



Dispensing and Monitoring of Schedule 8 and Schedule 4 (with dependency properties) Drugs

**Final Report
November 2006**

Chief Researcher: Chris Lynton-Moll

**This research was funded by the Australian Government Department of
Health and Ageing through the Third Community Pharmacy Agreement
Research and Development Program.**

The program is managed by the Pharmacy Guild of Australia.

Acknowledgements

The Collaborative Centre for eHealth (CCeH), University of Ballarat, acknowledges that this project is funded by the Australian Government Department of Health and Ageing as part of the Third Community Pharmacy Agreement. CCeH also acknowledges the contribution of the Guild as managers of the Third Community Pharmacy Agreement Research and Development Grants (CPA R&D Grants) Program.

The research team for this project consisted of the following people:

Chris Lynton-Moll, Project Manager

Linda Goralski, Project Assistant (Jan-05 – Oct-05)

Susan La Pira, Project Assistant (Oct-05 – Apr-06)

Dr Jack Harvey, Senior Research Fellow

Dr Michelle O'Brien, Researcher (Jan-05 – June-05)

The Steering Committee for this project consisted of the following people:

Chris Lynton-Moll, Project Manager

Linda Goralski, Project Assistant (Jan-05 – Oct-05)

Susan La Pira, Project Assistant (Oct-05 – Apr-06)

Andrew Howard, CEO, Ballarat & District Division of General Practice

Dr. Linda Danvers, Expert General Practitioner – 03 5331 6303

Prof. Greg Peterson, University of Tasmania, Expert Pharmacy Advisor

Colin Dorn, UFS Pharmacy, Expert Pharmacist

Peter Fell, Daylesford Pharmacy, Expert Pharmacist

Denis Leahy, Pharmacy Guild of Australia

Jane Mitchell, Pharmaceutical Society of Australia (Jul-05 – Apr-06)

Dhannu Daniel, Pharmaceutical Society of Australia (Feb-05 – June-05)

Janet Lowe, Consumer Representative

Erica Vowles, Pharmacy Guild of Australia (Dec-05 – Apr-06)

Simone Jones, Pharmacy Guild of Australia (Jul-05 – Nov-05)

Kiah McGregor, Pharmacy Guild of Australia (Feb-05 – Jun-05)

John Primrose, Department of Health and Ageing (Feb-05 – June-05)

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Contact Details

Tenderer Name	University of Ballarat
Australian Business Number	51 818 692 256
Registered for GST	Yes
Trading and Business Names	University of Ballarat
Date and Place of Incorporation	Proclaimed by the State of Victoria under the 'University of Ballarat Act 1993'
Registered Office	University Drive, Mount Helen, Victoria
Principal Place of Business	Mount Helen
Internet Address	www.ballarat.edu.au/cceh
Representative Details	<p>Mr. Chris Lynton-Moll</p> <p>Manager, Collaborative Centre for eHealth</p> <p>University of Ballarat</p> <p>(Postal) PO Box 691, Ballarat Vic 3353</p> <p>(Street) Suite 15, Greenhill Enterprise Centre</p> <p>University Drive, Mount Helen Vic 3350</p> <p>Tel: 03 5327 9302</p> <p>Fax: 03 5327 9307</p> <p>Email: c.lynton-moll@ballarat.edu.au</p>

1. Executive Summary

Illicit diversion and misuse of prescription Schedule 4 and Schedule 8 (S4 and S8) drugs which have dependency properties has been recognised as a significant problem in Australia and overseas. Furthermore the level of prescribing, dispensing and consumption of these drug schedules in Australia is increasing.

The role of the community pharmacist in managing consumers with dependency issues has been expanding. Services provided by pharmacists to assist with this problem include: needle exchange; methadone dispensing; notification of addicts; treatment services such as monitoring and feedback to the prescriber; and advice to consumers.

Another role of the community pharmacist in managing consumers with dependency issues is the practice of dispensing using 'supervised dosing' for drugs other than methadone and buprenorphine.

The Pharmacy Guild of Australia (the Guild), the Australian Government Department of Health and Ageing (DHA) and Collaborative Centre for eHealth (CCeH) have collaborated on a project to develop dispensing protocols for unit dose medication to patients who may be at risk from drugs with dependency properties (Schedule 4 and Schedule 8), and to identify an appropriate level of remuneration for this service. This project trialled and evaluated the role, and cost for the pharmacists within this drug management strategy.

The aim of the project was to develop dispensing and counselling protocols for unit dose medication to patients who may be at risk from drugs with dependency properties (S4 and S8) and to identify an appropriate level of remuneration for this service. The project has developed a best-practice model which was trialled and evaluated in seven community pharmacies.

The project examined the role, effectiveness and the cost for the pharmacist within this drug management strategy. It developed, trialled and evaluated dispensing and counselling protocols, and sought to identify and recommend an appropriate fee structure for unit dose medication to patients who may be at risk from drugs with dependency properties.

1.1 Remuneration

During the project data were collected from the trial pharmacies and information was received from survey and interview of pharmacists involved in the trial and the general population.

The survey-based estimate of the time required and hence the estimated costs are considerably greater than the trial-based estimates. This is in part due to a small number of very high estimates in the survey data. However, this does not completely account for the discrepancy between the survey data and the trial data. In the view of the research team, more credence should be given to the trial data because it is based on the evidence of actual occurrences (albeit recorded only approximately, and recorded in a limited number of pharmacies), whereas the survey-based data consists of generalized estimates which may well be worst-case or high-end estimates.

Thus, a labour remuneration figure of \$2.61 is recommended and a container remuneration figure of \$0.97 is recommended where the re-usable dosette container is paid by the consumer.

1.2 Future Use of the Best Practice Model

The forms used during the trial should to be simplified to make them less research focused and more operationally orientated:

The Consumer Register (RF-02), Prescriber Register (RF-05) and consent forms would not be required.

The Dispensing in Instalments Record Form (RF-03):

- Needs the Consumer Code field deleted and the client name and identifying criteria added to the header so that a single A4 sheet could be used.
- Needs the Prescriber Code field to be deleted and a field for the doctor's name to be added.
- Needs a coded field for the reason for dispensing in instalments to be added although it would not be essential.
- Needs the time taken for the dispensing, instalment and consultations removed as these were placed on the form to enable costs to be calculated.
- The initial dispensing quantity, the instalment quantity supplied and held and the client /pharmacist or technician signatures need to be retained.
- During the trial it was suggested that a single form should be used for each prescription dispensed. This would not be necessary if the data were purely for internal pharmacy use.

The Protocols would also need to be altered to allow for the variations set out above; these would then be distributed across the board to all community pharmacies members in Adobe files to prevent alteration.

These forms and protocols should be incorporated into the dispensing software used by the pharmacies.

Problems appear to be rife regarding communication and expectations between doctors and pharmacists. An educational package for GPs be put together and distributed prior to the rollout of the best-practice model to pharmacies in general.

This educational pack should include legal limitations and requirement for pharmacist regarding S4 and S8 dispensing.

1.3 General comments

Many pharmacists in the general survey highlighted the problems they face dealing with a client who is often confused, abusive and sometimes violent. The research group recommends that a private area for consumer interaction be used. This may not be feasible in many pharmacies; strategies used by some pharmacies was encouragement of the consumer to attend the pharmacy in quiet times and have the script ready to immediately give to the client.

