured with reference to the INR for patients receiving anticoagulation therapy. All patients in the pharmaceutical care intervention group attained the desired INR target, compared to only 25% of control-group patients (p=0.048).

### ***Evidence for effectiveness with respect to level 3 outcomes***

#### *Disease-specific risk: coronary heart disease (CHD), stroke, cardiovascular events*

Two studies targeting patients with diabetes estimated patients' 10-year disease-specific risk. Clifford et al (2005) measured 10-year CHD and stroke risk for patients without a history of cardiovascular disease. Ten-year CHD risk decreased significantly in intervention-group patients (p=0.002), but did not change in control-group patients. Ten-year stroke risk did not change for intervention patients but significantly increased for control patients (p=0.001). Simpson et al (2004) used the Framingham equation to estimate 10-year risk for cardiovascular events in their intervention group only (because measurements of BP and total cholesterol levels were not part of usual pharmacy practice, they could not be done for control-group patients). Patients in the intervention group experienced significant reductions in risk from baseline to follow-up.

#### *Medication use*

Four studies measured medication use as an endpoint. One study targeting patients with diabetes did not find any significant changes in the use of key medications between intervention and control patients (Clifford, Davis et al. 2005). The other three studies, however, had a significant effect on the medication usage of intervention patients, i.e. greater use of aspirin for cardiovascular risk prevention in patients with diabetes, a drop in the mean number of beta-agonist doses taken by patients with asthma, and a greater use of prescribed medication by the elderly (McLean, Gillis et al. 2003; Sturgess, McElnay et al. 2003; Rothman, Malone et al. 2005).

### *Medication appropriateness: Medication Appropriateness Index (MAI)*

Two studies targeting patients with diabetes and those considered to be at risk of drug-related problems measured the effect of pharmaceutical care on medication appropriateness compared to usual care using the MAI (Taylor, Byrd et al. 2003; Odegard, Goo et al. 2005).

Odegard et al (2005) found no significant difference in the mean MAI scores for all drugs and diabetes drugs between intervention and control groups at 12 months, despite a 50% improvement in six-month MAI scores for diabetes drugs by the intervention group.

On the other hand, in the study by Taylor et al (2003) which targeted individuals at risk of drug-related problems, the intervention group had large decreases in inappropriate prescribing for all 10 domains of the MAI, while the control group had small decreases in five MAI domains and small increases in the other five MAI domains. The statistical significance of the changes and differences was not reported.

### *Medication compliance*

Medication compliance did not differ between intervention and control groups in three studies which respectively targeted patients with diabetes, patients suitable for cholesterol risk management, and patients at risk of drug-related problems (Taylor, Byrd et al. 2003; Peterson, Fitzmaurice et al. 2004; Odegard, Goo et al. 2005). All three studies relied on patients' self-reports.

One study which targeted patients with heart failure found significantly better compliance among patients in the intervention group than those in the control group (Bouvy, Heerdink et al. 2003). Another study found that elderly patients also responded positively to pharmaceutical care (Sturgess, McElnay et al. 2003). Self-report data showed that an intervention group of elderly patients were significantly more compliant and were more likely to change from being non-compliant than a control group of elderly patients. Data on medication refill rates also showed that intervention patients were more compliant than control patients. The change in the overall compliance status did not differ between the two groups.

### *Medication or disease-state knowledge*

The studies by Rothman et al (2005) targeting patients with diabetes and by Taylor et al (2003) targeting those considered at risk of drug-related problems found significant improvements in knowledge among intervention patients receiving pharmaceutical care compared with patients in control groups. (Taylor, Byrd et al. 2003; Rothman, Malone et al. 2005). Both studies used patients' self-report to assess changes in medication and disease-state knowledge.

In a study targeting asthma patients, significant improvements in knowledge occurred equally in both intervention and control groups (McLean, Gillis et al. 2003). Both groups improved in all the domains of the knowledge assessment except for knowledge of peak-flow monitoring, which was significantly greater in the intervention group. Little change was

reported by Sturgess et al (2003) in the knowledge scores of the elderly patients who participated in their study.

#### *Medication problems*

This refers to specific problems encountered by patients with their medicines, e.g. swallowing medicines, opening containers, getting medicines out of packaging, unpleasant taste of medicines, troublesome side-effects, difficulty reading labels and information leaflets, and confusion on when to take medicines.

One study targeting elderly patients assessed the level of medication problems being experienced by the participants through self-report (Sturgess, McElnay et al. 2003). Differences between intervention and control patients were not significant in the first 12 months of the study. At 18 months, intervention patients reported significantly fewer medication problems than control patients ( $p < 0.05$ ).

#### *Health or clinical services use and costs*

A study targeting patients with diabetes measured the proportion of patients who had their fasting serum cholesterol levels tested (Simpson, Johnson et al. 2004). A higher proportion of intervention-group patients had a cholesterol test than the control-group, with this effect being significantly greater in patients with diabetes than those without ( $p = 0.01$ ).

A study targeting elderly patients showed that intervention patients receiving pharmaceutical care had significantly more contact with GPs and specialists than controls receiving usual care ( $p < 0.05$ ) (Sturgess, McElnay et al. 2003).

On the other hand, patients with asthma targeted by the study conducted by McLean et al (2003) experienced significant reduction in the number of medical visits only if they received pharmaceutical care, from 1.33 to 0.39 visits per month.

Rothman et al (2005) assessed, through self-report, the use of services in their study targeting patients with diabetes. Services were combined to give one measure and included general medicine visits, emergency department visits and hospitalisations. No statistically significant difference was found in the level of use of services between intervention and control patients.

#### *Primary outcome measure – a composite measure of GP performing a fasting lipid profile, adding a cholesterol-lowering drug, or increasing dosage of a cholesterol-lowering drug*

This was measured by Simpson et al (2004) in their study which included patients with and without diabetes and randomised to either an intervention group to receive pharmaceutical or a control group to receive usual care. Patients with diabetes in the intervention group were five times more likely to reach the endpoint than patients with diabetes who received usual care. Patients without diabetes in the intervention group were twice as likely to reach the endpoint than those who receive usual care. The difference in effect size between patients with and without diabetes was statistically significant ( $p = 0.01$ )



### *Days off from work or school*

A study targeting patients with asthma compared the number of days taken off work or school by intervention patients receiving pharmaceutical care and the number of days taken off by control patients (McLean, Gillis et al. 2003). An observed decrease in days off in the intervention group was not statistically significant in comparison with the control group.

### ***Evidence for effectiveness with respect to level 4 outcomes***

#### *Patient satisfaction survey*

Patient satisfaction surveys were conducted in four studies that targeted elderly patients, patients with diabetes and asthma, and patients who were considered possibly to benefit from cholesterol risk management (McLean, Gillis et al. 2003; Sturgess, McElnay et al. 2003; Peterson, Fitzmaurice et al. 2004; Rothman, Malone et al. 2005). In general, most patients were very satisfied with the service they received, although a response rate of 48% and 34% were reported for two of the studies. Intervention-group patients had a significantly greater increase in treatment satisfaction than control-group patients (Rothman, Malone et al. 2005). In one study, over eighty percent of intervention-group patients indicated that they would readily approach their pharmacists, had a better relationship with them, and were satisfied with the advice given to them (Sturgess, McElnay et al. 2003).

#### *GP satisfaction survey*

The study by Peterson et al (2004), which assessed pharmaceutical care for the management of cholesterol in an adult population, involved sending a satisfaction survey to the GPs of intervention-group patients. A response rate of 50% was obtained with 16 GPs returning the questionnaire. Most were satisfied with the intervention and found it to be a worthwhile service.

## **2.6 Economic assessment**

None of the nine RCTs that we found included a full economic assessment of the interventions that they tested. Two studies provided limited information on the overall costs of specific interventions and possible savings that would result from these interventions in comparison with the costs of usual usual care.

The pharmaceutical care program implemented in the study by McLean et al (2003) for patients with asthma showed an overall cost saving of C\$201 per patient per month (the cost per intervention patient was C\$150 per month, whereas the cost per control patient was C\$351 per month). Costs included in this calculation were from medical and emergency visits, hospitalisations, prescription drugs, pharmacists' fees and days off from work or school.

No significant long-term cost savings were found by Sturgess et al (2003) in their study targeting elderly patients when comparing those who received pharmaceutical care with those who received usual care. In the first six months of the study, however, an average cost saving of Sterling £307 per patient in the intervention group compared to the control group was made. This figure may be slightly affected by one control patient having been hospitalised for three months.

## 2.7 Australian research

As described in section 2.2, we found two Australian studies that met our inclusion criteria. Both were conducted in a community setting. Clifford et al (2005) conducted a study in Western Australia targeting patients with diabetes mellitus. Study participants were a subset of another trial already being conducted. The study compared pharmaceutical care for these patients with usual care, and a follow-up period of one year. The pharmacist intervention consisted of face-to-face goal-directed medication and lifestyle counselling, provision of educational material, and regular follow-up with the patient. Reports were regularly sent to GPs and other health professionals involved in the care of the patients. Peterson et al (2004) assessed the effect of pharmacist-conducted home visits on the outcomes of lipid-lowering drug therapy with a six-month follow-up period. Control patients received usual care. Intervention patients received further education on their therapy, given dietary and lifestyle recommendations, and they were assessed for any drug-related problems by their pharmacist.

We also found a third Australian RCT that met the inclusion criteria (Hughes, Keen et al. 2004). It was not included in the review because it failed to recruit the required sample by a very large margin (power calculations indicated a need for at least 300 subjects, but only 34 were enrolled and only 21 patients, who were randomly allocated to three groups, completed 12 months of participation). The pharmacist intervention consisted of provision of education, monitoring of BP and weight, progress assessment, and identification of and interventions to overcome barriers to adherence.

## 2.8 Comment

The nine RCTs that we reviewed all provided evidence affirming the value of pharmaceutical care in improving a wide range of outcomes for patients with chronic disease, the management of risk factors, elderly patients, and patients at high risk of drug-related problems. The RCTs were conducted in Australia, North America and Europe.

In the RCTs, pharmaceutical care was demonstrably associated with improvements in outcomes and disease severity for patients with chronic diseases such as heart failure and diabetes, as well improvements in compliance with medication regimens and knowledge, and reductions both in 10-year CHD risk and individual risk factors. Evidence for the

effectiveness of pharmaceutical care in improving outcomes for patients with asthma was slightly weaker. However, improvements in symptom severity, quality of life, respiratory function, medication use and health resource use were significant.

Pharmaceutical care was also associated with improvements for other target populations such as those requiring cholesterol risk management, the elderly, and those at high risk of drug-related problems. Improvements were evident in physiological parameters, medication knowledge and compliance, and health resource use. Drug-related problems also decreased, especially in the elderly.

The pharmacist interventions that were shown to be effective in the nine RCTs included a combination of activities. The development of a care plan in consultation with the patient and GP, and the provision of education and counselling regarding medications, lifestyle and diet were common. Additional components of effective pharmaceutical care were forming better relationships with GPs and other primary care providers, and pharmacists conducting regular consultations with patients for the review of medications and monitoring. The level of pharmacist training required for these interventions varied. For the interventions in three of the RCTs further education was not required for the pharmacist. In two of the RCTs further training was provided for the pharmacists carrying out the interventions, and in one RCT the intervention depended on pharmacists who had received appropriate prior training.

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**Table 2.1** Randomised controlled trials of pharmaceutical care services

Reference	Level	Setting	Subjects, intervention	Evaluable sample	Study outcomes	Results
<b>Pharmaceutical care for diabetes mellitus</b>						
Clifford R et al (2005). Diabetes Care 28(4): 771-776	1+	Community setting Fremantle, WA Australia  Single site No further training for pharmacist	Community-based adult patients (subset of patients already enrolled in a previous trial) with type 2 diabetes who were of self-identified southern European or Anglo-Celt ethnicity (the largest ethnic groups in the previous trial's cohort) and taking at least 1 prescribed medication.  Intervention patients had face-to-face goal-directed medication and lifestyle counselling (baseline, 6-, 12-months) plus 6-weekly telephone assessments through the entire study period and provision of educational material. Patient reports sent regularly to GP and other health professionals involved.  Control patients received usual care.	Int = 92 C = 88  Total = 180  12-month follow-up	Level 2 BMI HbA <sub>1c</sub> Fasting plasma glucose BP  Serum lipids Urinary albumin-to-creatinine ratio  Level 3 Change in risk for CHD, stroke	Reductions significantly greater in the intervention group than in the control group for these four outcomes at 12 months. Change in: BMI (kg/m <sup>2</sup> ) is -0.6 intervention vs. 0.1 control (p=0.005), HbA <sub>1c</sub> (%) is -0.5 intervention vs. 0 control (p=0.002), Fasting plasma glucose (mmol/l) is -0.8 intervention vs. 0.4 control (p<0.001), SBP (mmHg) is -14 intervention vs. -7 control (p=0.024), DBP is -5 intervention vs. -2 control (p=0.043)  There were non-significant improvements for these two outcomes  Only measured for patients without a history of cardiovascular disease, more likely to be younger and female (n=94) 10-year CHD risk decreased significantly in intervention patients, 25.1 to 20.3% (p=0.002) but no change in controls 10-year stroke risk did not change for intervention patients but increased significantly for control patients, 15 to

Reference	Level	Setting	Subjects, intervention	Evaluable sample	Study outcomes	Results
					Medication use	16.8% (p=0.001) No differences found between the two groups in the percentage change in use of key medications
Odegard S et al (2005). Annals of Pharmacotherapy 39(March): 433-39	1+	University of Washington Medicine Clinics  Multi-site: 70 providers 8 clinics  Greater Seattle area, USA	Eligible patients were aged $\geq 18$ with type 2 diabetes, taking at least one oral diabetes medication, $HbA_{1c} \geq 9\%$ .  Exclusion criteria: non-English-speaking, with unstable psychiatric conditions, with terminal prognosis within 6 months  Control group - To continue usual care with the primary care provider. Diabetes education was not provided during the baseline interview.  Intervention group - To receive pharmacist intervention on a weekly basis via phone or visits which consisted of: development of a diabetes care plan (DCP) (changes in drug therapy, nutrition and exercise counselling referrals, ophthalmology evaluation referrals), pharmacist-provider communication, pharmacist-patient communication (via telephone, in-person contact).  Outcomes measured at baseline, 6-, and 12-months.	Int = 43 C = 34  Total = 77  6-month intervention period  12-month follow-up	Level 2 $HbA_{1c}$  Level 3 • Medication appropriateness (MAI)  • Self-reported adherence	<ul style="list-style-type: none"> <li>• Mean <math>HbA_{1c}</math> in intervention group decreased from 10.2% at baseline to 8.7% (6-month), 8.2% (12-month), not statistically significant compared to reductions in control group</li> <li>• Significant decrease in both groups between 6 and 12-month <math>HbA_{1c}</math>, <math>p=0.001</math></li> <li>• At baseline, 48% intervention and 52% control patients were using inappropriate drugs; 4.2% of drugs used by intervention patients were deemed inappropriate, 3.5% for controls.</li> <li>• Mean MAI for all drugs during follow-up was not significantly different between groups, <math>p=0.65</math></li> <li>• Mean MAI for diabetes drugs not significantly different between groups despite intervention MAI 6-month scores improving by 50%.</li> <li>• At baseline, intervention patients reported more difficulty in remembering to take medications as prescribed but was not significant (56% intervention vs. 35% control,</li> </ul>

Reference	Level	Setting	Subjects, intervention	Evaluable sample	Study outcomes	Results
						<p>p=0.07)</p> <ul style="list-style-type: none"> <li>Intervention had no effect on improving adherence during the study period. Control patients reported better adherence than intervention patients throughout the study, p=0.003</li> </ul>
Rothman R et al (2005). The American Journal of Medicine 118: 276-84	1+	Academic general medicine practice, University of North Carolina, USA  Single site Pharmacists had previous training	<p>Patients ≥18 yrs with type 2 diabetes and poor glycaemic control (HbA<sub>1c</sub> level ≥8.0%), spoke English, with a life expectancy &gt;6 months.</p> <p>All patients received a 1 hour diabetes education session with a clinical pharmacist. Treatment recommendations given to GP.</p> <p>Intervention group received usual care with intensive diabetes management (education, counselling, evidence-based treatment algorithms, medication management), being in contact with the pharmacist every 2-4 weeks by telephone or in person. GP notified of results. Had access to diabetes care coordinator who addressed issues related to health behaviour, health education, barriers to care, and reminded them of appointments, etc.</p> <p>Control group received usual care from their GP.</p>	<p>Baseline: Int = 112 C = 105 Total = 217</p> <p>6-month: Int = 105 C = 99 Total = 204</p> <p>12-month: Int = 99 C = 95 Total = 194</p> <p>12-month follow-up</p>	<p>Level 1 Adverse drug events (ADEs)</p> <p>Level 2 HbA<sub>1c</sub></p> <p>BP</p> <p>Serum lipids</p> <p>Level 3 • Medication use</p>	<p>No statistically significant differences between groups</p> <ul style="list-style-type: none"> <li>Significantly improved in intervention group, 2.5% decrease vs. 1.6% in control group, difference of 0.8%, 95%CI 0-1.7%, p=0.05</li> <li>SBP, DBP improved significantly among intervention patients compared to controls SBP intervention -7 mm Hg, control 2 mm Hg, a difference of 9 mm Hg, 95% CI 1-9 mm Hg, p=0.008 DBP intervention -4, control 1, difference 5 mm Hg, 95% CI 1-9 mm Hg, p=0.02</li> <li>Only measured for patients who required statin therapy</li> <li>Improved more in the intervention group but the difference with control group was modest and not significant</li> <li>Aspirin use among eligible patients</li> </ul>

Reference	Level	Setting	Subjects, intervention	Evaluable sample	Study outcomes	Results
					<ul style="list-style-type: none"> <li>Diabetes knowledge</li> <li>Use of clinical services</li> </ul> <p>Level 4</p> <ul style="list-style-type: none"> <li>Treatment satisfaction</li> </ul>	<p>for cardiovascular risk prevention was significantly higher for intervention group (91%) compared to control group (54%), <math>p &lt; 0.0001</math></p> <ul style="list-style-type: none"> <li>More improvements in the intervention group (+27) vs. control group (+13), significant difference of +14 (95% CI 9–20)</li> <li>No statistically significant differences between groups</li> <li>Greater increase in satisfaction in the intervention group (+8) vs. control group (+4), significant difference of +3 (95% CI 1–6)</li> </ul>
<p>Simpson SH et al (2004). <i>Pharmacotherapy</i> 24(3): 389–94</p> <p>A study based on a subset of patients from the SCRIP study (Tsuyuki 2002)</p>	1+	<p>Community setting in Alberta and Saskatchewan, Canada</p> <p>Multi-site: 54 centres No further training mentioned for pharmacists</p>	<p>Patients with existing cardiovascular disease (CHD, previous revascularisation, cerebrovascular disease, PVD), or diabetes with one or more other cardiovascular risk factors.</p> <p>Intervention patients received an enhanced care program from community pharmacists consisting of an interview to identify cardiovascular risk factors, clinical measurements, recommendations, five follow-ups (phone or in person).</p> <p>Control patients received only general advice and two follow-ups from the community pharmacist.</p>	<p>With diabetes Int = 156 C = 138 Total = 294</p> <p>No diabetes Int = 188 C = 193 Total = 381</p> <p>Study total = 675</p> <p>4-month follow-up</p>	<p>Level 2</p> <ul style="list-style-type: none"> <li>Total cholesterol levels (mg/dl)</li> <li>SBP</li> </ul> <p>Level 3</p> <ul style="list-style-type: none"> <li>10-yr risk for cardio-vascular events Framingham equation</li> </ul>	<ul style="list-style-type: none"> <li>Intervention group only: Patients with diabetes had a significant reduction in total cholesterol levels (<math>p &lt; 0.01</math>) but did not change for patients without diabetes (<math>p = 0.5</math>)</li> <li>Intervention group only: Reduction similar in patients with and without diabetes at follow-up and was not significant (<math>p = 0.7</math>)</li> <li>Intervention group only: Patients with diabetes had significantly higher risks than patients without diabetes at baseline (<math>p &lt; 0.001</math>) and at follow-up (<math>p &lt; 0.001</math>)</li> </ul> <p>Both patients with and without</p>



Reference	Level	Setting	Subjects, intervention	Evaluable sample	Study outcomes	Results
					<ul style="list-style-type: none"> <li>• Primary outcome measure (composite)</li> <li>• Fasting cholesterol profile performed</li> </ul>	<p>diabetes experienced significant reductions in risk from baseline to follow-up. Difference in reduction between them was not significant (1.3% w/diabetes, 0.7% w/o diabetes, p=0.26)</p> <ul style="list-style-type: none"> <li>• A composite measure of 1) GP performing a fasting lipid profile, 2) adding a cholesterol-lowering drug, or 3) increasing dosage of a cholesterol-lowering drug</li> <li>• Patients with diabetes in intervention group were 5 times more likely to reach end point than patients with diabetes who received usual care</li> <li>• Patients w/o diabetes in intervention group were twice as likely to achieve end point compared to patients w/o diabetes who received usual care.</li> <li>• The difference in effect size of achieving end point between patients with diabetes and without was statistically significant (p=0.01)</li> <li>• Higher proportion of intervention patients had profile performed than in the control group with this effect being significantly greater in patients with diabetes (OR=4.5, 95% CI 2.7-7.3 ) than those without diabetes (OR=1.9, 95% CI 1.3-2.9), p=0.01</li> </ul>
<b>Pharmaceutical care for heart failure</b>						
Bouvy M et al (2003).	1+	Community setting in the	Patients with heart failure treated with loop diuretics, presenting to a cardiology	Int = 74 C = 78	Level 1 • QoL	<ul style="list-style-type: none"> <li>• Improved in the control group and</li> </ul>

Reference	Level	Setting	Subjects, intervention	Evaluable sample	Study outcomes	Results
Journal of Cardiac Failure 9(5): 404-11		Netherlands  Multi-site: 7 hospitals 79 pharmacists (training provided)	outpatient clinic or admitted to hospitals.  Intervention patients received an initial structured interview and monthly consultations from their community pharmacist to discuss drug use, reasons for non-compliance. Pharmacist forwarded a short report to the GP.  Control patients received usual care, and did not receive an interview or any follow-up from the pharmacist.	Total = 152  6-month follow-up	(COOP/WONCA)  • Disease-specific QoL (MHFQ) • Mortality • Hospital admissions  Level 3 • Medication compliance	worsened slightly in the intervention group (p=0.03) • Improved in both groups, slightly higher in the control group but not statistically significant (p=0.07) • 25.7% Intervention, 24.4% Control patients were either readmitted to hospital or dead (p>0.05), not statistically significant  • No. of days w/o use of loop diuretics - Intervention 140/7656, Control 337/6196 (RR=0.33, 95% CI 0.24-0.38) • Two days of consecutive nondosing occurred on 18/7656 days Intervention, 46/6196 days Control (RR=0.32, 95%CI 0.19-0.55)
<b>Pharmaceutical care for asthma</b>						
McLean W et al (2003). Canadian Respiratory Journal 10(4): 195-202	1-	Community setting in British Columbia, Canada  Multi-site: 27 pharmacies Pharmacists previously trained	Asthma patients from the local community.  Control patients received usual care which involved an initial and a final interview with the patient (education, consultation). This is typical of what most patients receive in a pharmacy.  Intervention patients received usual care plus the teaching of asthma self-management (education, development of an action plan, use of a peak flow meter). Consultations with the pharmacist occurred	Int = 119 C = 105  Total = 224  12-month follow-up (minimum 9 months)	Level 1 • Symptom severity   • QoL	• Incl. dyspnea, cough, wheeze, chest tightness, phlegm production, nasal symptoms • Mean cough scores and symptom total improved significantly in both groups. For all individual symptoms and the total score, improvements were significantly greater in the intervention group • Measured by the Juniper questionnaire • Intervention group had a significantly greater improvement than the control

Reference	Level	Setting	Subjects, intervention	Evaluable sample	Study outcomes	Results
			every 2 to 3 weeks for at least three appointments, and follow-up appointments at least every three months or when necessary.		<ul style="list-style-type: none"> <li>Emergency department admissions (ED)</li> <li>Hospital admissions</li> </ul> <p>Level 2</p> <ul style="list-style-type: none"> <li>PEFRs</li> </ul> <p>Level 3</p> <ul style="list-style-type: none"> <li>Knowledge</li> <li>Medication use</li> </ul>	<p>group</p> <ul style="list-style-type: none"> <li>Intervention group showed significant improvement on all scales</li> <li>Control group only showed a significant improvement in relation to activity limitation</li> <li>Significant reduction in the mean number of ED visits between the first and last pharmacy visit for the intervention group only (p=0.03)</li> <li>No significant differences between hospitalisations in either group</li> </ul> <p>Level 2</p> <ul style="list-style-type: none"> <li>Peak expiratory flow rates were significantly improved in the intervention group with virtually no change seen in the control group</li> <li>Difference between the two groups was approx. 11% and was highly significant</li> </ul> <p>Level 3</p> <ul style="list-style-type: none"> <li>Significant improvements in both groups for all domains of the knowledge assessment except for knowledge of peak flow monitoring which was significantly greater in the intervention group than in the control group</li> <li>Significant drop in the mean number of beta-agonist doses used by the intervention group only</li> <li>No significant changes in the number</li> </ul>

