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The Pharmacy
Guild of Australia

Documenting Clinical Interventions in Community Pharmacy: PROMISe III

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FULL FINAL REPORT

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Acronyms

Acronym	Explanation
#	Number
AACP	Australian Association of Consultant Pharmacy
ACE	Angiotensin Converting Enzyme
ADR	Adverse Drug Reaction
AMT	Australasian Medicines Terminology
APESMA	Association of Professional Engineers, Scientists and Managers, Australia
APN	Australian Product Number
ASCEPT	Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists
ATC	Anatomic Therapeutic Chemical
Aust-L	Australian Listed
Aust-R	Australian Registered
BD	Twice a day
BNF	British National Formulary
BP	Blood Pressure
CAC	Care Activity Code
CATI	Computer Assisted Telephone Interview
CEA	Cost Effectiveness Analysis
CGA	Computer Generated Alert
CI	Clinical Intervention, or Confidence Interval
DCI	Documented Clinical Intervention
ACI	Actual Clinical Intervention
CIR	Consumer Information Record
CMI	Consumer Medicine Information
COPD	Chronic Obstructive Pulmonary Disease
CPA	Community Pharmacy Agreement
CPD	Continuing Professional Development

CUA	Cost Utility Analysis
DAA	Dose Administration Aid
DMAS	Diabetes Medication Assistance Service
DOCUMENT	Drug selection, Over or underdose, Compliance, Undertreated, Monitoring, Education or information, Not classifiable, Toxicity or adverse reaction
DRP	Drug Related Problem
EQ-5D	European Quality of Life – 5 Dimensions
FTE	Full Time Equivalent
GDP	Gross Domestic Product
GI	Gastrointestinal
GORD	Gastro-Oesophageal Reflux Disease
GP	General Practitioner
EHR	Electronic Health Record
HMG CoA	HydroxyMethylGlutaryl Coenzyme A
HMR	Home Medication Review
HPIR	Health Professional Information Record
HV	High Value
ICER	Incremental Cost Effectiveness Ratio
ICT	Information and Communications Technology
ID	Identifier
IMSANZ	Internal Medicine Society of Australia and New Zealand
IQR	Inter Quartile Range
IT	Information Technology
L2	Level 2
L3	Level 3
L4	Level 4
L5	Level 5
M	Million
MATES	Medicines Advisory and Therapeutic Education Services, Veterans Program
MBS	Medicare Benefits Scheme

N	Number
NCI	Non-Clinical Intervention
NEHTA	National E-Health Transition Authority
NEI	Not Enough Information
NHHRC	National Health and Hospitals Reform Commission
NPS	National Prescribing Service
NSAID	Non-Steroidal Anti-Inflammatory Drug
OTC	Over The Counter
P	Patients
PAMS	Pharmacy Asthma Management Service
PBS	Pharmaceutical Benefits Scheme
PGA	Pharmacy Guild of Australia
PhARIA	Pharmacy Access/Remoteness Index of Australia
PIF	Prescription Intervention Form
PMP	Patient Medication Profile
POM	Prescription Only Medicine
POS	Point Of Sale
PPI	Proton Pump Inhibitor
PROMISe	Pharmacy Recording Of Medication Incidents and Services electronically
PSA	Pharmaceutical Society of Australia
QALY	Quality Adjusted Life Year
QOL	Quality Of Life
QUM	Quality Use of Medicine
RV	Reasonable Value
Rx	Prescription
S1	Significance – consequences related to information
S2	Significance – prevented mild symptom or improved compliance
S3	Significance – prevented or required a GP visit
S4	Significance – prevented or required a hospital admission
SD	Standard Deviation

SNOMED CT	Systematised Nomenclature of Medicine – Clinical Terminology
SSL	Secure Socket Layer
TDS	Three times a day
TIA	Transient Ischemic Attack
UMORE	Unit for Medication Outcomes Research and Education
VALMER	Value of Medication Reviews
VNV	Virtually No Value
XML	eXtensible Mark-up Language

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Chapter 1 Introduction, Background and Objectives

The use of medications (drugs) is an integral part of the management of most chronic and acute medical conditions. All drugs carry some risk of having effects other than those intended, and this risk is balanced against the potential benefit to be gained in a particular therapeutic situation.

There are a number of terms that are used to describe the manifold situations where a drug results in other than the intended consequences. The term “medication-related problem”, or “drug related problem” (DRP) has been defined as “...any undesirable event experienced by the patient that is thought to involve drug therapy, and that actually or potentially interferes with a desired patient outcome.”¹⁻² Thus, the term drug related problems/DRPs can be considered to be all encompassing, covering adverse drug events, errors in prescribing (and dispensing) and adherence issues. DRPs may be *evident*, for example, when the patient taking the drug is exhibiting a known adverse event, or the DRP may be *potential*, for example, where the patient is at increased risk of a known adverse event.

One of the major roles for pharmacists and other professionals involved in the medication management cycle is to identify and resolve *evident* DRPs and identify and prevent *potential* DRPs. This process of identifying and resolving an evident DRP or identifying and preventing a potential DRP may be termed a “clinical intervention”.

In this chapter, the scope and consequences of DRPs are briefly discussed and the international and Australian literature related to the role of community pharmacists in the detection and resolution of DRPs is reviewed.

DRPs are common and may be responsible for morbidity, hospital admissions and/or mortality. There is a wide range of literature concerning the frequency and consequences of DRPs in many countries around the world, including Australia. Most of the literature concerns adverse drug events and errors due to prescribing and/or adherence,³⁻³⁰ while some of the literature specifically addresses prescribing and other errors.³¹⁻⁴⁸

International Perspective

A systematic review of the international literature regarding drug-related admissions found that 7.1% of hospital admissions (interquartile range (IQR) = 5.7-16.2) resulted from DRPs.²⁸ A Canadian study estimated that approximately 40% of the DRPs identified were preventable.⁴ A prospective analysis of adverse drug reactions (ADRs) as a cause of admission to hospitals in the United Kingdom found a prevalence of 6.5% (1,225 of 18,820) admissions were related to an ADR.⁴⁹ The authors stated that “most reactions were either definitely or possibly avoidable”.⁴⁹

The problems that result in hospitalisation often originate, however, in the community, and much less information is available regarding the extent of DRPs in the ambulatory situation. A prospective cohort study conducted by Ghandi et al. in the United States of America (USA) found that 25% (95% CI = 20-29%) of community patients experienced an adverse drug event within four weeks of receiving a prescription.²⁹ These authors also found that 11% of these adverse events were preventable, and 28% were able to be ameliorated in some way.²⁹

Australian Perspective

Drug-related hospital admissions are also a significant and expensive public health problem in Australia, and many of these problems may be preventable. In 2002, it was estimated that more than 140,000 people were hospitalised every year as a result of DRPs, and that approximately 50% of these DRPs were potentially preventable.³⁰ The rate of ADRs causing admission to hospital in older Australians increased dramatically during the period from 1981 to 2002, with the largest increases occurring in men aged over 80 years.⁵⁰ Overall the standardised rate of hospital stay associated with ADRs increased from 2.5 per 1,000 person years in 1981 to 12.9 per 1,000 person years in 2002. In the over 80-year old group, the increase was from 4.8 per 1,000 person years to 34.3 per 1,000 person years.⁵⁰

In 1998, Roughead et al. reviewed all available literature regarding drug-related hospital admissions in Australia.²³ They identified 14 studies and found that 2.4% to 3.6% of all hospital admissions were reported to be drug related. They also found that between 32% and 69% of drug-related admissions were reported as definitely or possibly

preventable.²³ In 2003, a comprehensive review of adverse drug events and medication errors in Australia was undertaken.⁵¹ These authors found that 2% to 4% of all hospital admissions, and up to 30% of admissions for patients over 75 years of age, were medication related, and up to three-quarters of these were potentially preventable.⁵¹ They identified anticoagulants, anti-inflammatory drugs and cardiovascular drugs as major contributors, making up over half of the adverse drug events reported.⁵¹ More recently, Ehsani et al. reviewed the incidence and cost of adverse events in Victorian hospitals.⁵² They found that 67,435 of 979,834 admissions had at least one adverse event (a prevalence of 6.88%). Although these adverse events were not specifically drug related, many of the events may have been related to inappropriate drug use.

DRPs that cause hospitalisation have most often originated in the course of the patient's community-based care. In addition, although DRPs that lead to hospitalisation are common, there are many DRPs that occur in the community setting and do not result in attendance to a hospital. Information concerning the nature and frequency of DRPs in the Australian community healthcare setting is not widely available. In 2004, Roughead et al. reviewed the case notes of 1,000 community dwelling patients who were considered to be at high risk of DRPs and identified a total of 2,222 DRPs.²⁴

During 2003 and 2004, Miller et al. investigated the frequency, cause and severity of adverse drug events among general practice patients.⁵³ They reported that 852 of 8,215 patients (10.4%) had experienced an ADR (predominantly recognised from side effects) in the previous six months. The general practitioners (GPs) who identified the adverse event classified 23% of them as preventable and 45.8% of the events as either moderate or severe.⁵³ Although these figures seem high, the authors point out that the denominator for their calculation of frequency was all patients attending the GP, regardless of whether or not they were receiving drug therapy. Given that many patients attending GPs are not regular medication users, the frequency of adverse drug events in regular medication users would undoubtedly be higher than that reported.⁵³ In addition, many patients "self-manage" adverse drug events and do not contact their GPs. DRPs that originate in the community are therefore likely to occur more frequently than indicated in the literature, as many of these would not result in presentation to a hospital or GP.

Thus, DRPs occur frequently both in hospital and community settings, and are responsible for a significant proportion of hospital admissions and health expenditure. There is a need to reduce the number of DRPs and also to increase the identification, prevention and, when needed, the resolution of DRPs. Many of the DRPs occur in patients who choose not to present to a GP, or are not aware that their symptoms may be indicative of a DRP. Pharmacists are well-respected, available health professionals and are in the ideal position to detect, prevent, and where needed, resolve DRPs in the community setting.

In the following sections, the role of pharmacists (more specifically, community pharmacists) in the detection, resolution and prevention of DRPs is reviewed.

1.1 Pharmacist-based Strategies to Reduce DRPs

DRPs can arise as a result of issues in all phases of the medicines management cycle, from the initial decision to prescribe a medication to the desired outcome being achieved. As a result, strategies to reduce DRPs can target particular aspects of the cycle (see Figure 1-1), or can act at an "over-arching" level and are intended to alter practices utilising widespread educational activities.

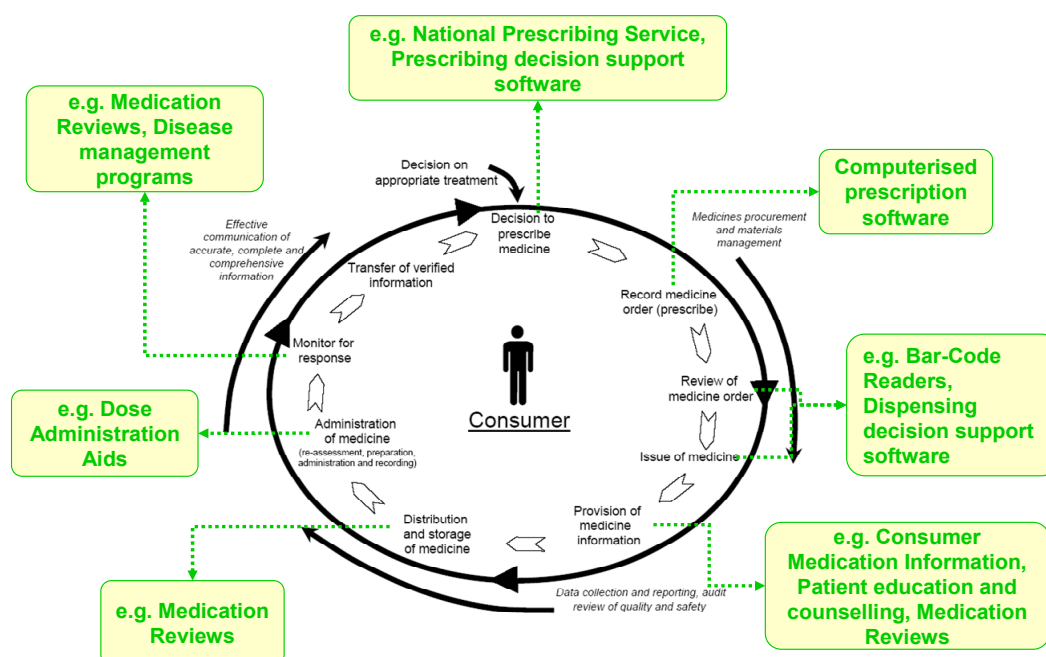


Figure 1-1: Strategies to Reduce DRPs (Modified from Stowasser et al.⁵⁴)

The National Prescribing Service (NPS) was established to provide evidence-based information to health professionals and consumers on Quality Use of Medicines (QUM). The express purpose of the NPS is to support the best use of medicines in order to improve health and well being (see www.nps.org.au). The Australian Commission on Safety and Quality in Healthcare (formerly the Australian Council of Safety and Quality in Healthcare) aims to lead and coordinate improvements in safety and quality of healthcare in Australia by identifying issues and policy directions and recommending priorities for action. One of its activities is to implement a National Inpatient Medication Chart in order to reduce the harm to patients caused by medication errors (see www.safetyandquality.gov.au).

Process improvements to reduce the risk of medication errors have also been put in place in medical and pharmacy practices. Computerised prescribing is now commonplace in medical practices and is beginning to be used more frequently in hospitals and other healthcare institutions. The use of this technology is intended to reduce errors associated with poor handwriting.⁵⁵⁻⁶¹ A comparison of pharmacist interventions with handwritten and computerised prescriptions in Western Australian community pharmacies indicated that, although there was a reduction of “administrative” prescribing interventions associated with wrong package sizes or specification of dose, the “clinical” intervention frequency was either the same or increased (see discussion of Whitehead et al. on page 44).⁶²

In the dispensing process, technology has assisted in reducing human error rate by the introduction of bar-code readers to “double-check” against the prescription.⁶³ The use of dose administration aids (compartmentalised box or blister pack devices) in high-risk patients has been shown to improve compliance with medications and reduce error rates during medication administration.⁶⁴

Pharmacists are involved in most of the steps in the medication management cycle, and are in an ideal position to detect and prevent or resolve DRPs. Rollason and Vogt systematically reviewed the role of the pharmacist, specifically in relation to reducing polypharmacy in the elderly.⁶⁵ They reviewed 14 studies published up to February 2003. These authors concluded that “any kind of intervention by a pharmacist can reduce the number of drugs prescribed to elderly patients”.⁶⁵

Pharmacy-based services and activities that reduce DRPs have become an accepted part of the drug-related management of patients in both hospital and community settings. Many of the services involve ongoing review of the appropriateness, effectiveness and potential adverse effects of medications. As such, the involvement of

pharmacists in the management of medications in various clinical settings is an established and important component of reducing DRPs.

1.1.1 Clinical Pharmacy Services in Hospitals

Clinical pharmacy services have been present in varied forms in hospital settings in Australia since the early 1970s. Fundamentally, a clinical pharmacy service involves the application of a clinical pharmacist's specialised knowledge to the multidisciplinary management of the patient. This includes a review of the appropriateness of the therapy and its monitoring as well as enhancing adherence to the treatment plan. Such general and specialised clinical pharmacy services have been shown to lead to the detection and resolution of DRPs and thereby have the potential to substantially reduce healthcare costs.^{37, 41-42, 66-113}

Clinical pharmacists in hospital settings provide a number of services during the course of a patient's stay in hospital. The nature and consequences of DRPs that are identified during the patient's inpatient care will likely differ from those identified at the point of admission or discharge (the "interface").

Inpatient Care

The benefits of specialised clinical pharmacists have been shown in the areas of emergency medicine,^{73, 81, 83} intensive care,^{92, 97} oncology,^{112, 114} and a range of medical and surgical wards.^{37, 90, 103, 107} Kaboli et al. systematically reviewed 36 studies concerning the role of clinical pharmacists in inpatient medical care.¹¹⁵ These authors concluded "*The addition of clinical pharmacist services in the care of inpatients generally resulted in improved care, with no evidence of harm. Interacting with the healthcare team on patient rounds, interviewing patients, reconciling medications, and providing patient discharge counselling and follow-up all resulted in improved outcomes.*"

The value of clinical interventions (CIs) that result from clinical pharmacy services in Australian hospital settings has also been shown. Dooley et al. conducted a study across eight major teaching hospitals and estimated the annualised cost savings of almost \$4.5M.¹¹⁶

The Community/Hospital Interface

It is acknowledged that the interface between hospital and the community is one of the high risk times for causing confusion that may lead to DRPs. At the time of admission, an accurate medication history can reduce DRPs that occur during the hospital stay,^{71-72, 75-76, 94, 117-118} while adequate discharge processes can reduce early DRPs following a hospital stay.^{46, 68, 72, 76, 80, 93, 101, 106, 119-121} In the Australian hospital setting, Stowasser et al. demonstrated that an admission and discharge pharmacist service reduced the number of healthcare professional visits at 30 days after discharge, and increased the number of medication changes and pharmacist CIs.¹²²

1.1.2 Comprehensive Medication Reviews of Non-hospitalised Patients

The success of clinical pharmacy services in hospital settings led to the implementation of similar services for high-risk community patients.

As stated earlier, the fundamental aspect of a clinical pharmacy service is a review of the patient's medications in order to identify and resolve any DRPs. The terminology for the provision of a community-based review of the patient's medications varies, although the nature of the service is similar. Terms such as "pharmaceutical care", "medication review", or "clinical pharmacy services" have all been used to describe a process that involves a pharmacist conducting a review of the patient's therapy. Notwithstanding the different terminology, these services have been investigated in community-based institutional settings such as nursing homes and hostels.^{34, 123-129} In the USA, monthly pharmacist-led medication reviews for all residents of nursing homes are now mandatory.

The benefits of medication reviews for high-risk patients in residential care facilities has led to an investigation of the role of medication review in the community non-institutional setting (that is, comprehensive reviews of patients who still live at home).¹³⁰⁻¹⁴⁷ Royal et al. conducted a systematic review of 17 studies that included a pharmacist-led medication review in the intervention arm.¹⁴⁸ These authors found that there was "*relatively weak evidence that*

pharmacist-led medication reviews are effective in reducing hospital admissions". Their systematic review excluded medication reviews conducted after hospital discharge.¹⁴⁸ Holland et al. reported on a trial of home-based medication review (by a pharmacist) after discharge from acute or community hospitals in the United Kingdom.¹⁴⁹ The main end-point for the study was hospital re-admissions, and these authors found a relative risk of 1.3 (95% CI = 1.07-1.58) for readmission in the intervention group. This result was considered "counter-intuitive" by the authors and further research is needed to explain the finding of increased hospitalisation following medication review.

In Australia, regular comprehensive medication management reviews for residents of long-term care facilities and high-risk patients in the community are funded by the Federal government. There are a number of seminal Australian trials that were responsible for the implementation of these medication reviews.

In 2001, Roberts et al. published the results of an evaluation of a year-long clinical pharmacy program in 13 of 52 nursing homes in Australia (the study was completed in 1995).¹⁵⁰ There were no significant differences between the intervention homes and the control homes in terms of frequency of hospitalisation, annual mortality rate, number of adverse events reported and changes in measures of disability. The clinical pharmacy program was, however, associated with a reduction in the overall medication use and medication-related expenditure.¹⁵⁰

The relative success of the model in the nursing home environment led to the provision of funding of two studies to examine the use of clinical pharmacy services for patients with a lower level of care, in hostel accommodation.¹⁵¹⁻¹⁵² The first of these studies, conducted in Queensland, found that the organisational structure of the hostel facility determined whether there was a decrease in medication use.¹⁵¹ Hostels that had structures in place that "facilitated change" had an average reduction in medication use of 13.8% associated with the intervention. In contrast, in those hostels that had different organisational structures, the clinical pharmacy intervention was associated with an increase in medication use. The second study, conducted in Tasmania, demonstrated that the consultant pharmacist intervention resulted in an overall increase in medication use and an increase in quality of life (QOL), compared to the control group of hostel patients.¹⁵²

A randomised study of medication reviews in the community has also been conducted in Australia.¹⁵³ Sorensen et al. found positive trends, but no significant differences, in clinical outcomes, QOL or costs of healthcare in the six months following the review. The authors stated that the short duration of follow-up in the study may have contributed to the lack of clinical significance.¹⁵³

Thus, a formal medication review service, conducted by a pharmacist, is likely to have some value, but this may not be directly related to reductions in medication costs.

1.1.3 Professional Services in Community Pharmacies

Roughead et. al. published a systematic review of the literature concerning the value of professional pharmacist services in the community setting in 2003.¹⁵⁴⁻¹⁵⁵ These authors reviewed the literature up to 2002 concerning the value of:

- pharmaceutical care services;¹⁵⁵
- continuity of care services;
- pharmacist clinic services;
- medication reviews (for repeat prescribing, in aged care facilities and in the outpatient setting);
- educational services (for patients and for healthcare providers);
- pharmacist participation in therapeutic decision-making;
- pharmacist involvement in non-prescription medicines;
- smoking cessation services;
- immunisation services; and

- other services.

They concluded that, overall, there was considerable high quality evidence to support the value of professional pharmacy services in the community setting.¹⁵⁴

1.2 Role of Community Pharmacists in Detecting and Resolving DRPs

The strategies to reduce DRPs outlined in section 1.1 are based on the introduction of an expanded service model, where pharmacists (often more highly trained pharmacists) conduct a formal review of a patient's medications, or carry out other professional services as an *extension* of their normal daily activities. These additional processes and services increase the information available to the pharmacist concerning the patient and thereby present increased opportunities to detect DRPs. For example, a prescription for an antihypertensive agent may appear to be without problems, but if the blood pressure is taken in the pharmacy which indicates under-treatment, then the patient may require re-assessment. In this example, the additional activity of taking the blood pressure has provided the information that indicates a DRP is present.

As shown in section 1.1.3, community pharmacies are providing a range of additional professional activities as an extension of their traditional dispensing and counselling roles. It is likely that these expanded activities will increase the number of DRPs detected and resolved.

Community pharmacists, however, still detect and resolve DRPs during the course of their routine prescription-related activities within their pharmacies (predominantly dispensing and counselling). During the various stages of the dispensing process, pharmacists may detect a range of different DRPs (see Figure 1-2).

Stage of Dispensing Process	Examples of Common Types of DRPS Identified
Prescription Presented	<ul style="list-style-type: none"> • Prescription legal issues • Missing directions
Patient Medication History Checked	<ul style="list-style-type: none"> • Drug interactions • Duplication of medications
Medication Assembled and Labelled	<ul style="list-style-type: none"> • Supply issues
Medication Provided to Patient	<ul style="list-style-type: none"> • Adverse effects • Adherence issues

Figure 1-2: Common Types of DRPs Identified During the Dispensing and Counselling Process

These basic dispensing activities often provide sufficient information to demonstrate the presence of an actual or potential DRP. The extent of the documentation regarding the patient (for example, previous prescriptions) in the pharmacy, and the extent of the interaction with the patient (for example, counselling) will determine the amount of information available on which to assess the presence of a DRP. Some DRPs will be evident purely from the prescription order (for example, drug interactions, incorrect doses), while others require information from the patient (for example, compliance problems, adverse effects).

As stated previously, the term DRPs can be considered an all encompassing description for situations where a drug's desired outcome is actually or potentially interfered with. DRPs can broadly be related to errors, adverse events or adherence issues. Many of the studies discussed below use definitions of events that vary from this or specifically address prescription errors. Consequently, comparisons between the studies are difficult. In addition, many studies consider DRPs identified in community pharmacy practice settings around the world, which will inherently be different. Interpretation and comparisons between studies is further complicated by the use of different methodologies for the collection of the information.

In the following section, available international and Australian studies of the role of the community pharmacist in detecting and resolving DRPs are reviewed. The studies are summarised in section 1.3.1 and there is a focus on the methodology, frequency of identification of the DRPs and the definitions used for the documented events. The various methods of describing the value of community pharmacists' interventions are described in section 1.3.1 and the classification systems for the types of DRPs identified are discussed in section 1.5.

1.3 Community Pharmacists and CIs: A Review of the International Literature

The nature and frequency of DRPs reported in the literature reviewed hereafter will necessarily be related to the definitions used for the event, and the methodology used to collect the information. Many of the studies focus on identification of problems detected directly from the prescription and therefore only report on a proportion of possible DRPs. Indeed, one paper reviewed prescription records in order to identify a rate of *potential* CIs.¹⁵⁶ Further, many of the studies, although using the term "clinical interventions" or DRPs, actually report on interventions relating to correction of prescriptions due to administrative or legislative requirements (for example, missing or incorrect patient details) which would not usually be considered clinical in nature. In this section, each relevant paper is reviewed and a CI frequency is re-calculated by examining the definitions used for the events documented. These CI frequencies are a more relevant method of comparison between the studies.

Papers relating to CIs conducted in community pharmacies are summarised in Table 1-1. For each of the papers, a brief review of the methods and main results are presented, along with a discussion regarding methodology and the resulting frequency of CIs. The literature selected has been limited to that which involves community pharmacists' detection and resolution of DRPs in their routine daily activities. That is, articles that report on interventions associated with enhanced service provision models are not considered in this section. In Chapter 4, the issues relating to methodology and determining the frequency and nature of CIs are discussed.

Primary Author and Date of Publication	Practice Setting	Method and Duration of Recording Period	Definition of Documented Intervention	Types of DRP Recorded	Documentation Method	Published Frequency of DRPs and Estimated/Calculated Clinical Intervention (CI) Frequency
Rupp, 1988 ¹⁵⁷	9 community pharmacies in Indiana, USA	2 weeks	Anything that requires a pharmacist to interrupt their routine dispensing activities to resolve	<input checked="" type="checkbox"/> Prescription Errors <input checked="" type="checkbox"/> Adverse Events <input checked="" type="checkbox"/> Adherence Issues		156 of 5,874 new prescriptions (2.6%)
Rupp, 1992 ¹⁵⁸	89 pharmacies in 5 states of the USA	Recording of interventions by an observer for 5 days	Any prescription related problem that required pharmacists to interrupt their routine dispensing activities	<input checked="" type="checkbox"/> Prescription Errors <input checked="" type="checkbox"/> Adverse Events <input checked="" type="checkbox"/> Adherence Issues	Paper-based "Pharmacy Intervention Record"	673 problems from 53,941 prescriptions (1.25%) 365 CIs from 53,941 prescriptions (0.68%)
Rogers, 1994 ¹⁵⁹	28 community pharmacies in the United Kingdom	Prospective recording by dispensing pharmacists for 18 months	Not stated	<input checked="" type="checkbox"/> Prescription Errors <input checked="" type="checkbox"/> Adverse Events <input checked="" type="checkbox"/> Adherence Issues	Paper-based intervention recording form	1,862 interventions (denominator not reported) 832 CIs, no denominator reported
Dobie, 1994 ¹⁶⁰	4 community pharmacies in Texas, USA	Prospective recording by dispensing pharmacists for 1,500 consecutive new prescriptions	Not stated, but used other techniques from Rupp ¹⁵⁸	<input checked="" type="checkbox"/> Prescription Errors <input checked="" type="checkbox"/> Adverse Events <input checked="" type="checkbox"/> Adherence Issues	Paper-based "Pharmacy Intervention Record"	47 interventions from 6,000 new prescriptions (0.78%) 27 CIs from 6000 new prescriptions (0.45%)
Irvine-Meek, 1994 ¹⁶¹	21 community pharmacies in New Brunswick, Canada	Prospective recording for 10 consecutive weeks	Not stated	<input checked="" type="checkbox"/> Prescription Errors <input checked="" type="checkbox"/> Adverse Events <input checked="" type="checkbox"/> Adherence Issues	Paper-based "standard forms"	555 interventions from ~180,000 prescriptions (0.31%) 165 CIs from ~180,000 prescriptions (0.09%)

Primary Author and Date of Publication	Practice Setting	Method and Duration of Recording Period	Definition of Documented Intervention	Types of DRP Recorded	Documentation Method	Published Frequency of DRPs and Estimated/Calculated Clinical Intervention (CI) Frequency
Greene, 1995 ¹⁶²⁻¹⁶³	23 community pharmacies in West London	Prospective self reports over 4 months	All possible medication and prescription related problems that might be encountered by a community pharmacist, including those arising from OTC medications.	<input checked="" type="checkbox"/> Prescription Errors <input checked="" type="checkbox"/> Adverse Events <input checked="" type="checkbox"/> Adherence Issues	Incident report forms	174 incidents from 281,900 prescriptions (0.06%) 166 CIs from 181,100 prescriptions in actively participating pharmacies (0.09%)
Claesson, 1995 ¹⁶⁴	36 community and hospital discharge pharmacies in Sweden	Prospective recording by dispensing pharmacist for 2 weeks	Errors which, in the opinion of the dispensing pharmacist, called for an intervention	<input checked="" type="checkbox"/> Prescription Errors <input checked="" type="checkbox"/> Adverse Events <input checked="" type="checkbox"/> Adherence Issues	Paper-based intervention recording form	2176 errors requiring intervention from 76,956 prescriptions (2.83%) 243 CIs from 76,956 prescriptions (0.32%)
Poston, 1995 ¹⁶⁵	681 pharmacies in Canada	Prospective recording by dispensing pharmacist for 2 weeks	All interventions that led to a check or change in drug therapy during the screening, dispensing and monitoring process for new and repeat prescriptions	<input checked="" type="checkbox"/> Prescription Errors <input checked="" type="checkbox"/> Adverse Events <input checked="" type="checkbox"/> Adherence Issues	Paper-based interventions recording form	8,933 interventions (2%) (denominator not reported) 5,192 CIs from 446,650 prescriptions (1.16%)
Smith, 1996 ¹⁶⁶	9 small hospitals and 9 health centres in 3 states of the USA	Prospective recording of by dispensing pharmacist for 6 months	"Cognitive service interventions", definition not stated	<input checked="" type="checkbox"/> Prescription Errors <input checked="" type="checkbox"/> Adverse Events <input checked="" type="checkbox"/> Adherence Issues	Paper form or computerised quality assurance system (Resource Patient Management System)	1,446 interventions (0.6%) (denominator not reported) 285 CIs from 241,000 prescriptions (0.12%)
Caleo, 1996 ¹⁶⁷⁻¹⁶⁸	29 community pharmacies in 3 States of Australia	Prospective recording of interventions for 4 weeks	Any change effected by a pharmacist to a PBS prescription item and/or contact with a health professional concerning a PBS prescription item	<input checked="" type="checkbox"/> Prescription Errors <input checked="" type="checkbox"/> Adverse Events <input checked="" type="checkbox"/> Adherence Issues	Paper-based intervention recording form	1,273 interventions from 89,326 prescriptions (1.4%) 258 CIs from 89,326 prescriptions (0.29%)

Primary Author and Date of Publication	Practice Setting	Method and Duration of Recording Period	Definition of Documented Intervention	Types of DRP Recorded	Documentation Method	Published Frequency of DRPs and Estimated/Calculated Clinical Intervention (CI) Frequency
Hulls, 1996 ¹⁶⁹	25 community pharmacies in New Zealand	Prospective recording by dispensing pharmacists for 2 weeks	Any action taken to clarify a prescription to optimise the patients' drug therapy and/or minimise the risk of harmful effects	<input checked="" type="checkbox"/> Prescription Errors <input checked="" type="checkbox"/> Adverse Events <input checked="" type="checkbox"/> Adherence Issues	Paper-based "pharmacy Intervention Form" modified from Rupp's work. ¹⁵⁷⁻¹⁵⁸	354 intervention forms from 19,581 new prescriptions (1.7%) 154 CIs from 21,284 new prescriptions (0.72%)
Knapp, 1998 ¹⁷⁰	31 community pharmacies in California	Retrospective analysis of all interventions for 1 year (1995)	Presumed Rupp definition, ¹⁵⁸ also documented actions and outcomes	<input checked="" type="checkbox"/> Prescription Errors <input checked="" type="checkbox"/> Adverse Events <input checked="" type="checkbox"/> Adherence Issues	Paper-based "pharmacy Intervention Form" modified from Rupp's work. ¹⁵⁷⁻¹⁵⁸	688 DRPs from 93,483 prescriptions (0.74%) 295 CIs from 93,483 prescriptions (0.32%)
Hawthornth, 1999 ¹⁷¹	14 community pharmacies	Prospective recording by dispensing pharmacists for 1 week of each month for 1 year	Where the prescribed item could have been dispensed without contact with the prescriber	<input checked="" type="checkbox"/> Prescription Errors <input checked="" type="checkbox"/> Adverse Events <input checked="" type="checkbox"/> Adherence Issues	Not clearly stated, "recorded all clinical pharmacy interventions made"	1,503 interventions from 201,000 prescriptions (0.75%) 1,503 CIs from 201,000 prescriptions (0.75%)
Westerlund, 1999 ¹⁷²	144 Pharmacists, prescriptionists and pharmacy technicians from 128 different pharmacies in Sweden	Prospective recording on alternate days, half a day at a time, for 2 months	A broad definition of DRPs: "A circumstance of drug therapy that may interfere with a desired therapeutic objective"	<input checked="" type="checkbox"/> Prescription Errors <input checked="" type="checkbox"/> Adverse Events <input checked="" type="checkbox"/> Adherence Issues	Data collection form designed as a postcard	1,098 DRPs from 82,200 prescriptions (1.34%) 966 DRPs from 82,200 prescriptions (1.18%)
Van Mil, 2001 ¹⁷³	17 community pharmacies in the Netherlands	Prospective recording by dispensing pharmacists for 4 weeks	Pharmaceutical services (care activities) that resulted from all alerts (computer generated or not)	<input checked="" type="checkbox"/> Prescription Errors <input checked="" type="checkbox"/> Adverse Events <input checked="" type="checkbox"/> Adherence Issues	Computerised recording of care activity codes (CACs) in the medication history	12,487 CACs from 134,132 prescriptions (9.3%) 3,206 CIs from 134,132 prescriptions (2.4%)

Primary Author and Date of Publication	Practice Setting	Method and Duration of Recording Period	Definition of Documented Intervention	Types of DRP Recorded	Documentation Method	Published Frequency of DRPs and Estimated/Calculated Clinical Intervention (CI) Frequency
Buurma, 2001 ¹⁷⁴	141 Dutch community pharmacies	Prospective case-control study, data collected on 1 nominated day	Prescriptions requiring modification, excluding minor administrative aspects	<input checked="" type="checkbox"/> Prescription Errors <input checked="" type="checkbox"/> Adverse Events <input checked="" type="checkbox"/> Adherence Issues	Paper "registration form"	2,014 prescription modifications from 47374 prescriptions (4.3%) 400 CIs for 36,625 prescription only medicine prescriptions (1.1%)
Westein, 2001 ¹⁷⁵	23 community pharmacies in the Zeeland region of the Netherlands	Case control study. Controls and cases recorded by dispensing pharmacists for 1 week	Any action taken by a pharmacist that led to clarification or change of a prescription	<input checked="" type="checkbox"/> Prescription Errors <input checked="" type="checkbox"/> Adverse Events <input checked="" type="checkbox"/> Adherence Issues	Standardised intervention log forms	337 interventions from 39,357 prescriptions (0.86%) 255 CIs from 39,357 prescriptions (0.65%)
Whitehead, 2002 ⁶²	18 community pharmacies in Perth, Western Australia	Prospective recording by dispensing pharmacists for 4 weeks	Any actions taken that result in a change in the patient's therapy and/or the written prescription	<input checked="" type="checkbox"/> Prescription Errors <input checked="" type="checkbox"/> Adverse Events <input checked="" type="checkbox"/> Adherence Issues	Prescription Intervention Form	222 interventions from 34,491 prescriptions (0.64%) 75 CIs from 34,491 prescriptions (0.22%)
Quinlan, 2002 ¹⁷⁶	34 community pharmacies in England	Prospective recording by dispensing pharmacists for 2 weeks	Not stated	<input checked="" type="checkbox"/> Prescription Errors <input checked="" type="checkbox"/> Adverse Events <input checked="" type="checkbox"/> Adherence Issues	Royal Pharmaceutical Society's Intervention audit form	419 interventions from 60,525 prescription items (0.69%) 238 CIs from 60,525 prescriptions (0.39%)

Primary Author and Date of Publication	Practice Setting	Method and Duration of Recording Period	Definition of Documented Intervention	Types of DRP Recorded	Documentation Method	Published Frequency of DRPs and Estimated/Calculated Clinical Intervention (CI) Frequency
Leemans, 2003 ¹⁷⁷	124 community pharmacies in Finland	Prospective recording by dispensing pharmacists for 2 weeks	Not stated	<input checked="" type="checkbox"/> Prescription Errors <input checked="" type="checkbox"/> Adverse Events <input checked="" type="checkbox"/> Adherence Issues	Paper-based form	3,552 interventions from 87,647 prescriptions (4%); 1,044 CIs from 87,647 prescriptions (1.2%) 588 CIs from 87,647 prescriptions (0.67%)
Andersson, 2003 ¹⁷⁸	20 pharmacies in Sweden	Prospective recording by dispensing pharmacists for 2 weeks	"A circumstance of drug therapy that may interfere with a desired therapeutic objective", as per Westerlund et al. ¹⁷²	<input checked="" type="checkbox"/> Prescription Errors <input checked="" type="checkbox"/> Adverse Events <input checked="" type="checkbox"/> Adherence Issues	Postcard sized data collection form as per Westerlund et al. ¹⁷²	1,465 DRPs from 104,000 prescriptions and OTC sales (1.4%) 637 CIs from 63,929 prescriptions (1.0%)
Benrimoj, 2003 ¹⁷⁹	40 community pharmacies in Sydney, Australia	Prospective recording by dispensing pharmacists for 1 week, followed by 2 weeks of recording after an education program	Definitions for 19 different CIs provided. Interventions further categorised as proactive (could be dispensed without further contact with the prescriber or patient) or reactive (could not be dispensed without further contact)	<input checked="" type="checkbox"/> Prescription Errors <input checked="" type="checkbox"/> Adverse Events <input checked="" type="checkbox"/> Adherence Issues	Intervention documentation form	762 interventions from 87,130 prescriptions (0.87%) 375 proactive interventions from 87,130 prescriptions (0.43%)
Chen, 2005 ¹⁸⁰	9 community pharmacies in Nottingham, England	Prospective recording by dispensing pharmacists for 1 month	Any problems identified in the process of dispensing that might: 1) interfere with the dispensing of prescriptions, or 2) be potentially harmful to patients	<input checked="" type="checkbox"/> Prescription Errors <input checked="" type="checkbox"/> Adverse Events <input checked="" type="checkbox"/> Adherence Issues	Paper-based intervention recording form	196 prescribing problems from 32,403 items dispensed (0.6%) 65 CIs from 32,403 items (0.2%)

Primary Author and Date of Publication	Practice Setting	Method and Duration of Recording Period	Definition of Documented Intervention	Types of DRP Recorded	Documentation Method	Published Frequency of DRPs and Estimated/Calculated Clinical Intervention (CI) Frequency
Hämmerlain, 2007 ¹⁸¹	1,146 community pharmacies in Germany	Prospective recording by dispensing pharmacists for 1 week (NB:- Pharmacies were allowed to choose which week they would record the DRPs)	An event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes. Definitions for 10 DRP types (with a total of 72 subtypes) were identified.	<input checked="" type="checkbox"/> Prescription Errors <input checked="" type="checkbox"/> Adverse Events <input checked="" type="checkbox"/> Adherence Issues	Standardised paper form	10,427 interventions recorded from an estimated 1,833,600 prescriptions (actual number not reported) (0.57%) 6,628 CIs from 1,833,600 prescriptions (0.36%)
Krähenbühl, 2008 ¹⁸²	20 community pharmacies in the French-speaking part of Switzerland	Prospective recording by dispensing pharmacists for 4 weeks	An event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes. Definitions for 17 DRP types were identified and management of the intervention was also recorded.	<input checked="" type="checkbox"/> Prescription Errors <input checked="" type="checkbox"/> Adverse Events <input checked="" type="checkbox"/> Adherence Issues	Computerised documentation system integrated into the dispensing software	287 CIs from 38,663 prescriptions (0.74%)

Table 1-1: Summary of Studies of Community Pharmacists' Involvement in DRP Resolution

Rupp et al. (USA)^{157-158, 183}

Probably the earliest fully published study in the area of community pharmacists' interventions was a pilot study conducted by Rupp et al. in 1987.¹⁵⁷ These authors found that 2.6% (153) of 5,874 *new* prescription orders screened in a two-week period at nine pharmacies contained one or more prescription related problems that required intervention by the pharmacist. They defined an intervention as "anything that requires a pharmacist to interrupt their routine dispensing activities to resolve". This broad definition was presumably related only to prescription or patient issues as opposed to routine interruptions such as phone calls, hold-ups, calls of nature and so on. Of the problems identified, 50.6% (77) were related to "deficiencies" in the prescription which meant that the prescription could not be dispensed without further clarification. This left 76 interventions that could be termed clinical in nature (for example, errors, dose anomalies). The CI rate in this early pilot study could more correctly be described as 76 CIs from 5,874 new prescriptions (1.3%). It would be more appropriate to calculate a CI frequency from a denominator that includes all prescriptions dispensed. However, it is unclear from the information available in the paper what the intervention frequency was in repeat prescriptions, or the proportion of repeat prescriptions.¹⁵⁷

The authors considered the study's range of pharmacies and pharmacists limited (all nine pharmacies were from the USA state of Indiana), and used the techniques piloted to form the basis for a larger study which was conducted in 1990.¹⁵⁸

The larger study involved the documentation of prescription problems by trained observers (final year pharmacy students) in 89 pharmacies in five states of the USA. The results were published in two papers, one specifically relating to the Ohio state results,¹⁸³ and one covering all five states.¹⁵⁸ No clear definition of the types of problems that were documented was given, but the observers were asked to record any prescription problem that required the pharmacist to interrupt his or her routine dispensing process in order to resolve it. They collected information relating to pharmacy and pharmacist workload and also intervention information using a "Prescription Intervention Report" form which included:

- general descriptive information about the prescription order, the prescriber and the patient,
- a narrative description of the pharmacist's intervention, including the reason for the intervention and the names of all drugs involved,
- a list of all prescription medications that the patient was taking at the time of the intervention,
- all sources of information that the pharmacist consulted during the intervention, and
- outcome(s) of the intervention and the final state of the prescription.

These authors reported 673 interventions from 53,941 prescriptions (1.25 interventions every 100 prescriptions), and focused their publication on the 623 interventions that involved 33,011 new prescriptions (1.9 interventions per 100 prescriptions). Each of these occasions had reasons for the pharmacist's intervention assigned. There were 683 reasons assigned to the 623 new prescription order interventions (1.1 reasons per intervention). Of these reasons, 312 (45.6%) were related to omitted information on the prescription (for example, incomplete or unavailable form or strength, quantity or duration not specified), leaving 371 reasons that would be considered clinical in nature (for example, incorrect dose, drug interactions, duplicate therapy). Assuming the 50 interventions that occurred in repeat prescriptions had a similar pattern of reasons for intervention, then a total of 401 reasons for 365 interventions can be estimated. Thus, the true CI frequency could therefore be more accurately calculated as 365 CIs from 53,941 prescriptions, or 0.68%.

Although 20 years have passed since this study was conducted, the publication remains a landmark paper referred to by almost all authors in the area. The methodology was clearly presented and a number of authors have utilised some or all of the techniques in other studies (see following sections). One of the most innovative aspects of Rupp's methodology is the use of observers to record the interventions. This meant that the pharmacists did not have any significant additional workload in terms of recording their activities.

Rogers et al. (United Kingdom)¹⁵⁹

In 1994, Rogers et al. reported on a study that involved reporting of CIs by 28 pharmacies in the United Kingdom.¹⁵⁹ Pharmacists were asked to record CIs for 18 months, and return their written intervention reporting forms every six weeks. Pharmacies provided records for 1,862 CIs (range = 1-473) during the data collection. These authors used an intervention collection form that included information on the type of intervention, the drugs involved (using the British National Formulary (BNF) classification system) and the type of patient (from a list of “at-risk” patient types).

No clear definition of the events to be documented was given in the paper, but the types of CIs reported indicate that the events were predominantly related to prescription modifications and errors. Interventions involving a prescription error (incorrect strength, incorrect dose, incorrect drug or incorrect patient details) accounted for 55.3% (1,030) of the interventions. A further 27.4% (511) were interventions relating to drug interactions, either with prescription or over the counter (OTC) medications. There were no problems reported that related to adverse events or adherence or compliance issues.

Where the type of patient was specified, they found that 35.4% (512 of 1,445) of the interventions occurred in geriatric patients and a further 21% (303) in patients with cardiovascular disease. Common groups of drugs involved in the CIs were cardiovascular (657; 25.6%), central nervous system (450; 17.6%), infectious disease (347; 13.5%) and respiratory system (319; 12.5%).

There are two main difficulties in interpreting this paper. First, there is a lack of a denominator in terms of patient and prescription numbers. This does not enable a frequency of intervention to be calculated. Secondly, the long data collection period, and the relatively passive data collection process has led to a large variation in reporting rates. Indeed the authors mention that 13 of the 28 pharmacies ceased participation for eight months of the data collection period due to changes of ownership and/or management. Even allowing for the lack of participation of 13 pharmacies, 1,862 interventions from the remaining 15 pharmacies over 18 months is approximately seven interventions per month. Thus, it is likely that the documented interventions are highly selected by the documenting pharmacists.

Dobie and Rascati (USA)¹⁶⁰

In a small study published in 1994, Dobie and Rascati aimed to measure the incidence and types of interventions in community settings in two rural Texas counties.¹⁶⁰ They also attempted to assign a dollar value to these services and compared their results to those obtained by Rupp et al. in a previous American study.¹⁵⁸ They used methods very similar to those used by Rupp et al., with the exception that interventions were not recorded by an observer. No operational definition of an intervention is given in the paper, but considering the use of Rupp et al.’s training methods and recording forms, it is assumed that the types of events documented are the same as those in the earlier studies. These authors also only asked pharmacists to record interventions from new prescriptions, with each pharmacy recording interventions until 1,500 consecutive new prescriptions were dispensed.

Pharmacists recorded 47 interventions from 6,000 new prescriptions, a frequency of 0.78 interventions per 100 new prescriptions. A total of 60 reasons for intervention were assigned to the 47 problematic prescriptions, of which 26 (43.3%) were “errors of omission” which would be unlikely to directly affect the clinical outcome of the patient. The remaining 34 reasons (56.7%) were clinical in nature (for example, inappropriate drug or dose, drug interactions). Assuming the proportion of reasons could be applied to the number of problematic prescriptions, the CI frequency can be estimated as 56.7% of 47 (27) from 6,000 new prescriptions, a frequency of 0.45 CIs per 100 new prescriptions.

It is interesting to compare the overall intervention frequency reported by these authors (0.78%) with that reported by Rupp et al.¹⁵⁸ (1.89%). Given the methodology was identical except for the use of observers to document the activities, this gives some indication of the potential difference in frequency achievable using the observer technique. Whether the increased frequency relates to an increased proportion of *documentation* of interventions that were undertaken, or an increased frequency of actually undertaking interventions requires further investigation.

*Irvine-Meek et al. (Canada)*¹⁶¹

In 1994, Irvine-Meek et al. published a paper concerning a study of drug therapy interventions undertaken in community pharmacies in the South-Western New Brunswick region of Canada.¹⁶¹ The study was conducted over a 10-week period from June to August 1992, and all pharmacies in the region were invited to participate. The authors used a “check box” recording form which involved the pharmacist selecting a major category and subcategory for each intervention. Information concerning daily prescription workload and staffing levels was also collected from each pharmacy. No definition of the types of interventions that pharmacists were asked to record was given in the paper; however, it seems from the nature of the results that many of the recorded events were non-clinical, and involved clarification of third-party payments and confirmation of dose and authenticity of the prescription (see Table 1-2).

These authors reported a total of 555 interventions in five major categories. Based on each pharmacy’s estimate of its daily prescription volume, it is possible to estimate that the total number of prescriptions dispensed during the course of the study was 179,900. This gives an intervention frequency of 0.31 interventions per 100 prescriptions. The categories and subcategories of interventions reported are shown in Table 1-2.

Category of Intervention	Subcategory of Intervention	Number			
		Subcategory		Category	
		#	%	#	%
Clarification	Drug	26	4.7%	119	21.4%
	Dose	64	11.5%		
	Quantity	16	2.9%		
	Signature	5	0.9%		
	Physician	3	0.5%		
	Authenticity	5	0.9%		
Changes	Drug	40	7.2%	76	13.7%
	Dose	35	6.3%		
	Quantity	1	0.2%		
	Signature	0	0.0%		
Notification to Physician	Drug Allergy	9	1.6%	139	25.0%
	Drug Interaction	6	1.1%		
	Side Effects	3	0.5%		
	Drug Duplication	3	0.5%		
	Pregnancy	0	0.0%		
	Breast-Feeding	0	0.0%		
	Over-Compliance	6	1.1%		
	Non-Compliance	3	0.5%		
	Additional Refill	92	16.6%		
	Other	17	3.1%		
Involving Third Party Insurers	Generic requests	4	0.7%	179	32.3%
	Non-benefit	16	2.9%		
	Call Third Party	120	21.6%		
	Income Assistance	39	7.0%		
Drug Information	In Pharmacy	7	1.3%	42	7.6%
	Halifax	8	1.4%		
	Manufacturer	8	1.4%		
	Other	19	3.4%		
Total		555			

Table 1-2: Interventions Recorded in Study by Irvine-Meek et al.¹⁶¹

As can be seen, the majority of the interventions were either related to contact with third-party insurers (179; 32.3%) or clarification of the intent of the prescriber or administrative issues with the prescription (119; 21.4%). In addition, it is unlikely that the organising of an additional repeat prescription (92; 16.6%) would have a clinical basis. Thus the CI frequency can be estimated as 165 CIs from approximately 180,000 prescriptions or 0.09%.

As with many of the studies reviewed, there was a variation in the intervention reporting rate amongst the participating pharmacies. Using the published information for daily volume of prescriptions, it was possible to calculate a CI frequency for 19 of the participating pharmacies. This calculated frequency is compared to the reported daily prescription volume in Figure 1-3.

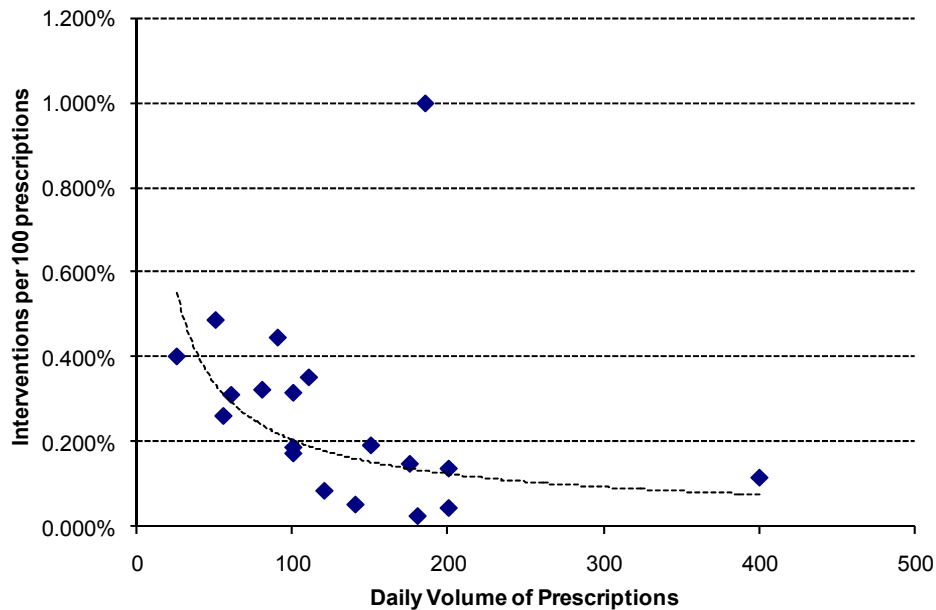


Figure 1-3: Intervention Rate Compared to Prescription Workload (Calculated from Irvine-Meek et al.¹⁶¹)

The graph indicates a lower intervention frequency in pharmacies with a higher reported daily prescription volume. The outlying point relates to a single pharmacy who reported 83 of the 179 interventions relating to third-party insurers. An increase in the number of prescriptions dispensed presents a greater number of opportunities for identification of DRPs. However, as workload increases, the available time for each prescription is reduced, and the time available to investigate and thereby uncover information that indicates the presence of a DRP is reduced. This is an interesting proposition, indicating that interventions may, to some extent, be discretionary.

While there are many factors involved in the frequency of reporting of interventions, this is one of the few studies with sufficient published information to enable the establishment of a relationship between workload and intervention frequency.

Greene (United Kingdom)¹⁶²⁻¹⁶³

In 1995, Greene published the results of a study of prescription incidents that were recorded from October 1986 to January 1987 by pharmacists in 23 pharmacies in West London. Pharmacists were asked to record all possible medication and prescription related problems that might be encountered by a community pharmacist, including those arising from OTC or pharmacist recommended medications. Participating pharmacists were discouraged from recording self-evident errors, such as obvious inadvertent overdoses or “indispensable” prescriptions with missing or invalid entries. This constraint was intended to restrict the incidents to those where the pharmacist required the use of his or her professional skills to resolve the problem. In addition, the study also excluded problems that were brought to the pharmacist’s attention by the patient. Greene supplied stamped, addressed envelopes and pharmacists were asked to complete an incident report form and return them at intervals during the study.

A total of 207 incidents were reported during the main study period, of which 34 (16.4%) referred to “self evident” or patient detected problems. The remaining 174 valid incidents were associated with an estimated 281,900 prescriptions (a frequency of 0.06 incidents per 100 prescriptions). As with many other studies, there was significant variation in reporting rates between pharmacies, with 10 pharmacies providing less than a post hoc determined threshold of one incident per month. The remaining 13 “active participation” pharmacies were responsible for 166 incident reports associated with an estimated 181,100 prescriptions (a frequency of 0.09 incidents per 100 prescriptions).

This intervention frequency is one of the lowest reported in the literature and may be related to the relatively passive process for recording interventions and the strict exclusion of trivial administrative interventions.

*Claesson et al. (Sweden)*¹⁶⁴

In 1995, Claesson et al. published a study of prescription errors identified by personnel at 36 Swedish community and hospital pharmacies during March 1992. Pharmacists were asked to record all prescription errors, including those not requiring a pharmacist's intervention, on specially designed forms for a two-week period.

The authors reported a total of 32,132 errors from 76,956 prescriptions, an error frequency of 42%. Of these, 2,176 were considered by the dispensing pharmacist to require an intervention before the prescription could be dispensed (2,176 of 76,956, 2.8%). The majority of these errors (1781, 82%) were "errors of omission", where various necessary aspects of the prescription were absent (for example, strength, dose, quantity). Of these errors, 338 were interventions that were considered "errors of commission" and were stated to have the potential to harm the patient. These 338 errors of commission were classified into 20 different types, some of which were related to specific Swedish administrative requirements (for example, correct financial benefit required, indication required on prescription). Two hundred and forty-three of the errors of commission were not of an administrative nature and could be considered as errors requiring CIs (243 of 76,956 prescriptions, a frequency of 0.32%).

This study focused on prescription errors only and DRPs related to patient adherence or adverse effects were not recorded. Indeed, as stated by the authors, at the time of the study, Swedish pharmacists were not permitted to keep pharmacy records of previous medication, further limiting the range of DRPs that could be identified.

*Poston et al. (Canada)*¹⁶⁵

In 1993, a Canadian Pharmaceutical Society-funded nationwide study of community pharmacists' interventions took place. The initial results of this study were published in 1995.¹⁶⁵ This paper reports on the largest single community pharmacy intervention study in the literature, with 681 pharmacies participating in the data collection process. Information was separately collected on interventions relating to prescriptions and OTC medications, and interventions prompted by discussion with the patient (that is, adverse reactions or adherence issues) were included. All interventions that led to a check or change in drug therapy during the screening, dispensing and monitoring process for new and repeat prescriptions were recorded. The authors specifically excluded routine administrative interventions such as incomplete or illegible prescriptions. Separate data collection periods, each of two weeks duration, took place for interventions relating to prescription and OTC medications.

They reported 8,933 DRPs from prescriptions at a mean frequency of two interventions per 100 prescriptions (implied 446,650 prescriptions). Of these, 3,466 (38.8%) were related to distribution or supply issues and 275 (3.1%) were formulation or product-related issues. The remaining 5,192 (58.1%) were clinical problems as shown in Table 1-3.

Category of Problem	Number of Problems	% of Problems (n= 8933)
Drug Distribution and supply	3466	38.80%
Patient Information	927	10.40%
Drug interactions/drug allergies/drug side effects	871	9.80%
Dose different from previous script	775	8.70%
Wrong strength/clarify strength	563	6.30%
Dose too high	437	4.90%
Wrong drug	352	3.90%
Dose too low	303	3.40%
Formulation and product-related issues	275	3.10%
Drug duplication	270	3.00%
Contraindications	119	1.30%
Abuse/misuse	95	1.10%
Other	480	5.40%
Total	8933	100.00%

Table 1-3: Drug-related Problems Reported by Poston et al.¹⁶⁵

The CI frequency can therefore be estimated as 5,192 CIs from 446,650 prescriptions, or 1.16%. This frequency is considerably higher than most of the other reports. One contribution to this higher rate is the inclusion of patient information requests.

Smith and Christensen (USA)¹⁶⁶

In 1996, Smith and Christensen published the results of a study of pharmacists' interventions that was conducted for six months during 1992 by pharmacies servicing an American Indian population. Nine small hospital dispensaries and nine clinic dispensaries in the Aberdeen Area Indian Health Service (based in North and South Dakota and Nebraska) participated in the study. Pharmacists recorded interventions either on a purpose designed form, or using an existing quality assurance software system if it was present in the pharmacy.

These authors grouped DRPs into four general types:

- incorrect information (for example, wrong dosage, non-formulary medication, wrong dosage form);
- inappropriate drug (for example, suboptimal drug based on patient's condition and drug of choice);
- clinical problems (for example, contraindications, drug interactions, adverse drug effects); and
- prescription clarification (for example, necessary components missing, transcription errors).

There were 1,446 interventions reported over the six months, an average frequency of 0.6 interventions per 100 prescriptions (implying 241,000 prescriptions dispensed). The authors noted, however, that several pharmacies did not report interventions for the entire study period. The range of intervention frequencies when calculated monthly was 0.03 to 3.42 interventions per 100 prescriptions.

The authors also noted that the majority of the problems detected involved missing and incorrect information on the prescription order (39.6% and 40.7% respectively) and that the remainder of the problems (285; 19.7%) were clinical or inappropriate drug problems. The CI frequency could therefore be estimated as 285 CIs from 241,000 prescriptions (0.12%).

This study is one of only a few that utilised an electronic intervention recording system, albeit only for some of the pharmacies involved. The authors did not estimate the frequency of reports that were manually prepared compared to those that were submitted in electronic form.

*Caleo et al. (Australia)*¹⁶⁷⁻¹⁶⁸

In 1996, Caleo et al.¹⁶⁷⁻¹⁶⁸ published two papers regarding a study of CIs recorded in 29 pharmacies in three states of Australia. Pharmacists recorded 1,273 interventions from 89,326 prescription items dispensed over a four-week data collection period (an average rate of 1.4 interventions per 100 prescriptions). The authors stated that there was a reduction in intervention rates with time, but this is not quantified in either of the papers.

The authors divided the interventions into reactive and proactive interventions based on whether the prescription could be dispensed without the intervention occurring (reactive interventions were those where dispensing could not have occurred without further consultation). Of the 1,273 interventions recorded, 1,015 (79.7%) were reactive and related to issues of clarification of prescription issues. Common reactive interventions were:

- omission of dose/directions (368; 36.2%);
- omission of strength (160; 15.8%);
- incorrect quantity (130; 12.8%); and
- omission of quantity (121; 11.8%).

These clarification interventions are unlikely to have had any clinical consequences, as once the prescription is clarified, it could then be dispensed.

The remaining 258 (20.3%) interventions were termed proactive and the majority of types were made up of:

- incorrect strength (64; 24.8%);
- drug/drug interaction (47; 18.2%);
- incorrect dose (35; 13.6%); and
- inappropriate or incorrect dosage form (32; 12.4%).

Thus the true *clinical* intervention frequency from this study could more accurately be reported as 258 CIs from 89,326 prescriptions or 0.29 interventions per 100 prescriptions.

As with many other studies, there seemed to be no reports of detection of problems relating to compliance or the presence of actual or potential adverse effects.

*Hulls and Emmerton (New Zealand)*¹⁶⁹

In 1996, Hulls and Emmerton published the results of a study conducted in 25 pharmacies in New Zealand over a period of two weeks. They largely used the data collection techniques described by Rupp et al.,¹⁵⁷⁻¹⁵⁸ but used a definition for a recordable event based on that used in a Western Australian study of clinical pharmacist interventions in hospital settings.¹⁸⁴ This definition was: “any action taken to clarify or change a prescription to optimise the patient’s drug therapy and/or minimise the risk of harmful effects”. Hulls and Emmerton specifically excluded routine counselling activities, the use of cautionary and advisory labels, and clerical alterations for government reimbursement purposes.

These authors collected information using a prescription intervention form (PIF) that included the:

- patient’s gender and approximate age;
- reason for intervention (grouped into four categories: prescribing omission, prescribing error, drug interaction and drug therapy monitoring problem);
- details of the problem (free text);
- action(s) taken;
- outcome(s); and
- estimated time taken in resolving the problem.

The authors reported an intervention rate of 1.5% (range = 0.3-6.7%) for new prescriptions, based on 297 PIFs completed in the 23 pharmacies that provided prescription workload statistics (a total of 19,581 new prescriptions). Overall, pharmacists recorded 370 interventions on 310 intervention recording forms during the two-week study (1.2 interventions per PIF). Of the 370 interventions, 216 (58.4%) were errors of omission relating to prescription requirements (for example, dose not specified, directions incomplete, illegible). Thus, the remaining 154 CIs (for example, dose inappropriate, duplication, over or underuse of drug) can be used to calculate a CI frequency. Assuming the two pharmacies that did not submit their prescription statistics are typical of the others, a CI frequency of 154 CIs from 21,284 new prescriptions (0.72%) can be estimated. It would, however, be more appropriate to calculate intervention frequency from total prescriptions dispensed (including repeat prescriptions), but this information was not provided in the paper.

Knapp et al. (USA)¹⁷⁰

In 1998, Knapp et al. published the results of a study of documented interventions that were undertaken in a structured pharmacy services program for 22,000 patients in California.¹⁷⁰ Information concerning the interventions was collated retrospectively, and the publication pertains to the interventions documented in the 1995 calendar year. The patient population was predominantly young women and their dependent children and there were 31 pharmacies that provided their intervention information. Pharmacies were required to document any problems relating to a prescription, the action taken and the outcome on forms based on the work of Rupp et al.^{157-158, 183, 185} Documentation of interventions was a component of a service contract to the patients and remuneration of \$40-\$80 per intervention was provided to the pharmacists.

No clear definition of the DRP was mentioned in the article, but as other aspects of the Rupp et al.¹⁵⁸ definition were used, and as such it is assumed that this definition was used.

A total of 637 interventions were claimed during the calendar year, and the authors were able to analyse information pertaining to 595 of these interventions. From these 595 interventions, 688 DRPs were identified. During the 1995 calendar year, 93,483 prescriptions were dispensed, giving a DRP frequency of 0.74 problems per 100 prescriptions. Many of the documented problems (412; 60%) related to drug selection issues (for example, brand substitutions or therapeutic interchanges) or errors in the writing of the prescription. The remaining 276 problems were either clinical problems (209; 30.4%) or direct patient requests for information (67; 9.7%). An estimate of the CI rate can therefore be made as $276 \times 637/595$, or 0.32 CIs per 100 prescriptions.

Information concerning the frequency of interventions for each of the pharmacies was available, and showed a wide variation in the percentage of prescriptions generating an intervention. Of the 31 pharmacies, 10 dispensed 23,597 prescriptions but did not record any interventions. A further nine pharmacies recorded a total of 104 interventions from 39,289 prescriptions (each pharmacy at a frequency of less than one intervention per 100 prescriptions). The remaining 11 pharmacies recorded 533 interventions from 30,597 prescriptions at frequencies varying from 1 to 4.1 per 100 prescriptions. The authors suggested that benchmarking the pharmacies may help to reduce the inconsistency in reporting and increase the relatively low rate of interventions.

Westerlund et al. (Sweden)¹⁷²

In 1999, Westerlund et al. published the results of a study conducted in 1996 in Sweden.¹⁷² These authors obtained documentation relating to the nature of DRPs in 128 different pharmacies by recruiting 144 staff members from these pharmacies. Staff included 34 pharmacists, 71 "prescriptionists" (trained dispensers), and 39 pharmacy technicians. Staff were asked to record DRPs on a postcard-sized data collection form for half a day on alternate days, rotating between morning and afternoon, for two months. Staff also tallied the number of patients they served during the eligible data collection period. It is important to note that the information collected pertained to both prescription and non-prescription medicines.

Westerlund's group used a broad definition of DRPs in order to maximise the scope of the problems detected – "A circumstance of drug therapy that may interfere with a desired therapeutic objective". Consequently, the information collected contained DRPs that related to prescription errors, adverse events and adherence issues.

Definitions were provided for each of 14 categories of DRP and the participants were also requested to document the interventions made in order to resolve the problem.

A total of 1,098 DRPs were recorded from an estimated 82,200 prescriptions dispensed. From the published graphs, it is possible to estimate that 12% (132) of the DRPs were related to OTC medications, but no estimate was made of the number of OTC sales made during the data collection period. Thus, the prescription-related DRP frequency can be estimated as 966 DRPs from 82,200 prescriptions or 1.18%. The relative proportion of DRPs for prescription-related and OTC medications is shown in Figure 1-4.

The most common type of DRP identified from prescription medications was uncertainty of the purpose of the medication (159; 14.5%), which could be deemed an adherence issue. Other common adherence issues included practical difficulty using devices (129; 11.75%), opening containers (33; 3%), language deficiency or swallowing the medication (25; 2.25% each).

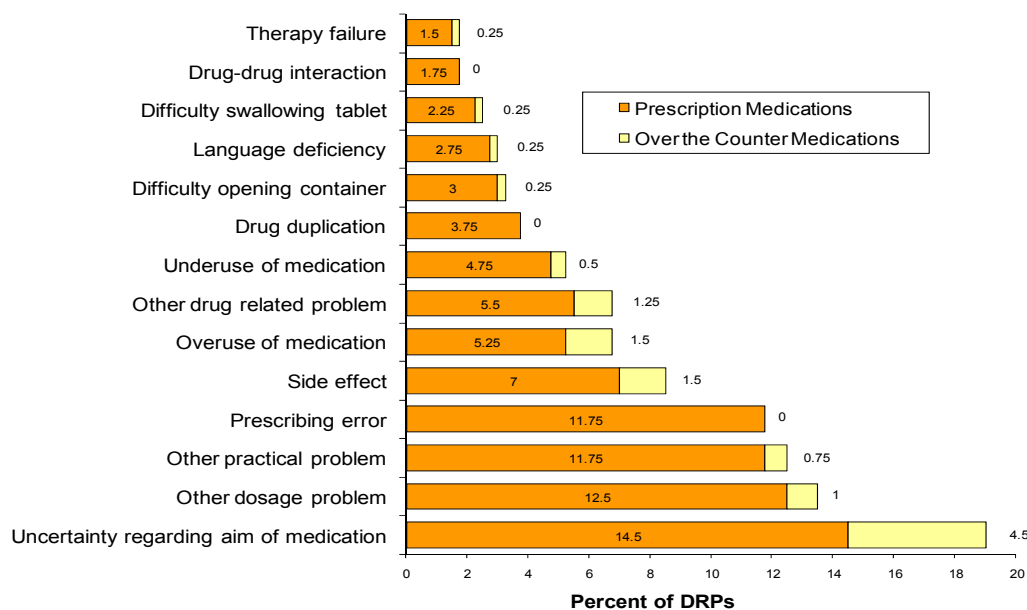


Figure 1-4: Distribution of Types of DRPs, n = 1098 (estimated from Westerlund et al.¹⁷²)

As a result of the large proportion of the DRPs detected that related to adherence issues, the interventions made to resolve the DRPs frequently involved patient counselling or some form of practical instruction to the patient (see Figure 1-5).

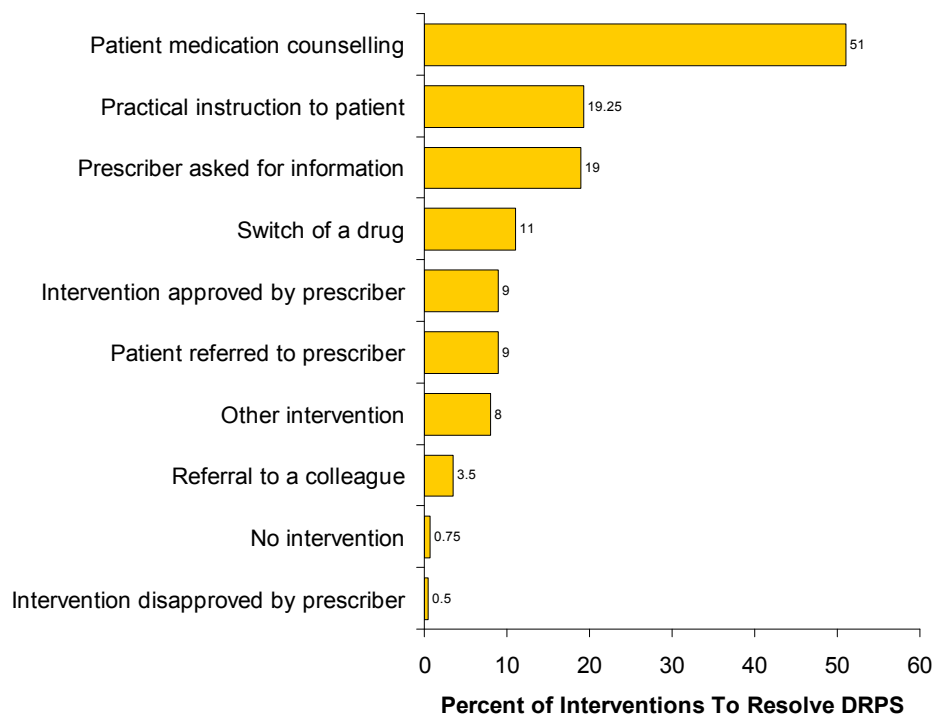


Figure 1-5: Distribution of Types of Interventions, n = 1469 (estimated from Westerlund et al.¹⁷²)

There were a number of other interesting aspects of this Swedish study. Information concerning the main drug involved in the DRP was also collected, along with information on the sales related to particular products. This enabled the authors to calculate a frequency of DRPs adjusted for sales and a “top 10” league table (see Table 1-4).

The types of problems identified in this study frequently related to adherence issues, particularly in terms of usage of devices. It would be reasonable to assume that “routine” counselling with regard to instructions for use would be provided in association with the sale of a product. It is difficult to determine whether a distinction was made between this routine-style counselling for a patient newly prescribed a particular device-based product, compared to a patient with ongoing difficulty using the product, where a DRP is evident.

Rank	Compound	Most Common Problem(s)
1	Budesonide nasal turbuhaler	Practical problems
2	Timolol eye drops	Difficulty opening container; Other practical problems
3	Salmeterol diskhaler	Practical problems; Uncertainty of aim or function of drug
4	Budesonide turbuhaler	Practical problems; Uncertainty of aim or function of drug
5	Dextropropoxyphene	Uncertainty of aim or function of drug; Dosage problems
6	Terbutaline turbuhaler	Practical problems; Uncertainty of aim or function of drug
7	Dextropropoxyphene + paracetamol in combination	Dosage problems; Overuse; Drug duplication
8	Codeine + paracetamol in combination	Side effects; Drug duplication; Difficulty swallowing tablets
9	Furosemide slow release	Underuse; Prescribing errors
10	Citalopram	Dosage problems

Table 1-4: Top 10 Problem-related Drugs (from Westerlund et al.¹⁷²)

Hawksworth et al. (United Kingdom)^{171, 186}

In 1999, Hawksworth et al. published the results of a study where 14 community pharmacies recorded CIs for one week of each month for a 12-month period.¹⁷¹ These authors had previously conducted a pilot study in one of the pharmacies that participated in the major study.¹⁸⁶

Pharmacists were specifically asked *not* to record reactive interventions (where the prescribed item could not be dispensed without contacting the prescriber), or non-clinical interventions relating to administrative or legal issues. Thus, the interventions recorded in this study were all clinical in nature. The interventions were classified into types and the proportion of interventions of each type was as follows:

- missing drug; 75 interventions (5%);
- drug not required; 63 interventions (4.2%);
- discuss information about a drug; 209 interventions (13.9%);
- change a drug; 191 interventions (12.7%);
- alter a formulation; 213 interventions (14.2%);
- enquiry about the dose; 358 interventions (23.8%);
- enquiry about the dosage interval; 174 interventions (11.6%);
- recommend the monitoring of plasma parameters to check efficacy and safety of a drug regimen; 35 interventions (2.3%);
- discuss with prescriber a complete drug review of the patient's therapy; 111 interventions (7.4%); and
- others; 42 interventions (2.8%).

This study seems to have identified a number of DRPs that were related to patient education or information issues and a smaller number of DRPs related to monitoring of efficacy and safety.

*van Mil et al. (The Netherlands)*¹⁷³

In 2001, van Mil et al. published the results of a study conducted in 17 Dutch community pharmacies.¹⁷³ One of the main objectives of their study was to determine the pharmaceutical services (interventions) that resulted from the use of a computer generated alerting (CGA) program that had been in use in the Netherlands since 1985. All dispensing software in the pharmacies involved in the study had the capacity to generate these alerts and the alerts were based on a database provided by the Royal Dutch Association for the Advancement of Pharmacy. The dispensing system also allowed for the recording of care activity codes (CACs) in each patient's medication history.

These CACs were:

- IA: Interaction
- CI: Contraindication
- OV: Allergy
- DB: Possible duplicate medication
- NM: Unclear prescription
- ST: Questionable strength
- DS: Dosage different from previous prescription
- EU: Drug dispensed for the first time
- PT: Possibly incorrect patient data
- HV: Unusual quantity

For each of the CACs documented in the dispensing system, an outcome was documented. Fundamentally, this consisted of an active change (for example, change made, advice provided, information provided), or effectively no change (for example, problem previously solved or not relevant, no change made, no information provided).

During the course of the study, 12,487 active changes were documented from 134,132 prescriptions (9.3 interventions per 100 prescriptions). However, as can be seen by the CACs used, not all of these interventions could be considered clinical. If non-clinical interventions relating to codes NM (unclear prescription), EU (drug dispensed for the first time), PT (possibly incorrect patient data) and HV (unusual quantity) are removed, 3,206 CACs remain as an estimate of the CIs recorded. This would result in a CI frequency of 2.4% (3,206 interventions from 134,132 prescriptions). This frequency is considerably higher than that reported in most of the other studies reviewed.

One possible reason for this high frequency is the method of identification of potential DRPs and the way these were brought to the attention of the dispensing pharmacist. In this study, 45,404 computer generated alerts were raised (33.8% of all prescriptions). These alerts prompted the pharmacist to examine potential drug interactions, contraindications, inappropriate dosages etc. Although the majority of these alerts did not result in an active change (that is, they had been addressed previously, or were not relevant), 12,487 CACs with active changes were documented (27.5% of CGAs resulted in a change or advice being provided).

A second possible reason for the high frequency of interventions is the nature of the documentation. Most of the other studies used a paper-based recording system, whereas this study used a computerised system. Given the frequency of documentation of CACs from CGAs (overall 33.8% of prescriptions had a CGA raised and 24.6% of all prescriptions had a CAC documented), presumably entering the CACs is a relatively routine task that does not interrupt workflow. This is an important consideration for any documentation system (see Chapter 2).

*Buurma, et al. (The Netherlands)*¹⁷⁴

In 2001, Buurma et al. examined the nature, frequency and determinants of prescription modifications undertaken by Dutch community pharmacists.¹⁷⁴ Pharmacists were asked to record modifications to prescriptions on a single pre-determined day and also to collect a random control prescription to match the one

with the modification. They found 2,014 modifications from 47,374 prescriptions dispensed in 141 pharmacies. The average rate of modification of prescriptions was 4.3 for every 100 prescriptions overall, but varied significantly between pharmacies (the range of interventions recorded was 0 to 100 per pharmacy). They also found that there was a significantly higher rate of modifications for “prescription only medicines” (POM) compared to non-medicines such as dressings and syringes and needles (4.9 modifications for every 100 POM prescriptions compared to 1.4 modifications for every 100 non-medicine prescriptions). The majority of modifications involved clarification of the prescription or were related to non-specification of dose, insufficient patient data, wrong or non-specified strength or wrong dosage form (a total of 71.8% of the modifications were of this type). Only 22.2% (400) were classified as corrections of prescription errors which could have led to clinical consequences. As none of these clinical modifications occurred with non-medicine prescriptions, the “clinical” intervention frequency for the study could more accurately be reported as 400 clinical modifications for 36,625 POM prescriptions (1.1 clinical modifications for every 100 POM prescriptions). Over 80% of these corrections related to wrong dose, wrong medicine or wrong patient data.

This study used a definition for the type of problem documented that resulted in a large number of changes based on simple clarification of the prescription. There were no problems documented relating to adherence issues and no problems relating to adverse effects during the use of a prescription medicine.

Westein et al. (The Netherlands)¹⁷⁵

In 2001, Westein et al. published the results of a study conducted in May 1998 of intervention reports from 23 pharmacies in the Zeeland region of the Netherlands.¹⁷⁵ Pharmacists were asked to record details of interventions on a standardised intervention log form and also to collect details of a control prescription from the same day in the same pharmacy for a patient of the same gender and age. Interventions were defined as “any action taken by a pharmacist that led to a clarification or change of a prescription”. The 23 pharmacies reported 337 interventions from 39,357 prescriptions dispensed during the week-long study (0.86 interventions per 100 prescriptions). The authors were able to determine an odds ratio for the presence of an intervention based on comparison of a number of parameters relating to the prescription details for the cases and the controls. They examined the following parameters and determined the odds ratios shown (95% confidence intervals in brackets):

- first versus other prescription: 1.75 (1.18-2.33);
- specialist prescription: 1.21 (0.69-1.72);
- >three prescribers: 1.75 (0.51-2.99);
- >15 prescriptions in three months before: 1.60 (0.80-2.40);
- >three different medications: 1.48 (0.98-1.99);
- antibiotics: 2 (0.90-3.10);
- respiratory drugs: 1.71 (0.85-2.57); and
- cardiovascular drugs: 1.40 (0.81-1.98).

As can be seen, the confidence intervals for all but the first parameter (original prescription) indicate that the parameter was not a significant predictor of the presence of an intervention.

The authors classified the reasons for the interventions in the same manner as Rupp et al.¹⁵⁷⁻¹⁵⁸ These authors determined that 24.1% (82) of the 337 interventions were classified as errors of omission (that is, the prescription could not be dispensed without further clarification). The remaining 255 interventions can therefore be termed CIs and thus the CI frequency for this study can be calculated as 255 interventions from 39,357 prescriptions or 0.65%.

Whitehead et al. (Australia)⁶²

A study of prescription interventions recorded in 18 community pharmacies in Perth, Western Australia was published in 2002 by Whitehead et al.⁶² The information was collected over a four-week period in 2001 using a

paper-based intervention recording form. Pharmacists recorded any actions taken that resulted in a change in the patient's therapy and/or the written prescription and the researchers further classified the interventions as clinical or administrative in nature.

They recorded a total of 222 interventions from 34,491 prescriptions, a frequency of 0.64 interventions per 100 prescriptions (0.64%). Interventions were more common in new (1.14%) compared to repeat (0.16%) prescriptions and CIs occurred more frequently than expected in computer generated compared to manually written prescriptions (see Table 1-5).

Prescription Status	Type of Intervention		Total
	Administrative	Clinical	
Computer-generated	25	47	72
Manually Written	96	28	124
Total	121	75	196

Table 1-5: Types of Interventions for Computer Generated vs Manually Written Prescriptions⁶²

Unfortunately, the authors did not publish the number of computer generated compared to hand-written prescriptions, so it is not possible to determine if the frequency of CIs in computer generated compared to hand written prescriptions is different.

As with other studies, the focus was on prescription-related problems, and few of the problems were patient-related issues such as adverse reactions and adherence issues.

*Quinlan et al. (United Kingdom)*¹⁷⁶

In 2002, Quinlan et al. published a short article concerning a study aimed at assessing the frequency and rates of intervention and the reasons for interventions in community pharmacies. They recruited 38 pharmacies and received information concerning interventions from 34 of these over a two-week period in October 2001. Information was collected using the Royal Pharmaceutical Society's Intervention Audit Form. No clear definition of an intervention was given in the paper, but a list of intervention types indicated that they collected information on prescription anomalies and administrative errors as well as CIs such as possible adverse effects.

Pharmacies recorded 419 prescription interventions from 60,525 prescription items (an intervention frequency of 0.69%). Of these interventions, 89 (21.2%) related to prescription administrative problems (no GP signature, 52; illegible, 12; not conforming with legal requirements, 11; or not remunerated in drug tariff, 14). A further 81 (19.3%) related to queries regarding the quantity on the prescription (53 interventions) or had a supply or availability problem (29 interventions).

The remaining 238 *clinical* interventions can be used to calculate a CI frequency of 0.39% (238 interventions from 60,525 prescriptions).

*Leemans et al. (Finland)*¹⁷⁷

In 2003, Leemans et al. published the results of a study conducted in 124 community pharmacies in Finland over two weeks during October 2000.¹⁷⁷ These authors initially tested a data collection form and then used this form to differentiate between technical and CIs. No definition of events to be documented was given in the paper, but a list of technical and CIs was provided (see Table 1-6).

Overall, 3,552 interventions were reported from 87,647 prescriptions (a frequency of 4%) during the two weeks of the study. Of these, 1,044 interventions were classified as clinical according to the classifications shown in Table 1-6. Their reported CI frequency was 1.2% (1,044 interventions from 87,647 prescriptions) with a high degree of variability between the pharmacies (range was 0 to 127 CIs per pharmacy).

Technical Interventions	Clinical Interventions
Insufficient or excessive number of drugs (e.g. number of tablets)	Interactions
Number of packages incompatible with reimbursement guidelines	Contraindications
Incorrect name of the drug	Missing or incorrect advice
Way of administration incorrect or missing	Missing or incorrect dose regimen
Supply problems (e.g. running out of stock)	Duplication of therapy
Illegible	Non compliance
Product does not exist	Follow up necessary
Wrong drug prescribed (due to similar packages)	Abuse

Table 1-6: Types of Interventions Reported by Leemans et al.¹⁷⁷

However, when the categories of CIs are closely examined, categories such as missing advice (342 interventions) and missing dose (114 interventions) were included. A more appropriately calculated CI frequency would therefore be 588 CIs from 87,647 prescriptions, or 0.67%.

*Andersson et al. (Sweden)*¹⁷⁸

In 2003, Andersson et al. published the results of a study of pharmacist interventions collected over two weeks in 1998.¹⁷⁸ These authors randomly selected 20 pharmacies and generally utilised the methods and definitions employed by their Swedish colleagues, Westerlund et al.¹⁷² (see earlier).

This group reported 1,465 DRPs, most of which were associated with prescription and OTC sales, but some of which were identified in persons seeking advice without buying any medicines. During the course of the study 63,929 prescriptions were dispensed and an estimated 40,000 OTC sales took place. The overall DRP detection frequency was therefore 1,465/104,000, or 1.4%. The authors categorised the nature of the DRPs and the interventions to resolve the problem in a similar way to Westerlund's group, although an attempt was made to hierarchically group the DRPs (see Table 1-7).

Interestingly, the intervention frequency for OTC products was higher than that reported for prescription agents (1.35 DRPs per 100 OTC sales compared to one DRP per 100 prescriptions). This finding is influenced by the large number of DRPs identified from OTC sales relating to patients being uncertain about the purpose or use of the medicine (see Table 1-7).

Type of DRP	Prescription Medications		Over the Counter Medications		Other		Total	
	#	%	#	%	#	%	#	%
Patient Uncertain about Purpose or Use of the Medicine	167	26.2%	395	72.9%	125	43.7%	687	46.9%
Uncertain of purpose of medicine	117	18.4%	325	60.0%	90	31.5%	532	36.3%
Incorrect use or handling	50	7.8%	28	5.2%	11	3.8%	89	6.1%
Self-care not appropriate	0	0.0%	42	7.7%	24	8.4%	66	4.5%
Interactions, Side effects or Lack of effect	102	16.0%	71	13.1%	85	29.7%	258	17.6%
Drug-drug interactions	34	5.3%	13	2.4%	16	5.6%	63	4.3%
Side effects	62	9.7%	40	7.4%	59	20.6%	161	11.0%
Lack of effect	6	0.9%	18	3.3%	10	3.5%	34	2.3%
Problems Caused by the Prescriber	124	19.5%	0	0.0%	6	2.1%	130	8.9%
Drug Duplication	16	2.5%		0.0%	1	0.3%	17	1.2%
Prescribing Error	108	17.0%		0.0%	5	1.7%	113	7.7%
Practical Handling Problems	80	12.6%	8	1.5%	16	5.6%	104	7.1%
Difficulty swallowing tablet	12	1.9%	2	0.4%	4	1.4%	18	1.2%
Difficulty opening container	9	1.4%	1	0.2%	0	0.0%	10	0.7%
Other practical problem	59	9.3%	5	0.9%	12	4.2%	76	5.2%
Dosage Problems	68	10.7%	11	2.0%	12	4.2%	91	6.2%
Underdosage	25	3.9%	3	0.6%	5	1.7%	33	2.3%
Overdosage	43	6.8%	8	1.5%	7	2.4%	58	4.0%
Other Problems	96	15.1%	57	10.5%	42	14.7%	195	13.3%
Language problems	6	0.9%	2	0.4%	0	0.0%	8	0.5%
Problems cause by the pharmacy	11	1.7%	1	0.2%	2	0.7%	14	1.0%
Other	79	12.4%	54	10.0%	40	14.0%	173	11.8%
Total	637	100%	542	100%	286	100%	1465	100%

Table 1-7: Classification System for DRPs and Number and Type of Problems Detected (from Andersson et al.)¹⁷⁸

As with the earlier Swedish study, there is an issue of distinction between routine counselling compared to patients with a DRP. For example, 325 of the OTC-related DRPs were related to patients being uncertain about the intent of the medicine. It is unclear what proportion of these patients were simply explained the purpose of the medication as a routine part of the sale process. As expected, a large number of the interventions conducted to resolve the problem were related to improving the patient's understanding of the therapy or improving the practical handling of the medication form (26% of the interventions were in one of these two categories).

*Benrimoj et al. (Australia)*¹⁷⁹

In 2003, Benrimoj et al. published the results of a comprehensive study of CIs in community pharmacies in New South Wales, Australia.¹⁷⁹ The study was designed with multiple arms and examined the effect of remuneration and two different educational programs on CI rates in the pharmacies.

These authors used information recorded by pharmacists in 40 community pharmacies in Sydney, Australia. Pharmacists recorded intervention details on a purpose-designed intervention reporting form. Thirty of the pharmacies were randomly selected and 10 were conveniently sampled, comprising pharmacists who had previously attended additional educational sessions. Baseline data were collected from all participating pharmacies, and the educational programs and remuneration were provided to the pharmacists after this baseline data collection period (see Figure 1-6).

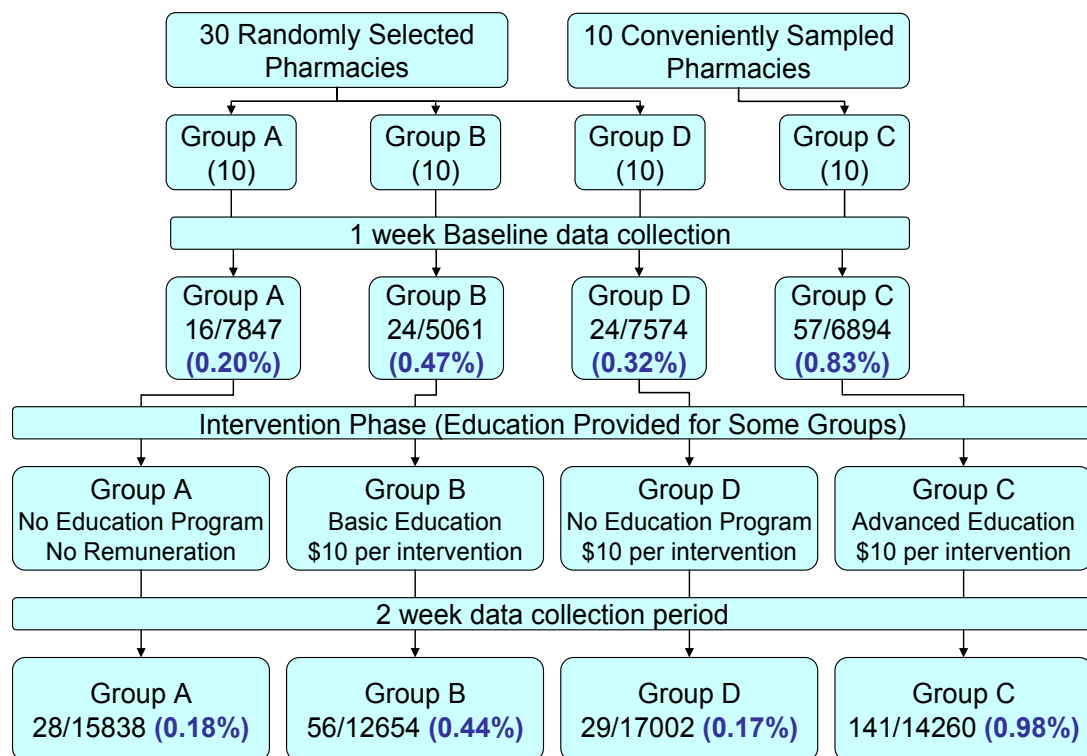


Figure 1-6: Study Design and Results for Proactive Interventions from Benrimoj et al.¹⁷⁹

Definitions for 19 different CIs were provided and interventions were then further categorised as proactive (that is, they could be dispensed without further contact with the prescriber or patient) or reactive (they could not be dispensed without further contact). The definitions covered a range of situations relating to errors in prescriptions and potential adverse effects. There were no problems that directly addressed issues of patient education resulting in adherence issues. A list of the 19 types of interventions and the presumed category is shown in Table 1-8.

Clinical Intervention Types
Incorrect Strength (Reactive)
Incorrect or Inappropriate Dose (Reactive)
Incorrect Drug (Reactive)
Incorrect or Inappropriate Dosage Form (Reactive or Proactive)
Incorrect Quantity (Reactive)
Illegible Handwriting (Reactive)
Adverse or Side Effect (Proactive)
Drug/Drug Interaction (Proactive)
Drug Allergy (Proactive)
Omission of Dose or Directions (Reactive)
Omission of Dosage Form (Reactive)
Omission of Strength (Reactive)
Omission of Quantity (Reactive)
Dose or Strength Query (Proactive)
Drug Query (Proactive)
Not on PBS (Reactive)
Item Unavailable (Reactive)
Organising an Prescription for a Patient (Reactive)
Prescribing Information (Reactive)

Table 1-8: Types of CIs Defined by Benrimoj et al.¹⁷⁹

Reactive interventions were predominantly related to errors or omissions in required information on the prescription, and would not usually be regarded as clinical in nature.

The authors reported a total of 762 interventions resulting from 87,130 prescriptions (0.87%) during the course of the study. Of these, 375 were proactive interventions (more likely to be clinical in nature), resulting in a CI frequency of (345/87,130 or 0.43%).

There were significant differences amongst the pharmacies in terms of proactive intervention frequency at baseline and differences in the effects of the educational program and remuneration. The pattern of changes in proactive intervention rates for each of the groups is shown in Figure 1-7.

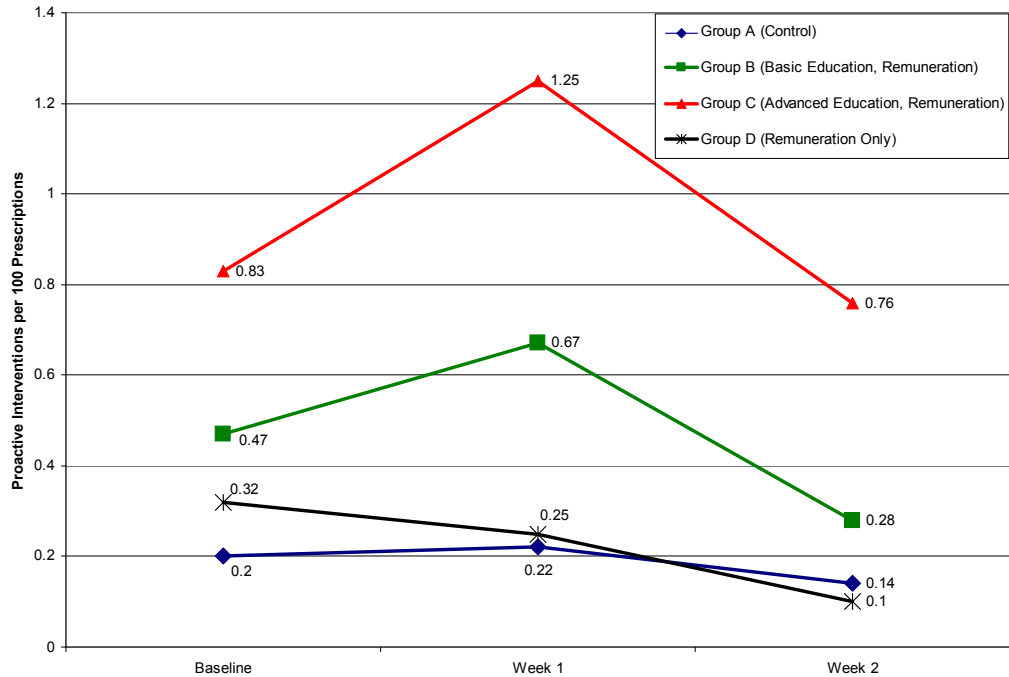


Figure 1-7: Pattern of Intervention Rates for Different Weeks of Data Collection (from Benrimoj et al.¹⁷⁹)

Groups B and C (the groups that had educational programs provided) had a short-lived increase in intervention rates during Week 1, but rates for both groups fell below their baseline levels at Week 2. Groups A and D showed a gradual decline in intervention rates. All pharmacies showed a rate of interventions below baseline levels at two weeks.

The authors concluded that payment of a fee for service alone did not increase CI rates and that a specific educational program together with a fee for service remuneration led to a short-term increase in intervention rates.

The variation between the groups' intervention rates at baseline indicates that there may be characteristics of particular pharmacists and pharmacies that either influence intervention rates or rates of documentation of interventions. Group C, whose pharmacists had a higher level of previous continuing education participation, had the highest baseline proactive intervention rate. This implies that clinical knowledge is a factor in intervention rate.

Chen et al. (United Kingdom)¹⁸⁰

In 2005, Chen et al. published the results of a study of community pharmacists' interventions which was undertaken during 2000 and 2001.¹⁸⁰ Pharmacists in nine community pharmacies were asked to record situations where problems were detected in the dispensing process that either:

- interfered with the dispensing of prescriptions (for example, incomplete prescriptions, prescriptions with incorrect information); or
- were potentially harmful to the patient (for example, potentially hazardous drug interactions, inappropriate doses or directions, contraindications, ADRs, allergies or drug duplications).

Information was collected regarding the age and gender of patients, the time spent by pharmacists dealing with the problem, the type of problem, the possible cause of the problem and the total number of prescriptions dispensed at each pharmacy.

There were 196 problems identified from 32,403 items dispensed (0.6 interventions per 100 prescriptions). The range of intervention frequency was from 0.2 interventions per 100 prescriptions to 1.9 interventions per 100 prescriptions. The authors indicated a negative correlation between dispensing volume and problem reporting rate (Pearson's correlation coefficient -0.69, $p = 0.041$). The majority of problems reported were related to incomplete, illegible or incorrect prescriptions (131; 67%) and can be considered non-clinical in nature. Thus, the true CI rate could more accurately be reported as 65 interventions from 32,403 items, or 0.2 interventions per 100 prescriptions.

Hämmerlein (Germany) 2007¹⁸¹

In 2007, Hämmerlein et al. published the results of a study documenting DRPs in 1,146 German pharmacies for one week during 2005. Pharmacists were asked to record any event or circumstance that actually or potentially interfered with desired health outcomes. The authors designed a standardised form for the pharmacists to document the DRP including patient age and gender, drug involved, whether the prescription was an original or repeat, time needed for resolution of the DRP, free-text description of the DRP and its management. After the trial, two members of the research team classified each of the DRPs into the PI-Doc System¹⁸⁷ which had been modified to include a total of 72 categories.

The study reported that on average each pharmacy served 900 patients and dispensed 1,600 prescriptions and OTC drugs during the week. Overall, 10,427 DRPs were recorded from approximately 1,833,600 prescriptions, which is an intervention rate of approximately 0.57% and is equivalent to 9.1 DRPs per pharmacy per week. The PI-Doc System records all types of DRPs, including technical problems; therefore, of the 10,427 DRPs, only 6,628 were considered a CI under the PROMISE definition (see Section 1.7). This results in an adjusted intervention rate of 0.36 DRPs in 100 prescriptions. The most common DRPs identified were wrong data on the prescription (such as wrong dose or drug) with 1,889 (28.5%), safety or effectiveness issues (such as interactions or contraindications) with 1,872 (28.2%), and patient knowledge issues (such as patients ignorant of correct dose or insufficient knowledge about their condition or medication) with 1,468 (22.2%).

The main limitations of this study were the short time frame of only one week and the pharmacies were able to choose which week they wished to record their DRPs, which may have increased the actual intervention rate.

Krähenbühl (Switzerland) 2008¹⁸²

In 2008, Krähenbühl et al. published the results of a study documenting DRPs in 20 Swiss pharmacies over four weeks in 2005. Pharmacists were asked to record any event or circumstance that actually or potentially interfered with desired health outcomes. The authors designed an electronic intervention recording system that was integrated with the dispensing software which is similar to the PROMISE design. Pharmacists were asked to electronically categorise the DRPs based on the Pharmaceutical Care Network Europe (PCNE) classifications which included the type of DRP, its potential negative outcome, its management and the individuals involved. This four-step plan allowed documentation of 17 different DRP types, of which 10 would be considered CIs according to the PROMISE definition.

Resulting from the 38,663 prescriptions dispensed over the four weeks, pharmacists documented 287 clinical DRPs corresponding to an average intervention rate of 0.74%. The most common DRPs identified were wrong dosage (91; 31.7%), drug-drug interactions (45; 15.7%), wrong drug regimens (33; 11.5%) and adherence problems (27; 9.4%).

This recent study closely resembled the main methodological points of the broader PROMISE study because it was one of the only studies that used an integrated electronic system to document the DRPs. The participating pharmacies also volunteered and they received no incentives for participation, which is similar to the proposed PROMISE III methodology. Therefore, it could be expected that the results of the PROMISE III trial might resemble this trial.

1.3.1 Summary of the Literature

As can be seen in Table 1-1, and the summary of each of the studies, there is a wide range of reported frequencies of DRPs in community pharmacies. The calculated CI rate varies from 0.09% (approximately one intervention every 1,000 prescriptions) to over 2.5% (approximately one intervention every 40 prescriptions) (see Figure 1-8). Many of the studies reported pharmacies where little or no documentation occurred. Given the reactive nature of many interventions, it is felt to be unlikely that the interventions simply did not occur in these pharmacies; rather, they were not recorded. However, it is conceded that it is difficult to surmise, since the definition of DRPs that should be recorded is not consistent.

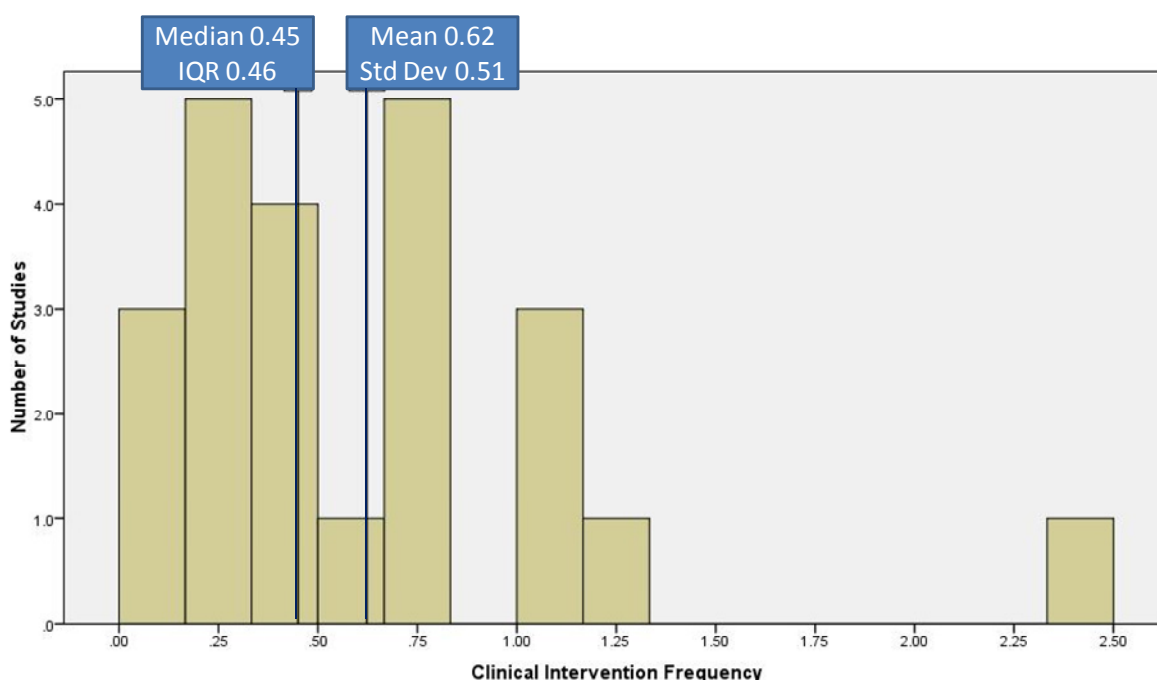


Figure 1-8: Range of CI Frequencies Reported in 23 Studies in the Literature

There is a multitude of factors that may be responsible for the variable rates reported. Many of these are methodological issues, but there are issues that are independent of the data collection and analysis methods that will alter the documentation rate. The most obvious (and probably the most difficult to maintain and measure) is the motivation, clinical expertise and availability of the recording pharmacist. Factors such as the prescription workload and ongoing feedback or remuneration will clearly influence the frequency of documentation, while factors such as clinical knowledge may influence the actual intervention frequency.

There is another set of studies which have not, as yet, been discussed. These are, of course, the earlier PROMiSe projects. These studies are of particular relevance to this work, offering insights into many of the factors outlined above. Interestingly, the overall recorded intervention frequency in the PROMiSe II project was 0.55 per 100 prescriptions, very similar to that in the international literature described above.