During the study and highlighted in the general survey, pharmacists raised that there may be legal issues regarding the storage and handling of S4 and S8 drugs after initial dispensing. The laws may need to be updated to allow for dispensing in instalments where after initial dispensing drugs are still kept on the pharmacy premises until all instalments are distributed.

1.4 Key findings and Recommendations

It is concluded that there is a clear need to use dispensing and counselling protocols for unit dose medication to patients who may be at risk from drugs with dependency properties (Schedule 4 and Schedule 8) and that this service needs to be appropriately remunerated.

Recommendation 1

Based on the key finding that there is a *need to establish appropriate remuneration for this service as justified by a combination of survey and trial evidence* it is recommended that:

an appropriate remuneration package should consist of a labour figure of \$2.61 per instalment and, a container remuneration figure of \$0.97 per instalment.

Recommendation 2

Based on the key finding that there is a *need to identify an efficient communication mechanism between general practitioners and pharmacists* it is recommended that:

2.1. a sustainable system to support the communication process (e.g. computer software) should be provided to support referral systems and medication continuance programs.

2.2. an education package for GPs should be developed and distributed using the general practice network prior to the rollout of the best-practice model to pharmacies nationally

Recommendation 3

Based on the key finding that there is a *need for appropriate recording and monitoring of dispensing in instalments* it is recommended that:

The forms used during the trial should form the basis of this practice with the some modifications to make them more operationally oriented.

Recommendation 4

Based on the key finding that there is a *need to facilitate appropriate communication between consumers and pharmacists* it is recommended that:

Pharmacies providing the service of dispensing in instalments should have a designated private area in the pharmacy where appropriate consultation between pharmacist and consumer can take place.

Recommendation 5

Based on the key finding that *there were concerns raised by pharmacists regarding legal and PBS regulations in relation to the storage of drugs that are dispensed in instalments* it is recommended that:

5.1. The current state and territory legislations regarding dispensing and storage may require amendment to allow for dispensing in instalments, where drugs are still kept on the pharmacy premises after initial dispensing until all instalments are distributed.

5.2. The issue of incomplete supply and legal requirements for storage should be further investigated.

5.3. The procedures for dispensing in instalments should be incorporated into all community pharmacy dispensing computer systems to facilitate electronic claiming.

5.4. The system should require the prescriber to clearly endorse the prescription that is to be dispensed in instalments, as this is required by Medicare Australia for pharmacy reimbursement.

Recommendation 6

Based on the key finding that *diazepam and oxycodone are the most likely drugs which have the highest risk of dependency and diversion* it is recommended that:

Diazepam and oxycodone should be included in the category for dosing by instalments as a routine practice as per Quality Use of Medicines Principles.

2. Introduction

The Collaborative Centre for eHealth, University of Ballarat was commissioned by The Guild to undertake a project to develop a best-practice model for dispensing Schedule 4 and Schedule 8 (S4 and S8) drugs (with dependency properties) to patients who may be at risk.

The aim of the project was to develop dispensing and counselling protocols for unit dose medication to patients who may be at risk from drugs with dependency properties (S4 and S8) and to identify an appropriate level of remuneration for this service. The project has developed a best-practice model which was trialled and evaluated in seven community pharmacies.

The project examined the role, effectiveness and the cost for the pharmacist within this drug management strategy. It developed, trialled and evaluated dispensing and counselling protocols, and sought to identify and recommend an appropriate fee structure for unit dose medication to patients who may be at risk.

The specific aims of this project were:

1. to identify the scope of the practice of dispensing by instalments, with respect to:
 - the range of S8 and S4 drugs involved
 - the categories of patient at risk
 - the prevalence of the practice in seven pharmacies in three test regions
2. to identify the key elements of the process
3. to formulate protocols for dispensing, packaging, storage, supply, security, record keeping, and provision of feedback to medical practitioners
4. to trial the protocols in a sample of community pharmacies
5. to maintain “activity records” throughout the trial for evaluation purposes.
6. to further evaluate and analyse the trial on the basis of interviews with participating
7. pharmacists, dispensing staff, medical practitioners and consumers
8. to survey a wider group of pharmacists in order to further quantify current practices and to elicit their reactions to the outcomes of the trial and to provisional recommendations.

3. Project Summary

The project commenced in February 2005 and concluded in 2006.

The project team consisted of project management and research from the Collaborative Centre for eHealth, University of Ballarat, evaluation from the School of Information Technology and Mathematical Science, University of Ballarat, expert pharmacy advisor from the School of Pharmacy, University of Tasmania, expert pharmacists from pharmacies in the Ballarat region and General Practitioner (GP) representative from the Ballarat and District Division of General Practice.

The project team consisted of the following people:

Chris Lynton-Moll, Project Manager

Linda Goralski, Project Assistant (Jan-05 – Oct-05)

Susan La Pira, Project Assistant (Oct-05 – Apr-06)

Dr Jack Harvey, Senior Research Fellow

Dr Michelle O'Brien, Researcher (Jan-05 – June-05)

Colin Dorn, Expert Pharmacist

Peter Fell, Expert Pharmacist

Professor Greg Peterson, Expert Pharmacy Advisor

Dr Linda Danvers, General Practitioner

The project team worked together to design the project in line with the tender response from CCeH. All participants of the team were involved in the project design and the processes for developing the project outputs.

The proposed methodology was to conduct a literature review of Australian and International experience with dispensing in instalments. Included in the methodology was a series of interviews with health professionals associated with prescribing and dispensing S4 & S8 drugs. The literature review and interviews were then used to formulate the best practice model for the trial period.

During the literature review period, consultation was carried out with health professionals associated with S4 & S8 dispensing. Interviews were carried out with two local General Practitioners who are actively involved in prescribing S4 & S8 drugs, five local pharmacists who are actively involved with dispensing S4 & S8 drugs, one local Allied Health Professional who has patients who take S4 & S8 drugs and the Victorian Drug and Poisons Unit. Feedback from these health professionals was also included in the design of the best practice model. The interviews were carried out on a face to face basis where the comments of the interviewees were recorded and then sent back to them for verification.

The project team worked closely to formulate the best practice model from information gathered during the literature review and the interviews with local health professionals. Drafts of the best practice model were sent to the Steering Committee and the Expert Advisory Group (EAG) for approval and ratification. The model went through several iterations before being signed off by the Steering Committee.

Community pharmacies were recruited to trial the best practice model. The original proposal was to carry out the trial in three local pharmacies in the Ballarat area; after consultation with The Guild, the trial size was increased to seven community pharmacies, three in New South Wales and one in Northern Territory. The trial was planned to run for six months, after which

an evaluation was to be conducted of the information gathered from the participating pharmacies.

To gather information on dispensing practices from a larger number of community pharmacies and to help inform the design of the best practice model, a large Internet based survey was proposed to be carried out in the early stages of the project.

On completion of the trial and evaluation a draft final report was to be prepared for approval by the EAG and passed to external assessors for comment.

3.1 Definitions

During the early stages of the project one of the issues to arise was how to define the terms used in the process, as the terminology is not standardised. The following list of definitions were finalised at an early stage.

