



School of Pharmacy



# **PROMISe**

## **Phase One**

### **Final Report**

## **Pharmacy Guild of Australia**

### **Research Tender**

### **RFT 2003-01**

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## **1 Executive Summary**

The primary aim of this phase of the project was to develop and test a system for the electronic recording, collation and management of medication incidents in community pharmacies.

An electronic communications system (Pharmacy Recording of Medication Incidents and Services or PROMISe) which interfaces seamlessly with two dispensing systems (Rex and WiniFRED) and sends encrypted, HL7 compliant messages to a secure server was developed. The information at the server was de-identified but can be interrogated by users with different levels of access to provide reports at pharmacist, pharmacy, State and National level concerning any aspect of the information available.

The system was pilot tested in seven pharmacies in Tasmania to evaluate its functionality and initial user acceptance, and to provide some preliminary data for examination. 513 interventions were documented over 2 weeks in pharmacies that dispensed 9012 prescriptions for 6077 patients over that time. Interventions were documented at an overall rate of approximately 5.7 every 100 prescriptions, or 8.4 for every 100 patients. Higher rates of interventions were noted for original prescriptions, patients with more than one prescription item, and pharmacies where a PROMISe observer was present. Preliminary analysis of 352 non brand substitution interventions indicated that there was a significant saving in terms of hospital admissions avoided (~\$14,000) and general practitioner visits avoided (~\$700).

At all stages in the development of the technical and clinical aspects of the project, consideration was given to the potential for the techniques to be used in a national system. Thus, in addition to fulfilling the primary aim, a number of unique techniques and tools were developed that are applicable to a larger scale study.

Further, examination of the preliminary data has identified a number of significant opportunities for the information that would be gained from a larger study. In particular, factors which may result in, or be associated with, an increase in intervention rate could be examined, as these would be associated with an increase in potential benefits.

## **New Techniques and Research/Assessment Tools**

### **D.O.C.U.M.E.N.T. Classification System**

The D.O.C.U.M.E.N.T. intervention classification system has been applied to almost 1000 community pharmacy interventions. The system covers aspects of the interventions type, the actions taken by the pharmacist, the recommendations made to resolve the issue, the clinical significance of the event and whether the recommendation was accepted. The system has been validated by over 150 pharmacists from various practice backgrounds throughout Australia. The system's architecture is sound and flexible, allowing for addition or modification of subtypes or new actions or recommendations, or collapsing of subtypes for simplification. This unique categorisation system allows for assessment of these aspects of the intervention in relation to each other (e.g. significance by type or recommendation made) or in relation to the other information collected regarding the event (e.g. significance by pharmacist demographics, drugs involved, type of prescription).

### **Web Based Categorisation Training and Validation**

Pharmacists can undertake preliminary training in the use of the categorisation system from an internet connection. This allows for a reduction in face-to-face training time as well as providing ongoing information to validate the useability and appropriateness of the classification system. Individual feedback was provided to each pharmacist validating the categorisation system.

### **Identification of Proactive and Reactive Interventions**

It appears the intervention rate is increased by increasing the proportion of interventions that are proactive interventions (those that are initiated by the pharmacist). In the pilot study, this was partially explored, but the enhanced training provided in the form of an observer seemed to increase proactive intervention numbers. Other factors that could influence proactive intervention rate should be explored in future studies with a view to providing increased support for those factors that increase intervention rate. It is proposed that education, assistance with training, reduced workload and payment will influence the rate of proactive interventions.

### **Use of Observer / Support in Pharmacies**

The observation technique described in the pilot study report resulted in a significant increase in proportion of proactive interventions in pharmacies when observers were present. These interventions were more likely to be of higher significance and were therefore more likely to be of economic or health benefit than reactive interventions. Further exploration of factors that can increase the frequency of proactive interventions would enable a strong case to be built for developing aspects of education and training to increase proactive intervention rates.

### **Dispensing Interface and Repository Communications**

The communications modules and messaging formats that have been used are efficient (functional even with dial up connection speeds) and compliant with National e health standards. This means that they are easily expandable to a larger number of pharmacies.

### **Clinical Review Panel Polling Method**

The clinical review methodology trialled enabled a unique approach. Each panel member was asked to assign a probability of an event of a particular level of clinical significance occurring. The technique is expandable, and multiple judges could be used to determine a variation around the probability estimate. Using the variation, a probabilistic sensitivity analysis can be undertaken which will establish the confidence intervals for the true estimate of clinical significance. The technique was based on technology that used an internet database to collate input from several judges. The potential for the system to utilise clinical expertise of judges from an internet connection allows for wide-ranging input.

## **Potential Uses of the Information**

### **Link to Pharmacist/Pharmacy Prescription Data**

By collecting information concerning prescription information and using links to the intervention database, relationships between prescription characteristics and the intervention characteristics can be explored for those interventions that are related to a prescription. Common drug groups that were involved in the more significant interventions were respiratory drugs, antithrombotic agents, analgesics and antidepressants. Interventions were over four times more frequent with original prescriptions than with repeat prescriptions.

The collection of this data allows for interrogation of interventions and this can be related to particular drugs or drug groups. A larger sample size could lead to developing a greater understanding of the prevalence of particular drug issues. Also there would be the potential to monitor the impact of educational strategies on pharmacists practice.

### **Evaluation of Pharmacy Characteristics and Business Style**

Preliminary work has been undertaken in this project to establish pharmacy and pharmacist business types and styles. This has the potential to assist in the development of specific change management and motivational techniques for the implementation of new technologies. By exploring the relationship between particular pharmacist/pharmacy characteristics and utilisation of the system, it may be possible to establish a predictive model for uptake and explore response to different motivational factors. These techniques, once refined, would enhance the success of a broad scale implementation of this or other new technologies or practice changes.

### **Factors Influencing Frequency and Type of Interventions**

The methods used in the pilot study allowed for the collection of a wide range of data concerning the pharmacist, the pharmacy, the prescriptions, the workload and the various aspects of the intervention. Given the sample size in the pilot study, these have not been explored. However, there is the capacity to examine relationships between these aspects and the overall intervention rate or nature. It may be possible to determine particular characteristics that are associated with interventions that are more significant (e.g. prior clinical experience, accreditation for medication reviews, lower workload), and these characteristics would form the basis for further education and training.

### **Professional Development/Educational Aspects**

The reporting module on the PROMISe server enables detailed reports of intervention activity to be explored. The potential exists to enable pharmacists to have access to their own intervention reports, thereby providing an indicator of their professional activities. A form of regular feedback of intervention information to individual pharmacists could again be used to enhance involvement and uptake of the system.

Identification of common issues and current trends in interventions with respect to particular types, drugs, or recommendations would enable regular feedback to pharmacists. This information would also provide targets for educational strategies to modify rates of intervention, and the PROMISe ongoing data could be used to monitor the impact of any such strategies.

### **Conclusions**

The main objective of this project was to develop an electronic recording system that enables the collection of data from community pharmacies regarding medication incidents.

Testing of the documentation system and research techniques in a larger group of pharmacies would allow more detailed examination of the factors that increase intervention rates and provide an estimate of the potential economic and health benefits of these activities.

## 2 Summary of Major Project Outcomes

Major Outcomes		Description/Comments	Core Deliverable Or Value Added
1	Development and validation of an intervention classification system suitable for use in a community pharmacy setting	Feedback received from stakeholders and reference groups. Novel web based validation methodology successfully utilized to achieve wide input.	Core deliverable and value added component in the web-based validation methodology.
2	Engagement of dispensing software vendors Phoenix Corp and PCA NU Systems and full integration of the DOCUMENT classification system into vendors software	Initial work carried out with Phoenix Corp. product REX. Iterative refinement of the intervention recording interface prior to final deployment in and feedback from community pharmacies.	Core deliverable
3	Development and deployment of an ICT infrastructure to permit secure and robust transfer of intervention records to a central data repository.	ICT structure based on the MediConnect and HealthConnect models to permit future integration. HL7 used to transmit clinical fields when appropriate standards have been defined.	Core deliverable
4	Implement pilot studies to confirm capacity to transfer intervention records from community pharmacy sites to the data repository.	Communication capability confirmed with REX and WiniFRED. Use of observers in the pilot rollout proved a highly successful engagement model. High quality training materials and programs developed to assist pharmacists in using the intervention recording software and understanding the use of the DOCUMENT classification system.	Core deliverable with value added component in terms of generation of comprehensive implementation materials and establishing a role for observers in the engagement of community pharmacy owners

5	Development of a Web Reporting Interface which allows easy access to a variety of reports generated from the 'live' intervention database.	This was seen as a useful tool for providing feedback to community pharmacies participating in future trials as well as allowing authorised parties immediate access to current data.	Value added project outcome
6	Development of techniques for data analysis of economic benefits.	Techniques for exploration of relationships between intervention characteristics and various aspects of pharmacy, pharmacist and workload have been developed and tested on over 500 interventions.	Value added project outcome
7	Development of the web based 'polling tool'.	Assists clinical panel in Delphi analysis of recorded intervention events to ascertain probable health economic value. Could also be used to run an interactive clinical panel with off-site panel members.	Value added project outcome

**Table 2-1: Summary of Major Project Outcomes**



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## **4 Introduction**

### ***4.1 Research Requirements***

The Tender document for this project identified the following key requirements.

#### **4.1.1 Anticipated aspects of the System**

These included the following features of the system:

- data standards and a dictionary
- address issues of privacy and confidentiality
- integrate with existing systems and software in pharmacy and other relevant health areas
- integrate with at least one major dispense software, preferably a Windows based product
- that only minimal keystrokes will be needed to record information
- link with existing incident reporting systems such as the Australian Adverse Drug Reaction Reporting System (ADRAC) coordinated by the Therapeutic Goods Administration (TGA) and AIMS hosted by the Australian Patient Safety Foundation (APSF)
- map to health information initiatives such as HealthConnect and consumer reporting
- able to provide feedback to pharmacy and other relevant health sectors
- be an ongoing system with voluntary reporting capacity
- provide de-identified data on request for specific issues of concern
- provide feedback for Business Improvement Plans and change management or workflow redesign

#### **4.1.2 Key requirements of the Project**

- develop and pilot a pharmacy based incident reporting and management system
- provide recommendations for national implementation
- based on results and recommendations, identify strategic processes for the implementation of a national system.

### ***4.2 Addressing the Research Requirements***

An electronic system was developed to collect data regarding the frequency and nature of clinical interventions undertaken by community pharmacists. Many of the anticipated outcomes of the system have been integrated into the architecture of the system developed.

The classification system that has been developed is easily modifiable and the electronic messaging process is simple and expandable. The messaging formats conform to HealthConnect and MediConnect standards and integrated seamlessly with two dispensing systems. De-identified data is held in a repository that can be interrogated to provide information relating to issues of concern or to provide feedback to individual pharmacist or pharmacies.

The system developed does not link in with existing patient safety databases, as the nature of the information gathered differs.

A research strategy was developed (see below Figure 4-1) which formed the basis for the project undertakings.

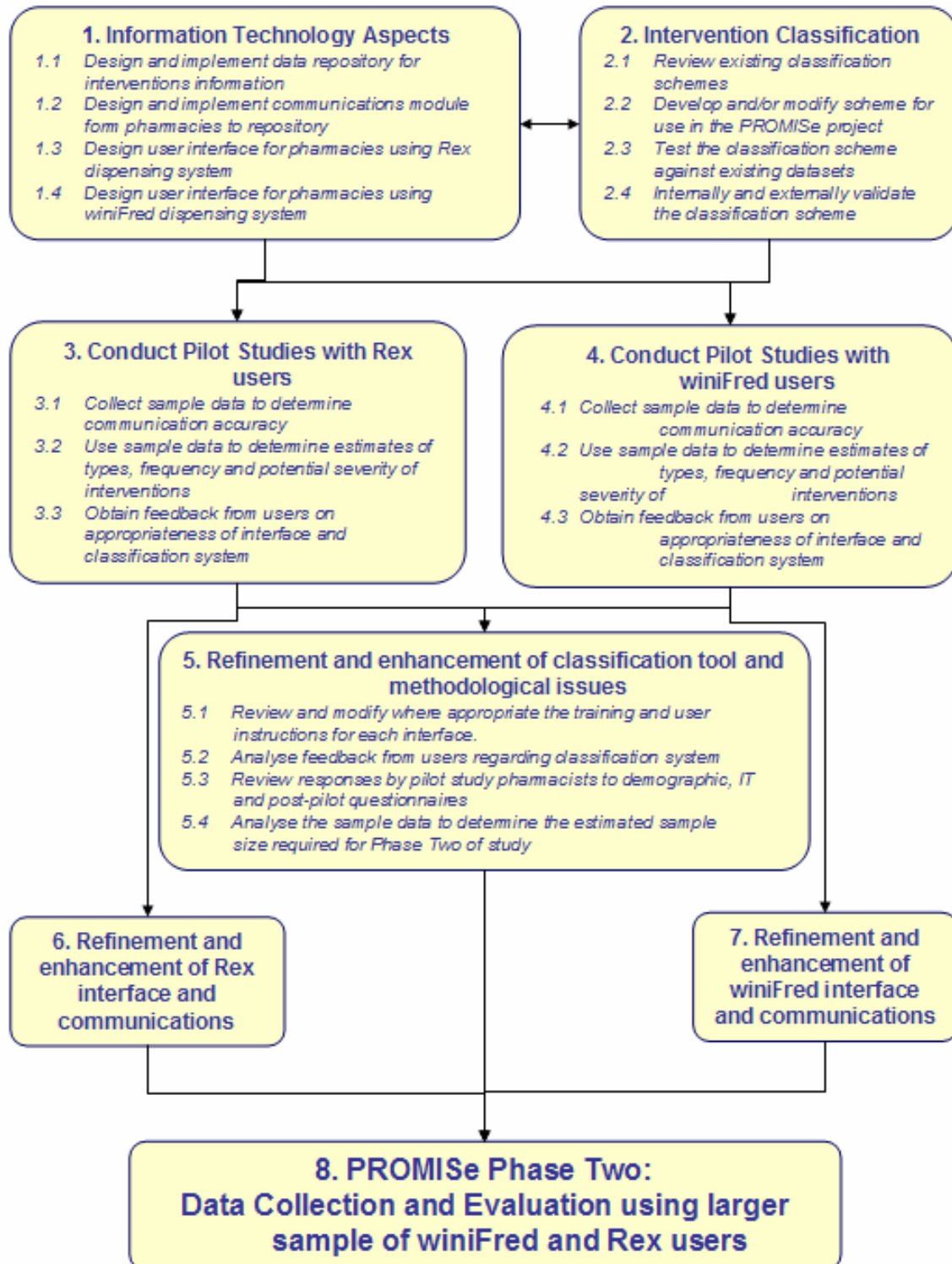


Figure 4-1 Research plan for PROMISe Project

## 5 Systems of Clinical Intervention Classification

A number of systems for categorisation of drug related problems and clinical activities exist in the literature. This section provides a summary of some of the major accepted systems available.

### 5.1 Definition of Clinical Interventions

The classification categories of clinical interventions used in a documentation system depend on the definition that is used for the term “clinical intervention”. There have been various definitions of this term in the literature in hospital and community based studies of interventions. There is a significant degree of disparity in these definitions.

The word intervention is derived from the: Latin *intervenire*, from *inter-* + *venire* to come, meaning to come between. The dictionary definitions <sup>12</sup>of the word intervene are:

- 1) to occur, fall, or come between points of time or events
- 2) to enter or appear as an irrelevant or extraneous feature or circumstance
- 3) to come in or between by way of hindrance or modification (eg *intervene* to stop a fight)
- 4) to occur or lie between two things
- 5a) to become a third party to a legal proceeding begun by others for the protection of an alleged interest
- 5b) to interfere usually by force or threat of force in another nation's internal affairs especially to compel or prevent an action

An intervention therefore implies either a space or period of time between two things or a stepping in to prevent a conflict.

Many physicians, doctors and other health professionals use the term intervention to mean something much closer to the dictionary definition, rather than the definition promulgated in the clinical pharmacy literature.

The definition in the pharmacy literature has a “warm fuzzy” feel to it, being described in various ways as things that pharmacists do to improve patient care. The word however, has stronger connotations for doctors and others than it does when being used in the pharmacy literature, and there is an unavoidable degree of emotional response to the use of the word “intervention”.

Many of the classification systems include definitions for types of interventions that really do not fit into the dictionary definition, and as a result the sometimes negative response to the use of the word “intervention” could be avoided if an alternative word was used. A more appropriate documentation system might only document the “true” (dictionary definition) interventions (i.e. the actual *changes* that occur in the patient's therapy as a result of the pharmacists actions), but also document the other clinical

or cognitive services that are undertaken that may potentially have led to these changes in drug therapy.

### **5.1.1 Clinical versus Administrative Interventions**

Some studies define an intervention as “any activity undertaken by the pharmacist that is intended to result in an improvement in patient care”, while others limit the term to actual changes in the patient's therapy. As a result of this disparity in what is included as a clinical intervention, there are significant differences in intervention rates in the literature. In many cases the rates are higher than the true *clinical* intervention rate, because many articles include interventions that on closer examination are not truly clinical.

For the purposes of this project, a classification system that accommodates clinical and non-clinical interventions and also other clinical services was required.

### **5.1.2 Factors Affecting Intervention Frequency and Quality**

There are a number of factors that could affect the nature and frequency of interventions and services provided in a community pharmacy. These can broadly be grouped into factors that are related to;

- a) The patient
- b) The drug involved
- c) The prescriber
- d) The pharmacist
- e) Workload issues

There are also additional factors which influence the rate of documentation. Aspects of each of these factors were assessed within the methodology of this project.

#### **5.1.2.1 Factors Affecting Documentation Rates and Literature Reported Rates of Interventions**

Although there are a number of studies of pharmacist interventions in hospital settings, information on the nature and significance of interventions in community settings (particularly Australian community pharmacy settings) is uncommon. Those papers that are available differ in their operational definitions of an intervention, and in their intervention reporting methods.

A wide range of intervention rates have been reported in the literature, from 0.43% to 8.6% (see Table 5-1). It is important to note that the denominator for some of these rate calculations varies. Although it is generally accepted that the intervention rate in hospitals is higher than in community, one has to remember that a medication chart includes many individual items, and so the intervention rate per item may be significantly lower than the reported rates per medication chart.

Many factors contribute to the wide range of intervention rates reported in these studies.

### Definition of intervention

The operational definition of an intervention will determine the nature of problems detected which will ultimately affect the intervention rate. Different individuals may have different interpretations of the definitions and this can lead to inconsistency in intervention documentation. For example, Beebee and Freitag,<sup>3</sup> defined an intervention as 'an occasion where a clinical pharmacist provided unsolicited advice to a medical officer if it was thought that a change in drug choice, dose, frequency, route or any other aspect of drug therapy was considered advisable'. Routine clarification (eg misspelt drug name) and addition of instruction (eg take with food) were not 'usually' reported as interventions. This meant that some pharmacists may have recorded such as intervention, and some did not.

Setting	Intervention Rate (per 100 items)
<i>Hospital Pharmacy</i>	
Beebee and Freitag <sup>3</sup>	1.57 (per medication chart reviews)
Hawkey et al <sup>4</sup>	2.9 (per prescriptions)
Reynolds et al <sup>5</sup>	4.1 (per new medication order)
Dooley et. al <sup>6</sup>	5.6 (per patient separations)
Tenni <sup>7</sup>	5.7 (per clinical services)
Hughes et al <sup>8</sup>	7.7 (per medication chart reviews)
Leversha <sup>9</sup>	8.4 (per medication chart reviews)
Tenni et al <sup>10</sup>	8.6 (per medication chart reviews)
<i>Community Pharmacy</i>	
Benrimoj et. al. <sup>111213</sup>	0.43 – 1.96 (per prescription items)
Whitehead et al <sup>14</sup>	0.64 (per prescribed item)
Hawksworth et al <sup>15</sup>	0.75 (per prescribed items)
Dobie and Rascati <sup>16</sup>	0.78 (per new prescriptions)
Hulls and Emmerton <sup>17</sup>	1.5 (per new prescriptions)
Caleo et al <sup>18</sup>	1.5 (per prescription items)
Rupp et al <sup>19</sup>	1.9 (per new prescriptions)
Rupp et al <sup>20</sup>	2.6 (per new prescriptions)

Table 5-1: Intervention rates from intervention studies

### Duration of the recording period

There are two aspects to the duration of the recording period. The first is the initial Hawthorne effect, where the pharmacist's awareness of particular activities is heightened. In effect, this may mean that the number of events documented more closely approaches the true number. Although, the longer the period of study, the more reliable the results, there can be considerable loss of enthusiasm for documentation.

Over a two week period, an intervention rate of 2.6 per 100 new prescriptions was found by Rupp et al.<sup>17</sup> In comparison, a similar study conducted two-and-a-half years later utilising the same methodology, but involving a larger sample size (89 community pharmacies compared to nine), yielded an intervention rate of 1.9 per 100 new prescriptions over an eight month period.<sup>20</sup>

**Professional Allowance and Education**

Benrimoj et. al.<sup>11,12,13</sup> studied the effect of education and a professional allowance on clinical intervention rates in community pharmacies. Three groups of 10 community pharmacies in New South Wales were randomly selected (A = control, B = professional fee and basic education, D = professional fee with no education) and a fourth group was conveniently sampled (C = professional fee and “advanced” education). Following a one-week education program, total intervention rates increased from 1.19% to 1.63% in group B, and from 1.57% to 1.96% in group C. The intervention rates documented by groups A and D fell during the same period (0.68% to 0.47%, and 0.59% to 0.43% respectively).

An important observation made in the study was the increase in proactive intervention rates made by groups B and C after the educational program. The proactive intervention rates of groups A and D either remained relatively static or fell during the same period.

Thus, the provision of a professional allowance, was not an incentive for pharmacists to undertake clinical interventions to a level different to the control group. This could suggest that despite being remunerated, other factors such as lack of ability, time management, and confidence or knowledge are limiting factors for documentation of community pharmacist interventions.

**5.1.2.2 Patient Factors**

The type of patient and the amount of information known about the patient has a major impact on the rate of intervention. Pharmacies that are involved with providing supply services to nursing homes or other long term care institutions will have a different pattern of clients compared to suburban pharmacies in areas where the population demographic is different. Elderly patients are more likely to have a wider range of medications prescribed, and may also be more likely to have issues with their medication.

Community pharmacists often lack important patient data such as medical history, biochemistry and therapeutic drug monitoring results. This has an impact on the detection of drug related problems, and also on the significance of the problems once detected. Tenni,<sup>8</sup> found that the availability of these data was associated with a high proportion of significant interventions in hospital pharmacist's interventions.

**5.1.2.3 Workload Factors**

Workload is commonly mentioned as a factor influencing the time available for documentation. Pharmacists frequently report not having enough time to document their activities, even if the system for documentation is relatively straight forward. There seems to be change management issues in creating a culture where documentation of activities becomes a priority. The introduction of a payment model may contribute to the uptake of documentation, but the results of a trial of a professional allowance for documentation of interventions are not encouraging.

The issue of correlating workload to intervention documentation rates has not been formally explored, however the data published in the Benrimoj<sup>11</sup> study indicated a decrease in intervention rates with an increase in prescription numbers.



Conceptually, one can envisage a difference in the impact of workload, depending on the type of intervention that is considered. “Reactive” intervention is a term used to describe interventions that are not initiated by the pharmacist, and would require attention regardless of the workload. For example an issue on a prescription that does not allow completion of the dispensing process, or a direct question from a prescriber or patient regarding a medication. A “Proactive” intervention, on the other hand would be initiated by the pharmacist and could be considered to be a little more “discretionary” and therefore more likely to be impacted upon by workload factors.

#### **5.1.2.4 Prescriber Factors**

There are a number of factors concerning the prescriber that may impact on the intervention rate. Prescribers may see a particular client demographic, and therefore have a range of medications that relate to that particular demographic. Also, prescribers develop a range of medications with which they become familiar and frequently prescribe, for example, the same particular ACE inhibitor, when considering a drug of that class. Particular habits relating to abbreviations and prescription writing may also be an issue, although computer-generated prescriptions are largely replacing hand-written prescriptions.

#### **5.1.2.5 Drug Factors**

The nature of the drug being prescribed has an impact on the frequency of drug related problems. There are a number of high risk medications that are associated with a higher frequency of drug-related problems; these medications often require close monitoring. In pharmacies which dispense a large number of these medications it was anticipated that the rate of drug related problems and hence interventions would be higher.

#### **5.1.2.6 Pharmacist Factors**

A number of aspects of the pharmacists background, training, confidence and experience may impact on the pharmacist's ability to identify a drug related problem and also the actions undertaken to resolve the problem,

### **5.1.3 Addressing these Factors in the PROMISe Project**

As discussed many factors affect the frequency of interventions and the frequency of documentation of clinical interventions in community pharmacy. These factors had an impact on the number of interventions documented during the PROMISe pilot study. They also are likely to have an ongoing impact during the implementation of a national system of recording. To minimise the difference between the recorded intervention rate and the true intervention rate required the development of a simple and efficient reporting system

One method of minimising the difference was to observe the pharmacist and “document over their shoulder”. This method has not been previously described in the literature and has the advantage that the activities could be recorded with no additional work by the pharmacist, and that all of the activities undertaken could be recorded. This and other methods to address various aspects of each of the factors affecting interventions were investigated in the pilot studies. These will be refined with a view to providing a more robust set of methods for a larger study of interventions in the second phase of the study.

## 5.2 Background Considerations for a Documentation System

The fundamental consideration in assessing the documentation systems was their ability to document the information required. Identifying and resolving drug related problems follows a basic process that is common in all practice settings (Figure 5-1)

The pharmacist is undertaking an activity (1) which brings to light the information that they recognise indicates the presence of a potential problem (2). The pharmacist seeks further information (3) (if necessary) to clarify the extent and possible causes of the problem, and once sufficient information is obtained they make a recommendation to resolve the problem (4). This recommendation is either accepted or rejected (5). The other, overarching aspect of the problem is the clinical significance of the problem.

### 5.2.1 Clinical Activity

This is the specific activity that the pharmacist actually undertakes that leads to the key piece of information that in turn leads to detection of the problem. The main activity is obviously dispensing, but particular steps within dispensing may be more relevant. The steps in dispensing that are more likely to lead to detection of problems have partially been looked at in the community setting. Previous work, by Whitehead et al.<sup>14</sup> has shown that interventions are more likely to occur at the initial “taking in” step of the prescription, and at the data entry (presumably when other history is seen) step of the process.

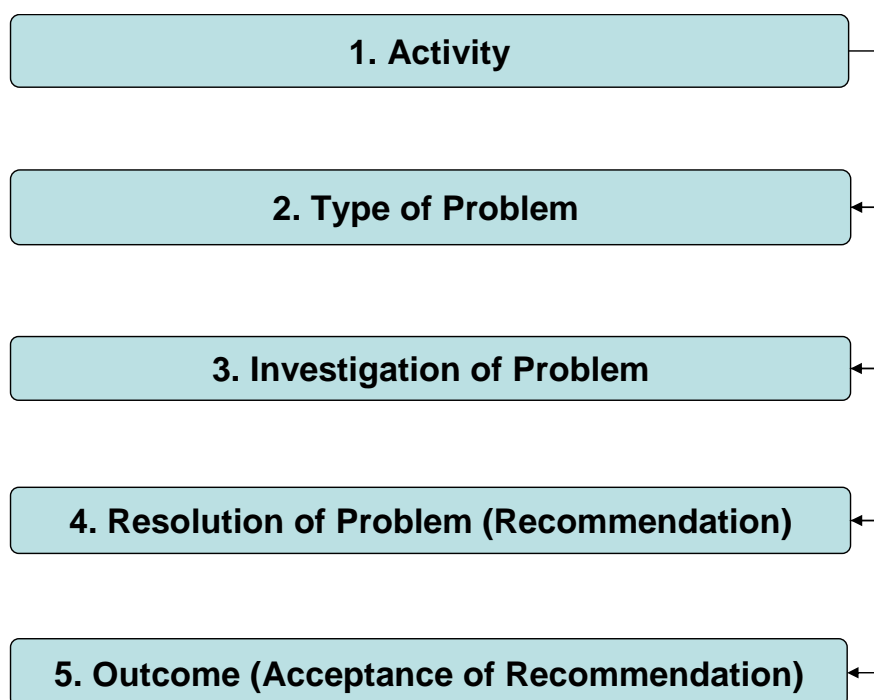


Figure 5-1: Process of detection and resolution of drug related problems

Not all pharmacies have exactly the same processes and checks in place. Variation in these processes may lead to a lower rate of detection of particular problems. The processes in place in each pharmacy are another factor in the variability of the rate of interventions in this study.

Other activities that may lead to the detection of problems include the many monitoring and screening activities undertaken in pharmacies.

### **5.2.2 Detection of the drug related problem:**

Having obtained the key piece of information (e.g. the fact that the patient says they are allergic to penicillin, or that they have previously had an ACEI ceased because of problems with a cough) the pharmacist identifies that there is a problem.

Many factors relating to the pharmacist's previous practice experience and clinical knowledge will impact on whether the information is recognised as being important.

### **5.2.3 Investigation of the problem:**

The investigation of the potential problem will reveal the necessity for action and also will clarify the potential cause of the problem. Once details of the problem are known, the most likely recommendation for resolution should become apparent.

In many situations, the investigation may lead to clarification that the potential problem doesn't warrant a recommendation or that it is not sufficiently serious to warrant resolution.

### **5.2.4 Suggested resolution of the problem**

A number of recommendations could be made to either the doctor or the patient after investigation of the problem. The appropriateness of these recommendations may vary, depending on the amount of information that pharmacist has available concerning the issue.

### **5.2.5 Outcome**

The outcome of the whole process is based on whether the recommendation that was made (after appropriate detection and investigation) was accepted.

## ***5.3 Review of existing classification schemes***

Different documentation systems use varying terminology to describe the steps outlined above, and different systems also have categories for different aspects of the process. Many systems describe only categories for types of problems, and without some detail of other aspects of the problem, the ability to use the information for the determination of health or economic benefits is limited.

The recording of interventions or drug related problems (DRPs) using pre-existing software is a relatively new concept to community pharmacy. Documentation of DRPs and adverse drug reactions (ADRs) has occurred, primarily in the hospital setting where actual problems and events are recorded, after an event has occurred. One of the aims of this project is to create a set of categories for recording of DRPs that will encompass not only actual events but also pre-emptive clinical measures taken by pharmacists to prevent potential DRPs and ADRs. There is also some interest in documenting the range of non-clinical situations and incidents. Thus the categorisation system will be required to document activities as well as drug related problems.

Further, given the discussion above, a system that documents each of the steps in the resolution of the problem is important, perhaps more important than the actual categories for types of interventions.

Categories have been used in previous studies to classify interventions. The aim of developing categories is to minimise the amount of work required to record an intervention, reducing the need for free text entry. Using categories is also

advantageous for statistical analysis as it allows patterns and problem areas in prescribing to be drawn from the data.

However, it is difficult to put all DRPs into one all-encompassing classification because there are countless possible events to include. All classifications have their limitations. Ideally one should be comprehensive, easy to understand, simple in construction and practical. It is important to classify DRPs so that they can be looked at in a structured way. Those with common origin can be grouped together; relationships can be drawn, recognised and explained.

This ultimately allows strategies to be put into place to prevent recurrence. In 2002, Schaefer described eight criteria that define a suitable coding system.<sup>21</sup>

- The coding system should be suitable not only for, sometimes very specific, scientific studies but for the broader implementation of pharmaceutical care in pharmacy.
- The suitable coding system must be easy to use in daily routine and consist of three parts:
  - the classification of drug-related problem,
  - the intervention taken to solve the problem and
  - the degree to which the problem could be solved.
- The coding system is preferably structured like a decision tree with main groups and subgroups, supporting later computer aided use
- The coding system should have an open structure able to include new problems, preferably on subgroup levels. Additional coding levels can be introduced without changing the basic structure and still allowing international comparison on the more aggregated levels of the main groups
- Problems defined should be clear and if possible leading to only one choice of coding. This will also require clear definitions of the categories.
- Coding should focus on the problem itself not on its cause or consequence. The coding system should also be suitable for the documentation necessary for the remuneration of the cognitive service.

More recently, van Mil et. al.<sup>22</sup> defined five major requirements for drug-related problem classifications as shown below.

- Classification should have a clear definition, both for the drug-related problem in general and for each drug-related problem category.
- the Classification should have a published validation.
- the Classification should be usable in practice and has been used in a published study.
- the Classification should have an open, hierarchical structure (with main groups, some groups, and an open structure to include new problems, preferably on subgroup levels).
- the Classification should have a focus on the drug use process and outcome and separate the problem itself from the cause.

With these principles in mind a review of the existing classification system was conducted.

### **5.3.1 Hepler and Strand**

A commonly used form of classification developed by Hepler and Strand,<sup>23</sup> divides the types of drug related problems into eight distinct categories into which the majority of clinically significant problems would fit.

- **Untreated Indication**  
The patient has a medical problem that requires drug therapy but is not receiving medication for that indication
- **Improper Drug Selection**  
The patient has a drug indication but is taking the wrong drug
- **Sub-Therapeutic Dose**  
The patient has a medical problem that is being treated with too little of the correct drug
- **Failure to receive drugs**  
The patient has a medical problem that is the result of not receiving a drug (e.g. for pharmaceutical, psychological, sociological or economic reasons)
- **Overdosage**  
The patient has a medical problem that is being treated with too much of the correct drug (i.e. toxicity)
- **Adverse Drug Reaction**  
The patient has a medical problem that is the result of an adverse drug reaction or adverse drug effect
- **Drug Interaction**  
The patient has a medical problem that is the result of a drug-drug, drug-food or drug-laboratory interaction
- **Drug Use Without Indication**  
The patient is taking a drug for no medically valid reason

Although in the initial publication these main categories were not subdivided, it is possible to divide these categories into sub-categories to be able to record more specific detail about sub optimal therapy.

A number of published classification systems have utilised the initial major categories in this publication and added more specific subcategories, depending on the purpose of the research.

### **5.3.2 Pharmaceutical Care Network of Europe (PCNE) Classification System**

PCNE was established in 1994 with the objective of “developing pharmacy along the lines of pharmaceutical care in the involved countries through establishment and accomplishment of projects that are carried out in more countries simultaneously”. Further information may be found at the PCNE website, [www.pcne.org](http://www.pcne.org).

Pharmaceutical Care Network Europe (PCNE) has developed a system for classifying DRPs. The purpose of the classification scheme is to aid research and documentation of the nature, prevalence and incidence of DRPs. The classification system is validated and updated regularly—the current iteration is Version 5.

The basic classification has 6 primary domains for Problems, 6 primary domains for Causes and 5 primary domains for Interventions. Recently, a new set of domains has been added to indicate if or to what extent the problem has been solved (Outcome).

On a more detailed level there are 21 grouped sub domains for problems, 33 grouped sub domains for causes, 17 grouped sub domains for interventions and 3 sub domains for outcome. Those sub domains can be regarded as explanatory for the principal domains.

The PCNE classification separates the real problem (that affects or is going to affect the outcome) from its cause. Often, a certain type of error causes such problems, eg prescribing errors, drug-use errors or administration errors. However, there might be no error at all involved.

The problem and cause main domains are listed below.

Problem domains

- Adverse reaction(s)
- Drug Choice Problem
- Dosing problem
- Drug Use/Administration Problem
- Interactions
- Other

Cause domains

- The cause is usually the behaviour that causes to the problem. A cause, or a combination of causes will usually lead to one or more interventions.
- Drug/Dose Selection
- Drug Use Process
- Information
- Patient/Psychological
- (Pharmacy) Logistics
- Other

A more detailed list, which includes sub-domains, is shown in Appendix 13.2.

PCNE recommends the classification can be used in two ways, depending on the level of information needed.

If only the main domains are used, there is in generally enough information for research purposes

If the system is used for documenting pharmaceutical care activities in practice, the sub-domains can be used.

The classification scheme has been validated, and has sufficient detail to enable classification of most types of drug related problems. It does not however have the facility to document non-clinical activities and situations where clinical services (eg screening for diabetes) are provided on a “pre-emptive” basis.

### **5.3.3 The Clinical Pharmacy Activity Classification System (CPACS)**

This system is a modification of the PCNE system above, designed specifically by a group at the Faculty of Pharmacy, Sydney University for analysis of a project which involved medication management review. The system is based on

Findings	7 major categories, of with 40 subcategories,
Recommendations	major categories, with 33 subcategories
Uptake	7 categories
Actions	major categories, with 37 subcategories
Outcomes	major categories, with 10 subcategories.

The pharmacist makes a finding and they can then make a recommendation either to the patient or the prescriber. The patient or prescriber can then either accept or reject the recommendation (this is the uptake), and an action is then taken by either the patient or the prescriber. A final outcome is then included, which is based on eventual drug, patient or prescriber related outcomes after the recommendation is implemented or not.

Although the classification includes a number of new subcategories compared to the PCNE system, is fundamentally similar with the exception of the outcome section. The major categories are broad and useful for medication management situations. The number of subcategories makes this a useful tool for research situations, but would probably be too cumbersome to be used in a community pharmacy setting. At the time of writing this classification scheme has only been published in abstract form and involves researchers using the scheme on a retrospective basis.

Full details of this scheme are shown in Appendix 13.3

### **5.3.4 NRLS Service Dataset (Community Pharmacy), 2003/4 Release**

In the United Kingdom, the National Patient Safety Agency (NPSA) coordinates a national effort for reporting, analysing and learning from adverse events and ‘near misses’ occurring in NHS-funded care. NPSA are developing a National Reporting and Learning System (NRLS) as a primary mechanism to collect information on patient safety incidents, including medication incidents. The NRLS Service Dataset defines the questions and reply options that will be used to collect this information.

The NPSA began rolling out the NRLS in November 2003. Information provided to the NPSA is stored anonymously and analysed to identify national patterns, to identify patient safety priorities and to develop practical solutions.

The NPSA has completed a testing and development phase for the NRLS with the aim of testing the following.

The capability of an electronic reporting form to provide a standardised method for collecting information, and the best way to tailor the form to each healthcare sector

The questions the NPSA should ask NHS organisations and staff to elicit the maximum amount of meaningful national learning (known as the dataset)

A process by which the data can be reported to the NPSA using Internet technology, and the use of the Internet to provide an alternative means of reporting for those NHS care providers that do not have access to the Internet.

Several NRLS datasets have been developed for different sectors of the health care industry. An NRLS dataset has been developed for community pharmacy. The portion of the dataset relevant to this project has been reproduced in Appendix 13.4. MD05-MD15 are titled '*drug details*' and relate to the medication.

The dataset is broken up into sections with questions specified in each section. The relevant sections of the dataset for medication-related incidents are sections MD01 to MD15. More specifically, the sections MD01 to MD03 relate to categorisation of the incident; these sections are termed '*what happened*'. MD02 terms mainly state the problem while MD03 terms relate more to the causes.

### **5.3.5 NCC MERP Taxonomy**

A taxonomy for classifying medication errors has been released by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). The 17-member Council has worked on its "Taxonomy of Medication Errors" over a period of three years. This tool has been designed to provide standard language and structure of medication error-related data for use in developing databases to analyse medication error reports. The taxonomy itself is not intended to be a reporting system or form but rather is a tool to categorise and analyse reports of medication errors for health care organisations with established reporting systems and forms. It also can be used to analyse medication error reports and abstract data elements. The taxonomy can be used to design local reporting forms and accompanying databases

The taxonomy's comprehensiveness reflects the complexity and system realities associated with medication errors. It consists of eight major categories:

10. Patient information
20. Medication error event
30. Patient outcome
50. Product information
60. Personnel involved
70. Type of medication error
80. Causes
90. Contributing factors

Each category contains multiple fields and data choices. Some fields require selection from a defined list of choices and other fields require entry of free text.

Several groups contributed significantly to development of the taxonomy, including the US Food & Drug Administration, the American Society of Health-System Pharmacists and the American Society of Consultant Pharmacists.

The sections relating to categorisation of medication errors are found under the following domains: Type of medication error, Causes and Contributing factors. The



taxonomy also describes categories for Patient outcome. These domains and their sub-domains are shown in Appendix [13.5](#)

### 5.3.6 ADRAC

The Adverse Drug Reactions Advisory Committee (ADRAC) encourages the reporting of all suspected adverse reactions to drugs and other medicinal substances, including herbal, traditional or alternative remedies. Reports of suspected adverse drug reactions are made by mailing a prepaid reporting form, available from the website or by lodging an electronic report. Although some aspects of the information collected in this project could be mapped across to ADRAC, the use of the reporting system would only enable selective reporting of adverse events and not other clinical events.

### 5.3.7 AIMS

The Australian Incident Monitoring System (AIMS) is a system that provides both incident reporting and incident monitoring services to 'health units', and has been developed primarily for acute care facilities. The system uses a single generic form to collect the data for both reporting and monitoring. The information collected is used to develop corrective strategies to try to prevent similar problems in the future.

The system documents both *actual* and *potential* problems, in contrast to ADRAC which records actual ADRs. In AIMS, an incident is defined as "any event or circumstance that *could have* or did cause unplanned harm, suffering, loss or damage."

The system attempts to provide a mechanism for identifying problems and their causes across the entire health care system. Many Australian hospitals use the AIMS system (or a modified version of the system) to document and monitor incidents, including medication incidents and pharmacy interventions. However, the form used to collect the data has limited relevance for documenting and reporting DRPs in the community pharmacy setting.

### 5.3.8 The Society of Hospital Pharmacists of Australia (SHPA) System

The convention adopted in these standards of practice is that an intervention is defined as any action by a pharmacist that directly results in a change in patient management or therapy. The SHPA specialty practice committee in clinical pharmacy has recommended that when documenting pharmacist interventions the data to be recorded should include:

- Drugs involved;
- Brief description of the intervention;
- Patient identifier;
- Date, pharmacist and medical/surgical unit, to allow follow-up

The SHPA also advises that where possible a risk assessment should be assigned and consideration given to formal reporting to selected institutional quality forums of those interventions of high and extreme risk.

The classification system is fundamentally related to four categories of activity, being:

- Therapeutic or prescribing recommendation not related to an error
- Therapeutic or prescribing recommendation related to an error
- Technical deficiency, cost or formulary requirement
- Other

One aspect of this categorisation system is that the clinical significance is also associated with a probability of occurrence. This overcomes one of the common problems associated with categorisation systems, that of variability in clinical significance categorisation. See details in Appendix 13.6.

#### **5.3.9 PI-Doc**

A hierarchical system for problem and intervention documentation was developed in Germany with an emphasis on the user-friendliness in community pharmacy practice.<sup>21</sup> The system is based on a categorisation system for problems and interventions only. The terminology of this German system is that the interventions referred to may in other systems be termed actions or investigations. In this system, the interventions are related to the type of problem, which would allow for automatic selection (or at least filtering) of interventions for a particular problem.

Full details of the coding system are shown in Appendix 13.7 Other Systems Reviewed Elsewhere

A number of other classification schemes were reviewed recently in the article by van Mil.<sup>22</sup> None of these have been tested in the Australian community pharmacy setting, and none of them support the addition of pre-emptive clinical activities or non-clinical activities.

### ***5.4 Comparison of Different Classification Systems***

The existing systems each have similarities and differences. Table 5-2 below indicates various characteristics of each system. It is clear that none of these systems meets all the requirements for this particular project.

# PROMISe Phase One Final Report

System	Clear Definitions	Published Validation	Useable in Practice*	Open Hierarchical structure	Separates problem from actions etc.	Supports “pre-emptive” activities	Supports Non-clinical Activities
Hepler and Strand	Y	N	Y	N	N	N	N
PCNE	Y	Y	N	Y	Y	N	N
CPACS	Y	N	N	Y	Y	N	N
NRLS	Y	N	N	N	N	N	N
NCC	Y	N	N	N	N	N	N
ADRAC	Y	N	Y	N	N	N	N
AIMS	Y	N	Y	N	N	N	N
SHPA	Y	N	Y	N	N	N	N
PI-Doc	N	N	Y	Y	Y	N	N

\* Focussed on useability in community pharmacy practice

**Table 5-2 Comparison of intervention classification systems modified from criteria from Van Mil <sup>22</sup>**

## **6 Development of scheme for use in the PROMISe project**

The most widely used scheme in the drug-related problems literature is that of Hepler and Strand. This has been modified by a number of authors in the international community and the main categories of interventions in this system seemed the most intuitive of those available. The Hepler and Strand system however, does not include coding for activities intended to resolve the drug-related problem (one that is, the actions and recommendations taken and made by the pharmacists). This was felt to be a major requirement for this project, as the activities and outcomes of recommendations would have direct consequences in terms of economic impact.

Of all the systems discussed above, the PCNE system came closest to meeting the requirements; however there were a number of shortcomings of this system.

Firstly, the system requires assessment of the cause of the drug-related problem, 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 the project team and representatives of a number of pharmacy organisations was held on the 19<sup>th</sup> December 2003 in order to clarify the intervention classification system which would be used in the project.

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 intervention 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 to use of algorithms, drop-down menus and touch-screens were employed.

A number of classification schemes discussed above were presented and details of these were circulated prior to the meeting. Several of the schemes involved a degree of interpretation by the pharmacist who was recording the intervention, and as discussed previously, some of the schemes involved multiple levels of classification.

Again it was felt that it would be ideal to keep the information and classification relatively simple, whilst ensuring that sufficient in detail was provided to enable meaningful analysis of the information when it is received. 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 constraints and required outputs of this project. The PROMISe project team developed a web site for feedback on these classification systems and utilised feedback to modify the final system.

A scheme based on the types of problems identified by Hepler and Strand was initially developed in late December 2003 and early January 2004. This was termed the DOCUMENT classification system and was chosen as the starting point for the development of the system for the final project. Significant modifications as the result of feedback at the stakeholder meeting and subsequent feedback through AusPharmList and testing by the PROMISe web site resulted in several iterations since that meeting.

### **6.1 The D.O.C.U.M.E.N.T. classification system**

This system was developed with seven main categories, 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      |

The DOCUMENT classification system covers each of the categories from Hepler and Strand and also adds other categories specific to the purposes of the project.

The logical sequence of events undertaken in interventions, were incorporated into the recording system developed.

- The pharmacists decision about what type of problem or issue they are dealing with
- The investigation and or queries undertaken to determine to clarify the problem
- The recommendations made by the pharmacist to resolve the issue
- The acceptance of the recommendations made
- Consideration of the potential severity of the situation

Codes, categories and definitions relevant to these events have been developed

- Type of activity/ problem
- Action(s) taken to clarify the extent of the problem
- Recommendation(s) made to resolve the problem
- Outcome (whether the recommendation was accepted)
- The clinical significance of the activity

## 6.2 Type of Activity or Problem

The types of activities as categorised by the DOCUMENT system is summarised in Table 6-1. The subcategories were determined following testing of the categorisation system on the information provided from a previous community pharmacist Intervention Documentation project.<sup>24</sup> A number of subcategories which existed in the previous version of the classification system were “rolled up “ into other categorisations to simplify the number of selections available.

Category (Type)		Sub-Type	Subtype Code
D	Drug selection	Duplication	D1
		Drug Interaction	D2
		Wrong drug	D3
		Wrong dosage form	D4
		Previous ADR/allergy	D5
		Other Drug selection problem (Specify)	D0
O	Over or underdose prescribed	Dose too high	O1
		Dose too low prescribed	O2
		Incorrect frequency	O3
		Other Dose related Problem (Specify)	O0
C	Compliance	Potential drug abuse	C1
		Taking too little	C2
		Taking too much	C3
		Difficulty using dosage form	C4
		Other Compliance problem (Specify)	C0
U	Untreated indications	Condition not adequately treated	U1
		Preventive therapy required	U2
		Other Untreated indication problem (Specify)	U0
M	Monitoring required	Drug levels	M1
		Laboratory Monitoring	M2
		Non-Laboratory monitoring	M3
		Other Monitoring problem (Specify)	M0
E	Education or Information	Patient drug information requests	E1
		Confusion about therapy or condition	E2
		Demonstration of device	E3
		Disease management or advice	E4
		Other Education/Information problem (Specify)	E0
N	Non-clinical	Not sub-classified	N0
T	Toxicity or Adverse reaction	Caused by dose too high	T1
		Caused by drug interaction	T2
		Other Toxicity problem (Specify)	T0

Table 6-1 Categories and subcategories for type of clinical problem

Each of the subtypes have been clarified with scope notes and examples of when the code would be most appropriate to use. The complete documentation system with examples and the scope notes can be found in Appendix 13.8. 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.

### ***6.3 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 6-2 below:

Action	Code
Investigation: Written material	A1
Investigation: Software	A2
Investigation: Internet	A3
Contacted Drug Information Service	A4
Investigation: Other (specify)	A5
Contacted prescriber	A6
Discussion with patient or carer	A7
Corrected without discussion	A8
Other Action (specify)	A0

**Table 6-2 Codes and categories for actions to clarify the drug related problem**

### ***6.4 Recommendations to Resolve the Problem***

The codes and categories for recommendations to resolve the drug-related problems were determined following evaluation of clinical interventions from the previous University of Tasmania community pharmacist intervention dataset<sup>24</sup>. 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 6-3.

Recommendation	Code
Education/counselling session	R1
Dose change	R2
Drug change	R3
Drug cessation	R4
Drug formulation change	R5
Monitoring: non-laboratory	R6
Drug addition	R7
Drug brand change	R8
Dose frequency/schedule change	R9
Refer to prescriber	R10
Refer to hospital	R11
Monitoring: Laboratory test	R12
Refer for medication review	R13
Commence dose administration aid	R14
No recommendation necessary	R15
Other recommendation (specify)	R0

**Table 6-3: Codes and categories for recommendations to resolve the drug related problem**

### **6.5 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 drug-related problem, a category for partial acceptance was created to allow for the situation where only some of the recommendations made by a pharmacist were accepted.

### **6.6 Clinical Significance**

Four levels of clinical significance (and a nil significance) level were chosen based on analysis of the previous intervention study. In the previous study, three levels of significance were used, with the result that the majority of interventions were classified by the pharmacist as of moderate clinical significance (see Table 6-4)

significance - pharmacist	No	%
High + - Potentially Prevented Hospital Admission	12	19.7%
Moderate - Improvement in Therapy	46	75.4%
Low - Cost saving or Information Only	3	4.9%
Total	61	100.0%

**Table 6-4: Clinical Significance of Interventions as reported in Previous UTAS study**



Re-analysis of the previous UTAS study, in particular considering the clinical significance of the events, provided information that was necessary for setting up the reclassification system. Of the 12 interventions listed in Table 6-4 rated as high significance, only four were considered as highly significant based on a review by a consultant pharmacist. Four of the remainder were downgraded to moderate significance, and four were not classified due to lack of sufficient information. This degree of misclassification would have significant consequences on the final economic evaluation for the highly significant category as it would be “adulterated” by interventions of lower significance (and therefore of lower potential benefit).