1.4 Documenting CIs in Australian Community Pharmacies: The PROMiSe I and II Projects

The research team involved with this current project had previously conducted projects relating to CI documentation. These projects in 2004 and 2005 provided some of the foundation principles for the architecture of the software and also the documentation process. During the early phases of these projects, an acronym was developed to enhance the recognition and branding of the series of projects. Pharmacy Recording Of Medication Incidents and Services electronically (PROMiSe) was used in both the pilot study (PROMiSe I) and the main study that followed (PROMiSe II).

As the third iteration of the PROMISe project, this study borrows and expands upon many of the methods and findings of the previous studies. The previous two studies are described in brief here, in order to provide the reader with a background to the further development undertaken in this current project.

1.4.1 PROMISe I

The first in the series of projects was conducted predominantly to determine the system requirements for documentation of interventions and to develop a workable software solution that would incorporate the documentation system and operate securely and effectively.

Aims

The primary aim of the pilot study was to ensure that the documentation and communication of CI information was technically feasible. In addition, a number of training and information collection techniques were tested for ease of use and appropriateness.

Methods

Development of the DOCUMENT DRP Classification System

This section outlines the development of a comprehensive DRP classification system which includes categories for type of problem, actions taken to investigate the problem, recommendations made, outcome and clinical significance.

The most widely used classification scheme in the DRP literature is that of Hepler and Strand.¹ This scheme has been modified by a number of authors in the international community and the main categories of interventions in this system seem the most intuitive of those available. The Hepler and Strand system, however, does not include coding for activities intended to resolve the DRP (that is, the actions and recommendations taken and made by the pharmacists). Of all the systems discussed above, the PCNE system seems the most appropriate; however, there were a number of shortcomings of this system. First, the system requires assessment of the cause of the DRP, and in many situations this would be impossible to obtain. Secondly, the outcomes in the PCNE classification system are not sufficiently detailed to allow economic analyses.

A meeting of key stakeholders from various pharmacy organisations and academic institutions assisted in clarifying the key aspects for a desirable documentation system. Central to the discussion on the methodology was the ease of use of the system. A simplified system would be much quicker to use and would provide less disruption to dispensing workflow; however, a certain minimum amount of information is required for each DRP in order to allow adequate assessment of its importance and economic benefit. In order to collect sufficient information while still having an easy-to-use system, the use of algorithms, drop-down menus and possibly touch-screens was suggested.

The major outcome of the meeting was general agreement that whilst various classification schemes were currently available for use in a variety of scenarios, none were particularly well suited to the documentation of DRPs and their resolution in community pharmacies in Australia.

A classification scheme based initially on the types of problems identified by Hepler and Strand¹⁸⁸ was developed and was termed the DOCUMENT classification system. Significant modifications were made to the system as a result of applying the schema to existing DRP information.

The DOCUMENT system had eight main categories for type of DRP, being:

- D** Drug choice
- O** Over/underdose prescribed
- C** Compliance

U	Untreated indications
M	Monitoring required
E	Education/Counselling/Advice
N	Non-clinical
T	Toxicity/Adverse effect

These categories covered each of the categories that were covered by Hepler and Strand and also added other categories specific to DRPs in community pharmacy in Australia.

In considering the wider aspects of the documentation system for this project, the logical sequence of events in detecting and resolving DRPs was closely followed. Initially the pharmacist decides what type of problem or issue they are dealing with (using the DOCUMENT categories), then they make some investigation or queries to determine if the problem exists or is an issue (action). The pharmacist then makes a recommendation to resolve the issue (either to the doctor or the patient) and the recommendation is either accepted or not (outcome). Consideration of the potential severity of the situation (significance) is also undertaken.

The pilot DOCUMENT system that was developed therefore has codes, categories and definitions for each of the following.

- type of activity;
- action(s) taken to clarify the extent of the problem;
- recommendation(s) made to resolve the problem;
- outcome (whether the recommendation was accepted); and
- clinical significance.

Type of Activity

The types of activities as categorised by the DOCUMENT system are summarised in Table 1-9. The subcategories were determined following testing of the DOCUMENT system on the information provided from a previous community pharmacist intervention documentation project.¹⁸⁹ A number of subcategories which existed in previous versions of the classification system were “rolled up” into other categorisations to simplify the number of selections available.

Each of the subtypes was clarified with scope notes and examples of when the code would be most appropriate to use. The order of the choices has been developed as a result of analysis of the frequency of particular subcategories of interventions in the previous intervention documentation set.

Type of DRP		Sub-Type of DRP
D	Drug selection	Duplication
		Drug interaction
		Wrong drug
		Wrong dosage form
		Previous ADR/allergy
		Other drug selection problem (Specify)
O	Over or underdose prescribed	Dose too high
		Dose too low prescribed
		Incorrect frequency
		Other dose related problem (Specify)
C	Compliance	Potential drug abuse
		Taking too little
		Taking too much
		Difficulty using dosage form
		Other compliance problem (Specify)
U	Untreated indications	Condition not adequately treated
		Preventive therapy required
		Other untreated indication problem (Specify)
M	Monitoring required	Drug levels
		Laboratory monitoring
		Non-laboratory monitoring
		Other monitoring problem (Specify)
E	Education or Information	Patient drug information requests
		Confusion about therapy or condition
		Demonstration of device
		Disease management or advice
		Other education/information problem (Specify)
N	Non-clinical	Not sub-classified
T	Toxicity or adverse reaction	Caused by dose too high
		Caused by drug interaction
		Other toxicity problem (Specify)

Table 1-9: Types and Subtypes of DRPs in the DOCUMENT Classification System

Actions to Investigate the Problem

The codes for actions associated with the problem were created following examination of previous community pharmacists' intervention studies. In considering the level of detail to be used in this section of the classification system, it was thought that these activities would be associated with a significant component of the total time involved with an intervention. Actions that were included in the classification scheme are shown in Table 1-10:

Action
Investigation: Written material
Investigation: Software
Investigation: Internet
Service
Investigation: Other (specify)
Contacted prescriber
Discussion with patient or carer
Corrected without discussion
Other action (specify)

Table 1-10: Actions to Clarify the DRP in the DOCUMENT Classification System

Recommendations to Resolve the Problem

The codes and categories for recommendations to resolve the DRPs were determined following evaluation of CIs from a previous University of Tasmania study on community pharmacists' interventions.¹⁸⁹ The order of the recommendations is based on the frequency of occurrence of the different recommendations in this dataset. Additional codes for recommendations which were thought likely to occur were also added. These are shown in Table 1-11.

Recommendation
Education/counselling session
Dose change
Drug change
Drug cessation
Drug formulation change
Monitoring: non-laboratory
Drug addition
Drug brand change
Dose frequency/schedule change
Refer to prescriber
Refer to hospital
Monitoring: Laboratory test
Refer for medication review
Commence dose administration aid
No recommendation necessary
Other recommendation (specify)

Table 1-11: Recommendations to Resolve the DRP in the DOCUMENT Classification System

Acceptance of the Recommendation

A simple acceptance code for the recommendation is present in the coding system. As multiple recommendations are possible for a single DRP, a category for partial acceptance was created to allow for the situation where only some of the recommendations made by a pharmacist were accepted.

Clinical Significance

Four levels of clinical significance (and a nil significance) level were chosen. A brief description of the clinical significance codes is shown in Table 1-12.

Clinical Significance	Brief Description
Nil	No consequence to the patient.
Low	Consequences to the patient are related to costs or information only
Mild	Consequences to the patient are that they have improved a minor sign or symptom, or if the intervention had not occurred they would have developed a minor symptom. The sign or symptom should be such that it does not require a doctor's visit to treat.
Moderate	When, if the intervention did not occur, it was likely that the patient would have had to go to the doctor because of the consequences. Also covers the situation where you need to refer the patient to the doctor because of the seriousness of the situation.
High	When, if the intervention did not occur, it was likely that the patient would have had to go to a hospital because of the consequences. Also covers the situation where you need to refer the patient to a hospital because of the seriousness of the situation. When, if the intervention did not occur, it was likely the patient would have had to receive assistance from a regular nurse visit, or would have had to be placed into residential care of some sort. Also includes the situation where the intervention prevents the additional nursing care or delays the admission to residential care.

Table 1-12: Clinical Significance Categories for DRPs in the DOCUMENT Classification System

Development of Documentation Software and Messaging System

The prototype electronic documentation system was developed to interface directly with the Rex[®] pharmacy dispensing software system distributed by Phoenix Computer Systems (see www.phoenixcorp.com.au). Phoenix Computer Systems also developed a communications module to de-identify and transfer information concerning the intervention to a central repository (RexComm).

Observer pharmacists were placed in the trial pharmacies in order to document more accurately the participation and difficulties the pharmacists had during the pilot study.

Results

The software was implemented in seven pharmacies and used by 14 pharmacists over a one-week documentation period in May 2004. A total of 352 CIs were undertaken in 322 patients in association with 9,012 prescriptions for 6,077 patients. Despite the limitations and the investigative and experimental nature of the pilot study, there were a number of significant findings worthy of mention.

Pharmacist and Pharmacy Characteristics

The small number of pharmacists involved in the pilot study, and the lack of comparative information concerning many of the factors determined by the pre- and post-pilot questionnaires used, made it difficult to make any firm conclusions.

Most of the pharmacists who participated in the study were happy with their choice of pharmacy as a career and felt that the intellectual stimulation and the fact that they were helping people was a strong element of their job satisfaction. It is possible that those pharmacists and pharmacies that elected to participate in the pilot study were, by showing an interest in the project, more likely to be staffed by motivated, intellectually stimulated pharmacists. This would need to be tested by asking similar questions of pharmacists who did not participate in the project.

Nature of DRPs Documented

Approximately one-third of the problems documented were related to patients requesting or requiring information or education either about their medications or the diseases being managed. During the training sessions for the pilot study, the types of clinical activities that could be documented were discussed. Emphasis

was placed on the fact that the documented activities should be those that were “over and above” the routine counselling that goes with each prescription. The fact that so many of the interventions were “counselling related” and were less significant (85% of the education or information interventions were rated as nil, mild or low significance) may indicate a degree of over-documentation.

In addition, over 20% of the documented “clinical” interventions were classified as non-clinical, when the emphasis on recordable events was on clinical activities that would have the potential to improve patient health outcomes. As with the education or information interventions, these non-CIs were largely less significant (88% nil, mild or low significance).

Taken together, these two pieces of information indicate that over 50% of the documented interventions were less significant and related to routine pharmacist activities such as counselling and administrative issues regarding prescriptions (non-clinical). This may indicate that interventions were documented that were not intended and consequently the intervention frequency in the pilot study may be overestimated.

As expected, the actions taken to investigate the problems were largely discussions with either the patient (84% of interventions) or the prescriber (24% of interventions). Situations where the prescriber was contacted in order to establish the details of the problem, or electronic decision support software was used were more likely to be of higher significance than situations where a patient discussion took place, or where written information sources were used to investigate the problem.

Over one-third of the recommendations that were made to resolve the problems related to the provision of an in-depth education or counselling session. This relates to the category of the problem, where problems that were related to lack of information required provision of the missing information in order to resolve the problem. Other recommendations were directly related to the category of problem, for example, a change in the dose of a drug was the most likely recommendation for a problem where the dose of the drug was thought to be inappropriate. In 16.5% of the interventions, the pharmacist referred the patient to the prescriber in order to resolve the underlying problem.

Frequency of DRPs

The overall documented CI frequency of 3.9 interventions per 100 prescriptions is substantially higher than any previously published frequencies. In addition to the possible over-documentation referred to in the previous section, there are a number of other possible reasons for this finding. First, the pharmacies were highly selected, in that they were all users of a particular dispensing software system (Rex®). This system has only a small share of the market and its users may not be typical of all pharmacies. Secondly, the pharmacies were all smaller than the average pharmacy, and their smaller workload may have an impact on the CI frequency. Thirdly, the use of regular observation in the pilot study may have altered the intervention behaviour of the pharmacists being observed.

Intervention frequency was related to the number of different medications for each patient, with a 100% frequency of at least one documented DRP in patients with 10 or more different medications in two weeks. There was no clear relationship between intervention frequency and prescription workload, but the small sample of pharmacies may not have allowed for adequate exploration of this possible relationship.

Clinical Significance of Interventions

Approximately one-third of the interventions were classified as either moderately or highly significant by the documenting pharmacist (moderate significance was defined as requiring or preventing a GP visit, while high significance was requiring or preventing a hospital visit). As stated earlier, this simplistic classification did not take into account the probability of the particular consequences being prevented by the intervention. However, the self-assessment of the clinical significance of the intervention by the documenting pharmacist enabled stratification of the sample that was used for further analysis by a panel of experienced clinical pharmacists.

While the experienced pharmacists rated the probability of a high significance event as approximately 10%, there was a correlation in the ranking of severity between the documenting and the assessing pharmacists.

Documentation Process

Participating pharmacists were reasonably accurate in selecting categories for DRPs and were able to stratify the interventions by clinical significance. Most pharmacists indicated that they documented over 75% of the CIs that they performed, and they estimated that each intervention took, on average, less than five minutes. In the presence of an observer pharmacist, the average time for an intervention was less than three minutes. The actual documentation proportion of this time is unclear, but given the number of interventions per prescription, the average time spent documenting CIs is not likely to exceed six minutes per 100 prescriptions.

Participants indicated that the software was easy to use and the classification system was logically structured.

Conclusions

The pilot study demonstrated that an electronic messaging system could adequately transfer information relating to an intervention from a pharmacy interface to a central repository in a secure manner.

1.4.2 PROMISe II

The second project in the series was intended to use the systems already developed in a wider sample of pharmacies and also to attempt to estimate the economic value of the CIs undertaken.

Aims

The second project had three primary aims:

- to evaluate the types of DRPs and the drugs involved in these problems;
- to determine the frequency with which Australian community pharmacists resolve or prevent DRPs (that is, undertake CIs); and
- to estimate the potential value of these CIs in health and economic terms.

Methods

Modifications were made to the classification system and intervention documentation software to allow it to be used in pharmacies that had the WiniFRED[®] dispensing system installed. A study using the modified communication and documentation software was conducted in 52 pharmacies in Melbourne, Victoria over eight weeks. Pharmacies were randomised to receive remuneration and an intervention prompt integrated into the dispensing system. Some pharmacies were allocated observers to assist in the documentation process. A sample of 291 documented clinical interventions (DCIs) was assessed by a panel of 16 experts using a web-based interface. Experts estimated the probability of particular consequences occurring before and after the DCI, enabling an estimate to be made of the value in terms of potential costs avoided, hospital and medical consultations avoided and days of adverse health avoided.

Results

Over the eight-week study, 435,520 prescriptions for 258,979 patients were dispensed and information concerning 2,385 DCIs was documented (a frequency of 0.55 DCIs per 100 prescriptions and 0.92 DCIs per 100 patients). The presence of an observer increased the frequency of DCIs recorded more than two-fold. Remuneration did not provide any additional effect in observed pharmacies, but remuneration had a short-term effect on DCI frequency in pharmacies that did not have an observer present. The intervention prompt was effective in prompting 201 specific DCIs in the pharmacies where it was installed. The prompt also increased the overall DCI frequency almost two-fold in pharmacies where the prompt was installed.

The majority of DCIs belonged to one of three categories: drug selection problems (22.7%), dosage problems (19.4%), or education or information problems (17.4%). Drug groups commonly associated with CIs were antibiotics, drugs for diabetes, cardiovascular drugs and drugs for respiratory disorders. Almost one-third of the DCIs were classified as either of moderate or severe level of clinical significance by the recording pharmacist. In

almost 90% of cases, the pharmacist investigated the DRP by discussing the issue with the patient or the carer. In one-third of cases, the pharmacist contacted the prescriber in order to clarify the problem. Recommendations for changes in therapy were made in 67% of cases, and information or education was provided in over 50% of DCIs.

The clinical and economic analysis suggested that the value of Australian community pharmacist interventions related to prescription medication is in the order of \$200M each year in direct costs avoided. In addition, around 170,000 hospital bed-days are avoided and 25M days of adverse health impact are avoided each year. As a result of each CI by a pharmacist, there is a mean reduction of:

- 34 days in a lowered health status (3.7 days of severe poor health, 16.6 days of moderate poor health and 13.4 days of mild poor health);
- 0.13 days in hospital at a cost of \$100;
- 0.7 GP consultations and 0.14 specialist consultations at a cost of \$23 to Medicare Benefits Schedule (MBS);
- further investigations at a cost of \$25 to MBS,; and
- a total of \$150 in total direct costs (MBS and hospital combined).

1.4.3 Discussion of Previous PROMISe Studies

The PROMISe II project, and the associated pilot study provide the most comprehensive information concerning CIs undertaken in community pharmacies in Australia.

The main aims of this project, in relation to community pharmacies in Australia, were to:

- evaluate the types of DRPs and the drugs involved in DRPs;
- determine the frequency with which pharmacists resolve or prevent DRPs; and
- estimate the potential value of CIs in health and economic terms.

Types of DRPs and Drugs Involved in DRPs

The majority of CIs belonged to one of three categories: drug selection problems (22.7%), dosage problems (19.4%), or education or information problems (17.4%). Drug groups commonly associated with DCIs were antibiotics, drugs for diabetes, cardiovascular drugs and drugs for respiratory disorders. The PROMISe project is one of the few studies where the denominator of the number of prescriptions for each drug involved was available. This enabled the calculation of a frequency of intervention for specific drugs and drug groups. When the frequency of prescribing was considered, drug groups commonly associated with DCIs were drugs for diabetes, anti-diarrhoeals, anti-anaemic preparations and corticosteroids. Further evaluation of the types of problems within specific drug groups of interest established that common interventions included:

- compliance problems with anti-diabetic medications;
- drug selection and dosage problems with antibiotics;
- provision of information with respiratory agents, most often relating to demonstration of a device;
- dose problems with corticosteroids;
- dose and drug selection problems with cardiac drugs;
- drug selection problems with anti-inflammatory agents; and
- untreated indications with antithrombotic agents.

Almost one-third of the DCIs were classified as either of moderate or severe level of clinical significance by the recording pharmacist. Cardiac drugs, antithrombotic agents and systemic corticosteroids were associated with DCIs of higher significance than other drug groups.

In almost 90% of cases, the pharmacist investigated the DRP by discussing the issue with the patient or the carer. In one-third of cases, the pharmacist contacted the prescriber in order to clarify the problem. Recommendations for changes in therapy were made in 67%, and information or education was provided in over 50% of DCIs.

Frequency of CIs

Over the eight-week study, 435,520 prescriptions for 258,979 patients were dispensed and information concerning 2,385 CIs was documented (a frequency of 0.55 DCIs per 100 prescriptions and 0.92 DCIs per 100 patients). The frequency was similar to the CI frequency calculated from a number of Australian and international studies.

The presence of an observer increased the frequency of DCIs recorded more than two-fold. Remuneration did not provide any additional effect in observed pharmacies, but remuneration had a short-term effect on DCI frequency in pharmacies that did not have an observer present. The intervention prompt was effective in prompting 201 specific DCIs in the pharmacies where it was installed. The prompt also increased the overall DCI frequency almost two-fold in pharmacies where the prompt was activated.

Increased prescription workload caused a marked decrease in intervention frequency in the majority of pharmacies. The single pharmacy with the highest workload was ranked in the lowest quintile of intervention frequency, and the pharmacy with the lowest workload was ranked in the highest intervention frequency quintile. The frequency of the specific intervention prompted by the electronic prompt did not decrease with workload.

Pharmacists in the “top 20” by intervention frequency were less likely to reduce their intervention frequency over the period of the study, compared to their colleagues. It is likely that specific characteristics of pharmacists (such as motivation and clinical knowledge) are important in determining the frequency with which they document CIs.

Value of CIs

The method of determination of value used in the PROMISE study was comprehensive and included evaluation of potential positive and negative consequences of the CI. This method is unique, and provides an estimate of value for a wide range of different types of interventions, including interventions involving compliance and adherence as well as provision of education and information.

The clinical and economic analysis suggests that the value of Australian community pharmacist interventions related to prescription medication is in the order of \$200M each year in direct costs avoided. In addition, around 170,000 hospital bed-days are avoided and 25M days of poor health impact are avoided each year.

CIs in a typical week of activity in an Australian community pharmacy resulted in a mean reduction of:

- 190 days in a poorer health status (21 days of severe poor health, 94 days of moderate poor health and 75 days of mild poor health);
- 0.73 days in hospital at a cost of \$570;
- 3.9 GP consultations and 0.8 specialist consultations at a cost of \$130 to MBS;
- further investigations at a cost of \$140 to MBS; and
- \$840 in total costs (MBS and hospital combined).

There is enormous potential for extending the recording and collation of information concerning CIs to prevent or resolve DRPs in community pharmacies. The electronic techniques tested in these projects enabled a seamless recording system to transfer relevant data to a distant repository. Appropriate collation and analysis of such information would provide invaluable up-to-the-minute knowledge concerning the nature of DRPs and the drugs involved. This knowledge could then be used to refine educational and other strategies to promote increased detection of DRPs. An increase in the frequency of these activities is likely to be associated with an

improvement in health outcomes and the avoidance of significant expenditure in the Australian healthcare system.

1.5 The Potential Value of Community Pharmacists' CIs

One of the major considerations in this project was to determine the value of the CIs. In order to develop a method to do this, we were required to review the existing literature.

Published studies of the clinical and economic value of community pharmacists' interventions are comparatively rare.^{160, 168, 190-193} Two additional papers that assessed value in a relative rather than absolute form were reviewed but are not considered in this section.^{171, 194}

In this section the six most relevant papers, which refer fundamentally to three different methods of determination of value, will be reviewed and some of the main methodological issues will be discussed. An attempt will be made to compare the value calculations made in each of the studies. This will be done by taking three common examples of CIs and using the system as outlined in the relevant paper to determine a value. Where inadequate information is available in the published method, assumptions are made and these are included in each of the analyses. Comments on any difficulties applying each method are also made. A discussion of the comparative benefits of the different methods will also be undertaken.

The three example interventions are shown in Table 1-13 and are intended to provide a range of different interventions in order to demonstrate how the different value assignment methods

Intervention Example 1: Aspirin Prophylaxis A 58-year old female patient with type 2 diabetes with a history of hypertension and mild ischaemic heart disease is advised to commence an anti-platelet agent (aspirin) to reduce her cardiovascular risk.
Intervention Example 2: NSAID Duplication A 65-year old male with osteoarthritis who is already taking celecoxib is prescribed meloxicam (in addition to the celecoxib). The pharmacist suggests changing the meloxicam to regular paracetamol.
Intervention Example 3: Paediatric Dose Increase A five-year old, 23kg child is prescribed amoxicillin suspension at a dose of 100mg three times daily. The pharmacist checks the paediatric dosing schedule and suggests an increased in dose to 250mg three times daily

Table 1-13: Example Interventions Used to Compare Methods of Assessment of Value

The studies outlined in section 1.3 are observational in nature in that there is reporting of DRPs and their resolution without a control group. This means that a direct comparison of prospective outcomes following an intervention compared to a group without an intervention is not possible. Fundamentally, the assessment of an observational intervention study therefore requires an assessment of the consequences of the patient *not* receiving the intervention in order to estimate the value of the action.

In each of the following sections, a summary of the methodology used is presented and the value of the example set of interventions is calculated.

Rupp Method (USA)

The method originally developed by Rupp was used in three publications concerning the value of community pharmacists' interventions.^{160, 190, 192} The results for each of these are discussed below, and the methodological issues are considered together thereafter.

*Rupp, 1988*¹⁹²

The prescribing errors identified in the pilot study conducted by Rupp in 1987 and discussed in section 1.3,¹⁵⁷¹⁹² were assessed for clinical significance in 1988.¹⁹⁰

Rupp used two experts in pharmacotherapy (one pharmacist and one physician) to evaluate each of 153 prescribing errors for clinical significance. He developed a standard evaluation form which required the assessors to address four questions regarding the error. The questions were as follows:

1. Could this error have resulted in adverse health consequences to the patient if the pharmacist had not intervened to correct or resolve the error? (yes/no response)
2. Please specify the adverse health consequence that you consider most likely to have resulted from this error if the pharmacist had not intervened to correct or resolve the error. (free text response)
3. Based on the available information, what is your estimate of the probability that this error would have resulted in the adverse health consequence outlined above? (response was a low and high probability estimate on a linear analogue scale)
4. What would be the most appropriate intensity of healthcare to treat the adverse health consequence specified above, assuming that it did occur? (response was one of: Hospital admission; Urgent or emergency care; Scheduled physician visit; Self care; or Other)

Rupp reported that the pharmacist evaluator indicated that 55 of the 153 (35.9%) errors would have resulted in adverse health outcomes. The physician estimate was slightly lower (38 of 153; 24.8%), and the level of agreement between the two assessors was good (kappa statistic 0.6; $p < 0.0001$).

For the “consensus” errors, where both assessors agreed there was a risk of harm, Rupp calculated the mean “likelihood of harm” based on the responses to question 3. The physician assessor estimated a slightly higher range of probabilities (0.55 to 0.76), compared to the pharmacist assessor (0.46 to 0.66). There was also a moderate level of agreement between the two assessors in terms of the potential severity of harm associated with the adverse health consequence (kappa statistic 0.47, $p < 0.0001$).

Rupp assigned a cost to each of the levels of healthcare that could be selected in question 4, and then multiplied by the relevant mean probability estimates to calculate the value. The value he calculated for the 38 “consensus” errors was spread across all 153 reported errors, and he determined a mean estimate of \$7.15 per error. Based on the then average pharmacist hourly pay rate of \$15, and assuming an average time of resolution of DRPs of five to 10 minutes, Rupp calculated a value to cost ratio of approximately 4:1.

Thus, the value of the pharmacist’s intervention in this study can be represented as:

$$V = P \times C$$

Where

V= Value (in terms of healthcare costs avoided)

P = Probability that most likely harmful outcome would have occurred

C = the cost of medical care associated with that outcome

As can be seen in Table 1-14, an estimate of value for each of the three example interventions is able to be made if some assumptions are made.

	1. Aspirin Prophylaxis	2. NSAID Duplication	3. Paediatric Antibiotic Underdose
1. Could this error have resulted in adverse health consequences to the patient if the pharmacist had not intervened to correct or resolve the error?	Yes	Yes	Yes
2. Please specify the adverse health consequence that you consider most likely to have resulted from this error in the pharmacist had not intervened to correct or resolve the error.	Angina ¹	Gastro-intestinal Discomfort ¹	Continuation of underlying Infection
3. Based on the available information, what is your estimate of the probability that this error would have resulted in the adverse health consequence outlined above?	0.3 ²	0.7	0.5
4. What would be the most appropriate intensity of healthcare to treat the adverse health consequence specified above, assuming that it did occur?	Scheduled Physician Visit US\$26	Scheduled Physician Visit US\$26	Scheduled Physician Visit US\$26
Value of Intervention	0.3 X \$26 = \$7.80	0.7 X \$26 = \$18.20	0.5 X \$26 = \$13.00
<i>Comments and Assumptions</i>	¹ May result in multiple consequences and the most likely may not be the most significant ² Probability depends on the timeframe (assumed one year)		

Table 1-15: Value Calculation for Example Interventions using Rupp, 1988 Method

*Rupp, 1992*¹⁹⁰

In 1992, Rupp published an economic evaluation of the interventions from his largest study.¹⁹⁰ On this occasion, Rupp used three assessors, one pharmacist, one physician and one additional pharmacist being “brought into play” if there was disagreement between the other two. Rupp used a slightly modified series of questions to assess the potential value of the intervention. Modifications to the second question (regarding the nature of potential harm) were made in order to enable easier grouping of responses (see Table 1-16). Similarly, question 3 (where the probability estimates were made) was modified to provide a fixed number of probability estimates and to remove the requirement to provide an upper and lower limit to the estimate. The costs of the medical care events were also updated and a modified structure for the severity of medical care was employed.

As in the previous study, agreement between the assessors was good in relation to whether or not there was potential for an adverse health event (question 1) with a kappa value of 0.88.¹⁹⁰ Similarly, there was good agreement regarding the type of patient harm (question 2) with a kappa value of 0.82. In addition, the mean probability estimate for the adverse health outcome occurring (question 3) for both of the two primary assessors was 0.78, showing excellent agreement. In question 4, however (the level of medical care required), there was a lower level of agreement, with the pharmacist assessor generally rating the level of care required higher than the rating by the physician assessor. Rupp then used the formula mentioned above to calculate a value for each

intervention where a health consequence was agreed to be likely to occur. On this basis, the average value calculated was \$122.98 per intervention, over 15 times greater than his estimate from 1988 (\$7.15).

It is surprising that, utilising the same methodology, the final results Rupp calculated are so different to his previous work. In the earlier study, none of the 38 “consensus” errors were thought to result in a hospitalisation, whereas in this study, between 20 and 30% of the approximately 150 interventions that were assessed as requiring medical care, were deemed to require an emergency department visit and hospitalisation. Given the magnitude of difference between the costs of this level of healthcare and the cost of the levels below it, this change alone could provide the reason for the altered result. The calculation of value for the three example interventions is shown in Table 1-16.

	Aspirin Prophylaxis	NSAID Duplication	Paediatric Antibiotic Underdose
1. Could this event have resulted in adverse health consequence to the patient if the pharmacist had not intervened?	Yes ¹	Yes	Yes
2. What adverse health consequence do you consider most likely to have resulted from this event if the pharmacist had not intervened? Toxic effects of drug(s) involved Inadequate control of patient's condition Allergy/ hypersensitivity reaction Other	Angina ²	Gastro-intestinal Discomfort ²	Continuation of underlying Infection
3. Based on the available information, what is your estimate of the probability that this event would have resulted in adverse health consequence specified above? (0.1, 0.3, 0.5, 0.7, 0.9)	0.3 ¹	0.7	0.5
4. What intensity of healthcare would be needed to treat the adverse health consequence specified above, assuming that it did occur? ³	Medical Attention US\$110	Un-scheduled physician contact US\$60	Un-scheduled physician contact US\$60
Value of Intervention	0.3 X \$110 = \$33	0.7 X \$60 = \$42	0.5 X \$60 = \$30
Comments and Assumptions	¹ Probability depends on the timeframe (assumed 1 year) ² May result in multiple consequences and the most likely may not be the most significant ³ Medical attention (hospitalisation) US\$1,891 Medical Attention (no hospitalisation) US\$110 Unscheduled physician contact US\$60 Scheduled physician contact US\$40 Self care \$0		

Table 1-16: Value Calculation for Example Interventions using Rupp, 1992 Method

As can be seen, the value estimate for all three interventions is below the average reported by Rupp in this study.

Dobie and Rascati, 1994¹⁶⁰

Dobie and Rascati used the same techniques that Rupp used to assign a value to interventions recorded in four community pharmacies in Texas.¹⁶⁰ These authors directly compared their results to those of Rupp,¹⁹⁰ and in order for this comparison to be accurate, they used the same cost weights for the medical care levels.

From the 47 intervention reports, their two assessors (one pharmacist and one physician) identified 22 interventions that would require medical care. The physician assessor suggested that 11 of these required emergency medical care with hospitalisation, while the pharmacist assessor suggested that nine of the cases required this level of medical care. As a result of this very high rate of serious consequences, Dobie and Rascati's estimates of value were quite high (approximately \$442 per intervention). It should be noted, however, that the frequency of interventions was much lower than that reported in Rupp's studies, and it may be that selective reporting of more serious interventions has caused this result. As the methods and cost weights in this study are identical to those used in the Rupp 1992 study,¹⁹⁰ the values calculated for the example interventions would be as shown in Table 1-16.

Issues with the Rupp Method of Economic Evaluation

There are a number of methodological issues that need to be considered in the Rupp method of economic evaluation. These become evident when attempting to answer the questions posed for a hypothetical case (or three).

The first of Rupp's assessment questions relates to the possibility that an adverse health consequence *could* have occurred if the pharmacist did not intervene. This question does not specify a timeframe, and it does not specify a lower limit of possibility. Based on this, the answer to "could this have resulted in...?" is almost always yes. The second question then asks "what is the *most likely* consequence". The assessor, in considering the first point, would be considering any adverse health impact, regardless of likelihood, whereas in the second question, they are directed to the most probable consequence. In many cases, the most probable consequence is not the consequence that contributes the most to the overall health impact of the intervention. In fact, most interventions will have multiple consequences, some of which may be negative. Each of these possible consequences would have its own probability of occurring. In the first example intervention, where aspirin is added to a patient's therapy, one possible consequence is a bleeding episode, while another is prevention of a stroke or heart attack.

In the third question, the assessor is asked to estimate the probability that the consequence *would* occur. Here, the probability estimates (in the revised version of the system) are set, and there is no scope for a consequence that occurs at less than 10% frequency (such as a stroke or heart attack in example intervention 1). The fourth question asks the assessor to estimate a level of treatment required for the consequence, assuming that it did occur.

By limiting the assessor to only one consequence, and by limiting that consequence to the most likely one, the value of the intervention may be *underestimated*. For example, a 2% probability of a stroke may incur more healthcare costs than a 30% probability of an angina attack.

The second methodological fault that occurs in this assessment of value (and also occurs in many of the studies outlined below) is that the cost associated with the situation before the intervention is not considered. For example, although the person in the example intervention 1 (aspirin prophylaxis) is most likely to have an angina attack as a result of not taking aspirin, there is some risk that the angina attack may still occur, despite the addition of aspirin. Similarly, in example intervention 2, the patient may suffer gastrointestinal (GI) discomfort without the addition of the second non-steroidal agent. By assuming that the cost of the situation without the intervention is nil, the value of the intervention is markedly *overestimated*. It would be more appropriate to consider the change in level of medical care with and without the intervention.

Loh et al. (Canada, 1996)¹⁹³

In 1996, Loh et al. published an economic analysis of the cost savings associated with the interventions reported by Poston et al.¹⁶⁵ (see section 1.3). They included three components in their analysis:

- changes in drug costs (for those situations where the drug was changed);
- changes in professional fees (for those prescriptions not dispensed); and
- estimated savings to the healthcare system.

The drug costs were calculated as the difference between the situation after the intervention, compared to the situation before the intervention. The cost of a drug was considered to be a saving to the healthcare system if it was not dispensed. The average reduction in drug cost across the 2,136 interventions where a drug was either not dispensed or changed was \$8.93 per intervention (\$6.88 for those where a drug was changed, \$21.86 where a drug was not dispensed). Professional fees were calculated in a similar way, with the fee being saved if the drug was not dispensed and the fee being incurred if a drug was added. The authors calculated an average saving of \$5.90 per intervention for this component of the value.

In undertaking their estimate of the savings to the healthcare system, the authors did not use any assessment process, they merely allocated costs according to the outcomes of the prescription. The authors decided to include only the costs of physician visits in the healthcare assessment and they made some assumptions regarding the necessity (or saving of) physician visits based on the nature of the intervention. First, for those interventions where the pharmacist contacted the prescriber, they argued that the pharmacist had the option of simply refusing to dispense the prescription and therefore the patient would have had to visit the prescriber to rectify the situation. They allocated a saving equal to the cost of a physician visit to interventions in this category. In addition, they allocated the cost of a physician visit to the interventions where the prescription was not dispensed, based on the assumption that patients would have to return to the prescriber for another treatment option.

They did not quote an amount for the visit to the physician and this element of the cost analysis is not reported separately in the paper. The authors report a combined average total savings (representing drug costs, professional fees and physician fees) of \$16.74 per intervention.

Thus, the value of the pharmacist's intervention in this study can be represented as:

$$V = D + PF + PV$$

Where

V = Value (in terms of healthcare costs avoided)

D = Drug cost (saved or incurred)

PF = Professional Fees cost (saved or incurred)

PV = Physician Visit (saved or incurred)

As the saving to the healthcare component of the economic analysis is not reported, it is difficult to assign value to the example interventions. However, if the average values for the drug and professional fees are assigned, then a value with and without the physician visit can be used as an estimate (see Table 1-17).

	Aspirin Prophylaxis	NSAID Duplication	Paediatric Antibiotic Underdose
Changes in drug costs	Drug added + \$21.86	Drug changed - \$8.93	Drug dose changed, Pack size unaltered
Changes in professional fees	Fee added + \$5.90	Fee saved - \$5.90	No change in fee
Estimated savings to the healthcare system ¹	Physician visit incurred + \$25	Physician visit incurred + \$25	Physician visit incurred + \$25
Value of Intervention	+ \$27.76	+ \$10.17	+ \$25
<i>Comments and Assumptions</i>	¹ Assume physician visit = \$25		

Table 1-17: Value Calculation for Example Interventions using Loh Method

As can be seen, applying the economic model proposed by Loh et al. results in additional expense rather than savings for each of the sample interventions. Although it is true that the addition of a drug is likely to incur some costs, the value of the health benefits of the drug should outweigh the cost of the medication and associated medical professional fees. The decision taken by these authors to merely include the cost of an estimated physician visit, without considering other health benefits has resulted in this finding. As such this would not be a useful model to pursue in terms of estimating the value of community pharmacists' interventions.

Benrimoj method (Australia, 1996 and 2000)¹⁶⁷⁻¹⁶⁸

In a pilot study published in 1996, Caleo et al. attempted to demonstrate the feasibility of a clinical and economic analysis of community pharmacists' CIs.¹⁶⁷⁻¹⁶⁸

These authors selected a random sample of 50 of 258 proactive interventions for clinical evaluation by a clinical review panel. The panel consisted of two clinical pharmacologists, a community pharmacist and a pharmacist expert in therapeutics. Each individual panel member assessed the treatment that may have been avoided due to the pharmacist's intervention by completing a clinical evaluation form for each situation. The combined expert opinions for each intervention (a total of 200 opinions) were used to estimate the costs of medical treatment avoided.

The paper does not clearly describe the instrument used, but based on the description of the results, it seems that each of the panel members was asked to determine:

- whether or not the potential for an adverse event was present;
- the nature of this adverse event;
- the probability of the adverse event occurring;
- the degree of patient discomfort expected if the adverse event had occurred; and
- the intensity of care that would be required in the course of management of the adverse event

The authors also estimated the costs incurred in the pharmacists' provision of the intervention in terms of pharmacist's and other staff members salary and phone calls. In addition medication costs were calculated for interventions where a change in medication resulted.

Thus, the value of the pharmacist's intervention in this study can be represented as:

$$V = HCA - CI$$

Where

V = Value (in terms of net costs saving)

HCA = Healthcare Costs Avoided [= (Probability of adverse event occurring) X (Cost of most likely medical treatment required)]

CI = Costs Incurred [= Cost of Pharmacist's Time + Cost of Assistant's time + Cost of Phone calls + Differential Cost of Medication where a change was made]

These authors reported that 179 of the 200 opinions (89.5%) indicated that the potential for an adverse event existed. Potential for toxic or side effects accounted for 82 (45.8%) of these, while inadequate control of the underlying condition accounted for a further 67 (37.4%). The authors calculated a mean probability of an adverse event of 0.43 ± 0.27 and a mean "degree of patient discomfort" of 0.36 ± 0.20 from the evaluators' estimates. In terms of intensity of medical care required, 81 of 180 opinions (45%) indicated that a regular physician visit would be required and a further 75 (41.7%) indicated that an urgent physician visit would be required.

The authors reported a net saving in medication costs of \$13.20 per 10,000 prescriptions and a cost of treatment avoided of \$336/10,000 prescriptions. It is unclear exactly how these figures are derived from the information available in the publication. Their estimate of pharmacists and shop assistants' wages and phone calls was \$130/10,000. In addition pharmacists recommended an urgent physician visit in four of the 50 random interventions, incurring a cost of \$27.42 per 10,000 prescriptions.

The authors calculated a net cost saving to society of $[(\$336 + \$13.30) - (\$130 + \$27.42)] = \$191.78$ per 10,000 prescriptions. This value of approximately two cents per prescription seems very low in comparison to other analyses. When the techniques are applied to the example interventions (see Table 1-18), the net cost savings vary from a cost incurred of \$1.68 to a cost saving of \$56.83.

	Aspirin Prophylaxis	NSAID Duplication	Paediatric Antibiotic Underdose
Healthcare costs avoided (HCCA) = Probability X cost of probable course of treatment	0.3 ¹ x Regular physician visit (\$26) ² = \$7.80	0.7 x Regular physician visit (\$26) ² = \$18.20	0.5 x Regular physician visit (\$26) ² = \$13.00
Costs Incurred = Healthcare costs incurred + Changes in medication cost + pharmacy time + telephone calls	cost of drug added \$6.36 + 4 minutes of pharmacists time \$2.42 + 2 phone calls \$0.70 = \$9.48	Cost/savings of drug ceased - \$32.98 + pharmacist time \$4 + phone calls \$0.35 = \$28.63	cost of drug dose increase \$0.00 + pharmacist time \$4 + phone calls \$0.35
Value of Intervention (Net Cost Saving)	\$7.80 - \$9.48 = - \$1.68	\$18.20 + \$28.63 = \$56.83	\$13.00 - \$4.35 = \$8.65
<i>Comments and Assumptions</i>	¹ Assumed a one year timeframe ² DoHA Manual of Resources and Their Associated Costs, 1993		

Table 1-18: Value Calculation for Example Interventions using Caleo et al. Method

The economic evaluation methods piloted in this study were refined and used later by Benrimoj et al.¹⁹¹

Benrimoj et al. published an economic evaluation of increased CI rates in community pharmacy in Australia.¹⁹¹ They modified the methodology developed in a pilot study published by Caleo et al.,¹⁶⁸ discussed earlier. This economic analysis related to the results of a study conducted in 1996 and published in 2003.^{179, 195} In addition, an analysis of the value of interventions in terms of clinical significance was published in 2003.¹⁹⁵

The economic analysis as described in this paper includes the sum of healthcare costs avoided and the healthcare costs incurred. Avoided costs were based on a five-member clinical panel's opinion on the probable course of treatment and the probability that the intervention would prevent an adverse outcome. By combining the probability of the adverse health outcome with the cost of the likely course, and subtracting the healthcare costs incurred, a net saving was arrived at. Incurred costs (GP or emergency department visits, changes in medication costs, pharmacy time and telephone calls) were estimated for each intervention assessed by the panel.

Thus, the value of the pharmacist's intervention in this study can be represented as:

$$V = HCA - HCI$$

Where

V = Value (In terms of net costs saving)

HCA = Healthcare costs avoided [= (Probability of adverse event occurring) x (Cost of most likely medical treatment required)]

HCI = Healthcare costs incurred [= Cost of Pharmacists Time + Cost of Assistants time + Cost of Phone calls + Differential cost of medication where a change was made (change or cancellation)]

In the 375 proactive CIs reported by the four groups of pharmacies, these authors calculated a net cost or saving as shown in Table 1-19.

Pharmacy Group and Randomisation Arm		Component of Value Calculation (per proactive clinical intervention)						
		Healthcare costs avoided	Healthcare costs Incurred	Changes in Medication Costs	Pharmacy time	Phone calls	Total	Net Change
Group A: Control Group	Baseline	-\$4.96	\$6.22	-\$1.33	\$2.63	\$0.53	\$3.09	-\$10.89
	Post-Intervention	-\$12.01	\$1.19	\$0.09	\$2.46	\$0.47	-\$7.80	
Group B: Fee plus Basic Education	Baseline	-\$4.11	\$1.38	\$1.37	\$2.27	\$0.47	\$1.38	-\$7.13
	Post-Intervention	-\$13.43	\$3.97	\$0.98	\$2.28	\$0.45	-\$5.75	
Group C: Fee Plus Advanced Education	Baseline	-\$4.88	\$2.91	-\$0.24	\$2.24	\$0.44	\$0.47	-\$9.12
	Post-Intervention	-\$13.76	\$3.53	-\$0.92	\$2.04	\$0.46	-\$8.65	
Group D: Fee Without Education	Baseline	-\$61.14	\$6.91	-\$0.28	\$2.62	\$0.47	-\$51.42	\$52.12
	Post-Intervention	-\$3.19	\$1.14	\$0.01	\$2.28	\$0.46	\$0.70	

Table 1-19: Economic Value Calculation by Benrimoj et al.¹⁹¹

As can be seen, there is a wide variation in the mean value of a proactive intervention, in the baseline samples, from a saving of \$51.42 to a cost incurred of \$3.09. It is unclear why the value of interventions (at baseline) should vary so much between pharmacies, with three of the four groups of pharmacies (A, B and C) undertaking interventions that by this analysis actually incurred costs. There are significant changes in the estimates after the education and remuneration components of the study were introduced, including in the control group. There was an increase in savings in three of the four groups of pharmacies (A, B and C). However, given that group A was a control group and the increase in savings in this group was larger than that in groups B and C, the impact of the education and remuneration cannot be estimated. In addition, the authors estimated that group D pharmacies actually increased costs after the intervention.

The sensitivity analysis for each component of the calculation was not provided in the paper, but a table of the 17 different types of interventions and their mean cost or saving with the 95% confidence intervals of the value estimates is presented. Overall, the mean value of all activities was \$7.82, with a standard deviation of \$62.42 and a 95% confidence interval of -\$14.13 to -\$1.50. Within the different types of interventions, only two were associated with value estimates where the confidence intervals did not span zero. These were:

Dose/Strength query

- mean **cost** \$4.09 (95% CI = \$0.70 to \$7.48)

Drug Allergy

- mean **saving** \$8.81 (95% CI = -\$15.42 to -\$2.20)

The proactive interventions with an estimated net saving of greater than \$20 were:

Provision of prescribing information

- mean **saving** \$53.83 (95% CI = -\$163.53 to \$55.83)

Avoiding a drug/drug interaction

- mean **saving** \$22.89 (95% CI = -\$47.25 to \$1.47)

Resolving an incorrect dosage

- mean **saving** \$21.98 (95% CI = -\$54.34 to \$10.38)

The economic impact of each intervention was then used to calculate a cost saving per 1,000 prescriptions which was then extrapolated to give an estimate for potential savings in New South Wales and Australia. Benrimoj et al. reported a value per 1,000 prescriptions that varied from \$10.12 to \$193.74 at baseline and from \$5.45 to \$136.01 after the intervention phase (see Table 1-20).¹⁹¹

Pharmacy Group and Randomisation Arm		Healthcare costs avoided per 1000 prescriptions	Net Change
Group A: Control Group	Baseline	\$10.12	\$11.11
	Post-Intervention	\$21.23	
Group B: Fee plus Basic Education	Baseline	\$19.47	\$20.89
	Post-Intervention	\$59.45	
Group C: Fee Plus Advanced Education	Baseline	\$40.36	\$95.65
	Post-Intervention	\$136.01	
Group D: Fee Without Education	Baseline	\$193.74	-\$188.29
	Post-Intervention	\$5.45	

Table 1-20: Healthcare Costs Avoided per 1,000 Prescriptions (from Benrimoj et al.¹⁹¹)

The confidence intervals for these estimates were not published, but the extrapolated estimates for Australia have confidence intervals that all span zero (see Figure 1-9).

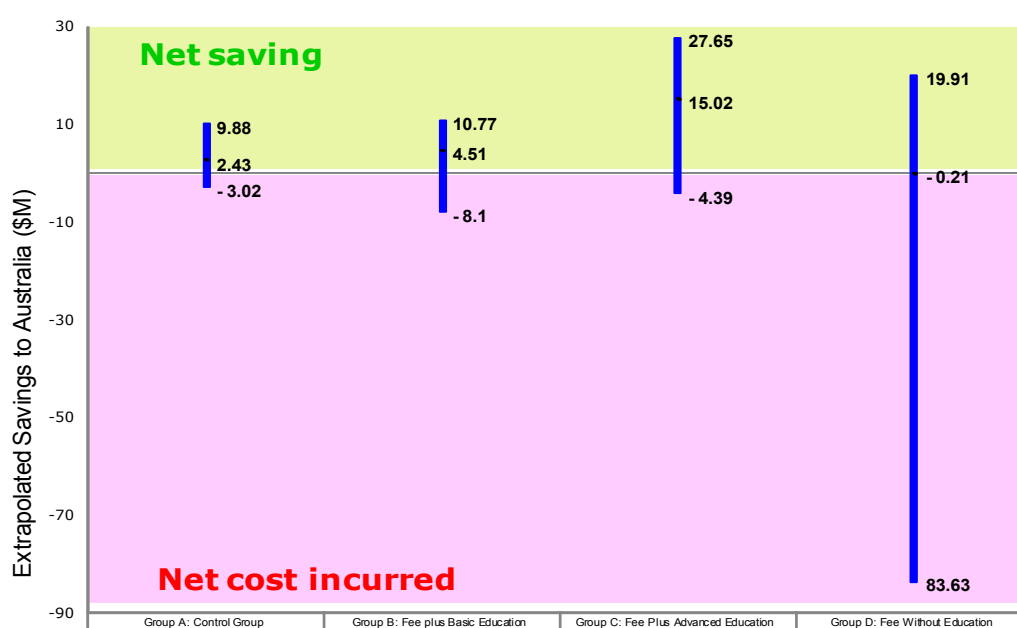


Figure 1-9: Extrapolated Savings for Proactive CIs for Australia (from Benrimoj et al.¹⁹¹)

Although the results of the analysis carried out by these authors are highly variable, and therefore unreliable, the methodology for calculation of the economic impact seems logical and includes all elements of savings and costs. The size of the clinical panel, the level of agreement between members of the panel, the nature of the healthcare requirements and the different probability estimates all influence the overall value estimate.

The results of the model being applied to the three example interventions are shown in Table 1-21.

	Aspirin Prophylaxis	NSAID Duplication	Paediatric Antibiotic Underdose
Healthcare costs avoided (HCCA)= Probability ¹ X cost of probable course of treatment	0.3 ² x ED visit cardiovascular (\$32) ³ = \$9.60	0.7 x ED visit digestive (\$49) ³ = \$34.30	0.5 x ED visit infection (\$37) ³ = \$18.50
Economic Impact = HCCA – (Healthcare costs incurred + Changes in medication cost + pharmacy time + telephone calls)	\$ 9.60 – (cost of drug added \$6.36 + 4 minutes of pharmacists time \$2.42 + 2 phone calls \$0.70)	\$ 34.30 - (cost of drug ceased - \$32.98 + pharmacist time \$4 + phone calls \$0.35)	\$18.50 - (cost of drug dose increase \$0.00 + pharmacist time \$4 + phone calls \$0.35)
Value of Intervention	\$9.60 - \$ 9.48 = \$0.12	\$34.30 - \$28.63 = \$5.67	\$18.50 - \$4.35 = \$14.15
Comments and Assumptions	¹ Probability is considered differently in the two Benrimoj papers, either the probability of an event occurring or the probability that the intervention would prevent an adverse outcome ² Assumed a one year timeframe ³ DoHA Manual of Resources and Their Associated Costs, 1993		

Table 1-21: Value Calculation for Example Interventions using Benrimoj et al. Method^{191, 195}

1.5.1 Value Estimates for Community Pharmacists' Interventions: A Summary of the Literature

As can be seen by the reviewed articles above, there is a wide variation in the methods of calculation of value of pharmacists' interventions. In Table 1-22, a rudimentary comparison of the results for each of the method for the sample interventions is made.

The results of this comparison indicate that the different methods may comparatively under or overestimate the value of the particular intervention. There are a number of key methodological factors that were addressed differently in these studies, and these different approaches are responsible for the widely variable results.

Method of Estimation	Example Intervention		
	Aspirin Prophylaxis	NSAID Duplication	Paediatric Antibiotic Underdose
Rupp et al. 1988 ¹⁹²	\$7.80	\$18.20	\$13.00
Rupp et al. 1992 ¹⁹⁰	\$33	\$42	\$30
Loh et al. 1996 ¹⁹³	-\$27.76	-\$10.17	-\$25
Caleo et al. 1996 ¹⁶⁸	-\$1.68	\$56.83	\$8.65
Benrimoj et al. 2000 ¹⁹¹	\$0.12	\$5.67	\$14.15

Table 1-22: Summary of Value Calculations using Literature Described Methods

These key issues and a brief discussion concerning approaches to the issues are considered in the following section.

Methodological Issues in Determining the Value of Community Pharmacists' Interventions

The intervention process begins with the detection and recognition of a DRP by the pharmacist, followed by a recommendation for the resolution of the problem.

In considering the value of the intervention process, a number of issues are raised at each step of the process (see Figure 1-10).

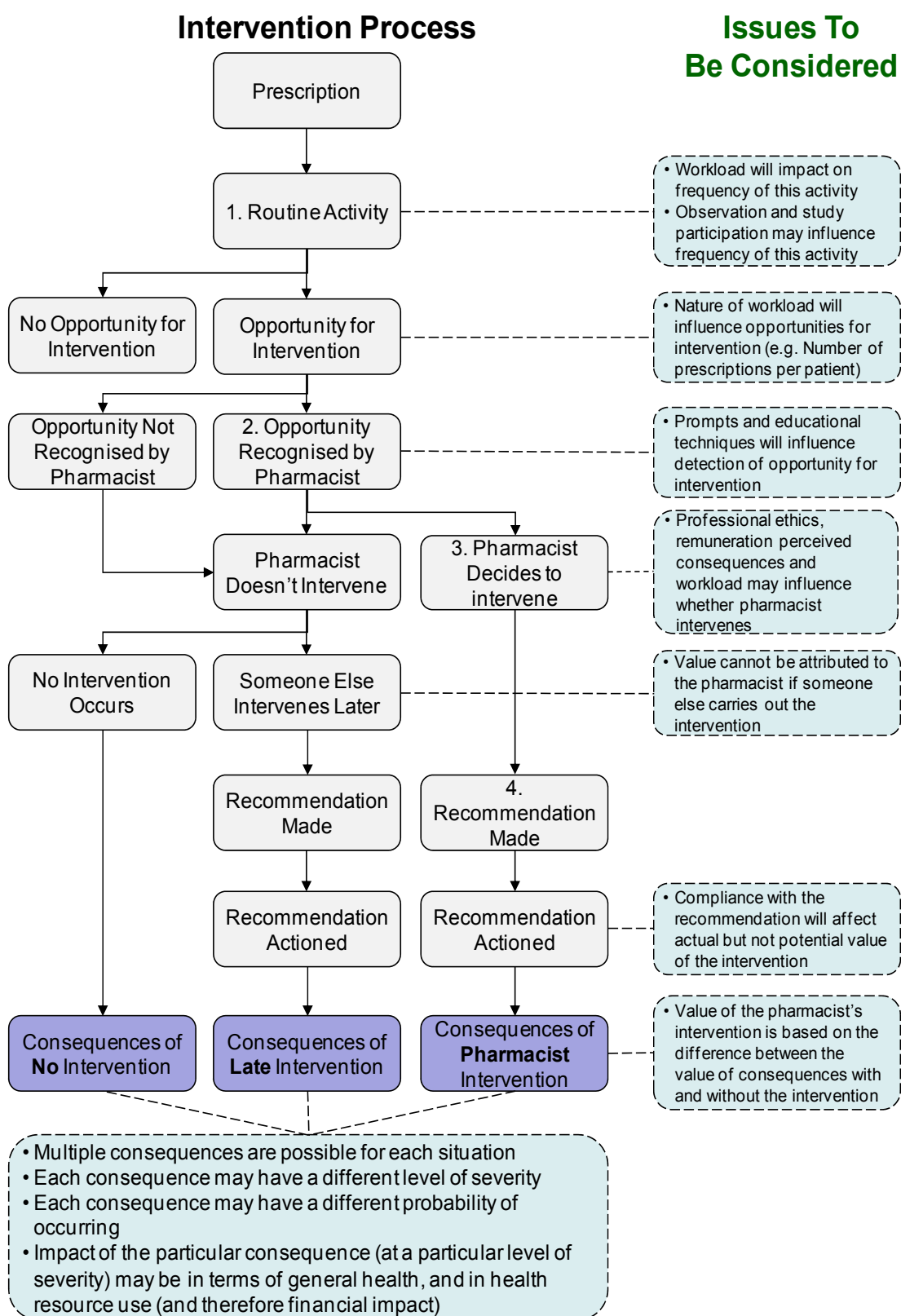


Figure 1-10: Issues to be Considered in Determining Value of the Intervention Process

The studies reviewed in the section above are primarily observational studies of the value of community pharmacists' activity at existing rates of intervention. Their primary intention appeared to be to justify the existing or expanded role of the pharmacist within the primary care setting. All of the studies assumed 100% compliance with the pharmacist's recommendation, and assumed 100% attribution to the pharmacist. That is, they estimated cost

avoidance based on the consequences of the pharmacist's intervention, without considering the consequences of no or a late intervention.

All of the studies used expert opinion in various ways to determine the value of the intervention in health or economic terms. One of the key issues in determining an appropriate value for an intervention in such hypothesised situations, is the definition of the before and after intervention states. In many of the studies reviewed, the effect of the pharmacist's intervention was inferred to be absolute and the costs associated with the "after intervention" state were not considered. The three example interventions considered previously all have potential costs associated with the "after intervention" state (see Table 1-23).

Example 1: Aspirin Prophylaxis A 58-year old female patient with type 2 diabetes with a history of hypertension and mild ischaemic heart disease is advised to commence an antiplatelet agent (aspirin) to reduce her cardiovascular risk.	
Before Intervention <ul style="list-style-type: none"> • Risk of cardiovascular event 	After Intervention <ul style="list-style-type: none"> • Potential adverse effects from aspirin • Reduced, not removed, risk of cardiovascular event

Example 2: NSAID Duplication A 65-year old male with osteoarthritis who is already taking celecoxib is prescribed meloxicam (in addition to the celecoxib). The pharmacist suggests changing the meloxicam to regular paracetamol.	
Before Intervention <ul style="list-style-type: none"> • Risk of gastro-intestinal effects from combination of meloxicam and celecoxib 	After Intervention <ul style="list-style-type: none"> • Potential adverse effects from paracetamol • Ongoing risk of gastro-intestinal effects from celecoxib • Risk of increased pain as a result of cessation of the meloxicam

Example 3: Paediatric Dose Increase A five-year old, 23kg child is prescribed amoxicillin suspension at a dose of 100mg three times daily. The pharmacist checks the paediatric dosing schedule and suggests an increase in dose to 250mg three times daily	
Before Intervention <ul style="list-style-type: none"> • Risk of ongoing infection 	After Intervention <ul style="list-style-type: none"> • Potential adverse effects from increased dose of amoxicillin • Reduced, not removed, risk of ongoing infection

Table 1-23: Potential "After Intervention" Consequences for Sample Interventions

In addition, there are a number of possible consequences of the intervention, some of which may be negative. These consequences may occur at different levels of severity (for example, a severe GI bleed requiring transfusion or a lesser bleed requiring blood tests and monitoring) and there is a difference in the probability of each consequence for each level of severity. So, for example, there may be a moderate probability of causing a mild GI bleed with the addition of aspirin and a lower probability of a major bleed associated with the aspirin addition. There is also a probability that the aspirin addition would decrease the risk of stroke, but this may be different to the probability that the addition of the aspirin will reduce the risk of an angina attack.

Thus, in order for an appropriate value for an intervention to be estimated, it seems that estimates of the probability of different consequences at different levels of severity need to be made for both the before and after intervention situations. By appropriately adjusting these probability differences using the attribution, and having some estimates of the costs associated with particular consequences, a reasonable estimate of the value of the intervention can be made (see Chapter 2 for final method used in this project).

1.6 Documentation of CIs in Community Pharmacies

While pharmacists seem to undertake CIs, the current practice is not to document these interventions unless there is some imperative. The imperative for documentation may be to facilitate communication to other pharmacists involved in the patient's care, or to adequately record details of a potentially litigious situation.

The appropriateness and functionality of currently available electronic systems for documenting these interventions (within pharmacy systems) is discussed in the following section.

1.6.1 Existing Recording Systems

Recording systems for interventions require the capacity to enter information and produce reports regarding intervention occurrences. Identifying and “tagging” patient records that have been the subject of an intervention is important, as it allows for information sharing and continuity of care amongst pharmacists within a pharmacy. The increased scope for awareness amongst pharmacy staff that a particular patient has been the subject of an intervention provides opportunities to follow up care with the patient to determine what outcomes have occurred, and to determine whether the patient requires further assistance. Reporting is considered important as common factors could be identified for improving patient healthcare, such as a prescriber consistently prescribing an inappropriate medication, or interventions occurring more frequently in a group of patients, such as those from a particular nursing home.

The majority of community pharmacists in Australia use one of the following dispensing systems: Amfac[®] windows, Simple Retail Aquarius[®] Dispense, CDC[®], FRED[®], Pharmasol LOTS[®], MINFOS[®], Phoenix Rex[®], or PharmacyPro Dispense[®].¹⁹⁶ Obtaining information about existing intervention recording capabilities of community pharmacy dispensing software is difficult, requiring a visit to a pharmacy that had the particular system installed, and asking the pharmacist to demonstrate how the recording aspect of the system worked. It was not possible to view CDC[®] or PharmacyPro Dispense[®] so the information regarding these was obtained via email from the vendors.

Amfac[®] Windows and Aquarius[®] Dispense dispensing systems both have the capability to record intervention information in the patient notes. This method is easy to use but does not prompt the pharmacist to provide categorising information, such as when the event occurred or what recommendations were made. Since the information is contained in the notes field in an inconsistent free text format, identifying and producing reports about intervention occurrences is not possible.

CDC[®] has the capability to record interventions, and several intervention classifications were provided, such as drug allergy or drug-to-drug interaction. Intervention notes can be made by the pharmacist, and the intervention severity classifications can be set up by the pharmacist. CDC[®] provides the option to record patient outcomes, and is able to produce intervention reports. Unfortunately, the time of an intervention is determined by the opening and closing of the intervention screen, which is a poor and unreliable indicator of the true time of an intervention.

FRED[®] has the capability to record interventions. However, this functionality is not made obvious to the user, being only accessible via a somewhat obscure keyboard shortcut, “Alt + I”. FRED[®] provides a list of intervention reasons, a numerical severity rating, and intervention notes. Reports can be generated for time periods, patient groups, and intervention types. This dispense vendor was involved with both of the previous PROMISe studies.

Pharmasol LOTS[®] has the capability to record interventions, activated using a button on the dispensing screen. Several intervention classifications options are available, such as change of dose, and correcting prescriber error. Intervention notes can be made by the pharmacist, and the time taken for the intervention can be recorded. In

addition, the intervention can be viewed and printed from the patient history. There is no option to produce reports or group interventions by type, patient group or time period.

The MINFOS[®] system is capable of recording basic information about an intervention. It has several options for the type of intervention, including change of dose, and doctor contacted. Once completed, an intervention symbol is shown in the patient history next to the intervened prescription. This system has several limitations though, including not having an option to provide intervention notes, produce reports, or group interventions by type, patient group or time period. In addition, the option to create an intervention is not obvious to the pharmacist. Consequently, an intervention recorded in this system would be of limited value.

Rex[®] also has the capability to record interventions, made accessible to the pharmacist via an intervention button located on the dispense screen. It provides a good range of categories for intervention types, severity levels and time taken. Intervention notes can be entered, and reports can be generated for time periods, patient groups and intervention types. This vendor was involved with the PROMISe I pilot study.

PharmacyPro[®] Dispense has the capability to record interventions. This can occur whilst dispensing a prescription, or in the patient history. It provides a list of intervention options and a numeric severity level classification. Highlighting and right-clicking a script provides the option of adding an intervention. Intervention notes, and the time taken could be entered, and a range of reports can be produced.

Dispensary software	Able to record interventions?	List of CI reasons given?	Severity of CI Recording	Time taken for CI Recording	Notes	Outcomes of CI	Reports
Amfac [®] windows							
Aquarius [®] dispense							
FRED [®]	✓	✓	✓	✓	✓		✓
MINFOS [®]	✓	✓					
Pharmasol LOTS [®]	✓	✓		✓	✓		✓
Phoenix [®] Rex	✓	✓	✓	✓	✓	✓	✓
PharmacyPro [®]	✓	✓	✓	✓	✓		✓
CDC [®]	✓	✓		✓	✓	✓	✓

Table 1-24: Summary of Intervention Recording Features Present in Current Dispensing Systems

Among the dispense systems there were a variety of intervention recording options; Amfac[®] and Aquarius[®] have no formal recording option, whereas CDC[®], FRED[®], Pharmasol LOTS[®], MINFOS[®], Rex[®] and Pharmacy Pro[®] Dispense have a number of options. Of those systems that could record interventions, there were no consistent approaches regarding classifying intervention types, recommendations made, intervention severity, time taken, or reporting options. In addition, several systems have extensive (but not standardised) options for classifying interventions, notes provision and reporting that would be useful for investigating intervention-related issues and for the transfer of information amongst staff. These systems include CDC[®], FRED[®], Rex[®] and Pharmacy Pro[®]. However, despite having the intervention documentation features, Pharmacy Pro[®] and FRED[®] do not make the feature obvious to the user.

Thus, although systems for recording CIs exist within some of the pharmacy software systems, there is no consistency of definitions, or accepted methodology in place.

1.7 Aims and Objectives

For the purposes of this study, a CI is defined as;

Any professional activity by the pharmacist directed towards improving the quality use of medicines and resulting in a recommendation for a change in the patient's medication therapy, means of administration or medication-taking behaviour.

The overall aim of this project was to establish the viability of, and requirements for, a national implementation of an electronic documentation system for the recording of medication issues (CIs) identified in community pharmacies. The reasons for doing this are simple, as it is believed, from experience gained through past studies, that it should be possible to both improve the QOL for consumers, as well as provide an overall cost saving to the government via a reduction in healthcare resource utilisation. In order to demonstrate these beliefs, however, it is necessary to discover a reasonable measure of:

- The value of CIs:
 - to the patient, through improved health; and
 - to the government, through reduced healthcare resource utilisation.
- The methods through which the frequency of CIs can be improved.
 - the effectiveness of these methods.

In addition to these measures, it is necessary to determine the opinions of consumers, pharmacists, and pharmacy owners, as they pertain to the roll-out of a CI documentation system nationally. Chiefly, it must be determined what incentives are appropriate in order to encourage the change in pharmacy practice required for such a system to be successful.

To these ends, a multi-faceted trial was developed, in which each of these requirements were addressed. These approaches are described in the next chapter.

Chapter 2 Methodology

The PROMISe III methodology involved four phases, as shown in Figure 2-1. The first phase of the project involved a review of the requirements for an intervention documentation system. Existing systems were reviewed, and the documentation system developed for the previous PROMISe projects was modified.¹⁹⁷ Focus groups and interviews relating to documentation of CIs were conducted with key stakeholders for the project, including participants in the earlier projects. The information collected from these sources assisted in the modification and consequent implementation of the DOCUMENT classification system and electronic recording system.

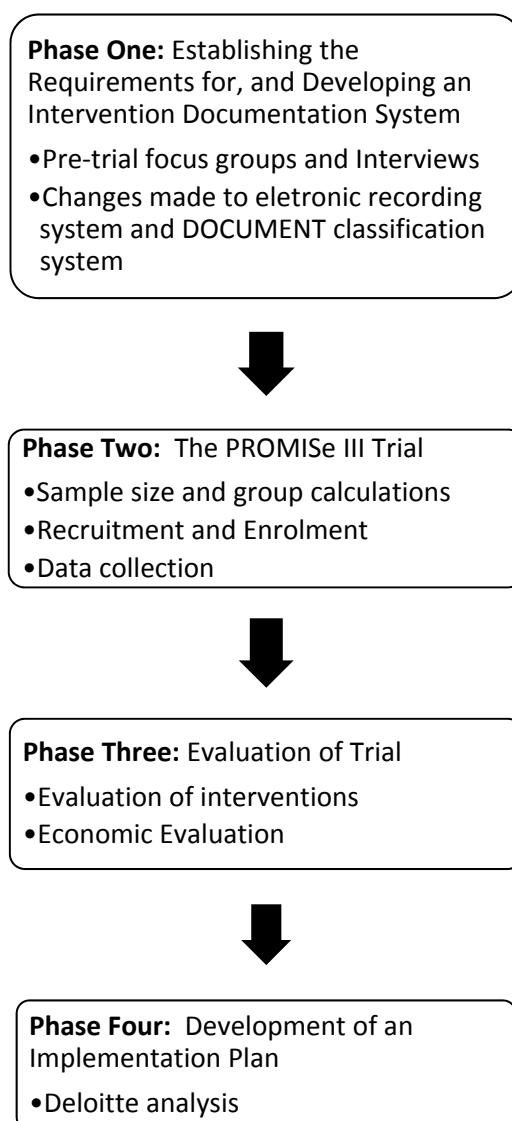


Figure 2-1: The Four Phases of the PROMISe III Project.

The second phase involved installing the systems in a representative sample of pharmacies. The systems were trialled in pharmacies over a 12-week period with all intervention data being sent to a secure repository. Pharmacies were allocated to one of four groups with differing levels of system support to determine the optimum software requirements that facilitated the conduct and recording of interventions. These groups are defined below.

- **No software pharmacies:** This group did not have the PROMISe intervention software (user interface) built into their local computers, and continued their usual practice. Please note that these pharmacies still had their normal dispensing software, they simply did not have the PROMISe interface installed.

- **Software pharmacies:** These groups had the PROMiSe intervention software installed to document their interventions.
 - *Group one:* Only included the base documentation and feedback features.
 - *Group two:* Included the base features, plus a timed reminder to document built into their systems to encourage documentation of interventions.
 - *Group three:* Included base features, the timed reminder, and a targeted intervention prompt built into their systems which was intended to influence a specific type of intervention.

A number of sub-studies were conducted during the course of the trial, including observations of a select number of pharmacists and interviews with consumers who had received a CI, as defined below. Furthermore, researchers visited participating pharmacies to collect additional information regarding pharmacy procedures, layout and staffing. This information, as well as the responses from the surveys the participants completed, were collated with the database of interventions for subsequent analysis.

- **Observational sub-study:** *No software pharmacists* were observed to collect information on current working practices. A select number of *software pharmacists* were observed on working practices incorporating the documentation of interventions on the installed software.
- **Consumer sub-study:** Consumers subject to an intervention both within and outside of the PROMiSe project were asked their views of community pharmacists and medication-related interventions.

In the third phase of the project, an evaluation of the interventions and the systems used took place. A sample of the recorded CIs was assessed by a team of experts to determine their economic value. Feedback from participants and consumers was gathered and this information was used to develop a range of remuneration models and additional requirements prior to possible implementation. The opinions of pharmacy owners who were not involved in the study (or in previous studies) were also sought regarding potential acceptance of different models of intervention documentation. In addition, the opinions of consumers who had not been involved in the project were gathered regarding these models.

In the fourth and final phase of the study, the information gained in the previous three phases, particularly that regarding the value and suggested remuneration models, was used to develop an implementation plan for establishing CI documentation in community pharmacies in Australia.

All aspects of this project were approved by the Tasmanian Health and Medical Research Ethics Committee as outlined in Table 2-1.

Study:	Approved by:	Reference Number:
Documenting Clinical Interventions in Community Pharmacy - PROMiSe III	Tasmanian Health and Medical Human Research Ethics Committee	H0010393
Documenting Clinical Interventions in Community Pharmacy - PROMiSe III. Sub-Study of Consumers Subject to a Clinical Pharmacy Intervention	Tasmanian Social Science Human Research Ethics Committee	H0010388
Documenting Clinical Interventions in Community Pharmacy - PROMiSe III. Sub-Study of Random Pharmacy Consumers	Tasmanian Social Science Human Research Ethics Committee	H0010388
An observational sub-study of pharmacists and the rate of interventions in the sales of non-prescription medicines	Tasmanian Social Science Human Research Ethics Committee	H0010623

Table 2-1: Outline of ethics approvals for PROMiSe III.

2.1 Phase One: Establishing the Requirements for, and Developing an Intervention Documentation System

Phase one involved gathering information for the requirements of the documentation system from focus groups and interviews held with previous PROMISE II participants and GPs. This informed the modification of the DOCUMENT classification system, and also assisted in developing the specifications for the documentation software in PROMISE III.

2.1.1 Pre-trial Focus Groups and Interviews

Feedback from participants in the PROMISE II project identified a range of implementation and documentation barriers and facilitators to the specific tasks of undertaking and documenting CIs.¹⁹⁷ Barriers and facilitators to the wider implementation of professional services have been closely investigated by Roberts and Benrimoj.⁹ In addition, a Computer Assisted Telephone Interview (CATI) survey of 400 community pharmacists across all states of Australia in 2005 also explored issues relating to the performance and documentation of CIs.

Mr Ian DeBoos of DeBoos Associates^[1] was contracted to facilitate in-depth focus groups and semi-structured interviews with key stakeholders of the PROMISE project. The research objectives of these focus groups and interviews were to determine the stakeholder positions and support of pharmacy CIs, the barriers and facilitators to the identification of DRPs and the subsequent documentation of pharmacy CIs, and the information needed for a successful documentation system, such as how documentation information should be used and by whom.

A total of 15 GPs participated in the semi-structured telephone interviews. The 36 participants of the five focus groups were comprised of nominated pharmacy owners, including representatives of the Pharmaceutical Society of Australia and the PGA; employee and accredited pharmacists; previous participating pharmacists from PROMISE II; consumers and representatives of QUM organisations, including the Australian Commission on Quality and Safety in Healthcare, the NPS and the Veterans' Medicines Advisory and Therapeutic Education Services (MATES).

The outcomes of the focus groups and interviews revealed that consumers and pharmacists regarded performing CIs as an important aspect of community pharmacy. Pharmacists saw interventions as their ethical responsibility and as second nature and stated they would always investigate and act on anything regarded to be a serious DRP irrespective of their work demands. Consumers said they were reassured knowing pharmacists could identify any potential DRPs and could also represent consumers' best interests within the health system, in this case to prescribers.

The focus group participants identified a number of factors that influence the appropriate identification of DRPs. The barriers and facilitators to identifying DRPs are detailed in Table 2-2.

^[1] Mr Ian DeBoos is a qualified pharmacist and qualified social statistician and market researcher. He works part time in a community pharmacy and has a unique combination of social researching skills and an understanding of community pharmacy issues.

Barriers	Facilitators
Lack of clinical knowledge	Reimbursement of interventions
Pharmacists have too many roles and there is not enough time to investigate some minor drug problems	Existing community pharmacy protocols could be adapted to allow pharmacists to better understand patient's health status
Pharmacist focus on their business rather than the clinical aspect of their role	Greater community interaction with consumers and other health professionals
Low interaction with customers especially by pharmacists who remain at their dispensing stations	More complete patient histories would enable pharmacists to have the full picture
Low confidence to contact prescribers	Improved clinical education

Table 2-2: Focus Group Findings: Barriers and Facilitators to Identification of DRPs.

Participants of the focus groups identified their requirements for an electronic recording system. The functionality for this documentation system is divided into *must have features*, *nice to have features* and *if possible features*. A summary of these findings can be seen in Table 2-3.

Must have features
Simple operation (quick and easy)
Dispensing aids or reminders such as flags or prompts
Reporting for incomplete and complete documented interventions
Nice to have features
Auto save function
Printing summary of interventions
Pop up window to have link to previous interventions for that patient
Transmission of intervention documentation to external party
Incomplete documentation reminder
Colour coded pop ups
Inclusion of diagnostic data i.e. space for INR recording
Inclusion of diagnosis space
Ability to turn off selected pop ups to a dispenser's initials
If possible features
Allergic reaction to drugs notification when that drug is dispensed for the patient

Table 2-3: Focus Groups Findings: Suggested Features for PROMiSe Software

Most GPs appreciated the professional relationship with pharmacies as they often needed information from pharmacies and both work for the benefit of the patient's health. They were satisfied with the level of contact from community pharmacies.

The interviews found that GPs accepted rather than encouraged pharmacy CIs. The GPs believed that CIs were an important second check for prescriptions. They expressed concerns over a possible increase in their workload and the possible encroachment on their role as GPs. These concerns included uncertainty around pharmacists' clinical expertise and abilities to provide detailed counselling, particularly in the absence of patient histories. Table 2-4 outlines the drivers and barriers to CIs, as identified by GPs.

Drivers
GPs desired more background information about their patients
Interventions act as a safety net to limit prescribing errors
Better patient care
Medico-legal issues for GPs are reduced because of good education and fewer prescribing errors
Barriers
A system that increases GP workload will not be well received by GPs
Increase in unnecessary communication between GPs and pharmacists
Encroachment of GP's roles
Pharmacists providing poor or inexperienced advice to patients

Table 2-4: Interview Findings: Drivers and Barriers for CIs as Identified by GPs.

The results of the pre-trial focus groups and interviews indicated changes necessary to the implementation of the PROMISE III project. Consequently, adaptations were applied to the DOCUMENT classification system and PROMISE software functions.

2.1.2 Modifications to DOCUMENT Classification System

As mentioned in Chapter 1, the DOCUMENT classification system was developed in PROMISE I to provide an efficient means of documenting interventions. The classification system for the types of DRPs and their resolution was refined on the basis of detailed examination of the interventions recorded in the PROMISE II project, and from the broader international experience (published and unpublished).¹⁹⁷ The main purpose of the revision was to simplify the documentation process to make it easier and quicker to use. In addition, the PROMISE II project documented almost 2,400 CIs in particular categories. The results of the frequency of different types of interventions in the PROMISE II study were analysed in order to modify the system.

Feedback from, and the behaviour demonstrated by, pharmacists who participated in the PROMISE II intervention study indicated that pharmacists are willing to provide a written description of an intervention as well as undertake a classification process. These anecdotal written summaries were important since they assisted in determining the appropriateness of the classifications chosen, and describe aspects of the intervention to expert assessors. In a national roll-out, anecdotal reporting may not be feasible for all interventions. In order for a more accurate assessment to be undertaken by expert assessors, it was mandatory that the documenting pharmacist provided a written description for interventions that he or she rated as highly significant (S3 = moderate and S4 = severe interventions, which would be expected to account for approximately 30% of the total, based on previous studies).¹⁹⁷

The classification system developed clearly indicated the type of DRP and the recommendation that was made to resolve it (Table 2-5 and Table 2-6). Detailed definitions for each of the categories of intervention and recommendation were developed. Documenting pharmacists were also required to select a level of clinical significance. The DOCUMENT classification system can be seen in Table 2-5 to Table 2-7, and the changes made from PROMISE II have been highlighted grey. More details on the DOCUMENT system can be found in the scope notes in Appendix A.

Drug Selection	Undertreated
D1 - Duplication	U1 - Condition undertreated
D2 - Drug interaction	U2 - Condition untreated
D3 - Wrong drug	U3 - Preventative therapy required
D4 - Incorrect strength	U0 - Other untreated indication problem
D5 - Inappropriate dosage form	Monitoring
D6 - Contraindications apparent	M1 - Laboratory monitoring
D7 - No indication apparent	M2 - Non-laboratory monitoring
D0 - Other drug selection problem	M0 - Other monitoring problem
Over or Underdose	Education or Information
O1 - Prescribed dose too high	E1 - Patient requests drug information
O2 - Prescribed dose too low	E2 - Patient requests disease management advice
O3 - Incorrect or unclear dosing instructions	E0 - Other education or information problem
O0 - Other dose problem	Not Classifiable
	N0 - Clinical interventions that cannot be classified under another category
Compliance	Toxicity or Adverse Reaction
C1 - Taking too little	T1 - Toxicity, allergic reaction or adverse effect present
C2 - Taking too much	
C3 - Erratic use of medication	
C4 - Intentional drug misuse	
C5 - Difficulty using dosage form	
C0 - Other compliance problem	

Table 2-5: Classification of DRPs

A number of additional sub-categories were added to the “Drug Selection” category. *Incorrect strength* was added to accommodate when an error has been made when selecting a drug strength not intended for that patient. *Inappropriate dosage form* has been reworded from *wrong dosage form*. *Contraindications apparent* has been added for situations where the pharmacist has determined that the patient has been prescribed drug therapy which is contraindicated with their medical condition. *No indication apparent* has been included for when there is no clear reason why the drug should be used in the patient.

In the “Over or Underdose” category, *Incorrect or unclear dosing instructions* has been included to accommodate situations where the specified dosage time is not optimal, or there are insufficient dosing instructions or an inappropriate dosage schedule.

Erratic use of medication has been added to the “Compliance” category to encompass when the patient is inconsistent with taking his or her medication, possibly due to poor memory or lack of care or knowledge.

The title of the “Undertreated” category has been changed from “Untreated Indications” as some indications may be treated, but not adequately. The sub-categories *Condition undertreated* and *Condition untreated* then allow distinctions to be made between them.

The “Education or Information” category has been condensed to three subcategories from the five subcategories in PROMISe II. The two main subcategories *Patient requests drug information* and *Patient requests disease management advice* encompass the majority of problems relating to education or information.

The “Not Classifiable” category was renamed from “Non-Clinical”. In PROMISe II, participants were recording administrative interventions; however, in PROMISe III pharmacists were asked not to record non-clinical interventions such as those relating to administration of the PBS. Therefore, this category was renamed to target situations where a pharmacist feels that a CI cannot be classified under other sections.

The “Toxicity” category was condensed to one option in PROMISe III, down from four in PROMISe II. This was to simplify classification of any problem relating to the presence of signs or symptoms of toxicity that may be attributed to a medication.

Recommendations
A Change in Therapy
R1 - Dose increase
R2 - Dose decrease
R3 - Drug change
R4 - Drug formulation change
R5 - Drug brand change
R6 - Dose frequency/schedule change
R7 - Prescription not dispensed
R8 - Other changes to therapy
A Referral Required
R9 - Refer to prescriber
R10 - Refer to hospital
R11 - Refer for medication review
R12 - Other referral required
Provision of Information
R13 - Education or counselling session
R14 - Written summary of medications
R15 - Recommend dose administration aid
R16 - Other written information
Monitoring
R17 - Monitoring: Non-laboratory
R18 - Monitoring: Laboratory test
Other
R19 - No recommendation necessary

Table 2-6: Recommendations to Resolve Interventions

The recommendation classifications have remained very similar to those used in PROMISe II. One change was made by dividing *Dose change* into *Dose Increase* and *Dose decrease* in order to assist researchers with interpretation of the intervention.

Significance
S1 - Consequences related to information
S2 - Prevented mild symptom or improved compliance
S3 - Prevented or required a GP visit
S4 - Prevented or required a hospital admission

Table 2-7: Clinical Significance of Interventions

The significance codes of the intervention as allocated by the pharmacist have been simplified in PROMISe III. They have been renamed, and have more detailed descriptions to enable easier allocation. *Nil significance* has been removed as PROMISe III pharmacists recorded only CIs, not administrative tasks.

The documentation system was implemented into the PROMISe software; therefore, the software accommodated these changes.

2.1.3 Development of User Interface and Data Repository for Interventions

The information technology (IT) requirements for this project required substantial modification from previous versions, since these were considered entirely unsuitable for a national roll-out, and did not facilitate the participation of multiple dispense vendors. An outline of the implemented solution for recording and sending the information to a secure repository is shown in Figure 2-2.

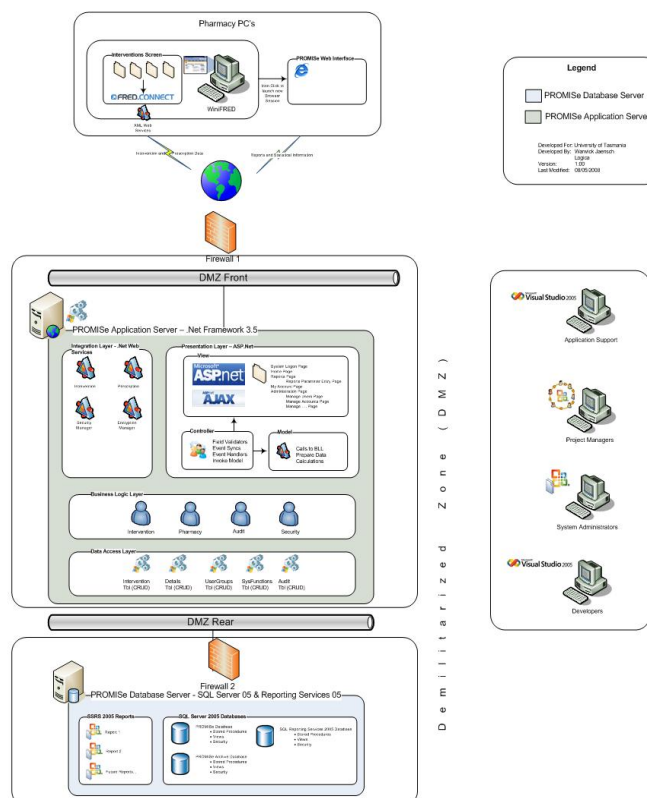


Figure 2-2: Implemented IT Structure

The IT changes required were in several key areas, including the interface with dispensing systems, the messaging systems, access to the information in the repository, and the development of intervention prompts.

PROMISE User Interface

In previous PROMISE projects, the dispensing vendors used were Rex[®] and WiniFRED¹⁹⁷ (now FRED[®]). In PROMISE III, FRED[®] was again involved, as was the first time PROMISE stakeholder, Simple Retail[®], with their product Aquarius Dispense[®]. The FRED[®] dispense system has over 50% of the market share in Australian pharmacies, allowing a large number of pharmacies to take part in the trial. Simple Retail[®] is established in over 500 pharmacies (approximately 10% of the market) and has significant penetration in the New South Wales, Victorian and Tasmanian markets. Both vendors have an already established connection to PBS Online which facilitates a smooth IT implementation process.

The PROMISE software was integrated into the dispensing systems to ensure that the PROMISE interface had the same “look and feel” as the dispensing system. In order to allow for different dispensing programs to use the documentation system, FRED[®] and Simple Retail[®] constructed specific data entry pages within their dispensing system to collect intervention information from pharmacists.

Specifications for the classification system and the required information were determined and documented, enabling current and future dispensing software vendors to incorporate the documentation system into their software, see Appendix PP.

The user interface was activated by pressing “Alt + I” on the keyboard, by clicking on the PROMISe icon, or in FRED® by selecting “New Intervention Note” from the “Activities” menu. If the interface was activated once a patient’s name had been highlighted from the patient list, the details of this patient would pre-populate in the PROMISe interface. These details included the patient’s name, age and gender as shown in Figure 2-3. Activation of the interface could be made at any stage of dispensing a prescription. If it was activated upon completion of the dispensing process, the drug and prescriber details of the prescription were pre-populated. Essentially, the majority of the fields in the intervention interface could be pre-populated by selecting the patient and linking the intervention to a dispensed prescription.

If an intervention was made on an unknown patient, a patient description could be entered together with patient gender and age range. Where the medication of concern was not listed, a description of the intervention could be entered as seen in Figure 2-3.

Figure 2-3 : Completing Patient Details (FRED®)

The DOCUMENT classifications and extra notes sections were available in a tabbed section of the screen as shown in Figure 2-4. The intervention classification tabs were listed in order from left to right to reflect workflow in both dispense systems – category, recommendations, significance, and notes or extra information. These tabs can be seen in Figure 2-4. The category tab detailed the DRP category (DOCUMENT), the recommendation tab listed the options for the pharmacist’s recommendations to the patient, and the significance tab contained the four possible significance categories for the intervention. The pharmacist was required to select the most appropriate sub-category(ies) from each of these tabs. The notes or extra information section provided a free text box for the pharmacist to write a short description of the intervention. More information about data collection can be found in section 2.2.3.

The time taken to undertake the intervention, and the pharmacist initials were mandatory fields. When a pharmacist did not wish to complete all the required intervention information, the intervention could be saved as a draft to be completed at a later time.

Figure 2-4 : Intervention Workflow Tabs (Aquarius)

By clicking the *Display Help Panel* checkbox, information about the selected sub-categories could be seen at the bottom of the intervention screen. Information displayed here included details of when to use and when not to use, and examples of use of each classification selection within the DOCUMENT system, as can be seen in Figure 2-5.

1. Category	2. Recommendations	3. Significance	4. Notes	<input checked="" type="checkbox"/> Display Help Panel
Intervention Category		Intervention Sub-Category		
D Drug selection O Over or under-dose C Compliance U Under-treated M Monitoring E Education or information N Not classifiable T Toxicity or adverse reaction		C1 Taking too little C2 Taking too much C3 Erratic use of medication C4 Intentional drug misuse (including OTCs) C5 Difficulty using dosage form C0 Other compliance problem		
Category Description	When to Use	When NOT to Use	Examples	
<ul style="list-style-type: none"> • If the overuse is due to an appropriate increase in use because of increased symptoms, then use "Condition undertreated (U1)". • If the overuse consists of inappropriately taking two different brands or forms of the same ingredient or drug class unknowingly, then use "Duplication (D1)". • If the patient takes too much and experiences signs or symptoms of toxicity as a result, then use "Toxicity, allergic reaction or adverse effect present (T1)". 				

Figure 2-5 : Help Panel (Aquarius)

Once an intervention was recorded against a patient, the PROMISE logo appeared in the patient's record indicating that the patient had been subject to an intervention, as shown in Figure 2-6.

Name:	A Patient #09
Street:	22 A Street
Suburb:	A Suburb NSW 2000
Nursing:	
Comment	
Allergies	



Patient History											
Script	Date	Days	Drug	Qty	Rpt	PH	DR	Price	MHS	RxDate	Instructions
KF00846	23/06/09 (63)		ABBOCILLIN-VK TAB 500mg	50	0/1	CC	DY	5.00	3028J	23/06/09	1 qid 1h ac uf INTERVENTION

Figure 2-6 : Patient Intervention Identifier (Aquarius)

In FRED[®], the PROMISE logo at the top of the dispensing screen turned green when the user was within the history of a patient subject to an intervention, as shown in Figure 2-7.

Fred Dispense

Fred Dispense Dispense Activities Reports Lists Setup Help










Patient Name or Repeat No

Figure 2-7 : Patient Intervention Identifier Green Icon (FRED[®])

Interventions that were started, but not submitted, could be saved as drafts. In FRED[®], drafts could be completed by clicking *Edit Drafts* in the toolbar at the top of the screen, highlighting the desired draft intervention and clicking "F4" to edit. If a patient had a saved draft against his or her name, the PROMISE icon in FRED[®] was red in colour whilst in that patient's history. In Aquarius[®], drafts could be edited by selecting *List* from the toolbar menu in the intervention interface, and clicking on *Edit Drafts*. The desired draft intervention could then be selected.

Two different reports could be produced by the pharmacist from the PROMISE intervention interface. The Consumer Intervention Record (CIR), which could be given to patients subject to an intervention, contained details of the intervention written in language suitable for a consumer, as shown in Appendix B. This report was designed to inform the patient that an intervention has been made, what it involved, and if the patient needed to follow up with any other health professionals.

A second report, the Health Professional Intervention Record (HPIR) contained the same information about the intervention as shown in the CIR. This report was designed to be sent to the patient's prescriber to inform them about the intervention performed by the pharmacist. This form was not to be given to the consumer as the language was only suitable for a health practitioner, as shown in Appendix C.

Intervention Prompt

The use of a prompt for one specific intervention (the prophylactic use of aspirin in patients with diabetes) was trialled in the PROMISe II project to test the function of influencing a specific type of intervention.¹⁹⁷ The presence of the prompt resulted in an increase in frequency of the targeted intervention, as well as an increase in other unrelated CIs.¹⁹⁸

In PROMISe III, the prescription of high-dose (40mg) proton pump inhibitors (PPIs), specifically pantoprazole (SOMAC®) and esomeprazole (NEXIUM®), was targeted with a specific intervention prompt. This particular intervention was chosen on the basis of high publicity from a NPS media release in [May 2009](#).¹⁹⁹ The prompt, shown in Figure 2-8, was activated when 40mg pantoprazole or 40mg esomeprazole was selected for dispensing. The pharmacists had the choice to continue dispensing, print the patient information leaflet or print the pharmacist/GP information leaflet. These leaflets can be found in Appendices D and E.

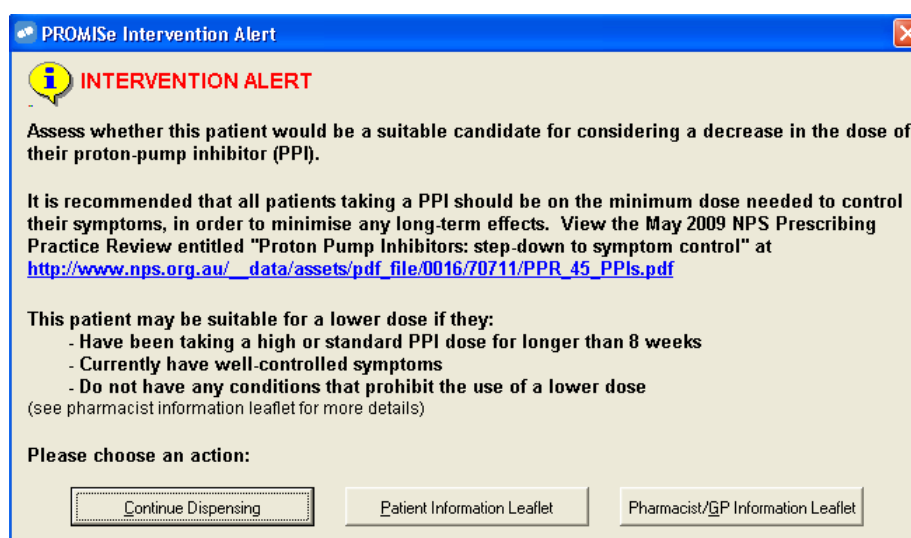


Figure 2-8: The Specific Prompt for Group Three Pharmacies.

Messaging System

Each software vendor was required to develop a communications client to facilitate the transmission of intervention and prescription data to a secure web server. This enabled the data to be accessed by researchers whilst still maintaining security integrity. The communications client then relayed encrypted messages to a secure web server via a Secure Socket Layer (SSL). The Aquarius software sent messages to the web server as they occurred, whilst the FRED® software sent message bundles every two hours.

The web server also had detailed specifications for connectivity, and software vendors were able to modify their software to enable sending and receiving of information relating to prescriptions and CIs. The underlying messaging structure of the web system utilised eXtensible Mark-up Language (XML) messaging which provided a simple and industry standard communications method for software vendors without requiring major modifications to their systems.

Repository

The repository securely stored prescription, patient and intervention information. Incoming XML messages were checked for validity against an XML schema, and all valid messages were entered into the repository. XML schema

validation requires that the data, type of data, and expected location of each piece of data matches a defined template. Messages which did not conform to the schema were discarded, and a response message was sent to the particular pharmacy system that generated it to indicate that its message was rejected.

A table was developed to match Simple Retail Aquarius[®] drug codes and FRED[®] drug codes to the Anatomic Therapeutic Chemical (ATC) classification coding system for data analysis.²⁰⁰ This was updated twice during the course of the trial and was able to match the vast majority of all incoming drug codes.

An interface for the repository was developed (the PROMISe web interface) which acted as the portal for information transfers. This PROMISe interface was also a portal for feedback from, and interrogation of, the PROMISe database. Three groups with varied levels of access were designated; trial participants, administrators and researchers. Trial participants were able to view pharmacy-specific and national reports from the system. Administrators were able to add and edit pharmacy and pharmacist details stored in the system. Researchers were able to obtain a larger range of reports and could export reports. Specifications for the repository can be found in Appendices QQ and RR.

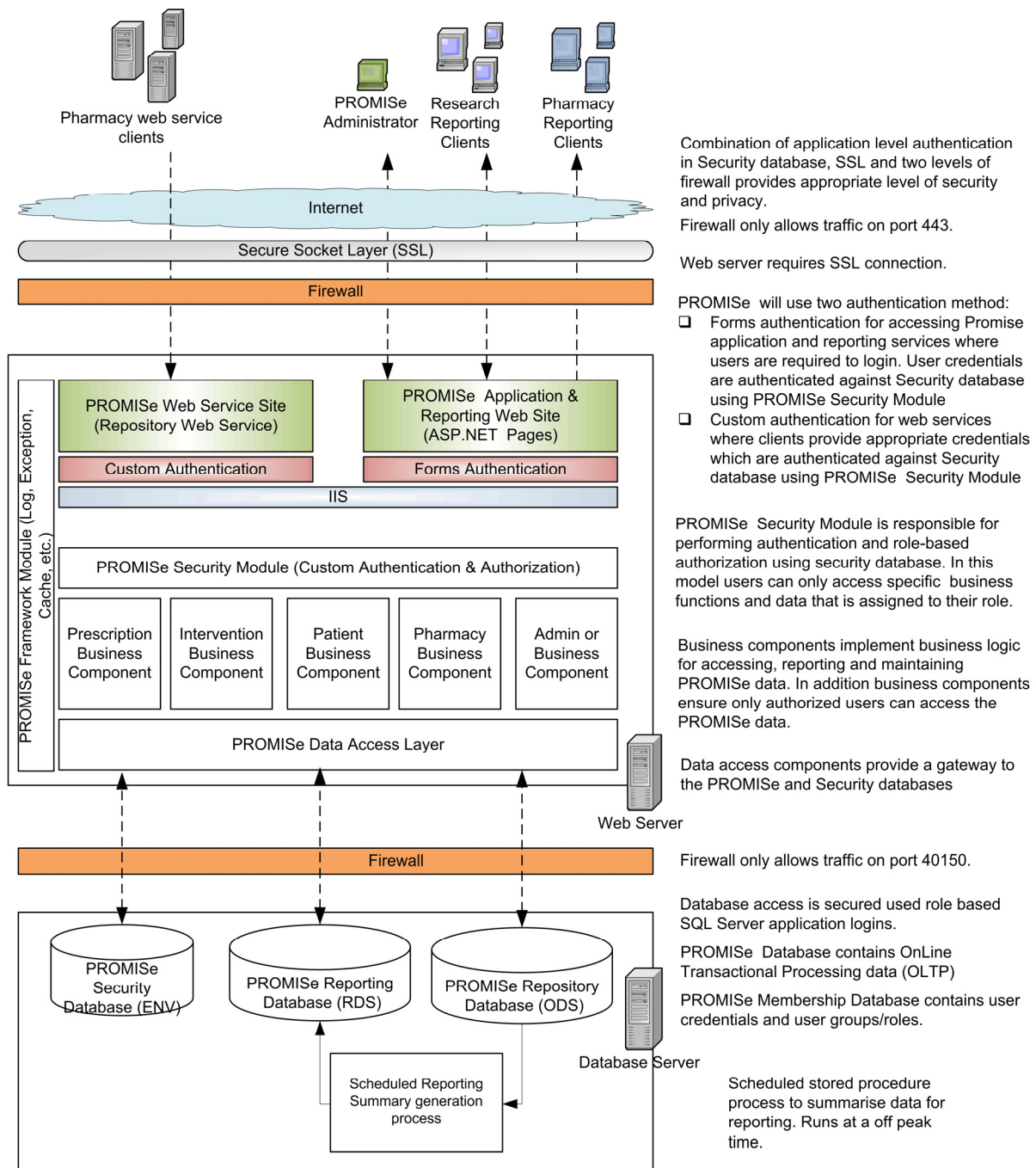


Figure 2-9: Implemented Information Technology Security Model

Feedback Mechanisms

Observers were present in some pharmacies during both the PROMISE I and PROMISE II projects for part of the study time in order to assist with documentation. The results showed that these pharmacies had a higher intervention frequency than pharmacies not allocated an observer, even after observation visits ceased. Feedback from participating pharmacists indicated that the encouragement and constant reminder due to observer presence prompted more interventions than would otherwise have occurred.

In PROMISE III, some aspects of the presence of the observer were replicated by several electronic feedback mechanisms including web-based reports, a statistic display, non-specific reminders and specific prompts.

Participants were able to access the web-based reports through the PROMISE website. The reports displayed pharmacist and pharmacy intervention details. The reports also provided the intervention rates for each state and a

breakdown of intervention types, recommendations, and drug groups, which were used as a motivational aid. Figure 2-10 outlines the overall intervention rates across the three states. Other reports are shown in Appendix F.

Report				
Overall Intervention Rates				
For Tuesday, 14 July 2009 to Wednesday, 9 September 2009				
Intervention Rates Per Prescription				
	Script Interventions	Prescriptions	Intervention Rate	Non-Script Interventions
Pharmacy Intervention Rate	32	18200	0.18%	20
TAS Intervention Rate	389	153162	0.25%	224
NSW Intervention Rate	1479	548409	0.27%	595
VIC Intervention Rate	1591	897659	0.18%	1090
Intervention Rates Per Patient				
	Script Interventions	Patients	Intervention Rate	Non-Script Interventions
Pharmacy Intervention Rate	32	5672	0.56%	20
TAS Intervention Rate	389	38328	1.01%	224
NSW Intervention Rate	1479	149962	0.99%	595
VIC Intervention Rate	1591	251453	0.63%	1090

Figure 2-10: Overall Intervention Rate Report

A real time statistic display was incorporated into the intervention screen to provide accessible motivational feedback to all pharmacists, an example of which can be seen in Figure 2-11. The PROMISE repository was polled several times daily to update the current overall trial intervention rate. The display showed the entire trial intervention rate as shown by *All* in the FRED[®] figure and *Global* in the Aquarius[®] figure. Each pharmacy intervention rate was shown as a percentage entitled *Site* in the FRED[®] figure and *Local* in the Aquarius[®] figure.

Intervention Rates			
Site:	84.31 %	All:	0.00 %

Aquarius	
Intervention Rates	
Local	74.00
Global	51.54

Figure 2-11: Statistics Display for FRED (left) and Aquarius (right)

For selected pharmacies only, a non-specific reminder was timed to appear at 11.00am and 3.00pm to remind the pharmacists to document their interventions or complete their draft interventions, as shown in Figure 2-12.



Figure 2-12: The Reminder Built into the Software

The software pharmacies were grouped to establish the optimum combination of feedback and support mechanisms to facilitate a high level of uptake of documentation using the recording system.

Feedback and support were also provided through pharmacy visits. The visits ranged in duration from 15 to 90 minutes depending on the needs of the pharmacists. During the visits, the pharmacists were shown how to access the online reports and they were also given the opportunity to ask any questions and relay any problems back to the project team. The other aim of the visits was to obtain additional pharmacy data. The details of this data collection can be found in section 2.2.3.

2.2 Phase Two: The PROMISe III Trial

The PROMISe III trial was conducted over a 12-week period and involved 210 Australian pharmacies from across three states; Tasmania, Victoria and New South Wales. Within the trial, a number of sub-studies were conducted that involved observing participating pharmacists performing their usual activities in the pharmacy, and interviewing consumers who were subject to a CI. These and other aspects of the trial are outline in Figure 2-13.

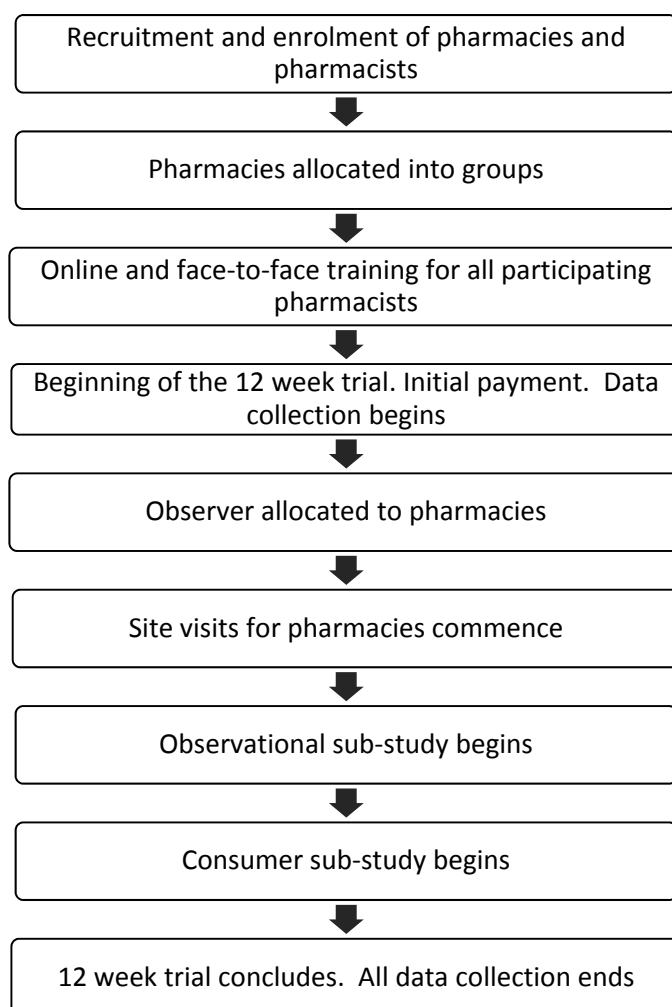


Figure 2-13: PROMISe III Trial Outline

2.2.1 Study Design

The power calculations for the sample used and the allocation of the pharmacies to different groups is outlined in the following sections.