'Supervised dosing' is the practice of dispensing a single dose of a medicine, and observing the consumer take the medication to minimise the risk of drug diversion. This practice is used extensively in opioid substitution programs, which are outside the scope of the project.

'Dispensing in instalments' (DII) describes the practice of dispensing a single prescription in multiple instalments (e.g. daily, biweekly, or weekly).

'Daily dosing' and **'controlled dispensing'** are alternative terms for dispensing in instalments used by health professionals.

'Unit Dosing' is the dispensing of medication in instalments either to consume dose on site or as a take home dose.

The term used in this and other documents within the project is **'dispensing in instalments' (DII)**.

'Dose Administration Aids' (DAA) are used for unit dose packing (where the dose of a single type of medication is packed in each compartment (blister or sachet) or for multi-dose packing where doses of more than one medicine can be packed in one compartment.

3.2 Trial Protocols

Extensive meetings of the research team, and consultations with key informants on the Steering Committee and Expert Advisory Group (EAG) were undertaken to establish the best practice model for dispensing in instalments. Several iterations of the model were reviewed by the above groups before the final best practice model was defined. This model resulted in a series of protocols being established to inform pharmacies participating in the trial of the best practice model. Decision support trees and reporting forms were also developed for the trial to assist the participating pharmacies.

The model was put together as a series of forms and documents as well as instructions on use of the model. The documents were put together as a training manual and delivered to each participating pharmacy along with a training session for all pharmacists and dispensing technicians taking part in the trial.

The following forms and documents constituted the model and are attached as Appendices 2-19:

- Best Practice Model Dosing in Instalments Decision Tree (DT-01) See A2
- Decision Tree for Reporting Anomalies (DT-02) See A3
- Dispensing in Instalments Trial Protocols See A4
- Dispensing in Small Quantities Record Sheet (RF-01) See A5
- Dispensing in Instalments Record Form (RF-03) See A6
- Prescriber Register (RF-05) See A7
- Storage and labelling guidelines See A8 & 9
- Information packs with protocols to trial pharmacies See A10 - 19

Each of these forms and documents were designed to support the pharmacies participating in the trial and to ensure that the relevant data was collected.

3.3 Ethics

As the research involved pharmacists, prescribers and consumers ethics, it was necessary to receive ethics approval from the University of Ballarat Human Research Ethics Committee (UBHREC). Ethical approval was granted for the trial itself and for other associated evaluations on 26th May 2005 and 11th November, 2005 respectively. Some of the ethical issues were complex, particularly with consumer and prescriber involvement in the project.

The forms and protocols required for the trial are attached to the report (A2-19). The ethics application (A20) and the questionnaires (A21), accompanying letter, and interview forms subsequent to that are attachments to this report.

4. Approach and Methodology

4.1 Approach

The approach the team took was a multifaceted one of literature review, a web based survey of the community pharmacy population at large and input from expert pharmacists and general practitioners to guide the development of the best practice model and then to trial this model in selected community pharmacies.

A project team was put together of local and interstate experts to carry out the project. The project team can be found in detail in Section 3 – Project Summary. The tender for S4 S8 drugs (with dependency properties) project prepared by CCeH proposed the following methodology. “This model will be developed from the research gathered during the early phase of this project. As part of this process, the expert input from Ballarat based pharmacists will be supplemented by a web-based survey of pharmacists in other areas of Australia”.

4.2 Methodology

The project team commenced the work with a comprehensive literature review, which can be found in the Appendix. A summary of the literature review can be found in the following section, Section 5. This research, along with the interviews of health professionals associated with dispensing and prescribing S4 & S8 drugs enabled the project team to design a best practice model for dispensing S4 and S8 drugs, using a dosing in instalments regime.

The model consisted of a series of protocols as outlined in Section 3.2 – Trial Protocols. This model was trialled in seven pharmacies, in Ballarat, Sydney and Darwin, for six months. Seven pharmacies were recruited for the trial by asking for suitable Ballarat pharmacies to volunteer and assistance from The Guild in recruiting the New South Wales and Northern Territory pharmacies. This best practice model included appropriate dispensing and counselling protocols, including development of an appropriate fee for unit dose medication. During this trial, data was collected on all S4 and S8 drugs dispensed using a “supervised dosing” regime, but consumer groups affected were limited to those who manage their own medication.

The rationale for this model was considered over several meetings with the project team, steering committee and EAG. The proposed best practice model was derived from current practices surrounding the management of controlled and restricted substances. The team wanted to design a best practice model that was easy to implement, easy to use and covered all of the required regulations necessary for dealing with S4 & S8 drugs. This issue was particularly important with regard to storage and labelling of S4 & S8 drugs. The team also wished to incorporate the ability to collect trial data for analysis. This required some modifications to the initial forms to allow this to happen. The inclusion of the trial data did not unduly hamper the use of the forms during the trial, but results from the post trial interview were suggestive of a much simpler form would be preferable. The proposed model was thought to be the most suitable as it allowed the participant pharmacies to control the dispensing of S4 & S8 drugs and allowed trial data to be collected for analysis.

During the course of the project, the team liaised closely with the EAG for guidance and clarification on a number of items that arose in the early stages. The issues that were clarified are outlined below (see Section 4.3, 4.4 & 4.5)

4.3 Clarification of survey methodology

The reality was that a web-based survey was considered by the Steering Committee to be of little value due to low level of Internet use among Pharmacy Guild members.

It was decided that after completion of the trial, to distribute a fax-based survey form to all members of The Guild; and to hold interviews with pharmacists and dispensing technicians involved in the trial, and with a sample of consumers. Conducting the survey at the end of the trial enabled the content of the survey to be focused and informed by the information gained and issues identified during the trial.

4.4 Change to the length of the trial

The original methodology proposed a six month trial of the best practice model in seven community pharmacies across Australia. This time frame was reduced to a five month trial to accommodate the post-trial survey and the comprehensive interviews of pharmacists and consumers. The commencement of data collection by the trial pharmacies was staged. Completion of data collection was December 31, 2005 to enable sufficient time for data analysis, interviews and report compilation.

4.5 Changes to project scope

As a result of the literature review, and the EAG response, some changes were incorporated into the project.

In summary four main areas were reviewed by the project team and clarified by EAG.

They were:

- Consumer groups to be included in the trial
- Including the use of dosing aids in the trial
- Information flow processes
- Diversion of S4 S8 drugs (with dependency properties)

The following decisions were made by the EAG:

4.5.1 Consumer groups

The scope of the initial tender was widened to incorporate the following three consumer groups:

- Consumers who have a drug dependency (illicit or prescription) who have a therapeutic need for a drug with dependency properties
- Consumers who have a psychiatric condition who may misuse the medication, in particular by taking too much of a medication for anxiety.
- Consumers who have a cognitive deficit which may be caused by a psychiatric condition, intellectual disability, or ageing.

Also further refinement of the consumer groups was as follows:

- Consumers involved in this work were community based rather than nursing home or hospital based;
- Consumers to be included within the trial were consumers where either the consumer collects his/her own medication, or an agent for the consumer (such as the parent of a child) collect the medication on behalf of the consumer;
- Cases where the medication was delivered to a hostel by the pharmacy or collected by a hostel staff member are not within scope of this work.