By introducing a further level of significance, the effects of any misclassification (that is interventions with moderate significance being classified high significance) would be reduced. Further, by providing clear guidelines and examples of the various levels of significance, more appropriate classification was achieved. Table 6-5 summarises the codes and definitions of the clinical significance categories chosen for this project.

Significance	Code	Scope Notes
Nil	S0	<p>When to Use: When there is no consequence to the patient.</p> <p>Examples: Prescription incomplete, contacted doctor and obtained directions</p>
Low	S1	<p>When to Use: When the consequence to the patient are related to costs or information only</p> <p>Examples: Pramin substituted for Maxolon Provided CMI on <i>Fosamax</i> at request of patient.</p>
Mild	S2	<p>When to Use: When the 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.</p> <p>Examples: Patient commences on a codeine based analgesic and you recommend to take prophylactic stool softeners</p>
Moderate	S3	<p>When to Use: 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.</p> <p>Examples: The patient was inadvertently taking twice the dose of sulphonylurea tablets and would have developed hypoglycaemia that required a trip to the GP to treat the symptoms.</p>
High	S4	<p>When to Use: 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.</p> <p>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 been 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.</p> <p>Examples: The patient was inadvertently taking double the dose of amiodarone and was taking warfarin. Presented with bleeding.</p>

**Table 6-5 Categories and codes for clinical significance of interventions**

## ***6.7 Test of the Classification Scheme against Existing Datasets***

In order to determine the appropriateness of the categories chosen for the classification system, the system was applied to a set of data from a previous project undertaken in community pharmacies in Tasmania.

There were 464 documentation episodes to consider, and initially each episode was reviewed to determine if the situation that occurred could be adequately reconstructed from the information available. In 277 of the episodes, this was possible, and these formed the basis of the testing of the classification system. For each episode a Type (DOCUMENT Code), Action, Recommendation, Significance and Outcome was assigned.

There were some limitations to re-classifying the data on a retrospective basis. Firstly, it was not possible to assign investigation (action) codes for any of these interventions as the degree of detail is insufficient to know what the pharmacist did to investigate the problem. However, the actions in some cases could be inferred from the situation, rather than clearly stated by the documenting pharmacist. Only one action and one recommendation have been assigned to each situation, although in the final documentation system, multiple actions and recommendations were possible.

Version 14 of DOCUMENT was initially used to test the categorisation system (see Appendix 13.9). This version had a much larger selection of subcategories than the final version. In assigning the Type code for each of these interventions, only 24 of the 41 codes available were used (see Table 6-6 below). As a result, there was a significant cull and reordering by frequency of the DOCUMENT codes which resulted in the newer versions.

Document Code	Category	Sub-category	Number
N0	Non-clinical	Not sub-classified	72
E2	Education/Information	Patient requests information	30
D1	Drug choice	Duplication of drug or therapeutic class	17
U2	Untreated indications	Condition or health problem not adequately treated or controlled	17
O2	Over/underdose prescribed	Too low dose prescribed	16
O1	Over/underdose prescribed	Too high dose prescribed	16
D9	Drug choice	Interaction with existing therapy	15
C7	Compliance	Potential drug misuse/abuse situation	12
T0	Toxicity/Adverse reaction	Other Toxicity/ADR related Problem (Specify in Free Text Box)	12
D3	Drug choice	Wrong drug prescribed in error	11
C1	Compliance	Confusion about therapy/condition	11
E3	Education/Information	Demonstration of therapeutic device	8
E1	Education/Information	Disease management/health care advice for patient	7
D2	Drug choice	Incorrect or inappropriate dosage form	6
T2	Toxicity/Adverse reaction	Actual/Suspected adverse reaction due to drug or disease interaction	6
C3	Compliance	Taking excessive doses/using for excessive duration	4
O3	Over/underdose prescribed	Incorrect frequency prescribed	3
C4	Compliance	Unwillingness to use drug	3
D8	Drug choice	Pre-existing severe ADR/allergy	3
E5	Education/Information	OTC medication advice	2
U1	Untreated indications	Preventive therapy required as a result of existing health problems, drug therapy or risk factors	2
C5	Compliance	Inability to appropriately administer drug	2
O0	Over/underdose prescribed	Other Over/underdose related Problem (Specify in Free Text Box)	1
C2	Compliance	Missing doses/inadequate duration of therapy	1

**Table 6-6 Frequency of subcategories within the Previous UTAS data**

Using the information obtained from reclassifying the previous data, the coding system was significantly simplified. The information obtained also allowed clarification of the requirements for each subtype and comprehensive scope notes were written for each subtype and code in the documentation system.

## 7 Validation of the Documentation System

In order to validate the classification system, 20 web-based scenarios were developed that included a problem. The classification system was converted into a web-based tool and it was then possible for pharmacists to select categories and view help files for each scenario.

The aim of the validation was to determine if pharmacists could use the classification system to allocate similar categories to the same scenario.

### 7.1 The PROMISe (DOCUMENT Classification) Validation Web Interface

The website was constructed to provide the user with a brief background to the validation process. The web-site included a demographics questionnaire. Information obtained about the demographics could then be used to link to results of the validation exercise.

In the following sequence of figures (Figure 7-1 through to Figure 7-7, the interface is shown. Initially the process is introduced and an example scenario provided

In Figure 7-4, the pop-up help screen is shown, providing information on the codes for classification of the scenario. These help files are available at all stages of the classification. From Figure 7-5 to Figure 7-7 the selection screens are shown for action, recommendation, and significance. For the purposes of validation, outcome was not included.

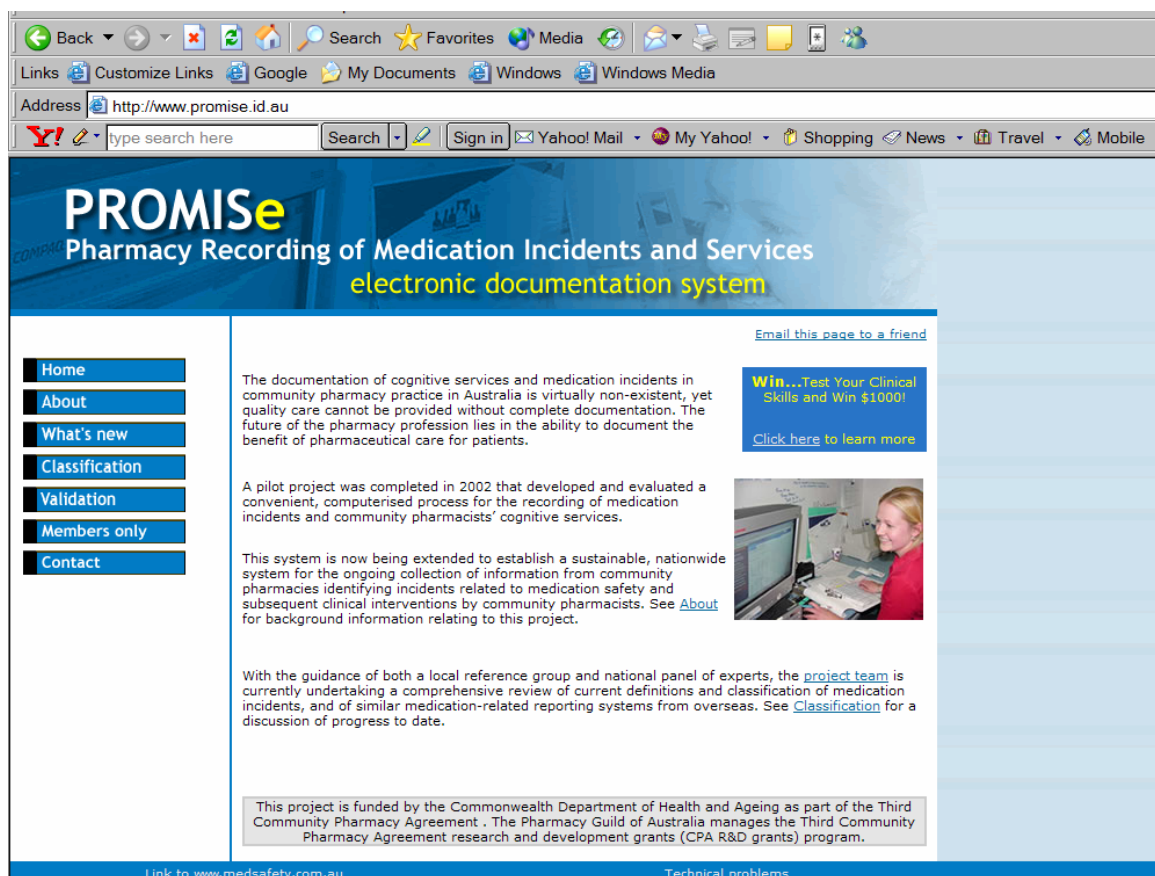


Figure 7-1 Promise Validation Website: Screenshot 1

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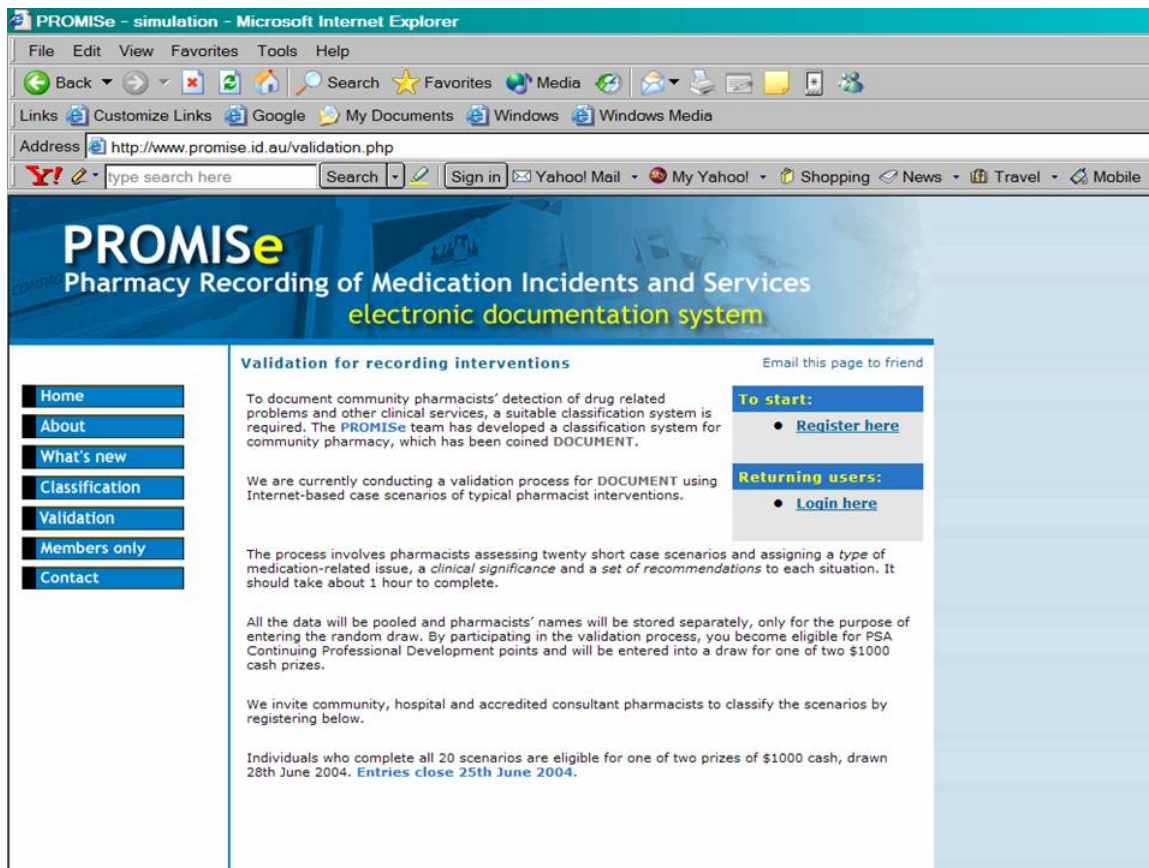


Figure 7-2: Promise Validation Website: Screenshot 2

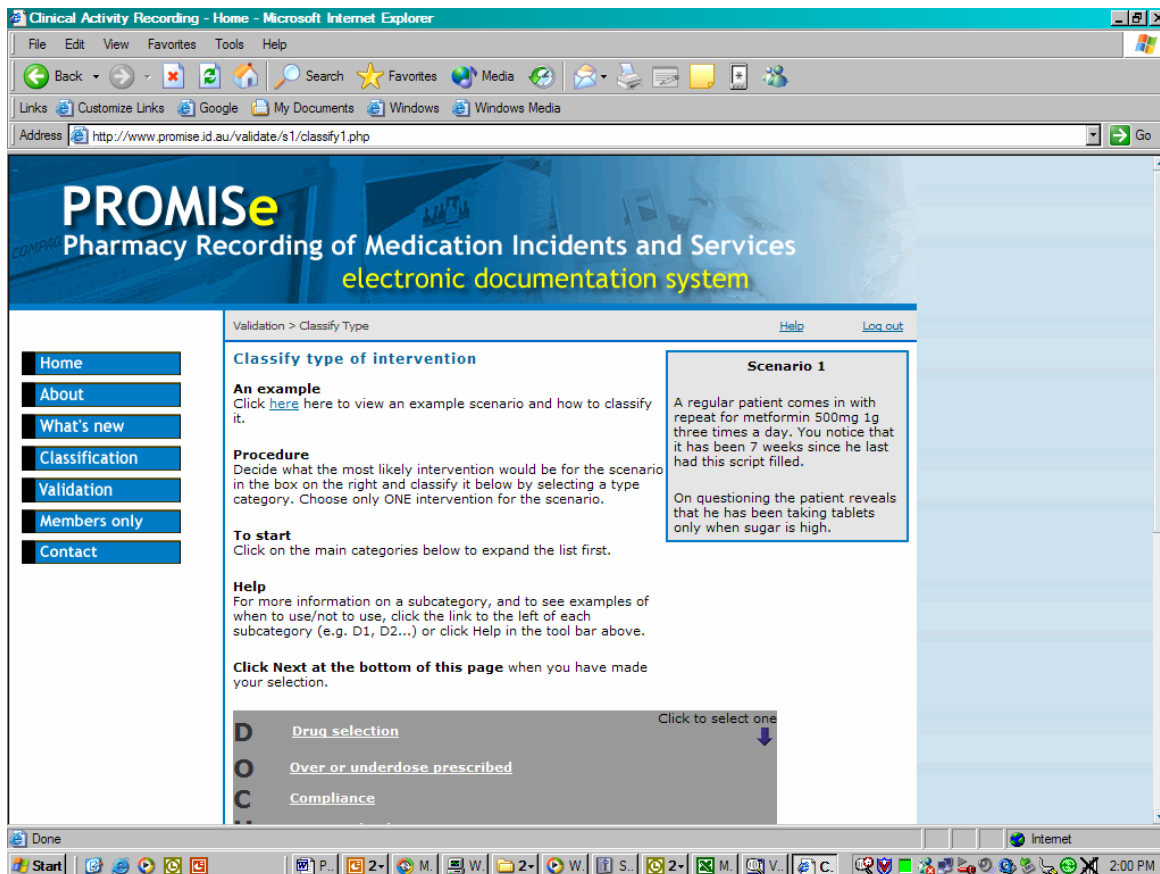


Figure 7-3 Promise Validation Website: Screenshot 3

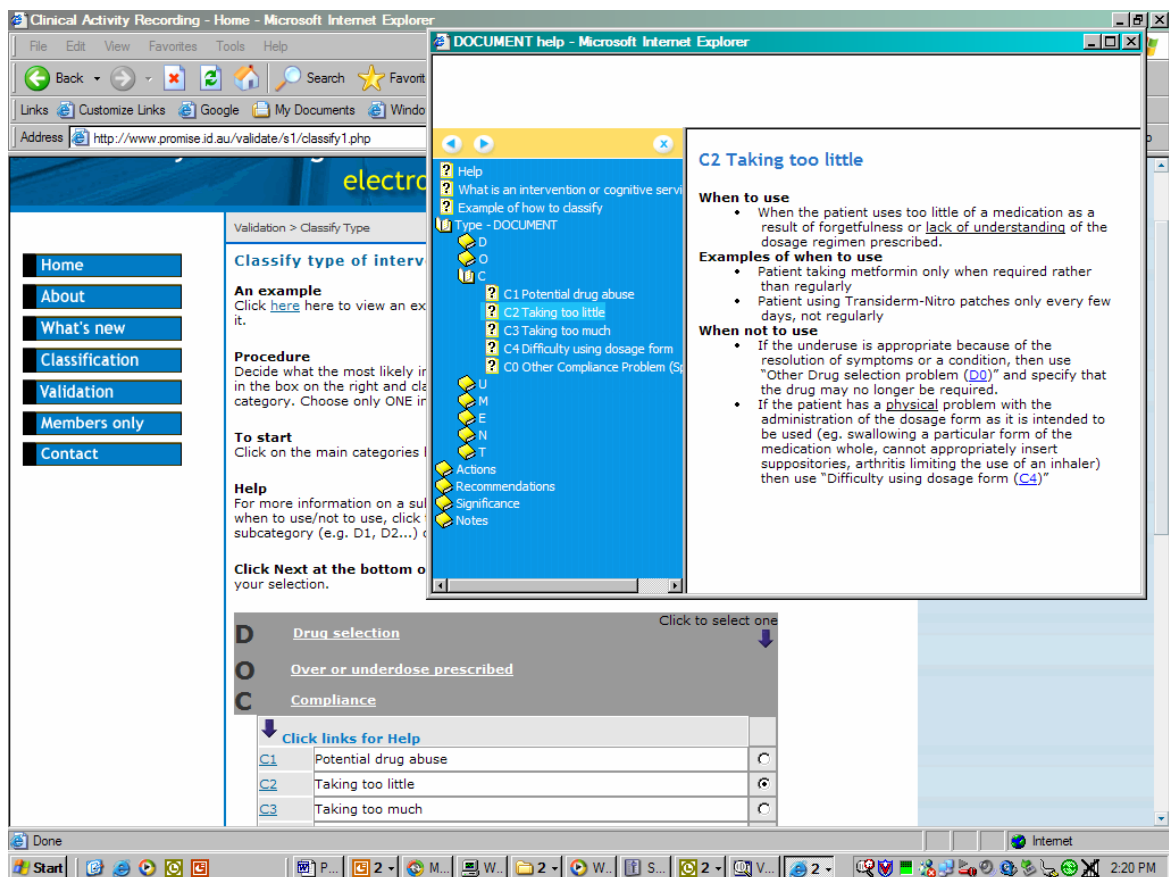


Figure 7-4 Promise Validation Website: Screenshot 4

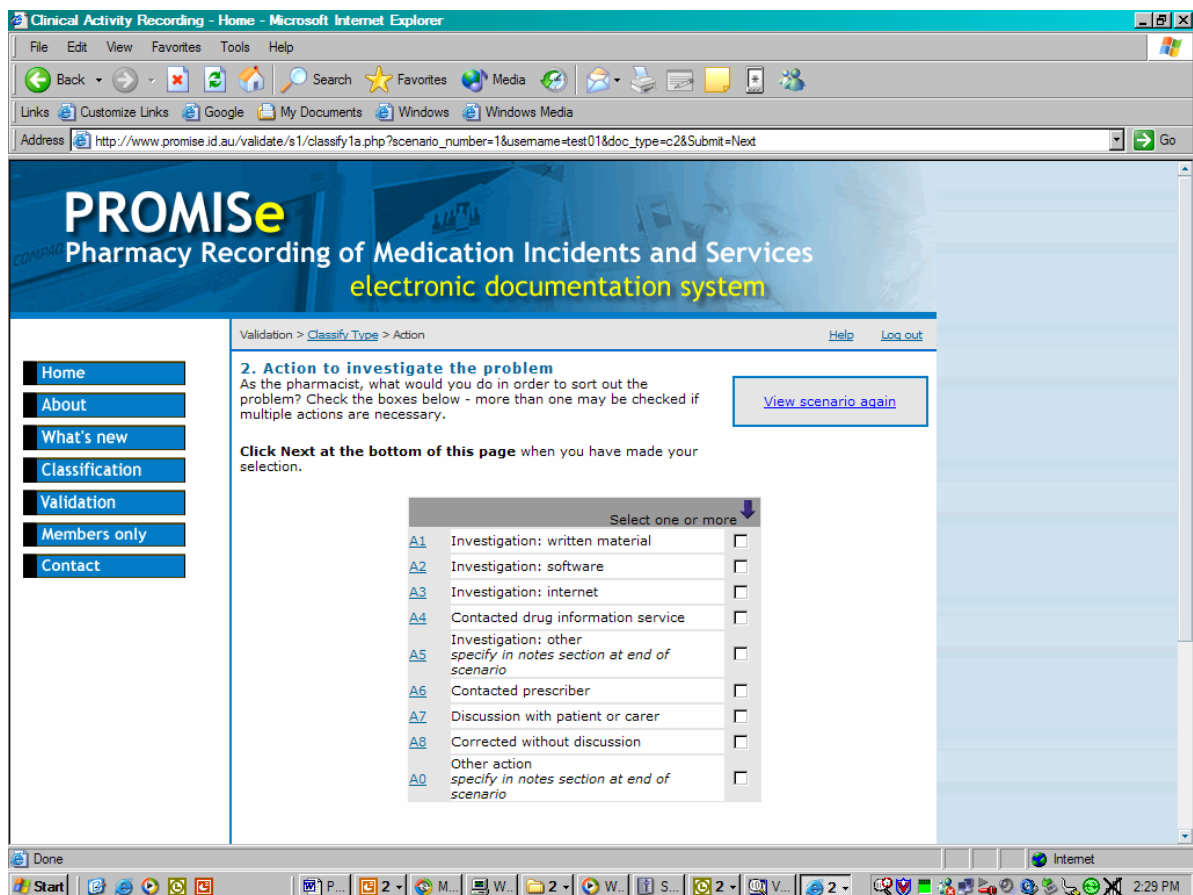


Figure 7-5 Promise Validation Website: Screenshot 5



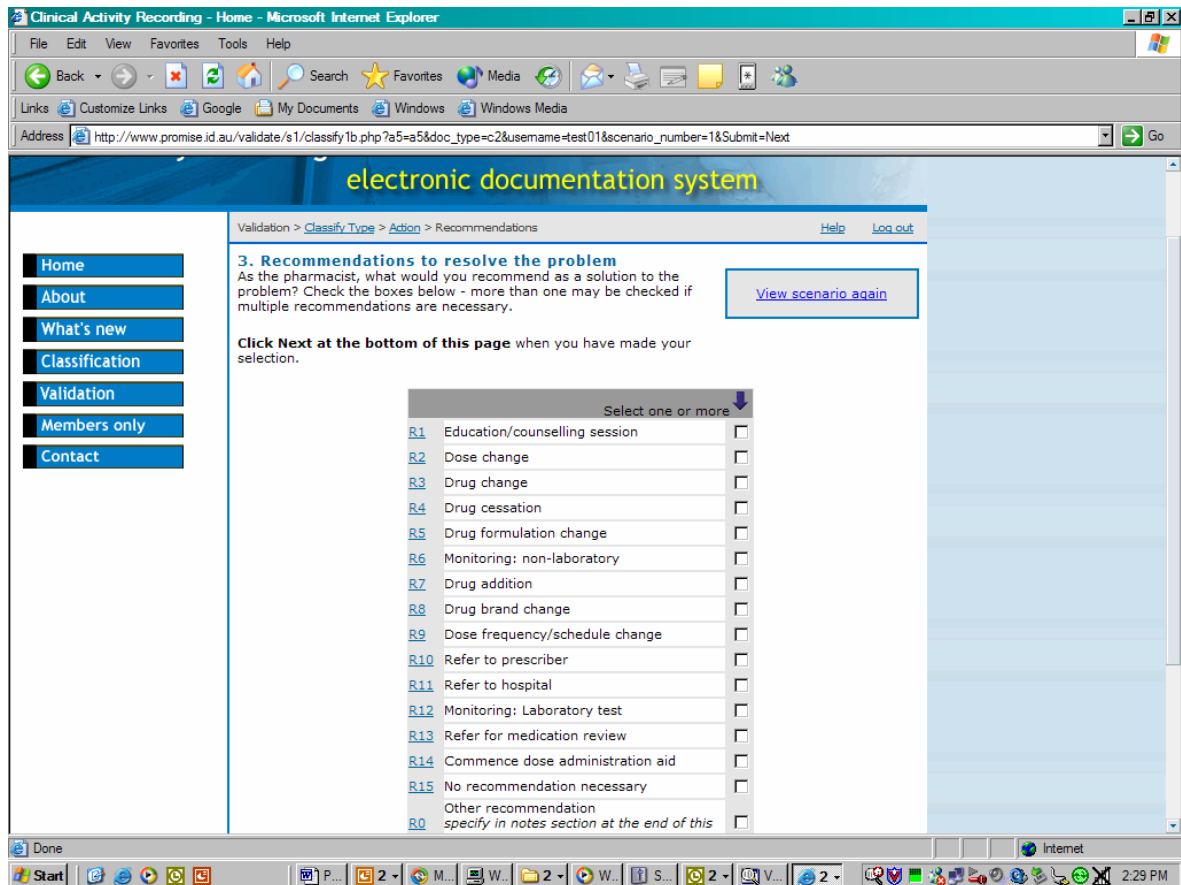


Figure 7-6: Promise Validation Website: Screenshot 6

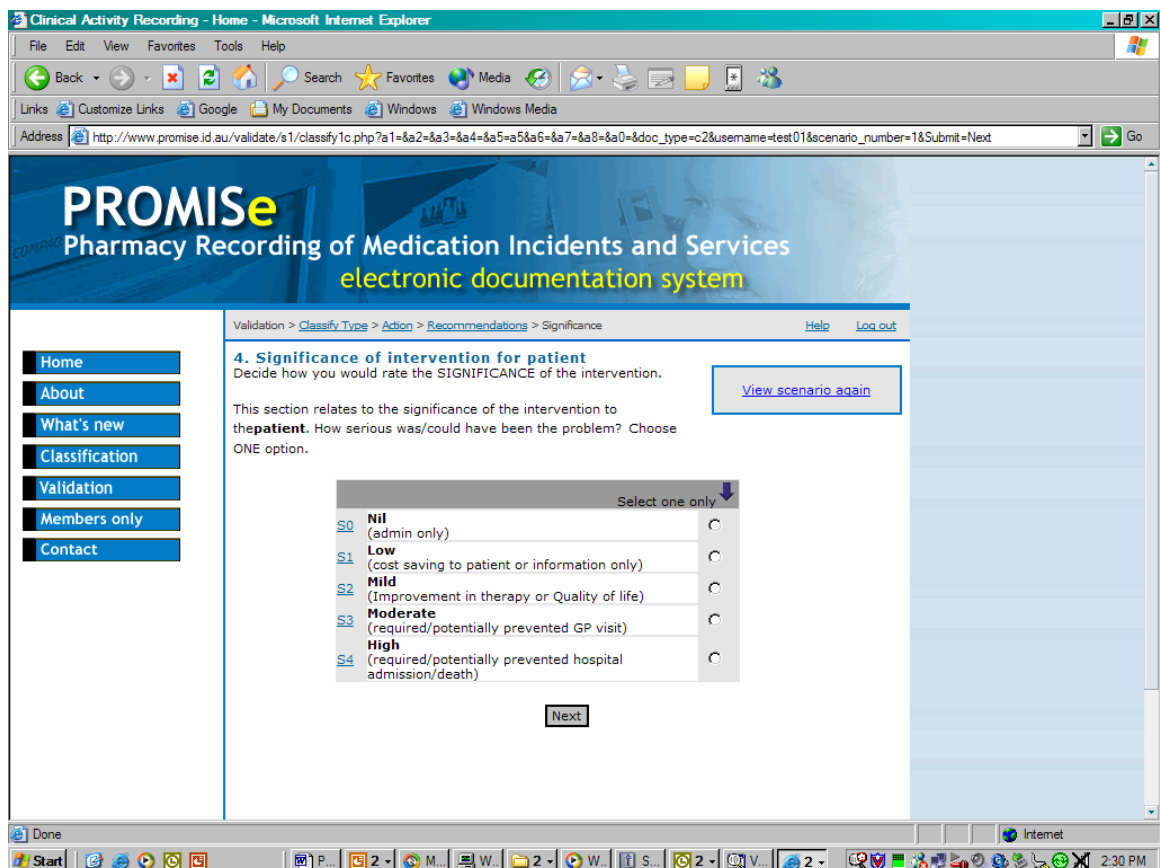


Figure 7-7: Promise Validation Website: Screenshot 7



## 7.2 Advertising

To encourage participation in the validation process, an incentive was offered for completion of the exercise. This was advertised in the Australian Pharmacist (twice), AusPharmlist (3 occasions), the SHPA newsletter, the AACP website and by personal email tree.

Examples of the advertisements are shown in Figure 7-8 and Figure 7-9.

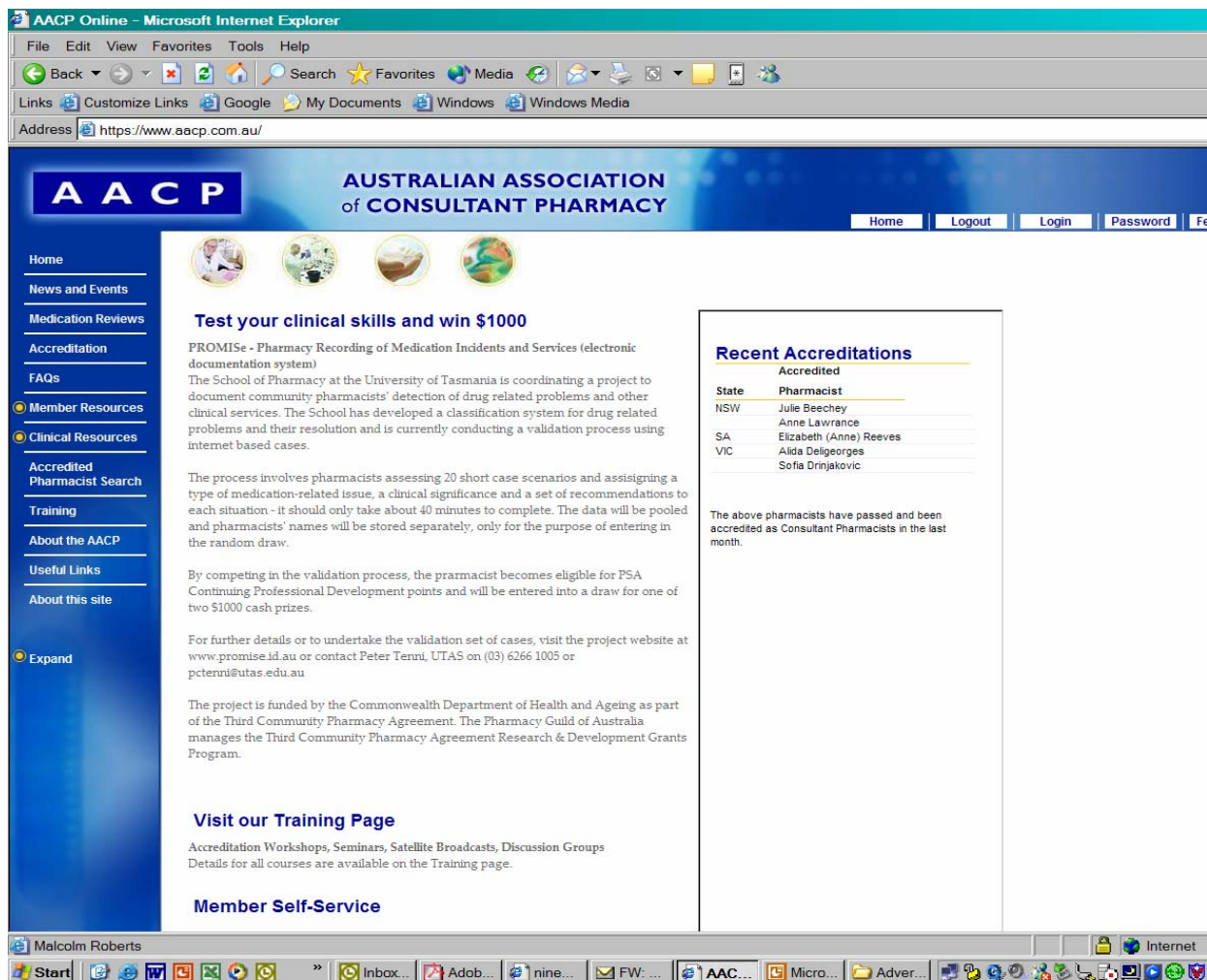


Figure 7-8: Advertisement on the AACP Website



### Test Your Clinical Skills and Win \$1000

The School of Pharmacy at the University of Tasmania is coordinating a project to document community pharmacists' detection of drug related problems and other clinical services. The School has developed a classification system for drug related problems and their resolution and is currently conducting a validation process using interest based cases.


The process involves pharmacists assessing twenty short case scenarios and assigning a type of medication-related issue, a clinical significance and a set of recommendations to each situation. It is painless and should only take about 40 minutes to complete. All the data will be pooled and pharmacists' names will be stored separately, only for the purpose of entering the random draw.

By participating in the validation process, the pharmacist becomes eligible for PSA Continuing Professional Development points and will be entered into a draw for one of two \$1000 cash prizes.

For further details about the PROMISe project, or to undertake the validation set of cases, please visit the project website at [www.promise.tas.au](http://www.promise.tas.au)

or contact Peter Tenni, Clinical Pharmacy Project Manager,  
School of Pharmacy, University of Tasmania.  
Email [pctenni@utas.edu.au](mailto:pctenni@utas.edu.au) or telephone (03) 62261005.

This project is funded by the Commonwealth Department of Health and Ageing as part of the Third Community Pharmacy Agreement. The Pharmacy Guild of Australia manages the Third Community Pharmacy Agreement Research and Development Grants Program.



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Figure 7-9 Advertisement in the Australian Pharmacist May 2004

## 8 Results of online Validation Exercise

From 21<sup>st</sup> April to 28<sup>th</sup> June 2004, 241 users registered on the website and provided some demographic information. 175 assessed at least one scenario and 123 assessed all 20 scenarios. Of the 123 that completed all scenarios, 20 were internal validation pharmacists who completed the scenarios twice. The purpose of the exercise was primarily to determine the appropriateness of the classification of the type and significance of the scenarios presented. Scenarios did not usually include the actions undertaken by the pharmacist or the recommendations made. This was intended to allow different pharmacists the freedom to choose particular actions and recommendations for the same scenario.

### 8.1 Validation Demographics

Information about the pharmacists who registered with the DOCUMENT validation website was gathered through an online questionnaire. This questionnaire was designed to assess the training and experience of the pharmacists involved. Also there was a section which involved the participants' views on pharmacy and their current work environment. The full questionnaire is attached in Appendix 13.10.

#### 8.1.1 Participants

There was participation in the validation website exercise from across Australia. (see Figure 8-1 )

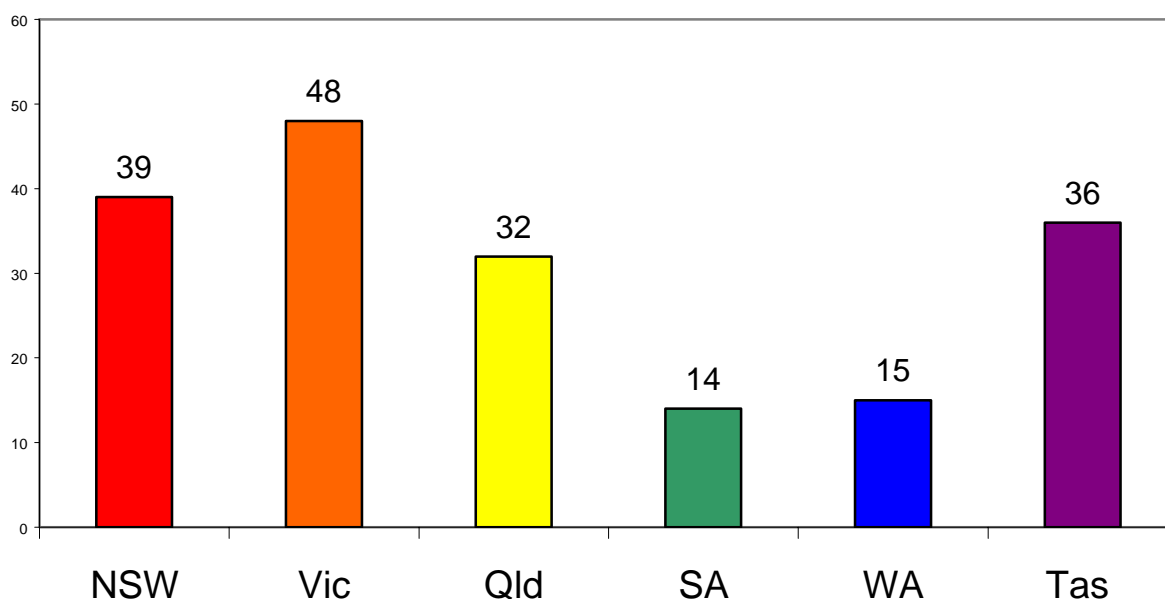


Figure 8-1 Number of Participants in DOCUMENT Validation Exercise within Australia

#### 8.1.2 Age and Gender of validation participants

There can be seen a large number of participants who were in their thirties and forties. In this group there were also a greater proportion of female participants.

age	Females		Males		Overall	
	Number	% within gender	Number	% within gender	Number	Overall %
20 to 25yo	24	19.2%	42	36.2%	66	27.4%
26 to 30yo	14	11.2%	9	7.8%	23	9.5%
31 to 40yo	43	34.4%	19	16.4%	62	25.7%
41 to 50yo	27	21.6%	28	24.1%	55	22.8%
51 to 60yo	15	12.0%	12	10.3%	27	11.2%
over 60yo	2	1.6%	6	5.2%	8	3.3%
<b>Total</b>	<b>125</b>		<b>116</b>		<b>241</b>	

Table 8-1 Age by Gender validation group

### 8.1.3 Undergraduate training of validation participants

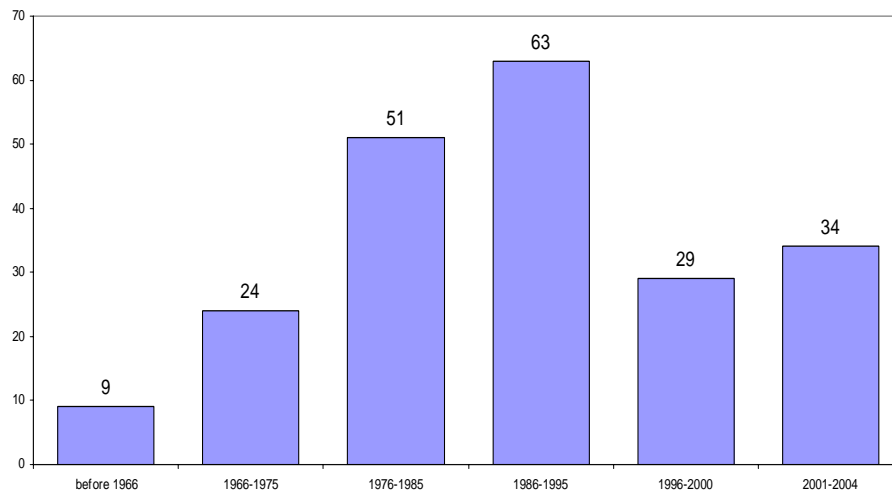
Each of the teaching institutions across Australia is represented in the group of pharmacists who participated in this process. In addition some of the participants were trained overseas. The majority of participants had trained at the University of Sydney (28.2%)

Institute	#	%
University of Sydney	68	28.2%
Monash University	46	19.1%
University of Tasmania	36	14.9%
International	25	10.4%
University of Queensland	20	8.3%
Curtin University	19	7.9%
University of South Australia	17	7.1%
Charles Sturt University	7	2.9%
James Cook University	2	0.8%
La Trobe University	1	0.4%
<b>Total</b>	<b>241</b>	<b>100.0%</b>

Table 8-2 Undergraduate training, validation group

### 8.1.4 Graduation

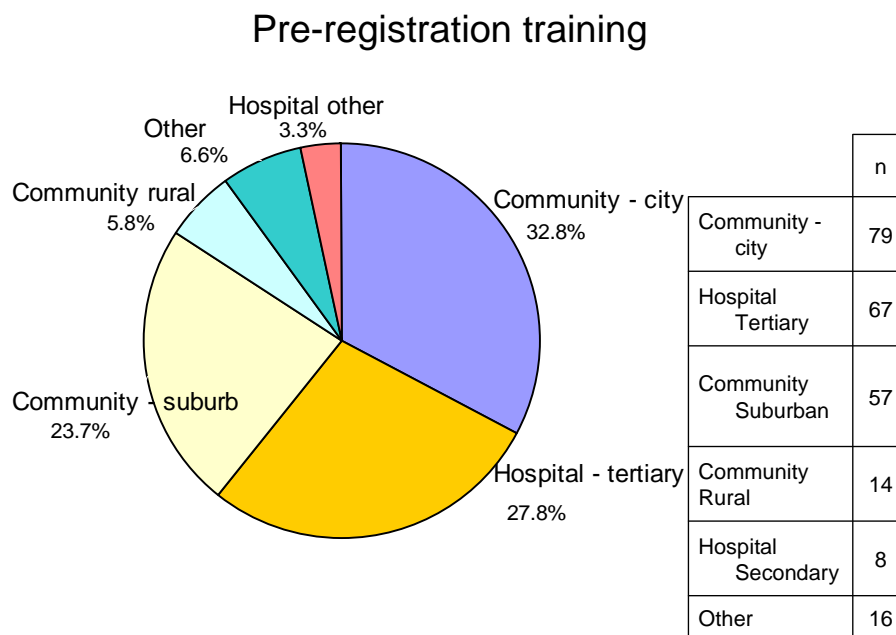
The date of graduation from these institutions ranged from 1954 to 2004, with a greater number of participants graduating in the later portion of that range.



**Figure 8-2 Year of graduation, validation group**

### 8.1.5 Pre-Registration Training

The majority of registrants completed their pre-registration training either in community or hospital pharmacies.



**Figure 8-3 Pre-registration training, validation group**

### 8.1.6 Practice profile

Experience since graduation encompassed for the majority time in either hospital or community pharmacy. Participants were asked to enter the number of whole years completed in each field of practice. These included community pharmacy - city, suburban and rural, hospital - tertiary and secondary and medication reviews.

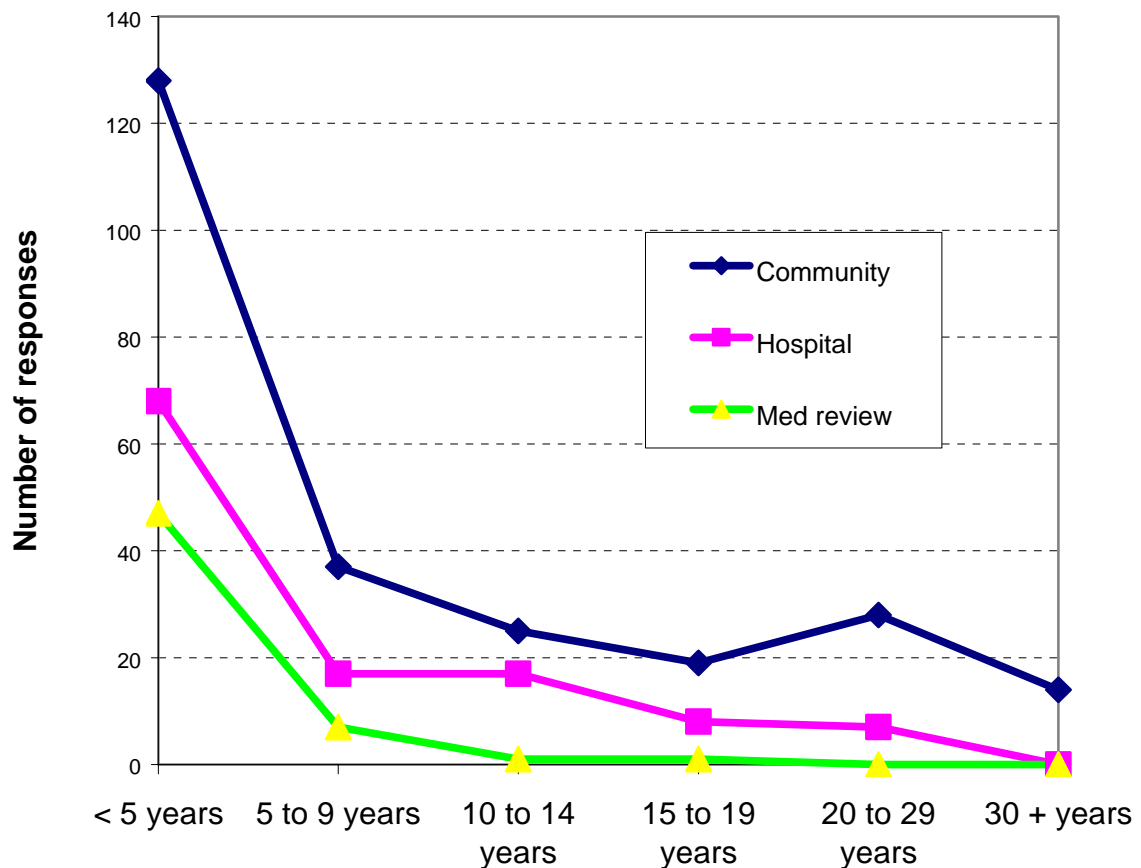
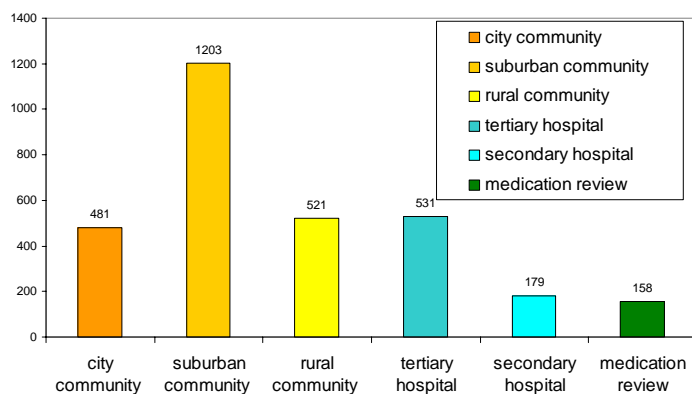


Figure 8-4 Practice profile, validation group

### 8.1.7 Years of Experience

In grouping these areas to community pharmacy, hospital pharmacy and medication reviews it can be seen that the level of experience varies across the area of pharmacy practice. In general each of these three areas had more respondents with 1-5 years of experience. Community pharmacy had the highest level of respondents with greater than 30 years' experience (14 compared with none). Medication reviews are still a relatively new area of practice; the profile of experience displays this.

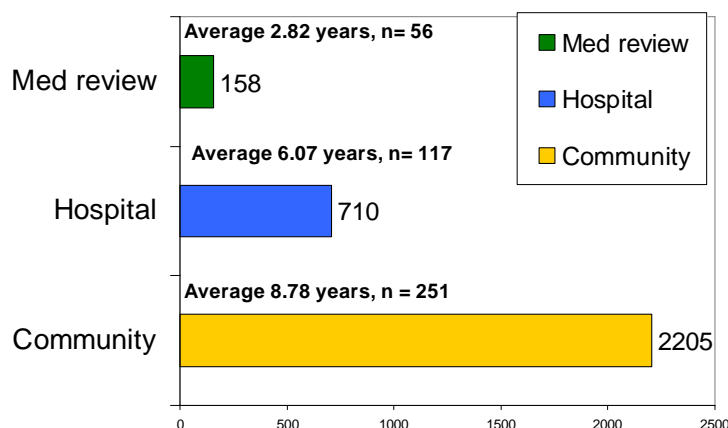
Cumulative years of practice provides a different view of from these responses.



	Community city	Community suburb	Community rural	Hospital tertiary	Hospital secondary	Med review
responses	77	115	59	81	36	56

**Figure 8-5 Experience in pharmacy, validation group**

When considering the cumulative years in practice the impact of those who have been working in pharmacy for a considerable period of time can be seen. Suburban community pharmacy far outreaches all the other areas of practice.



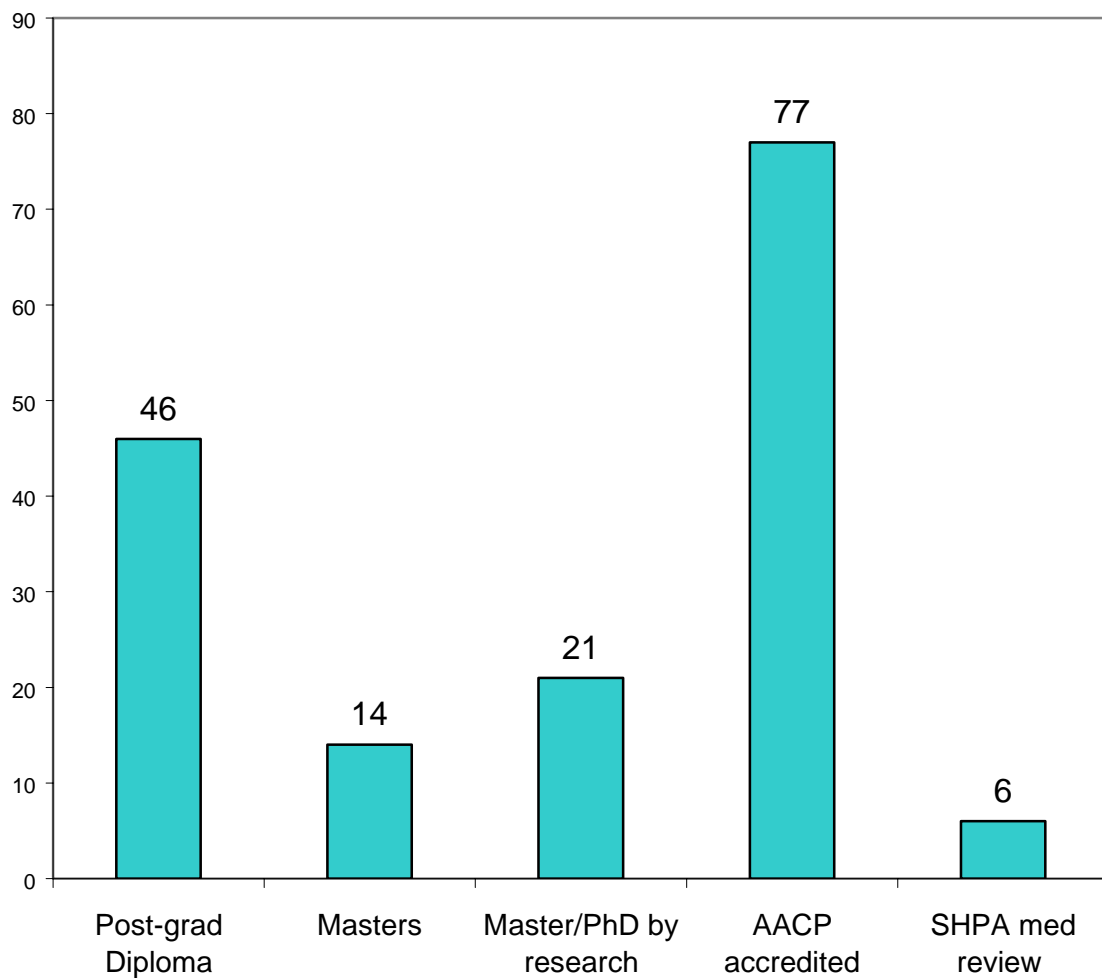
**Figure 8-6 Cumulative practice in pharmacy, validation group**

### 8.1.8 Continuing Education and Further Qualifications

The majority of pharmacists who took part in the validation exercise had undertaken more than 20 hours of continuing education (CE) in the previous 12 months, and over 1/3 were accredited to undertake medication reviews.