Reference	Level	Setting	Subjects, intervention	Evaluable sample	Study outcomes	Results
					<ul style="list-style-type: none"> <li>No. of medical visits</li> <li>Days off from work or school</li> <li>Medication costs</li> </ul> <p>Level 4</p> <ul style="list-style-type: none"> <li>Patient client survey</li> </ul>	<ul style="list-style-type: none"> <li>of corticosteroid doses in either group</li> <li>Significant reduction in the number of medical visits between the first and last pharmacy visits in the intervention group only, from 1.33/month to 0.39/month</li> <li>Number of medical visits increased for the control group but was not significant</li> <li>Differences between the two groups were significant</li> <li>No significant decrease in days off in the control group</li> <li>Intervention group experienced a 60% improvement but was not significant</li> <li>Total health costs per patient: C\$150 intervention vs. \$351 control per month</li> <li>48% response rate, score is 1=excellent or 2=good</li> <li>Both groups gave an overall evaluation of 1.2, suggesting excellent rapport between these patients and pharmacists</li> </ul>
<b>Pharmaceutical care for cholesterol risk management</b>						
Peterson G et al (2004). Journal of Clinical Pharmacy and	1-	Community setting in Hobart, Tasmania, Australia	Patients with established cardiovascular disease and an acute cardiovascular or cerebrovascular-related admission, and discharged on statin therapy were recruited from the Royal Hobart Hospital.	Int = 39 C = 42  Total = 81  6-month	Level 2  • Blood cholesterol levels	<ul style="list-style-type: none"> <li>Mean (SD) blood cholesterol level (mmol/L) at follow-up was 4.6±0.8 control vs. 4.4±0.6 intervention, p=0.24, difference between the groups was not significant</li> </ul>

Reference	Level	Setting	Subjects, intervention	Evaluable sample	Study outcomes	Results
Therapeutics 29: 23–30		Single site No mention of further training required	Pharmacist visited all patients 6 weeks after discharge to take baseline measurements and record current medication regimen. GP notified of all results.  Intervention patients received further education on their lipid-lowering therapy, dietary and lifestyle recommendations, medication compliance, identification of drug-related problems – monthly visits by the pharmacists.  Control patients received usual care.	follow-up	Level 3 • Medication compliance  Level 4 • Patient satisfaction questionnaire  • GP questionnaire	<ul style="list-style-type: none"> <li>• Improvement during the course of the study in the intervention group was significant (<math>p &lt; 0.005</math>), not significant in the control group</li> <li>• Self-reported medication compliance did not change and total cholesterol levels were not significantly related to compliance</li> <li>• Sent to intervention group only</li> <li>• 34% response rate, <math>n = 34</math></li> <li>• Patients extremely satisfied with the service, 80% prepared to pay typically \$1–5 for the service, 88% felt it would be best performed at home</li> <li>• Sent to GPs with patients in the intervention group</li> <li>• 50% response rate, <math>n = 16</math></li> <li>• Satisfied with intervention, found it to be a worthwhile service</li> </ul>
<b>Pharmaceutical care studies targeting general patient population at risk of drug-related problems</b>						
Taylor CT et al (2003) (Taylor, Byrd et al. 2003)	1–	Three Community-based family medicine clinics  Rural Alabama, USA	Eligible patients were aged $\geq 18$ , received care at participating clinics, and were identified as being high-risk for medication related adverse events.  High-risk = 3 or more of the following: $\geq 5$ medications in drug regimen; $\geq 4$ medication changes in past year; $\geq 12$ doses/day; $\geq 3$ concurrent diseases; history	Baseline: Total = 81  12-month: Int = 33 C = 36 Total = 69  12-month	Level 1 • Hospital admissions • ED admissions  • QoL  Level 2	<ul style="list-style-type: none"> <li>• Significantly decreased in intervention group, constant controls (<math>p = 0.003</math>)</li> <li>• Significantly decreased in intervention group, constant controls (<math>p = 0.04</math>)</li> <li>• Improved QOL scores in intervention patients, though not significant</li> </ul>

Reference	Level	Setting	Subjects, intervention	Evaluable sample	Study outcomes	Results
		Multi-site: 3 medical clinics No further training required for pharmacists	<p>of non-compliance; medication requiring therapeutic monitoring.</p> <p>Patients included: hypertension, diabetes, anti-coagulation, and dyslipidaemia.</p> <p>Excluded if cognitively impaired; history of missed office visits; scheduling conflicts; or life expectancy less than 12 months.</p> <p>Control group received standard medical care.</p> <p>Intervention group received standard medical care plus pharmaceutical care (therapeutic recommendations, medication history, drug education, monitoring, compliance-enhancing strategies). This involved a 20-min session with the pharmacist held prior to seeing their GP during regularly scheduled appointments with the GP.</p>	follow-up	<ul style="list-style-type: none"> <li>Hypertension: blood pressure</li> <li>Diabetes: HbA<sub>1c</sub> conc.</li> <li>Anti-coagulation: INR</li> <li>Dyslipidaemia: LDL cholesterol conc</li> <li>ADEs</li> </ul> <p>Level 3</p> <ul style="list-style-type: none"> <li>Medication Appropriateness (MAI)</li> <li>Self-reported compliance</li> <li>Medication knowledge</li> </ul>	<ul style="list-style-type: none"> <li>At 12-month follow-up intervention significantly more likely to have reached target BP (p=0.001)</li> <li>All intervention at therapeutic goal at 12-months vs. 26% controls (p=0.001)</li> <li>At 12-months all intervention at INR target, only 25% controls (p=0.048)</li> <li>Significant improvement in cholesterol in intervention group (p=0.001)</li> <li>Reported by both intervention and control group</li> <li>% of inappropriate prescribing decreased in intervention (all domains), increased in 5 and decreased in 5 domains for controls</li> <li>Increased number of intervention pts reporting 80-100% compliance, no change controls. Not significant though.</li> <li>Intervention increased medication knowledge, controls decreased (p&lt;0.0001)</li> </ul>
<b>Pharmaceutical care for elderly patients</b>						
Sturgess et al. (2003) (Sturgess, McElnay et al. 2003)	1+	Multi-site: 10 community pharmacies Training of pharmacists	Eligible patients were: aged ≥65; community dwelling; taking 2-4 prescribed medications; regularly visited the participating community pharmacy; orientated to self, time and place.	5 intervention pharmacies, 5 control pharmacies	Level 1 • QOL	<ul style="list-style-type: none"> <li>Intervention QOL better than control at baseline, significant. At 18-months, QOL in intervention declined and improved in control, significant</li> </ul>

Reference	Level	Setting	Subjects, intervention	Evaluable sample	Study outcomes	Results
		provided  Northern Ireland	Excluded if housebound or living in a nursing/residential home.  Pharmacists assessed patients for actual and potential DRPs, formulated an intervention and monitoring plan for each patient e.g. education and implementation of compliance-improving strategies. Conducted home medication review.  Control patients received usual services.	Only half the sites saw study through to completion (3,2)  Baseline: Int = 110 C = 81 Total = 191  6-month: Int = 86 C = 61 Total = 147  12-month: Int = 76 C = 43 Total = 119  18-month: Int = 75 C = 35 Total = 110  18-month follow-up	<ul style="list-style-type: none"> <li>• Hospital admissions</li> <li>• Symptom control</li> </ul> Level 3 <ul style="list-style-type: none"> <li>• Problems with medicines</li> <li>• Contact with health professionals</li> <li>• Medication knowledge</li> <li>• Number of changes in medicines</li> <li>• Compliance</li> </ul> <ul style="list-style-type: none"> <li>• Total cost of intervention</li> </ul>	but driven by one control pharmacy site. <ul style="list-style-type: none"> <li>• Fewer hospitalisations for intervention patients than control, not significant</li> <li>• Significant number of intervention pts managed their condition better during study</li> </ul> <ul style="list-style-type: none"> <li>• Intervention had significantly fewer problems in last 6 months of study vs. controls (<math>p &lt; 0.05</math>)</li> <li>• Intervention pts had more contact with GPs (in 1<sup>st</sup> and 2<sup>nd</sup> 6-months) and specialists (in 2<sup>nd</sup> and 3<sup>rd</sup> 6 months) than controls (for both, <math>p &lt; 0.05</math>)</li> <li>• Little change in pts medication knowledge in study</li> <li>• Intervention pts took significantly more prescribed medicines at 6,12,18 months. No change in controls pts.</li> <li>• <u>Self-reported</u>: Intervention pts significantly more compliant, and more likely to change from non-compliant</li> <li>• <u>Refill rates</u>: Intervention pts significantly more compliant at 6 months, no change in compliance status</li> <li>• Cost savings 1<sup>st</sup> 6 months for intervention pts (btw £307-£131/pt), no saving for the rest of the study.</li> <li>• Longitudinal analysis showed little change in drug costs between 2</li> </ul>

Reference	Level	Setting	Subjects, intervention	Evaluable sample	Study outcomes	Results
					Level 4 • Patient satisfaction	groups  • All patients rating the services as excellent or good • 80% of Intervention patients thought the new service was better than what they received previously • At the end of the study, 68.1% of intervention patients now readily approach the pharmacist with questions; 88% were satisfied with medicines advice given; 73.5% were satisfied with advice on medical conditions; 64.7% agreed that they had a better relationship with their pharmacist after being involved in the study





## 3 Continuity of care services

### 3.1 The service

As described by Roughead, Semple and Vitry (2003):

Continuity of care services aims to improve medication management for people as they move from hospital back to the community or between different institutions. The service can include activities such as provision of discharge and medication summaries to the patients and their local doctors and pharmacists, the development and co-ordination of care plans to assist medication management, education for the patients about their medicines and where necessary, home visits after discharge from hospital. The services may be provided by either hospital or community pharmacists.

### 3.2 Studies included

We included studies (Table 3) that aimed at providing continuity of care services by facilitating the flow of information between hospital- and community-based care providers, with or without home visits to patients after discharge from hospital.

Three further inclusion criteria were applied.

- The intervention had to involve liaison with at least one community practitioner.
- There had to be a control or comparison group
- The endpoint had to include at least one patient outcome, which could be any of the following: hospital admission or re-admission; adverse events; mortality; quality of life; symptoms; surrogate health endpoints (e.g. blood pressure control, serum cholesterol level, blood glucose level); knowledge or compliance with treatment recommendations (level 1, 2 or 3 outcomes).

### 3.3 Study design

A total of six level 1 studies evaluating continuity of care were found. Four of the studies dealt with elderly patients (Al-Rashed, Wright et al. 2002; Bolas, Brookes et al. 2004; Crotty, Rowett et al. 2004; Holland, Lenaghan et al. 2005), one evaluated the effect of pharmacists' interventions on the likelihood of paediatric patients' families obtaining medications within 24 hours of hospital discharge (Voirol, Kayser et al. 2004), and the sixth (Jackson, Peterson et al. 2004) assessed anticoagulation outcomes of home follow-up of warfarin initiation.

Of the four studies dealing with elderly patients, one assessed whether home-based medication reviews prevented hospital admissions of older people (Holland, Lenaghan et al. 2005), the second investigated the value of inpatient pharmaceutical counselling for elderly patients (Al-Rashed, Wright et al. 2002), the third investigated the effect of a hospital-based

community liaison pharmacy service on outcomes for elderly patients (Bolas, Brookes et al. 2004), and the fourth (Crotty, Rowett et al. 2004) assessed the effects of a pharmacist transition coordinator on patients moving from hospital to a long-term care facility.

Five of the studies involved patients receiving information, education and counselling about medications. In three studies the interventions (Al-Rashed, Wright et al. 2002; Bolas, Brookes et al. 2004; Voirol, Kayser et al. 2004) occurred prior to discharge, and in the other two studies (Jackson, Peterson et al. 2004; Holland, Lenaghan et al. 2005) the interventions took place during two home visits after discharge (at two and eight week intervals in one study, and on alternate days over an eight-day period in the other). The sixth study (Crotty, Rowett et al. 2004), focused on transferring information on medications to care providers within the long-term care facility.

In two studies, follow-up was by telephone – one at three and six months (Holland, Lenaghan et al. 2005), and the other at 48 hours (Voirol, Kayser et al. 2004). In the latter, the interviewers were blinded. In a third study, follow-up was either by home visit or by telephone at 10–14 days (Bolas, Brookes et al. 2004). In the fourth study (Al-Rashed, Wright et al. 2002), data were collected during two home visits, respectively 15–22 days and 3 months post-discharge. In the fifth study, patients were interviewed and medical records were reviewed (Jackson, Peterson et al. 2004), and in the sixth, (Crotty, Rowett et al. 2004) patients' medication charts and case notes were used.

Two trials (Al-Rashed, Wright et al. 2002; Jackson, Peterson et al. 2004) involved visits to both the intervention and the control groups. In the study by Al-Rashed et al (Al-Rashed, Wright et al. 2002), data were collected on compliance at both visits, and advice was provided to both groups during the first visit. At the second visit, there was an improvement in compliance for the intervention group, and within the intervention group, there was a significant change between the first and second visits. In the other, (Jackson, Peterson et al. 2004) the control group was visited on day eight only, with the sole purpose of assessing anticoagulation control.

Participants in one study were told after randomisation (Holland, Lenaghan et al. 2005) which group they were in. This creates a potential for bias.

### **3.4 Study outcomes**

A variety of outcomes were associated in the six studies. These included:

- Emergency re-admission rates (level 1);
- Unplanned visits to GP (level 1);
- Appropriate medication use (level 3);
- Patient knowledge and compliance (level 3);
- Discrepancies between drugs prescribed at discharge and those taken at home (level 3);

- General practitioner, pharmacist and/or other community practitioner satisfaction (level 4); and
- Secondary outcomes included death, quality of life, adverse drug events (level 1) and admissions to primary care facilities.

### 3.5 Evidence for effectiveness of practice

The evidence on the effectiveness of continuity of care services from the six studies is mixed. Overall, it appears that pharmacists' involvement in continuity of care services leads to better outcomes. Re-admissions and/or unplanned visits to hospital decreased significantly in most of the studies. However, in one study, the rate of re-admissions and/or unplanned visits to hospital increased in the intervention group (Holland, Lenaghan et al. 2005).

#### *Evidence of effectiveness with respect to morbidity and mortality outcomes (level 1)*

Five of the studies measured re-admission rates after intervention. Two showed no significant difference in the number of readmissions (Bolas, Brookes et al. 2004; Jackson, Peterson et al. 2004), while another two (Al-Rashed, Wright et al. 2002; Crotty, Rowett et al. 2004) showed significantly more unplanned GP visits and hospital re-admissions in the control group. The fifth study (Holland, Lenaghan et al. 2005), showed a 30% higher re-admission rate in the intervention group.

Several secondary outcomes were reported, and the findings mostly favoured the intervention group. For example, in one study there was significant difference at the eight-week follow-up for adverse events such as worsening pain. With regard to mobility, behaviours and confusion, the results favoured the intervention group, but did not reach statistical significance (Crotty, Rowett et al. 2004). In another study, there were mixed results in secondary outcomes: no significant difference in mortality data, but a significant difference in one aspect of the quality of life data and one aspect of the primary care data (Holland, Lenaghan et al. 2005).

#### *Evidence of effectiveness with respect to level 3 outcomes*

One study (Al-Rashed, Wright et al. 2002) concluded that patients' knowledge of the prescribed medicines was better in the intervention group. This group had better compliance rates, and were less inclined to self-medicate from their home medicine stocks. There was also a statistically significant improvement in compliance in the study group between the first and second visit. In all other comparisons between the two visits, the study and the control groups were similar (Al-Rashed, Wright et al. 2002).

There was significant improvement in correlation between discharge prescription medication and home medication, along with patients' knowledge of their drug therapy and the amount of medication being returned at discharge (Bolas, Brookes et al. 2004).

One study (Voirol, Kayser et al. 2004) demonstrated that pharmacist interventions could help families obtain medication significantly more promptly after discharge. There were also few problems in obtaining medications.

### **3.6 Economic assessment**

None of the studies provided a detailed economic assessment. Two (Al-Rashed, Wright et al. 2002; Bolas, Brookes et al. 2004), commented on and gave estimates of cost savings. The authors of the former assert that it is beneficial (and cost effective) to counsel elderly patients prior to discharge and during post discharge visits. The authors of the latter study (Bolas, Brookes et al. 2004) note that the cost of patients' own drugs being returned to the pharmacy for destruction was £10,095 (approximately A\$24,550) (xe.com 2005) based on an 8 month collection. They go on to estimate that the annual cost of patients' drugs that could have been returned was £4,582 (approximately A\$11,140) (xe.com 2005), based on a review of the drugs returned.

In both of these studies, the economic findings were impressions and estimates rather than the results of formal economic evaluations. Further studies focusing on economic analysis would be of great benefit in evaluating the effectiveness of pharmacist involvement in managing patients as they move from hospital back to the community.

No other economic assessments were presented in the included articles.

### **3.7 Australian research**

We identified two Australian studies. One assessed the effects a pharmacist transition coordinator on older adults moving from hospital to a long-term care facility (Crotty, Rowett et al. 2004), and the other assessed the anticoagulation outcomes of home follow-up of warfarin initiation (Jackson, Peterson et al. 2004).

The study by Crotty et al involved three metropolitan public hospitals and 85 long-term care facilities (Crotty, Rowett et al. 2004). The intervention comprised transferring information on medications to care providers within the long-term care facility. It represented an enhancement of the usual discharge process, with more specific information on in-hospital changes to medication being provided, along with information on the monitoring needed for each patient. After transfer, the transition pharmacist coordinator arranged an evidence-based medication review to be performed within 10–14 days by the community pharmacist associated with the facility, and a case conference with the transition coordinator, the community pharmacist, family physician and registered within 14–28 days, plus follow-up eight weeks after initial discharge. Out of 686 patients who were transferred, only 122 were eligible, and of these, a total of 110 patients gave their consent. Quality of prescribing was measured using the Medication Appropriateness Index (MAI) (level 3). Some secondary

outcomes included unplanned visits to the emergency department, hospital readmissions, adverse drug events, falls, worsening mobility, behaviours and pain, and increased confusion. These were assessed using case notes from the follow-up period.

There was no significant difference in the number of discrepancies noted between medications given to the patient and those listed the discharge summary (57.1% intervention vs 48.1% control). However, the mean MAI at the eight-week follow-up was significantly lower in the intervention group (2.5 vs 6.5) ( $p=0.007$ ). At follow-up, the intervention group (for those patient still alive) displayed a significant protective effect against worsening pain and hospital usage ( $P=0.023$ ). However, when all patients were included, the two groups was similar. Observation bias was minimised by blinding of the independent pharmacists who assessed the patients. However, the transition coordinator was involved in all aspects of the intervention as well as assessing the outcomes.

The study by Jackson and Peterson (Jackson, Peterson et al. 2004) involved patients from a tertiary referral hospital who were starting warfarin treatment during between February 2002 and June 2003. Intervention-group patients received four home visits from the project pharmacists on alternate days. During these visits the pharmacists assessed patients' coagulation status and provided education about the therapy. They contacted GPs with each result and any changes in dosages were discussed. Follow-up took place 90 days after initial discharge from hospital.

There were significant differences in coagulation control on the eighth day 8 after discharge (67% intervention, 41% control) ( $P<0.01$ ), with a difference in total ( $P=0.009$ ), major ( $P=0.05$ ) and minor ( $P=0.01$ ) bleeding events between the intervention and the control groups.

Overall, both studies showed some evidence that pharmacist involvement in the provision of continuity of care services. However, the study by Crotty et al was constrained by limitations such as small sample size. (Crotty, Rowett et al. 2004). In the study by Jackson and Peterson, although the pharmacists assessing the outcomes were blinded to the intervention status of the groups (Jackson, Peterson et al. 2004), they were involved throughout the whole process. It might have been better for an independent person to assess the outcomes of each study.

### **3.8 Comment**

A strength of all six studies was that they were RCTs, with individual patients as the units of randomisation.

Only one of the studies (Al-Rashed, Wright et al. 2002) used blind interviewers in their study. The lack of blinded assessment introduces a potential for observation bias.

However, the same study (Al-Rashed, Wright et al. 2002) introduced the potential for intervention bias by placing the control and intervention groups in two different wards. Although the same medical team covered both wards, different pharmacists were allocated to them. Consequently, there may have been inconsistencies in the medication information given to the two groups.

In the study by Voirol et al (2004), the authors attributed an insufficient sample size to fewer admissions than anticipated. Short hospital stays led to difficulties in involving families, who tended to visit at times (e.g. in the evenings and weekends) other than those when study activity was occurring.

In the study by Bolas et al (2004), emergency hospital admissions actually increased in the intervention group, compared with the control group. While this could have been a chance effect, it could also have been due to intervention patients having a better understanding of their disease and hence seeking appropriate assistance more readily. Alternatively, the intervention may have increased patients' anxiety and their dependence on health services.

All six studies included suggest that pharmacist involvement improved patient outcomes, mainly in relation to knowledge and concordance with treatment regimens, and in some instances hospital readmission rates were reduced. Further studies would shed more definitive light on the relationship between pharmacist involvement and continuity of services.

## References

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**Table 3.** Randomised controlled studies of continuity of care services

Reference	Level of evidence	Setting	Subjects	Intervention	Evaluable sample and follow-up	Study outcomes	Results
Al-Rashed, Wright, Roebuck, Sunter, Chrystyn (2002)	1+	Hospital –two elderly wards	<p>Patients over 65 years, prescribed 4 or more regular items, to be discharged to their own homes and identified by clinical pharmacist assessment as potentially having problems with their medicines.</p> <p>First language had to be English.</p>	<p>Patients in the intervention group received pre-discharge counselling, information about medicines and medicine reminder card.</p> <p>Patients in the control group received usual care i.e. patients and the GP together with the district nurse received a copy of the patient’s medication and information discharge summary sheet (MIDS), and a medicine reminder card.</p> <p>All patients were given 14 days’ medication and told to show their GP and community pharmacist the MIDS and medicine card during their first visit post discharge.</p> <p>All patients were</p>	<p>83 patients completed the study with 43 in the intervention group.</p> <p>Pharmacist collected data at 1<sup>st</sup> and 2<sup>nd</sup> home visits.</p>	<p>Provision of information and counselling to elderly patients, backed up with a simple medicine reminder card may help with compliance and increased drug knowledge (level 3); reduced unplanned visits to the doctor and hospital readmissions (level 1)</p>	<p>Study showed improvement in compliance for the intervention group.</p> <p>More specifically, there was a statistically significant improvement for compliance in the intervention group between the first and second visit (P&lt;0.001).</p> <p>Also showed significantly less unplanned GP visits and hospital readmission for intervention group (P&lt;0.05).</p> <p>On all other comparisons between the two visits, the intervention and control group were similar.</p>



Reference	Level of evidence	Setting	Subjects	Intervention	Evaluable sample and follow-up	Study outcomes	Results
				visited by pharmacist 15–22 days and then 3 months post discharge.			
Bolas, Brookes, Scott, McElroy (2004)	1+	Medical unit of district general hospital in Northern Ireland	Patients aged 55+ years with emergency or unplanned admission to a medical unit, regularly taking >3 drugs	<p>Intervention group received enhanced service involving taking of medication history, review of all medications, patient education, counselling, and liaison with GP and community pharmacist.</p> <p>Control group received standard service – at time of study did receive discharge counselling.</p>	<p>Total of 243 patients of which only 162 completed study with 81 in each group.</p> <p>Follow up was done by home visit or phone call at 10–14 days.</p>	<p>Discrepancies between drugs prescribed at discharged and those taken at home.</p> <p>Patients knowledge and compliance of drug regimen.</p> <p>Emergency readmission rates.</p> <p>Utilisation of patients own drugs.</p> <p>Use of medicine helpline.</p> <p>Community practitioner survey evaluating perception of enhanced service.</p>	<p>Significant improvement in correlation between discharge prescription medication and home medication.</p> <p>Significant increase in patients' knowledge of their drug therapy (P&lt;0.001).</p> <p>No significant difference in number of readmissions.</p> <p>Considerable improvement in amount of patients' own medication being returned at discharge (90% intervention vs. 50% control).</p> <p>Low uptake on the use of the helpline</p> <p>The survey produced no negative comments about the service provided. They did make some suggestions.</p>

Reference	Level of evidence	Setting	Subjects	Intervention	Evaluable sample and follow-up	Study outcomes	Results
Crotty, Rowett, Spurling, Giles, Phillips (2004)	1+	3 metropolitan public hospitals and 85 long-term care facilities in the region - SA, Australia	Older adults who were making a first-time transition from a hospital to a long-term residential care facility between October 2002 and July 2003 and who gave consent to participate.	<p>Intervention focused on transferring information on medications to care providers in the residential facility. On patient discharge from hospital to facility, the family physician and community pharmacist were faxed a medication transfer summary compiled by the transition pharmacist. This was in addition to the usual discharge process, and contained specific information on changes to medications that had been made while in the hospital and what required monitoring.</p> <p>After transfer, the transition pharmacist coordinated an evidence-based review to be performed by the community</p>	<p>686 patients transferred during the study period, of which only 122 were eligible. A total 110 patients gave consent.</p> <p>Follow-up at 8 weeks after discharge for both groups?</p>	<p>Primary outcome was to the quality of prescribing (level 3) consisting of number of pre-admission medications, changes to medication during hospital and number of medications at baseline and follow-up. Assessed using the Medication Appropriateness Index (MAI).</p> <p>Secondary outcomes included unplanned visits to the emergency department or hospital readmissions; adverse drug events; falls, mobility, behaviours, and pain, and confusion. These were assessed using case notes from follow-up period (level 1).</p>	<p>Number of discrepancies between the medications sent with the patient and the medications listed on the discharge summary was 57.1% (intervention) and 48.1% (control).</p> <p>Medication-management services provided by community pharmacists within 2 weeks of admission to facility were 64.3% (intervention) and 33.3% (control). Case conferencing within the first 4 weeks took place in only 14.3% (intervention) and 3.7% (control).</p> <p>The mean MAI at 8 week follow up was significantly lower in the intervention group (2.5 vs. 6.5) (P=0.007). The effect of the intervention remained significant number of drugs discontinued during admission (P=0.006).</p> <p>Among patients who were alive at 8 week follow-up, the intervention group</p>