4.5.2 The use of dosing aids and the part they play in dispensing in instalments.

Dosing aids were not part of the initial tender but were included on the recommendation of the EAG for the following reasons:

- The use of dosing aids is a practice that is not currently remunerated (some pharmacists charge a nominal fee for this service).
- This lack of remuneration is causing pharmacists to choose to limit the number of dosing aids they pack each week.
- The use of dosing aids is a significant proportion of a pharmacist's work.
- With the increased emphasis on quality use of medicines the use of dosing aids is increasing.

As a result an estimation of the number of dosing aids used in this consumer group and the impact on remuneration has been estimated.

4.5.3 Information flow

The information flows that relate to decisions surrounding dispensing in instalments can begin at the level of the State or Territory Regulatory Authority, and flow through the prescriber to the dispenser and consumer, as illustrated in Figure 1.

The focus of the tender request has been the dispensing component of this process. Data were gathered about the communication between the pharmacist and the consumer. The EAG recommended that two additional information flows be included in the original information flow diagram:

Prescriber to consumer;

Consumer to prescriber.

Dispensing in instalments information flow

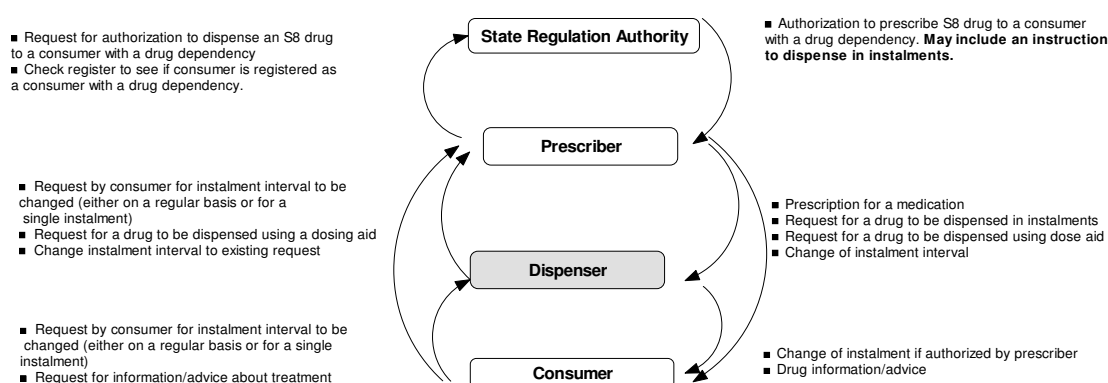


Figure 1 Information flows for dispensing in instalments

4.5.4 Diversion

The project issues surrounding potential diversion at all levels that arose from the literature were included within the literature review component of this work, but were omitted from the best practice model strategies thus focusing on consumer diversion only.

4.6 Remuneration of services

The literature review yielded very little information on remuneration to pharmacies for dispensing in instalments. The literature review yielded only two instances of regulated dispensing in instalment; the United Kingdom and the Republic of Ireland. There was no mention of remuneration to pharmacies in these references.

Dispensing in instalments is a practice that is informally used within Australia. According to the National Pharmacy Database Project (Berbatis et al., 2003b) up to 50% of community pharmacists performed supervised dosing in at least one of the five categories of drugs included in their survey each week. A total of 46.7% of pharmacies were reported to be supervising dosing of methadone and/or buprenorphine more than once a week and that the supervised dosing has been reported for drugs other than buprenorphine and methadone. . No literature, however, has been found on the practice of supervised dispensing for drugs other than opioid substitution programs. It is likely, therefore, that these authors have included the practice of dispensing in instalments within these figures, although it is not clear from the reporting of this data.

At this stage it is not known how frequently dispensing in instalments currently occurs in Australia, and the frequency it is likely to occur if pharmacists were remunerated and the practice was regulated.

From this sparse base of information, the project team decided the best way of determining a remuneration fee was to gather data during the trial, estimate the time taken by pharmacists and dispensing technicians, and then from this time allocation calculate a reasonable fee structure. The calculations for this fee structure can be found in Table 70 Estimates of total cost of a remuneration scheme.

These figures are such that the Guild can use these as a basis for negotiation with Medicare Australia to implement a new PBS fee for dispensing in instalments.

5. Literature review

An extensive literature review of Australian and overseas experience with dispensing in instalments was conducted. A copy of the full literature can be found as an Appendix to this report (see Appendix 22). The search strategy for the literature review was based on key words and terms from the aims of the project. The search strategy also included the key definitions in section 3.1 of this report.

The following is a summary of the literature review.

A number of components of a best practice model for dispensing S8 and S4 drugs with dependency properties have been identified from the literature. These have been summarised below:

Record keeping

Full details of the prescription as would be required for any other dispensing of a controlled drug;

- The date of each instalment;
- The quantity of tablets supplied and the quantity remaining on the premises;
- The name of the person supplying the drugs
- Labelling on the container the medication is supplied to the consumer indicating the name of the prescriber, and directions for use as set out on the prescription

Labelling

Ensure each instalment has a full label as outlined in Appendix D of the full literature review.

Storage

For drugs that have been dispensed but before they have been supplied:

- Ensure S8 drug as stored as per legislation
- Ensure S4 drugs are stored in the dispensary in an area that only the pharmacist has access

Dedicated prescription pad

Consider the development of a dedicated prescription pad for the practice of prescribing controlled drugs to be dispensed in instalments. The advantages may be:

- Clear processes and procedures
- Clear identification of instalment request to pharmacist
- Ensuring all required information about the dispensing in instalment request is conveyed from the prescriber to the dispenser

Medical practitioner dispensing

Recommend that medical practitioners only conduct dispensing in instalment practices in emergency situations or when there are no pharmacy services available such as in rural and remote locations.

Minimising Diversion

The medical practitioner requirements:

- ensure there is a valid therapeutic need;
- report consumers suspected of having a drug dependency;
- apply for permits as required by the state authority;
- for new consumers requesting S8 or S4 drugs with dependency properties, verify medical history prior to prescribing full prescription quantity. If unable to verify, supply small quantity until history has been verified;
- check state authority register for consumers who they suspect of diversion, to determine if they have been registered;
- ensure security measures for prescription pads are implemented as per state guidelines.

The pharmacist requirements:

- ensure security measures for controlled and restricted drugs are implemented as per the state regulation;
- ensure identity of consumer is ascertained prior to supply of the medication;
- ensure the prescription is valid;
- if the request for the controlled or regulated drugs appears inappropriate question it at the level of the state authority;
- if a consumer presents a prescription for controlled or regulated drugs from different prescribers, alert the prescribers;
- ensure only pharmacy staff supply S8 and S4 drugs with addictive properties.

Triplicate prescriptions

Consider the implementation of a triplicate prescription system for controlled drugs to ensure controlled drugs can be accounted for and audited with minimal delay.

Consumer, Pharmacist, Medical Practitioner communication

Consider the need for a separate section in the dispensary for dispensing in instalments to assist in maintenance of consumer privacy;

Consider trialling case conferences to initiate a dispensing in instalments program. The case conference would include the pharmacist, medical practitioner, consumer and consumer support (i.e. advocate, family member, family friend, case manager).