Amount of CE in last 12 months	Number	Percent
Don't Know	27	12.9%
1-9 Hours	18	8.6%
10-19 Hours	45	21.4%
20-29 Hours	37	17.6%
30+ Hours	83	39.5%
<b>Total</b>	<b>210</b>	<b>100.0%</b>

Table 8-3 : Amount of Continuing Education by Validation Exercise Pharmacists



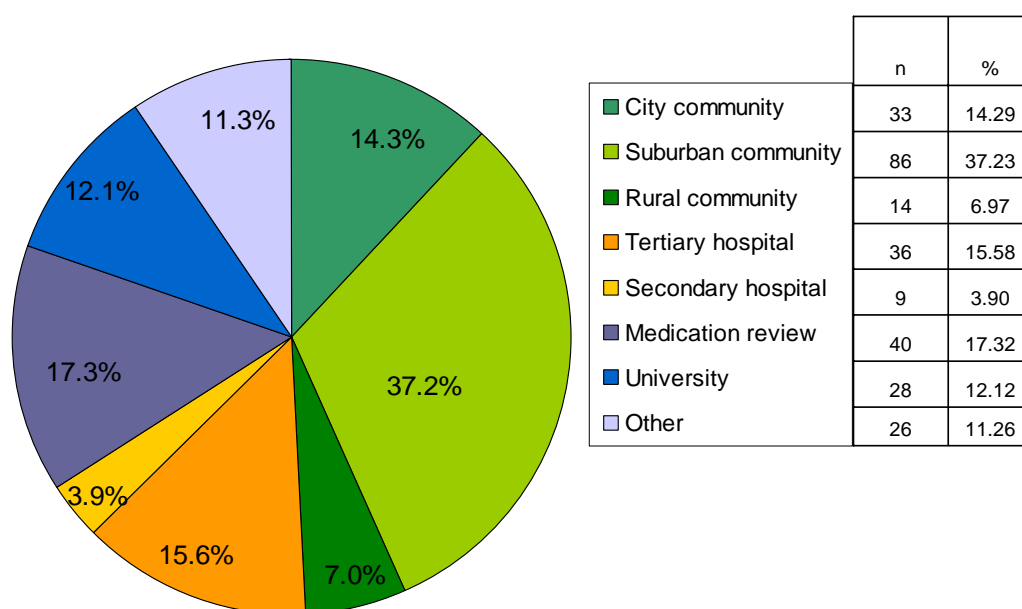
	Post-grad Diploma	Masters	Master/PhD by research	AACP accredited	SHPA med review
n	46	14	21	77	6
%	19.1%	5.8%	8.7%	32.0%	2.5%



**Figure 8-7: Further Formal Education of Pharmacists who Undertook Validation Exercise**

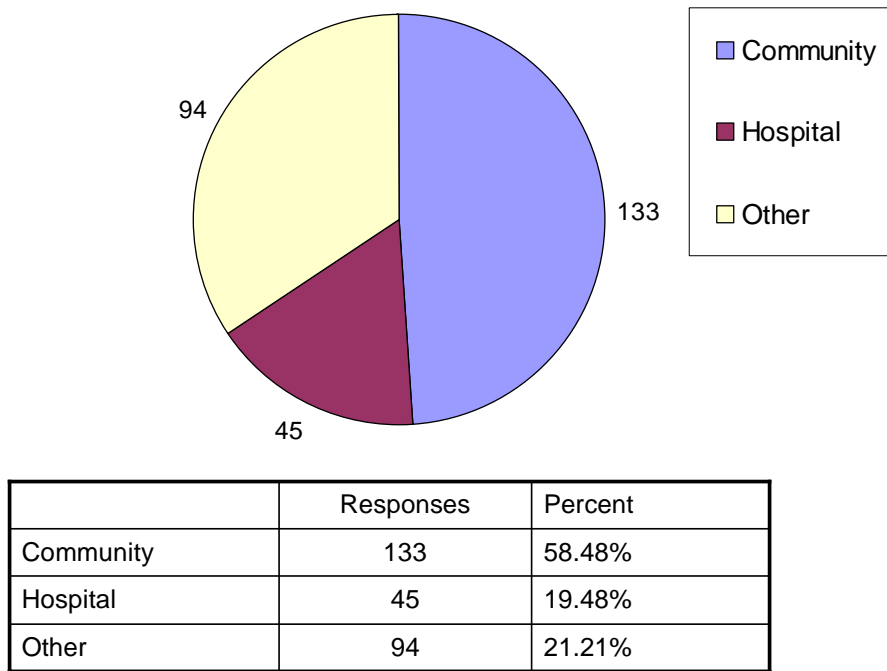
### 8.1.9 Current Practice of Validation participants

Each participant was asked to indicate their current area of practice. The questionnaire allowed for multiple responses. Along with the area's specified pharmacist listed a number of other area's they are currently working in. These included pharmacy liaison at division of general practices, remote indigenous health services, military and government departments. The participation by those who currently work in community pharmacy was particularly high (58.5% of responses). In the group who indicated they currently work in community pharmacy suburban community pharmacy was seen to be the largest section. This correlates with the question about the number of years of experience (1.6) and indicates that those who have practiced in suburban areas continue to do so. The number of people trained for conducting medication reviews was seen to be higher than those who listed this as a current area of practice. (83 accredited, with 40 responses as current area of practice).



**Figure 8-8Current area of practice, validation group**

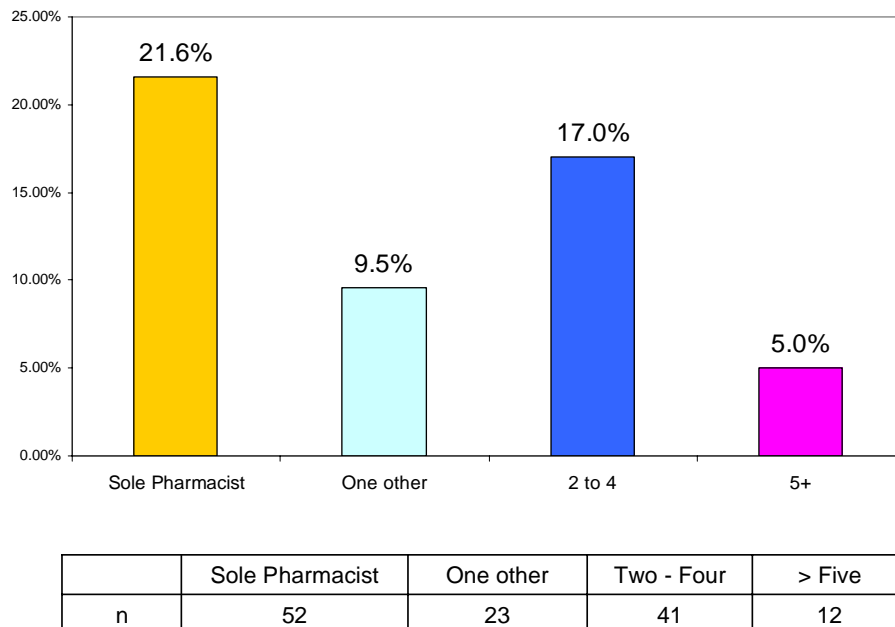
Around 30% of respondents indicated that their pre-registration training took place in hospital pharmacy, compared with the current area of practice where around 20% work in hospital pharmacy. Pre-registration training in community pharmacy included 62% of the respondents. Although there are many people who change between the area of training and that of current practice the proportion of people in community pharmacy has stayed relatively the same at 58%.



**Figure 8-9**Current area of practice; community, hospital, other

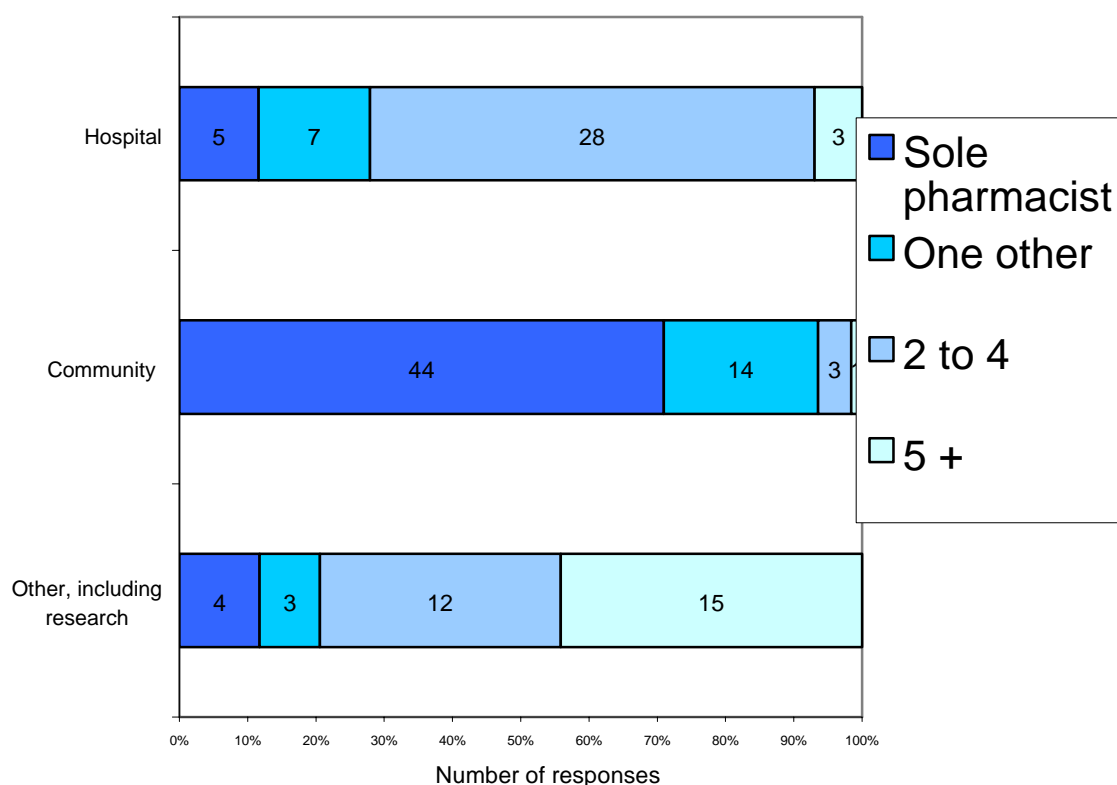
### 8.1.10 Number of Pharmacists

The number of pharmacists also present in the workplace at time of practice is an indicator of the size of the business or institution. Pharmacist were asked to indicate if they were the sole pharmacist, worked with one other, two to four others or more than five other pharmacists.



**Figure 8-10:** Work situation, validation group

This information can also be linked to the respondent's current area of practice



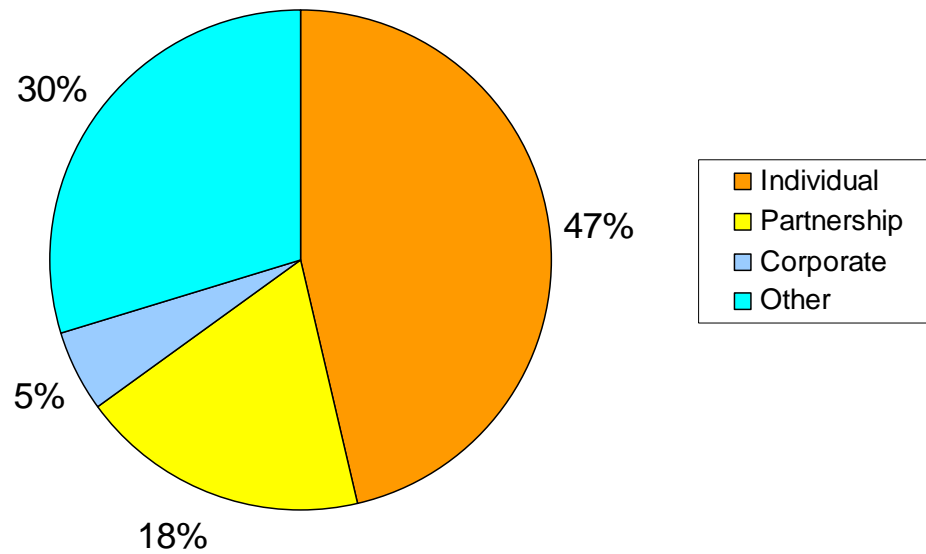
	Community	Hospital	Other
Sole pharmacist	71.0%	11.6%	11.8%
One other	22.6%	16.3%	8.8%
2 to 4	4.8%	65.1%	35.3%
5 +	1.6%	7.0%	44.1%

**Figure 8-11 Pharmacists work situation**

The area where the pharmacist is working either by themselves or with one other pharmacist is predominately in community pharmacy. In contrast to this those working in hospital pharmacy generally work with between two and four other pharmacists.

### 8.1.11 Ownership

The ownership of the pharmacy was predominantly an individual owner in those responding to this questionnaire.

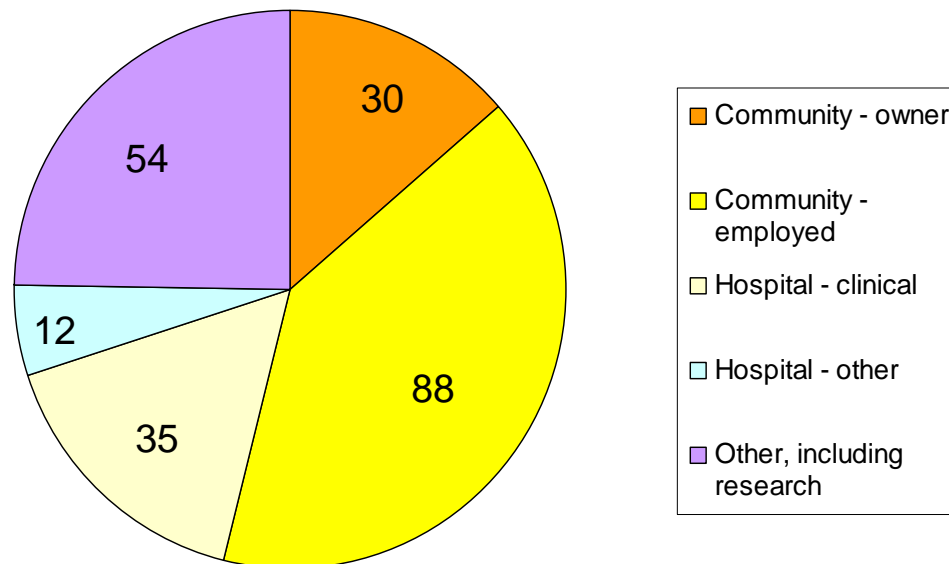


	Individual	Partnership	Corporate	Other
Responses	106	42	12	68

**Figure 8-12**Ownership of pharmacy

### 8.1.12 Current Position in Pharmacy

The area of current practice nominated by the pharmacists included a range of responses, for example city, suburban or rural community pharmacy. Across each of these areas of practice there are common positions owners, employees, clinical hospital employees etc. Of those who participated in the validation exercise the number of owner pharmacist was 30. When considering that 133 respondents indicated that they currently practice in community pharmacist, this alludes to a low participation rate among community pharmacy owners.

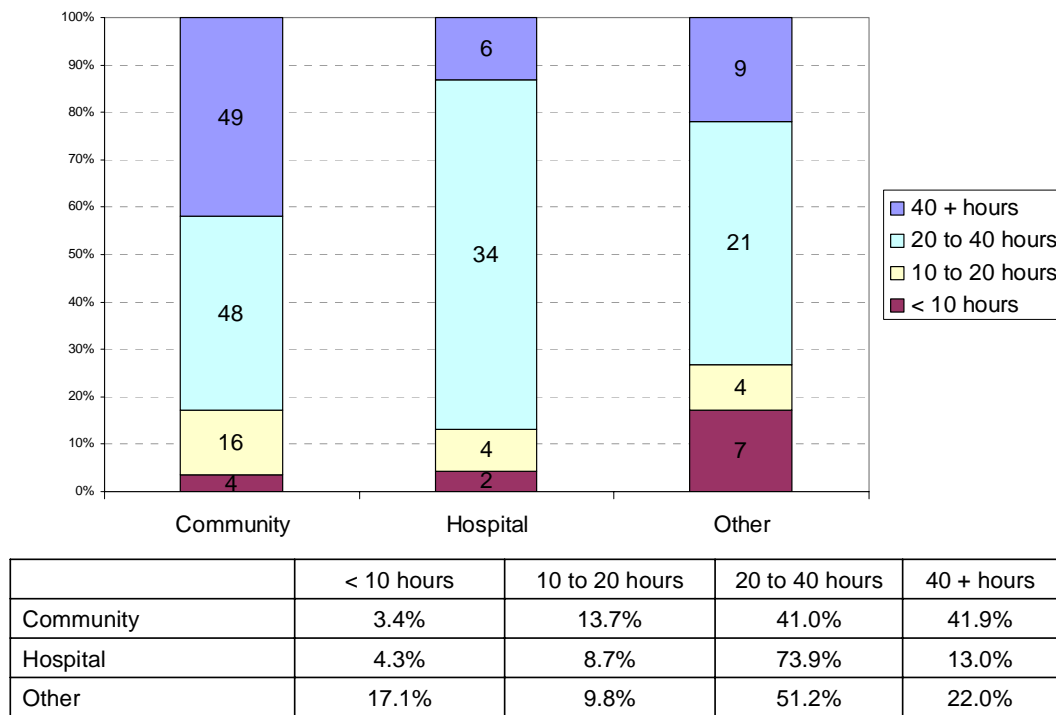


	Community - owner	Community - employed	Hospital - clinical	Hospital - other	Other – including research
N	30	88	35	12	54
Percent	11.0%	32.2%	12.8%	4.4%	19.8%

Figure 8-13Current position within the pharmacy

### 8.1.13 Hours per Week of Work

The number of hours worked per week in each area of practice was ascertained from each pharmacist.

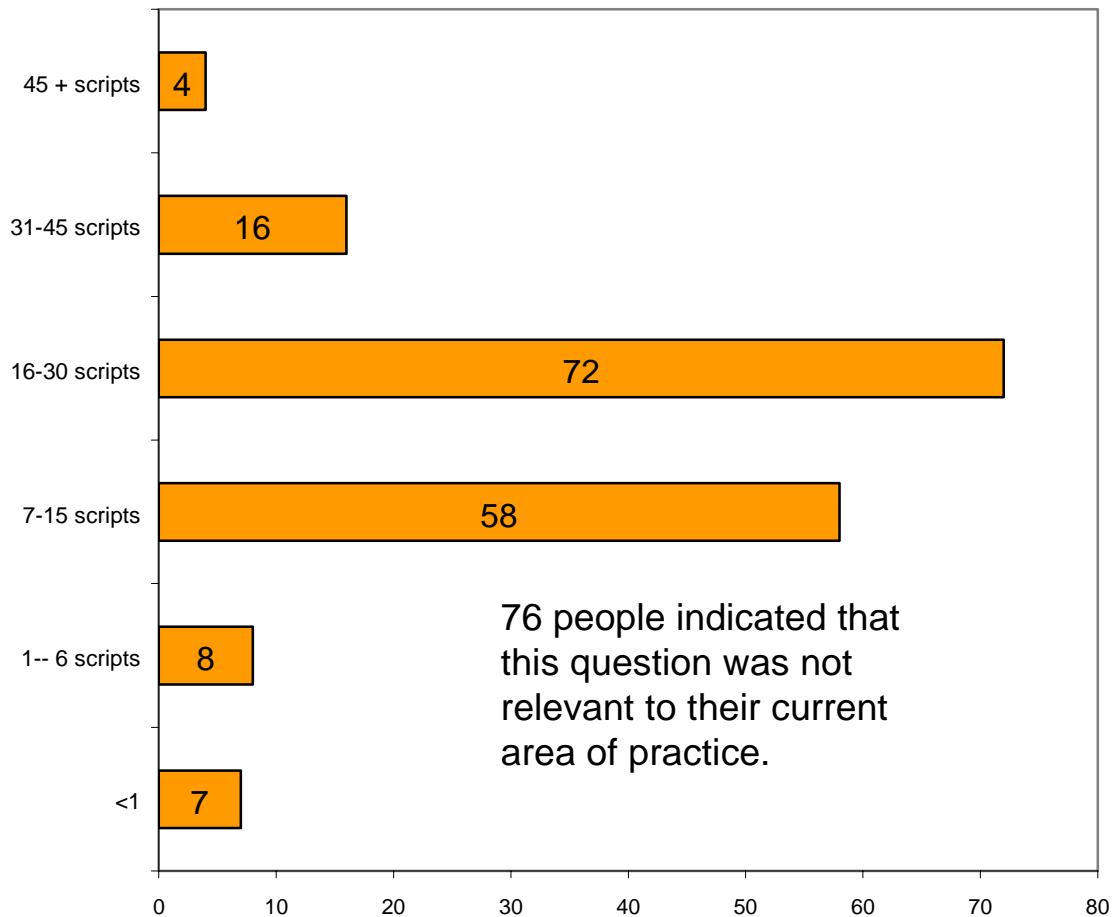


**Figure 8-14 Hours worked per week**

The greatest proportion of hospital pharmacist indicated they worked a 20 to 40 hour week. The number of part time hospital workers (<20 hours per week) was quite low in the sample.

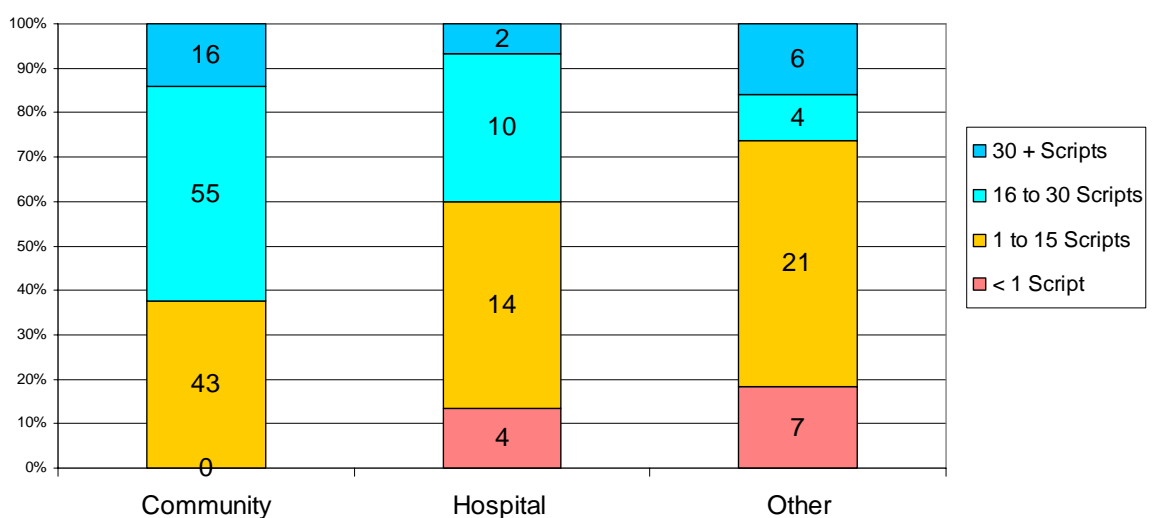
#### 8.1.14 Prescription per Hour

The prescription workload across all areas of practice show the majority of pharmacists dispensing/checking between 16 and 30 scripts per hour. To further assess this area of workload the total daily number of scripts would need to be analysed. This prescription rate covers a large variation in total daily scripts, from 120 to 240 scripts per day. It is proposed that in answering this question the pharmacists may have been considering the busier hours of the day and not estimating an average across the entire day.

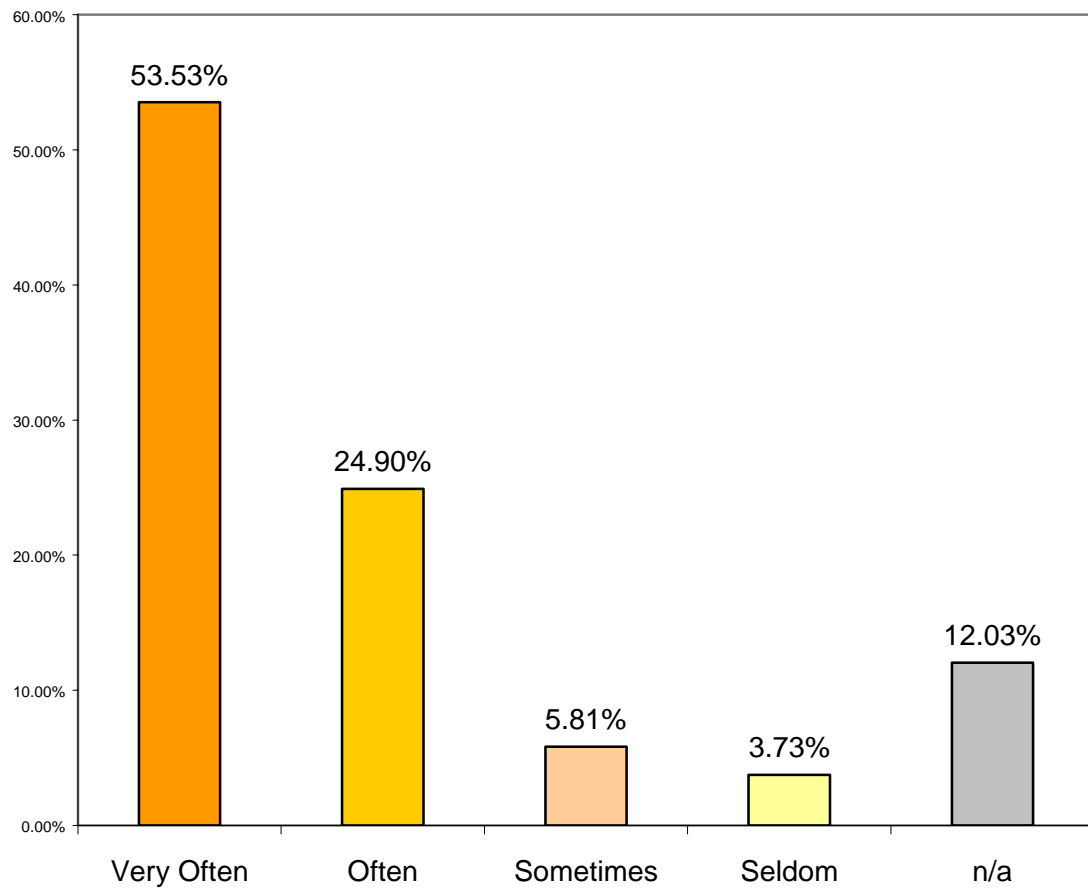


**Figure 8-15: Prescription workload**

When separating the prescription rates into the main areas of practice. It can be seen that the greater proportion of the high script rate lies in community pharmacy. The number of prescriptions dispensed per hour impacts on overall workload but would need to be more accurately determined for any further analysis.



**Figure 8-16 Prescriptions checked per hour across the different areas of practice**



Very Often	Often	Sometimes	Seldom	n/a
129	60	14	9	29

Figure 8-17Counselling of patients



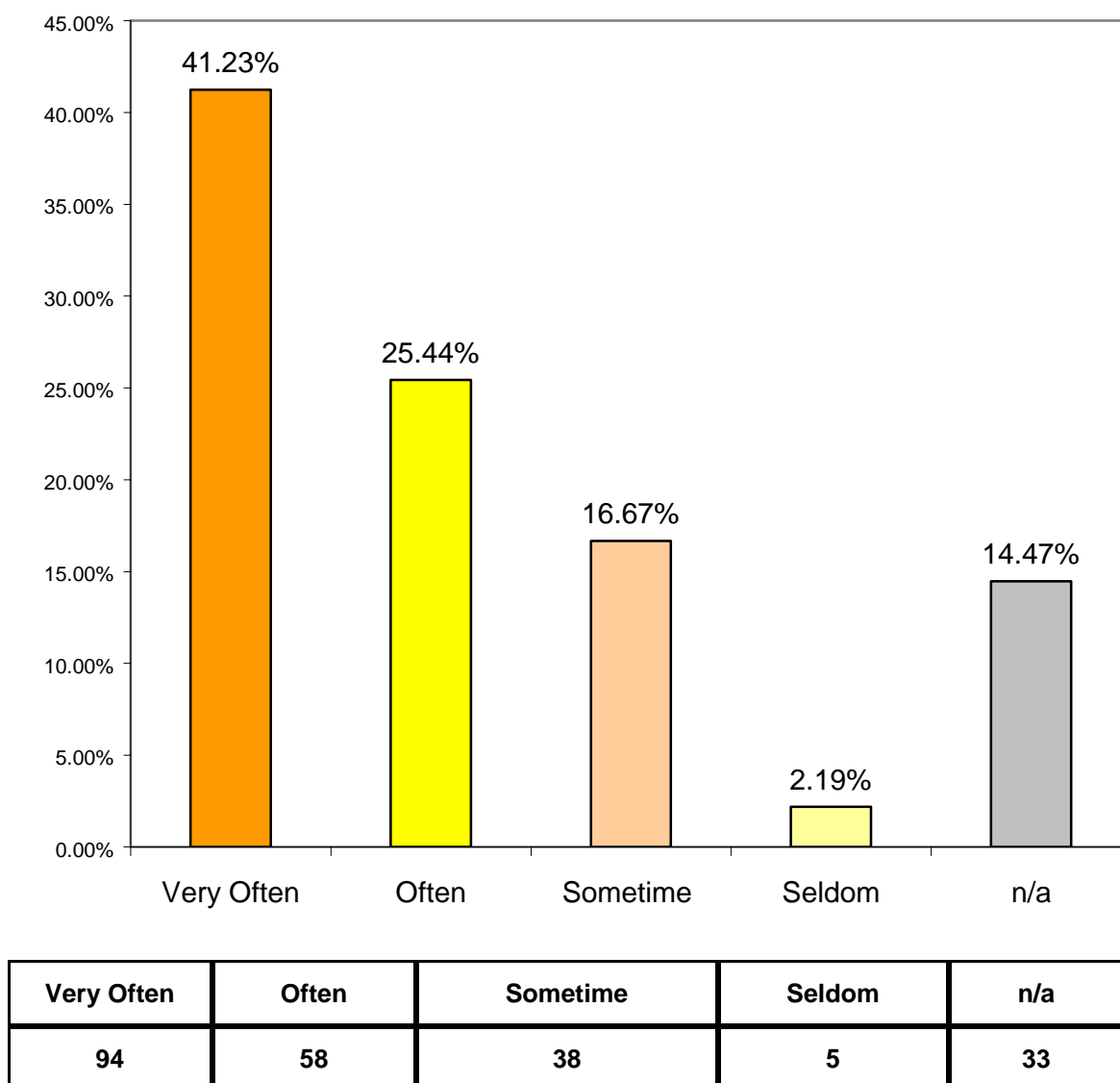


Figure 8-18 Interruption whilst filling a prescription

### 8.1.15 Characteristics of the Average Validation Person

Person in their 30's who graduated between 1986 and 1995 from an Australian university. In their career they have worked in community pharmacy with an average 8 years of practice. They complete at least 20 hours of continuing education each year, may have become accredited for medication reviews. Generally, will have spent some time in other areas of pharmacy practice including hospital. If currently working in community pharmacy they will be an employee who works by themselves in a pharmacy which is individually owned. They could work from 20 to 40+ hours each week dispensing and checking between 15 to 30 prescriptions an hour. They feel that interruption is common in their everyday practice, where around 80% of their work involved clinical aspects. Patients entering their pharmacy receive counselling on prescription items.

## 8.2 Factors Influencing Place of Work

Each registrant was asked to consider the factors which influenced their choice of place of work. The results of this analysis are shown in Table 8-4.

Overall	Strongly agree		Agree	Disagree	Strongly disagree	Total responses
	#	%				
Income	42	21.4%	135	17	2	196
Workload	81	41.1%	105	8	3	197
Multi pharm	44	22.3%	99	49	5	197
Flexible	69	35.2%	113	13	1	196
Intellect	119	60.4%	75	3	0	197
Helping	128	65.3%	63	5	0	196
Conditions	108	55.4%	83	4	0	195
Job Security	57	29.2%	117	17	4	195
<b>Community</b>						
Income	29	25.0%	79	8	0	116
Workload	50	43.1%	56	9	1	116
Multi pharm	29	25.0%	51	33	3	116
Flexible	36	31.3%	66	12	1	115
Intellect	61	52.6%	51	4	0	116
Helping	77	67.0%	36	2	0	115
Conditions	67	58.3%	43	5	0	115
Job Security	41	36.3%	62	10	0	113
<b>Hospital</b>						
Income	6	13.3%	34	5	0	45
Workload	18	39.1%	28	0	0	46
Multi pharm	9	19.6%	28	9	0	46
Flexible	17	36.2%	28	2	0	47
Intellect	34	73.9%	12	0	0	46
Helping	29	63.0%	15	2	0	46
Conditions	23	51.1%	22	0	0	45
Job Security	12	26.1%	31	1	2	46

Table 8-4 Factors influencing work environment

## 8.3 Web-based clinical scenarios

### 8.3.1 Classification of Type and Significance

Table 8-5 shows the main classification categories and sub categories chosen by participants in the validation exercise for all of the scenarios (shaded boxes indicate the most appropriate classification as determined by a panel of three experienced users of the DOCUMENT system). Table 8-6 to Table 8-26 and Figures Figure 8-19

to Figure 8-57 describe each scenario and show the results and percentages for each of type, subtype and clinical significance. There is also a short discussion concerning the results with each scenario.

Type		Subtype	Scenario Number																			
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
D	Drug selection	Duplication	1			12		85									61			2	31	
	Drug selection	Interaction		76		18		3	1				14		15						22	
	Drug selection	Wrong drug		7				1					19	1		88			13			
	Drug selection	Wrong dosage form							1		26							2				
	Drug selection	Pre-existing severe ADR/allergy					1															
	Drug selection	Other Drug selection problem		7		3	2				4		22	2		2			3		1	
O	Over or underdose prescribed	Too high dose prescribed			3	6						21	1		1		2	76		85		
	Over or underdose prescribed	Too low dose prescribed	1		126						1			4				2				
	Over or underdose prescribed	Incorrect frequency prescribed												28				18		7		
	Over or underdose prescribed	Other Dose Problem			1	4		3				2		5			3		1	3	2	
C	Compliance	Potential drug overuse/abuse situation (intentional)																1				
	Compliance	Taking too little	90						93		2								3			1
	Compliance	Taking too much						1						1			23	1		6	3	
	Compliance	Difficulty using dosage form							1	17	72											
	Compliance	Other Compliance Problem	4						7		1										3	
U	Untreated indications	Condition not adequately treated		1	1		18		1				2	31				2	69			
	Untreated indications	Preventive therapy required					58	1		1									1			
M	Monitoring required	Drug levels					8	1				17			12							
	Monitoring required	Laboratory Monitoring										1			71							
	Monitoring required	Non-Laboratory monitoring				1	2		2	1	1						2					
	Monitoring required	Other Monitoring Problem		1			6												1			
E	Education or Information	Patient requests information		1														2			1	
	Education or Information	Confusion about therapy/condition	38			1		5						3			9	1		2	35	
	Education or Information	Requires demonstration of therapeutic device								62	3											
	Education or Information	Requires disease management or health care advice	22	2	1	1	10	7	5		4			21				1	4		1	
	Education or Information	Other Education/Information Problem			3		1	2	1	4	1			6			1				1	
N	Non-clinical	Not sub-classified	1													13				1		103
T	Toxicity or Adverse reaction	Actual or suspected adverse reaction caused by dose too high				7				1		70					6	1				
	Toxicity or Adverse reaction	Actual or suspected adverse reaction caused by drug interaction		43		60	1	4					27		8						6	
	Toxicity or Adverse reaction	Other Toxicity problem		4		14	13	2		26		2	29		3	3			3			
Total			157	142	135	127	120	115	112	112	115	113	114	108	110	106	107	107	98	106	106	104

Table 8-5: Validation Exercise Type Classifications for All Scenarios

### 8.3.2 Scenario 1

Scenario Number 1						
A regular patient comes in with repeat for metformin 500mg 1g three times a day. You notice that it has been 7 weeks since he last had this script filled. On questioning the patient reveals that he has been taking tablets only when sugar is high.						
Type		Subtype	Scenario Number 2			
			#	%	#	%
D	Drug selection	Duplication	1	0.6%	1	0.6%
	Drug selection	Interaction				
	Drug selection	Wrong drug				
	Drug selection	Wrong dosage form				
	Drug selection	Pre-existing severe ADR/allergy				
	Drug selection	Other Drug selection problem				
O	Over or underdose prescribed	Too high dose prescribed			1	0.6%
	Over or underdose prescribed	Too low dose prescribed	1	0.6%		
	Over or underdose prescribed	Incorrect frequency prescribed				
	Over or underdose prescribed	Other Dose Problem				
C	Compliance	Potential drug overuse/abuse situation			94	59.9%
	Compliance	Taking too little	90	57.3%		
	Compliance	Taking too much				
	Compliance	Difficulty using dosage form				
	Compliance	Other Compliance Problem	4	2.5%		
U	Untreated indications	Condition not adequately treated				
	Untreated indications	Preventive therapy required				
M	Monitoring required	Drug levels				
	Monitoring required	Laboratory Monitoring				
	Monitoring required	Non-Laboratory monitoring				
	Monitoring required	Other Monitoring Problem				
E	Education or Information	Patient requests information			60	38.2%
	Education or Information	Confusion about therapy/condition	38	24.2%		
	Education or Information	Demonstration of therapeutic device				
	Education or Information	Disease management advice	22	14.0%		
	Education or Information	Other Education/Information Problem				
N	Non-clinical	Not sub-classified	1	0.6%	1	0.6%
T	Toxicity or Adverse reaction	Caused by dose too high				
	Toxicity or Adverse reaction	Caused by drug interaction				
	Toxicity or Adverse reaction	Other Toxicity problem				
Total			157	100.0%	157	100.0%

Table 8-6: Type Classification for Scenario 1

scenario\_number 1

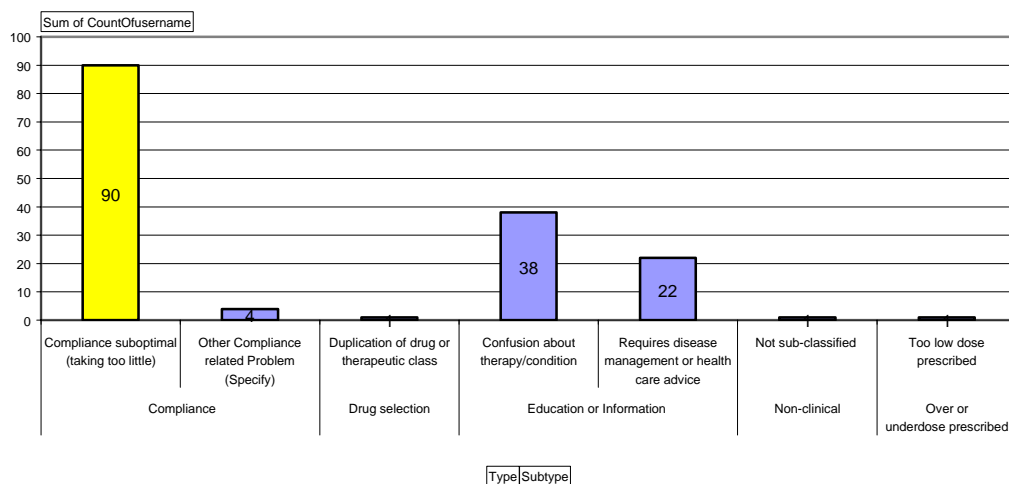


Table 8-7: Type Classification for Scenario 1

A regular patient comes in with repeat for metformin 500mg 1g three times a day. You notice that it has been 7 weeks since he last had this script filled. On questioning the patient reveals that he has been taking tablets only when sugar is high.

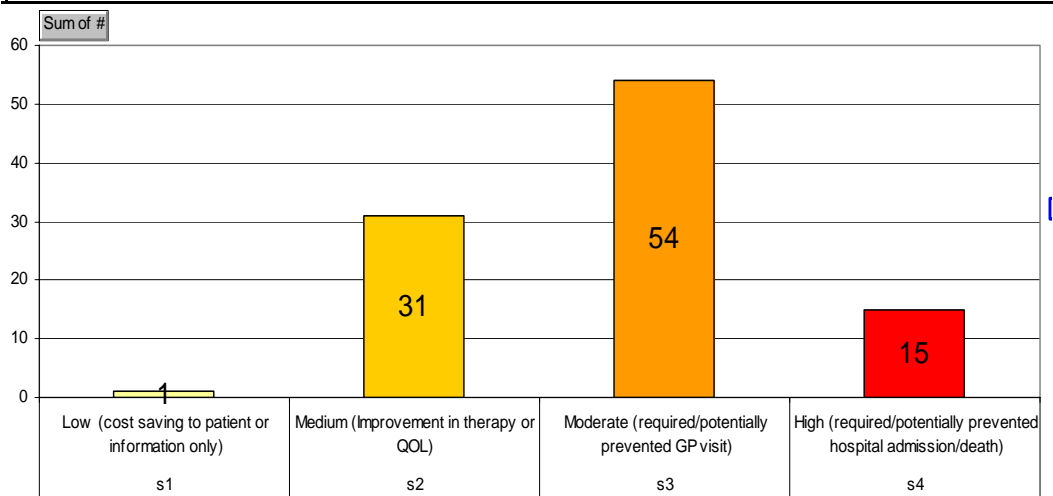


Figure 8-19: Significance Classifications for Scenario 1

This gentleman has been prescribed the correct drug at the correct dose, but has chosen to not take the medication as prescribed. This may be because he is confused about the need for regular intake of this type of medication, because he is forgetful, or he has simply chosen to take tablets as infrequently as possible. The correct categorisation of this intervention based on the information supplied, as most people have indicated would be ‘Compliance – taking too little.’ It could be argued that his confusion is the cause of the non-compliance, but documenting this as ‘taking too little’ provides more information about the problem to a third person.

The perceived level of significance of this intervention varied greatly, ranging from low to high, and a case could be argued for each. It is perhaps not unusual for a person to skip tablets, but the likelihood of this action causing hospitalisation in the near future is low. It is more likely to require a visit to the prescriber and therefore should be documented as of moderate significance, as the majority of the responders did.

### 8.3.3 Scenario 2

Scenario Number 2						
A 55 year old man with diabetes and ischaemic heart disease presents a new prescription for sildenafil (Viagra) 50 mg. His other medications include isosorbide mononitrate, metformin, glipizide, amiodarone, aspirin, perindopril and metoprolol. You are aware that Sildenafil should not be used with nitrates.						
Type		Subtype	Scenario Number 2			
			#	%	#	%
D	Drug selection	Duplication			90	63.4%
	Drug selection	Interaction	76	53.5%		
	Drug selection	Wrong drug	7	4.9%		
	Drug selection	Wrong dosage form				
	Drug selection	Pre-existing severe ADR/allergy				
	Drug selection	Other Drug selection problem	7	4.9%		
O	Over or underdose prescribed	Too high dose prescribed			0	0.0%
	Over or underdose prescribed	Too low dose prescribed				
	Over or underdose prescribed	Incorrect frequency prescribed				
	Over or underdose prescribed	Other Dose Problem				
C	Compliance	Potential drug overuse/abuse situation			0	0.0%
	Compliance	Taking too little				
	Compliance	Taking too much				
	Compliance	Difficulty using dosage form				
	Compliance	Other Compliance Problem				
U	Untreated indications	Condition not adequately treated	1	0.7%	1	0.7%
	Untreated indications	Preventive therapy required				
M	Monitoring required	Drug levels			1	0.7%
	Monitoring required	Laboratory Monitoring				
	Monitoring required	Non-Laboratory monitoring				
	Monitoring required	Other Monitoring Problem	1	0.7%		
E	Education or Information	Patient requests information	1	0.7%	3	2.1%
	Education or Information	Confusion about therapy/condition				
	Education or Information	Demonstration of therapeutic device				
	Education or Information	Disease management advice	2	1.4%		
	Education or Information	Other Education/Information Problem				
N	Non-clinical	Not sub-classified			0	0.0%
T	Toxicity or Adverse reaction	Caused by dose too high			47	33.1%
	Toxicity or Adverse reaction	Caused by drug interaction	43	30.3%		
	Toxicity or Adverse reaction	Other Toxicity problem	4	2.8%		
Total			142	100.0%	142	100.0%

Table 8-8: Type Classification for Scenario 2

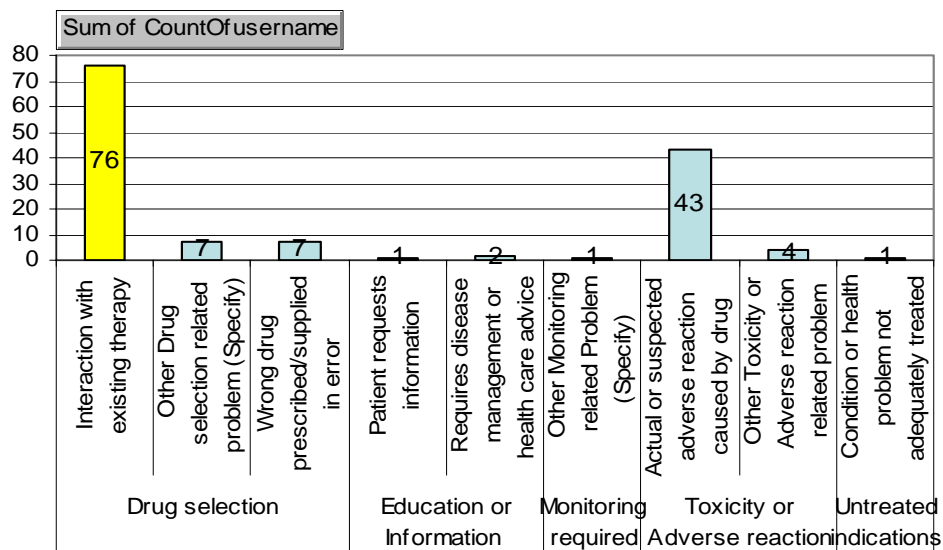


Figure 8-20: Type Classification for Scenario 2

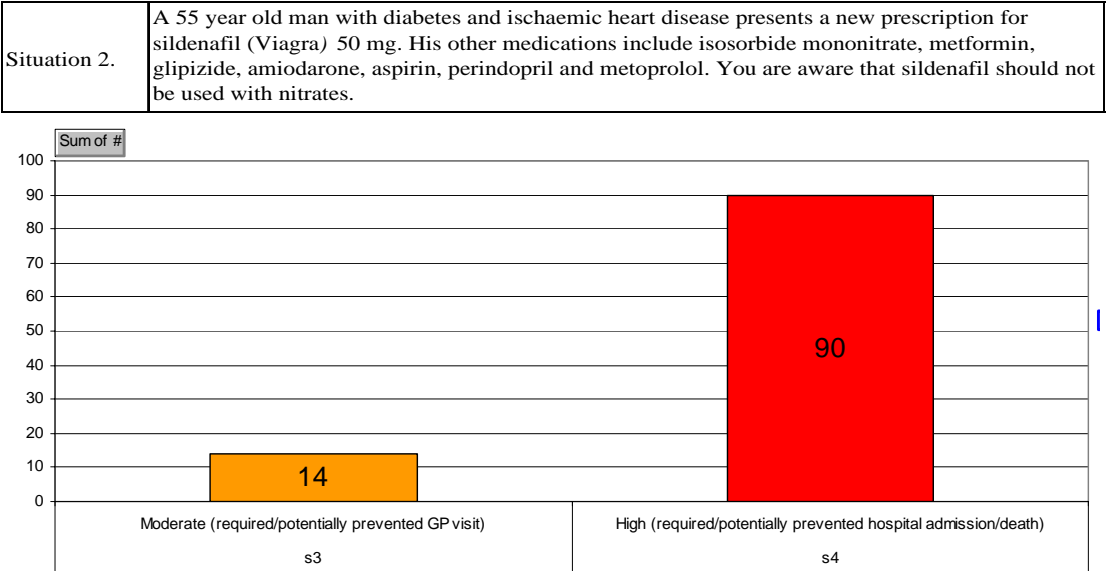


Figure 8-21: Significance Classifications for Scenario 2

In this scenario, a prescription has been presented for a drug that potentially could interact with the gentleman’s existing therapy, and should be classified as ‘Drug selection – interaction with existing therapy’, as most people have done. By definition, this is not an adverse drug reaction as he has not taken the interacting drug and is therefore not displaying any adverse effects or symptoms. Categorising this situation as ‘Drug selection – other’ would be satisfactory if the details of the problem were specified in the notes section.

This combination of drugs is contraindicated and can lead to very serious consequences if they are taken together. For this reason, it is reasonable to indicate that this intervention is of high significance.