Sample Size Calculation

The sample size selected was limited by the resources available and logistics. In order to obtain a representative sample, a decision was made to examine approximately 5% of the pharmacies in Australia. As there were 5,006 pharmacies in Australia at the time of the trial, a sample size of 210 pharmacies was selected.

Table 2-8 shows the statistical power of three scenarios, based on the 24 no software pharmacies and the remaining 186 in the software pharmacy groups.

Assumption	N [*] in treatment group	N in control group	Intervention rate in treatment group	Intervention rate in control group	Power
Full cohort – 1000 Rx/wk	2,232,000	288,000	0.0053	0.005	56%
			0.0055		94%
			0.006		100%
Full cohort – 900 Rx/wk	2,008,800	259,200	0.0053	0.005	52%
			0.0055		91%
			0.006		100%
90% of cohort – 900 Rx/wk	1,803,600	237,600	0.0053	0.005	49%
			0.0055		89%
			0.006		100%

*N refers to the number of prescriptions

Table 2-8: Power Calculation for 186 Software Pharmacies and 24 Control Pharmacies

This sample size will detect a difference in intervention rate of at least 0.001 (one in 1,000 prescriptions) with 100% power, provided the level of data loss is within tolerances. A difference of 0.0005 will in all cases be detected with a power of approximately 90%.

If the impact of the software was to be smaller, for example, 0.0003, then it appears that the study is not adequately designed. Indeed, such a difference would be appropriately detected in only approximately 50% of the cases (assuming no loss of data). However, this should be balanced with the fact that such a small difference might not be clinically or economically meaningful anyway.

All calculations were performed with the *sampsi* command in Stata, using a standard first-type error of $\alpha = 0.05$.

Groups

The intent of the 12-week trial was to determine differences between the frequency of recording of interventions between no software pharmacies and software pharmacies using PROMISE documentation software.

No software pharmacies

In order to collect a true representation of intervention and documentation behaviour in the absence of the PROMISE software, the no software pharmacies received only minimal information about the PROMISE project and did not have the PROMISE software installed. The no software pharmacy data was collected by pharmacy observation over a five-day period (see below for more information). The observers recorded the pharmacist's current methods of documenting interventions and obtained an actual clinical intervention (ACI) rate, as well as a DCI rate. The ACI rates recorded in the no software group were compared the ACI rates in the PROMISE software pharmacies to determine if the presence of the interface increased the ACI rate as well as the DCI rate. These figures were then used in the economic analysis and business case modelling (see Chapter 8).

Software pharmacies

Three groups of software pharmacies were established to determine the optimum combination of feedback and support mechanisms to facilitate a high level of uptake of documentation using the recording system. All groups had access to the online repository providing electronic feedback and reports of interventions specific to both the pharmacy and pharmacist. In addition, they all could view a live documentation intervention rate on the PROMISE interface, including the rate for the pharmacy and the overall trial rate. More specifically, the groups were defined by their software functions.

Group one had the PROMISe documentation software installed with no additional features.

Group two had the software installed with a reminder built into the system. The reminder, as mentioned in section 2.1.3, was activated at 11.00am and 3.00pm to encourage pharmacists to document interventions.

Group three had the software installed with the reminder and an additional intervention prompt feature. As discussed in section 2.1.3, this prompt was activated when dispensing a high-dose PPI (40mg pantoprazole or 40mg esomeprazole).

All software pharmacies received a \$600 upfront payment as well as a participation payment of \$600 upon full completion of the pharmacy's commitment in the trial. The definition of *adequate participation* was determined by the project team and involved the "documentation of interventions and response to surveys and other correspondence from the project team". Pharmacies selected for observation, including the no software pharmacies, received additional payment of \$500 for their participation.

Stratification

The group allocation is detailed in Figure 2-14. The software pharmacies were stratified based on the national average of Pharmacy Access/Remoteness Index of Australia (PhARIA) and estimated annual prescription volume categories, as outlined in the 2008 Guild Digest. Once stratified accordingly, pharmacies were then randomly allocated across the three software groups. The pharmacies in the no software group were recruited and stratified separately to the 186 software pharmacies as discussed in section 2.2.2. Chapter 3 will further detail group allocation and stratification.

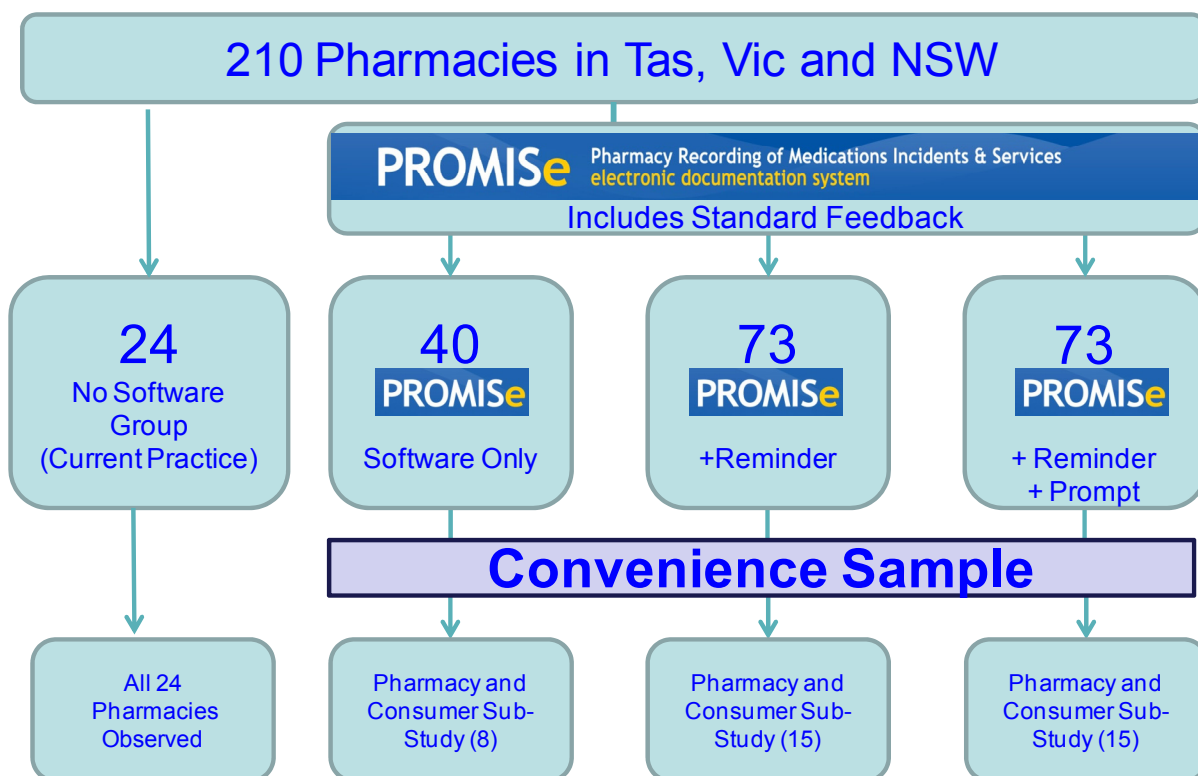


Figure 2-14: Allocation Schema for PROMISe III Project

Sub-studies

As can be seen in Figure 2-14, a sample of pharmacies from each group participated in two sub-studies; pharmacy and consumer sub-studies. Pharmacies were invited to participate on the basis of location and size. Pharmacies were able to decline participation in the sub-studies and obviously only those that agreed participated.

Pharmacy Observation Sub-study

The observational sub-study was designed to determine what barriers and facilitators influence pharmacists' performance and recording of interventions and to clarify the "usual practice" in terms of the frequency of interventions and their documentation. Selected pharmacists were observed performing their usual activities in the pharmacy by a trained pharmacist observer. The study had several main objectives:

- determine the ACI frequency as opposed to the DCI frequency by the participating pharmacist (see section 2.3.7 for details);
- observe the practical barriers and facilitators to the performing and documentation of CIs;
- observe and record the level of pharmacist intervention in regards to OTC medication;
- determine the resources used to undertake CIs; and
- establish the workload to staff ratio, the nature of the workload and the category of the pharmacy in terms of business style.

Sixty-two pharmacies participated in the observation sub-study; 24 from the no software pharmacies and 38 from the software pharmacies.

Twelve registered pharmacists across Tasmania, Victoria and New South Wales were recruited as observers for the sub-study. One Tasmanian-based observer was individually trained and undertook one week of pilot observation to detect any methodological issues with the study. This was undertaken prior to the training of the observers, as shown in the schedule in Table 2-9. The results of the pilot observation meant the data collection record forms could be optimised.

The observers "shadowed" one participating pharmacist over five days (Monday to Friday from 9.00am until 5.00pm). On some occasions, due to rostering and staff hours, this meant different pharmacists were observed during the week. Most observers were employed for seven weeks: they undertook observer training for one week and observed for the remaining six weeks. Some observers visited fewer pharmacies than others and therefore were employed for less time. They also completed their report writing within this observation period.

Observer	July 13-17	July 27-29	Aug 3-7	Aug 10-14	Aug 17-21	Aug 24-28	Aug 31-Sept 4	Sept 7-11
1	Tas*	Observer training (Tas)		Tas		Tas		
2			Tas	Tas	Tas	Tas	Tas	
3			NSW	Vic	Tas	Tas	Tas	Tas
4			NSW	NSW	NSW	NSW	NSW	NSW
5				NSW	NSW	NSW	NSW	
6				NSW	NSW	NSW		
7			Vic	Vic	Vic	Vic	Vic	NSW
8			Vic	Vic	Vic	Vic	Vic	Vic
9			Vic	Vic	Vic	Vic	Vic	Vic
10			Vic	Vic	Vic	Vic	Vic	Vic
11			Vic	Vic	Vic	Vic	Vic	Vic
12				Vic	Vic	Vic	Vic	Vic

*Pilot observation

Table 2-9: Schedule for Observers in Pharmacy Sub-study

Observer Allocation

Registered pharmacist observers were allocated to 38 (20%) of the software pharmacies and the nature of this allocation is discussed in Chapter 3. In addition to the 38 observed software pharmacies, the no software group was observed over a five-day week. All no software pharmacies were recruited in order to determine the current practice of recording interventions and to obtain a baseline level of performing interventions. The nature of the sample of no software pharmacies is discussed in Chapter 3.

Consumer Sub-study

The consumer sub-study was developed to determine consumers' attitudes towards community pharmacy interventions and ascertain the usefulness of pharmacy interventions from the consumer's perspective.

The consumer sub-study targeted two consumer populations:

1. **PROMISe Consumers:** consumers who had a documented intervention as part of the PROMISE project on:
 - a. any of their medication; or
 - b. only their PPI medication.
2. **Non-PROMISe Consumers:** consumers who had received an intervention from a pharmacy not actively participating in the PROMISe project.

The consumers from non-PROMISe pharmacies were recruited to compare their uptake and intervention outcomes with those of the consumers from PROMISe pharmacies. Furthermore, it was of interest to determine the uptake rate of interventions triggered by the software PPI prompt in group three software pharmacies to establish the effectiveness.

A select number of consumers, who had an intervention at participating pharmacies, were asked to participate in the sub-study by undertaking a telephone questionnaire. The questionnaire was designed to test their recall of the intervention that was undertaken, to determine if they had carried out the recommendation given by the pharmacist, to collect demographic information, and to assess their QOL. If the consumer had not acted upon the pharmacist's recommendation, a follow-up telephone call questionnaire was conducted approximately four weeks later. All questions were multiple choice or open-ended and all interviewers endeavoured to not lead the consumers in any way.

The consumers were recruited by giving them a consent form, either at the time of intervention, or sent via mail. The intention was to make the first telephone call within two working days of the research team receiving the assenting consent form. However, as it was difficult to contact some consumers, a number of weeks had passed before the telephone questionnaire was conducted. The follow-up phone call also posed challenges in contacting the consumers and in some cases more than four weeks had passed before contact could be made.

The second part of the study involving PROMISe consumers included consumers who received an intervention specifically on their high dose (40mg) PPI, in particular Nexium® and Somac® medication. Only the interventions from group three pharmacies were targeted as only this group had the PPI prompt installed. Eligible consumers were identified through analysis (by the participating pharmacist) of their recorded interventions. These pharmacists were asked to mail out the surveys to the consumers. These consumers were asked to complete a short written questionnaire and return it (using a provided reply-paid envelope) to the project team. The written questionnaire regarding the PPI prompt was designed to assess whether the pharmacist's intervention resulted in the consumer receiving a step-down from their 40mg PPI medication to 20mg or an alternative medication.

The second targeted consumer population were consumers who had received an intervention from a pharmacy not involved in the project. This part of the consumer sub-study was facilitated by Mr Ian DeBoos of DeBoos Associates. These consumers, who were recruited from an online panel, were asked to complete an online questionnaire, which was similar to the interview conducted with PROMISe consumers, as mentioned above. Again, the consumers were tested on their recall and asked to provide their opinion on community pharmacies and on CIs. All of these questionnaires will be discussed in section 2.2.3.

Included in all of the consumer questionnaires was a simplified version of the five-point QOL survey (EQ-5D). The results from the consumers with documented interventions were compared to a similar survey which obtained an estimate of the national average population. The national averages were collected from the results of a similar questionnaire targeting pharmacy consumers who represent the average population, and who had not received an intervention as part of the PROMISe trial.

2.2.2 Recruitment and Training

Recruitment for the project was extensive with a sufficient number of pharmacies stratified to the national average required for recruitment. In addition, observers and consumers were recruited for both sub-studies of the trial.

Pharmacies and Pharmacists

Participating pharmacies were recruited in several ways. Advertisements were run in *Pharmacy News* and *The Australian Pharmacist* in March and April 2009, targeting users of the FRED[®] and Aquarius[®] dispensing software. The advertisements directed interested parties to view the PROMISE website located at <http://www.promise.org.au>. However, the advertising did not produce the required number of participants. The PGA assisted by sending out a fax to all pharmacies within the three targeted states, asking interested parties to view the website, phone the project team or return the fax with their contact details.

The overwhelming response resulted in 334 pharmacies expressing interest. The researchers grouped these pharmacies according to their PhARIA and estimated annual prescription volume that were collected from the expression of interest form. Pharmacies were selected using the inclusion and exclusion criteria as shown in Table 2-10.

Inclusion Criteria	Exclusion Criteria
Fred or Aquarius dispensing software	Dispensing software other than Fred or Aquarius
Ability to be stratified according to the desired category of prescription turnover and PhARIA (see Chapter 3)	The appropriate prescription turnover/PhARIA category being at capacity
All employee pharmacists committed to the twelve weeks of the trial	Employee pharmacists inability to commit to the trial
Timely expression of interest	Application after the cut-off date

Table 2-10: Inclusion and Exclusion Criteria of Trial Pharmacies

From the 186 pharmacies invited to participate in the project, 531 pharmacists enrolled in the trial. A further 24 pharmacies were recruited to make up the no software group. These pharmacies did not receive the PROMISE intervention software, but were observed for one week to gain data on the current practice of recording interventions. This group is referred to as the no software group, or no software pharmacies. These pharmacies were recruited from the expressions of interest and included some pharmacies that did not have FRED[®] or Aquarius[®] dispensing systems. Inclusion and exclusion criteria for the no software group are shown in Table 2-11.

Inclusion Criteria	Exclusion Criteria
Any dispensing software	The appropriate prescription turnover/PhARIA category being at capacity
Ability to be stratified according to the desired category of prescription turnover and PhARIA (see Chapter 3)	Remote location (impractical to be visited by an observer)
Timely expression of interest	Application after the cut-off date

Table 2-11: Inclusion and Exclusion Criteria for No Software Pharmacies

Pharmacists participating in the PROMISE project were trained in the use of both the DOCUMENT classification system and the PROMISE intervention software. The training was presented in two ways: online and face-to-face. The online option provided practice for using the DOCUMENT classification system, and short videos showing the use of the PROMISE software. Online training was considered important as access to the six face-to-face training sessions would be impractical for the many pharmacists who worked in the more remote areas of the three states.

Thirty-one online training scenarios were prepared, based on a range of pharmacy specific situations. Scenario wording and classification codes were assigned and peer reviewed. Pharmacists were expected to complete at least 15 scenarios and encouraged to undertake a further 16 intervention scenarios.

Pharmacists had to evaluate each scenario using the classification system and assign a document recommendation and significance category to the case-based scenario. At the completion of each scenario the pharmacist was provided with immediate feedback which contained the peer reviewed classification codes and an explanation as to why these codes were chosen, as shown in Appendix G.

In addition, two videos demonstrating recording an intervention on both FRED® and Aquarius® PROMISe software were available online. The demonstrations were approximately 15 minutes in length. All pharmacists were encouraged to complete the online training and view the demonstrations.

Face-to-face training sessions were held in Tasmania, Victoria and New South Wales, with two training sessions being run per state. In these sessions, the attendees were asked to assign DOCUMENT, recommendation and significance classifications to intervention scenarios which were similar to those used in the online training. Each pharmacy received a training package that contained a welcome letter, information about their allocated group, a timeline of the trial, information about the sub-studies, a software cheat sheet guide, the DOCUMENT classification booklet and a monitor sticker. Pharmacies that did not have a representative at any of the face-to-face training sessions were sent their training package in the mail. The aforementioned demonstration videos were presented at the face-to-face training, and computers were set up with the PROMISe software for participants to access.

In order to reduce any implementation issues, the software pharmacies had a “rolling start” to the trial; the software was activated progressively over the course of two weeks. Each pharmacy was phoned by a member of the project team who provided them with an activation code. Once activated, the pharmacy computers automatically sent data to the repository. The activation code also enabled the additional features of the software for groups two and three: the reminder and specific prompt.

Observers

The observer positions were advertised in the Australian Association of Consultant Pharmacy (AACP) and Pharmaceutical Society of Australia (PSA) news bulletins. A total of 19 pharmacists expressed interest from which twelve observers were recruited. The final 12 were selected based on their experience and location; the selection criteria were as follows:

- at least five years of community pharmacy experience;
- ability to observe in one of the three trial states (Tasmania, Victoria or New South Wales); and
- preference was given to candidates who had experience in similar roles for other studies.

Of the selected group of 12 observers, 10 (83.3%) were female with a mean age of 39 ± 10.7 years. They had an average of 12.4 ± 8.5 years of community pharmacy experience. Two observers had previous experience with research projects. There were no particular conflicts of interest known to the project team.

The observers underwent a two and a half day training course in Tasmania. The course involved intensive training in the DOCUMENT classification system and in their observation tasks, as shown in Table 2-12. The observers all received two folders, one for their training information and another for all of their forms for data recording. They also received pre-paid A4 sized envelopes to post their data collection forms back to the PROMISe team.

Task	Description	Form
Explain study	Discuss the project and sub-study with each observed pharmacist: build rapport with the observed pharmacists, ensuring all observed pharmacists place a consumer notice in the pharmacy.	Consumer Notice
Determine actual intervention (ACI) frequency, as opposed to the documented intervention (DCI) frequency	Record each and every intervention they witness in the pharmacy regardless of whether the pharmacist documented it. Recorded daily workload details of each observed pharmacist for each day.	Intervention Record; Hourly Log
Determine the pharmacist intervention level for OTC medication	Observe and record details of any intervention regarding OTC medications, with a particular emphasis on non-steroidal anti-inflammatory drugs (NSAIDs). Record, the total number of OTC requests dealt with by the pharmacist to provide a denominator statistic for the interventions.	OTC Intervention Record Form; Hourly Log
Recruit consumers for the consumer sub-study	Assist the enrolled pharmacists with the recruitment of consumers for the consumer sub-study.	Consumer Envelopes
Undertake a Time and Motion analysis of the pharmacy	Record the workflow of the pharmacy the nature of the pharmacist's workload and staffing levels	Daily Log
Determine the practical barriers and facilitators to documenting clinical interventions	Record the observed barriers and facilitators for each pharmacist. For no software pharmacies, record the details of the current methods of documenting interventions.	Barriers and Facilitators Record Form
Complete data entry	Enter all of their collected data for ready access by the project team. Hard copies of the data collection forms to be mailed back to the project team.	Online Survey

Table 2-12: Outline of the Observer Tasks

Consumers

As mentioned in section 2.2.1, there were two populations of consumers targeted for this sub-study: PROMISE consumers who had received an intervention from a pharmacy participating in the project and non-PROMISE consumers who had received an intervention from a pharmacy outside of the project. The populations were recruited differently.

PROMISE Consumers

There were several improvements made to the process of recruiting PROMISE consumers for this sub-study. The initial strategy for recruitment was through the observational sub-study, when observers would be asked to recruit consumers in the pharmacy at the time of the intervention. However, when the observation was piloted, it was determined that recruiting consumers was a lengthy process and meant that the observer may miss other activities of the pharmacist at the time. In addition, some interventions were recorded once the consumer had left the pharmacy. Therefore, it was decided that each observed pharmacy was provided with 10 sub-study information packs (see Appendices H, I, and J) to post out to patients during the week of observation. The packs contained a detailed consumer information sheet, a letter from the pharmacist, a consumer consent form, and a reply-paid envelope. In addition, the enrolled pharmacists printed off two copies of the CIR from the PROMISE system; one copy was stapled to the consent form for the PROMISE team when the consumers posted back their signed consent forms, while the second copy was placed inside the envelope for the consumer to keep.

The observers or pharmacist posted the information pack to the targeted consumers. The observers were instructed not to recruit patients who they believed to be inappropriate for the questionnaire, such as potential drug misusers. Interested consumers would then post back the consent form, with the stapled CIR, to the project team in the reply-paid envelope. Consumers were offered a \$10 gift voucher for their participation. See Figure 2-15 for an overview of this process.

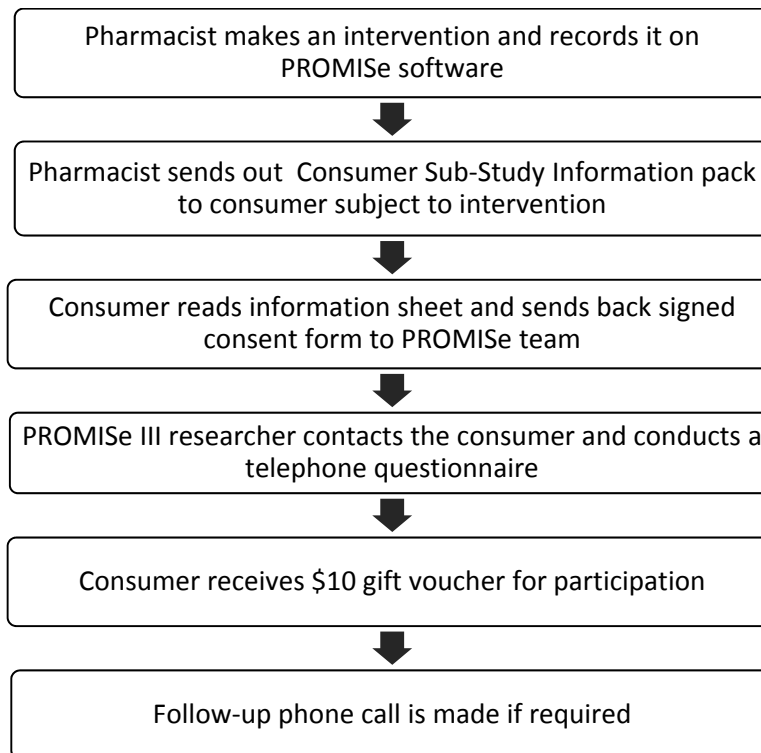


Figure 2-15: Overview of Consumer Sub-study

Due to a low recruitment rate from observed pharmacies for the sub-study, the team enlisted the assistance of pharmacies with high intervention frequencies. The PROMISE team identified which pharmacies had high intervention frequencies from the data already collected from the trial and telephoned them to ask for their participation. The interested pharmacists then sent out consumer sub-study packs to 80% of the consumers who had been the subject of an intervention.

PROMISE consumers who were subject to a prompted PPI step-down intervention were recruited by pharmacists in group three in the same way. Group three pharmacies were targeted if they had performed a significant number of PPI step-down interventions. Pharmacists agreed to send out a questionnaire accompanied by a consumer letter (see Appendices K and L) and a reply-paid envelope to consumers subject to a prompted intervention. The consumer then completed the questionnaire and posted it back to the project team. The consumers had the option of including their address if they wished to receive a \$10 gift voucher for their participation. Figure 2-16 shows an overview of this aspect of the consumer sub-study.

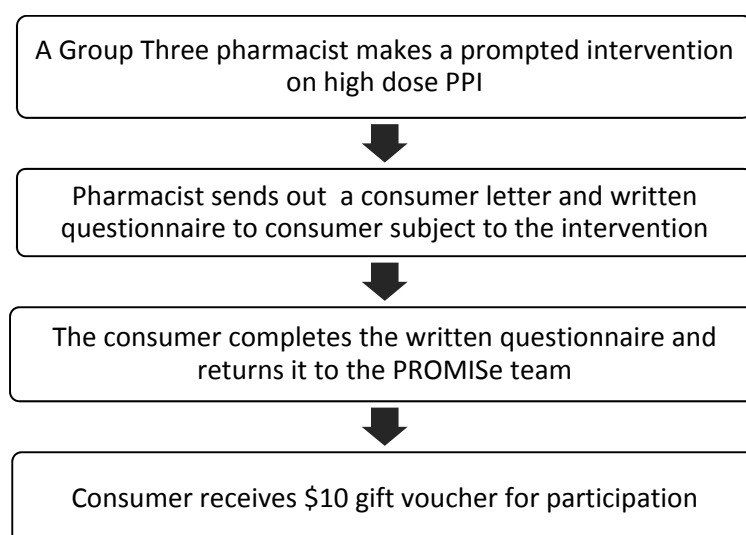


Figure 2-16: Overview of Consumer Sub-study – Consumers Subject to PPI Intervention

Non-PROMISe Consumers

Non-PROMISe consumers were recruited to determine their attitudes towards community pharmacy interventions and their usefulness, and to ascertain the level of intervention activity in the Australian population. DeBoos Associates were engaged to develop and facilitate the data collection for the general pharmacy consumers; consumers who had received an intervention outside of the project, as shown in Appendix M. DeBoos Associates recruited members from an online panel, which was managed by Research Now Pty Ltd.²⁰¹ A total 10,959 consumers on the online panel were invited to complete the online survey. Those agreeing to take part logged on to a website to complete the questionnaire. Screening questions were used to determine those who would qualify to complete the survey; consumers with a direct member of family in a medical or pharmacy role were excluded. Each bank of questions with the same scale was shown to respondents in a randomised manner to prevent any sequence bias.

Of those, 1,907 logged on to undertake the survey, giving a participation rate of 17%. Of the 1,907 who logged on to the website, 701 qualified for participation, and completed the questionnaire. Thus, 1,230 were screened out and the overall screen out rate for consumers was 63%. The sample was representative by Australian state population, age and gender.²⁰² Each successfully screened consumer of those who reported an intervention experience in the last 12 months was paid an incentive of \$2 for completion of the questionnaire.

Upon completion of recruitment, the PROMISe trial commenced. Data collection occurred over a 12-week period and included information from a number of different avenues such as the software, observers and consumers.

2.2.3 Data Collection

Data collection began once all software pharmacies were activated. Information collected during this project needed to be sufficiently detailed for a reasonable “reconstruction” of the situation at hand, while still being relatively straightforward for pharmacists to record. Information relating to the intervention, the patient, the pharmacy, and the pharmacist were obtained. As shown in Table 2-13, information was collected from the repository, surveys, site visits and from the sub-studies.

Source	Data Collected
Intervention Data Repository	Intervention Information
	Patient Information
	Prescription Information
Pharmacist Information	Background Survey
	Intervention Survey
	Empathy Survey
	Professionalism Survey
	Assessing Drug Related Problems Survey
	Software Survey
Pharmacy Information	Owner Manager Survey
	Site Visits
Observation Sub-Study	Intervention Record
	Hourly Log
	OTC Intervention Record
	Daily Log
Consumer Sub-Study Information	Barriers and Facilitators
	PROMISe Consumers
	Non-PROMISe Consumers

Table 2-13: Sources of Data Collection

Intervention data repository

The main source of data from the trial was collected through the PROMISe interface which was linked to the data repository.

Intervention Information

The type of intervention, according to the DOCUMENT classification system, was recorded by the pharmacist upon transmission of each individual recorded intervention. Up to four recommendation(s) made by the pharmacist could be recorded, as well as a clinical significance assigned by the recording pharmacist. Extra information could also be entered by the pharmacist as free text. The drug involved and the nature of the prescription, whether that was an original or repeat, was automatically assigned by the dispensing system if the intervention was directly linked to a prescription. Otherwise, the pharmacist nominated the drug involved. The time taken to conduct the intervention was also provided by the pharmacist. See Figure 2-17 and Figure 2-18 for the FRED[®] and Aquarius[®] PROMISe interfaces.

Figure 2-17: PROMISE Interface on the FRED® Dispensing System

Figure 2-18: PROMISE Interface on the Aquarius® Dispensing System

The intervention information collected from these interfaces were sent to the repository where a random sample of interventions were collected and assessed by experts to provide data for the economic evaluation, as discussed in Phase Three (section 2.3). Also collected was some information about the patient's history.

Patient Information

The dispensing history of the patient for the past six months was automatically collated and sent to the repository upon transmission of each individual recorded intervention. This allowed for a list of other medications to be constructed for each intervention patient, thereby allowing for some assessment of inferred medical conditions. The recording pharmacist also identified the gender, and was able to provide an estimate of the approximate age of the patient as seen in the screenshots provided above in Figure 2-17 and Figure 2-18.

Prescription Information

Details of all prescriptions dispensed in the pharmacy during the trial period were sent to the repository, allowing for use of specific drug or drug group denominators.

Pharmacist information

Information was gathered from the enrolled pharmacists before and after the trial period. The information was collected from the following surveys.

Background Survey

This survey collected data on gender, age, year of graduation, qualifications and memberships of professional groups. Also gathered was information on the pharmacists' experience in pharmacy, their main area of work and the nature of their work as community pharmacists. This is shown in Appendix N.

Intervention Survey

This survey collected the views of pharmacists concerning their current practice of performing CIs in a community pharmacy setting. This is shown in Appendix O.

Empathy Survey

This survey was derived from the "Toronto Empathy Questionnaire" developed by Spreng et al.²⁰³ which was a 16-item survey that enabled the team to allocate an empathy score to each pharmacist. The marking scheme is detailed in the original article where the least empathetic response possible was 0 and the most empathetic response was 64.²⁰³ The survey is shown in Appendix P.

Professionalism Survey

This survey was derived from the survey detailed by Chisholm et al. in the article "Development of an Instrument to Measure Professionalism".²⁰⁴ This 18-item survey looked at six factors of professionalism within the pharmacy profession (altruism, accountability, excellence, duty, honour/integrity, and respect for others) and allowed the team to allocate a professionalism score to each pharmacist. The marking scheme was poorly detailed in the original article; however, on review, the team assigned a valid score to all participants where the least professional response was 18 and the most professional response was 90. The survey is shown in Appendix Q.

Assessing DRP Survey

This survey consisted of clinical questions designed to assess the pharmacist's ability to identify, gather relevant information about and make relevant recommendations to resolve a DRP. It was written and validated by the PROMISE team and originally consisted of nine clinical cases with seven multiple-choice questions (63 questions in total). The questions required the pharmacist to select how relevant they felt each action was to the specific scenario using a seven-point Likert scale ranging from very relevant to not relevant at all (see Appendix R). Eighteen research pharmacists/academics were asked to validate the questionnaire. Their results triggered the removal of 23 multiple-choice questions. This was due to the answers being two standard deviations above the mean or the answers being different to the writer's answer (it was intended to be irrelevant, but the validators said it was very relevant). This resulted in 40 questions in total, with each clinical case having between three and six multiple-choice questions. The 40-question survey was then administered to 28 fourth-year and 41 third-year pharmacy undergraduates at the University of Tasmania. Scores were then calculated where the correct answer was defined as the mode of the 18 validator answers, provided the mean answer was similar to the mode. Each question received a score of 2, 1 or 0 depending on how far away the pharmacist's answer was from the validators. For example, if the validators agreed the answer was "Relevant", the pharmacist would receive a score of 2 for answering "Relevant", 1 for "Very Relevant" or "Slightly Relevant" as the answers either side and 0 for any other answer. For this survey, the lowest possible score was 0 and the highest was 80.

Group	N	Mean	SD
Validators	18	59.28	6.69
4th years	28	51.96	6.42
3rd years	41	47.85	6.87
Total	87	51.54	7.92
Statistics	$F(2,84) = 18.33, p < 0.001$		

Table 2-14: Differences in the DRP Survey Scores Between the Three Groups

This scoring system was then used to score the surveys completed by the PROMiSe pharmacists, as shown in Chapter 3 and as can be seen in Appendix R.

Software Survey

In order to gain feedback after the trial period, participating pharmacists were asked to complete a software survey. This survey provided enrolled pharmacists the opportunity to offer feedback about the software and make suggestions. See Appendix S.

Pharmacy Information

Pharmacy information was gathered in two ways. The first was a survey targeted to owners or managers of the pharmacy, and the second was site visits undertaken by the project team.

The Owner/Manager Survey

This survey gathered information about the size, turnover (prescription and financial), business style and staffing levels of the pharmacy. See Appendix T.

Site Visits

Site visits by the project team were carried out on 181 software pharmacies. Three of the four pharmacies who did not receive a site visit, due to being in an isolated location or a late entry into the trial, completed the data collection sheet over the phone, or via fax. One of the pharmacies did not complete the data collection sheet. The site visit data collection sheet and staff roster template can be found in Appendices U and V. Information was gathered on visibility and accessibility of the pharmacist and dispensary, counselling area and current health promotions. Staffing levels and workflow in the dispensary were also recorded. The site visitor was also asked to make notes on the general pace and feel of the pharmacy from a consumer's perspective.

Observer Information Collected

Observers collected additional information for 38 software pharmacies and 24 no software pharmacies. The data collection forms used by the observers and their content were as follows:

Intervention Record

This form was used to collect data about each actual intervention the pharmacist made, including patient demographics, drug involved, and classification according to the DOCUMENT classification system. Also collected was the time taken by the pharmacist to perform and document the intervention, the resources used, and whether the pharmacist had recorded it. Details of any prompt involved were also recorded. This form provided details on the actual intervention frequency as opposed to the documented frequency by the pharmacist. See Appendix W.

Hourly Log

This form recorded the date, approval number, pharmacist initials and opening hours. Also collected was hourly data on the pharmacist's workload, including prescription count and other procedures, such as dispensing daily pick-ups, providing consumer medication information (CMI), dealing with OTC requests and issuing safety net cards. This form also collected details of staffing levels for each hour, and whether CIs were performed and/or recorded. The number of consumer packs sent out was also noted. See Appendix X.

OTC Intervention Record Form

In order to gain information about the role of pharmacists in OTC interventions, the observers collected data on each OTC intervention in which the pharmacist was involved. Data included patient demographics, request type, questions asked by the pharmacist/pharmacy assistant, and the product sold, as well as any additional details of the intervention. Extra data was collected on interventions involving Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), including any questions about medications or medical conditions. See Appendix Y.

Daily Log

Completed daily, this log provided data concerning the approximate amount of time that the pharmacist spent on particular tasks during the course of the day. These tasks included dispensing, serving, administrative tasks, and ordering. Data on the workflow in the pharmacy was also recorded, allocating approximate levels of dispensing task distribution between non-dispensary staff, dispensary assistants and pharmacists. The workload analysis, and the nature of the pharmacist's workload, together with the staffing levels, allowed categorisation of similar pharmacies together to increase the value of economic analysis. See Appendix Z.

Barriers and Facilitators

Observers collected data on potential barriers and facilitators which may have influenced the observed pharmacist in the documentation of CIs. For the baseline pharmacies, information was also collected on the current level of recording interventions. See Appendices AA and BB.

Consumer Information

Two sets of data were gathered from consumers subject to PROMISe III CIs.

PROMISe Consumers

The first set of data was collected in the consumer sub-study. Information was gathered from the consumer regarding their recall of the intervention, the performance of the pharmacist and the importance of pharmacist attributes. Each consumer was also asked questions regarding pharmacist remuneration for interventions. Information about whether or not the consumer accepted the pharmacist's recommendation was gathered, in addition to the level of healthcare utilisation post intervention. A short form QOL tool (EQ-5D) was then used in the survey to assess the consumer's QOL, and year of birth was also recorded. See Appendix CC.

The PPI consumer sub-study was developed, in conjunction with the PPI prompt built into the software, to determine the uptake of pharmacist interventions in regard to the step-down in dose of Nexium[®] 40mg and Somac[®] 40mg. A short survey was used to gather information from the consumers on their recall of the intervention, and whether or not they had followed it up with their doctors. If they had followed up with their doctors, details of any changes in therapy were collected. Participants in this survey were also asked to complete the EQ-5D questions and provide their age. See Appendices K and L.

Non-PROMISe Consumer Information

As mentioned in section 2.2.1, DeBoos Associates were employed to conduct the survey for non-PROMISe consumers. The consumers were recruited from an online panel, of which 1,907 participated in the survey. The survey questions were similar to those given to the consumers who were subject to an intervention as part of the PROMISe III trial, as shown in Appendix M. In particular they focused on the consumer experience in pharmacies, the action taken from a CI, the attitudes to medication advice provided by GPs or pharmacists, and the consumer attitudes to payments to pharmacy for intervention documentation and the distribution of intervention data.

2.2.4 Summary

Phase 2 was the longest of the phases and it provided the main source of information for data analysis. Once all the data was collected, an evaluation of the data was undertaken.

2.3 Phase Three: Evaluation of Trial

Having collected a broad spectrum of data through the various arms of the PROMISe trial, extensive analysis was undertaken on each section, so as to be able to draw insight and meaning from it. The methods for analysis that were used for each set of data are described here.

2.3.1 Analysis of Demographics

Data was collected from the pharmacies participating in the trial through selected surveys, as detailed further in section 2.2.3. Where possible, this information was then compared to national figures to ensure the PROMISE sample was representative. The allocation of the PROMISE software groups was also analysed to ensure there was ample representation within each software group. Pharmacies were then grouped according to their PhARIA and location, and subsequently analysed according to these pharmacy “types” in order to determine trends within the pharmacies.

Data about each participating pharmacist was also collected through online surveys (see section 2.2.3) and their demographics were then analysed against national figures. The results of the professionalism, empathy and clinical knowledge surveys were also compared to participating pharmacist demographics to identify any trends within the pharmacist group.

The age and gender of each patient who was subjected to an intervention during the trial was also collected and compared to the national figures to determine if there were demographic trends within the group of intervened patients.

2.3.2 Analysis of the Frequency and Types of Interventions

The intervention database was analysed to determine the overall number of documented interventions per 100 prescriptions (defined as the intervention rate) and also the number of interventions per patient. The intervention data was broken down into DOCUMENT categories, recommendations and significance to determine any differences in the frequency between each of the categories. The drugs involved were also analysed according to their ATC coding to identify the most commonly intervened drugs. Drugs were also analysed according to their dispensing volume to determine if those with higher intervention rates were actually due to a higher frequency of prescriptions being dispensed. In addition to the general analysis, drug groups of special interest were explored in more depth to identify any persistent problems that could be used for education purposes in the future. The time taken to record and perform interventions was also analysed to ensure the documentation system was not significantly impacting on the pharmacist’s workload.

Another critical analysis was the differences in the intervention rates between each of the three software groups. This determined the effect of the general reminder and specific prompt that was built into the documentation system.

The OTC interventions recorded during the observation periods were also analysed to determine the types of questions the pharmacist asked to determine the suitability of the OTC product for each patient request, especially in the sale of NSAIDs. The analysis also examined any common trends in those patients who were denied the sale of OTC products.

2.3.3 Analysis of Factors Affecting Intervention Rate

The time of day data was analysed from each of the software groups to determine the effect of the general reminder. Original prescriptions were also compared to repeat prescriptions to determine whether it affected the documented intervention rate.

Many pharmacy factors were analysed to determine if any affected the overall intervention rate of the pharmacy. Factors that were compared to the intervention rate included PhARIA, pharmacy type, prescription volume, annual financial turnover, dispensary attribution to total turnover, trading hours, owner/manager operation, banner affiliation, dispensing system, pharmacist workload, presence of graduate pharmacists, number and types of professional services offered, type of counselling area and pharmacist accessibility.

Many pharmacist factors were analysed to determine if any affected the individual intervention rate of the pharmacist. Factors that were compared to the intervention rate included age, gender, graduation year, level of

PROMISE training, survey scores, current role and level of annual continuing professional development (CPD) activity.

The performance and documentation of interventions within observed pharmacies was also examined to quantify the effect that the documentation system had by comparing the software pharmacies with the no software pharmacies.

2.3.4 Analysis of the Effectiveness of the Intervention Prompt

The specific prompt which was included in the PROMISE software for some trial pharmacies was felt to be an integral component of the argument that documentation software could improve intervention frequency. As such, the efficacy of the prompt was measured and analysed extensively. A simple definition of a PPI step-down intervention was defined, such that it was possible to determine how many of these interventions occurred through inspection of the intervention data, and by comparing groups, estimate how many of these interventions occurred as a result of the prompt.

Further to this it was also possible to estimate the rate of uptake of the prompted interventions through two separate methods. The first method was to analyse the subsequent prescription data that was available for patients who were the target of a prompted intervention during the first four weeks of the trial, to determine if the step-down was later evident in the eight weeks of prescription data. The second method used consumer responses from the PPI survey.

Having an idea of the efficacy and uptake of the prompted interventions, as well as an understanding of the cost of the drugs involved before and after the intervention, some economic analysis could also be undertaken. This was done by extrapolating forward through a 12-month period, under the assumptions that the intervention “stuck” for that 12-month period, that is, the patient continued to take the lower (cheaper) dose of medication, and that the patient would not have lowered his or her dosage through other means.

2.3.5 Analysis of Consumer Satisfaction

The consumer opinions for interventions, as well as the specific prompted interventions, were collected. One part of the consumer sub-study sought the opinions of patients who had received interventions as part of the PROMISE trial; the second part involved the consumer panel, where patients who had received interventions independently from the PROMISE trial were considered.

Through analysis of these datasets it was possible to determine and compare the intervention uptake rates, as well as gain some insight into the types of interventions that were more often successful, through analysis of the recommendation, DOCUMENT and significance codes involved in these interventions. In addition to this, some analysis of the levels of consumer satisfaction with their interventions was undertaken.

The other valuable consumer opinion which was sought was their views on remuneration, which attempted to determine whether consumers would be happy if pharmacists were paid for performing interventions, and how much. Simple frequency analysis of the survey results was carried out to determine answers to these questions.

2.3.6 Analysis of User Satisfaction

A survey seeking to determine the pharmacist user’s opinions regarding the PROMISE documentation software was also undertaken, particularly with regards to its limitations and ways it might be improved. As well as the survey, information was also presented from the experience of developing the software. The results of both the survey and the developer reports were analysed via inspection, since the information was qualitative free-text. The key findings were summarised for easy review.

2.3.7 Determining the Economic Value of CIs

As outlined in Chapter 1, the determination of the value of CIs, where randomised trials are not possible, is difficult and involves effectively asking “what would have happened if the pharmacist did not intervene?” All published studies in this field have used some degree of expert opinion to estimate the value of the interventions.

After reviewing the literature and analysing the options available, we developed a value assessment process where experts provide estimates of the probability of a selection of clinical consequences at different levels of severity for both the before and after intervention situations. However, it is not sufficient to simply ask experts what the health outcomes of an intervention might be, since this step alone will not allow the determination of the economic value. In order to determine economic value it is necessary to also determine what health outcomes these clinical consequences are likely to correspond to in economic terms. As such, the methodology that was devised to facilitate the goal of determining the economic value of a CI in PROMise III broadly took the following form (see Figure 2-19 and later, Figure 2-24).

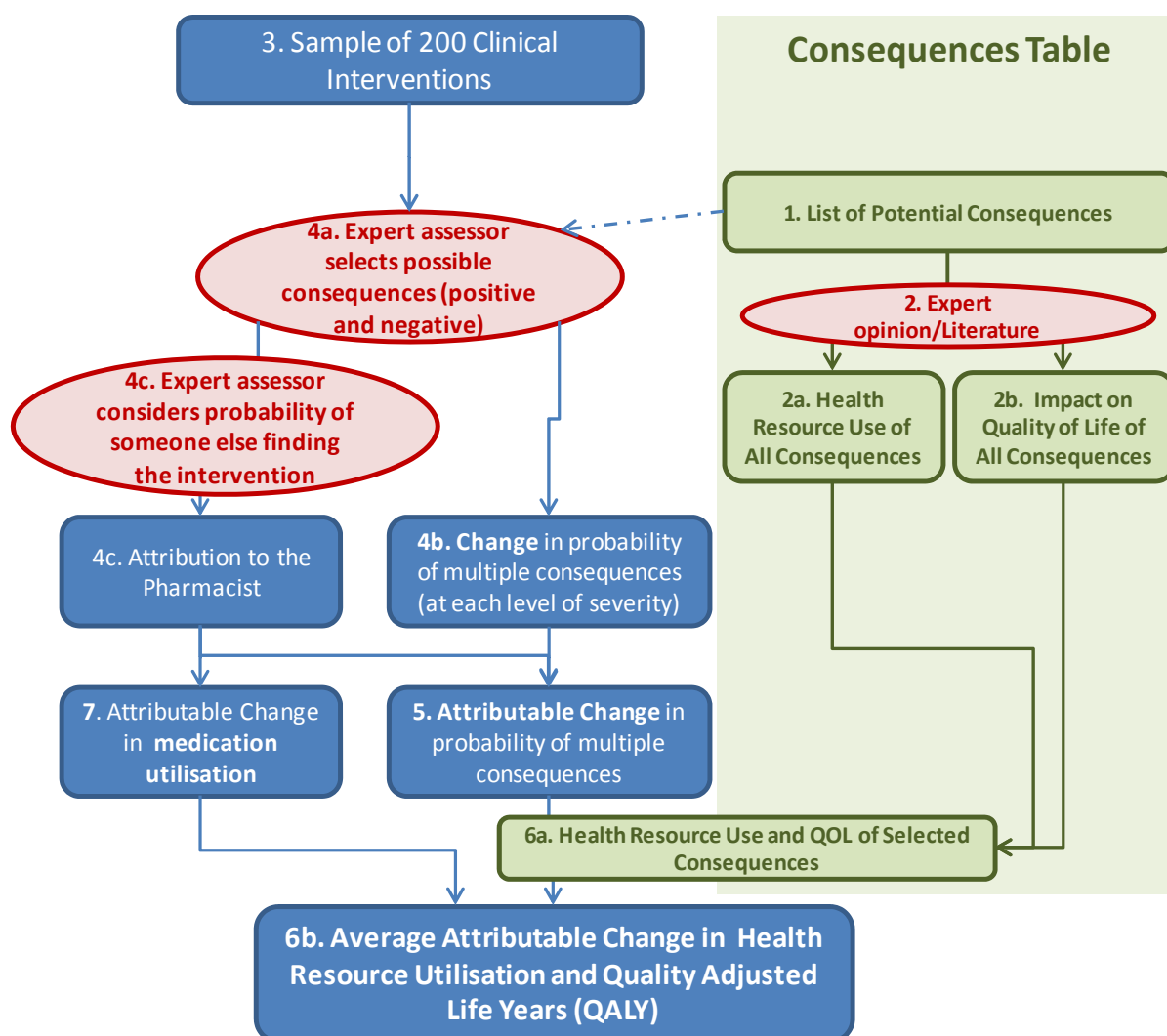


Figure 2-19: Outline of Value Estimates Provided by Expert Assessors

As can be seen from the diagram, we used expert opinions to estimate a number of important parameters. The role of each panel of experts and the makeup of each of the panels is described briefly in Table 2-15, and in more detail in the sections that follow.

Panel Details and Role	Panel Composition			
	Specialists	GPs	Pharmacists	Total
Expert Panel 1: Determine Disability Weights (impact on Quality of Life) for a range of consequences where literature values were not available	6	0	0	6
Expert Panel 2: Determine the GP and Specialist utilisation in a one year period associated with all consequences at three levels of severity	0	14	0	14
Expert Panel 3: Determine the probability of multiple consequences occurring for 200 clinical interventions at three levels of severity both with and without the intervention. Determine the attribution of the intervention to the pharmacist.	5	11	8	24

Table 2-15: Composition of the Three Separate Expert Panels used in PROMISe III

Interpreted chronologically, our method followed the following sequence (see Figure 2-19 and Figure 2-24):

1. Determine all the clinical consequences that are likely to be avoided or caused by CIs in the pharmacy.
2. Consult the available literature, and expert panels where literature not available, to form a “consequences table” that includes estimates of:
 - a. What the likely health resource utilisation outcomes of each clinical consequence will be, in terms of:
 - the duration of the illness;
 - the number and cost of GP visits;
 - the number and cost of specialist visits;
 - any likely investigations (such as pathology tests), and the associated costs; and
 - the duration and cost of any hospital admissions.
 - b. The impact on QOL (QOL).
3. Select a sample of suitable CIs for assessment by an expert panel.
4. Have the selected sample assessed by the expert panel, to determine:
 - a. which consequences are likely to occur;
 - b. the likelihood (probability) of each identified clinical consequence occurring with and without the intervention (estimating a change in probability); and
 - c. the likelihood that the pharmacist would have been the only health professional to detect the DRP and intervene (attribution).
5. Combine the expert estimates of probability and the attribution to the pharmacist to determine an attributed change in probability.
6. Combine the attributed change in probability for each consequence and the associated values (6a) in the consequences table to determine the economic impact of each intervention in terms of utility and health resource utilisation (6b).
7. Determine the cost of changes to medications that occur as a result of the CI and add these to the health resource utilisation.

However, beyond this, there are further important steps which enable us to relate the value of specific interventions from our sample back to the broader Australian perspective, and to determine an estimate of the *additional (or incremental) benefit* that the PROMISe program provides to the nation, when compared to current practice:

8. Calculate the cost of performing interventions.
9. Perform uncertainty analysis (that is, establish a model of uncertainty regarding the expert opinions relating to the estimated value of both the consequences and the interventions).
10. Determine the average economic value of CIs.
11. Conduct a cost utility analysis to determine the average cost utility of interventions.
12. Extrapolate these figures to the Australian perspective.
13. From the broader PROMISe study, determine the relative cost-driving variables and their differences in Current Practice vs. PROMISe Practice.
14. Conduct a second cost utility analysis to determine the *incremental* cost utility of interventions performed in PROMISe that would otherwise not have been performed in current practice.

15. Perform appropriate sensitivity analyses.

Steps 1 and 2: Consequences of Interventions

In order to develop a method that estimates the value of interventions, it was necessary to consider the possible consequences of interventions, and the cost of these consequences individually.

Medications are the cornerstone of management for a wide range of medical conditions and all medications carry some risk and some benefit. The consequences of inappropriate use of medicines almost universally relate to their efficacy or their toxicity. As an example, if aspirin was recommended for a patient with diabetes, there are several possible outcomes, each of a different severity level, and each with a different probability before and after the addition of the aspirin. One outcome may be a reduction in risk of a stroke (severe), or of a less severe event such as a transient ischemic attack (TIA) (mild). On the other hand, there may be an increased risk of severe GI bleeding or simple GI upset.

It is clear, therefore, that a fundamental aspect of determining the value of changes in probability of particular events is the cost to the health system of those particular events. A “consequences table” was developed which described 60 adverse medical conditions or symptoms commonly resulting from medication misadventure, through consultation from the earlier PROMISe II study, and the feedback provided by experts involved in that study. For each of the 60 consequences, an estimate of the healthcare resources and disability related to the consequence at three levels of severity was made. The parameters determined for each consequence (at each level of severity) were in three main areas:

- Hospitalisation costs
 - Duration and cost of hospital admission
 - The duration (in days) and cost of any hospital admission associated with the consequence.
- GP costs, specialist costs and cost of additional medical investigations
 - Number and cost of GP consultations
 - The number and cost of community based GP consultations required to manage the particular consequence.
 - Number and cost of specialist consultations
 - The number and cost of specialist consultations required to manage the particular consequence.
 - Investigations and pathology costs
 - The costs of typically required investigation or pathology tests required in the management of the particular consequence
- Quality of Life
 - The level of disability (also termed utility) associated with the consequence
 - The Duration of the disability associated with the consequence

Each of the parameters was estimated using a combination of literature, Australian government information and, in the absence of such sources, expert opinion, as outlined in the following sections.

Hospitalisation Costs

Extensive Australian data regarding the duration and cost of hospitalisation was available for many common conditions grouped according to Australian Refined Diagnosis Related Groups (AR-DRGs).²⁰⁵ For the PROMISe III consequences table, the cost and median length of hospital admission was derived from data in the 2006-2007 AR-DRG version 5.1 values for public hospitals Australia wide.²⁰⁶

For consequences associated with multiple diagnosis-related groups (DRGs), the number of separations (occurrences) was used as a proxy indicator for the probability of each DRG occurring. The following worked example illustrates the process used to calculate the hospitalisation costs used in the study.

The consequence of severe cerebrovascular event is described as “CVA resulting in severe symptoms and signs requiring hospitalisation and medical management (for example, stroke)”. There are four DRGs relating to hospital admissions due to stroke. These, the number of separations, their average length of stay (ALOS) and cost per separation are shown in Table 2-16. To calculate the mean cost and ALOS per separation for a severe cerebrovascular event, a relative weighting of each DRG according to proportion of separations was calculated (Table 2-16). Using this methodology, each level of consequence resulting in hospitalisation was costed and the length of stay determined.

DRG	Description	Number of separations	ALOS (days)	Mean cost per separation
B70A	Stroke with catastrophic complication or comorbidity	6,504	17	\$15,233
B70B	Stroke with severe complication or comorbidity	7,194	9.6	\$8,487
B70C	Stroke without catastrophic or severe complication or comorbidity	7,155	6.3	\$5,533
B70D	Stroke, died or transferred within five days	6,230	1.5	\$2,292

Table 2-16: DRG Data for "Cerebrovascular Event"²⁰⁵

DRG	Number of separations	Fraction of separations	ALOS (days) x fraction of separations	Mean cost per separation x Fraction of separations
B70A	6,504	0.2	4.1	\$3,658.20
B70B	7,194	0.3	2.6	\$2,254.40
B70C	7,155	0.3	1.7	\$1,461.80
B70D	6,230	0.2	0.3	\$527.20
TOTAL	27,083		8.60	\$7,901.59

Table 2-17: Calculation of ALOS and Hospitalisation Costs for “Cerebrovascular Event” from DRG Data

GP Costs, Specialist Costs and Cost of Additional Medical Investigations

Quantifying the health-resource utilisation for the remaining parameters was less clear as datasets equivalent to the Australian Hospital Statistics are not readily available for patients managed in general practice. The most extensive Australian database for GP encounters is the Bettering the Evaluation And Care of Health (BEACH project²⁰⁷); unfortunately, the PROMISe III budget did not permit for this database to be used. Subsequently, a small study to investigate the health-resource utilisation, and thus the cost, of each of the consequences was conducted.

We used an online panel of GPs to provide their opinions of the likely health-service utilisation for each severity level of each consequence. GPs were used as it was felt that they would be most familiar with the management of the consequences at the different levels of severity. Fourteen GPs completed the study.

Prior to commencing this sub-study, each participating GP was provided with an information sheet (see Appendix SS). Each GP provided his or her opinion using an online form.

Each GP was asked to give his or her opinion regarding each of the following parameters for each consequence at each level of severity:

- duration of health status impact (that is, how long would this level of disability be maintained in a patient with the consequence);
- number and cost of GP consultations required to manage the consequence;
- number and cost of specialist consultations required to manage the consequence; and
- investigations and pathology costs required to manage the consequence.

From the responses of the GPs, costs were then assigned to each level of each consequence using the MBS. The cost used for a GP consultation (MBS Item 23) was \$33.55. Pathology items were costed according to the appropriate MBS item number. The cost used for an initial specialist visit (MBS Item 104) was \$79.05. For subsequent specialist visits, the cost used was \$39.70 (MBS Item 105).²⁰⁸

It was observed that the opinions on which pathology investigations might be ordered for a given consequence varied substantially between experts. To resolve this, only those investigations which were agreed upon by at least six experts were included in the consequences table, and these were costed according to the appropriate MBS item number.

Quality of Life

The influence of a particular disease or condition on QOL can be expressed in terms of *utility* (also referred to as *utility weights*, *quality weights*, *preference weights* or *preference values*).²⁰⁹ These QOL values reflect the desirability of residing or existing in a particular health state. Typically, each health state is rated on a scale from 1.0 (the best health attainable) to 0 (dead).¹ Examples of QOL for various conditions are shown in Table 2-18. As can be seen in the table, more severe conditions result in a lower QOL than mild or moderate conditions.

Condition	Utility	Condition	Utility
<i>Osteoarthritis of the hip</i>		<i>Stroke resulting in cognitive deficit</i>	
• Mild	0.69	• Mild	0.54
• Moderate	0.38	• Moderate	0.37
• Severe	0.19	• Severe	0.08
Angina		Chronic hepatitis	
• Mild	0.88		0.94
• Moderate	0.832	Chronic renal disease	
• Severe	0.533		0.63

Table 2-18: Examples of Utilities for Various Medical Conditions²¹⁰

A related measure is the disability adjusted life year (DALY). In a similar fashion to the utility weights of quality adjusted life years (QALYs), DALYs are also calculated using measures of QOL anchored between 0 and 1, termed disability weights (*D*). A fundamental difference between *Qs* and *Ds*, however, is that a *D* of 0 indicates full health and a *D* of 1.0 is equivalent to death. This inversion is because the QALY measures equivalent healthy years lived, whereas the DALY measures years of lost health.

The *D* for a given condition *i* may therefore be converted to a *Q* using Equation 1, and vice versa.

$$Q_i = 1 - D_i$$

Equation 1 - Conversion of D weights to Q weights

Dutch weights provide an epidemiological profile of health status according to particular health states and are used extensively by the World Health Organization in their burden of disease research²¹¹⁻²¹². However, it is important to note that Dutch weights do not exist for the full spectrum of health states encountered in PROMISE III. Thus, where published literature was not available, we engaged the services of an expert panel to develop our own specific utility values.

¹ Some systems permit health states to be rated at less than 0, or “worse than death”.

The expert panel involved six specialist physicians that completed the EQ-5D instrument for a number of conditions. The EQ-5D is a multi-attribute utility instrument that has been well validated and used extensively to derive utility weights for a range of conditions. This work was also used in the VALMER study.²¹³ Once the full complement of utility weights were available, the overall increments (or decrements) in health status as a result of the intervention were then measured in terms of change in QALYs.

Steps 3 to 7: Expert Assessment of CIs

The expert assessment of CIs followed a three phase process. First, interventions were selected from the broader PROMISe sample of documented interventions. Then the situation that resulted in the intervention was documented, by creating a narrative in order to facilitate expert interpretation. The interventions were then presented to the expert panel via a web-based application, through which the panel could provide its assessment.

Selection of Interventions

To prepare the interventions for expert assessment, a random sample of 500 interventions from the first six weeks of the trial and 500 interventions from the second six weeks of the trial were generated. These interventions were then classified by project pharmacists into six different categories, based on the categorising pharmacist's expectations:

1. High Value (HV) interventions. This category included interventions which may have prevented or required a hospital admission, multiple GP visits, specialist visits or prevented severe consequences.
2. Reasonable Value (RV) interventions. This category included interventions which may have prevented or required a GP visit, pathology tests or prevented reasonably severe consequences.
3. Virtually No Value (VNV) interventions. This category included interventions which have little significance such as avoiding sick days or mildly improving the patient's QOL. Also included many education based interventions.
4. Not Enough Information (NEI). This category was applicable when the intervention details could not be determined from the DOCUMENT coding system and the pharmacist had provided little or no additional information to allow categorisation of the intervention.
5. Non-prescription intervention. This category was used when the intervention was not linked or incorrectly linked to a prescription or when the intervention did not involve a prescription medication such as a symptom-based intervention.
6. Not a Clinical Intervention (NCI). This category included interventions which, upon inspection, were found to not satisfy the definition of a CI, as defined by this study.

The expected value of the interventions were assigned by a project pharmacist and reviewed by two investigators. Having categorised several hundred interventions, it became apparent that HV interventions were the least common, yet the most likely to provide the greatest value. To ensure a representative sample of each group was available, it was determined to continue categorising interventions until there were at least 50 HV, 100 RV, and 50 VNV interventions available for expert assessment. To ensure this, the two random samples of 500 were assessed until 25 HV interventions were found in each group. From the first sample of 500, 418 needed to be assessed in order to find 25 HV interventions, resulting in 386 useable interventions (after excluding the NCI, NEI and Non-prescription interventions). From the second sample of 500, 475 needed to be assessed to find 25 HV interventions, resulting in 450 useable interventions (Table 2-19). From the first 100 interventions, the two investigators determined that five interventions classified as RV were actually HV, therefore resulting in a total of 55 HV interventions in the final 200. Once grouped into the categories, all HV interventions were included and the interventions in the RV and VNV categories were randomly selected using an online random number generator. In total, 196 interventions (consisting of 55 HV, 94 RV and 47 VNV) were selected. In addition to the prescription interventions, four cases were included from the observer data of OTC interventions, resulting in a total of 200 case studies for assessment by the expert panel.

	1st 100			2nd 100		
	Count	% all	% useable	Count	% all	% useable
HV	30	7.18	7.77	25	5.26	5.56
RV	170	40.67	44.04	198	41.68	44.00
VNV	186	44.50	48.19	227	47.79	50.44
Non-Prescription	1	0.24		3	0.63	
NCI	28	6.70		21	4.42	
NEI	3	0.72		1	0.21	
Total	418	100	100.00	475	100	100
Total useable	386			450		

Table 2-19: Breakdown of the Random Sample of 1000 Interventions

In order to prepare intervention scenarios for the expert assessment panel, information provided by the documenting pharmacist was used. This included the drug description, the DRP category, and the extra information provided by the pharmacist notes. Also used was the six-month medication history of the patient who was subject to the intervention.

The problem for each scenario was outlined using one sentence, and this was followed by the scenario which included the age range, gender and any other relevant medical history or allergies which may be recorded. Details of the problem or prescription presented to the pharmacist were then outlined, followed by what the pharmacist identified as an issue and what recommendations he or she made to resolve it. A one sentence outcome then concluded the scenario (an example of an intervention narrative can be seen in Figure 2-20). Every effort was made to ensure that the narratives that were written stayed true to the original scenario; however, to do this it was necessary to exclude interventions which did not have sufficient information in their notes. This factor may have added some bias towards HV interventions, as documenting pharmacists may have written more detailed notes in higher significance interventions more often than in lower value interventions.

Suggested positive and negative consequences were then selected for each scenario from the consequences table. These were selected by the project pharmacist writing the scenario then reviewed by at least two other pharmacists to ensure their suitability.

Selection of Experts

In order to recruit members for the expert assessment panel, a number of organisations were asked to advertise the positions to their members. These organisations included the AACP, the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT), Internal Medicine Society of Australia and New Zealand (IMSANZ) and GP divisions. In addition, experts who had previously participated successfully in similar UMORE projects were also contacted.

Six specialists expressed interest in participation; however, only five completed the contract and the other one was unable to be contacted. Four of the specialists were consultant physicians, and one was a pharmacologist and endocrinologist. All of the recruited specialists had previously participated in similar UMORE projects. Eighteen GPs expressed interest of which 11 were selected to participate on the panel on a first come first served basis, although with priority given to the five GPs who had previous experience with UMORE projects. A total of 88 pharmacists expressed initial interest in participating on the panel. Further information about the project was then emailed to respondents and if they were still interested, they were asked to reply with a brief outline of the following details:

- qualification(s);
- years of clinical pharmacy experience;
- years accredited to perform HMRs/RMMRs;
- average number of HMRs performed per month;
- any post-graduate qualifications; and
- any other experience they considered to be relevant to the task.

Fifty-seven pharmacists still expressed willingness to participate of which eight were selected based on their qualifications and experience. Pharmacists were invited to participate on the panel if they:

- had extensive clinical experience in a senior role; or
- regularly performed HMRs and/or RMMRs.

There were no conflicts of interest to the knowledge of the project team. Pharmacist applicants were excluded if they were participating pharmacists in the trial or if they were employed as an observer. The qualifications of the eight recruited pharmacist experts are listed below in Table 2-20.

Qualifications and Experience of the 8 Expert Pharmacists	
1	5 years clinical experience; Specialist pharmacist in infectious diseases
2	Performs 38 HMR/RMMRs per month; 15 years experience in retail and hospital pharmacy; Senior Poisons Information Specialist for 10 years
3	16 years clinical experience with 10 years as a geriatric pharmacist; performs 3-4 RMMRs per month
4	Senior clinical pharmacist with 14 years clinical experience; HMR accredited
5	20 years community pharmacy experience; Performs 100 HMR/RMMRs per month; Drug information pharmacist
6	10 years clinical experience; 13 years performing HMRs and RMMRs (20 HMRs per month)
7	30 years hospital experience, predominately geriatric; performs 20 RMMRs per month
8	11 years clinical experience; performs 80 HMR/RMMRs per month

Table 2-20: Qualifications of Expert Panel Pharmacists

Ultimately, there were 24 members of the expert panel, consisting of five specialists, 11 GPs and eight pharmacists. Of the 24 experts, 23 completed the assessment of 200 scenarios within the given timeframe. One expert, a GP, withdrew due to family issues outside of the project.

Validation of Expertise

As part of the assessment process, the 23 experts were asked to complete a survey of 15 questions. These 15 questions were administered through the LimeSurvey web-based survey tool and were clinical scenarios using data available from published literature. The aim of the survey was to determine if the expert panel's answers to the 200 scenarios could be weighted according to their 15 survey answers to provide a tighter confidence estimate. The questionnaire is attached in Appendix EE.

Of the 23 experts who completed the expert assessment process, 22 completed the survey (one was unable to complete the survey due to a family member's illness).

Intervention Assessment Process

The expert panel members were given access to a web-based application which enabled them to browse each of the 200 interventions. After selecting a particular intervention, the expert was presented with an interface which showed the available patient information including age, any allergies, any medicines which had been noted by the intervening pharmacist, and the narrative which described the scenario of the intervention. On this same interface, the experts were able to assign before and after probabilities for any consequences which had been pre-applied to the intervention for them, as well as to add new consequences they felt applied to the intervention and remove existing ones. A screenshot of the case viewer for a particular intervention is shown in Figure 2-20.

Case Viewer

Medical History	Allergies
None	None

Intervention Narrative

Problem: Inappropriate dosage form prescribed.

Male patient (65-81yo) presents a repeat prescription for Madopar® 200mg/50mg (levodopa/benserazide) capsules. Upon discussion with the patient, the pharmacist determines that the patient may need to use half a dose occasionally. As the capsules cannot be halved, the pharmacist recommends to the prescriber that the capsules be changed to tablets. The pharmacist then dispenses the tablets which can be halved if required.

Outcome: Patient improves the management of their Parkinson's disease.

Date Supplied	Generic	Quantity	Brand	Strength	Original?	Directions	Times Dispensed
2009-07-10	celecoxib	30	CELEBREX	200mg	Repeat	Take ONE capsule at night when required	4
2009-08-14	levodopa and decarboxylase inhibitor	100	MADOPAR	200mg/50mg	Repeat	Take ONE tablet FOUR times a day or as directed by your doctor	5
2009-07-10	levodopa and decarboxylase inhibitor	100	MADOPAR	200mg/50mg	Repeat	Take ONE capsule FOUR times a day	4

[Hide prescription history](#)

Consequences

Group	Consequence	Mild		Moderate		Severe		
		Before%	After%	Before%	After%	Before%	After%	
CNS	Parkinsonism	0	0	0	0	0	0	Delete

Add new consequence

[Add](#)

Attributability to pharmacist

Comments

[Save All Values](#)

[Mark for Review](#) [Mark as Assessed](#)

Figure 2-20: The Case Viewing Interface for Expert Assessors

This application was made available at all times between the 5 of October 2009 and the 8 of November 2009, which is when all experts had completed their assessments.

When assessing the interventions, the experts were asked to consider the before and after likelihoods of the various consequences occurring at each severity level within the next 12 months. This duration was chosen as it is short enough that the details of the case should not vary too greatly and sufficiently long enough that most of the clinical consequences as a result of therapy, or lack thereof, might surface. The other motivator for this duration was the fact that all the values in the clinical consequences table were also calculated assuming a one-year period. This period is admittedly short in terms of health outcomes, and will mean that some therapies which have little short-term benefit but strong long-term benefits will be underestimated by this method. However, the implication of this assumption is that the results should be considered conservative and may underestimate the complete health and economic value of interventions.

To mitigate the effects of fatigue or growing apathy on the expert's opinions, each expert was given the 200 interventions to assess in a different, random order.

In addition to collecting the before and after probabilities for each severity of each consequence for each intervention, the expert was also asked to indicate their estimate of how much of the "credit" for each intervention could go to the intervening pharmacist. That is, how likely is it that the drug-related issue would be detected and the intervention performed by the pharmacist, rather than another health professional, or health support mechanism? This value was used to discount the resultant values found through each expert's assessment of each intervention, thus producing an economic value that could be attributed to the pharmacist specifically, rather than other health workers or systems.¹⁹⁷

Calculation of Economic Value

Having collected each expert's opinion on the before and after probabilities of each consequence, a difference in probability for each consequence, each intervention, and each expert was calculated as shown in Figure 2-21. This

difference was then multiplied against the various parameters in the consequences table, including: the number of GP visits, specialist visits, hospital admission duration, and the cost of each of these, as well as any investigations. For example, if an expert felt that there was a 3% chance of a severe stroke before the intervention, and a 1% chance of a severe stroke after the intervention then this would reflect a 2% reduction in the chance of a severe stroke. Two per cent of each parameter in the consequences table which corresponds to a severe stroke would then be calculated, reflecting the actual value that the expert has indirectly attributed to the intervention for that consequence at that severity.

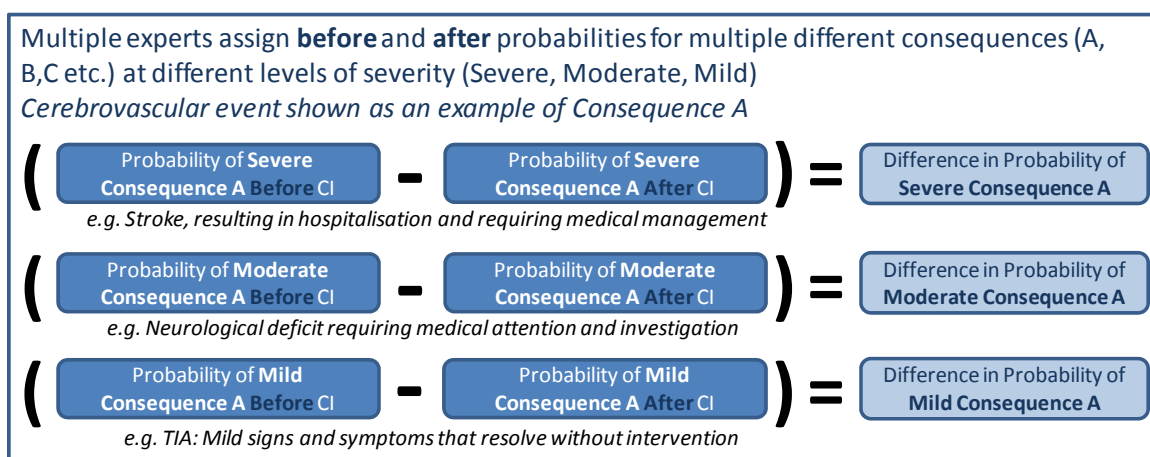


Figure 2-21 Determination of Difference in Probability of Different Consequences

The values associated at each severity level were then summed to present an aggregate value for each consequence. Then, the values associated with each consequence for each case were also summed to produce a total cost and utility for each case and for each expert assessor.

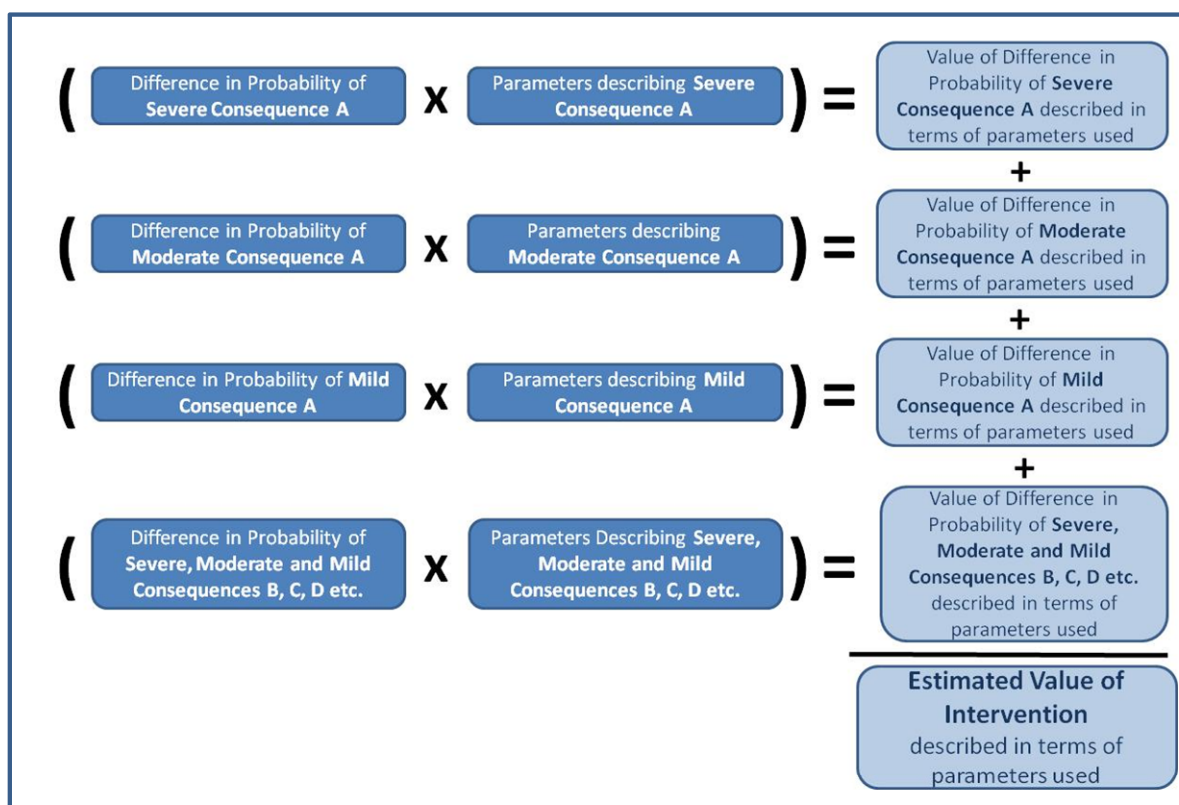


Figure 2-22: Calculation of Value of Intervention from Expert Opinion

Medication Costs

Changes to medication costs were determined by examining each of the 200 sample interventions for the impact on medication usage if the recommendation made by the pharmacist was implemented. Costs were calculated using the PBS cost and dose calculations were used to determine an annual medication cost.

Steps 8 to 15: Economic evaluation

With limited healthcare resources and competing demands for these limited resources, it is important to consider the efficiency of the electronic documentation system. To achieve this, an economic evaluation was conducted to assess if the interventions can generate sufficient cost savings to the government if implemented across Australia, so as to offset the cost of implementation. The primary analytic method chosen was cost-utility analysis (CUA), with outcomes expressed in terms of “cost per QALY”. The objective of the CUA is to examine the null hypothesis that the mean cost-effectiveness of the national implementation of an electronic documentation system for the recording of medication issues (CIs) identified in community pharmacy is no different to the mean cost-utility of that in usual care.

This involved a multistep, integrated process of estimating as many of the parameters as possible, and utilising uncertainty analysis at various points in order to provide the most robust result possible. An outline of these steps is shown in Figure 2-23.

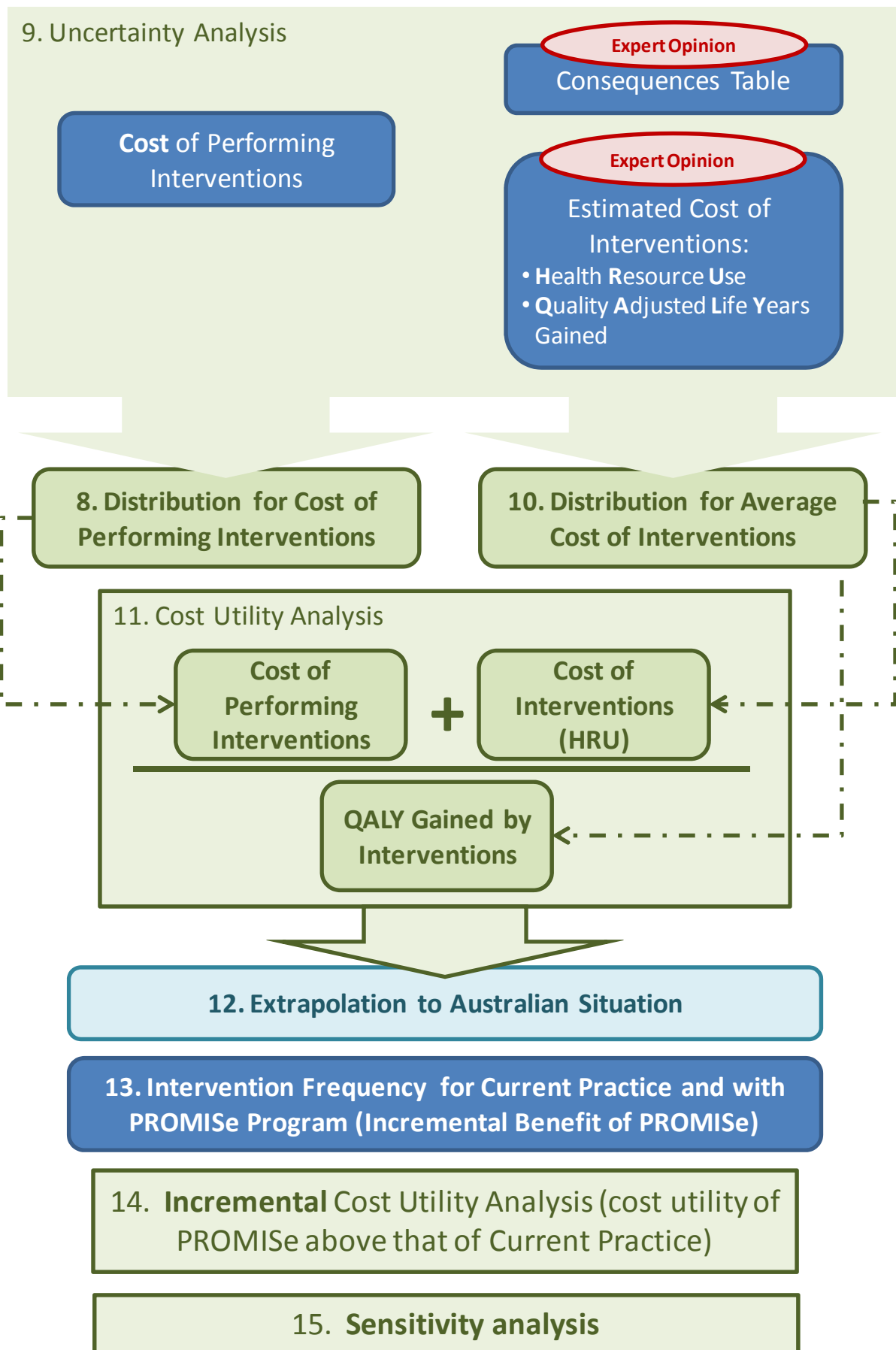


Figure 2-23: Economic Evaluation Method

These steps are outlined in further detail below.

Step 8: Calculate the Cost of Performing Interventions

In order to calculate the cost of performing interventions it is necessary to determine four factors: the intervention frequency, the amount of time it takes to *find* the intervention, the amount of time it takes to perform an intervention, and the opportunity cost of pharmacists time in terms of salary. Determining what a pharmacist is paid is a relatively simple process, and determining the time it takes to perform an intervention is also easy, since the documenting pharmacists were asked to record how long it takes them to perform the intervention and the observers were asked to record how long it took the documenting pharmacists to document the intervention. Unfortunately, the last variable – the time taken to *find* the intervention – is more difficult to determine.

To complicate the matter, it is known that since the intervention frequency is different in pharmacies with the PROMISE software, this ultimately means that the cost of performing interventions will differ in a PROMISE vs. no PROMISE environment. As such, when considering the incremental benefit that the PROMISE program provides over current practice, we must also consider this change in the cost of performing interventions.

Intervention Frequency

The predicted actual intervention frequency (interventions/prescriptions) for the no software group was used for the case of current practice, while the predicted actual intervention frequency for group 3 was used for the case of PROMISE practice. The steps outlining how the predicted actual intervention frequencies are calculated are shown in Step 13: Calculating the Difference between Current Practice and PROMISE Practice.

Time Taken to Find the Intervention

Since it is not known how long pharmacists spend, on a per prescription basis, thinking about whether an intervention is necessary or not, it is necessary to make some assumptions around this. Since it is known that prescriptions typically take less than a minute to dispense, it is safe to assume that the time spent trying to “find interventions” is only a portion of this.

For the case of current practice, an average figure per prescription was decided based only upon consultation with four pharmacists involved in the study. However, since it is known that the PROMISE program increases intervention frequency over current practice levels, it is assumed that pharmacists involved in the PROMISE program must be spending more time per prescription searching for interventions. Due to this, a conservative additional time per prescription of 30 seconds was applied for PROMISE practice.

However, since these figures are so uncertain, uncertainty analysis is performed upon them, as described in the following section, Step 9: Uncertainty Analysis.

Time to Perform an Intervention

To calculate the time taken to perform an intervention, the observer data for no software pharmacies (current practice) and the documented data for group 3 pharmacies (PROMISE practice) was used.

Amount Pharmacists are Paid

On consultation with several pharmacists involved in the study, it was determined that full-time pharmacists are typically paid between \$30 and \$35 per hour. The conservative estimate of \$35 per hour was chosen, plus 29% on-costs.

Calculating the Cost

Once all the variables are identified, the cost to find an intervention can be calculated. This is done in steps:

1. Find how many prescriptions must be screened to find an intervention (intervention frequency).
2. Multiply this number by the time it takes to screen a prescription.
3. Add the time to document and perform the intervention.
4. Convert the result (minutes to find an intervention) into hours.
5. Multiply the result by the hourly cost of a pharmacist's time (including on-costs).

Step 9: Uncertainty Analysis

The method we utilised necessarily involved expert opinion for both the value of the consequences and the impact of the interventions. Since there was rarely unanimous consensus between the experts opinions in each of these areas, it was considered wise to model the uncertainty around these estimates in each area in order to increase the confidence in our findings, and to demonstrate the range of possible outcomes that might occur.

The analyses are carried out in Excel (Microsoft Office 2007) using the add-in tool @RISK (Palisade, Version 5.5) for uncertainty analysis. The @RISK program to select best fit distributions which match the distributions found amongst the expert opinion, and to then re-sample each of these variables 10,000 times through their spectra of possible values. These processes are also termed non-parametric bootstrapping, and Monte Carlo simulation respectively. This software allows estimates and assumptions to be entered as probability distributions in a spreadsheet. The program then recalculates the spread of results using these distributions, each time picking a value out of all defined probability distributions, and provides summary statistics across all iterations for selected outcome variables. From the values generated by the iterations, a 95% uncertainty interval can be calculated. This uncertainty can be presented numerically as a range of values around the point estimate.

Uncertainty Analysis of Consequences Table

As previously outlined, there were a number of parameters describing the costs associated with each of the consequences in the three areas of:

- QOL impact and duration;
- hospitalisation costs; and
- GP/specialist/Investigations costs.

The distributions of opinions in each of these areas differed, and the possible values for some of these parameters were limited. As a result, it was necessary to place limitations on the standard @RISK processes. Each variable was assessed logically to determine whether certain distributions would be unsuitable and @RISK functions were limited to ensure that the distributions that were chosen for particular variables were appropriate to that variable. Additionally, if there were logical limits on variables (for example, duration could only be a maximum of one year) these were also imposed.

As some of the parameters (for example, hospitalisation data, consequences with known QOL values) were from literature sources, no uncertainty analysis was conducted on these particular variables. An outline of how the uncertainty analysis was conducted for each of the set of parameters where expert opinion was used is shown below.

QOL (Severity and Duration)

For each of the consequences that had a QOL utility derived from expert opinion, @RISK was used to undertake a 10,000 iteration re-sampling procedure from the best fit Beta distribution (constrained to values between 0 and 1). The Beta distribution was considered the most appropriate for this type of data, since there exists a known minimum and maximum value, and the data is continuous in nature. In the few instances where @RISK could not determine a best fit distribution for the provided data, a Beta distribution was calculated manually, based on the mean and variance of the data.

For the parameter “Duration of Disability”, @RISK was also limited to selecting a Beta distribution, constrained to a minimum and maximum of 0 and 365 respectively. This was chosen since the duration was clearly a continuous variable, with clinical consequences being able to last any duration within the bounds of 0 and 365 days. Under these conditions the only other distributions which could have been fitted were “uniform” (all values equal) and “triangular” (values from 0 to a peak and back to zero), both of which are considered unsuitable, since they are unrealistic in nature.

GP/Specialist Visits

A 14-member GP expert panel was used to determine the number of GP visits and the number of specialist visits for each consequence at each level of significance. For these variables, the @RISK best-fit function was used to select, for the given data, from any of its available discrete distributions. In the relatively few situations where a

distribution could not be fit due to the data having no distribution (that is, all experts chose the same value), the average was used with no uncertainty around it.

Uncertainty Analysis of CIs

As outlined previously, 23 experts were asked to provide an estimate of the before and after intervention probabilities of particular consequences at three different levels of severity for each of 200 CIs. In addition, an estimate of the attribution of the intervention to the pharmacist was provided by each assessor.

Once again Beta distributions were used to model each set of 23 opinions for each consequence of each intervention, this time with a minimum and maximum set to -100 and 100 respectively. Again, in the instances where distributions could not be fit by @RISK's best fit function, a calculated Beta distribution was used based upon the mean and variance of the relevant data.

Uncertainty Analysis of the Cost to Perform Interventions

Since there was some uncertainty surrounding the cost of performing interventions, uncertainty analysis was also applied here. The two uncertain variables were the actual performed intervention frequency and the time taken to screen prescriptions to find interventions. The intervention frequency was modelled with a Beta distribution around our expected low, likely, and high intervention frequencies. The time taken to screen a prescription was modelled using another Beta distribution, this time using the low as 50% of our expected value, average as our expected value, and high as 150% of the expected value.

These additions add a form of sensitivity analysis to these key cost driving variables.

Step 10: Determine the Average Economic Value of CIs

As has been previously discussed, the sample of interventions which were assessed by the experts were selected to ensure a good distribution of high, reasonable, and low value interventions. However, this selection provided a bias which skews the costing process. As such, it was not sufficient to simply find the average cost of the sample and assume this is the same thing as the average cost of an intervention.

To correct for this, we used a feature of the interventions as a proxy for "high, reasonable, and low" value, and then weighted the sampled cases according to the true distributions of this proxy variable in the broader PROMISE dataset.

The most obvious variable to use for this purpose was the Significance Code, which is by definition intended to serve as this proxy. S1 and S2 interventions are thought to be interventions of minimal worth, while S3 (requiring or preventing a GP visit) and S4 (requiring or preventing a hospital visit), are likely to be of significant worth.

The process undertaken to correct for the selection bias was as follows:

1. Determine the average values for S1, S2, S3, and S4 interventions in the assessed sample.
2. Determine the proportion of interventions from the broader dataset for each of these significance codes.
3. Weight each of the average values by their relevant proportion.
4. Sum each of these resultant weighted values to find the resultant "average intervention" value.

Having now determined an "average intervention" value for each of the parameters (QOL, GP visits etc.), it was possible to extrapolate to the Australian perspective in a number of ways. This is discussed in Step 12: Extrapolation to PROMISE dataset and Australian Situation.

Step 11: Cost Utility Analysis

The CUA adopted a "health sector" perspective; costs to sectors other than health (for example, education and housing) were not included. Although a social perspective is considered the gold standard in economic evaluation, a healthcare perspective was considered appropriate due to the nature of the intervention and the potential improvements in population health, and subsequent savings to the healthcare system. To this extent, variables such as time spent off from work, family and carers' time and costs and patients' transport costs were not included.

A distinction was also made between the estimated impact of the programs on health resources and resources committed to the trial (that is, the cost of the study). The latter costs were not formally included in the costing.

The combination of the reduction in costs of health resource utilisation and medicines was compared with the intervention cost. The method used to cost potential savings to the healthcare system are previously discussed in Steps 3-7, while the actual cost of the intervention (and current practice) are discussed in Step 8. The outcomes measure used in the CUA is health improvement measured by QALYs. The methods used to measure changes in QOL as a consequence of intervention are discussed in Steps 1-7.

The analysis for the CUA involved both an average and incremental assessment (see Step 14). Both analyses involved a comparison of costs (intervention costs less health service utilisation and medicine costs) with changes in health (QALYs). The results of the average CUA use the actual trial data to consider the cost-effectiveness of the overall sample and the cost-effectiveness of S1, S2, S3 and S4 interventions.

Step 12: Extrapolation to PROMISe dataset and Australian Situation

The process we used for extrapolating to the Australian perspective was a relatively simple process. Having already determined the average value of an intervention in Step 10, it was necessary to determine how many interventions were expected to occur in the broader sense, then to multiply the average values by this factor.

In order to provide a richer set of information this was done in three steps:

1. Extrapolate to a single “average pharmacy” week.
This required determining how many interventions would occur in an average pharmacy in a week.
2. Extrapolate to an Australian pharmacy week.
This was done by multiplying the average pharmacy week by the number of pharmacies in Australia.
3. Extrapolate to an Australian pharmacy year.
This was done by multiplying the Australian pharmacy week by 52.

This process was done twice, once for current practice, and once for PROMISe practice using the relevant corrected figures from the observed no software and the observed group 3 pharmacies. The method used to determine these figures is outlined in the proceeding section.

Step 13: Calculating the Difference between Current Practice and PROMISe Practice

There are key differences between a pharmacy environment in which the PROMISe program has been introduced, and one which conforms to the current practice. Of these differences, there are several which affect the economic outcomes:

1. intervention frequency;
2. time spent finding interventions;
3. time spent performing interventions; and
4. the significance of the interventions found.

Points 2, 3 and 4 can be determined or assumed through methods previously described, and do not need to be repeated here. However, point 1 is a challenging problem. The frequency with which interventions were actually performed is only known in the observer data. However, it is also known that the presence of observers has an impact on the frequency of intervention. Thus, to determine what the intervention frequency will actually be in an unobserved environment requires that we attempt to remove the effect of observation from the observer data.

Observers documented the actual number of interventions undertaken, as well as the number of these that were documented. We used the observation information from the non-software pharmacies and the observed information from the prompted PROMISe software group (group 3) to estimate what the unobserved intervention frequencies would be in the current practice and PROMISe practice pharmacies, respectively.

This was done by:

1. Determining the effect of observation.

The effect was calculated from the ratio of the observed versus the unobserved documented intervention frequency in the middle six weeks of the trial² in the Group 3 pharmacies.

2. Estimating the actual (unobserved) PROMiSe intervention frequency.

The observer effect ratio was applied to the unobserved documented intervention rate

3. Estimating the current practice (unobserved) intervention frequency.

The observer effect was applied to the actual (observed) intervention rate in the non-software pharmacies.

An outline of how this estimate was made can be seen in Figure 2-24.

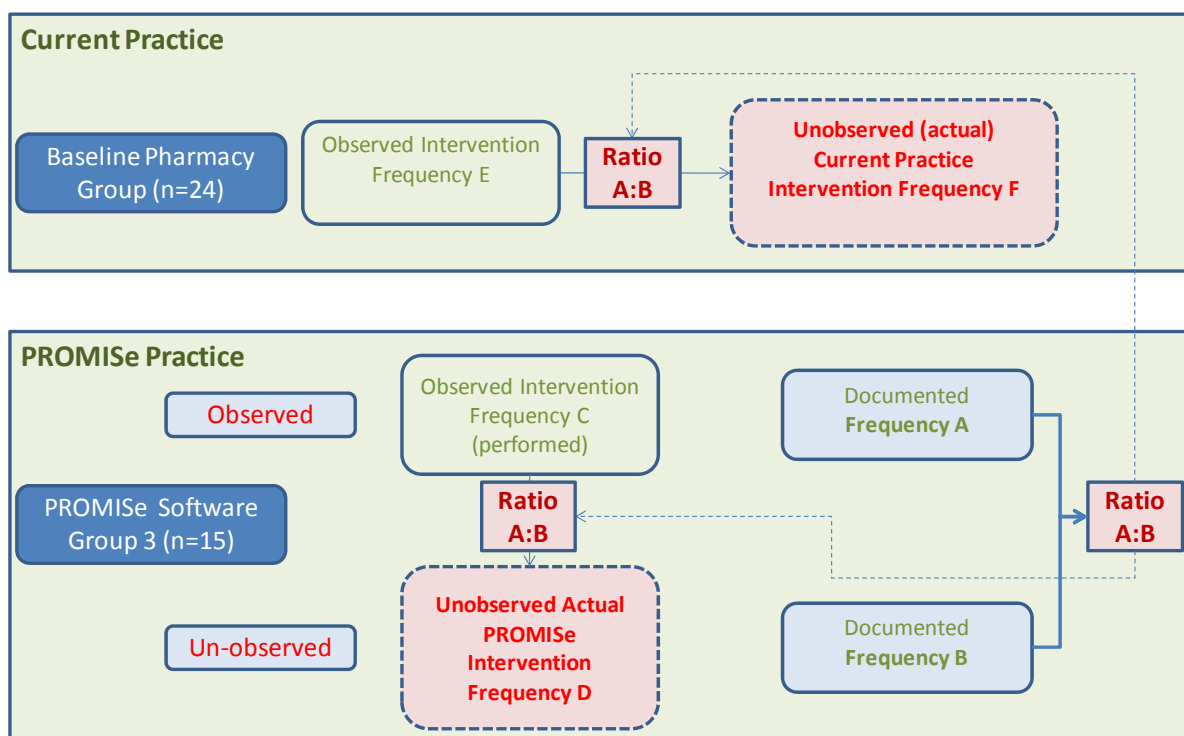


Figure 2-24: Calculating Current Practice and PROMiSe Intervention Performed Frequency

In order to demonstrate the incremental benefit that the PROMiSe program can provide to the Australian health system, this is expressed in terms of difference between the cost of current practice and the cost of PROMiSe practice. Factors such as the cost of implementing and maintaining the PROMiSe program are thought to be trivial when compared to the immense differences in healthcare resource utilisation and pharmacist time, and as such have not been considered here. They are, however, considered in some detail in the attached report provided by Deloitte in Appendix FF.

Step 14: Incremental Cost Utility Analysis

In addition to the average cost utility analysis performed in step 11, an incremental analysis was also undertaken. Through this analysis it is made clear what the additional benefits of the program are expected to be. The incremental CUA uses extrapolated data to compare the incremental costs and health outcomes of the intervention with current practice. Extrapolation was necessary given the trial data was biased and in addition, provides a more meaningful answer to the research objective examining the efficiency of a national implementation of an electronic documentation system for the recording of medication issues (CIs) identified in community pharmacy.

² The middle six weeks were chosen for two reasons. First, they remove both the “enthusiasm” effect of the first three weeks and the “fatigue” effect of the last three weeks (there were no on-going payments in this PROMiSe trial). Secondly, it allowed us to perform logical sensitivity analysis using the first three weeks and last three weeks as representations for a “high” and “low” value respectively.

Step 15: Sensitivity Analysis

Consistent with guidelines for conducting an economic evaluation, in addition to the uncertainty analyses described earlier, sensitivity analyses were conducted to explore the robustness of results to variations in input parameters. Although the uncertainty analysis that was applied throughout the whole model is a form of sensitivity analysis, traditional sensitivity analysis were also applied to two variables in the model – time required to screen a prescription and intervention frequencies. These analyses aimed to demonstrate the specific effects of these key cost driving variables increasing or decreasing.

The sensitivities that were applied are simple. The effects on the mean economic outcomes of a lower and higher value were tested. For the case of the intervention frequency, these low and high values used the documented intervention frequencies from the last three weeks and the first three weeks of the trial respectively. The time to screen an intervention was altered to 50% and 150% of the base value for its respective high and low values.

2.4 Phase Four: Development of an Implementation Plan

Deloitte Australia were contracted to build a business case and implementation plan for Phase Four of the project. The report is presented in Appendix FF. Deloitte used a three-part methodology to develop a suggested business case and implementation plan.

2.4.1 Part One: Background and Policy

Part one focuses on the background and policy in which PROMISE will be introduced and outlines the features of the project to be rolled out nationally.

Background and Policy Context

Deloitte reviewed the healthcare challenges facing Australian communities and identified the improvement of quality and sustainability of care as a main health concern.²¹⁴ Healthcare spending has outpaced economic growth and is predicted to exceed 12% of gross domestic product (GDP) by 2030. Furthermore, the ageing population and below-replacement birth rates are widely projected to lead to declines in labour force participation and productivity.

Deloitte's reported that research has shown that Australia could deliver higher quality care in use of medicines, in particular in reducing prescribing errors and increasing medication compliance. Given the changing demographic context and fiscal environment, as well as a recent assessment of options for improving the quality, safety and affordability of care, the Australian government has become increasingly focused on prevention and improving the continuity in primary care settings.²¹⁴ The Minister for Health and Ageing has signalled that prevention will be a key focus in the Australian healthcare system in the future, stating that more will be done at the "front end" to keep people healthier and save money at the "back end".²¹⁴

Health Reform Agenda

Deloitte summarised the key reviews and policy frameworks that set out the government and community's primary objectives for the Australian healthcare system, the major policy reforms being implemented by the government, the role of pharmacy within the system and opportunities for pharmacists to help the government deliver its package of reforms. The reviews highlight a strong focus on prevention, greater continuity of care among primary health providers and the QUM.²¹⁴

The frameworks that were reviewed included:

- The National Health and Hospitals Reform Commission (NHHRC)
 - The National Primary Health Care strategy
 - QUM
 - The Fourth Community Pharmacy Agreement (the Fourth Agreement)

Deloitte determined that the project has the capacity to enhance the delivery of primary care services in a way that is strongly aligned to the government's healthcare reform agenda, including in particular the objectives of the National Primary Health Care strategy, the NHHRC's reform goals for positioning the healthcare system to respond to emerging challenges and the National Medicines Policy.²¹⁴

In addition, Deloitte identified which aspects of the PROMISE project align with the health reform agenda. These aspects include:

- DOCUMENT classification system;
- training and CPD points for participants;
- de-identified intervention records being sent to a national data repository; and
- ongoing incentives.

2.4.2 Part Two: Remuneration Options

Part two involved developing five pharmacy remuneration options which were comparatively analysed and assessed for their appropriateness, effectiveness and efficiency. The base option was determined by which one had the optimum net benefit to the community whilst also minimising the total cost to government and the risk that the program provided the greatest net benefit in the scenario where only low-value interventions were undertaken (and documented). Therefore, the base option is:

- \$4,000 upfront payment per pharmacy, \$20 per prescription intervention, \$1,000 quarterly payment and CPD points for pharmacists.

An additional four other options were developed to examine the costs and benefits which flow from varying aspects of the remuneration option such as the value of the upfront cost, or the presence or absence of the quarterly payment. This analysis is outlined in Table 2-21. These four other options included:

- a lower upfront payment;
- tiered payment for high and low value interventions;
- payment for only HV interventions; and
- no quarterly payment.

It was considered that CPD points should be included in all options as the withdrawal of CPD points reduced the expected participation by 13% on average across all remuneration options.

Option name	Upfront Payment per pharmacy	Per intervention payment	Per 'high value' intervention payment ²⁵	Payment for other general interventions ²⁶	Quarterly Payment	CPD Credits
Base Case	4,000	20	-	-	1,000	Yes
Lower Upfront Payment	2,000	20	-	-	1,000	Yes
Tiered Per Intervention Payment	4,000	-	20	2	1,000	Yes
High Value Intervention Only Payment	4,000		20	0	1,000	Yes
No Quarterly Payment	4,000	20	-	-	-	Yes

Table 2-21: Remuneration Options as Developed by Deloitte (Appendix FF)

The expected participation (uptake) rate of pharmacies under varying remuneration options was determined using the results obtained by DeBoos Associates when surveying two groups of participants: PROMISE trial participants and non-participants.²¹⁵

To determine the preferred remuneration option for the PROMISe program, a multi-criteria scorecard approach was adopted. This method was selected in order to balance against the multiple objectives of government. For example, while one option may result in a high level of interventions increasing the QUM, this may come at an extreme cost to government and thus, reducing scope for expenditure. This method also enjoys credibility with government. Using a multi-criteria scorecard, different remuneration models can be assessed against both budgetary impacts and the full range of Australian health policy goals.

The criteria used to select the preferred option were derived from definitions of “effectiveness” and “efficiency” as they relate to the PROMISe program and broader health reform goals. The assessment of the remuneration against the two criterion resulted in the assignment of ticks or crosses. The expected outcome of the PROMISe program under each remuneration option informed the assignment of scores.

- Three ticks if the option performed at least 10% better than average in all performance measures.
- Two ticks if the option performed better than average in all performance measure.
- One tick if the option performed better than average in at least one performance measure.
- A cross if the option performed worse than average on all performance measures.

2.4.3 Chapter 3: Implementation plan

Chapter 3 provides a discussion of an implementation plan and a review of any potential risks and mitigation strategies. This final part involved analysing the direct health and economic benefits of the PROMISe program and the timing of implementation. Both state and local legislation were assessed to determine what legislation the program would be bound by. Finally, Deloitte conducted a detailed risk assessment of the PROMISe program and provided strategies to overcome them. The outcome of this final part of Phase four is detailed in Chapter 11.

Chapter 3 Results and Discussion: Demographics

Throughout the PROMISe trial, a large amount of data was collected on each pharmacy and pharmacist through the PROMISe software, online surveys, site visits, and observation weeks.