Reference	Level of evidence	Setting	Subjects	Intervention	Evaluable sample and follow-up	Study outcomes	Results
				pharmacist contracted to the facility (between days 10 and 14), and a case conference with themselves, the family physician, the community pharmacist and a nurse (between days 14 and 28).			<p>displayed a significant protective effect against adverse events such as worsening pain and hospital usage compared to the control group (P=0.023). However when all patients were considered (both dead and alive), hospital usage was similar between the groups.</p> <p>There was no other statistically significant difference between the group (who were alive) at 8 week follow-up, although there was a trend suggesting the intervention was protective against worsening mobility and behaviours</p>
Holland, Lenaghan, Harvey, Smith, Shepstone, Lipp, Christou, Evans, Hand (2005)	1-	Acute or community hospitals in Norfolk and Suffolk, UK	Patients from 10 hospitals, aged >80 years, admitted to emergency departments, intended to be discharged to their own homes or warden controlled accommodation, and taking two or more drugs	Intervention group and carers received education and information during two home visits conducted at 2 and 8 weeks from pharmacist who from liaisons with local practitioners	<p>Total of 872 patients with 429 in intervention group.</p> <p>Follow up was by phone at 3 and 6 months with all patients</p>	<p>Primary outcome was total number of emergency admissions to hospital over six months. (level 1)</p> <p>Compliance aids and pharmacists' view of intervention visits (level 3)</p>	<p>Resulted in 933 recommendations or comments to GPs. 120 of these (81 patients) were regarding possible drug reactions or interactions.</p> <p>Compliance aids were recommended for 11% of patients receiving first visits</p>

Reference	Level of evidence	Setting	Subjects	Intervention	Evaluable sample and follow-up	Study outcomes	Results
			daily.	<p>regarding possible drug reactions or interactions and compliance aids.</p> <p>Review pharmacist also received copy of discharge letter.</p> <p>Control group received usual care.</p> <p>All participants were told what group they were in.</p>	& practices with more than 10 trial patients.	Secondary outcomes included mortality, quality of life, admissions to primary care facilities (nursing/residential homes) (level 1)	<p>and pharmacists felt that visits were useful for 73%.</p> <p>30% greater re-admission in intervention group (P=0.009)</p> <p>Mixed results in the secondary outcomes with no significant difference in mortality, but significant difference in one aspect of the quality of life data and one aspect of the primary care data.</p>
Jackson, Peterson (2004)	1+	Acute care teaching hospital, Tasmania, Australia	<p>Inpatients who were started on warfarin between February 2002 and June 2003 and who consented to participate.</p> <p>Exclusions included patients who were not discharged home, had dementia, were unable to answer basic questions about their therapy, or were entering a hospital in the home programme.</p>	Intervention group received a home visit from the project pharmacist on alternate days on four occasions, with the first 2 days after discharge from the hospital. Project pharmacist tested international normalised ratio (INR), and using a standard warfarin booklet as the basis of counselling, provided education regarding anticoagulant therapy	128 patients enrolled in the study (60 intervention; 68 control). One patient from the intervention group was excluded after 8 days' follow up (changed therapy from warfarin to other on advice from GP). Follow-up was at 90 days after discharge using	<p>Primary outcomes were the achievement of a therapeutic INR value on day 8 after discharge (level 2); total, major and minor bleeding complications (level 1); readmissions to hospital due to complications with anticoagulant therapy within 90 days of discharge (level 3)</p> <p>Secondary outcomes were unplanned readmissions (level 3); death (cause determined by death certificates) and</p>	<p>No significant difference between group regarding anticoagulant control at point of discharge, however significant difference at day 8 after discharge - 67% intervention, 41% control (P&lt;0.01)</p> <p>There was no significant difference in the median INR at either discharge or 8 days after between either group, however there appeared to be some significant difference between the sub-therapeutic, therapeutic and</p>

Reference	Level of evidence	Setting	Subjects	Intervention	Evaluable sample and follow-up	Study outcomes	Results
				<p>(i.e. goals, adverse effects and interactions with other medicine). Additionally they developed a warfarin document to assist in education.</p> <p>GPs whose patients were in the intervention group were contacted with each INR result during the visits and any subsequent changes in dosages were discussed and implemented.</p> <p>GPs for control group informed that their patient would receive a visit from the project pharmacist 8 days after discharge to determine anticoagulant control.</p> <p>All patients received regular care during their hospitalisation. At discharge, they were</p>	<p>patient interview and medical record review for all patients.</p>	<p>proportion of patients remaining on anti-coagulant therapy.</p> <p>Adverse events (level 1) assessed through a mixture of self-report events and medical record reviews.</p>	<p>supra-therapeutic INRs. For the intervention group the difference was generally positive, while for the control group it was more likely they would have a poorer outcome on day 8.</p> <p>There was a significant difference in total (P=0.009), major (P=0.05) and minor (P=0.01) bleeding events between both groups.</p>

Reference	Level of evidence	Setting	Subjects	Intervention	Evaluable sample and follow-up	Study outcomes	Results
				<p>all sent a personalised information letter indicating the group the patient was in and what follow-up they would receive.</p> <p>All patients were interviewed at 90 days after discharge to assess type and frequency of anticoagulant related complications.</p> <p>Medical record notes were examined for all patients readmitted during study period to assess outcomes.</p>			
Vioril, Kayser, Chang, Chang, Youmans (2004)	1-	Paediatric ward – USA Medical Centre Children’s Hospital	Patients whose family spoke English and who were discharged on at least one new medication.	Intervention included verification of the family’s choice of pharmacy, prescription insurance coverage, completeness and accuracy of discharge medication prescriptions; and assistance in procurement of medications.	81 control and 91 intervention patients participated in study over 4 week period.  Follow up was done by blind interviewers by phone within 48 hours of discharge	Pharmacists’ intervention may increase likelihood that caregivers of paediatric patients can obtain medication in timely fashion and know how to use drugs correctly.	<p>Study results demonstrated that interventions provided by the pharmacist may help families to obtain medications more promptly (P=0.027) and with fewer problems following discharge, although the latter result was not statistically significant.</p> <p>No difference was observed in the knowledge on the</p>

Reference	Level of evidence	Setting	Subjects	Intervention	Evaluable sample and follow-up	Study outcomes	Results
				<p>Families were also provided with 3 days of medication to prevent interruption of treatment.</p> <p>Caregivers were provided with education and information about medication.</p> <p>Control group received usual care, which was assistance from the pharmacy team only at the request of the medical team, nursing staff or patient's caregiver.</p>			proper administration of drugs.

## 4 Pharmacist clinic services

### 4.1 The service

Roughead, Semple and Vitry (2003) describe pharmacist-managed or pharmacist-run clinics as those that

'...provide care to patients with chronic conditions, including diabetes mellitus, hypertension, hyperlipidaemia, coronary artery disease, asthma, and epilepsy and to those receiving anticoagulant therapy. Pharmacist services provided in these clinics include monitoring drug therapy outcomes, ordering and interpreting laboratory tests, making recommendations to physicians, providing education to patients, providing a point of contact for patients for queries or concerns and providing follow-up. In some clinics pharmacists have prescribing rights or, using approved protocols, make drug therapy selections and adjustments to drug therapy including dosage changes.'

They also describe pharmacists' services in pre-admission clinics, where patients are assessed prior to elective admission to hospital, as follows.

'These services include medication history taking, prescription transcription and provision of information and advice to patients and health care professionals.'

In this chapter we examine the literature on pharmacist-managed and pharmacist-run clinics separately from the literature on pre-admission clinic services. Sections 4A.2 to 4A.8 deal with the former, and sections 4B.2 to 4B.8 with the latter.

## 4A PHARMACIST-MANAGED CLINICS

### 4A.2 Studies included

Studies were included (Table 4A) if they assessed a service described as a pharmacist-managed, pharmacist-operated or pharmacist-run clinic. Studies evaluating services provided to outpatients or ambulatory-care patients and those evaluating clinics located in community settings were also included. Studies evaluating clinics for hospital inpatients were excluded, as were studies relying on patient satisfaction or opinion (i.e. level 4 outcomes).

Two further inclusion criteria were applied.

- There had to be a control or comparison group
- The endpoint had to include at least one patient outcome, which could be any of the following: hospital admission or re-admission; adverse events; mortality; quality of life; symptoms; surrogate health endpoints (e.g. blood pressure control, serum cholesterol



level, blood glucose level); knowledge or compliance with treatment recommendations (level 1, 2 or 3 outcomes).

### 4A.3 Study design

Only one study met eligibility criteria and was considered relevant. It was an RCT conducted in a pharmacist-operated adherence clinic (Rathbun, Farmer et al. 2005). It assessed the adherence of adult patients with human immunodeficiency virus (HIV) infection to active antiretroviral therapy (with HAART) and viral suppression, when commencing new treatment at a HIV clinic. The study provided level 1+ evidence.

Two randomised controlled trials (level 1 evidence) were considered relevant. One study (level 1+ evidence) was conducted in a pharmacist-operated adherence clinic assessing adult HIV patients' adherence to active antiretroviral therapy (HAART) and viral suppression, when commencing new treatment at a HIV clinic (Rathbun, Farmer et al. 2005). The other trial (level 1+ method) was carried out in a hospital-based outpatient clinic and targeted patients at risk of non-compliance (Lim, Low et al. 2004).

Pharmacists provided intervention-group patients with education about appropriate HAART administration, food restrictions, and adverse event management. Each patient was monitored 4, 16, and 28 weeks after therapy initiation. Those patients in the intervention group were also eligible for additional visits. The control group received standard care, comprising information provided by a physician or nurse practitioner for education and monitoring.

Lim et al. conducted pharmacist-led consultations with intervention patients assessing medication related problems and provided counselling on medication knowledge, inhaler technique, insulin administration, disease management, adverse drug reactions, diet and the use of non-prescription medications (Lim, Low et al. 2004). The follow-up period was 2 months.

### 4A.4 Study outcomes

The outcomes were as follows.

- Medication adherence (level 3): measured with an electronic monitoring system;
- Surrogate outcomes: virologic response (level 2) measured by plasma HIV-1 RNA reverse-transcription polymerase chain reaction (RT-CPR) assay;
- Patient self-report using a questionnaire assessing adverse events (level 1); patient perception of treatment (level 4) and adherence (level 3);
- GPs assessed patients clinical status (level 1);
- Patient medication knowledge (level 3); and

- The number of pharmacist recommended interventions and the GP acceptance rate of those interventions were recorded (level 3).

## 4A.5 Evidence for effectiveness of practice

Although there was no significant difference between the intervention and control groups in medication adherence and virologic response, patients in the intervention group adhered better to the treatment regimen. The present study was regarded as a pilot study. Further research using a larger number of subjects could possibly reveal a difference between intervention and control groups in the other outcomes.

The involvement of a pharmacist consult clinic in the management of selected geriatric outpatients may have an impact on compliance as well as improve medication knowledge and reduced residual adverse drug reactions (Lim, Low et al. 2004).

### *Evidence of effectiveness with respect to morbidity and mortality outcomes (level 1)*

The clinical status of intervention patients improved, although not significantly when compared to patients in the control group in the Lim study (Lim, Low et al. 2004). This result may be explained by the fact that the control patients had poorer pre-morbid health status at baseline.

### *Evidence of effectiveness with respect to level 2 outcomes*

There was a significant difference between the intervention and control groups at week 16 in the patients' HIV-1 RNA (at level <400 copies/mL) but no significant difference at weeks 4 and 28. No significant differences were observed at any time in patients' HIV-1 RNA (at level <50 copies/mL) (Rathbun, Farmer et al. 2005).

The authors asserted that patients who received the intervention, and therefore displayed better adherence early in the study, would be more likely to achieve viral suppression and maintain it over time than those in the control group, who demonstrated lower adherence.

### *Evidence of effectiveness with respect to level 3 outcomes*

Adherence rates were observed to be higher in the intervention group, but the difference between the intervention and control groups in this respect did not reach statistical significance. In addition, reductions in adherence occurred in both the intervention and control groups over the 28-week study period. This reduction was greater in the control group than in the reduction group (Rathbun, Farmer et al. 2005).

Patient self-reported adherence was considered to be over-rated compared to the electronic monitoring results, but again did not differ between the intervention and control group (Rathbun, Farmer et al. 2005).

Intervention patients in the study by Lim et al demonstrated improved self-reported compliance during the study when compared to the controls. This was only significant when adjusted for factors associated with compliance (for example activities of daily living status, hospitalisation rates, and supervision of medications) (Lim, Low et al. 2004).

The intervention in the Lim study significantly improved patient's medication knowledge and reduced the number of residual adverse drug reactions (Lim, Low et al. 2004). However, the overall number of adverse drug reactions increased in the intervention group during the course of the study.

#### *Further supporting evidence*

The authors refer to other studies. Their own work provides no further data that supports pharmacist involvement in education and medication monitoring within a pharmacy-managed clinic, with respect to medication adherence and or significant clinical outcomes.

## **4A.6 Economic assessment**

Lim et al calculated cost avoidance (level 1 economic outcome) by deducting the cost incurred by the pharmacist's recommendations from the cost saving of avoided, discontinued or altered medications (Lim, Low et al. 2004). The net cost saving was Singapore \$387.28 (equivalent to A\$309.75) (xe.com 2005).

No other economic assessments were presented in the article, and no other studies that met the criteria were found.

## **4A.7 Australian research**

We found no Australian studies that had been published between 2002 and March 2005 and met the selection criteria.

## **4A.8 Comment**

Lim et al demonstrated that using a pharmacist clinic for the management of geriatric patients at risk of non-compliance improves patient's compliance and medication knowledge and reduces residual adverse drug reactions (Lim, Low et al. 2004). They also calculated a significant cost saving based on the recommended medication changes.

It must be remembered that the study by Rathbun et al was a pilot study with a very limited number of participants. As the authors state, 'the greater adherence observed in the study among the adherence clinic group has the potential to provide a beneficial effect on disease outcomes', and this could be confirmed or refuted with a larger sample size (Rathbun, Farmer et al. 2005).

## References

Lim, W. S., H. N. Low, et al. (2004). "Impact of a pharmacist consult clinic on a hospital-based geriatric outpatient clinic in Singapore." Annals Academy of Medicine Singapore **33**(2): 220-227.

Rathbun, R. C., K. C. Farmer, et al. (2005). "Impact of an adherence clinic on behavioral outcomes and virologic response in the treatment of HIV infection: A prospective, randomized, controlled pilot study." Clinical Therapeutics **27**(2): 199-209.

**Table 4A.** Randomised controlled trials evaluating pharmacist-managed clinics

Reference	Level	Setting	Subjects	Intervention	Evaluable sample & follow-up	Study outcomes	Results
Rathbun, Farmer, Stephens, Lockhart (2005)	1+	Early intervention HIV Clinic, University of Oklahoma - USA	Adult HIV-infected patients newly starting HAART therapy, who were responsible for self-administration of the medication.	<p>Education about appropriate HAART administration, food restrictions, and adverse-event management.</p> <p>Monitoring of patient progress after therapy initiation at 4, 16, and 28 weeks.</p> <p>Intervention group eligible for additional visits.</p>	<p>43 patients initially randomised in the study, of whom 33 were included (16 intervention group; 17 control group)</p> <p>Evaluated at 4, 16, and 28 weeks.</p>	<p>Level 3 Primary measure was medication adherence. Electronic monitoring used to measure Adherence to one antiretroviral agent.</p> <p>Patient self-report assessing adverse events (level 1) using questionnaire administered at 4, 16 and 28 weeks</p> <p>Level 2 secondary outcome - percentage of patients with plasma HIV-1 RNA &lt;50 copies/mL (i.e. virologic response)</p>	<p>At baseline patients in the intervention group had higher CD 4 counts - no other statistical difference existed.</p> <p>At 4 weeks, proportion of patients with adherence &gt;90% and &gt;95% was 81% and 62% for intervention group and 47% and 41% in control group respectively.</p> <p>The decline in adherence between 4 and 28 weeks was 12% (intervention) and 22% (control).</p> <p>Patients in intervention group more likely to take their medication at appropriate interval - 4 weeks (69% intervention, 42% control); 28 weeks (53% intervention, 31% control)</p> <p>Overall, mean adherence was higher but not statistically significant.</p> <p>Patients self reported adherence was overestimated when compared with electronic monitoring results. No difference in the rate of adherence observed between the 2 groups.</p> <p>Virologic response - proportion of patients with HIV-1 RNA &lt;400 copies/mL at 4, 16 and 28 weeks was 63%; 100% and 94% (treatment group) and 29%, 71% and 65% (control group) - significant at 16 weeks. HIV-1 RNA &lt;50 copies/mL at 4, 16 and 28 was 19%, 63% and 63% (intervention) and 0%, 35% and 53% (control group. Not significance.</p>

Reference	Level	Setting	Subjects	Intervention	Evaluable sample & follow-up	Study outcomes	Results
Lim et al. (2004)	1+	Hospital-based geriatric outpatient clinic  Singapore	Eligible patients: required drug therapy monitoring; evidence of polypharmacy (>3 medications and >9 doses/day); documentation of non-compliance self-administered drugs that require psychomotor skill and co-ordination; were on nasogastric tube feeding; had >1 doctor managing care or were hospitalised within the last 6 months. Excluded if stable on follow-up, cognitive impairment, life expectancy <6 months, medications supervised by healthcare professional.	10 – 30 min consultation with pharmacist, evaluated for medication-related problems. Also provided counselling on medication knowledge, inhaler technique, insulin administration, disease management, ADRs, diet and use of non-prescription medication.	126 patients were randomised to intervention (64) and control (62).  At follow-up, intervention (51) and control (49).  Study used intention-to-treat analysis  2-month follow-up	Level 1 • Clinical status  Level 3 • No. of pharmacist interventions • GP acceptance rates • Medication knowledge • ADRs at 2-month follow-up • compliance  Level 4 • Patient's perception  Economic outcomes • Cost avoidance	<ul style="list-style-type: none"> <li>Improved clinical status in intervention pts vs controls, but not significant (p=0.23)</li> <li>104 patient counselling points and 41 interventions</li> <li>GP acceptance of interventions was 76%</li> <li>Significant improvement in medication knowledge (p=0.03)</li> <li>Residual ADRs complaints decreased in intervention pts vs. controls. But increase in number of ADRs in intervention pts at 2-months.</li> <li>Unadjusted compliance improved in intervention, but not significantly. When adjusted for factors associated with poor vs. good compliance the improvement was significant.</li> <li>Patient's perception of severity of illness, usefulness of medications, and number of medications did not change.</li> <li>Over 2-months the cost avoidance in the intervention group was SGD\$387.28 (equiv to AUD\$309.75)</li> </ul>

## **4B PRE-ADMISSION CLINICS**

### **4B.2 Studies included**

Studies were included if they clearly involved a pharmacist in patient assessment services in a clinic prior to hospital admission.

### **4B.3 Study design**

We found no level 1 or level 2 studies. However, we found one article of interest (Table 4B). It investigated the role of the community pharmacist in identifying discrepancies in medication histories for patients admitted to hospital. (Wilcock and Lawrence 2004) It aimed to assess the extent of discrepancies, and to determine the value the of community pharmacy patient medication records (PMRs) in identifying these discrepancies.

Data were collected on acute adult admissions to a UK hospital emergency medical unit over an 18-month period. A clinical pharmacist visited the unit twice daily and collected data on patients' medication histories, both from patients and as recorded by patients' general practitioners (GPs) or hospital doctors. Letters were then sent to the patients' nominated community pharmacy requesting a copy of the patients' medication details (from the PMR) for at least three months prior to the index admission. Comparisons were made between the three sources of information of medication history information – that recorded by the GP or hospital doctor, that by the clinical pharmacist in the study, and that recorded in the PMR – and discrepancies were noted.

A score between 1 (no added value) and 4 (extreme added value) was assigned to each patient's PMR, based on the question "How would immediate access to the details held on the PMR have changed the management of the patient when admitted to hospital?" A clinical panel was convened to validate the scoring system.

### **4B.4 Study outcomes**

The outcomes evaluated were the number of discrepancies between the three sources of information and the score described in section 4B.3.

### **4B.5 Evidence for effectiveness of practice**

Little research has been conducted on pharmacist involvement in pre-admission clinics. Since the review by Roughead, Semple and Vitry (2003), which reported that only one level 2 study was found, no other study providing level 1 or 2 evidence appears to have been done.

### *Evidence of effectiveness with respect to morbidity and mortality outcomes (level 1)*

No evidence is available.

### *Evidence of effectiveness with respect to level 3 outcomes*

A total of 257 patients were enrolled in the study by Willcock and Lawrence. Details were available for 250 patients. There was a 44% agreement between clinical pharmacist and the GP or hospital doctor; a 43% agreement between the clinical pharmacist and the PMR, and only a 21% for among the pharmacist, the doctors, and the PMR. Agreement between the hospital doctor and PMR was low (24%). This suggests that the clinical pharmacist is more able to obtain more accurate information and, by acting as a 'go-between', could assist doctors in making better informed decisions regarding a patient's drug therapy.

### *Further supporting evidence*

Access to the PMR would have added no value to the information gained by the clinical pharmacist for two-thirds of patients. However, for 10 patients, the PMR would have greatly added to the information available at the time of admission.

## **4B.6 Economic assessment**

No economic assessments were presented in the article described, and no other studies that met the criteria were found.

## **4B.7 Australian research**

No Australian studies were found.

## **4B.8 Comment**

There is insufficient evidence to comment on the effectiveness of pharmacist involvement in pre-admission clinics.

## **References**

Willcock, M. and J. Lawrence (2004). "Is there a role for community pharmacists in identifying discrepancies in medication histories for patients admitted to hospital?" Pharmaceutical Journal **272**(7288): 253–256.



**Table 4B.** Studies evaluating pre-admission clinics

Reference	Level	Setting	Subjects	Intervention	Evaluable sample & follow-up	Study outcomes	Results
Wilcock M & Lawrence J 2004	3	Hospital emergency medical unit - UK	Aged over 16 years, taking two or more regular oral medicines at time of admission. Able to communicate with clinical pharmacist; provide written consent; and nominate regular community pharmacy	<p>Clinical pharmacist visited emergency unit twice daily. Medication history was acquired from the patient, their carers, patients' medicines, and GPs - information recorded on a data collection form as were medicines prescribed by the hospital doctor.</p> <p>Letter and consent form then sent to nominated pharmacy explaining study, requesting copy of the patient's medication details (all oral and inhaled medicines) for a period of at least 3 months before the index admission.</p> <p>Comparisons made between the sources of information - medication history obtained by doctor, history obtained by clinical pharmacist, and the medication listed in the PMR. If details needed clarification, contact made with community pharmacy, otherwise details of medication and discrepancies between the sources were noted.</p>	568 patients approached - only 257 eligible to enrol in the study, of which details were received for 250 patients (97% response).	<p>Level 3 Survey of acute adult admissions over an 18-month period. Tracking number of discrepancies between the three sources of information.</p> <p>Level 3 A score for the value of the PMR was deduced based on the question "How would immediate access to the details held on the PMR have changed the management of the patient when admitted to hospital?"</p> <p>1 = no added value to the admission process; 2 = little added value; 3 = some added value; and 4 = extreme added value.</p> <p>Friedman's test (two-way analysis variance) used to compare the scores.</p>	<p>Complete agreement between all sources for 54 (21%) of patients.</p> <p>Agreement between two of the sources was higher i.e. between clinical pharmacist and hospital doctor (44%); between clinical and PMR (43%). However, agreement between hospital doctor and the PMR low (24%).</p> <p>Authors assert that access to the PMR at the time of admission would not have added value for two-thirds of the patients. However, for 10 patients would have added value.</p>

## 5 Medication review for repeat prescriptions

### 5.1 The service

As described by Roughead, Semple and Vitry (2003):

'Repeat prescribing allows a patient to obtain a repeated supply of medication without the need for a doctor's consultation. Studies have been undertaken to assess whether a service involving the review of repeat prescriptions by a pharmacist achieves similar or improved patient outcomes compared to usual care, where review is undertaken by another health professional.'

### 5.2 Studies included

Studies were included if they involved the pharmacist as the identified person responsible for review of the repeat prescription and actively assessed the continuing need for the medication.

Two further inclusion criteria were applied.

- There had to be a control or comparison group.
- The endpoint had to include at least one patient outcome, which could be any of the following: hospital admission or re-admission; adverse events; mortality; quality of life; symptoms; surrogate health endpoints (e.g. blood pressure control, serum cholesterol level, blood glucose level); knowledge or compliance with treatment recommendations (level 1, 2 or 3 outcomes).

Studies assessing only level 4 outcomes, such as changes in satisfaction with or opinion of a service, were excluded.

### 5.3 Study designs

Three randomised controlled trials assessing the review of repeat prescribing by pharmacists were found. Two were conducted in Australia (Penrose-Wall, Bell et al. 2004; Sorensen, Stokes et al. 2004) and one in Canada (Sellors, Kaczorowski et al. 2003). All three studies were undertaken in community settings and involved patient interviews by pharmacists. In the two Australian studies, interviews took place in patients' homes, while in the Canadian study, interviews took place in the physician's office.