### 8.3.4 Scenario 3

Scenario Number 3						
A prescription for a 12 year old boy for amoxycillin 250mg/5mL, 4mL three times a day for acute otitis media. You check the dose in the product information and find that it is meant to be 500mg three times a day.						
Type		Subtype	Scenario Number 3			
			#	%	#	%
D	Drug selection	Duplication				
	Drug selection	Interaction				
	Drug selection	Wrong drug				
	Drug selection	Wrong dosage form				
	Drug selection	Pre-existing severe ADR/allergy				
	Drug selection	Other Drug selection problem				
O	Over or underdose prescribed	Too high dose prescribed	3	2.2%	130	96.3%
	Over or underdose prescribed	Too low dose prescribed	126	93.3%		
	Over or underdose prescribed	Incorrect frequency prescribed				
	Over or underdose prescribed	Other Dose Problem	1	0.7%		
C	Compliance	Potential drug overuse/abuse situation				
	Compliance	Taking too little				
	Compliance	Taking too much				
	Compliance	Difficulty using dosage form				
	Compliance	Other Compliance Problem				
U	Untreated indications	Condition not adequately treated	1	0.7%	1	0.7%
	Untreated indications	Preventive therapy required				
M	Monitoring required	Drug levels				
	Monitoring required	Laboratory Monitoring				
	Monitoring required	Non-Laboratory monitoring				
	Monitoring required	Other Monitoring Problem				
E	Education or Information	Patient requests information			4	3.0%
	Education or Information	Confusion about therapy/condition				
	Education or Information	Demonstration of therapeutic device				
	Education or Information	Disease management advice	1	0.7%		
	Education or Information	Other Education/Information Problem	3	2.2%		
N	Non-clinical	Not sub-classified				
T	Toxicity or Adverse reaction	Caused by dose too high				
	Toxicity or Adverse reaction	Caused by drug interaction				
	Toxicity or Adverse reaction	Other Toxicity problem				
Total			135	100.0%	135	100.0%

Table 8-9: Type Classification for Scenario 3

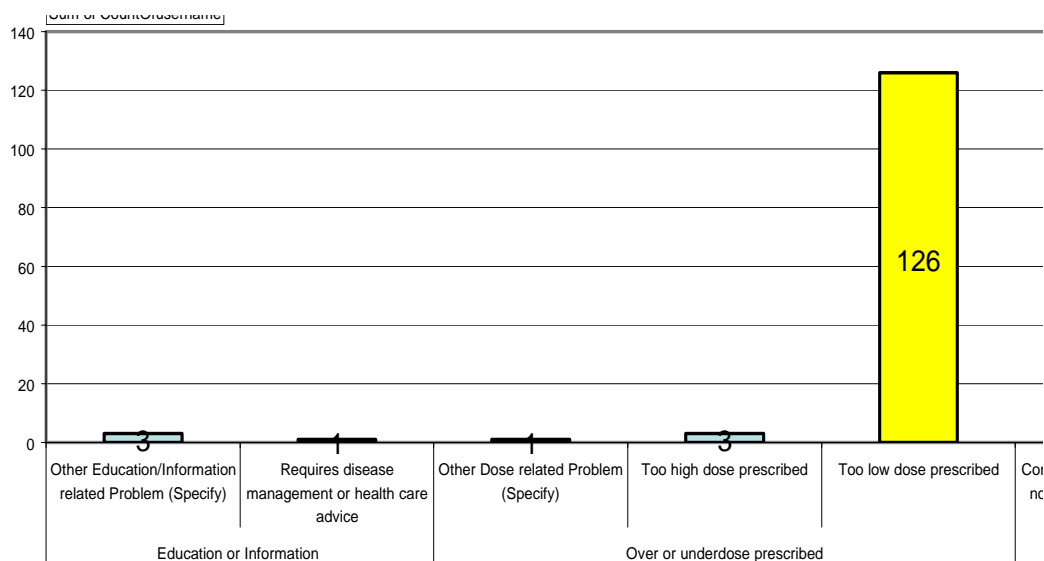
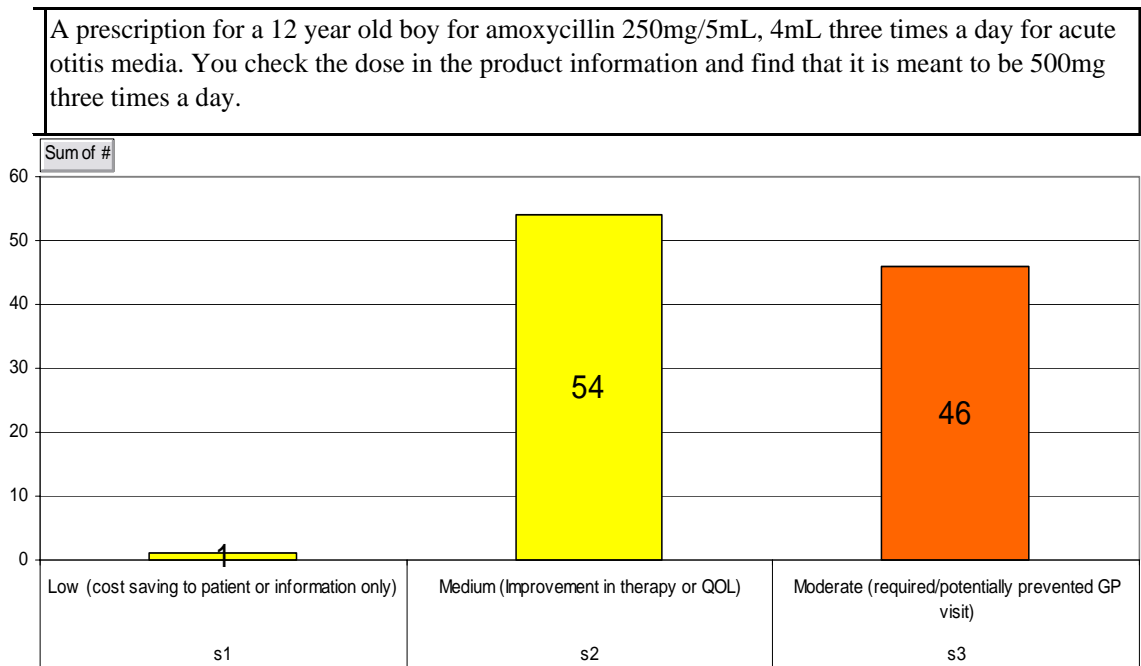


Figure 8-22: Type Classification for Scenario 3



**Figure 8-23: Significance Classifications for Scenario 3**

Most people have categorised this intervention correctly as ‘Over- or under-dose prescribed – dose too low’. There was perhaps a miscalculation on behalf of the person who indicated the dose was too high.

If this antibiotic was taken at the prescribed dose it is likely that the infection would not resolve, and a repeat visit to the general practitioner would be required. For this reason, it is best to indicate this intervention is of moderate significance.

### 8.3.5 Scenario 4

Scenario Number 4						
A 56 year old man comes into your pharmacy complaining of drowsiness. He tells you he commenced on mirtazapine one week ago and is currently taking 30mg each night. His other medications include diazepam 10mg tds and temazepam 20mg at night.						
Type		Subtype	Scenario Number 4			
			#	%	#	%
D	Drug selection	Duplication	12	9.4%	33	26.0%
	Drug selection	Interaction	18	14.2%		
	Drug selection	Wrong drug				
	Drug selection	Wrong dosage form				
	Drug selection	Pre-existing severe ADR/allergy				
	Drug selection	Other Drug selection problem	3	2.4%		
O	Over or underdose prescribed	Too high dose prescribed	6	4.7%	10	7.9%
	Over or underdose prescribed	Too low dose prescribed				
	Over or underdose prescribed	Incorrect frequency prescribed				
	Over or underdose prescribed	Other Dose Problem	4	3.1%		
C	Compliance	Potential drug overuse/abuse situation				
	Compliance	Taking too little				
	Compliance	Taking too much				
	Compliance	Difficulty using dosage form				
	Compliance	Other Compliance Problem				
U	Untreated indications	Condition not adequately treated				
	Untreated indications	Preventive therapy required				
M	Monitoring required	Drug levels			1	0.8%
	Monitoring required	Laboratory Monitoring				
	Monitoring required	Non-Laboratory monitoring	1	0.8%		
	Monitoring required	Other Monitoring Problem				
E	Education or Information	Patient requests information			2	1.6%
	Education or Information	Confusion about therapy/condition	1	0.8%		
	Education or Information	Demonstration of therapeutic device				
	Education or Information	Disease management advice	1	0.8%		
	Education or Information	Other Education/Information Problem				
N	Non-clinical	Not sub-classified				
T	Toxicity or Adverse reaction	Caused by dose too high	7	5.5%	81	63.8%
	Toxicity or Adverse reaction	Caused by drug interaction	60	47.2%		
	Toxicity or Adverse reaction	Other Toxicity problem	14	11.0%		
Total			127	100.0%	127	100.0%

Table 8-10: Type Classification for Scenario 4

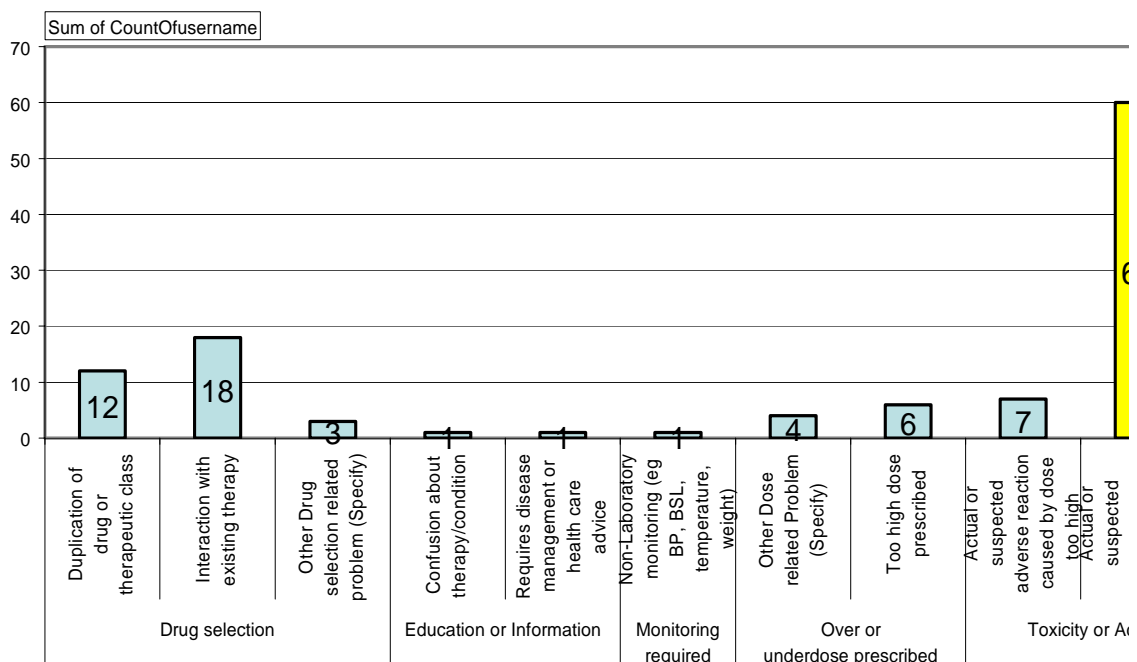


Figure 8-24Type Classification for Scenario 4

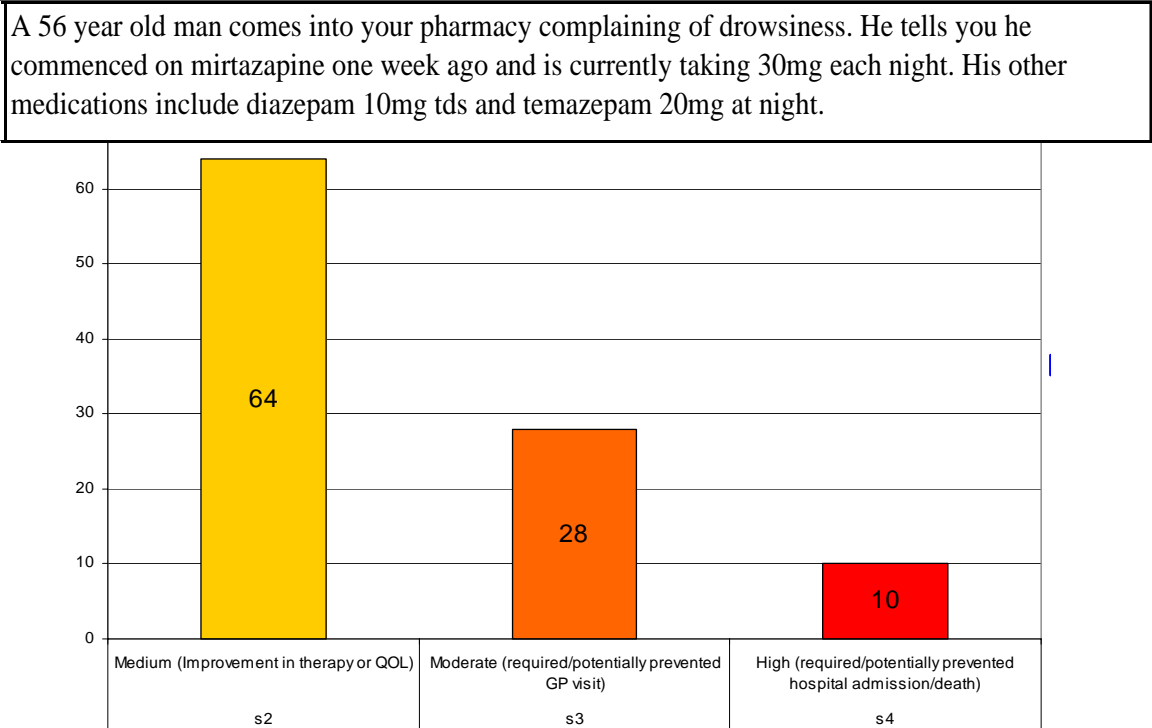


Figure 8-25: Significance Classifications for Scenario 4

This scenario is similar to scenario 2 in that there are potentially 2 interacting drugs, but in this case the two drugs have been taken and have caused an adverse effect or symptom. Therefore the most appropriate categorisation is ‘Toxicity or Adverse reaction – caused by drug interaction’. We are unsure if the patient was instructed to start at a half dose of mirtazapine to minimise side effects such as drowsiness, or exactly how much of each benzodiazepine he is taking. It is not appropriate to document this intervention as ‘Drug selection – duplication’ as the drugs are not of the same therapeutic class.

The significance of this intervention is probably not high; it is unlikely that the patient would need to be hospitalised due to the excessive drowsiness. Either medium or moderate would be appropriate.

### 8.3.6 Scenario 5

Scenario Number 5						
A 65year old woman presents a prescription for prednisolone 5mg daily for management of polymyalgia rheumatica. She is frail and appears to weigh approximately 45kg. Although she tells you that she is taking calcium supplements, you believe she is still at risk of osteoporosis						
Type		Subtype	Scenario Number 5			
			#	%	#	%
D	Drug selection	Duplication			3	2.5%
	Drug selection	Interaction				
	Drug selection	Wrong drug				
	Drug selection	Wrong dosage form				
	Drug selection	Pre-existing severe ADR/allergy	1	0.8%		
	Drug selection	Other Drug selection problem	2	1.7%		
O	Over or underdose prescribed	Too high dose prescribed				
	Over or underdose prescribed	Too low dose prescribed				
	Over or underdose prescribed	Incorrect frequency prescribed				
	Over or underdose prescribed	Other Dose Problem				
C	Compliance	Potential drug overuse/abuse situation				
	Compliance	Taking too little				
	Compliance	Taking too much				
	Compliance	Difficulty using dosage form				
	Compliance	Other Compliance Problem				
U	Untreated indications	Condition not adequately treated	18	15.0%	76	63.3%
	Untreated indications	Preventive therapy required	58	48.3%		
M	Monitoring required	Drug levels			16	13.3%
	Monitoring required	Laboratory Monitoring	8	6.7%		
	Monitoring required	Non-Laboratory monitoring	2	1.7%		
	Monitoring required	Other Monitoring Problem	6	5.0%		
E	Education or Information	Patient requests information			11	9.2%
	Education or Information	Confusion about therapy/condition				
	Education or Information	Demonstration of therapeutic device				
	Education or Information	Disease management advice	10	8.3%		
	Education or Information	Other Education/Information Problem	1	0.8%		
N	Non-clinical	Not sub-classified				
T	Toxicity or Adverse reaction	Caused by dose too high			14	11.7%
	Toxicity or Adverse reaction	Caused by drug interaction	1	0.8%		
	Toxicity or Adverse reaction	Other Toxicity problem	13	10.8%		
Total			120	100.0%	120	100.0%

Table 8-11: Type Classification for Scenario 5

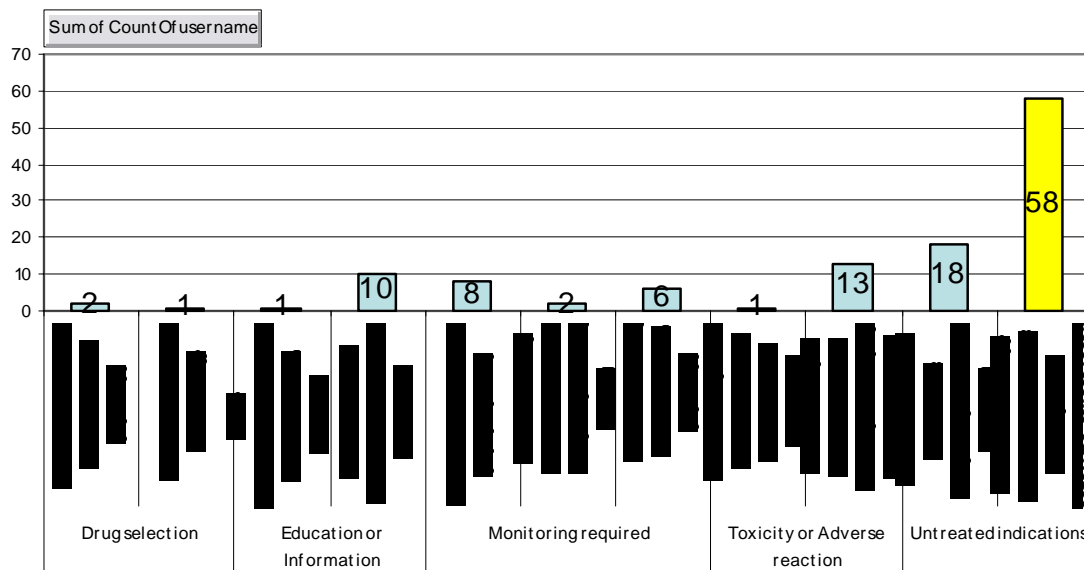
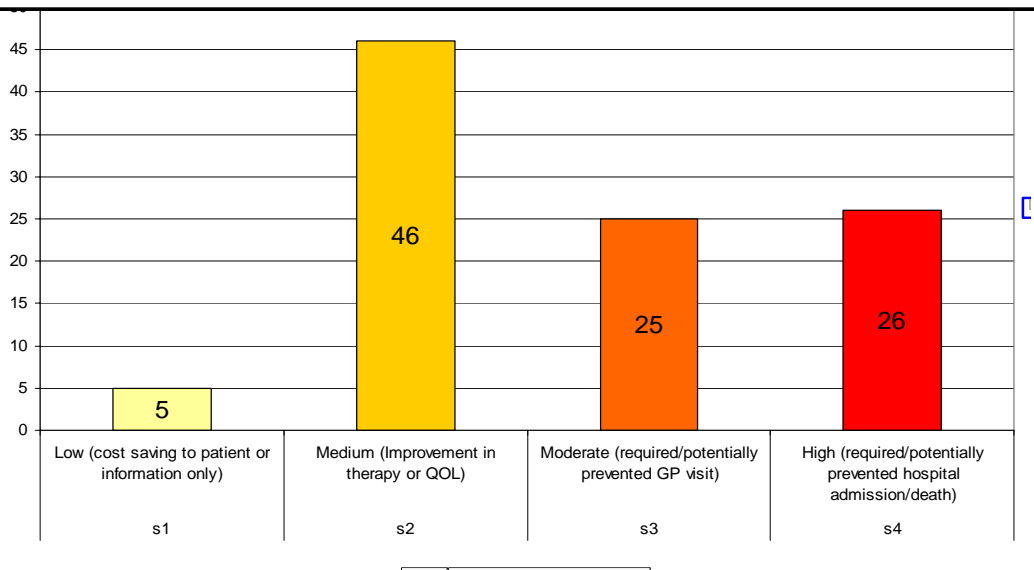


Figure 8-26Type Classification for Scenario 5

A 65year old woman presents a prescription for prednisolone 5mg daily for management of polymyalgia rheumatica. She is frail and appears to weigh approximately 45kg. Although she tells you that she is taking calcium supplements, you believe she is still at risk of osteoporosis.



**Figure 8-27: Significance Classifications for Scenario 5**

This scenario drew a large variation in responses, but the most appropriate categorisation would be ‘Untreated indication – condition not adequately treated’. The majority of respondents categorised the intervention correctly as an ‘untreated indication’, but only 15% as a ‘condition not adequately treated’. It could be argued that this intervention does fit into either category quite satisfactorily, and this is confirmed by referral to the scope notes. Some people suggested that monitoring is required, for example a bone densitometry test, but this is probably a recommendation as opposed to the category of intervention. It could also be argued that the lady only requires disease management advice regarding her diet and lifestyle activities.

The significance of this intervention is probably ‘mild – improvement in therapy or quality of life’. If left unchecked, the situation may lead to a hospitalisation post fracture, but not likely in the near future.

### 8.3.7 Scenario 6

Scenario Number 6						
An elderly male patient presents repeat scripts for diamicon and amaryl. His dispensing history shows patient has had diamicon for over 12months, but has only received amaryl in previous month. You are aware that amaryl and diamicon are both sulphonylureas.						
Type		Subtype	Scenario Number 6			
			#	%	#	%
D	Drug selection	Duplication	85	73.9%	89	77.4%
	Drug selection	Interaction	3	2.6%		
	Drug selection	Wrong drug	1	0.9%		
	Drug selection	Wrong dosage form				
	Drug selection	Pre-existing severe ADR/allergy				
	Drug selection	Other Drug selection problem				
O	Over or underdose prescribed	Too high dose prescribed			3	2.6%
	Over or underdose prescribed	Too low dose prescribed				
	Over or underdose prescribed	Incorrect frequency prescribed				
	Over or underdose prescribed	Other Dose Problem	3	2.6%		
C	Compliance	Potential drug overuse/abuse situation			1	0.9%
	Compliance	Taking too little				
	Compliance	Taking too much	1	0.9%		
	Compliance	Difficulty using dosage form				
	Compliance	Other Compliance Problem				
U	Untreated indications	Condition not adequately treated			1	0.9%
	Untreated indications	Preventive therapy required	1	0.9%		
M	Monitoring required	Drug levels			1	0.9%
	Monitoring required	Laboratory Monitoring	1	0.9%		
	Monitoring required	Non-Laboratory monitoring				
	Monitoring required	Other Monitoring Problem				
E	Education or Information	Patient requests information			14	12.2%
	Education or Information	Confusion about therapy/condition	5	4.3%		
	Education or Information	Demonstration of therapeutic device				
	Education or Information	Disease management advice	7	6.1%		
	Education or Information	Other Education/Information Problem	2	1.7%		
N	Non-clinical	Not sub-classified				
T	Toxicity or Adverse reaction	Caused by dose too high			6	5.2%
	Toxicity or Adverse reaction	Caused by drug interaction	4	3.5%		
	Toxicity or Adverse reaction	Other Toxicity problem	2	1.7%		
	Total			115		

Table 8-12: Type Classification for Scenario 6

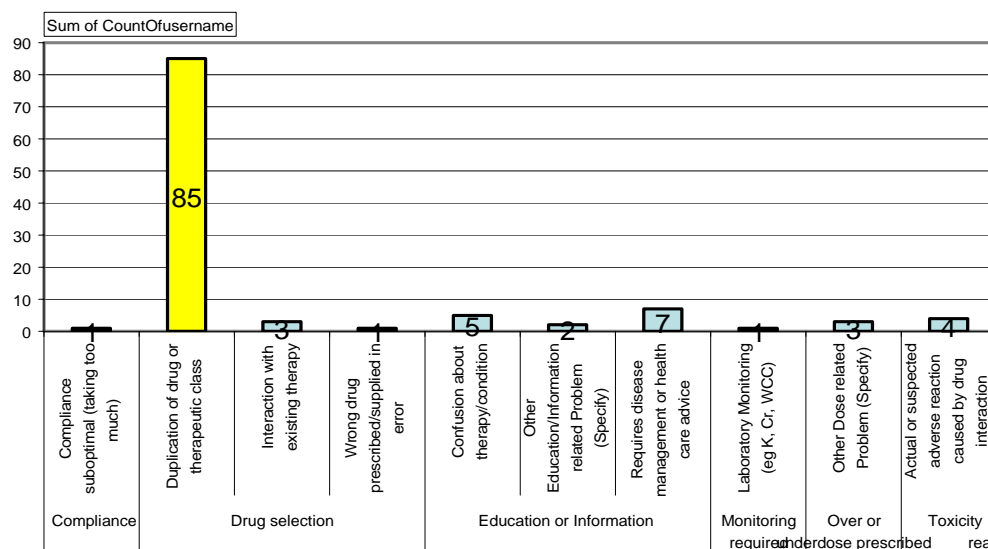


Figure 8-28: Type Classification for Scenario 6

An elderly male patient presents repeat scripts for diamicon and amaryl. His dispensing history shows patient has had diamicon for over 12months, but has only received amaryl in previous month. You are aware that amaryl and diamicon are both sulphonylureas.

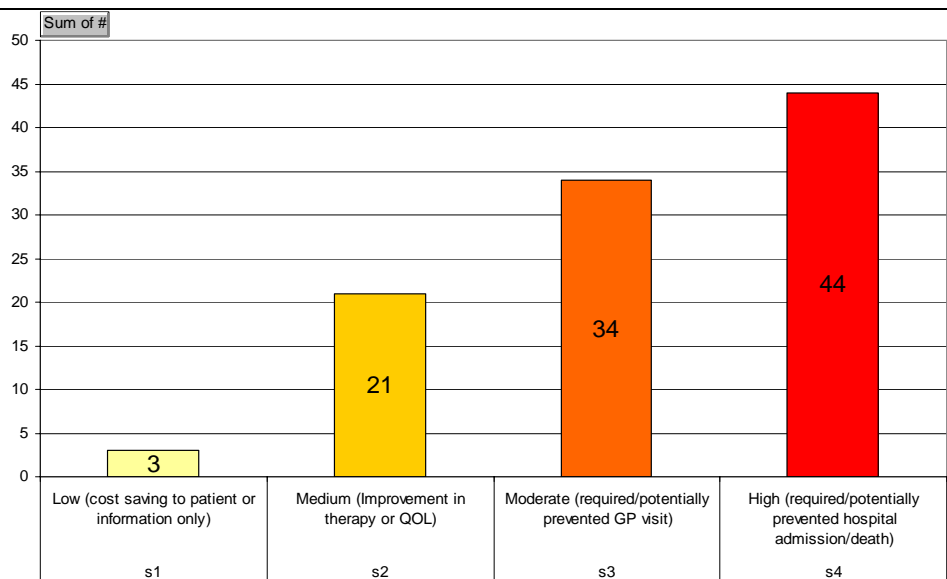


Figure 8-29: Significance Classifications for Scenario 6

This scenario is clearly a ‘Drug selection – duplication’ intervention, as 73.9% of responders have indicated. The patient has not reported any adverse effects from taking the combination, so this rules out the possibility of it being a toxicity problem. It could be a problem of patient confusion or misunderstanding of the doctor’s directions, if the prescriber had advised the patient to cease the diamicon.

The significance of this intervention is probably moderate as a consultation with the prescriber for monitoring of the BSL/HbA1C is advisable. Many people indicated that this is of high significance and were probably concerned that the patient would develop severe hypoglycaemia requiring hospitalisation. The fact that he had already been taking the therapy for 1 month and has not reported any adverse effects, suggests that it probably is not of high significance.



### 8.3.8 Scenario 7

Scenario Number 7						
A 61 year old, overweight, man has been diagnosed as having Type 2 Diabetes Mellitus (NIDDM) for 10 years and ischaemic heart disease (angina). He has been prescribed glipizide each morning and metformin three times a day. He admits that he misses his medication sometimes (approximately 3-6 doses per week) because he simply forgets.						
Type		Subtype	Scenario Number 7			
			#	%	#	%
D	Drug selection	Duplication			2	1.8%
	Drug selection	Interaction	1	0.9%		
	Drug selection	Wrong drug				
	Drug selection	Wrong dosage form	1	0.9%		
	Drug selection	Pre-existing severe ADR/allergy				
	Drug selection	Other Drug selection problem				
O	Over or underdose prescribed	Too high dose prescribed				
	Over or underdose prescribed	Too low dose prescribed				
	Over or underdose prescribed	Incorrect frequency prescribed				
	Over or underdose prescribed	Other Dose Problem				
C	Compliance	Potential drug overuse/abuse situation			101	90.2%
	Compliance	Taking too little	93	83.0%		
	Compliance	Taking too much				
	Compliance	Difficulty using dosage form	1	0.9%		
	Compliance	Other Compliance Problem	7	6.3%		
U	Untreated indications	Condition not adequately treated	1	0.9%	1	0.9%
	Untreated indications	Preventive therapy required				
M	Monitoring required	Drug levels			2	1.8%
	Monitoring required	Laboratory Monitoring				
	Monitoring required	Non-Laboratory monitoring	2	1.8%		
	Monitoring required	Other Monitoring Problem				
E	Education or Information	Patient requests information			6	5.4%
	Education or Information	Confusion about therapy/condition				
	Education or Information	Demonstration of therapeutic device				
	Education or Information	Disease management advice	5	4.5%		
	Education or Information	Other Education/Information Problem	1	0.9%		
N	Non-clinical	Not sub-classified				
T	Toxicity or Adverse reaction	Caused by dose too high				
	Toxicity or Adverse reaction	Caused by drug interaction				
	Toxicity or Adverse reaction	Other Toxicity problem				
Total			112	100.0%	112	100.0%

Table 8-13 Type Classification for Scenario 7

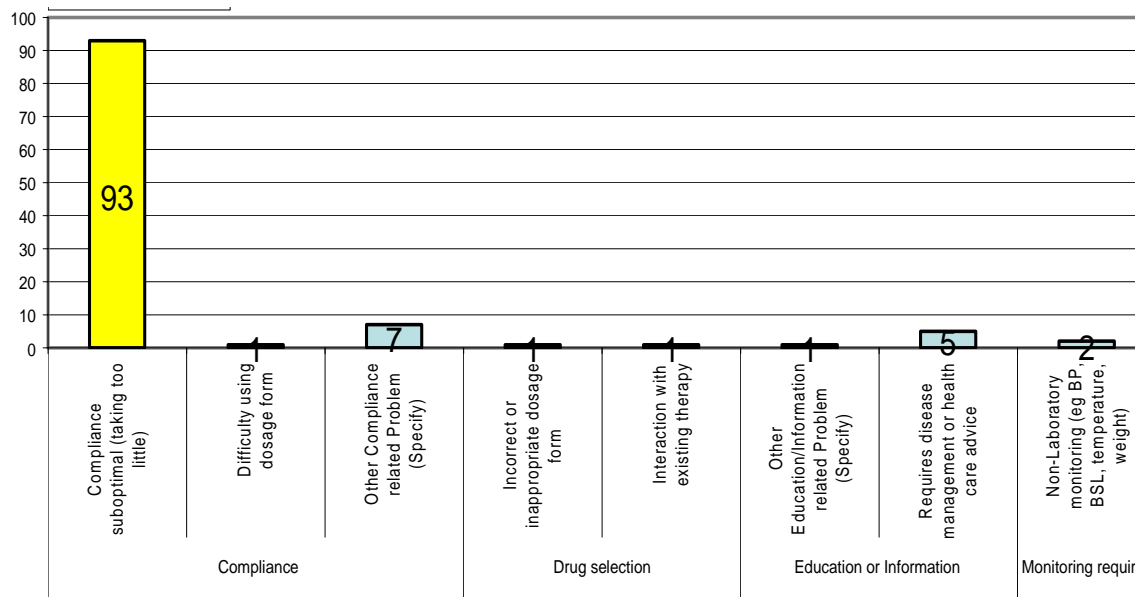
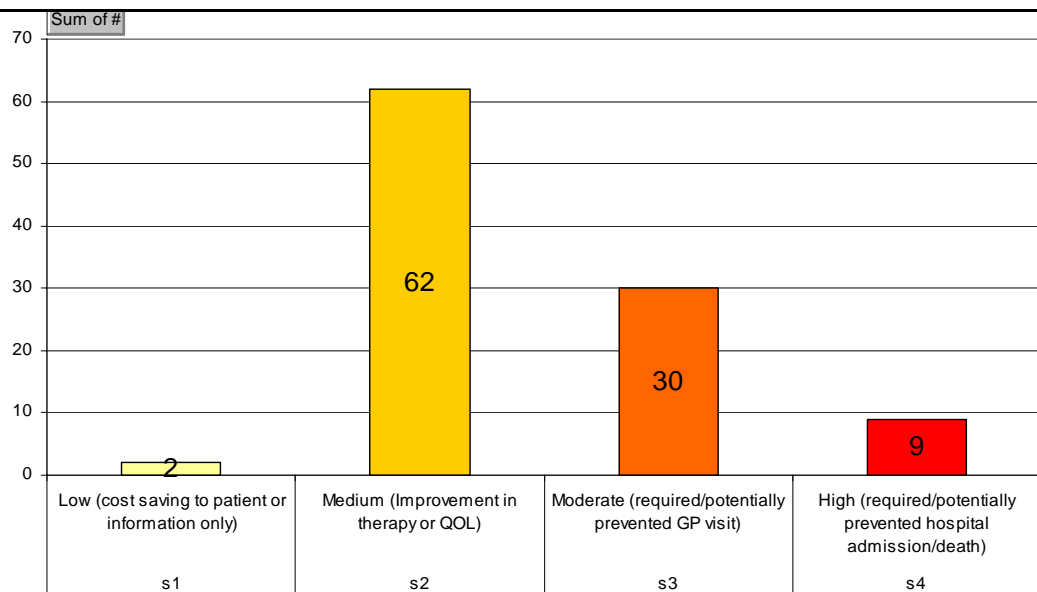


Figure 8-30: Type Classification for Scenario 7

A 61 year old, overweight, man has been diagnosed as having Type 2 Diabetes Mellitus (NIDDM) for 10 years and ischaemic heart disease (angina). He has been prescribed glipizide each morning and metformin three times a day. He admits that he misses his medication sometimes (approximately 3-6 doses per week) because he simply forgets.



**Figure 8-31 Significance Classifications for Scenario 7**

This is clearly a compliance problem and 'taking too little' the most appropriate selection. The scope notes clearly explain that 'difficulty using dosage form' is to apply to a physical problem with using a particular device, and does not relate to forgetfulness. There is no indication that his prescribed medications are inappropriate, unless you feel that tds dosing for an older gentleman was complicating the issue. Monitoring (HbA1C) may be required to establish the extent of this gentleman's non-compliance (an 'action' or 'recommendation') but this is not the cause of the problem, as two people indicated.

The significance of this intervention is most likely mild. Explaining the importance of taking his medications regularly and providing a dose administration aid will improve this gentleman's therapy.

### 8.3.9 Scenario 8

Scenario Number 8					
An 84 year old woman presents complaining of oral thrush. She is a chronic asthmatic using inhaled corticosteroids. You check her inhaler technique and notice that she does not inhale properly. You arrange a large volume spacer device, and give her a demonstration on how to use the device appropriately.					
Type	Subtype	Scenario Number 8			
		#	%	#	%
D	Drug selection	Duplication			
	Drug selection	Interaction			
	Drug selection	Wrong drug			
	Drug selection	Wrong dosage form			
	Drug selection	Pre-existing severe ADR/allergy			
	Drug selection	Other Drug selection problem			
O	Over or underdose prescribed	Too high dose prescribed			
	Over or underdose prescribed	Too low dose prescribed			
	Over or underdose prescribed	Incorrect frequency prescribed			
	Over or underdose prescribed	Other Dose Problem			
C	Compliance	Potential drug overuse/abuse situation			
	Compliance	Taking too little			
	Compliance	Taking too much		17	15.2%
	Compliance	Difficulty using dosage form	17	15.2%	
	Compliance	Other Compliance Problem			
U	Untreated indications	Condition not adequately treated			
	Untreated indications	Preventive therapy required	1	0.9%	1 0.9%
M	Monitoring required	Drug levels			
	Monitoring required	Laboratory Monitoring			
	Monitoring required	Non-Laboratory monitoring	1	0.9%	1 0.9%
	Monitoring required	Other Monitoring Problem			
E	Education or Information	Patient requests information			
	Education or Information	Confusion about therapy/condition			
	Education or Information	Demonstration of therapeutic device	62	55.4%	66 58.9%
	Education or Information	Disease management advice			
N	Non-clinical	Not sub-classified			
	Non-clinical	Other Education/Information Problem	4	3.6%	
T	Toxicity or Adverse reaction	Caused by dose too high	1	0.9%	
	Toxicity or Adverse reaction	Caused by drug interaction			27 24.1%
	Toxicity or Adverse reaction	Other Toxicity problem	26	23.2%	
Total			112 100.0%	112 100.0%	

Table 8-14: Type Classification for Scenario 8

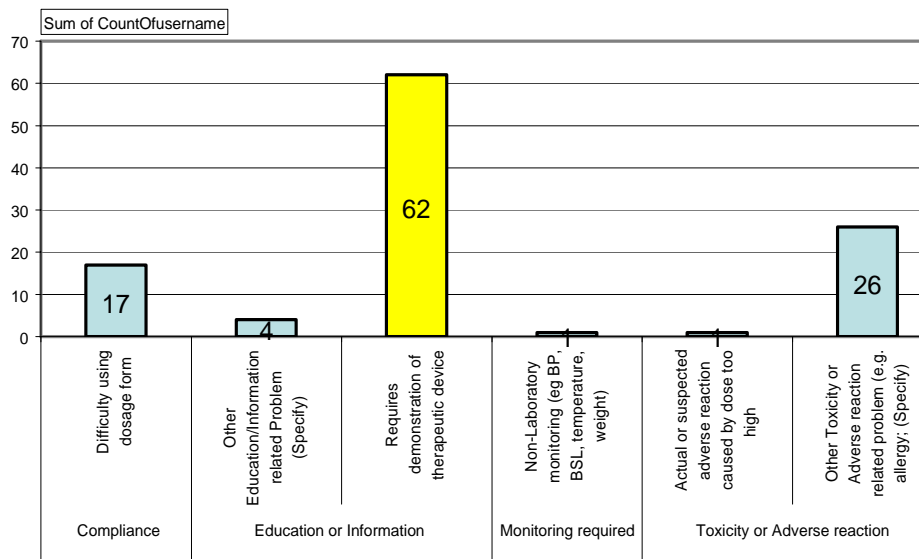
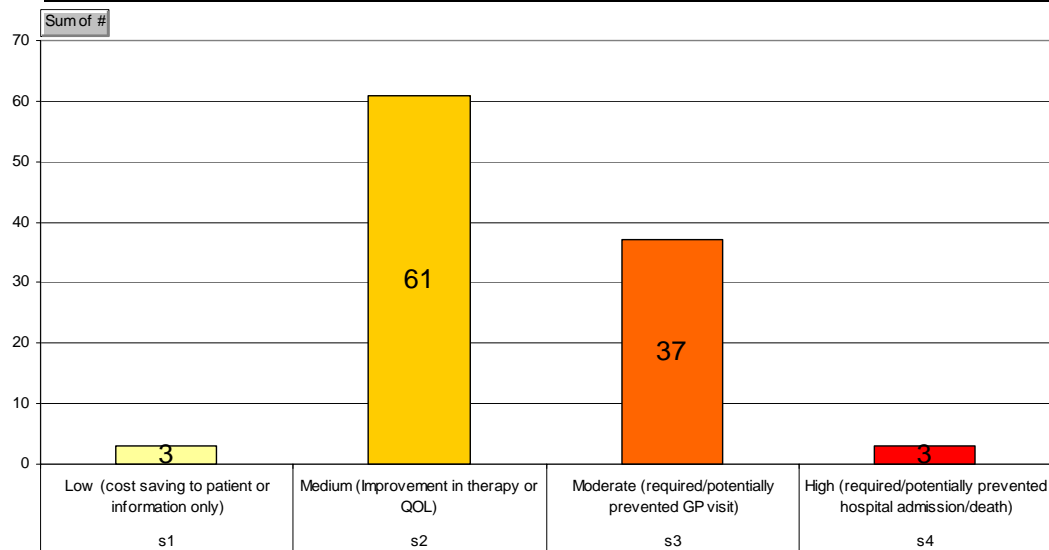


Figure 8-32: Type Classification for Scenario 8

An 84 year old woman presents complaining of oral thrush. She is a chronic asthmatic using inhaled corticosteroids. You check her inhaler technique and notice that she does not inhale properly. You arrange a large volume spacer device, and give her a demonstration on how to use the device appropriately.



**Figure 8-33Significance Classifications for Scenario 8**

This scenario could be documented as two separate interventions because she requires a demonstration of her inhaler device to improve her technique, (Education or Information – demonstration of device), and she has presented to the pharmacy with an adverse effect from her usual therapy at normal doses (Toxicity of adverse reaction – other toxicity problem). The majority of responders indicated that either of these two categories were the most appropriate, but another 15.2% indicated that this was a compliance problem as the person was having difficulty using the dosage form. Referral to the scope notes quite clearly instructs that this category is to be used when the person has a physical problem with the device eg arthritis limiting the use of the inhaler, not just using the device inappropriately. (See scenario 9).

The significance of this intervention could be regarded as mild or moderate, as most people have indicated. If left unchecked, the patient may have required a visit to her GP, but at the very least the treatment of her asthma has been improved.

### 8.3.10 Scenario 9

Scenario Number 9						
An 82 year old lady presents with script for <i>ventolin</i> inhaler one to two puffs four times a day when required. During counselling, you discover that her rheumatoid arthritis is preventing her from actuating the inhaler.						
Type		Subtype	Scenario Number 9			
			#	%	#	%
D	Drug selection	Duplication			30	26.1%
	Drug selection	Interaction				
	Drug selection	Wrong drug				
	Drug selection	Wrong dosage form	26	22.6%		
	Drug selection	Pre-existing severe ADR/allergy				
	Drug selection	Other Drug selection problem	4	3.5%		
O	Over or underdose prescribed	Too high dose prescribed			1	0.9%
	Over or underdose prescribed	Too low dose prescribed	1	0.9%		
	Over or underdose prescribed	Incorrect frequency prescribed				
	Over or underdose prescribed	Other Dose Problem				
C	Compliance	Potential drug overuse/abuse situation			75	65.2%
	Compliance	Taking too little	2	1.7%		
	Compliance	Taking too much				
	Compliance	Difficulty using dosage form	72	62.6%		
	Compliance	Other Compliance Problem	1	0.9%		
U	Untreated indications	Condition not adequately treated				
	Untreated indications	Preventive therapy required				
M	Monitoring required	Drug levels			1	0.9%
	Monitoring required	Laboratory Monitoring				
	Monitoring required	Non-Laboratory monitoring	1	0.9%		
	Monitoring required	Other Monitoring Problem				
E	Education or Information	Patient requests information			8	7.0%
	Education or Information	Confusion about therapy/condition				
	Education or Information	Demonstration of therapeutic device	3	2.6%		
	Education or Information	Disease management advice	4	3.5%		
	Education or Information	Other Education/Information Problem	1	0.9%		
N	Non-clinical	Not sub-classified				
T	Toxicity or Adverse reaction	Caused by dose too high				
	Toxicity or Adverse reaction	Caused by drug interaction				
	Toxicity or Adverse reaction	Other Toxicity problem				
Total			115	100.0%	115	100.0%

Table 8-15: Type Classification for Scenario 9

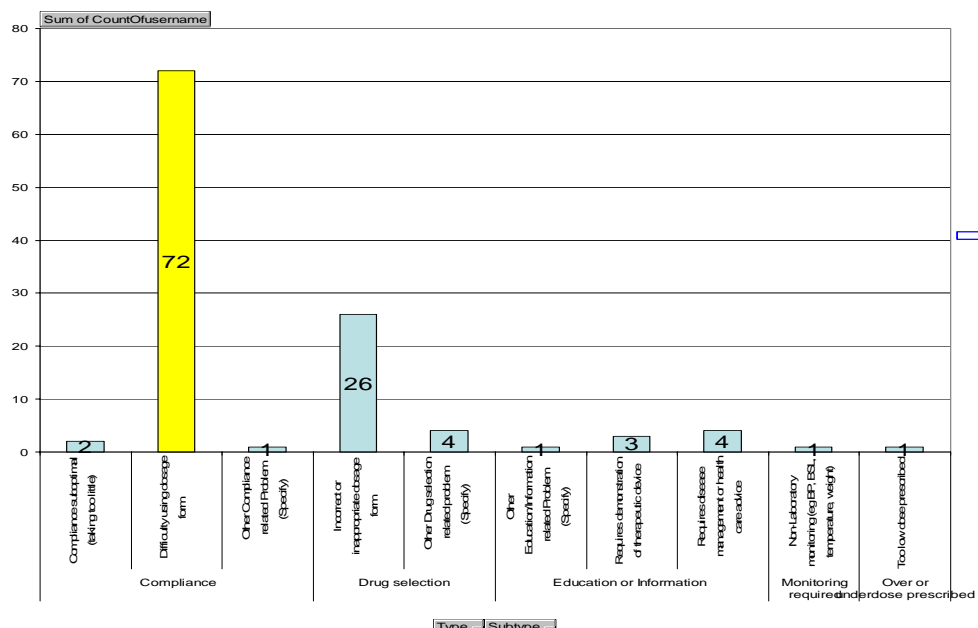
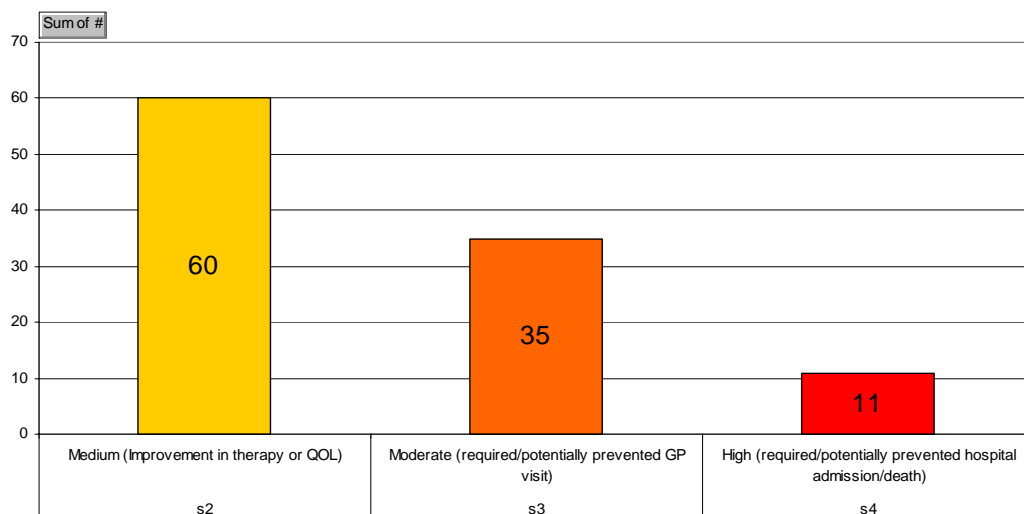


Figure 8-34: Type Classification for Scenario 9

An 82 year old lady presents with script for *ventolin* inhaler one to two puffs four times a day when required. During counselling, you discover that her rheumatoid arthritis is preventing her from actuating the inhaler.



**Figure 8-35: Significance Classifications for Scenario 9**

Quite clearly, this intervention should be categorised as ‘Compliance – difficulty using dosage form’ as most people have indicated. It could be argued that the doctor could have prescribed a different device that would have been easier for her to use (Drug selection – incorrect or inappropriate dosage form) as the inhaler device is clearly inappropriate for this person. A demonstration of the device is still not going to enable her to use it satisfactorily, so ‘Education or Information’ is not going to assist the patient to become more compliant.

The significance of this intervention is mild to moderate. It is difficult to be more specific than this without additional knowledge of the patients other therapy, or knowledge of the severity of her asthma.