6. Data Collection

6.1 Trial pharmacies

Pharmacists from around Australia were recruited via professional organisations to participate in a survey to provide further input into the best practice model. Seven trial pharmacies were ultimately enrolled in the project:

- | | |
|-----------------------|----------------------|
| ▪ Daylesford | Rural Town, VIC |
| ▪ Ballarat | Regional Centre, VIC |
| ▪ Ballarat2 | Regional Centre, VIC |
| ▪ Darwin | Outer suburb, NT |
| ▪ Sydney Inner West 1 | Inner suburb, NSW |
| ▪ Sydney Inner West 2 | Inner suburb, NSW |
| ▪ Sydney Inner West 3 | Inner suburb, NSW |

The Ballarat 2 Pharmacy did not collect any data during the trial period. This was due to a change in the staffing situation at this pharmacy which made it difficult for that pharmacy to participate. Therefore all data processed in this report is from 6 pharmacies.

These pharmacies were required to collect and record a variety of activities. The recording of these activities was in addition to current recording requirements. This included the following recording sheets:

- Dispensing in instalments recording sheet (including both dispensing data, and time and activity records (Form RF 03)
- Dispensing in small quantities recording sheet (Form RF 01)
- Consumer register (Form RF 02)

They then forwarded the completed, de-identified activity sheets to the project leader on a monthly basis.

The trial pharmacies also recruited suitable consumers for an in-depth interview at the end of the trial to assess the impact of the new protocols. Participating pharmacies found it very difficult to recruit consumers for interview. These consumers are basically unreliable due to their underlying medical conditions. Only one consumer was interviewed at the completion of the trial. This interview did not yield much in the way of informative information.

An in-depth interview at the end of the trial was performed to ascertain whether the pharmacists thought the trial reflected a best practice model.

6.2 Forms and compliance

Expert advisors and trial participants advised that paper work must be minimised to ensure compliance, which led to some compromise in form design. Hence, a single form was designed to collect best practice record keeping and “time & motion” trial record keeping.

Ethical considerations (blinding of researchers to the identity of consumers and prescribers) further complicated form layouts & procedures. So too did the dependence on fax and the lack of Internet usage.

It is also important to distinguish between documentation which is part of the protocol (names, signatures, dates, amounts, consultation notes) and documentation which was for the purpose of record keeping for the trial (times, containers).

Data collection was complicated in some cases because of conflict between the trial forms and established local protocols, and in some cases disregard for the instructions on how the forms were to be filled out.

In particular, two assumptions:

- that instalments would be much smaller than amounts prescribed, so that one dispensing would lead to many instalments; and
- that the form should make provision for dispensing details to be entered for every new dispensing

were agreed to by expert advisors. However, the first of these was not always the case, and the second was not always complied with when repeat dispensing of identical prescriptions occurred.

Notwithstanding these problems, the integrity of the trial data was not significantly compromised by failure to comply precisely with the specified recording procedures.

7. Results and Findings

Data were received regarding 407 prescriptions and 2015 instalments, which related to 102 consumers.

The results were analysed and the findings are set out below.

7.1 Presentation, terminology and interpretation

Statistical analyses have been carried out using Statistical Package for Social Sciences (SPSS) software. Not all questions were answered by all respondents. In the individual frequency tables, the **percent** column shows the frequency of each response expressed as a percentage of the total number of respondents. Generally more informative is the **valid percent** column, which shows the frequency as a percentage of those cases for which the particular question was answered. All cases for which a question was not answered (either through omission or because particular respondents were not required to answer the question) have been tagged automatically by the statistical software, and are labelled as “**missing - system**”.

Some composite frequency tables are presented in a simpler format, without explicit enumeration of missing cases. The percentages in these tables correspond to the ‘valid percent’ in the individual frequency tables.

The percentages in cross-tabulations are percentages of all respondents to the questions being tabulated. Again, there is no reference to missing cases.

With regard to “missing data”, a distinction must be drawn between incomplete data due to failure to answer relevant questions on the form, and null data - blanks occurring because particular items of data were not applicable in particular circumstances. The first of these is a potential source of bias, and is discussed under “limitations” below; the second is not.

Large proportions of legitimate null data occurred in the questions relating to activities that did not occur with every instalment, including dispensing, delivery and consultation. In the statistical analysis of staff time requirements, these null values were interpreted as zeroes in order to distribute the costs of intermittent activities across all instalment events.

With **multiple response items** (those for which respondent could select more than one response) two types of percentage can be reported – the **percentage of all responses** (which add to 100% but are usually of relatively little interest) and the **percentage of cases** i.e. respondents (which generally add to more than 100% and are generally of more interest). All such percentages in this report are of the latter type. Again, there is no explicit reference in multiple response tables to missing cases i.e. those who made no responses at all.

Unless otherwise stated, ‘significant’ should be taken to mean ‘statistically significant at the 0.05 level’.

7.2 Trial pharmacy dispensing data

Location	Trial Period		Duration	Frequency	Percent	Total clients	Dispensing in small quantities
	From	Until	Weeks	No. of scripts	%		
Ballarat	8-Aug	31-Dec	21	144	35.4	28	-
Darwin	10-Oct	31-Dec	12	75	18.4	9	-
Daylesford	15-Aug	31-Dec	20	67	16.5	43	57
Sydney inner west 1	22-Aug	31-Dec	19	36	8.8	11	5
Sydney inner west 2	5-Sep	31-Dec	17	69	17.0	8	1
Sydney inner west 3	5-Sep	31-Dec	17	16	3.9	3	-
Total				407	100.0	102	63

Table 1 Trial Pharmacies

The table shows the amount of data collected by each of the pharmacies in the trial. Note that the second pharmacy in Ballarat which did not produce any data has been omitted.

A total of 102 patients were reported which created 407 prescription items, 2015 instalment items and 63 dispensing in small quantity items from the trial pharmacies. The pharmacy producing the most information was Ballarat closely followed by Daylesford with the least data coming from Sydney inner west 3.

The variation in Table 1 arise from the time that the Pharmacies started the trial. The Ballarat Pharmacy was the first to start the trial followed closely by the Daylesford Pharmacy. The Darwin Pharmacy was the last to start the trial. The Daylesford Pharmacy had the largest number of clients and the Ballarat Pharmacy had the largest number of scripts. Two of the three Sydney Pharmacies had the lowest number of scripts.

Pharmacy	Prescribers		Reason for Dispensing in Instalments					
	GP	Psych	Dependency	Psychiatric condition	Intellectual Disability	Cognitive problem	Other	Not Known
Ballarat	10	-	10	-	-	10	-	8
Darwin	7	1	9	1	-	-	-	-
Daylesford	4	-	34	-	1	2	2	4
Sydney inner west 1	2	1	8	7	-	1	-	-
Sydney inner west 2	1	3	4	3	-	-	1	-
Sydney inner west 3	2	1	2	-	-	1	-	-
Total	26	6	67	11	1	14	3	12
%	81.3	18.7	74.4	12.2	1.1	15.6	3.3	-

Note: Percentages of consumers in each category sum to 106.6% because a few consumers were classified by pharmacists into more than one category

Table 2 Reasons for DII and Prescriber types

Initiator of DII		Frequency	Percent	Valid Percent
Valid	Consumer	9	2.2	2.6
	Prescriber	323	79.4	94.2
	Carer	2	.5	.6
	Other pharmacist	2	.5	.6
	Prescriber & consumer	6	1.5	1.7
	Prescriber & community nurse	1	.2	.3
	Total	343	84.3	100.0
Missing	System	64	15.7	
Total		407	100.0	

Table 3 DII proposed by

The table shows which entity initiated the dispensing by instalments for the patients. Overwhelmingly, dispensing by instalment was initiated by the GP in 94% of cases when the missing data are omitted.