The Canadian study involved family practices in 24 sites in Ontario (Sellors, Kaczorowski et al. 2003). The family physicians were randomly allocated, in a concealed fashion, to either the control or intervention group. Patients aged 65-plus years who were taking five or more medications daily were randomly selected from their practices. After the allocation process,

physicians and patients were not blinded to their allocation group. Patients in the control group received usual care from their physicians. For the intervention group, pharmacists conducted a face-to-face structured medication assessment with the participants in the physician's offices. Written reports of the pharmacists' findings, including identified drug-related problems and recommended actions, were then given to the physicians. This was followed by several meetings at three and five months between pharmacists and physicians. At these meetings, discussions about the report, the implementation of the recommendations and its progress took place. Through semi-structured telephone interviews, pharmacists continued to monitor intervention patients' drug therapy one and three months after the initial meeting with physicians.

One Australian study examined the effectiveness of a multidisciplinary service model which delivers medication reviews to patients in the community who are at risk of drug-related problems (Sorensen, Stokes et al. 2004). The study was conducted in rural and urban areas of NSW, Queensland and Western Australia. As in the Canadian study, the primary physician was the unit of randomisation. Participants were selected if they met at least one of the ten inclusion criteria which included taking five or more regular medications, taking 12 or more doses of medication per day, and having three or more medical conditions. GPs and pharmacists allocated to the intervention group were encouraged to take part in two educational sessions dealing with prescribing issues, utilising other members of the primary healthcare team, and the implementation of medication reviews. In this study, the predominant intervention was a home visit by a pharmacist to identify medication-related risk factors and other issues, and to conduct a medication review. Following each home visit, the pharmacist prepared a medication review report for the GP, using home-visit findings and clinical information supplied by the GP. Pharmacist recommendations were discussed in a multidisciplinary conference involving the GP, the pharmacist, and another health professional. An action plan was then developed by the GP in consultation with the patient, based on the outcome of the conference.

Both of the above studies compare the effect of having a pharmacist conduct a face-to-face medication review compared with usual care. Review reports were also prepared by pharmacists in both the studies, followed by meetings with the GP, with or without the presence of another health professional involved in the patient's care.

The third study compares Home Medicines Reviews (HMRs) that involve case conferencing between GPs and pharmacists and standard written HMRs, with respect to patient and health practitioner outcomes (Penrose-Wall, Bell et al. 2004). The study was conducted in metropolitan Sydney, Australia. Eligible patients were aged 17-plus years, attended selected general practices in Sydney with any illness, and were proficient in English. Patients allocated to the intervention group underwent an HMR followed by a face-to-face case conference meeting between the pharmacist and GP. The control group also underwent an HMR followed by the usual means of communication between the pharmacist and GP about the HMR findings, i.e. a written report sent or faxed report to the GP.

## 5.4 Study outcomes

Outcome measures used in the three RCTs included the following.

- Quality of life (level 1)
- Duke's Severity of Illness Visual Analogue Scale (DUSOI-A) – a 10-cm visual analogue scale, where 0 indicates low severity of illness and 100 high severity of illness (level 1)
- Adverse drug events (level 2)
- Number of drug-related problems and recommendations (level 2)
- Number and cost of medications (level 2)
- Number of GP visits (level 2)
- Health care use and cost (level 2)
- Proportion of recommendations accepted and implemented by the physicians (level 2)
- Patient satisfaction (level 4)
- Implementation success (level 4)

## 5.5 Evidence for effectiveness of practice

In two of the RCTs, no statistically significant differences were found between intervention and control groups on any of the outcomes (Sellors, Kaczorowski et al. 2003; Sorensen, Stokes et al. 2004). It was suggested by Sorensen et al (2004) that “a longer follow-up period may have shown a larger difference in outcome measures”. The two studies encompassed patients with a wide range of ages and two health systems, i.e. the Australian and Canadian health systems.

The study by Penrose-Wall et al (2004) showed no difference between intervention group patients, who received HMRs with case conferencing between pharmacists and GPs, and control group patients, who received HMRs with written reporting from the pharmacist to the GP.

### *Evidence of effectiveness with respect to morbidity and mortality outcomes (level 1)*

In the two studies which reported quality of life (QOL) and severity of illness as outcomes, no significant differences were found between intervention and control groups (Sellors, Kaczorowski et al. 2003; Sorensen, Stokes et al. 2004). However, the Canadian study showed a decline in the mean QOL scores in both groups from baseline to study exit (Sellors, Kaczorowski et al. 2003). In one of the Australian studies (Sorensen, Stokes et al. 2004), the mean of DUSOI-A, a severity of illness measure, was reduced by 4.92 for intervention patients and by 1.34 for controls.

### ***Evidence of effectiveness with respect to level 3 outcomes***

In the three studies that assessed level 3 outcomes, no significant differences were found between the intervention and control groups. Sellors et al (2003) reported similar numbers of medication units and medications being taken per day between the two groups, as well as similar levels of health care utilisation and costs. Physicians declared an intention to implement 72% of pharmacist recommendations. At the five-month follow-up, 46% had been successfully implemented.

Although not statistically significant, Sorensen et al (2004) reported a reduction in disease severity and frequency of adverse drug events in intervention patients compared to controls. Results from the medication reviews conducted for the intervention group show that 54.5% of pharmacists' recommendations were implemented by GPs, with 23.4% coming from the medication review report and 14.9% from the medication review report with modifications. From these implemented actions, approximately 71% resulted in a positive outcome. No differences were detected between intervention and control groups in the number of hospital admissions and services, and the number of GP visits.

In the study by Penrose-Wall et al (2004), GP acceptance and action rates in relation to pharmacist recommendations were reported but were considered to be unreliable estimates. The GP acceptance rate for the intervention group was 92% and was recorded at case conference meetings. The acceptance rate was not measured in the control group. The action rate for the intervention group was 38%, an estimate based on previous Australian studies. The action rate for the control group was 18%, calculated using GP Medication Management Plans (MMP) which were only received for 11 out of 45 HMR cases. Results suggest a greater uptake and implementation of HMR recommendations if a case conference meeting occurred.

### ***Evidence for of effectiveness with respect to level 4 outcomes***

Sorensen et al (2004) assessed patient satisfaction and implementation success in their study but did not report any significant differences between the groups. The overwhelming majority of patients (97% of those in the intervention group, and 94% of controls) reported benefitting from their participation.

## **5.6 Economic assessment**

None of the three studies included a full economic evaluation. Sorensen et al (2004) assessed the costs involved when a medication review by a pharmacist was added to the patient's care, compared with usual care (Sorensen, Stokes et al. 2004). The cumulative cost per patient over the eight months from enrolment was A\$5,730 for the control group and A\$5,401 for the intervention group. After subtracting trial costs, the net cost saving per intervention patient (marginal cost benefit) was A\$54 per patient relative to controls. The calculated incremental cost-effectiveness ratio in reducing adverse drug events for the groups was A\$69 and in improving DUSOI-A was A\$65.

## 5.7 Australian research

As described above, two RCTs assessing pharmacist review of repeat prescribing were carried out in Australia (Penrose–Wall, Bell et al. 2004; Sorensen, Stokes et al. 2004). These are described above.

## 5.8 Comment

Two of the three studies (Sellors, Kaczorowski et al. 2003; Sorensen, Stokes et al. 2004) that we found, set in the Australia and Canada, clearly show that, when added to usual care provided by doctors, review services by pharmacists have no effect on patient and other outcomes. Some limitations of study design were evident, including short follow-up time, very general eligibility criteria, and lack of blinding of observers.

The findings from these two studies accord with the results of two earlier UK studies that were included in the review by Roughead, Semple and Vitry (2003).

The third study (Penrose–Wall, Bell et al. 2004) adds to the evidence that the addition of case conferencing between the GP and pharmacist improves uptake and implementation of HMR recommendations. However, more evidence is needed to confirm this.

## References

Penrose–Wall, J., S. Bell, et al. (2004). Case Conferences and Care Plans: Collaboration between community pharmacists and GPs, after HMR in primary mental health care. Third Community Pharmacy Agreement Research and Development Grants Program. Sydney, The University of Sydney.

Sellors, J., J. Kaczorowski, et al. (2003). "A randomized controlled trial of a pharmacist consultation program for family physicians and their elderly patients." Canadian Medical Association Journal **169**(1): 17–22.

Sorensen, L., J. A. Stokes, et al. (2004). "Medication reviews in the community: results of a randomized, controlled effectiveness trial." British Journal of Clinical Pharmacology **58**(6): 648–664.

**Table 5.1.** Randomised controlled trials (Level 1) assessing pharmacist review of repeat prescribing

Reference	Level of evidence	Setting	Subjects, intervention	Evaluable sample	Study outcomes	Results
Penrose–Wall J, Bell S, et al (2004).	1–	General practices in metropolitan Sydney	<p>Patients aged <math>\geq 17</math> yrs with any illness who presented to the selected practices and who were proficient in English.</p> <p>A comparative two–group intervention study where patients in the control group participate in a standard Homes Medicines Review (HMR) with a pharmacist who then sends the report back to the GP.</p> <p>Intervention patients also undergo an HMR. Post–HMR, a face–to–face case conferencing between their GP and pharmacist is held.</p>	<p>Analysed: Intervention n = 44. Control n = 45.  Total = 89  3–month follow–up</p>	<p>Level 3 Number of potential problems and recommendations from HMR GP acceptance and action rate of recommendations from HMR</p>	<ul style="list-style-type: none"> <li>• There were no significant differences between intervention and control groups for any of the study outcomes.</li> <li>• 89 HMRs were conducted: 601 potential problems (average 6.8 potential problems per HMR); and 521 recommendations.</li> <li>• GP acceptance rate – 92% Intervention group (as recorded at case conference meetings), not measured in control group.</li> <li>• GP action rate – 38% Intervention group (estimate only based on previous studies), 18% Control group (based on 11/45 HMR cases and measured using GP Medication Management Plans).</li> </ul>
Sorensen L, Stokes J, et al (2004). Br J Clin Pharmacol 58(6): 648–664	1++	Australian community setting	<p>Participants from urban and rural areas of Qld, NSW, WA. Satisfied <math>\geq 1</math> of 10 inclusion criteria which included: taking <math>\geq 5</math> regular medications, <math>\geq 12</math> doses of medication per day, <math>\geq 3</math> medical conditions.</p> <p>Randomised controlled trial with the GP as the unit of randomisation, with pharmacists linked to a specific GP. Patients of GPs randomised to the intervention group were subject to the intervention strategy while patients of GPs in the control group received usual care.</p> <p>Intervention – implement a multidisciplinary service model whose goal is to enable</p>	<p>Analysed: Intervention: n = 177. Control: n = 223  Total = 400  6–month follow–up</p>	<p>Level 1: QOL. Severity of illness (DUSOI–A)  Level 3: Adverse drug events. Medication and healthcare service costs. Number of GP visits. Hospital services.  Level 4:</p>	<ul style="list-style-type: none"> <li>• Differences between intervention and control groups were not significant for any of the study outcomes.</li> <li>• Intervention group – average of 5.5 problems were identified per medication review (e.g. potential adverse drug event, sub–optimal monitoring), total number of problems = 602. – average of 6.8 recommendations were suggested in each review, total number of suggestions = 747. – reduction in disease severity (DUSOI–A) and frequency of adverse drug events compared to controls.</li> <li>• Recommendations taken up by GP:</li> </ul>

Reference	Level of evidence	Setting	Subjects, intervention	Evaluable sample	Study outcomes	Results
			effective intervention for patients at risk of medication misadventure in a community setting through collaboration between health professionals. The model included educational sessions dealing with prescribing issues for GPs and pharmacists in the intervention group. The predominant process in the intervention was a home visit undertaken by an accredited pharmacist to conduct a medication review. A medication review report was then prepared by the pharmacist and forwarded to the GP. GP to discuss recommendations at a multidisciplinary conference, develop an action plan and implement the plan in consultation with the patient.		Patient satisfaction. Implementation success.	<p>23.9% from medication review report, 14.9% from MR with modifications, 6.0% from MR including action taken at home visit, 9.6% from action plan/follow-up but not in MR (total=54.5% recommendations implemented).</p> <ul style="list-style-type: none"> <li>• From the implemented actions, 70.9% had a positive outcome.</li> <li>• Functional status, number of hospital admissions and services, and number of GP visits were not different between intervention and control groups.</li> <li>• 92% of intervention GPs found the model improved patient care and 94% of pharmacists found it useful</li> <li>• Most patients reported benefiting from participating in the trial (97% of intervention patients, 94% of control patients).</li> <li>• Net cost saving per intervention patient was AUS\$54 relative to controls.</li> <li>• Incremental cost-effectiveness ratio for the groups in reducing ADEs was AUS\$69 and in improving DUSOI-A was AUS\$65</li> </ul>
Sellors J, Kaczorowski J, et al (2003). CMAJ 169(1): 17-22	1+	Family practices in 24 sites in Ontario	<p>48 randomly selected family physicians from 24 sites – randomised to intervention or control.</p> <p>889 of their patients who were community-dwelling, aged <math>\geq 65</math>, and taking 5 or more medications daily.</p>	<p>Baseline: Int evention: n = 431 Control: n = 458 Total = 889</p>	<p>Level 1: Quality of Life measures (SF-36)</p> <p>Level 3: Number of drug-related problems</p>	<ul style="list-style-type: none"> <li>• Differences between intervention and control groups were not significant for any of the study outcomes.</li> <li>• Medication units being taken per day were similar between the groups – 12.4 (intervention) vs. 12.2 (control), <math>p=0.50</math></li> <li>• Number of medications taken per day</li> </ul>



Reference	Level of evidence	Setting	Subjects, intervention	Evaluable sample	Study outcomes	Results
			Intervention – pharmacists conducted face-to-face medication reviews with patients, gave written recommendations to physicians to resolve any drug-related problems.	Analysed: Intervention: n = 379 Control: n = 409 Total = 788  5-months' follow-up	Number and cost of medications Health care use and cost Proportion of recommendations implemented by the physicians	were also similar between the groups – 8.0 (intervention) vs. 7.9 (control), p=0.87 <ul style="list-style-type: none"> <li>• There were no statistically significant differences in health care use, quality of life scores, nor on costs between the two groups</li> <li>• Physicians intended to implement 72.3% of recommendations. After 5 months, 46.3% were successfully implemented</li> <li>• Intervention had no significant effect on patient outcomes</li> <li>• Physicians receptive to pharmacist's recommendations</li> </ul>

## 6 Medication review in aged care facilities

### 6.1 The service

As described by Roughead, Semple and Vitry (2003):

'The elderly living in long-term care facilities are considered to be at particular risk of medication-related problems, including adverse drug reactions. Medication review services have been implemented in aged care facilities to address this problem. Pharmacist-conducted medication review (also known as drug regimen review) involves a review of the medication record and medical case notes with an assessment of all factors likely to influence therapeutic outcomes. This involves collection of information about a patient's medications, their relevant medical history and laboratory test results. This information is used to identify and resolve medication-related problems.'

### 6.2 Studies included

Medication review services were considered primarily to be reviews of medication charts and medical case notes, without active involvement of the patient. Studies were included if they assessed medication review services conducted by a pharmacist for residents of an aged care facility. Studies including medication review as part of a pharmaceutical care intervention were not included in this section, but are reviewed elsewhere in this report.

Two further inclusion criteria were applied.

- There had to be a control or comparison group.
- The endpoint had to include at least one patient outcome, which could be any of the following: hospital admission or re-admission; adverse events; mortality; quality of life; symptoms; surrogate health endpoints (e.g. blood pressure control, serum cholesterol level, blood glucose level); knowledge or compliance with treatment recommendations (level 1, 2 or 3 outcomes).

Studies assessing only level 4 outcomes, such as changes in satisfaction with or opinion of a service, were excluded.

### 6.3 Study design

We found no level 1 or 2 studies that assessed medication review services in aged care facilities and that fulfilled the inclusion criteria listed in section 6.2, and no economic assessment of the service.

### *Evidence for the effectiveness of the service*

In their review, Roughhead, Semple and Vitry (2003) reported that pharmacist-conducted medication reviews in aged care facilities had no effect on morbidity measures. One of the studies that they reviewed found an association between medication reviews and quality of life, as measured by the SF-36. Two of the three studies that they reviewed reported significant changes in medication use associated with medication reviews.

## 7 Medication review in the outpatient setting

### 7.1 The service

As described by Roughead, Semple and Vitry (2003):

‘Pharmacist-conducted medication review (also known as drug regimen review) involves a review of the medication record and medical case notes with an assessment of all factors likely to influence therapeutic outcomes. This involves collection of information about a patient’s medications, their relevant medical history and laboratory test results. This information is used to identify and resolve medication-related problems.’

### 7.2 Studies included

Studies were included in this section if they were undertaken in the outpatient setting and involved a review of medical records and case notes to identify and resolve medication-related problems, but did not involve pharmacists interviewing patients for this purpose. Studies involving medication review as part of a pharmaceutical care intervention are reviewed elsewhere in this report. Unlike pharmaceutical care studies, medication review studies did not mention a patient interview conducted by the pharmacist. To be included, studies had to cover patient outcomes or changes in medication use as end-points.

### 7.3 Study design

We found one RCT that assessed medication review services in an outpatient setting (level 1) (Williams, Pulliam et al. 2004). The study is summarised in Table 7.1. Study participants were randomly assigned to either an intervention or usual-care control group, with each group stratified to maintain a balance of age, sex and race. Each patient in the intervention group received a medication review conducted by a practising consultant pharmacist. The pharmacist wrote a report that included recommendations on whether or not each medication should be continued, and whether or not the dose should be changed. The pharmacist then submitted the report to an interdisciplinary medication adjustment team comprising of a physician, a nurse and a pharmacist. Changes to the patient’s medication regimen were made only after consultation between the patient, the patient’s primary physician and the medication adjustment team. The control group received usual care, with no medication review. Follow-up was conducted after six weeks. Medication cost and usage were recorded for both groups.

## 7.4 Study outcomes

Outcome measures used in the RCT included the following:

- Physical function (level 1):
- Timed manual performance, physical performance tests, functional reach.
- Cognitive function (level 1):
- Digit–symbol and digit span Wechsler Adult Intelligence Scale (WAIS), Randt memory test.
- Affective function (level 1):
- Depression scale, self–rating anxiety scale, Rand 36–item health survey.
- Medication usage (level 3):
- Number of prescription and non–prescription drugs, number of drugs in use, monthly wholesale cost.

## 7.5 Evidence for the effectiveness of the service

Evidence is limited for the effectiveness of pharmacist–conducted medication reviews in the outpatient setting because we found only one RCT that met the eligibility criteria for inclusion in this review.

Recruitment response rates for the RCT conducted by Williams et al were very low, despite aggressive advertising, community presentations and mass mailing to 1,000 persons. No significant differences were found between the intervention and control groups in cognitive, affective or physical functioning. Patients in the intervention group were generally unwilling to follow recommendations to change their drug regimen, decreasing their medications by only an average of 1.5 drugs instead of the recommended 4.5 drugs per patient. However, the number of medications dropped and the associated cost savings for the intervention group were significantly greater than those for the control group.

Six intervention subjects and one control subject withdrew from the study. In some instances participants withdrew because they were unwilling to discontinue psychoactive drugs, such as hypnotics, benzodiazepines and narcotic analgesics.

The results of the RCT are in accord with the findings reported in the review by Roughead, Semple and Vitry (2003). They included two RCTs which similarly showed no effect associated with medication reviews conducted by pharmacists in outpatient settings.

## 7.6 Economic assessment

In the study by Williams et al, patients in the intervention group decreased their medication intake by an average of 1.5 drugs per patient. This resulted in a significant monthly saving

for the intervention group of US\$26.92 compared to US\$6.75 for the control group, based on the wholesale costs of drugs.

## 7.7 Australian research

We found no RCTs that were undertaken in the Australian setting and assessed patient outcomes.

## 7.8 Comment

Evidence is lacking for the effectiveness of pharmacist-conducted medication reviews in outpatient settings. We found only one RCT that met inclusion criteria for this review. In this study, an interdisciplinary team was responsible for communicating the review recommendations directly to patients in the intervention group. There were no significant differences between the intervention and control groups in relation to their cognitive, affective and physical functioning, but the decrease in the number of medications taken and the decrease in patients' monthly drug expenses was significantly greater for the intervention group than the control group. However, patient resistance to reducing adverse polypharmacy was evident.

## References

Williams, M. E., C. C. Pulliam, et al. (2004). "The short-term effect of interdisciplinary medication review on function and cost in ambulatory elderly people." Journal of the American Geriatrics Society 52(1): 93-8.

**Table 7.1** Medication review services to outpatients

Reference	Level	Setting	Subjects, intervention	Evaluable sample	Study outcomes	Results
Williams ME, Pulliam CC, et al (2004). J Am Geriatr Soc 52: 93-98	1-	Health centre ambulatory clinic.  North Carolina, USA	Community-dwelling adults aged $\geq 65$ years, cognitively intact, and taking five or more prescription medications (two of which are classified as potentially problematic for common geriatric problems).  Recruited from General Medicine Clinic of UNCH, and private practices in the area.  Primary intervention - a comprehensive medication regimen review and recommended modification of a patient's medication regimen by a consultant pharmacist. Recommendations were then discussed by an interdisciplinary team comprised of a physician, nurse, and pharmacist.	Analysed: Intervention: n = 57 Control: n = 76 Total: n = 133  6-week follow-up	Level 1: Cognitive, physical performance, and affective function measures. Health status  Level 3: Medication usage	<ul style="list-style-type: none"> <li>• No differences in functioning were observed between intervention and control groups.</li> <li>• Intervention participants decreased medications by an average of 1.5 drugs, although an average of 4.5 drugs per patient were recommended by the team to be discontinued.</li> <li>• Intervention participants saved an average of US\$26.92 per month in wholesale medication costs while control subjects saved an average of US\$6.75 (<math>P &lt; .006</math>)</li> <li>• The intervention significantly reduced the medications taken and monthly cost.</li> <li>• Most patients were resistant to reducing medications to the recommended level</li> </ul>

## **8 Pharmacist services providing education to patients or consumers**

### **8.1 The service**

As described by Roughead, Semple and Vitry (2003):

'Patient education or counselling services include the provision of verbal and/or written information and advice for patients and consumers. Verbal education may be provided individually (one-to-one) or to small groups. Education services are generally provided through face-to-face interactions between the pharmacist and patient but may also be conducted by telephone or using video technology. Education services may be single or multiple session services.'

### **8.2 Studies included**

Studies were included if they assessed a pharmacist intervention described as counselling, education or oral information provision to patients or consumers, with or without the provision of written information, compliance aids or self-monitoring. Pharmacist interventions described as adherence or compliance programs were also included if education, counselling or the provision of information was a major component.

Studies involving patient education as part of a pharmaceutical care intervention, a drug information service, discharge liaison, smoking cessation or immunisation services are reviewed elsewhere in this report.

Studies were included in this section if they were conducted in community setting or ambulatory care settings or in outpatient clinics. Studies conducted in hospitals were included only if they assessed discharge education or counselling services.

Studies must have included at least one patient outcome, which could have included quality of life, symptoms of disease, adverse events, hospital admissions or emergency visits, surrogate health endpoints (laboratory or other tests such as BP, pulmonary function tests), patient knowledge, compliance/adherence with medication or technique in the use of medication devices. Studies that only included patient satisfaction with or opinion of the service (level 4 outcomes) were excluded.

Studies that employed educational strategies at discharge or outpatient clinics were included in this review, but studies that conducted hospital education were excluded.



## 8.3 Study design

We found seven RCTs (level 1 evidence) that met the inclusion criteria and were described in eight publications (two of the publications outlined different outcome measures from the same RCT (Brook, van Hout et al. 2003; Brook, van Hout et al. 2003). Six RCTs assessed one-to-one educational interventions (Barbanel, Eldridge et al. 2003; Brook, van Hout et al. 2003; Gonzalez–Martin, Joo et al. 2003; Grant, Devita et al. 2003; Hoffman, Enders et al. 2003; Yuan, Hay et al. 2003), and one assessed a group-based intervention (Sarkadi and Rosenqvist 2004). Three of the RCTs were conducted in Europe, three in the USA, and one in South America. In addition to the seven RCTs, we found one report that described an RCT but did not give its results (Charrois, Newman et al. 2004), and two non-randomised controlled studies (level 2 evidence) (Gonzales, Sauaia et al. 2004; Lee, Cheung et al. 2004). However, in keeping with our use of the highest level of evidence, we confined our review to RCTs that evaluated the effectiveness of pharmacist education services.

Of the six RCTs that assessed one-to-one educational interventions, four studies involved at least one face-to-face interaction between pharmacists and patients in the intervention group. These interactions took place in a variety of settings including a consultation area within a pharmacy, over the counter within a pharmacy, and primary care clinics. Two studies did not specify where the educational session occurred. The length of time taken for the education sessions varied among the studies from 10–25 minutes to 45–60 minutes (some of the reports did not mention the duration of the session). Single face-to-face educational sessions between the pharmacist and patient were evaluated in two of the studies (Grant, Devita et al. 2003; Yuan, Hay et al. 2003), while multiple educational sessions were evaluated in the other three studies (Barbanel, Eldridge et al. 2003; Brook, van Hout et al. 2003; Gonzalez–Martin, Joo et al. 2003). Only one RCT (Barbanel, Eldridge et al. 2003) evaluated follow-up phone calls in addition to the face-to-face consultation. One RCT assessed the effect of a monthly mail-out to patients and their GPs. This included educational materials on the importance of compliance as well as feedback on their rates of compliance (Hoffman, Enders et al. 2003). In this study there was no direct contact between the pharmacist and either the patient or the medical practitioner.

Five of the six studies assessing one-to-one education used a single intervention and control group design. One study compared two models for delivering the educational message with a control group (Yuan, Hay et al. 2003).