### 8.3.11 Scenario 10

Scenario Number 10						
An 87 year old woman has been taking digoxin 125 micrograms daily for her atrial fibrillation for 3 years. Recently you have noticed that she is getting increasingly frail and may have lost weight. It is a Saturday morning and she presents a new prescription for digoxin. While you prepare the prescription she tells you that she has been having visual disturbances and wonders if she needs her glasses replaced. You recognise the possible side effect of the digoxin.						
Type		Subtype	Scenario Number 10			
			#	%	#	%
D	Drug selection	Duplication			23	20.4%
	Drug selection	Interaction				
	Drug selection	Wrong drug				
	Drug selection	Wrong dosage form				
	Drug selection	Pre-existing severe ADR/allergy				
	Drug selection	Other Drug selection problem				
O	Over or underdose prescribed	Too high dose prescribed	21	18.6%	23	20.4%
	Over or underdose prescribed	Too low dose prescribed				
	Over or underdose prescribed	Incorrect frequency prescribed				
	Over or underdose prescribed	Other Dose Problem	2	1.8%		
C	Compliance	Potential drug overuse/abuse situation			18	15.9%
	Compliance	Taking too little				
	Compliance	Taking too much				
	Compliance	Difficulty using dosage form				
	Compliance	Other Compliance Problem				
U	Untreated indications	Condition not adequately treated			18	15.9%
	Untreated indications	Preventive therapy required				
M	Monitoring required	Drug levels	17	15.0%	18	15.9%
	Monitoring required	Laboratory Monitoring	1	0.9%		
	Monitoring required	Non-Laboratory monitoring				
	Monitoring required	Other Monitoring Problem				
E	Education or Information	Patient requests information			18	15.9%
	Education or Information	Confusion about therapy/condition				
	Education or Information	Demonstration of therapeutic device				
	Education or Information	Disease management advice				
	Education or Information	Other Education/Information Problem				
N	Non-clinical	Not sub-classified				
T	Toxicity or Adverse reaction	Caused by dose too high	70	61.9%	72	63.7%
	Toxicity or Adverse reaction	Caused by drug interaction				
	Toxicity or Adverse reaction	Other Toxicity problem	2	1.8%		
Total			113	100.0%	113	100.0%

Table 8-16: Type Classification for Scenario 10

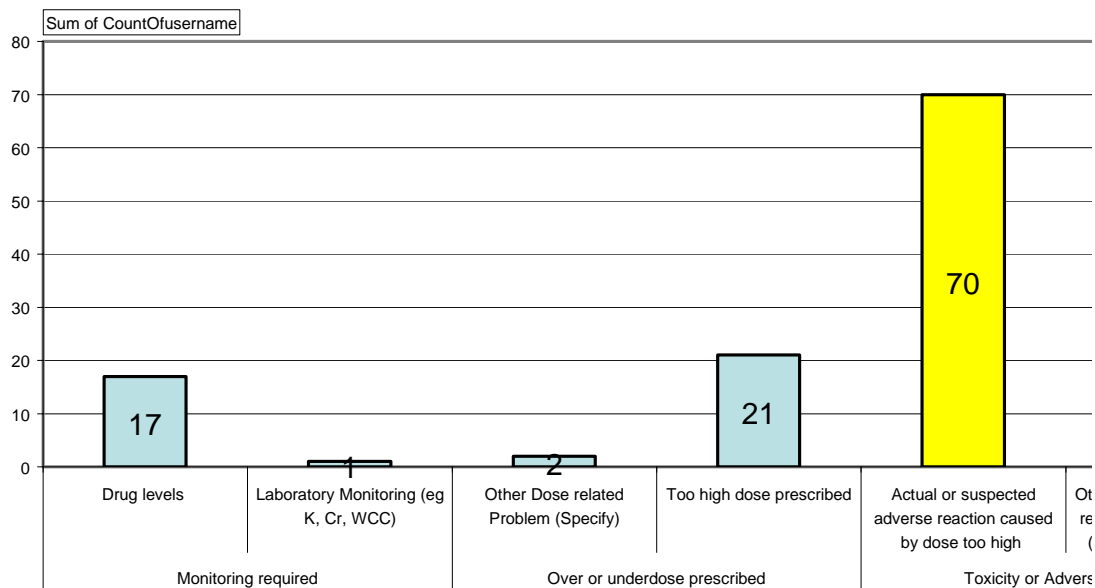
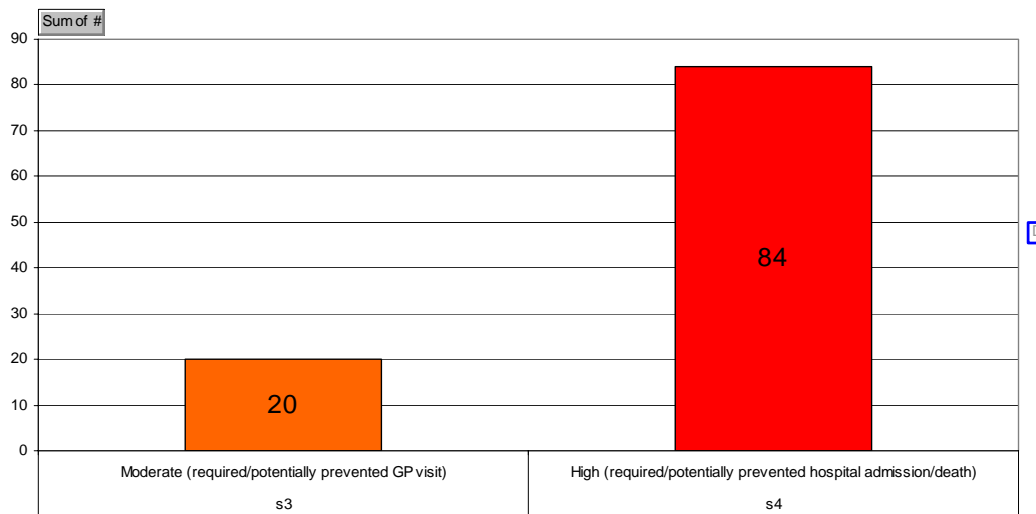


Figure 8-36: Type Classification for Scenario 10

An 87 year old woman has been taking digoxin 125 micrograms daily for her atrial fibrillation for 3 years. Recently you have noticed that she is getting increasingly frail and may have lost weight. It is a Saturday morning and she presents a new prescription for digoxin. While you prepare the prescription she tells you that she has been having visual disturbance and wonders if she needs her glasses replaced. You recognise the possible side effect of the digoxin.



**Figure 8-37 Significance Classifications for Scenario 10**

In this scenario, the patient has noticed an adverse effect that can be attributed to her current medication therapy, although has not made the link between her visual disturbance and current medications. In assigning an intervention category, most people have indicated that the visual disturbance is a sign of 'Toxicity or adverse effect'. It could also be quite reasonably be categorised as 'Over- or under-dose prescribed – dose too high' as reference to the scope notes quite clearly explains that this category is to be used "...where the dose is too high because of a particular parameter of the patient such as renal function.", although the dose has been fine up until now. Some people have indicated that monitoring is required, and although this is true, this is a recommendation and not the cause of the pharmacist performing the intervention.

The significance of this intervention is moderate to high. The patient felt that the visual disturbance was due to her glasses and may not have done anything about it, and therefore may have been admitted to hospital. If she takes your advice, she will return to the doctor for perhaps digoxin levels, renal function tests and adjustment of her dose which makes this an intervention of moderate significance by definition.



### 8.3.12 Scenario 11

Scenario Number 11						
A 45 year old man who is a regular patient of your pharmacy arrives for a repeat prescription of metoprolol for his hypertension. He has a history of asthma and tells you he has been using salbutamol inhaler 3 times daily in the last couple of weeks. He also uses a fluticasone inhaler, 250mcg twice a day, and presents a new prescription for salmeterol. It seems that he is suffering from an increase in his asthma symptoms and this could be due to the metoprolol.						
Type		Subtype	Scenario Number 11			
			#	%	#	%
D	Drug selection	Duplication			55	48.2%
	Drug selection	Interaction	14	12.3%		
	Drug selection	Wrong drug	19	16.7%		
	Drug selection	Wrong dosage form				
	Drug selection	Pre-existing severe ADR/allergy				
	Drug selection	Other Drug selection problem	22	19.3%		
O	Over or underdose prescribed	Too high dose prescribed	1	0.9%	1	0.9%
	Over or underdose prescribed	Too low dose prescribed				
	Over or underdose prescribed	Incorrect frequency prescribed				
	Over or underdose prescribed	Other Dose Problem				
C	Compliance	Potential drug overuse/abuse situation				
	Compliance	Taking too little				
	Compliance	Taking too much				
	Compliance	Difficulty using dosage form				
	Compliance	Other Compliance Problem				
U	Untreated indications	Condition not adequately treated	2	1.8%	2	1.8%
	Untreated indications	Preventive therapy required				
M	Monitoring required	Drug levels				
	Monitoring required	Laboratory Monitoring				
	Monitoring required	Non-Laboratory monitoring				
	Monitoring required	Other Monitoring Problem				
E	Education or Information	Patient requests information				
	Education or Information	Confusion about therapy/condition				
	Education or Information	Demonstration of therapeutic device				
	Education or Information	Disease management advice				
	Education or Information	Other Education/Information Problem				
N	Non-clinical	Not sub-classified				
T	Toxicity or Adverse reaction	Caused by dose too high			56	49.1%
	Toxicity or Adverse reaction	Caused by drug interaction	27	23.7%		
	Toxicity or Adverse reaction	Other Toxicity problem	29	25.4%		
Total			114	100.0%	114	100.0%

Table 8-17: Type Classification for Scenario 11

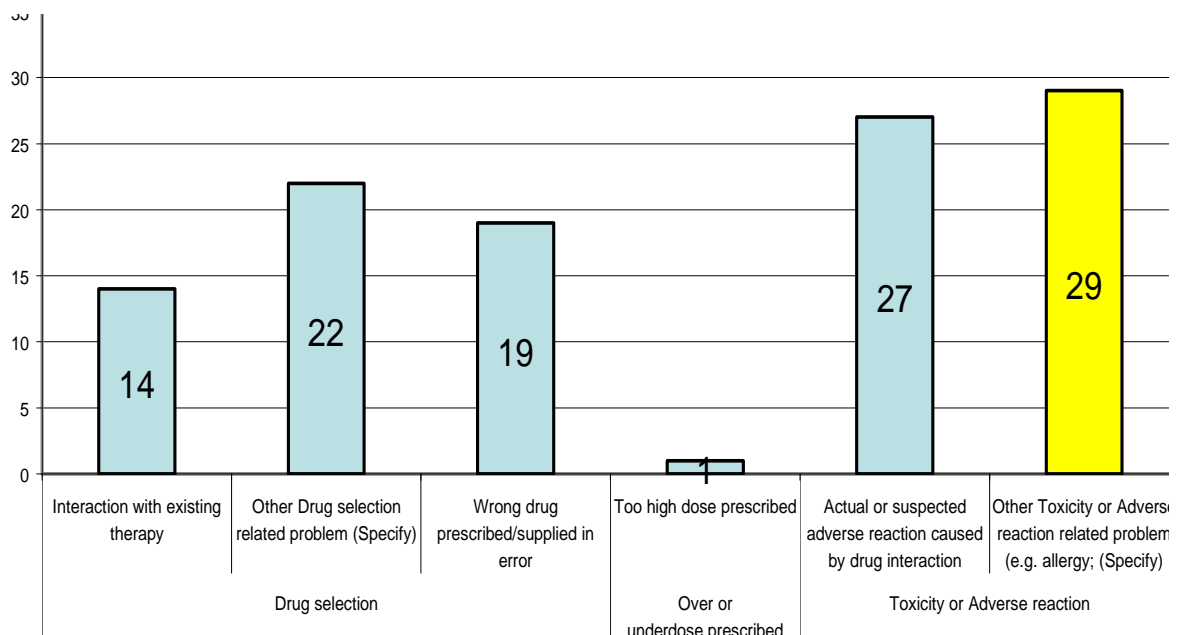
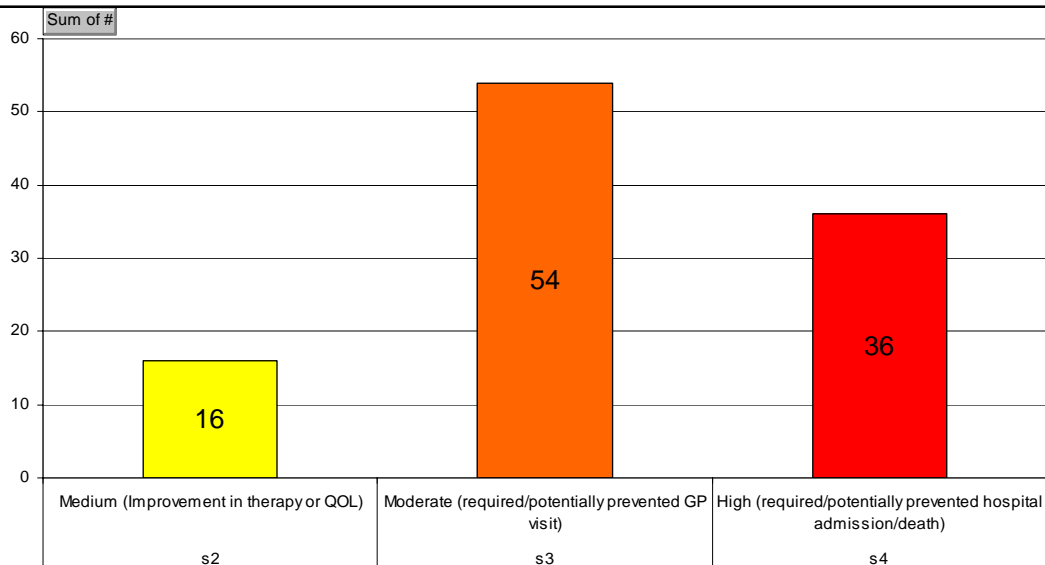


Figure 8-38: Type Classification for Scenario 11

A 45 year old man who is a regular patient of your pharmacy arrives for a repeat prescription of metoprolol for his hypertension. He has a history of asthma and tells you he has been using salbutamol inhaler 3 times daily in the last couple of weeks. He also uses a fluticasone inhaler, 250mcg twice a day, and presents a new prescription for salmeterol. It seems that he is suffering from an increase in his asthma symptoms and this could be due to the metoprolol.



**Figure 8-39: Significance Classifications for Scenario 11**

This gentleman is displaying a symptom or adverse effect and therefore this intervention should be documented as 'Toxicity or adverse reaction – caused by drug interaction'. It could also be documented as 'Toxicity or adverse effect – other' as long as the details are specified in the notes section. Almost half of the responders indicated that this was a 'Drug selection' intervention. It could be argued that metoprolol is an inappropriate drug in an asthmatic and therefore should not have been prescribed, but reference to the scope notes indicates that these categories should be selected only "When there are no obvious adverse clinical effects..." and there appears to be an adverse effect in this case. In fact, the patient has just seen his GP who has prescribed an additional asthma management medication, which indicates loss of asthma control. Two people indicated that this intervention should be categorised as 'Untreated indication – condition not adequately treated'. An additional medication has just been prescribed so the GP is attempting to gain control of his asthma, and this may well be possible if an alternative antihypertensive is selected.

The significance of this intervention is moderate, as it will probably require a return visit to the GP. It is unlikely to require a hospital visit as he has been taking the metoprolol for at least a month, and has only been using the salbutamol three times a day. The deterioration of his asthma appears to be a slow process.

### 8.3.13 Scenario 12

Scenario Number 12						
A 54 year old woman arrives at your pharmacy to collect her monthly omeprazole 40mg daily prescription. She mentions in the course of counselling that she takes it daily after breakfast, for convenience but she still has some reflux problems in the evening.						
Type		Subtype	Scenario Number 12			
			#	%	#	%
D	Drug selection	Duplication			3	2.8%
	Drug selection	Interaction				
	Drug selection	Wrong drug	1	0.9%		
	Drug selection	Wrong dosage form				
	Drug selection	Pre-existing severe ADR/allergy				
	Drug selection	Other Drug selection problem	2	1.9%		
O	Over or underdose prescribed	Too high dose prescribed			37	34.3%
	Over or underdose prescribed	Too low dose prescribed	4	3.7%		
	Over or underdose prescribed	Incorrect frequency prescribed	28	25.9%		
	Over or underdose prescribed	Other Dose Problem	5	4.6%		
C	Compliance	Potential drug overuse/abuse situation			7	6.5%
	Compliance	Taking too little				
	Compliance	Taking too much	1	0.9%		
	Compliance	Difficulty using dosage form				
	Compliance	Other Compliance Problem	6	5.6%		
U	Untreated indications	Condition not adequately treated	31	28.7%	31	28.7%
	Untreated indications	Preventive therapy required				
M	Monitoring required	Drug levels				
	Monitoring required	Laboratory Monitoring				
	Monitoring required	Non-Laboratory monitoring				
	Monitoring required	Other Monitoring Problem				
E	Education or Information	Patient requests information			30	27.8%
	Education or Information	Confusion about therapy/condition	3	2.8%		
	Education or Information	Demonstration of therapeutic device				
	Education or Information	Disease management advice	21	19.4%		
	Education or Information	Other Education/Information Problem	6	5.6%		
N	Non-clinical	Not sub-classified				
T	Toxicity or Adverse reaction	Caused by dose too high				
	Toxicity or Adverse reaction	Caused by drug interaction				
	Toxicity or Adverse reaction	Other Toxicity problem				
Total			108	100.0%	108	100.0%

Table 8-18: Type Classification for Scenario 12

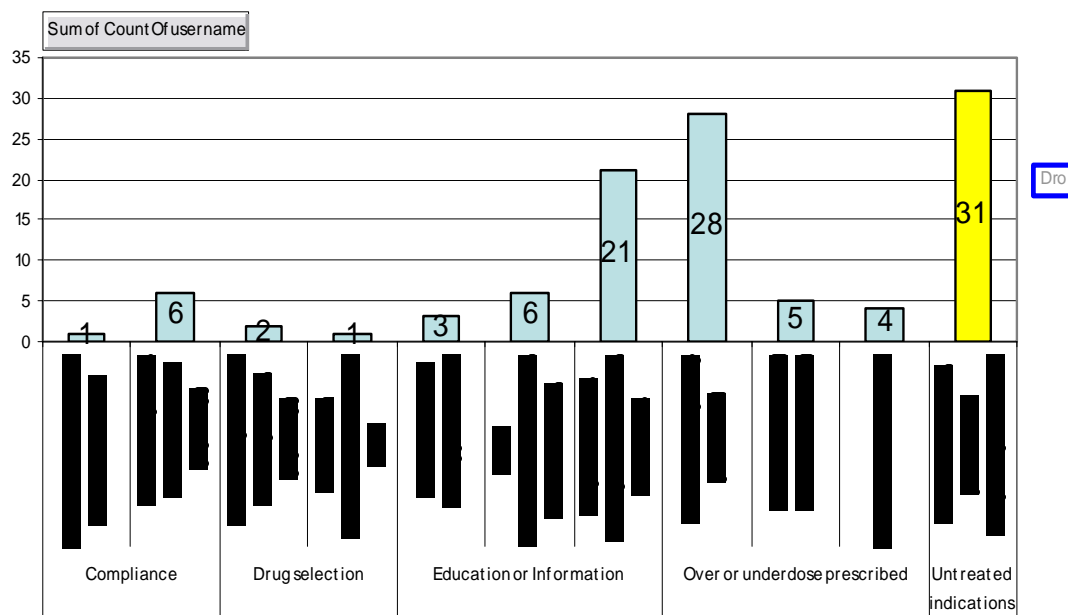


Figure 8-40: Type Classification for Scenario 12

A 54 year old woman arrives at your pharmacy to collect her monthly omeprazole 40mg daily prescription. She mentions in the course of counselling that she takes it daily after breakfast, for convenience but she still has some reflux problems in the evening.

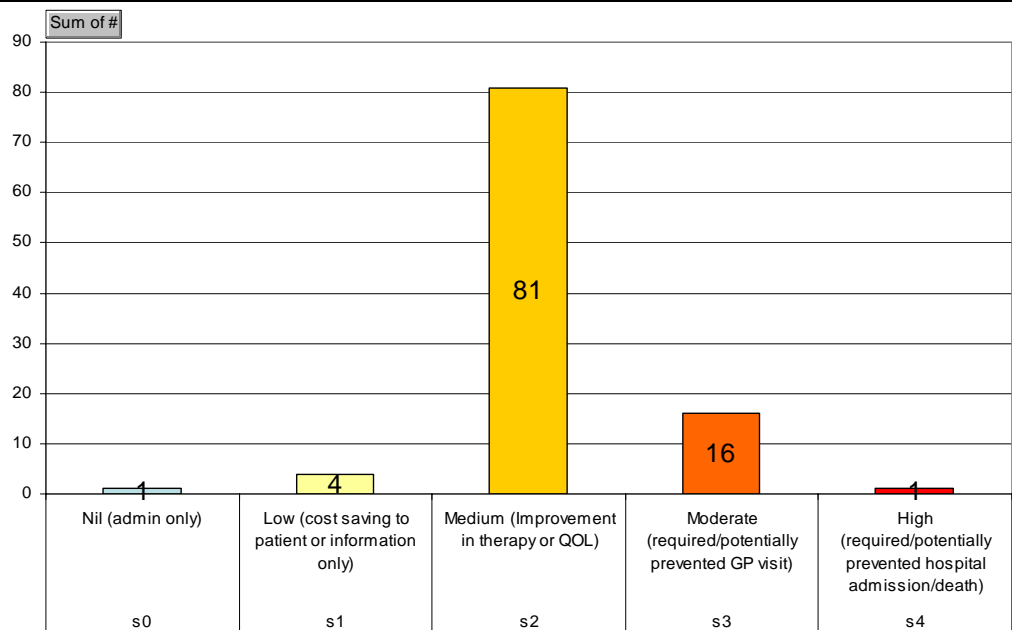


Figure 8-41: Significance Classifications for Scenario 12

This scenario received a wide range of categories allocated to it. The correct category is ‘Untreated indication – condition not adequately treated’, as 31 respondents indicated. This is the reason the intervention was brought to the pharmacist’s attention. The other suggested categories are more likely actions or recommendations that could be made to resolve the problem, for example changing the frequency of dosing to bd or the total dose taken at night.

The significance of this intervention is mild as the implementation of the pharmacists suggestions will improve the patient’s therapy and/or quality of life and should not require a return visit to the GP to achieve.

### 8.3.14 Scenario 13

Scenario Number 13						
A 76yo male patient presents repeat prescriptions for imdur, warfarin, clopidogrel, atenolol, ramipril, digoxin and frusemide. He mentions he doesn't need his amiodarone any more as the doctor has just ceased it. You are aware of the interaction between amiodarone and warfarin and on questioning, you discover that he has not been asked to have follow-up INR testing.						
Type		Subtype	Scenario Number 13			
			#	%	#	%
D	Drug selection	Duplication			15	13.6%
	Drug selection	Interaction	15	13.6%		
	Drug selection	Wrong drug				
	Drug selection	Wrong dosage form				
	Drug selection	Pre-existing severe ADR/allergy				
	Drug selection	Other Drug selection problem				
O	Over or underdose prescribed	Too high dose prescribed	1	0.9%	1	0.9%
	Over or underdose prescribed	Too low dose prescribed				
	Over or underdose prescribed	Incorrect frequency prescribed				
	Over or underdose prescribed	Other Dose Problem				
C	Compliance	Potential drug overuse/abuse situation				
	Compliance	Taking too little				
	Compliance	Taking too much				
	Compliance	Difficulty using dosage form				
	Compliance	Other Compliance Problem				
U	Untreated indications	Condition not adequately treated				
	Untreated indications	Preventive therapy required				
M	Monitoring required	Drug levels	12	10.9%	83	75.5%
	Monitoring required	Laboratory Monitoring	71	64.5%		
	Monitoring required	Non-Laboratory monitoring				
	Monitoring required	Other Monitoring Problem				
E	Education or Information	Patient requests information				
	Education or Information	Confusion about therapy/condition				
	Education or Information	Demonstration of therapeutic device				
	Education or Information	Disease management advice				
	Education or Information	Other Education/Information Problem				
N	Non-clinical	Not sub-classified				
T	Toxicity or Adverse reaction	Caused by dose too high			11	10.0%
	Toxicity or Adverse reaction	Caused by drug interaction	8	7.3%		
	Toxicity or Adverse reaction	Other Toxicity problem	3	2.7%		
Total			110	100.0%	110	100.0%

Table 8-19: Type Classification for Scenario 13

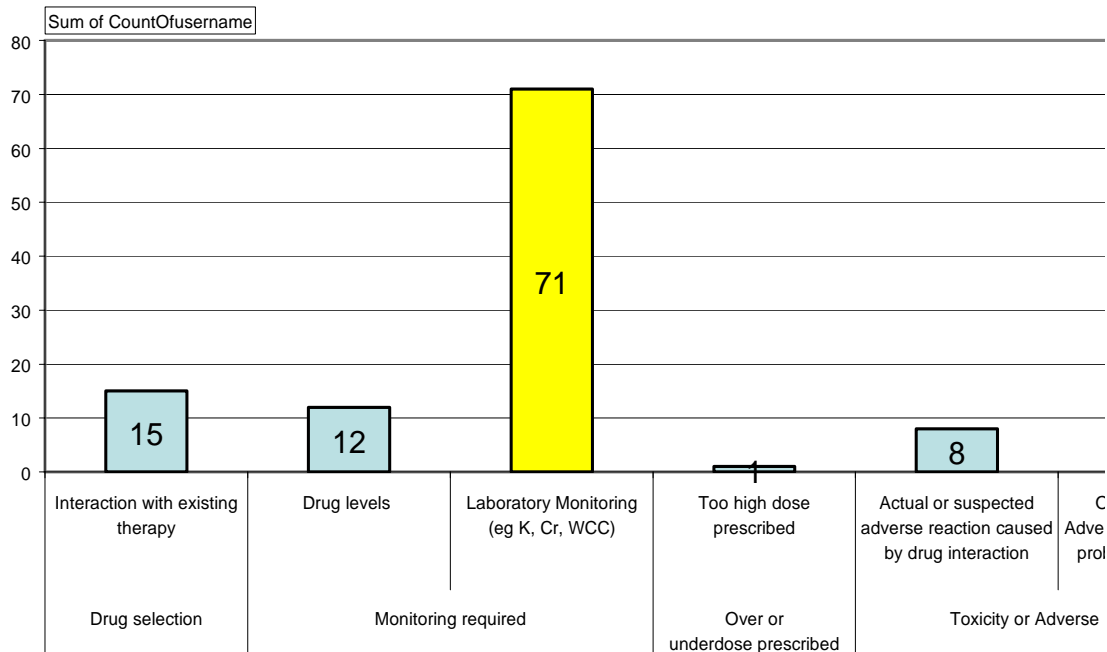
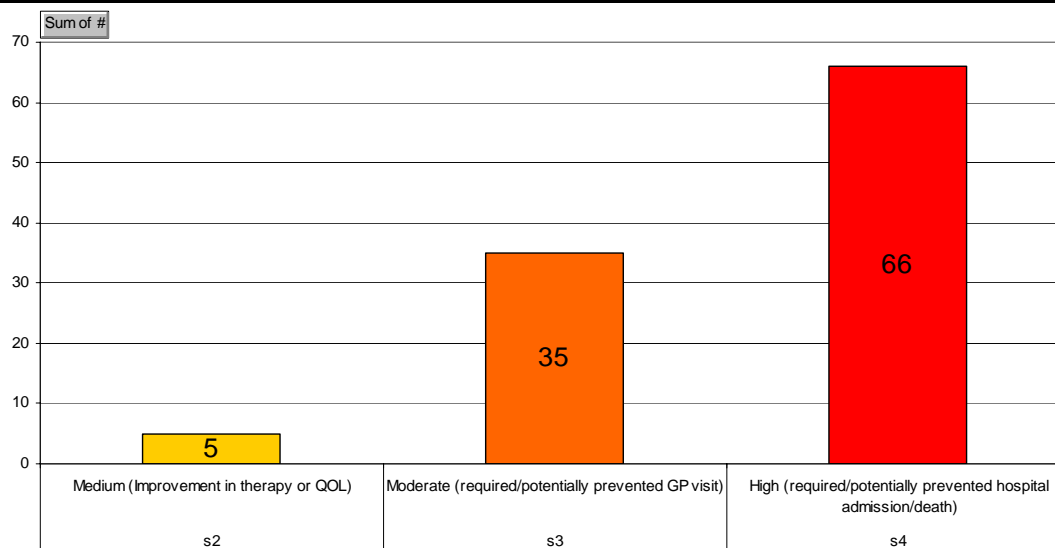


Figure 8-42: Type Classification for Scenario 13

A 76yo male patient presents repeat prescriptions for imdur, warfarin, clopidogrel, atenolol, ramipril, digoxin and frusemide. He mentions he doesn't need his amiodarone any more as the doctor has just ceased it. You are aware of the interaction between amiodarone and warfarin and on questioning, you discover that he has not been asked to have follow-up INR testing.



**Figure 8-43: Significance Classifications for Scenario 13**

It can be assumed that the patients INR had been stabilised while he was taking amiodarone, and it will therefore need to be readjusted now his amiodarone is to be ceased. INR monitoring will be required over this period to restabilise his warfarin therapy at an appropriate dose, therefore 'Monitoring required – Laboratory monitoring' is the correct category. Drug levels of warfarin are not performed, the effect of the drug in the form of an INR test is carried out; hence 'drug levels' is not a suitable category. Ceasing one of these drugs is not going to lead to a drug interaction, and therefore "Drug selection – interaction' is not a suitable category in this instance. The amiodarone has just been ceased and no time has elapsed to allow the appearance of any adverse effect, therefore this intervention does not fit under the 'Toxicity' banner. Hopefully the adverse effects will be avoided by prompt and appropriate monitoring.

The significance of this intervention is moderate to high. The patient is going to have to return to his GP for INR monitoring, and if the monitoring does not take place he may have a thromboembolic event which would lead to hospitalisation.

### 8.3.15 Scenario 14

Scenario Number 14						
A 56 year old woman with hypertension comes in to ask you about the change in her diuretic tablets ( <i>Hydrene</i> ). She brings in the bottle that was dispensed elsewhere and you note that the medication is hydroxyurea ( <i>Hydrea</i> ). The medication is labelled as Hydrea 2m and you find that she has been taking these for seven days.						
Type		Subtype	Scenario Number 14			
			#	%	#	%
D	Drug selection	Duplication			90	84.9%
	Drug selection	Interaction				
	Drug selection	Wrong drug	88	83.0%		
	Drug selection	Wrong dosage form				
	Drug selection	Pre-existing severe ADR/allergy				
	Drug selection	Other Drug selection problem	2	1.9%		
O	Over or underdose prescribed	Too high dose prescribed				
	Over or underdose prescribed	Too low dose prescribed				
	Over or underdose prescribed	Incorrect frequency prescribed				
	Over or underdose prescribed	Other Dose Problem				
C	Compliance	Potential drug overuse/abuse situation				
	Compliance	Taking too little				
	Compliance	Taking too much				
	Compliance	Difficulty using dosage form				
	Compliance	Other Compliance Problem				
U	Untreated indications	Condition not adequately treated				
	Untreated indications	Preventive therapy required				
M	Monitoring required	Drug levels				
	Monitoring required	Laboratory Monitoring				
	Monitoring required	Non-Laboratory monitoring				
	Monitoring required	Other Monitoring Problem				
E	Education or Information	Patient requests information				
	Education or Information	Confusion about therapy/condition				
	Education or Information	Demonstration of therapeutic device				
	Education or Information	Disease management advice				
	Education or Information	Other Education/Information Problem				
N	Non-clinical	Not sub-classified	13	12.3%	13	12.3%
T	Toxicity or Adverse reaction	Caused by dose too high			3	2.8%
	Toxicity or Adverse reaction	Caused by drug interaction				
	Toxicity or Adverse reaction	Other Toxicity problem	3	2.8%		
Total			106	100.0%	106	100.0%

Table 8-20: Type Classification for Scenario 14

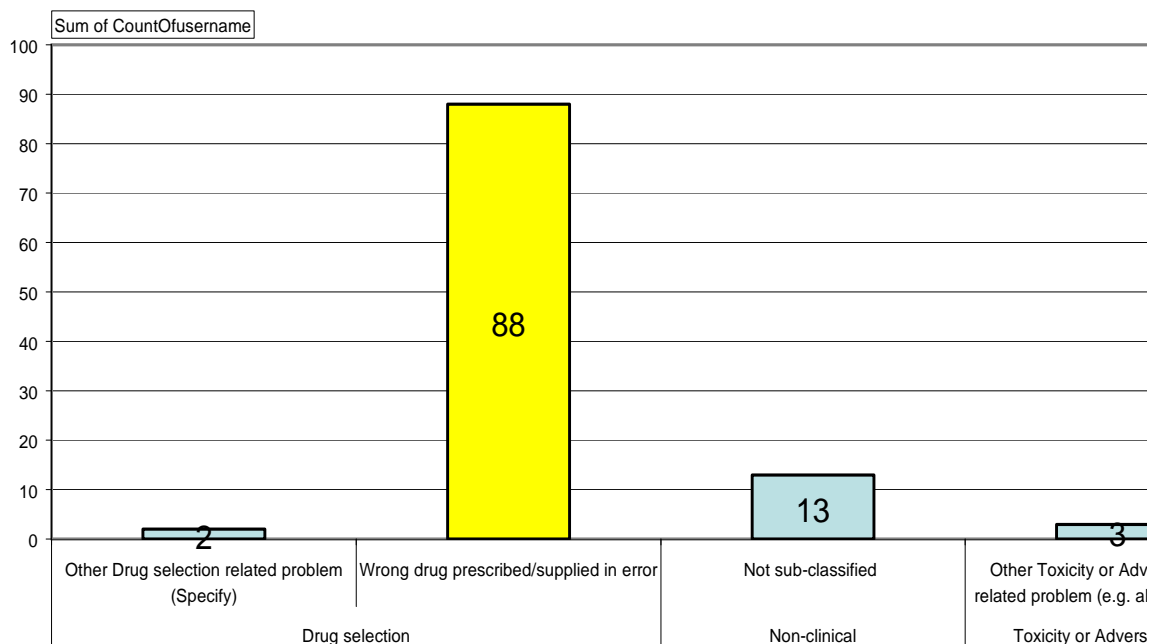


Figure 8-44: Type Classification for Scenario 14

A 56 year old woman with hypertension comes in to ask you about the change in her diuretic tablets (*Hydrene*). She brings in the bottle that was dispensed elsewhere and you note that the medication is hydroxyurea (*Hydrea*). The medication is labelled as Hydrea 2 m and you find that she has been taking these for seven days.

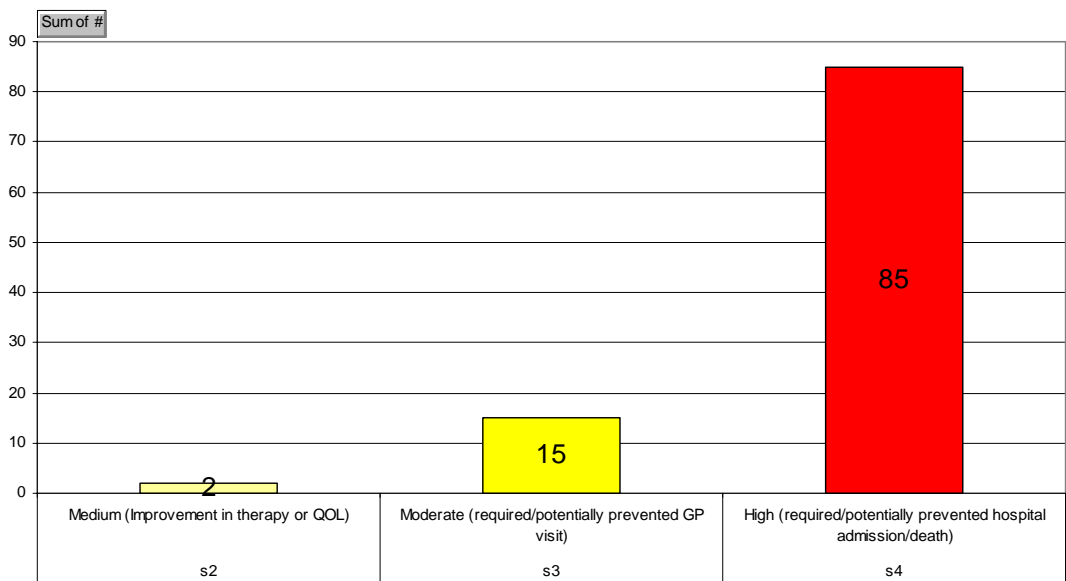


Figure 8-45: Significance Classifications for Scenario 14

Most people (83%) correctly indicated that this intervention should be categorised as ‘Drug selection – wrong drug prescribed/supplied in error’. It is likely the patient will develop symptoms if this therapy is continued, but there is no evidence that she has yet, therefore ‘toxicity’ is not an appropriate category. The category of ‘Non-clinical’ should be used for administrative type errors related to the ‘script’.

The significance of this intervention is high. The patient has been inappropriately supplied with a cytotoxic agent instead of a diuretic.



### 8.3.16 Scenario 15

Scenario Number 15					
The husband of a 76 year old woman brings in a script for amiodarone 200mg daily. You find that the script was last dispensed 2 weeks ago and question the early repeat. You find that the lady has been taking both <i>Aratac</i> and <i>Cordarone</i> for the last 2 weeks, thinking they are different drugs.					
Type	Subtype	Scenario Number 15			
		#	%	#	%
D	Drug selection	61	57.0%	61	57.0%
	Drug selection				
	Drug selection				
	Drug selection				
	Drug selection				
O	Over or underdose prescribed	2	1.9%	5	4.7%
	Over or underdose prescribed				
	Over or underdose prescribed				
	Over or underdose prescribed	3	2.8%		
C	Compliance			23	21.5%
	Compliance				
	Compliance	23	21.5%		
	Compliance				
U	Untreated indications				
	Untreated indications				
M	Monitoring required			2	1.9%
	Monitoring required				
	Monitoring required	2	1.9%		
	Monitoring required				
E	Education or Information			10	9.3%
	Education or Information	9	8.4%		
	Education or Information				
	Education or Information	1	0.9%		
T	Non-clinical			6	5.6%
	Toxicity or Adverse reaction	6	5.6%		
	Toxicity or Adverse reaction				
	Toxicity or Adverse reaction				
Total		107	100.0%	107	100.0%

Table 8-21: Type Classification for Scenario 15

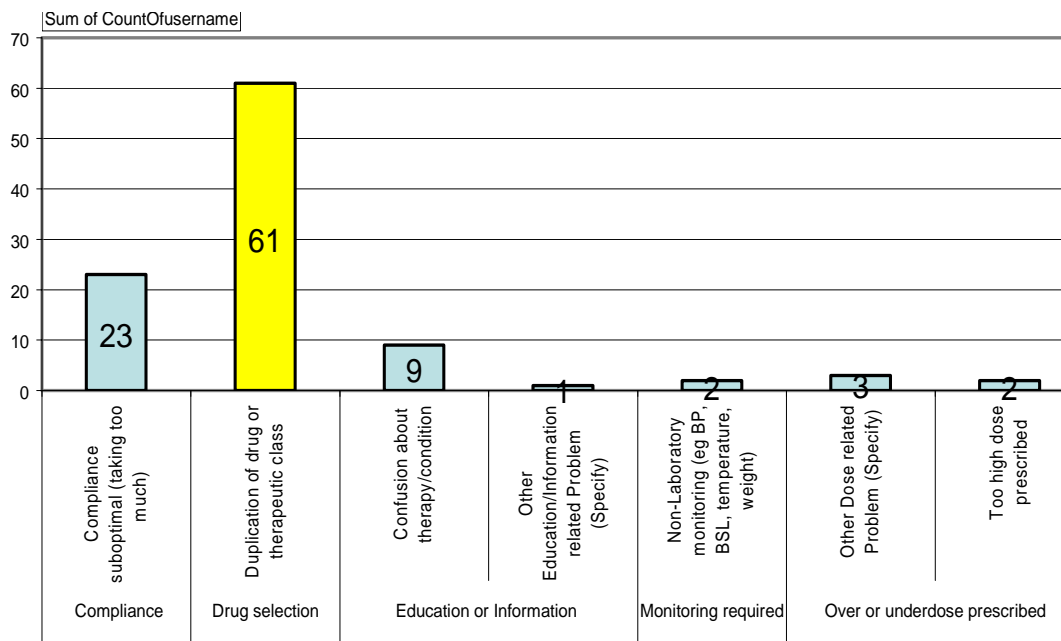
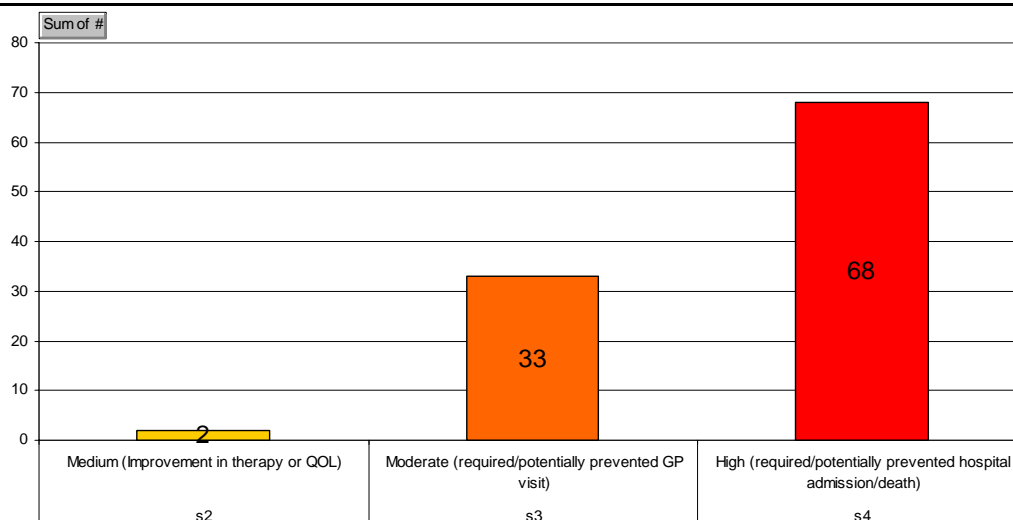


Figure 8-46: Type Classification for Scenario 15

The husband of a 76 year old woman brings in a script for amiodarone 200mg daily. You find that the script was last dispensed 2 weeks ago and question the early repeat. You find that the lady has been taking both *Aratac* and *Cordarone* for the last 2 weeks, thinking they are different drugs.



**Figure 8-47: Significance Classifications for Scenario 15**

Some people indicated that this intervention should be documented as ‘Compliance – taking too much’. Review of the scope notes for this category clearly states that “If the overuse consists of inappropriately taking two brands or forms of the same ingredient unknowingly, then use “Drug selection – duplication”. The duplication may have stemmed from the patients confusion or misunderstanding and this will need to be rectified. Monitoring for adverse effects may be required and this should be recommended, but at this stage no adverse effects have been reported. This eliminates the ‘Monitoring’ and ‘Toxicity’ categories in this scenario. Categorising this intervention as ‘Over- or under-dose prescribed’ is incorrect as the dose *prescribed* was correct.

When all parameters (patient age, 2 bradycardic agents, and long half-life) are taken into account, the significance of this intervention is high.

### 8.3.17 Scenario 16

Scenario Number 16						
A 45 year old patient with chronic back pain was previously stabilised on tramadol 50mg qid. He brings in a new prescription for <i>Tramal</i> 200mg SR qid and tells you the doctor increased the dose as a result of his increasing pain.						
Type		Subtype	Scenario Number 16			
			#	%	#	%
D	Drug selection	Duplication			2	1.9%
	Drug selection	Interaction				
	Drug selection	Wrong drug				
	Drug selection	Wrong dosage form	2	1.9%		
	Drug selection	Pre-existing severe ADR/allergy				
	Drug selection	Other Drug selection problem				
O	Over or underdose prescribed	Too high dose prescribed	76	71.0%	96	89.7%
	Over or underdose prescribed	Too low dose prescribed	2	1.9%		
	Over or underdose prescribed	Incorrect frequency prescribed	18	16.8%		
	Over or underdose prescribed	Other Dose Problem				
C	Compliance	Potential drug overuse/abuse situation	1	0.9%	2	1.9%
	Compliance	Taking too little				
	Compliance	Taking too much	1	0.9%		
	Compliance	Difficulty using dosage form				
	Compliance	Other Compliance Problem				
U	Untreated indications	Condition not adequately treated	2	1.9%	2	1.9%
	Untreated indications	Preventive therapy required				
M	Monitoring required	Drug levels				
	Monitoring required	Laboratory Monitoring				
	Monitoring required	Non-Laboratory monitoring				
	Monitoring required	Other Monitoring Problem				
E	Education or Information	Patient requests information	2	1.9%	4	3.7%
	Education or Information	Confusion about therapy/condition	1	0.9%		
	Education or Information	Demonstration of therapeutic device				
	Education or Information	Disease management advice	1	0.9%		
	Education or Information	Other Education/Information Problem				
N	Non-clinical	Not sub-classified				
T	Toxicity or Adverse reaction	Caused by dose too high	1	0.9%	1	0.9%
	Toxicity or Adverse reaction	Caused by drug interaction				
	Toxicity or Adverse reaction	Other Toxicity problem				
Total			107	100.0%	107	100.0%

Table 8-22: Type Classification for Scenario 16

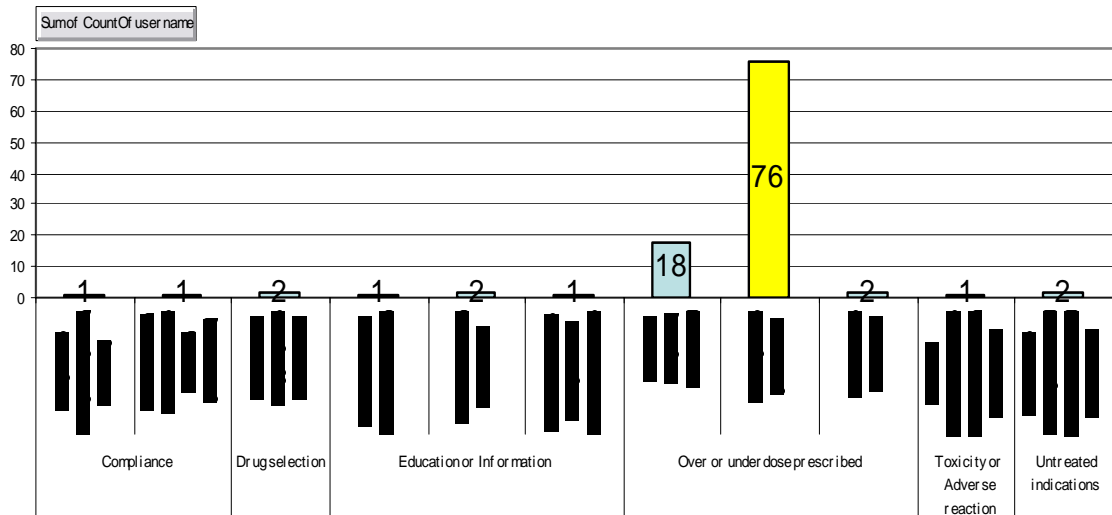


Figure 8-48 Type Classification for Scenario 16

A 45 year old patient with chronic back pain was previously stabilised on tramadol 50mg qid. He brings in a new prescription for *Tramal* 200mg SR qid and tells you the doctor increased the dose as a result of his increasing pain.

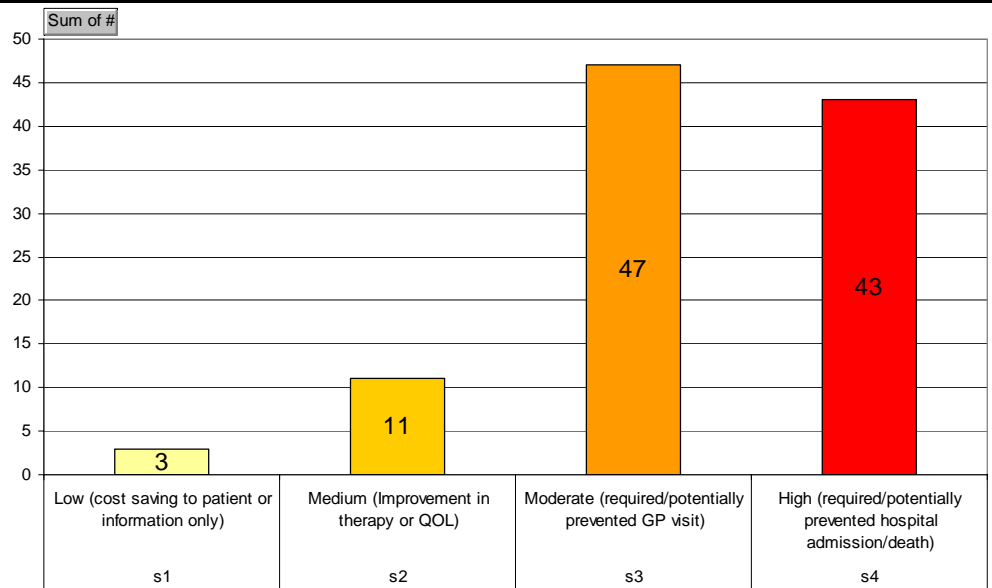


Figure 8-49: Significance Classifications for Scenario 16

Increasing the dose of tramadol in this patient is an appropriate course of action, but the size of the increase and/or the dosage frequency is too much. There were many different categories selected, but ‘Over- or under-dose prescribed – dose too high’ is the most suitable. The higher dose has not been taken yet, so no adverse effect can be noted, and the problem is not one of compliance. It is not an untreated indication as the doctor has already addressed the inadequate treatment.

The significance of this problem is at least moderate, and may be high depending on other medications and circumstances. The majority of responders (87%) indicated moderate or high.

### 8.3.18 Scenario 17

Scenario Number 17						
A 35 year old woman had been commenced amoxicillin 500mg tds 3 days previously for prophylaxis of infection after a dental extraction. She presents to the pharmacy to enquire about her swollen, increasingly painful jaw.						
Type		Subtype	Scenario Number 17			
			#	%	#	%
D	Drug selection	Duplication			16	16.3%
	Drug selection	Interaction				
	Drug selection	Wrong drug	13	13.3%		
	Drug selection	Wrong dosage form				
	Drug selection	Pre-existing severe ADR/allergy				
	Drug selection	Other Drug selection problem	3	3.1%		
O	Over or underdose prescribed	Too high dose prescribed			1	1.0%
	Over or underdose prescribed	Too low dose prescribed				
	Over or underdose prescribed	Incorrect frequency prescribed				
	Over or underdose prescribed	Other Dose Problem	1	1.0%		
C	Compliance	Potential drug overuse/abuse situation			3	3.1%
	Compliance	Taking too little	3	3.1%		
	Compliance	Taking too much				
	Compliance	Difficulty using dosage form				
	Compliance	Other Compliance Problem				
U	Untreated indications	Condition not adequately treated	69	70.4%	70	71.4%
	Untreated indications	Preventive therapy required	1	1.0%		
M	Monitoring required	Drug levels			1	1.0%
	Monitoring required	Laboratory Monitoring				
	Monitoring required	Non-Laboratory monitoring				
	Monitoring required	Other Monitoring Problem	1	1.0%		
E	Education or Information	Patient requests information			4	4.1%
	Education or Information	Confusion about therapy/condition				
	Education or Information	Demonstration of therapeutic device				
	Education or Information	Disease management advice	4	4.1%		
	Education or Information	Other Education/Information Problem				
N	Non-clinical	Not sub-classified				
T	Toxicity or Adverse reaction	Caused by dose too high			3	3.1%
	Toxicity or Adverse reaction	Caused by drug interaction				
	Toxicity or Adverse reaction	Other Toxicity problem	3	3.1%		
Total			98	100.0%	98	100.0%

Table 8-23: Type Classification for Scenario 17

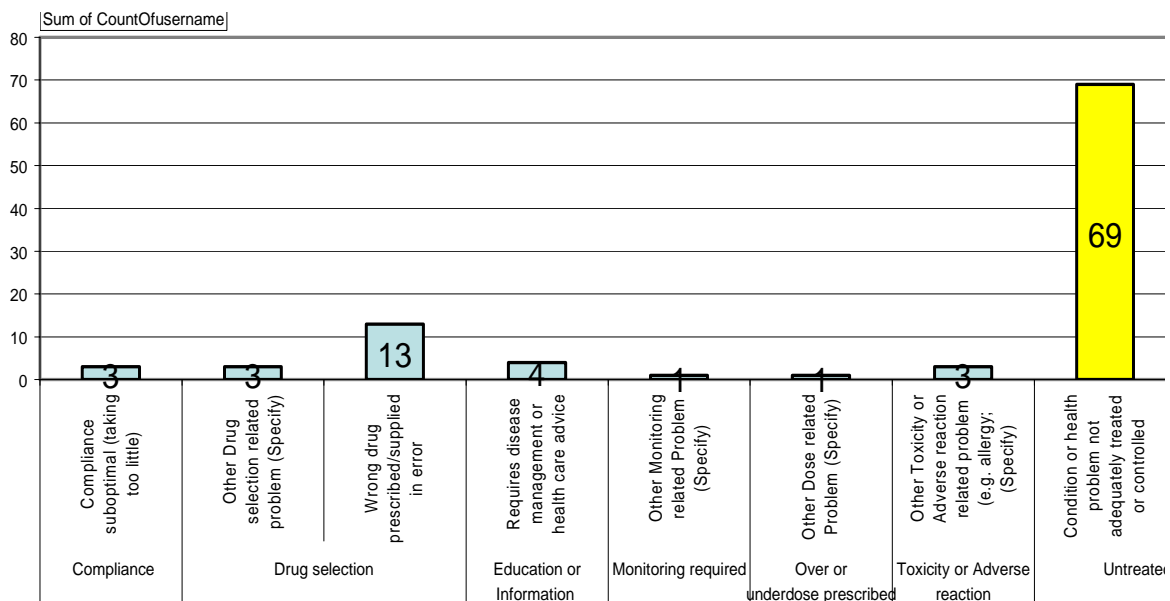


Figure 8-50: Type Classification for Scenario 17

A 35 year old woman had been commenced amoxicillin 500mg tds 3 days previously for prophylaxis of infection after a dental extraction. She presents to the pharmacy to enquire about her swollen, increasingly painful jaw.