Method of request		Frequency	Percent	Valid Percent
Valid	Script	263	64.6	80.4
	Phone	37	9.1	11.3
	Script & phone	16	3.9	4.9
	Script & fax	5	1.2	1.5
	Script, phone & fax	6	1.5	1.8
	Total	327	80.3	100.0
Missing	System	80	19.7	
Total		407	100.0	

Table 4 DII requested via

The table describes how the prescription was requested. The majority of requests were received by script at the counter, 80.4% when the missing data are omitted. The next highest request came over the telephone from reliable sources (11.3%).

Private Prescription		Frequency	Percent	Valid Percent
Valid	Yes	18	4.4	6.3
	No	270	66.3	93.8
	Total	288	70.8	100.0
Missing	System	119	29.2	
Total		407	100.0	

Table 5 Private Prescription

The table describes the number of private prescriptions. The majority of scripts were not private with only 18 out of 288 scripts private.

Generic drug name	Frequency	Percent
Alprazolam	4	1.0
Clonazepam	4	1.0
Clozapine	12	2.9
Dexamphetamine	6	1.5
Diazepam	164	40.3
Methadone	4	1.0
Methylphenidate	15	3.7
Morphine	41	10.1
Nitrazepam	11	2.7
Olanzapine	1	.2
Oxazepam	20	4.9
Oxycodone	59	14.5
Oxycodone (controlled release)	21	5.2
Paracetamol & codeine	20	4.9
Paroxetine	8	2.0
Temazepam	11	2.7
Venlafaxine	5	1.2
Zolpidem	1	.2
Total	407	100.0

Table 6 Drug Names

The data has been sorted into generic drug names to simplify and make more meaningful the information to be gained from it. The most commonly prescribed drug for dispensing in instalments during the trial was the tablet Diazepam at 40% with Oxycodone following at only 14.5%, Morphine at 10.1% and the rest of the drugs each makes up less than 5% of the sample.

Month		Frequency	Percent	Valid Percent
Valid	Aug	61	15.0	19.2
	Sept	65	16.0	20.4
	Oct	70	17.2	22.0
	Nov	65	16.0	20.4
	Dec	57	14.0	17.9
	Total	318	78.1	100.0
Missing	System	89	21.9	
Total		407	100.0	

Table 7 Dispensing by Month

The table denotes the amount of data collected by month. Similar amounts of data were collected in each month from August to November; even though the pharmacies began collecting data in a staggered fashion from 8 August to 10 October (see Table 1). Slightly fewer data were collected in December which may indicate some seasonality due to holidays.

7.2.1 Trial Pharmacy Dosing

A table for dosing was created to display the dosage given and the frequency of administration of the drug. Certain types of dose administration are more common than others, however, the information varied so much that any summary interpretation is difficult.

Generic drug name	N	Median	Mean	Std. Dev.
Alprazolam	3	50	50.0	0.0
Clonazepam	4	200	200.0	0.0
Clozapine	11	210	149.3	96.8
Dexamphetamine	6	200	200.0	0.0
Diazepam	146	50	49.8	2.1
Methadone	4	180	180.0	0.0
Methylphenidate	14	196	196.0	0.0
Morphine	38	48	44.4	29.3
Nitrazepam	11	25	25.0	0.0
Olanzapine	1	60	60.0	
Oxazepam	20	25	25.0	0.0
Oxycodone	58	20	18.9	4.1
Oxycodone (controlled release)	16	84	77.0	21.6
Paracetamol & codeine	18	60	120.0	71.3
Paroxetine	7	150	150.0	0.0
Temazepam	11	25	23.6	4.5
Venlafaxine	5	56	56.0	0.0
Total	373	50	62.0	54.9

Table 8 Full Script Quantity by Drug

The table shows summary statistics for the number of tablets prescribed on scripts for each drug type. For over half (nine) of the drugs, all scripts were for the same number of tablets, indicated by a standard deviation of zero. The drugs for which variation in the number prescribed was greatest were clozapine, morphine, oxycodone (controlled release), and paracetamol & codeine,

Frequency of instalments	Frequency	Percent	Cumulative Percent
Daily	85	20.9	20.9
Daily except weekend/Sunday	14	3.4	24.3
Alternate days/Three times per week	147	36.1	60.4
Twice per week	50	12.3	72.7
Every five days	5	1.2	74.0
Weekly	95	23.3	97.3
Every ten days	5	1.2	98.5
Fortnightly	2	.5	99.0
As requested by consumer	4	1.0	100.0
Total	407	100.0	

Table 9 Frequency of instalments

The table show how often instalments were supplied. The vast majority, 60.4%, were dispensed either daily or alternate days. The other significant group was those being dispensed weekly, 23.3%.

Type of Container		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Own container	126	31.0	31.9	31.9
	Capped container	87	21.4	22.0	53.9
	Disposable pack	119	29.2	30.1	84.1
	Disposable dosing aid	42	10.3	10.6	94.7
	Reusable dosing aid	16	3.9	4.1	98.7
	No container - consumed in pharmacy	5	1.2	1.3	100.0
	Total	395	97.1	100.0	
Missing	System	12	2.9		
Total		407	100.0		

Table 10 Container

The table shows that in 66.8% of cases the pharmacist provided a container of some sort for the dispensing in an instalment dose, 31.9% of clients provided their own container and 1.3% consumed the dose at the pharmacy.

7.2.2 Generic drug name / frequency of instalments cross tabulation

The following table shows an analysis of the drugs by generic name and the frequency at which the drugs were supplied. The majority of the drugs appear to be supplied at a single frequency with the exception of a small group of drugs – Diazepam, Morphine, Nitrazepam, Oxazepam, Oxycodone (controlled release), and Temazepam. This group of drugs was involved in 65.8% of the total scripts dispensed.

	Frequency of instalments									Total
Generic drug name	Daily	Daily except weekend/ Sunday	Alternate days/ 3X per wk	Twice per week	Every five days	Weekly	Every ten days	Fortnightly	As requested by consumer	
Alprazolam	0	0	0	0	0	4	0	0	0	4
Clonazepam	0	0	0	0	0	4	0	0	0	4
Clozapine	0	0	0	0	0	12	0	0	0	12
Dexamphetamine	0	0	0	6	0	0	0	0	0	6
Diazepam	59	13	47	14	2	29	0	0	0	164
Methadone	0	0	0	0	0	0	0	0	4	4
Methylphenidate	15	0	0	0	0	0	0	0	0	15
Morphine	2	0	0	8	3	21	5	2	0	41
Nitrazepam	0	0	7	4	0	0	0	0	0	11
Olanzapine	0	0	0	0	0	1	0	0	0	1
Oxazepam	0	0	15	0	0	5	0	0	0	20
Oxycodone	0	0	59	0	0	0	0	0	0	59
Oxycodone (controlled release)	7	1	0	9	0	4	0	0	0	21
Paracetamol & codeine	0	0	19	0	0	1	0	0	0	20
Paroxetine	0	0	0	8	0	0	0	0	0	8
Temazepam	2	0	0	0	0	9	0	0	0	11
Venlafaxine	0	0	0	0	0	5	0	0	0	5
Zolpidem	0	0	0	1	0	0	0	0	0	1
Total	85	14	147	50	5	95	5	2	4	407

Table 11 Frequency of instalments by Generic drug name

7.3 Trial pharmacy instalment data

The following analysis is at the instalment level with 2015 items assessed.