The patient group targeted in the studies varied. Of the seven RCTs, one study targeted members of a particular medical care program (Yuan, Hay et al. 2003). The other six studies targeted patients with specific conditions (two studies targeted patients with asthma (Barbanel, Eldridge et al. 2003; Gonzalez–Martin, Joo et al. 2003), two targeted patients with diabetes (Grant, Devita et al. 2003; Sarkadi and Rosenqvist 2004), and two targeted patients diagnosed with depression (Brook, van Hout et al. 2003; Hoffman, Enders et al. 2003). The follow-up periods varied: 9 weeks (Gonzalez–Martin, Joo et al. 2003); 3 months (Barbanel, Eldridge et al. 2003; Brook, van Hout et al. 2003; Grant, Devita et al. 2003); 6 months

(Hoffman, Enders et al. 2003); and 2 years (Yuan, Hay et al. 2003; Sarkadi and Rosenqvist 2004).

A variety of additional materials that complemented the pharmacist-run education sessions were provided to patients in the studies. These included written materials (Barbanel, Eldridge et al. 2003; Gonzalez-Martin, Joo et al. 2003; Sarkadi and Rosenqvist 2004), a mail-out including feedback (Hoffman, Enders et al. 2003), a video (Brook, van Hout et al. 2003; Sarkadi and Rosenqvist 2004), and a game (Sarkadi and Rosenqvist 2004). Other materials that were provided by the pharmacist to aid patient compliance with medication were a personalised credit card self-management plan (Barbanel, Eldridge et al. 2003), and a self-monitoring diary (Sarkadi and Rosenqvist 2004). In one study, the pharmacist arranged for referral to social services and e-mailed the general practitioner as required (Grant, Devita et al. 2003).

In most of the RCTs, the patient was the unit of randomisation. In one study the pharmacy, as well as the patients, were randomised (Yuan, Hay et al. 2003). Studies were judged to have more rigorous methods with less chance of bias (level 1+ evidence) if they used independent researchers, blinded to group allocation, to assess baseline and follow-up outcome measures. Most studies were rated as level 1- for method due to the potential for observation bias in the outcomes assessment process.

Sample sizes of the studies varied widely, from small (around 20 patients, (Barbanel, Eldridge et al. 2003; Gonzalez-Martin, Joo et al. 2003) to large (thousands of patients, (Hoffman, Enders et al. 2003; Yuan, Hay et al. 2003). Power calculations were reported for three of the seven RCTs included in this review (Brook, van Hout et al. 2003; Grant, Devita et al. 2003; Sarkadi and Rosenqvist 2004). In the studies that did not report power calculations and had a small sample size, it was not possible to tell whether the result was a real observation or due to inadequate numbers (Barbanel, Eldridge et al. 2003; Gonzalez-Martin, Joo et al. 2003).

## 8.4 Study outcomes

Outcome measures employed in the studies varied. Five of the studies measured at least one health outcome (level 1 outcome).

Outcomes measured included:

- Self-completed: North of England asthma symptom scale (level 1);
- Self-rating 90-items (Hopkins) symptom checklist – psychological symptoms (level 1);
- Non-elective hospital admission (level 1);
- Mortality (level 1);
- Paediatric asthma quality of life questionnaire (PAQLQ) (level 1);
- Surrogate endpoints: glycosylated haemoglobin (HbA<sub>1c</sub>) levels (level 2) and cholesterol levels (level 2);
- Spirometry measurements (level 2);

- Drug attitude (level 3);
- Resolution of medication discrepancies (level 3);
- Compliance rates (level 3) either self-reported or by using pharmacy claims data; and
- Patient satisfaction (level 4).

## 8.5 Evidence for effectiveness of practice

### 8.5.1 Overview

For the purposes of the review, studies were assessed in the following categories:

- Single-session counselling at the point of dispensing
  - Extended counselling for prescription medicines compared with usual care.
- Single-session counselling for long-term therapy.
- Multiple-session education.
- Multiple-session education plus active self-monitoring.

The results of studies assessing one-to-one educational interventions suggest that both single session and multiple session education can have an effect on patient health outcomes. Two of the studies that we reviewed evaluated single-education sessions and five studies assessed multiple-education sessions. The effect of pharmacist-led education on health outcomes was varied, with two studies showing no benefit to patients in the intervention group when compared to the control group. However, based on the combined evidence from this review and the previous review, multiple education sessions give stronger evidence and better outcomes.

The previous review (Roughead, Semple et al. 2003) noted a lack of RCTs assessing the effects of small group education delivered by pharmacists for patients or consumers. This is still the case.

There is level 1+ evidence that single-session extended counselling of patients at the time of filling a prescription is effective in reducing hospitalisation. In addition, counselling focused specifically on high-risk patients results in reduced mortality.

Multiple-session education (level 1- evidence) was effective in improving quality of life for asthmatic children. Multiple-session education plus active self-monitoring effectively improved asthmatic symptoms in adults and resulted in long-term improvements of glycosylated haemoglobin levels in diabetic patients. Multiple newsletters and compliance feedback to both patients and their practitioners had a positive impact on patient compliance.

No Australian controlled studies assessing education by pharmacists to patients in the community setting were found.

There is a lack of economic assessments of patient education delivered by pharmacists, so it is impossible to draw conclusions about the cost-effectiveness of this form of pharmacy intervention.

## 8.5.2 Single-session counselling

### *Single-session counselling at the point of dispensing – extended counselling for prescription medicines compared with usual care*

One study assessed three models of patient counselling at the point of dispensing (Yuan, Hay et al. 2003), Table 8.1). At the time of dispensing the pharmacist would either: (1) discuss drug information topics, including when and how to take the medication, potential treatment interactions and side effects ('State Model'); (2) focus resources on more comprehensive pharmaceutical care for high-risk patients that included patient education and medication reviews ('KP Model') (Kaiser Permanente Medical Care); or (3) provide a consultation and information at the request of the patient ('Control Model').

#### *Mortality and emergency hospitalisations (level 1 outcomes)*

Both intervention models (KP and State) were associated with reduced emergency hospital admissions compared to the control group. The State Model was associated with fewer urgent and emergency admissions in low-risk patients. The KP Model was associated with lower mortality risk compared with the State and Control Models for both the total population of patients and certain high-risk sub groups. In this study both the pharmacies and patients were randomised to the three arms of the trial. The risk of bias was low as pharmacists did not know the identity of the patients, but the study relied on patients visiting the one pharmacy for the duration of the study (two years).

### *Single-session counselling for long-term therapy*

One study assessed single-session counselling for long-term therapy (Grant, Devita et al. 2003), Table 8.2) in patients with diabetes. Patients in the intervention arm received a tailored education program detailing medication use and help with appointment referrals. Medication discrepancies were identified and forwarded to the primary care provider.

#### *Compliance rates and barriers (level 3 outcomes), and surrogate outcomes (level 2 outcomes)*

Patients in the intervention arm did not report lower medication use barriers or increased compliance rates when compared to the control group at follow-up. Intervention and control patients' glycosylated haemoglobin and cholesterol levels were measured at the commencement of the study period and again at follow-up. No change in the levels of either measure was detected over the study period and there was no difference in levels between the two groups at pre- or post-intervention.

### *Medication discrepancies (level 3 outcome)*

The pharmacist reviewed medication records of patients in the intervention group and contacted the primary care provider if medication discrepancies were found. The majority of discrepancies identified (60 percent) had been resolved at the time of follow-up. However, the study did not identify medication discrepancies for patients in the control group.

The participants in this study were well connected to the health system and had high compliance levels at the beginning of the study. Education sessions may have had a greater impact if targeted at those with minimal contact with the health system.

### *Comment*

We found only two RCTs published between 2002 and March 2005 that assessed one-to-one single session patient counselling. The effect of pharmacist-led counselling sessions differed in the two studies.

Yuan et al (2003) conducted a larger, more extensive study. They found the two models of counselling, targeted at either a wide population, or at more specifically identified patients who had higher health risks, had a positive effect on the risk of hospitalisation when compared to patients who received no counselling (Yuan, Hay et al. 2003).

The second study assessed compliance and perceived barriers for compliance by patients following a pharmacist-led education intervention. The intervention did not alter patient's self-assessed compliance or barriers, compared to patients who did not receive the education sessions (Grant, Devita et al. 2003).

Taken together it is difficult to determine the effect of single-session pharmacist counselling on patient outcomes.

## **8.5.3 Multiple-session education**

We found three RCTs that evaluated multiple-session education, published in four articles (Table 8.3 (Brook, van Hout et al. 2003; Brook, van Hout et al. 2003; Gonzalez-Martin, Joo et al. 2003; Hoffman, Enders et al. 2003). A further two studies that assessed multiple-session education with active self-monitoring are discussed later.

One of the three RCTs examined the effects of three pharmacist-led coaching sessions over a six-month period on patients who had newly been prescribed non-tricyclic antidepressant medication (Brook, van Hout et al. 2003; Brook, van Hout et al. 2003). Another of the RCTs involved three educational sessions for children with asthma and their parents (Gonzalez-Martin, Joo et al. 2003). The third RCT examined the effect of a monthly mail-out to patients and their GPs with education materials on the importance of compliance as well as individual compliance feedback (Hoffman, Enders et al. 2003). In this study there was no direct contact between the pharmacist and either the patient or practitioner.

#### *Self-rating (Hopkins) symptom checklist (level 1 outcome)*

Brook et al (2003) analysed their data using Intention-to-Treat (ITT) analysis performed using two different methods to fill in missing data: (i) Last Observation Carried Forward (LOCF); and (ii) Group Mean Imputation (GMI) (Brook, van Hout et al. 2003). Data analysed by ITT using LOCF found patients in the intervention group less depressed and less anxious than controls. However, analysis using GMI showed no difference in psychological symptoms between the intervention and control groups. The differences between the two methods were ascribed to the attrition rates amongst the two arms of the study. Taken together these results suggest that a pharmacist-led education program did not significantly change patients' symptom scores.

#### *Paediatric Asthma Quality of Life Questionnaire (level 1 outcome)*

One RCT evaluated the effect of education sessions on the patients' quality of life, as assessed using the Paediatric Asthma Quality of Life Questionnaire. The intervention group demonstrated a significant improvement in activities, emotions and symptoms compared to the control group (Gonzalez-Martin, Joo et al. 2003). However, it should be noted that, the sample size was very small.

#### *Spirometry measurements (level 2 outcome)*

No significant improvement in spirometry measurements occurred in either the intervention or control group following the study period (Gonzalez-Martin, Joo et al. 2003).

#### *Compliance and drug attitude (level 3 outcome)*

Patients in the intervention arm of the study were more stimulated and motivated to continue taking their antidepressant medication (Brook, van Hout et al. 2003), but no data on this outcome was provided in the article. Hoffman et al (2003) found that patients and practitioners who received feedback on their compliance significantly improved their compliance rates compared to controls (Hoffman, Enders et al. 2003).

#### *Patient satisfaction (level 4 outcome)*

At the three-month follow-up, patients in both the intervention and control arms of the RCT rated the contact with the pharmacist as positive, though the intervention group was more positive (Brook, van Hout et al. 2003).

### **8.5.4 Multiple-session education plus active self-monitoring**

Two RCTs evaluated multiple-session education plus active self-monitoring (Barbanel, Eldridge et al. 2003; Sarkadi and Rosenqvist 2004). In one study, patients with diabetes participated in group education sessions and also received take-home material including self-monitoring diaries (Sarkadi and Rosenqvist 2004). The self-monitoring diaries were shared with the group and comprised an important foundation for discussions. The other study assessed an asthma self-management program that included patient education, take-home materials and a self-management plan, delivered by a pharmacist (Barbanel, Eldridge et al. 2003).

### *Symptom scores (level 1 outcome)*

Symptoms were measured using the North of England asthma symptom scale (Barbanel, Eldridge et al. 2003). Symptom scores for patients in the control group worsened slightly over the study period while a seven-point improvement was observed in the intervention patients. This difference between the two groups was significant. The study was limited by only including a small number of patients and allocation by the pharmacist was not blinded. Additionally it appeared that no prior power calculations had been done.

### *Surrogate outcomes (level 2 outcomes)*

HBA<sub>1c</sub> levels were the principal outcome measure used by Sarkadi and Rosenqvist (2004) and were measured at baseline, six, 12, and 24 months. Patients in the intervention arm significantly decreased HBA<sub>1c</sub> levels by 0.4 percent at 24 months following baseline. Other factors that were directly related to glycaemic outcomes included initial HBA<sub>1c</sub> levels, and patients' satisfaction with their own diabetes-related knowledge and treatment.

### ***Comment***

There is some evidence for the effectiveness of multiple-session education in improving patient outcomes. Multiple-education sessions that included active self-monitoring seemed to result in better outcomes than education sessions alone, although no studies compared intervention alone with intervention plus self-monitoring.

All the evidence reviewed in this report is level 1 – evidence. RCTs demonstrated the effectiveness of multiple-session education in improving patient outcomes such as asthma symptoms (Barbanel, Eldridge et al. 2003; Gonzalez-Martin, Joo et al. 2003), and surrogate outcomes in patients with diabetes (Sarkadi and Rosenqvist 2004). However, educational sessions had no apparent effect on symptoms associated with depression (Brook, van Hout et al. 2003), but were associated with increased medication compliance in patients with depression (Hoffman, Enders et al. 2003). The Brook study indicates that care must be taken in applying methods to correct for missing data (Brook, van Hout et al. 2003).

## **8.5.5 Single- versus multiple-session education**

We found no RCTs that evaluated the effectiveness of single-session versus multiple-session education in community settings.

## **8.5.6 One-to-one versus group education**

We also found no RCTs that evaluated the effectiveness of one-to-one education compared to group-based educational sessions in community settings.

## 8.6 Economic assessment

We found no RCTs that provided economic assessments of pharmacist services providing education to patients or consumers.

## 8.7 Australian research

No RCTs (level 1 or 2 evidence) evaluating patient education by pharmacists were published from 2002 to March 2005.

## 8.8 Comment

Seven RCTs that evaluated educational services delivered by pharmacists were published between 2002 and March 2005. The educational approaches that these RCTs evaluated and the end-points that they measured varied, reflecting the different objectives, settings and target populations.

The results overall indicate that pharmacist-led patient education sessions can have a beneficial effect on health outcomes, although two of the studies did not show significant changes following the intervention (Brook, van Hout et al. 2003; Grant, Devita et al. 2003). Multiple education sessions were more likely to affect health outcomes, especially those that included active self-monitoring (Barbanel, Eldridge et al. 2003; Sarkadi and Rosenqvist 2004). The provision of education and feedback to both patients and their practitioners had a positive effect on compliance in depressed patients (Hoffman, Enders et al. 2003). One of the RCTs evaluated group education sessions (Sarkadi and Rosenqvist 2004). The group sessions were effective in improving surrogate measures in patients in the intervention group. No studies were found that compared group versus one-to-one education.

The majority of the studies that we reviewed used quality of life or symptom measures (level 1 outcome) or surrogate outcomes (level 2).

The seven RCTs were conducted in Europe, including the UK; the USA; and South America. There is a lack of published research examining the effect of pharmacist education services on patient outcomes in Australian community settings.

## 8.9 Studies excluded

Studies retrieved but excluded from the review as they did not compare the intervention group to a control group included: Hogue *et al.* (2003), Liu *et al.* (2003), Liu *et al.* (2003),



Odegard *et al.* (2004) and Zeolla and Cerulli (2004). (Hogue, Babamoto *et al.* 2003; Liu, Yiu *et al.* 2003; Odegard, Lam *et al.* 2004; Rodis, Green *et al.* 2004; Zeolla and Cerulli 2004).

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**Table 8.1:** Single-session counselling at the point of dispensing – Extended counselling for prescription medicines compared with usual care

Reference	Level of evidence	Setting	Target population	Education	Evaluable sample & follow-up	Measure	Effect
Yuan et al (2003)	1+	Three medical centres, each with three associated outpatient pharmacies devoted to filling new prescriptions, Southern California, USA	Kaiser Permanente (KP) Medical Care Program members	2 year program, evaluating 3 pharmacist consultation models 1) <u>State Model</u> – drug information topics discussed with pts during consultation, when and how to take medication, potential treatment interaction, side effects 2) <u>KP Model</u> – focuses resources to more comprehensive pharm care for high-risk patients 3) <u>Control Model</u> – Patient requests consultation	5499 patients continuously enrolled and filled at least 1 prescription in any of the models during the 2-year period. Based on the number and type of drugs taken patients were assigned to three risk categories: a) polypharmacy and target medication population; b) target-only population; and c) low-risk population.  Follow up at 2 years	Hospitalisation rates Mortality (level 1 outcome)	KP and State Models both significantly reduced emergency hospital admissions over 2 years compared to controls models in all risk-groups  State Model associated with fewer urgent and emergency admissions.  KP Model associated with lower total mortality per new prescription filled, and significantly lower hospitalisation and mortality in high-risk patient groups

**Table 8.2:** Single-session counselling for long-term therapy

Reference	Level of evidence	Setting	Target population	Education	Evaluable sample & follow-up	Measure	Effect
Grant et al (2003)	1-	A community health centre, Boston, USA	Type 2 diabetes patients who had undergone laboratory testing in the previous 12 months and had visited the clinic in the previous 6 months	Tailored education session covering medication use, help with appointment referrals, and summary of adherence barriers. Medication discrepancies were sent to the GP	232 patients were randomised between intervention (118) and control (114) groups.  The study analysed 62 intervention, 58 control patients  Follow-up at 3 months	Self-reported adherence rates and barriers (level 3 outcome)  Medication discrepancies detected for intervention patients at baseline were assessed for resolution at 3 months (level 3 outcome)  HbA <sub>1c</sub> and cholesterol levels (level 2 outcome)	At follow-up, patients in the intervention arm did not report significantly lower medication use barriers or increased rates of adherence compared with control group.  At follow-up, 60% of the medication discrepancies in intervention group had been resolved. Did not assess for controls.  No difference between intervention and controls, and no change following intervention

**Table 8.3:** Multiple-session education

Reference	Level of evidence	Setting	Target population	Education	Evaluable sample & follow-up	Measure	Effect
Brook et al (2003a)	1-	19 pharmacists in community pharmacies, Utrecht, Netherlands	Patients filling a prescription for 'new episode' non-tricyclic anti-depressant medication	3 coaching sessions over a 6 month period. Patients were informed about appropriate use, benefits and side-effects of medication. Given a take-home video on psychological symptoms of depression using antidepressants	151 patients were randomly allocated 69 intervention 78 control  The study analysed 61 intervention and 74 control patients	Self-rating 90-items (Hopkins) symptom checklist - psychological symptoms (level 1 outcome) Used Intention-To-Treat analysis filling in missing data by last observation carried forward (LOCF) & group mean imputation (GMI)	<u>LOCF analysis</u> 6-month follow-up, intervention pts less depressed and less anxious than controls  <u>GMI analysis</u> No differences in psychological symptoms  <u>Overall</u> The intervention patients did not show a significant improvement in symptoms compared to the control patients
Brook et al (2003b)	1-	19 pharmacists in community pharmacies, Utrecht, Netherlands	Patients filling a prescription for 'new episode' non-tricyclic anti-depressant medication	3 coaching sessions over a 3 month period. Patients were informed about appropriate use, benefits and side-effects of medication. Given a take-home video on psychological symptoms of depression using antidepressants	151 patients were randomly allocated 69 intervention 79 control  The study analysed 61 intervention and 74 control patients  3 month follow-up	Drug attitude index (level 3 outcome)  Patient satisfaction (level 3 outcome)	Intervention group showed a significant improvement in Drug Attitude Index score compared to controls at the 3 month follow-up (P = 0.03)  Intervention group evaluated the coaching by the pharmacist as more positive.

**Table 8.3:** Multiple session education, continued

Reference	Level of evidence	Setting	Target population	Education	Evaluable sample & follow-up	Measure	Effect
Gonzalez–Martin et al (2003)	1–	Outpatient clinic, Santiago, Chile	Children, aged 7–17 with moderate asthma	Written and verbal instructions given to parents and children in intervention group including 30 min face-to-face educational information sessions, plus booklets, follow-up visits at 2 & 9 weeks include reinforcement	21 children recruited to study – 11 in intervention, 10 in control  Follow up at 2 and 9 weeks	Paediatric asthma quality of life questionnaire (PAQLQ) assessing emotions, activity limitations, and symptoms. Questionnaire filled in at baseline, 15 days and 9 weeks after baseline  Spirometry measurement beginning and 9 weeks	No difference between groups at baseline and 2 weeks in PAQLQ. At 9 weeks the intervention group showed a significant improvement in all three scores, control group showed no change  No spirometry differences observed during course of study in either group
Hoffman et al (2003)	1–	GPs and patients in Florida, USA	Patients newly prescribed with anti-depressants	Education of GPs and patients. Monthly letter sent to non-compliant patients and their GPs outlining the importance of compliance	9564 patients and 7021 GPs, follow-up period 180 days	Used pharmacy claims data to determine compliance (level 3 outcome)	Compliance of intervention patients was significantly higher than the control patients at 90 and 180 days

**Table 8.4:** Multiple session education plus active self-monitoring

Reference	Level of evidence	Setting	Target population	Education	Evaluable sample & follow-up	Measure	Effect
Barbanel et al (2003)	1-	Community Pharmacy, East London, UK	Patients receiving routine asthma medication	Self-management advice including a 45-60 min education session, weekly telephone follow-up for 3 months, Control patients received no pharmacist input	24 patients randomly assigned to intervention or control group  Follow up at 3 months	Self-completed North of England asthma symptom scale (level 1 outcome)	Scale improved in intervention group and worsened slightly in control during the study period, the difference between the groups was significant at 3 months.
Sarkadi and Rosenqvist (2004)	1-	Community pharmacists, Uppsala, Sweden	Type 2 diabetes patients, who had been recently diagnosed or treated with insulin for less than 2 years.	Year-long educational program - met once per month. Plus other educational materials, video, game, booklet, Self-monitoring diaries etc. Control assigned to waiting list, following study participated in program	77 patients randomised to intervention (39) and control (38) groups.  The study analysed 33 intervention and 31 control patients  Follow up at 2 years.	HbA <sub>1c</sub> at 0, 6, 12 and 24 months (level 2 outcome)	Intervention group decreased HbA <sub>1c</sub> levels significantly more than control, in short-term follow-up (6 months). At the long-term (24 months) follow-up the intervention patients showed prevailing decrease compared to controls. Levels in the control patients had increased, though not significantly

## 9 Education services for health care professionals

### 9.1 The service

As described by Roughead, Semple and Vitry:

'Pharmacists may provide educational services for health-care professionals on either a one-to-one or a group basis. These services are often provided in the course of 'outreach visits', i.e. visits to the health-care provider in their practice settings, that are conducted with the intention of improving practice. Some educational services for health-care professionals are described as 'detailing'. The term 'detailing' refers to an educational approach based on principles of communication theory and behaviour change. Detailing may involve identifying baseline knowledge and barriers to change, developing focused educational programs, clearly defining objectives, providing authoritative and unbiased sources of information, encouraging involvement of the physician (or health care professional) in the education session, and highlighting and reinforcing important messages.'

### 9.2 Studies included

Studies were included if :

- they described education services provided by pharmacists to medical practitioners or other health-care professionals;
- they described educational outreach visiting or detailing (with or without the provision of additional materials such as prescribing guidelines, promotional leaflets, mailed education campaigns) where a face-to-face visit was conducted by a pharmacist; and
- the intervention was carried out in one of the following settings: community (e.g. general practice), aged-care or other long-term care facilities, or hospital outpatient or ambulatory-care clinics.

To be included, studies had to have included at least one measure of health-care provider performance or a health-care outcome including changes to prescribing (quality and/or quantity), changes in medication use, changes in a health-care provider's medication knowledge, hospital admissions, mortality, morbidity, or surrogate health endpoints.

- Studies were excluded if:
- they only reported health-care providers' satisfaction with or opinion of a service as an outcome measure (level 4 outcomes);
- they described outreach visiting conducted by a multidisciplinary team, or a physician and a pharmacist;
- it was unclear whether a pharmacist had conducted the educational visit; or
- they described interventions directed at physicians prescribing medications for inpatients.



### 9.3 Study design

We found one RCT (level 1 evidence) that was published between 2002 and March 2005 and met our inclusion criteria (Crotty, Whitehead et al. 2004). It evaluated face-to-face pharmacist education of general practitioners and nurses in nursing homes in Australia.

We found a second RCT that evaluated an intervention comprising a series of mail-outs giving feedback to physicians on their prescribing practices and including educational materials. It was not, strictly, a one-to-one intervention (Pimlott, Hux et al. 2003). However, we include this RCT because the intervention provided ongoing education and feedback to the physician.

We also found a report that described an RCT but gave no results (Fretheim, Oxman et al. 2003), and seven non-randomised controlled trials (level 2 method) (Bieszk, Patel et al. 2003; McDonald, Winkle et al. 2003; Siegel, Lopez et al. 2003; de Maat, de Boer et al. 2004; Hilleman, Faulkner et al. 2004; Naunton, Peterson et al. 2004; Gonzales, Corbett et al. 2005). However, in keeping with our use of the highest level of evidence, we confined our review to RCTs that evaluated the effectiveness of pharmacist education targeted at health care professionals.

The study by Pimlott et al assessed educational services directed at physicians working in a community setting (Pimlott, Hux et al. 2003). The study by Crotty et al (2004) evaluated educational services for general practitioners and nurses working in aged-care settings. It was not clearly stated whether the education sessions in the aged care facility were held as one-to-one or group sessions (Crotty, Whitehead et al. 2004). In this study both general practitioner and nurses undertook two education sessions each.