3.1 Characteristics of the Pharmacies

PROMISe pharmacies were selected to ensure they were a representative sample of all pharmacies within Australia. PhARIA and estimated annual prescription volume were chosen as the two key measures for selection, since these factors give some indication of location and workload, but also have easily accessible national data from the PGA.²¹⁶ The pharmacies were then statistically compared to the national figures from the PGA. The composition of the software groups were also examined to ensure there were no statistical differences between the groups. In total, 210 pharmacies were recruited which were then divided into the two groups of 24 no software pharmacies and 186 software pharmacies. The 186 software pharmacies were further divided into the three software groups. The no software pharmacies were not required to complete the same surveys as the software pharmacies, and so could not be compared in all categories, therefore the two groups are described separately in the following sections.

3.2 No Software Pharmacies

Twenty-four pharmacies were recruited for the no software group. As the title suggests, this group had no software, but instead they had an impartial observer present for five working days to collect data. These pharmacies were selected according to their PhARIA and estimated annual prescription volume so as to provide a nationally representative sample.

3.2.1 Pharmacy Access/Remoteness Index of Australia

There was no significant difference between the PhARIA of the participating pharmacies with no software and the national distribution obtained from the PGA (Table 3-1), helping to ensure that the no software group was representative of pharmacies nationwide.

	PROMISe		National	
	N	%	N	%
PhARIA 1	20	83.3	4166	83.2
PhARIA 2-6	4	16.7	840	16.8
Total	24	100	5006	100
Statistics	$\chi^2 = 0.00, df = 1, p = 0.99$			

Table 3-1: PhARIA of PROMISe Pharmacies With No Software Compared to National Average

3.2.2 Estimated Annual Prescription Volume

There was no significant difference between the estimated annual prescription volume of the participating pharmacies with no software and the national average from the PGA (Table 3-2); therefore, the no software group was considered representative of pharmacies nationwide.

		PROMISe		National	
		N	%	N	%
Estimated Weekly Prescription Volume	Less than 30,000	7	29.2	1526	30.6
	30,000 - 55,000	8	33.3	1792	35.9
	55,000 - 90,000	8	33.3	1188	23.8
	Over 90,000	1	4.2	486	9.7
	Total	24	100	4992	100
Statistics		$\chi^2 = 1.73, df = 3, p = 0.63$			

Table 3-2: Annual Prescription Volume of PROMISe Pharmacies With No Software Compared to National Average

3.2.3 Pharmacy Location

No software pharmacies were asked to describe the location of their pharmacy, with most pharmacies being located on a shopping strip (Table 3-3). There was no statistical difference between the location of no software pharmacies and the remaining trial pharmacies ($\chi^2 = 0.73, df = 4, p = 0.95$). The location of the pharmacies could not be compared to national averages as the PGA does not collect this data.

	No Software Pharmacies		Software Pharmacies	
	N	%	N	%
Local shopping centre (less than 25 shops)	4	16.67	41	22.16
Major shopping centre (more than 25 shops)	3	12.50	17	9.19
Medical centre	2	8.33	17	9.19
Shopping Strip	15	62.50	109	58.92
Other	0	0.00	1	0.54
Total	24	100.0	185	100

Table 3-3: Location of Trial Pharmacies With No Software

3.3 Software Pharmacies

The remaining 186 pharmacies had the PROMISe software installed into their dispensing systems for the 12-week trial. These pharmacies were also selected according to their PhARIA and estimated annual prescription volume in an effort to provide a nationally representative sample.

3.3.1 PhARIA and Weekly Prescription Volume

Of the 186 participating pharmacies, 185 completed the trial successfully, with one pharmacy withdrawing due to the sale of the business. Out of the 185 pharmacies that completed the trial, 184 (99.5%) completed the owner survey, and the data was compared to statistics from the PGA,²¹⁶ where PhARIA data was available for 5,006 pharmacies, and prescription volume data for 2,395 pharmacies. When the PhARIA (Table 3-4) and weekly prescription volume (Table 3-5) data was compared, there were no statistically significant differences between the 185 pharmacies that completed the trial and the population of pharmacies within Australia. There were no significant differences when all groups were compared (Table 3-6).

	PROMiSe N	Expected N (National Average)
PhARIA 1	159	154.0
PhARIA 2-6	26	31.0
Total	185	
Statistics	$\chi^2 = 0.98, df = 1, p = 0.32$	

Table 3-4: PhARIA of PROMiSe Pharmacies Compared to National Average (Guild data)

	PROMiSe N	Expected N (National Average)
Up to 400	9	9.3
400 - 800	60	65.3
801 - 1200	53	48.3
1201 - 2000	46	43.8
Over 2000	16	17.3
Total	184	
Statistics	$\chi^2 = 1.10, df = 4, p = 0.89$	

Table 3-5: Weekly Prescription Volume of PROMiSe Pharmacies Compared to National Average (Guild Data)

	Weekly Prescription Turnover	PROMiSe N	Expected N (National Average)
PhARIA 1	Up to 400	8	6.7
	401 - 800	53	51.9
	801 - 1200	46	37.5
	1201 - 2000	38	35.1
	Over 2000	14	14.8
PhARIA 2-6	Up to 400	1	2.6
	401 - 800	7	13.4
	801 - 1200	7	10.8
	1201 - 2000	8	8.7
	Over 2000	2	2.5
	Total	184	
	Statistics	$\chi^2 = 8.02, df = 9, p = 0.53$	

Table 3-6: PhARIA and Weekly Prescription Volume Compared to National Average (Guild data)

The estimated weekly prescription volume was compared to the actual average weekly prescription volume from the pharmacies during the trial. A Wilcoxon Signed Ranks test was used for the comparison, which showed no significant difference between the owner/manager's estimate of the weekly prescription volume, and the actual volume recorded during the trial ($z = -0.63, N = 184, p = 0.53$).

3.3.2 Dispensing Software

Within Australia, the FRED[®] dispensing software system has approximately 50% market share²¹⁷ and Aquarius[®] has approximately 10%,²¹⁸ therefore the PROMiSe sample would be expected to be approximately 83% FRED[®] and 17% Aquarius[®]. There were 158 FRED[®] pharmacies and 27 Aquarius[®] pharmacies in the PROMiSe sample, which was not statistically different from the expected numbers (Table 3-7).

	PROMiSe N	Expected N (National Average)
FRED	158	154.2
Aquarius	27	30.8
Total	185	
Statistics	$\chi^2 = 0.57, df = 1, p = 0.45$	

Table 3-7: Dispensing Software of PROMiSe Pharmacies Compared to National Average

3.3.3 Pharmacy Location and Identification of Pharmacy Types

During the enrolment process, pharmacies were asked if they were located in a shopping centre, medical centre or shopping strip, with the majority of PROMiSe pharmacies (58.9%) being located in a shopping strip (Table 3-8). The pharmacies were separated into six major groups based on PhARIA and pharmacy location, which will be referred to throughout the report. A Pearson chi-square analysis was conducted which showed no significant differences between the distributions of pharmacies within each of the three principal pharmacy types across the PhARIA groups (Table 3-9).

Location of the pharmacy	N	%
Local shopping centre (less than 25 shops)	41	22.16
Major shopping centre (more than 25 shops)	17	9.19
Medical Centre	17	9.19
Shopping Strip	109	58.92
Other	1	0.54
Total	185	100

Table 3-8: Frequency of Pharmacy Locations

			PhARIA		Total
			1	2-6	
Location	Shopping Centre	PROMiSe N	51	7	58
		% of Total	27.6%	3.8%	31.4%
	Medical Centre	PROMiSe N	17	0	17
		% of Total	9.2%	.0%	9.2%
	Shopping Strip or Other	PROMiSe N	91	19	110
		% of Total	49.2%	10.3%	59.5%
Total		PROMiSe N	159	26	185
		% of Total	85.9%	14.1%	100.0%
		Statistics	$\chi^2 = 3.91, df = 2, p=0.14$		

Table 3-9: The Six Pharmacy Types Sorted by PhARIA and Location

3.3.4 Group Allocation

The software group pharmacies were allocated to one of three groups using their annual prescription volume and PhARIA as the determinants. The groups are detailed below.

- Group one: software only.
- Group two: software with reminders.
- Group three: software with reminders and prompts.

From the original 186 pharmacies, the allocation resulted in 40 in group one and 73 each in groups two and three. After removing the pharmacy that did not complete the trial successfully, the pharmacies were still evenly spread between the three groups with 40 in group one, 72 in group two and 73 in group three (Table 3-10).

PhARIA	Weekly Prescription Volume	Group One: Software only		Group Two: Software with reminders		Group Three: Software with prompts and reminders		Total	
		N	%	N	%	N	%	N	%
PhARIA 1	Up to 400	3	1.6%	0	0.0%	5	2.7%	8	4.3%
	401 - 800	8	4.3%	20	10.9%	25	13.6%	53	28.8%
	801 - 1200	11	6.0%	20	10.9%	15	8.2%	46	25.0%
	1201 - 2000	11	6.0%	17	9.2%	10	5.4%	38	20.7%
	Over 2000	1	0.5%	5	2.7%	8	4.3%	14	7.6%
PhARIA 2-6	Up to 400	0	0.0%	0	0.0%	1	0.5%	1	0.5%
	401 - 800	2	1.1%	2	1.1%	3	1.6%	7	3.8%
	801 - 1200	3	1.6%	2	1.1%	2	1.1%	7	3.8%
	1201 - 2000	1	0.5%	3	1.6%	4	2.2%	8	4.3%
	Over 2000	0	0.0%	2	1.1%	0	0.0%	2	1.1%
Total		40	21.7%	71	38.6%	73	39.7%	184	100.0%
Statistics		$\chi^2 = 20.74, df = 18, p = 0.29$							

Table 3-10: Software Groups Compared by PhARIA and Weekly Prescription Volume

As the groups were quite small in the table above (Table 3-10), the prescription volume groups were consolidated to give a larger sample within each cell and therefore more accurate statistics. However, a Pearson chi-square test still showed no significant differences between the groups in relation to their PhARIA or weekly prescription volume.

	Weekly Prescription Volume	Group One: Software only		Group Two: Software with reminders		Group Three: Software with prompts and reminders		Total	
		N	%	N	%	N	%	N	%
PhARIA and Turnover group	Metro 0 - 1200	22	12.0%	40	21.7%	45	24.5%	107	58.2%
	Metro 1200+	12	6.5%	22	12.0%	18	9.8%	52	28.3%
	Country 0 - 1200	5	2.7%	4	2.2%	6	3.3%	15	8.2%
	Country 1200+	1	.5%	5	2.7%	4	2.2%	10	5.4%
Total		40	21.7%	71	38.6%	73	39.7%	184	100.0%
Statistics		$\chi^2 = 3.28, df = 6, p = 0.77$							

Table 3-11: Software Groups Compared by Compressed PhARIA and Weekly Prescription Volume

A Pearson chi-square test also showed no significant differences between the three software groups when compared by the pharmacy types (Table 3-12).

				Group One: Software only	Group Two: Software with reminders	Group Three: Software with prompts and reminders	Total
Pharmacy Type	PhARIA 1	Shopping Centre	PROMiSe N	12	20	19	51
			%	6.5%	10.8%	10.3%	27.6%
		Medical Centre	PROMiSe N	5	6	6	17
			%	2.7%	3.2%	3.2%	9.2%
		Shopping Strip/ Other	PROMiSe N	17	36	38	91
			%	9.2%	19.5%	20.5%	49.2%
	PhARIA 2-6	Shopping Centre	PROMiSe N	0	5	2	7
			%	.0%	2.7%	1.1%	3.8%
		Shopping Strip/ Other	PROMiSe N	6	5	8	19
			%	3.2%	2.7%	4.3%	10.3%
		Total	PROMiSe N	40	72	73	185
			%	21.6%	38.9%	39.5%	100.0%
		Statistics	$\chi^2 = 6.56, df = 8, p = 0.59$				

Table 3-12: Pharmacy Types Compared to Group Allocation

3.3.5 Pharmacy Size

Each pharmacy owner was asked to categorise themselves into the same sizing groups used by the Pharmacy Guild Digest. According to the Guild Digest 2008,²¹⁶ the average pharmacy area was 150m² with pharmacies located in shopping centres being larger on average at 169m², shopping strip pharmacies 147m² on average, and medical centres being a smaller 87m² on average. Of the 184 pharmacies that answered the survey, 62 pharmacies (33.7%) were 101-150m² and 37 pharmacies (20.1%) were 151-250m², therefore 54.4% of the participating pharmacies were close to the national average (Table 3-13). The most common type of PROMiSe pharmacy was a small pharmacy (less than 150m²) located on a metropolitan shopping strip (31.0%). A chi-square test showed no statistical difference between pharmacy size and the three software groups ($\chi^2 = 6.00, df = 6, p = 0.42$), showing an even spread of different pharmacy sizes across the three groups.

			Pharmacy Size in m ²					Total
			Less than 100	101 - 150	151 - 250	251 - 500	Over 500	
Pharmacy Type	Metro Shopping Centre	N	3	14	16	14	4	51
		%	1.6%	7.6%	8.7%	7.6%	2.2%	27.7%
	Metro Medical Centre	N	6	8	1	1	1	17
		%	3.3%	4.3%	.5%	.5%	.5%	9.2%
	Metro Shopping Strip/Other	N	28	29	18	13	3	91
		%	15.2%	15.8%	9.8%	7.1%	1.6%	49.5%
	Country Shopping Centre	N	0	3	1	3	0	7
		%	.0%	1.6%	.5%	1.6%	.0%	3.8%
	Country Shopping Strip/Other	N	2	8	1	7	0	18
		%	1.1%	4.3%	.5%	3.8%	.0%	9.8%
Total		N	39	62	37	38	8	184
		%	21.2%	33.7%	20.1%	20.7%	4.3%	100.0%

Table 3-13: Frequency of Pharmacy Size of PROMISE III Pharmacies

3.3.6 Pharmacy Trading Hours

The majority of PROMISE pharmacies were open six days per week (mean= 6.4 ± 0.6, mode = 6) trading for an average of 60 hours per week (mean = 59.2 ± 12.5, range = 40-103) (Table 3-14), which matches the Guild data where pharmacies recorded opening an average of 59 hours per week.²¹⁶ A chi-square test showed no statistical difference between pharmacy weekly trading hours and the three software groups ($\chi^2 = 5.79$, $df = 6$, $p = 0.45$), showing an even spread of pharmacy opening hours across the three groups.

			Pharmacy Weekly Opening Hours						Total	
			Up to 50	51 - 60	61 - 70	71 - 80	81 - 90	Over 91		
Number of days per week pharmacy is open	5	N	3	2	0	0	0	0	5	
		%	1.6%	1.1%	0.0%	0.0%	0.0%	0.0%	2.7%	
	6	N	49	37	6	1	0	0	93	
		%	26.6%	20.1%	3.3%	0.5%	0.0%	0.0%	50.5%	
	7	N	4	25	27	15	11	4	86	
		%	2.2%	13.6%	14.7%	8.2%	6.0%	2.2%	46.7%	
	Total		N	56	64	33	16	11	4	184
			%	30.4%	34.8%	17.9%	8.7%	6.0%	2.2%	100.0%

Table 3-14: Weekly Opening Days and Hours of PROMISE Pharmacies

3.3.7 Pharmacy Ownership

Of the 184 owner survey respondents, 133 (72.3%) were owner-operated, with the remainder being run by a manager. Owners were asked how many pharmacists were responsible for business decisions within the pharmacy, with an even split of 92 pharmacies (50%) having one pharmacist responsible and the other 92 pharmacies having two or more pharmacists responsible (Table 3-15). On average, the pharmacies had the same owner for 10 years, ranging from one year to 47 years. There was also an even split between independent pharmacies and banner group pharmacies, with 95 pharmacies (51.6%) identifying themselves as independent. Within the 89 pharmacies that had an identified banner group, the most common groups were Amcal, Guardian and Pharmore (Table 3-16). A chi-square test showed no statistically significant difference between the operation of the pharmacy (owner vs. manager) and the three software groups ($\chi^2 = 2.11$, $df = 2$, $p = 0.35$). There was also

no significant difference between membership in a banner group and the three software groups ($\chi^2 = 2.96$, $df = 2$, $p = 0.23$), which showed an even spread of the two pharmacy types across the three groups.

			Manager	Owner	Total
Number of pharmacists responsible for business decisions	1	N	23	69	92
		%	12.5%	37.5%	50.0%
	2 or more	N	28	64	92
		%	15.2%	34.8%	50.0%
Total		N	51	133	184
		%	27.7%	72.3%	100.0%

Table 3-15: Number of Pharmacists Responsible for Business Decisions in Owner or Manager-operated Pharmacies

Banner Group	Count
Amcal	18
Guardian	16
Pharmore	12
Priceline Pharmacy	8
Capital	6
Quality Pharmacy	5
UFS Dispensary	5
Health Information Pharmacy	4
Mediadvise	4
Healthwise	2
Nova	2
Other Banner Group	7
Independent Pharmacy	95
Total	184

Table 3-16: Frequency of Each Banner Group in PROMISE Pharmacies

3.3.8 Staff Mix

On average, a PROMISE pharmacy had 6.7 full-time equivalent (FTE) staff (range = 2.1-21.4) consisting of 2.3 pharmacists, 1.1 dispensary assistants and 3.3 pharmacy assistants. An analysis of variance showed significant differences between the six pharmacy types ($F(4,179) = 5.98$, $p < 0.01$) (Table 3-17), with both metropolitan and country shopping centre pharmacies employing more staff than shopping strip or medical centre pharmacies.

		FTE Pharmacists		FTE Non-Pharmacist Staff		FTE All Staff	
		Mean	SD	Mean	SD	Mean	SD
Pharmacy Type	Metro Shopping Centre	2.64	1.22	5.70	3.36	8.33	4.14
	Metro Medical Centre	2.77	1.40	3.55	2.02	6.32	2.82
	Metro Shopping Strip/Other	2.16	.99	3.43	2.68	5.58	3.32
	Country Shopping Centre	2.82	1.08	7.08	3.73	9.91	4.72
	Country Shopping Strip/Other	1.75	.72	5.19	3.71	6.94	4.25
Total		2.33	1.12	4.39	3.18	6.72	3.88

Table 3-17: Number of Full-time Equivalent Staff in PROMISE Pharmacies

3.3.9 Number of FTE Pharmacists

On average, there were 2.3 full-time pharmacists per pharmacy (range = 1-6.6), which is very similar to the Guild Digest 2008 average of 2.4. An analysis of variance showed significant differences between the number of full-time pharmacists and the six pharmacy types ($F(4,179) = 4.06$, $p = 0.04$), with both metropolitan and country shopping strip pharmacies employing fewer pharmacists than shopping centre or medical centre pharmacies (

Table 3-17). However, a Kruskal-Wallis test showed no significant differences between the number of full-time pharmacists and the three software groups ($\chi^2 = 0.40$, $df = 2$, $p = 0.82$). During the last two years, 64 pharmacies (34.8%) had employed a pre-registration pharmacist, with 43 (23.4%) pharmacies currently employing a pre-registration pharmacist. A chi-square test showed no significant differences between those pharmacies employing a pre-registration pharmacist in the last two years and the three software groups ($\chi^2 = 1.12$, $df = 2$, $p = 0.57$).

3.3.10 Annual Turnover and Dispensary Attribution

The annual turnover of the PROMiSe pharmacies was fairly evenly distributed, with the majority of pharmacies stating a turnover of less than two million dollars per annum (Table 3-18). This was slightly lower than the average turnover of \$2.4 million in 2007 as reported in the Guild Digest 2008.²¹⁶ Since the pharmacies were asked to select from the categories shown in Table 3-18 rather than state their actual turnover value, it is likely that the average turnover in PROMiSe pharmacies may be higher. This is because the pharmacies in the “over 5.0M” group may have a much higher turnover than 5M, which would elevate the average turnover and therefore it could be presumed that this would likely compare to the Guild data. A chi-square test showed no significant differences between the pharmacies’ annual turnover and the three software groups ($\chi^2 = 4.45$, $df = 6$, $p = 0.62$).

Annual Turnover (\$)	N	%
Less than 1.0M	20	10.9
1.0 - 1.5M	38	20.7
1.5 - 2.0M	37	20.1
2.0 - 2.5M	23	12.5
2.5 - 3.0M	18	9.8
3.0 - 4.0M	22	12.0
4.0 - 5.0M	16	8.7
Over 5.0M	10	5.4
Total	184	100.0

Table 3-18: Annual Turnover of PROMiSe Pharmacies (Expressed as Million Dollars)

As expected, most PROMiSe pharmacies attributed the majority of their turnover to their dispensary, with only 19 pharmacies (10.3%) having less than 60% of their turnover attributable to the dispensary (Table 3-19). An analysis of variance showed no significant difference between the pharmacy’s estimated dispensary attribution and the three software groups ($F(2,181) = 0.93$, $p = 0.40$).

Attribution %	N	%
Less than 60%	19	10.33
60 - 69%	21	11.41
70 - 79%	58	31.52
80 - 89%	70	38.04
90 - 99%	16	8.70
Total	184	100

Table 3-19: Percentage Turnover Attributed to the Dispensary in PROMiSe Pharmacies

The available data from the Pharmacy Guild was not broken down into the six pharmacy types used in PROMISE; therefore, there was no available data to compare the six pharmacy types with the national average. However, when PhARIA and location were examined separately, there did not appear to be any differences between the PROMISE pharmacies and the national averages (Table 3-20).

Pharmacy Location/Region		% Turnover Attributed to Dispensary		
		PROMISE N	PROMISE Mean %	National Mean %
Location	Shopping Centre	58	71.33%	68.14%
	Medical Centre	17	80.94%	83.77%
	Shopping Strip or Other	110	72.57%	72.95%
Region	Metro	159	72.84%	68.37%
	Country	26	73.64%	71.99%
	Total	185	72.95%	70.25%

Table 3-20: Average Attribution to Dispensary Compared to Pharmacy Location and Region

3.3.11 Services Provided by the Pharmacy

When answering the owner/manager survey, the pharmacists were asked to indicate which professional services their pharmacy offered in order to determine the type of pharmacies that participated in the trial.

Aged Care

Sixty-two of the PROMISE pharmacies (33.7%) catered for aged care facilities, within the period of the PROMISE trial. There was a significant difference between the pharmacy type and whether they catered for aged care facilities, with a higher percentage of country pharmacies (60%) providing aged care services compared to their metropolitan counterparts (29.6%) (Table 3-21). A chi-square test showed no significant differences between the pharmacies catering for aged care and the three software groups ($\chi^2 = 3.23$, $df = 2$, $p = 0.20$).

		Yes		No		Total	
		N	%	N	%	N	%
Pharmacy Type	Metro Shopping Centre	18	9.8%	33	17.9%	51	27.7%
	Metro Medical Centre	3	1.6%	14	7.6%	17	9.2%
	Metro Shopping Strip/Other	26	14.1%	65	35.3%	91	49.5%
	Country Shopping Centre	4	2.2%	3	1.6%	7	3.8%
	Country Medical Centre	0	.0%	0	.0%	0	.0%
	Country Shopping Strip/Other	11	6.0%	7	3.8%	18	9.8%
	Total	62	33.7%	122	66.3%	184	100.0%
	Statistics	$\chi^2 = 10.87$, $df = 4$, $p = 0.03$					

Table 3-21: Number of Pharmacies Providing Pharmacy Services to Aged Care Facilities

Number of Professional Services Offered

The majority of pharmacies offered two to four Community Pharmacy Agreement (CPA) funded professional programs (Table 3-22) and three to five additional professional services (Table 3-23). An analysis of variance showed no significant difference between the number of professional services offered by a pharmacy and the three software groups ($F(2,181) = 0.82$, $p = 0.44$).

	N	%
0	12	6.52
1	17	9.24
2	45	24.46
3	67	36.41
4	35	19.02
5	8	4.35
Total	184	100.0

Table 3-22: Number of CPA-funded Professional Programs Offered by PROMISe Pharmacies

	N	%
0	1	0.54
1	5	2.72
2	16	8.70
3	30	16.30
4	55	29.89
5	44	23.91
6	19	10.33
7	11	5.98
8	3	1.63
Total	184	100.0

Table 3-23: Number of Additional Professional Services Offered by PROMISe Pharmacies

Type of CPA-funded Programs

One hundred and seventy PROMISe pharmacies (92.4%) were also participating in other professional programs run through the Guild, with the most common programs being the Dose Administration Aid (DAA) Program (164, or 89.1%, of pharmacies) and the Patient Medication Profile (PMP) Program (140 or 76.1% of pharmacies) (Figure 3-1).

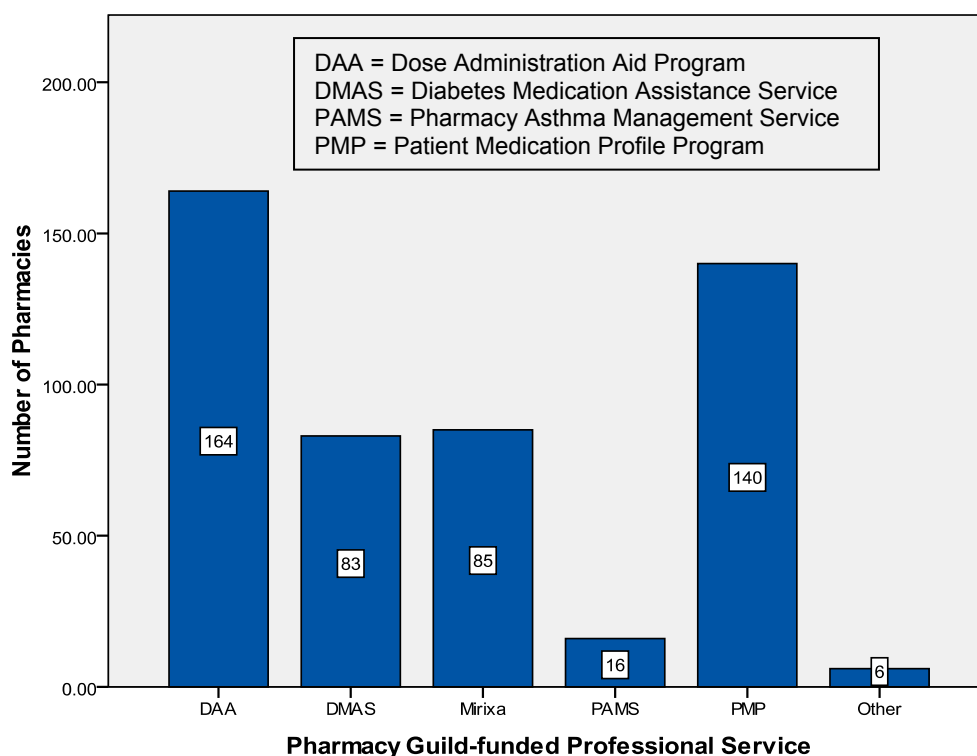


Figure 3-1: Number of Pharmacies Participating in Other CPA-funded Professional Programs

Type of Professional Services Offered

The most common professional services offered were dose administration aid packing (94.6% of pharmacies), Home Medication Reviews (89.1%) and blood pressure monitoring (83.2%) (Figure 3-2). Of the 184 pharmacies data was collected for, only one stated that it did not offer any professional services. However, this pharmacy was actually a compounding pharmacy, which could be considered a professional service.

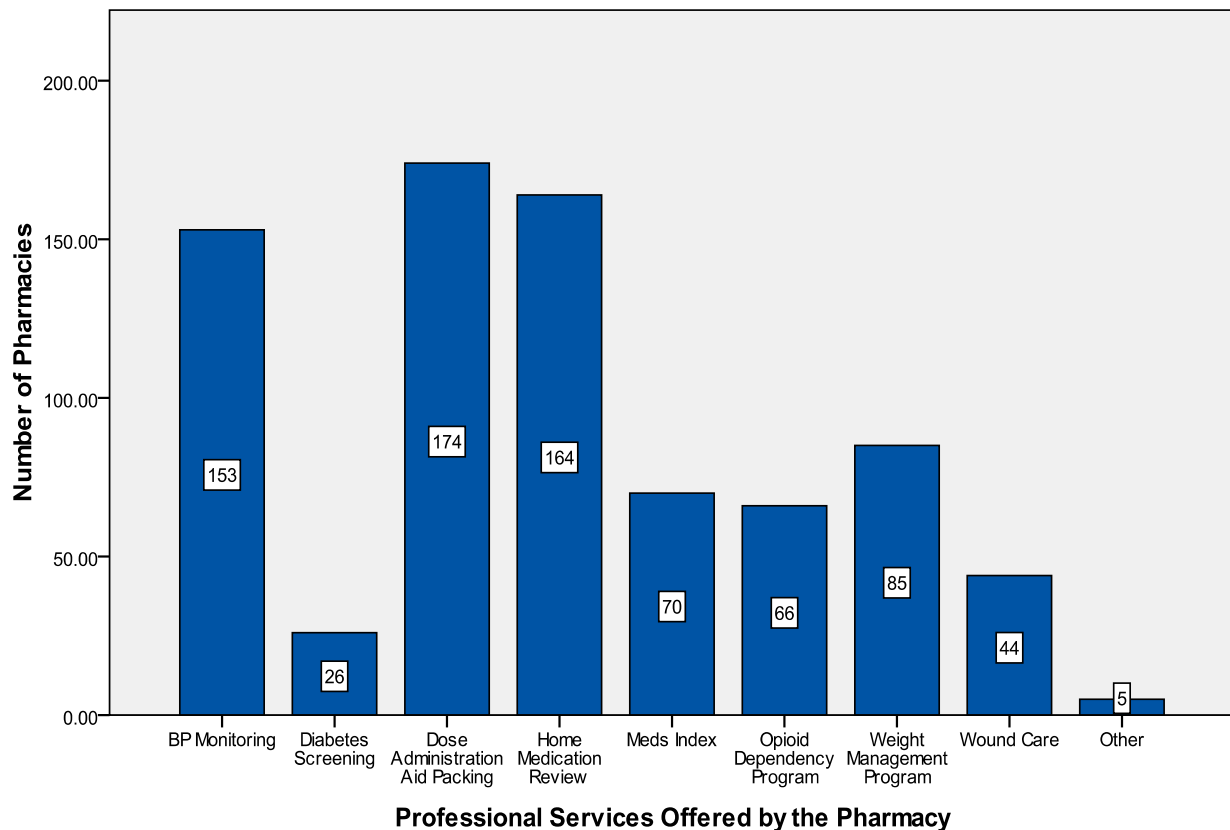


Figure 3-2: Number of Pharmacies Offering Professional Services

3.3.12 Visibility of Dispensary and Pharmacist

In total, 184 pharmacies received a site visit from a member of the project team. Each visitor had a checklist of questions to ask the pharmacist, and observations to make regarding the pharmacy (see Appendix U). From the site visits, it was found that the dispensaries of 167 pharmacies (90.8%) and 155 pharmacists (84.2%) were considered to be clearly visible from the front entry. Of the 27 pharmacies (14.7%) that possessed a back entry, the dispensary could be clearly seen in 17 of those pharmacies (63.0%) and the pharmacist could be clearly seen in 15 pharmacies (55.6%). Site visitors believed that the pharmacist was easily accessible to the public in 159 pharmacies (86.4%), with reasons for inaccessibility including elevated dispensaries, high aisle shelving, pharmacists behind two counters or the need to ask staff to speak to the pharmacist.

3.3.13 Counselling Area

Of the 184 pharmacies that received a site visit, 78 (42.4%) had a permanent counselling area (such as an office with a locked door), 71 (38.6%) had a temporary counselling area (such as a removable screen) and 35 (19.0%) had no designated counselling area. A Kruskal-Wallis test showed significant differences between the pharmacy type and the type of counselling area present (Table 3-24). A chi-square test showed a significant difference between the type of counselling areas in the three software groups ($\chi^2 = 9.85$, $df = 4$, $p = 0.04$), with group one having more pharmacies than expected with no counselling areas, group two having more pharmacies than expected with permanent counselling areas, and group three having more pharmacies than expected with temporary counselling areas.

		Yes (closed office with door)		Yes (temporary area with screen)		No		Total	
		N	%	N	%	N	%	N	%
Pharmacy Type	Metro Shopping Centre	27	14.7%	21	11.4%	3	1.6%	51	27.7%
	Metro Medical Centre	6	3.3%	8	4.3%	3	1.6%	17	9.2%
	Metro Shopping Strip/Other	29	15.8%	33	17.9%	28	15.2%	90	48.9%
	Country Shopping Centre	6	3.3%	1	.5%	0	.0%	7	3.8%
	Country Shopping Strip/Other	10	5.4%	8	4.3%	1	.5%	19	10.3%
Total		78	42.4%	71	38.6%	35	19.0%	184	100.0%
Statistics		$\chi^2 = 18.85, df = 4, p = 0.03$							

Table 3-24: Pharmacy Type Compared to Type of Counselling Area

3.3.14 Number of Dispensing Terminals

On average, there were 2.3 ± 1.1 dispensing terminals in each PROMISE pharmacy (mode = 2; range = 1-6) with only 23 (12.5%) having four or more terminals (Figure 3-3). An analysis of variance showed no significant difference between the number of dispensing terminals and the three software groups ($F(2,181) = 0.42, p = 0.66$).

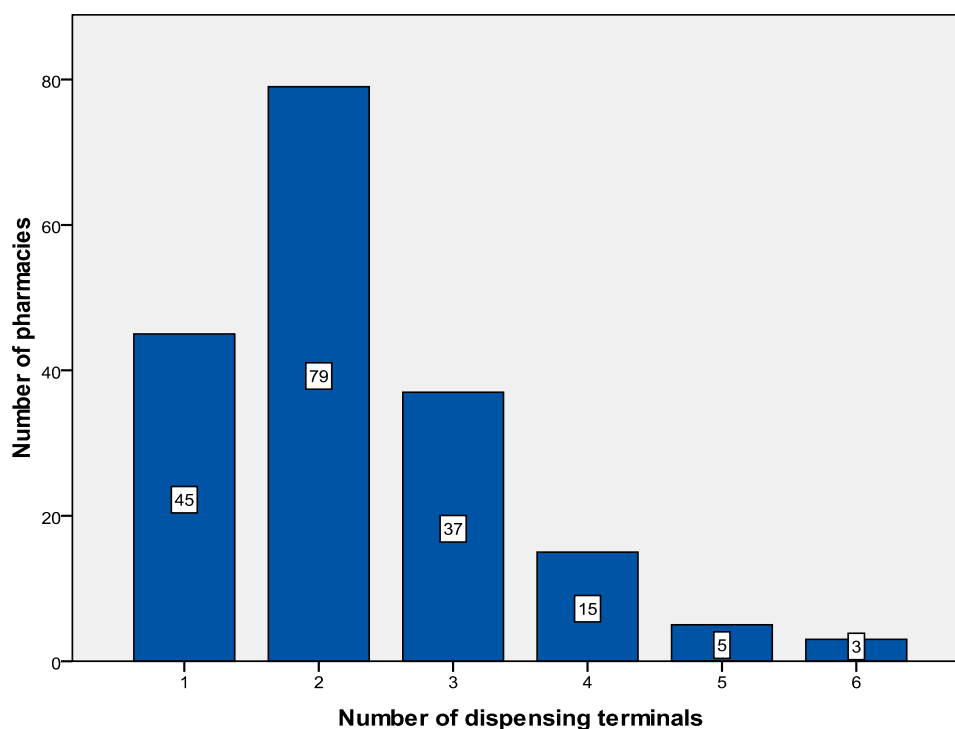


Figure 3-3: Number of Dispensing Terminals in PROMISE Pharmacies

3.4 Pharmacist Characteristics

Prior to the PROMISE trial, participating pharmacists were asked to answer a number of surveys whilst completing their online training. This information was then compared to their individual intervention rate during the trial to determine if there were any significant influencing factors.

3.4.1 Training

Of the 561 enrolled pharmacists, 30 were “duplicate” pharmacists as they were also working at another pharmacy enrolled in the trial, resulting in 531 individual pharmacists in total. A total of 215 (40.5%) pharmacists attended the face-to-face PROMISE training and 413 (77.8%) pharmacists completed the online training scenarios, with 195 pharmacists (36.7%) completing both the face-to-face and online training. Although the training was compulsory, there were still 101 (19.0%) enrolled pharmacists that completed neither the face-to-face or online training. The training was incentivised by awarding 1.5 CPD points and a \$50 Coles/Myer gift voucher for completion of the 15 training scenarios, plus an additional \$50 Coles/Myer gift voucher for attending the face-to-face training; however, the project team was still unable to achieve 100% training rate as there was no way to force participation in the training. The type of training of participant pharmacists is shown in Table 3-25. It should be noted that the project team included results from the untrained pharmacists during the PROMISE analysis. Before accessing the online training module, the pharmacists were asked to complete five surveys examining their background, opinions regarding interventions, empathy, professionalism and clinical knowledge.

	Frequency	Percent
No Training	101	19.0
Online Training Only	215	40.5
Face-to-Face Training Only	19	3.6
Both Training	196	36.9
Total	531	100.0

Table 3-25: Type of Training of Participating Pharmacists

A chi-square test showed no statistical difference between the level of training that the pharmacist undertook and the software group their pharmacy was in ($\chi^2 = 6.65$, $df = 6$, $p = 0.35$).

3.4.2 Demographics

Of the 531 pharmacists, 458 (86.3%) completed the background survey. Of these 458 pharmacists, 258 (56.3%) were female (Table 3-26). This matches the national demographics displayed by the Pharmacy Workforce Planning Study²¹⁹ conducted in 2008, which showed there were 15,337 pharmacists nationwide in 2006 (from ABS population data), of whom 56% were female.

As seen in Table 3-26, the age range with the largest number of pharmacists was 20-30 years old with 167 (36.5%) pharmacists. Unfortunately, the Pharmacy Workforce Planning Study²²⁰ had different age categories (for example 15-24 years and 25-34 years) compared to the PROMISE survey (for example 20-29 years and 30-39 years); therefore, the PROMISE pharmacists were compared to the Victorian Pharmacy Workforce 2007 Study.²²⁰ The Victorian data was chosen as the majority of PROMISE pharmacists (58.6%) were Victorian-based. There were significant differences between the demographics of the PROMISE pharmacists and the Victorian averages (Table 3-26), which may indicate that younger pharmacists were more willing to participate in the PROMISE trial.

		Male			Female			Total		
		Expected	PROMISE		Expected	PROMISE		Expected	PROMISE	
		%	N	%	%	N	%	%	N	%
Age Range	20-30	13.73	62	13.54	25.49	105	22.93	19.61	167	36.46
	31-40	15.69	52	11.35	22.55	64	13.97	19.12	116	25.33
	41-50	20.59	40	8.73	21.57	50	10.92	21.08	90	19.65
	51-60	19.61	27	5.90	19.61	30	6.55	19.61	57	12.45
	Over 60	30.39	19	4.15	10.78	9	1.97	20.59	28	6.11
	Total	100	200	43.67	100	258	56.33	100.00	458	100
Statistics		$\chi^2 = 89.57, df = 4, p < 0.01$			$\chi^2 = 45.67, df = 4, p < 0.01$					

Table 3-26: Age Range of PROMISE Pharmacists Compared to Victorian Pharmacist Data From the Victorian Pharmacy Workforce 2007 Study²²⁰

As seen in Figure 3-4, the largest proportion of pharmacists had graduated post year 2000, accounting for 180, or 39.3%, of pharmacists.

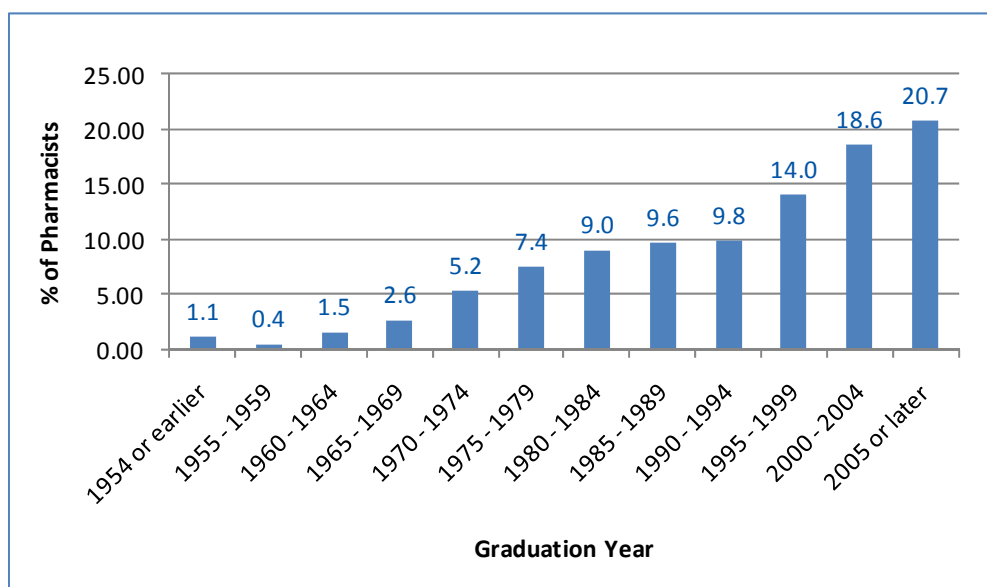


Figure 3-4: Graduation Year of the PROMISE Pharmacists

A chi-square test showed no statistical difference between the pharmacist's gender or age and the software group their pharmacy was in ($\chi^2 = 0.90, df = 2, p = 0.64$) and ($\chi^2 = 14.23, df = 10, p = 0.16$) respectively).

3.4.3 Qualifications

Of the 458 respondent pharmacists, only 49 (10.7%) had additional qualifications to their pharmacy degree, including graduate certificates, graduate diplomas, and additional degrees (Honours, Masters and Doctor of Philosophy). There was substantial variety in the subject of the additional qualifications, including pharmacy-based certificates in wound care, herbal medicine, clinical pharmacy, and geriatrics, as well as additional qualifications outside of pharmacy such as health economics, business administration, and commerce. Eighty-one pharmacists (17.7%) were accredited to conduct home medication reviews, with 14 pharmacists (3.1%) being accredited as well as holding an additional qualification.

3.4.4 Professional Memberships

Of the 458 respondents, 347 (75.8%) were members of the Pharmaceutical Society of Australia, 12 (2.6%) were members of the Society of Hospital Pharmacists of Australia, 104 (22.7%) were members of the Australian Association of Consultant Pharmacists, 18 (3.9%) were members of APESMA, 70 (15.3%) were members of the PGA, 14 (3.1%) were members of the Australian College of Pharmacy Practice and Management, nine (2.0%) were members of other societies (such as the Pharmaceutical Societies of England or Ireland) and 75 pharmacists (16.4%) were not a member of any societies. There were 229 (50.0%) pharmacists who were members of only one society, 122 (26.6%) pharmacists were members of two societies, and 32 (7.0%) pharmacists were a member of three or more societies. The most common membership combinations were PSA and AACP (65 or 14.2%), PSA and PGA (36 or 7.9%) or PSA and PGA and AACP (16 or 3.5%).

3.4.5 Continuing Education

The majority of pharmacists (72.9%) stated that they undertook 10-50 hours per year of CPD activity (Table 3-27). A chi-square test showed no statistical difference between the hours of CPD activity per year and the software group their pharmacy was in ($\chi^2 = 3.90$, $df = 6$, $p = 0.70$).

Hours of CPD activity completed each year	N	%
None	3	0.66
Less than 10 hours	45	9.83
10 - 25 hours	175	38.21
25 - 50 hours	159	34.72
More than 50 hours	76	16.59
Total	458	100

Table 3-27: CPD Activity by PROMISe Pharmacists

3.4.6 Practice Background

During their pharmacy careers, 286 (62.4%) had only ever worked in community pharmacy, with 104 (22.7%) having worked in both community and hospital settings, and 33 (7.2%) having worked in both community and medication review settings. Thirty-three pharmacists (7.2%) had worked in all three areas (community, hospital and medication reviews). Twenty-eight pharmacists had also worked in other areas of pharmacy, such as academia/research, military/government, industry and international. The largest proportion of pharmacists (206 or 49.3%) had worked in community pharmacy practice for 10 years or less (Table 3-28).

Number of years in community pharmacy practice	N	%
Less than 5 years	130	31.10
5-10 years	76	18.18
10-15 years	56	13.40
15-20 years	49	11.72
20-25 years	32	7.66
25-30 years	32	7.66
30-35 years	17	4.07
35-40 years	15	3.59
Over 40 years	11	2.63
Total	418	100.00

Table 3-28: Number of Years Spent in Community Pharmacy Practice by PROMISe Pharmacists

3.4.7 Current practice

As expected, 436 (95.2%) pharmacists currently spent the majority of their working week in community pharmacy practice, with 168 (36.7%) working over 40 hours per week, and 213 (46.5%) working 20 to 40 hours per week (Table 3-29). Of the other pharmacists, 10 (2.2%) worked mainly in hospital, six (1.3%) mainly undertook medication reviews and six (1.3%) mainly worked in other sectors (such as clinical trials, industry and research). Employee pharmacists made up the largest majority of participating pharmacists with 211 (46.1%), and 360 (78.6%) had worked in their current role for less than 10 years (Table 3-30). A chi-square test showed no statistical difference between the current role of the pharmacist and the software group their pharmacy was in ($\chi^2 = 2.02$, $df = 6$, $p = 0.92$).

Hours worked in community pharmacy practice each week	N	%
Less than 10 hours	22	4.80
10 - 20 hours	55	12.01
20 - 40 hours	213	46.51
Over 40 hours	168	36.68
Total	458	100

Table 3-29: Average Number of Hours Worked Weekly by PROMISE Pharmacists

	Employee	Owner	Manager	Locum	Other	Total N	%
Less than 2 years	62	6	28	3	5	104	22.71
Between 2 and 5 years	88	32	30	7	4	161	35.15
Between 5 and 10 years	39	40	11	5	0	95	20.74
Between 10 and 20	18	46	3	1	0	68	14.85
20 years or more	4	23	1	2	0	30	6.55
Total N	211	147	73	18	9	458	100
%	46.07	32.10	15.94	3.93	1.97	100	

Table 3-30: Current Role of PROMISE Pharmacists and Years in the Role

3.4.8 Workload

Of the 458 respondents, 175 (38.2%) generally worked as the sole pharmacist in their community pharmacy and 178 (38.9%) worked with only one other pharmacist (Table 3-31). Pharmacists were asked to select from five prescription categories to determine their current daily workload (see Table 3-32 for categories). The majority of pharmacists indicated that they dispensed an average of 100-150 or 150-200 prescriptions per day during a nine-hour shift with 167 (36.5%) and 118 (25.8%) pharmacists respectively (Table 3-32). In Australia, an APESMA survey revealed that the average number of prescriptions dispensed ranged from 11 to 33 per hour with an average of 19, which is equivalent to 171 per nine-hour shift.²²¹ The Pharmacy Board of Tasmania (and its other state equivalents) recommend dispensing no more than 170 prescriptions per nine-hour shift;²²² therefore, the PROMISE participants are dispensing prescriptions at a lower or similar rate to the national average. A chi-square test showed no statistical difference between the average number of prescriptions dispensed daily and the software group their pharmacy was in ($\chi^2 = 9.86$, $df = 10$, $p = 0.45$), indicating an even spread of pharmacies with differing workloads over the three groups.

Number of other pharmacists working during the pharmacist's general shift	N	%
None	175	38.21
1	178	38.86
2	72	15.72
3 - 4	31	6.77
5 or more	2	0.44
Total	458	100

Table 3-31: Number of Other Pharmacists Each PROMISE Pharmacist Works With During an Average Shift

Prescriptions per day	N	%
Less than 100	95	20.74
100 - 150	167	36.46
150 - 200	118	25.76
200 - 250	39	8.52
Over 250	37	8.08
Not appropriate to my area of practice	2	0.44
Total	458	100

Table 3-32: Average Number of Prescriptions Dispensed by Each PROMISE Pharmacist During a Nine-Hour Shift

3.4.9 Empathy Score

Of the 531 participating pharmacists, 450 (84.7%) completed the “Empathy Survey” (see Appendix P) and the mean score was 46.8 ± 6.1 (range = 25-62) (Table 3-33). This was comparable to the results in the original article, which surveyed university students studying healthcare, where the mean score over three studies was 46.25 ± 7.55 in undergraduate students. An independent T-test showed that female pharmacists had a significantly higher empathy score than male pharmacists (Table 3-33) with a mean difference of 2.69 (95% CI = 1.58-3.80), which is comparable to the original article which also illustrated a higher empathy score in female students. A bivariate correlation showed no statistical significance between the pharmacist’s graduation year and his or her empathy scores (*Pearson’s* $r = -0.04$, $N = 445$, $p = 0.43$). An analysis of variance showed no statistical difference between the pharmacist’s empathy score and the software group his or her pharmacy was in ($F(2,451) = 0.78$, $p = 0.46$).

	Count	Mean	Standard Deviation	Minimum	Maximum
Female	253	48.01	5.82	33.00	62.00
Male	197	45.32	6.09	25.00	61.00
Total	450	46.83	6.08	25.00	62.00
Statistics	$t = -4.77$, $df = 448$, $p < 0.01$				

Table 3-33: PROMISE Pharmacist Empathy Scores Compared to Gender

3.4.10 Professionalism Score

Of the 531 participating pharmacists, 451 (84.9%) completed the “Professionalism Survey” (see Appendix Q) and the mean score was 79.98 ± 7.73 (range = 19-90) (Table 3-34). This was slightly higher than results in the original article where the mean score was 77.8 ± 5.9 , achieved with 231 pharmacy students and recent pharmacy

graduates in the USA. An independent T-test showed that the female PROMISE pharmacists had a significantly higher professionalism score than male pharmacists (Table 3-34) with a mean difference of 1.73 (95% CI = 0.29-3.16); unlike the original article that showed no differences in professionalism between genders. A bivariate correlation showed no statistical significance between the pharmacist's graduation year and his or her professionalism scores (*Pearson's* $r = -0.02$, $N = 446$, $p = 0.64$). An analysis of variance showed no statistical difference between the pharmacist's professionalism score and the software group his or her pharmacy was in ($F(2,452) = 0.15$, $p = 0.86$).

	Count	Mean	Standard Deviation	Minimum	Maximum
Female	254	80.73	8.33	19.00	90.00
Male	197	79.01	6.78	32.00	90.00
Total	451	79.98	7.73	19.00	90.00
Statistics	$t = -2.37$, $df = 449$, $p = 0.02$				

Table 3-34: PROMISE Pharmacist Professionalism Scores Compared to Gender

3.4.11 Clinical Knowledge

Of the 531 pharmacists participating in the trial, 435 (81.9%) completed the DRP Survey (see Appendix R) and the mean score was 52.4 ± 8.1 (range = 23-76) (Table 3-35). An independent T-test showed that female pharmacists had a significantly higher clinical knowledge score than male pharmacists (Table 3-33), with a mean difference of 2.56 (95% CI = 0.98-4.13). Interestingly, a bivariate correlation showed no statistical significance between the pharmacist's graduation year and his or her clinical knowledge scores (*Pearson's* $r < 0.01$, $N = 427$, $p = 0.94$) indicating that a pharmacist's clinical knowledge does not substantially decrease after graduation. An analysis of variance showed no statistical difference between the pharmacist's clinical knowledge score and the software group his or her pharmacy was in ($F(2,431) = 0.24$, $p = 0.79$).

	Count	Mean	Standard Deviation	Minimum	Maximum
Female	245	53.54	7.04	31.00	76.00
Male	187	50.98	9.05	23.00	68.00
Total	432	52.43	8.06	23.00	76.00
Statistics	$t = -3.19$, $df = 342$, $p < 0.01$				

Table 3-35: PROMISE Pharmacist Clinical Knowledge Scores Compared to Gender

3.5 Patient Demographics

For all patients subject to an intervention, the pharmacist was asked to enter their age group and gender. The number of medications that were dispensed to each patient was also recorded within the PROMISE database.

3.5.1 Age Range and Gender

Age range and gender statistics were collected for the 6,755 interventions that were recorded using the PROMISE software. Out of the 6,755 interventions, 421 were "duplicates" which meant that several patients had more than one intervention recorded against their unique identification number. Due to a technical problem early in the trial, 109 of these interventions had no age or gender recorded for the patients, resulting in 6,225 unique patient records that could be used for this analysis. Of the 6,225 patients, 3,514 (56.5%) were female, which was slightly higher than the Australian Bureau of Statistics 2009 report of 50.2% female for the Australian population. This increase

also follows the trend of females accessing healthcare on a more regular basis which may account for the higher percentage of females in the PROMISe results.²²³

Of the 6,225 patients, 3,159 (50.8%) were in the adult age range of 21-64 years old and 2,390 (38.4%) were aged 65 years or over. As expected, these results are significantly different from the Australian Bureau of Statistics 2009 projected population demographics in 2010 (Table 3-36). This is explained by the fact that the older population take more medications and are therefore more likely to be subjected to an intervention, when compared to younger people. The higher percentage of females in the PROMISe sample could be explained by the older population, which has a higher proportion of females, having more interventions recorded during the PROMISe trial.

	PROMISe N	% N	ABS 2010 Projected N	% N
0-20 years	676	10.86	1182.8	19.00
21-64 years	3159	50.75	4189.4	67.30
65+ years	2390	38.39	852.8	13.70
Total	6225	100	6225	100
Statistics	$\chi^2 = 1011.1$, df = 2, p < 0.01			

Table 3-36: PROMISe Patient Demographics Compared to Expected Population (taken from the Australian Bureau of Statistics 2010 Projections²⁰²)

3.5.2 Average Number of Medications

Of the 6,225 patients with interventions, only 5,558 could be matched to one or more prescriptions in the dataset. This is due to the fact that a number of the prescription interventions which were recorded in the system were not actually entered as such by the intervening pharmacist, resulting in the intervention being given a unique patient identifier. Since it is known that these patients must have received at least one prescription – despite the fact that none could be found – it was elected to treat these values as missing for the purpose of calculating the average number of medications per patient, instead of treating them as zeros. Of these 5,558 patients, a further 73 were discounted since all of their prescriptions could not be mapped to ATC codes by the system. For each of the remaining 5,485 patients who had a number of medications which could be reliably counted, a count of unique medications, as defined by ATC level 5, was determined for the three-month trial period. The median number of unique medications per patient was four, while 25% of patients had two or fewer, and 25% had seven or more. The incidence of each figure is shown in Figure 3-5, which reveals that the maximum number of unique medications a patient was found to have during this trial was 25.

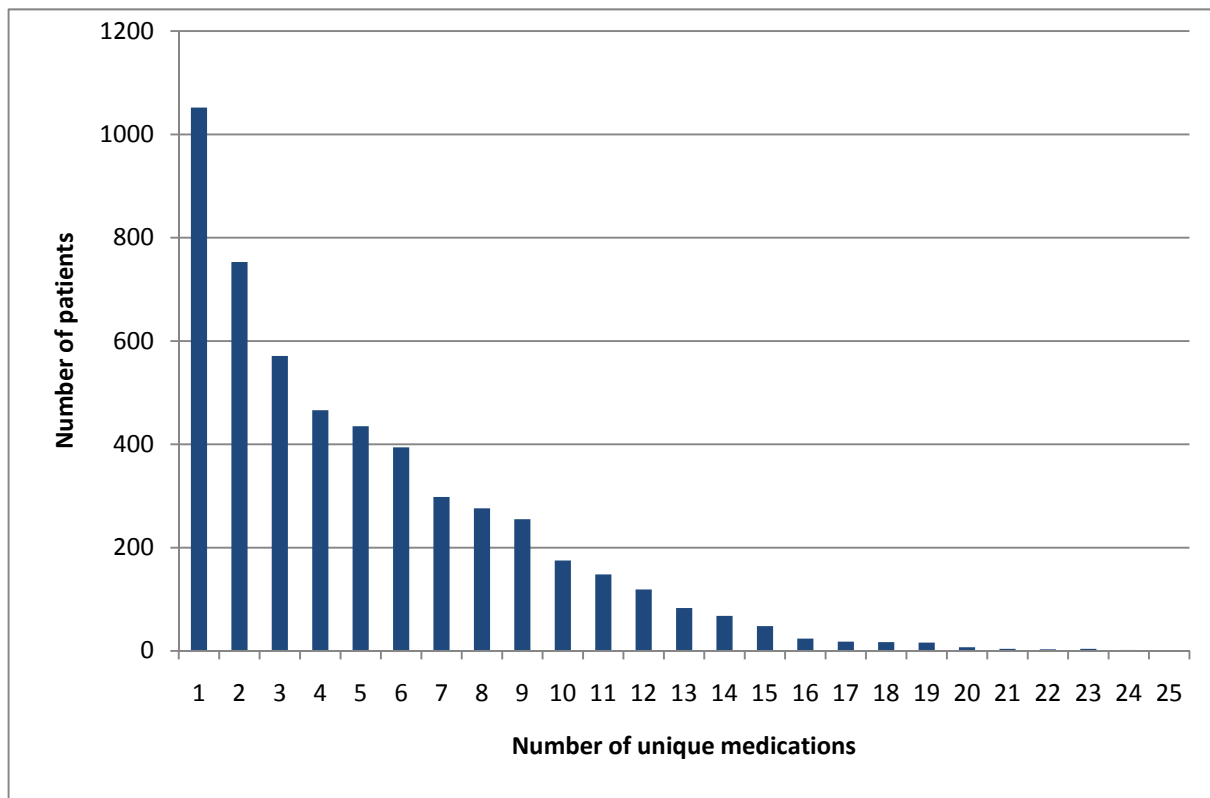


Figure 3-5: The Number of Patients With the Number of Unique Medications over the Three-month Trial Period

It can be seen in Figure 3-6 that the average number of interventions tended to rise as the patient was taking increasing numbers of unique medications. The effect seems to tail off around the 20 medications per patient region, although this is likely to be because the sample sizes were so small in this region. The error bars indicate one standard deviation in each direction.

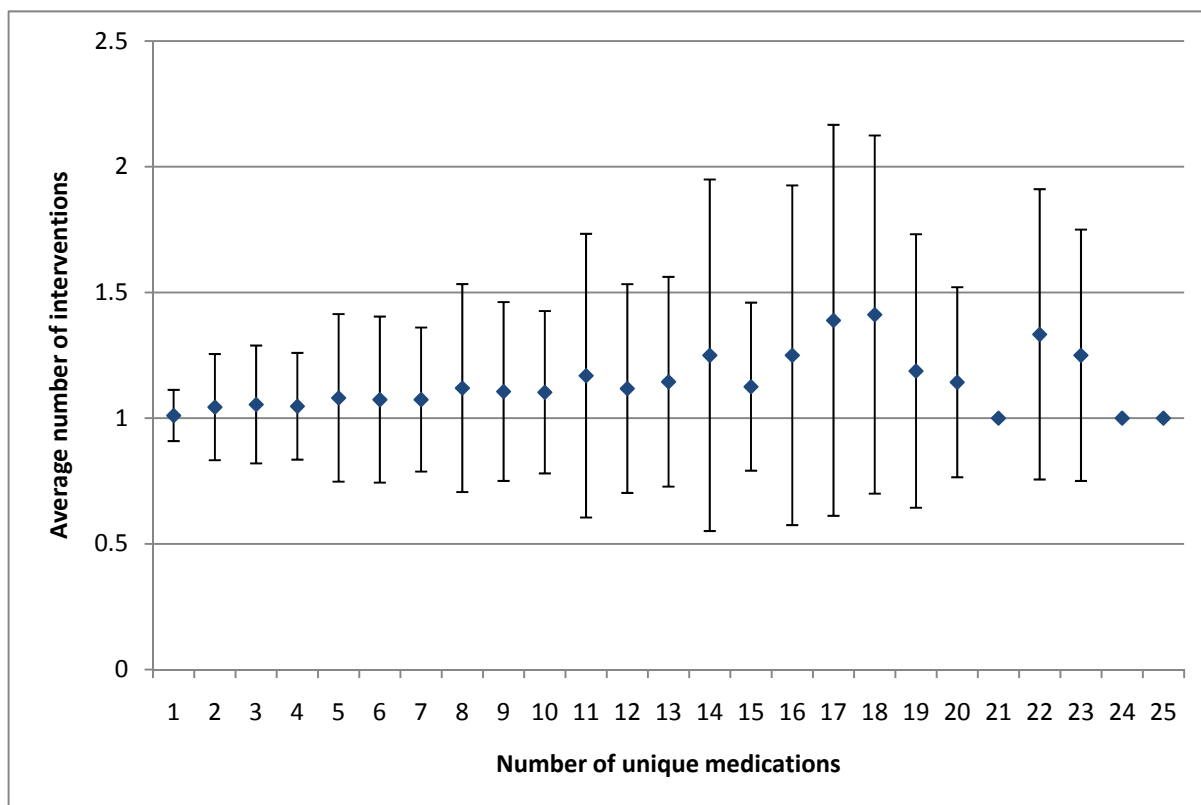


Figure 3-6: The Average Number of Interventions Documented for Patients with a Given Number of Unique Medications

3.6 Observer Allocations

The observed pharmacies were selected according to their PhARIA and weekly prescription volume to be a representative sample of the PROMISe pharmacies. A Chi-squared test showed no significant differences between the observed pharmacies and the non-observed pharmacies within the PROMISe sample with regards to PhARIA ($\chi^2 = 0.76$, $df=1$, $p=0.43$) or weekly prescription volume ($\chi^2 = 1.29$, $df = 4$, $p=0.86$). A total of 38 (20%) of the software pharmacies were allocated observers as shown in Table 3-37.

	Pharia Classification and Estimated Annual Prescription Volume								
State	PhARIA 1				PhARIA 2-6				
	<30000	30-55000	55-90000	>90000	<30000	30-55000	55-90000	>90000	Total
TAS	0	2	1	1	1	0	0	0	5
NSW	3	3	2	0	0	2	0	0	10
VIC	4	9	4	2	0	1	2	1	23
Sub total	7	14	7	3	1	3	2	1	38
Total	31				7				

Table 3-37: Software Pharmacies Observer Allocations

Chapter 4 Results and Discussion: Number, Frequency and Types of Clinical Interventions

For the purposes of reporting results, clinical interventions documented in the PROMiSe system will be referred to as documented clinical interventions (DCI). Results pertaining to observed clinical interventions whether recorded or not will be referred to as actual clinical interventions (ACI). An outline of the interventions documented and prescriptions dispensed during the study is shown in Figure 4-1. During the course of the study, 531 enrolled pharmacists dispensed 2,396,451 prescriptions for 546,717 patients. An additional 245 pharmacists who were not enrolled in the study dispensed 292,528 prescriptions for 63,570 patients.

There were 7,000 DCI documented, of which 6,755 were documented by the enrolled pharmacists. DCI documented by pharmacists not enrolled in the study, locums for example, are not included in the following analyses.

A total of 525 of the DCI were related to either over the counter medications, or symptom based requests to the pharmacist (see Figure 4-1). These DCI were not included in the analyses and are discussed separately in section 4.8.

The remaining 6,230 DCI involved prescription medications and were distributed across the three software trial groups. Group three pharmacies undertook 263 DCI that were specifically prompted by the software prompt. These DCI are discussed in detail in Chapter 6 and are not included in the analyses in this chapter.

It should also be noted that the observational periods determined that only 49% of ACI were actually documented (see Chapter 5). Therefore, it should be taken into consideration that all analyses have been completed only on those DCI documented however the actual rate of intervention performance is likely to be much higher.

Ultimately once invalid data was removed, it can be seen in Figure 4-1 that there were 3.1 DCI documented for every 1,000 prescriptions dispensed on average for the trial. However, there were only 2.6 per 1,000 in the software only group, and there was 3.5 per 1,000 in the group with prompts.

In this chapter the characteristics of the DCI and their overall frequency are shown and discussed. An examination of the types of DCI, their recommendations and the drugs involved precedes a preliminary examination of the different rates in the different trial groups.

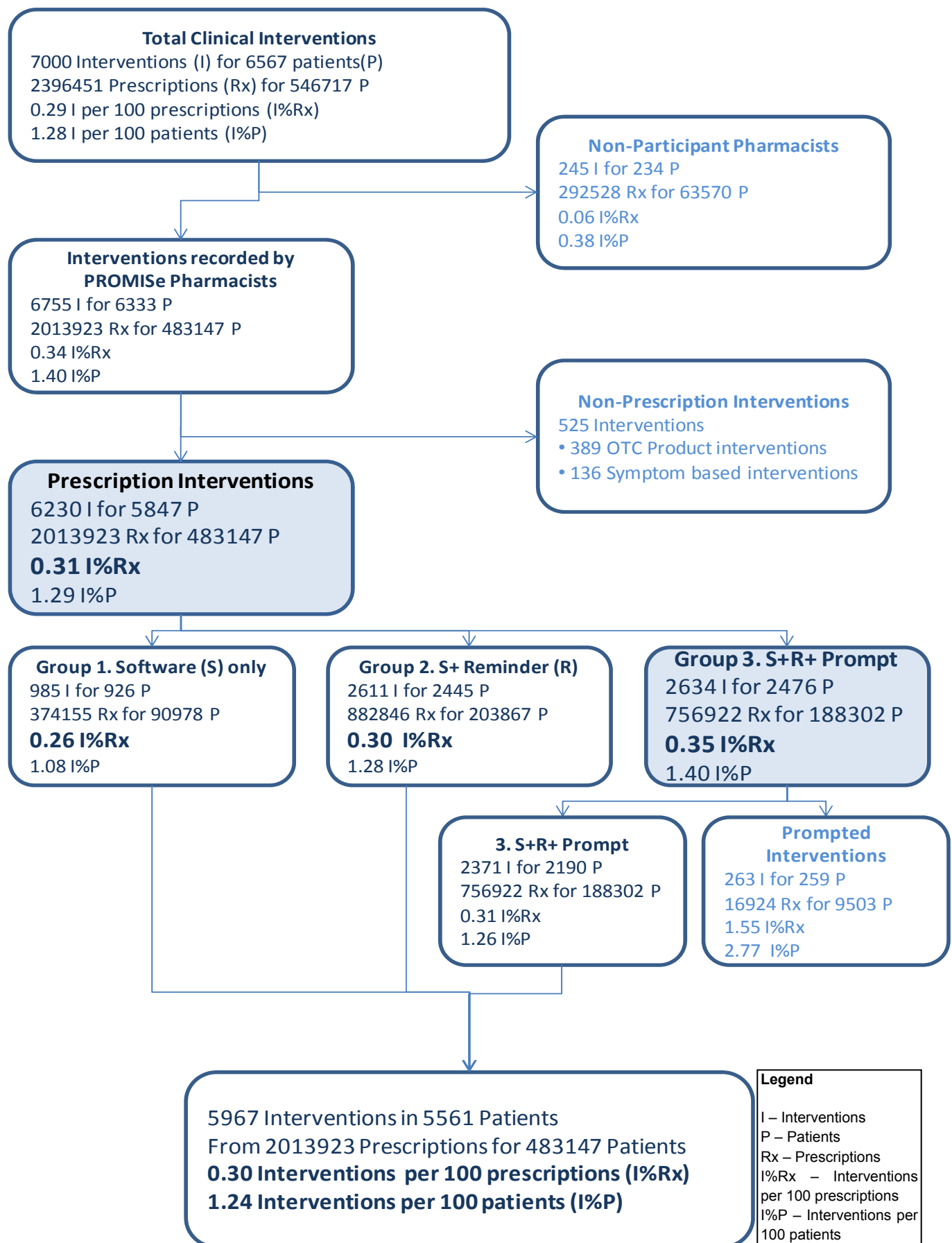


Figure 4-1: Overall DCI Recorded in PROMISE III Project

4.1 Overall Number and Rate of Clinical Interventions

There were 6230 DCI documented over the 84 days of the trial. Of these 263 were specifically prompted by the software prompt in group three pharmacies. The remaining 5967 are considered in this section.

There was a decline in recording of DCI with time as shown in Figure 4-2.

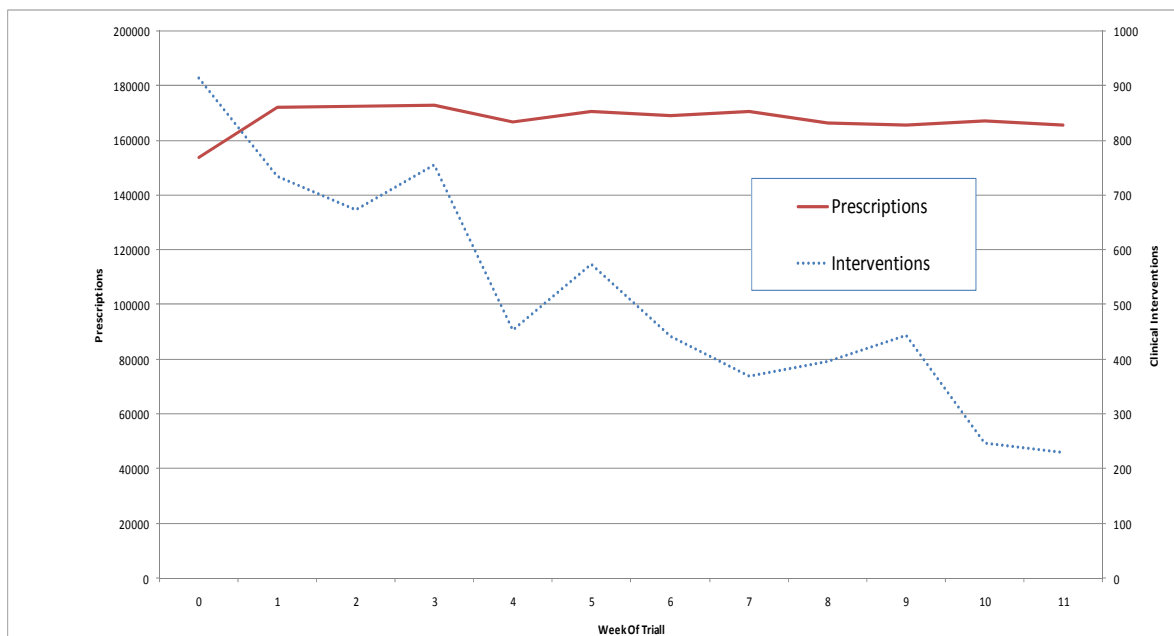


Figure 4-2: Number of DCI Recorded and Number of Prescriptions Dispensed

The overall rate of prescription-related DCI across the entire study period and all active study groups was 0.31 DCI per 100 prescriptions (approximately 1 intervention every 300 prescriptions), or 1.4 DCI per 100 unique patients (approximately 1 intervention every 70 patients) (see Figure 4-3).

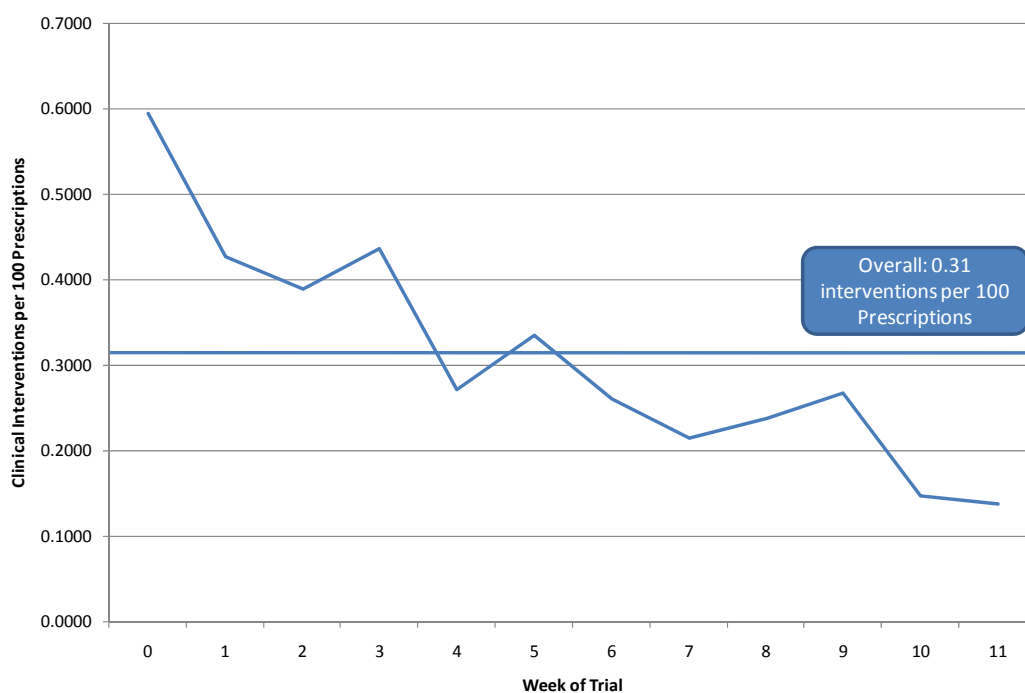


Figure 4-3: Frequency of DCI Over Duration of Study

4.2 Categories and Subcategories of Interventions

The types of DCI are shown in Table 4-1 below. The majority of DCI were related to either drug selection problems (1837; 31%) or educational issues prompted by patient requests (1421; 24%). Examples of the different types of DCI are included in Appendix GG.

The range of categories and subcategories which were documented for the DCI was in keeping with the previous PROMISe study,¹⁹⁷ and with our understanding of the types of drug-related problems identified in routine community pharmacy practice.

Category	Subcategory	#	% of Cat	#	%
Drug Selection	D1 Duplication	233	12.7	1837	30.8
	D2 Drug Interaction	265	14.4		
	D3 Wrong Drug	223	12.1		
	D4 Incorrect Strength	347	18.9		
	D5 Inappropriate Dose Form	211	11.5		
	D6 Contraindications Apparent	141	7.7		
	D7 No Indication Apparent	48	2.6		
	D0 Other Drug Selection Problem	369	20.1		
Over/Underdose	O1 Dose Too High	384	32.4	1185	19.9
	O2 Dose Too Low	316	26.7		
	O3 Incorrect Dose Instructions	392	33.1		
	O0 Other Dose Problem	93	7.8		
Compliance	C1 Taking Too Little	116	20.8	557	9.3
	C2 Taking Too Much	101	18.1		
	C3 Erratic Use of Medication	100	18.0		
	C4 Intentional Misuse	34	6.1		
	C5 Difficulty Using Dose Form	56	10.1		
	C0 Other Compliance Problem	150	26.9		
Undertreated	U1 Condition Undertreated	164	60.3	272	4.6
	U2 Condition Untreated	42	15.4		
	U3 Preventive Therapy required	58	21.3		
	U0 Other Undertreated Problem	8	2.9		
Monitoring	M1 Laboratory Monitoring	42	30.0	140	2.3
	M2 Non-Laboratory Monitoring	81	57.9		
	M0 Other Monitoring Problem	17	12.1		
Education/Information	E1 Patient Drug Info Request	668	47.0	1421	23.8
	E2 Patient Disease Info Request	280	19.7		
	E0 Other Education Problem	473	33.3		
Not Classifiable	N0 Not Classifiable	110	100	110	1.8
Toxicity/ADR	T1 Toxicity/ADR present	445	100	445	7.5
Total		5967		5967	100

Table 4-1: Categories and Subcategories of DCI

4.3 Intervention Recommendations

In over 30% of the DCI, the pharmacist recommended referral to the prescriber to resolve the problem (1794 occasions, 30.1%; see Table 4-2).

In 2441 (41%) of the DCI, a counselling and education session was provided to the patient to resolve the problem. These two recommendations (referral to the prescriber and an education or counselling session) accounted for over 70% of the recommendations made by pharmacists to resolve the drug-related problems identified. Again, this is consistent with our understanding of community pharmacy practice, where potential problems are resolved by discussion with the patient, their prescriber or both.

An average of 1.6 recommendations were made for each intervention, indicating that multiple recommendations were common.

The most common type of recommendation related to a change in therapy, with 40% (3841 occasions) of DCI receiving these types of recommendations. These changes were commonly a change of drug (847 occasions), or a dose change (642 dose increases, 656 dose decreases).

Provision of information was the next most common type of recommendation, with 34.3% (3325) of DCI receiving recommendations of this type. Within this type, approximately 75% (2441 occasions) of recommendations related to, presumably, verbal provision of information in the form of a counselling or education session.

When a referral recommendation was made, this was almost uniformly to the prescriber (91%; 1794 occasions).

Category	Subcategory		#	% of Category	#	%	% of Recommendations	% of Interventions
A Change in therapy	R1	Dose increase	642	16.7	3841	39.6	6.7	10.8
	R2	Dose decrease	656	17.1			6.8	11.0
	R3	Drug change	847	22.1			8.8	14.2
	R4	Drug formulation change	384	10.0			4.0	6.4
	R5	Drug brand change	96	2.5			1.0	1.6
	R6	Dose frequency/schedule change	529	13.8			5.5	8.9
	R7	Prescription not dispensed	307	8.0			3.2	5.1
	R8	Other changes to therapy	380	9.9			4.0	6.4
A referral required	R9	Refer to prescriber	1794	91.3	1964	20.3	18.7	30.1
	R10	Refer to hospital	36	1.8			0.4	0.6
	R11	Refer for medication review	76	3.9			0.8	1.3
	R12	Other referral required	58	3.0			0.6	1.0
Provision of information	R13	Education or counselling session	2441	73.4	3325	34.3	25.5	40.9
	R14	Written summary of medications	261	7.8			2.7	4.4
	R15	Recommend dose administration aid	75	2.3			0.8	1.3
	R16	Other written information	548	16.5			5.7	9.2
Monitoring	R17	Monitoring: Non-laboratory	277	61.6	450	4.6	2.9	4.6
	R18	Monitoring: Laboratory test	173	38.4			1.8	2.9
Other	R19	No Recommendation Necessary	112	100.0	112	1.2	1.2	1.9
Total			9580		9692	100	100	160.5

Table 4-2: Recommendations Made to Address DRPs Identified for DCI

When the types of recommendations were compared to the initial categories of interventions, a number of relationships were identified. Interventions where the recommendation was for a change in therapy were more likely to be either drug selection problems or dosage problems. DCI where a referral was required were more likely to involve a drug-related problem associated with toxicity or an untreated indication requiring addition of therapy. Recommendations associated with provision of information were more likely to be associated with education or compliance issues (see shaded portions of Table 4-3).

Recommendation Type	A Change in Therapy			Referral Required			Information Provision			Monitoring			Total
Category	#	% of Cat	% of Recc	#	% of Cat	% of Recc	#	% of Cat	% of Recc	#	% of Cat	% of Recc	
Drug Selection	1626	42.3	56.2	605	30.8	20.9	537	16.2	18.6	123	27.3	4.3	2891
Over/Underdose	1111	28.9	62.9	349	17.8	19.8	269	8.1	15.2	37	8.2	2.1	1766
Compliance	307	8.0	32.6	221	11.3	23.5	382	11.5	40.6	32	7.1	3.4	942
Undertreated	193	5.0	35.8	193	9.8	35.8	126	3.8	23.4	27	6.0	5.0	539
Monitoring	20	0.5	7.3	63	3.2	22.9	94	2.8	34.2	98	21.8	35.6	275
Education/Information	208	5.4	9.6	177	9.0	8.2	1705	51.3	78.8	74	16.4	3.4	2164
Not Classifiable	51	1.3	36.2	56	2.9	39.7	30	0.9	21.3	4	0.9	2.8	141
Toxicity/ADR	325	8.5	37.7	300	15.3	34.8	182	5.5	21.1	55	12.2	6.4	862
Total	3841			1964			3325			450			9580

Table 4-3: Recommendations Made by Category of Intervention

4.4 Clinical Significance

During the documentation process, pharmacists were asked to assign a clinical significance to the intervention. As will be discussed in the economic evaluation section, the pharmacists' assignment of clinical significance correlated well with the outcomes of the expert panel assessment.

Almost half of the DCI (43%; 2538 occasions) were classified as either of moderate or severe level of clinical significance by the recording pharmacist (see Figure 4-4). Moderate clinical significance interventions were those that were likely to require medical intervention to resolve, and severe clinical significance interventions were those that were likely to require hospitalisation to resolve.

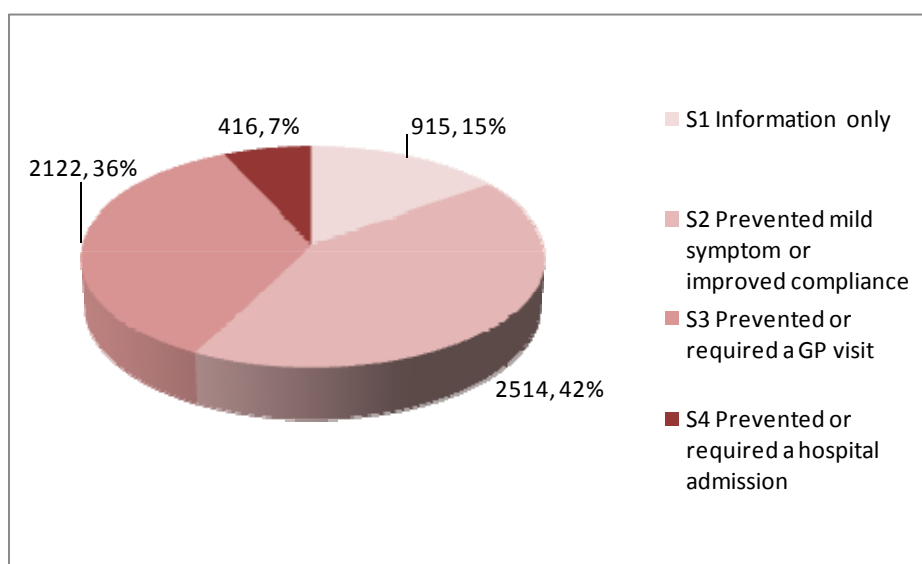


Figure 4-4: Pharmacist Assigned Significance of DCI

More significant interventions were associated with a drug change, contact with the prescriber or referral to a hospital, or a monitoring recommendation. Less significant interventions were more commonly associated with information or educational recommendations. These types of DCI were perceived by many pharmacists as being of lower clinical significance. DCI where a referral was recommended were also associated with a higher level of clinical significance interventions (see green shaded portions of Table 4-4).

Category	Subcategory		Low Clinical Significance		High Clinical Significance		Total
			#	%	#	%	
A Change in therapy	R1	Dose increase	326	50.8	316	49.2	642
	R2	Dose decrease	298	45.4	358	54.6	656
	R3	Drug change	273	32.2	574	67.8	847
	R4	Drug formulation change	240	62.5	144	37.5	384
	R5	Drug brand change	62	64.6	34	35.4	96
	R6	Dose frequency/schedule change	330	62.4	199	37.6	529
	R7	Prescription not dispensed	115	37.5	192	62.5	307
	R8	Other changes to therapy	184	48.4	196	51.6	380
A referral required	R9	Refer to prescriber	642	35.8	1152	64.2	1794
	R10	Refer to hospital	5	13.9	31	86.1	36
	R11	Refer for medication review	36	47.4	40	52.6	76
	R12	Other referral required	23	39.7	35	60.3	58
Provision of information	R13	Education or counselling session	1649	67.6	792	32.4	2441
	R14	Written summary of medications	182	69.7	79	30.3	261
	R15	Recommend dose administration aid	44	58.7	31	41.3	75
	R16	Other written information	450	82.1	98	17.9	548
Monitoring	R17	Monitoring: Non-laboratory	131	47.3	146	52.7	277
	R18	Monitoring: Laboratory test	56	32.4	117	67.6	173
Total			5046	52.7	4534	47.3	9580

Table 4-4: Recommendations Made and their Clinical Significance

The interventions of higher significance (i.e. moderate or severe) were more likely to be undertreatment or toxicity problems (see shaded portions of Table 4-5). Educational interventions were graded as less significant by the documenting pharmacists.

Category	Low Clinical Significance		High Clinical Significance		Total
	#	%	#	%	#
Drug Selection	852	46.4	985	53.6	1837
Over/Underdose	612	51.6	573	48.4	1185
Compliance	357	64.1	200	35.9	557
Undertreated	87	32.0	185	68.0	272
Monitoring	66	47.1	74	52.9	140
Education/Information	1225	86.2	196	13.8	1421
Not Classifiable	67	60.9	43	39.1	110
Toxicity/ADR	163	36.6	282	63.4	445
Total	3429	57.5	2538	42.5	5967

Table 4-5: Clinical Significance of Different Intervention Types

4.5 Drugs Involved

For 5668 of the 5967 DCI discussed in this chapter, a specific drug was identified by the documenting pharmacist as the drug involved. A wide range of drugs (299 different generic entities) were involved, indicating that at least some types of interventions were being performed in relation to many different groups of drugs. It should be noted at this stage, however, that each intervention is listed in the database as being associated with the dispensed drug, although other drugs may be associated with the intervention. This design issue has some ramifications, as DCI in

which a drug change was made may appear to suggest that a particular drug is the problem, when in fact it is the solution.

4.5.1 Number of Clinical Interventions

When the drugs involved in the DCI are considered by generic drug name (see Table 4-1), the most common drug involved was the widely used antibiotic, amoxycillin (associated with 204, or 3.6%, of the DCI). One third of all the DCI were related to the 21 generic entities shown in Table 4-6. Despite the removal of 263 specific “step-down” PPI DCI from analyses, this class of medications was responsible for 287 (5.1%) of the overall DCI (see Table 4-8). It should be noted that there were 112 DCI in the 72 group 2 pharmacies (without the prompt) and 123 DCI in the 73 group 3 pharmacies (with the prompt). Thus the DCI examined in this chapter seem to be unrelated to the prompt. The high number of DCI in this drug group are more likely therefore, to be related to the high frequency of dispensing of this class of agents (see Table 4-12).

The vast majority of medications involved in DCI can be grouped using a multilevel anatomical therapeutic category (ATC) classification code. The groupings of the drugs involved are shown from Table 4-7 to Table 4-9. Codes are included in the tables to enable determination of members of particular therapeutic classification groups.

L5 ATC code	Generic Drug name	#	% of total
J01CA04	amoxycillin	204	3.6
A02BC05	esomeprazole	116	2.0
H02AB06	prednisolone	113	2.0
A10BA02	metformin	107	1.9
J01DB01	cephalexin	104	1.8
J01CR02	amoxycillin and enzyme inhibitor	98	1.7
N02AA05	oxycodone	95	1.7
C10AA05	atorvastatin	94	1.7
N02AA59	codeine; combinations excl. psycholeptics	92	1.6
R03AK06	salmeterol and other drugs for obstructive airway diseases	92	1.6
R03AC02	salbutamol	89	1.6
C09AA04	perindopril	83	1.5
J01FA06	roxithromycin	82	1.4
N02BE01	paracetamol	78	1.4
N02AX02	tramadol	75	1.3
J01FA01	erythromycin	68	1.2
B01AA03	warfarin	67	1.2
M01AC06	meloxicam	61	1.1
C09DA04	irbesartan and diuretics	60	1.1
A02BC02	pantoprazole	57	1.0
J01AA02	doxycycline	57	1.0
	278 others (<1% each)	3776	66.6
Total		5668	100

Table 4-6: Number of DCI Associated with Drugs (ATC L5 Coded)

L4 ATC code	Drug Group Name	#	% of total
A02BC	Proton pump inhibitors	252	4.4
C10AA	HMG CoA reductase inhibitors	210	3.7
J01CA	Penicillins with extended spectrum	204	3.6
J01FA	Macrolides	199	3.5
N02AA	Natural opium alkaloids	199	3.5
C09AA	ACE inhibitors; plain	171	3.0
H02AB	Glucocorticoids	140	2.5
N06AB	Selective serotonin reuptake inhibitors	132	2.3
N06AX	Other antidepressants	130	2.3
C09CA	Angiotensin II antagonists; plain	116	2.0
C08CA	Dihydropyridine derivatives	111	2.0
A10BA	Biguanides	107	1.9
J01DB	First-generation cephalosporins	105	1.9
R03AC	Selective beta-2-adrenoreceptor agonists	104	1.8
C09DA	Angiotensin II antagonists and diuretics	102	1.8
J01CR	Combinations of penicillins; incl. beta-lactamase inhibitors	98	1.7
R03AK	Adrenergics and other drugs for obstructive airway diseases	92	1.6
C07AB	Beta blocking agents; selective	90	1.6
N05BA	Benzodiazepine derivatives	86	1.5
N02BE	Anilides	85	1.5
R03BA	Glucocorticoids	76	1.3
N02AX	Other opioids	75	1.3
B01AA	Vitamin K antagonists	67	1.2
M01AB	Acetic acid derivatives and related substances	66	1.2
M01AC	Oxams	65	1.1
D07AC	Corticosteroids; potent (group III)	64	1.1
J01AA	Tetracyclines	62	1.1
S01AA	Antibiotics	62	1.1
B01AC	Platelet aggregation inhibitors excl. heparin	61	1.1
M05BA	Bisphosphonates	58	1.0
J01CE	Beta-lactamase sensitive penicillins	56	1.0
	232 others (<1% each)	2223	39.2
Total		5668	100.0

Table 4-7: Number of DCI Associated with Drugs (ATC L4 Coded)

L3 ATC code	Drug Group Name	#	% of total
J01C	BETA-LACTAM ANTIBACTERIALS; PENICILLINS	388	6.8
N02A	OPIOIDS	320	5.6
N06A	ANTIDEPRESSANTS	311	5.5
A02B	DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	287	5.1
C10A	LIPID MODIFYING AGENTS; PLAIN	242	4.3
M01A	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS; NON-STERIODS	216	3.8
J01F	MACROLIDES; LINCOSAMIDES AND STREPTOGRAMINS	212	3.7
R03A	ADRENERGICS; INHALANTS	196	3.5
C09A	ACE INHIBITORS; PLAIN	171	3.0
A10B	BLOOD GLUCOSE LOWERING DRUGS; EXCL. INSULINS	166	2.9
J01D	OTHER BETA-LACTAM ANTIBACTERIALS	144	2.5
H02A	CORTICOSTEROIDS FOR SYSTEMIC USE; PLAIN	141	2.5
B01A	ANTITHROMBOTIC AGENTS	140	2.5
C07A	BETA BLOCKING AGENTS	130	2.3
C09C	ANGIOTENSIN II ANTAGONISTS; PLAIN	116	2.0
C08C	SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS	111	2.0
R03B	OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES; INHALANTS	104	1.8
C09D	ANGIOTENSIN II ANTAGONISTS; COMBINATIONS	103	1.8
N02B	OTHER ANALGESICS AND ANTIPYRETICS	93	1.6
N05A	ANTIPSYCHOTICS	93	1.6
M05B	DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION	88	1.6
N05B	ANXIOLYTICS	86	1.5
D07A	CORTICOSTEROIDS; PLAIN	78	1.4
N03A	ANTIEPILEPTICS	68	1.2
J01A	TETRACYCLINES	62	1.1
S01A	ANTIINFECTIVES	62	1.1
J05A	DIRECT ACTING ANTIVIRALS	57	1.0
N05C	HYPNOTICS AND SEDATIVES	57	1.0
N07B	DRUGS USED IN ADDICTIVE DISORDERS	56	1.0
	111 others (<1% each)	1370	24.2
Total		5668	100

Table 4-8: Number of DCI Associated with Drugs (ATC L3 Coded)

L2 ATC code	Drug Group Name	#	% of total
J01	ANTIBACTERIALS FOR SYSTEMIC USE	866	15.3
C09	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	428	7.6
N02	ANALGESICS	428	7.6
N06	PSYCHOANALEPTICS	318	5.6
R03	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	302	5.3
A02	DRUGS FOR ACID RELATED DISORDERS	290	5.1
C10	LIPID MODIFYING AGENTS	264	4.7
N05	PSYCHOLEPTICS	236	4.2
M01	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	216	3.8
A10	DRUGS USED IN DIABETES	193	3.4
S01	OPHTHALMOLOGICALS	155	2.7
C08	CALCIUM CHANNEL BLOCKERS	150	2.6
H02	CORTICOSTEROIDS FOR SYSTEMIC USE	141	2.5
B01	ANTITHROMBOTIC AGENTS	140	2.5
C07	BETA BLOCKING AGENTS	130	2.3
G03	SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	111	2.0
D07	CORTICOSTEROIDS; DERMATOLOGICAL PREPARATIONS	106	1.9
M05	DRUGS FOR TREATMENT OF BONE DISEASES	88	1.6
C03	DIURETICS	81	1.4
C01	CARDIAC THERAPY	79	1.4
S02	OTOLOGICALS	69	1.2
N03	ANTIEPILEPTICS	68	1.2
N07	OTHER NERVOUS SYSTEM DRUGS	61	1.1
J05	ANTIVIRALS FOR SYSTEMIC USE	57	1.0
	47 others (< 1% each)	691	12.2
Total		5668	100.0

Table 4-9: Number of DCI Associated with Drugs (ATC L2 Coded)

As can be seen from the above tables, drugs most commonly associated with DCI were in the groups of antibiotics, analgesics and psychoactive agents, cardiovascular drugs and drugs for respiratory disorders.

4.5.2 Frequency of Clinical Interventions for Particular Drug Groups

Although some conclusions can be drawn from the frequency of DCI associated with different generic drugs and drug groups, it is more appropriate to consider the frequency of DCI in relation to the frequency of prescriptions for those drugs. In Table 4-10 to Table 4-13 the number of prescriptions dispensed at the trial pharmacies are shown at different grouping levels. It should be noted that this information represents all prescriptions dispensed (i.e. not only PBS information), hence there are some differences in the ranking when compared to PBS data.

L5 ATC Code	Description	# prescriptions	% of all prescriptions	PBS drugs Highest Volume Rank*
C10AA05	atorvastatin	75424	3.75%	1
A02BC05	esomeprazole	50079	2.49%	2
J01CA04	amoxicillin	48469	2.41%	17
C10AA01	simvastatin	42934	2.13%	3
C09AA04	perindopril	40387	2.01%	4
J01DB01	cephalexin	33870	1.68%	21
N02BE01	paracetamol	33520	1.66%	5
C09CA04	irbesartan	31824	1.58%	10
A10BA02	metformin	31381	1.56%	7
C10AA07	rosuvastatin	31087	1.54%	9
C07AB03	atenolol	29709	1.48%	8
R03AC02	salbutamol	28414	1.41%	15
N02AA59	codeine; combinations excl. psycholeptics	28386	1.41%	20
C09DA04	irbesartan and diuretics	27329	1.36%	14
J01CR02	amoxicillin and enzyme inhibitor	27050	1.34%	27
A02BC02	pantoprazole	26749	1.33%	6
C09AA05	ramipril	26163	1.30%	18
A02BC01	omeprazole	24967	1.24%	12
C08CA01	amlodipine	23840	1.18%	22
B01AA03	warfarin	23310	1.16%	19
B01AC04	clopidogrel	21848	1.08%	16
R03AK06	salmeterol and other drugs for obstructive airway diseases	21446	1.06%	-
J01FA06	roxithromycin	20953	1.04%	43
C09CA06	candesartan	20849	1.04%	25
N02AA05	oxycodone	20748	1.03%	26
N05CD07	temazepam	20726	1.03%	24
	Unknown	58559	2.91%	
	Others less than 1%	1143902	56.80%	
	Total	2013923	100.00%	

*Year ending Jun 2009 From: www.health.gov.au/internet/main/publishing.nsf/Content/pbs-stats-pbexp-jun09 Table 10(b)

Table 4-10: Number of Prescriptions for Particular Drugs (ATC L5 Coded)

The top 26 specific medications similarly match the top PBS ranked medications for the year ending June 2009. The PROMISE trial was conducted across the winter months from July to August 2009. The comparatively higher PROMISE prescription ranking for antibiotics (amoxicillin, cephalexin, amoxicillin with enzyme inhibitor and roxithromycin) likely reflects the timing of the trial.

L4 ATC Code	Description	# prescriptions	% of all prescriptions
A02BC	Proton pump inhibitors	122911	6.10%
C09AA	ACE inhibitors; plain	85587	4.25%
C09CA	Angiotensin II antagonists; plain	72812	3.62%
C08CA	Dihydropyridine derivatives	57275	2.84%
N02AA	Natural opium alkaloids	56519	2.81%
N06AB	Selective serotonin reuptake inhibitors	54757	2.72%
C09DA	Angiotensin II antagonists and diuretics	49299	2.45%
J01CA	Penicillins with extended spectrum	48490	2.41%
C07AB	Beta blocking agents; selective	46614	2.31%
B01AC	Platelet aggregation inhibitors excl. heparin	37743	1.87%
N02BE	Anilides	36063	1.79%
J01FA	Macrolides	35371	1.76%
N05BA	Benzodiazepine derivatives	35251	1.75%
N06AX	Other antidepressants	35056	1.74%
J01DB	First-generation cephalosporins	34256	1.70%
R03AC	Selective beta-2-adrenoreceptor agonists	31695	1.57%
A10BA	Biguanides	31381	1.56%
J01CR	Combinations of penicillins; incl. beta-lactamase inhibitors	27146	1.35%
N05CD	Benzodiazepine derivatives	25863	1.28%
H02AB	Glucocorticoids	25264	1.25%
B01AA	Vitamin K antagonists	23310	1.16%
R03AK	Adrenergics and other drugs for obstructive airway diseases	21446	1.06%
D07AC	Corticosteroids; potent (group III)	21095	1.05%
C09BA	ACE inhibitors and diuretics	20613	1.02%
	Unknown	58559	2.91%
	Others less than 1%	919547	45.66%
	Total	2013923	100.00%

Table 4-11: Trial Prescriptions (ATC L4 Coded)

L3 ATC Code	Description	# prescriptions	% of all prescriptions
C10A	LIPID MODIFYING AGENTS; PLAIN	173169	8.60%
A02B	DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	132910	6.60%
N06A	ANTIDEPRESSANTS	109020	5.41%
N02A	OPIOIDS	87490	4.34%
J01C	BETA-LACTAM ANTIBACTERIALS; PENICILLINS	85703	4.26%
C09A	ACE INHIBITORS; PLAIN	85587	4.25%
C09C	ANGIOTENSIN II ANTAGONISTS; PLAIN	72812	3.62%
B01A	ANTITHROMBOTIC AGENTS	63572	3.16%
C07A	BETA BLOCKING AGENTS	58996	2.93%
C08C	SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS	57275	2.84%
A10B	BLOOD GLUCOSE LOWERING DRUGS; EXCL. INSULINS	56766	2.82%
R03A	ADRENERGICS; INHALANTS	53141	2.64%
M01A	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS; NON-STERIODS	49956	2.48%
C09D	ANGIOTENSIN II ANTAGONISTS; COMBINATIONS	49907	2.48%
J01D	OTHER BETA-LACTAM ANTIBACTERIALS	44419	2.21%
N02B	OTHER ANALGESICS AND ANTIPYRETICS	37176	1.85%
J01F	MACROLIDES; LINCOSAMIDES AND STREPTOGRAMINS	36364	1.81%
N05B	ANXIOLYTICS	35288	1.75%
R03B	OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES; INHALANTS	33077	1.64%
S01E	ANTIGLAUCOMA PREPARATIONS AND MIOTICS	31487	1.56%
N05C	HYPNOTICS AND SEDATIVES	30607	1.52%
D07A	CORTICOSTEROIDS; PLAIN	29158	1.45%
N05A	ANTIPSYCHOTICS	27889	1.38%
H02A	CORTICOSTEROIDS FOR SYSTEMIC USE; PLAIN	25443	1.26%
M05B	DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION	24382	1.21%
C09B	ACE INHIBITORS; COMBINATIONS	22109	1.10%
	Unknown	58559	2.91%
	Others less than 1%	441661	21.93%
Total		2013923	100.00%

Table 4-12: Trial Prescriptions (ATC L3 Coded)

L2 ATC Code	Description	# prescriptions	% of all prescriptions
C09	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	230415	11.44%
J01	ANTIBACTERIALS FOR SYSTEMIC USE	196806	9.77%
C10	LIPID MODIFYING AGENTS	183423	9.11%
A02	DRUGS FOR ACID RELATED DISORDERS	134696	6.69%
N02	ANALGESICS	130181	6.46%
N06	PSYCHOANALEPTICS	115374	5.73%
N05	PSYCHOLEPTICS	93784	4.66%
R03	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	88009	4.37%
S01	OPHTHALMOLOGICALS	77343	3.84%
C08	CALCIUM CHANNEL BLOCKERS	76654	3.81%
B01	ANTITHROMBOTIC AGENTS	63572	3.16%
A10	DRUGS USED IN DIABETES	62499	3.10%
C07	BETA BLOCKING AGENTS	58996	2.93%
M01	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	50028	2.48%
G03	SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	49119	2.44%
D07	CORTICOSTEROIDS; DERMATOLOGICAL PREPARATIONS	32333	1.61%
H02	CORTICOSTEROIDS FOR SYSTEMIC USE	25443	1.26%
C01	CARDIAC THERAPY	25077	1.25%
M05	DRUGS FOR TREATMENT OF BONE DISEASES	24382	1.21%
C03	DIURETICS	23446	1.16%
	Unknown	58559	2.91%
	Less than 1%	213784	10.62%
	Total	2013923	100.00%

Table 4-13: Trial Prescriptions (ATC L2 Coded)

In the next series of tables, the number of DCI and the number of prescriptions are combined, providing a ranking for different drugs and drug groups in terms of intervention frequency.

Table 4-14 shows the rate (number of DCI per 100 prescriptions) of DCI for individual generic drugs where more than 1% of the total number of DCI were recorded against that particular generic drug. Subsequent tables show similar information at ATC level 4, 3 and 2 codes.

L5 ATC Code	Description	# interventions (>1% of interventions)	# prescriptions	interventions percent of prescription group
J01CE02	phenoxymethylpenicillin	55	4748	1.16
J01FA01	erythromycin	68	6963	0.98
H02AB06	prednisolone	113	17788	0.64
N02AX02	tramadol	75	16067	0.47
N02AA05	oxycodone	95	20748	0.46
R03AK06	salmeterol and other drugs for obstructive airway diseases	92	21446	0.43
J01CA04	amoxycillin	204	48469	0.42
J01AA02	doxycycline	57	13615	0.42
J01FA06	roxithromycin	82	20953	0.39
J01CR02	amoxycillin and enzyme inhibitor	98	27050	0.36
M01AC06	meloxicam	61	17569	0.35
A10BA02	metformin	107	31381	0.34
N02AA59	codeine; combinations excl. psycholeptics	92	28386	0.32
R03AC02	salbutamol	89	28414	0.31
J01DB01	cephalexin	104	33870	0.31
B01AA03	warfarin	67	23310	0.29
N02BE01	paracetamol	78	33520	0.23
A02BC05	esomeprazole	116	50079	0.23
C09DA04	irbesartan and diuretics	60	27329	0.22
C09AA05	ramipril	56	26163	0.21
A02BC02	pantoprazole	57	26749	0.21
C09AA04	perindopril	83	40387	0.21
C10AA07	rosuvastatin	55	31087	0.18
C10AA05	atorvastatin	94	75424	0.12
Unknown		87	52260	0.17
Others less than 1%		3523	1283849	0.27
Total		5668	2007624	0.28

Table 4-14: DCI as a Proportion of ATC L5 Coding

The medications with the highest proportions of DCI were the antibiotics phenoxymethylpenicillin and erythromycin. Several different penicillins are represented in this table. Typical concerns with penicillins include allergies and correct paediatric dosing. Erythromycin has a large number of drug interactions perhaps indicating its number two position in the table as well as similar concerns to penicillins. As mentioned previously the PROMISe trial was conducted over the winter months of July to September 2009 with higher volumes of antibiotic prescriptions by rank compared to PBS data. This is likely to have led to more DCI within these particular drug groups.