Note: An instalment refers to any transaction recorded in the instalments section of the Dispensing in Instalments Record Form. This includes the initial instalment supplied at the time of dispensing. In a small number of cases, a consultation was recorded but there was no actual supply of medication.

Location	Frequency	Percent	Weeks	Instalments per week
Ballarat	308	15.3	21	14.7
Darwin	504	25.0	12	42.0
Daylesford	538	26.7	20	26.9
Sydney inner west 1	258	12.8	19	13.6
Sydney inner west 2	294	14.6	17	17.3
Sydney inner west 3	113	5.6	17	6.6
Total	2015	100.0	106	19.0

Table 12 Instalments by Pharmacy

By location the majority of instalments were dispensed from Daylesford, 26.7% followed by Darwin with 25%.

Generic Drug name	Frequency	Percent
Alprazolam	20	1.0
Clonazepam	25	1.2
Clozapine	29	1.4
Dexamphetamine	60	3.0
Diazepam	942	46.7
Methadone	10	.5
Methylphenidate	165	8.2
Morphine	132	6.6
Nitrazepam	81	4.0
Olanzapine	6	.3
Oxazepam	62	3.1
Oxycodone	71	3.5
Oxycodone (controlled release)	161	8.0
Paracetamol & codeine	126	6.3
Paroxetine	62	3.1
Temazepam	28	1.4
Venlafaxine	29	1.4
Zolpidem	6	.3
Total	2015	100.0

Table 13 Generic drug name

This table correlates with the findings on dispensing – the drug most often given in instalments is Diazepam with 942 instances occurring or 46.7% of the total instalments

dispensed. Other drugs with greater than 100 instalments include Methylphenidate, Morphine, Oxycodone (controlled release) and Paracetamol & Codeine.

Month		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Aug	137	6.8	6.8	6.8
	Sept	404	20.0	20.1	26.9
	Oct	605	30.0	30.1	56.9
	Nov	518	25.7	25.7	82.7
	Dec	349	17.3	17.3	100.0
	Total	2013	99.9	100.0	
Missing	System	2	.1		
Total		2015	100.0		

Table 14 Instalments by Month

This table verifies the dispensing data that most of the instalments were dispensed during September to November with a tapering off of dispensing in December. This is possibly due to pharmacies becoming busier with annual safety net dispensing rush.

Number supplied		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	0	7	.3	.3	.3
	1	38	1.9	1.9	2.2
	2	184	9.2	9.1	11.4
	3	323	16.1	16.0	27.5
	4	6	.3	.3	27.8
	4	57	2.8	2.8	30.6
	5	2	.1	.1	30.7
	6	174	8.7	8.6	39.4
	7	191	9.5	9.5	48.9
	8	47	2.3	2.3	51.2
	9	105	5.2	5.2	56.4
	10	79	3.9	3.9	60.4
	11	1	.0	.0	60.4
	12	171	8.5	8.5	68.9
	13	1	.0	.0	69.0
	14	154	7.7	7.6	76.7
	15	6	.3	.3	77.0
	15	18	.9	.9	77.8
	16	97	4.8	4.8	82.7
	18	83	4.1	4.1	86.8
	20	61	3.0	3.0	89.8
	21	19	.9	.9	90.8
	23	1	.0	.0	90.8
	24	16	.8	.8	91.6
	25	12	.6	.6	92.2
	26	1	.0	.0	92.3
	27	27	1.3	1.3	93.6
	28	10	.5	.5	94.1
	29	1	.0	.0	94.2
	30	3	.1	.1	94.3
	32	14	.7	.7	95.0
	36	33	1.6	1.6	96.7
	40	1	.0	.0	96.7
	42	22	1.1	1.1	97.8
	44	1	.0	.0	97.9
	45	1	.0	.0	97.9
	49	8	.4	.4	98.3
	50	2	.1	.1	98.4
	53	2	.1	.1	98.5
	56	9	.4	.4	99.0
	60	10	.5	.5	99.5
	70	4	.2	.2	99.7
	98	2	.1	.1	99.8
	140	5	.2	.2	100.0
	Total	2009	100.0	99.7	
Missing	System	6		.3	
Total		2015	100.0		

Table 15 Number supplied

Of the number supplied 3 appears to be the most frequent number of tablets dispensed in 16% of the data collected. Other common quantities are 2, 6, 7, 12 and 14, indicative of the predominant daily, biweekly and weekly patterns of delivery.

7.3.1 Time in minutes taken for the various component tasks

The times taken in minutes for pharmacists and dispensing technicians to perform the various tasks involved in DII are summarised, in the following set of tables.

Dispense and Setup time of Pharmacists		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1.00	50	2.5	12.6	12.6
	1.50	13	.6	3.3	15.8
	2.00	200	9.9	50.3	66.1
	2.50	6	.3	1.5	67.6
	3.00	46	2.3	11.6	79.1
	3.50	4	.2	1.0	80.2
	4.00	20	1.0	5.0	85.2
	5.00	31	1.5	7.8	93.0
	6.00	5	.2	1.3	94.2
	7.00	8	.4	2.0	96.2
	8.00	4	.2	1.0	97.2
	9.00	2	.1	.5	97.7
	10.00	6	.3	1.5	99.2
	12.00	1	.0	.3	99.5
	15.00	2	.1	.5	100.0
	Total	398	19.8	100.0	
Missing	System	1617	80.2		
Total		2015	100.0		

N	Minimum	Maximum	Mean	Median	Std. Deviation
398	1.00	15.00	2.79	2	1.99

Table 16 Dispense and setup (mins) pharmacist

In 93% of cases, dispensing and setting up took less than or equal to 5 minutes for pharmacists. The mean time was 2.79 minutes.

Dispense and Setup time of Technicians		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1.00	121	6.0	65.4	65.4
	2.00	20	1.0	10.8	76.2
	3.00	23	1.1	12.4	88.6
	4.00	16	.8	8.6	97.3
	5.00	5	.2	2.7	100.0
	Total	185	9.2	100.0	
Missing	System	1830	90.8		
Total		2015	100.0		

N	Minimum	Maximum	Mean	Median	Std. Deviation
185	1.00	5.00	1.72	1	1.14

Table 17 Dispense and setup (mins) dispensing technician

In 100% of cases dispensing and setting up took less than or equal to 5 minutes for technicians. This information will be used in estimating the cost of dispensing in instalments. The mean was 1.72 minutes.

Analysing the information in the previous two tables suggests that the pharmacist dispenses the more complicated and time consuming scripts as 7% of their data are outside the greatest time value of the technicians.