Pimlott et al assessed benzodiazepine prescribing practices, and evaluated the effects of a mail-out of feedback on prescribing practices and educational materials relating to benzodiazepines (Pimlott, Hux et al. 2003). The feedback and educational materials were sent to general practitioners every two months for six months. Physicians in the control group received similar feedback and educational material relating to prescribing anti-hypertensive drugs.

Both studies evaluated the effect of education on the prescribing behaviour of physicians. One was targeted at benzodiazepine prescribing (Pimlott, Hux et al. 2003) and the other assessed wide range of prescription medication including psychotropic drugs, warfarin, aspirin and anti-hypertensives (Crotty, Whitehead et al. 2004).

In addition to assessing the effects of education on prescribing rates, Crotty et al (2004) also examined a range of other health outcomes, including fall rates; blood pressure; Activity of Daily Living (ADL) score; nursing home life-space diameter; and nursing home problem behaviour scale.

Both studies provided physicians with evidence-based guidelines and had a similar follow-up period of six or seven months.

The unit of randomisation in the RCTs was the individual practitioner (Pimlott, Hux et al. 2003) or the nursing home (Crotty, Whitehead et al. 2004). To prevent contamination between the study arms, physicians with the same address as other participants were not included in the study (Pimlott, Hux et al. 2003). Studies were also assessed to have more rigorous methods (level 1+) if independent or blinded researchers were employed to take base-line and follow-up outcome measures. Studies were judged to have significant potential for bias (level 1-) if the pharmacist delivering the intervention assessed the outcome measures. Studies that used administrative databases for determining prescribing or dispensing rates were considered to be less likely to be affected by bias, than those using self-recording by the GP. Crotty et al achieved randomisation by using a computer-generated allocation program (2004) (Crotty, Whitehead et al. 2004). Pimlott et al did not describe the randomisation process that they used, but it did involve the Zelen method whereby randomisation was carried out before consent (2003) (Pimlott, Hux et al. 2003).

## **9.4 Study outcomes**

Changes in prescribing patterns (level 3 outcome) were used as an outcome measure in both of the RCTs. Crotty et al also assessed level 1 patient outcomes including fall rates (2003) (Crotty, Whitehead et al. 2004).

## **9.5 Evidence for effectiveness of practice**

### **9.5.1 Overview**

For the purposes of this review, studies were assessed in the following two categories:

- Educational sessions by pharmacists in the aged-care setting; and

- Educational sessions by pharmacists for medical practitioners in the community setting.

Pharmacist-led education targeting health professionals has previously been shown to improve psychoactive drug use in aged-care settings. In the community setting education of physicians generally targets specific classes of drugs and has been associated with improved medication use.

Two RCTs (level 1+ evidence) were included in this review. One of the RCTs evaluated pharmacist education directed at health-care practitioners in the aged-care setting (level 1+ evidence) (Crotty, Whitehead et al. 2004). The intervention focused on the prevention of falls (level 1 outcome) in residents, as well as psychotropic medication use (level 3 outcome) and

stroke risk reduction. The intervention described in this study had little effect on any of the outcomes measured.

The other RCT assessed feedback and educational material mailed to practitioners in the community setting (level 1+ method) (Pimlott, Hux et al. 2003). Although it did not involve a face-to-face educational session, this study was included because of the high level of evidence that it provided. The intervention included repeated feedback and mail-outs. Only a small change in prescribing patterns resulted from the intervention. It was not considered to be a clinically significant.

Australian data on pharmacist education of health practitioners is limited. One level 1–study found no effect on health outcomes of patients or prescribing habits of practitioners in the aged-care setting. Level 2 and 3 evidence, however, suggests that pharmacist education can have an effect on prescribing rates in the community setting when targeting medication use in specific conditions.

We found no studies that provided an economic assessment of education services provided by pharmacists to health practitioners.

### **9.5.2 Educational sessions by pharmacists in the aged-care setting**

#### *Evidence for efficacy in health outcomes (level 1 outcome)*

Crotty et al (level 1+ evidence) assessed the effect of GP and nurse education on fall rates and blood pressure measurements of patients living in hostels and nursing homes (2003) (Crotty, Whitehead et al. 2004). The baseline measurements of the intervention and control groups were similar. At the completion of the intervention, there was no change in the percentage of residents who had had a fall in the previous three months, and no significant change in blood pressure measurements, in either the intervention or control group.

There was a high rate of patient attrition and staff turnover during the seven-month study period, perhaps accounting for the lack of effect of the education on health outcomes.

#### *Evidence for efficacy for changes in prescribing (level 3 outcome)*

Prescribing rates of psychotropic medication, warfarin, aspirin and anti-hypertensive medications were assessed (Crotty, Whitehead et al. 2004). No changes in the patterns or rates of the prescription of these medications were observed in either the intervention or control group. There was a significant increase in the 'as required' use of anti-psychotropic medications in the intervention group at follow-up.

### **9.5.3 Educational sessions by pharmacists to medical practitioners in the community setting**

#### *Evidence for efficacy for changes in prescribing (level 3 outcome)*

Pimlott et al. (level 1+ method) examined the effect of multiple mail-outs to general practitioners on benzodiazepine prescription rates (2003) (Pimlott, Hux et al. 2003). The mail-out included feedback for practitioners on their benzodiazepine prescribing patterns as well as evidence-based guidelines on the use of benzodiazepine medication. The percentage of prescribed benzodiazepines that were long-acting decreased slightly in the intervention group and increased slightly in the control group, but the changes were not considered clinically significant. There was no significant difference over the study period in either combination prescribing of benzodiazepines or in prescriptions for long-term benzodiazepine therapy.

## **9.6 Economic assessment**

No economic assessments of pharmacist-led education of health professionals were found.

## **9.7 Australian research**

One of the RCTs that we included in this chapter was carried out in Australian nursing homes (Crotty, Whitehead et al. 2004). A further two Australian studies were found with non-randomised study designs (level 2 method) (McDonald, Winkle et al. 2003; Naunton, Peterson et al. 2004). These two publications are summarised in Table 9.3.

The Australian RCT evaluated pharmacist education directed at health practitioners in the aged-care setting (level 1+ evidence) (Crotty, Whitehead et al. 2004). The intervention focussed on the prevention of falls (level 1 outcome) in residents, as well as psychotropic medication use (level 3 outcome) and stroke risk reduction practices. The intervention described in this study had little effect on any of the outcomes measured, highlighting the challenges of delivering an evidence-based intervention in a complex patient care setting.

One of the studies that provided level 2 evidence was undertaken in general practice settings in Tasmania (Naunton, Peterson et al. 2004). GPs and community pharmacies were sent educational material. GPs were then visited by the pharmacist conducting the study to discuss corticosteroid-induced osteoporosis. All GPs in southern Tasmania were included in the intervention group, and northern Tasmania was used as the control. Following the intervention, the number of patients receiving osteoporosis preventative treatment in the intervention group was significantly increased compared to the control region. In particular there was an increase in the prescription of calcium and raloxifene among prednisolone users.

The other level 2 trial was carried out in Brisbane and assessed the effect of academic detailing visits to general practitioners addressing the pharmacological management of heart failure in phase 1, and chronic pain associated with osteoarthritis in phase 2 (McDonald, Winkle et al. 2003). Following phase 1, use of non-steroidal anti-inflammatory (NSAID) medication decreased, and as a result of phase 2, long-acting NSAID use decreased and the use of low-dose tricyclic antidepressants increased. These changes were consistent with the pharmacist-delivered message. Inconsistent with the message, angiotensin-converting enzyme inhibitor prescribing did not change in phase 1.

## 9.8 Comment

Two RCTs (level 1 evidence) that evaluated educational services provided by pharmacists to health practitioners were published between 2002 and March 2005. Both of these studies measured the effect of the education with respect to changes in prescribing (level 3 outcome). Only one of these studies also evaluated patient outcomes (Crotty, Whitehead et al. 2004).

One of the trials evaluated pharmacist education directed at health practitioners aged-care settings (level 1+ evidence) (Crotty, Whitehead et al. 2004). The intervention focused on the prevention of falls (level 1 outcome) in residents, as well as psychotropic medication use (level 3 outcome) and stroke risk reduction practices. The intervention described in this study had little effect on any of the outcomes measured.

The other study assessed feedback and educational material mailed to practitioners in the community setting (level 1+ method) (Pimlott, Hux et al. 2003). Despite not involving a face-to-face educational session, this study was included in the review because of the high level of evidence that it contributed, and the fact that intervention included repeated feedback and mail-outs. Only a small change in prescribing patterns resulted from the intervention, and this was not considered to be a clinically significant change.

Collectively, the level 1 studies did not demonstrate an effect of pharmacist education in either aged-care or community settings. This finding differs from the conclusions reached in the previous review. Studies included in the previous review demonstrated that pharmacist education resulted in:

- significant improvements in prescribing without adversely affecting patient outcome measures in the aged-care setting, and
- a modest effect on medication use in the community setting, where the intervention was directed at specific types of drugs and where use was known to be inappropriate.

## 9.9 Studies excluded

Three studies were excluded from the review as the education service was conducted by a multi-disciplinary team or it was not clear if a pharmacist conducted the education session (Feucht and Rice 2003; Majumdar, Guirguis et al. 2003; Witt, Knudsen et al. 2004).

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**Table 9.1:** Education session by pharmacists in the aged-care setting

Reference	Level of evidence	Setting	Intervention	Evaluable sample	Study outcomes	Results
Crotty et al. (2004)	1+	Aged-care setting, including hostels and nursing homes (NH), Adelaide, Australia	2 outreach visits by pharmacist educating: (1) GPs (30min session) Including evidence based guidelines on falls prevention; and (2) nurses (4h session) on management of dementia behaviour, medication management, and falls prevention	10 hostels 10 NH  1 <sup>st</sup> audit 897 patients, 2 <sup>nd</sup> audit 902 (202 from 1 <sup>st</sup> not available for 2 <sup>nd</sup> )  98 GPs involved in study, 61 intervention, and 37 control	<u>Primary outcome</u> 3 month fall rate prior to follow-up assessment  <u>Secondary Outcomes</u> Blood pressure Psychotropic medication  Prescription of warfarin, aspirin, and anti-hypertensives  <u>Other outcomes</u> 12 month fall rate, rate injurious falls, Activity of Daily Living Score, Nursing Home Life-Space Diameter and Nursing Home Problem Behaviour Scale	No difference between intervention and control  No change No change, except for a significant increase of 'as required' antipsychotics in the intervention group following intervention.  No change  No results for these outcomes measures were mentioned in the report

**Table 9.2:** Education session by pharmacist to medical practitioners in the community setting

Reference	Level of evidence	Setting	Intervention	Evaluable sample	Study outcomes	Results
Pimlott et al (2003)	1+	Primary care physicians prescribing benzodiazepines, Ontario, 1998-1999	Mail out of prescribing feedback and evidence-based education materials - every 2 months for 6 months	168 GPs in intervention group, 206 in control group	Benzodiazepine prescribing rates	Small reduction in the percentage of long-acting benzodiazepines prescribed in intervention group from baseline levels compared to a small increase in the control group. This change represented an improvement in the intervention group compared to the control (p = 0.036), but was not clinically significant. There was no change in combination benzodiazepine prescribing or long-term therapy.



**Table 9.3:** Education of health professionals in Australia

Reference	Level of evidence	Setting	Intervention	Evaluable sample	Study outcomes	Results
Naunton et al (2004)	2	General practices in southern Tasmania, Australia	Academic detailing (15 min) visits to all GPs and pharmacists in southern Tasmania on osteoporosis preventative therapy. Education materials and guidelines posted.	200 GPs and 69 pharmacies were visited, (Northern Tasmania used as control)	Prescription data on osteoporosis preventative therapy	Increased use of osteoporosis prevention strategies in long-term oral corticosteroid users.
McDonald et al (2003)	2	General practice setting, Brisbane, Australia	Two academic detailing visits to general practitioners. An initial 30min visit and a 15min follow up 6–8 weeks later conducted by teaching-hospital clinical pharmacists. The education included oral presentations, and written resource material	115 GPs with three or more patients enrolled in intervention arm of the TEAMCare Health Coordinated Care Trial.	PBS data on number of prescriptions for: <u>Heart Failure</u> Oral NSAID  ACE inhibitor  <u>Osteoarthritis</u> Paracetamol  Long-acting oral NSAIDs  Tricyclic anti-depressants	<u>Heart Failure</u> NSAID decreased (84 pre-study, 53 post-study), consistent with message. No change in ACE inhibitor prescribing, was inconsistent with message advocating ACE inhibitors for all patients  <u>Osteoarthritis</u> Paracetamol unchanged, but used in large proportion of study group. Long-acting oral NSAIDs decreased (35 vs 19), consistent with message Tricyclic anti-depressants increased (42 vs 85), consistent with message

## 10 Drug information services

### 10.1 The service

Drug information services are specialised services that provide drug information and answer general and specialist enquiries concerning medicines and their use.

### 10.2 Studies included

We included studies that focused on the provision of a stand-alone drug information service, i.e. drug information provided separately from another pharmacist service. Studies must have utilised patient outcomes as endpoints.

Studies that incorporated the provision of drug information as part of the education provided in the course of medication supply, pharmaceutical care or medication review services are covered elsewhere in this report.

### 10.3 Study design

We could find no RCTs (level 1) that evaluated the effect of drug information services on patient outcomes and that had been published since the previous review. We found two descriptive studies (level 3). One had a retrospective design (Maywald, Schindler et al. 2004), and the other was a prospective survey (Hayashi, Mukai et al. 2003). They are summarised in Table 10.1. The retrospective study evaluated a drug information service in Germany (Maywald, Schindler et al. 2004), and prospective study evaluated a service in Japan (Hayashi, Mukai et al. 2003).

A systematic review examining the effect on patients of drug information given to health care professionals provides a critical assessment of methodological issues (Spinewine and Dean 2002). This review does not draw conclusions on the value and effect of drug information services, but it does provide a summary of publications on the topic and their findings. Its authors identified literature by searching Medline, EMBASE and International Pharmaceutical Abstracts from 1970 – 2001. Nine studies were found. They were all descriptive, and none used a control group. The majority used a retrospective design. The majority of studies were carried out in North America. Two were undertaken in the UK (Spinewine and Dean 2002).

## 10.4 Study outcomes

Patient outcomes were determined by questionnaire and assessed patients' satisfaction with services (level 4); patient characteristics; or the types of information requested. The more recent studies assessed the actual effects of the information using an expert panel (Spinewine and Dean 2002). Conclusions were difficult to draw because most of the studies did not provide enough information to comment on the potential patient outcome.

## 10.5 Evidence for effectiveness of practice

No controlled studies have been undertaken assessing the effect of drug information services.

The outcomes assessed by the uncontrolled studies were of the lower levels only, but indicated improved patient knowledge and understanding of medications (Maywald, Schindler et al. 2004). A large proportion of interventions that were assessed led to a positive patient outcome (Spinewine and Dean 2002). High levels of patient satisfaction with services were recorded (Hayashi, Mukai et al. 2003).

## 10.6 Economic assessment

We found no economic assessments of the provision of drug information services.

## 10.7 Australian research

No Australian studies that evaluated pharmacist-provided drug information services were found.

## 10.8 Comment

As noted in the review by Roughead, Semple and Vitry (2003), there has been no rigorous research to demonstrate the effect of drug information services on patient outcomes (Roughead, Semple et al. 2003). Studies that have been carried out did suggest that drug information services were likely to have a positive influence on patient outcomes. There has been no change in the level of evidence available since 2002.

Studies evaluating the effect of a service should ideally be carried out experimentally, contain a control group, and compare outcomes before and after the intervention. RCTs may be impracticable because the provision of drug information is an essential part of health

care and cannot ethically be withheld from members of a control group who might request it.

## References

Hayashi, S., T. Mukai, et al. (2003). "Patient perspectives on provision of drug information services in japan." Yakugaku Zasshi – Journal of the Pharmaceutical Society of Japan **123**(8): 697–706.

Maywald, U., C. Schindler, et al. (2004). "First patient-centered drug information service in Germany – A descriptive study." Annals of Pharmacotherapy **38**(12): 2154–2159.

Spinewine, A. and B. Dean (2002). "Measuring the impact of medicines information services on patient care: methodological considerations." Pharmacy World & Science **24**(5): 177–181.

**Table 10.1:** Drug information services

Reference	Level of evidence	Setting	Evaluable sample	Study outcomes	Results
Maywald <i>et al.</i> (2004) (Maywald, Schindler <i>et al.</i> 2004)	3	Drug information and therapy information centre, Germany	2049 calls to the Centre made over 24 months	Type of enquiry  Medication Knowledge  Visits to physician	The majority of callers wanted more information on their medication such as adverse drug reactions (31%) and drug interactions (27%).  Medication knowledge improved in 81% of callers  18% of callers reported a reduction in physician visits as a result of the service
Hayashi <i>et al.</i> (2003)	3	Drug information service, Japan	Calls made to the service over a 9 month period were evaluated	Type of enquiry    Patient satisfaction	The majority of callers wanted more information on their medication such as Efficacy and indications (45%), adverse drug reactions (45%) and dosage information (15%).  The majority of patients were satisfied with the service.
Spinewine and Dean (2002) (Spinewine and Dean 2002)	3	Systematic review of the “ <i>impact of medicines information services on patient care</i> ”, published between 1970–2001	Nine papers identified, all descriptive (level 3)	Included: use of information; action taken; and patient outcome.	Results of the available studies indicated that Medicines Information Services provided effective information to health care practitioners, and in many cases resulted in improved patient outcomes.

# 11 Pharmacist participation in therapeutic decision-making

## 11.1 The service

In their review, Roughead, Semple and Vitry (2003) examined the effectiveness of pharmacist participation in therapeutic decisions. This involves pharmacists collaborating as part of a team with physicians and other health professionals, and taking an active role in the decision-making process, rather than simply providing a service or carrying out a medication review and reporting or making recommendations to the prescriber.

## 11.2 Studies included

We adopted the inclusion criteria used by Roughead, Semple and Vitry (2003).

We concentrated on studies that provided level 1 evidence, that examined at least one patient outcome (level 1, 2 or 3 outcomes). We also describe an Australian study that measured patient outcomes in their research, but only reported pharmacist outcomes (level 4).

We excluded studies that assessed services for hospital inpatients. We also excluded studies where pharmacists were part of a multi-disciplinary team and it was impossible to distinguish their effect on outcomes.

## 11.3 Study designs

We found five RCTs (level 1) in which an intervention group received services that involved pharmacists in collaborative or partnership decision-making roles, and a control group received the care usually provided by a clinic or physician. Four of these RCTs found were done in the USA, and one in Australia.

## 11.4 Study outcomes

Various combinations of outcomes were examined in the five RCTs. They comprised level 1 patient outcomes (such as changes in severity of depression, physical and mental functioning summaries, and QOL measures); level 2 patient outcomes (such as proportion of patients achieving blood pressure targets, and appropriateness of and adherence to anti-depressant or blood pressure medications); level 3 patient outcomes (such as knowledge); and level 4 outcomes (such as patient satisfaction).

## 11.5 Evidence for the effectiveness of the service

The four US studies all showed that pharmacist decision-making partnerships did not produce improved clinical patient outcomes, in comparison with usual standard primary health care. Three of the studies followed patients for six months, and one followed patients for 12 months.

Three of the four US studies however, did demonstrate that when compared to regular primary health care, pharmacist decision-making partnerships delivered greater improvements in some intermediate patient outcomes (levels 2 and 3). These outcomes included patients' adherence to medication regimens (for treating depression and blood pressure) (Adler, Bungay et al. 2004) (Finley, Rens et al. 2003); blood pressure control and blood pressure targets (Borenstein, Graber et al. 2003); and patient satisfaction (Finley, Rens et al. 2003).

The authors of one of these three US studies (Adler, Bungay et al. 2004) suggested that policy makers should differentiate between two categories of patients with depression that was not effectively controlled: (i) those who could benefit from standard drug therapy but had not yet begun it, and (ii) those who were already receiving treatment and were not improving. They considered that the patients in category (i) had more potential to benefit from pharmacist involvement in helping them to begin and continue treatment, while the patients in category (ii) may require more complex treatment regimens and may not improve despite treatment.

The fourth US study (Capoccia, Boudreau et al. 2004) found no additional benefit from a pharmacist decision-making partnership with respect to clinical outcomes (depression symptoms) or intermediate outcomes (medication adherence and patient satisfaction), when compared to the usual care provided in a primary care clinic. However, patients' symptoms of depression improved significantly from baseline measures in both the intervention and the control groups, and medication adherence and patient satisfaction were also very high in both groups. The authors' explanation was that patients in the control group already received high-quality care in an academic setting (University of Washington Family Medical Centre) so the intervention could not provide any incremental benefit.

There was one other study (Wong, Campion et al. 2004) which comprised a large RCT in which elderly patients received shared care from GPs and community pharmacists. It involved 20 general practices (each linked to some three pharmacies) in 5 Primary Care Trusts in Yorkshire, and aimed to recruit 700 patients. However, results had not been published at the time of writing.

## 11.6 Economic assessment

One of the US studies examined the potential economic effect of pharmacist–physician collaborations (Borenstein, Graber et al. 2003). This study reported that the average provider–visit costs per patient were lower for the intervention group than the control group, and that the difference was statistically significant. The difference was due to a lower average number of visits to the primary care physician during the study period. However, there was some indication of a trend towards more visits overall to providers (e.g. physicians and pharmacists) in the intervention group ( $p=0.06$ ).

No statistically significant differences were noted in average monthly drug costs between the two groups at end of study. However, there was some indication of a trend (not statistically significant over the time period studied) towards greater increases in drug costs in the pharmacist–physician collaboration group compared to the usual care group \$11.31 vs \$4.25 ( $p=0.12$ ).

## 11.7 Australian research

We found only one Australian study on pharmacist decision–making partnerships (Nissen and Tett 2002). It examined the effectiveness of a new model of integrated care in which community pharmacists collaborated with GPs and other health care providers in rural and remote settings. The pharmacist role included providing information to patients on their diseases and medications, monitoring parameters such as blood pressure and blood glucose levels, providing patients with encouragement and general support, and coordinating or organising other services such as referrals to a dietitian or physiotherapist, as well as addressing medication–specific issues, providing dose aids, and conducting medication reviews.

However, although the Australian study was an RCT designed to assess the effect on patient outcomes, the only available published report focused on the pharmacists' role and their reported experience. (We contacted the author to ask about other existing or intended publications reporting on patient outcomes, but had not received a reply at the time of writing.)

Some of the pharmacists participating in the Australian study commented that participation in the intervention required extra time and they lacked adequate staff and locum relief to assist them. They also reported that some of their patients were at first unsure about receiving this type of intervention from a pharmacist, but once trust was gained the patients were very satisfied with the additional service. Local GPs reportedly gave a high level of support.



The positive outcomes reported by pharmacists were recognition by consumers and health care providers of the potential expanded role of pharmacists, and pharmacists' enjoyment of the opportunity to use their clinical knowledge and skills

## 11.8 Comment

The review by Roughead, Semple and Vitry (2003) found evidence from two US RCTs that pharmacist involvement in therapeutic decision making led to improved patient outcomes, as measured by the surrogate endpoints of cholesterol levels and blood pressure (level 2 patient outcomes).

Our review confirms and reinforces these findings. We found evidence from three further RCTs that pharmacist involvement in therapeutic decision-making can lead to greater improvements in patient outcomes than usual care, as measured by the surrogate endpoints of adherence to medication regimens, blood pressure control, and the achievement of blood pressure targets, and patient satisfaction (level 2 and 3 outcomes).

However, we also found evidence from one RCT that, when the quality of physician-only patient care and monitoring is high, pharmacist involvement in therapeutic decision-making is unlikely to produce additional benefit.

Neither the RCTs examined in the review by Roughead, Semple and Vitry (2003) nor those that we reviewed showed any benefits of pharmacist involvement in therapeutic decision-making in relation to clinical (level 1) patient outcomes. However, this may in part be in part due to the relatively short follow-up periods of the trials that showed a positive effect on surrogate endpoints (six months).

## References

Adler, D. A., K. M. Bungay, et al. (2004). "The impact of a pharmacist intervention on 6-month outcomes in depressed primary care patients." General Hospital Psychiatry **26**(3): 199–209.

Borenstein, J. E., G. Graber, et al. (2003). "Physician-pharmacist comanagement of hypertension: a randomized, comparative trial." Pharmacotherapy **23**(2): 209–16.

Capoccia, K. L., D. M. Boudreau, et al. (2004). "Randomized trial of pharmacist interventions to improve depression care and outcomes in primary care." American Journal of Health-System Pharmacy **61**(4): 364–72.

Finley, P. R., H. R. Rens, et al. (2003). "Impact of a collaborative care model on depression in a primary care setting: a randomized controlled trial." Pharmacotherapy **23**(9): 1175–85.

Nissen, L. M. and S. E. Tett (2002). "Community pharmacists improving health outcomes in rural and remote Queensland." Australian Pharmacist **21**(11): 874–876, 878–880.

Wong, I., P. Campion, et al. (2004). "Pharmaceutical care for elderly patients shared between community pharmacists and general practitioners: a randomised evaluation. RESPECT (Randomised Evaluation of Shared Prescribing for Elderly people in the Community over Time) [ISRCTN16932128]." BMC Health Services Research 4(1): 11.