L4 ATC Code (>1% of interventions)	Description	# interventions	# prescriptions	interventions percent of prescription group
J01CE	Beta-lactamase sensitive penicillins	56	5162	1.08
M01AB	Acetic acid derivatives and related substances	66	11528	0.57
J01FA	Macrolides	199	35371	0.56
H02AB	Glucocorticoids	140	25264	0.55
N02AX	Other opioids	75	16067	0.47
R03BA	Glucocorticoids	76	16988	0.45
R03AK	Adrenergics and other drugs for obstructive airway diseases	92	21446	0.43
J01CA	Penicillins with extended spectrum	204	48490	0.42
S01AA	Antibiotics	62	15977	0.39
J01AA	Tetracyclines	62	16208	0.38
N06AX	Other antidepressants	130	35056	0.37
J01CR	Combinations of penicillins; incl. beta-lactamase inhibitors	98	27146	0.36
N02AA	Natural opium alkaloids	199	56519	0.35
M05BA	Bisphosphonates	58	16828	0.34
A10BA	Biguanides	107	31381	0.34
M01AC	Oxicams	65	19087	0.34
R03AC	Selective beta-2-adrenoreceptor agonists	104	31695	0.33
J01DB	First-generation cephalosporins	105	34256	0.31
D07AC	Corticosteroids; potent (group III)	64	21095	0.30
B01AA	Vitamin K antagonists	67	23310	0.29
N05BA	Benzodiazepine derivatives	86	35251	0.24
N06AB	Selective serotonin reuptake inhibitors	132	54757	0.24
N02BE	Anilides	85	36063	0.24
C09DA	Angiotensin II antagonists and diuretics	102	49299	0.21
A02BC	Proton pump inhibitors	252	122911	0.21
C09AA	ACE inhibitors; plain	171	85587	0.20
C08CA	Dihydropyridine derivatives	111	57275	0.19
C07AB	Beta blocking agents; selective	90	46614	0.19
B01AC	Platelet aggregation inhibitors excl. heparin	61	37743	0.16
C09CA	Angiotensin II antagonists; plain	116	72812	0.16
C10AA	HMG CoA reductase inhibitors	210	160129	0.13
	Unknown	87	52260	0.17
	Others Less than 1%	2136	688049	0.31
	Total	5668	2007624	0.28

Table 4-15: DCI as a Proportion of ATC L4 Coding

L3 ATC Code (>1% of interventions)	Description	# intervention s	# prescription s	interventions percent of prescription group
N07B	DRUGS USED IN ADDICTIVE DISORDERS	56	5649	0.99
J05A	DIRECT ACTING ANTIVIRALS	57	6701	0.85
J01F	MACROLIDES; LINCOSAMIDES AND STREPTOGRAMINS	212	36364	0.58
H02A	CORTICOSTEROIDS FOR SYSTEMIC USE; PLAIN	141	25443	0.55
J01C	BETA-LACTAM ANTIBACTERIALS; PENICILLINS	388	85703	0.45
M01A	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS; NON-STERIODS	216	49956	0.43
J01A	TETRACYCLINES	62	16208	0.38
S01A	ANTIINFECTIVES	62	16226	0.38
R03A	ADRENERGICS; INHALANTS	196	53141	0.37
N02A	OPIOIDS	320	87490	0.37
N03A	ANTIEPILEPTICS	68	18732	0.36
M05B	DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION	88	24382	0.36
N05A	ANTIPSYCHOTICS	93	27889	0.33
J01D	OTHER BETA-LACTAM ANTIBACTERIALS	144	44419	0.32
R03B	OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES; INHALANTS	104	33077	0.31
A10B	BLOOD GLUCOSE LOWERING DRUGS; EXCL. INSULINS	166	56766	0.29
N06A	ANTIDEPRESSANTS	311	109020	0.29
D07A	CORTICOSTEROIDS; PLAIN	78	29158	0.27
N02B	OTHER ANALGESICS AND ANTIPYRETICS	93	37176	0.25
N05B	ANXIOLYTICS	86	35288	0.24
C07A	BETA BLOCKING AGENTS	130	58996	0.22
B01A	ANTITHROMBOTIC AGENTS	140	63572	0.22
A02B	DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	287	132910	0.22
C09D	ANGIOTENSIN II ANTAGONISTS; COMBINATIONS	103	49907	0.21
C09A	ACE INHIBITORS; PLAIN	171	85587	0.20
C08C	SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS	111	57275	0.19
N05C	HYPNOTICS AND SEDATIVES	57	30607	0.19
C09C	ANGIOTENSIN II ANTAGONISTS; PLAIN	116	72812	0.16
C10A	LIPID MODIFYING AGENTS; PLAIN	242	173169	0.14
	Unknown	87	52260	0.17
	Others less than 1%	1283	431741	0.30
	Total	5668	2007624	0.28

Table 4-16: DCI as a Proportion of ATC L3 Coding

L2 ATC Code (>1% of interventions)	Description	# interventions	# prescriptions	interventions percent of prescription group
J05	ANTIVIRALS FOR SYSTEMIC USE	57	6701	0.85
S02	OTOLOGICALS	69	8120	0.85
N07	OTHER NERVOUS SYSTEM DRUGS	61	7229	0.84
H02	CORTICOSTEROIDS FOR SYSTEMIC USE	141	25443	0.55
J01	ANTIBACTERIALS FOR SYSTEMIC USE	866	196806	0.44
M01	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	216	50028	0.43
N03	ANTIEPILEPTICS	68	18732	0.36
M05	DRUGS FOR TREATMENT OF BONE DISEASES	88	24382	0.36
C03	DIURETICS	81	23446	0.35
R03	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	302	88009	0.34
N02	ANALGESICS	428	130181	0.33
D07	CORTICOSTEROIDS; DERMATOLOGICAL PREPARATIONS	106	32333	0.33
C01	CARDIAC THERAPY	79	25077	0.32
A10	DRUGS USED IN DIABETES	193	62499	0.31
N06	PSYCHOANALEPTICS	318	115374	0.28
N05	PSYCHOLEPTICS	236	93784	0.25
G03	SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	111	49119	0.23
C07	BETA BLOCKING AGENTS	130	58996	0.22
B01	ANTITHROMBOTIC AGENTS	140	63572	0.22
A02	DRUGS FOR ACID RELATED DISORDERS	290	134696	0.22
S01	OPHTHALMOLOGICALS	155	77343	0.20
C08	CALCIUM CHANNEL BLOCKERS	150	76654	0.20
C09	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	428	230415	0.19
C10	LIPID MODIFYING AGENTS	264	183423	0.14
	Unknown	87	52260	0.17
	Others less than 1%	604	173002	0.35
	Total	5668	2007624	0.28

Table 4-17: DCI as a Proportion of ATC L2 Coding

4.5.3 Clinical Significance of Interventions related to Specific Groups of Drugs

Those drug groups allocated with one percent or more of DCI were investigated in terms of lower or higher significance. The significance was assigned by the intervening pharmacist, high significance indicating the need for general practitioner consultation or hospitalisation.

L5 ATC code (≥1% of interventions)	Description	Low Significance	High Significance	proportion high significance for drug
C09DA04	irbesartan and diuretics	25	35	0.58
B01AA03	warfarin	28	39	0.58
C09AA04	perindopril	36	47	0.57
N02AX02	tramadol	36	39	0.52
M01AC06	meloxicam	30	31	0.51
J01FA06	roxithromycin	41	41	0.50
J01FA01	erythromycin	34	34	0.50
J01CR02	amoxycillin and enzyme inhibitor	52	46	0.47
A10BA02	metformin	57	50	0.47
H02AB06	prednisolone	61	52	0.46
C10AA05	atorvastatin	51	43	0.46
N02BE01	paracetamol	44	34	0.44
N02AA59	codeine; combinations excl. psycholeptics	52	40	0.43
R03AC02	salbutamol	53	36	0.40
J01AA02	doxycycline	35	22	0.39
J01CA04	amoxycillin	127	77	0.38
J01DB01	cefalexin	66	38	0.37
N02AA05	oxycodone	64	31	0.33
R03AK06	salmeterol and other drugs for obstructive airway diseases	68	24	0.26
A02BC05	esomeprazole	88	28	0.24
A02BC02	pantoprazole	45	12	0.21
	Others less than 1%	2190	1586	0.42
	Total	3283	2385	0.42

Table 4-18: DCI Ranked by Proportion of Higher Significance (ATC L5 Coded)

Combination irbesartan and diuretics, warfarin and perindopril recorded the most DCI with a higher significance (doctor visit/avoidance or hospitalisation/avoidance) Table 4-18. These three medications were listed in Table 4-14 with DCI as a proportion of that medication type.

Irbesartan and diuretic combinations were responsible for the greatest proportion of high significance interventions. This is likely to be due to a combination of factors, including potential interactions involving either of the ingredients with other medications or medical conditions.

Warfarin was, not surprisingly, high on this list with its many interactions, narrow therapeutic range, and potential for serious sequelae.

Perindopril was third on the list; ACE inhibitors having a number of potential medication and disease interactions, including commonly a dry cough side effect which typically requires a doctor consultation for a change of therapy. It was also the most commonly prescribed ACE inhibitor see Table 4-19.

L4 ATC code (≥1% of interventions)	Description	Low Significance	High Significance	proportion high significance for drug
C09DA	Angiotensin II antagonists and diuretics	39	63	0.62
B01AA	Vitamin K antagonists	28	39	0.58
J01FA	Macrolides	89	110	0.55
C07AB	Beta blocking agents; selective	42	48	0.53
N02AX	Other opioids	36	39	0.52
B01AC	Platelet aggregation inhibitors excl. heparin	30	31	0.51
M01AC	Oxicams	32	33	0.51
C08CA	Dihydropyridine derivatives	55	56	0.50
C09AA	ACE inhibitors; plain	89	82	0.48
N06AB	Selective serotonin reuptake inhibitors	70	62	0.47
J01CR	Combinations of penicillins; incl. beta-lactamase inhibitors	52	46	0.47
A10BA	Biguanides	57	50	0.47
C09CA	Angiotensin II antagonists; plain	64	52	0.45
H02AB	Glucocorticoids	78	62	0.44
N02BE	Anilides	48	37	0.44
C10AA	HMG CoA reductase inhibitors	124	86	0.41
J01CE	Beta-lactamase sensitive penicillins	34	22	0.39
N06AX	Other antidepressants	79	51	0.39
J01AA	Tetracyclines	38	24	0.39
N02AA	Natural opium alkaloids	122	77	0.39
R03AC	Selective beta-2-adrenoreceptor agonists	64	40	0.38
N05BA	Benzodiazepine derivatives	53	33	0.38
M01AB	Acetic acid derivatives and related substances	41	25	0.38
J01CA	Penicillins with extended spectrum	127	77	0.38
M05BA	Bisphosphonates	37	21	0.36
J01DB	First-generation cephalosporins	67	38	0.36
S01AA	Antibiotics	42	20	0.32
R03BA	Glucocorticoids	53	23	0.30
A02BC	Proton pump inhibitors	176	76	0.30
D07AC	Corticosteroids; potent (group III)	47	17	0.27
R03AK	Adrenergics and other drugs for obstructive airway diseases	68	24	0.26
	Others less than 1%	1302	921	0.41
	Total	3283	2385	0.42

Table 4-19: DCI Ranked by Proportion of Higher Significance at ATC L4 Coding

L3 ATC code (≥1% of interventions)	Description	Low Significance	High Significance	Proportion high significance for drug
C09D	ANGIOTENSIN II ANTAGONISTS; COMBINATIONS	39	64	0.62
B01A	ANTITHROMBOTIC AGENTS	61	79	0.56
J01F	MACROLIDES; LINCOSAMIDES AND STREPTOGRAMINS	95	117	0.55
C07A	BETA BLOCKING AGENTS	64	66	0.51
C08C	SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS	55	56	0.50
A10B	BLOOD GLUCOSE LOWERING DRUGS; EXCL. INSULINS	83	83	0.50
J05A	DIRECT ACTING ANTIVIRALS	29	28	0.49
C09A	ACE INHIBITORS; PLAIN	89	82	0.48
M01A	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS; NON-STERIODS	114	102	0.47
N05A	ANTIPSYCHOTICS	51	42	0.45
C09C	ANGIOTENSIN II ANTAGONISTS; PLAIN	64	52	0.45
H02A	CORTICOSTEROIDS FOR SYSTEMIC USE; PLAIN	79	62	0.44
N02B	OTHER ANALGESICS AND ANTIPYRETICS	53	40	0.43
N02A	OPIOIDS	183	137	0.43
N03A	ANTIEPILEPTICS	39	29	0.43
N06A	ANTIDEPRESSANTS	179	132	0.42
J01C	BETA-LACTAM ANTIBACTERIALS; PENICILLINS	226	162	0.42
J01D	OTHER BETA-LACTAM ANTIBACTERIALS	86	58	0.40
C10A	LIPID MODIFYING AGENTS; PLAIN	145	97	0.40
J01A	TETRACYCLINES	38	24	0.39
M05B	DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION	54	34	0.39
N05B	ANXIOLYTICS	53	33	0.38
R03B	OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES; INHALANTS	70	34	0.33
R03A	ADRENERGICS; INHALANTS	132	64	0.33
S01A	ANTIINFECTIVES	42	20	0.32
A02B	DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	200	87	0.30
N05C	HYPNOTICS AND SEDATIVES	40	17	0.30
N07B	DRUGS USED IN ADDICTIVE DISORDERS	42	14	0.25
D07A	CORTICOSTEROIDS; PLAIN	59	19	0.24
	Others less than 1%	819	551	0.40
	Total	3283	2385	0.42

Table 4-20: DCI Ranked by Proportion of Higher Significance at ATC L3 Coding

L2 ATC code (≥1% of interventions)	Description	Low Significance	High Significance	Proportion high significance for drug
C03	DIURETICS	35	46	0.57
B01	ANTITHROMBOTIC AGENTS	61	79	0.56
C01	CARDIAC THERAPY	37	42	0.53
C09	AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	208	220	0.51
C07	BETA BLOCKING AGENTS	64	66	0.51
C08	CALCIUM CHANNEL BLOCKERS	75	75	0.50
A10	DRUGS USED IN DIABETES	97	96	0.50
J05	ANTIVIRALS FOR SYSTEMIC USE	29	28	0.49
M01	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	114	102	0.47
S02	OTOLOGICALS	38	31	0.45
J01	ANTIBACTERIALS FOR SYSTEMIC USE	480	386	0.45
H02	CORTICOSTEROIDS FOR SYSTEMIC USE	79	62	0.44
N02	ANALGESICS	245	183	0.43
N03	ANTIEPILEPTICS	39	29	0.43
N06	PSYCHOANALEPTICS	184	134	0.42
C10	LIPID MODIFYING AGENTS	159	105	0.40
N05	PSYCHOLEPTICS	144	92	0.39
M05	DRUGS FOR TREATMENT OF BONE DISEASES	54	34	0.39
S01	OPHTHALMOLOGICALS	101	54	0.35
R03	DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	203	99	0.33
A02	DRUGS FOR ACID RELATED DISORDERS	203	87	0.30
D07	CORTICOSTEROIDS; DERMATOLOGICAL PREPARATIONS	76	30	0.28
G03	SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	83	28	0.25
N07	OTHER NERVOUS SYSTEM DRUGS	46	15	0.25
	Others less than 1%	429	262	0.38
	Total	3283	2385	0.42

Table 4-21: DCI Ranked by Proportion of Higher Significance at ATC L2 Coding

4.5.4 Nature of Clinical Interventions for Specific Groups of Drugs

Groups of drugs of interest (for example, groups with either a high number of DCI, a high rate of DCI, or drug groups that are known from the literature to have a high rate of drug-related problems) were examined for different characteristics. The following high rates of DCI per drug group were examined in terms of the category of intervention and the clinical significance as assigned by the recording pharmacist:

- Antivirals for systemic use
- Other nervous system drugs
- Corticosteroids for systemic use
- Antibacterials for systemic use
- Antiinflammatory and antirheumatic products

The otologicals drug group also had a high rate of DCI, but many of these were due to specific products (Sofradex® and Otodex®) being out of stock during the course of the trial, so this group was not further examined.

The following high frequency intervention groups were examined in terms of the category of intervention and the clinical significance as assigned by the recording pharmacist:

- Proton pump inhibitors
- HMG CoA reductase inhibitors

- Natural opium alkaloids
- Ace inhibitors; plain

Antivirals for systemic use

The DCI relating to antivirals are examined in Table 4-22. Problems with correct dosing, drug selection, and education occurred frequently in association with this group of medications.

Problems relating to dose being too high accounted for 12 of the DCI in this group of medications. The majority of these concerned paediatric dosing of Tamiflu®. These DCI occurred during a period of time where there was significant concern regarding an outbreak of Swine Flu and it is unlikely that such DCI would form a significant part of future interventions.

Int Code	Int Category	Int Sub Category	Number	%	%
D1	Drug Selection	Duplication	0	0.0%	22.8%
D2		Drug Interaction	0	0.0%	
D3		Wrong Drug	2	3.5%	
D4		Incorrect Strength	3	5.3%	
D5		Inappropriate Dose Form	2	3.5%	
D6		Contraindications Apparent	1	1.8%	
D7		No Indication Apparent	0	0.0%	
D0		Other Drug Selection Problem	5	8.8%	
O1	Over/Underdose	Dose Too High	12	21.1%	45.6%
O2		Dose Too Low	7	12.3%	
O3		Incorrect Dose Instructions	6	10.5%	
O0		Other Dose Problem	1	1.8%	
C1	Compliance	Taking Too Little	0	0.0%	1.8%
C2		Taking Too Much	0	0.0%	
C3		Erratic Use of Medication	1	1.8%	
C4		Intentional Misuse	0	0.0%	
C5		Difficulty Using Dose Form	0	0.0%	
C0		Other Compliance Problem	0	0.0%	
U1	Undertreated	Condition Undertreated	1	1.8%	3.5%
U2		Condition Untreated	1	1.8%	
U3		Preventive Therapy required	0	0.0%	
U0		Other Undertreated Problem	0	0.0%	
M1	Monitoring	Laboratory Monitoring	0	0.0%	0.0%
M2		Non-Laboratory Monitoring	0	0.0%	
M0		Other Monitoring Problem	0	0.0%	
E1	Education/Information	Patient Drug Info Request	4	7.0%	22.8%
E2		Patient Disease Info Request	8	14.0%	
E0		Other Education Problem	1	1.8%	
N0	Not Classifiable	Not Classifiable	2	3.5%	3.5%
T1	Toxicity/ADR	Toxicity/ADR present	0	0.0%	0.0%
Total			57	100.0%	100.0%

Table 4-22: Categories and Subcategories of DCI Associated with Antivirals for Systemic Use

A higher proportion of DCI associated with antiviral agents prevented or required a doctor visit (S3) compared with the proportion in the entire PROMISE dataset, Table 4-23. There was no significant difference between Antiviral Agents and the PROMISE Dataset ($\chi^2=3.05$, $df=3$, $p= 0.38$).

Clinical Significance	Antiviral Agents		PROMISE Dataset	
	Number	%	Number	%
S1	7	12.3%	865	15.3%
S2	22	38.6%	2418	42.7%
S3	26	45.6%	2007	35.4%
S4	2	3.5%	378	6.7%
Total	57	100.0%	5668	100.0%

Table 4-23: Clinical Significance of DCI Associated with Antivirals for Systemic Use

Other nervous system drugs

The DCI relating to other nervous system drugs are examined in Table 4-24. Problems with education, over/underdosage and drug selection occurred frequently in association with this group of medications.

Problems relating to patient drug information requests accounted for 20 of the DCI in this group of medications.

Int Code	Int Category	Int Sub Category	Number	%	%
D1	Drug Selection	Duplication	0	0.0%	14.8%
D2		Drug Interaction	1	1.6%	
D3		Wrong Drug	3	4.9%	
D4		Incorrect Strength	3	4.9%	
D5		Inappropriate Dose Form	1	1.6%	
D6		Contraindications Apparent	1	1.6%	
D7		No Indication Apparent	0	0.0%	
D0		Other Drug Selection Problem	0	0.0%	
O1	Over/Underdose	Dose Too High	2	3.3%	19.7%
O2		Dose Too Low	4	6.6%	
O3		Incorrect Dose Instructions	6	9.8%	
O0		Other Dose Problem	0	0.0%	
C1	Compliance	Taking Too Little	0	0.0%	6.6%
C2		Taking Too Much	1	1.6%	
C3		Erratic Use of Medication	2	3.3%	
C4		Intentional Misuse	0	0.0%	
C5		Difficulty Using Dose Form	0	0.0%	
C0		Other Compliance Problem	1	1.6%	
U1	Undertreated	Condition Undertreated	2	3.3%	4.9%
U2		Condition Untreated	0	0.0%	
U3		Preventive Therapy required	1	1.6%	
U0		Other Undertreated Problem	0	0.0%	
M1	Monitoring	Laboratory Monitoring	0	0.0%	0.0%
M2		Non-Laboratory Monitoring	0	0.0%	
M0		Other Monitoring Problem	0	0.0%	
E1	Education/Information	Patient Drug Info Request	20	32.8%	49.2%
E2		Patient Disease Info Request	4	6.6%	
E0		Other Education Problem	6	9.8%	
N0	Not Classifiable	Not Classifiable	0	0.0%	0.0%
T1	Toxicity/ADR	Toxicity/ADR present	3	4.9%	4.9%
Total			61	100.0%	100.0%

Table 4-24: Categories and Subcategories of DCI Associated with Other Nervous System Drugs

Clinical Significance	Other Nervous System Drugs		PROMISe Dataset	
	Number	%	Number	%
S1	14	23.0%	865	15.3%
S2	32	52.5%	2418	42.7%
S3	13	21.3%	2007	35.4%
S4	2	3.3%	378	6.7%
Total	61	100.0%	5668	100.0%

Table 4-25: Clinical Significance of DCI Associated with Other Nervous System Drugs

The clinical significance of a high proportion of DCI associated with other nervous system drugs were information related (S1), or prevented mild symptoms or improved compliance (S2) compared with the proportion in the entire

PROMISe dataset, Table 4-25. There was a significant difference between Other Nervous System Drugs and the PROMISe Dataset ($\chi^2=8.13$, $df=3$, $p= 0.04$).

Corticosteroids for systemic use

The DCI relating to corticosteroids are examined in Table 4-26. Problems with over/under dose, education, and drug selection occurred frequently in association with this group of medications. Problems relating to incorrect dosage instructions accounted for 30 of the DCI in this group of medications, many of these involving no defined duration of use.

Int Code	Int Category	Int Sub Category	Number	%	%
D1	Drug Selection	Duplication	0	0.0%	12.1%
D2		Drug Interaction	1	0.7%	
D3		Wrong Drug	2	1.4%	
D4		Incorrect Strength	3	2.1%	
D5		Inappropriate Dose Form	1	0.7%	
D6		Contraindications Apparent	2	1.4%	
D7		No Indication Apparent	1	0.7%	
D0		Other Drug Selection Problem	7	5.0%	
O1	Over/Underdose	Dose Too High	10	7.1%	36.2%
O2		Dose Too Low	8	5.7%	
O3		Incorrect Dose Instructions	30	21.3%	
O0		Other Dose Problem	3	2.1%	
C1	Compliance	Taking Too Little	1	0.7%	8.5%
C2		Taking Too Much	2	1.4%	
C3		Erratic Use of Medication	2	1.4%	
C4		Intentional Misuse	0	0.0%	
C5		Difficulty Using Dose Form	2	1.4%	
C0		Other Compliance Problem	5	3.5%	
U1	Undertreated	Condition Undertreated	4	2.8%	9.2%
U2		Condition Untreated	1	0.7%	
U3		Preventive Therapy required	8	5.7%	
U0		Other Undertreated Problem	0	0.0%	
M1	Monitoring	Laboratory Monitoring	1	0.7%	2.8%
M2		Non-Laboratory Monitoring	1	0.7%	
M0		Other Monitoring Problem	2	1.4%	
E1	Education/Information	Patient Drug Info Request	22	15.6%	25.5%
E2		Patient Disease Info Request	6	4.3%	
E0		Other Education Problem	8	5.7%	
N0	Not Classifiable	Not Classifiable	4	2.8%	2.8%
T1	Toxicity/ADR	Toxicity/ADR present	4	2.8%	2.8%
Total			141	100.0%	100.0%

Table 4-26: Categories and Subcategories of DCI Associated with Corticosteroids for Systemic Use

The clinical significances of DCI associated with corticosteroids for systemic use were closely matched with the proportion in the entire PROMISe dataset Table 4-27. There was no significant difference between Systemic Corticosteroidal Agents and the PROMISe Dataset ($\chi^2=0.66$, $df=3$, $p= 0.88$)

Clinical Significance	Systemic Corticosteroidal		PROMISe Dataset	
	Number	%	Number	%
S1	20	14.2%	865	15.3%
S2	59	41.8%	2418	42.7%
S3	54	38.3%	2007	35.4%
S4	8	5.7%	378	6.7%
Total	141	100.0%	5668	100.0%

Table 4-27: Clinical Significance of DCI Associated with Corticosteroids for Systemic Use

Antibacterials for systemic use

The DCI relating to antibacterials for systemic use are examined in Table 4-28. Problems with drug selection, under/overdosing and education occurred frequently in association with this group of medications.

Problems relating to dose too low accounted for 95 of the DCI in this group of medications, and incorrect dose instructions accounted for another 83 DCI in this group.

Int Code	Int Category	Int Sub Category	Number	%	%
D1	Drug Selection	Duplication	10	1.2%	32.1%
D2		Drug Interaction	65	7.5%	
D3		Wrong Drug	25	2.9%	
D4		Incorrect Strength	38	4.4%	
D5		Inappropriate Dose Form	46	5.3%	
D6		Contraindications Apparent	46	5.3%	
D7		No Indication Apparent	2	0.2%	
D0		Other Drug Selection Problem	46	5.3%	
O1	Over/Underdose	Dose Too High	63	7.3%	28.8%
O2		Dose Too Low	95	11.0%	
O3		Incorrect Dose Instructions	83	9.6%	
O0		Other Dose Problem	8	0.9%	
C1	Compliance	Taking Too Little	0	0.0%	2.4%
C2		Taking Too Much	2	0.2%	
C3		Erratic Use of Medication	1	0.1%	
C4		Intentional Misuse	0	0.0%	
C5		Difficulty Using Dose Form	7	0.8%	
C0		Other Compliance Problem	11	1.3%	
U1	Undertreated	Condition Undertreated	19	2.2%	2.9%
U2		Condition Untreated	5	0.6%	
U3		Preventive Therapy required	0	0.0%	
U0		Other Undertreated Problem	1	0.1%	
M1	Monitoring	Laboratory Monitoring	6	0.7%	2.4%
M2		Non-Laboratory Monitoring	13	1.5%	
M0		Other Monitoring Problem	2	0.2%	
E1	Education/Information	Patient Drug Info Request	66	7.6%	21.4%
E2		Patient Disease Info Request	33	3.8%	
E0		Other Education Problem	86	9.9%	
N0	Not Classifiable	Not Classifiable	11	1.3%	1.3%
T1	Toxicity/ADR	Toxicity/ADR present	76	8.8%	8.8%
Total			866	100.0%	100.0%

Table 4-28: Categories and Subcategories of DCI Associated with Antibacterials for Systemic Use

The clinical significance of DCI associated with Antibiotics for Systemic Use were representative of the entire PROMISe dataset Table 4-29. There was no significant difference between Systemic Antibacterials and the PROMISe Dataset ($\chi^2=6.64$, $df=3$, $p= 0.08$).

Clinical Significance	Systemic Antibacterial		PROMISe Dataset	
	Number	%	Number	%
s1	116	13.4%	865	15.3%
s2	364	42.0%	2418	42.7%
s3	310	35.8%	2007	35.4%
s4	76	8.8%	378	6.7%
Total	866	100.0%	5668	100.0%

Table 4-29: Clinical Significance of DCI Associated with Antibacterials for Systemic Use

Antiinflammatory and antirheumatic products

The DCI relating to anti-inflammatory and antirheumatic products are examined in Table 4-30. Problems with drug selection, education, under/overdosing and toxicity occurred frequently in association with this group of medications.

Problems relating to drug interactions accounted for 35 and drug duplication accounted for 26 of the DCI in this group of medications. A large proportion of the drug interactions involved warfarin, concomitant usage of ACE inhibitors and diuretics, and duplication of OTC NSAIDs. The drug duplication DCI involved OTC NSAID requests, and duplication of prescribed NSAIDs.

Int Code	Int Category	Int Sub Category	Number	%	%
D1	Drug Selection	Duplication	26	12.0%	42.1%
D2		Drug Interaction	35	16.2%	
D3		Wrong Drug	3	1.4%	
D4		Incorrect Strength	3	1.4%	
D5		Inappropriate Dose Form	0	0.0%	
D6		Contraindications Apparent	16	7.4%	
D7		No Indication Apparent	1	0.5%	
D0		Other Drug Selection Problem	7	3.2%	
O1	Over/Underdose	Dose Too High	13	6.0%	10.6%
O2		Dose Too Low	2	0.9%	
O3		Incorrect Dose Instructions	5	2.3%	
O0		Other Dose Problem	3	1.4%	
C1	Compliance	Taking Too Little	1	0.5%	3.7%
C2		Taking Too Much	3	1.4%	
C3		Erratic Use of Medication	2	0.9%	
C4		Intentional Misuse	1	0.5%	
C5		Difficulty Using Dose Form	0	0.0%	
C0		Other Compliance Problem	1	0.5%	
U1	Undertreated	Condition Undertreated	5	2.3%	3.7%
U2		Condition Untreated	1	0.5%	
U3		Preventive Therapy required	2	0.9%	
U0		Other Undertreated Problem	0	0.0%	
M1	Monitoring	Laboratory Monitoring	6	2.8%	4.6%
M2		Non-Laboratory Monitoring	2	0.9%	
M0		Other Monitoring Problem	2	0.9%	
E1	Education/Information	Patient Drug Info Request	22	10.2%	23.1%
E2		Patient Disease Info Request	11	5.1%	
E0		Other Education Problem	17	7.9%	
N0	Not Classifiable	Not Classifiable	4	1.9%	1.9%
T1	Toxicity/ADR	Toxicity/ADR present	22	10.2%	10.2%
Total			216	100.0%	100.0%

Table 4-30: Categories and Subcategories of DCI Associated with Antiinflammatory and Antirheumatic Products

A higher proportion of DCI associated with anti-inflammatory and antirheumatic products prevented or required a hospital admission (S4) compared with the proportion in the entire PROMISe dataset Table 4-31. There was a significant difference between Antiinflammatory and Antirheumatic Products and the PROMISe Dataset ($\chi^2=9.73$, $df=3$, $p= 0.02$).

Clinical Significance	Antiinflammatory Agents		PROMISe Dataset	
	Number	%	Number	%
S1	29	13.4%	865	15.3%
S2	85	39.4%	2418	42.7%
S3	76	35.2%	2007	35.4%
S4	26	12.0%	378	6.7%
Total	216	100.0%	5668	100.0%

Table 4-31: Clinical Significance of DCI Associated with Antiinflammatory and Antirheumatic products

The following groups had high frequencies of DCI recorded.

Proton Pump Inhibitors

The DCI relating to proton pump inhibitors are examined in Table 4-32. Problems with other education occurred frequently in association with this group of medications. Many of the DCI classified here could have been classified under more appropriate selections such as drug interaction, incorrect strength, and condition undertreated.

Problems relating to dose too high (some prompt-related) and duplication accounted for another 52 DCI in this group.

Int Code	Int Category	Int Sub Category	Number	%	%
D1	Drug Selection	Duplication	25	9.9%	33.3%
D2		Drug Interaction	8	3.2%	
D3		Wrong Drug	5	2.0%	
D4		Incorrect Strength	10	4.0%	
D5		Inappropriate Dose Form	8	3.2%	
D6		Contraindications Apparent	2	0.8%	
D7		No Indication Apparent	18	7.1%	
D0		Other Drug Selection Problem	8	3.2%	
O1	Over/Underdose	Dose Too High	27	10.7%	16.7%
O2		Dose Too Low	6	2.4%	
O3		Incorrect Dose Instructions	5	2.0%	
O0		Other Dose Problem	4	1.6%	
C1	Compliance	Taking Too Little	3	1.2%	9.1%
C2		Taking Too Much	7	2.8%	
C3		Erratic Use of Medication	5	2.0%	
C4		Intentional Misuse	1	0.4%	
C5		Difficulty Using Dose Form	4	1.6%	
C0		Other Compliance Problem	3	1.2%	
U1	Undertreated	Condition Undertreated	10	4.0%	6.7%
U2		Condition Untreated	0	0.0%	
U3		Preventive Therapy required	7	2.8%	
U0		Other Undertreated Problem	0	0.0%	
M1	Monitoring	Laboratory Monitoring	0	0.0%	0.4%
M2		Non-Laboratory Monitoring	1	0.4%	
M0		Other Monitoring Problem	0	0.0%	
E1	Education/Information	Patient Drug Info Request	19	7.5%	29.8%
E2		Patient Disease Info Request	10	4.0%	
E0		Other Education Problem	46	18.3%	
N0	Not Classifiable	Not Classifiable	4	1.6%	1.6%
T1	Toxicity/ADR	Toxicity/ADR present	6	2.4%	2.4%
Total			252	100.0%	100.0%

Table 4-32: Categories and Subcategories of DCI Associated with Proton Pump Inhibitors

Clinical Significance	Proton pump inhibitors		PROMISe Dataset	
	Number	%	Number	%
S1	46	18.3%	865	15.3%
S2	130	51.6%	2418	42.7%
S3	72	28.6%	2007	35.4%
S4	4	1.6%	378	6.7%
Total	252	100.0%	5668	100.0%

Table 4-33: Clinical Significance of DCI Associated with Proton Pump Inhibitors

A lower proportion of DCI associated with proton pump inhibitors prevented or required a hospital admission (S4) compared with the proportion in the entire PROMISE dataset. There was a significant difference between Proton Pump Inhibitors and the PROMISE Dataset ($\chi^2=18.74.05$, $df=3$, $p<0.001$).

HMG CoA reductase inhibitors

The DCI relating to HMG CoA reductase inhibitors are examined in Table 4-34. Problems with incorrect strength and toxicity occurred frequently in association with this group of medications. Incorrect strengths were commonly prescribed. The common toxicity symptoms described were muscle aches and pains.

Int Code	Int Category	Int Sub Category	Number	%	%
D1	Drug Selection	Duplication	6	2.9%	27.1%
D2		Drug Interaction	2	1.0%	
D3		Wrong Drug	4	1.9%	
D4		Incorrect Strength	37	17.6%	
D5		Inappropriate Dose Form	0	0.0%	
D6		Contraindications Apparent	1	0.5%	
D7		No Indication Apparent	1	0.5%	
D0		Other Drug Selection Problem	6	2.9%	
O1	Over/Underdose	Dose Too High	12	5.7%	18.6%
O2		Dose Too Low	15	7.1%	
O3		Incorrect Dose Instructions	8	3.8%	
O0		Other Dose Problem	4	1.9%	
C1	Compliance	Taking Too Little	17	8.1%	14.3%
C2		Taking Too Much	2	1.0%	
C3		Erratic Use of Medication	5	2.4%	
C4		Intentional Misuse	0	0.0%	
C5		Difficulty Using Dose Form	2	1.0%	
C0		Other Compliance Problem	4	1.9%	
U1	Undertreated	Condition Undertreated	1	0.5%	1.4%
U2		Condition Untreated	0	0.0%	
U3		Preventive Therapy required	2	1.0%	
U0		Other Undertreated Problem	0	0.0%	
M1	Monitoring	Laboratory Monitoring	1	0.5%	0.5%
M2		Non-Laboratory Monitoring	0	0.0%	
M0		Other Monitoring Problem	0	0.0%	
E1	Education/Information	Patient Drug Info Request	22	10.5%	20.0%
E2		Patient Disease Info Request	7	3.3%	
E0		Other Education Problem	13	6.2%	
N0	Not Classifiable	Not Classifiable	2	1.0%	1.0%
T1	Toxicity/ADR	Toxicity/ADR present	36	17.1%	17.1%
Total			210	100.0%	100.0%

Table 4-34: Categories and Subcategories of DCI Associated with HMG CoA Reductase Inhibitors

Clinical Significance	HMG CoA reductase inhibitors		PROMISe Dataset	
	Number	%	Number	%
S1	30	14.3%	865	15.3%
S2	94	44.8%	2418	42.7%
S3	84	40.0%	2007	35.4%
S4	2	1.0%	378	6.7%
Total	210	100.0%	5668	100.0%

Table 4-35: Clinical Significance of DCI Associated with HMG CoA Reductase Inhibitors

A higher proportion of DCI associated with HMG CoA reductase inhibitors prevented or required a general practitioner consultation compared with the proportion in the entire PROMISe dataset. There was a significant difference between HMG CoA reductase Inhibitors and the PROMISe Dataset ($\chi^2=11.77$, $df=3$, $p= 0.01$).

Natural opium alkaloids

The DCI relating to natural opium alkaloids use are examined in Table 4-36. Patient drug information requests occurred frequently in association with this group of medications.

Problems relating to other education and intentional misuse accounted for another 30 DCI in this group.

Int Code	Int Category	Int Sub Category	Number	%	%
D1	Drug Selection	Duplication	11	5.5%	24.6%
D2		Drug Interaction	6	3.0%	
D3		Wrong Drug	6	3.0%	
D4		Incorrect Strength	6	3.0%	
D5		Inappropriate Dose Form	9	4.5%	
D6		Contraindications Apparent	3	1.5%	
D7		No Indication Apparent	2	1.0%	
D0		Other Drug Selection Problem	6	3.0%	
O1	Over/Underdose	Dose Too High	8	4.0%	15.1%
O2		Dose Too Low	7	3.5%	
O3		Incorrect Dose Instructions	10	5.0%	
O0		Other Dose Problem	5	2.5%	
C1	Compliance	Taking Too Little	3	1.5%	16.1%
C2		Taking Too Much	9	4.5%	
C3		Erratic Use of Medication	3	1.5%	
C4		Intentional Misuse	13	6.5%	
C5		Difficulty Using Dose Form	0	0.0%	
C0		Other Compliance Problem	4	2.0%	
U1	Undertreated	Condition Undertreated	7	3.5%	7.0%
U2		Condition Untreated	1	0.5%	
U3		Preventive Therapy required	6	3.0%	
U0		Other Undertreated Problem	0	0.0%	
M1	Monitoring	Laboratory Monitoring	0	0.0%	2.0%
M2		Non-Laboratory Monitoring	1	0.5%	
M0		Other Monitoring Problem	3	1.5%	
E1	Education/Information	Patient Drug Info Request	21	10.6%	23.6%
E2		Patient Disease Info Request	9	4.5%	
E0		Other Education Problem	17	8.5%	
N0	Not Classifiable	Not Classifiable	7	3.5%	3.5%
T1	Toxicity/ADR	Toxicity/ADR present	16	8.0%	8.0%
Total			199	100.0%	100.0%

Table 4-36: Categories and Subcategories of DCI Associated with Natural Opium Alkaloids

Clinical Significance	Natural Opium Alkaloids		PROMISe Dataset	
	Number	%	Number	%
S1	29	14.6%	865	15.3%
S2	93	46.7%	2418	42.7%
S3	67	33.7%	2007	35.4%
S4	10	5.0%	378	6.7%
Total	199	100.0%	5668	100.0%

Table 4-37: Clinical Significance of DCI Associated with Natural Opium Alkaloids

The clinical significance of DCI associated with natural opium alkaloids closely matched the clinical significance of the entire PROMISe dataset. There was no significant difference between Natural Opium Alkaloids and the PROMISe Dataset ($\chi^2=1.76.05$, $df=3$, $p=0.63$).

ACE inhibitors; plain

The DCI relating to ACE inhibitors are examined in Table 4-38. Problems with toxicity occurred frequently in association with this group of medications. The main noted toxicity issue was dry cough. Several notes were made regarding symptoms of low blood pressure such as dizziness.

Problems relating to incorrect strength accounted for 23 DCI in this group.

Int Code	Int Category	Int Sub Category	Number	%	%
D1	Drug Selection	Duplication	10	5.8%	26.3%
D2		Drug Interaction	2	1.2%	
D3		Wrong Drug	2	1.2%	
D4		Incorrect Strength	23	13.5%	
D5		Inappropriate Dose Form	2	1.2%	
D6		Contraindications Apparent	3	1.8%	
D7		No Indication Apparent	0	0.0%	
D0		Other Drug Selection Problem	3	1.8%	
O1	Over/Underdose	Dose Too High	11	6.4%	19.9%
O2		Dose Too Low	10	5.8%	
O3		Incorrect Dose Instructions	8	4.7%	
O0		Other Dose Problem	5	2.9%	
C1	Compliance	Taking Too Little	6	3.5%	12.3%
C2		Taking Too Much	3	1.8%	
C3		Erratic Use of Medication	5	2.9%	
C4		Intentional Misuse	0	0.0%	
C5		Difficulty Using Dose Form	1	0.6%	
C0		Other Compliance Problem	6	3.5%	
U1	Undertreated	Condition Undertreated	4	2.3%	2.9%
U2		Condition Untreated	0	0.0%	
U3		Preventive Therapy required	0	0.0%	
U0		Other Undertreated Problem	1	0.6%	
M1	Monitoring	Laboratory Monitoring	1	0.6%	5.3%
M2		Non-Laboratory Monitoring	8	4.7%	
M0		Other Monitoring Problem	0	0.0%	
E1	Education/Information	Patient Drug Info Request	10	5.8%	13.5%
E2		Patient Disease Info Request	2	1.2%	
E0		Other Education Problem	11	6.4%	
N0	Not Classifiable	Not Classifiable	2	1.2%	1.2%
T1	Toxicity/ADR	Toxicity/ADR present	32	18.7%	18.7%
Total			171	100.0%	100.0%

Table 4-38: Categories and Subcategories of DCI Associated with ACE Inhibitors; Plain

Clinical Significance	ACE inhibitors; plain		PROMISe Dataset	
	Number	%	Number	%
S1	25	14.6%	865	15.3%
S2	64	37.4%	2418	42.7%
S3	73	42.7%	2007	35.4%
S4	9	5.3%	378	6.7%
Total	171	100.0%	5668	100.0%

Table 4-39: Clinical Significance of DCI Associated with ACE Inhibitors; Plain

A higher proportion of DCI associated with ACE inhibitors; plain prevented or required a general practitioner consultation (S3) compared with the proportion in the entire PROMISE dataset. There was no significant difference between ACE Inhibitors Plain and the PROMISE Dataset ($\chi^2=4.1$, $df=3$, $p=0.25$).

4.6 Time Taken to do Clinical Interventions

The recording pharmacists were asked to note the time, in minutes, that it took to perform each clinical intervention. Additionally, the observing pharmacists were asked to record the time taken to document interventions.

4.6.1 Time to Perform the Intervention

When documenting interventions, pharmacists were asked to record how long the intervention took to perform (not to document). Some pharmacists recorded times in excess of one hour for performing interventions. These situations were considered to include time waiting for responses (such as a message left with GP and had to wait for over 2 hours to get response) and were excluded from the time analysis.

The median time for the remaining 5846 DCI was 4 minutes (Interquartile Range (IQR) = 4; range 0-45min) (see Figure 4-5). As the recording system in FRED had selection option for 2 minute intervals (with an option to enter a more precise number), the most frequently recorded times for DCI were 4, 2 and 6 minutes (see Figure 4-5). The Aquarius recording system did not have preselect time options.

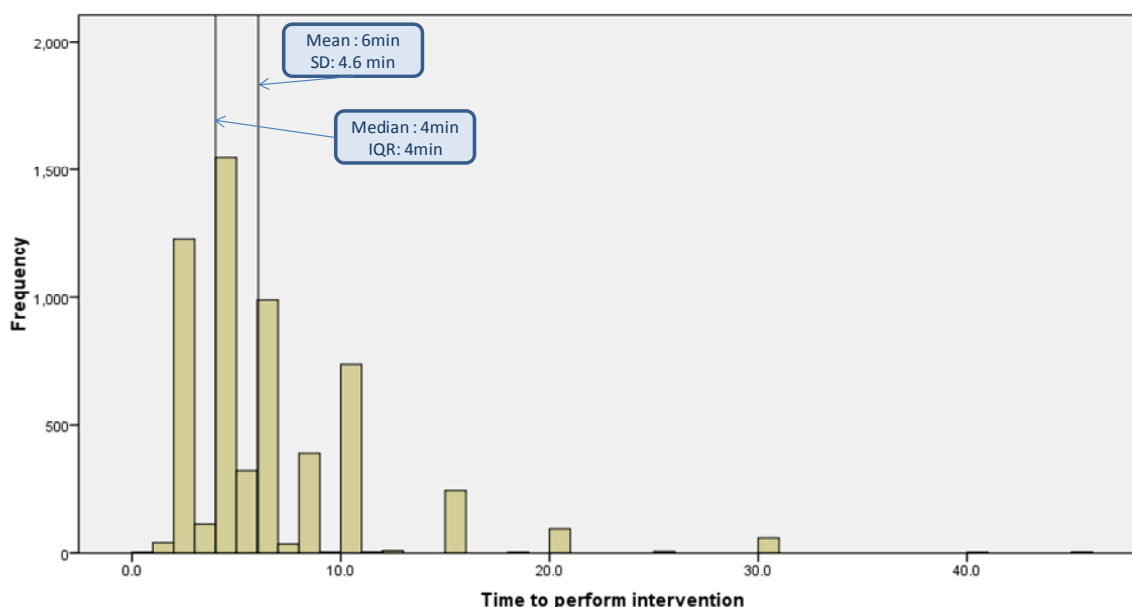


Figure 4-5: Time Taken to Perform DCI

There was no clear relationship between the time taken to perform the intervention and the category of intervention (see Table 4-40). There were however differences between the groups the relevance of which is uncertain (ANOVA $df=7$, $p<0.001$).

Category	Time to Perform Interventions (minutes)					
	Count	Mean	Standard Deviation	Median	Percentile 25	Percentile 75
Drug Selection	1837	6.0	4.6	4.0	4.0	8.0
Over/Underdose	1185	5.7	4.3	4.0	3.0	7.0
Compliance	557	7.3	5.9	6.0	4.0	10.0
Undertreated	272	6.9	5.2	6.0	4.0	10.0
Monitoring	140	7.6	5.7	6.0	4.0	10.0
Education/Information	1421	5.3	3.7	4.0	2.0	6.0
Not Classifiable	110	7.9	8.6	4.5	2.0	10.0
Toxicity/ADR	445	6.4	4.2	6.0	4.0	8.0
Total	5967	6.0	4.65	4.0	4.0	8.0

Table 4-40: Time Taken to Perform Intervention Compared to Category of Intervention

There was, however, a significantly greater time required to complete interventions that were associated with some types of referrals and for situations where a dose administration aid was recommended (Kruskall –Wallis Chi Square 9691, 18 df , $p<0.001$) (see Table 4-41).

Category	Subcategory		Time to Perform Interventions (minutes)					
			Count	Mean	Standard Deviation	Median	Percentile 25	Percentile 75
A Change in therapy	R1	Dose increase	642	5.8	4.4	4.0	4.0	6.0
	R2	Dose decrease	656	6.2	4.7	5.0	4.0	8.0
	R3	Drug change	847	6.8	5.1	6.0	4.0	10.0
	R4	Drug formulation change	384	5.9	4.6	4.0	4.0	7.0
	R5	Drug brand change	96	5.2	3.7	4.0	2.0	6.0
	R6	Dose frequency/schedule change	529	5.9	4.3	5.0	3.0	8.0
	R7	Prescription not dispensed	307	7.5	5.6	6.0	4.0	10.0
	R8	Other changes to therapy	380	6.6	4.9	6.0	4.0	8.0
	<i>Subtotal Change in Therapy</i>		3841	6.3	4.7	5.0	4.0	8.0
A referral required	R9	Refer to prescriber	1794	7.1	5.2	6.0	4.0	10.0
	R10	Refer to hospital	36	10.6	9.0	10.0	4.0	15.0
	R11	Refer for medication review	76	10.2	7.8	7.0	5.0	12.0
	R12	Other referral required	58	11.1	7.8	10.0	6.0	15.0
	<i>Subtotal Referral Required</i>		1964	7.4	5.5	6.0	4.0	10.0
Provision of information	R13	Education or counselling session	2441	6.2	4.4	5.0	4.0	8.0
	R14	Written summary of medications	261	6.7	5.3	4.0	4.0	10.0
	R15	Recommend dose administration aid	75	10.2	7.8	8.0	5.0	15.0
	R16	Other written information	548	5.7	4.1	4.0	4.0	8.0
	<i>Subtotal Provision of Information</i>		3325	6.2	4.5	5.0	4.0	8.0
Monitoring	R17	Monitoring: Non-laboratory	277	7.2	5.9	6.0	4.0	8.0
	R18	Monitoring: Laboratory test	173	7.4	5.7	6.0	4.0	10.0
	<i>Subtotal Monitoring</i>		450	7.3	5.8	6.0	4.0	8.0
	R19	No Recommendation Required	112	4.5	4.5	2.5	2.0	6.0
Total			9692	6.0	4.65	4.0	4.0	8.0

Table 4-41: Time Taken to Perform Intervention Compared to Recommendation Made

There was also a clear relationship between the time taken to perform an intervention and the documented clinical significance (see Table 4-42), with those DCI that were deemed more significant taking a longer time to perform.

Category	Time to Perform Interventions					
	Count	Mean	Standard Deviation	Median	Percentile 25	Percentile 75
S1: Information Only	915	4.9	3.9	4	2	6
S2: Minor Symptom	2514	5.2	3.7	4	2	6
S3: Medical Assistance	2122	6.8	4.9	6	4	10
S4: Hospitalisation	416	9.9	7.1	8	5	12
Total	5967	6.0	4.65	4.0	4	8

Significant differences (Chi Square 455, Df=3, p<0.001) with an upwards trend (Std J-T statistic 20.7, p< 0.001)

Table 4-42: Time Taken to Perform Intervention Compared to Clinical Significance

4.6.2 Time to Document the Intervention

The participating pharmacists were asked to record only the time taken to perform the intervention, not to document the intervention. Each observer was asked to note how long each observed intervention took to perform and document, therefore the observer data was used to determine the time required to document interventions. Out of the 567 observed interventions, 279 were documented and therefore the time taken to document was also recorded. The average time taken for documentation was 2.02 ± 1.06 minutes (range 0-8) (Figure 4-6).

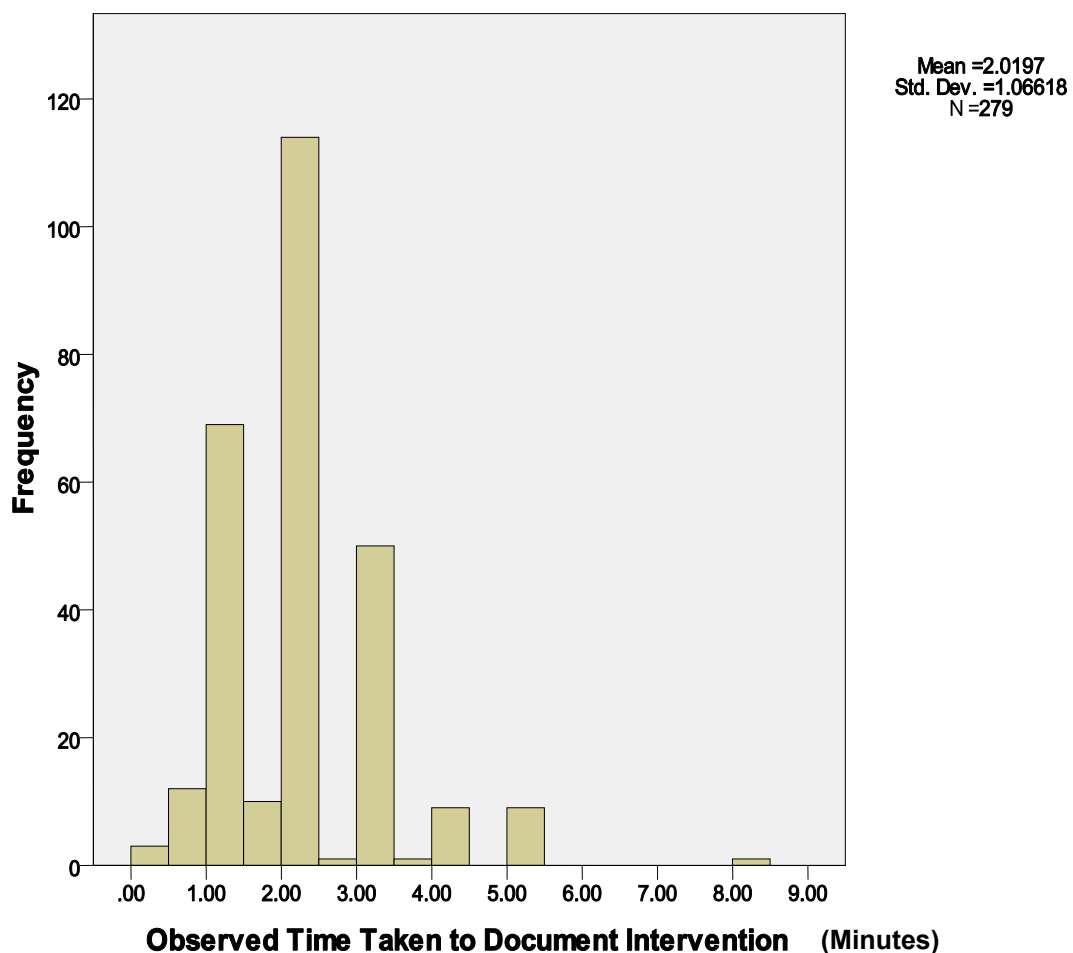


Figure 4-6: Observed Time Taken to Document DCI

4.7 Allocated Software Groups

The following section outlines the intervention frequencies for pharmacies based on weeks of activity in each pharmacy.

4.7.1 Trial Groups

The data was amalgamated into weeks of pharmacy activity. A total of 2193 weeks of activity were analysed. An intervention frequency was calculated for each week (see Figure 4-7).

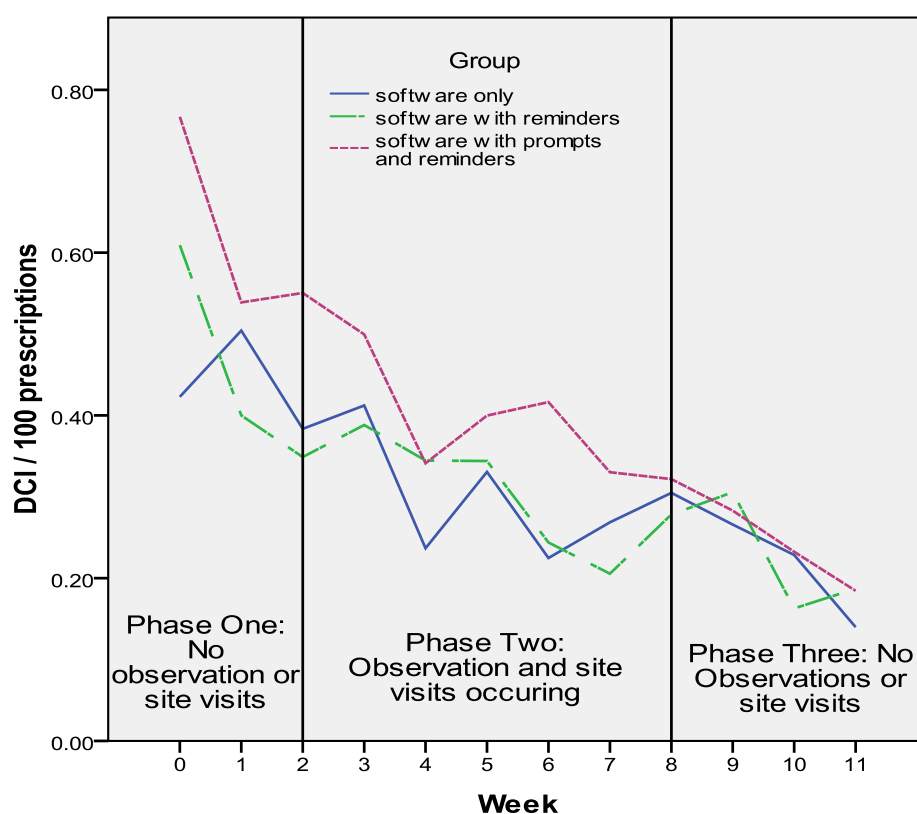


Figure 4-7: Frequency of DCI for each Software Group over the Trial Period

As shown in Figure 4-7, there was a slow decline in the intervention frequency and a gradual loss of difference between the three groups. Overall, there was a significant difference between the three groups (Kruskal Wallis Chi Sq= 14.7, 2df, $p=0.001$) with a trend to an increased intervention rate from groups one, to two to three (J-T Statistic 3.88, $p<0.001$). This is of interest, as the prompted DCI from the third group have been removed from this analysis, indicating that the prompt increased DCI generally rather than only the specific prompted intervention.

When each phase of the study was considered, the differences between the groups were not evident during phase 3 (see Figure 4-8 and Table 4-43).

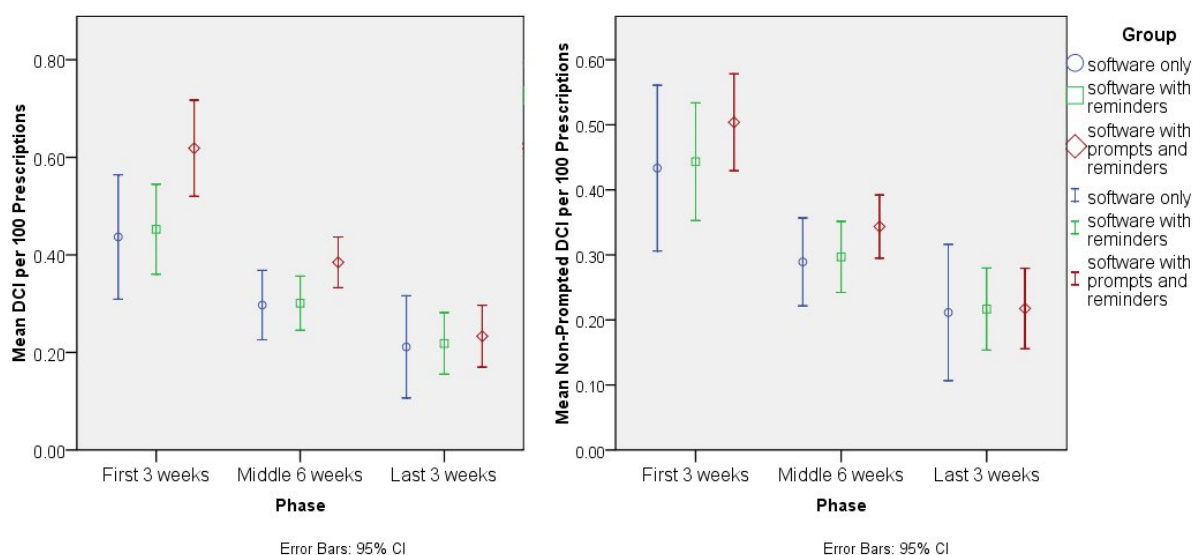


Figure 4-8: Clinical Intervention Frequency for the Different Pharmacy Groups in Each Phase of the Study

	Difference between Trial Groups	Trend from Group 1 to 3
Phase 1	No (Chi Sq 5.26, 2df, p=0.07)	Yes, (J-T test 2.31, p=0.02)
Phase 2	No (Chi Sq 4.34, 2df, p=0.11)	Yes, (J-T test 2.09, p=0.037)
Phase 3	No, (Chi Sq 2.13, 2df, p=0.34)	No, (J-T test -0.42, p=0.97)

Table 4-43: Differences Between Trial Groups Over the Phases of the Study.

4.8 Observed OTC Interventions

Although pharmacists were not encouraged to record OTC interventions on the PROMISE software, the observers collected data on pharmacists involvement in these actual clinical interventions. In particular, observers were asked to gain additional data on OTC interventions involving non-steroidal anti-inflammatory drugs (NSAIDs).

Of the 457 observed OTC ACI, 51 were recorded as involving an OTC oral NSAID analgesic. Of these 51 DCI, 31 involved specific product requests for NSAIDs and 5 were product requests not specifically for NSAIDs (for example for paracetamol or 'a pain killer'). Of the 31 product requests for NSAIDs, 22 resulted in a sale for an NSAID, 5 resulted in no product sold and 4 resulted in a non-NSAID analgesic being sold. All 5 product requests not specifically for NSAIDs resulted in the sale of an NSAID product, as shown in Table 4-44.

Of the 51 DCI, 17 involved symptom requests. Eleven of these symptom requests resulted in the sale of an NSAID. Four of the symptom requests resulted in the sale of a non-NSAID and 2 symptom requests resulted in no product sold, as shown in Table 4-44.

	Sale of NSAID	Sale of non-NSAID analgesic	No product sold	Total
NSAID product-based request	22	4	5	31
General analgesic request	5	0	0	5
Symptom-based request	10	3	2	15

Table 4-44: Types of NSAID Requests Resulting in DCI

Of particular interest are the questions asked of the patient by the pharmacist about their other medications and/or medical conditions.

Of the 51 DCI, 29 pharmacists asked about both medical conditions and other medicines, seven pharmacists asked about other medications only and 6 pharmacists asked about other medical conditions only. Nine pharmacists involved in an NSAID intervention did not ask the patient about either their medical conditions or other medicines, as shown in Table 4-45.

Of the 31 requests for NSAID products, 9 DCI resulted in an NSAID being sold. The reasons for this included stomach problems, misuse, duplication with a prescription NSAID, breastfeeding and asthma in two cases. The other three DCI involved counseling only. Of the 18 NSAID requests that did result in an NSAID sale, five were against pharmacist recommendation due to overuse, history of stomach ulcers, previous side effects to celecoxib, GI upset and a drug interaction. Of the 37 sales of an NSAID, there were 6 referrals to GP, as shown in Table 4-45.

		Asked about other medications	Asked about other medical conditions	Asked about both medicines and medical conditions	Did not ask either	Totals
NSAID Request	No product sold	2 ^a	0	1 ^b	2 ^c	5
	Non-NSAID product sold	1 ^d	0	3 ^e	0	4
	NSAID sold	0	2 ^f	18 ^g	2	22
Non-NSAID Request	No product sold	0	0	0	0	0
	Non-NSAID product sold	0	0	0	0	0
	NSAID sold	0	1	3 ^h	1	5
Symptom Request	No product sold	2	0	0	0	2
	Non-NSAID product sold	1	0	1	1	3
	NSAID sold	0	4 ⁱ	3	3	10
Totals		6	7	29	9	51

a Counselling only

b Due to stomach problems

c Due to misuse and counselling only

d Due to duplication with prescription NSAID

e Due to asthma (x2) and breastfeeding

f 1 sale was against pharmacist recommendation due to overuse

g 5 sales were against pharmacist recommendation due to overuse, history of stomach ulcers, previous side effects to celecoxib, GI upset, and drug interaction. Also includes 2 referrals to GP

h Includes 1 referral to GP

i Includes 3 referrals to GP

Table 4-45: Questions Asked by Pharmacists for Different Request Types

Of the 35 pharmacists who asked about other medications, 33 asked if the patient took any other medications, one pharmacist asked only if the patient took any stomach medications and one pharmacist asked only if the patient took any other prescription NSAIDs. See Table 4-46.

Questions	N
Asked if any other medication	33
Asked if any stomach medications	1
Asked if any other prescription NSAIDs	1

Table 4-46: Breakdown of Questions About Medications

Of the 36 pharmacists who asked about other medical conditions, 30 asked if the patient suffered any other medical conditions, six pharmacists asked about stomach problems, one asked about heart conditions, five asked about high blood pressure, one asked about kidney problems and one asked about pregnancy. See Table 4-47.

Question	N
Asked if any other medical conditions	30
Asked if any stomach problems	6
Asked if any heart conditions	1
Asked if high blood pressure	5
Asked if any kidney problems	1
Asked if pregnant	1

Table 4-47: Breakdown of Questions About Medical Conditions

The most common age group subject to an intervention regarding OTC NSAIDs were those aged 21-65. See Table 4-48.

Age Group	N
Under 21	5
Aged 21-65	40
Aged 65-80	5
Over 80	1

Table 4-48: Age Groups Subject to NSAID Intervention

Females were more likely to be involved in an NSAID intervention than males accounting for 29 of the 51 DCI. See Table 4-49.

Gender	N
Female	29
Male	22

Table 4-49: Gender Breakdown of NSAID DCI

4.9 Documented Non-Prescription Interventions

Although PROMISe III was focused on prescription interventions, a number of pharmacists still recorded interventions which did not relate directly to a patient's prescription or disease state. Of the 7000 DCI, 525 were classified as non-prescription interventions. These interventions were classified into OTC product interventions and symptom-based interventions. The breakdown of these interventions can be seen in Table 4-50.

OTC Product Interventions	389
Symptom-based interventions	136
Total	525

Table 4-50: Breakdown of Non-Prescription DCI

The most common drug related problem categories for the OTC product DCI were 'Drug Selection' with 31.1% of DCI and 'Education/Information' with 32.1% of DCI. The least common categories were 'Monitoring' with 1.8% and 'Not Classifiable' with 1.3%. See Table 4-51 for the breakdown of classification.

Category	Subcategory		#	% of Cat	#	%
Drug Selection	D1	Duplication	12	9.9	121	31.1
	D2	Drug Interaction	8	6.6		
	D3	Wrong Drug	33	27.3		
	D4	Incorrect Strength	0	0.0		
	D5	Inappropriate Dose Form	5	4.1		
	D6	Contraindications Apparent	39	32.2		
	D7	No Indication Apparent	5	4.1		
	D0	Other Drug Selection Problem	19	15.7		
Over/Underdose	O1	Dose Too High	11	36.7	30	7.7
	O2	Dose Too Low	5	16.7		
	O3	Incorrect Dose Instructions	5	16.7		
	O0	Other Dose Problem	9	30.0		
Compliance	C1	Taking Too Little	5	17.2	29	7.5
	C2	Taking Too Much	9	31.0		
	C3	Erratic Use of Medication	3	10.3		
	C4	Intentional Misuse	10	34.5		
	C5	Difficulty Using Dose Form	1	3.4		
	C0	Other Compliance Problem	1	3.4		
Undertreated	U1	Condition Undertreated	24	44.4	54	13.9
	U2	Condition Untreated	25	46.3		
	U3	Preventive Therapy required	4	7.4		
	U0	Other Undertreated Problem	1	1.9		
Monitoring	M1	Laboratory Monitoring	1	14.3	7	1.8
	M2	Non-Laboratory Monitoring	5	71.4		
	M0	Other Monitoring Problem	1	14.3		
Education/Information	E1	Patient Drug Info Request	51	40.8	125	32.1
	E2	Patient Disease Info Request	47	37.6		
	E0	Other Education Problem	27	21.6		
Not Classifiable	N0	Not Classifiable	5	100	5	1.3
Toxicity/ADR	T1	Toxicity/ADR present	18	100	18	4.6
Total			389		389	100

Table 4-51: Classification of OTC Product Related DCI

The most common drug related problem categories for the symptom based DCI were 'Education/Information' with 48.5% of DCI and 'Undertreated' with 33.1%. The least common categories were 'Over/Underdose' and 'Compliance' both with no DCI in that category. See Table 4-52.

Category	Subcategory		#	% of Cat	#	%
Drug Selection	D1	Duplication	0	0.0	9	6.6
	D2	Drug Interaction	0	0.0		
	D3	Wrong Drug	5	55.6		
	D4	Incorrect Strength	0	0.0		
	D5	Inappropriate Dose Form	1	11.1		
	D6	Contraindications Apparent	3	33.3		
	D7	No Indication Apparent	0	0.0		
	D0	Other Drug Selection Problem	0	0.0		
Over/Underdose	O1	Dose Too High	0	0.0	0	0.0
	O2	Dose Too Low	0	0.0		
	O3	Incorrect Dose Instructions	0	0.0		
	O0	Other Dose Problem	0	0.0		
Compliance	C1	Taking Too Little	0	0.0	0	0.0
	C2	Taking Too Much	0	0.0		
	C3	Erratic Use of Medication	0	0.0		
	C4	Intentional Misuse	0	0.0		
	C5	Difficulty Using Dose Form	0	0.0		
	C0	Other Compliance Problem	0	0.0		
Undertreated	U1	Condition Undertreated	14	31.1	45	33.1
	U2	Condition Untreated	25	55.6		
	U3	Preventive Therapy required	3	6.7		
	U0	Other Undertreated Problem	3	6.7		
Monitoring	M1	Laboratory Monitoring	0	0.0	2	1.5
	M2	Non-Laboratory Monitoring	2	100.0		
	M0	Other Monitoring Problem	0	0.0		
Education/Information	E1	Patient Drug Info Request	5	7.6	66	48.5
	E2	Patient Disease Info Request	46	69.7		
	E0	Other Education Problem	15	22.7		
Not Classifiable	N0	Not Classifiable	5	100	5	3.7
Toxicity/ADR	T1	Toxicity/ADR present	9	100	9	6.6
Total			136		136	100

Table 4-52: Classification of Symptom Based DCI

The majority (77.4%) of OTC product DCI were classified by the pharmacist as S2 or S3. Only 5.9% of these DCI were considered highly significant. See Table 4-53.

Clinical Significance		#	%
S1	Information only	65	16.7
S2	Prevented mild symptom or improved compliance	175	45.0
S3	Prevented or required a GP visit	126	32.4
S4	Prevented or required a hospital admission	23	5.9
Total		389	100.0

Table 4-53: Clinical Significance of OTC Product DCI

The S2 and S3 categories made up 86% of the symptom based OTC DCI and 3.7% of DCI were classified as S4, as shown in Table 4-54.

Clinical Significance		#	%
S1	Information only	14	10.3
S2	Prevented mild symptom or improved compliance	49	36.0
S3	Prevented or required a GP visit	68	50.0
S4	Prevented or required a hospital admission	5	3.7
Total		136	100.0

Table 4-54: Clinical Significance of Symptom Based DCI

4.10 Discussion of Types of Clinical Interventions

Pharmacists in the PROMiSe study were required to categorise the nature of the problem that they identified and resolved. This process is unusual, with the vast majority of published studies of clinical interventions in community pharmacies utilising researchers to categorise the problem from information provided by the documenting pharmacist.^{159 163 170 175 178 181 224} Consequently, a degree of training in the classification system was required. Participating pharmacists were able to adequately categorise the types of problems and the recommendations made in a series of training scenarios.

Over 50% of the DRPs identified related to either the selection or dose of the medication. A further 24% of problems related to education or information. Patients often received more than one recommendation to resolve the problem (average of 1.6 recommendations per intervention). In almost 65% of problems, a change in therapy was suggested, and in over 30%, a referral to the General Practitioner was made. In addition, education or counselling was required to resolve the problem in over 55% of DCI.

The nature of the problems and the recommendations made is in keeping with the typical problems detected by community pharmacists in published studies.^{172 181 182 190 192} In addition, this study documented a significant number of DRPs related to adherence issues (approximately 9%), that are not routinely documented in the literature (see Chapter 1).

Over 40% of the DRPs were rated as either of moderate or high clinical significance by the documenting pharmacist. DRPs that were related to possible toxicity or related to the undertreatment with medications were commonly rated as more significant. As expected, more significant DCI were often associated with contacting the prescriber for clarification and often resulted in a referral to the GP as a recommendation.

Pharmacists were asked to identify a single drug involved with the DRP. Common drugs involved included proton pump inhibitors, HMG CoAse inhibitors, antibiotics, analgesics and agents acting on the renin-angiotensin system. When the number of prescriptions for each group of medications was taken into account, a number of commonly used drug groups had higher than the average intervention frequency. These were drugs used in addictive disorders (smoking cessation agents and methadone), macrolides and other anti-infectives (including penicillins, direct acting antivirals and tetracyclines), corticosteroids (predominantly prednisolone), NSAIDs, inhaled respiratory drugs, a range of neurologic drugs (including opioids, antiepileptics and antipsychotics) and drugs affecting bone structure and mineralisation (vitamin D and bisphosphonates). DCI of higher clinical significance were more commonly associated with cardiac therapy drugs (agents affecting angiotensin, beta blockers and calcium channel blockers), antithrombotic agents and antihyperglycaemic agents compared to other agents.

The results of this study allow the examination of the types of problems commonly associated with particular drug groups of interest. There is potential to use information of this nature to establish foci of educational programs to increase intervention frequency in specific areas and to develop specific prompted interventions. Many of the DCI involving incorrect drug or dose selection could also be viewed as prescribing errors, therefore targeting these medications could lead to improved prescribing practices.

4.10.1 Frequency of DRP Detection

The average frequency of DRPs detected and DCI undertaken was disappointing, at approximately 1 intervention every 300 prescriptions. This frequency (0.31 DCI per 100 prescriptions) is similar to the average frequency of 0.65 in the 23 studies evaluated in Chapter 1.

An approximately four-fold decline in intervention reporting over the 12 weeks of the study was seen in the majority of pharmacies. The most important reason for this decline is that the documentation of clinical interventions is not a routine part of pharmacy practice. The observers showed that only 49% of interventions were documented, therefore if all interventions were documented, the intervention rate could double. There are several factors that could contribute to this, with the most common being that pharmacists believe they do not have enough time to document. However this is unlikely because when timed by observers during the week of observation, nearly 75% of all DCI were documented in 2 minutes or less. Therefore once the documentation process becomes part of the dispensing process, the intervention rate could increase considerably.

Chapter 5 Results and Discussion: Factors Influencing the Frequency of Clinical Interventions

The performance and the documentation of clinical interventions can be potentially influenced by many factors within the pharmacy environment. This chapter focuses on the factors that were measured during the PROMISE trial to determine which factors had the largest influence on the performance and documentation of clinical interventions.

Over the course of the twelve week trial, several factors were examined to determine if they affected the intervention rate of the pharmacy or the intervention rate by the individual pharmacist. Software, prescription, pharmacy and pharmacist factors were all examined to determine their effect.

5.1 Software Factors

As discussed in Chapter 2, there were three software groups within the PROMISE trial: software only (group one), software and reminder (group two) and software, reminder and prompt (group three). The effect of the reminder and prompt was measured by comparing intervention rates across the three groups.

5.1.1 Reminders

During the twelve week trial, pharmacies in group two and three (n=145) received an automatic pop-up reminder everyday at 11am and 3pm which encouraged the pharmacist to document their interventions (see Chapter 2). Collation of all DCI showed the highest peak at 11am with 984 DCI and the second highest peak at 3pm with 804 DCI (Table 5-1 and Figure 5-1), however this does not necessarily reflect the time of day that interventions were performed, only the time they were documented and submitted as complete. For this analysis, all DCI have been included (including those identified as PPI step-downs and non-script DCI) in order to accurately determine the effect of the general reminder.

		Group One: Software only		Group Two: Software with reminders		Group Three: Software with reminders and prompts		Total	
		N	%	N	%	N	%	N	%
Hour of day	8	5	0.50%	37	1.30%	22	0.80%	64	0.90%
	9	89	8.40%	197	7.00%	192	6.70%	478	7.10%
	10	108	10.10%	241	8.50%	327	11.40%	676	10.00%
	11	130	12.20%	423	15.00%	431	15.00%	984	14.60%
	12	105	9.90%	344	12.20%	315	11.00%	764	11.30%
	13	102	9.60%	264	9.30%	263	9.20%	629	9.30%
	14	121	11.40%	203	7.20%	299	10.40%	623	9.20%
	15	108	10.10%	375	13.30%	321	11.20%	804	11.90%
	16	109	10.20%	324	11.50%	332	11.60%	765	11.30%
	17	117	11.00%	242	8.60%	220	7.70%	579	8.60%
	18	35	3.30%	90	3.20%	89	3.10%	214	3.20%
	19	20	1.90%	53	1.90%	31	1.10%	104	1.50%
	20	15	1.40%	26	0.90%	18	0.60%	59	0.90%
	21	1	0.10%	5	0.20%	5	0.20%	11	0.20%
	22	0	0.00%	1	0.00%	0	0.00%	1	0.00%
Total		1065	100	2825	100	2865	100	6755	100

Table 5-1: Number of DCI Within the Three Groups compared to Hour

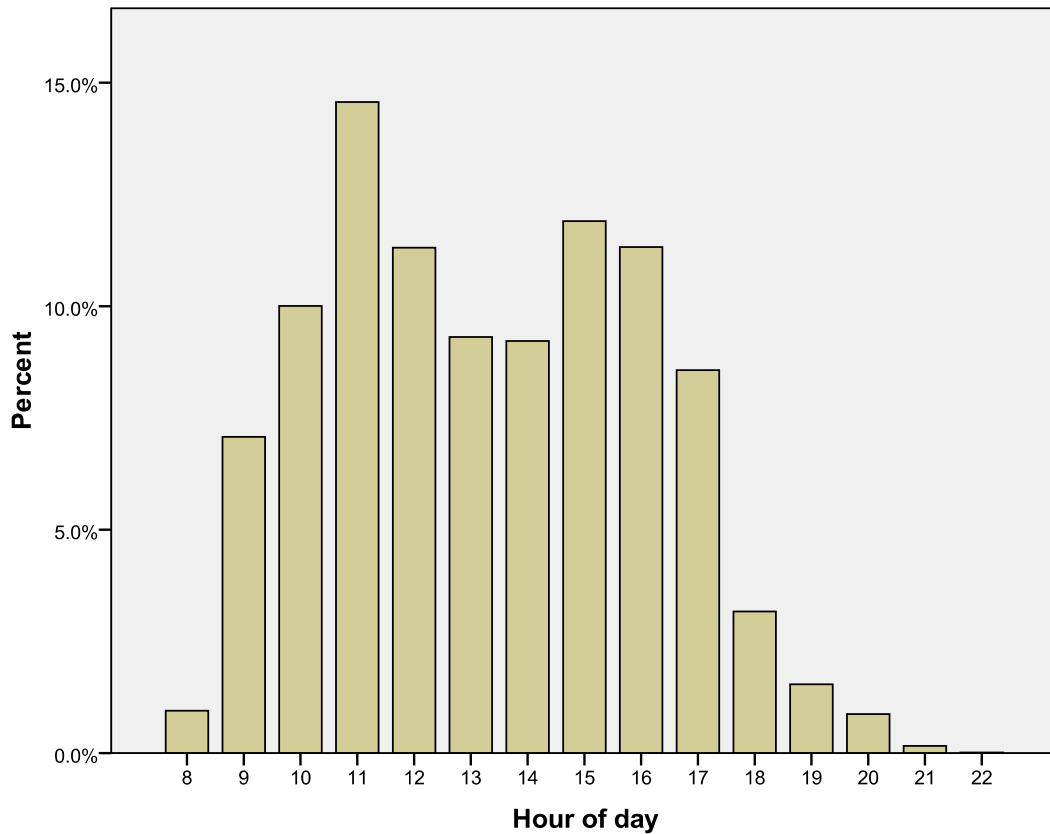


Figure 5-1: DCI compared to Hour

There appeared to be a significant difference in the times of day that the DCI were recorded between group one and the other two groups (Figure 5-2). Group one only had the software with neither reminders nor prompts which resulted in a more consistent recording rate. Groups two and three both had the reminder and displayed a peak of recordings at 11am, with group two showing another high peak at 3pm (Figure 5-2). This graph shows that the reminder provided a significant increase in the number of DCI in the hour following the reminder ($\chi^2 = 76.12$, $df = 22$, $p < 0.01$).

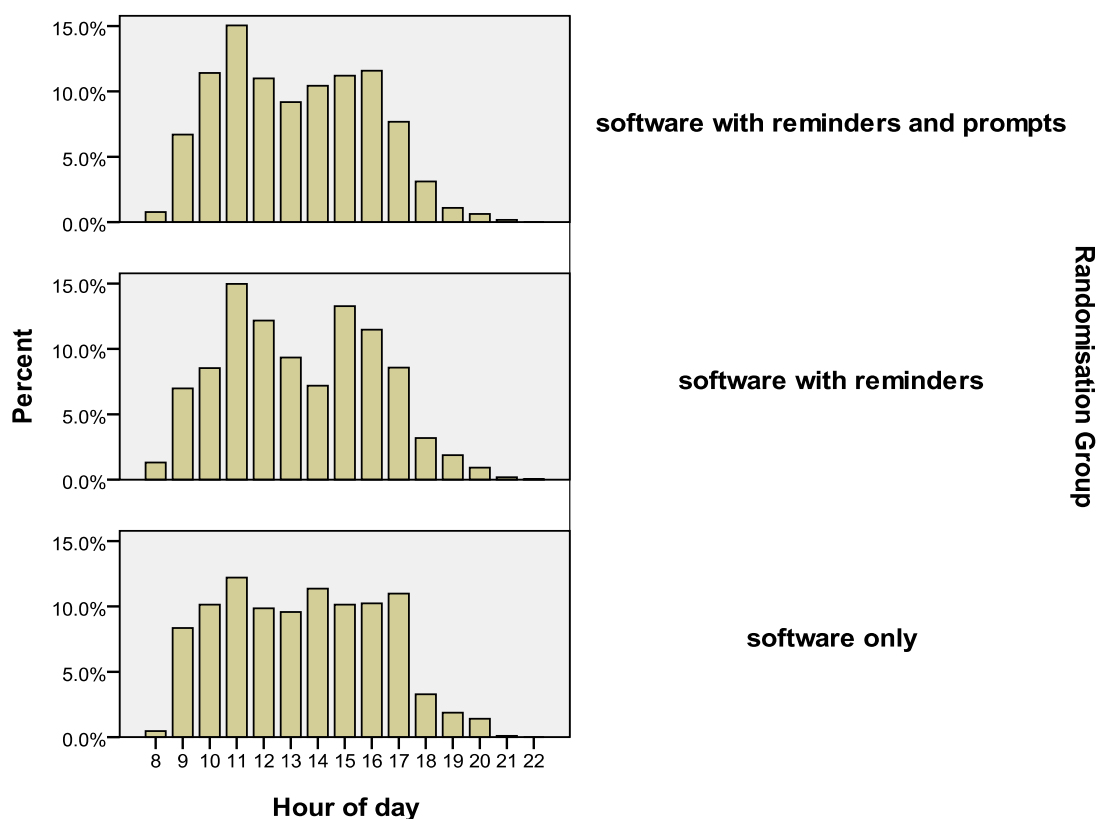


Figure 5-2: DCI Within Each Software Group Compared to Hour

5.1.2 Prompts

Group three pharmacies had a significantly higher overall intervention rate, for the first eight weeks of the trial, to which the specific prompt on PPI step-downs is likely to have been a contributor. Further details regarding the effect of the prompt can be seen in Chapter 6.

5.2 Prescription Factors

Prescription factors including original versus repeat and drug involved (see Chapter 4) were collected and examined to determine their effect on the intervention rate.

5.2.1 Original versus Repeat Prescriptions

During the trial, the PROMISE software also collected whether the intervention was recorded against an original or a repeat prescription. An original prescription identified prescription items that were dispensed from a new prescription; however, the item may not have been a new item for the patient (for example, the patient may have taken the item before but was presenting a prescription on original paperwork to the pharmacy that day). A repeat prescription identified items that had already been dispensed using that particular prescription including deferred prescriptions. The intervention rate was calculated on the total sample of 6755 DCI and then re-calculated for the valid sample of 5967 DCI (after prompt-related DCI and non-script DCI were removed). There were DCI where this data was missing (n=2368 in Table 5-2 and n=1780 in Table 5-3) and this occurred because the database did not have adequate information recorded for analysis. This was due to incorrect coding by the pharmacist or due to a technical data transfer problem. When all DCI were considered, there was a much higher intervention rate in the original prescription category, with 77.9% of all DCI occurring on original prescription items despite originals only making up 45.4% of all dispensed prescriptions (Table 5-2). This was equivalent to a rate of 0.37% (3.7 DCI in 1000 prescriptions), whereas the intervention rate on repeat prescriptions was much lower at only 0.09% (0.9 DCI

in 1000 prescriptions). A chi-square test showed a significant difference between the two groups (Table 5-2). This difference is most likely due to original prescriptions having a higher incidence of drug selection errors, drug interactions and education requirements, compared to repeat prescriptions. Also, the pharmacist would be more likely to speak with a patient about an original prescription which also increases the opportunity to intervene. When prompted DCI and non-script DCI were removed, there was still a significantly higher intervention rate on original prescriptions (Table 5-3).

	Intervention Frequency	%	Valid Percent	Dispensing Frequency	%	Intervention Rate per 100 Prescriptions
Repeat	971	14.4	22.1	1098864	54.6	0.09
Original	3416	50.6	77.9	915059	45.4	0.37
Total	4387	64.9	100.0	2013923	100.0	
Missing	2368	35.1	Statistics: $\chi^2 = 1856.49$, $df = 1$, $p < 0.01$			
Total	6755	100.0				

Table 5-2: Number of All DCI Within each Prescription Category

	Intervention Frequency	%	Valid Percent	Dispensing Frequency	%	Intervention Rate per 100 Prescriptions
Repeat	862	14.4	20.6	1098864	54.6	0.08
Original	3325	55.7	79.4	915059	45.4	0.36
Total	4187	70.2	100.0	2013923	100.0	
Missing	1780	29.8	Statistics: $\chi^2 = 1945.01$, $df = 1$, $p < 0.01$			
Total	5967	100.0				

Table 5-3: Number of Valid DCI Within each Prescription Category

5.3 Pharmacy Factors

Several pharmacy factors were assessed to determine which pharmacy factors may impact on the pharmacy's overall intervention rate.

5.3.1 PhARIA

Pharmacies were categorised as metropolitan (PhARIA 1) or country (PhARIA 2-6) and assessed to determine if location influenced intervention rate. A Mann-Whitney test showed no significant differences between the intervention rate in metropolitan versus country pharmacies (

Table 5-4).

	Pharmacy		Intervention Rate				
	Count	%	Median	Minimum	Maximum	Percentile 25	Percentile 75
Metro	159	85.95	0.21	0.00	2.28	0.10	0.42
Country	26	14.05	0.20	0.00	2.34	0.10	0.45
Total	185	100	0.21	0.00	2.34	0.10	0.42
Statistics	$U = 1938.00$, $Z = -0.51$, $p = 0.61$						

Table 5-4: PhARIA Compared to Pharmacy Intervention Rate

5.3.2 Pharmacy Type

The pharmacies were divided into the six pharmacy types that resulted from combining the PhARIA and location of the pharmacy (see Chapter 3). A Kruskal-Wallis test showed no significant differences between the pharmacy type and the pharmacy's intervention rate.

	Pharmacy		Intervention Rate				
	Count	%	Median	Minimum	Maximum	Percentile 25	Percentile 75
Metro Shopping Centre	51	27.57	0.19	0.02	0.69	0.08	0.25
Metro Medical Centre	17	9.19	0.25	0.07	1.40	0.18	0.88
Metro Shopping Strip/Other	91	49.19	0.23	0.00	2.28	0.10	0.46
Country Shopping Centre	7	3.78	0.21	0.03	2.34	0.05	1.62
Country Medical Centre	0	0.00
Country Shopping	19	10.27	0.20	0.00	1.35	0.12	0.43
Total	185	100	0.21	0.00	2.34	0.10	0.42

Table 5-5: Pharmacy Type Compared to Intervention Rate

5.3.3 Prescription Volume

The prescription volume dispensed by participating pharmacists within each pharmacy was collected over the twelve week trial period. The prescription volume was then compared to the intervention rate within the pharmacy using a Spearman's correlation. There was a moderately weak, but statistically significant, negative correlation between the two groups (*Spearman's rho* = -0.17, *N* = 185, *p* = 0.02), showing that as the prescription volume increased, the intervention rate tended to decrease (Figure 5-3). As seen in Chapter 3, there was no significant difference in the pharmacy's weekly prescription volume between the three software groups, therefore it is proposed that the weekly prescription volume is an influencing factor on intervention rate, independent of the type of installed software.

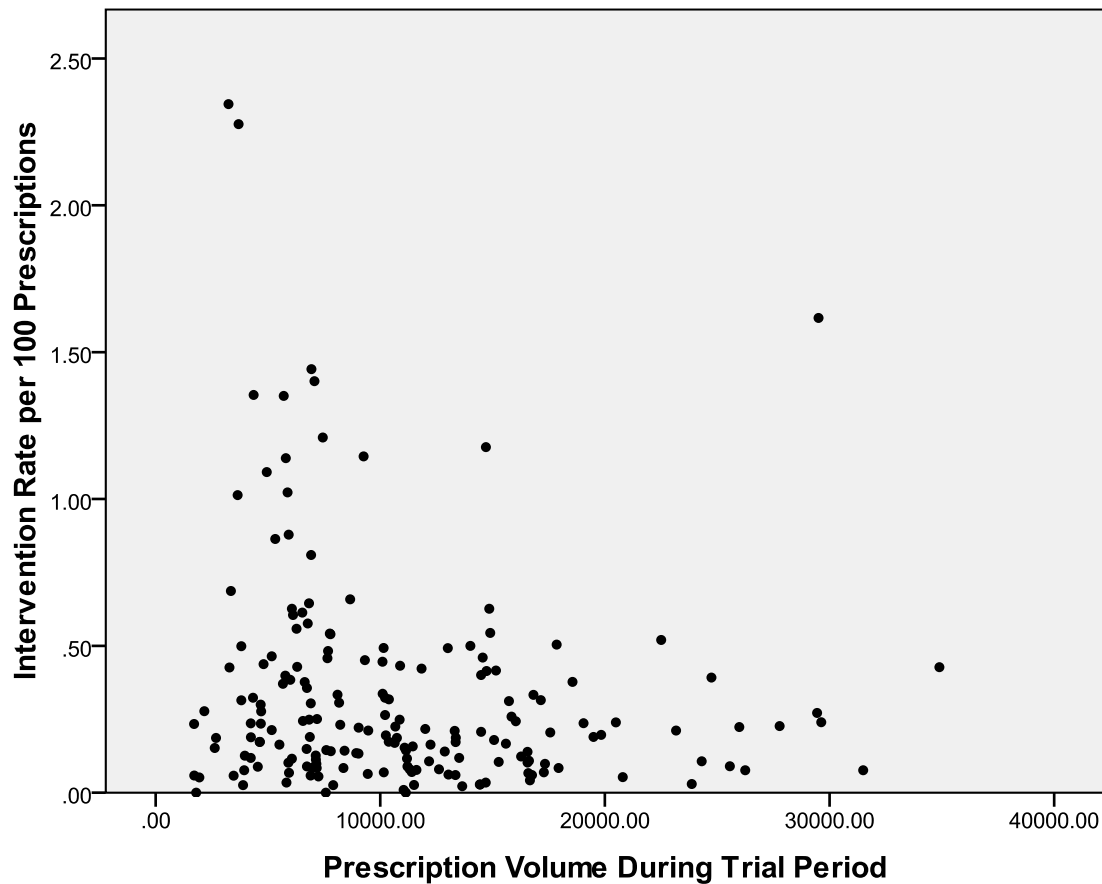


Figure 5-3: Relationship Between Prescription Volume on Intervention Rate per 100 Prescriptions

Note: The outlying value near $x = 30000$ is almost certainly the result of the pharmacist erroneously recording routine counselling when dispensing as DCI, however all data was still included in the analyses.

5.3.4 Pharmacist Workload Within Each Pharmacy

The pharmacist workload was calculated by determining the actual number of prescriptions dispensed per week by the pharmacy during the trial and dividing it by the number of FTE pharmacists per week, resulting in the average number of prescriptions dispensed by a pharmacist during a 38-hour week. This figure was then compared to the overall intervention rate of the pharmacy to determine how much impact a pharmacist's workload had on the intervention rate. A bivariate correlation test showed a moderately weak, but statistically significant, negative correlation between the two factors (*Spearman's rho* = -0.18, $N = 184$, $p = 0.02$), showing that as the pharmacist's workload increased, the pharmacy's intervention rate decreased (Figure 5-4). An analysis of variance also showed no significant difference in the average weekly workload of the pharmacist between the three software groups ($F(2,181) = 1.81$, $p = 0.17$), therefore it is proposed that the average weekly prescription workload of the pharmacist is an influencing factor on intervention rate, independent of the type of installed software.

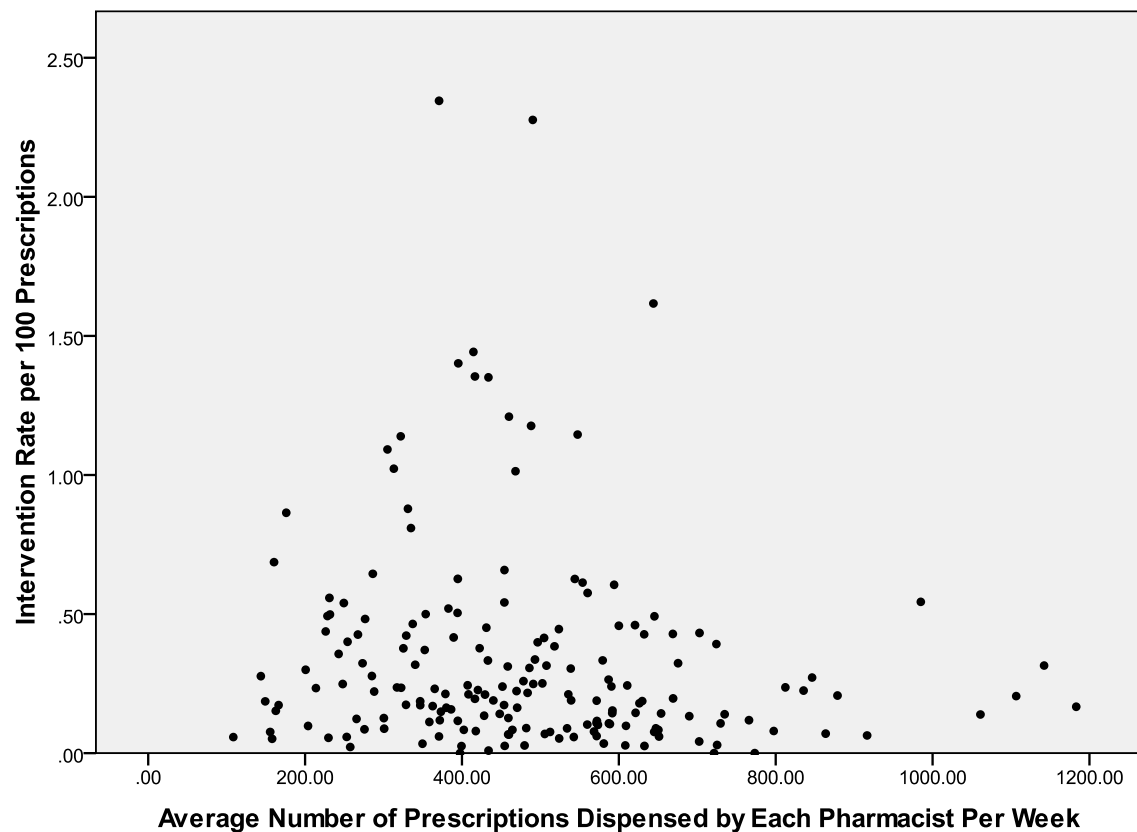


Figure 5-4: Average Pharmacist Workload Per Week Compared to Intervention Rate

5.3.5 Annual Turnover

The pharmacies were divided into four groups according to their annual financial turnover which was then compared to their intervention rate. A Kruskal-Wallis test showed significant differences between the pharmacy's annual turnover and their intervention rate (Table 5-6). The medians show a possible J-curve where the pharmacies with the lowest turnover had a higher intervention rate, which sharply decreased with the next turnover category and then increased again, with the highest turnover category showing the second highest intervention rate. This could possibly be explained by staffing levels and workload, where the pharmacies with the lower turnover have a smaller workload and the pharmacies with the higher turnover perhaps have adequate staffing levels and therefore both have more time to perform and document their interventions. The pharmacies with turnovers in the two middle groups may have larger workloads relative to their staffing levels, but also do not have the turnover to warrant employing more staff, which may lead to less time to perform and document their interventions. As seen in Chapter 3, there was no significant difference in the pharmacy's annual turnover between the three software groups, therefore it is proposed that the annual turnover is an influencing factor on intervention rate, independent of the type of installed software.

		Pharmacy		Intervention Rate				
		Count	%	Median	Minimum	Maximum	Percentile 25	Percentile 75
Annual Turnover	Less than 1.5M	58	31.5%	0.26	0.05	2.34	0.16	0.61
	1.5 - 2.5M	60	32.6%	0.17	0.00	1.01	0.08	0.41
	2.5 - 4.0M	40	21.7%	0.19	0.02	1.21	0.07	0.31
	Over 4.0M	26	14.1%	0.22	0.03	1.62	0.11	0.41
	Total	184	100.0%	0.21	0.00	2.34	0.10	0.42
	Statistics	$\chi^2 = 13.11, df = 3, p < 0.01$						

Table 5-6: Annual Turnover Compared to Pharmacy Intervention Rate

5.3.6 Attribution of Dispensary to Total Pharmacy Turnover

A bivariate correlation test showed no significant differences between their estimated dispensary attribution percentage and the pharmacy's intervention rate (*Spearman's rho* = -0.05, *N* = 184, *p* = 0.54).

5.3.7 Trading Hours

Pharmacies were asked to report their weekly trading hours which was then compared to their intervention rate. A bivariate correlation test showed a moderately weak, but statistically significant negative correlation between the trading hours and the pharmacy's intervention rate (*Spearman's rho* = -0.19, *N* = 184, *p* = 0.01), illustrating that as the number of trading hours increased, the intervention rate decreased (Figure 5-5). This is most likely due to a pharmacy's trading hours reflecting their prescription volume, therefore as the prescription volume increased, the number of trading hours also increased. Another contributing factor may be that the pharmacies with longer opening hours may employ more locum pharmacists who may not have been aware of the PROMISE trial and therefore may have caused an overall decrease in the intervention rate. As seen in Chapter 3, there was no significant difference in the pharmacy's weekly trading hours between the three software groups, therefore it is proposed that the weekly trading hours is an influencing factor on intervention rate, independent of the type of installed software.

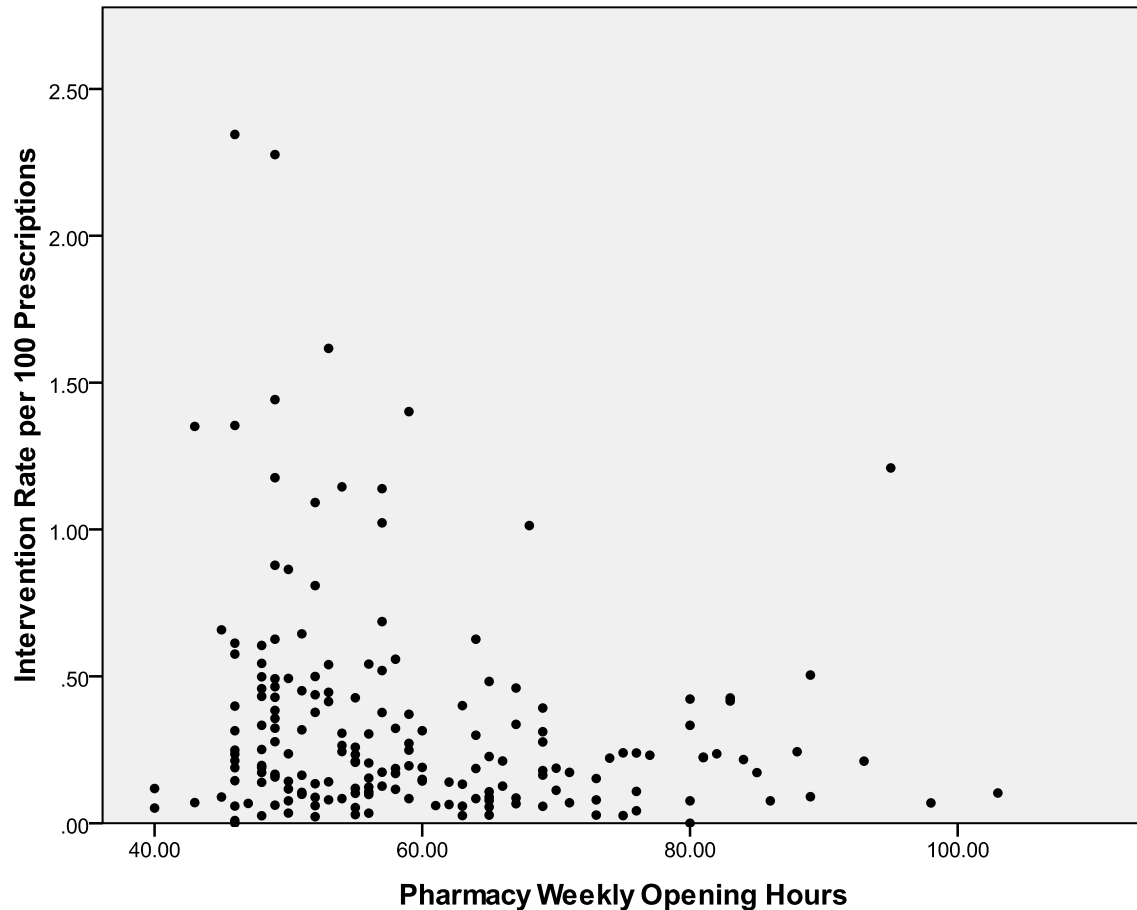


Figure 5-5: Relationship Between Pharmacy Trading Hours on Intervention Rate per 100 Prescriptions

5.3.8 Owner vs Manager Operation

Pharmacies were asked to indicate whether the pharmacy was primarily operated by an owner or a manager; this was then compared to their intervention rate. A chi-square test showed no significant differences between the intervention rates of pharmacies who were owner-operated compared to manager-operated (*Mann-Whitney U* = 3188.00, $z = -0.63$, $p = 0.53$).

5.3.9 Banner Groups

Pharmacies were asked to state whether they were an independent pharmacy or part of a banner group (for example Amcal®, Priceline®, Pharmore®) (See Chapter 3). A Mann-Whitney test showed significant differences between the groups, with independent pharmacies having a higher intervention rate (Table 5-7). As seen in Chapter 3, there was no significant difference between the three software groups and the number of pharmacies affiliated with a banner group, therefore it is proposed that affiliation with a banner group is an influencing factor on intervention rate, independent of the type of installed software.

	Pharmacy		Intervention Rate				
	Count	%	Median	Minimum	Maximum	Percentile 25	Percentile 75
Banner Group	89	48.40%	0.19	0.02	1.62	0.08	0.38
Independent pharmacy	95	51.60%	0.24	0.00	2.34	0.13	0.50
Total	184	100.00%	0.21	0.00	2.34	0.10	0.42
Statistics	$U = 3477.00, Z = -2.08, p = 0.04$						

Table 5-7: Pharmacy Branding Compared to Intervention Rate

Independent T-tests showed that independent pharmacies had a significantly lower average weekly prescription volume and lower average pharmacist workload (Table 5-8) with mean differences of 498.09 (95% CI = 335.90-660.28) and 97.28 (95% CI = 41.77-152.80) respectively. It could therefore be suggested that the higher rate of interventions was possible because of a lower average workload in the independent pharmacies during the trial.