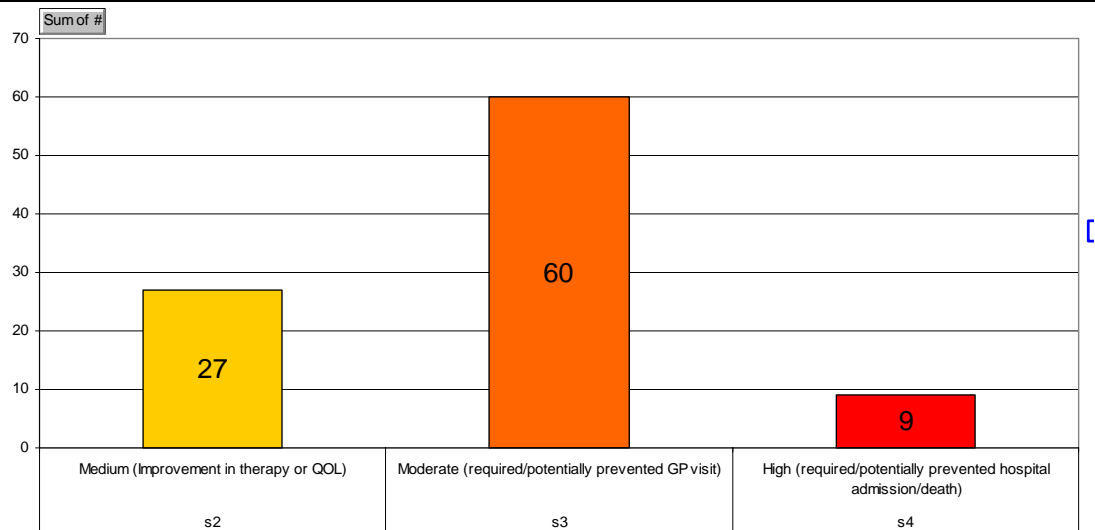


Figure 8-51: Significance Classifications for Scenario 17

As most (70.4%) responders indicated, this scenario should be categorised as ‘Untreated indications – condition or health problem not adequately treated or controlled.’ She is receiving prophylactic antibiotics post dental extraction, but it appears to have not worked. Some people indicated that this was a ‘Toxicity ‘ problem, but the presenting complaint is not an adverse effect of the medication, it is an apparent failure of the medication. It perhaps could be categorised as a ‘Drug selection - other’ problem, as long as it is accompanied by explanatory notes, as it appears that this may not have been the most suitable drug in this instance. Referral to the scope notes makes it clear that this is not a ‘wrong drug’ scenario.

The significance of this intervention has been correctly listed as ‘moderate’ by most responders, as the patient will require a return visit to the prescriber for additional treatment to rectify the problem.

### 8.3.19 Scenario 18

Scenario Number 18						
A 76 year old man with hypothyroidism presents with an order for thyroxine 50mcg three daily and thyroxine 100mcg three daily. On checking previous patient records and discussion with patient, you find that he is meant to be taking 150mcg daily.						
Type		Subtype	Scenario Number 18			
			#	%	#	%
D	Drug selection	Duplication	2	1.9%	2	1.9%
	Drug selection	Interaction				
	Drug selection	Wrong drug				
	Drug selection	Wrong dosage form				
	Drug selection	Pre-existing severe ADR/allergy				
	Drug selection	Other Drug selection problem				
O	Over or underdose prescribed	Too high dose prescribed	85	80.2%	95	89.6%
	Over or underdose prescribed	Too low dose prescribed				
	Over or underdose prescribed	Incorrect frequency prescribed	7	6.6%		
	Over or underdose prescribed	Other Dose Problem	3	2.8%		
C	Compliance	Potential drug overuse/abuse situation			6	5.7%
	Compliance	Taking too little				
	Compliance	Taking too much	6	5.7%		
	Compliance	Difficulty using dosage form				
	Compliance	Other Compliance Problem				
U	Untreated indications	Condition not adequately treated				
	Untreated indications	Preventive therapy required				
M	Monitoring required	Drug levels				
	Monitoring required	Laboratory Monitoring				
	Monitoring required	Non-Laboratory monitoring				
	Monitoring required	Other Monitoring Problem				
E	Education or Information	Patient requests information			2	1.9%
	Education or Information	Confusion about therapy/condition	2	1.9%		
	Education or Information	Demonstration of therapeutic device				
	Education or Information	Disease management advice				
	Education or Information	Other Education/Information Problem				
N	Non-clinical	Not sub-classified	1	0.9%	1	0.9%
T	Toxicity or Adverse reaction	Caused by dose too high				
	Toxicity or Adverse reaction	Caused by drug interaction				
	Toxicity or Adverse reaction	Other Toxicity problem				
Total			106	100.0%	106	100.0%

Table 8-24: Type Classification for Scenario 18

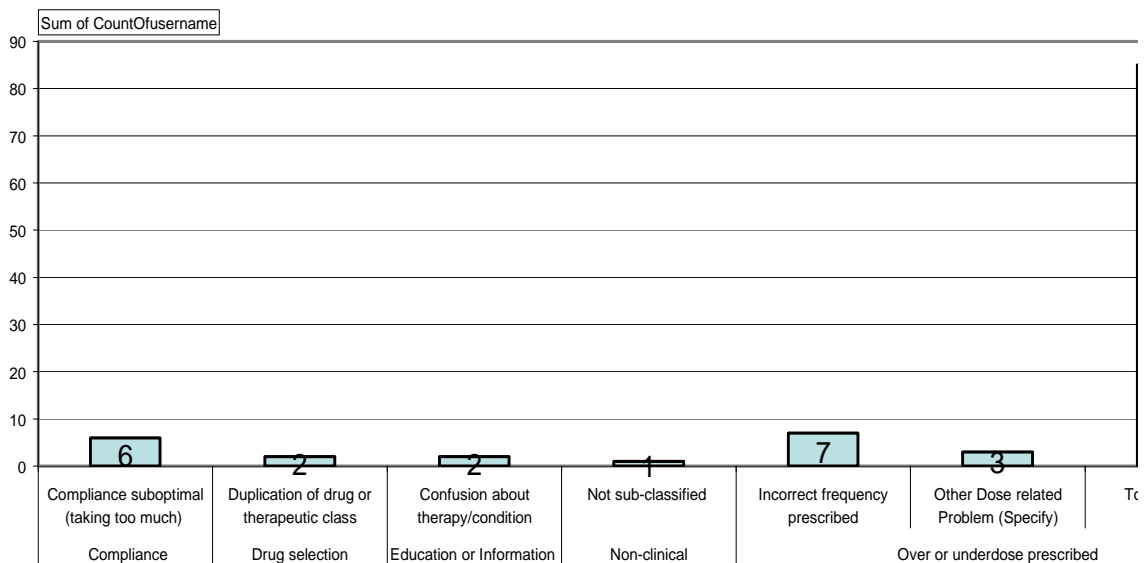
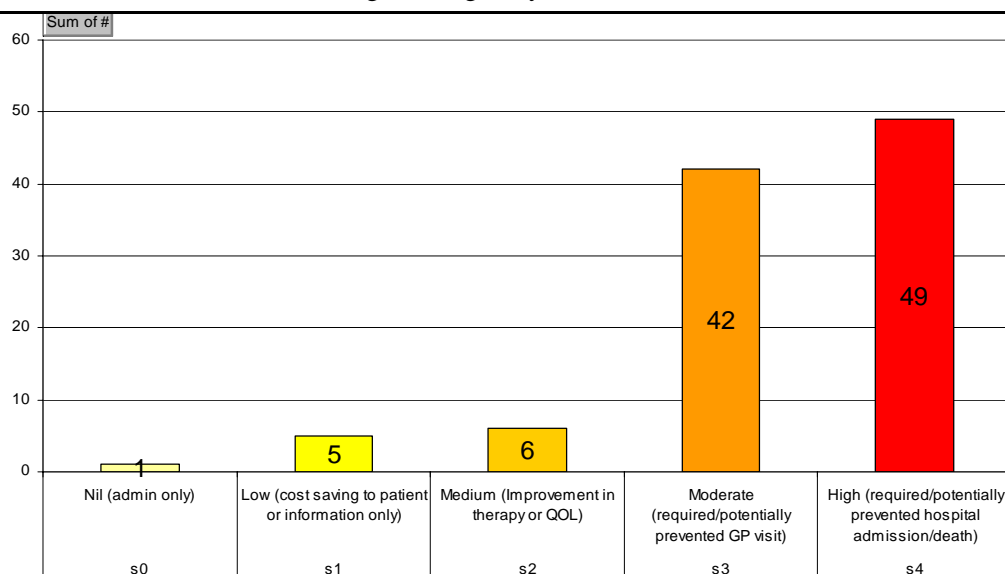


Figure 8-52: Type Classification for Scenario 18

A 76 year old man with hypothyroidism presents with an order for thyroxine 50mcg three daily and thyroxine 100mcg three daily. On checking previous patient records and discussion with patient, you find that he is meant to be taking 150mcg daily.



**Figure 8-53: Significance Classifications for Scenario 18**

There is no indication in this scenario that the patient has taken any of the prescribed medication at this dose, therefore this is not a compliance problem. It is not unusual for a patient to be prescribed two different strengths of thyroxine to achieve the required dose; therefore this is not a duplication problem. The patient himself has not displayed any confusion about his therapy to this point, apart from presenting a 'script which might not be correct, so 'Education or Information' would not be the correct category in this case. Clearly the dose prescribed is too high based on previous therapy, and referral to the scope notes makes it clear that 'Over- or under-dose prescribed – dose too high' is the most appropriate categorisation in this scenario, as 80.2% of responders indicated.

The significance of this intervention would be moderate to high, considering the age of the patient and the size of the overdose.



### 8.3.20 Scenario 19

Scenario Number 19						
A 76 year old woman present with a new prescription for mirtazapine. She is currently receiving sertraline 100mg daily. She was unclear about the doctor's instructions regarding the sertraline, and was going to continue taking both antidepressants.						
Type		Subtype	Scenario Number 19			
			#	%	#	%
D	Drug selection	Duplication	31	29.2%	54	50.9%
	Drug selection	Interaction	22	20.8%		
	Drug selection	Wrong drug				
	Drug selection	Wrong dosage form				
	Drug selection	Pre-existing severe ADR/allergy				
	Drug selection	Other Drug selection problem	1	0.9%		
O	Over or underdose prescribed	Too high dose prescribed				
	Over or underdose prescribed	Too low dose prescribed				
	Over or underdose prescribed	Incorrect frequency prescribed				
	Over or underdose prescribed	Other Dose Problem				
C	Compliance	Potential drug overuse/abuse situation	2	1.9%	5	4.7%
	Compliance	Taking too little				
	Compliance	Taking too much				
	Compliance	Difficulty using dosage form	3	2.8%		
	Compliance	Other Compliance Problem				
U	Untreated indications	Condition not adequately treated	3	2.8%	3	2.8%
	Untreated indications	Preventive therapy required				
M	Monitoring required	Drug levels				
	Monitoring required	Laboratory Monitoring				
	Monitoring required	Non-Laboratory monitoring				
	Monitoring required	Other Monitoring Problem				
E	Education or Information	Patient requests information	1	0.9%	38	35.8%
	Education or Information	Confusion about therapy/condition	35	33.0%		
	Education or Information	Demonstration of therapeutic device				
	Education or Information	Disease management advice	1	0.9%		
	Education or Information	Other Education/Information Problem	1	0.9%		
N	Non-clinical	Not sub-classified				
T	Toxicity or Adverse reaction	Caused by dose too high			6	5.7%
	Toxicity or Adverse reaction	Caused by drug interaction	6	5.7%		
	Toxicity or Adverse reaction	Other Toxicity problem				
Total			106	100.0%	106	100.0%

Table 8-25: Type Classification for Scenario 19

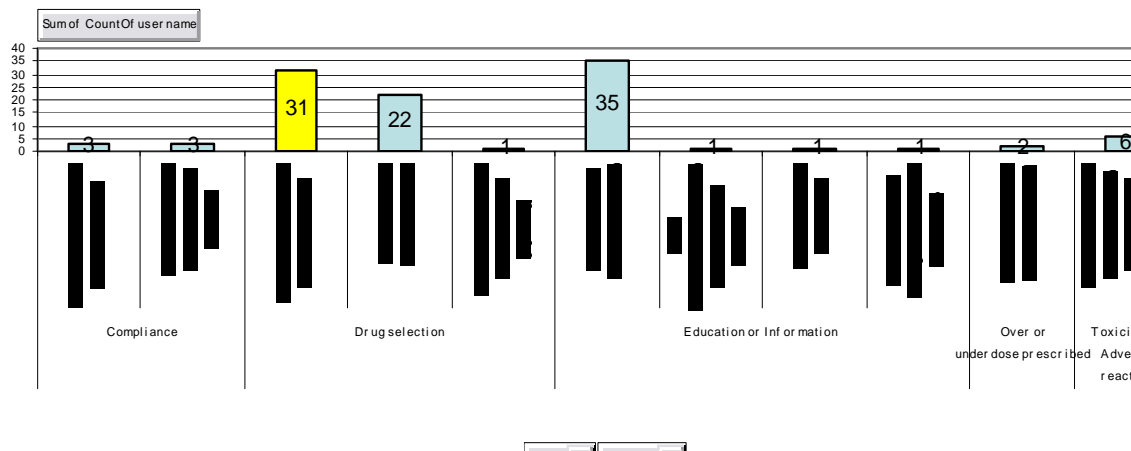
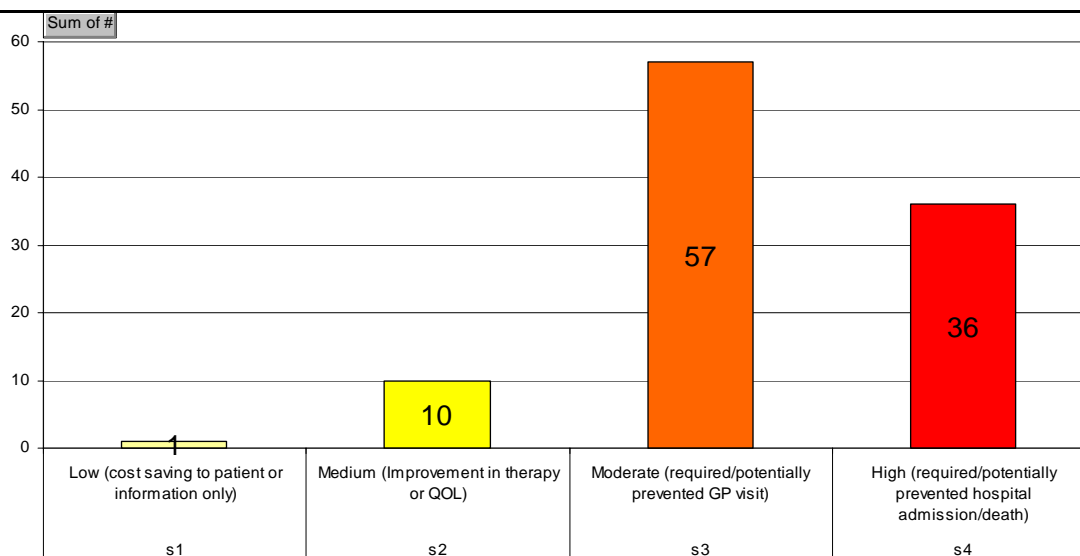


Figure 8-54: Type Classification for Scenario 19

A 76 year old woman present with a new prescription for mirtazapine. She is currently receiving sertraline 100mg daily. She was unclear about the doctor's instructions regarding the sertraline, and was going to continue taking both antidepressants.



**Figure 8-55: Significance Classifications for Scenario 19**

This scenario received a wide range of categorisation, but referral to the scope notes clarifies the most appropriate section, albeit in a long winded way. The largest number of people selected 'Education or Information – confusion about therapy or condition' as the most suitable category, but referral to the scope notes directs that "If the confusion would have (or did) resulted in a change in compliance (either taking too much or too little of the medication), then an appropriate 'Compliance' code should be selected". Referral to the 'Compliance – other' scope notes directs "If the compliance issue results in two drugs of the same therapeutic class being taken inadvertently, then use 'Duplication'". 'Drug selection – duplication' is therefore the most appropriate category for this scenario. 'Drug selection – drug interaction' can appear to be correct at first glance, but the scope notes clearly indicate "If the interacting drug is of the same therapeutic class as part of the patient's existing therapy, then use 'Duplication'". The patient has not taken the two drugs together therefore there are no adverse effects at this point, so 'Toxicity' is not a suitable category. The doses prescribed are within recommended dose ranges therefore the dose prescribed of each individual drug is not too high.

Most people indicated that the significance of this intervention was moderate which is most likely correct. If undetected, this problem was unlikely to result in a hospital admission, but may well have required a GP consultation.

### 8.3.21 Scenario 20

Scenario Number 20						
A 76 year old woman presents in January with a prescription for prednisolone that is dated January the previous year. You check with the doctor who tells you he wrote the wrong year on the script.						
Type		Subtype	Scenario Number 20			
			#	%	#	%
D	Drug selection	Duplication				
	Drug selection	Interaction				
	Drug selection	Wrong drug				
	Drug selection	Wrong dosage form				
	Drug selection	Pre-existing severe ADR/allergy				
	Drug selection	Other Drug selection problem				
O	Over or underdose prescribed	Too high dose prescribed				
	Over or underdose prescribed	Too low dose prescribed				
	Over or underdose prescribed	Incorrect frequency prescribed				
	Over or underdose prescribed	Other Dose Problem				
C	Compliance	Potential drug overuse/abuse situation			1	1.0%
	Compliance	Taking too little	1	1.0%		
	Compliance	Taking too much				
	Compliance	Difficulty using dosage form				
	Compliance	Other Compliance Problem				
U	Untreated indications	Condition not adequately treated				
	Untreated indications	Preventive therapy required				
M	Monitoring required	Drug levels				
	Monitoring required	Laboratory Monitoring				
	Monitoring required	Non-Laboratory monitoring				
	Monitoring required	Other Monitoring Problem				
E	Education or Information	Patient requests information				
	Education or Information	Confusion about therapy/condition				
	Education or Information	Demonstration of therapeutic device				
	Education or Information	Disease management advice				
	Education or Information	Other Education/Information Problem				
N	Non-clinical	Not sub-classified	103	99.0%	103	99.0%
T	Toxicity or Adverse reaction	Caused by dose too high				
	Toxicity or Adverse reaction	Caused by drug interaction				
	Toxicity or Adverse reaction	Other Toxicity problem				
Total			104	100.0%	104	100.0%

Table 8-26: Type Classification for Scenario 20

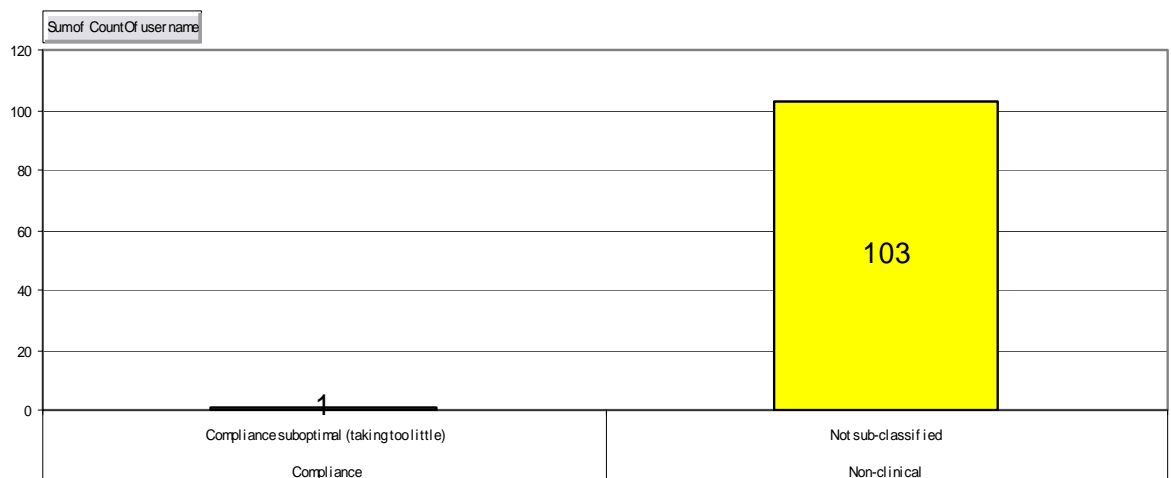


Figure 8-56: Type Classification for Scenario 20

A 76 year old woman presents in January with a prescription for prednisolone that is dated January the previous year. You check with the doctor who tells you he wrote the wrong year on the script.

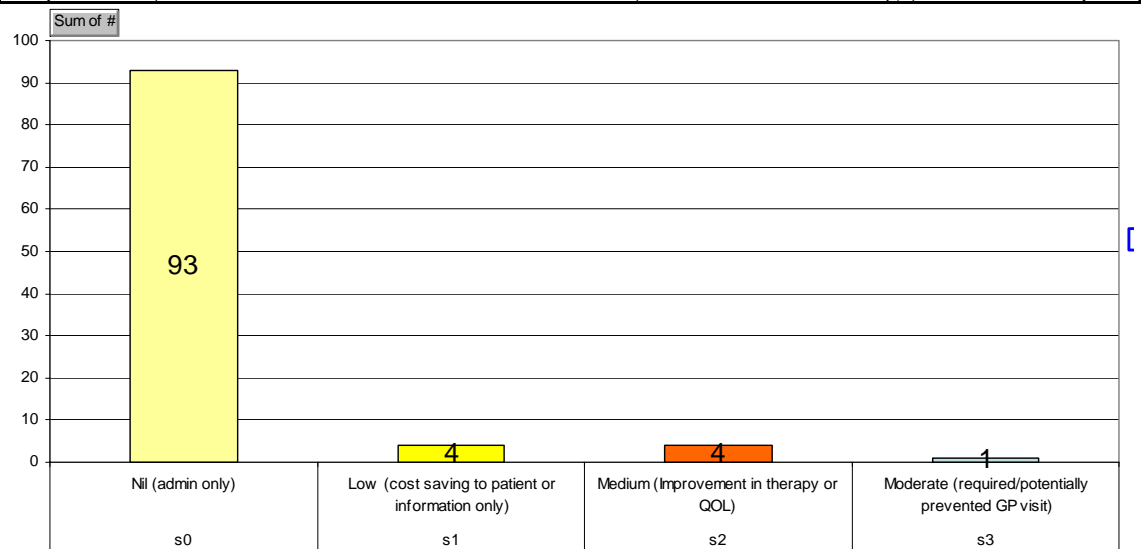


Figure 8-57: Significance Classifications for Scenario 20

Most people agreed that this scenario was basically an administrative error on behalf of the doctor, and correctly classified this intervention as 'Non-clinical'.  
The significance of this intervention is 'Nil – administrative only'.

#### ***8.4 Appropriate Classification of Type and Subtype***

Each of the validation scenarios were carefully coded by type by three pharmacists who were very experienced with the documentation system and the scope notes. A consensus category and subcategory was agreed upon and this was used in determining the appropriateness of the classification in the validation exercise. (see Table 8-27 and Table 8-28)

As discussed above, there was some degree of mis-classification in many of the scenarios, predominantly due to differences in interpretation of the subtype title. Many of the mis-classifications could be clarified by reference to the scope notes, although it would seem that many participants either did not refer to these or did not clearly understand the different interpretations of the definitions.

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Situation Number	Description	Code	Type	Subtype
Situation 1.	A regular patient comes in with repeat for metformin 500mg 1g three times a day. You notice that it has been 7 weeks since he last had this script filled. On questioning the patient reveals that he has been taking tablets only when sugar is high.	C2	Compliance	Compliance suboptimal (taking too little)
Situation 2.	A 55 year old man with diabetes and ischaemic heart disease presents a new prescription for sildenafil (Viagra) 50 mg. His other medications include isosorbide mononitrate, metformin, glipizide, amiodarone, aspirin, perindopril and metoprolol. You are aware of the interaction between sildenafil and the other medications.	d2	Drug selection	Interaction with existing therapy
Situation 3.	A prescription for a 12 year old boy for amoxycillin 250mg/5mL, 4mL three times a day for acute otitis media. You check the dose in the product information and find that it is meant to be 500mg three times a day.	o2	Over or underdose prescribed	Too low dose prescribed
Situation 4.	A 56 year old man comes into your pharmacy complaining of drowsiness. He tells you he commenced on mirtazapine one week ago and is currently taking 30mg each night. His other medications include diazepam 10mg tds and temazepam 20mg at night.	t2	Toxicity or Adverse reaction	Actual or suspected adverse reaction caused by drug interaction
Situation 5.	A 65year old woman presents a prescription for prednisolone 5mg daily for management of polymyalgia rheumatica. She is frail and appears to weigh approximately 45kg. Although she tells you that she is taking calcium supplements, you believe she is still a	u1	Untreated indications	Condition or health problem not adequately treated or controlled
Situation 6.	An elderly male patient presents repeat scripts for diamicon and amaryl. His dispensing history shows patient has had diamicon for over 12months, but has only received amaryl in previous month. You are aware that amaryl and diamicon are both sulphonylu	d1	Drug selection	Duplication of drug or therapeutic class
Situation 7.	A 61 year old, overweight, man has been diagnosed as having Type 2 Diabetes Mellitus (NIDDM) for 10 years and ischaemic heart disease (angina). He has been prescribed glipizide each morning and metformin three times a day. He admits that he misses his med	c2	Compliance	Compliance suboptimal (taking too little)
Situation 8.	An 84 year old woman presents complaining of oral thrush. She is a chronic asthmatic using inhaled corticosteroids. You check her inhaler technique and notice that she does not inhale properly. You arrange a large volume spacer device, and give her a dem	e3	Education or Information	Requires demonstration of therapeutic device
Situation 9.	An 82 year old lady presents with script for ventolin inhaler one to two puffs four times a day when required. During counselling, you discover that her rheumatoid arthritis is preventing her from actuating the inhaler.	c4	Compliance	Difficulty using dosage form
Situation 10.	An 87 year old woman has been taking digoxin 125 micrograms daily for her atrial fibrillation for 3 years. Recently you have noticed that she is getting increasingly frail and may have lost weight. It is a Saturday morning and she presents a new prescript	t1	Toxicity or Adverse reaction	Actual or suspected adverse reaction caused by dose too high
Situation 11.	A 45 year old man who is a regular patient of your pharmacy arrives for a repeat prescription of metoprolol for his hypertension. He has a history of asthma and tells you he has been using salbutamol inhaler 3 times daily in the last couple of weeks. He	t0	Toxicity or Adverse reaction	Other Toxicity or Adverse reaction related problem (e.g. allergy; (Specify)
Situation 12.	A 54 year old woman arrives at your pharmacy to collect her monthly omeprazole 40mg daily prescription. She mentions in the course of counselling that she takes it daily after breakfast, for convenience but she still has some reflux problems in the evening	u1	Untreated indications	Condition or health problem not adequately treated or controlled
Situation 13.	A 76yo male patient presents repeat prescriptions for imdur, warfarin, clopidogrel, atenolol, ramipril, digoxin and frusemide. He mentions he doesn't need his amiodarone any more as the doctor has just ceased it. You are aware of the interaction between a	m2	Monitoring required	Laboratory Monitoring (eg K, Cr, WCC)
Situation 14.	A 56 year old woman with hypertension comes in to ask you about the change in her diuretic tablets (Hydrene). She brings in the bottle that was dispensed elsewhere and you note that the medication is hydroxyurea (Hydrea). The medication is labelled as Hyd	d3	Drug selection	Wrong drug prescribed/supplied in error
Situation 15.	The husband of a 76 year old woman brings in a script for amiodarone 200mg daily. You find that the script was last dispensed 2 weeks ago and question the early repeat. You find that the lady has been taking both Aratac and Cordarone for the last 2 weeks,	d1	Drug selection	Duplication of drug or therapeutic class
Situation 16.	A 45 year old patient with chronic back pain was previously stabilised on tramadol 50mg qid. He brings in a new prescription for Tramal 200mg SR qid and tells you the doctor increased the dose as a result of his increasing pain.	o1	Over or underdose prescribed	Too high dose prescribed
Situation 17.	A 35 year old woman had been commenced amoxicillin 500mg tds 3 days previously for prophylaxis of infection after a dental extraction. She presents to the pharmacy to enquire about her swollen, increasingly painful jaw.	U1	Untreated indications	Condition or health problem not adequately treated or controlled
Situation 18.	A 76 year old man with hypothyroidism presents with an order for thyroxine 50mcg three daily and thyroxine 100mcg three daily. On checking previous patient records and discussion with patient, you find that he is meant to be taking 150mcg daily.	o1	Over or underdose prescribed	Too high dose prescribed
Situation 19.	A 76 year old woman present with a new prescription for mirtazapine. She is currently receiving sertraline 100mg daily. She was unclear about the doctor's instructions regarding the sertraline, and was going to continue taking both antidepressants.	c0	Compliance	Other Compliance related Problem (Specify)
Situation 20.	A 76 year old woman presents in January with a prescription for prednisolone that is dated January the previous year. You check with the doctor who tells you he wrote the wrong year on the script.	n0	Non-clinical	Not sub-classified

**Table 8-27 Most Appropriate Classifications of Validation Scenarios according to Scope Note Definitions**

<b>Scenario</b>	<b>Type Correct (%)</b>	<b>Subtype Correct (%)</b>
1	59.9	57.3
2	63.4	53.5
3	96.3	93.3
4	63.8	47.2
5	63.3	15
6	77.4	73.9
7	90.2	83
8	58.9	55.4
9	65.2	62.6
10	63.7	61.9
11	49.1	25.4
12	28.7	28.7
13	75.5	64.5
14	84.9	83
15	57	57
16	89.7	71
17	71.4	70.4
18	89.6	80.2
19	50.9	29.2
20	99	99
<b>Average</b>	<b>69.9</b>	<b>60.6</b>

Table 8-28: Correctly selected type and subtype for the 20 scenarios

### ***8.5 Changes to DOCUMENT as a result of Validation Exercise***

As a result of this exercise, some refinement to the DOCUMENT categories has been undertaken.

The necessity of some of the subtypes and use of the decision support algorithm will be considered along with the possibilities of re-naming and adjusting some of the categories to assist in more accurate classification. In addition, emphasis has been placed on the initial training in the areas where common confusions have been demonstrated.

### ***8.6 Selection of Actions***

Completion of the validation scenarios included nominating appropriate actions to each scenario; compilation of results can be seen in Table 8-29. Common actions nominated included discussion the prescriber and/or the patient/carer. These sources of information for clarifying potential and actual clinical problems were also of high incidence in the pilot study.

Common sources of reference were also consulted when investigating the problem these included written material and computer facilities. From the results of the validation process the pharmacists who participated were able to nominate a number of appropriate actions for each scenario. There were a number of actions where the frequency of use was fairly low for example 'use of internet' (2.1%). The responses from the validation process together with those from the pilot study have been used to refine the DOCUMENT system.

Scenario	Investigation										Discussion						Other		Number of Respondents
	A1		A2		A3		A4		A5		A6		A7		A8		A9		
	Written Materials		Software		Internet		Drug Info Service		Other		Prescriber		Patient/Carer		No Discussion		Other		
	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	
1	15	9.0%	8	4.8%	4	2.4%	0	0.0%	7	4.2%	52	31.1%	157	94.0%	3	1.8%	8	4.8%	167
2	38	25.7%	34	23.0%	5	3.4%	10	6.8%	0	0.0%	135	91.2%	88	59.5%	0	0.0%	3	2.0%	148
3	50	36.2%	29	21.0%	2	1.4%	1	0.7%	3	2.2%	127	92.0%	55	39.9%	0	0.0%	1	0.7%	138
4	34	26.0%	48	36.6%	6	4.6%	2	1.5%	1	0.8%	89	67.9%	104	79.4%	1	0.8%	1	0.8%	131
5	35	28.7%	28	23.0%	11	9.0%	5	4.1%	4	3.3%	67	54.9%	96	78.7%	2	1.6%	5	4.1%	122
6	25	21.4%	27	23.1%	4	3.4%	7	6.0%	3	2.6%	99	84.6%	92	78.6%	1	0.9%	4	3.4%	117
7	5	4.4%	1	0.9%	0	0.0%	0	0.0%	1	0.9%	25	21.9%	109	95.6%	1	0.9%	9	7.9%	114
8	3	2.6%	1	0.9%	0	0.0%	1	0.9%	3	2.6%	7	6.1%	108	94.7%	7	6.1%	15	13.2%	114
9	3	2.6%	2	1.7%	3	2.6%	1	0.9%	0	0.0%	76	65.5%	96	82.8%	2	1.7%	6	5.2%	116
10	18	15.9%	21	18.6%	0	0.0%	1	0.9%	3	2.7%	104	92.0%	68	60.2%	0	0.0%	2	1.8%	113
11	19	16.7%	25	21.9%	1	0.9%	0	0.0%	0	0.0%	106	93.0%	79	69.3%	0	0.0%	2	1.8%	114
12	13	11.8%	19	17.3%	4	3.6%	4	3.6%	0	0.0%	29	26.4%	100	90.9%	1	0.9%	5	4.5%	110
13	19	17.1%	23	20.7%	1	0.9%	6	5.4%	1	0.9%	99	89.2%	81	73.0%	0	0.0%	1	0.9%	111
14	21	19.3%	30	27.5%	0	0.0%	22	20.2%	11	10.1%	95	87.2%	74	67.9%	0	0.0%	25	22.9%	109
15	20	18.5%	15	13.9%	0	0.0%	7	6.5%	0	0.0%	83	76.9%	91	84.3%	0	0.0%	1	0.9%	108
16	18	16.5%	19	17.4%	0	0.0%	2	1.8%	0	0.0%	99	90.8%	59	54.1%	0	0.0%	0	0.0%	109
17	16	15.0%	14	13.1%	1	0.9%	1	0.9%	1	0.9%	78	72.9%	79	73.8%	1	0.9%	3	2.8%	107
18	2	1.9%	2	1.9%	0	0.0%	0	0.0%	1	0.9%	92	85.2%	71	65.7%	3	2.8%	1	0.9%	108
19	32	29.9%	32	29.9%	7	6.5%	4	3.7%	1	0.9%	84	78.5%	87	81.3%	0	0.0%	0	0.0%	107
20	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	80	74.8%	25	23.4%	31	29.0%	6	5.6%	107
Total	386	16.3%	378	15.9%	49	2.1%	74	3.1%	40	1.7%	1626	68.6%	1719	72.5%	53	2.2%	98	4.1%	2370

Table 8-29: Actions combined for all scenarios



## 8.7 Selection of Recommendations

For each scenario the pharmacist nominated a number of recommendations, see Table 8-30. There was potential for each of these recommendations to be accepted or rejected, for the validation process this step was not included but information can be seen in the pilots study data regarding 'outcome'. Where appropriate pharmacist nominated dose changes (eg Scenario 3 where an underdose of amoxycillin was prescribed, 93.3%) and drug changes (eg Scenario 11 metoprolol in an asthmatic, 87.7%). From the extensive use of the recommendation categories and the pilot study data refinements have been made. Results from the clinical panel and review of the pilot data indicated that in some circumstances more information on recommendations was needed. For example when a dose change was recommended (R3), what were the details of the change and when a new drug was added (R7) the details of the addition. Further training of the pharmacist in subsequent phases of this project and changes to the interface will be undertaken to address this issue.

Scenario	R1		R2		R3		R4		R5		R6		R7		R8		R9		R10		R11		R12		R13		R14		R15		R16		Number of Respondants
	Education/ counselling		Dose change		Drug change		Drug cease		Formulation change		Monitoring non-lab		Drug addition		Brand change		Frequency change		Refer to prescriber		Refer to hospital		Monitoring lab		Refer for med review		Dosage admin- istration aid		Other		No recom- mendation		
	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	
1	150	95.5%	3	1.9%	0	0.0%	0	0.0%	0	0.0%	48	30.6%	0	0.0%	1	0.6%	8	5.1%	49	31.2%	0	0.0%	23	14.6%	23	14.6%	10	6.4%	0	0.0%	11	7.0%	157
2	45	31.7%	2	1.4%	45	31.7%	62	43.7%	1	0.7%	3	2.1%	1	0.7%	0	0.0%	0	0.0%	111	78.2%	1	0.7%	2	1.4%	13	9.2%	0	0.0%	0	0.0%	6	4.2%	142
3	20	14.8%	126	93.3%	2	1.5%	1	0.7%	23	17.0%	2	1.5%	1	0.7%	0	0.0%	1	0.7%	38	28.1%	1	0.7%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	2	1.5%	135
4	57	44.9%	65	51.2%	29	22.8%	45	35.4%	0	0.0%	6	4.7%	0	0.0%	1	0.8%	28	22.0%	81	63.8%	2	1.6%	0	0.0%	17	13.4%	0	0.0%	0	0.0%	7	5.5%	127
5	75	62.5%	2	1.7%	5	4.2%	1	0.8%	0	0.0%	12	10.0%	67	55.8%	0	0.0%	0	0.0%	68	56.7%	1	0.8%	42	35.0%	11	9.2%	1	0.8%	1	0.8%	9	7.5%	120
6	60	52.2%	3	2.6%	32	27.8%	77	67.0%	1	0.9%	26	22.6%	3	2.6%	0	0.0%	1	0.9%	56	48.7%	0	0.0%	12	10.4%	13	11.3%	3	2.6%	0	0.0%	5	4.3%	115
7	86	76.8%	2	1.8%	3	2.7%	0	0.0%	3	2.7%	17	15.2%	2	1.8%	0	0.0%	4	3.6%	17	15.2%	0	0.0%	7	6.3%	30	26.8%	91	81.3%	0	0.0%	5	4.5%	112
8	106	94.6%	0	0.0%	0	0.0%	0	0.0%	2	1.8%	10	8.9%	26	23.2%	0	0.0%	1	0.9%	7	6.3%	0	0.0%	0	0.0%	7	6.3%	40	35.7%	0	0.0%	14	12.5%	112
9	75	65.2%	2	1.7%	16	13.9%	3	2.6%	61	53.0%	7	6.1%	0	0.0%	6	5.2%	2	1.7%	34	29.6%	0	0.0%	0	0.0%	5	4.3%	31	27.0%	0	0.0%	22	19.1%	115
10	30	26.5%	74	65.5%	2	1.8%	7	6.2%	1	0.9%	3	2.7%	1	0.9%	0	0.0%	3	2.7%	75	66.4%	9	8.0%	100	88.5%	13	11.5%	1	0.9%	0	0.0%	5	4.4%	113
11	41	36.0%	6	5.3%	100	87.7%	25	21.9%	2	1.8%	19	16.7%	6	5.3%	0	0.0%	0	0.0%	79	69.3%	0	0.0%	4	3.5%	9	7.9%	0	0.0%	0	0.0%	0	0.0%	114
12	70	64.8%	11	10.2%	7	6.5%	0	0.0%	0	0.0%	6	5.6%	6	5.6%	0	0.0%	77	71.3%	28	25.9%	0	0.0%	7	6.5%	4	3.7%	0	0.0%	0	0.0%	6	5.6%	108
13	48	43.6%	17	15.5%	1	0.9%	2	1.8%	0	0.0%	7	6.4%	0	0.0%	0	0.0%	1	0.9%	67	60.9%	1	0.9%	106	96.4%	19	17.3%	3	2.7%	0	0.0%	1	0.9%	110
14	28	26.4%	1	0.9%	40	37.7%	66	62.3%	0	0.0%	13	12.3%	1	0.9%	0	0.0%	0	0.0%	88	83.0%	10	9.4%	51	48.1%	3	2.8%	0	0.0%	1	0.9%	14	13.2%	106
15	81	75.7%	11	10.3%	1	0.9%	48	44.9%	0	0.0%	12	11.2%	0	0.0%	15	14.0%	2	1.9%	65	60.7%	7	6.5%	41	38.3%	19	17.8%	7	6.5%	0	0.0%	5	4.7%	107
16	40	37.4%	72	67.3%	3	2.8%	1	0.9%	5	4.7%	4	3.7%	3	2.8%	0	0.0%	40	37.4%	34	31.8%	0	0.0%	0	0.0%	3	2.8%	0	0.0%	1	0.9%	0	0.0%	107
17	23	23.5%	2	2.0%	42	42.9%	2	2.0%	1	1.0%	2	2.0%	33	33.7%	0	0.0%	1	1.0%	82	83.7%	3	3.1%	1	1.0%	1	1.0%	0	0.0%	0	0.0%	0	0.0%	98
18	45	42.5%	81	76.4%	3	2.8%	3	2.8%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	13	12.3%	29	27.4%	1	0.9%	15	14.2%	6	5.7%	3	2.8%	1	0.9%	1	0.9%	106
19	75	70.8%	8	7.5%	5	4.7%	81	76.4%	0	0.0%	8	7.5%	1	0.9%	1	0.9%	11	10.4%	31	29.2%	0	0.0%	0	0.0%	5	4.7%	2	1.9%	0	0.0%	4	3.8%	106
20	14	13.5%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	15	14.4%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	52	50.0%	31	29.8%	104
Total	1169	50.5%	488	21.1%	336	14.5%	424	18.3%	100	4.3%	205	8.9%	151	6.5%	24	1.0%	193	8.3%	1054	45.5%	36	1.6%	411	17.8%	201	8.7%	192	8.3%	56	2.4%	148	6.4%	2314

Table 8-30 Recommendation selection for the 20 scenarios

## 8.8 Relationship of significance to Other Aspects of the Validation Scenarios

The categorisation of significance of the validation scenarios was varied in many cases (see discussion previously). In the following sections, relationships between significance and other aspects of the intervention or pharmacist characteristics are explored.

### 8.8.1 Significance Related to Type of Intervention

Type	Significance										Total
	Nil		Low		Mild		Moderate		High		
	#	%	#	%	#	%	#	%	#	%	
Drug selection Subtotal	1	0.2%	5	0.9%	90	16.5%	160	29.3%	290	53.1%	546
Over or underdose prescribed Subtotal	1	0.2%	10	2.5%	118	29.1%	159	39.2%	118	29.1%	406
Compliance Subtotal	1	0.3%	4	1.2%	150	44.6%	132	39.3%	49	14.6%	336
Untreated indications Subtotal			2	1.1%	83	44.6%	74	39.8%	27	14.5%	186
Monitoring required Subtotal			3	2.4%	15	11.8%	39	30.7%	70	55.1%	127
Education or Information Subtotal	2	0.8%	7	2.7%	115	43.9%	92	35.1%	46	17.6%	262
Non-clinical Subtotal	94	79.7%	4	3.4%	6	5.1%	4	3.4%	10	8.5%	118
Toxicity or Adverse reaction Subtotal			5	1.5%	74	22.2%	104	31.2%	150	45.0%	333
Total	99	4.3%	40	1.7%	651	28.1%	764	33.0%	760	32.8%	2314

Table 8-31: Significance of Intervention by Major Type of Intervention

More respondents selected high significance in scenarios that were of the drug selection, monitoring required or toxicity or adverse reaction types.

Type	Subtype	Significance										Total
		Nil		Low		Mild		Moderate		High		
		#	%	#	%	#	%	#	%	#	%	
Drug selection	Duplication of drug or therapeutic class			5	2.6%	35	18.2%	66	34.4%	86	44.8%	192
Drug selection	Interaction with existing therapy	1	0.7%			16	10.7%	41	27.5%	91	61.1%	149
Drug selection	Wrong drug prescribed/supplied in error					10	7.8%	28	21.7%	91	70.5%	129
Drug selection	Incorrect or inappropriate dosage form					18	62.1%	7	24.1%	4	13.8%	29
Drug selection	Pre-existing severe ADR/allergy							1	100.0%			1
Drug selection	Other Drug selection related problem					11	23.9%	17	37.0%	18	39.1%	46
Drug selection Subtotal		1	0.2%	5	0.9%	90	16.5%	160	29.3%	290	53.1%	546
Over or underdose prescribed	Too high dose prescribed	1	0.5%	6	3.1%	12	6.2%	79	40.5%	97	49.7%	195
Over or underdose prescribed	Too low dose prescribed			1	0.7%	74	55.2%	58	43.3%	1	0.7%	134
Over or underdose prescribed	Incorrect frequency prescribed			2	3.8%	26	49.1%	15	28.3%	10	18.9%	53
Over or underdose prescribed	Other Dose related Problem			1	4.2%	6	25.0%	7	29.2%	10	41.7%	24
Over or underdose prescribed Subtotal		1	0.2%	10	2.5%	118	29.1%	159	39.2%	118	29.1%	406
Compliance	Potential drug overuse/abuse situation (intentional)							1	100.0%			1
Compliance	Compliance suboptimal (taking too little)	1	0.5%	3	1.6%	90	47.6%	77	40.7%	18	9.5%	189
Compliance	Compliance suboptimal (taking too much)					2	5.7%	14	40.0%	19	54.3%	35
Compliance	Difficulty using dosage form					49	54.4%	29	32.2%	12	13.3%	90
Compliance	Other Compliance related Problem			1	4.8%	9	42.9%	11	52.4%			21
Compliance Subtotal		1	0.3%	4	1.2%	150	44.6%	132	39.3%	49	14.6%	336
Untreated indications	Condition or health problem not adequately treated or controlled			1	0.8%	54	43.2%	58	46.4%	12	9.6%	125
Untreated indications	Preventive therapy required as a result of existing health problems, drug therapy or risk factors			1	1.6%	29	47.5%	16	26.2%	15	24.6%	61
Untreated indications Subtotal				2	1.1%	83	44.6%	74	39.8%	27	14.5%	186
Monitoring required	Drug levels					1	3.4%	8	27.6%	20	69.0%	29
Monitoring required	Laboratory Monitoring (eg K, Cr, WCC)			2	2.5%	8	9.9%	25	30.9%	46	56.8%	81
Monitoring required	Non-Laboratory monitoring (eg BP, BSL, temperature, weight)			1	11.1%	3	33.3%	3	33.3%	2	22.2%	9
Monitoring required	Other Monitoring related Problem (Specify)					3	37.5%	3	37.5%	2	25.0%	8
Monitoring required Subtotal				3	2.4%	15	11.8%	39	30.7%	70	55.1%	127
Education or Information	Patient requests information			1	25.0%	2	50.0%	1	25.0%			4
Education or Information	Confusion about therapy/condition	1	1.1%	1	1.1%	20	21.3%	42	44.7%	30	31.9%	94
Education or Information	Requires demonstration of therapeutic device			2	3.1%	39	60.0%	23	35.4%	1	1.5%	65
Education or Information	Requires disease management or health care advice	1	1.3%	2	2.5%	44	55.7%	18	22.8%	14	17.7%	79
Education or Information	Other Education/Information related Problem			1	5.0%	10	50.0%	8	40.0%	1	5.0%	20
Education or Information Subtotal		2	0.8%	7	2.7%	115	43.9%	92	35.1%	46	17.6%	262
Non-clinical Subtotal		94	79.7%	4	3.4%	6	5.1%	4	3.4%	10	8.5%	118
Toxicity or Adverse reaction	Caused by dose too high					7	8.2%	19	22.4%	59	69.4%	85
Toxicity or Adverse reaction	Caused by drug interaction			2	1.3%	38	25.5%	48	32.2%	61	40.9%	149
Toxicity or Adverse reaction	Other Toxicity or Adverse reaction related problem (e.g. allergy)			3	3.0%	29	29.3%	37	37.4%	30	30.3%	99
Toxicity or Adverse reaction Subtotal				5	1.5%	74	22.2%	104	31.2%	150	45.0%	333
Total		99	4.3%	40	1.7%	651	28.1%	764	33.0%	760	32.8%	2314

Table 8-32: Significance of Intervention by Subtype of Intervention (Validation Exercise Data)

The categorisation of significance of the validation scenarios was varied in many cases (see discussion previously). In the following sections, relationships between significance and other aspects of the intervention or pharmacist characteristics are explored.

### 8.8.2 Significance Related to Actions to Investigate Intervention

Registrants rated as of high significance those scenarios where assistance from an outside drug information source was required.