**Table 11.1** Randomised controlled trials of pharmacist involvement in therapeutic decision-making

Reference	Level	Setting	Subjects, intervention	Evaluable sample and follow-up	Study outcomes	Results
Adler et al, 2004	1 RCT	Primary care practices in 9 sites, Boston, Massachusetts USA	<p>Depressed patients who screened positive manic depressive disorder or depressive disorder in self-administered survey (regardless whether currently using Anti-depressive medication).</p> <p>Pharmacist consulted with primary care practitioner (PCP) and patient to select medication, dose, and regimen – in line with AHCPR depression guidelines. Pharmacist obtained thorough medication history, assessed patients’ regimen for side-effects and interactions, monitored drug efficacy and toxicity, educated patient, encourages to start the maintain anti-depressive (AD) therapy, and facilitated communication with PCP (min contact 9 times over 18 months). Intervention compared to standard PCP care.</p>	<p>Intervention n=268 (94% follow-up);</p> <p>Control n=265 (89% follow-up)</p> <p>6 months</p>	<p>Self-reported rates of AD use (level 2), changes in severity of depression (level 1), changes in physical and mental summaries in SF-12 (level 2)</p>	<p>Differences between intervention and control in AD medication use at 6 months were not statistically significant (when examined as whole group).</p> <p>Subgroup analysis – for patients not on ADs at study entry, rates of AD use were higher in the intervention group at 3 and 6 months. However, the study did not demonstrate a difference in the mental health outcomes between the intervention and control group overall, or among patients not on ADs at study entry.</p> <p>Authors suggest policy makers need to differentiate between categories of “untreated” depression: 1) those not yet screened who could benefit from standard therapy (potential for benefit from pharmacist intervention to assist them to begin and continue AD treatment); and 2) those receiving treatment but not improving (may require more complex treatments or may not improve despite treatment)</p>

Reference	Level	Setting	Subjects, intervention	Evaluable sample and follow-up	Study outcomes	Results
Capoccia KL et al, 2004.	1 RCT	Primary care clinic in academic setting (Uni Washington Family Medical Centre)	<p>Patients diagnosed with new episode of depression and started on antidepressant (AD) medication.</p> <p>Pharmacist intervention in collaboration with Primary Care Physician (PCP) and staff psychiatrist (Enhanced Care or EC) compared to usual care (UC).</p> <p>EC involved an additional follow-up by a clinical pharmacist or resident, in conjunction with PCP and study psychiatrist, consisting of weekly telephone calls for 4 weeks, phone contact every 2 weeks until week 12, and a call every other month during months 4-12. Patients were also encouraged to visit PCP in weeks 4 and 12.</p> <p>At each contact, symptoms and medication concerns were addressed. Support and education provided, as well as dosage adjustment and management of side effects. Medication refill authorisation provided, access to patient assistance programs facilitated, changes in time of dose, medication change or discontinuation if required, plus other pharmacotherapy for insomnia or sexual dysfunction as needed. Appointments with mental health providers facilitated as required.</p>	<p>EC n=41 UC n=33</p> <p>Baseline, 3, 6, 9 and 12 months.</p>	<p>Depression symptoms at baseline, 3, 6, 9 and 12 months (level 1).</p> <p>Also, AD medication adherence (level 2), patient satisfaction and clinic visits (level 4).</p>	<p>No overall difference between EC and UC in study outcomes. Depression symptoms improved significantly in both groups from baseline to 3 months and beyond. Also, medication adherence and patient satisfaction were high in both the UC group and the EC group, and study did not show significant difference between the two.</p> <p>Anticipate that usual care in the academic setting is already very high quality, and thus additional collaborative care from pharmacist (EC) did not give additional benefit.</p>

Reference	Level	Setting	Subjects, intervention	Evaluable sample and follow-up	Study outcomes	Results
Borenstein JE et al, 2003	1 RCT	Group medical practice affiliated with large community hospital, USA	<p>Patients with hypertension.</p> <p>Compared physician pharmacist comanagement (PPCM) with usual care (UC).</p> <p>Evidence-based treatment algorithm / guideline for management of hypertension developed by multidisciplinary team of physicians, pharmacists and nurses. Guideline used as basis for physician education sessions conducted by pharmacists and principal investigator. Patients in intervention group attended pharmacist run clinic – measured BP and assessed patients medication, adherence, side effects, lifestyle – then called physician with recommendations based on guideline.</p>	<p>PPCM n=635 UC n=637</p> <p>12 months</p>	<p>Difference between PPCM and UC groups in changes in blood pressure over 12 months (level 2).</p> <p>Differences between groups in proportion of patients achieving goal BP (level 2).</p> <p>Also assessed costs of antihypertensive drugs, and total provider costs (economic).</p>	<p>Difference in changes in BP and the greater reduction in Systolic BP in the PPCM group compared to the UC group was statistically significant. (22mm Hg compared to 11 mm Hg).</p> <p>Difference in proportion of patients achieving BP goals also statistically significant. BP goals achieved in 60% PPCM and 43% of UC patients.</p> <p>Average provider visit costs/patient were lower for PPCM than UC patients (statistically significant difference) – resulting from lower average number of visits to primary care physician during the study.</p> <p>However, start of a trend towards more provider (physician and pharmacists) visits in the PPCM group was indicated (p=0.06).</p> <p>No statistically significant differences noted in average monthly drug costs between groups at end of study (although beginnings of a trend towards greater increase in drug costs from baseline was observed in PPCM versus UC \$11.31 vs \$4.25, p=0.12).</p>

Reference	Level	Setting	Subjects, intervention	Evaluable sample and follow-up	Study outcomes	Results
Finley, PR et al, 2003	1 RCT	Large non-profit medical centre (staff model) in San Francisco, California.	<p>Patients diagnosed with depression starting anti-depressive medication.</p> <p>Interdisciplinary treatment model (Medication Alliance Clinic) implemented at the HMO facility. Care manager (or pharmacist) conducts intake interview after randomisation to intervention to assess severity of psychopathology, stressors and predisposing factors and medical, psychiatric and drug therapy histories.</p> <p>Care manager / pharmacist conducts a patient education undertaken, titrates dose of antidepressant drugs, prescribes ancillary drugs if required (eg sleeping pills) but change of antidepressant drugs requires approval of primary care provider. Follow up conducted by phone and clinic appointments - final appt 24 weeks.</p>	<p>Intervention n=75</p> <p>Control n=50</p> <p>6 months</p>	Adherence to AD drug therapy (level 2), clinical and functional severity (level 1), resource utilisation (economic), and patient satisfaction (level 4).	<p>At 6 months, there was significantly greater adherence to AD medication in the intervention group, and significantly greater patient satisfaction.</p> <p>Both groups showed clinical improvement, but no significant difference in clinical function was found between the intervention and control.</p>

Reference	Level	Setting	Subjects, intervention	Evaluable sample and follow-up	Study outcomes	Results
Nissen LM & Tett SE, 2002	1 RCT	General practice + community pharmacy in Queensland (Blackall, Biloela, Stanthorpe)	<p>Rural and remote patients with complex health care needs.</p> <p>Intervention = new model of care involving community pharmacist in care integration, in collaboration with the GP, using care plan proformas.</p> <p>Patient underwent care planning as collaborative activity with pharmacist and GP. This included health assessment, medication management review, care plan development and implementation. Care plans used disease specific care plan proformas designed for the project (now published through Pharmacy Guild).</p>	<p>Intervention n=50</p> <p>Control n=49</p> <p>6 months</p>	<p>This paper focused on the role of the pharmacist and their reported benefits and outcomes (level 4)</p> <p>Patient outcomes not reported in this paper (emailed author to inquire re other publications of this RCT)</p>	<p>Pharmacists role went well beyond medication issues – eg:</p> <ul style="list-style-type: none"> <li>– providing information on disease or medication,</li> <li>– directly monitor /check patient such as BP, glucose</li> <li>– encouragement / general support</li> <li>– medication issues such as dose aids, medication review</li> <li>– coordination of other services eg dietician, physiotherapist.</li> </ul> <p>Difficulties for pharmacists – used up extra time and lack of staff / locum relief for participation. Some patients at first unsure about intervention from a pharmacist and not familiar with their level of expertise in this role – once trust gained most very satisfied with the additional service. Support from GPs was high.</p> <p>Positive outcomes for pharmacists – recognition by consumers and other health care providers of their potential role in care integration, and was an opportunity to use their clinical knowledge and skills</p>

## **12 Pharmacist involvement in non-prescription medicine use**

### **12.1 The service**

In their review, Roughead, Semple and Vitry (2003) examined the evidence for the additional benefit that pharmacists can provide in achieving quality use of medicines by giving advice and assistance and making recommendations regarding non-prescription medication use.

### **12.2 Studies included and evidence for effectiveness of practice**

Like Roughead, Semple and Vitry (2003), we searched for controlled studies that assessed patient outcomes associated with pharmacist involvement in the provision or use of non-prescription medicines, not prescribed by another health practitioner.

### **12.3 Study designs**

We found no controlled studies on this topic. However, we found two pilots of cohort studies that developed and tested relevant models (Table 12.1).

The first study was a pilot test of the feasibility of conducting pharmaco-vigilance of over-the-counter (OTC) medicines in community pharmacies in Scotland and England, and an exploration of related methodological issues (Layton, Sinclair et al. 2002) This study identified several challenges in recruiting pharmacies to participate in such research, particularly with regard to the additional time and/or staff required.

The second study developed and pilot-tested a model or algorithm for community pharmacies to identify and treat misuse or abuse of OTC drugs (Fleming, McElnay et al. 2004). Although the algorithm was useful in helping pharmacists to identify patients who were likely to use (or misuse) OTC drugs, recruiting such patients into a formal study proved unfeasible.

### **12.4 Study outcomes**

We were unable to add any evidence to the one RCT identified previously by Roughead, Semple and Vitry (2003), which reported positive outcomes (health-related quality of life) resulting from pharmacists being trained to provide counselling to patients with dyspepsia, compared to usual pharmacy care.



Clearly, more research is needed to assess the effect of a pharmacist intervention on patient outcomes following the purchase of non-prescription medications. There are however, various practical challenges facing researchers and pharmacists seeking to collect data on patient outcomes following the purchase of non-prescribed medications.

## References

Fleming, G. F., J. C. McElroy, et al. (2004). "Development of a community pharmacy-based model to identify and treat OTC drug abuse/misuse: a pilot study." Pharmacy World & Science **26**(5): 282-8.

Layton, D., H. K. Sinclair, et al. (2002). "Pharmacovigilance of over-the-counter products based in community pharmacy: methodological issues from pilot work conducted in Hampshire and Grampian, UK." Pharmacoepidemiology & Drug Safety **11**(6): 503-13.

**Table 12.1:** Studies of pharmacist involvement in non-prescription medicine use

Reference	Level	Setting	Subjects, intervention	Evaluable sample and follow-up	Study outcomes	Results
Fleming GF, et al, 2004	2 Cohort	UK pharmacies	<p>Customers purchasing opioid, antihistamine and laxative products from 2 pharmacies.</p> <p>Development and pilot of a harm minimisation model (algorithm) which is a structured attempt by community pharmacists in the UK to address the abuse/misuse of OTC medication.</p> <p>First UK study aimed at prospectively identifying rates of misuse and abuse.</p>	Two pharmacists, identified total of 18 clients over 1 month, suspected of misusing or abusing OTC medications.	Usefulness of the model to identify clients suspected of misuse or abuse of OTC medicines, number of clients identified, clients approached by pharmacist regarding potential misuse/abuse, and subsequent response and outcomes of intervention.	<p>Records of sales as an identification process was a useful tool.</p> <p>Of the 18 clients suspected of abusing or misusing OTC products, 14 were approached by the pharmacists. Both reported it was easier to approach those suspected of misusing products (incorrect use for medical purpose) than those abusing products (non-medical purpose eg mind altering purpose).</p> <p>Pharmacists' advice was not always accepted and some negative reactions from clients were reported. Some sales were eventually refused (figures not given).</p> <p>Neither pharmacist reached the stage of formally enrolling clients into the pilot project. Both reported they believed these clients would be unwilling to provide the necessary details or complete questionnaires. Both thought that communication training received had been useful, but more intensive training on this aspect was required.</p>

Reference	Level	Setting	Subjects, intervention	Evaluable sample and follow-up	Study outcomes	Results
Layton D et al, 2002	2 Cohort	Community pharmacies in Scotland and England, UK	<p>Customers purchasing ibuprofen from pharmacy for their own use, aged 18 or over and able to give informed consent</p> <p>Aim was to explore feasibility and potential for pharmaco-vigilance studies of OTC medicines in a community pharmacy setting. Intervention was the recruitment of customers into a study monitoring the dose, pattern of use, symptoms, and advice sought in relation to ibuprofen.</p> <p>Following piloting of various recruitment methods in Scotland, a shop bag method of recruitment was selected for the UK follow-up (staff inserting a patient information leaflet, recruitment questionnaire and reply paid envelope) - this was method was selected because it required minimal staff time, although it was the least effective in response rates.</p> <p>In addition, a gratuity of 5 UK pounds per patient was paid to each participating pharmacy in England (had not been paid in Scotland in earlier pilot)</p>	<p>1021 eligible customers recruited (466 in England and 555 in Scotland)</p> <p>Exposure variables assessed at 1 week, and 2 and 6 months on dose and pattern of use (past and present) of ibuprofen.</p>	<p>Pharmacist – participation in the study, and their feedback on barriers and the feasibility of the study, and their rates of recruiting customers (level 4).</p> <p>Patients – study monitored symptoms experienced, reasons for discontinued use, and action taken for symptoms (level 1).</p>	<p>Just under half the pharmacies approached participated in the study.</p> <p>Pharmacists felt that ‘shop bag’ method of recruitment was acceptable for staff, however some felt that a more pharmacist involvement would have been preferable as the minimalist approach could reduce the effect of the pharmacist on outcomes.</p> <p>Time, staff shortages and longer working hours were factors limiting participation in such research. Remuneration was not considered to be a major contributing factor on customer recruitment, and the Scottish pharmacies that were not paid reported higher customer recruitment rates using the shop-bag method (18.1%) than those in the England (6.5%).</p> <p>Around 1 in 20 patients reported at 7 days that ibuprofen had led to some symptoms. At 6 months they were again asked about selected symptoms in the last 7 days. Most of those with symptoms did not consult a health care professional and those who did, most consulted their GP.</p>

## 13. Smoking cessation services

### 13.1 The service

Smoking cessation programs are offered by community pharmacists to help their customers quit smoking. The programs typically include training of pharmacists, patient assessment, counselling, monitoring, and ongoing follow-up. Nicotine replacement therapy is often included. The programs are offered to hospital outpatients or carried out within community pharmacies.

### 13.2 Studies included

Our inclusion criteria were the same as those used in the review by Roughead, Semple and Vitry (2003). We included studies evaluating programs that were designed to increase smoking cessation rates, that were run by pharmacists, and that were based either in the community or in hospital outpatient settings.

### 13.3 Study design

We found two systematic reviews that addressed smoking cessation programs in community pharmacies.

The more recent of these, by Sinclair et al was published by the Cochrane Collaboration in 2005. This review concentrated on community pharmacy clients who were smokers and wished to stop. The review involved a search of MEDLINE, SCISEARCH, PsychINFO, EMBASE, and the Cochrane Tobacco Addiction Group Trials Register to March 2003, in order to identify RCTs of interventions by community pharmacy personnel promoting smoking cessation amongst their clients. Hand searching was also carried out on conference abstracts. The review did not include controlled pharmaceutical trials of the use of nicotine replacement therapy in a community pharmacy setting.

A previous review, published by Blenkinsopp et al in 2003, examined the effectiveness of pharmacy-based interventions in reducing risk behaviours and risk factors for coronary heart disease. It involved a search of MEDLINE, EMBASE, Cochrane Library and International Pharmaceutical abstracts from January 1990 to February 2001. Hand searches of a range of relevant journals and conference abstracts were also done for the same period.

Both of these reviews covered two RCTs that had also been examined in the review by Roughead, Semple and Vitry (2003). These were by Maguire et al (2001), and Sinclair et al (1998).

## 13.4 Study Outcomes

In summary:

Maguire et al 2001, reported a significant improvement in smoking cessation rates in patients who had received counselling and follow-up from pharmacists, as opposed to those who had received usual care. They also observed higher rates of smoking cessation for pharmacies that assisted clients to quit smoking than for control pharmacies that provided usual care, but this difference was not statistically significant. Sinclair et al (1998) have argued that the lack of statistically significant differences in their study was due to their failure to meet recruitment targets, thereby reducing the power of the study. Conversely, it was suggested that the positive findings of Maguire et al (2001) could have been affected by observation bias associated with a lack of blinding of pharmacists to subjects' allocation to intervention and control groups, and by the fact that the pharmacists involved interacted with both groups.

## 13.5 Evidence for effectiveness of practice

The reviews by Sinclair et al (2005), Blenkinsopp et al (2003) and Roughead, Semple and Vitry (2003) all examined the two RCTs summarised in section 13.4. In addition, Roughead, Semple and Vitry (2003) examined an Australian RCT by Vial et al (2002). This Australian trial was excluded from the other two reviews because the subjects were hospital inpatients and their first consultation was carried out by a research pharmacist (and then continued by a community pharmacist). It showed a trend towards improved smoking cessation rates in the community pharmacy intervention group, but this result did not reach statistical significance.

Blenkinsopp et al (2003, p 147) concluded that

‘... findings demonstrate the effectiveness and cost effectiveness of smoking cessation services provided by community pharmacists who have been trained in behavioural change methods.’

Sinclair et al (2005) concluded that

‘... the limited number of studies to date suggest that trained community pharmacists, providing a counselling and record keeping programme for their customers, may have a

positive effect on smoking cessation rates. The strength of the evidence is limited because only one of the trials showed a statistically significant effect’.

Roughead, Semple and Vitry (2003 p.155) concluded

‘...currently, there is a lack of good evidence for the effectiveness of smoking cessation programs in community pharmacy. This has been due to studies failing to recruit sufficient samples, or studies with open designs where the pharmacist delivering the intervention is aware of group allocation and interacts with both groups, leading to the potential for significant bias’.

The limited number of studies, to date, indicates that community pharmacists trained in smoking cessation techniques which include counselling and monitoring, can achieve improved smoking cessation rates in their clients. However, this trend was found to be statistically significant in only one RCT trial.

Initial economic studies, some of which are based on modelling, suggest that smoking cessation services provided by community pharmacist are cost effective.

## **13.6 Economic assessment**

In addition to the cost-effectiveness studies reported in the review by Roughead, Semple, Vitry (2003), we found an economic assessment by Sinclair et al (1999), using the data collected by Sinclair et al (1998) in their RCT. In their analysis, Sinclair et al (1999), calculated that the cost of achieving one successful attempt to stop smoking using intensive pharmacist support rather than usual pharmacist care was Sterling £300, and the cost per year of life saved was £83. Tran et al (2002) modelled the cost-effectiveness of smoking cessation programs in community pharmacy practices based on published literature on the topic. Depending on the smoker’s age at the time of cessation, the incremental discounted cost-effectiveness was US\$720–\$1,418 per life-year saved when implementing pharmacist-directed program alternatives as opposed to self-directed quit attempts.

## **13.7 Australian research**

We found no Australian RCT that was conducted during the period 2003–2005.

## **References**

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Sinclair, H., J. Silcock, et al. (1999). "The cost-effectiveness of intensive pharmaceutical intervention in assisting people to stop smoking." International Journal of Pharmaceutical Practice **7**: 107–112.

Sinclair, H. K., C. M. Bond, et al. (1998). "Training pharmacists and pharmacy assistants in the stages of change model of smoking cessation: a randomised controlled trial in Scotland." Tobacco Control **7**(3): 253–61.

Sinclair, H. K., C. M. Bond, et al. (2005). Community pharmacy personnel interventions for smoking cessation. The Cochrane database of systematic reviews. The Cochrane Library. The Cochrane Collaboration. Vol 1.

Tran, M. T., D. A. Holdford, et al. (2002). "Modeling the cost effectiveness of a smoking cessation program in a community pharmacy practice." Pharmacotherapy **22**(12): 1623–1631.

Vial, R. J., T. E. Jones, et al. (2002). "Smoking cessation program using nicotine patches linking hospital to the community." Journal of Pharmacy Practice & Research **32**(1): 57–62.

**Table 13.1** Systematic reviews of smoking cessation services in community pharmacies

Reference	Level	Setting	Intervention	Evaluable sample	Study outcomes	Results
Sinclair, Bond and Stead, 2005	1	Community pharmacies in London, Northern Ireland and Scotland	The review covered two studies. One study randomised patients and the other randomised the pharmacies. Both RCTs reviewed included: 1. Training/workshops for pharmacists, and 2. Structured programmes for the patients that included counselling, information leaflet, monitoring and follow-up.	111 pharmacies and approx 1000 patients	Self-reported abstinence to 9 or 12 months. Perceptions of the clients and pharmacy personnel about the pharmacy support staff	In one trial, twelve percent of the intervention and 7% of the controls reported abstinence at nine months ( $p=0.09$ )(Sinclair et al, 1998). In the other trial, 14.3 % of the intervention and 2.7 % of the controls reported abstinence at 1 year ( $P<0.001$ ) (Maguire et al,2001).
Blenkinsopp, Anderson and Armstrong, 2003	1	As above	The review covered the same two studies as in Sinclair, Bond and Stead, 2005	As above	As above	As above





## 14 Pharmacist immunisation services

### 14.1 The service

As Roughead, Semple and Vitry (2003) note:

'Pharmacist services related to immunisation that are described in the international literature include:

- (a) immunisation advocacy programs in which the pharmacist identifies patients requiring immunisation and provides information and education with the aim of raising awareness and improving vaccination rates;
- (b) administration or provision of vaccinations in the pharmacy setting to improve vaccine access.'

### 14.2 Studies included

We adopted the same inclusion criteria as those used by Roughead, Semple and Vitry (2003). Studies were included if they:

- aimed to improve immunisation rates, or to improve access to immunisation through the provision of information or education; or
- assessed provision of pharmacy-based or pharmacist-managed immunisation programs, including the administration of vaccinations in pharmacies; or
- referred to services provided to pharmacy clients, hospital outpatients or patients discharged from hospital.

Studies evaluating services provided to hospital inpatients were excluded.

### 14.3 Study designs

We found no RCTs (level 1) that were published between 2003 and March 2005 and met the inclusion criteria.

However, we found one relevant level 2 study. This assessed whether influenza vaccination rates increased in states of the USA where legislation allows pharmacies to administer vaccines, as opposed to states that do not have such legislation (Steyer et al, 2004). The study involved a secondary analysis of an annual telephone survey of health risks in the USA, carried out by the US Centers for Disease Control and Prevention. A matched pair design was used to compare eight states that had introduced vaccine administration by pharmacists with eight states that had not.

## 14.4 Study outcomes

In the study by Steyer et al (2004), greater improvements occurred between 1995 and 1999 in immunisation rates for individuals aged 65-plus compared to states where legislation allows pharmacies to administer vaccines than in states that do not allow pharmacists to administer immunisations. In states where pharmacists were allowed to vaccinate, individuals aged 18-plus were more likely to have had influenza vaccinations. While demographic differences did not appear to influence these results, other possible explanations for the differences among states include variations in state health initiatives, pricing of the vaccines, and advertising or public awareness levels within each state. With the available data from the study, the researchers could not ascertain which health professionals were responsible for the increase in immunisations, and in which settings the immunisation were given.

Recent interviews of community pharmacists in Australia revealed that community pharmacists themselves were mostly reluctant to administer vaccinations (Dawes, Cousins and Bailey, 2004) (see section 14.7).

## 14.5 Evidence for effectiveness of practice

We found no level 1 studies that had been done since the review by Roughead, Semple and Vitry (2003), which concluded that:

‘further studies of rigorous methodology (level 1 method) are required to evaluate pharmacist services to improve immunisation rates. The existing evidence suggests the services should target customers and that the additional targeting of community health providers makes no further difference. Cost effectiveness is still to be evaluated.’

In our review, we identified a level 2 study from the USA which suggested that allowing pharmacists to administer vaccinations was associated with improved the rates of immunisation. However, this ecological study did not take account of several important potential confounding factors.

## 14.6 Economic assessment

We found no relevant economic assessments.

## 14.7 Australian research

We found no Australian RCTs that had been published from 2003 to March 2005. The Pharmacy Guild of Australia has recently published a report of interviews with pharmacists and other health professionals about immunisation services in Australia (Dawes, Cousins, Bailey 2004). The report reaffirmed the high rates of immunisation prevalent in Australia, and drew attention to some remaining under-immunised groups, such as Indigenous children and high-risk adults who had not been immunised against influenza. The interviewed pharmacists were positive about contributing to immunisation programs through education, promotion, and the provision of advice. Half the pharmacists interviewed indicated that they would consider holding vaccination clinics. However, most were reluctant to administer vaccinations to their customers.

## References

Dawes, J., J. Cousins, et al. (2004). The Role of Pharmacy in Immunisation in Australia – Draft report. Canberra, The Pharmacy Guild of Australia.

Steyer, T. E., K. R. Ragucci, et al. (2004). "The role of pharmacists in the delivery of influenza vaccinations." Vaccine 22: 1001–1006.



## 15 Other services

### 15.1 The services

In this chapter we examine studies evaluating clinical interventions provided by pharmacists. Clinical interventions refer to a wide range of professional pharmacist services, including the detection of medication errors, the identification of inappropriate medication use, involvement of pharmacists in hospital-in-the-home services, screening services, monitoring of pre-determined endpoints (such as blood pressure and serum cholesterol levels) for disease states, and prescribing of prescription medicines by pharmacists.

### 15.2 Studies included

We included only studies that provided level 1 evidence (RCTs) and that evaluated interventions in relation to level 1, 2 or 3 patient outcomes.