	Pharmacy		Average scripts per week pharmacy dispensed		Average Pharmacist Dispensing Workload Per Week	
	Count	%	Mean	SD	Mean	SD
Banner Group	89	48.4%	1337.42	647.47	528.64	177.71
Independent pharmacy	95	51.6%	839.33	439.16	431.35	201.01
Total	184	100.0%	1080.25	602.45	478.14	195.81
Statistics	$t = -6.07, df = 153.5, p < 0.01$				$t = -3.46, df = 181, p < 0.01$	

Table 5-8: Differences in Prescription Volume and Pharmacist Dispensing Workload Within Banner Groups

5.3.10 Dispensing Systems

The pharmacy's dispensing system (FRED® or Aquarius®) was compared to their intervention rate to determine any differences that may indicate functional differences between the systems. A chi-square test showed no significant differences between the dispensing systems and the pharmacy's intervention rate (*Mann-Whitney U* = 2100.00, $z = -0.13, p = 0.90$).

5.3.11 Pre-Registration Pharmacists

Sixty-four pharmacies indicated that they had employed a pre-registration pharmacist during the past two years, which was then compared to the pharmacy's intervention rate. A Mann-Whitney U test showed significant differences between the intervention rates of those pharmacies who had employed a pre-registration pharmacist compared to those pharmacies that had not (Table 5-9), with the pharmacies that had employed a pre-registration pharmacist tending to have a lower intervention rate. As seen in Chapter 3, there was no significant difference between the three software groups and whether the pharmacy had employed a pre-registration pharmacist in the past two years, therefore it is proposed that the presence of a pre-registration pharmacist is an influencing factor on intervention rate, independent of the type of installed software.

		Pharmacy		Intervention Rate				
Pre-Registration Pharmacist Within Last Two Years?		Count	%	Median	Minimum	Maximum	Percentile 25	Percentile 75
	Yes	64	34.8%	0.19	0.00	1.62	0.09	0.28
	No	120	65.2%	0.24	0.00	2.34	0.11	0.46
	Total	184	100.0%	0.21	0.00	2.34	0.10	0.42
	Statistics	$U = 3117.50, z = -2.10, p = 0.04$						

Table 5-9: Presence of a Pre-Registration Pharmacist Within the Last Two Years Compared to the Pharmacy Intervention Rate

However, independent T-tests showed that pharmacies that had employed a pre-registration pharmacist within the last two years had a significantly higher average weekly prescription volume (Table 5-10) with a mean difference of 461.67 (95% CI = 277.26-646.08). Therefore, the lower intervention rate in pharmacies that employed a pre-registration pharmacist may be explained by the fact that these pharmacies had a higher weekly prescription volume during the trial which has already been explored as a factor that can significantly affect intervention rate.

Pre-Registration Pharmacist Within Last Two Years?		Pharmacy		Average scripts per week pharmacy dispensed	
		Count	%	Mean	SD
	Yes	64	34.78	1381.34	642.24
	No	120	65.22	919.67	514.80
	Total	184	100.0%	1080.25	602.45
	Statistics	$t = -4.96, df = 106.93, p < 0.01$			

Table 5-10: Prescription Volume Differences Between Those Pharmacies Who Employed a Pre-Registration Pharmacist and Those That Did Not

5.3.12 Number of Professional Services Offered

Pharmacies were asked to state which additional services they offered within the pharmacy, including which CPA-funded professional programs they were currently participating in (See Chapter 3). The total number of professional services offered was then compared to the pharmacy's intervention rate. A bivariate correlation test showed a moderately weak, but statistically significant negative correlation between the two factors (*Spearman's rho* = -0.14, $N = 184, p < 0.01$), showing that as the number of professional services offered increased, the pharmacy's intervention rate tended to decrease (Figure 5-6). As seen in Chapter 3, there was no significant difference in the number of professional services offered between the three software groups, therefore it is proposed that the number of professional services offered is an influencing factor on intervention rate, independent of the type of installed software.

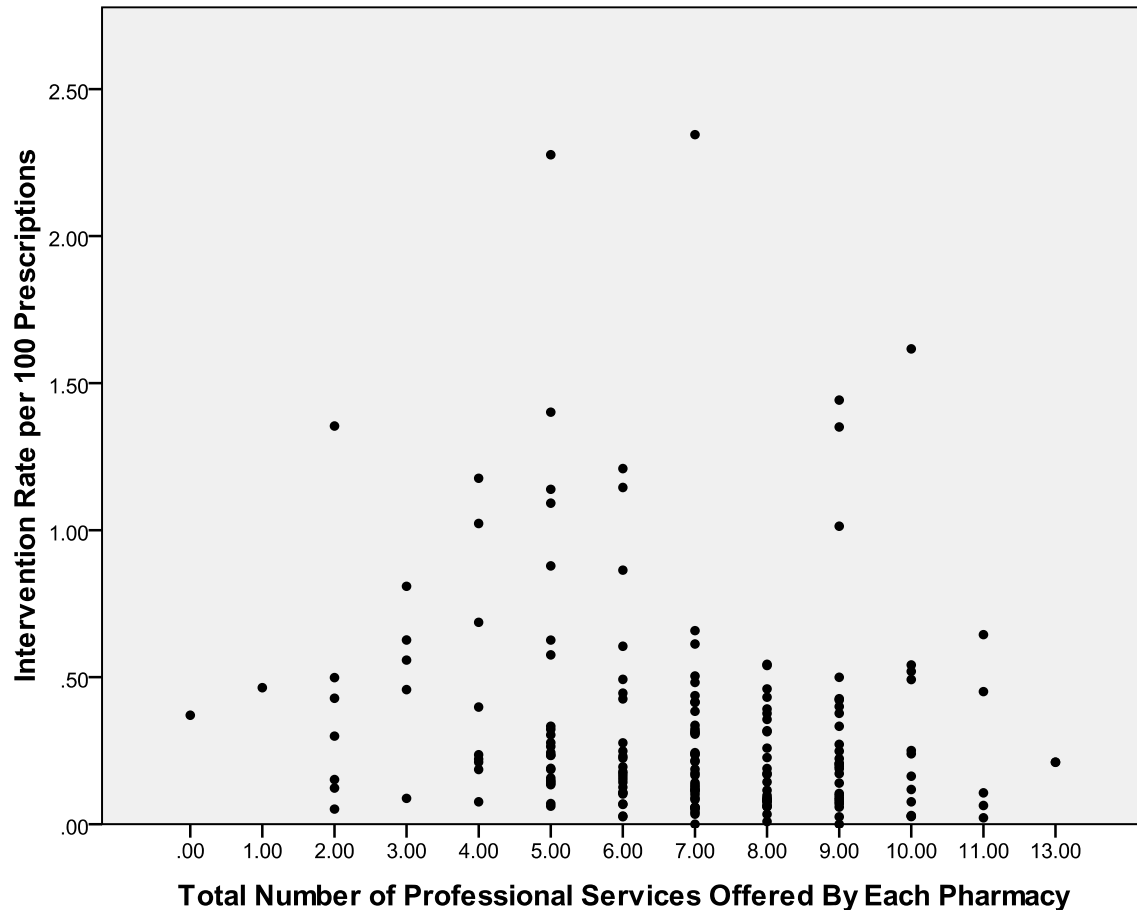


Figure 5-6: Professional Services Offered by Pharmacy

When the number of additional services (including CPA-funded programs) offered by pharmacies were condensed into five groups, a Kruskal-Wallis test still showed significant differences between the number of services offered and the intervention rate (Table 5-11). A Jonckheere-Terpstra test showed a generally negative trend where as the number of services offered increased, the intervention rate decreased ($t = -2.62, p = 0.01$).

		Pharmacy		Intervention Rate				
		Count	%	Median	Minimum	Maximum	Percentile 25	Percentile 75
Number of Professional Services Offered	0	1	0.50%	0.37	0.37	0.37	0.37	0.37
	1-3	13	7.10%	0.46	0.05	1.35	0.15	0.56
	4-6	58	31.50%	0.23	0.03	2.28	0.14	0.49
	7-9	93	50.50%	0.19	0.00	2.34	0.09	0.36
	Over 10	19	10.30%	0.21	0.02	1.62	0.06	0.49
	Total	184	100.00%	0.21	0.00	2.34	0.10	0.42
Statistics		$\chi^2 = 8.13, df = 3, p = 0.04$						

Table 5-11: Count of Additional Services Offered by the Pharmacy Compared to Intervention Rate

5.3.13 Participation in Other Professional Programs

Over 93% of participating pharmacies were also participating in other CPA-funded professional programs whilst completing the PROMISE trial. A Kruskal-Wallis test showed no significant difference between the number of programs currently being run and the intervention rate (Table 5-12). Interestingly, the 12 pharmacies that were not

participating in any other CPA-funded program had the highest median intervention rate whereas the 8 pharmacies concurrently providing 5 other programs had the lowest median intervention rate, which was statistically significant (*Mann-Whitney U* = 18.00, *z* = -2.32, *p* = 0.02). Although based on small numbers, this may indicate that pharmacists can become 'fatigued' which decreases their ability to effectively provide all programs to an optimal rate.

		Pharmacy		Intervention Rate				
		Count	%	Median	Minimum	Maximum	Percentile 25	Percentile 75
Number of CPA-funded Professional Programs	0	12	6.5%	0.35	0.12	1.35	0.24	0.64
	1	17	9.2%	0.19	0.05	1.14	0.13	0.50
	2	45	24.5%	0.23	0.03	1.40	0.13	0.41
	3	67	36.4%	0.20	0.00	2.34	0.09	0.43
	4	35	19.0%	0.21	0.00	0.64	0.10	0.40
	5	8	4.3%	0.10	0.02	1.44	0.04	0.21
Total		184	100.0%	0.21	0.00	2.34	0.10	0.42
Statistics		$\chi^2 = 8.60, df = 5, p = 0.13$						

Table 5-12: Number of CPA-Funded Programs Run by Each Pharmacy Compared to Intervention Rate

5.3.14 Counselling Area

During the site visits, PROMISE team members noted if each pharmacy had a counselling area and if it was a temporary or permanent area. When compared to the intervention rate, there were no significant differences between the three types of counselling area within the pharmacies and the intervention rate (*Kruskal-Wallis* $\chi^2 = 3.05$, *df* = 2, *p* = 0.22). The pharmacies were then recoded into two groups where they either had a permanent counselling area or no counselling area, with those pharmacies with a temporary counselling area being coded as having no counselling area. When compared to the intervention rate, there was still no significant differences between the presence of a permanent counselling area and the pharmacy's intervention rate (*Mann-Whitney U* = 3513.00, *z* = -1.74, *p* = 0.08).

		Pharmacy		Intervention Rate				
		Count	%	Median	Minimum	Maximum	Percentile 25	Percentile 75
Type of Counselling Area	No/Temporary	106	57.6%	0.24	0.00	2.34	0.12	0.44
	Permanent	78	42.4%	0.18	0.00	2.28	0.08	0.38
	Total	184	100.0%	0.21	0.00	2.34	0.10	0.42

Table 5-13: Type of Counselling Area Compared to Pharmacy Intervention Rate

5.3.15 Pharmacist Accessibility

During the site visits, PROMISE team members noted if the pharmacists were easily accessible to the public (see Chapter 3). A chi-square test showed no significant differences in the intervention rate between pharmacies where the pharmacist was considered to be easily accessible compared to those where the pharmacist was not easily accessible (*Mann-Whitney U* = 1471.00, *z* = -1.51, *p* = 0.13).

5.4 Pharmacist Factors

Several pharmacist factors were compared against their valid intervention rate to determine which pharmacist factors may impact on their individual intervention rate.

5.4.1 Number of pharmacists

Of the 531 pharmacists enrolled in the trial, 22 pharmacists (4.1%) did not dispense any prescriptions during the trial and were therefore considered “inactive”. These pharmacists were presumed to have stopped working at the participating pharmacy before the trial. The remaining 509 (95.9%) were considered “active” as they dispensed at least one prescription during the trial, however only 427 (83.9%) of those “active” pharmacists recorded an intervention using the PROMiSe software during the trial period.

5.4.2 Intervention Rates

Two different intervention rates were calculated for each pharmacist using the prescription and non-prescription DCI, plus the prescriptions dispensed during the trial period. The ‘Total Intervention Rate’ refers to the number of DCI (both prescription and non-prescription, such as over-the-counter medications) recorded by that pharmacist divided by the number of prescriptions dispensed by that pharmacist during the trial period. The ‘Valid Intervention Rate’ refers to the number of DCI recorded by that pharmacist divided by the number of prescriptions dispensed by that pharmacist during the trial period, however the over-the-counter DCI and prompted DCI have been removed. Although the ‘Total Intervention Rate’ is higher, it is less accurate as the denominator only accounts for prescriptions dispensed and not over-the-counter medication sales. The ‘Valid Intervention Rate’ is therefore used for the following calculations, as it is considered the base prescription intervention rate with no prompts artificially boosting the rate (Table 5-14 and Figure 5-7).

	N	Median	Percentile 25	Percentile 75	Minimum	Maximum
Total Intervention Rate	509	0.185	0.057	0.445	0.000	5.128
Valid Intervention Rate	509	0.162	0.050	0.341	0.000	3.835

Table 5-14: Median Intervention Rate For All Pharmacists During the PROMiSe Trial

The median valid intervention rate during the trial was 0.16% (range 0.00 – 3.84) or 1.6 DCI in every 1000 prescriptions (Table 5-14). When including the prompted and non-prescription DCI, the median intervention rate rose to 0.19% (range 0.00 – 5.13) or 1.9 DCI in 1000 prescriptions (Table 5-14).

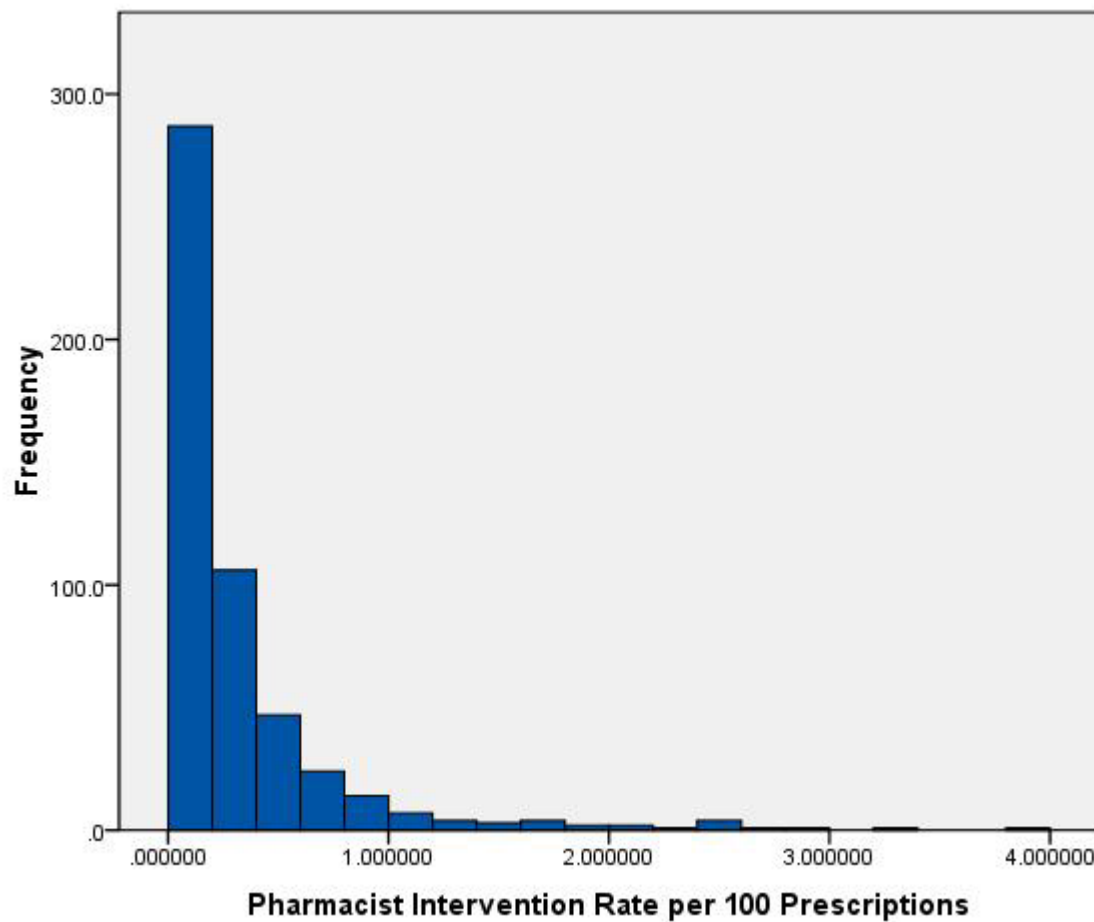


Figure 5-7: PROMISe Pharmacists Intervention Rate per 100 Prescriptions

The pharmacists were separated into quartiles according to their valid intervention rate. The first quartile contained 85 pharmacists who did not record a valid intervention during the trial, resulting in a median of zero. The fourth quartile had a much higher median intervention rate of 0.63 DCI in 100 prescriptions (range 0.34 – 3.84) or 6.3 DCI in 1000 prescriptions (Table 5-15).

		Pharmacy Count	Intervention Rate				
			Median	Minimum	Maximum	Percentile 25	Percentile 75
Quartile Group	1	127	0.000	0.000	0.048	0.000	0.025
	2	127	0.107	0.051	0.160	0.076	0.130
	3	128	0.238	0.162	0.338	0.197	0.280
	4	127	0.629	0.343	3.835	0.498	0.994
	Total	509	0.162	0.000	3.835	0.051	0.338

Table 5-15: Median Intervention Rate for Pharmacists Within Each Quartile

5.4.3 Effect of training

All pharmacists were encouraged to attend both face-to-face training and complete the online training. Of the 531 pharmacists enrolled in the trial, 101 completed neither type of training, 215 completed online training only, 19 completed face-to-face training only and 196 completed both the face-to-face training and online training. A Kruskal-Wallis test showed significant differences between the groups (Table 5-16) and the Jonckheere-Terpstra test showed a positive trend between the level of training and the intervention rate ($t = 7.58$, $p < 0.01$), with those

pharmacists who completed both types of training having a higher intervention rate. This is most likely due to the training increasing the awareness and understanding of the project and therefore increasing the number of DCI recorded during the trial period. As seen in Chapter 3, there was no significant difference in the level of training that the pharmacist undertook between the three software groups, therefore it is proposed that the level of training is an influencing factor on intervention rate, independent of the type of software installed.

		Pharmacy		Intervention Rate				
		Count	%	Median	Minimum	Maximum	Percentile 25	Percentile 75
Level of Training	Neither web or face-to-face training	101	19.0%	0.04	0.00	2.73	0.00	0.15
	Web training only	215	40.5%	0.16	0.00	2.86	0.06	0.31
	Face-to-face training only	19	3.6%	0.10	0.00	1.17	0.03	0.36
	Web and face-to-face training	196	36.9%	0.26	0.00	3.84	0.12	0.52
Total		531	100.0%	0.16	0.00	3.84	0.05	0.34
Statistics		$H = 62.81, df = 3, p < 0.01$						

Table 5-16: Effect of Training on Pharmacist Intervention Rate

5.4.4 Demographics

A Mann-Whitney U test showed no significant differences between the gender of the pharmacist and their intervention rate ($\chi^2 = 23949.50, Z = -0.41, p = 0.68$). A Kruskal-Wallis test showed no significant differences between the age of the pharmacist and their intervention rate ($\chi^2 = 6.72, df = 4, p = 0.15$). A bivariate correlation test also showed no correlation between the pharmacist's graduation year and their intervention rate (*Spearman's rho* = -0.03, $N = 443, p = 0.48$).

5.4.5 Survey Scores

Pharmacists were asked to complete three surveys evaluating empathy, professionalism and clinical knowledge. Only the clinical knowledge score showed a significant difference when compared to intervention rates (Table 5-17) illustrating that as the pharmacist's clinical knowledge increased, their intervention rate also tended to increase (Figure 5-8). As seen in Chapter 3, there was no significant difference in the pharmacist's clinical knowledge score between the three software groups, therefore it is proposed that the clinical knowledge score is an influencing factor on intervention rate, independent of the type of installed software.

	Survey		
	Empathy	Professionalism	Clinical Knowledge
<i>Spearman's rho</i>	0.05	0.03	0.16
<i>N</i>	442	443	422
<i>p-value</i>	0.34	0.48	<0.01

Table 5-17: Statistical Results From Correlation Tests For Pharmacist Survey Scores Compared to Intervention Rate

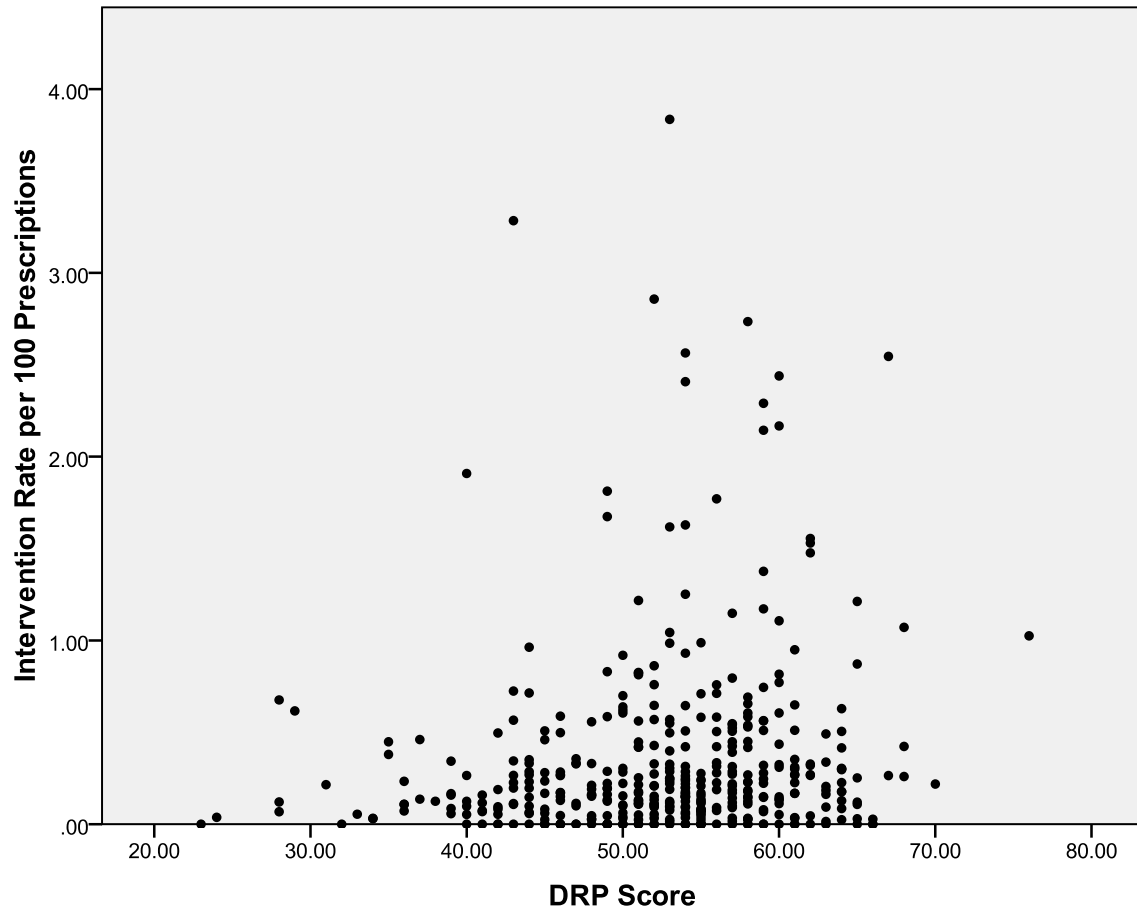


Figure 5-8: Relationship Between Pharmacist's Drug-Related Problem Survey Score and Intervention Rate per 100 Prescriptions

5.4.6 Role of Pharmacist

During the survey administration, pharmacists reported their current role in community pharmacy which was then compared to their intervention rate. A Kruskal-Wallis showed no significant difference between the role of the pharmacist and their intervention rate (Table 5-18).

		Pharmacy		Intervention Rate				
		Count	%	Median	Minimum	Maximum	Percentile 25	Percentile 75
Role of Pharmacist	Owner	146	31.9%	0.21	0.00	3.84	0.10	0.44
	Manager	74	16.2%	0.19	0.00	2.29	0.08	0.31
	Employee	211	46.1%	0.17	0.00	3.28	0.05	0.42
	Locum	18	3.9%	0.11	0.00	2.41	0.00	0.25
	Other	9	2.0%	0.11	0.00	1.25	0.01	0.37
	Total	458	100.0%	0.18	0.00	3.84	0.07	0.42
Statistics		$\chi^2 = 6.86, df = 4, p = 0.14$						

Table 5-18: Role of Pharmacist Compared to Intervention Rate per 100 Prescriptions

5.4.7 Continuing Professional Development Activity

Pharmacists were asked to report how many hours of continuing professional development (CPD) activity they completed on average per year, which was then compared to their intervention rate. A Kruskal-Wallis test showed a significant difference between the level of CPD activity and intervention rate (Table 5-19). A Jonckheere-Terpstra test confirmed a positive trend between the level of CPD activity and the intervention rate ($t = 4.08$, $p < 0.01$), showing that as the level of CPD activity per year increased, the intervention rate also increased. As seen in Chapter 3, there was no significant difference in the level of CPD activity between the three software groups, therefore it is proposed that CPD activity is an influencing factor on intervention rate, independent of the type of software installed.

		Pharmacy		Intervention Rate				
		Count	%	Median	Minimum	Maximum	Percentile 25	Percentile 75
Level of CPD Activity	None	3	0.7%	0.00	0.00	0.00	0.00	0.00
	Less than 10 hours	45	9.8%	0.11	0.00	0.92	0.07	0.31
	10 - 25 hours	175	38.2%	0.15	0.00	2.17	0.05	0.28
	25 - 50 hours	158	34.5%	0.22	0.00	3.84	0.07	0.51
	More than 50 hours	77	16.8%	0.27	0.00	2.14	0.13	0.58
	Total	458	100.0%	0.18	0.00	3.84	0.07	0.42
Statistics		$\chi^2 = 19.58$, $df = 4$, $p < 0.01$						

Table 5-19: Level of CPD Activity Compared to Pharmacist Intervention Rate per 100 Prescriptions

5.5 Effect of Observation

The PROMISE project involved pharmacists documenting interventions in their pharmacies. In order to determine what proportion of interventions actually undertaken were documented, observers were placed in a sample of pharmacies for a period of five consecutive days (Monday to Friday).

Observers were present in the pharmacy for the day and documented all situations that were classified as an intervention and whether or not the intervention was documented on the PROMISE system. Observers were placed in pharmacies that had no PROMISE software installed, the 'no software' group, and in all three pharmacy software groups (group one - software only, group two - software and reminder and group three - software, reminder and prompt). The ultimate aim of the observation period was to determine what percentage of performed actual clinical interventions (ACI) were recorded.

5.5.1 Undertaking Interventions and Documenting Interventions

Observers recorded each intervention that was undertaken by the observed pharmacist as well as whether the pharmacist recorded the intervention (either in their existing system or on the PROMISE software system). The results are shown in Figure 5-9 and indicate that when the software was installed, 49% of ACI were documented (Table 5-10). In the control group, the documentation rate was much lower with only 7% of all ACI being documented.

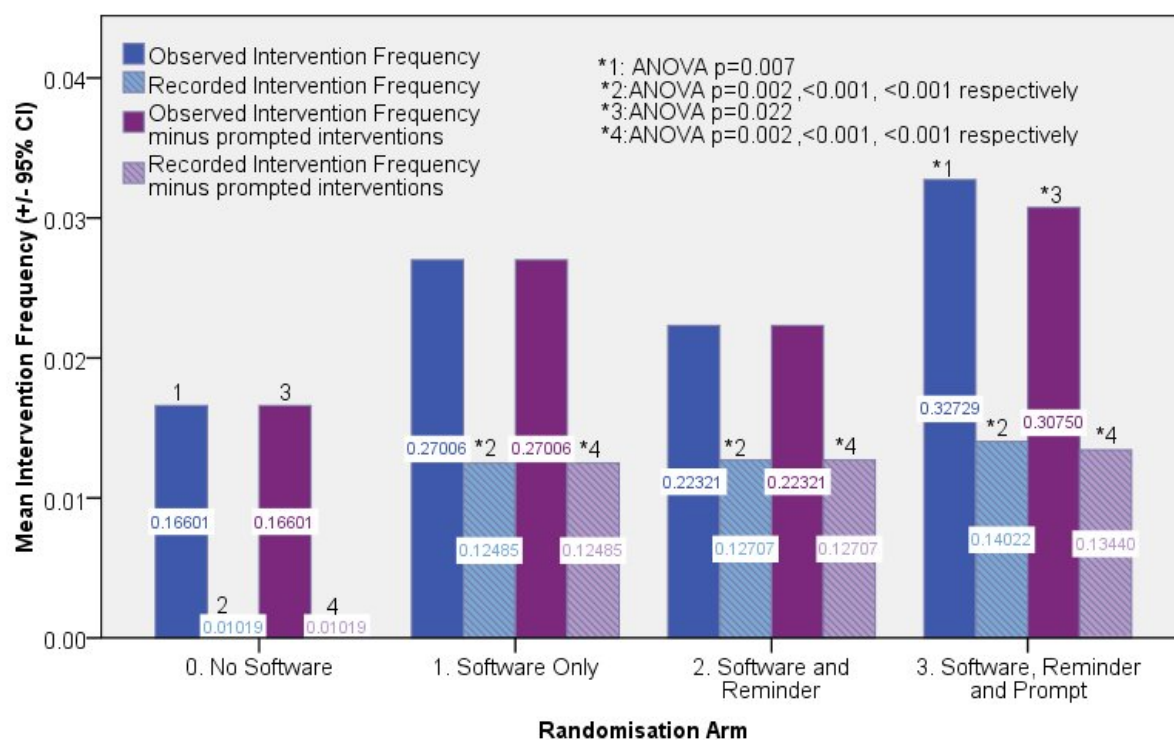


Figure 5-9: Observed and Documented Intervention Frequency per 100 prescriptions in each Study Group

There was no difference between the three software groups in terms of the documentation rate or in terms of the observed rate. The observed intervention frequency in group three was higher than the 'no software' group, even after removal of prompted DCI.

When the significance of the DCI in all three software groups was compared to the ACI, there was a significant difference ($Pearson \chi^2 = 18.95$, $df = 1$, $p < 0.001$), with the more significant ACI being documented more frequently (62% and 43% of the higher and lower significance interventions, respectively, being recorded; see Table 5-20).

Clinical Significance	Documented						Total
	Yes			No			
	#	% of Sig	% of Doc	#	% of Sig	% of Doc	
Lower	160	43	57	215	57	75	375
Higher	119	62	43	73	38	25	192
Total	279	49	100	288	51	100	567

Table 5-20: Clinical Significance of DCI vs. ACI in the Three Software Groups

5.5.2 Effect of Observation within each Pharmacy

Observers were present in each of the pharmacy software allocation groups. The effect of the observers was then measured by comparing observed and non-observed pharmacies.

Intervention Rate in Observed Pharmacies

The overall DCI rate in the pharmacies that were observed (note: for one of 12 weeks only) was significantly higher than in those pharmacies that were not observed (Mann-Whitney $Z = -7.75$, $p < 0.001$) (see Figure 5-10).

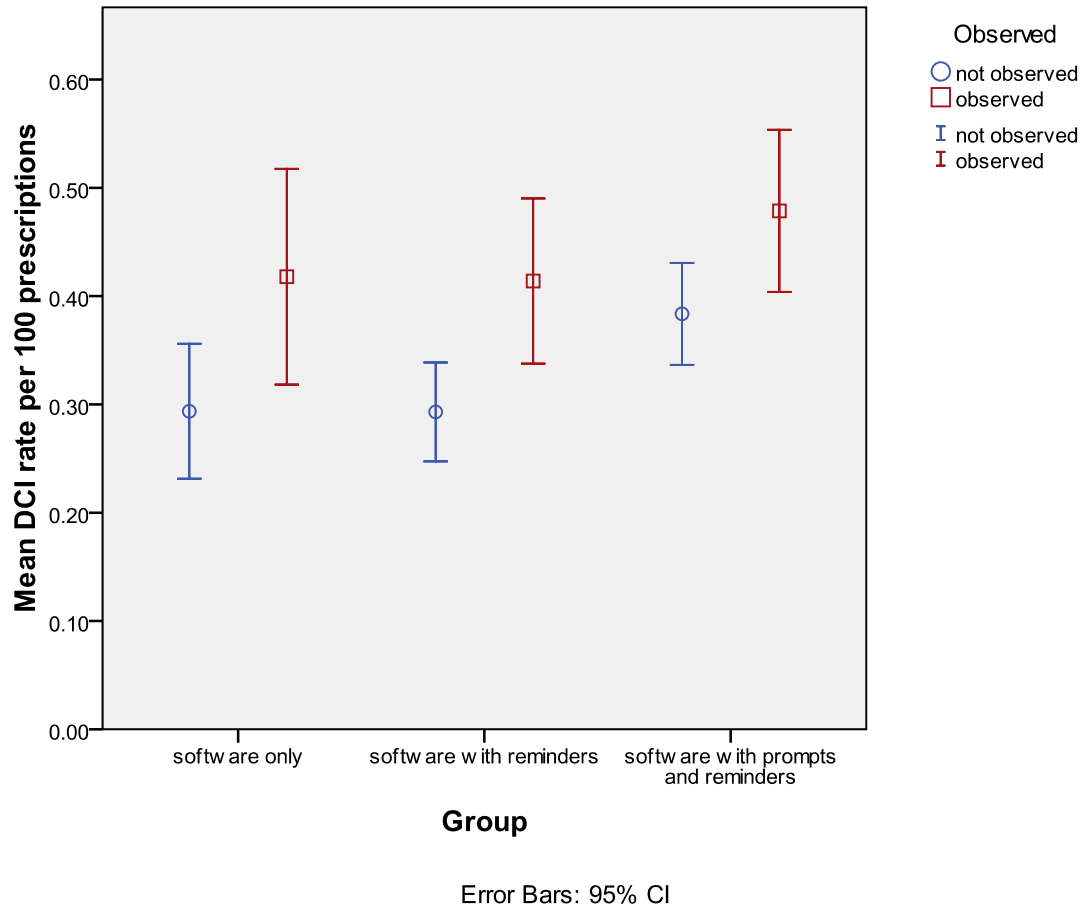


Figure 5-10: Overall DCI Frequency for Observed vs Unobserved Pharmacies

This difference was present despite the fact that the first three weeks of the study did not include any observation visits (see Figure 5-11).

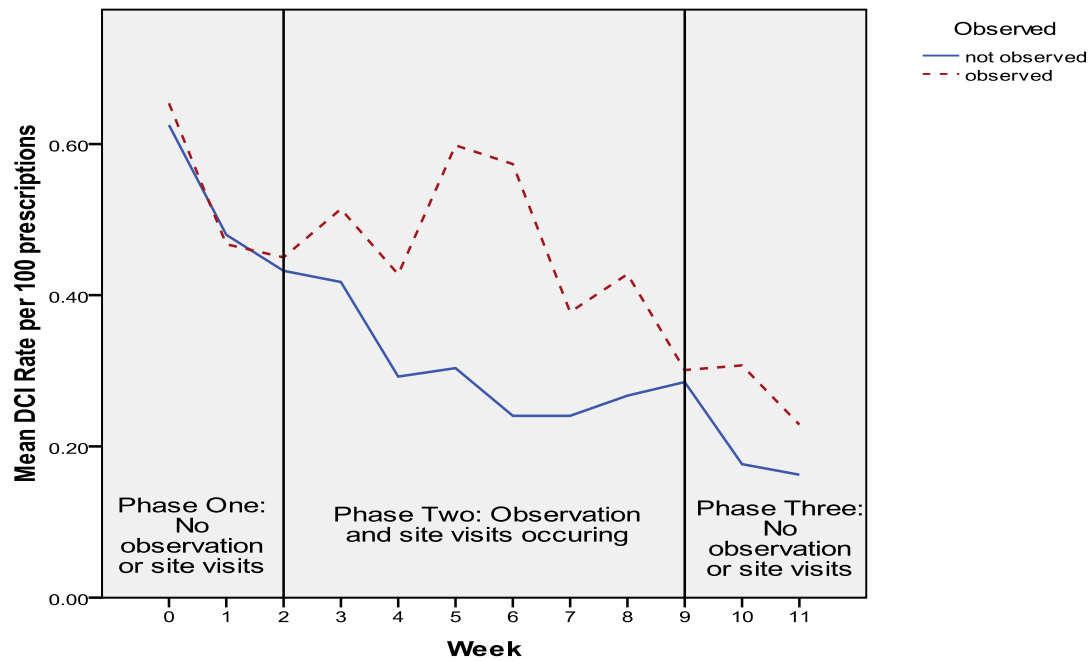


Figure 5-11: Effect of Observation on DCI Frequency

Effect of the Observation Week on Intervention Rate

When the DCI rate for the actual observed week was compared to the DCI rate in the remainder of the trial (even in the non-observed weeks in pharmacies allocated observers), the differences were even more marked (see Figure 5-12). This is most likely due to the Hawthorne effect²²⁵ where the presence of the observer would be expected to increase the documentation of interventions. This would be due to the observer increasing the pharmacist's awareness of the program but also the pharmacist would have a sub-conscious desire to 'please' the observer by documenting their interventions, therefore resulting in a higher intervention rate.

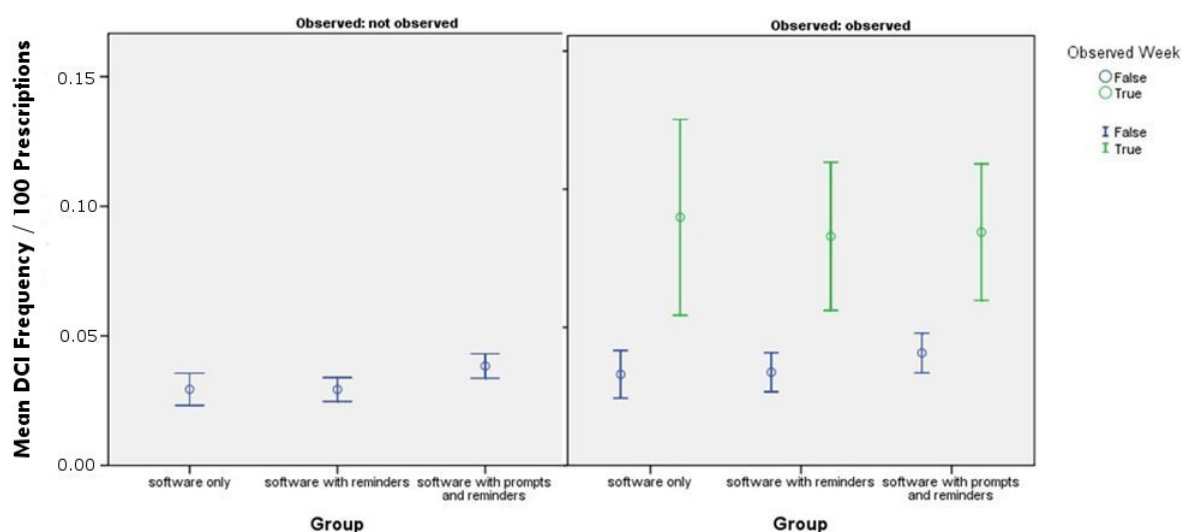


Figure 5-12: Intervention Frequency During the Observed Week

The data from each observed pharmacy was then separated into three groups (Before Observation, Observation Week and After Observation) to determine if the observation period increased their DCI rate for the remaining weeks of the trial. It is important to note that although each pharmacy was only observed for a five-day period

during the trial, the rolling start meant that the observation 'week' could span two weeks in the dataset. For example, if a pharmacy was activated on a Wednesday, their pharmacy week would be coded as Wednesday to Tuesday (day 1-7). Therefore, although the observation week followed a calendar week, the dataset for that pharmacy may not have. This resulted in two observation weeks being presented in Figure 5-13.

Figure 5-13 shows that the weeks of observation (displayed as Week 0 and Week 1) had a significantly higher weekly DCI rate compared to the Before and After Observation periods ($Kruskal-Wallis \chi^2 = 62.89$, $df = 2$, $p < 0.01$).

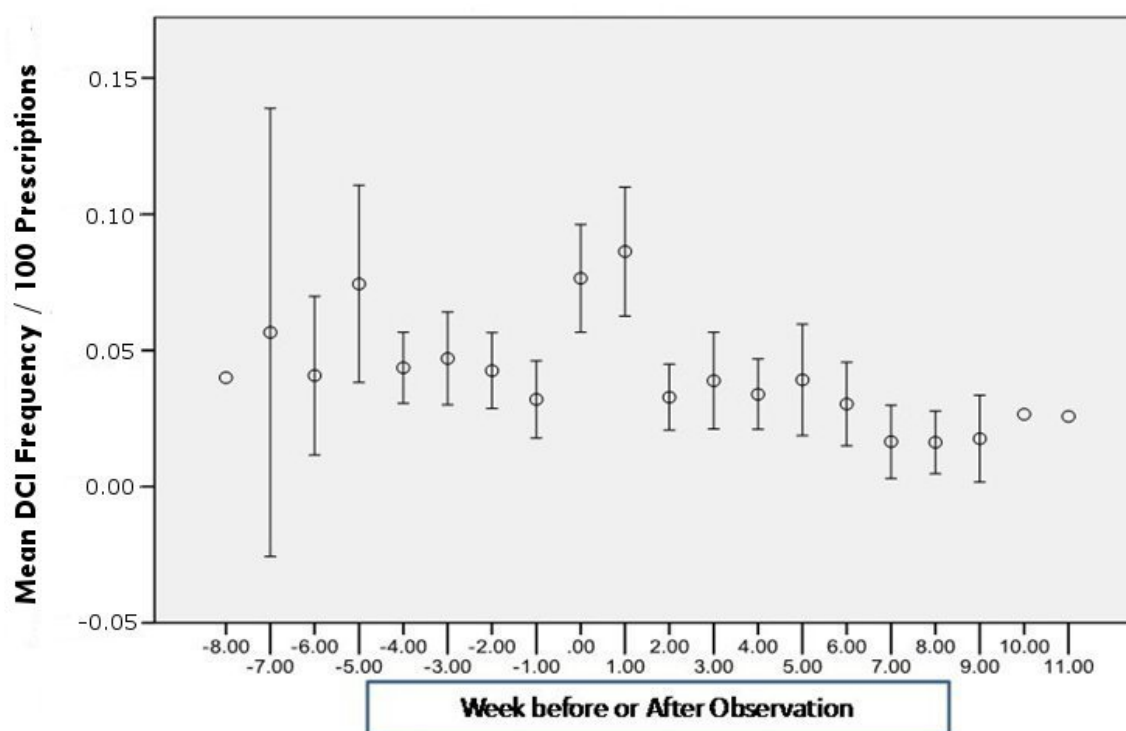


Figure 5-13: Variation in Intervention Frequency by weeks before and after Observation Week

When the Before and After observation periods were compared to each other, the Before period still had a significantly higher DCI rate than the After period ($Mann-Whitney U = 13060.00$, $z = -4.05$, $p < 0.01$) (Figure 5-14). Therefore, the observation appeared to only affect the pharmacy whilst the observer was present, with no lasting effects once the observation week had finished, as the DCI rate of the observed pharmacies continued to decline like the remaining trial pharmacies.

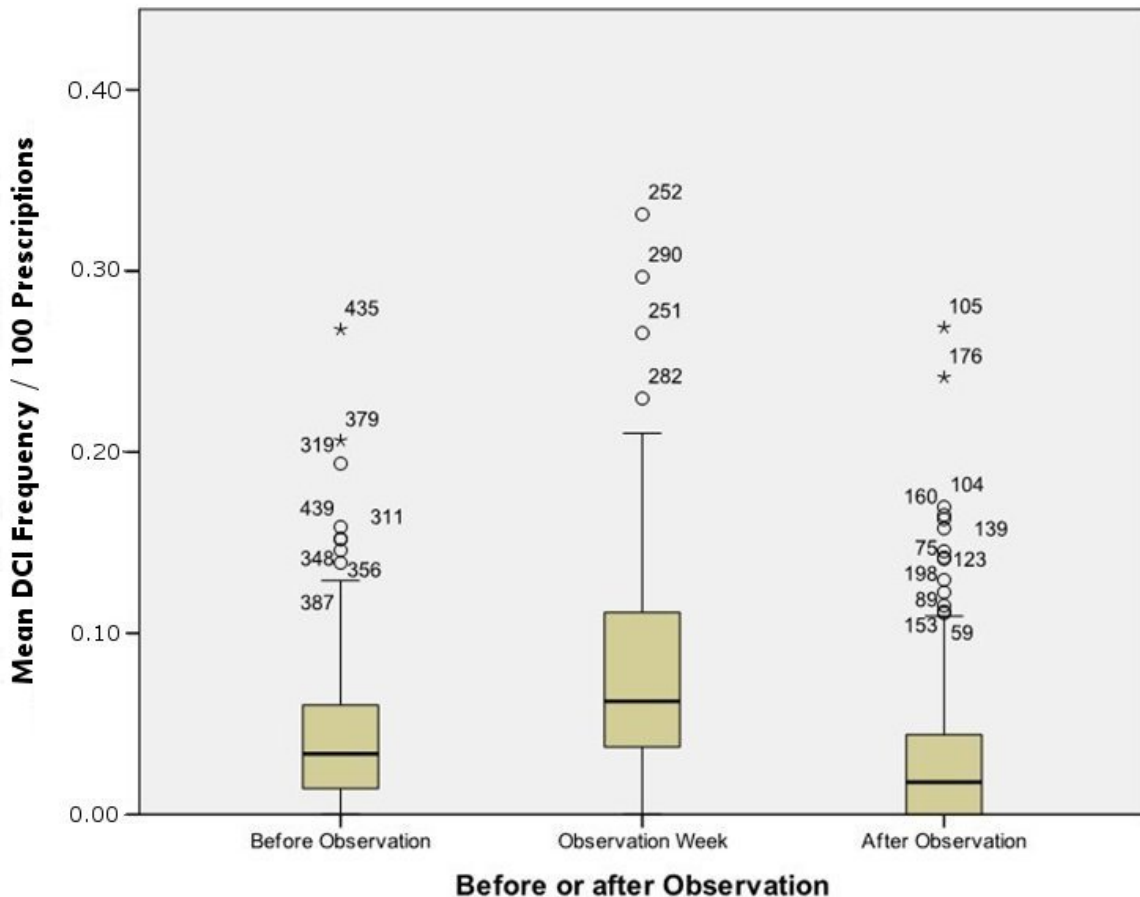


Figure 5-14: Variation in DCI Frequency Before and After Observation Week

Comparisons Between the Intervention Rate of Observed and Non-Observed Pharmacies

The data from the observed weeks was then removed and the DCI rate from the non-observed pharmacies was compared to the DCI rate in the non-observed weeks of the observed pharmacies. A Mann-Whitney U test still showed a significant difference ($U = 279872.00$, $z = -4.88$, $p < 0.01$), with the observed pharmacies having a higher DCI rate overall. Given that the observed pharmacies had a higher DCI rate before observation began (Figure 5-13), the difference cannot be explained by the observer's influence continuing on after the observation week had finished. It is more likely due to a selection bias, where although the pharmacies were selected according to their PhARIA and prescription volume, it was still the pharmacy's choice if they wanted to be involved in the observational sub-study. Therefore, the observed pharmacies may have been biased towards having a higher DCI rate already, as they may have been more pro-active and keener participants in the PROMISE trial because they chose to be part of the observation group.

Overall Effect of Observation on Intervention Rate

The data shows that the observer made a large difference in the DCI rate of a pharmacy, but only during the week whilst they were there. It also indicates that the single observed week was a major contributor to the DCI rate differences between the observed and non-observed pharmacies (Figure 5-10). This difference cannot be solely accounted for by the observer presence increasing the rate of documentation, therefore the observer appears to have also increased their performance of interventions.

Similarly, the large peak in the DCI rate during the observation week may also show that the observed documentation rate of 49% (see Paragraph 5.5.1) may also be over-inflated, as the presence of an observer significantly increased the documentation (and possibly the performance) of clinical interventions. This may

indicate that the actual proportion of interventions that were documented during the trial may be lower than the observed documentation rate of 49%.

5.6 Discussion of Frequency of Clinical Interventions

There appeared to be several factors that influenced the frequency of DCI. The reminder at 11am and 3pm significantly increased the number of DCI recorded during those hours in Group 2 and Group 3.

Original prescriptions were subjected to a much higher DCI rate than repeat prescriptions, accounting for 77.9% of all DCI at a rate of 0.37% (3.7 DCI in 1000 original prescriptions) which was significantly different to the DCI rate of 0.09% (0.9 DCI in 1000 repeat prescriptions).

The pharmacy factors that appeared to influence DCI rate were weekly prescription volume, annual financial turnover, pharmacy trading hours and average pharmacist workload (Table 5-21), where as the turnover and workload in the pharmacy increased, the intervention rate decreased. This is most likely due to less busy pharmacies having better dispensary workflow and therefore increased time available for the pharmacist to perform and record their interventions. Banner groups also had a lower DCI rate compared to independent pharmacies; however, this is likely to be due to independent pharmacies having a significantly lower prescription volume and lower pharmacist workload (Table 5-8). As the number of offered professional services increased, the DCI rate decreased, which may indicate that there is a saturation level to the number of services a pharmacy can offer. Pharmacies that had employed a pre-registration pharmacist within the last two years also had a lower DCI rate compared to pharmacies that had not employed a pre-registration recently. However, this is also likely to be due to the pharmacies employing pre-registration pharmacists having a significantly higher prescription volume (Table 5-10).

The pharmacy factors that did not appear to be related to DCI rate included PhARIA, pharmacy type, dispensary attribution, owner/manager operation, dispensing software, the type of counselling area and the accessibility of the pharmacist (Table 5-21).

Summary	p-value
Number of Professional Services Offered	<0.01
Annual Turnover	<0.01
Trading Hours	0.01
Weekly Prescription Volume	0.02
Pharmacist Workload	0.02
Banner Groups	0.04
Employs Pre-Registration Pharmacists	0.04
Pharmacy Type	0.10
Pharmacist Accessibility	0.13
Participation in Other Programs	0.13
Counselling Area	0.22
Owner vs Manager Operation	0.53
% Dispensary Attribution	0.54
PhARIA	0.61
Dispensing Software	0.90

Table 5-21: Impact of Each Pharmacy Factor on the Pharmacy DCI Rate

The pharmacist factors that appeared to influence DCI rate were the level of training the pharmacist had received, their clinical knowledge score and the number of CPD hours they completed per year. This may indicate that the more time the pharmacist puts into their professional development, the higher their intervention rate could be. Pharmacist factors that did not appear to influence intervention rate were gender, age, graduation year, empathy score, professionalism score and their role within the pharmacy.

Observation only influenced the DCI rate whilst the observer was present within the pharmacy. There did not appear to be any lasting effect on the DCI rate from the observation period, however the observed pharmacies did have a higher DCI rate overall. However, observers found that only 49% of ACI were being documented, which means that the overall ACI rate may be double what the current documentation rate is.

Chapter 6 Results and Discussion: Efficacy of the Proton-pump Inhibitor Step-down Prompt

As described previously in Chapter 2, pharmacies allocated to group three received a specific prompt which was activated upon the dispensing of original or repeat prescriptions involving Nexium® (esomeprazole 40mg tablets) and Somac® (pantoprazole 40mg tablets). Throughout this chapter, these drugs will be referred to as high dose PPIs.

The purpose of the prompt was to encourage pharmacists to advise patients to approach their medical practitioner for a review of their therapy and consider changing their long term PPI therapy from higher dose therapy to a lower dose therapy (as advocated by the National Prescribing Service and contemporary guidelines).¹⁹⁹

6.1 Opportunities to Intervene

Among group three pharmacies in the PROMiSe III trial, 16,924 prescriptions for esomeprazole 40mg tablets (7,967 prescriptions for 4,647 individual patients) and pantoprazole 40mg tablets (8,957 prescriptions for 4,856 individual patients) were dispensed. The prompt appeared on the dispensing screen part way through the dispensing process of the specified drug (see Figure 6-1). Each time a targeted drug was dispensed, the prompt allowed the pharmacist to print an information leaflet for either the patient or pharmacist/GP, or click a button to continue dispensing.

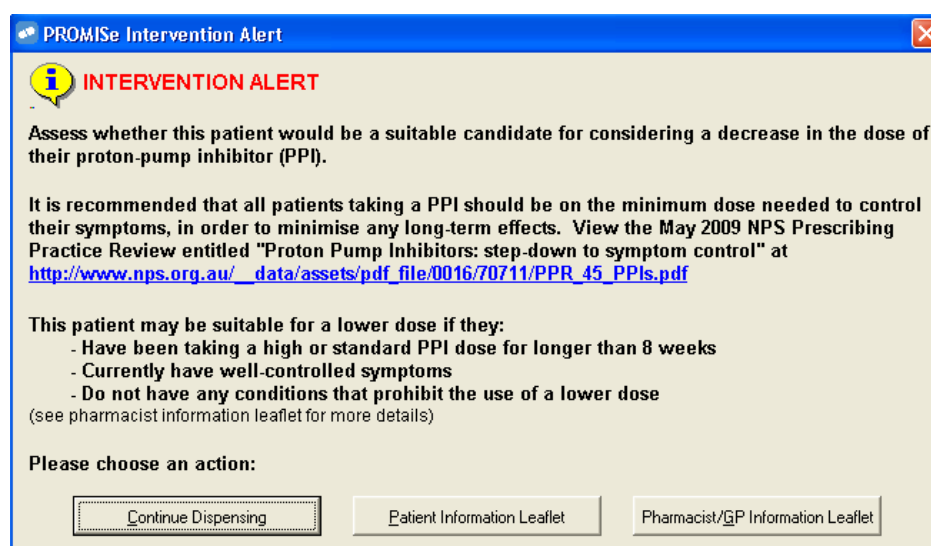


Figure 6-1: The Proton Pump Inhibitor (PPI) Prompt

The number of actual opportunities to intervene would be lower to a certain extent since some patients may have been using high dose PPIs for a short time period or have specific medical conditions warranting continued treatment at the current regimen. Therefore in some cases, targeting particular patients for the step-down DCI would not be clinically appropriate.

6.2 Identification of Clinical Interventions Relating to PPI Step-down

All pharmacist-initiated step-down recommendations for high dose PPIs were identified by selecting DCI from the repository concerning high dose PPIs and the following recommendation categories: R2 *dose decrease*, R3 *drug change*, R7 *Prescription not dispensed* and/or R13 *education session*. The R2 category clearly indicates a step-down recommendation (half of the recommendations were in this category). These categories also typically appeared to be related to step-down DCI as indicated by the notes composed by pharmacists. In addition, a search through the remaining high dose PPI DCI and reading pharmacist notes for each one identified another 25 PPI step-down DCI.

In total, there were 330 PPI recommendations during the trial and the median time taken for a pharmacist to complete a PPI step-down DCI was 4 minutes, as shown in Table 6-1.

Time to perform intervention (minutes)	
Mean	4.41
Median	4.00

Table 6-1: Length of Time to Perform PPI Step-Down intervention (minutes)

The cost of a pharmacist's time at median of 4 minutes per DCI and an average base hourly pharmacist rate of \$36.71 is \$2.45.²²⁶ *The median time taken to perform this DCI is the same as aspirin prompt intervention which was reported in the PROMISE II project¹⁹⁷.*

A much higher DCI rate for high dose PPIs was observed in group three pharmacies, when the rate of PPI DCI per pharmacy across each pharmacy group was compared (Table 6-2).

Total step-down DCI and average per pharmacy - entire trial						
Group	Number of Pharmacies	Esomeprazole 40mg		Pantoprazole 40mg		Total
		Count	DCI per pharmacy	Count	DCI per pharmacy	
1	40	8	0.20	5	0.13	13
2	72	24	0.33	11	0.15	35
3	73	158	2.16	124	1.70	282
Total		190		140		330

Table 6-2: Step-down Interventions by Pharmacy Group Shown as Rate per Pharmacy

A much higher DCI rate for high dose PPIs was also observed in group three pharmacies, when the rate of DCI per esomeprazole (40mg) and pantoprazole (40mg) prescriptions across each pharmacy group was compared (

Table 6-3 and Figure 6-2).

Group	Esomeprazole 40mg			Pantoprazole 40mg		
	Esomeprazole 40mg DCI	Number of Esomeprazole 40mg prescriptions	DCI per prescription (%)	Pantoprazole 40mg DCI	Number of Pantoprazole 40mg prescriptions	DCI per prescription (%)
1	8	3730	0.21%	5	4600	0.11%
2	24	8854	0.27%	11	10283	0.11%
3	158	7967	1.98%	124	8957	1.38%
Total	190	20551	0.92%	140	23840	0.59%

Table 6-3: Step-down DCI by Pharmacy Group as Rate per Number of High Dose PPI Prescriptions

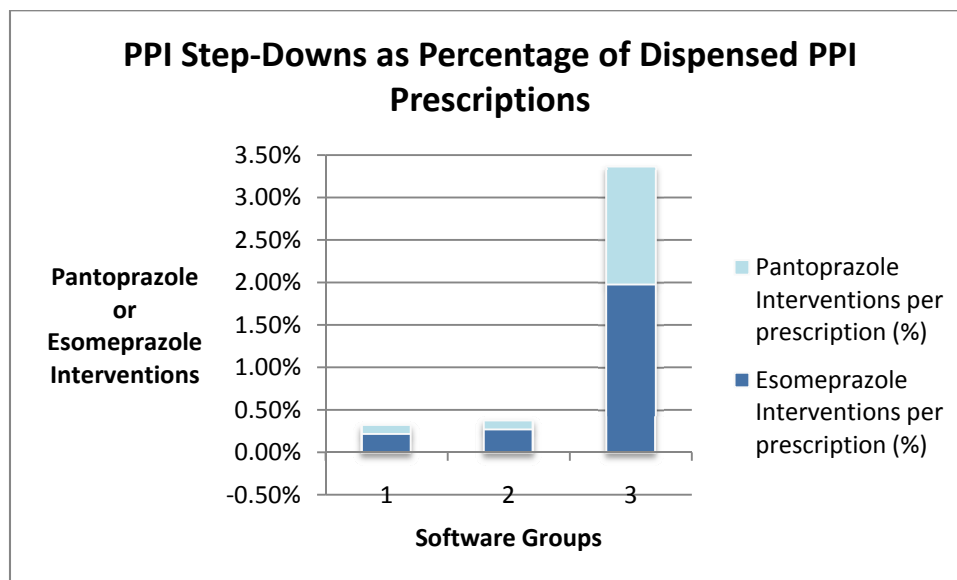


Figure 6-2: Step-downs as Percent of Each Type of Dispensed PPI Prescription

A Mann-Whitney test showed that group three pharmacies performed statistically significant more PPI step-down DCI per week than groups one and two ($p < 0.05$ for both), as shown in Table 6-4.

Pharmacy Week PPI Stepdown Rate	Mann-Whitney U	<i>p</i>
Group 1 compared to Group 2	204091	0.10
Group 1 compared to Group 3	177970	0.00
Group 2 compared to Group 3	325761	0.00

Table 6-4: Statistical Significance of Pharmacy Week Step-down Rates by Pharmacy Group

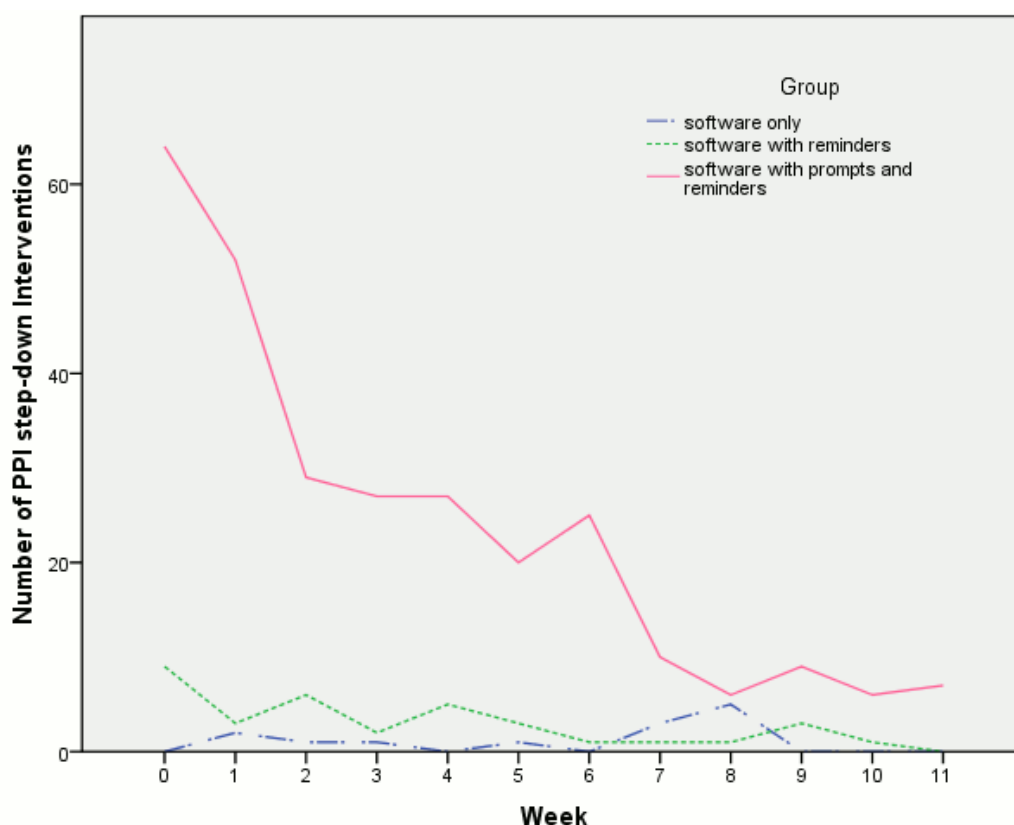


Figure 6-3: Number of DCI Each Week for Each Pharmacy Group

The number of PPI step-down DCI documented each week in the prompted group showed a downwards trend over the twelve weeks of the trial. During the trial, over two thirds of the DCI were classified as education or dose-related problems.

The software only pharmacies (group one) had a slow trickle of DCI throughout the trial. A hump of six DCI by one pharmacist occurred during week 8. The intervention notes compiled by this pharmacist indicate that the pharmacist had just undertaken the NPS pharmacy practice review; Quality use of prescription PPIs²²⁷, which would have improved their PPI knowledge independently of the PROMISe software.

The software with reminders pharmacies (group two) had a very gradual decline in recording of PPI step-down DCI reflecting the overall decline of intervention recording. About half of the DCI in this group consisted of therapy duplication, patient education and prescribed dose being too high.

6.2.1 Other PPI Prompt Related Interventions

Ten DCI in group three appeared to be related to the prompt, but not for the purpose of step-down as the pharmacist notes showed that generally the patient was unable to reduce their dose. Instead the notes indicate that the pharmacist recommended vitamin supplementation, as vitamin B₁₂ malabsorption was mentioned in the pharmacist information leaflet accessed through the displayed prompt (see Appendix E).

6.3 Consumer Adoption of the Intervention Recommendation

Consumer uptake of PPI step-downs was calculated using both objective and subjective methods; from patient prescription data collected in the repository during the twelve weeks of the trial and from the consumer survey responses.

6.3.1 Consumer Adoption of the Recommendation – Evidence from Prescription Data

Each of the 330 PPI step-down DCI was collated with the individual patient's prescription data. All prescription information relating to gastro-oesophageal medication subsequent to the DCI was investigated in order to identify any dose reduction or therapy change.

In order to assess adequate data to follow up consumer changes in the use of high dose PPIs, high dose PPI DCI from the first month (28 days) of pharmacy intervention data were used. This potentially allows for the investigation of two months of subsequent prescription data per patient of interest, where the fullest effect of the prompt would be expected. During the first month of data collection, 195 appropriate high dose PPI step-down DCI were identified. Thirty-two DCI in this sub-set were subsequently observed to contain evidence of a dose reduction or a reduced-cost change of therapy.

PPI Step-Down DCI Month 1 by Pharmacy Group				
		Count of PPI step-downs	Count of outcome (dose reduction or changed therapy)	Identified Uptake Rate (%)
Group	1	4	1	25%
	2	20	5	25%
	3	171	28	16%
Total		195	34	

Table 6-5: PPI Step-downs Month One of Trial

6.3.2 Consumer Adoption of Recommendation: Evidence from the Consumer PPI Survey

A consumer PPI survey was developed in order to obtain another source of information regarding the consumer's responses to pharmacist interventions. Consumers who received a prompted intervention on their high dose PPI medication were asked to complete a written questionnaire (see Appendix L for survey).

An estimated 252 surveys were posted to consumers who were subjected to a PPI prompted intervention from their respective pharmacies. On completion of the trial during the telephone deactivations of the PROMISe software, pharmacists were asked how many surveys were sent to consumers, and the figures provided to PROMISe staff were considered an estimate as they could not be verified. Seventy-seven surveys were received, of which one survey was not used due to incompleteness or late return. One of the seventy-six used surveys contained an incomplete response to one question – 'Did your GP change your therapy?'. The number of surveys sent and the response rate can be seen in Table 6-6.

Total sent to consumers	252*
Total returned to the project team	77 (30.5%)
Total used for analysis	76**

*This is an estimation of how many questionnaires were posted based on what the pharmacists told the project team. It is estimated that the actual amount of surveys sent out may be lower.

**One questionnaire was not included as it was incomplete.

Table 6-6 Response Rate of PPI Step-down Consumer Sub-study

Consumer Demographics

The demographics of the respondents are shown in Table 6-7, with the majority of respondents indicating they were over sixty years of age (81%). Consumers were also asked to complete the EQ-5D quality of life assessment, which showed that the disability weighting decreased with age for both male and female, which is expected (Table 6-8).

Respondent Demographics		
Age (years)	Female	Male
Unknown	1	0
30-39	0	2
40-49	3	3
50-59	3	2
60-69	7	14
70-79	14	10
80-89	12	5
Total	40	36

Table 6-7: Consumer Age and Gender of Consumer PPI Survey

Averaged EQ-5D Disability Weight Demographics*				
Sex	20-39	40-59	60-79	80-99
Female	n/a	0.85	0.78	0.57
Male	1	0.81	0.65	0.54

*Lower numbers indicate increasing disability

Table 6-8: Consumer EQ-5D Disability Weight of Consumers Participating in Sub-Study

Consumer Follow-up with a General Practitioner

According to the survey results, forty-eight (63%) of the consumer respondents had acted upon the pharmacist's advice regarding reviewing/stepping-down their PPI therapy and had followed up with their general practitioner. A further nineteen (25%) of the respondents intended to follow up with their general practitioner. The overall acceptance of the pharmacist's advice by 88% of consumers provides an indication of the confidence that consumers place in their pharmacist's recommendations (see Figure 6-4).

Twenty-eight consumers had not followed up the intervention with their GP; of these, 19 consumers intended to follow up with their general practitioner, as mentioned above, and nine consumers did not intend to follow up with their GP.

Of the forty-eight consumers who had followed up the intervention with their general practitioner, thirty of these consultations resulted in a change of therapy. The majority of these consultations resulted in a reduction or cessation of therapy. Three respondents had their therapy increased when reviewed by their GP.

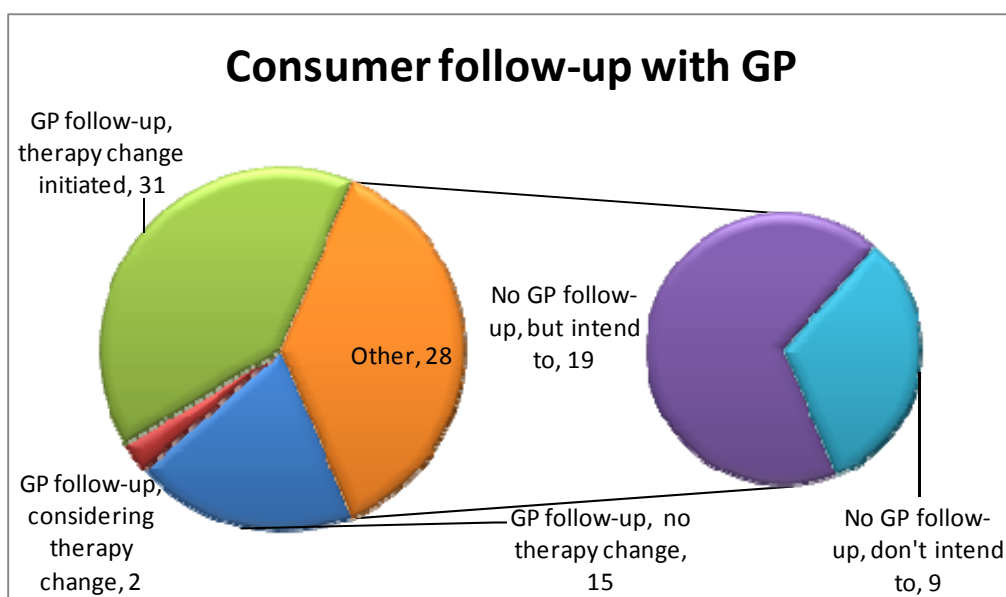


Figure 6-4: Consumer Survey Responses for the PPI Step-down Intervention

Therapy Change	Total
Decrease	20
Increase	3
Stopped	6
Swapped (Nexium to Somac unknown strength)	1
No Response (survey question not completed)	1
Total	31

Table 6-9: Consumer Therapy Changes

6.4 Drug Cost Reduction

Potential cost savings of the PPI step-down DCI were investigated. Costing calculations can be sub-divided into several categories:

- reduction of medication strength
- use of another medication indicated for the treatment of gastro-oesophageal reflux disease (GORD), and
- utilisation of health care resources.

Two approaches have been taken, where one approach was to use the patient prescription history trial data and identify evidence of a PPI step-down for each intervened patient, and the second approach was to obtain consumer feedback using the consumer survey responses.

Using the trial data patient prescription history approach, the pre- and post-intervention drug costs for each of the thirty-four patients were identified. An average cost reduction per intervention was calculated.

Using the patient survey approach, the specific drugs involved were not able to be identified, but an estimate of before and after costs was developed. Three hundred and thirty potential step-down interventions were identified, as discussed previously, and a proportional average cost for esomeprazole 40mg tablets and pantoprazole 40mg tablets was used for the pre-intervention cost. A proportional average cost of esomeprazole 20mg tablets and pantoprazole 20mg tablets was used for the post-intervention cost.

Change of cost calculations for both of the above approaches are based on the 'Schedule of Pharmaceutical Benefits – July 2009' available through the Pharmaceutical Benefits Scheme (PBS).²⁰⁸ A table of the particular item

costs used can be found in Appendix HH. The cost changes represent the combined cost of PBS contributions and patient copayments. A proportional cost to the PBS can be estimated as follows:

- Identifying the number of PBS services for esomeprazole 40mg and pantoprazole 40mg by patient payment category.
- Determining the total cost of patient contributions.
- Determining the total cost of the PBS services.
- Determining the total cost to PBS after subtracting the patient cost.
- The proportion of total cost to PBS by the total cost of PBS services can be used to determine the cost to PBS for extrapolation calculations.

The resultant proportional costing to the PBS is 75.07% of the total cost (Table 6-10). This proportion is used in later calculations in an attempt to allocate specific costing to government. Each service is a payment per prescription dispensed.

	Esomeprazole 40		Pantoprazole 40		Patient Contribution		Totals	
PBS Patient Service Types	Services*	PBS Item Cost	Services**	PBS Item Cost	Per Service	Total of Services	Total PBS Cost	Total PBS Payment
General - Ordinary	58954	58.67	70783	39.14	\$33	\$4,268,347	\$6,229,278	\$1,960,931
General - Safety Net	2125	58.67	2110	39.14	\$5	\$22,446	\$207,259	\$184,814
Concessional - Ordinary	117195	58.67	173661	39.14	\$5	\$1,541,537	\$13,672,922	\$12,131,385
Concessional - Safety Net	23568	58.67	25386	39.14	\$0	\$0	\$2,376,343	\$2,376,343
RPBS - Ordinary	9889	58.67	15232	39.14	\$5	\$133,141	\$1,176,368	\$1,043,227
RPBS - Safety Net	2434	58.67	3092	39.14	\$0	\$0	\$263,824	\$263,824
Cost Totals						\$5,965,471	\$23,925,994	\$17,960,523
Proportion attributed to PBS payment								75.07%

*PBS code 8601Q

** PBS codes 9423Y 9424B 8008L 8007K

Table 6-10: July 2009 PBS Services and Associated Costing (Data obtained 14 Dec 2009)²⁰⁸

6.4.1 Using Evidence from Trial Prescription Data

One hundred and ninety five step-down DCI were identified during the first twenty-eight days of the trial. Of these interventions, 34 PPI step-down outcomes were identified from the subsequent patient prescription data. Of the 171 PPI step-down DCI in group three, 28 step-down outcomes were identified. As previously discussed, the PPI prompt increased the number of DCI undertaken. A step-down outcome is identified as a reduction in medication strength, reduction due to dosage instructions, or a change to another similar medication. This change appeared to be sustained post-intervention.

For each identified outcome regarding a change of therapy, a pre-cost and post-cost of therapy was determined using item costs from the Pharmaceutical Benefits (PBS) Schedule July 2009.²⁰⁸ The PBS July 2009 Schedule was chosen as the intervention data collected during the trial most closely matched this time period. A cost reduction was determined by subtracting the post-cost from the pre-cost. An average monthly cost reduction was determined for group three for the purposes of economic extrapolation calculations.

Costing of each identified outcome step-down intervention for one month					
Group	Original Drug	Pre-Cost	Final Drug	Post-Cost	Cost Reduction
1	esomeprazole 40mg	\$58.67	esomeprazole 20mg	\$38.54	\$20.13
2	esomeprazole 40mg	\$58.67	esomeprazole 20mg	\$38.54	\$20.13
2	pantoprazole 40mg	\$39.14	Omeprazole20mg	\$29.34	\$9.80
2	pantoprazole 40mg	\$39.14	pantoprazole20mg	\$22.37	\$16.77
2	esomeprazole 40- Omeprazole20- Famotidine40mg	\$105.42	Lansoprazole30mg- BD*	\$75.72	\$29.70
2	esomeprazole 40mg	\$58.67	Lansoprazole30mg	\$37.86	\$20.81
3	esomeprazole 40mg	\$58.67	esomeprazole 20mg	\$38.54	\$20.13
3	esomeprazole 40mg	\$58.67	esomeprazole 20mg	\$38.54	\$20.13
3	esomeprazole 40mg	\$58.67	esomeprazole 20mg	\$38.54	\$20.13
3	esomeprazole 40mg	\$58.67	pantoprazole40 mg	\$39.14	\$19.53
3	esomeprazole 40mg	\$58.67	esomeprazole 20mg	\$38.54	\$20.13
3	esomeprazole 40mg	\$58.67	esomeprazole 20mg	\$38.54	\$20.13
3	esomeprazole 40mg	\$58.67	esomeprazole 20mg	\$38.54	\$20.13
3	esomeprazole 40mg	\$58.67	esomeprazole 20mg	\$38.54	\$20.13
3	esomeprazole 40mg	\$58.67	esomeprazole 20mg	\$38.54	\$20.13
3	esomeprazole 40mg	\$58.67	esomeprazole 20mg	\$38.54	\$20.13
3	esomeprazole 40mg	\$58.67	Rabeprazole20mg	\$37.78	\$20.89
3	esomeprazole 40mg	\$58.67	esomeprazole 20mg	\$38.54	\$20.13
3	esomeprazole 40mg	\$58.67	esomeprazole 20mg	\$38.54	\$20.13
3	esomeprazole 40mg	\$58.67	esomeprazole 20mg	\$38.54	\$20.13
3	esomeprazole 40mg	\$58.67	esomeprazole 20mg	\$38.54	\$20.13
3	pantoprazole 40mg	\$39.14	Ranitidine300mg	\$17.87	\$21.27
3	esomeprazole 40mg	\$58.67	esomeprazole 20mg	\$38.54	\$20.13
3	esomeprazole 40mg	\$58.67	esomeprazole 20mg	\$38.54	\$20.13
3	esomeprazole 40mg	\$58.67	esomeprazole 20mg	\$38.54	\$20.13
3	esomeprazole 40mg	\$58.67	esomeprazole 20mg	\$38.54	\$20.13
3	esomeprazole 40mg	\$58.67	esomeprazole 20mg	\$38.54	\$20.13
3	esomeprazole 40mg	\$58.67	pantoprazole 40mg	\$39.14	\$19.53
3	pantoprazole 40mg	\$39.14	pantoprazole 20mg	\$22.37	\$16.77
3	pantoprazole 40mg	\$39.14	pantoprazole 20mg	\$22.37	\$16.77
3	pantoprazole 40mg	\$39.14	pantoprazole 20mg	\$22.37	\$16.77
3	pantoprazole 40mg	\$39.14	pantoprazole 20mg	\$22.37	\$16.77
3	pantoprazole 40mg	\$39.14	pantoprazole 20mg	\$22.37	\$16.77
3	esomeprazole 40mg- bd	\$117.34	esomeprazole 40mg	\$58.67	\$58.67
3	esomeprazole 40mg	58.67	esomeprazole 20mg	38.54	\$20.13
3	pantoprazole 40mg	39.14	pantoprazole 20mg	22.37	\$16.77
Average monthly cost reduction (group 3 PPI Prompt)					\$20.81
Average monthly cost reduction (all groups)					\$20.59

*BD: Twice a day dosing

Table 6-11: Pre- and Post-Intervention Changes in Medications and Costs (July 2009 PBS costs)²⁰⁸

6.4.2 Cost Saving for One Year of Therapy: PBS Cost and Patient Cost Combined

As there are 73 pharmacies in group three (Table 6-5) and the identified intervention recommendation adoption rate is 28 out of the 171 PPI step downs DCI (Table 6-5), the expected rate of recommendation adoption in each pharmacy is 0.38 per pharmacy per month (28 outcomes/73 pharmacies) (Table 6-13). As the average monthly cost savings were \$20.81 (Table 6-11), this results in an average monthly cost reduction of \$7.98 per pharmacy (Table 6-13). In a twelve month period, this accumulates to \$95.76 (see Table 6-12). There are also cost savings accruing each month for each pharmacy from intervention uptake in previous months. In a twelve month period, the aggregate for this is about five and half times more (\$526.84) (see Table 6-12). Hence in the first year of implementation, the total cost savings per pharmacy is \$622.63, which translates to \$3.1 million for the whole of Australia (Table 6-13).

Month	Intervention recommendation adoption per pharmacy (28 outcomes / 73 group three pharmacies)	Cost Savings for recommendation adoption discovered that month (intervention uptake rate times average cost savings)	Cumulative cost saved of previously recommendation adoptions	Total Cost saving per month
0	0.38	\$7.98	\$0.00	\$7.98
1	0.38	\$7.98	\$7.98	\$15.96
2	0.38	\$7.98	\$15.96	\$23.95
3	0.38	\$7.98	\$23.95	\$31.93
4	0.38	\$7.98	\$31.93	\$39.91
5	0.38	\$7.98	\$39.91	\$47.89
6	0.38	\$7.98	\$47.89	\$55.88
7	0.38	\$7.98	\$55.88	\$63.86
8	0.38	\$7.98	\$63.86	\$71.84
9	0.38	\$7.98	\$71.84	\$79.82
10	0.38	\$7.98	\$79.82	\$87.81
11	0.38	\$7.98	\$87.81	\$95.79
Total of 12 months		\$95.76	\$526.84	\$622.63

Table 6-12: Cost Saving Accumulation Calculation

Description	Monthly	Yearly
Number of recommendation adoptions per pharmacy	0.38	4.56
Cost Savings for recommendation adoptions in that month	\$7.98	\$95.76
Cost Savings in that month for recommendations adopted in earlier months	(\$7.98-\$87.81)	\$526.84
Total cost savings per pharmacy	(\$7.98-\$87.81)	\$622.63
Total cost savings for Australia (5006 pharmacies)	(\$39,947.88 - \$439576.86)	\$3,116,897

Table 6-13: Cost Savings for First Year of Implementation

These are very conservative estimations since they are based on examining trial prescription data which most likely understate true levels. Nevertheless, it still provides insight that there is sufficient cost savings in the first year of interventions to justify implementation. The average number of intervention recommendation adoptions per pharmacy assumed above is only 0.38 which is low. If it were 1.0 (1 step-down per pharmacy per month), which is reasonable to expect, the total cost savings for Australia will increase almost three fold from \$3.1 million to \$8.2 million per annum.

The above estimates also do not take into account the savings beyond the first year which will be largely from the cost savings accruing from intervention recommendation adoptions in the earlier period.

6.4.3 Cost Saving for One Year of Therapy: PBS Apportioned Cost

The proportional cost to the PBS of 75.07% was determined previously (see Table 6-10). When this PBS apportioned cost is attributed to the cost savings of \$3,116,897 in all 5006 Australian pharmacies (Table 6-13), the resultant PBS yearly cost reduction is \$2.3 million.

6.4.4 Cost Saving for One Year of Therapy Using Two Months of Interventions: PBS Cost and Patient Cost Combined

As mentioned in paragraph 6.4.2, the expected rate of recommendation adoption in each pharmacy is 0.38 per pharmacy per month, translating to an average monthly cost reduction of \$7.98 (Table 6-13).

To mimic the stronger effect of the prompt during the first two months followed by a wane, the following cost accumulation calculation has been provided, showing two months of prompted interventions per year for five years. The remained of the year has no prompted interventions. In the first year of implementation, the total cost savings per pharmacy is \$183.55 (Table 6-14), which equates to almost \$1 million for the whole of Australia. Over five years of two months prompted interventions per year, the cost savings amount to over fourteen million dollars.

Month	Intervention uptake per pharmacy (28 outcomes / 73 group three pharmacies)	Cost Savings for intervention uptake discovered that month (intervention uptake rate times average cost savings)	Cost saved per previously discovered intervention	Total per month
0	0.38	\$7.98	\$0.00	\$7.98
1	0.38	\$7.98	\$7.98	\$15.96
2	0.00	\$0.00	\$15.96	\$15.96
3	0.00	\$0.00	\$15.96	\$15.96
4	0.00	\$0.00	\$15.96	\$15.96
5	0.00	\$0.00	\$15.96	\$15.96
6	0.00	\$0.00	\$15.96	\$15.96
7	0.00	\$0.00	\$15.96	\$15.96
8	0.00	\$0.00	\$15.96	\$15.96
9	0.00	\$0.00	\$15.96	\$15.96
10	0.00	\$0.00	\$15.96	\$15.96
11	0.00	\$0.00	\$15.96	\$15.96
Year One Accumulated Savings				\$183.55
Year One Total extrapolated to all pharmacies				\$918,838
Year Two Total extrapolated to all pharmacies				\$2,796,672
Year Three Total extrapolated to all pharmacies				\$5,633,552
Year Four Total extrapolated to all pharmacies				\$9,429,477
Year Five Total extrapolated to all pharmacies				\$14,184,448

Table 6-14: Cost Saving Accumulation Calculation

6.4.5 Using Consumer Survey Responses

The responses from the consumer survey do not contain the actual medication involved before or after changed therapy, so an estimate is used. Based on the step-down DCI data 57.6% (190 of 330 PPI DCI) relate to esomeprazole 40mg and 42.4% (140 of 330 PPI DCI) relate to pantoprazole 40mg. Therefore, using a weighted average pre-intervention cost for esomeprazole 40mg (\$58.67 PBS July 09) and pantoprazole 40mg (\$39.14 PBS July 09) gives a total cost of $57.6\% * \$58.67 + 42.4\% * \$39.14 = \$50.39$. A weighted average post-intervention cost for esomeprazole 20mg (\$38.54 PBS July 09) and pantoprazole 20mg (\$22.37 July 09) gives a total cost of $57.6\% * \$38.54 + 42.4\% * \$22.37 = \$31.68$

6.4.6 Cost Change Using Pre-intervention Cost of \$50.39 and Post-intervention Cost of \$31.68

Of the 31 consumer responses relating to GP initiated therapy change, one was excluded from extrapolation calculations because of insufficient information (one response regarding therapy change was incomplete and one response resulted in a swap from Nexium® 40mg to Somac® but the strength of the Somac® was not reported).

Twenty respondents indicated a decrease in therapy and six indicated ceasing therapy. Three respondents indicated increased therapy, possibly because their conditions were undertreated.

Change of cost using weighted average costs				
Change type	Number	Pre Cost	Post Cost	Change of Cost
Reduced	20	\$1,007.80	\$633.60	-\$374.20
Stopped	6	\$302.34	\$0.00	-\$302.34
Average monthly change				-\$26.02

Table 6-15: Average Monthly Cost Reduction per Intervention Based on Consumer Survey Responses

6.4.7 Cost Saving for One Year of Therapy – PBS Cost and Patient Cost Combined

Given that the recommendation adoption rate is 26 out of the 75 survey responses received across 73 group three pharmacies, the expected rate of recommendation adoptions in each pharmacy is 0.36 per month (Table 6-16 and Table 6-17). This translates to an average monthly cost reduction of \$9.27 (Table 6-16 and Table 6-17).

Month	Intervention uptake per pharmacy (26 outcomes / 73 group three pharmacies)	Cost Savings for intervention uptake discovered that month (intervention uptake rate times average cost savings)	Cost saved of previously discovered interventions	Total per month
0	0.36	\$9.27	\$0.00	\$9.27
1	0.36	\$9.27	\$9.27	\$18.54
2	0.36	\$9.27	\$18.54	\$27.81
3	0.36	\$9.27	\$27.81	\$37.08
4	0.36	\$9.27	\$37.08	\$46.35
5	0.36	\$9.27	\$46.35	\$55.62
6	0.36	\$9.27	\$55.62	\$64.89
7	0.36	\$9.27	\$64.89	\$74.16
8	0.36	\$9.27	\$74.16	\$83.43
9	0.36	\$9.27	\$83.43	\$92.70
10	0.36	\$9.27	\$92.70	\$101.97
11	0.36	\$9.27	\$101.97	\$111.24
Total of 12 months		\$111.24	\$611.82	\$723.06

Table 6-16: Cost Saving Accumulation Calculation

Description	Monthly	Yearly
Number of intervention recommendation adoptions per pharmacy	0.36	4.32
Cost Savings for intervention recommendation adoptions up in that month	\$9.27	\$111.24
Cost Savings in that month for intervention recommendation adoptions in earlier months	(\$9.27 - \$111.24)	\$611.82
Total cost savings per pharmacy	(\$9.27 - \$111.24)	\$723.06
Total cost savings for Australia	(\$46,406 - \$556,867)	\$3,619,638

Table 6-17: Cost Savings During First Year of Implementation Using Consumer Survey Data

In a twelve month period, this accumulates to \$111.24 of cost savings. There are also cost savings accruing each month for each pharmacy from intervention recommendation adoptions that had previously occurred. In a twelve month period, the aggregate for this is about five and half times more (\$611.82). Hence in the first year of implementation, the total cost savings per pharmacy is \$723.06, which equates to \$3.6 million for the whole of Australia.

The survey response rate being only 30% makes these estimates very conservative, however it does show that the interventions can still generate sufficient overall cost savings.

6.4.8 Cost Saving for One Year of Therapy: PBS Apportioned Cost

The proportional cost to the PBS of 75.07% was determined previously (see Table 6-10), therefore the PBS apportioned yearly cost reduction is \$2.7 million (Table 6-17).

6.5 Health Care Utilisation

Using the results of the expert assessment of the four PPI step-down cases provides a median yearly health care cost saving of \$27.16 per DCI. This is a summary of the estimated healthcare costs including GP and specialist consultations.

Using the uptake rate of DCI (28) and the number of pharmacies in group three (73), the expected number of step down outcomes for 5006 pharmacies across Australia is 1920. Using this and the average healthcare utilisation cost saving (\$27.16), this translates to an estimated total healthcare resource utilisation cost saving of \$52,150 per year across all Australian pharmacies. However, as this figure is an estimate, it has not been used in economic calculations.

6.6 Discussion

The PPI step-down prompt significantly increased the number of DCI on PPI medications in group three pharmacies when compared to either of the other pharmacy groups. This is not surprising, considering that the prompt was unavoidable. It appeared as a dialog box during the dispensing of Nexium® 40mg and Somac® 40mg, and had to be acknowledged by the dispensing pharmacist by clicking to remove the prompt and continue the dispensing process. In essence, it was interruptive and had to be dealt with before dispensing workflow could continue.

The prompt intervention that was chosen had been brought to the attention of GPs and pharmacists via the NPS during May 2009. This may have assisted in pharmacists being more comfortable with performing this type of pro-active intervention. When the prompt was displayed, leaflets for patients and pharmacists/GPs could be opened and printed, and links to the NPS article were available. This supportive information is also likely to encourage pharmacists to perform the prompted intervention.

The number of step-down DCI decreased over the period of the trial, which could indicate pharmacist fatigue with the PPI alert. *Additionally*, those regular patients who were suitable for the intervention would have been expected to receive the intervention within the early weeks of the trial, therefore the subsequent weeks of the trial would provide a limited number of patients requiring such an intervention. The intervention did not attract any payment, and therefore did not provide any great incentive for the performing of the intervention. In fact, this prompt actually decreased the financial gain to pharmacy owners, as dispensing high dose PPIs attract a higher pharmacy payment from the PBS, therefore lowering the patient's dose would consequently result in a lower payment. Despite this, many interventions were still performed due to the prompt. It is considered that payment for interventions, especially for those actively promoted through the prompt mechanism would slow the rate of decrease over time. Regularly changing the prompt message would also combat prompt fatigue and therefore may also stop the associated decrease in DCI.

The consumer survey produced positive results with the majority of consumer respondents having consulted or intending to consult their GP. Three respondents after consulting their GP indicated they had their therapy increased, which may have been due to inadequate control of symptoms or an incorrectly completed survey response.

A possible limitation of the consumer survey is consumer selection bias since each individual pharmacist recruited the relevant consumers. Results obtained cannot be necessarily extrapolated towards excluded sub-groups of consumers such as the confused or forgetful, which may result in an overestimation of positive outcomes.

The trial prescription data method would have only identified a proportion of intervention recommendation adoptions due to several limitations and is likely to underestimate the true figure. The limitations for finding evidence of recommendation adoptions in the PROMISE study of step-down interventions are:

- Patients may visit multiple pharmacies, which prevents follow-up of prescription evidence via complete medical history.
- Due to the length of the trial period, patients may not have had time or the need to follow up with their doctor. Patients could have waited until all prescription repeats were dispensed prior to follow-up. This is particularly a problem for pantoprazole since authorisation for five repeats is commonplace.
- Patients may simply forget to ask their doctor about reducing their PPI therapy.
- Observer information suggests that approximately one third of interventions undertaken were actually recorded, therefore a higher number of step-downs may have occurred.

- Cessation of therapy would not be directly detected.

Chapter 7 Consumer Satisfaction and Opinions

This chapter examines the uptake levels of interventions undertaken in PROMiSe III in comparison with the type of intervention and the recommendations made.

The views of consumers regarding involvement of pharmacists in clinical interventions were also of interest in this study. The Consumer Sub-Study, outlined in the methodology, gathered information on the views of consumers who had been subject to interventions undertaken by PROMiSe pharmacists. Non-PROMiSe consumer data was gathered via an online survey.

7.1 Determining Uptake of Random Sample of Interventions

Using the random sample of 196 prescription DCI selected for expert assessment and economic analysis from the total of 5,967 DCI, the level of uptake of the intervention was determined. DCI were classified into three levels of uptake by a member of the PROMiSe team. '*Definite Uptake*' indicates the intervention was completely resolved at the time it was made. This category includes situations where the doctor had been contacted to approve a change in drug or dose, or the pharmacist had calculated the dose. '*Up to Consumer Compliance*' indicates that a recommendation had been made to the consumer; however, it was not a guaranteed uptake as it was reliant on the consumer to comply. These recommendations are such that the consumer could uptake without assistance, such as improved compliance, or a schedule or frequency change. '*Up to Consumer to Follow Up*' is for interventions where a recommendation was made to a consumer which required them to follow up with their general practitioner or another health professional in order to be resolved. Also included in this category are situations where the patient required laboratory monitoring. The totals for each category can be seen in Table 7-1.

Uptake Level	N	%
Definite Uptake	102	52
Up to Consumer Compliance	55	28
Up to Consumer to Follow Up	39	20
Total	196	100

Table 7-1: Patient Uptake of Recommendations in the Sampled DCI

7.1.1 Recommendations

It was possible for pharmacists to select up to four recommendations for each DCI. As such, for the 196 sampled DCI, there was a total of 352 recommendations made by the documenting pharmacists. This translates to an average of 1.80 recommendations per DCI.

The most common recommendations for the 'Definite Uptake' DCI are recommendations for *A Change in Therapy* accounting for 69.7% of this uptake level as seen below in Table 7-2. In particular, the most common recommendations include *dose increase*, *dose decrease* and *drug change*. It is likely that these recommendations were made to the prescriber who was contacted at the time of the intervention. *Prescription not dispensed* was also a recommendation in 7.2% of 'Definite Uptake' DCI, accounting for 68.8% of this recommendation, which is an expected result. Interestingly, 18.4% of the 'Definite Uptake' DCI also involved a referral. Pharmacists may have recorded this recommendation when they themselves had contacted the prescriber. In addition, following an intervention, pharmacists may have recommended a follow up appointment with the prescriber. The other significant recommendation for 'Definite Uptake' was *education or counselling session* which may have included situations where consumers requested information on medications or disease states, but did not involve consumer compliance. As expected, there were no recommendations for monitoring in this category.

Three main recommendations were made in 'Up to Consumer Compliance' outcome DCI, as seen in Table 7-2. *Dose increase* was reported most commonly (32.4%) in this category. It is likely this represents situations where there may have been a compliance issue for which the pharmacist had recommended increasing the actual dose

being used by the patient. *Provision of Information* recommendations accounted for 27.8% of DCI in this category. These recommendations were likely to involve improving patient compliance with existing therapy. There were also twelve referrals to the prescriber in this category, which is significantly lower than the other categories of uptake, representing just 16.1% of this recommendation category. Five of the seven recommendations for non-laboratory monitoring were made on DCI in this category. These are likely to have included home blood glucose and blood pressure monitoring by the patient recommended by the pharmacist to improve disease management.

Referral to prescriber was the most common recommendation in the 'Up to Consumer to Follow Up' category with a total of 31.5% of the recommendations, as seen in Table 7-2. This is expected as it is likely the pharmacist referred these consumers to their prescriber to follow up on their intervention. Monitoring was also recommended in nine of the DCI, which accounts for 64.7% of the total of this recommendation. Other common recommendations included *education or counselling session, dose decrease, dose increase, other changes to therapy* and *drug change*, with *A Change in Therapy* recommendations accounting for 33.7% of recommendations in this uptake level. It is likely that these recommendations would have accompanied *referral to prescriber* in many cases.

Category	Subcategory		Definite Uptake			Up to consumer compliance			Up to consumer to follow up			Total
			N	%U	%R	N	%U	%R	N	%U	%R	
A Change in therapy	R1	Dose increase	31	20.4	43.1	35	32.4	45.0	6	6.5	8.3	72
	R2	Dose decrease	16	10.5	57.1	5	4.6	16.5	7	7.6	25.0	28
	R3	Drug change	25	16.4	71.4	5	4.6	13.2	5	5.4	14.3	35
	R4	Drug formulation change	10	6.6	90.9	0	0.0	0.0	1	1.1	9.1	11
	R5	Drug brand change	1	0.7	50.0	0	0.0	0.0	1	1.1	50.0	2
	R6	Dose frequency/schedule change	8	5.3	61.5	4	3.7	28.5	1	1.1	7.7	13
	R7	Prescription not dispensed	11	7.2	68.8	1	0.9	5.8	4	4.3	25.0	16
	R8	Other changes to therapy	4	2.6	28.6	4	3.7	26.5	6	6.5	42.9	14
Sub Total for A Change in Therapy			106	69.7	55.5	54	50.0	28.3	31	33.7	16.2	191
A referral required	R9	Refer to prescriber	26	17.1	38.8	12	11.1	16.6	29	31.5	43.3	67
	R10	Refer to hospital	1	0.7	100.0	0	0.0	0.0	0	0.0	0.0	1
	R11	Refer for medication review	0	0.0	0.0	0	0.0	0.0	0	0.0	0.0	0
	R12	Other referral required	1	0.7	100.0	0	0.0	0.0	0	0.0	0.0	1
Sub Total for A Referral Required			28	18.4	40.6	12	11.1	17.4	29	31.5	42.0	69
Provision of information	R13	Education or counselling session	13	8.6	35.1	16	14.8	40.0	8	8.7	21.6	37
	R14	Written summary of medications	2	1.3	20.0	7	6.5	64.8	1	1.1	10.0	10
	R15	Recommend dose administration aid	0	0.0	0.0	0	0.0	0.0	0	0.0	0.0	0
	R16	Other written information	3	2.0	27.3	7	6.5	58.9	1	1.1	9.1	11
Sub Total for Provision of Information			18	11.8	31.0	30	27.8	51.7	10	10.9	17.2	58
Monitoring	R17	Monitoring: Non-laboratory	0	0.0	0.0	5	4.6	66.1	2	2.2	28.6	7
	R18	Monitoring: Laboratory test	0	0.0	0.0	1	0.9	9.3	9	9.8	90.0	10
Sub Total for Monitoring			0	0.0	0.0	6	5.6	35.3	11	12.0	64.7	17
Total			152	100.0	43.2	108.0	100.0	30.7	92	100.0	26.1	352

N = Number of interventions; %U = Percentage of Uptake Category; %R = Percentage of Recommendation Category

Table 7-2: Uptake of Recommendations from Intervention Sample

In summary, as seen in Table 7-2, the recommendations for *A Change in Therapy* resulted in definite uptake in 55% of DCI. In addition, 40.6% of DCI which include a recommendation for referral are also classified as 'Definite Uptake.' The 'Up to Consumer to Follow Up' category accounted for 42.0% of recommendations resulting in a referral. A total of 47.9% of the *Provision of Information* recommendations were associated with 'Up to Consumer Compliance' DCI. 'Up to Consumer to Follow Up' DCI accounted for 64.7% of the recommendations for monitoring. Interestingly, 'Up to Consumer to Follow Up' DCI represented 90% of all referrals for laboratory monitoring and 'Up to Consumer Compliance' accounted for 66.1% of all non-laboratory monitoring recommendations.

7.1.2 Drug Related Problem Category

As seen in Table 7-3, the most common uptake level for the *Drug Selection* and *Over/Underdose* categories is 'Definite Uptake' with 61.1% and 77.8% respectively. These drug related problem categories also represented

77.4% of this uptake level. This is expected, as these types of drug related problems often require immediate resolution, and can often be addressed by contacting the prescriber or calculation of the dose.

The *Compliance* category is predominately associated with 'Up to Consumer Compliance' DCI with 58.3% which is also an expected outcome. These DCI are reliant on consumer compliance to resolve the issue. This category accounts for 25.5% of this uptake level, however together with *Education/Information* problems, makes up for 51% of 'Up to Consumer Compliance' DCI.

'Up to Consumer to Follow Up' DCI held the majority of *Undertreated* DCI with 63.6%. This may have resulted from conditions being undertreated and in need of review by the prescriber, rather than just a dosing issue. 'Up to Consumer to Follow Up' DCI also accounted for 75% of *Monitoring* problems, which indicates that most of these problems required follow up by the consumer.

As expected, 'Up to Consumer Compliance' accounted for 66.7% of the *Education and Information* DCI. These DCI are likely to have involved attempts to improve patient compliance with their current therapies. It was also shown that 40% of *Toxicity* DCI were in the 'Definite Uptake' category. This is likely to be due to the fact that toxicity-based DCI are often resolved immediately, due to a cessation of the problem medication.

Category	Definite Uptake			Up to consumer compliance			Up to consumer to follow up			Total
	N	%U	%D	N	%U	%D	N	%U	%D	
Drug Selection	44	43.1	61.1	16	29.1	22.2	12	30.8	16.7	72
Over/Underdose	35	34.3	77.8	2	3.6	4.4	8	20.5	17.8	45
Compliance	7	6.9	29.2	14	25.5	58.3	3	7.7	12.5	24
Undertreated	2	2.0	18.2	2	3.6	18.2	7	17.9	63.6	11
Monitoring	0	0.0	0.0	1	1.8	25.0	3	7.7	75.0	4
Education/Information	6	5.9	28.6	14	25.5	66.7	1	2.6	4.8	21
Not Classifiable	2	2.0	50.0	1	1.8	25.0	1	2.6	25.0	4
Toxicity/ADR	6	5.9	40.0	5	9.1	33.3	4	10.3	26.7	15
Total	102	100.0	52.0	55	100.0	28.1	39	100.0	19.9	196
N = Number of Interventions; %U = Percentage of Uptake Category; %D = Percentage of Drug Related Problem Category										

Table 7-3: Uptake of Drug Related Problem Category from Intervention Sample

7.1.3 Significance Category

A comparison between uptake level and clinical significance can be seen in Table 7-4. This table indicates that DCI classified as 'Definite Uptake' have been categorised by the pharmacist as *S3: Prevented or Required a GP visit* in 49% of cases. This can be explained by pharmacists placing a high importance upon resolving highly significant DCI as soon as possible, often by contacting the prescriber. 'Definite Uptake' DCI accounted for 53.3% of all *S3* DCI and 69.2% of all *S4* DCI in this sample.

It was shown that 45.5% of DCI with an uptake level classified as 'Up to Consumer Compliance' fall into *S2: Prevented mild symptom or improved compliance*. This uptake level also accounted for 41% of DCI in the *S2* category. This result is expected as many of these DCI involved education to consumer to improve compliance. Interestingly, 34.5% of this uptake level had been classified into *S3* significance by pharmacists. This may be explained by pharmacists intervening on poor compliance with high-risk and multiple medications, preventing a more significant outcome. This uptake level also represented 46.7% of all low significance DCI in this sample.

As expected, 64.1% of DCI relying on consumers to follow up were classified as S3 significance. This is explained by many of these DCI requiring the consumer to follow up with their GP.

Category	Definite Uptake			Up to consumer compliance			Up to consumer to follow up			Total
	N	%U	%S	N	%U	%S	N	%U	%S	
S1: Information Only	5	4.9	33.3	7	12.7	46.7	3	7.7	20.0	15
S2: Minor Symptom	29	28.4	47.5	25	45.5	41.0	7	17.9	11.5	61
S3: Medical Assistance	50	49.0	53.2	19	34.5	20.2	25	64.1	26.6	94
S4: Hospitalisation	18	17.6	69.2	4	7.3	15.4	4	10.3	15.4	26
Total	102	100.0	52.0	55	100.0	28.1	39	100.0	19.9	196

N = Number of DCI; %U = Percentage of Uptake Category; %S = Percentage of Significance Category

Table 7-4: Significance of Uptake Levels of Intervention Sample

7.2 Consumers Sub-Study

The consumer sub-study gathered data on the consumers' uptake of the pharmacist recommendations. Seventy five consumers were interviewed, one of whom was interviewed about four DCI undertaken on different occasions to give a total of seventy eight DCI, with each considered a separate intervention.