Action	Nil		Low		Mild		Moderate		High		Total
	#	%	#	%	#	%	#	%	#	%	
Investigation: Written Material			10	2.6%	99	25.8%	150	39.1%	125	32.6%	<b>384</b>
Investigation: Software	1	0.3%	3	0.8%	93	25.1%	136	36.7%	138	37.2%	<b>371</b>
Investigation: Internet			2	4.0%	22	44.0%	16	32.0%	10	20.0%	<b>50</b>
Investigation: Contact DIC			1	1.5%	14	20.9%	17	25.4%	35	52.2%	<b>67</b>
Investigation: Other					9	22.5%	12	30.0%	19	47.5%	<b>40</b>
Contact Prescriber	71	4.5%	16	1.0%	314	19.7%	535	33.6%	656	41.2%	<b>1592</b>
Discussion with Patient	21	1.3%	26	1.5%	526	31.3%	577	34.4%	528	31.5%	<b>1678</b>
Correct Without Discussion	29	55.8%	3	5.8%	11	21.2%	8	15.4%	1	1.9%	<b>52</b>
Other	6	6.2%			30	30.9%	30	30.9%	31	32.0%	<b>97</b>
<b>Total</b>	<b>128</b>	<b>3.0%</b>	<b>61</b>	<b>1.4%</b>	<b>1118</b>	<b>25.8%</b>	<b>1481</b>	<b>34.2%</b>	<b>1543</b>	<b>35.6%</b>	<b>4331</b>

Table 8-33 Significance by Action (Validation Exercise Data)

### 8.8.3 Significance Related to Recommendations of Intervention

Participants rated as of high clinical significance those situations where laboratory test monitoring was recommended, where drug cessation was recommended and where referral to the prescriber was recommended.

Recommendation	Nil		Low		Mild		Moderate		High		Total
	#	%	#	%	#	%	#	%	#	%	
Education/Counselling	11	0.9%	28	2.4%	386	33.1%	392	33.6%	348	29.9%	1165
Dose Change			6	1.2%	134	27.0%	177	35.7%	179	36.1%	496
Drug Change			2	0.6%	79	23.5%	128	38.1%	127	37.8%	336
Drug Cessation			3	0.7%	47	11.0%	131	30.7%	246	57.6%	427
Drug Formulation Change			1	1.0%	49	50.5%	38	39.2%	9	9.3%	97
Monitoring: Non-Laboratory			1	0.5%	53	26.5%	79	39.5%	67	33.5%	200
Drug Addition			2	1.2%	66	40.5%	66	40.5%	29	17.8%	163
Drug Brand Change			1	3.8%	5	19.2%	8	30.8%	12	46.2%	26
Dose Frequency or Schedule Change	2	1.0%	4	2.1%	93	48.4%	58	30.2%	35	18.2%	192
Refer to Prescriber	15	1.4%	8	0.7%	226	21.1%	354	33.1%	466	43.6%	1069
Refer to Hospital			1	2.7%	3	8.1%	4	10.8%	29	78.4%	37
Monitoring: Laboratory Test	1	0.2%	2	0.5%	43	10.5%	108	26.5%	254	62.3%	408
Refer for Medication Review					68	33.3%	53	26.0%	83	40.7%	204
Commence Dose Administration Aid			6	3.2%	88	46.3%	68	35.8%	28	14.7%	190
No Recommendation Necessary	50	86.2%	4	6.9%	3	5.2%	1	1.7%			58
Other Recommendation	30	20.4%			44	29.9%	40	27.2%	33	22.4%	147
<b>Total</b>	<b>109</b>	<b>2.1%</b>	<b>69</b>	<b>1.3%</b>	<b>1387</b>	<b>26.6%</b>	<b>1705</b>	<b>32.7%</b>	<b>1945</b>	<b>37.3%</b>	<b>5215</b>

**Table 8-34 Significance by Recommendation (Validation Exercise Data)**

## 8.9 Internal Validation

A random selected sample of 40 of the pharmacists who completed the scenarios were approached to re-attempt the classification as an internal validity process. Of these, 18 completed the 20 scenarios again.

### 8.9.1 Type of Intervention

There was significant concordance between the first and second trials in the selection of types and subtypes, indicating that the same pharmacist would code the same scenario the same way on two separate occasions.

scenario number	Intervention Main Type Concordance		
	n	y	%
1	5	13	72.2%
2	5	13	72.2%
3	1	17	94.4%
4	5	13	72.2%
5	5	13	72.2%
6	2	16	88.9%
7	3	15	83.3%
8	8	10	55.6%
9	7	11	61.1%
10	5	13	72.2%
11	6	12	66.7%
12	4	14	77.8%
13	6	12	66.7%
14		18	100.0%
15	6	12	66.7%
16	4	14	77.8%
17	6	12	66.7%
18	2	16	88.9%
19	2	16	88.9%
20	2	16	88.9%
<b>Total</b>	<b>84</b>	<b>276</b>	<b>76.7%</b>

Table 8-35: Concordance of Internal validation in Selection of Type of Intervention

## 8.9.2 Subtype of Intervention

scenario number	Subtype Concordance		
	n	y	%
1	7	11	61.1%
2	7	11	61.1%
3	1	17	94.4%
4	10	8	44.4%
5	7	11	61.1%
6	2	16	88.9%
7	6	12	66.7%
8	8	10	55.6%
9	7	11	61.1%
10	5	13	72.2%
11	9	9	50.0%
12	5	13	72.2%
13	8	10	55.6%
14		18	100.0%
15	6	12	66.7%
16	5	13	72.2%
17	6	12	66.7%
18	4	14	77.8%
19	6	12	66.7%
20	2	16	88.9%
<b>Total</b>	<b>111</b>	<b>249</b>	<b>69.2%</b>

Table 8-36: Concordance of Internal validation in Selection of Subtype of Intervention

### 8.9.3 Significance of Intervention

scenario number	Significance Concordance		
	n	y	%
1	10	8	44.4%
2	2	16	88.9%
3	5	13	72.2%
4	6	12	66.7%
5	10	8	44.4%
6	7	11	61.1%
7	9	9	50.0%
8	6	12	66.7%
9	9	9	50.0%
10	4	14	77.8%
11	9	9	50.0%
12	2	16	88.9%
13	10	8	44.4%
14	3	15	83.3%
15	7	11	61.1%
16	12	6	33.3%
17	10	8	44.4%
18	8	10	55.6%
19	10	8	44.4%
20	5	13	72.2%
<b>Total</b>	<b>144</b>	<b>216</b>	<b>60.0%</b>

Table 8-37: Concordance of Internal validation in Selection of Significance of Intervention

## 9 Development of Communications and Repository infrastructure and software

The major software development effort of the project has been the design and coding of the communications module RexComm used by the dispensing software to transmit the collected interventions from individual pharmacies, and the development of the central data repository server which receives and stores the data. Phoenix Corp. have utilised their previous experience with MediConnect and HealthConnect connectivity to plan and execute a versatile, reliable, enterprise level solution.

The data repository server has been built and fully functional (although undergoing usual tuning) since Feb 19<sup>th</sup> 2004. The Microsoft SQL Server based database has been custom designed to hold records which include all the fields required for the intervention data and to enable effective record management. Experimental connectivity to the server from the communication module was initially achieved in the first week of February. Continuous development of the RexComm module has produced a fully functional, secure and robust communication link between pharmacies and the central data repository. A functional diagram of the components of the system appears below (Figure 9-1)

### 9.1 Technical Architecture - Summary

Below is a simple graphical representation of the PROMISe project's technical architecture.

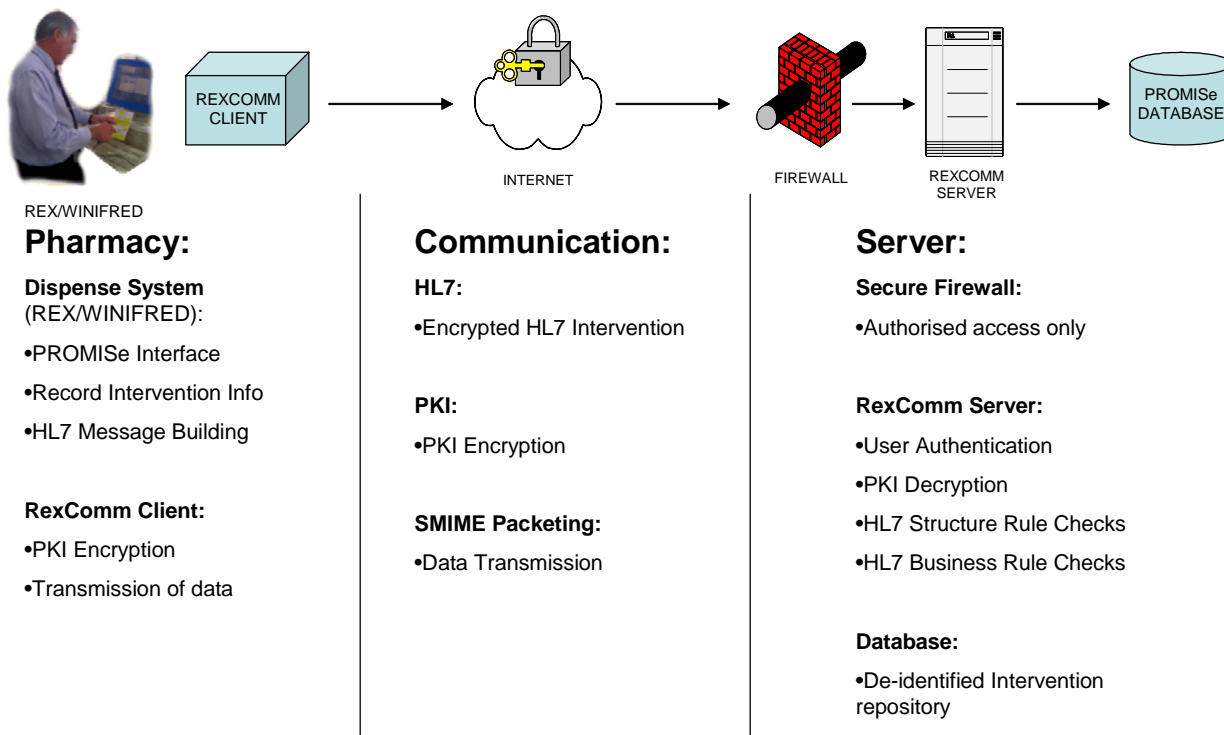


Figure 9-1 Technical Architecture for PROMISe Project



The workflow process is as follows (for prescription based interventions):

- Patient presents at pharmacy with prescription.
- Pharmacist notices issue with prescription, makes necessary investigations, and takes corrective actions where necessary.
- Pharmacist records intervention in their dispense software. De-identified intervention record consequently sent to PROMISe repository.

The main components in more detail:

### **9.1.1 Pharmacy Dispensing software:**

The REX and WINIFRED pharmacy dispense software systems were enhanced to record interventions via the D.O.C.U.M.E.N.T interface. This functionality is defined in the Functional Requirements – see Appendix 13.11.

### **9.1.2 Client Communication Application**

The Client Communications Application (namely RexComm Client and NU Exchange products), were designed to handle the PKI encryption and real-time transmission of intervention data sent to it by the dispense system, to the PROMISe Repository via the internet.

### **9.1.3 The Internet**

The internet is the communications medium through which the intervention information is sent. The messages transmitted over the internet are in secure SMIME packets using the Hyper-Text Transfer Protocol (HTTP) as the delivery mechanism. The data inside these packets is HL7 intervention messages encrypted using PKI. For the purpose of the PROMISe pilot, 5 of the participating pharmacies had ADSL broadband connectivity, and 2 had dial-up access.

### **9.1.4 RexComm Server**

RexComm Server is a Phoenix product that has been configured to work with the PROMISe framework. More specifically, RexComm Server handles the decryption of incoming messages, security and authentication, HL7 Integrity checking (i.e. – Business and Structure rule checking), and message parsing to store the incoming data in the PROMISe database. RexComm Server is also responsible for generating message acknowledgements and error responses, and transmitting them back the client pharmacy.

The server is protected from unauthorised access by a secure firewall, which only allows authorised traffic through.

## **9.2 *PROMISe server***

The PROMISe server is to act as an open repository of intervention information easily available to any pharmacies using a dispensing system. Participating pharmacies are able to send interventions data via their dispensing software to be stored in a database.

The data in the repository will be available to generate, view and save specific reports from the database. The main component of the system referred to as the 'PROMISe Server' consists of the custom configured RexComm server and the database of intervention activity generated by pharmacy users.

### 9.2.1 PROMISe Server Client Interaction

The PROMISe server listens on a socket interface for client requests. The server will service each request and send back an associated response. In all cases, the client will receive a single message response to a request.

Communication to the system is achieved using a lightweight HTTP server, which carries base64 encoded S/MIME messages (in both directions). The content of the S/MIME message is the HL7 message, which conveys data to the repository, and acknowledgement back to the sender.

The server only supports HTTP 1.0 and for security, only supports the HTTP POST method and ignores all other HTTP methods, such as GET, HEADER and PUT. The 'HTTP content-type' in the header of the HTTP message must be 'application/x-hic-pkcs7-mime'. Each request received by the PROMISe server is checked to make sure it does not contain errors.

below shows the basic processes required for sending and retrieving data via the PROMISe server.

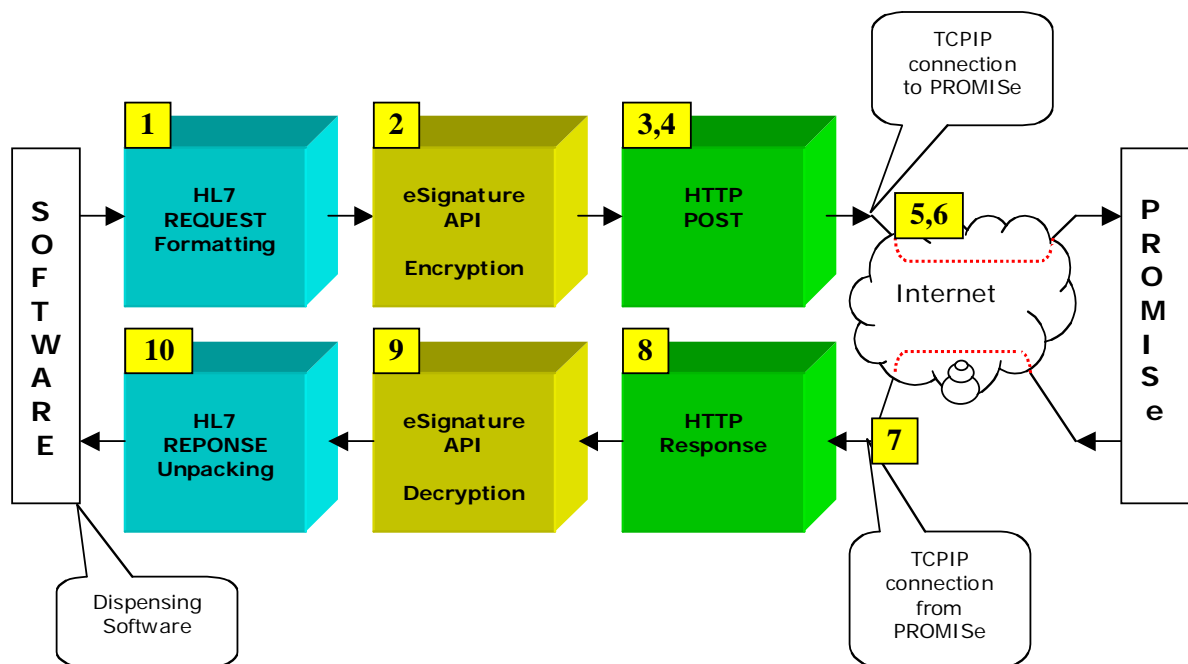


Figure 9-2: PROMISe Communication Process

This process consists of the following steps:

- Formats data into a HL7 message meeting the business rules for both the formatting and provision of required fields.
- Encrypts, Signs, Compresses, and Base64 encodes the above HL7 message using the eSignature API supplied by HeSA.

- Encapsulates the above encrypted message into a S/MIME message.
- Encapsulates the S/MIME message into a HTTP message.
- Connects to the PROMISe server via the Internet.
- Sends the HTTP message to the PROMISe server.
- Waits for the HTTP response from the PROMISe server.
- Strips the HTTP header and checks the HTTP error codes.
- Decrypts the S/MIME message.
- Unpacks HL7 data.

Documentation covering the record and field structure in the database has been completed (Appendix 13.12). In addition, business rules for connecting to the data repository server have been constructed (Appendix 13.13).

Together this documentation can be passed to third party dispensing software vendors who can utilise their own communication modules to successfully connect to the data repository and upload intervention data.

### **9.2.2 Security and Access Functionality (PKI)**

Participating pharmacies had access to the Internet. Participants registered with the University of Tasmania. A registration form containing relevant pharmacy details was stored on the PROMISe server and managed by the University of Tasmania.

The PROMISe Server used the HeSA PKI cryptography API to secure and de-secure the S/MIME messages. Pharmacy systems that currently have MediConnect or Health Connect keys and certificates were able to use these certificates to access the repository. Otherwise, keys and certificates would be obtained from HeSA.

To ensure security of the interventions data, the PROMISe server was loaded with all individual pharmacy certificates. Likewise, Pharmacy dispensing systems were installed with the PROMISe server certificates.

## **9.3 Privacy Measures**

The dispensing system does NOT send information (encrypted or otherwise), which relates to the identification of a person. This includes information such as names or Medicare number.

## **9.4 Web Reporting Interface**

### **9.4.1.1 Web Reporting Interface**

Data collected during trials was available to appropriately registered and authorised parties for immediate display from the live PROMISe database via the Web Reporting Interface. This interface was accessed from the PROMISe website and was hosted on the same machine which receives and resends the encrypted intervention data from pharmacies using DOCUMENT enhanced dispensing software. To ensure the confidentiality and integrity of the PROMISe database, the accessible web server was separated from the database server by a secondary firewall.

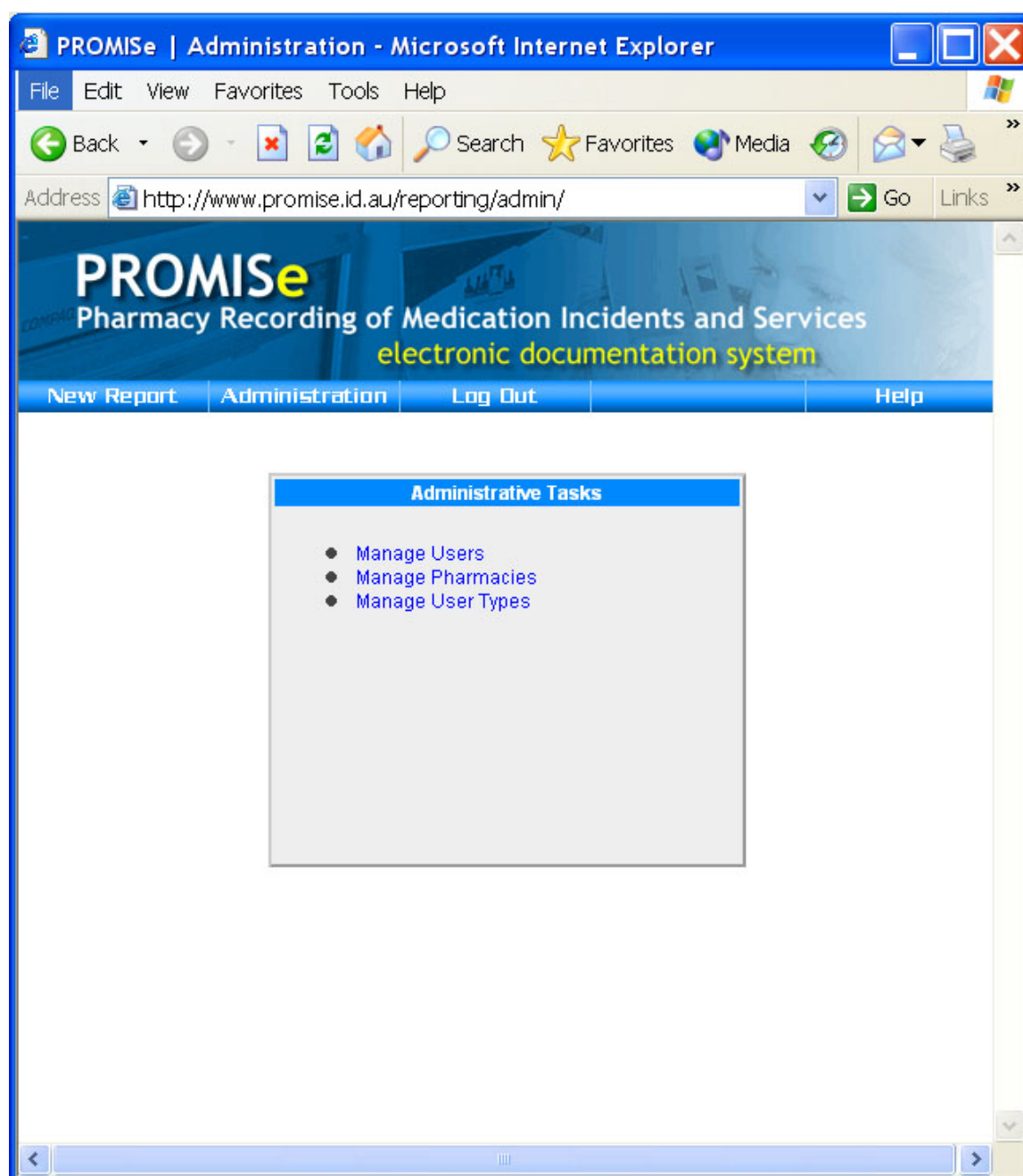
The PROMISe server maintains a database of authorised users and their access control lists which determine functionality and data made available to the user. The access control lists are fully configurable by the database administrator (University of Tasmania) via the Web Reporting Interface.

Pharmacists involved in trials were provided with a user name and password. This permitted simple one-way views of state level data. The Pharmacy Guild of Australia login was configured to access all state and pooled national data items. The University of Tasmania login permitted many views of the pooled data to be generated, including multi-way associations, and the incorporation of constraints, which effectively reduced the number of active categories within a particular data class (examples shown in screenshots below).



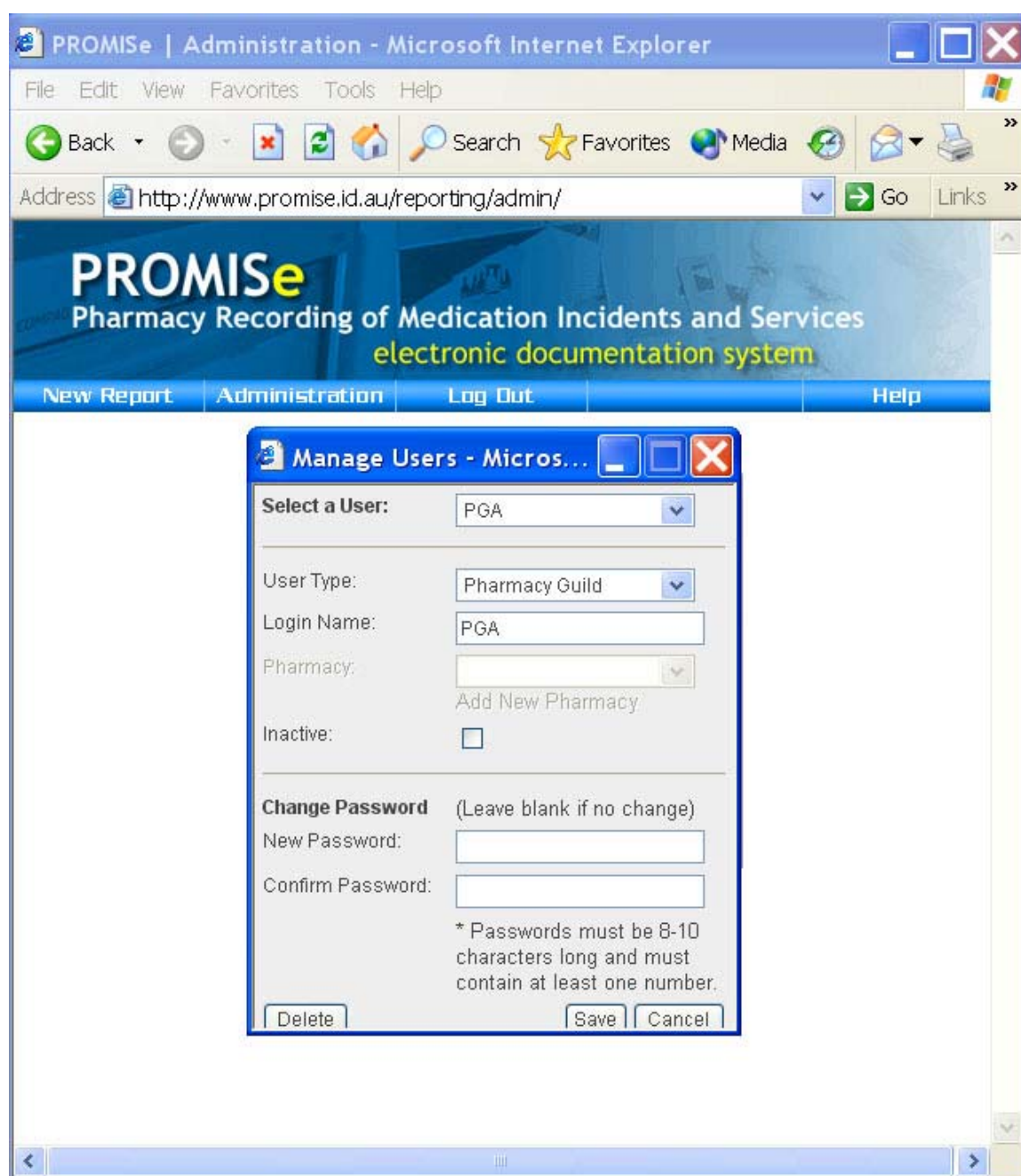
**Figure 9-3 Logon Screen for Promise Web Reporting Module**

The first screen displayed in the Web Reporting Interface Figure 9-3 was the logon screen. This sets the data range and data presentation functionalities available to the user. There was no provision for persons or parties without explicit authority to progress beyond the logon screen.



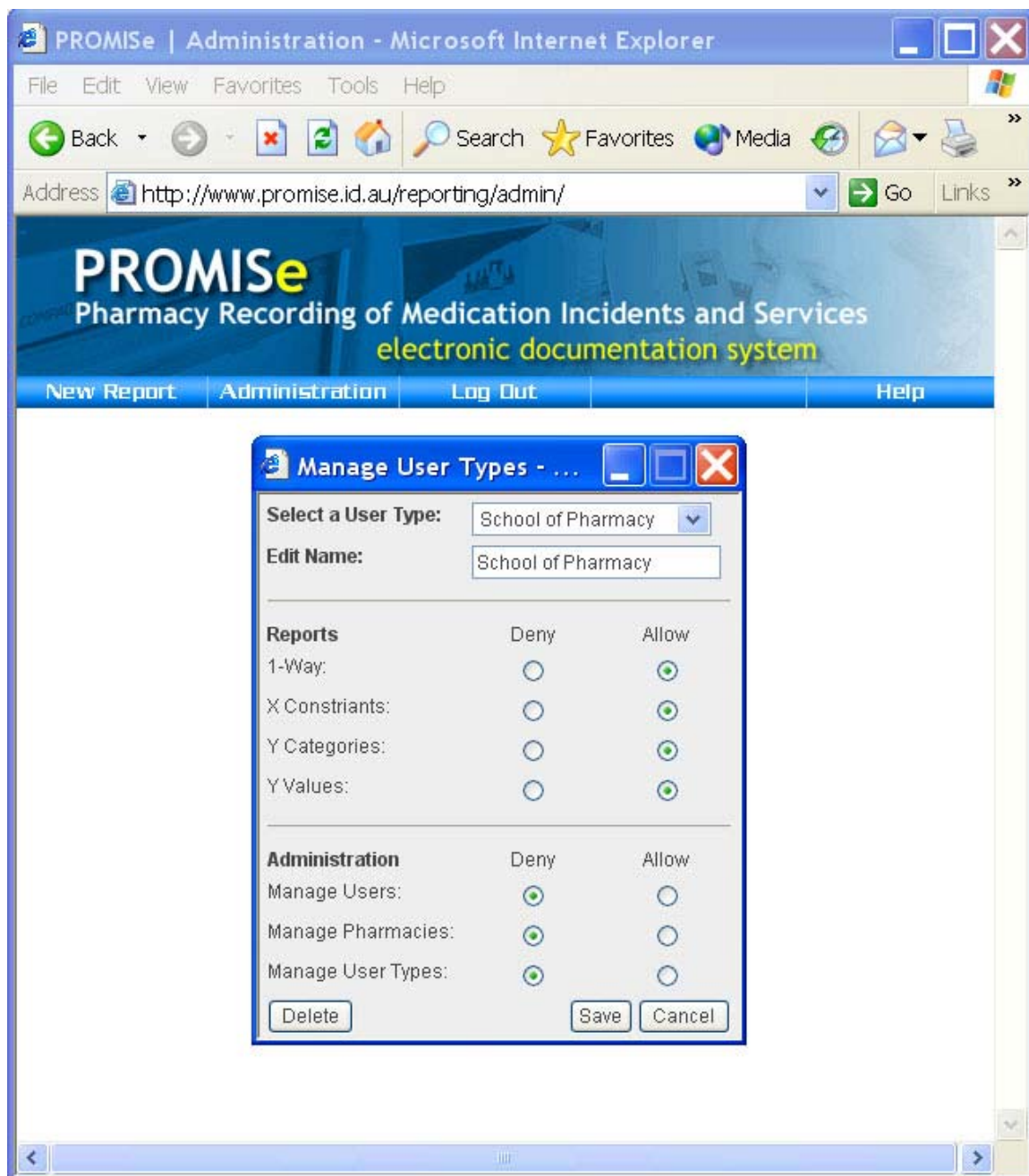
**Figure 9-4 Management of Users in PROMISe web reporting Module**

An administrator login permits management of the Web Reporting Interface user database. Three choices are available, as indicated in Figure 9-4.



**Figure 9-5 Management of Users in Promise Web Reporting Module**

Management of users allows the administrator to assign logins (or a particular user type) and associated passwords to users.



**Figure 9-6 Management of User Types for PROMISe web reporting Module**

Management of user types allows manipulation of the access control lists for each user type, as well as permitting the production of custom user types. Each reporting and administrative function was made available or denied to each user type by simply selecting the corresponding radio buttons on the interface.



**PROMISEe | Administration - Microsoft Internet Explorer**

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Media Print

Address <http://www.promise.id.au/reporting/admin/> Go Links

**PROMISEe**  
Pharmacy Recording of Medication Incidents and Services  
electronic documentation system

New Report Administration Log Out Help

**Manage Pharmacies - Microsoft Internet Explorer**

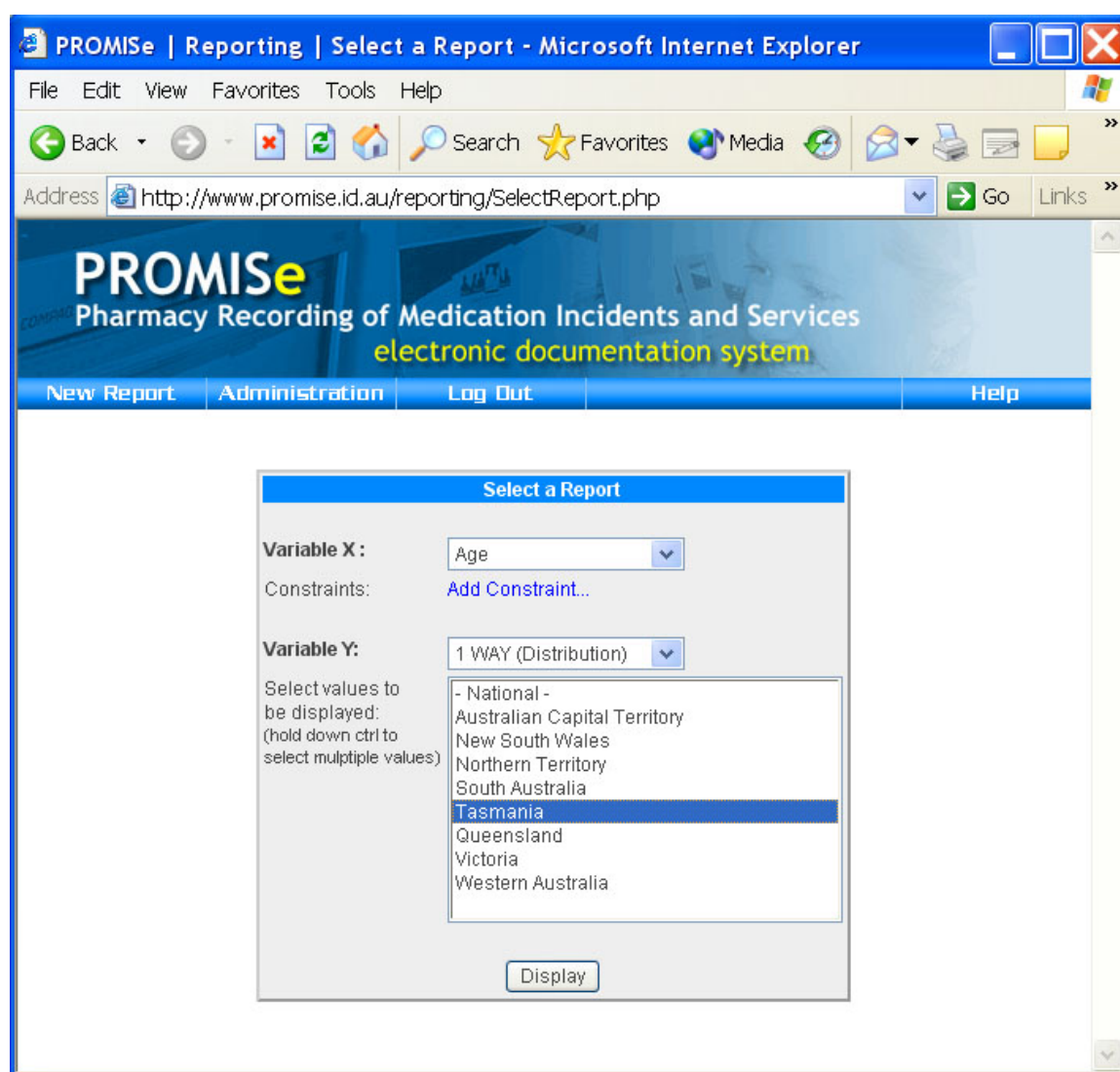
Select a Pharmacy: <New Pharmacy>

Pharmacy Name:	<input type="text" value="St Peters Pharmacy"/>	Approval Number:	<input type="text" value="08113C"/>
Contact Name:	<input type="text" value="George Riad"/>	Certificate Number:	<input type="text" value="111111"/>
Postal Address:	<input type="text" value="12 Northbound Lane Oxville"/>	Key Expiry Date:	<input type="text" value="31 December 2004"/>
State:	<input type="text" value="Tasmania"/>	Email Return Address:	<input type="text" value="G.Riad@onenet.com.au"/>
Postcode:	<input type="text" value="7301"/>	Software Vendor:	<input type="text" value="1: Phoenix"/>
Phone Number:	<input type="text" value="03 642 56 367"/>	Active:	<input checked="" type="checkbox"/>
Administration Email:	<input type="text" value="G.Riad@onenet.com.au"/>	<input type="button" value="Save"/> <input type="button" value="Cancel"/>	

**Figure 9-7 Pharmacy User Management in PROMISE Reporting Module**

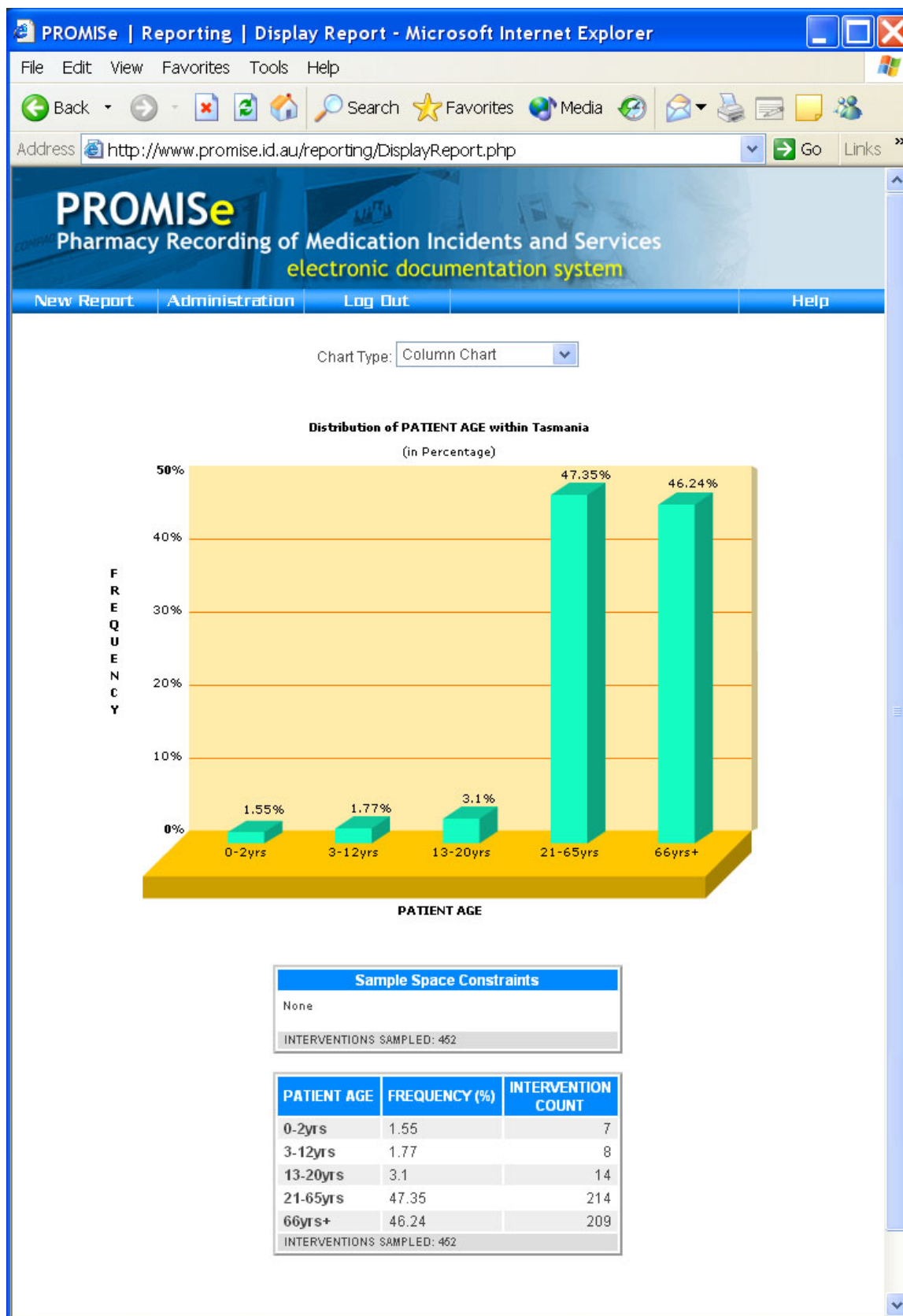
The Manage Pharmacies facility maintains a database of contact information for each pharmacy enrolled in the trial. Importantly, the PKI certificate information for each Pharmacy was maintained within this database to allow data authenticity verification in the RexServer module. In addition this data is used to permit pharmacies actively recording interventions to view their own data and compare these with state averages. This was the only way that data from individual pharmacies can be accessed through the Web Reporting Interface, thus ensuring the privacy of participant pharmacies' data, whilst providing a useful feedback mechanism.





**Figure 9-8 Selection of variables in PROMISE reporting module**

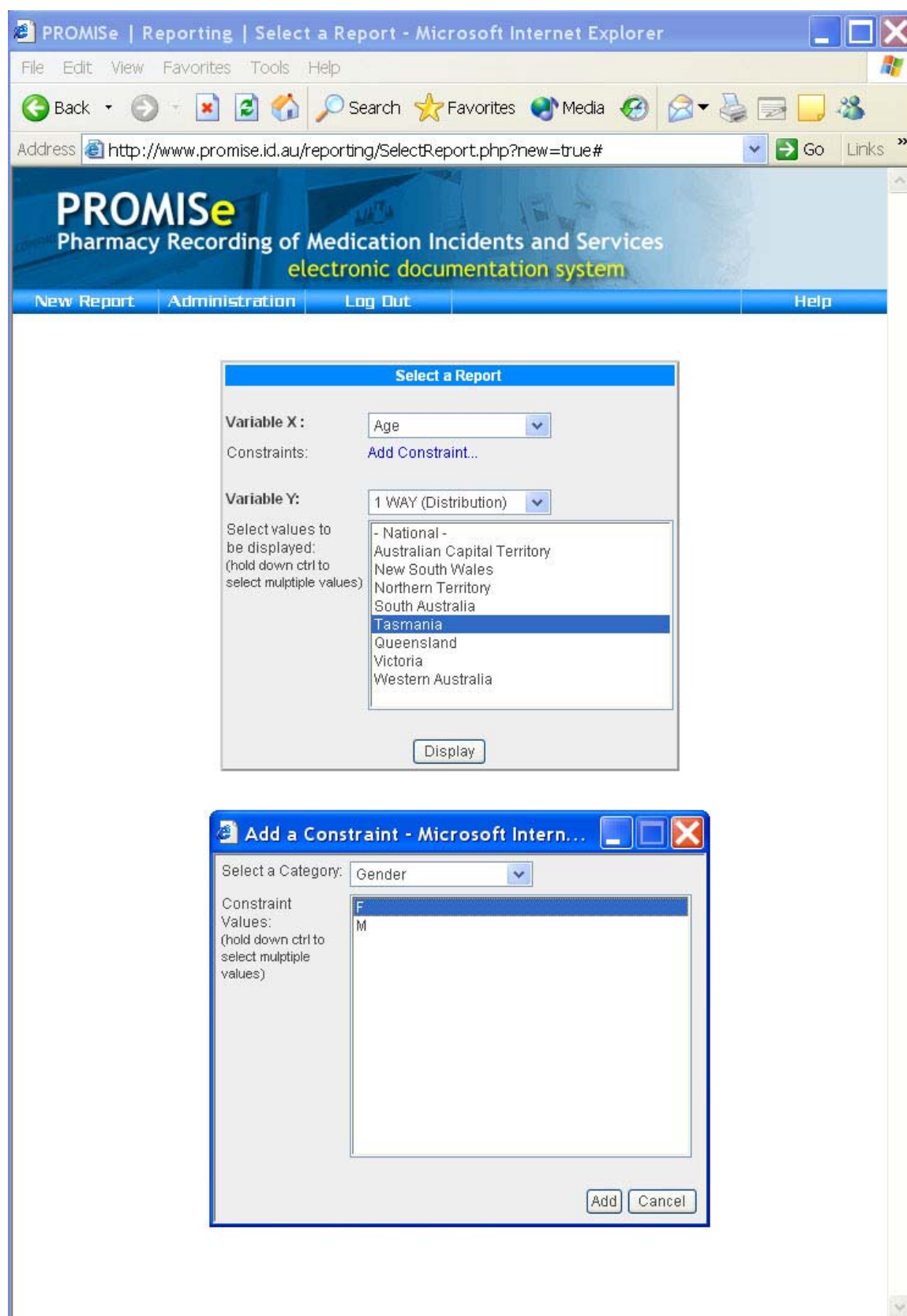
Simple but informative reports can be generated with as few as three mouse clicks. The above request for an indication of age variation in Tasmanian intervention data generates the report shown following in Figure 9-9.



**Figure 9-9 One Variable report Generated from PROMISe web reporting Module**

The report consists of a graphical interpretation of the categorical data, with category values appearing below the bar and percentages for each bar height shown above the bar. In addition, by 'mousing over' any of the bars, a text bubble is generated identifying the bar currently being indicated by the mouse pointer. Following the graph is a box which lists any data constraints (in this case none), then the raw data

is repeated in tabular form. This permits further statistical analysis using third party statistical software solutions.



**Figure 9-10 Adding Constraints to Reports Generated in PROMISe Web Reporting Module**

Adding a constraint serves to dissect the dataset further by reducing the number of represented data points in some way. In the example above, the age of Tasmanian patients with recorded intervention events is constrained to include only females. The output of the above command set is shown below.

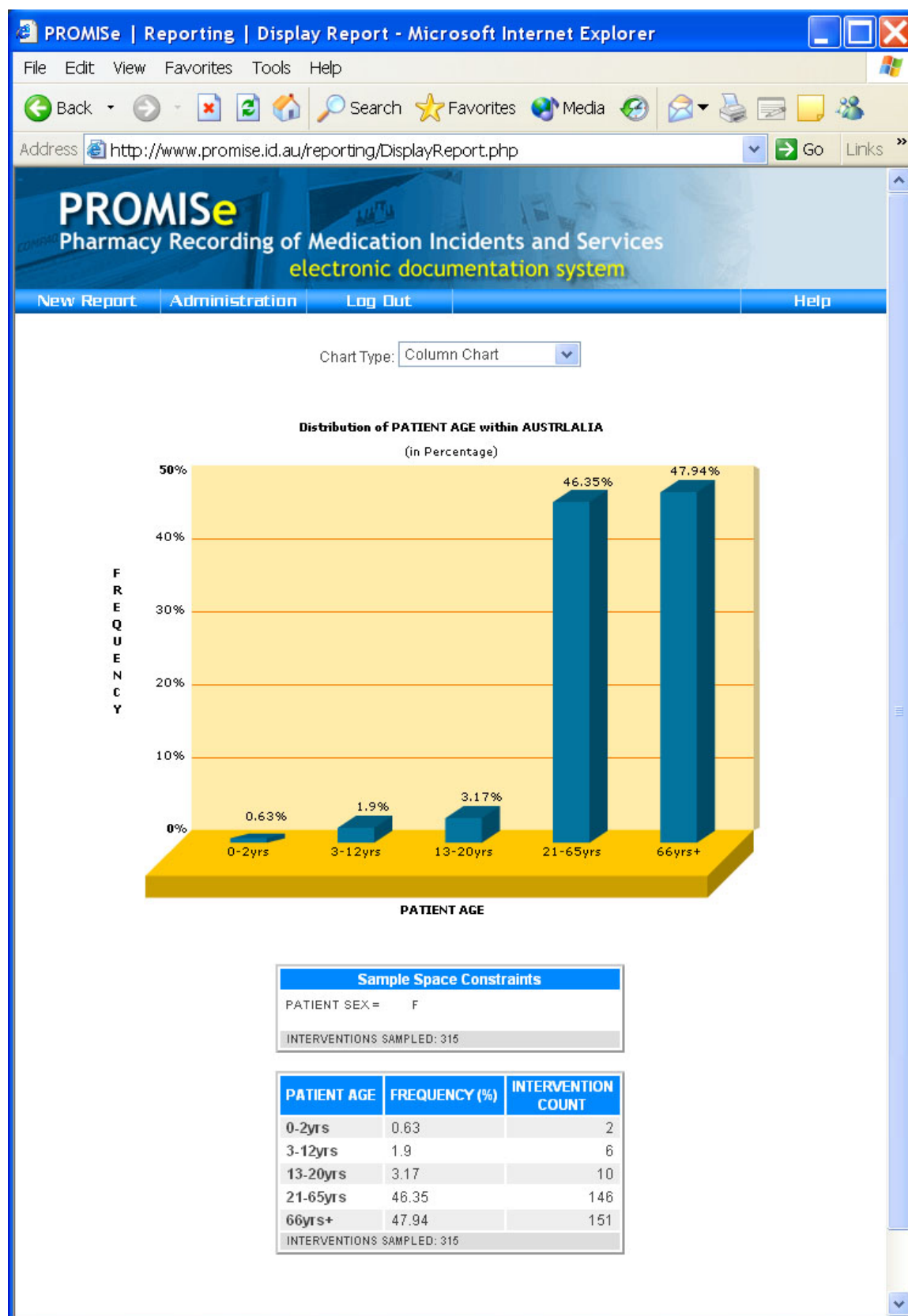
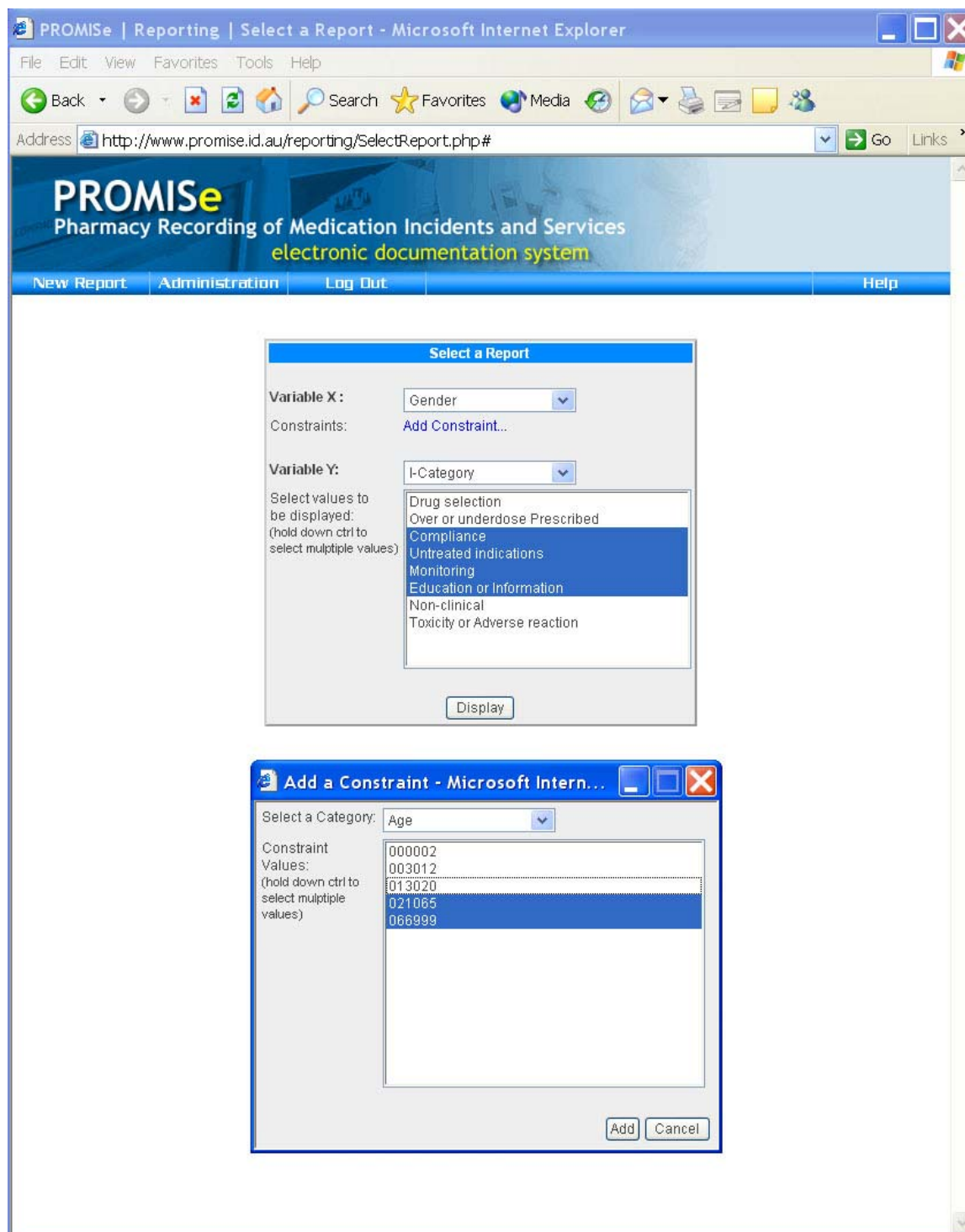


Figure 9-11 Report Generated from PROMISe web reporting Module with Constraint Added

Appropriately authorised parties can also request two way data comparisons. With the addition of constraints, this enables simple yet powerful graphical representations of the database to be generated.