We excluded studies that evaluated services for hospital inpatients.

### 15.3 Study design

The only studies of pharmacist clinical interventions that fulfilled the inclusion criteria were two evaluations of monitoring services and one that included screening services for participants.

We found two RCTs that in which patients in intervention groups received individualised monitoring of blood pressure and drug-related problems associated with anti-hypertensive medication, while patients in control groups received usual care from a community pharmacist. Both of the RCTs were conducted in rural community pharmacy settings. One was done in Portugal (Garçao and Cabarita, 2002) and the other in Thailand (Sookaneknun et al, 2004).

An Australian RCT (Taylor et al 2004) evaluated services for osteoporosis involving pharmacists. The intervention and control groups received screening for osteoporosis risk. The intervention group additionally underwent bone mass density measurements. Both the intervention and the control groups received help from pharmacists in making treatment decisions based on the risk assessment that they received, and referral where indicated.

## 15.4 Study outcomes

The studies by Garçao and Cabarita (2002) and Sookaneknun et al (2004) evaluated monitoring services and interventions in relation to similar patient outcomes, combining level 2 and level 3 outcomes. The level 2 patient outcomes referred to blood pressure control or reduction. The level 3 patient outcomes included the prevention, identification, and amelioration of drug-related problems (DRPs) as well as patients' response to pharmacists' recommendations for medication changes.

The study by Taylor et al (2004) combined level 3 and level 4 outcomes. The level 3 patient outcomes referred to participants' rates of adherence to pharmacist-recommended treatments as well as their rate of referral uptake. The level 4 patient outcome addressed the participants' satisfaction with the information and services provided by the pharmacists. A cost-benefit analysis of participants' willingness to pay for the additional service was conducted (level 3 economic analysis).

## 15.5 Evidence for effectiveness of practice

The studies by Garçao and Cabarita (2002) and Sookaneknun et al (2004) showed that that monitoring of hypertensive subjects' blood pressure by pharmacists was effective in reducing blood pressure and, subsequently, cardiovascular disease attributable to hypertension.

The study by Garçao and Cabrita (2002) was designed to evaluate the benefits of community pharmacist clinical interventions for subjects living in rural areas who were taking antihypertensive medications. The authors emphasised the importance of preventing, detecting and resolving drug-related problems (DRPs) in reducing morbidity and mortality. Approximately 40% of potential DRPs were prevented, although the effect of these specific instances on morbidity or mortality was not stated. The proportion of subjects with uncontrolled blood pressure in the intervention group decreased by 77.4% ( $p < .0001$ ), while the proportion in the control group fell by 10.3% ( $p = .48$ ).

The study by Sookaneknun et al (2004) also evaluated the benefits of pharmacist clinical interventions for patients with hypertension. Endpoints were control of blood pressure, reductions in systolic and diastolic blood pressure, and adherence to pharmacists' recommendations. The difference between the intervention and control groups in the proportions of subjects attaining blood pressure control was not statistically significant ( $p = .061$ ), but reductions in systolic and diastolic blood pressure were significantly greater in the intervention group ( $p < .001$ ). Greater proportions of subjects in the intervention group than the control group followed pharmacists' recommendations.

The study by Taylor et al (2004) evaluated the benefit of pharmacy-based bone mass density measurements in conjunction with an osteoporosis risk assessment and treatment

recommendation. There was no significant difference in modifiable osteoporosis risk factors between intervention and control groups. Pharmacists within the control group were significantly more likely to identify participants as being at higher risk of osteoporosis (10%). There was no significant difference between the intervention and control groups' likelihood of adhering to pharmacist treatment recommendations or participants' referral uptake. However, participants who received the bone mass density measurement were more likely to be satisfied with the information offered and the health screening provided by the pharmacist than the control group ( $p < .005$ ). Of the subjects within the control group, 30% were disappointed by the lack of bone mass density testing.

## 15.6 Economic findings

The study by Taylor et al (2004) found that 72% of participants were willing to pay for bone mass density testing in addition to the traditional risk assessment, compared with risk assessment only. The cost benefit analysis of the service determined that the cost outweighs the benefit measured (level 3). Participants indicated that the maximum Willing to Pay (WTP) value of bone mass density measurement and conventional risk assessment was A\$30, and the actual cost of providing the service was A\$81.40.

## 15.7 Australian studies

The study by Taylor et al (2004) is described above. We found no other Australian studies that had been published between 2002 and March 2005 and met our inclusion criteria.

## 15.8 Comment

The studies by Garçao and Cabrita (2002) and Sookaneknun et al (2004) reaffirmed the value of community pharmacist clinical interventions in rural communities. They were consistent with the findings of the review by Roughead, Semple and Vitry (2003).

The study by Taylor et al (2004) did not show any difference between intervention and control groups, other than satisfaction with services provided by pharmacists. However, it should be noted that the control group was deprived of a service that the authors reported as being 'routinely offered' in many community pharmacies.



## References

Garcao, J. A. and J. Cabrita (2002). "Evaluation of a pharmaceutical care program for hypertensive patients in rural Portugal." Journal of the American Pharmaceutical Association **42**(6): 858-64.

Sookaneknun, P., R. M. Richards, et al. (2004). "Pharmacist involvement in primary care improves hypertensive patient clinical outcomes." Annals of Pharmacotherapy **38**(12): 2023-8.

Taylor, S. J., J. A. Crockett, et al. (2004). An integrated service, initiated by community pharmacists, for the prevention of osteoporosis., Third Community Pharmacy Agreement Research and Development Grants Program: 1-61.

**Table 15.1:** Randomised controlled trials of pharmacist involvement in monitoring

Reference	Level of evidence	Setting	Intervention	Evaluable sample	Study outcomes	Results
Garçao and Cabrita, 2002	1	Private community pharmacy in rural Portugal	Pharmacists provided individualised health promotion on a monthly basis for a total of 6 months. Individualised health promotion consisted of: Blood pressure monitoring. Assessment of treatment adherence. Prevention and detection of drug-related problems (DRPs). Provision of advice on non-pharmacological approaches to reduce BP	1 pharmacy with 1 pharmacist and a pharmacist technician. 82 patients.	Control of BP (level 2). Decreases in systolic diastolic BP (level 2). Number of detected, prevented or resolved DRPs. (level 3).	The decrease in BP in the intervention group was statistically significant ( $p < .0001$ ), but not in the control group. There was a statistically significant decrease between the baseline and final means of systolic BP and diastolic BP in the intervention group but not the control group. Of the 29 DRPs detected, 24 were resolved by the pharmacist.
Sookaneknun et al., 2004	1	Community pharmacy in Mahasarakham, Thailand and primary care unit in rural areas surrounding.	Subjects in the intervention group were monitored by pharmacist for 6 months. Monitoring consisted of: 1. Blood pressure (BP) measured each month. 2. 30–50 minute interview which addressed understanding and use of medication, lifestyle habits, and DRPs, as well as a non-pharmacologic approaches to BP control.	1 pharmacy and two primary care units. 227 patients	Control of BP (level 2). Differences in reduction rates of systolic and diastolic BP between treatment and control groups (level 2). Pharmacist medication modification recommendations (level 3).	The treatment group experienced a statistically significant reduction in both systolic BP ( $p = 0.037$ ) and diastolic BP ( $p = 0.027$ ) in comparison with the control group. A greater number of subjects in the control group, whose BP $\geq 140/90$ mm Hg at the beginning of the study had stabilized at the end of the study.

Taylor et al., 2004	1	Rural and urban community pharmacies surrounding Sydney, NSW	Pharmacists provided risk assessment of osteoporosis to subjects. Experimental group also received bone mass density (BMD) testing.	12 pharmacists and 193 participants.	Subjects' adherence to advice or referrals given by pharmacists (level 3). Subjects' value of the BMD service (level 4). Cost effectiveness of the intervention (level 3 economic evaluation).	After 3 months, there was no statistical significance in participants' adherence to pharmacist treatment recommendations. No statistically significant difference between experimental groups' rates of referral uptake. Participants who received the BMD were more likely to be satisfied with the information offered as well as their health screening ( $p < .005$ ). 30% of control group participants were disappointed by the lack of BMD provision.
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## 16 Conclusion

### 16.1 The scope of this review

We were commissioned by the Pharmacy Guild of Australia to review research evaluating professional pharmacy practice in the community. Our brief was to examine research that had been published since the completion of a previous review commissioned by the Guild. The previous review, by Roughead, Semple and Vitry, covered the literature that had been published between 1990 and October 2002. Roughead, Semple and Vitry had themselves built on a previous review by Emerson, Whitehead and Benrimoj, issued by the Guild in 1998.

Because our review represented an extension of the review by Roughead, Semple and Vitry, we adopted their definitions, methods and format as closely as possible.

In accordance with our commission, we concentrated on RCTs, which provided evidence designated as level 1. We included systematic reviews where available.

An important finding from our literature search was an increase in the volume of evaluative research on professional pharmacy practice. Roughead, Semple and Vitry reported on a total of 73 RCTs published over a period of almost 13 years. We reported on a total of 40 RCTs published between October 2002 and March 2005, a period of less than two and a half years.

### 16.2 Evidence for effect

Overall, our review indicates that many aspects of professional pharmacy practice in the community are effective in improving treatment processes and outcomes for specific groups of patients, as shown by various measures of morbidity, risk factor levels, treatment compliance, and (in a few situations) mortality. Specific findings for each group of patients (defined by disease conditions or patient characteristics) are given in detail in Chapters 2–15 and are summarised in Table 16.1. In general, the findings from our review reaffirmed the findings of the earlier review.

Several of the RCTs that we reviewed incorporated limited economic assessments, for example an examination of the relative costs of interventions. The following interventions appeared to lead to reduced costs: pharmaceutical care and continuity of care for the elderly (different studies gave different cost outcomes for medication reviews in the elderly); pharmaceutical care for patients with asthma; pharmacist involvement in therapeutic decisions for patients with cardiovascular disease; and medication reviews for patients taking multiple drugs. It should be noted that economic assessments were not undertaken for many of the interventions covered in the RCTs.

## 16.3 Methodological considerations

The RCTs that we reviewed encompassed a wide range of designs. They variously used individual randomisation (with individual patients as the units of randomisation) or randomised block designs (where pharmacies or pharmacists were the units of randomisation, representing patients assigned or not assigned to particular interventions). Most of the RCTs had a single intervention group and a single control group. A few had two or more intervention arms. In some instances, the intervention could only be evaluated in the intervention group. Such instances usually involved 'before–after' comparisons.

Many of the RCTs appeared to have been well designed and conducted, with careful attention to the avoidance of observation bias by blinding. Some studies, however, had significant methodological weaknesses. The single most frequent weakness was a lack of information about important aspects of study design, such as calculations of sample size, the method of randomisation, and whether or not observers were blinded to the allocation status of subjects. Other frequent weaknesses were small sample sizes, resulting in insufficient statistical power to detect any real effects that may have existed; lack of blinding, leading to possible observation biases; and failure to carry out intention–to–treat analyses. In a small number of studies, it was possible for subjects to break randomisation and move between comparison groups (intervention and control) or select a preferred group.

## 16.4 Policy implications

Changes over the next 10 years in the health of the Australian population and in health–care delivery are likely to be influenced some demographic, disease and service trends that are clearly evident today. These include:

- the growth and ageing of the Australian population;
- the increasing prominence of chronic, complex diseases;
- recognition of deficiencies in the safety, quality and management of health services;
- health–care workforce shortages, and a maldistribution of the workforce in relation to community needs;
- changing community expectations, with a growth of shared professional and consumer decision–making about health matters;
- increasing community interest in health promotion and the early detection of disease;
- the proliferation of technology, especially communication and information technology; and
- a community demand for good access to health services at convenient locations and times.

Our review, and the previous review by Roughead, Semple and Vitry, provide substantial evidence for policy initiatives relating to professional pharmacy practice in the community.

In relation to the ageing of the population, we identified several interventions that have demonstrably benefitted elderly patients in a variety of settings. These include pharmaceutical care interventions, pharmacist involvement in enhancing the continuity of care, and pharmacist clinic services. Most of these interventions worked by promoting quality use of medicines. Perhaps surprisingly, medication reviews were shown to be effective in one RCT, yet to have no significant effect on outcomes in another RCT.

In relation to the increasing prominence of chronic, complex diseases, the various RCTs that we reviewed evaluated interventions in groups of patients with diabetes, asthma, cardiovascular diseases, and depression. While the findings were not always consistent, it appeared that pharmaceutical care interventions had the potential to improve the management of diabetes and outcomes for patients with diabetes. Again perhaps surprisingly, patient education was shown to be effective in reducing glycated haemoglobin levels in one RCT, yet to have no effect on glycated haemoglobin, cholesterol and medication use by patients with diabetes in another RCT. For patients with asthma, pharmaceutical care interventions were effective in improving symptoms, respiratory function, and quality of life, and patient education was also associated with improvements in symptoms and quality of life. For patients with cardiovascular disease, pharmaceutical care interventions did not have significant beneficial effects. However, pharmacist involvement in therapeutic decision-making and in patient monitoring was associated with improvements in blood-pressure levels and reductions in the incidence of drug-related problems. For patients with depression, patient education and pharmacist involvement in therapeutic decision-making were associated with improvements in adherence to medication regimens.

Our review suggested that there was great potential for community pharmacy to improve the safety and quality of health services, especially by promoting the quality use of medicines and helping patients to understand their health problems and medication regimens. These effects were perhaps most clearly manifest among patients who were at high risk of drug-related problems, such as those taking multiple medications and those using potentially dangerous medications such as oral anticoagulants.

One of the major problems currently facing the Australian health-care system is a workforce shortage, particularly affecting the medical and nursing workforces. Our review and the review by Roughead, Semple and Vitry provide strong evidence that community pharmacists have the potential to relieve the some of the pressure on the medical and nursing workforces through partnership with doctors and nurses, assuming selected medical and nursing roles (i.e. workforce substitution), and enhancing the quality of community-based health care. Community pharmacy is uniquely placed to provide the population with an excellent access point for primary care.

## 16.5 Corollaries

From our experience of conducting this review, we draw the following five corollaries for consideration in the future development and evaluation of pharmacist professional services in the community setting.

First, while the focus on RCTs is desirable for a rigorous evaluation of specific services, it means that informative literature is overlooked. Published and unpublished (or 'grey') literature generating lower levels of evidence are often important in determining or qualifying policy directions and practices.

Second, for the development of Australian policy and practice, it is especially important to consider Australian studies of all types. While studies from other countries contribute to the stock of knowledge about the effectiveness of pharmacy interventions, many interventions are highly context-dependent. Studies conducted in Australia are likely to provide a more accurate representation of the context in which evaluated interventions might be implemented.

Third, in evaluating professional services by pharmacists, it may be preferable to classify interventions according to the type of service provision that they represent, rather than the subdivision of interventions by their purpose or the setting in which they are applied. For example, 'medication review for repeat prescription', 'medication review in aged-care facilities', 'medication review in the outpatient setting' could be grouped in an overall evaluation of medication reviews.

Fourth, while we have been careful to evaluate effects of interventions that can reasonably be attributed to the specific involvement of pharmacists (as distinct from a multi-disciplinary team), we acknowledge that multi-disciplinary interventions are likely to dominate many aspects of health care in the future. It will therefore become increasingly difficult to isolate the role of pharmacists for the purpose of evaluation. Future evaluations will inevitably consider the effects of multi-disciplinary interventions that involve pharmacists and other professionals working together.

Finally, our experience has highlighted the difficulties of comprehensively assessing a wide range of interventions in a single review. These difficulties relate to the limitations that result from need to use review methods that can be applied to a wide range of types of interventions. We recommend that future reviews concentrate on particular types of pharmacy service provision, as suggested above, and that they include studies using all types of analytical and descriptive designs, not just RCTs. Evidence from any rigorous, well-conducted piece of research warrants consideration.

**Table 16.1:** Summary of evaluations of pharmacist professional services: findings in relation to types of interventions and conditions or patient groups

Condition or patient group and chapter number	Intervention							
	2. Pharmaceutical care	3. Continuity of care	4. Pharmacist clinic services	5. /6./7. Medication reviews	8. Patient education	9. Educating health professionals	11. Therapeutic decision making	15. Other – monitoring
Elderly Patients	<p><u>Sturgess</u>                      ↓ – QOL, DRP                      Not sig ↓ hospital visits                      ↑ – condition mgt., contact with GP &amp; specialist,                      # medications, compliance                      ↓ – medication cost/pt early in study</p>	<p><u>Al-Rashed</u>                      ↑ compliance,                      ↓ GP/hospital visits                      \$ effective  <u>Bolas</u>                      ↑ drug knowledge                      No change compliance, readmission rates                      ↓ medication discrepancies  <u>Crotty 04</u>                      ↑ quality of prescribing                      No change medication discrepancies  <u>Holland</u>                      ↑ ED visits                      Mixed results secondary outcomes  <u>Jackson</u>                      No change INR                      ↓ bleeding event                      Improved anti-coagulant control day 8</p>	<p><u>Lim</u>                      ↑ compliance, medication knowledge                      ↓ residual adverse drug reactions</p>	<p><u>Sellors</u>                      No sig change \$, DRP, QOL, # medications, healthcare use and cost, uptake of recommendations   <u>William</u>                      ↓ # medications                      sig \$ saving</p>		<p><u>Crotty</u>                      no change falls or other outcomes</p>		



Condition or patient group and chapter number	Intervention								
	2. Pharmaceutical care	3. Continuity of care	4. Pharmacist clinic services	5. /6./7. Medication reviews	8. Patient education	9. Educating health professionals	11. Therapeutic decision making	15. Other – monitoring	
Diabetes	<p><u>Clifford</u>  ↓ BMI, HBA<sub>1c</sub>, fasting plasma glucose, BP, 10-yr CHD risk  Not sig change - serum lipids, urinary albumin: creatine, % change medications</p> <p><u>Odegard</u>  Not sig change HBA<sub>1c</sub>, MAI, adherence</p> <p><u>Rothman</u>  ↓ HBA<sub>1c</sub>, BP,  Not sig change ADEs, use clinical services,  ↑ use aspirin, diabetes knowledge</p> <p><u>Simpson</u>  ↓ cholesterol levels,  Not sig change BP, risk  ↑ # Pts likely to reach end-point, # pts that had fasting cholesterol profile performed</p>					<p><u>Grant</u>  no sig change - medication use, HBA<sub>1c</sub> and cholesterol</p> <p><u>Sarkadi</u>  ↓ HBA<sub>1c</sub></p>			

Condition or patient group and chapter number	Intervention							
	2. Pharmaceutical care	3. Continuity of care	4. Pharmacist clinic services	5. /6./7. Medication reviews	8. Patient education	9. Educating health professionals	11. Therapeutic decision making	15. Other – monitoring
Depression					<u>Brook</u> Not sig change symptoms, ↑ drug attitude <u>Hoffman</u> ↑ compliance		<u>Adler</u> Not sig change AD use <u>Cappoccia</u> Not sig change adherence, symptom <u>Finley</u> ↑ compliance Not sig change clinical function	
Asthma	<u>McClean</u> ↓ symptoms, ED visits, use β-agonist, # medical visits, total \$ health cost ↑ QoL, peak expiratory flows Not sig change hospital visits, # corticosteroids				<u>Barbanel</u> ↓ symptoms <u>Gonzalez-Martin</u> ↑ QOL Not sig change spirometry			

Condition or patient group and chapter number	Intervention							
	2. Pharmaceutical care	3. Continuity of care	4. Pharmacist clinic services	5. /6./7. Medication reviews	8. Patient education	9. Educating health professionals	11. Therapeutic decision making	15. Other – monitoring
<b>Cardiovascular disease</b>	<u>Bouvy</u> Not sig difference QoL, mortality, hosp admissions ↓ # days without use of loop diuretics <u>Peterson</u> Not sig change compliance ↓ cholesterol						<u>Borenstein</u> ↓ BP ↑ # pts achieve target ↓ costs No diff drug cost/month	<u>Garcao</u> 40% potential DRPs prevented, ↓ BP <u>Sookaneknun</u> ↓ systolic & diastolic BP ↑ adherence to recommendations
<b>Polypharmacy and patient at risk of drug related problems</b>	<u>Taylor</u> ↓ hospital and ED visits Not sig ↑ QOL ↑ # pts reaching BP, HBA1c, INR and cholesterol targets ↑ # compliant pts ↑ MAI, medication knowledge			<u>Sorensen</u> Found an average of 5.5 DRPs/Med Review Of implemented recommendations, 70% had +ve outcome, No diff in hospitalisation, functional status, GP visits etc. \$ saving				

Condition or patient group and chapter number	Intervention							
	2. Pharmaceutical care	3. Continuity of care	4. Pharmacist clinic services	5. /6./7. Medication reviews	8. Patient education	9. Educating health professionals	11. Therapeutic decision making	15. Other – monitoring
Paediatric		<u>Vioril</u> Obtained medicines promptly No diff medication knowledge ↑ readmissions						
HIV			<u>Rathburn</u> ↑ short-term virological response No change overall compliance					
Benzodiazapine Prescribing						<u>Pimlott</u> no change prescribing patterns		

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# Appendix I

## Search terms used to identify published studies about professional pharmacist services

Multiple searches were conducted using the following databases: MEDLINE, International Pharmaceutical Abstracts, Current Contents, Australasian Medical Index (via Meditext) and the Cochrane Library. Terms were searched as subject headings and keywords. Due to differences in searching subject structures between the different databases, the subject heading searches differed in the various databases. The search terms used in each database are detailed below.

### *Medline (via Ovid): 2002 – March 2005*

Pharmacist or pharmacists  
Pharmacy  
Pharmaceutical care  
Academic detailing  
Advocacy  
Clinic or clinics  
Counsel or counselling or counseling  
Detailing  
Drug information  
Drug information service or services  
Immunization or immunisation  
Intervention or interventions  
Medication information  
Medication management  
Medication review  
Medicine or medicines information  
Outreach  
Physician education  
Pre-admission or preadmission  
Screening  
Smoking cessation  
Vaccine or vaccination

Community pharmacy services (subject heading)  
Drug information (subject heading)  
Drugs, non-prescription (subject heading)  
Patient education (subject heading)  
Pharmacy service, hospital (subject heading)  
Physicians (subject heading)

International Pharmaceutical Abstracts: 2002 – March 2005

Pharmacist or pharmacists  
Pharmacy  
Pharmaceutical care  
Advocacy  
Clinic or clinics  
Counsel or counselling or counseling  
Detailing  
Drug information  
Drug information service or services  
Hospital in the home  
Immunisation or immunization  
Intervention or interventions  
Medication management  
Medication review  
Outreach  
Pre-admission or preadmission  
Screening  
Smoking cessation  
Vaccine or vaccination

Ambulatory care, pharmacy services (subject heading)  
Drugs, over-the-counter (subject heading)  
Education, physicians (subject heading)  
Health care home (subject heading)  
Interventions (subject heading)  
Nursing homes (subject heading)  
Patient education (subject heading)  
Pharmaceutical care, pharmacy community (subject heading)  
Pharmaceutical care, pharmacy practice (subject heading)  
Pharmaceutical care, pharmacy services  
Pharmacists community, patient education (subject heading)  
Pharmacists community, services (subject heading)  
Pharmacists community, tests, laboratory (subject heading)  
Pharmacists, community interventions (subject heading)  
Pharmacists, education (subject heading)  
Pharmacists, hospital ambulatory care (subject heading)  
Pharmacy services, community (subject heading)  
Pharmacy services, home health care (subject heading)  
Prescriptions pharmacists, community (subject heading)  
Residential care facilities (subject heading)

***Current Contents: 2002 – March 2005***

Pharmacist or pharmacists  
Pharmacy or pharmacies  
Pharmaceutical care  
Academic detailing  
Clinic or clinics  
Continuity and care  
Counsel or counselling or counseling  
Drug information  
Drug information service or services  
Education  
Immunization or immunisation  
Intervention or interventions  
Medication information  
Medication management  
Medication review  
Medicine or medicines or medication  
Medicine or medicines information  
Over-the-counter or non-prescription or nonprescription  
Patient education  
Pre-admission or preadmission  
Screening  
Service or services  
Smoking cessation  
Vaccination or vaccine or vaccines

***Australasian Medical Index (via Meditext): 2002 – March 2005***

Pharmacist or pharmacists or pharmacist- pr pharmacists-  
Pharmacy or pharmacies  
Pharmaceutical care  
Academic detailing or academic detail  
Clinic or clinics  
Community pharmacy service or services  
Continuity and care  
Counsel or counselling  
Detail or detailing  
Drug information  
Education or education-  
Health professional education  
Immunization or immunisation  
Intervention or interventions  
Medication information

Medication management  
Medication review  
Medicine or medicines information  
Outreach  
Over-the-counter or non-prescription or nonprescription  
Physician education  
Pre-admission or preadmission  
Professional  
S2 or S3 or S2-S3 or S2S3 or S2-3  
Schedule or schedule-  
Screening  
Service or services  
Smoking cessation  
Vaccination

EMBASE.com: 2002 - March 2005

Pharmacist or pharmacists  
Pharmacy  
Pharmaceutical care  
Academic detailing  
Clinic or clinics  
Counsel or counselling or counseling  
Detailing  
Drug information  
Drug information service or services  
Intervention or interventions  
Medication information  
Medication management  
Medication review  
Medicine or medicines information  
Outreach  
Physician education  
Pre-admission or preadmission  
Screening  
Smoking cessation

***The Cochrane Library: 2002 - March 2005***

Pharmacist (no restrictions)  
Pharmacists (MESH heading)  
Immunisation or immunization  
Smoking cessation  
Vaccination