7.2.1 Consumer Recruitment

Consumer packs were sent out to consumers subjected to an intervention as outlined in Chapter 2. The number of packs sent and the response rate are outlined in Table 7-5.

Total sent to consumers	870*
Total returned to project team	82 (9.4%)
Total initial phonecall	75**
Total secondary phonecall	3

*This is an estimation of how many consumer information packs were posted out based on what the pharmacists told the project team. It is thought that the actual amount of packs sent out to consumers may be lower.

**7 consumers were not included as they were unable to be contacted or their consent form was returned too late.

Table 7-5: Response Rate of Consumer Sub-Study

7.2.2 Consumer Demographics

As shown in Table 7-6, the age of the consumers who participated in the consumer sub-study is significantly different to that of the general population ($\chi^2 = 35.76$, $df = 2$, $p = <0.01$). There is also a significant difference between the age of consumers subjected to PROMiSe DCI and those who wished to participate in the sub-study ($\chi^2 = 10.68$, $df = 2$, $p = <0.01$).

	Consumer study N	%N	PROMISe N	% N	ABS 2010 Projected N	% N
0-20 years	7	9.2	676	10.86	14.4	19.00
21-64 years	26	34.2	3159	50.75	51.1	67.30
65+ years	43	56.6	2390	38.39	10.4	13.70
Total	76*	100.0	6225	100.0	76	100.0

*Two consumers are not included in this data due to unknown age

Table 7-6: Age Group of Participants in Consumer Sub-Study, PROMISe Trial and Population

As shown in Table 7-7, the gender of participants in the consumer sub-study was not significantly different to that of the population ($\chi^2 = 0.03$, $df = 1$, $p = 0.87$). There was also no significant difference between the gender of consumers subjected to PROMISe DCI and sub-study participants ($\chi^2 = 0.39$ $df = 1$, $p = 0.53$).

	Consumer study N	%N	PROMISe N	% N	ABS 2010 Projected N	% N
Female	40	51.3	3517	56.50	39.1	50.20
Male	38	48.7	2708	43.50	38.8	49.80
Total	78	100.0	6225	100.0	78	100.0

Table 7-7: Gender of Participants in Consumer Sub-Study, PROMISe Trial and Population

This data indicates that consumers may have been more likely to participate in the sub-study if they are over 65 years of age. This may be explained by this age group being less likely to work full-time and were more likely to be available during the day for the telephone questionnaire.

7.2.3 Uptake Level

Each intervention that formed part of the consumer sub-study was categorised into uptake levels.

For each intervention the consumer was asked "Based on what the pharmacist recommended to you, have you done any of what he/she suggested?" The results to this question are presented in Table 7-8. This table shows that consumers followed the pharmacist recommendation in 86.2% of 'Definite Uptake' DCI. Due to the nature of this category, it was expected that 100% of consumers would have followed the pharmacist's recommendation. It is likely this discrepancy has occurred due to consumers believing that the pharmacist did not make a recommendation to them, they were unaware of the intervention or they may have forgotten about the intervention. It was shown that 87.5% of consumers followed the pharmacist's recommendations in the 'Up to Consumer Compliance' category and 88.2% in the 'Up to Consumer to Follow Up' category. A total of 87.2% of consumers followed the pharmacist's recommendations overall in the consumer sub-study.

Patient Followed Pharmacist's Recommendation?	Definite Uptake		Up to consumer compliance		Up to consumer to follow up		Total	
	N	%	N	%	N	%	N	%
Yes	25	86.2	28	87.5	15	88.2	68	87.2
Unsure	3	10.3	0	0.0	0	0.0	3	3.8
No	1	3.4	4	12.5	2	11.8	7	9.0
Total	29	100.0	32	100.0	17	100.0	78	100.0

Table 7-8: Assumed Uptake Level Compared with Consumer Reported Uptake in Consumer Sub-Study

7.3 Overall Uptake

The data gained from the consumer sub-study gave information about the number of consumers who had followed the suggestions and recommendations made by the pharmacist. These values can be extrapolated back to the random sample of DCI. It should be noted that the sample size of the consumer sub-study was smaller than expected, with a total of seventy five consumers being interviewed about a total of seventy eight DCI. In addition, the nature of the consumers who chose to participate in the study is likely to be those who may be more willing to follow recommendations made by the pharmacist. This may have resulted in a higher level of uptake of recommendations than would be expected from the population.

As can be seen in Table 7-9, the number from each uptake level is multiplied by the percentage of consumer uptake determined from the consumer sub-study. A value of 100% has been used for the 'Definite Uptake' category as these DCI have been classified as resolved at the time and are not reliant on consumers for uptake. The total uptake rate of the 196 random sample DCI has been determined as 94.4%. It is thought that this uptake rate may be higher than the actual rate as mentioned above. In addition, it should be noted that some consumers may have followed just one of the pharmacist's average of 1.80 recommendations. Therefore, it is possible that just 56% (196 DCI out of 352 recommendations) of the pharmacist's recommendations may have been acted upon, giving a minimum overall uptake rate of 52.9% (56% of 94.4% uptake rate). It is likely that the uptake rate may fall between 52.9% and 94.4% depending on how many recommendations the consumer acted upon.

Category	Number from random 196	% of Consumer uptake (from consumer sub-study)	Total
Definite Uptake	102	100.0*	102
Up to Consumer Compliance	55	87.5	48.1
Up to Consumer to Follow Up	39	88.2	34.4
Total	196	Mean = 91.9	185
Total % uptake of 196 random sample			94.4
*This value has been adjusted to 100% due to the nature of the 'Definite Uptake' category.			

Table 7-9: Extrapolation of Uptake Rate from Consumer Sub-Study

7.4 Consumer Satisfaction

Consumers participating in the consumer sub-study were asked to score two statements out of 10, where 10 was the most positive response and 0 was the most negative response. These statements were 'I was appreciative the pharmacist identified the issues that he/she did on that day' and 'Overall I was satisfied with my experience at the pharmacy on that particular day.'

As seen in Table 7-10, it was determined that consumers gave a mean score of 9.6 out of 10 for the statement 'I was appreciative the pharmacist identified the issues that he/she did on that day'. The mean score for 'Overall I was satisfied with my experience at the pharmacy on that day' was also a very high 9.9. As the data was not normally distributed, the median was also calculated resulting in a median score of 10 for each of the questions. It is again expected that this result may be higher than the actual views of the population due to the nature of the consumers who participated in the study. It is likely that consumers who may have been dissatisfied with the service may also have been unlikely to participate in a study.

Consumer Rating 0 = Low 10 = High	I was appreciative the pharmacist identified the issues that he did on that day		Overall I was satisfied with my experience at the pharmacy on that day		Means
	N	%	N	%	
0	1	1.3	0	0.0	I was appreciative the pharmacist identified the issues that he/she did on that day. Mean = 9.6 ± 1.5 (Median = 10)
1	0	0.0	0	0.0	
2	0	0.0	0	0.0	
3	0	0.0	0	0.0	
4	0	0.0	0	0.0	
5	2	2.6	0	0.0	Overall I was satisfied with my experience at the pharmacy on that day. Mean = 9.9 ± 0.4 (Median = 10)
6	0	0.0	0	0.0	
7	2	2.6	1	1.3	
8	2	2.6	1	1.3	
9	2	2.6	2	2.6	
10	69	88.5	74	94.9	
Total	78	100.0	78	100.0	

Table 7-10: Consumer Satisfaction and Appreciation of Pharmacist

7.5 Consumer Views on Remuneration

During the consumer sub-study questionnaire, consumers were asked if they thought pharmacists should be paid for investigating drug related problems. If they answered yes, they were given a scale of fees to select from. If they answered no, they were asked for a reason why not.

As seen in Table 7-11, 68% of consumers believe that pharmacists should be paid for interventions. Of these, 32.1% of consumer thought pharmacists should be paid between \$10 and \$14 per intervention. As expected, 30.2% of the consumers who thought pharmacists should be paid could not suggest a specified amount. This may be explained by many consumers not being aware of the current salary for pharmacists and similar professions. A total of 17% of consumers who thought pharmacists should be paid, thought a sum in excess of \$20 was appropriate.

Also seen in Table 7-11, 32% of consumers believed pharmacists should not be paid for interventions. The majority, 91.3%, of these consumers believed that investigating drug related problems is part of the pharmacists' duty of care.

Should pharmacists be paid for interventions?	If yes, then how much do you think they should be paid for a service that required 6 or 7 minutes of their time?		N	%
	If no, why don't you think pharmacists should be paid for their advice on drug related problems?			
Yes	53 (68%)	0 to 5\$	2	3.8
		Between \$5 and \$9	7	13.2
		Between \$10 and \$14	17	32.1
		Between \$15 and \$19	2	3.8
		More than \$20	9	17.0
		Cannot Say	16	30.2
Sub Total			53	100.0
No	25 (32%)	It is part of their duty of care	21	91.3
		Pharmacist's receive enough money now	0	0.0
		Pharmacist do it now without being paid	0	0.0
		Other	4	8.7
Sub Total			25	100.0
Total			78	

Table 7-11: Consumers' Views on Remuneration for Pharmacists

7.6 Non PROMISe Consumers

An online consumer panel was used to gain information from non-PROMISe consumers who had experienced a clinical intervention in the past twelve months. This was co-ordinated by Mr Ian DeBoos of DeBoos Associates and the full report can be found in Appendix M. Screening questions were used to select those consumers with recent pharmacy intervention experience. From the sample of 1561 participants, 82% had visited a pharmacy for a prescription in the last twelve months. Participants were selected if the pharmacist performed an intervention the last time they visited a pharmacy. The resultant sample was 674 participants.

It was determined that in 20.6% of occasions, the pharmacist recommended the consumer seek further information or advice from GP or specialist, or undergo medical tests. Interestingly, the number of consumers in the PROMISe sub-study required to follow-up was a similar 21.8%. From the non-PROMISe consumers, it was determined that 70.3% of consumers acted upon the advice of the pharmacist if they were referred to their GP or to other medical professions. This was significantly lower than the uptake rate from PROMISe consumers of 88.3%; however, it is still a very high rate of uptake of pharmacist interventions. Of the 674 participants, 379 (56.2%) said they had acted upon or will act upon the pharmacist's suggestion(s).

As shown in Table 7-12, in most cases, the pharmacist performed higher than the expectations or desires of the consumer. Interestingly, the importance of attributes was rated higher by PROMISe consumers compared with non-PROMISe consumers. Similarly, PROMISe consumers also rated the performance of the pharmacist as higher than the non-PROMISe consumers. This may be explained by consumers who were willing to participate in a pharmacy-based questionnaire having higher expectations of their community pharmacist, whilst also having greater respect for them.

Characteristic of Pharmacist	PROMISe Consumers (n=78)			Non-PROMISe Consumers (n=674)		
	Performance (Out of 5)	Importance (Out of 5)	Δ	Performance (Out of 5)	Importance (Out of 5)	Δ
Listened to what I said	4.8	4.9	-0.1	4.2	4.3	-0.1
Gave useful information	4.5	3.9	0.6	4.2	4.2	0.0
Explained so I fully understood the problem	4.5	4.9	-0.4	4.2	4.2	0.0
Was genuine in his/her approach	4.9	5.0	-0.1	4.3	4.2	0.1
Dealt with the issue efficiently	4.9	4.8	0.1	4.3	4.1	0.2
Spoke in a private area so other customers could not hear what was discussed	3.9	3.5	0.4	3.3	3.6	-0.3

Table 7-12: Importance of Attributes and Performance of Pharmacist from Views of Consumers

Consumers rated pharmacists strongly on their attributes with 88% believing pharmacists play an extremely important role in providing advice and information on drugs, 71% thought pharmacists provided excellent advice on general health issues, and 69% thought they provided excellent advice for those with existing medical conditions. In addition, 87% of consumers thought pharmacists provided good advice and information on drugs/prescriptions, compared with 61% of GPs. Only 12% of consumers believed that pharmacists do not provide enough advice and information on prescribed drugs.

Of the 674 consumers who received advice from the pharmacist, 37.7% supported pharmacists being paid for performing interventions. The main reason for not thinking pharmacists should be paid is because they think pharmacists have a duty of care to provide this service. Of those who thought pharmacists should be paid, they believed around \$10 to be an appropriate fee.

7.7 Discussion

It is estimated that around 52% of DCI made by pharmacists are resolved at the time, commonly by contacting the prescriber or through adjustment of the dose. The recommendations which resulted in a high rate of definite uptake of the intervention included *A Change in Therapy*, in particular *dose increase*, *dose decrease* and *drug change*. Other recommendations which also had a high rate of definite uptake included *prescription not dispensed*, *referral to prescriber* and *education or counselling session*. It was also shown that the higher significance (S3 and S4) DCI were most likely to be in the 'Definite Uptake' category.

The PROMISe consumer sub-study showed that most of the surveyed consumers were willing to follow the recommendations made by pharmacists. It showed that around 87.5% of consumers followed recommendations that relied on consumer compliance, and 88.2% of consumers followed-up with another health professional after a recommendation by their pharmacist. Taking into account the DCI which had a 100% uptake rate ('Definite Uptake' DCI), the overall uptake rate was shown to be 94.4%. It was noted, however, that this value may have been higher than the actual rate of uptake due to the nature of the consumers willing to participate in the study. From information gathered from the non-PROMISe consumers, it was determined that 70.3% of consumers acted upon the advice of the pharmacist if they were referred to their GP or other medical professionals. This does indicate that there is a very high rate of uptake of pharmacist interventions. Interestingly, 56.2% of non-PROMISe consumers said they had acted upon or will act upon the pharmacist's suggestion(s), compared with 87.2% of PROMISe consumers.

Overall it was shown that consumers had a high degree of satisfaction when dealing with their pharmacist. PROMISe consumers gave a median score of 10 out of 10 for both appreciation and satisfaction with their experience at the pharmacy. It was also evident that both PROMISe and non-PROMISe consumers rated the performance of the pharmacists highly compared with their expectations. PROMISe consumers had higher expectations which the pharmacists exceeded in most cases. Non-PROMISe consumers had slightly lower expectations, but these were still met by their pharmacists.

A higher proportion of PROMISe consumers (68%) believed that pharmacists should be paid for performing clinical interventions compared with 37.7% of non-PROMISe consumers. Of those who thought pharmacists should be paid, both consumer groups believe \$10-\$14 to be an appropriate fee. Of those who did not think pharmacists should be paid, the main reason was because they thought pharmacists already have a duty of care to provide this service.

Chapter 8 Results and Discussion: Value of Clinical Interventions

Presented in this chapter are the analyses of the data which was collected through the expert assessment of 200 selected DCI (196 prescription based DCI and 4 OTC), including extrapolations to the broader PROMISe dataset, and to the Australian perspective. The methods used are outlined in detail in Chapter 2.

8.1 Consequences Table

As previously stated, the development of the consequences table was a key element of the economic analysis process. Sixty common clinical consequences were selected, and definitions for each of these at three levels of severity were prepared. For each of these consequence/severity pairs, parameters of health resource utilisation and quality of life were assigned, based on the literature where available, or from expert opinion. The resultant consequences table therefore contained information on the following parameters for each consequence: -

- Quality of Life (QOL)
- Duration of QOL impact
- Number of GP visits
- Cost of GP visits
- Number of Specialist visits
- Cost of Specialist visits
- Duration of hospitalisation
- Cost of hospitalisation
- Cost of additional investigations

Some examples of this information for common consequences are shown in Table 8-1, while the full consequences table can be found in Appendix DD. A total of 60 conditions were included that covered the spectrum of issues likely to be encountered in association with clinical interventions.

Consequence	Severity	Description	Duration	Raw QOL	QALY	GP visits	Cost of GP visits	Specialist visits	Cost of specialist visits	Cost of inv.	Duration of admission	Cost of admission
Cerebrovascular event	Mild	Mild symptoms which resolve (e.g. transient ischemic attack)	3.8	0.697	0.003	3.4	\$113	1.5	\$99	\$187		
	Moderate	Resulting in significant signs and symptoms requiring medical management (e.g. reversible ischaemic neurological deficit)	10.1	0.461	0.015	5.1	\$170	2.8	\$151	\$382	3.6	\$3,173
	Severe	Resulting in severe symptoms and signs requiring hospitalisation and medical management (e.g. stroke)	146.0	-0.052	0.421	8.0	\$268	5.8	\$270	\$382	8.6	\$7,902
Heart Failure	Mild	Mild signs or symptoms of heart failure (e.g. NYHA class II) which resolve without intervention	33.1	0.705	0.027	3.0	\$101	0.9	\$73	\$17		
	Moderate	Resulting in significant signs and symptoms of heart failure (e.g. NYHA class III) requiring medical management by modification of medication regimen	49.4	0.436	0.076	6.4	\$216	2.1	\$122	\$248		
	Severe	Significant signs and symptoms of heart failure (e.g. NYHA class IV) requiring hospitalisation and medical management (e.g. acute pulmonary oedema)	112.6	-0.380	0.426	8.9	\$300	4.9	\$232	\$309	6.6	\$5,518

Table 8-1 Example of Clinical Consequences

Due to the variability involved when using expert opinion, an uncertainty model was applied to those parameters generated by expert opinion. The distribution model which defined this uncertainty was based upon the variability in the raw data (see Chapter 2 for a comprehensive description of this approach). By applying this distribution model

to these parameters, it was possible to later employ Monte Carlo re-sampling techniques in order to better demonstrate the potential variability in the outcomes. Re-sampling techniques were used in relation to the expert opinions that generated the consequences table and also for the expert opinions that were applied to the sample of consequences.

8.2 Expert Assessment Process

Of the 24 expert assessors contracted for the project, 23 completed assessment of the 200 sampled DCI.

8.2.1 Consequences of Clinical Interventions

Over 30,000 assessments for the probability of particular consequences at each of three levels of severity were assigned by the experts (an average of 2.2 consequences per intervention per assessor).

Over 10,000 consequences were selected by the expert assessors (including those consequences which had been “suggested” for each intervention). The most frequent consequences used by the experts on this sample were a reduction in cerebrovascular events, a reduction in the risk of infection and a reduction in hypertension (see Table 8-2).

Consequence		#	%
C03	Cerebrovascular event	708	6.9
I01	Infection, general	682	6.7
C06	Hypertension	594	5.8
G04	Gastrointestinal discomfort	544	5.3
N02	CNS Depression/ sedation	449	4.4
C07	Hypotension	431	4.2
C08	Myocardial Ischaemia	398	3.9
P01	Pain	367	3.6
D01	Hyperglycaemia	362	3.5
G03	Gastrointestinal bleeding	362	3.5
G06	Nausea and vomiting	355	3.5
C01	Arrhythmia (incl. tachy- and bradycardia)	352	3.4
A02	Accident and injury (incl. falls risk)	266	2.6
A01	Allergic reaction	251	2.4
C02	Bleeding, non-specific	228	2.2
M02	Osteoporosis	225	2.2
U01	Renal Dysfunction	216	2.1
C04	Clotting (non-cerebral)/tissue ischaemia	215	2.1
R01	Asthma	212	2.1
N05	Depression	186	1.8
G02	Diarrhoea	185	1.8
N06	Headache	184	1.8
B02	Bone marrow suppression	162	1.6
G05	Liver Disease	139	1.4
R04	Respiratory depression	135	1.3
H01	Skin conditions	134	1.3
M01	Myopathy	131	1.3
G01	Constipation	125	1.2
G07	Oral disorder	114	1.1
N09	Psychosis	107	1.0
B01	Anaemia	104	1.0
Others less than 1%		1324	
Total		10247	

Table 8-2: Consequences Selected by Expert Assessors

8.2.2 Validation of Experts Using Questionnaire

An attempt was made to determine a relative weighting for the different experts in terms of their knowledge of risk reduction and estimation of frequency of consequences. The PROMISE research team developed a 15 item multiple choice questionnaire that related to common clinical situations which would require assessment of increased or decreased risk of particular consequences (see Chapter 2). The participants were scored based on how many questions they answered correctly.

The results of the assessment did not appear to relate to the expert's professional group (see Figure 8-1). As can be seen in Figure 8-2, they also did not appear to correlate well with the assessments the experts provided. In light of these results, it was determined that the expert validation scores would not be used to weight the results in this study.

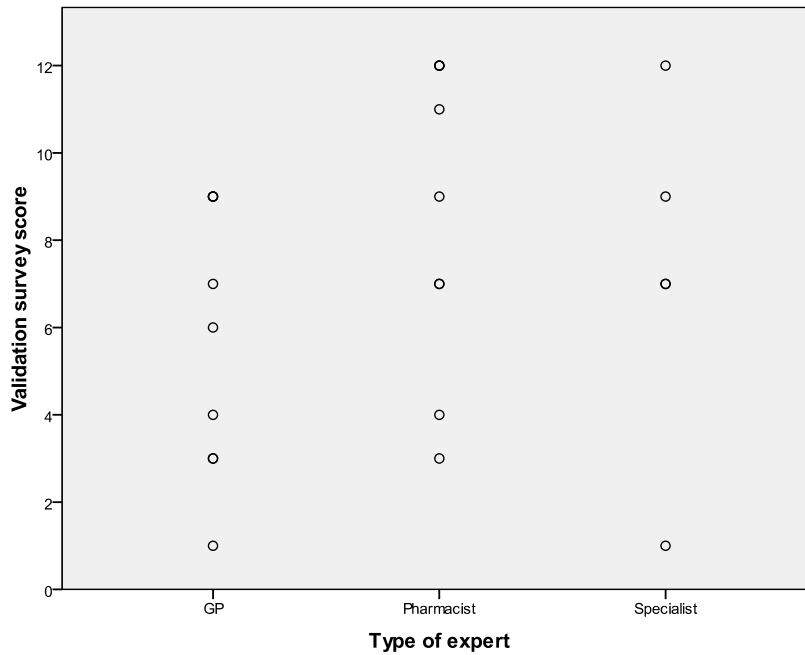


Figure 8-1: Results of Experts for Validation Test

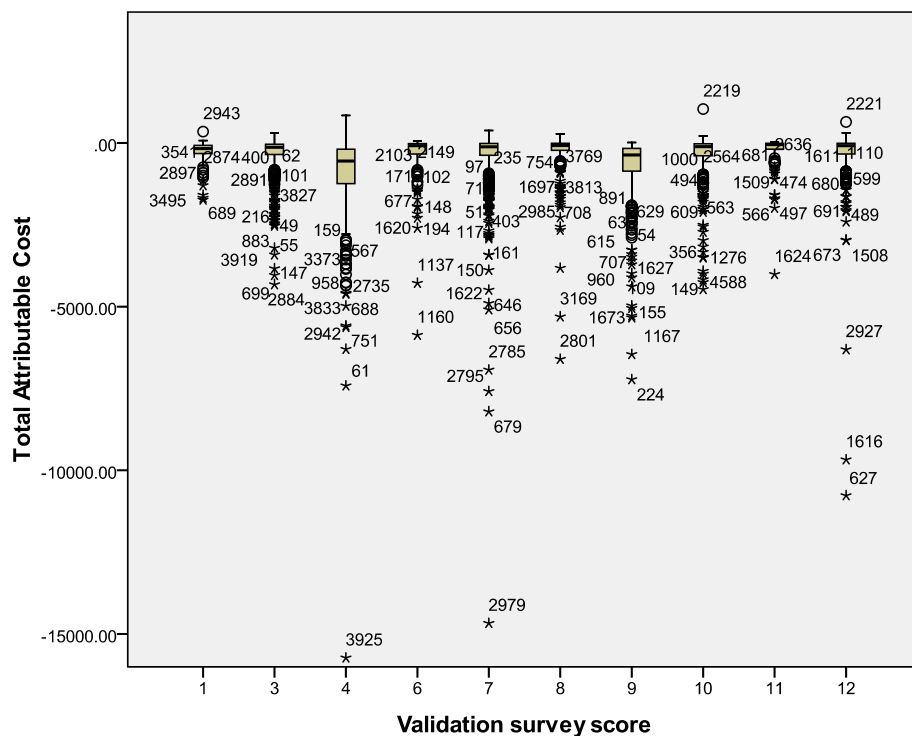


Figure 8-2 Spread of Costs Assigned to the Sampled Cases by Experts in Each Score Category

8.2.3 Determination of Health Resource Utilisation

A total of 4600 assessments (23 opinions for each of 200 cases) were analysed in order to determine an appropriate cost for clinical interventions.

As outlined in Chapter 2, the expert assessment method results in a description of the estimated changes in health care costs based on a number of parameters. There was considerable variation between assessors for the same

intervention, although this is encapsulated through the application of the uncertainty model. Experts were also asked to provide an estimate of the attribution of the intervention to the pharmacist in terms of a percentage. For example, if the expert believed that the DRP would *not* have been detected without the involvement of the pharmacist, they awarded a 100% attribution to that intervention. The average attribution was 92% with over 50% of the assessments suggesting 100% attribution. The individual attribution for each case was used to discount the estimates for each assessor. Table 8-3 shows that the average total attributed healthcare costs using information from all assessors for all cases.

Parameter	Mean	Standard Deviation	Maximum	Minimum
Attributed QALY	0.011	0.023	0.069	-0.067
Attributed Number of GP visits	-1.744	2.414	3.538	-53.820
Attributed Cost of GP visits (\$)	-\$58.52	\$80.97	\$119.38	-\$1,804.55
Attributed Number of specialist visits	-0.537	0.973	-1.220	-28.152
Attributed Cost of specialist visits (\$)	-\$31.63	\$54.06	\$72.68	-\$1,475.27
Attributed Cost of investigations (\$)	-\$39.17	\$72.86	\$66.45	-\$1,765.62
Attributed Duration of hospital admission	-0.287	0.636	0.626	-14.080
Attributed Cost of hospital admissions (\$)	-\$280.10	\$607.60	\$1,455.30	-\$12,329.92
Attributed Total Healthcare Resource Costs (\$)	-\$409.42	\$816.77	\$1,719.27	-\$17,472.10

Table 8-3: Estimates of Total Healthcare Resource Changes as a result of Interventions (all assessors included)

As can be seen from the table, the results were not normally distributed, with a range from a cost of \$1,700 to a saving of \$17,000 (see Figure 8-3). Ordinarily a distribution of this nature would necessitate the use of non-parametric analysis, such as the use of medians rather than means. However, since rare, high value events do occur, and may contribute significantly to the overall worth of clinical interventions, the use of medians is highly undesirable since it effectively eliminates these outliers from the analysis.

Instead, all values were included in the uncertainty analysis that was undertaken as part of the economic analysis. In this way, uncommonly occurring unusual values are “built in” to the analysis as possible results on some occasions.

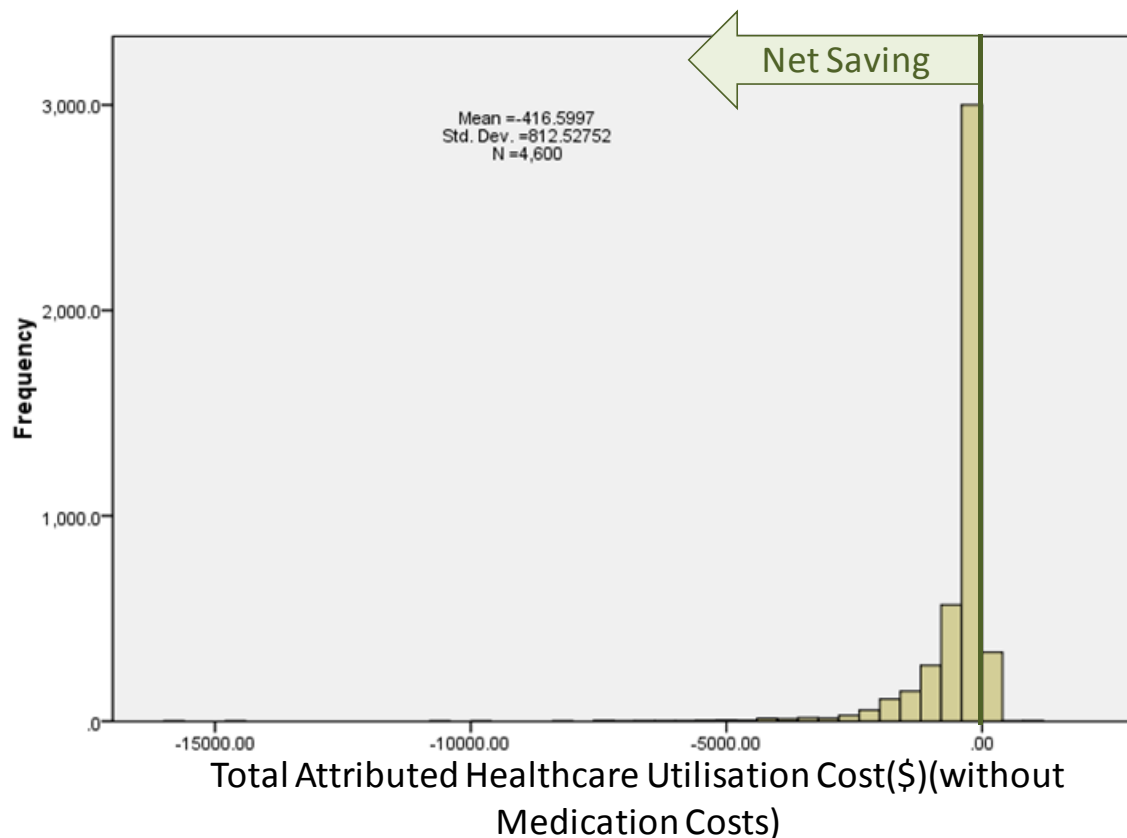


Figure 8-3: Range of Total Attributable Healthcare Savings Estimated by Expert Panel

There was substantial variation between the experts' results for the same group of sampled DCI (see Figure 8-4). However, this will again be fed into the uncertainty analysis to provide an idea of the potential range of outcomes that might occur.

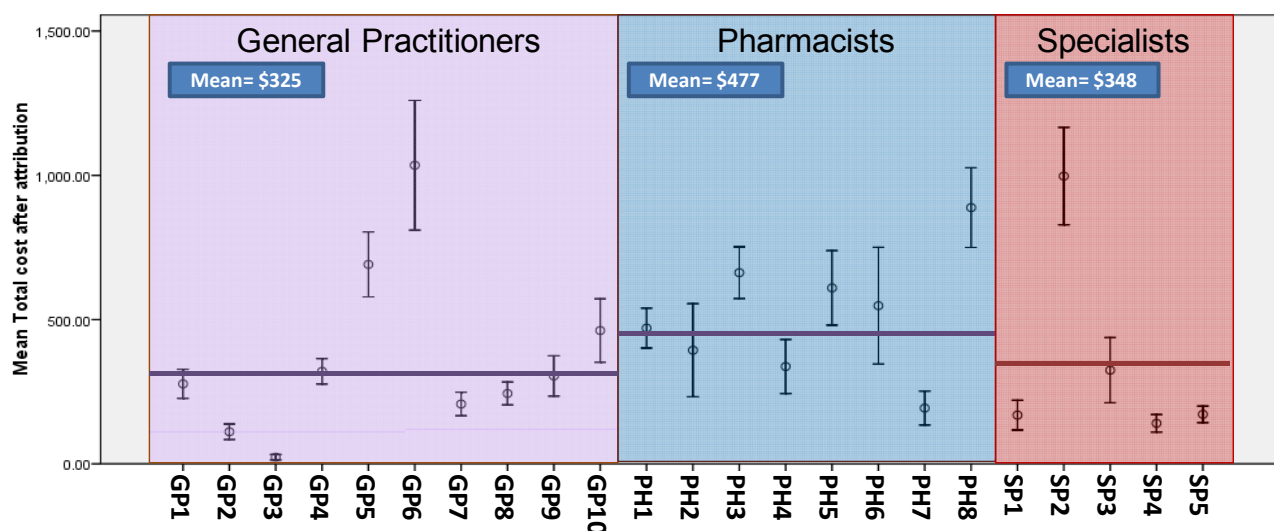


Figure 8-4: Mean Attributed Total Cost Estimated by Each of the 23 Expert Assessors for the 200 Sample DCI

8.2.4 Incorporation of Medication Cost Changes

Once the expert opinions were amalgamated into a 'per intervention' format, it was possible to examine each intervention in order to determine the changes in medication costs. Since the intent was to add these medication

costs to the health resource utilisation costs for each intervention, it was necessary to apply attribution to the medication costs, as was done for the DCI values. However, since the attribution of medication costs cannot be applied in the same way as they are to the health resource utilisation estimates, they are instead applied using the average attribution for each respective intervention (see Chapter 2). Having done this, the mean attribution found was 92%, causing the mean medication cost per case to shift from -\$21.29 to -\$20.35, and the standard deviations to change from \$286 to \$260.

The attributed medication cost for each intervention was then added to the attributed health resource utilisation costs associated with that intervention. Detailed results for the health resource costs and medication costs for each intervention with estimates from each assessor are shown in Appendix II. This is summarised in Figure 8-5.

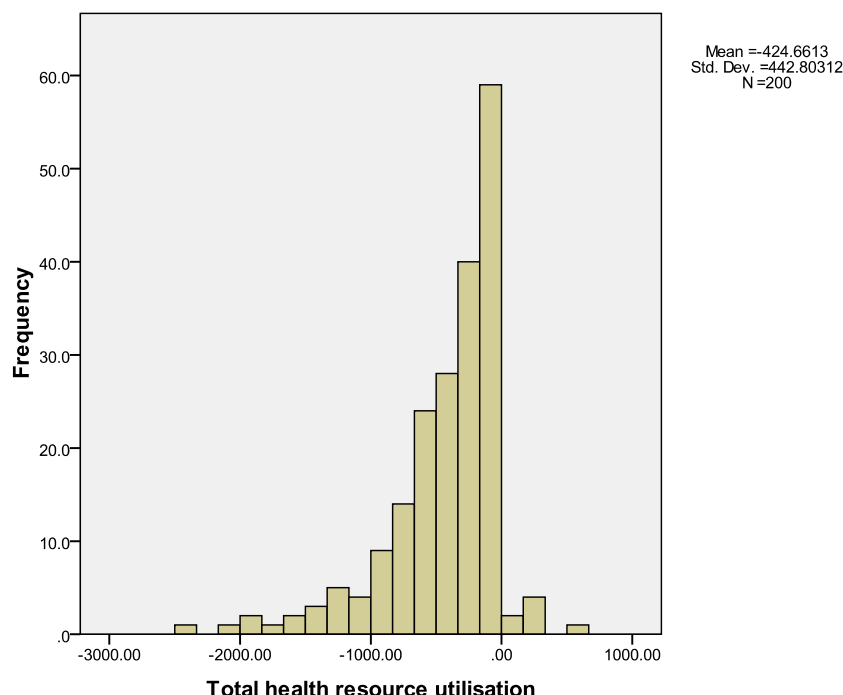


Figure 8-5: Total Attributed Health Resource Utilisation and Medication Costs for the 200 DCI

Approximately 95% of the DCI comprised 80% of the total cost of the sampled DCI (see Figure 8-6), and 164 of the DCI (82%) were responsible for 50% of the total estimated cost. Since the top 5% of the sampled DCI were responsible for only 20% of the cost, it cannot be said that the majority of cost savings were due to only a few DCI. Indeed, the top 18% of cases are required in order to account for 50% of the cumulative cost of the sample.

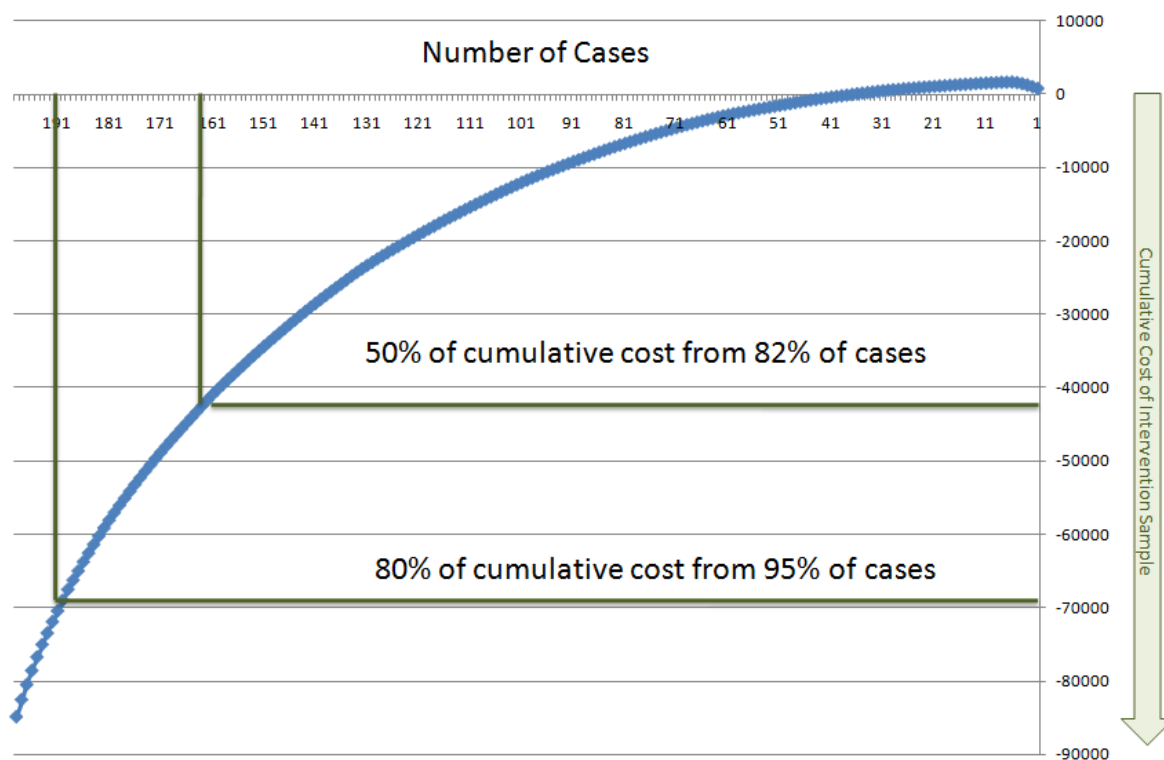


Figure 8-6: Cumulative Value of the Sampled DCI

8.3 Case Studies

In order to gain insight into how this economic evaluation method performs, a few case examples are shown in the next sections. DCI were selected to highlight both the strengths and weaknesses of the method, and to enable discussion of these issues. A brief discussion of the findings for each case is included and the first case is fully worked through in terms of using the expert assessors' values. The intent of this section is also to demonstrate how the method that was utilised dealt with a range of situations where medication costs outweighed the health resource cost avoidance. Finally, a section comparing these different examples in terms of cost effectiveness is included.

8.3.1 Case 3171: Olanzapine Compliance

A summary of the intervention is shown in Table 8-4 with the outcomes of the economic evaluation.

Problem: Poor compliance with bipolar therapy.	
Male patient (21-65yo) has had two recent hospitalisations due to flare-ups of his bipolar. The pharmacist noted that he has not been taking his olanzapine 10mg. The pharmacist recommends to the patient and his carer that the olanzapine be packed into webster pack. The patient agreed and the olanzapine is now being packed.	
Outcome: Improved compliance with bipolar therapy.	
Parameter	Case 3171
Attributed GP visits Avoided	0.79
Attributed Cost of GP visits avoided	-\$26.51
Attributed Specialist visits avoided	1.59
Attributed Cost of specialist visits avoided	-\$75.97
Attributed Cost of investigations avoided	-\$94.08
Attributed duration of admission (days)	2.70
Attributed Cost of admission avoided	-\$1,294.77
Subtotal 1: Attributed Healthcare Utilisation Costs	-\$1,491.33
Drug Cost	\$2,328.00
Attributability	0.90
Subtotal 2: Attributed Drug Cost	\$2,085.19
Total Attributed Cost	\$593.86
QALY	0.0450
Time to Perform (min)	6
Cost to Perform*	68.00
Cost Utility	\$14,698
*See Chapter 2 for details of calculation, and section 1.4 for the assumptions used.	

Table 8-4: Case 3171: Olanzapine compliance

As can be seen, this intervention was assessed as likely to prevent a hospital admission and as such, there was a major cost avoidance in terms of cost of admission (responsible for 86% of the health resource utilisation). On the other hand, as the medication is expensive, and the increased compliance will increase medication costs, there was an offset of the cost of medication against the cost avoidance from the health resource utilisation. Indeed, despite the considerable cost avoidance due to the reduced health resource utilisation, the total attributable cost of this intervention was almost \$600 due to the increased cost of the medication. The benefit of the intervention was, however significant in terms of the quality of life gained, and as a result the overall cost utility of the intervention was considered cost effective, costing only \$14,700 per QALY gained. While there is no specific literature to support the fact that compliance with antipsychotics is cost effective, hospitalisation associated with psychotic illness is often of long duration and high cost. As this patient had been admitted previously with psychotic exacerbations, it is reasonable to expect the likelihood of this occurring again as high.

8.3.2 Case 2728: Lipid Reduction Therapy

An outline of this example intervention is shown in Table 8-5 along with the results of its economic evaluation.

<p>Problem: Patient not compliant with rosuvastatin.</p> <p>Male patient (21-65yo) with a history of smoking presents to collect a repeat of rosuvastatin. From the dispensing history, the pharmacist notices that the patient has not collected the rosuvastatin for six months. The pharmacist counsels the patient on the importance of taking his statin regularly.</p> <p>Outcome: Possible improved compliance with his statin therapy.</p>	
Parameter	Case 2728
Attributed GP visits Avoided	0.06
Attributed Cost of GP visits avoided	-\$1.90
Attributed Specialist visits avoided	0.01
Attributed Cost of specialist visits avoided	-\$0.34
Attributed Cost of investigations avoided	-\$0.27
Attributed duration of admission (days)	0.01
Attributed Cost of admission avoided	-\$9.72
Subtotal 1: Attributed Healthcare Utilisation Costs	-\$12.22
Drug Cost	\$1,345.48
Attributability	0.9
Subtotal 2: Attributed Drug Cost	\$1,210.93
Total Attributed Cost	\$1,198.71
QALY	0.0003
Time to Perform (min)	8
Cost to Perform*	69.6
Cost Utility	\$4,939,836
*See Chapter 2 for details of calculation	

Table 8-5: Case 2728 Rosuvastatin compliance

In this example, the overall cost avoidance from health resource utilisation was minimal, totalling approximately \$12. This was for two main reasons. Firstly, the experts were asked to consider a 12 month timeframe when assigning probabilities. The use of medications such as rosuvastatin has been shown to reduce the frequency of strokes and heart attacks in an incremental fashion over a number of years. In this case, the one year limit placed on the assessors is likely to have resulted in a reduced (annual) estimate of risk reduction. Secondly, the patient is not yet 65 years of age, and the benefits associated with rosuvastatin use may be more clinically evident in older patients where the risk of the cardiovascular events is higher. The annual cost of the medication is significant and consequently the total attributed cost of this intervention is significant at over \$1000 for the year being considered.

Consequently, the low quality of life change and the additional drug cost make this intervention (according to the conservative economic estimates used here) not cost effective. However, in cases such as this, the health benefits are likely to be more significant when considered over a longer timeframe. It is felt that if a 3 or 4 year period were used cases such as this would begin to appear cost effective once more. It is felt that cases such as these contribute to make the economic methodology used here somewhat conservative. It is, at least, clear from the literature that the use of lipid reduction therapy is associated with an improvement in outcomes in terms of reduced strokes and heart attacks²²⁸. The fact that our economic method does not estimate increased compliance with statins as cost effective indicates that our findings are likely to be conservative.

8.3.3 Case 4371: Diabetes Renoprotection

An outline of this example intervention is shown in Table 8-6 along with the results of its economic evaluation.

Problem: Patient is not receiving optimal diabetes management.	
A male patient (65-80yo) presents to the pharmacy to collect his monthly prescriptions. Whilst dispensing, the pharmacist notices that he is a diabetic, but is currently not taking an ACE-inhibitor. The pharmacist recommends the patient talk to his GP at his next appointment about starting an ACE-inhibitor to maintain optimal renal function. During the following fortnight, the patient is started on ramipril.	
Outcome: The patient is commenced on a drug that may delay the decline in renal function.	
Parameter	Case 4371
Attributed GP visits Avoided	1.12
Attributed Cost of GP visits avoided	-\$37.61
Attributed Specialist visits avoided	0.13
Attributed Cost of specialist visits avoided	-\$6.80
Attributed Cost of investigations avoided	-\$39.20
Attributed duration of admission (days)	0.10
Attributed Cost of admission avoided	-\$80.19
<i>Subtotal 1: Attributed Healthcare Utilisation Costs</i>	<i>-\$163.80</i>
Drug Cost	\$168.00
Attributability	0.8543
<i>Subtotal 2: Attributed Drug Cost</i>	<i>\$143.52</i>
Total Attributed Cost	-\$20.28
QALY	0.0022
Time to Perform (min)	6
Cost to Perform*	68
Cost Utility	\$22,063
*See Chapter 2 for details of calculation	

Table 8-6: Case 4371: Diabetes Renoprotection

This intervention provides an example of a situation where the medication costs associated with the intervention are approximately equivalent to the health resource cost avoidance estimated. As there is some small quality of life gain from the intervention, the small net cost still makes the intervention cost effective. The literature supports the use of this type of medication in this indication and the benefits are well accepted in current medical practice²²⁹. It is thought that if a longer duration were considered here, this case may become more obviously cost effective, since the quality of life improvements would likely be more marked in the longer term.

8.3.4 Case 5460: Prednisolone Complications

An outline of this example intervention is shown in Table 8-7 along with the results of its economic evaluation.

Problem: Patient prescribed high dose prednisolone.	
A female patient (65-81yo) presents with a prescription for prednisolone 50mg QID. The pharmacist recognises that the dose is very high and contacts the prescriber. The prescriber confirms the intended dose was 50mg daily for five days.	
Outcome: Patient avoids inappropriate dosing with prednisolone.	
Parameter	Case 5460
Attributed GP visits Avoided	3.52
Attributed Cost of GP visits avoided	-\$117.94
Attributed Specialist visits avoided	0.36
Attributed Cost of specialist visits avoided	-\$19.23
Attributed Cost of investigations avoided	-\$56.44
Attributed duration of admission (days)	0.32
Attributed Cost of admission avoided	-\$305.59
<i>Subtotal 1: Attributed Healthcare Utilisation Costs</i>	<i>-\$499.20</i>
Drug Cost	-\$61.98
Attributability	0.937
<i>Subtotal 2: Attributed Drug Cost</i>	<i>-\$58.08</i>
Total Attributed Cost	-\$557.27
QALY	0.0107
Time to Perform (min)	6
Cost to Perform*	68
Cost Utility	Dominant

Table 8-7: Prednisolone Complications

In this case the use of this medication is associated with significant health resource implications, while the cost of the medication is minimal. Thus, there is a net saving as well as an improvement in quality of life, meaning that this is a “dominant” intervention in economic terms.

8.3.5 Case 2637: Nexium Dose Error

An outline of this example intervention is shown in Table 8-8 along with the results of its economic evaluation.

Problem: Prescribed dosage too high.	
Female patient (65-81 yo) presents to the pharmacy with a prescription for Nexium® (esomeprazole 40mg) enteric-coated tablets. The pharmacist recognises an error with the prescription with a dosage of two tablets per day recommended by the doctor. The pharmacist dispenses correct directions of one tablet per day after telephoning the doctor.	
Outcome: Patient receives the correct dosage of medication in order to improve compliance and reduce the possibility of adverse drug reactions	
Parameter	Case 2637
Attributed GP visits Avoided	1.82
Attributed Cost of GP visits avoided	-\$60.91
Attributed Specialist visits avoided	0.56
Attributed Cost of specialist visits avoided	-\$28.94
Attributed Cost of investigations avoided	-\$22.64
Attributed duration of admission (days)	0.10
Attributed Cost of admission avoided	-\$89.72
Subtotal 1: Attributed Healthcare Utilisation Costs	-\$202.21
Drug Cost	-\$704.04
Attributability	0.9696
Subtotal 2: Attributed Drug Cost	-\$682.64
Total Attributed Cost	-\$884.85
QALY	0.0145
Time to Perform (min)	30
Cost to Perform	86.15
Cost Utility	Dominant

Table 8-8: Case 2637: Nexium Dose Error

In this example, the majority of the cost avoided is in terms of drug savings and there is some quality of life improvement. Fundamentally, this means that the intervention saves money and also improves quality of life. Consequently this intervention is also termed “dominant” according to this economic evaluation method.

8.3.6 Comparison of Examples

The five examples chosen include DCI of different levels of cost avoidance as well as different levels of changes in quality of life. In Table 8-9 and Figure 8-7 these five DCI are compared and represented on a cost effectiveness diagram. Note that none of the DCI resulted in a negative quality of life, but that some have a lower “return for investment”.

Parameter	Case				
	3171	2728	4371	5460	2637
Attributed GP visits Avoided	0.79	0.06	1.12	3.52	1.82
Attributed Cost of GP visits avoided	-\$26.51	-\$1.90	-\$37.61	-\$117.94	-\$60.91
Attributed Specialist visits avoided	1.59	0.01	0.13	0.36	0.56
Attributed Cost of specialist visits avoided	-\$75.97	-\$0.34	-\$6.80	-\$19.23	-\$28.94
Attributed Cost of investigations avoided	-\$94.08	-\$0.27	-\$39.20	-\$56.44	-\$22.64
Attributed duration of admission (days)	2.70	0.01	0.10	0.32	0.10
Attributed Cost of admission avoided	-\$1,294.77	-\$9.72	-\$80.19	-\$305.59	-\$89.72
Subtotal 1: Attributed Healthcare Utilisation Costs	-\$1,491.33	-\$12.22	-\$163.80	-\$499.20	-\$202.21
Drug Cost	\$2,328.00	\$1,345.48	\$168.00	-\$61.98	-\$704.04
Attributability	0.90	0.9	0.8543	0.937	0.9696
Subtotal 2: Attributed Drug Cost	\$2,085.19	\$1,210.93	\$143.52	-\$58.08	-\$682.64
Total Attributed Cost	\$593.86	\$1,198.71	-\$20.28	-\$557.27	-\$884.85
QALY	0.0450	0.0003	0.0022	0.0107	0.0145
Time to Perform (min)	6	8	6	6	30
Cost to Perform	68.00	69.6	68	68	86.15
Cost Utility	\$14,698	\$4,939,836	\$22,063	-\$45,737	-\$55,005
	High Cost, High Benefit	High Cost, Low Benefit	Low Cost, Low Benefit	Negative Cost, High Benefit	Negative Cost, High Benefit

Table 8-9: Comparison of Example DCI

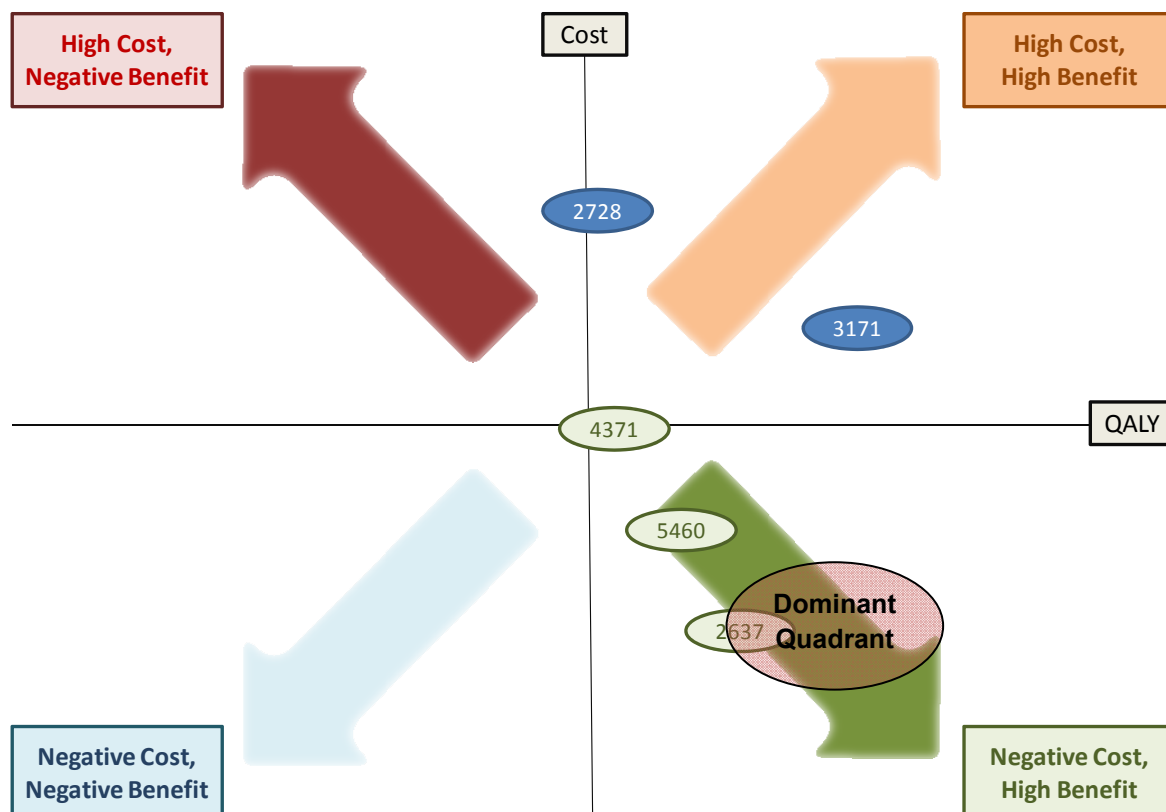


Figure 8-7: Comparison of Intervention Examples

Interventions that are dominant will be represented in the south-east quadrant, as these interventions have a negative cost (they save money) and a positive impact on quality of life. As outlined later in this section, the majority of the DCI in the PROMISE study were of this type (see cost effectiveness results in section 8.5)

8.4 Extrapolation of Value

In order to both determine the net cost of a clinical intervention, and to extrapolate the values found for an intervention to a broader perspective, it is first necessary to determine a set of assumptions with which to extrapolate. The set of assumptions were determined from the appropriate data collected from the PROMISe trial. Extrapolation of the value of the sample of DCI was done to an average pharmacy week, Australian pharmacy week, and Australian pharmacy year level. In order to facilitate this, a number of assumptions were determined, using the methods described in Chapter 2. These assumptions can be seen in Table 8-10.

Since the trial data does not indicate the actual intervention rate, it was necessary to estimate this. A reasonable estimate was achieved by using a combination of the documented and observed intervention rates, as described in Chapter 2. The calculation steps are shown here:

Determine the observation effect:

- Documented intervention frequency during middle 6 weeks in the software with prompts and reminders group = 0.003848 (0.3848 per 100 scripts)
- Observed documented intervention frequency in the same group was 0.01402 (1.402 per 100 scripts)
- Therefore the observation effect is $0.01402/0.003848 = 3.64$

Estimate the actual intervention rate in the no software group:

- The observed actual intervention rate in the no software group was 0.0166 (1.66 per 100 scripts)
- Therefore the non-observed intervention rate in this group can be estimated at $0.0166/3.64 = 0.00456$ (0.456 per 100 scripts)

Estimate the actual intervention rate in the PROMISe practice group:

- The observed actual intervention rate in the software with prompts and reminders (PROMISe practice) group was 0.03273 (3.273 per 100 scripts)
- Therefore the non-observed intervention rate in this group can be estimated at $0.03273/3.64 = 0.00898$ (0.898 per 100 scripts)

When applying this method, an ACI rate of 0.456 per 100 prescriptions for the Current Practice figure, and 0.898 per 100 prescriptions for PROMISe practice is reached. These figures suggest that the incremental improvement in the rate at which clinical interventions in the pharmacy are performed of PROMISe practice over current practice is 0.4427 per 100 prescriptions.

Row	Assumptions	Current Practice	PROMISe Practice	Source
1	Prescriptions per week	907.17	907.17	Trial Data
2	Actual intervention frequency	0.00456	0.00898	See above
3	Interventions performed per pharmacy week	4.13318	8.14933	Row1*Row2
4	Pharmacies	5006	5006	Guild Digest 2009
5	S1 (%)	19%	20%	Observed and Documented Data
6	S2 (%)	45%	40%	
7	S3 (%)	31%	34%	
8	S4 (%)	5%	5%	
9	Scripts to screen per intervention	219.49	111.32	1/Row2
10	Time to screen 1 script (mins)	0.25	0.75	Conservative Assumption
11	Time to document intervention (mins)	1.0	1.0	Observer Data
12	Cost of pharmacist time (per hour)	\$35.00	\$35.00	Assumed
13	On costs multiplier	1.29	1.29	Conservative Assumption
14	Cost of pharmacist time (per hour) incl. On-costs	\$45.15	\$45.15	Row12*Row13
15	Time to perform S1 intervention (mins)	2.0	4.0	Observed and Documented Data
16	Time to perform S2 intervention (mins)	3.0	4.0	
17	Time to perform S3 intervention (mins)	4.0	6.0	
18	Time to perform S4 intervention (mins)	6.0	7.5	
19	Average time spent performing intervention (mins)	3.27	4.86	Time to perform weighted by incidence
20	Time to find an intervention (mins)	59.14	89.35	Row9*Row10+Row19+Row11
21	Time to find an intervention (hours)	0.99	1.49	Row20/60
22	Cost to find and do an intervention	\$ 44.50	\$ 67.24	Row21*Row14

Table 8-10: Assumptions used for Extrapolation

As was previously mentioned in Chapter 2, it is not sufficient to simply determine the average values for DCI in the assessed sample and to extrapolate based upon this, due to the selection bias of the sample. Instead it is necessary to correct this sample to appropriate proportions through a weighting process. As such, the extrapolation process involved first determining a truer set of average values for S1, S2, S3 and S4 DCI by finding the average for DCI in each significance class and then weighting them according to their ratios in the broader documented dataset, as can be seen in Table 8-11.

Parameter		Mean
S1	Quality Adjusted Life Years	0.0090
	Number of GP visits	1.3103
	Cost of GP visits	-\$43.96
	Number of specialist visits	0.2987
	Cost of specialist visits	-\$16.71
	Cost of investigations	-\$23.91
	Duration of hospital admission	0.1382
	Cost of hospital admissions	-\$137.57
	Cost of Medications	-\$9.04
Total Health Resource Utilisation Change		-\$230.91
S2	Quality Adjusted Life Years	0.0077
	Number of GP visits	1.1554
	Cost of GP visits	-\$38.76
	Number of specialist visits	0.3278
	Cost of specialist visits	-\$18.61
	Cost of investigations	-\$38.67
	Duration of hospital admission	0.2412
	Cost of hospital admissions	-\$224.35
	Cost of Medications	\$15.93
Total Health Resource Utilisation Change		-\$304.47
S3	Quality Adjusted Life Years	0.0113
	Number of GP visits	1.7468
	Cost of GP visits	-\$58.60
	Number of specialist visits	0.4590
	Cost of specialist visits	-\$26.26
	Cost of investigations	-\$36.99
	Duration of hospital admission	0.2683
	Cost of hospital admissions	-\$274.17
	Cost of Medications	-\$58.95
Total Health Resource Utilisation Change		-\$454.97
S4	Quality Adjusted Life Years	0.0200
	Number of GP visits	2.4479
	Cost of GP visits	-\$82.13
	Number of specialist visits	0.9390
	Cost of specialist visits	-\$50.21
	Cost of investigations	-\$68.21
	Duration of hospital admission	0.6060
	Cost of hospital admissions	-\$555.00
	Cost of Medications	\$24.46
Total Health Resource Utilisation Change		-\$731.09

Table 8-11: The average values for S1, S2, S3, and S4 DCI.

Having found the average values for these types of interventions, they can be converted to a current practice and PROMISE practice average intervention by utilising the relative proportions of S1-4 DCI found in each of these respective datasets. These figures are shown in Table 8-12. Also shown here is the difference between PROMISE and current practice, calculated by subtracting the current practice figure from PROMISE practice. This represents the additional benefit and cost that the PROMISE program provides over current practice.

	Current Practice	PROMISe Practice	
	Average Intervention	Average Intervention	Incremental
	No Software	PROMISe sample	Difference
Quality Adjusted Life Years	0.010	0.010	0.000
Number of GP visits	1.43	1.46	0.02
Cost of GP visits	-\$ 48.11	-\$ 48.83	-\$ 0.73
Number of specialist visits	0.39	0.40	0.00
Cost of specialist visits	-\$ 22.23	-\$ 22.48	-\$ 0.25
Cost of investigations	-\$ 36.84	-\$ 36.65	\$ 0.19
Duration of hospital admission	0.25	0.25	0.00
Cost of hospital admissions	-\$ 240.08	-\$ 240.98	-\$ 0.89
Cost of Medications	-\$ 11.51	-\$ 14.14	-\$ 2.63
Total healthcare utilisation cost	-\$ 358.78	-\$ 363.08	-\$ 4.30
Total cost to pharmacies	\$ 44.50	\$ 67.24	\$ 22.73
Net Cost	-\$ 325.78	-\$ 309.98	\$ 15.80

Table 8-12: The Average Value of an Individual Intervention

The figures in the above table can then be further extrapolated by considering the number of DCI per week that a pharmacy will make, thus estimating the average improvements at an average pharmacy week level. This is calculated by considering the actual intervention frequency of the group, and the average number of prescriptions a pharmacy will process per week. The results of this are shown in Table 8-13.

	Current Practice	PROMISe Practice	
	Per Pharmacy Week	Per Pharmacy Week	Incremental
	4.13 Ints/week	8.15 Ints/week	Difference
Quality Adjusted Life Years	0.040	0.080	0.040
Number of GP visits	5.93	11.86	5.93
Cost of GP visits	-\$ 198.84	-\$ 397.96	-\$ 199.12
Number of specialist visits	1.63	3.25	1.62
Cost of specialist visits	-\$ 91.88	-\$ 183.18	-\$ 91.31
Cost of investigations	-\$ 152.28	-\$ 298.67	-\$ 146.39
Duration of hospital admission	1.03	2.03	1.00
Cost of hospital admissions	-\$ 992.31	-\$ 1,963.78	-\$ 971.47
Cost of Medications	-\$ 47.58	-\$ 115.23	-\$ 67.65
Total healthcare utilisation cost	-\$ 1,482.88	-\$ 2,958.83	-\$ 1,475.94
Total cost to pharmacies	\$ 183.95	\$ 547.94	\$ 363.99
Net Cost	-\$ 1,298.94	-\$ 2,410.89	-\$ 1,111.95

Table 8-13: The Average Value of all Interventions Produced by an Average Pharmacy per Week

The figures from the above table can then be further extrapolated to the Australian perspective, since it is known that there were 5006 pharmacies in Australia in the year 2009.²¹⁶ After applying this extrapolation the results show the figures at an Australian pharmacy week level, as seen in Table 8-14.

	Current Practice	PROMISe Practice	
	Per Australia Week	Per Australia Week	Incremental
	5006 Pharmacies	5006 Pharmacies	Difference
Quality Adjusted Life Years	200.09	400.28	200.19
Number of GP visits	29668.57	59379.18	29710.61
Cost of GP visits	-\$ 995,380.65	-\$ 1,992,171.51	-\$ 996,790.86
Number of specialist visits	8153.79	16255.62	8101.82
Cost of specialist visits	-\$ 459,931.16	-\$ 917,011.91	-\$ 457,080.75
Cost of investigations	-\$ 762,316.06	-\$ 1,495,152.10	-\$ 732,836.04
Duration of hospital admission	5143.08	10141.64	4998.56
Cost of hospital admissions	-\$ 4,967,518.49	-\$ 9,830,706.94	-\$ 4,863,188.45
Cost of Medications	-\$ 238,172.23	-\$ 576,837.87	-\$ 338,665.64
Total healthcare utilisation cost	-\$ 7,423,318.58	-\$ 14,811,880.33	-\$ 7,388,561.75
Total cost to pharmacies	\$ 920,829.52	\$ 2,742,976.70	\$ 1,822,147.18
Net Cost	-\$ 6,502,489.07	-\$ 12,068,903.63	-\$5,566,414.57

Table 8-14: The Average Value of all Interventions Performed per Week in Australia

These figures can be extrapolated to the yearly figure by multiplying the pharmacy week figures by 52. This is shown in Table 8-15. At this level, the PROMISe program represents an additional cost in terms of pharmacist time of 2,098,597 hours. If it is assumed that the typical work week is 40 hours, this represents 52,465 full-time pharmacists. However, since some pharmacists will not currently be under a full load, this figure may be significantly less in practice. If the incremental cost effectiveness ratio of the program is considered at this level, the PROMISe program is dominant, providing both an additional improvement to health outcomes, as well as reduction in cost.

	Current Practice	PROMISe Practice	
	Per Australia Year	Per Australia Year	Incremental
	5006 Pharmacies	5006 Pharmacies	Difference
Quality Adjusted Life Years	10404.50	20814.38	10409.89
Number of GP visits	1542765.83	3087717.39	1544951.56
Cost of GP visits	-\$ 51,759,793.64	-\$ 103,592,918.50	-\$ 51,833,124.86
Number of specialist visits	423997.34	845292.08	421294.74
Cost of specialist visits	-\$ 23,916,420.06	-\$ 47,684,619.18	-\$ 23,768,199.11
Cost of investigations	-\$ 39,640,435.17	-\$ 77,747,909.42	-\$ 38,107,474.25
Duration of hospital admission	267440.39	527365.39	259925.00
Cost of hospital admissions	-\$ 258,310,961.35	-\$ 511,196,760.84	-\$ 252,885,799.49
Cost of Medications	-\$ 12,384,955.98	-\$ 29,995,569.21	-\$ 17,610,613.23
Total healthcare utilisation cost	-\$ 386,012,566.21	-\$ 770,217,777.14	-\$ 384,205,210.93
Total cost to pharmacies	\$ 47,883,134.83	\$ 142,634,788.30	\$ 94,751,653.48
Net Cost	-\$ 338,129,431.38	-\$ 627,582,988.84	-\$ 289,453,557.46

Table 8-15: The Value of all Interventions Performed per Year in Australia

8.5 Cost-effectiveness Results

As has been described above, the cost effectiveness was described in terms of the cost per QALY of the interventions. Presented below are both the average and incremental cost effectiveness of the interventions, as shown on a cost effectiveness plane.

8.5.1 Average Cost Effectiveness

Figure 8-8 presents the average cost effectiveness plane for S1, S2, S3 and S4 DCI under current practice. Each red point on the graph represents the average cost effectiveness of all S1 DCI in the model for a single iteration of the Monte Carlo simulation, similarly the blue points represent S2 DCI, green S3, and purple S4. The clusters conform to expectations, with the S4 DCI tending to be worth more than the S3's which are in turn worth more than the S2 and S1 DCI. Since each point on the graph represents the average value of all the DCI in its class through the iterations of the Monte Carlo simulation, there is a high degree of scatter being introduced through all the uncertain variables in the model. However, this scatter is entirely intentional, and it shows us that in the vast majority of cases considered by the model (99.9%), all four classes of DCI were dominant on average, both saving money and improving quality of life, with only 12 of the 40,000 points on this graph falling outside the dominant quadrant. Of those 12, only 3 represented an average cost, but still appear to fall well inside the \$50,000 per QALY cost effective threshold. The remaining 9 were cost reducing, but represented a negative improvement in the quality of life. This suggests that, on balance, clinical interventions performed by the pharmacist – even ones they themselves deem to be of low value – are almost certainly cost dominant.

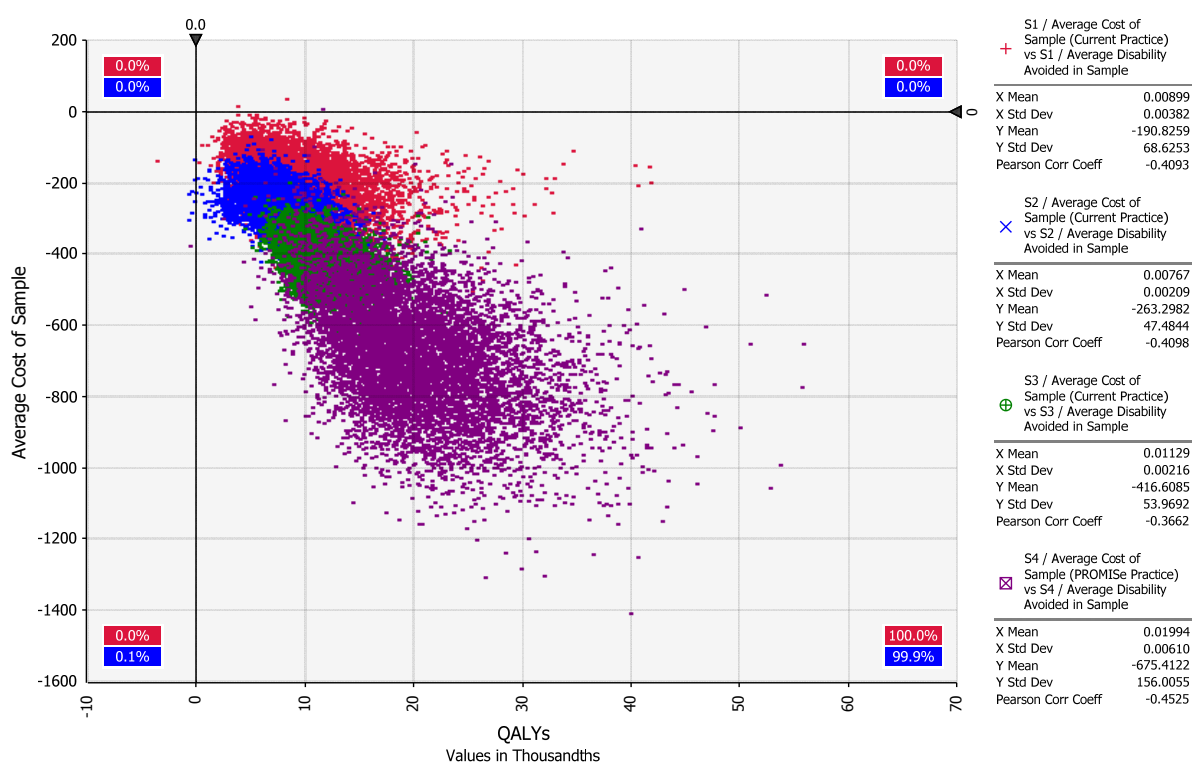


Figure 8-8: Average Cost Effectiveness Plane for S1, S2, S3 and S4 DCI in Current Practice

Figure 8-9 draws a similar scenario, although the additional cost to find and perform the intervention that exists within PROMISE practice results in a few more potential models of the average S1 and S2 DCI falling out of the dominant quadrant. This suggests perhaps that non-cost-effective DCI are marginally more likely in PROMISE practice, as you would expect since the cost of finding and performing that intervention tends to be higher. However, the increase is so marginal that the same proportion of iterations were found to be dominant as was the case in current practice when rounded to 3 significant figures (99.9%). Since the PROMISE program is not modelled to improve the performance of the *sampled* DCI, it is impossible to see the benefits at this level. In order to see these improvements an extrapolation must be made, such that the improvements to both the actual and documented intervention frequencies that PROMISE offers can be considered.

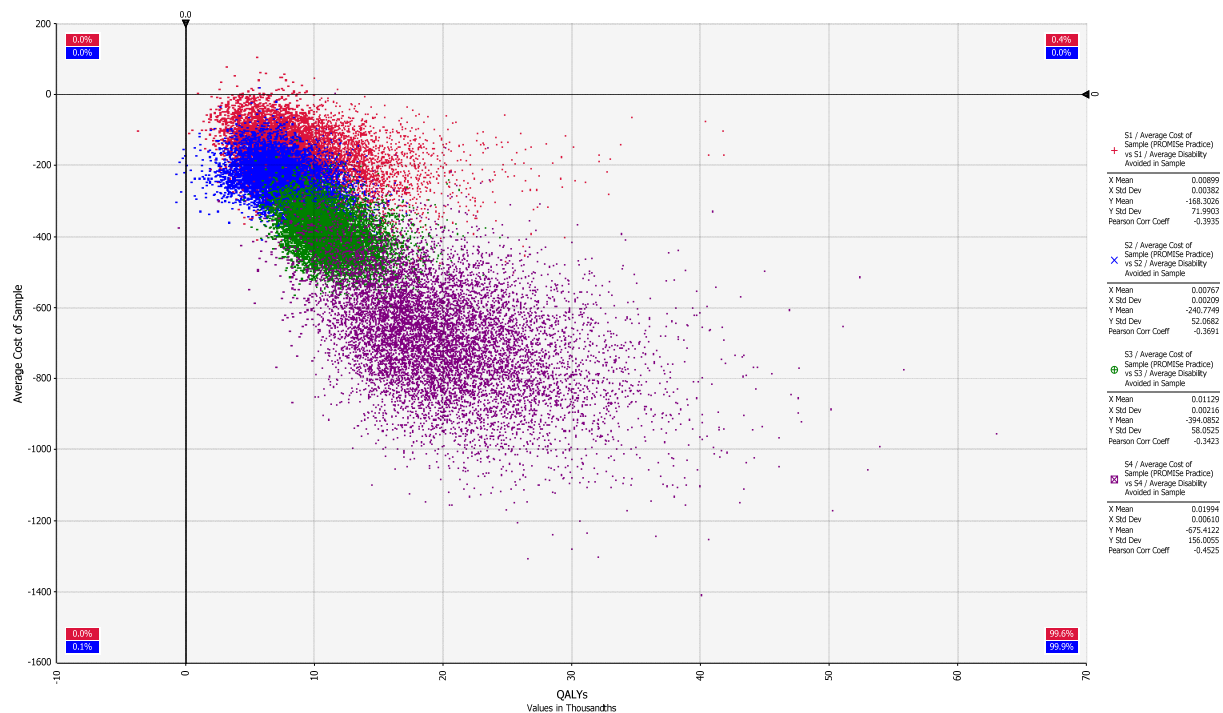


Figure 8-9: Average Cost Effectiveness Plane for S1, S2, S3 and S4 DCI in PROMIS Practice

8.5.2 Incremental Cost Effectiveness

Extrapolation was applied to extend the results of the model, which show what an “average” intervention looks like, through to the predicted outcomes of a current vs. PROMIS practice environment. Figure 8-10 shows the incremental cost effectiveness of PROMIS over current practice. Each point represents the overall incremental cost effectiveness that was found for each of the 10,000 iterations of the Monte Carlo simulation. As can be seen, 94.9% of the iterations resulted in the incremental benefit being dominant, a further 4.3% were positioned in the “improves quality of life yet costs money to implement” quadrant, although many of these appear to be under the generally accepted threshold of \$50,000 per QALY. Some 0.8% of the iterations show PROMIS practice actually producing a worse outcome than current practice, which seems surprisingly high. However, when the nature of the uncertainty analysis is considered, this is not an unsurprising result, since these are likely to be iterations in which the PROMIS practice variables were set to unusually poor levels, while concurrently the current practice variables were set to unusually high levels, and it is known that many of our assumptions are conservative. Despite this level of conservatism, the model still shows an overwhelming tendency towards PROMIS practice being both highly effective at improving quality of life, and reducing the costs of healthcare resource utilisation and medications.

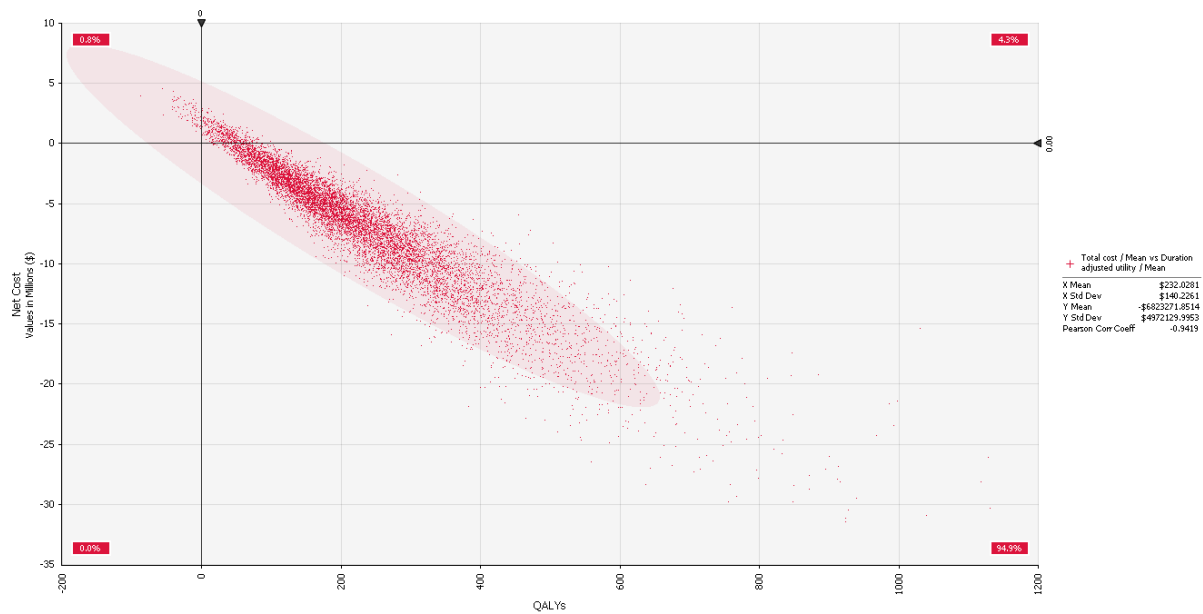


Figure 8-10: Incremental Cost Effectiveness Plane at the Australian Pharmacy Week Level

Another way of representing these results is a cost-effectiveness acceptability curve, which is a cumulative distribution of each iteration's ICER result. Figure 8-11 suggests that 98.9% of the outcomes for the PROMISE program were found to be lower than the cost effectiveness threshold of \$50,000 / QALY.

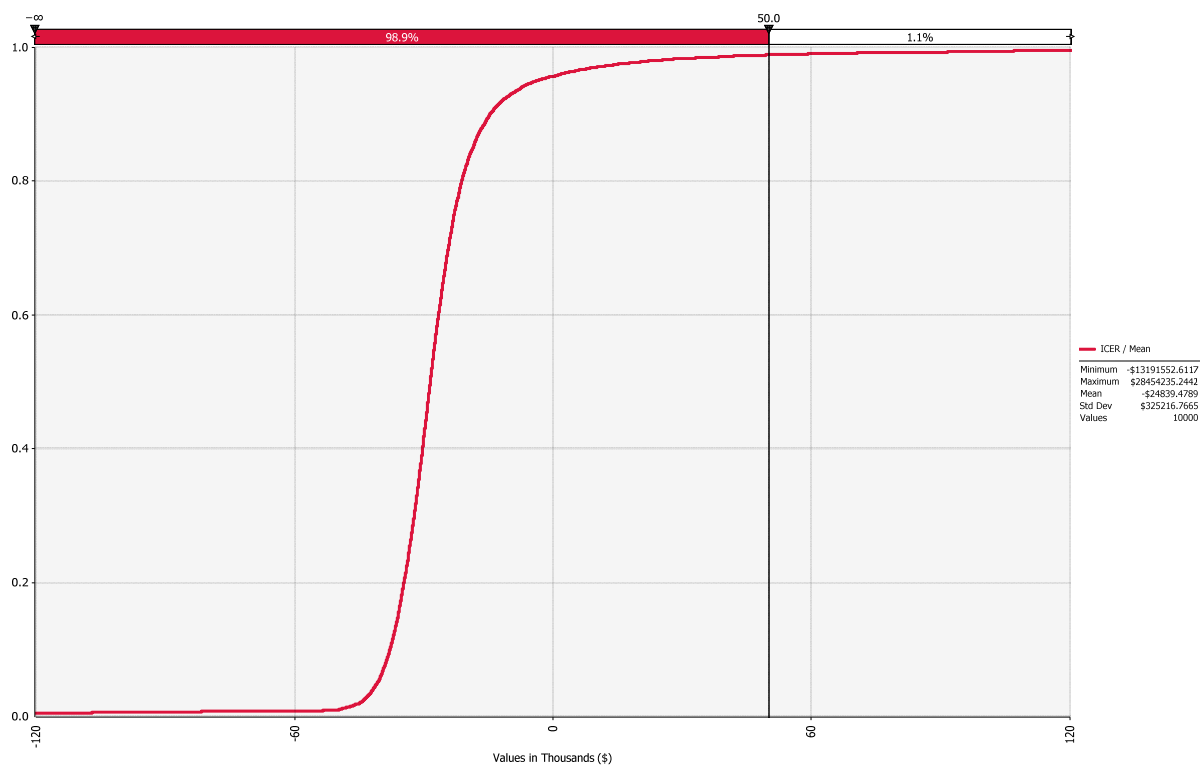


Figure 8-11: Incremental Cost Effectiveness Curve

8.6 Sensitivity Analysis

As was discussed in Chapter 2, sensitivity analysis was run with low-expected-high values for both the documented intervention frequency, and the time to screen for an intervention. As can be seen in Table 8-16 and Table 8-17, for even the very low documented intervention frequency of 0.00233, and the very high time to screen of 67.5

seconds, a net cost improvement over the calculation of current practice. In all instances the ICER remains dominant, indicating that even if the PROMISE program were to perform substantially worse than is anticipated, it would still provide cost savings *and* quality of life improvements.

	PROMISE	Per Australia Week	
	Intervention frequency documented	Net Cost	ICER
<i>Low</i>	0.00233	-\$ 2,702,136.96	Dominant
<i>Expected</i>	0.00384	-\$ 5,566,414.57	Dominant
<i>High</i>	0.006187	-\$ 9,988,556.70	Dominant

Table 8-16: Sensitivity Analysis for the Documented Intervention Frequency

	PROMISE	Per Australia Week	
	Time to screen 1 prescription (s)	Net Cost	ICER
<i>Low</i>	22.5	-\$ 6,847,910.69	Dominant
<i>Expected</i>	45	-\$ 5,566,414.57	Dominant
<i>High</i>	67.5	-\$ 4,284,918.44	Dominant

Table 8-17: Sensitivity Analysis for the Time to Screen a Prescription

8.7 Discussion: Value of Interventions

Having applied an extensive and advanced expert panel assessment process to a range of DCI performed by pharmacists, it has been shown that the economic and health value of these DCI are substantial. The results presented here indicate that interventions provided under the proposed remuneration model are economically dominant – providing both health improvement and cost savings beyond the investment required.

The PROMISE model suggests that the average Australian pharmacy with the PROMISE program could be expected to save \$1476 in health resource utilisation and \$68 in medications by spending an additional ~ hours per week (valued at \$364). These figures were achieved despite the fact that experts were asked to only consider the consequences which would occur within the 12 month period after intervening, which is likely to have been the cause of many of the seemingly low value DCI found by this study, since some preventative therapies are unlikely to show significant benefits within this short period. Extended to the entire nation, these figures would represent a cost saving of ~\$290 million per year over current practice, and an additional ~10,000 quality adjusted life years.

In light of the results presented here, which both indicate that clinical interventions are of substantial worth to the economy, and that the PROMISE program improves the rate of performance of these interventions, it is felt that the PROMISE program should be implemented as soon as possible.

The model discussed in this chapter fails to consider the costs of implementing the PROMISE program on a broader scale, or the complexities involved in implementing it successfully. This problem is tackled in Chapter 11, which builds on the results presented here.

Chapter 9 Results and Discussion: Barriers and Facilitators for Clinical Interventions

One of the main aims of the PROMISe project was to identify the barriers and facilitators to performing and documenting clinical interventions. This was achieved via three methods; focus groups,^{230 231} observation and a software usability survey.

Focus groups were conducted with 30 owners and managers of participating pharmacies to establish their opinions and perspectives on clinical interventions. The final report can be found in Appendix JJ.

Each observer was asked to document the barriers and facilitators they noticed for each pharmacist and pharmacy they observed. These observations were then discussed and explored in a focus group attended by all observers, as shown in Appendix KK.

A software usability survey (see Appendix S) was sent to 531 participating pharmacists. A total of 304 completed surveys were returned giving a response rate of 57%.

A summary of the barriers and facilitators identified is shown in Figure 9-1.

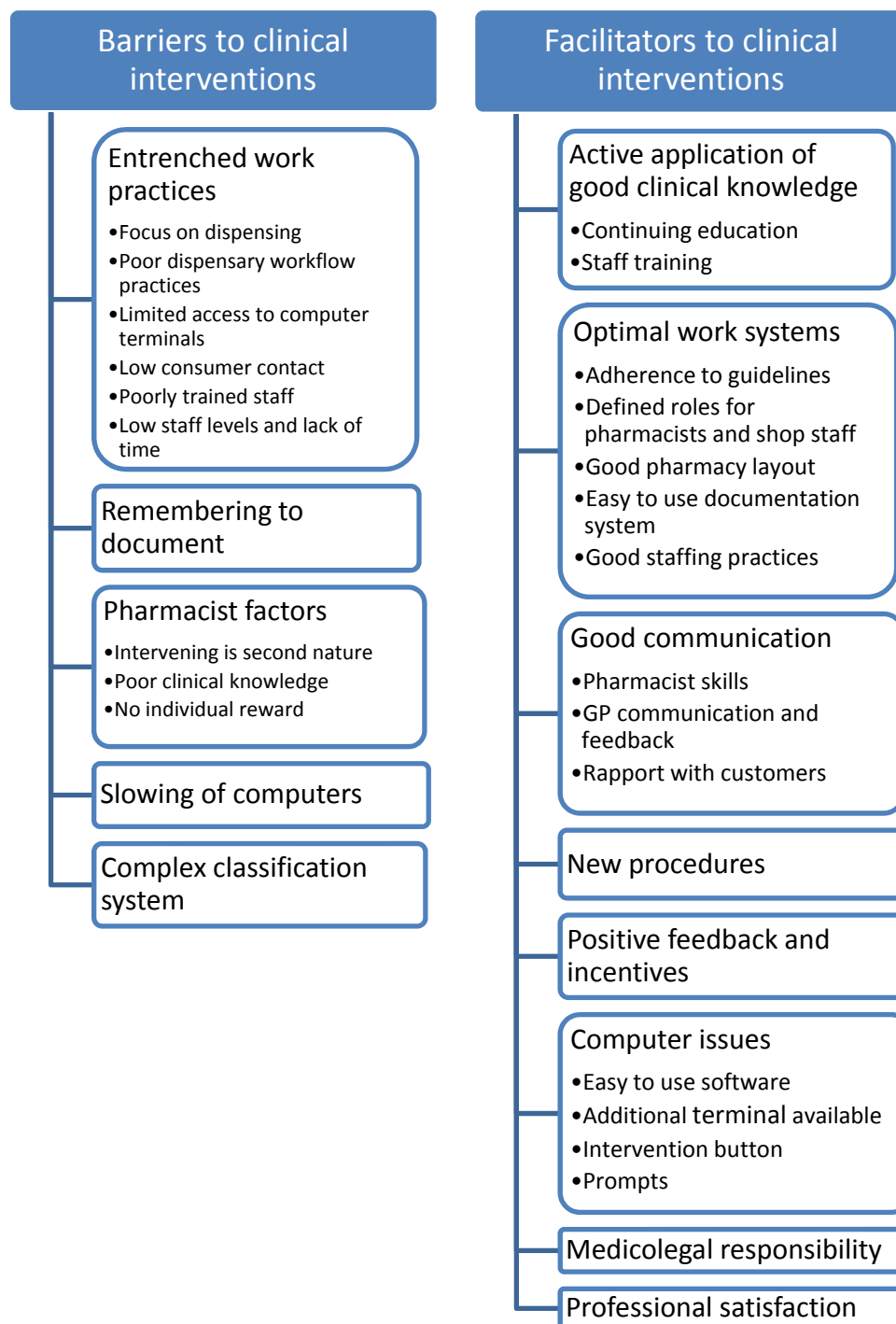


Figure 9-1: Summary of Barriers and Facilitators to Performing and Documenting Interventions

9.1 Barriers

A number of barriers were identified by the participants of the focus groups and the respondents of the software survey. Figure 9-1 illustrates these barriers to performing and documenting clinical interventions.

9.1.1 Entrenched Work Practices

Participants of the owner/manager focus groups reported entrenched work practices, developed over many years and based on training from undergraduate courses, as one of the main barriers to documenting interventions. Entrenched work practices, such as focusing on dispensing, meant a reduction in time with customers. In addition,

a heavy workload and having limited time available, meant that pharmacists were often too busy to immediately record interventions, and then forget to recall or document the intervention later.

Focus on dispensing

Some observers commented that in some pharmacies with high prescription volume, the pressure to maintain a high prescription output lessened the chances for the identification of drug related problems. This was also raised in the owner/manager focus groups who reported that pharmacies focus on processing the greatest number of prescriptions possible, as they are remunerated largely through the dispensing of prescriptions. Both focus groups reported that this focus reduces the pharmacists' ability to recognise and document clinical interventions as they are spending little time with consumers.

Dispensary workflow practices and routine

Both the owner/manager and observer focus group participants reported the physical dispensing routine being a barrier to identifying interventions. The owner/managers reported that pharmacists have difficulty incorporating the documentation of clinical interventions into the current workflow of pharmacies, as it requires a change to their current dispensing routine.

"You would not put a script (sic) through and not put a label on as it is part of the process... if you make interventions (and documentation) part of the process by saving a draft then it will happen"

Observers reported that some pharmacists had poor dispensing systems, where, for example, the supervision of Pharmacist Only medicines was not always performed, patient history checks were not always completed during the dispensing process if conducted by a dispensary assistant, and where pharmacy assistants would take in prescriptions and hand out dispensed items.

Access to computer terminals

The observers reported that pharmacies with only one computer terminal were less likely to document their interventions. This is due to the terminal being used for dispensing purposes and pharmacists did not want to stop the dispensary work flow. One observer commented;

"Sometimes it is about the number of computers. I had one pharmacy that had one computer and if they are dispensing, they were dispensing, they are not going to record as well"

Low consumer contact

The observers stated that some pharmacists had low consumer contact due to them being 'wedded' to their dispensing terminals. The owner/manager focus group reinforced this conclusion and reported that one way to overcome this and to drive an increase in the level of interventions would be to encourage pharmacists to always counsel consumers when handing out prescriptions.

Both focus groups agreed that the minimal interaction with customers reduced the chance of pharmacists identifying drug related problems. One observer reported;

"They (some pharmacists) put the dispensed script (sic) there for someone else to hand out. They don't want to go out into the pharmacy"

Poorly trained staff

Observers reported that poorly trained staff were a barrier to interventions. Staff who are poorly trained and receiving/handing out prescriptions to consumers, may not bring potential drug related problems to the attention of the pharmacist. One observer stated that;

"Your staff should have a minimum amount of training to recognise when there could be a potentially dangerous situation and refer back to you."

Another observer described an experience as;

“There was an instance where a girl in the shop came into the dispensary and got a pack of 72 Nurofen Plus and sold it before the pharmacist had a chance to stop it. That was because the staff weren’t trained or didn’t care”

Low staff levels and lack of time

Both observer and owner/manager focus groups revealed that time restrictions were a barrier to performing some interventions and to documenting them. The observers reported that some pharmacies with low staffing levels (high prescription to dispensary staff ratio) had less time for consumer counselling. One observer stated;

“I think the staff are a major issue... if you haven’t got that support you are overwhelmed and you can’t make interventions that you should do”

Furthermore, low staffing levels meant that many pharmacists worked longer shifts with few meal breaks which increased fatigue, reduced concentration and ultimately inhibited the chance to recognise drug related problems. One of the observers reported that;

“I think one of the barriers is the long hours, they are almost there 12 hours, and they are stuffed and tired. It is mind numbing. They are not interested in doing any interventions”

The observers reported that when pharmacists were busy only the more potentially serious interventions were performed. In addition, the owner/manager respondents reported that some pharmacies were so busy in periods that there was no time to document immediately after an intervention occurred. Pharmacists would document later in the day if they remembered. An observer stated that;

“It is not the time taken to document but rather when it happens you may not have time to deal with it then”

9.1.2 Remembering to Document

Owner/manager pharmacists reported that one of the greatest causes of low documentation rates was due to forgetting to enter the intervention details into the computer software. Some of the owner/managers reported that even when there was time to create a draft and save it under the patient history, they could not recall the specific intervention details when it came time to completing the draft at the end of the day. It was suggested that unless dispensing routines were modified to include documentation, then documentation was often forgotten. One respondent reported;

“If they were in a middle of a pile of scripts (sic) and they needed to document something then often it was forgotten”

Another observer stated that;

“I have been in both Promise II and Promise III so I have a good idea what an intervention is, but it is remembering to document it”

Similarly, observers reported that pharmacists would become distracted by internal and external factors which meant that the rate of which interventions were performed was reduced. One observer reported;

“There were always things that were distractions which prevented them from doing it. Another script comes in and they forget”

The observers identified some busy pharmacies with a high prescription and front of shop trade as being distracting for dispensers, as they had to do a myriad of activities resulting in less focus on the clinical aspects of their role. In contrast, they also identified some quiet pharmacies as having too many distractions, since the staff were focused on business activities rather than clinical interventions. Nursing home dose administration aid packing and related administrative issues were also considered a distraction from dispensing, as well as telephone calls, and customers talking to the pharmacist during the dispensing process.

9.1.3 Pharmacist Factors

The findings from both focus groups revealed that some interventions may not have been documented because pharmacists failed to recognise them as an intervention or were not rewarded for them. It appears the reasons for this are twofold; intervening is instinctive for pharmacists and therefore not considered an intervention, or because some pharmacists lack the clinical knowledge to recognise a clinical intervention.

Intervening is second nature

The owner/manager group discussion revealed that pharmacists often did not identify their recommendations for minor drug related problems as interventions, since intervening is second nature to most pharmacists. This conclusion was supported by the results of the observer debrief which showed that pharmacists would perform interventions instinctively, without actually recognising their actions were an intervention. The observers estimated that approximately 50% of the interventions they noted were actually documented by pharmacists and those that were missed were suspected not to be recognised as interventions.

Clinical knowledge

The observers reported many interventions were missed by pharmacists who were not equipped with adequate clinical knowledge. As one observer said;

“I was in two pharmacies that were really, really quiet and things that could have been done were completely missed and that probably goes back to the knowledge of the pharmacist. So staffing is not the only reason interventions are not done.”

Not surprisingly, the results of the software survey showed that 83% of participants believed that they had good clinical knowledge compared to 2% who disagreed and 15% who reported neutral feelings. In addition, 79% of participants believed that the trial had increased their awareness of how many clinical interventions they performed.

No individual reward

The outcome of the observer focus group found that the observers believed there was little incentive for employee pharmacists to document interventions because participation payments were made only to pharmacy owners. Furthermore, it was reported that some employee pharmacists believed that there was no tangible purpose to documenting minor interventions. They perceived no health benefits and in turn saw documenting as adding to the workload.

The observers suggested that allocating CPD points to employee pharmacists for improved intervention rates could overcome this issue.

9.1.4 Slowing of Computers

The results of the software survey showed that respondents reported no barriers to the use of the PROMISe software interface. However, there appears to be mixed reports regarding the effect of the PROMISe interface on the speed of pharmacy computers. As Figure 9-2 shows, 28% of participants reported the speed of their computer slowed due to the PROMISe software, whereas, 48% of participants disagreed (see Chapter 10 for more information). In addition, two pharmacists (one from each vendor group) reported that during the trial that the user interface slowed their computer to the extent that they required vendor support.

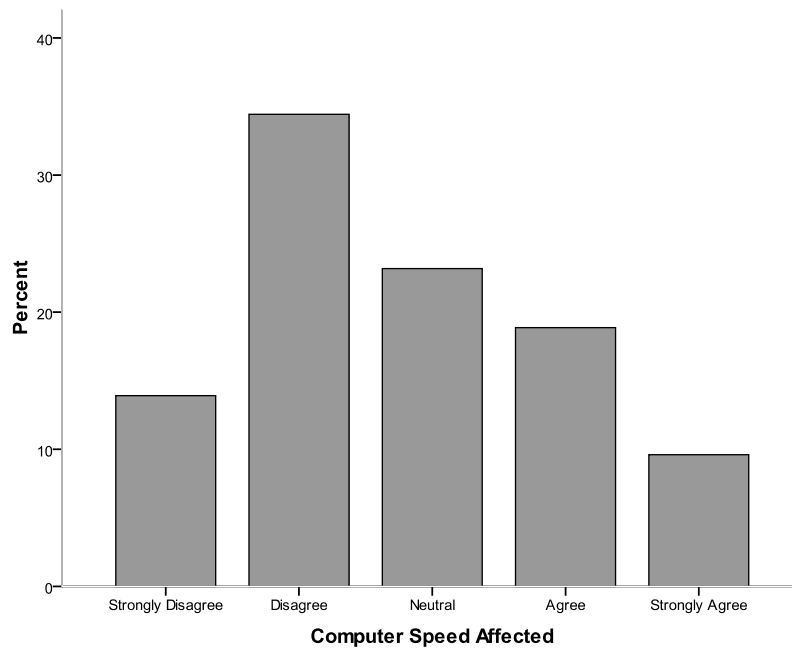


Figure 9-2: Participating Pharmacist's Opinions of the PROMISe Software.

9.1.5 Complex Classification System

The findings from the owner/manager focus group revealed that some pharmacists had difficulties with the classification of interventions. Some respondents reported that when problems arose with classifying interventions, there was a tendency to delete the intervention rather than spend time on its categorisation. One of the respondents stated that;

"If I am still not sure how to classify an intervention, I just cancel out of it."

In addition, respondents to the software survey reported that;

"Sometimes I find it hard to classify the type of intervention and putting into category as each scenario tends to be unique."

"Even with all the practice examples and "DOCUMENT" system help, I personally still find it difficult to categorise interventions and it tends to stop me doing them."

Despite these results, it appears that the majority of the participants were satisfied with the number of classifications. When asked if more classifications were needed 87% of respondents said no and when asked if less classifications were needed 85% said no, as shown in Table 9-1. This is discussed further in Chapter 8.

Question	Yes (%)	No (%)	Total (%)
More Classifications?	13.2	86.8	100.0
Less Classifications?	15.5	84.5	100.0

Table 9-1: Opinions of Participating Pharmacists Regarding the Number of Classifications in the DOCUMENT System.

9.2 Facilitators

The observer focus group findings revealed that good clinical knowledge, optimal workflow systems and communications were three important facilitators of performing and documenting interventions. Whereas, the owner/manager focus groups identified a number of strategies that would facilitate interventions.

9.2.1 Active Application of Good Clinical Knowledge

The observers reported that a pharmacist's good clinical knowledge and how they used this knowledge, was an important driver in the identification of drug related problems. One observer stated that;

"The knowledge has to be there to do interventions..."

And another extended this by saying;

"I think it is more about the practice, which is to say, if you have got into the habit of being vigilant for interventions then you are more likely to do it... You can have all the knowledge... but it doesn't occur to you to make an intervention"

The observers said that continuing education and staff training assisted to improve clinical knowledge. The observers found that accredited pharmacists tended to be more clinically aware and performed a greater number of actual clinical interventions than other pharmacists. One observer reported that;

"Accredited pharmacists on staff made a difference as they were looking for them (interventions)"

Training

This underscores the importance of continuing education to maintain a high standard of clinical and practical knowledge and thereby identify drug related problems. Furthermore, good staff training means that pharmacy assistants are more likely to recognise potential drug related problems.

The owner/managers also recognised both the face to face and online PROMISe III training as facilitators for identifying and recording of interventions, as they improved the pharmacist's knowledge in the area. The respondents said that case histories with the inclusion of the classification and likely outcome should an intervention not occur were a good means of training in PROMISe III. The owner/managers mentioned that including the documentation of clinical interventions into undergraduate training would be important if documentation becomes commonplace.

9.2.2 Optimal Work Systems

Adherence to guidelines

The findings of the observer focus group showed pharmacists who adhered to quality practice guidelines were more likely to identify drug related problems. This included Pharmacist Only medicine counselling and checking patients' histories.

Defined roles

Observers reported that pharmacists and pharmacy assistants that have clearly defined roles within the pharmacy facilitated clinical interventions. They suggested having one pharmacist concentrating on counselling consumers and another on dispensing tasks. This increases consumer contact and incorporates more routine counselling whilst improving the potential for identifying drug related problems.

Observers suggested that pharmacy assistants should have a clear understanding of their role, and of the other staff's responsibilities. When there are no gaps in responsibilities, there will be an increased chance of drug related problems being identified.

Good pharmacy layout

Observers reported that pharmacy layouts including forward dispensing arrangements and easily accessible consumer counselling areas enabled pharmacists to interact more with consumers and facilitated the performance of interventions. This was supported by the owner/managers who said that in some cases it was easier to record the intervention into a patient's history at the forward terminal. They reported that only a few pharmacists had terminals at the receiving point for dispensed prescriptions so there was potential to improve the level of documentation with additional computer terminals.

"We've got enough computers too....We've got them on the front, we've got one on each bench, and then one in the consulting rooms as well, so it doesn't matter, you've got to take like 5 steps and you're on a computer, it makes it easy"

Easy to use documentation system

The observers reported that the existence of an easy to use documentation system for clinical interventions itself created greater awareness of drug related problems and their documentation.

Good staffing practices

The observers identified two main work systems that facilitate clinical interventions. The first was adequate dispensary staffing. Pharmacies with adequate dispensing staff numbers or with work rosters that avoided long dispensary shifts tiring pharmacists, which facilitated the performance of interventions. The owner/managers also noted that some pharmacy dispensaries had above the recommended 150 prescriptions per day per dispenser.²³⁰ They suggested that some pharmacies need to employ more staff. Two of the owner/managers stated that;

"If you are doing 500 to 600 prescriptions a day the last thing they will want to do is document clinical interventions."

"A lot of places are working on (a basis of) staff turnover but we need to think of staff to workload in the dispensary. There needs to be adequate dispensary staff to enable adequate staff to customer contact."

The observers also recognised that balanced pharmacy roles facilitate clinical interventions. In particular, pharmacists should have equilibrium between their business and clinical roles. One observer reported that;

"Some (pharmacists) get into stock control and they don't want to do anything else."

9.2.3 Good Communication

The observers reported that pharmacists with good communication skills and a willingness to engage consumers in conversation were more likely to identify drug related problems. One observer described a situation with a pharmacist who engaged the customer;

"There were so many things that came up in conversation which were not directly asked about"

Furthermore, the observers noticed that recommendations from pharmacists were more accepted by consumers when a rapport and trust had been established in the relationship. They also recognised that good communication between GPs and pharmacists encouraged pharmacists to intervene and make clinical interventions, particularly when GPs provided pharmacists with feedback of action taken as a result of any recommendation.

9.2.4 New Procedures

The owner/managers pointed out that the adoption of a new procedure took time to establish into a dispensary workflow. During the trial, pharmacists adapted their workflow by using strategies to incorporate the documentation of interventions. These included saving an empty draft in a patient's history as a reminder to later document (see Chapter 1), having a highlighted tag system so dispensing assistants can initiate a draft in a patient's history for the

pharmacist to complete at a later time, and making notes on a writing pad with the patient's name. An owner/manager reported that strategies such as these should be included in training;

"It would be good to have it as the first point of training...It is like scanning as that was hard to get used to."