**Figure 9-12 Two Way Comparison Report Generated from PROMISe web reporting Module**

In the above figure, we have chosen to investigate any gender difference in four of the possible eight categories of Interventions. In addition, the data has been constrained to include only 'adults' (age range 21 years and over). The following graphical and tabular output was returned by the reporting system.



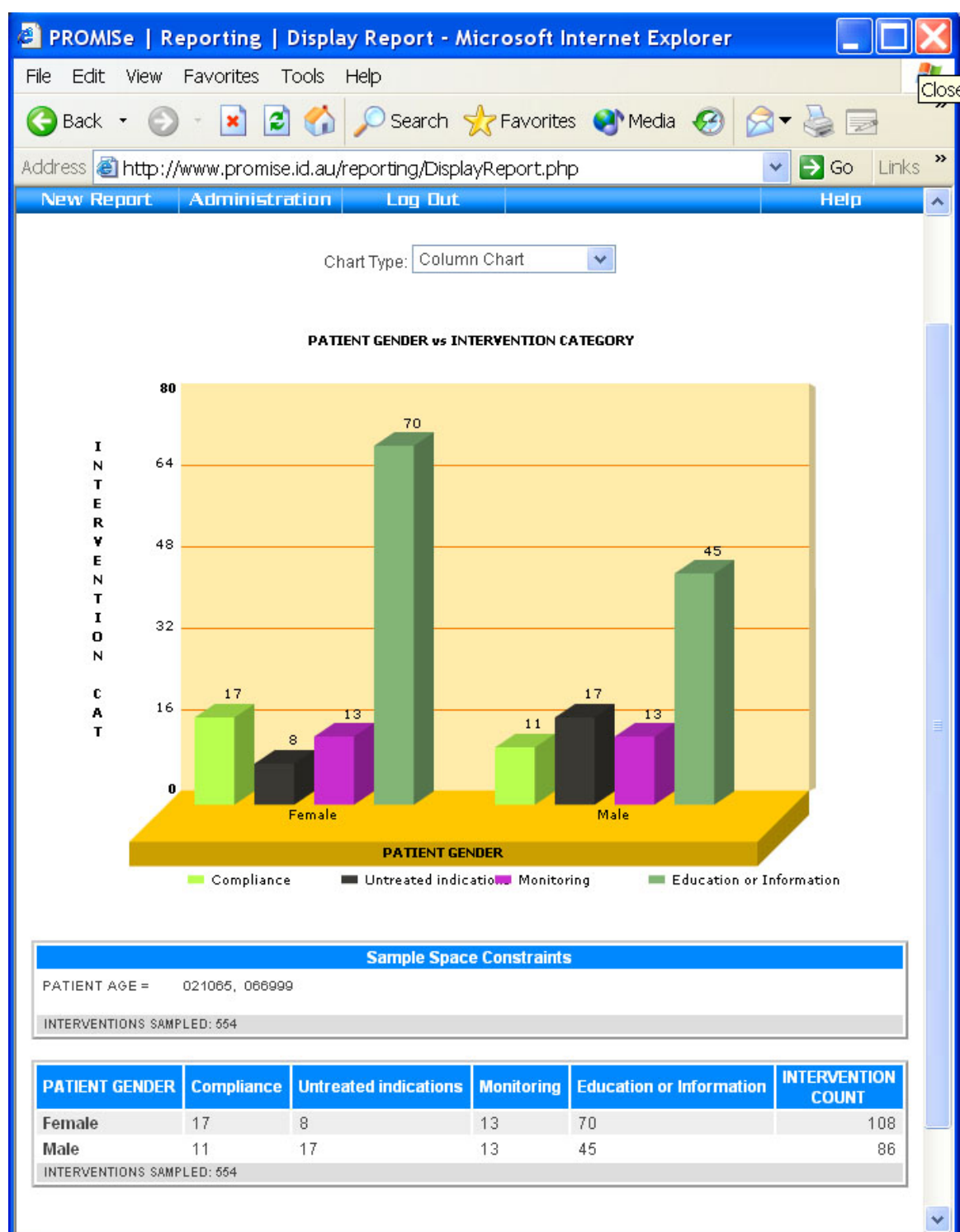
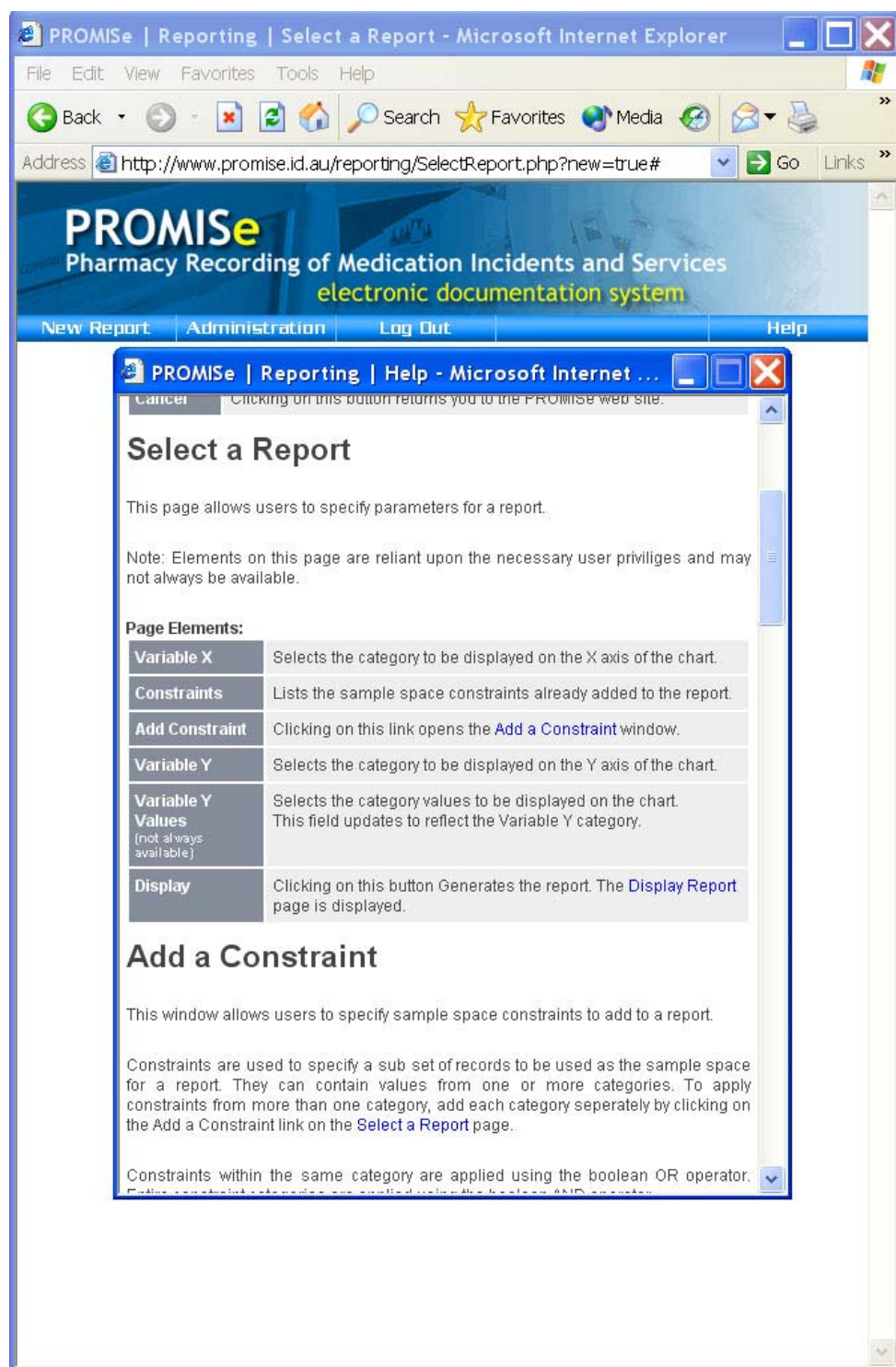


Figure 9-13 Two Way Report Generated from PROMISE reporting Module

An on-line help screen is available to assist new users in generating reports.



**Figure 9-14 Help Screen for PROMISE Reporting Module**

The Web Reporting Interface is fully operational, as indicated in the previous pages. However we expect user feedback to lead to changes and additions. This ongoing development is catered for by the modular architecture of the site.

## **10 Software Interface Development**

Having established a classification system, the user interface was developed. The classification aspects of the intervention are only a part of the required information.

In order to make the information useful for the Pharmacy Guild of Australia, a number of critical fields required collection. Previous research identified that each of the following data fields are related to one or more of the clinical activity type, actions and recommendations that occur or clinical significance of the activity.

### ***10.1 Information for each Clinical Activity***

#### **10.1.1 Patient demographics**

##### **Age**

The age group of the patient has an impact on the clinical significance of the activity. The specific age was not critical, but whether the patient is a baby, child, teenager, adult or elderly was relevant to the potential outcomes and severity of certain clinical activities.

##### **Gender**

The gender of the person also has an impact on the types of activities that occur, with females being predictably more sensitive to many adverse effects.

##### **Number of different items for patient in past 6 months**

There is good evidence that the rate of clinical services is related to the number of medications and that those patients with multiple medications have a higher rate of clinical services. The number of different medications prescribed for the patient in the last 6 months provided a measure of the degree of “polypharmacy” in the particular patient. It was also possible to determine the number of prescriptions received by a unique (de-identified) patient, as a more acute indicator of the frequency of attendance and medication requirements.

#### **10.1.2 Items that relate to the clinical activity**

Below is an outline of the reasoning behind the different categorisation items to be collected for each activity.

##### **10.1.2.1 Type of Intervention**

This aspect of the activity codes the nature of the problem or potential problem. Drug related problems fall into many categories, and within each category there are many possible subcategories. In the D.O.C.U.M.E.N.T. system, there are eight major types of activities recordable, with each category having three to five subcategories. Activities which do not fit into particular subcategories are coded at the main category level and details are specified.

The reasons for collecting the type of activity are manifold.

- The frequency of each type of activity will provide information on the pattern of activities undertaken in community pharmacies.
- The type of each activity is likely to be related to other aspects such as clinical significance. When such relationships are clarified, this will enable targeting of particular activities that are more likely to result in more significant outcomes.



- The type of activity will likely be related to the particular actions taken by the pharmacist to investigate the activity (i.e. the actions). As the actions are the main area of the clinical activity where time is spent by the pharmacist researching the potential problem, then this will be the area where the greatest “expense” occurs in terms of pharmacist time. Being able to relate the type to the most likely duration of time required to sort out the problem, may lead to a remuneration model for different types of activities.
- The recommendations made by the pharmacist will also be likely to be related to the types. Recommendations and their acceptance or not (outcome) will have major impact on the economic impact of the activity.
- Type of activity will also likely be related to various aspects of the pharmacy, in terms of the socio-economic background of the customers, pharmacy type (chain vs. privately owned) and also aspect of the pharmacist’s background.

#### **10.1.2.2 Actions taken**

The actions associated with the activity are actions that the pharmacist takes in order to clarify or investigate the potential problem. The actions include various types of investigation, written references, software and different types of contact with either the patient or the prescriber. The different actions will be used in determining the overall economic benefit of the activities.

#### **10.1.2.3 Recommendations made**

The recommendations are relevant to the type of activity and impact upon the economic aspects of the activity. Recommendations are made to the patient, the doctor or both. The nature of the recommendation were be reviewed by a clinical panel in order to ascertain the “quality” of the clinical activity by assessing the appropriateness of the recommendation. Accuracy in this process was increased by recording pertinent patient details.

#### **10.1.2.4 Outcome**

The recording interface included an overall outcome statement relating to the acceptance or otherwise of the recommendation(s) made. In future versions, it may be possible to determine the outcome for each recommendation. Whether the recommendation was accepted will have direct implications for the economic impact of the activity.

#### **10.1.2.5 Clinical Significance**

The clinical significance of the activity was critical to the economic analysis of the activity. The system has five levels of significance from the highest (potentially life saving) to nil significance. It was important for the trial phase that all true high level significance activities be captured and reviewed. Extra information was recorded for activities that were rated as either of the two top levels of significance. The clinical significance the each activity was correlated with all other characteristics of the activity in order to determine any relationships.

#### **10.1.2.6 Other areas which relate to recording clinical activities**

##### **Time**

The pharmacists were asked to provide an estimate of the time involved in the clinical activity. During the pilot studies, each action was accurately timed by the observers. The average time for each of the actions may be incorporated into future versions of the software.

##### **Date/time of intervention**

The actual day and time of the intervention was relevant as it was subsequently related to workload statistics for the pharmacies. It was also relevant to determine the “busy times” for interventions and may inform proposals about the optimum workload in order to optimise clinical service rates.

##### **Drug involved (and Code)**

The actual drug involved and a unique code was required. The drug code was linkable to the World Health Organisation drug codes ([www.whocc.no](http://www.whocc.no)). The final clinical services database was proposed to be a resource that enabled reports on individual drugs and drug groups could be prepared.

##### **Pharmacist unique identifier**

In multiple pharmacist pharmacies, determining which pharmacist was responsible for the activity was relevant. In the pilot studies, various aspects of the pharmacist’s training, education and employment background was related to the clinical activity nature and rate.

##### **Pharmacy unique identifier (includes postcode)**

The pharmacy unique identifier was required as future remuneration models will need to be linked to the pharmacy details. It may also be possible to link to other demographic information in the health area by using postcode or other means.

##### **Number of Prescriptions from pharmacy per day/month**

The denominator for all clinical activities will be the number of prescriptions. This will be an estimate of the workload in the pharmacy. A rate of clinical activities (per 100 prescriptions) will be one of the fundamental indicators for the performance of the pharmacy. The number of prescriptions will also be required in order to extrapolate the findings of the study to the overall Australian situation.

##### **Prescription type (repeat, original etc)**

There is evidence that the rate of clinical services is higher in original compared to repeat prescriptions. This should be confirmed in these pilot studies. Once confirmed, this may again be used as a factor in preparing a remuneration model.

#### **10.1.3 Interface Workflow**

There is a logical sequence of events in clarifying and addressing issues related to a clinical activity. The sequence is discussed previously and consists of a series of questions relating to the problem and its resolution.

- a) Initially you decide what **type** of problem or issue you are dealing with
- b) Then you make some investigation or queries to determine if the problem exists (**action**)
- c) Then you make a **recommendation** to resolve the issue

d) The recommendation is either accepted or not (**outcome**)

e) Then you consider the potential severity of the situation (**significance**)

These parts of the Categorisation systems are closely linked to the questions as outlined in Figure 10-1 below.

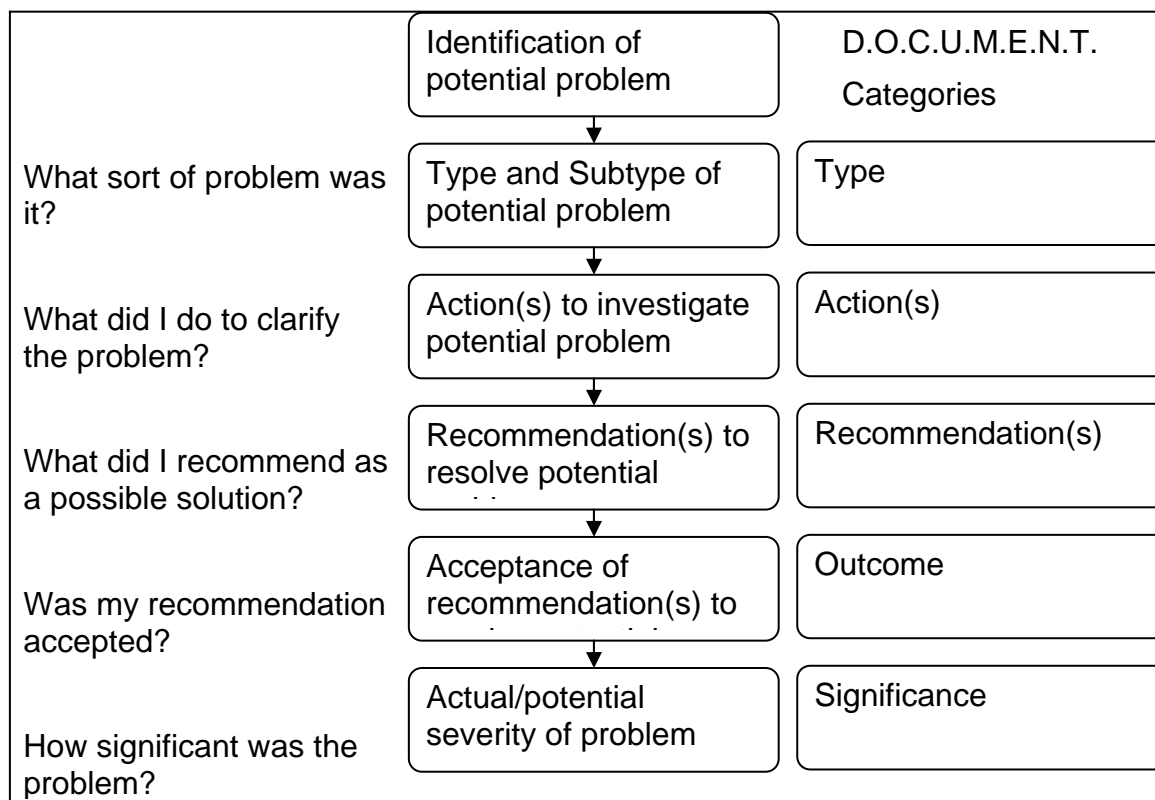


Figure 10-1: Relationship of categorisation system to D.O.C.U.M.E.N.T. Classification system

The user interface has been developed to follow this logical sequence. Initial entry relates to demographic aspects of the patient, followed by the stepwise classification of the event as outlined above. Additional fields for clarifying notes and other information are included.

## 10.2 Development of the Functional Specifications of the PROMISe Project

The information in the sections above was used to develop a comprehensive set of functional specifications for the project. These, in turn, were used to develop the software interface for both dispensing program platforms.

The full specifications are included in Appendix 13.11.

## 10.3 Sample screenshots of the Rex Interface

### 10.3.1 Initial Intervention Screen

Figure 10-2 Initial intervention screen

In this screen the information on the left hand side of the screen was automatically imported from the dispensing system when the intervention was related to a prescription. If the clinical activity was not related to a the prescription, the information could be manually entered.

Patient demographics were located in the top left hand corner. These remain visible to the pharmacist entering the clinical activity.

A traffic light system was set up to track completion of each stage of the recording process.

10.3.2 Commenced Intervention Screen

### Intervention Details

- Rx Number: 1-149145
- Patient: Mr Barry Bruce
- Age Group: 21-65 years old (adult)
- Prescriber: SMITH J.W.
- Drug: TRAMAL CAPS 50mg
- Med Count: 2

- Category
- Sub-Category
- Action
- Recommendation
- Outcome
- Significance
- Notes
- Time Taken

Rx Number: 1-149145

Rx Form Type: Original Rx

Patient Name: Mr Barry Bruce

Date of Birth:  ♂

Prescriber Name: SMITH J.W.

Prescriber Number: 0852012

Drug: TRAMAL CAPS 50mg

Medication Count: 2

Age Group:

A 0-2 years old (baby/toddler)

B 3-12 years old (child)

C 13-20 years old (teenager)

D 21-65 years old (adult)

E over 65 years old (elderly)

Patient AND SCRIPT

Category SUB CATEGORY

Action SELECT

Recommendation SELECT

Outcome

Significance

Notes AND TIME

Summary

SAVE

Back

Figure 10-3 Initial interface cont

Figure 10-3 displays the process described above



### 10.3.3 Category Screen

On this screen the main category or type of clinical activity was determined, with the subtype. Help screens were available for each of the codes, and these could be enlarged for easy viewing.

**Intervention Details**

Rx Number: 1.149145  
 Patient: Mr Barry Bruce  
 Age Group: 21-65 years old (adult) Sex: ♂  
 Prescriber: SMITH J.W. 0662012  
 Drug: TRAMAL CAPS 50mg  
 Med Count: 2

Category: Over or underdose Prescribed  
 Sub Category:  
 Action:  
 Recommendation:  
 Outcome:  
 Significance:  
 Notes:  
 Time Taken:

**F2 Intervention Category:**  
 D Drug selection  
 O Over or underdose Prescribed  
 C Compliance  
 U Untreated indications  
 M Monitoring  
 E Education or Information  
 N Non-clinical  
 T Toxicity or Adverse reaction

**a Intervention Sub Category:**  
 A Dose too high  
 B Dose too low  
 C Wrong frequency  
 D Other Dose Problem (Specify)

**z Category - Notes:**  
 (Empty text area)

**x Sub Category - Help Information:**  
 (Empty text area)  
 Click for larger view and more info...

**Patient AND SCRIPT**  
**Category SUB CATEGORY**  
**Action SELECT**  
**Recommendation SELECT**  
**Outcome**  
**Significance**  
**Notes AND TIME**  
**Summary**  
**SAVE** **Back**  
 F11 Escape

Figure 10-4 Initial interface cont

### 10.3.4 Action Screen

In the screen below, each of the actions which relate to the clinical activity were selected. Multiple actions are possible for each clinical activity, the selection process allowed for these multiple selections to be made.

The screenshot displays the 'Action recording interface' with the following components:

- Intervention Details (Top Left):**
  - Rx Number: [Blank]
  - Patient: **Barry Bruce**
  - Age Group: **21-65 years old (adult)**
  - Sex: ☐ Male ☒ Female
  - Prescriber: **JW Smith**
  - Drug: **Tramadol 100mg SR**
  - Med Count: **2**
- Category/Status (Top Right):**
  - Category: **Over or underdose Prescribed**
  - Sub Category: **Dose too high**
  - Action: **3 Actions Selected**
  - Recommendation: **1 Recommendations Selected**
  - Outcome: **Accepted**
  - Significance: **Moderate (GP visit required/prevented)**
  - Notes: [Blank]
  - Time Taken: [Blank]
- Actions List (Middle Left):**
  - Actions:**
    - A Investigation: Written material
    - B Investigation: Software
    - C Investigation: Internet
    - D Contacted Drug Information Service
    - E Investigation: Other (specify)
    - F Contacted prescriber
    - G Discussion with patient or carer
    - H Corrected without discussion
    - I Other Action (specify)
- Action Controls (Middle):**
  - Add ITEM** (Green button)
  - Remove ITEM** (Yellow button)
  - Remove ALL** (Yellow button)
- Selected Actions (Middle Right):**
  - Selected Actions:**
    - A Investigation: Software
    - B Contacted prescriber
    - C Discussion with patient or carer
- Action - Help Information (Bottom Left):**
  - Action - Help Information:**
  - Click for larger view and more info...
- Action - Notes (Bottom Right):**
  - Action - Notes:**
- Navigation Bar (Far Right):**
  - Patient AND SCRIPT** (F1)
  - Category SUB CATEGORY** (F2)
  - Action SELECT** (F3)
  - Recommendation SELECT** (F4)
  - Outcome** (F5)
  - Significance** (F6)
  - Notes AND TIME** (F7)
  - Summary** (F8)
  - SAVE** (F11)
  - Back** (Escape)

Figure 10-5 Action recording interface

### 10.3.5 Recommendation and Outcome Screen

Although multiple recommendations are possible, it was not possible to select the same recommendation more than once.

The outcome of the recommendation was included on the same screen and related to a composite outcome for all of the recommendations made.

The screenshot displays the 'Intervention Details' screen for a patient named Barry Bruce. The interface is divided into several sections:

- Intervention Details (Top Left):**
  - GP Number: [Redacted]
  - Patient: Barry Bruce
  - Age Group: 21-65 years old (adult)
  - Sex: [Redacted]
  - Prescriber: JN Smith
  - Drug: Tramadol 100mg SR
  - Med Count: 2
- Category and Summary (Top Right):**
  - Category: Over or underdose Prescribed
  - Sub Category: Dose too high
  - Action: 3 Actions Selected
  - Recommendation: 1 Recommendations Selected
  - Outcome: Accepted
  - Significance: Moderate (GP visit required/prevented)
  - Notes: [Redacted]
  - Time Taken: [Redacted]
- Recommendations (Middle Left):**
  - A Education/counselling session
  - B No recommendation necessary
  - C Dose change
  - D Drug change
  - E Drug cessation
  - F Drug formulation change
  - G Monitoring: non-laboratory
  - H Drug addition
  - I Drug brand change
  - J Dose frequency/schedule change
  - More...
- Selected Recommendations (Middle Right):**
  - A Dose change
- Recommendation - Help Information (Bottom Left):**
  - Click for larger view and more info...
- Recommendation - Notes (Bottom Right):**
  - Outcome: [Redacted]
  - Unknown Accepted Partially Accepted Not Accepted
- Right Side Navigation (Vertical Strip):**
  - Patient AND SCRIPT
  - Category SUB CATEGORY
  - Action SELECT
  - Recommendation SELECT
  - Outcome
  - Significance
  - Notes AND TIME
  - Summary
  - SAVE
  - Back

Figure 10-6 Recommendation recording interface



### 10.3.6 Significance Screen

The clinical significance screen, allows the selection for the appropriate level of clinical significance for the clinical activity. Activities that were rated as moderate or high, required additional information to be collected to enable examination by the external clinical panel. On the interface, a reminder of the importance of this additional information was presented when either moderate or high clinical significance were selected.

**Intervention Details**

☐ Rx Number:   
☒ Patient: Barry Bruce   
☒ Age Group: 21-45 years old (adult) ☐ Sex: ☒ Male ☐ Female   
☒ Prescriber: JAV Smiths   
☒ Drug: Tramadol 100mg SR   
☒ Med Count: 2

☒ Category: Over or underdose Prescribed   
☒ Sub Category: Dose too high   
☒ Action: 3 Actions Selected   
☒ Recommendation: 1 Recommendations Selected   
☒ Outcome: Accepted   
☒ Significance: Moderate (GP visit required/prevented)   
☐ Notes:   
☐ Time Taken:

**Significance:**

☐ A Nil   
☐ B Low (Cost saving or Information provided)   
☐ C Mild (Mild symptoms developed/prevented)   
☒ D Moderate (GP visit required/prevented)   
☐ E High (Hospital visit required/prevented)

**Relevant Current Medications:**

Tramal 50mg

**Relevant Medical Conditions:**

**Any other clarifying notes:**

Total dose prescribed the is a danger of accumulation of a toxic metabolite

**Significance - Help Information:**

**When to Use:**  
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.

**Examples:**  
Click for larger view and more info...

**This is a potentially important intervention. Please ensure relevant information is provided in the appropriate text boxes above.**

Figure 10-7 Significance recording interface

10.3.7      **Notes and Time Screen**

Any additional clarifying notes and the total estimated time for the clinical activity were recorded.

**Intervention Details**

Rx Number:   
 Patient: Barry Bruce   
 Age Group: 21-65 years old (adult)   
 Sex: Male   
 Prescriber: Amy Smith   
 Drug: Tramadol 100mg SR   
 Med Count: 2

Category: Over or underdose Prescribed   
 Sub Category: Dose too high   
 Action: 2 Actions Selected   
 Recommendation: 1 Recommendations Selected   
 Outcome: Accepted   
 Significance: Moderate (OP visit required/prevented)   
 Notes:   
 Time Taken:

**Intervention Notes:**

Total Time Taken: (mins)

Patient AND SCRIPT   
 Category SUB CATEGORY   
 Action SELECT   
 Recommendation SELECT   
 Outcome   
 Significance   
 Notes AND TIME   
 Summary   
 SAVE Back

Figure 10-8 Notes section

### 10.3.8 Summary Screen

In the final summary screen, a summary of all information was shown to the user prior to submission to the PROMISe repository. Any items that have not been entered are highlighted in red.

The screenshot displays the 'Intervention Summary' screen from the PROMISe interface. The header includes 'TASMANIAN SCHOOL OF PHARMACY', 'Intervention Summary', and a date '10:57 - 20 Apr 2004'. The 'Patient and Script' section contains fields for Rx Number, Patient (Barry Brown), Age Group (21-65 years old (adult)), Sex (Male), Prescriber (Jill Smith), Drug (Tylenol 100mg SR), and Med Count (2). The 'Category' section shows Category (Over or under dose Prescribed), Sub Category (Dose too high), and Category Notes. The 'Actions' section lists Selected Actions (Investigation: Software, Confirmed problem, Consultation with patient or carer) and Action Notes. The 'Recommendations' section shows Selected Recommendations (Dose change). A 'Page 1 of 2' indicator is at the bottom left. On the right, a vertical toolbar contains buttons for 'Next PAGE', 'Previous PAGE', 'First PAGE', 'Last PAGE', 'ZOOM IN', 'ZOOM OUT', 'Submit AND SAVE', 'PRINT', 'Patient AND SCRIPT', 'Category SUB CATEGORY', 'Action SELECT', 'Recommendation SELECT', 'Outcome', 'Significance', 'Notes AND TIME', 'Summary', 'SAVE', and 'Back'.

Figure 10-9 Summary of documentation

Iterations of the Rex interface were reviewed and tested before the interface to be used in the Pilot Studies was finalised.

## 10.4 Sample Screenshots from the WiniFRED Interface

On the below screen the main category or type of clinical activity was determined, with the subtype. Help screens were available for each of the codes, and these could be enlarged for easy viewing.

Subsequent screens use the same functionality as the Rex interface described earlier.

**WiniFred Dispense**

**Interventions**

Patient: **MR KEITH GORDIJN** Gender: **Male** Birthdate: **14/07/1963** Age Group: **21-65 years old (adult)**

Script No: **259534** Script Type: **Original** Drug: **AMOXIL CAP 250mg** 1884E -GK

Prescriber: **SHUMACK, K** Prescriber No: **799893** Pharmacist Initials: **TL** Med Count: **12**

**1. Categories** **2. Actions** **3. Recommendations & Outcomes** **4. Significance** **5. Notes**

Intervention category

- D Drug selection**
- O Over or underdose prescribed
- C Compliance
- U Untreated indications
- M Monitoring
- E Education or information
- N Non-clinical
- T Toxicity or adverse reaction

Intervention sub-category

- A Duplication**
- B Drug interaction**
- C Wrong drug
- D Wrong dosage form
- E Previous ADR/allergy
- F Other drug selection problem (specify)

Category Notes

**Edit Intervention** **Help** **Summary** **Delete** **Edit Draft** **Save Draft** **Save** **Cancel**

Press <Enter> to Continue or  
Use Cursor Keys to Select an Item then Press <F4> to Edit or <F11> to Re-Dispense Item

**OVR** **20/07/04** **13:13**

Figure 10-10: Winifred PROMISE Interface, Screen One

## PROMISE Phase One Preliminary Final Report

**WiniFred Dispense**

**Interventions**

Patient: **MR KEITH GORDIJN** Gender: **Male** Birthdate: **14/07/1963** Age Group: **21-65 years old (adult)**

Script No: **259534** Script Type: **Original** Drug: **AMOXIL CAP 250mg** 1884E -GK

Prescriber: **SHUMACK, K** Prescriber No: **799893** Pharmacist Initials: **TL** Med Count: **12**

**1. Categories** **2. Actions** **3. Recommendations & Outcomes** **4. Significance** **5. Notes**

Actions

- A Investigation: written material
- B Investigation: software
- C Investigation: internet
- D Contacted drug information service
- E Investigation: other (specify)
- F Contacted prescriber
- G Discussion with patient or carer
- H Corrected without discussion
- I Other action (specify)

Selected Actions

- A Investigation: written material

Action notes

**Edit Intervention** **Help** **Summary** **Delete** **Edit Draft** **Save Draft** **Save** **Cancel**

Press <Enter> to Continue or  
Use Cursor Keys to Select an Item then Press <F4> to Edit or <F11> to Re-Dispense Item

**OVR** **20/07/04** **13:14**

Figure 10-11: WiniFRED PROMISE Interface, Screen Two



## PROMISE Phase One Preliminary Final Report

**WiniFred Dispense**

**Interventions**

Patient: **MR KEITH GORDIJN** Gender: Birthdate: Age Group:

Script No: **259534** Script Type: **Original** Dr. **AI**

Prescriber: **SHUMACK, K**

**1. Categories** **2. Actions**

**Actions**

- A Investigation: written mate
- B Investigation: software
- C Investigation: internet**
- D Contacted drug informatio
- E Investigation: other (speci
- F Contacted prescriber
- G Discussion with patient or
- H Corrected without discuss
- I Other action (specify)

Action notes

**Edit Intervention**

**Help**

**Actions to Investigate the Problem**

**Action:** *Investigation: Internet*

**When to Use:**  
When the pharmacist consults decision support software that is located on the internet.

**Examples of when to use**

- Pharmacist conducts a PubMed search
- Pharmacist is a subscriber to an internet based set of resources such as Medscape, or a Uni

**When Not to Use:**  
If the information source is not from the internet, then use another investigation source (either A1 A4 or A5).  
If the internet is used to make email contact with another healthcare professional for assistance, use "Investigation: Other (A5)".  
If the internet is used to make email contact with the National Prescribing Service or other State National information support service, then use "Contacted State or National Drug information sen (A4)".

Print Close wi

Press <Enter> to Continue or  
Use Cursor Keys to Select an Item then Press <F4> to Edit or <F11> to Re-Dispense Item

OVR 20/07/04 13:15

Figure 10-12: WiniFRED PROMISE Interface, Screen Three

## PROMISE Phase One Preliminary Final Report

**WiniFred Dispense**

**Interventions**

Patient: **MR KEITH GORDIJN** Gender: **Male** Birthdate: **14/07/1963** Age Group: **21-65 years old (adult)**

Script No: **259534** Script Type: **Original** Drug: **AMOXIL CAP 250mg** 1884E -GK

Prescriber: **SHUMACK, K** Prescriber No: **799893** Pharmacist Initials: **TL** Med Count: **12**

**1. Categories** **2. Actions** **3. Recommendations & Outcomes** **4. Significance** **5. Notes**

Recommendations

- A Education/counselling session
- B Dosage change
- C Drug change
- D Drug cessation
- E Drug formulation change
- F Monitoring: non-laboratory
- G Drug addition
- H Drug brand change
- I Dose frequency/schedule change

Selected Recommendations

- A Education/counselling session

Recommendation notes

Outcome

☒ Unknown ☐ Partially accepted

☐ Accepted ☐ Not accepted

**Edit Intervention** **Help** **Summary** **Delete** **Edit Draft** **Save Draft** **Save** **Cancel**

Press <Enter> to Continue or  
Use Cursor Keys to Select an Item then Press <F4> to Edit or <F11> to Re-Dispense Item

**OVR** **20/07/04** **13:14**

Figure 10-13: WiniFRED PROMISE Interface, Screen Four

# PROMISE Phase One Preliminary Final Report

**WiniFred Dispense**

**Interventions**

Patient: **MR KEITH GORDIJN** Gender: **Male** Birthdate: **14/07/1963** Age Group: **21-65 years old (adult)**

Script No: **259534** Script Type: **Original** Drug: **AMOXIL CAP 250mg** 1884E -GK

Prescriber: **SHUMACK, K** Prescriber No: **799893** Pharmacist Initials: **TL** Med Count: **12**

**1. Categories** **2. Actions** **3. Recommendations & Outcomes** **4. Significance** **5. Notes**

Significance

A Nil

B Low

C Mild

**D Moderate**

E High

**Required or potentially prevented GP visit**

**This is a potentially important intervention.**

Please ensure relevant information is provided in the appropriate textboxes above.

Relevant current medications

Current medical conditions

Any other clarifying notes

**Edit Intervention** **Help** **Summary** **Delete** **Edit Draft** **Save Draft** **Save** **Cancel**

Press <Enter> to Continue or  
Use Cursor Keys to Select an Item then Press <F4> to Edit or <F11> to Re-Dispense Item

**OVR** **20/07/04** **13:14**

Figure 10-14: WiniFRED PROMISE Interface, Screen Five



PROMISE Phase One Preliminary Final Report

WiniFred Dispense

WiniFred Dispense Interventions Records Help About Help

Interventions

Patient:MR KEITH GORDIJNGender:MaleBirthdate:14/07/1963Age Group:21-65 years old (adult)

Script No:259534Script Type:OriginalDrug:AMOXIL CAP 250mg1884E -GK

Prescriber:SHUMACK, KPrescriber No:799893Pharmacist Initials:TLMed Count:12

1. Categories

2. Actions

3. Recommendations & Outcomes

4. Significance

5. Notes

Intervention notes

This is line one.  
This is line two.

Time taken in minutes:2

2 min

4 min

6 min

8 min

10 min

15 min

20 min

30 min

Edit Intervention

Help

Summary

Delete

Edit Draft

Save Draft

Save

Cancel

Press <Enter> to Continue or  
Use Cursor Keys to Select an Item then Press <F4> to Edit or <F11> to Re-Dispense Item

OVR

20/07/04

13:14

Figure 10-15: WiniFRED PROMISE Interface, Screen Six

**VPE Report**

**Detailed Report of Interventions**

Generated on: 20 July 2004

**Filter Conditions**

**Patient:** Mr Keith Gordijn  
**Date:** From 01/01/2004 To: 20/07/2004

---

**Patient:** Mr Keith Gordijn **Gender:** Male  
**Age Group:** 21-65 years old (adult)

---

**Intervention ID:** 10 **Date:** 20/07/2004 01:15:53 PM **Time taken:** 2  
**Rx Number:** 259534 **Rx Form Type:** Original **Med Count:** 12  
**Drug:** Amoxil Cap 250mg  
**Prescriber:** K Shumack 799893  
**Category:** Drugselection  
**Sub Category:** Druginteraction  
**Selected Actions:** Investigation: written material  
**Recommendations:** Education/counselling session  
**Outcome:** Unknown  
**Significance:** Low - Cost saving to patient or information only  
**Intervention Notes:**  
 This is line one.

x 0.9 1 / 1 Ready

Figure 10-16: WiniFRED PROMISe Interface, Screen Seven

## 11 Conclusions

The primary aim of this project; the development of a system for the electronic recording of medication incidents in community pharmacy has been fulfilled. The project has also established a number of unique techniques and assessment tools. The recording system was piloted in both Rex and WiniFRED users in Tasmania and Victoria. The system built had the capacity to transfer the information from a variety of community pharmacy sites to the data repository. Economic and statistical data analysis techniques were developed these have the potential to be applied to a larger data set.

The DOCUMENT classification system was developed after review of current classification systems with consideration of the requirements for documentation in community pharmacy. The system has been applied to around 1000 community pharmacy interventions. The areas considered and recorded were the type of intervention, the action taken by the pharmacist, the recommendation made to resolve the issue, the clinical significance and the acceptance of the pharmacist's recommendations.

Validation of the DOCUMENT system was carried out on-line by 150 pharmacists. This process has developed into a training tool for participants in the PROMISe study. Instant feedback was developed for the participants to ensure accurate classification.

The PROMISe server received the HL7 compliant messages and allowed reports to be generated from the de-identified information. It was set-up with different levels of access from which reports can be generated with different level of specificity. There is potential for this to provide a range of information from individual pharmacist feedback to national reports on intervention trends.

The interface for the recording system was successfully incorporated into the existing dispensing software for WiniFRED and Rex Users. The interface was designed to allow the efficient entry of data relating to the intervention. Feedback from the community pharmacists who used the interface was encouraging. They were able to suggest ways in which the interface could be further enhanced and these changes will be reflected in the second phase of the project.

Clinical significance of the intervention was assessed by the pharmacist recording the intervention. A review of the assessment was made by a clinical panel. The key areas assessed were that of pharmacist attributability and the probability of the event occurring. The clinical panel was set up with a web-based polling tool. There is potential for this tool to be further utilised. The members of the clinical panel assessed the probability of certain events occurring as a result of this intervention hence reflecting the complete clinical picture of the intervention.

A number of potential uses for the information gathered were developed. These included

- Intervention linked to pharmacist, pharmacy and prescription data
- Evaluation of pharmacy characteristics
- Factors influencing frequency and type of intervention
- Educational aspects of interventions

Each of these aspects developed techniques to be incorporated and further explored by application to a larger data set gathered in subsequent testing.

Proactive or discretionary interventions were compared to reactive interventions in the preliminary data gathered from the pilot study. The inclusion of a clinical observer was seen to increase the level of proactive intervention. Data from the pilot study was indicative of trends which will be further explored. The observer had a number of roles in the pilot study pharmacy, including encouraging recording of interventions and accurate timing of events related to the intervention.

The readily expandable and flexible system developed, which incorporated unique assessment techniques, has undergone testing in community pharmacy. Further expansion will provide further insight into the factors associated with increasing the rate of interventions and thereby increasing health and economic benefits.

## 12 Recommendations

### 12.1.1 Modifications to DOCUMENT

A post pilot review of the usage of the DOCUMENT system was completed. The usage of each category and sub-category was assessed. This led to changes in certain sub-categories; in particular the usage of the 'other' subcategory was clarified. A summary of the changes can be seen in Figure 12-1 with the full expansion of the categories with scope notes in Appendix. 13.14

#### **D**rug selection

*(Problems related to the choice of drug prescribed or taken)*

- Duplication (D1)
- Drug interaction (D2)
- Wrong drug (D3)
- Wrong dosage form (D4)
- Other drug selection problem (D0)

#### **O**ver or underdose prescribed

*(Problems related to the prescribed dose or schedule of the drug)*

- Dose too high (O1)
- Dose too low (O2)
- Other Dose Problem (O0)

#### **C**ompliance

*(Problems related to the way the patient takes the medication)*

- Taking too little (C1)
- Taking too much (C2)
- Intentional drug misuse (C3)
- Difficulty using dosage form (C4)
- Other Compliance Problem (C0)

#### **U**ntreated indications

*(Problems relating to actual or potential conditions that require management)*

- Condition not adequately treated (U1)
- Preventive therapy required (U2)
- Other Untreated indication Problem (U0)

#### **M**onitoring

*(Problems related to monitoring the efficacy or adverse effects of a drug)*

- Laboratory Monitoring (M2)
- Non-Laboratory monitoring (M3)
- Other Monitoring Problem (M0)

## **E**ducation or Information

*(Problems related to knowledge of the disease or its management)*

- Patient drug information request (E1)
- Confusion about therapy (E2)
- Demonstration of device (E3)
- Disease management or advice (E4)
- Other Education or Information Problem (E0)

## **N**on-clinical

*(Problems related to administrative aspects of the prescription)*

## **T**oxicity or Adverse reaction

*(Problems related to the presence of signs or symptoms which are suspected to be related to an adverse effect of the drug)* Dose related (T1)

- Toxicity/ Adverse reaction evident (T2)
- Caused by drug interaction (T3)
- Other Toxicity/Adverse Effect problem (T0)

**Figure 12-1 DOCUMENT categories and subcategories**

The usage of the action and recommendation fields was assessed. This led to some alterations to this area see Figure 12-2

### **Actions to Investigate the Problem**

*What did the pharmacist do in order to sort out the problem?*

- Investigate, Written material (A1)
- Investigation: Software (A2)
- Investigation: Patient History (A3)
- Investigation: Other (A4)
- Contacted prescriber (A5)
- Discussion with patient or carer (A6)
- Corrected without discussion (A7)

### **Recommendations to Resolve the Problem**

*What did the pharmacist recommend as a solution to the problem?*

#### **A Change in Therapy**

- Dose change (R1)
- Drug change (R2)
- Drug formulation change (R3)
- Drug brand change (R4)
- Dose frequency/schedule change (R5)

<p>Prescription not dispensed (R6)</p> <p>Other changes to therapy (R7)</p> <p><b>A referral required</b></p> <p>Refer to prescriber (R8)</p> <p>Refer to hospital (R9)</p> <p>Refer for medication review (R10)</p> <p>Other referral required (R11)</p> <p><b>Provision of information</b></p> <p>Education/counselling session (R12)</p> <p>Written summary of medications (R13)</p> <p>Commence dose administration aid (R14)</p> <p>Other written information (R15)</p> <p><b>Monitor</b></p> <p>Monitoring: non-laboratory (R16)</p> <p>Monitoring: Laboratory test (R17)</p> <p><b>No recommendation necessary (R18)</b></p>
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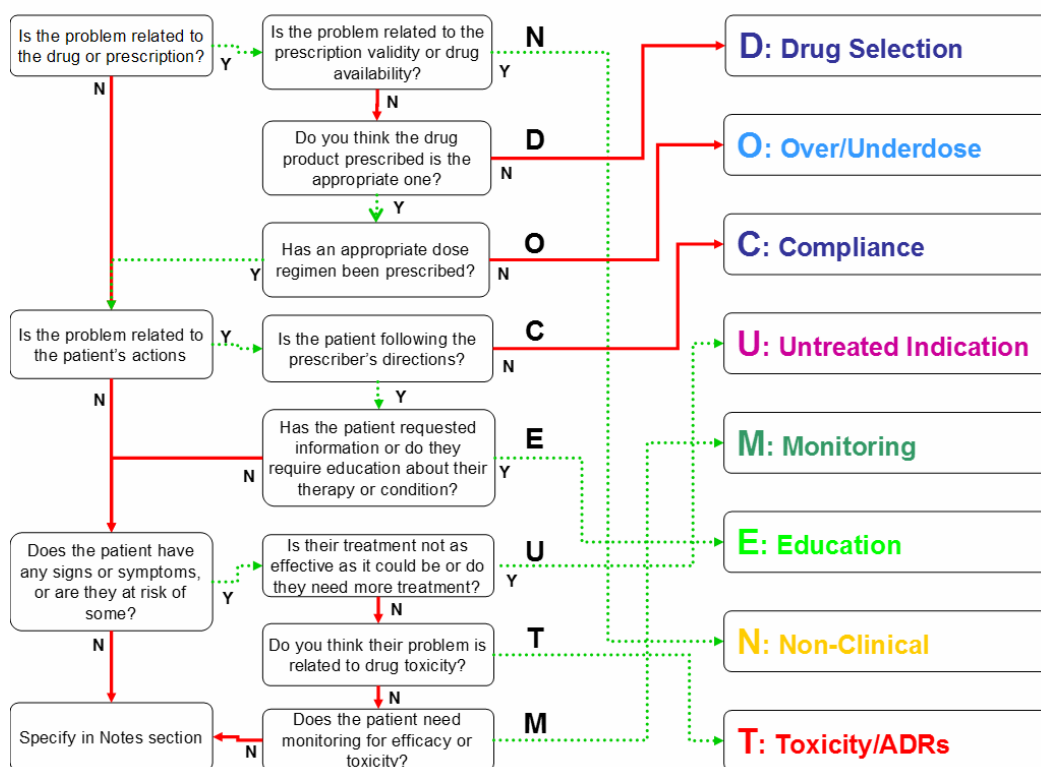
**Figure 12-2** Action and recommendations for recording interventions

### **12.1.2 Refine clinical panel process**

The clinical panel was set up to review the clinical significance of interventions from the pilot study. Feedback from the members of this group was promising and the technique will be further explored in the next phase of this project. There was concern about the amount of information recorded by the pharmacist, particularly for interventions considered to be of high or moderate clinical significance. These issues will be re-enforced in the training of the participants in the next phase of the project as well as appropriate changes to the interface. The aim is to ensure a balance between the information required by the clinical panel and the time taken for the pharmacist to enter the information.

### **12.1.3 Reduce mis-classification rate**

The issue of mis-classification was identified in the validation process. A number of strategies have been suggested to assess this within the second phase of the study. Training and usage of the system were suggested as having an influence and these factors will be studied further in the second phase of the study by completion of the validation process before and after the data collection period. Also ongoing feedback has been incorporated in the validation website. This feedback is provided instantly between each scenario it is envisaged that this will lead to greater understanding of the classification system. To assist with primary classification a question-based algorithm was developed, see Figure 12-3, this will be available to those using the classification system.



**Figure 12-3 Algorithm to assist with classification within the DOCUMENT system**

### 12.1.4 Changes to interface

The pilot study participants provided feedback on a number of areas of DOCUMENT. These have been integrated into the classification system and appropriate changes to the interface are being carried out. These changes include clarification of certain areas and the employment of short cut keys for frequent events which were of low clinical significance.

### 12.1.5 Define and collect information on Reactive vs. Proactive interventions

The use of observers will be extended into phase two of the project, it is envisaged that their role will expand and include evaluating whether the intervention was 'proactive' or 'reactive'.

It is proposed that changes are to be made to the repository and messaging functions to allow prescription data to be sent directly to the centralised database. This will be linked to the intervention data and will allow for online reporting with the denominator data taken into consideration. Expansion and refinement of the statistical and economic models relating to the intervention data will also occur. The preliminary data from the pilot study indicated it may be possible to formulate relationships between clinical significance and particular intervention types or recommendations.



## **13 Appendices**

### ***13.1 Appendix One - PROMISe pilot study***

## ***13.2 Appendix Two: PCNE Classification for Drug Related Problems***

***13.3 Appendix Three: The Clinical Pharmacy Activity  
Classification System (CPACS)***

***13.4 Appendix Four: NRLS Community Pharmacy Dataset (MD01-MD04)***

### ***13.5 Appendix Five: NCC MERP Taxonomy for Medication Error***

***13.6 Appendix Six: SHPA Standards of Practice for Clinical Pharmacy***

***13.7 Appendix Seven: PI Doc- Drug Related Problem  
Classification System***



### ***13.8 Appendix Eight: Final DOCUMENT Classification System***

**13.9 Appendix Nine: *DOCUMENT* Classification System Version  
14**

**13.10   *Appendix Ten: Demographics Questionnaire for  
Validation Exercise***

**13.11    *Appendix Eleven: PROMISe Functional Specifications  
Version 0.6***

**13.12 Appendix Twelve: *PROMISe Technical Specifications*  
Version 0.2**

**13.13   *Appendix Thirteen: PROMISe HL7 Formats- Technical Specifications Version 0.8***

**13.14    *Appendix Fourteen; Expanded DOCUMENT with scope notes post pilot review***

## 13.15 References

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