9.2.5 Good Feedback

The observers noted that a driver for documenting interventions was for pharmacists to receive good feedback. Pharmacists would benefit from positive reinforcement on interventions and it would be useful to know that a GP had responded to a recommendation and the outcome. As one observer put it;

"At the end of the day ultimately we are all like lab rats... we all like a pat on the back... now whether that reward is money, CPD points or the knowledge that you have done a good thing... we all want that pat on the back...But what we want is payback, some reward for doing a good job"

The owner/managers reported a similar facilitator stating that there was a need to reward employee pharmacists to ensure that documentation of clinical interventions were carried out. The suggested incentives included providing continuing professional development points which could be used to support pharmacy re-registration.

9.2.6 Computer Issues

Computer issues were one of the main barriers to documenting interventions and as such it seems appropriate that the observers and owner/managers recognised good computer capabilities as a main facilitator.

Easy to use software

An easy to use software package would facilitate the documentation of clinical interventions and increase the focus of clinical interventions in Australia. An observer reported that;

"If the documentation process is easy and simple then they will document... or if they perceive it to be easy"

Available terminal for data entry

The focus on dispensing prescriptions was mentioned as a barrier to clinical interventions. In particular, the pharmacists do not want to interrupt other pharmacists dispensing prescriptions to document interventions. An additional computer terminal to allow documentation without interrupting the dispensing process would facilitate documentation. The observers suggested that it could be in the counselling area, as used in forward dispensing, or in the dispensary.

Intervention button on main screen

The observers noted that the main dispensing screen enabling direct access to the documentation software would make it easier for pharmacists to document. This would provide direct access or enable a quick means of establishing a draft for later completion.

Prompts

There were differing opinions of the use of the pop-up prompts from the owner/managers; some thought they were useful whereas others found them annoying. The most annoying times for the pop-ups to appear were when a patient had been counselled at a previous dispensing on the same issue and when the dispensary was busy and the drug related problem identified was minor. As such, the owner/managers suggested that pharmacists should have control over the appearance of the pop-ups. These suggestions included the ability to turn them off, restricting pop-ups to a dispenser's initials and restricting pop-ups to certain times of the year or public health events.

The respondents of the software survey were also asked about their preferences for the prompt, as shown in Table 9-2. The majority reported wanting the function to switch off the prompt for patients and/or switch off the prompt

completely (79% and 92% respectively). Interestingly, 82% preferred not to restrict the prompt to pharmacist's initials.

Question	Yes (%)	No (%)	Total (%)
Switch off prompt for patient	85 (78.8)	23 (21.3)	108 (100)
Switch off prompt	99 (91.7)	9 (8.3)	108 (100)
Restrict to pharmacist's initials	19 (17.6)	89 (82.4)	108 (100)

Table 9-2 : Results of Software Survey Regarding Control Over the PPI Prompt

The respondents also reported wanting the prompt to change during certain times of the year or restricting it to certain public health events, 88% and 81% respectively. As Table 9-3 shows, 67% of respondents reported wanting the prompt to change regularly.

Question	Yes (%)	No (%)	Total (%)
Change prompt regularly	72 (66.7)	36 (33.3)	108 (100)
Certain times of the year	13 (12)	95 (88)	108 (100)
Certain public health events	21 (19.4)	87 (80.6)	108 (100)
Coincide with NPS or similar pharmacy education	50 (46.3)	58 (53.7)	108 (100)

Table 9-3: Results of Software Survey Regarding Change of the PPI Prompt

All owner/managers agreed that it is beneficial to coordinate pop-ups with public health initiatives, such as diabetes and heart disease campaigns.

"I've seen some very clever pop ups ... you've got somebody on diabetic medication and it does a check and sees if they're on aspirin, ..., and then you go out and say 'are you on aspirin' and then you do that until you've done it to death, and you go in and switch it off and say 'I've had enough of that pop up' you know, and you've got a function in there that you can actually turn it off, and then next month you might get another one and you can have a go at..."

The observers pointed out that a prompt or report to remind dispensers of incomplete documentations would facilitate recording. However, the majority of respondents to the software survey (70%) reported that a more prominent reminder to complete draft interventions was not necessary, while 30% reported it was necessary. In saying that, 59% of respondents believed that a button on the dispensing screen to log a draft intervention for later completion would be beneficial, while 41% disagreed. See Chapter 10 for more information.

Reports

The majority of owner/managers reported that they wanted to determine how their pharmacy was performing against other pharmacies in the trial and that this acted as a facilitator for documenting interventions. Furthermore, they believed that internal reports could generate a competition type atmosphere which in turn could facilitate interventions. One owner/manager stated that;

"I really like the comparison thing as I like to see how I am going in relation to others."

9.2.7 Medicolegal Concerns

The observers reported that pharmacists were most likely to document clinical interventions in cases where they have dispensed an item against their better judgement. For example, when there has been a disagreement with the prescriber. An observer reported that;

"Some who have their hand forced to dispense something they are not completely comfortable with, will document"

9.2.8 Professional Satisfaction

The owner/managers reported that a pharmacist's sense of personal satisfaction was a facilitator for performing and recording interventions. In particular, the recording of the intervention was a confirmation of its importance and this perceived importance would induce some pharmacists to conduct and record more interventions. One owner/manager reported that;

"I found it pretty rewarding as it reminds you of the job you are actually doing. All the things you can take for granted you are actually documenting."

9.3 Discussion

It appears that entrenched work practices such as dispensary workflow practices, number of computer terminals, the focus on dispensing, low staff levels and poorly trained staff were a major barrier to performing and documenting interventions. A number of these factors also caused pharmacists to have low consumer contact, which restricted the chance to perform interventions, and limited time meaning that only some interventions were performed and then forgotten about before being recorded.

Not surprisingly, the main suggested facilitators focused around the optimisation of workflow practices to incorporate the recording of interventions. These included having more defined roles to allow the pharmacist more customer time, additional terminals to document and training in specific strategies to remember to document. Other facilitators included good communication and relationships with patients and health practitioners, and continued education of pharmacists to improve their clinical knowledge. In addition, positive reinforcement and incentives either through feedback, remuneration or continuing education points were considered an important driver for documenting interventions.

Overall, there were a few limitations with the software. The main concern involved the slowing of computers which was likely to have been caused by the inadequate capabilities of the local setup and internet connection. A complex classification system was noted by some as a barrier to documenting, but the number of classifications was not. The main facilitators included an easy to use software system, a software reminder to complete draft pop-up, an intervention button on the main PROMISE screen and more control over the pop-up prompts.

Chapter 10 Limitations and Potential Improvements

Although the PROMISe III project has been an outstandingly successful trial, it is obviously not perfect. There are a host of improvements that might be made for future implementations, particularly if the project is to be expanded nationally. These limitations, and the improvements that might be made to overcome them, are outlined in this chapter.

10.1 Limitations of Research

One of the main limitations for the PROMISe project was that the uptake and outcome of the interventions could not be measured over a long time (as in a prospective controlled trial). In previous PROMISe projects, an *Outcomes* section was created in the PROMISe software interface. This section allowed pharmacists to record whether the consumer had actively changed their medication-taking behaviour as a result of the pharmacist's recommendation. This had obvious limitations, as it relies on the pharmacist knowing the outcome. In this project, the uptake and outcomes of interventions were measured through the consumer follow-up sub-study. However, this only targeted a small number of interventions. Future research into the area should include an intervention outcomes measurement in the project. Ideally, a long term, twelve month study including a control group for comparison (if ethically feasible) would follow intervention outcomes.

Another possible limitation relates to the consumer sub-study, in that pharmacists may have only recruited consumers who they considered to have benefited from their interventions. As a consequence, the consumers may not have been representative of the true PROMISe consumer population.

A further potential limitation of the research was that pharmacies were invited to participate; as such it is possible that only pro-active pharmacy owners were recruited. This selection bias could have resulted in a positively skewed intervention frequency. However, it is felt that this self-selection bias may have been tempered, since many of the involved pharmacists were told to participate by their pharmacy owner, rather than choosing to participate themselves.

10.2 Software

The PROMISe software was intuitive and easy to use for the trial pharmacists. It was seamlessly integrated into the two dispensing systems and it captured the required data for subsequent analysis. The software was very successful and the feedback gained from participants was very positive. Overall, the system worked extremely well and was able to capture the information required for the project with minimal problems.

Designing the requirements of the software from high level ideas of an intervention documentation system through to the intricate details of the system, required an understanding of the main data concepts involved. These concepts included:

- details of the intervention (for example, name, drug and time),
- the user interface located on pharmacy dispensing terminals,
- communication between the pharmacy server application and the repository,
- web interface for pharmacists and researchers to access information, and
- the data repository.

Other dispensing software modifications taken into consideration included decision support prompts, intervention reports and software activation and deactivation.

The functional specifications for the user interface and the repository were developed in close collaboration with Logica and the two dispensing system vendors, FRED® and Aquarius®. This development resulted in a successful user interface, successful communications modules and a successful information storage system.

Abstracting the PROMISE methodology into a working program required an intimate knowledge of each process involved. The requirements analysis was deemed successful, based on smooth running of the software. However, in the post-trial analysis, several potential improvements were identified. Suggested improvements associated with the software are listed under heading 10.2.1, although these are thought to be relatively minor when considered in the context of the overall success of the software.

The web repository successfully received and stored the prescription, patient and intervention data. Trial pharmacists were able to view repository reports which provided them with the intervention rate for their pharmacy, their state's average, and a breakdown of their intervention classifications. Administrators had the ability to add and modify pharmacist and pharmacy details held in the repository, and researchers could view intervention details and export data. Overall this module of the PROMISE software functioned well.

The user interface was also successfully implemented, with the majority of pharmacists finding the interface easy to use, as has been previously discussed in Chapter 9. Issues impeding the use of the software within the dispensing computer were minimal, showing that the PROMISE software could be successfully deployed across the varied computer configurations found in community pharmacy.

The PROMISE user interface within the FRED[®] dispensing system and the Aquarius[®] dispensing system had a very similar appearance and functionality. A pharmacist working with the PROMISE interface in the FRED[®] dispense system would have been able to easily use the PROMISE interface in the Aquarius[®] dispense system, and vice versa. It is envisaged that other software companies would also be able to match the look and functionality of the PROMISE interface, allowing pharmacists working in a number of different pharmacies to easily access and use the PROMISE system.

10.2.1 Limitations and Enhancements of the Software

Although overall the software was deemed very successful, a number of avenues for potential enhancements to the PROMISE software for national implementation were identified. Some typical suggestions from pharmacist responses in the Software Survey included;

'I would like to be able to enter follow up/outcome information if the person comes back and something has changed as a result of the intervention' – PROMISE participant

'Incorporate it into the dispense program so that interventions made are then visible in the patient history' – PROMISE participant.

These issues are addressed below.

10.2.2 Software Modifications

Various recommendations for improvements to the design of the software are listed below.

Date-time of prescription-linked interventions not captured

In the initial design brief, the date-time of the activation of a prescription-linked intervention screen was not passed from the vendor to the repository. The activation date-time of the screen is a reasonable indicator of the date and time of the actual intervention, as most pharmacists would enter at least some intervention details soon after the intervention occurred. This functionality was identified and a method of storing the date-time in the notes field was developed for the trial period.

Recommendation

For future designs the activation date-time of the intervention screen should be passed as a separate field from the vendor to the repository for all interventions. This is to ensure an accurate time record of when the intervention occurred and to assist with the audit process.

Intervening pharmacist initials not captured

The system design did not allow for the capture of the intervening (as opposed to dispensing) pharmacist's initials for prescription-linked interventions. This functionality was identified and a work-around method of storing pharmacist initials in the notes field was developed for the trial period.

Recommendation

The pharmacist who initiates a prescription-linked intervention needs to have their initials recorded in a separate field against the intervention. This identifies the pharmacist who undertakes the prescription-linked intervention rather than the initials of the pharmacist who dispensed the prescription, who may not have been actually involved in the intervention.

Separation of prescription-linked and non-prescription interventions

One of the limitations of the current system was the separation of prescription-linked interventions from non-prescription interventions. Non-prescription interventions were designed to record interventions relating to situations not necessarily related to a medication, such as disease or health management. The separation of the two types of intervention made displaying reports more complex as two sets of numbers had to be displayed.

Prescription-linked interventions were displayed as a total and as a rate of all prescriptions dispensed. Non-prescription interventions were displayed separately as a total, unlike prescription linked interventions, which were displayed as a total and percentage. It was considered they could not be displayed as a rate of all prescriptions dispensed as they were not directly related to the prescription workload. This separation of results provided greater complexity for the end user in interpreting intervention rates.

To ensure the intervention was recorded as a prescription-linked intervention, the pharmacist was required to activate the PROMISE intervention interface after dispensing a prescription from the print screen menu in FRED® or from the print options screen in Aquarius®, or in either system by selecting a prescription from the patient history. For this reason, pharmacists often unintentionally recorded non-prescription interventions for interventions involving prescriptions, simply by not activating the PROMISE intervention interface at the specified point in the dispensing process. This resulted in many prescription interventions being collected in the repository as non-prescription interventions.

The similarities between the two types of interventions, those that are linked to prescriptions and non-prescription, were not taken into consideration in the development of the software. This would have resulted in more complex software development from the dispensing software vendors as it required additional testing.^{232 233}

Recommendation

It is recommended to have a single intervention record which can be linked to the patient, rather than a prescription-linked or non-prescription intervention record linking to a patient. Once a patient is selected, this intervention record can be completed with prescription details, non-prescription details and any other relevant information. Details of recommended improvements to the intervention message are made available from the FRED® Final Report as shown in Appendix LL²³³.

The identification of prescription details for the intervention should be achieved by providing a selector for the pharmacist to choose whether the intervention is related to a prescription or not. If the pharmacist selects the option to relate the intervention to a prescription, the user interface should provide a list of the selected patient's prescriptions, beginning with the most recent, or allow searching for a particular prescription. The pharmacist should then select the appropriate prescription and the intervention record will then fill with the particular details of that prescription.

Recording of unknown patient interventions

A major limitation to the recording of non-script interventions is the identification of the patient. In order to record an intervention, it is important for the patient's name to be known for the purpose of subsequently searching for and

reporting on that patient's intervention. If the patient details were stored in the dispensing system, the intervention could easily be linked to that patient. Where the patient was unknown to the pharmacy, recording an intervention was achieved by using a patient descriptor consisting of a free text description provided by the pharmacist. In a national rollout situation where a pharmacy may have many interventions recorded, this method would limit the ability to easily find and follow up on a particular intervention. Unclear patient details would also hinder the requirements of an accurate audit process.

Recommendation

A consistent approach to recording interventions would be to obtain the patient's details and then link the intervention to this patient. This is discussed further under 0. Unfortunately, for patients who have never submitted a prescription to the pharmacy, no patient identifier will be available, so an "unknown" patient placeholder must also be available.

Displaying interventions in patient history

Displaying of interventions in the patient drug history was not accepted by the FRED® vendor during the course of developing the functional specifications. However, on software deactivation at the completion of the trial, the interventions recorded during the FRED® vendor pharmacies' trial period were converted, such that they could be displayed in the alternate history of the patient profile. During the trial, FRED® pharmacists could view their interventions only by identifying them through the interface where interventions were listed by date and patient, or by selecting the patient and viewing the intervention in the FRED® alternate history screen (using 'alt and F2' to open this screen). Nearly 60% of the post-trial survey respondents were unaware that interventions could be viewed in the alternate history. Although additional training may have improved this number, it is important to note that a further 12% did not know how to view the alternate history at all. This indicates that this method of displaying interventions was not ideal.

Recommendation

It is recommended to display all interventions in the patient's drug history. This is to ensure pharmacists who are less familiar with the FRED® system, or any other dispensing software, are able to view patient specific interventions with a minimum of difficulty and also to ensure that the dispensing pharmacist is automatically made aware of past interventions.

Toxicity, and Non-classifiable categories

'Had problem with the TOXICITY issue. The software did not allow me to proceed'- Participating Pharmacist

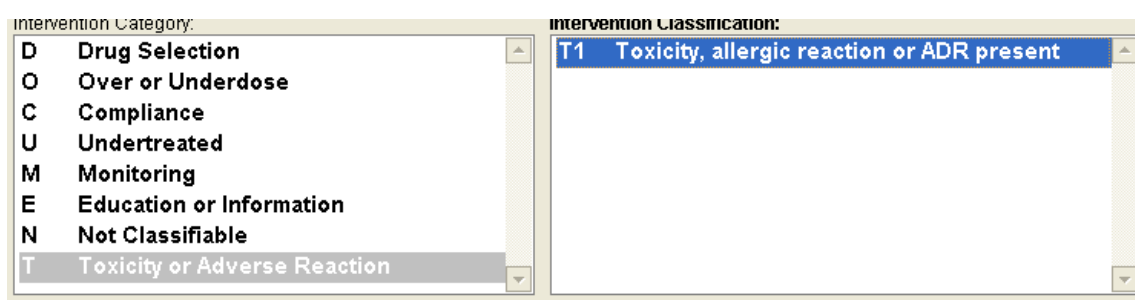


Figure 10-1: Selecting the Toxicity Option in FRED

The DOCUMENT system is based on a main category and sub-category system. Two main categories – Toxicity and Non-classifiable, had only one sub-category option. Using the FRED® system, it was necessary to highlight a main category in the left panel and then also highlight the specific sub-category in the right panel. Where there was only one option available in the right panel, some pharmacists were unaware that this required highlighting in order to complete the selection of the DOCUMENT code.

Recommendation

Where there is only one sub-category, it would be beneficial to have the software automatically select the sub-category when the main category is selected.

Intervention Clarification

In some cases it was difficult for researchers to interpret whether the drug linked to the intervention was the drug intervened on, or the resolution (i.e. replacing the problematic drug). There were several reasons for this situation. One reason was that sometimes pharmacists did not provide any notes to assist interpretation of an intervention. Another reason was that, for some interventions, a change of medication or directions was required. It was reasonably assumed that the prescription item in the prescription-linked interventions was the resolution medication/directions because the item was dispensed. However, if intervention notes were not provided, it was difficult to determine the drug and/or directions intervened on. This could limit the ability of future researchers and auditors to appropriately analyse interventions on a case by case basis.

Recommendation

It is recommended that a context sensitive input box appears within the intervention screen based on the recommendation categories chosen by the pharmacist. This will help to clarify difficult to interpret interventions. The intelligent prompt will obtain further information from the pharmacist depending on the recommendations they have selected. Some suggestions are listed in Table 10-1.

Recommendation Code	Recommendation Description	Suggested Resolution
R1	Dose increase	List boxes: Strength before/after , and/or text boxes: Directions before/after
R2	Dose decrease	List boxes: Strength before/after , and/or text boxes: Directions before/after
R3	Drug change	List boxes: Medication before/after
R4	Formulation change	List boxes: Medication before/after, and/or text boxes: Formulation before/after
R5	Brand change	List boxes: Brand before/after
R6	Dose or schedule change	Text boxes: directions before/after

Table 10-1: Context Sensitive Intelligent Input Recommendations.

It would also be reasonable to make the notes field mandatory to ensure pharmacists enter some extra information to help clarify an intervention. This is because interpreting what actually happened during an intervention can be limited when relying only on DOCUMENT categories and pharmacist recommendations. Other pharmacists working in the pharmacy, for instance, should be able to interpret the details of the recorded intervention.

Draft Interventions

As discussed previously in Chapter 9, remembering to complete drafts was a challenge for some pharmacists. One pharmacist reported that;

‘I can never remember how to edit my saved drafts - can you make it so you can just click on the saved draft to edit it?’ - Participating Pharmacist

‘I was unable to open drafts that I had saved and had to do it all again.’ - Participating Pharmacist

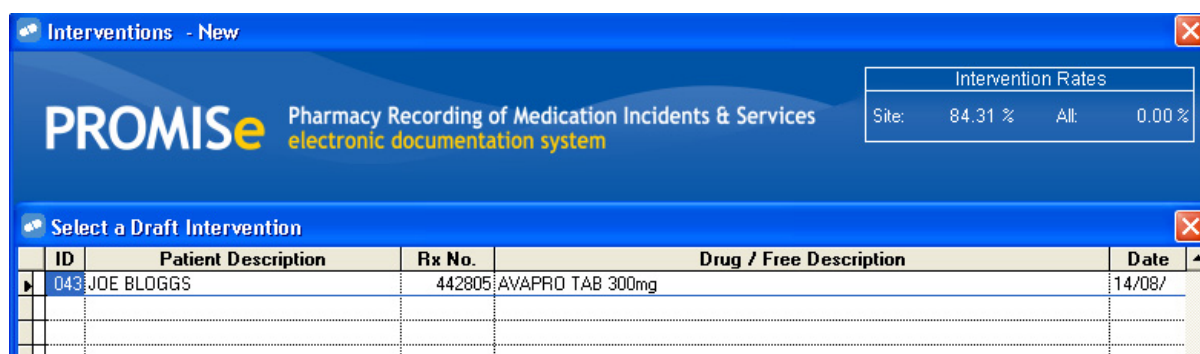


Figure 10-2: Selecting a Draft Intervention in FRED®

Several participating pharmacists found draft interventions difficult to edit and complete in the FRED® version of the PROMISe software. The draft intervention could be easily found by clicking 'Edit Drafts', but the next step was to press 'F4' to edit, complete or cancel the draft. Despite being written in fine print along the bottom of the draft intervention screen and all pharmacies receiving 'software cheat sheets' outlining this process, pharmacists believed it was not sufficiently clear how to access their saved drafts.

Recommendation

An 'edit draft' button and 'cancel draft' button should be made available and obvious in the draft intervention screen, and users should be able to access the edit draft interface by double clicking on the relevant entry.

Preparation for integration with the national e-Health strategy

The data collected was primarily used for proof of concept of a wider scale implementation of intervention software, and for related research purposes. The potential for linking to patient e-Health records was not investigated at this stage, primarily because the national rollout and development of the electronic health records (EHRs) was considered to be insufficiently mature at this stage.

Recommendation

It would be highly desirable to have access to a national EHR system for the purposes of this study. For this trial, an in-house data representation of all patient data was developed, including information regarding prescriptions, patient demographics, medical history and allergies. If it were possible to simply attach interventions, as defined by the DOCUMENT system and pharmacist notes, to the broader EHR, a substantially deeper level of analysis would be achievable, as a richer and more accurate set of data would be available for each intervention. Further to this, a better system might be implemented at the community pharmacy level, as it would be possible to more intelligently tailor intervention prompts to target patients whose EHR profile more specifically matches particular characteristics. However, until a broad implementation and uptake of EHRs is seen, these benefits will remain out of reach.

Inconsistent data

Some data passed successful validation via the XML web schema to be stored in the repository, yet was incorrect or inconsistent with expected values. Examples include; patient date of birth in the future, place holder patients not being updated (required for linking an intervention information packet prior to the arrival of the actual patient details information packet), ATC codes not being populated due to inconsistent passing and matching of vendor drug codes, and age range values being sent in an incorrect format.²³⁴ Many issues only became apparent once the trial had started. The reports from Logica, Simple Retail®, and FRED® Health have indicated that the limited time available for testing was not sufficient to resolve data inconsistencies.²³²⁻²³⁴

The XML schema was considered to be excessively restrictive in accepting field values passed in from the dispense vendors. Vendors had to modify some data to fit the validation rule, rather than the validation rule being relaxed to accept the correct data.²³³

Recommendation

An extensive and thorough testing process should be employed to eliminate these mistakes before going live. Adequate time needs to be provided for software testing. Testing should involve thorough static testing to confirm communications between PROMISE pharmacy software and the repository, and dynamic testing involving large amounts of live pharmacy data in a real-world situation.

The restrictiveness of the XML schema needed to be thoroughly tested before the system went live. In the future, XML schema versions will need to be thoroughly tested across many dispense vendors prior to the schema's live use.

The issue of placeholder patients not being updated could be resolved by avoiding the sending of patient details as separate transmission records (see the issue of Multiple Message Types below). This would ensure patient details were linked to all interventions.

Ongoing data audits would need to be regularly scheduled to ensure any inconsistencies were identified and resolved as soon as practicable. This would ensure the greatest accuracy of stored data.

Multiple Message Types

The communications interface transmitted four basic types of message to the web server – prescription, prescription intervention, non-prescription intervention, and patient. Inconsistencies occurred with regards to receiving an intervention without the corresponding patient. Separation of the two types of intervention message was not considered an ideal situation by either pharmacy software developer because the increased number of message types resulted in increased messaging complexity.^{232 233}

Recommendation

The message types should be reduced so that fewer transaction types need to be sent.²³² This would also assist with the receipt of inconsistent data, as noted previously. Two messaging types are recommended – prescription messages and intervention messages.²³³ Combining the prescription and non-prescription intervention messages into a single message type would be ideal, as many of the fields for both types of message are identical. Specific recommendations for the intervention message contents are available from the FRED[®] Report, as shown in Appendix LL.²³³

Cessation of Data Transfer

Several pharmacies ceased transmitting data during the active trial period. The causes of lack of transmission were as follows: -

- A major cyber-attack on Telstra and other web sites mid September caused loss of communications from many Aquarius[®] pharmacy sites using BigPond[®], and to a lesser extent other Internet Service Providers, as mentioned in the Aquarius[®] Final Report, Appendix MM.²³²
- One FRED[®] pharmacy was unable to send data due to switching from standard http web-service calls to using message encryption via Secure Sockets Layer (SSL). This issue was unable to be resolved, but may have been related to firewall or other network security within the trial pharmacy.²³³
- Control characters were inserted by FRED[®] software into the directions data. The control characters were rejected on repository validation and the bundle of FRED[®] messages was rejected. This issue was the major cause of data cessation from FRED[®] pharmacies, and was rectified with a FRED[®] dispense update.²³³
- Several isolated cases of non-transmission occurred where the FRED[®] communications module was manually updated and the PROMISE plug-ins were not activated.²³³

Recommendation

Regular auditing of participant pharmacy transmissions would be required to identify non-transmitting pharmacies. Each non-transmitting pharmacy should be promptly investigated to identify the cause, and to develop a solution.

A register of causes and solutions should be maintained to provide a reference to aid the rapid resolution of communication problems.

Where messages are rejected at the repository because they are found to not match the XML schema, a failed message register should be maintained to provide feedback to the dispense vendors to rapidly locate and correct these messaging inconsistencies.

The issue regarding the repository rejection of bundled messages from FRED[®] due to control characters would have been resolved if adequate time was allocated to testing prior to going live. It is essential that future software vendors collaborate, develop solutions, and are allowed a suitable allocation of time to conduct testing.

Noticeable slowing of pharmacy computer

'The slowing down of the Winifred dispensing software and 'time to print' was also mildly annoying.' – Participating Pharmacist

The software survey showed a third of respondents indicated their pharmacy computers were slowed with the addition of the PROMISe software. Two pharmacies (one FRED[®] and one Aquarius[®]) required vendor support for this issue. This issue was mentioned in the Aquarius[®] final report.²³² The cause was indicated by Aquarius[®] to be a large amount of additional processing due to the PROMISe software.²³² Other causes may have included not having vendor control over the exact configuration of each pharmacy computer.²³² For each intervention patient, the prescription history for the previous six months was collated and sent to the repository. The searching of six months of patient prescription history could slow the dispensing software, although it is felt that with appropriate design and indexing strategies, the PROMISe requirements should not significantly affect general use. Again, this was largely a symptom of inadequate development and testing periods, and possibly slow and outdated pharmacy computer hardware.

One FRED[®] specific issue relating to improving the software programming was identified and rectified during the course of the trial. This occurred as a result of logically deleting, but not physically deleting, prescription messages as they were generated and sent to the repository. As a consequence, the prescription message tables continued to grow in line with pharmacy prescription throughput, causing a performance hit when saving a prescription and submitting it to the repository.²³³

Recommendation

The collecting of six months of patient history would not be required for a broader, longer time line implementation, as it was primarily needed for the expert clinical and economic analyses within the research project.

Greater efficiency could be obtained with the development of improved algorithms for data manipulation. This would require extensive testing prior to a live roll-out. The advantage to the end user should be no noticeable reduction in computer speed.

Pharmacy computer configurations (both hardware and software setup) either need to follow strict standardised guidelines, which is considered unlikely to be a practical solution, due to the broad range of pharmacy computer configurations and requirements, or the vendor's software with the PROMISe additions needs to be tested under a wide range of pharmacy computer configurations prior to a live roll-out.

Other recommendations include sending intervention messages once a day as they are substantially smaller by volume than prescription messages, and reducing the prescription message to the smallest size that is needed to convey the required information, although once electronic health records are established across the healthcare system a more timely update of intervention messages would be required. This would include reviewing the requirements of the original date of prescription, medical conditions and allergies.²³³

Patient follow-up reminder

Pharmacist end-of-trial survey feedback indicated patient follow-up post intervention is preferred. Once an intervention was recorded for a patient, there was not an option to record the outcome of the recommendation.

Recommendation

It is recommended when a previously intervened patient is selected, a prompt to finalise the outcome appears. The pharmacist should be able to mark the intervention outcome as complete by ticking a 'finalised outcome' box, and a text box appears to add any outcome-related notes regarding the intervention. If the pharmacist chooses not to finalise the intervention, every subsequent time the particular patient is selected, the 'finalise' reminder should appear.

10.2.3 Software Feedback

Feedback was obtained from pharmacists, managers and pharmacy owners to determine satisfaction with the PROMISE software and garner any opinions relating to future improvements or enhancements.

Owner and Manager Group Discussions

Pharmacists participating in the owner manager focus groups were generally satisfied with the user interface, as discussed in Chapter 9. Feedback concerning the software was obtained through focus groups facilitated by DeBoos Associates.²³⁰

The overall response from pharmacy owners and managers regarding the software was very positive. The user interface was not considered a barrier to documenting interventions. On the contrary, the ease of use, intervention prompts and ability to enter drafts were considered drivers to the recording of interventions.

Owners and managers provided the following suggestions for improvements:

- Documentation notes should be listed in the drug history and not the alternate patient history (FRED®).
- A button on the main dispensing screen should enable activation of the software without using key strokes.
- A prominent prompt to remind pharmacists to finish documenting their incomplete (draft) interventions.
- Ability to turn off the pop-up prompts.
- Ability to restrict pop-up prompts to a user's initials.
- Ability to restrict pop-up prompts to certain public health events or times of the year.

The viewing of intervention notes in patient history has been discussed earlier. Intervention activation buttons were available on the title menu bar in FRED®, and in the prescription print options menu in Aquarius®. The ability to add a button on the intervention screen was discussed and dismissed due to limitations of the screen real estate, and due to the intervention not being linked to the prescription until the prescription data entry was finalised. An issue of concern to owners and managers was the reminder prompt and the specific prompt. This will be discussed later, under pharmacist feedback.

Pharmacist Software Survey

Pharmacists overall were happy to use the PROMISE software and generally did not have any difficulty using the interface, as discussed in Chapter 9. Further pharmacist comments from the end-of-trial survey regarding the software in general include:

- 'I think the software was quite easy to use'
- 'happy as it is'
- 'I thought the software was well integrated with Fred® and easy to use (mostly)'

General themes for software improvement from survey comments were:

- Software to provide feedback that an intervention had been submitted.
- Difficulties using the draft function – unable to edit draft interventions, as discussed in Chapter 7.
- Too many intervention classifications to choose from, as discussed in Chapter 9.

- More variation in the Specific Prompt.

Pharmacists were asked yes/no questions about the need for particular improvements to the software. The various suggestions for software improvement were obtained from comment themes from the end-of-trial survey and from the focus groups.

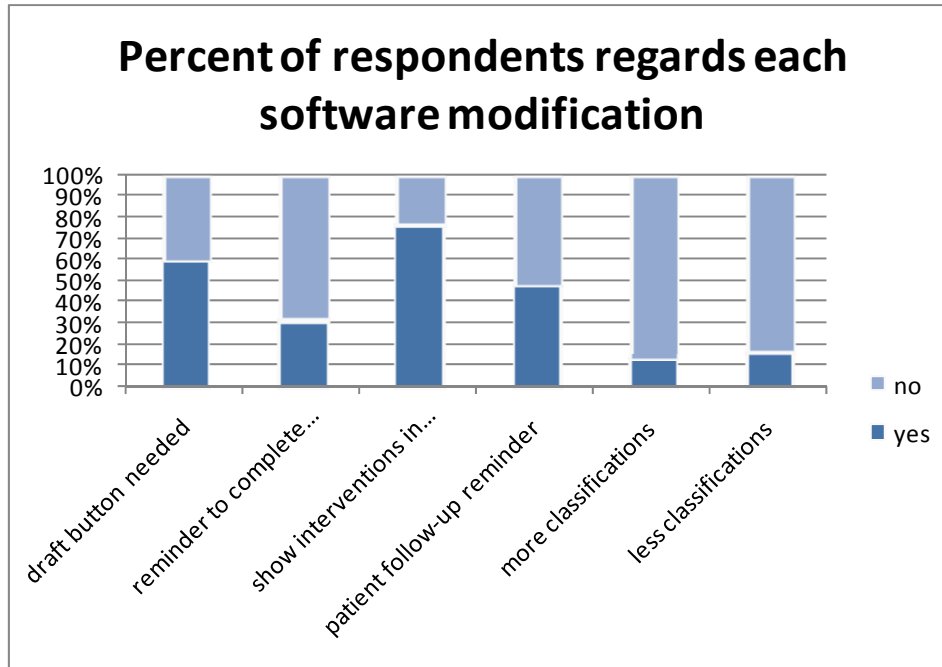


Figure 10-3: Pharmacist Opinions Regarding Specific Software Modifications

The majority of pharmacists wanted a draft intervention button for the purpose of beginning the recording of an intervention. However, two thirds of pharmacists believed that a reminder to complete their draft interventions was not necessary. It is important to note that this function was not implemented in PROMISE III, therefore they may be unaware of its usefulness. A draft reminder was considered a facilitator to documenting interventions in Chapter 9. A suitable approach is for a reminder message to appear in the dispensing program once or twice a day in a similar way to which the reminder message appeared during the trial. The reason for this is that over half of the software survey respondents found the reminder encouraged documentation, and only a third of the respondents found the reminder annoying. It is important that this reminder should contain a link to the draft interventions that require finalising as with the general reminder trialled in PROMISE III.

Pharmacists wanted interventions to be shown in the patient history, as viewing patient history is generally a standard procedure when dispensing prescriptions. This has been mentioned under the Future Improvements section.

Nearly half of the trial pharmacists wanted a patient follow-up reminder. It is suggested when a previously intervened patient is selected, there is a prompt to finalise the outcome and a text box is added to the intervention notes.

Draft interventions were considered by pharmacists to be difficult to edit and complete in the FRED® system. The draft intervention could be easily found by clicking 'edit drafts', but the next step was to press 'F4' to edit, complete or cancel the draft. This step was apparently not made sufficiently clear to pharmacists, even though it was on the software help sheet provided to each pharmacy, and written in fine print along the bottom of the drafts screen. In the future, an obvious edit button should be made available in the intervention screen, as mentioned previously.

The ability to control pop-up prompts is considered an important issue to the pharmacists responding to the end of trial survey and was identified as an issue in the owner manager group discussions. Over a third of surveyed pharmacists considered both the specific and reminder prompts to be annoying.

Despite the software survey indicating the specific prompt was sometimes annoying for pharmacists, it did encourage pharmacists to undertake the specific intervention, and is therefore a very valuable intervention tool. The majority of respondents from the software survey and group discussions indicated a desire for options to turn off the prompt for a particular patient or for particular dispensing pharmacists. As the purpose of the specific prompt is to ultimately encourage a course of action to improve the quality use of medicine, this option needs to be considered very carefully. It may be appropriate to have the ability to deactivate the prompt for specific patients if that particular issue had been addressed with the patient, or they were deemed unsuitable for the intervention by the pharmacist. This alone would reduce subsequent inappropriate display of the prompt, and also reduce the prompt fatigue effect as fewer irrelevant prompts would subsequently be displayed. Certainly if there were an option to deactivate the prompt, it may be appropriate for it to automatically reactivate after a certain time frame so the patient can be reassessed by the pharmacist.

Future versions of the software should allow more control over the prompt feature, perhaps by restricting to pharmacist initials, by strobing the prompt – e.g. on for a week then off for a week, or by the number of times a specific prompt can be displayed per patient. Variation of the content of the specific prompt is recommended to combat prompt fatigue and stimulate pharmacists regarding other health or medication issues as further discussed in Chapter 9.

Effectiveness of the online training

Online training was considered important for this trial as the physical locations of the 185 software pharmacies were widespread across three states. The ability of all the trial pharmacists to access one of the six face-to-face training locations was unlikely due to distances and working times. Likewise, the practicalities and cost of hosting face-to-face training sessions to suit the majority of pharmacists in these varied locations may not have been cost effective.

Details concerning the training of pharmacists have been discussed previously in Chapters 3 and 5 with three quarters of the enrolled pharmacists having attempted the online training. Pharmacists who undertook online training without face-to-face training showed improved intervention rates, although those pharmacists who also attended a face-to-face training session showed the highest intervention rates.

Online training using DOCUMENT scenarios and videos of how to use the software interface helped to increase pharmacist understanding and awareness of the project. This in turn resulted in increased documentation of interventions due to increased confidence and ability to use the PROMISe software and classification system.

In a future national implementation, the cost of web-based training would be much lower than the cost of holding numerous face-to-face training sessions across the country. In addition, with web-based training, pharmacists are able to view training information at any time they choose, and they can return to that information at a later time if required to refresh their memory on the subject at hand. Access to the web training package was straightforward with no unexpected problems arising during the pharmacist training stage of the trial.

10.2.4 Integration of PROMISe Software into other Software Systems, and for handling Non-prescription Clinical Interventions

Other dispensary systems

Two dispensary systems have been successfully used for the implementation of the PROMISe software and specifications for the pharmacist user interface have been developed. Specifications for the type and format of transmission data have also been developed. Other dispensary software developers could use these specifications to create the user interface and transmission software. The XML Schema used for data transmission and validation would need to be closely scrutinised by the software developers to identify any possible causes for invalidation. Invalidation causes may include data that exceeds field length limits, or inclusion of characters that do not match a specified range for any particular field, or data submitted in the wrong type, e.g. a number for a date.

Drug codes for each dispensary vendor are not standardised, so providing a solution to standardised drug code data from various vendors would be a priority. This is considered essential for the creation of reports, and for auditing, and is discussed further later.

Point Of Sale (POS) intervention recording

Interventions involving over the counter (OTC) products were recorded by pharmacists through the PROMISE user interface located on the dispensing terminal. Intervention modules for POS terminals using FRED® or Aquarius® software were not developed as this was not a requirement of the Tender.

There are many vendors of POS software and hardware. To develop an intervention user interface for a POS, each vendor would be required to re-create the software based on the PROMISE functional specifications. This module would naturally need to integrate with the vendor's system, including links to its list of stock items, and if possible be able to link to a dispensary stock list and dispensary patient list.

Entering an intervention at a POS terminal in order to store information in dispensing software would require an extra communications module. Information sent from the POS to the dispensary software would include the intervention, patient details and medication details (if any). Information sent from the dispensing software to the intervention module would need to include a list of patients to select from and a list of medications to select from.

Data communications from pharmacies to the repository during the PROMISE trial involved a standardised approach using an XML Schema. This method could be used by the POS software vendor to transmit intervention data to an external repository, and internally to a repository within the pharmacy. The internal repository should be a part of the pharmacy dispensary software to allow identification of patients with these interventions, whether during the dispensing process or not, and for a secure, central point for referencing interventions.

Pharmacies may use different software companies for dispensary software and for POS. This could affect two things; obtaining a suitably formatted patient list from the dispensary system, and POS stock items being transferred to the dispensary system (unless sent in plain text and not POS codes). This would be expected to require significant work to clarify the sending, receiving and viewing of this information.

Many OTC interventions involve patients who are unknown to pharmacy staff. Recording interventions for these patients is potentially problematic, as referencing these interventions can be difficult. The approach used in PROMISE was to store the intervention based on date and time, and for the pharmacist to enter a short patient descriptor. A more substantial approach, which may not be practical, would be to obtain the patient details in order to store and appropriately reference these interventions. Patients may not appreciate being asked personal details in order for a pharmacist to satisfactorily record an intervention. This would be a significant change in the current culture of pharmacy and patient relations, where medication and health matters are often discussed with patient anonymity. Recording of patient details has been successfully enacted specifically for the purpose of recording pseudoephedrine sales (ProjectSTOP).²³⁵ The success of this may in part be due to consumer awareness through pharmacy media and general public media. This implies recording patient details for interventions is not unrealistic, and raising consumer awareness regarding the recording of OTC interventions may assist this process.

Recording OTC interventions involving patients who have information stored in the dispensary software would require connectivity between the POS and the dispensary software. This may not be possible or may be difficult to achieve due to several reasons:

- A pharmacy may not use a POS.
- Dispensing software and POS may not be connected.
- Potential compatibility issues with differing dispense software and POS software.

The ability to record interventions at a POS terminal also raises the issue of non-pharmacist staff entering interventions. Consideration could be given to suitably trained pharmacy undergraduates, dispensary technicians, pharmacy assistants and other health care workers within a pharmacy, such as nurses. Appropriate guidelines would need to be developed to ensure patient privacy for recording of interventions for previously unknown patients, and for who should be able to record interventions and what training is required.

External repository and medication coding

In order to transfer medication information from POS software or dispensary software to an external repository, the information would require any medication, including OTC medication, to be coded to a standard reference for the purposes of analysis for research and auditing. Data analysis for PROMISe required the creation of a table linking FRED[®] and Aquarius[®] drug codes to ATC codes for data analysis. To create a table covering all dispensary vendor medication codes would require significant work, and need to be regularly updated. This could be achieved as a repository administration task. For the purposes of only analysing PBS medication data, using the current PBS codes may suffice, although brand specific information would not be captured.

To extend the standardised coding capacity to include OTC medications stored in individual POS systems would be almost impossible as each POS system would have its own unique coding system which, typically, numbers each stocked item according to when the item was entered into the system. APNs could be used but are not recommended as the APN for a product can readily change due to packaging or minor formulation changes.

Ultimately, dispensary software should be encouraged to adopt standardised medication coding in place of vendor unique coding, in accordance with the NEHTA AMT extensions to SNOMED CT. This would be ideal for the collection and analysis of prescription-related intervention information, and prepare community pharmacy for integration into future national e-health programs.

10.3 Discussion

Overall, the majority of data required for analysis was able to be collected accurately and efficiently. Pharmacists were successfully able to enter intervention details and notes, and link interventions to medications. Prescription data was automatically collected without difficulty from almost all pharmacies within the trial. The transfer of information to the repository was an equally effective component of the system.

The recommendations for improving program efficiency, data collection and user interface have been detailed previously. Analysis of the limitations and feedback from the trial has assisted in identifying some changes to the data requirements and data structure to benefit the recording and interpreting of interventions from a research and auditing perspective.

POS intervention recording may be possible, but is considered impractical considering the extra amount of work required for software development and integration testing between the many POS systems and dispensing systems. A secondary issue involves access to the intervention software at the POS.

Obtaining constructive medication-related reports for research and auditing would rely upon a standardised system for referencing medication from various pharmacies and ideally to also include non-prescription medication. No current medication coding system is ideal. A national standard for medication coding would offer many substantial advantages if it were introduced and ultimately enforced across the various vendors of dispensing systems.

Several software limitations could have been prevented if adequate time for software testing had been available. Future development work should ensure appropriate time for software testing, and that testing with various pharmacies' computer configurations is performed.

Feedback from participants identified that some key improvements might enhance the PROMISe software, making it even more user friendly and efficient. These improvements included having more control over the specific prompt, a reminder to complete saved drafts and creating a history note for each intervention in the patient's profile. The online training used in PROMISe III was a very successful method of training participants and will be essential and effective in future implementation.

Chapter 11 Proposed Business Case

As mentioned in Phase Four of Chapter 2, Deloitte Australia was engaged by the PROMISe Project Team to develop a suggested implementation plan. Deloitte undertook a three part process: part one involved a review of the background and policies, part two was the development of remuneration options and part three involved the development of a business case for the program. This chapter will outline a proposed business case as recommended by Deloitte.

It is important to note that there are some practice issues that arose from the PROMISe III project that may have some influence on the design of a proposed business plan. These are also outlined below.

11.1 Practical Issues from PROMISe III

A number of issues were identified in the trial that may assist with facilitating a seamless implementation for a future national professional program. A number of successful aspects of the trial have been recognised, together with identification of areas that need improvement.

11.1.1 Software

Chapter 10 reported the limitations discovered in the design and implementation of the software and proposed recommendations for future software implementation. Some of these recommendations were based on user feedback and some on the effectiveness at encouraging intervention recording.

Slowing of computers

As discussed in Chapter 10, a small number of participating pharmacies found that their computers slowed when the PROMISe software was installed. Some pharmacies found the slowing of computers occurred every two hours when the data was sent from the local network to the secure repository, and some experienced it more frequently. This was most likely due to the software searching through six months of patient history to find all the prescriptions for that patient when an DCI was created. This was done principally to construct a patient history for use by the clinical expert panel when assessing the significance of DCI. FRED[®] users who experienced this problem were given a software patch by the vendor, which consequently solved their slow computer problem as it amended the design of prescription messaging tables. This may not impact nationally as the collection of the six months of patient history may not be required for implementation of a future program. Regardless, this highlights the need for adequate live testing prior to future implementation.

Given that the majority of pharmacies had no problems with their computers slowing, it appears that this issue may have been more likely amongst pharmacies with larger prescription volumes, or outdated hardware. These issues must be considered if a national implementation is to go ahead.

Feedback, reminders and prompts

It is intended to provide reports of pharmacy and pharmacist specific DCI as well as national collated information to pharmacies on a regular basis. In addition, administrators of the database generated in this project will be able to interrogate the database and detect specific strategic information (for example, trends in drugs involved in DCI, and frequency of DCI of different types).

The PROMISe III trial showed that software modifications in the form of reminders and prompts significantly promoted the performance and documentation of interventions. It is recommended that future implementation includes reminders and prompts to facilitate the pharmacist's documentation of interventions, perhaps aligned with National Prescribing Service campaigns.

11.1.2 Training

The PROMISE III trial showed that educating pharmacists in the use of the documentation system through online training and instruction on the use of PROMISE software significantly increased the number of interventions recorded by the pharmacist as seen in Chapter 5. Therefore, training in the use of both the documentation classification system and the PROMISE software would be important, with all training being able to be delivered online.

Extensive online pharmacist training modules have been developed by UMORE and these were successfully implemented in PROMISE III. These modules could easily be modified by UMORE, as necessary, for training of pharmacists for a national program.

11.1.3 Clinical Knowledge

The outcomes of the observer focus groups showed that a main barrier and facilitator to performing clinical interventions was the clinical knowledge of pharmacists. Due to the respect for, and trust in pharmacists shown by consumers in the consumer sub-study, it is important that pharmacists undergo continued professional development to improve and maintain their clinical knowledge. It is recommended that professional development modules be provided regularly in conjunction with the intervention recording software. The Pharmaceutical Society of Australia and National Prescribing Service could be key providers of this ongoing education.

11.1.4 Awareness of Specific Health Issues

A number of observers and GPs suggested that the decision support prompts should change to target a number of specific health-related issues. Prompts could be rotated periodically, for example one month it may be triggered by certain diabetic medications encouraging pharmacists to discuss issues related to diabetes and the next month it may target asthma related medications. Related professional development modules could be provided corresponding with each prompt. This suggestion has beneficial outcomes as the pharmacist's clinical knowledge improves through the use of educational material linked to the prompt, patients who require the targeted intervention are expected to have better medication or disease management as a result of the ACI. In addition, the database of DCI is increased providing opportunities to identify and improve upon the successes obtained through the promotion of each monthly health issue.

11.1.5 Pharmacy Factors

Pharmacy factors such as increased prescription volume and workload were shown in PROMISE III to significantly reduce the pharmacy's DCI rate as shown in Chapter 5. Strategies to overcome these barriers in order to improve documentation of interventions need to be developed. Pharmacy owners and managers need to be educated about balancing the workload of their pharmacists with professional services such as performing and recording interventions. The National Pharmacy Registration Body may have a role here in enforcing satisfactory workload models. An appropriate remuneration model may also assist with overcoming this barrier due to the potential for employing additional staff.

Pharmacies that are part of a banner group were also shown to have a decreased DCI rate when compared with independent pharmacies (shown in Chapter 5). This suggests that a targeted education campaign within banner groups may be valuable in future programs. It could also indicate the underlying philosophy of some of the banner groups, with an emphasis on commercialism rather than professionalism.

11.1.6 Incentives for Pharmacists

Chapter 5 shows that those pharmacists who completed more continued professional development (CPD) per year have an increased DCI rate. In addition, one of the main facilitators that arose from both the focus groups and the online survey was that incentives for pharmacists will encourage the performance and recording of interventions. Discussion was undertaken about what type of incentive would be beneficial and it was concluded that CPD points would be sufficient.

11.2 Pharmacy Recruitment and Awareness

Although PROMISe was not a mandatory project, it seems obvious that mandatory recruiting would facilitate a greater DCI rate. However, it may be suggested that this be a gradual process as some pharmacies may have a very low DCI rate if participation is mandatory and they have very little awareness of the program. In the future, one can envisage that the National Pharmacy Registration Body may require community pharmacists to submit their DCI as a component of re-registration requirements.

Raising awareness of the program nationally before implementation will be necessary. It is suggested that awareness should begin with pharmacy students at university, where documentation of interventions should be established as routine pharmacy workflow. It is essential that pharmacists begin to recognise that routine documentation of interventions will not only raise their professional profile and secure their future, but also improve their job satisfaction.

Due to the success of UMORE with the recruitment campaign for PROMISe III, it is recommended that UMORE coordinate the national awareness and recruitment campaign for the future implementation of the program.

11.3 Consumer Awareness Campaign

It was evident from the consumer sub-studies undertaken in PROMISe III that many consumers are unaware of the role of pharmacists in performing interventions. It may be beneficial to develop and implement a consumer awareness campaign to further improve consumer satisfaction with community pharmacists. In addition, raised consumer awareness and expectations may facilitate pharmacists in performing and documenting interventions, and promoting the quality and safe use of medicines.

11.4 IT Implementation

A planned, managed release of software updates by pharmacy dispensing software developers to pharmacies, and from the repository software developers to the pharmacy dispensing software developers is essential in order to minimise the potential for unwanted results, such as software communication failures or other failure of data capture.

Appropriately scheduled communications and data audit checks will need to be implemented at the repository level. Appropriate communications and software checks will also need to be implemented at the pharmacy dispensing software developers' level in order to minimise communication failures between pharmacies and the repository, and to minimise any potential adverse effects within each community pharmacy's day-to-day operations. This, however, should not be difficult as it has been achieved previously for PBS online.

The repository structure would need to be redesigned in order to cater for the greater time period of data collection and the greater quantity of data. This has been suggested by Logica to consist of a separate live data server, and a separate reporting server designed to handle archived data, log files and reports, see Appendix NN.

Calculations by Logica based on the PROMISe III trial suggest that an average load of 250 transactions per second would be transferred across the network, and increasing during peak times, see Appendix NN. A network analyst would be essential to plan and design an appropriate network for a national rollout.

A standardised coding system for medications is recommended for the purposes of data analysis. It is recommended that pharmacy dispensing software developers are encouraged to adopt a consistent drug coding standard through the encouragement and direction of NEHTA.

11.5 Deloitte Proposed Implementation Plan

Deloitte Australia were contracted to develop a proposed business case for the PROMISe project using the data collected from the PROMISe trial. The business case involved identifying a preferred remuneration model and

predicted economic outcomes. The key elements of this plan are outlined below, while the full report is available in Appendix FF.

11.5.1 Determining the elements of a preferred remuneration model

In order to fully compensate pharmacies for their participation and facilitate optimal levels of clinical intervention and documentation, it was determined through consultation of the work performed by DeBoos associates that the remuneration options should include four main elements. These included:

1. *An upfront payment* to cover private costs to pharmacists associated with training on the model.
2. *A per-intervention payment* that is either general or targeted for high and low value products.
3. *A minimum intervention threshold payment* that is made quarterly to pharmacists who have an intervention rate of at least 3 interventions per 1,000 prescriptions.
4. *Continuing Professional Development points* to incentivise participation.

The different combination of payments to the pharmacists will influence the levels of participation by pharmacists and the rates of interventions. This in turn will determine the net benefit which the community will gain from the presence of the PROMiSe program, depending on the total costs to Government as compared with the potential health and economic benefits of the clinical interventions.

The remuneration model provided to pharmacists for participation in the PROMiSe program will determine the uptake rate and the intervention rate.

- Uptake rate refers to the number of pharmacists who will participate in the PROMiSe program. The expected uptake rate of pharmacies under varying remuneration options was determined using the results obtained in the Choice Modelling Sub-Study of PROMiSe II. (DeBoos associates, 2009)
- Intervention rate is the number of clinical interventions (and potential types of interventions) that pharmacists undertake and document under the PROMiSe Program.

From the Choice Based Modelling facilitated by DeBoos Associates (2009), two base case options were decided upon which were then compared against two criteria. The first criteria involved the program reducing the risk that pharmacies will take a high upfront payment and then subsequently only perform a few interventions in any given year. It is therefore recommended that >50 per cent of the total incentive payment per year depends upon performing a certain level of intervention rate in each year.

The second criteria involved adequately compensating pharmacists for the costs of screening, intervening and documenting interventions as opposed to overcompensating pharmacists for such activities. This was termed the Base Case Option. On the basis of these criterion it was determined that the Base Case Option should comprise of;



An additional four other remuneration options were developed for the purpose of examining the costs and benefits which flow from varying different elements of the remuneration options. These included;

- A lower upfront payment
- Tiered payment for high and low value interventions
- Payment for only high value interventions
- No quarterly payment.

The following options were analysed to identify the remuneration model that would optimise the net benefits to the community. As shown in Table 11-1, the Base Case option was expected to drive the highest level of uptake by pharmacies and in turn the number of interventions in community pharmacy.

Option No.	Option name	Upfront Payment per pharmacy	Per intervention payment	Per 'high value' intervention payment ³	Payment for other general interventions ⁴	Quarterly Payment	CPD Credits?
1	Base Case	\$4,000	\$20	-	-	\$1,000	Yes
2	Lower Upfront Payment	\$2,000	\$20	-	-	\$1,000	Yes
3	Tiered Per Intervention Payment	\$4,000	-	\$20	\$2	\$1,000	Yes
4	High Value Intervention Only Payment	\$4,000		\$20	\$0	\$1,000	Yes
5	No Quarterly Payment	\$4,000	\$20	-	-	-	Yes

Table 11-1: Potential Remuneration Options Evaluated as part of the Business Case

11.5.2 Expected outcomes

Deloitte identified a number of expected outcomes under the five selected remuneration options in terms of the expected health outcomes for patients, impacts on pharmacies and pharmacists, net benefit to the Government and the net benefit to the Community. In order to calculate the expected outcomes under each remuneration option, several assumptions were employed.

Assumption 1: Intervention Frequency

To calculate the expected outcomes of each remuneration option, Deloitte needed to determine the intervention frequency from the PROMISE data. The trial data used to calculate the intervention rates was gathered in the middle six weeks of the study.

11.5.3 Calculations for intervention and documentation rates

The desire is to calculate the increase in the rate of interventions that would be *performed* (both documented (DCI) and undocumented (ACI)) if the PROMISE Software were rolled out, accounting for the intervention rate that would *already exist if the PROMISE Software was not rolled out*.

In order to calculate this, we need to know both the rate at which pharmacists *perform* interventions (including both DCI and ACI) if the PROMISE program is used, as well as the rate at which pharmacists *perform* interventions if the PROMISE program is not used.

The data we have, source and potential biases are as follows in Table 11-2:

Reference label	Data	Figure	Source	Potential bias
(a)	Rate of performing then documenting interventions with PROMISE Software	3.85 out of every 1000 prescriptions	UMORE: PROMISE III Trial Data	Only captures number of interventions <i>documented</i> not number of interventions <i>performed</i>
(b)	Rate of interventions observed to be	1.40 out of every 100	UMORE: PROMISE III	Performance of pharmacist may be effected by presence of observer

³ Where 'high value' is defined as S3 and S4 interventions.

⁴ Where 'low value' is defined as S1 and S2 interventions.

Reference label	Data	Figure	Source	Potential bias
	documented with PROMISe Software	prescriptions	Observer Study	Sub-
(c)	Rate of interventions observed to be performed with PROMISe Software	3.27 out of every 100 prescriptions	UMORE: PROMISe Observer Study	III Sub-
(d)	Rate of interventions observed to be performed without PROMISe Software	1.66 out of every 100 prescriptions	UMORE: PROMISe Observer Study	III Sub-

Table 11-2: Known Data

The method employed to complete the calculation was essentially the same as was previously used by the PROMISe team to the same ends, only with slight variation in order to be able to calculate:

Using the relationship between (b) and (c), calculate rate of interventions performed if (a) is the rate at which interventions performed are documented:

- Relationship between (c) and (b): $0.00327/0.00140 = 2.34$
- Then: $0.00385 \times 2.4 = 0.00899$
- So, the rate of interventions performed is 8.99 per 1,000 prescriptions

Using the relationship between (c) and (d), calculate the rate of ACI performed in a no PROMISe Software environment, given that the rate of documenting interventions performed is in a PROMISe Software environment is (a):

- Relationship between (c) and (d): $0.0327/0.0166 = 1.97$
- Then: $0.00899/1.97 = 0.00456$
- So, the rate of ACI performed with no PROMISe Software is 4.56 per 1,000 prescriptions

Subtract the rate of performing ACI in a no software environment from the rate of performing ACI in a software environment to calculate the change in intervention rate from rolling out PROMISe Software:

- $0.00899 - 0.00456 = .00443$

Thus, the intervention rates used in the study were:

- **Additional ACI performed because of PROMISe Software: 4.43 per 1000 interventions**
- **Number of DCI (and hence paid for by Government): 3.85 per 1000 interventions**

Assumption 2: High vs. low value interventions

Pharmacists were asked as a part of the trial to rank the significance of the intervention. The expected significance of the intervention was measured according to the following scale: -

- *S1 — consequences related to information.* Pharmacists were instructed to use the rating when the consequences to the patient were related to costs or information only.
- *S2 — prevented mild symptom or improved compliance.* Pharmacists were instructed to use this rating when the consequences to the patient were an improvement in a minor symptom, or, if a minor symptom would have developed if the intervention had not occurred. A 'minor symptom' was defined as one which did not require a doctor's visit to investigate or treat.

- *S3 — prevented or required a GP visit.* Pharmacists were instructed to use this rating when it was likely that the patient would have had to go to a GP if the intervention had not occurred. This was also used when the recommendation was to refer the patient to a GP for further medical attention.
- *S4 — prevented or required a hospital admission.* Pharmacists were instructed to use this rating when it was likely that the patient would have had to go to the hospital if the intervention had not occurred. This was also used when the recommendation was to refer the patient to a hospital for further medical attention.

The trial data showed that the ratio of high-value interventions to low-value interventions was constant across all remuneration options. It was a concern for the researchers that if pharmacists are paid at a 'per intervention rate' as is the case in the Base Case Option (Option 1), Lower Upfront Payment Option (Option 2) and the No Quarterly Payment Option (Option 5), then there is no explicit incentive for performing high-value interventions over low-value interventions. In this case, it is possible that the low-value intervention rate would be *higher* than the high-value intervention rate. If this were to be the case, the expected net benefit of these options as presented in this report would be an overestimate.

Alternately, it was assumed that even when pharmacists were paid less or nothing for low value interventions that they would continue to perform these interventions at the same intervention rate as high value interventions, even though their remuneration was lower (say \$0 per low value documented intervention as in Option 4, or \$2 per low value documented intervention as in Option 3). This assumption was made because the trial data did not consider remuneration options to test different rates of DCI given different payment environments. Therefore it is possible that, under Options 3 and 4, the DCI rate for low-value interventions could be overestimated.

Assumption 3: Clinical interventions adopted by rates of significance value

Based on the Consumer Sub-study, it was estimated that consumers would implement 90% of all recommendations made by pharmacists as part of the clinical interventions. These are outlined in Table 11-3.

- The expected uptake rate.
- The expected number of interventions performed per annum.
- The expected proportion of those interventions adopted (90%) each year.
- The expected proportion of adopted interventions which were classed as high-value each year.
- The expected proportion of adopted interventions which were classed as low-value each year.

Option	Uptake Rate	Interventions Performed p.a.	Interventions Adopted p.a.	Proportion that were high-value	Proportion that were low-value
Base Case	68%	751,670	676,503	281,425	395,078
Lower Upfront Payment	62%	685,346	616,811	256,593	360,218
Tiered Per Intervention Payment	60%	663,238	596,914	248,316	348,598
High Value Intervention Only Payment	52%	574,806	517,326	215,207	302,118
No Quarterly Payment	46%	508,482	457,634	190,376	267,258

Table 11-3: Intervention rates of Remuneration Options

Assumption 4: Value of interventions

The value of avoided healthcare expenditure to the Australian Government as a result of interventions was estimated from an expert assessment review of a subset of interventions (200 cases), as has been discussed earlier. The change in costs to households was estimated based on historical averages of Government and non-Government sources of funding for hospital and medical services. According to AIHW data, Government funding

accounts for 82% of hospital spending and 79% of medical purchasing.⁵ The remaining funding is provided by the private sector, including private health insurance funds, injury compensation insurers and individuals. This assumption was used to calculate the expected direct economic benefits and costs to the private sector.

Combined, the change in costs to Government and the change in costs to the private sector represented the total value to the Community.

Assumption 5: Clinical interventions prompt campaigns

During the operation of the PROMiSe Program, pharmaceutical products or groups of products will be identified based on research conducted of the National Data Repository to create Clinical Intervention Prompt Campaigns. These prompts will generate value for the Community above and beyond the net benefits to the Community indicated by the Trial Data as these prompts will encourage higher rates of targeted interventions for products or groups of products that are commonly misused, similar to what was observed for the PPI products as part of the trial.

Six Clinical Intervention Prompt Campaigns were selected by searching the Trial Data for interventions which happened with high frequency and interventions which resulted in high levels of healthcare savings. The Trial Data indicated that prompting certain interventions significantly increased the rate of intervention for targeted products.⁶ The products selected were:

- Atorvastatin
- NSAIDs (all)
- Prednisolone
- Clopidogrel
- Oxycodone
- Metformin

Each Clinical Intervention Prompt Campaign was assumed to run for three months. At the end of a three month campaign for one product, a campaign for a different product was assumed to begin. The six campaigns were cycled through the operational years of the product. It is possible that some campaigns are re-run but it would also be expected that over time more campaigns would be identified; again the analysis here is useful only for indicative, order of magnitude estimates of the value of the database and potential prompt campaigns.

It was assumed that each campaign would result in the full incremental increase in interventions observed for PPI products when PPI products were prompted in the PROMiSe III study.⁷ For the three months following each campaign, it was assumed that there would still be an incremental increase in interventions associated with that product, but this would be a 29% of the original increase. After this second three-month period, it was assumed that the prompt would have no additional impact at all.

11.5.4 Uptake Rate

Based on the Consumer Sub-study, it was estimated that consumers would implement 90% of all recommendations made by pharmacists as part of the clinical interventions.

Thus in total, Table 11-4 lists, by Option:

- The expected uptake rate.

⁵ AIHW (2009), accessed online: http://d01.aihw.gov.au/cognos/cgi-bin/ppdscgi.exe?DC=Q&E=/expenditure/hex_aust2_2009, last accessed 16.12.09

⁶ Proton Pump Inhibitors were prompted during the trial

⁷ PPI products were tested as Clinical Intervention Prompt Campaigns in the PROMiSe III study

- The expected number of interventions performed per annum.
- The expected proportion of those interventions adopted (90%) each year.
- The expected proportion of adopted interventions which were classed as high-value each year.
- The expected proportion of adopted interventions which were classed as low-value each year.

Option	Uptake Rate	Interventions Performed p.a.	Interventions Adopted p.a.	Proportion that were high-value	Proportion that were low-value
Base Case	68%	751,670	676,503	281,425	395,078
Lower Upfront Payment	62%	685,346	616,811	256,593	360,218
Tiered Per Intervention Payment	60%	663,238	596,914	248,316	348,598
High Value Intervention Only Payment	52%	574,806	517,326	215,207	302,118
No Quarterly Payment	46%	508,482	457,634	190,376	267,258

Source: Deloitte analysis of DeBoos Associates (2009); PROMISe III Trial Data (2009)

Table 11-4: Intervention rates of Remuneration Options

11.5.5 Outcomes for Patients

Once the assumptions were established, Deloitte determined the outcomes for patients, pharmacies and pharmacists, and to the Australian Government and its community.

Table 11-5 summarises the major expected clinical and health utilisation outcomes if the Base Case Option (the Preferred Remuneration Option) is adopted.⁸ By driving a higher frequency of clinical interventions and documentation by pharmacists — approximately 708,000 each year — the Base Case Option would be expected to prevent:

- 3.5 million days of illness
- 1 million GP visits
- 167,016 hospital days or approximately 52,521 potentially avoidable admissions.

By significantly improving the Quality Use of Medicines patients would be expected to have both a higher quality of life and reduce demand on the healthcare system.

Health outcome measure	Expected benefits
Expected reduction in number of days of illness in the Community	An expected reduction of 3.5 million days of sickness within the Community
Reduction in the number of visits to GPs	Expected to reduce by 1 million visits
Reduction in the number of days in hospital	Expected to reduce approximately 167,016 hospital days

Table 11-5: Expected Health Outcomes if the Base Case Option is Adopted

11.5.6 Outcomes for Pharmacies and Pharmacists

Participation in the PROMISe Program will impact on the 'business-as-usual' operation of a pharmacy. For the typical community pharmacy, participation in the PROMISe Program will result in:

- An increase in private costs to the business .

⁸ Assumptions employed to calculate these expected outcomes are detailed in Chapter 5

- An increase in revenues to the business from remuneration associated with participation in the Program.
- Improvements in the quality of the services provided through the receipt of additional training and information through the PROMiSe website and Clinical Intervention Prompt Campaigns.

11.5.7 Outcomes for the Government and Community

Table 11-6 summarises the quantifiable expected direct economic benefits and costs to the Government and Community, which is comprised of both Government and Households, under the Base Case Option.

The expected healthcare utilisation savings to the Community under the Base Case Option would be \$732 million over five years. This represents an average saving of \$367 per intervention performed to Government alone.⁹ The investment would offer a direct benefit cost ratio of 4.7 to Government, with a payback period of less than two years.

Impact	Value (Years 1-5)
Benefit to Government	
Saving from reduced healthcare utilisation costs	\$865 million
Savings from reduced healthcare utilisation costs resulting from Prompt Campaigns*	\$66 million
<i>Total Benefits to Government</i>	\$931 million
Benefits to Community (Government plus Households)	
Savings from reduced healthcare utilisation costs	\$1.0 billion
Savings from reduced healthcare utilisation costs resulting from Prompt Campaigns	\$92 million
<i>Total Benefits to Community</i>	\$1.1 billion
Costs to Government	
Implementation costs	\$14 million
Cost of PROMiSe Program	\$175 million
Additional costs from Clinical Intervention Prompt Campaigns	\$9 million
<i>Total Costs to Government</i>	\$198 million
Costs to Community (Government plus Households)	
Implementation costs	\$14 million
Cost of PROMiSe Program	\$189 million
Additional costs from Clinical Intervention Prompt Campaigns	\$10 million
<i>Total Costs to Community</i>	\$214 million
Net Benefit to Government (Years 1-5)	\$732 million
Net Benefit to Community (Years 1-5)	\$918 million

Table 11-6: Expected Total Direct Economic Benefits under the Base Case Option (Years 1-5)

11.5.8 Assessment

A set of further assumptions were made about the operation of the PROMiSe Program upon rollout. These were that:

⁹ The average represents the average healthcare utilisation savings weighted by significance of intervention.

- There would be a graduated uptake of the Program in its first year of operation. That is, while all participating pharmacies were expected to join the Program within its first year of operation, only half were assumed to participate in the first half of the year and the rest were assumed to have enrolled in the latter part of the year.

Certain interventions will require further healthcare utilisation (for example, a GP visit or a test) before they can be adopted. This is true of approximately 30% of all interventions carried out in PROMISE III. These costs are listed in Table 11-7 below. It was assumed that a certain proportion of costs would require this further attention, and therefore, the costs of these were built into the total costs of the PROMISE Program.

Recommendation category	Recommendation sub-category	Additional healthcare utilisation required to implement	Proportion of interventions where recommendation was made* (%)
A change in therapy	Dose increase	✖ - implementation at pharmacy	11.0%
	Dose decrease	✖	11.3%
	Drug change	✖	14.0%
	Drug formulation change	✖	6.6%
	Drug brand change	✖	1.7%
	Dose frequency	✖	9.1%
	Prescription not dispensed	✖	5.2%
	Other changes to therapy	✖	6.2%
A referral required	Refer to prescriber	✓ - GP visit (\$33.55)	29.9%
	Refer to hospital	✓ - Hospital admission for signs and symptoms (\$2,432)	0.5%
	Refer for medication review	✓ - HMR (\$330)	1.2%
	Other referral required	✓ - Other primary care visit (\$33.55)	0.9%
Provision of information	Education or counselling session	✖	40.3%
	Written summary of medications	✖	4.4%
	Recommended dose administration aid	✖	1.1%
	Other written information	✖	9.0%
Monitoring	Monitoring: non-laboratory	✓ - GP Visit (\$33.55) Hospital admission (\$2,432)	1.5% 0.1%
	Monitoring: laboratory test	✓ - Diagnostic investigation (\$17.50)	2.8%

Table 11-7: Recommendations which require healthcare utilisation to be actioned

All five options were assessed using a multi-criteria score-card approach to determine the preferred remuneration option. The options were assessed against the multiple objectives of Government to identify the remuneration option that maximises outcomes for the community. Using a multi-criteria scorecard, different remuneration models can be assessed against both budgetary impacts and the full range of Australian health policy goals.

The criteria used to select the Preferred Option were derived from definitions of 'effectiveness' and 'efficiency' as they relate to the PROMISE program and broader Health Reform Goals. The assessment of the remuneration against the two criterion resulted in the assignment of ticks or crosses, as shown in Table 11-8. The expected outcome of the PROMISE program under each remuneration option informed the assignment of scores.

- Three ticks if the option performed at least 10% better than average in all performance measures.
- Two ticks if the option performed better than average in all performance measure.
- One tick if the option performed better than average in at least one performance measure.
- A cross if the option performed worse than average on all performance measures.

Criteria and related performance measures	Base Case	Lower Upfront Payment	Tiered Per Intervention Payment	High Value Only Payment	No Quarterly Payment
Effectiveness					
Effectiveness Criterion 1 — The safe use of pharmaceuticals	✓✓✓	✓✓	✓✓	✗	✗
Reduction in GP visits	856,765	781,168	755,950	655,173	579,576
Reduction in hospital days	90,884	82,864	80,191	64,499	61,480
Effectiveness Criterion 2 — Prevention of the inappropriate use of pharmaceuticals	✓✓✓	✓✓	✓✓	✗	✗
Reduction in non-compliance	21,014	19,160	18,541	16,069	14,215
Reduction in moderate events	236,775	215,883	208,919	181,063	160,172
Reduction in severe events	44,649	40,709	39,396	34,143	30,203
Reduction in health utilisation costs (ex pharmaceuticals)	\$319 million	\$291 million	\$282 million	\$244 million	\$216 million
Effectiveness Criterion 3 — Promotes the fiscal sustainability	✓✓✓	✓✓	✓✓	✓	✗
Reduction in total healthcare expenditure	\$329 million	\$300 million	\$290 million	\$251 million	\$222 million
Reduction in expenditure on pharmaceuticals	\$9.8 million	\$8.9 million	\$8.6 million	\$7.5 million	\$6.6 million
Number of interventions performed	676,503	616,811	596,914	517,326	457,634
Effectiveness Criterion 4 — Promotes the continuing professional development of pharmacists	✓✓✓	✓✓	✓✓	✓	✗
Number of interventions performed	676,503	616,811	596,914	517,326	457,634
Number of low value interventions performed	395,078	360,217	348,597	302,118	267,258
High-value intervention performed	281,425	256,593	248,316	215,207	190,375
Uptake rate of the PROMISE Program by pharmacies	68%	62%	60%	52%	46%
Efficiency					
Efficiency Criterion 1 — Allocative efficiency	✓✓✓	✓✓	✓✓	✗	✗
Total net benefit of the Program (to the Community) (Y1-Y5)	\$988 million	\$906 million	\$891 million	\$773 million	\$697 million
Efficiency Criterion 2 — Administrative efficiency	✓	✓	✗	✗	✓

Efficiency Criterion 3 — Dynamic efficiency	✓✓✓	✓✓✓	✓✓✓	✓✓	*
Number of low value interventions performed	395,078	360217	348597	302118	267258
High-value intervention performed	281,425	256,593	248,316	215,207	190,375
Ranking	1	2	3	4	5

Table 11-8: The multi-criteria Scorecard (per annum, except by exception)

As shown above, the Base Case option (option one) performs the best against each criterion. Due to the higher levels of uptake expected by pharmacies (68%), the Base Case Option was expected to drive;

- The greatest reduction in avoidable GP visits and hospital admissions,
- The greatest improvements in medication compliance,
- The greatest savings to government and households (total net benefit to the community of \$988 million).

In addition, by driving the greatest level of uptake by pharmacists, the Base Case Option was expected to result in the development of the most comprehensive dataset of clinical interventions upon which future research would be able to be conducted; limiting remuneration to only a subset of potential clinical interventions (such as in Options 3 and 4) was expected to reduce the dynamic efficiency potential of the Program. Moreover, by funding all clinical interventions, the Base Case Option was expected to be administratively simpler than alternative remuneration models.

Sensitivity analysis testing conducted on the Base Case Option indicated that:

- The Program would deliver a net benefit to the community even if only S1 valued interventions were implemented.
- The Program would deliver a net benefit to the community if a cap of \$15,000 per pharmacy were introduced.

11.5.9 Phased Approach Remuneration Model

As mentioned, the Base Case remuneration model would be the most suitable option to optimise uptake and in turn the health and net economic returns from the program's development. Due to the global financial crisis and the consequential short term impact on the governments budgetary position, an additional six remuneration option was considered. The 'Phased Approach' does not include the \$20 documentation incentive but instead comprises of,

- an upfront payment of \$4000,
- a quarterly payment of \$1000 available to each pharmacy, contingent on the pharmacy documenting a minimum number of interventions, and
- CPD points for pharmacists from participation.

The results from the Choice Modelling survey conducted by DeBoos Associates revealed that the uptake by pharmacists under the phased approach would be 31%, which is 37% lower than the Base Case option. As the participation would be far less with the Phased Approach than the Base Case option, the net benefit for the government would also be substantially less when compared to the Base Case option, as shown in Table 11-9.

Despite this, using this approach will still be expected to deliver a net economic benefit to the Community of approximately \$433 million, and a net savings to Government of approximately \$348 million. As the participation in the Program would be expected to be lower under this Phased Approach remuneration model there would need to be a very strong focus on the change management strategy as a part of the Program (which is also required for the Base Case remuneration model as well).

Impact	Outcomes under Base Case	Outcomes under Phased Approach
Benefit to Government		
Saving from reduced healthcare utilisation costs	\$865 million	\$394 million
Savings from reduced healthcare utilisation from Prompt Campaigns	\$66 million	\$30 million
<i>Total Benefits to Government</i>	\$931 million	\$424 million
Benefits to Community (Government plus Households)		
Savings from reduced healthcare utilisation costs	\$1.0 billion	\$474 million
Savings from reduced healthcare utilisation from Prompt Campaigns	\$92 million	\$42 million
<i>Total Benefits to Community</i>	\$1.1 billion	\$516 million
Costs to Government		
Implementation costs	\$14 million	\$14 million
Cost of PROMISe Program	\$175 million	\$59 million
Additional costs from Clinical Intervention Prompt Campaigns	\$9 million	\$3 million
<i>Total Costs to Government</i>	\$198 million	\$76 million
Costs to Community (Government plus Households)		
Implementation costs	\$14 million	\$14 million
Cost of PROMISe Program	\$189 million	\$66 million
Additional costs from Clinical Intervention Prompt Campaigns	\$10 million	\$3 million
<i>Total Costs to Community</i>	\$214 million	\$83 million
Net Benefit to Government (Years 1-5)	\$732 million	\$348 million
Net Benefit to Community (Years 1-5)	\$918 million	\$433 million

Table 11-9: Direct Costs and Benefits to Government and the Community of the Base Case and Phased Approach Remuneration Models (Sum over Years 1-5)

11.5.10 Conclusion of Preferred Method

The Assessment Framework indicates that the remuneration option which most effectively addresses the objectives of the PROMISe Program in the most efficient manner is the Base Case Option. Due to the higher levels of uptake expected by pharmacies (68 per cent), the Base Case Option was expected to drive:

- the greatest reduction in avoidable GP visits and hospital admissions,
- the greatest improvements in medication compliance,
- the greatest savings to government and households (total net benefit to the community of \$988 million).

The expected outcomes under the Preferred Options demonstrated strongest alignment with the objectives of the Australian Health Reform Agenda. This suggests that if the Government opts to remunerate pharmacists for participation in the PROMISe Program in the recommended manner, they will ensure that the Program is used to best further the broader Australian health reform goals.

In addition, by driving the greatest level of uptake by pharmacists, the Base Case Option was expected to result in the development of the most comprehensive dataset of clinical interventions upon which future research could be conducted; limiting remuneration to only a subset of potential clinical interventions (such as in Options 3 and 4) was expected to reduce the dynamic efficiency potential of the Program. Moreover, by funding all clinical interventions, the Base Case Option was expected to be administratively simpler than alternative remuneration models.

Sensitivity analysis testing conducted on the Base Case Option indicated that:

- The Program would deliver a net benefit to the community even if only S1 valued interventions were implemented
- The Program would deliver a net benefit to the community if a cap of \$15,000 per pharmacy were introduced.

On this basis, it is recommended that pharmacists are remunerated in the following manner for participation in the PROMISE Program:

- \$4,000 upfront payment per pharmacy.
- \$20 per prescription intervention.
- \$1000 quarterly payment.

In addition to which CPD points will also be provided to pharmacists for participation in the program.

11.6 Implementation Plan

The following suggested implementation plan was developed by Deloitte Australia,²¹⁴ with the full report available in Appendix FF. Deloitte based their report, in part, on information gathered by DeBoos Associates Quantitative Report on PROMISE III Participant and Non-participant Pharmacists Findings²¹⁵ as seen in Appendix OO.

It is expected the PROMISE Program will be administered by the Pharmacy Guild, with funding for remuneration and implementation costs being provided by the Department of Health and Ageing through the 5th Community Pharmacy Agreement. The National Data Repository of clinical interventions, however, was expected to be owned and operated by the Department.

To implement the Preferred Option for the PROMISE Program, the Pharmacy Guild will need to implement a program of work to ensure the necessary investments are made and business change processes are implemented. The program of work is comprised of two phases: the ICT Development Phase (Year 1) and an Operational Phase (Years 2-5). Details of both phases are summarised in Table 11-10.

Phase	Description	Key workstreams
ICT Development Phase (Year 1)	This phase will ensure the ICT infrastructure is operational to support the national rollout of the program. It will take approximately 12 months to complete.	<p><i>Software Development and deployment</i> - The promise III study has tested the concept of the PROMiSe Program. A number of modifications would be required, as recommended by post-trial analysis, before the Program is rolled out nationally. It is recommended that the software is developed as a fully integrated component of dispensing software by relevant software vendors.</p> <p><i>Repository Development</i> – A number of design modifications will be recommended as a result of the post-trial performance analysis and the scale up of the repository capacity for national expansion. These recommendations will need to be incorporated into the technical and functional specification</p>
The Operational Phase (Years 2-5)	This phase will involve the rollout of training, change management and compliance programs to drive uptake of the Program and ensure the Program achieves its outcomes and objectives. The Operational Phase will run from Year 2 through Year 5.	<p><i>ICT Support for the PROMiSe Software</i> – ICT support for the PROMiSe software will be provided by vendors as a part of their normal role as providers of dispensing software services to pharmacists</p> <p><i>Education Support</i> - Education support for pharmacists for questions regarding interventions will be provided by the Pharmacy Guild through an email query built-into the national website and a national hotline</p> <p><i>Training in the use of the software, the DOCUMENT system</i> – pharmacists will be required to undertake basing training in the use of the software and the types of clinical interventions in order to access payments from the PROMiSe Program. It was recommended that training be provided through a mix of virtual classroom courses and face-to-face seminars.</p> <p><i>Change Management</i> - The change management program will support the successful deployment of the PROMiSe Program nationally. This will require the following steps:</p> <ul style="list-style-type: none"> • Development of a change and adoption strategy • Implementation of change and adoption activities • Ongoing training strategy and needs analysis. <p><i>Monitoring and compliance</i> – The key objectives for a monitoring and compliance framework for the PROMiSe Program are to:</p> <ul style="list-style-type: none"> • Prevent fraud within the system • Ensure documentation is compliant with the Program requirements • Evaluate the quality of the clinical interventions. <p>In turn, there are three levels of auditing which should be implemented as part of the Program:</p> <ul style="list-style-type: none"> • Identification of possible fraud through Data analytics and trending analysis • Compliance and enforcement of documentation requirements through random audits of pharmacies • Quality assurance of clinical interventions through peer audits. <p>The cost of monitoring and compliance will be a function of the level of auditing required by Government and the number of participating pharmacies.</p>

Table 11-10: Details of the Proposed Implementation Plan

The PROMiSe Program will also be required to demonstrate compliance with all relevant legislation. Particular consideration must be given to the legislative requirements of:

- *Pharmacy and pharmacist specific legislation* – Refers to legislation with which Pharmacists must comply. Commonwealth legislation in this category includes the *National Health Act 1953* which sets out statutory requirements for the administration of the Pharmaceutical Benefits Scheme. Each State and Territory has a “Pharmacy Act” which regulates the dispensing and recording of prescriptions
- *Privacy legislation* – Pharmacists must comply with the requirements of the Commonwealth *Privacy Act 1988* and, in addition, some jurisdictions have State-based privacy legislation and legislation specifically covering the privacy of health-related information.

It is not anticipated that any regulatory changes will be required to implement the policy. However, Deloitte are not legal practitioners and it is recommended that, as part of the implementation process, professional legal advice is sought.

11.6.1 Risk Assessment and Mitigation Strategies

The implementation of any major project involves some risks. To formulate a plan to mitigate the risks that the Government and the Pharmacy Guild will face in the implementation of the preferred option, a register of risks and mitigation strategies was developed as part of the implementation plan. Table 11-11 provides an overview of the types of risks associated with the PROMISE Program and the major mitigation strategies developed to control these risks.

Risk	Description	Example in PROMISE Program	Related mitigation strategies
Investment planning risk	Relates to the risk that the investment has not been robustly or rigorously prepared so that issues critical to its success have been overlooked.	Inadequate scoping of the ICT systems and costing	Peer review of plan through UMORE review and Advisory Committee. Consultations with multiple experts. Contingency allowances (10%).
Completion risk	Arises from the potential for the investment not to occur within the time and budget parameters set	A large number of dispense vendors developing the PROMISE software extend the development phase of the project	Stagger dispense vendor development schedules. Allow additional development time to reduce dependencies of subsequent tasks.
Demand risk	Risk that attaches to the demand for the product of service which is to be provided	The risk that more pharmacists participate than projected	Contingency costs built into financial modelling. Cap per pharmacy of \$15,000 limits total risk to Government.
Implementation risk	Risk that the outcomes and outputs expected from a project are not able to be realised.	For the PROMISE Program, there is the potential risk that pharmacists will only perform low-value interventions	Ensure remuneration package maximises participation while minimising risk that program delivers no value. The introduction of prompt campaigns.
Management risk	Risk that arises from relying on the skills of the proposed project team to deliver the project.	The risk that the Guild Project Office lacks the skills to deliver the project	Employ the same team that is managing 4 th Community Pharmacy Agreement Programs.
Operations risk	Risk related to the operation and management of a program	Software release versions become out of sync between dispense vendors and the repository	Set up central management/control point to coordinate the development and deployment of future revisions and updates.
Financial risk	Risks such as unanticipated levels of expenditure.	Inadequate scoping of the implementation plan and costing	Peer review of plan through UMORE review and Advisory Committee. Consultations with multiple experts from the GUILD, PSA and Deloitte experts.

Table 11-11: Description of Risks and their Potential Application to the PROMISE Program

In particular, the implementation plan provides for three major strategies to be deployed as part of the ICT and Operations Phase that will significantly control the risks associated with the PROMISE Program. These include:

- The provision of education support and training to pharmacies,
- The rollout of a comprehensive change management strategy,
- The development of a monitoring and compliance framework.

11.6.2 Training and Education Support

DeBoos Associates research showed that one of the largest major non-monetary barriers to performing clinical interventions and documentation was inadequate knowledge of clinical interventions by pharmacists. Thus, both training and ongoing education support for pharmacists is seen as essential to ensure that pharmacists are able to identify appropriate clinical interventions and perform/document these interventions accurately.

It is recommended as part of the Implementation Plan and Risk Management Strategy that an Education Support help desk is established to support pharmacists with questions they may have regarding the nature of interventions (rather than software questions). It was expected that an email query function would be built-into the national website and a national hotline would be established. Such an approach would be consistent with the rollout of the Guild's Mirixa software, which provides, through the Pharmacy Guild, a help desk that employs 5 staff members. It was assumed that three additional people would be required in Year 2 (the first year of operation) but that this may be able to be scaled down over time.²¹⁴

Pharmacists would also be required to undertake basic training in the use of the software and the types of clinical interventions (the DOCUMENT system) in order to access payments from the PROMISE Program (specifically the \$4,000 up front program payment to the pharmacy). Based partly on the experience of the Diabetes Program (DMAS), where a pharmacy employs multiple pharmacists, it is recommended that at least two pharmacists from each pharmacy be required to complete the training in order to ensure the information is translated back to the pharmacy. It was recommended that training be provided through a mix of virtual classroom (online) courses and face-to-face seminars. This would provide for a minimisation of total training costs while also ensuring that some pharmacists, particularly older pharmacists, would not be discouraged to participate in the Program due to lack of comfort with an online delivery environment.

11.6.3 Change Management Strategy

DeBoos Associates research also revealed that the other major non-monetary barrier to clinical interventions and documentation was poorly trained staff and entrenched practices of non-recording, which have been developed as a result of pharmacists' inability to see any tangible purpose for the documentation of interventions.²³⁰

To drive more frequent interventions by pharmacists that serve to improve the quality use of medicines and prevent avoidable GP visits and hospital admissions, it is recommended as part of the Implementation Plan and Risk Management Strategy that a comprehensive change management strategy be developed to support the successful deployment of the PROMISE Program nationally. The goal of the change management program will be to overcome people-related barriers and, in parallel, utilise the drivers identified by DeBoos Associates research to ultimately improve the quality use of medicines. The change management strategy will focus on:

- Improving the *level of readiness* of pharmacists for change
- Increasing the *level of adoption* of the PROMISE Program
- Supporting changes to the way pharmacists *engage with and manage clients*
- *Increasing the rate of documentation* by pharmacists through the PROMISE Program.

Building on the analysis of barriers to implementation undertaken by Ian DeBoos, the change management program will include the following key streams of work:

- *Develop Change and Adoption Strategy* — This stream of work will involve a change and adoption team, engaged by the Pharmacy Guild, to work in collaboration with the Guild and other key bodies to establish the stakeholder engagement and communication activities that will assist pharmacies to overcome the barriers to clinical interventions. The stakeholder engagement and communication activities will need to be implemented in a manner that engages and addresses the unique requirements of different pharmacy types. The Change and Adoption Strategy would define the strategies and activities to be conducted in the lead up to, and during, implementation of the PROMISE program.

The major areas of the Change and Adoption Strategy will be:

- *Development of the Stakeholder Engagement Strategy*: The stakeholder engagement work stream will develop and implement a strategy to determine the activities needed to increase pharmacists' understanding, acceptance, and ownership of the PROMISE program. The area will be managed nationally, and work on both a 'Program level' and 'product-specific' level.
- *Development of a Communications Strategy and Plan*: The communications work stream will develop a communication strategy and plan to ensure a coordinated and consistent approach to national communications. It will also provide a comprehensive view of the communication channels, timing and

messages being sent to stakeholders. This area of work will also need to be managed nationally and work on both a 'Program level' and 'product-specific' level.

- *Conduct Change Readiness Assessment:* The change readiness work stream will assess stakeholder understanding of, and commitment to, the performance and documentation of clinical interventions. The work stream will develop and launch online surveys to key stakeholder groups and analyse the results.
- *Implementation of Change and Adoption Activities:* The implementation of stakeholder engagement and communication activities, identified in the Change and Adoption Strategy, will take place during the planning for, and implementation of the PROMISE program.
- *Ongoing Training Strategy and Needs Analysis:* This stream of work will determine the training needs of pharmacists and develop a strategy that will provide the direction, goals, and objectives of the training delivery.

11.6.4 Monitoring and Compliance Framework

Finally, it was recommended that a rigorous monitoring and compliance framework is established as part of the Program: to prevent fraud within the system; to ensure documentation is compliant with the Program requirements; and to evaluate the quality of the clinical intervention. To meet these objectives there will be three levels of auditing that will be required:

- Identification of possible fraud through Data Analytics reviews and trending analysis
- Compliance and enforcement of documentation requirements through random audits of pharmacies
- Quality assurance of clinical interventions through peer audits.

Prevention of Fraud

There will be very significant data available for the Guild and Department of Health and Ageing to use to identify potential fraud within the system. The data repository will provide the following information:

- De-identified patient key
- Patient history, including the prescription that prompted the intervention
- Records of the medication error identified by the pharmacist
- Records of the pharmacist's recommendation
- The outcome of the intervention
- Pharmacist's initials or other form of identification.

This will enable very sophisticated data analysis to be undertaken to identify irregularities in pharmacist documentation behaviour, which will enable additional targeting of compliance actions to be undertaken as necessary. Data analysis would be undertaken on a quarterly basis, aligned with the quarterly payments to pharmacists.

Compliance and Enforcement of Documentation Requirements: Recommended Approaches

The second level of auditing would be focused on ensuring pharmacists are compliant with all aspects of documentation required to receive payment, including the nature of the medication problem (according to the DOCUMENT system) and their recommendation. There are two potential ways of providing this compliance function:

- *Minimum compliance framework* — The Guild, as the administrators of the program, could engage a third party to undertake randomised audits of pharmacies, which would involve reviews of available information.
- *Enhanced compliance framework* — In this option, pharmacists would be required to obtain documentation from the patient at the time of service that the intervention did occur, including the reason for the intervention, the pharmacist's recommendation and the outcome of the intervention. This would be similar

to the HICAPS requirements for patient signatures for dental claims. This would, however, constitute a more invasive approach to compliance that may adversely impact on documentation rates. In combination with the data analytics approach to managing fraud, this may be an unnecessary additional level of compliance.

Importantly, the documentation compliance and enforcement systems should be linked to the training and change management programs.

Response to non-compliance

The Guild will need to determine the enforcement approach to take in instances of fraud and non-compliance, taking into account all the circumstances of the matter. The enforcement measures that will be available to the Guild are likely to range from less formal and less punitive options to progressively more substantive legal responses (Figure 11-1).

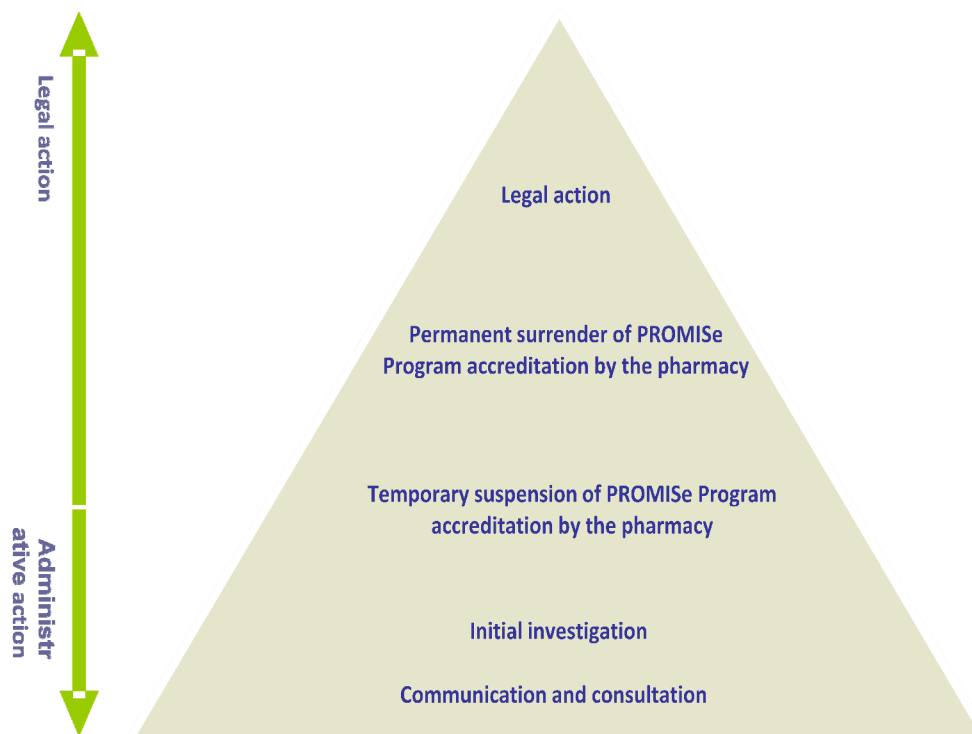


Figure 11-1: Compliance and Enforcement Framework – potential responses to fraud

The Guild/Department of Health and Ageing may proceed with more serious enforcement actions in appropriate circumstances and when other measures have not had the desired effect. This approach is consistent with the pyramid of enforcement model, as shown above.

Quality assurance of clinical interventions through peer audits

In addition, the Department of Health and Ageing and the Guild may wish to audit the quality of the clinical interventions being made by pharmacists. This could be done through a randomised audit of pharmacies but would, importantly, require clinical input to ensure the validity of the audit findings. This could be accomplished through the introduction of a peer review process, which is currently routinely undertaken in hospital pharmacy settings.

11.7 Conclusions and Recommendations

The PROMISE Program has four key objectives:

- To improve and promote the *safe* use of pharmaceutical products
- To *prevent* the inappropriate use of pharmaceutical products
- To promote the *fiscal sustainability* of the Australian healthcare system
- To promote the continuing *professional development* of pharmacists to strengthen the delivery of primary health care services.

These objectives are strongly aligned with the recent directions of Australian healthcare policy more broadly and the objectives of the National Medicines Policy. As a result of the strong alignment between the objectives of the PROMISE Program and the broader Government Healthcare Reform objectives, outcomes which successfully meet the Program goals will also contribute towards the broader Government health policy objectives.

The analysis and business case presented in this report recommends that in order to optimise the net benefits to the community, clinical benefits, uptake and benefits to pharmacists from the operation of the PROMISE Program, the Government should remunerate participating pharmacists as follows:

- \$4,000 upfront payment per pharmacy
- \$20 per prescription intervention
 - With a \$15,000 cap per pharmacy per year
- \$1,000 quarterly payment
- Non-monetary allowance for the accrual of CPD points from participation in the Program.

The national rollout of the PROMISE Program should be supported by a comprehensive change management strategy and the development of a strong monitoring and compliance framework.

A cap of \$15,000 per pharmacy per annum (excluding the upfront payment of \$4,000 per pharmacy) should also be implemented to limit the financial risk to the Government. This cap should be subject to review over time as the outcomes of the Program are also monitored and reviewed. The expected cost to the Government of a capped Base Case remuneration model would be \$370 million over five years (assuming an uptake rate of 68 per cent by all pharmacies). The potential total cost, if all pharmacies participated, would be \$601 million.

The Phased Approach remuneration model was suggested as an alternative to the Base Case remuneration model. As the participation in the Program would be expected to be far less under this Phased Approach remuneration model than the Base Case remuneration model, the net benefit would be substantially less. The Program would still be expected, however, to deliver a net economic benefit to the Community of approximately \$433 million, and a net savings to Government of approximately \$348 million. The total cost to Government of the Program under this option would be expected to be \$76 million over five years, based on an expected uptake rate of 31 per cent by community pharmacy. The potential total cost, if all pharmacies participated, would be \$208 million.

As the participation in the Program would be expected to be much lower under this Phased Approach remuneration model there would need to be a very strong focus on the change management strategy as a part of the Program (which is required for the Base Case remuneration model as well). Moreover, it is recommended that if such a remuneration model is implemented that the Government review participation rates over time to ensure the objectives and outcomes of the Program are being achieved. The change management and training strategies, which should be strongly integrated, should be modified over time to ensure the goals of the Program are being achieved. It is recommended that a review of Program outcomes is undertaken at the end of Years 2, 3 and 4 in the implementation plan.

Chapter 12 Conclusions and Recommendations

The project outlined in this report is the largest study of clinical pharmacy interventions in Australia and one of the largest in the world. The project has shown that Australian community pharmacists routinely undertake clinical interventions that have the potential to reduce healthcare utilisation and medication costs, as well as improve quality of life.

12.1 Key Conclusions

Overall, the PROMISE III trial recorded 6,230 valid DCI on 2,013,923 prescriptions at a rate of 0.31% or 3.1 DCI in 1000 prescriptions. However, the DCI rates of individual pharmacies ranged from 0.00% to 2.34%, which indicates the potential intervention frequency that could be achieved.

Of the 6230 prescription DCI, 282 were triggered by the electronic decision support prompt and the majority of these DCI were considered separately in the data analysis. Despite removing the prompted DCI, ten of the twenty pharmacies with the highest DCI rates were still in group three which had the specific prompt. This indicates that the presence of the prompt not only increases the frequency of DCI triggered by the prompt, but also increases the frequency of DCI overall. This was confirmed more strongly in the observer data and there was also a significant difference confirmed with the first eight weeks of trial data.

The PROMISE III trial found several factors that appeared to affect the overall DCI rate of pharmacies, as well as the individual DCI rate of participating pharmacists. These factors were anticipated. Generally, the pharmacy's DCI rate was significantly affected by the workload in the pharmacy, therefore as the busyness of a pharmacy increased, the overall DCI rate of that pharmacy decreased. This suggests that adequate staffing levels with appropriate workloads would increase the level of interventions performed and recorded within pharmacies.

The level of training on the PROMISE system significantly increased the pharmacist's individual DCI rate, with those pharmacists who completed both face-to-face and online PROMISE training achieving a higher DCI rate than other pharmacists. A higher clinical knowledge score also appeared to increase the DCI rate of the pharmacist, which may be due to these pharmacists having a higher DRP detection rate. The trial's results suggest that by providing ample PROMISE training and additional clinical training, the DCI rate of community pharmacists may increase two-fold. It is felt that UMORE are ideally situated to provide the training of the program.

Such improvements will be of immense value to the community, since the average DCI is estimated to be worth approximately \$360 in healthcare utilisation (including medication savings). Considering this alongside the estimated true level of intervention frequency for current vs. PROMISE practice, it is anticipated that the average PROMISE pharmacy might save an additional ~\$1,476 in healthcare utilisation, and 0.04 quality adjusted life years per week. After considering the opportunity cost in terms of pharmacist time to find and perform interventions, this would translate to an incremental benefit of ~\$290M and ~10000 quality adjusted life years per year, if PROMISE were implemented in all pharmacies nation-wide.

Deloitte Australia's business case and implementation plan suggested that if the PROMISE program were fully funded and implemented in the proposed way it would have a net benefit to the government of ~\$900M over a 5 year period. A secondary, phased, implementation plan was also costed, whereby the program would be fully implemented, but only select interventions would be remunerated. The expected uptake rate of this program would be a smaller 31%, but would still result in a net benefit of ~\$430M over 5 years.

12.2 Potential

The software has the potential to improve communication between pharmacists and GPs. An electronic record of the DCI provides an evidence base which can be presented to GPs as issues arise. If a medication-related incident occurs at some point in the future, the pharmacist has a written record of the drug-related problem and recommendations made to resolve the problem. GPs can be reluctant to change patient therapy due to a range of reasons. As GPs become aware of pharmacists making permanent records of recommendations to improve

patient therapy, they will become more aware of the need to provide pharmacists with appropriate reasons for their therapeutic decisions. Likewise pharmacists would be obliged to update their patient records to include GP decision making. The process overall is an exercise in improving communication between the two professions in order to maximise best outcomes for patients.

The repository of DCI and prescriptions would be a great source of identifying trends associated with drug-related problems. Common interventions relating to issues such as toxicity of medications, adherence to best practice guidelines dosing complexities and patient education could be identified. Once identified educational bodies would be in a position to target educational campaigns to doctors, pharmacists or patients as needed to minimise harm and maximise benefits of medication therapy.

Another potential of the system is the capability to prompt pharmacists into undertaking clinical interventions as discussed below.

12.3 Recommendations

Following the PROMISE III trial, there are several recommendations to move forward with this innovative professional program.

12.3.1 Widespread Implementation

PROMISE III trialled the software in 185 pharmacies. A widespread implementation in all pharmacies is now recommended. This would include developing the PROMISE software for all dispensing systems used in Australia to allow all pharmacies to participate. There were no significant issues in the trial to indicate that there are major barriers to a national rollout. The use of the system could be further improved through the provision of adequate training on the PROMISE documentation system, which significantly increased the DCI rate during the trial. A key component of the rollout is the use of data and case scenarios from the central database for the ongoing continuing professional education of pharmacists and by providing pharmacists with additional clinical knowledge training, the DCI rate could be further increased. This database could also be used to improve prescribing practices through analysis of DCI by groups, showing another fundamental benefit of the PROMISE system.

This study has shown that CPD points could be used as an incentive to increase a pharmacist's intervention documentation rate. There would be a need to ensure CPD points were allocated appropriately for the performance and documentation of valid interventions, and not just awarded to a pharmacist for performing their necessary professional duties.

12.3.2 Prompt Software

It would be crucial that the prompt function be implemented within the PROMISE software, as the prompt appeared to significantly increase the number of DCI performed by the pharmacists. It would also be recommended that the prompt be rotated, as the effect of the prompt appeared to diminish after eight weeks, resulting in all groups having similar DCI rates during the last four weeks. A changing prompt every eight to twelve weeks, depending on the frequency with which a patient would be expected to present their prescription for the targeted drug, would help to ensure that an optimal DCI rate was maintained for the whole year.

An inbuilt prompt mechanism provides a method of delivering targeted education to pharmacists regarding selected healthcare issues. It would also allow specific prompts to be hand-picked to increase the benefits to the consumers and the healthcare system. This may include high value DCI, but also those DCI of moderate value that occur more frequently, thus resulting in large health savings. One option is to develop a program of decision support prompts with the National Prescribing Service.

The use of a targeted prompt would also allow for a quality assurance cycle to be implemented. A drug-related problem would be identified using the PROMISE database and a prompt would be created, providing education to the pharmacists when it appeared. The prompt would remain in-situ for a defined period of time, after which the database could be reanalysed to determine the effect of the prompt, thus creating a quality assurance cycle.

12.3.3 Prospective Trial

A prospective trial conducted on data collected by the implemented program would also allow confirmation of the healthcare resource utilisation benefits that could only be predicted within the constraints of the PROMISe trial. It is envisaged that all consumers subjected to a prompted DCI could be identified and contacted to determine their actual health resource utilisation. This would allow more accurate economic values to be assigned to the DCI and therefore more precise extrapolations to be applied nationwide. This prospective study would in turn allow policy makers to better measure the efficacy of the program, and to better target high value areas throughout the health system.

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