Time in supplying of instalments - pharmacist		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	.50	96	4.8	5.1	5.1
	1.00	491	24.4	26.1	31.2
	1.50	27	1.3	1.4	32.7
	2.00	405	20.1	21.5	54.2
	2.20	2	.1	.1	54.3
	2.50	150	7.4	8.0	62.3
	3.00	279	13.8	14.8	77.1
	3.50	9	.4	.5	77.6
	4.00	255	12.7	13.6	91.2
	4.50	27	1.3	1.4	92.6
	5.00	132	6.6	7.0	99.6
	6.00	4	.2	.2	99.8
	7.00	1	.0	.1	99.9
	8.00	2	.1	.1	100.0
	Total	1880	93.3	100.0	
Missing	System	135	6.7		
Total		2015	100.0		

N	Minimum	Maximum	Mean	Median	Std. Deviation
1880	.50	8.00	2.39	2	1.34

Table 18 Supply the instalment (mins) pharmacist

In 77.1% of cases supplying an instalment took less than or equal to 3 minutes for pharmacists. The mean time was 2.39 minutes

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1.00	60	3.0	36.8	36.8
	2.00	11	.5	6.7	43.6
	2.50	6	.3	3.7	47.2
	3.00	86	4.3	52.8	100.0
	Total	163	8.1	100.0	
Missing	System	1852	91.9		
Total		2015	100.0		

N	Minimum	Maximum	Mean	Median	Std. Deviation
163	1.00	3.00	2.18	3	0.94

Table 19 Supply the instalment (mins) dispensing technician

In 100% of cases supplying took less than or equal to 3 minutes for technicians. The mean time was 2.18 minutes.

Analysing the information in the previous two tables suggests that the pharmacists tend to supply the more complicated and time consuming scripts as 32.9% of their data are outside the greatest time value of the technicians.

Deliver the instalment - pharmacist		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1.00	23	1.1	12.8	12.8
	2.00	155	7.7	86.1	98.9
	3.00	1	.0	.6	99.4
	7.00	1	.0	.6	100.0
	Total	180	8.9	100.0	
Missing	System	1835	91.1		
Total		2015	100.0		

N	Minimum	Maximum	Mean	Median	Std. Deviation
180	1.00	7.00	1.91	2	0.51

Table 20 Deliver the instalment (mins) pharmacist

Deliver the instalment - technician		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1.00	4	.2	4.5	4.5
	2.00	84	4.2	95.5	100.0
	Total	88	4.4	100.0	
Missing	System	1927	95.6		
Total		2015	100.0		

N	Minimum	Maximum	Mean	Median	Std. Deviation
88	1.00	2.00	1.95	2	0.21

Table 21 Deliver the instalment (mins) dispensing technician

Participants in the trial were briefed on the terms dispense, supply and deliver. In most cases, delivery presumably involved a handover to a delivery person who did the actual physical delivery.

Data were received for this item on behalf of the pharmacy in only a small proportion of cases for both pharmacists (8.9%) and technicians (4.4%). This implies that the pharmacist or technician rarely delivered the instalment.

Pharmacists time consulting with prescriber		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	.50	2	.1	1.7	1.7
	1.00	36	1.8	31.0	32.8
	2.00	36	1.8	31.0	63.8
	3.00	9	.4	7.8	71.6
	4.00	8	.4	6.9	78.4
	5.00	13	.6	11.2	89.7
	6.00	1	.0	.9	90.5
	7.00	6	.3	5.2	95.7
	8.00	2	.1	1.7	97.4
	9.00	3	.1	2.6	100.0
	Total	116	5.8	100.0	
Missing	System	1899	94.2		
Total		2015	100.0		

N	Minimum	Maximum	Mean	Median	Std. Deviation
116	.50	9.00	2.79	2	2.11

Table 22 Consult with prescriber (mins) pharmacist

The pharmacist spoke to the prescriber in only 116 or 5.8 % cases. In 63.8% of consultations the pharmacist spoke to the prescriber for no more than 2 minutes.

Technician time consulting with the prescriber		Frequency	Percent	Valid Percent
Valid	1.00	8	.4	100.0
Missing	System	2007	99.6	
Total		2015	100.0	

N	Minimum	Maximum	Mean	Median	Std. Deviation
8	1.00	1.00	1.00	1	0.00

Table 23 Consult with prescriber (mins) dispensing technician

The technician spoke to the prescriber in only 8 instances or 0.4% of cases for less than one minute.

Pharmacist consult with other than prescriber		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	.50	33	1.6	21.6	21.6
	1.00	44	2.2	28.8	50.3
	2.00	34	1.7	22.2	72.5
	3.00	14	.7	9.2	81.7
	4.00	8	.4	5.2	86.9
	5.00	18	.9	11.8	98.7
	6.00	1	.0	.7	99.3
	7.00	1	.0	.7	100.0
	Total	153	7.6	100.0	
Missing	System	1862	92.4		
Total		2015	100.0		

N	Minimum	Maximum	Mean	Median	Std. Deviation
153	.50	7.00	2.00	1	1.55

Table 24 Consult with other than prescriber (mins) pharmacist

In only 7.6% of instalments the pharmacist spoke to someone other than the prescriber. In 81.7% of cases this conversation took less than or equal to 3 minutes. This includes communication with the patient/carer.

Technician consult with other than prescriber		Frequency	Percent	Valid Percent
Valid	2.00	1	.0	100.0
Missing	System	2014	100.0	
Total		2015	100.0	

N	Minimum	Maximum	Mean	Median	Std. Deviation
1	2.00	2.00	2.00	2	.

Table 25 Consult with other than prescriber (mins) dispensing technician

There was only one reported case of a technician speaking to someone other than the prescriber; the conversation took 2 minutes.

7.3.2 Statistical summary and comparison of instalment data

Tables 26 and 27 present composite summaries of times taken to perform the DII component tasks.

Table 26 shows the number of times each component task was reported and summarises the reported times. The means in this table represent the average time each task took when it was actually performed. Means for different tasks cannot be meaningfully added because the tasks were performed different numbers of times.

As can be seen in this table and the foregoing individual tables, some of the distributions of responses are very positively skewed, with the majority of times clustered toward the lower end of the scale and a minority forming a long tail of larger values. With such data, the median, which represents the middle value when the data are sorted in order of magnitude, is more indicative of a “typical” value than the mean. Notwithstanding this, the mean is a better indication of the long term average time cost of providing the DII service, because it is based on spreading the total cost incurred evenly across all instalments. The occasional instalment requiring an unusually long time does in fact incur a high cost, which should properly be reflected in an increased estimate of average cost.

Item	N	Minimum	Maximum	Mean	Median	Std. Deviation
Dispense & set up (mins): pharmacist	398	1.00	15.00	2.79	2	1.99
Dispense & set up (mins): dispensing technician	185	1.00	5.00	1.72	1	1.14
Supply the instalment (mins): pharmacist	1880	.50	8.00	2.39	2	1.335
Supply the instalment (mins): dispensing technician	163	1.00	3.00	2.18	3	0.94
Deliver the instalment (mins): pharmacist	180	1.00	7.00	1.91	2	0.51
Deliver the instalment (mins): dispensing technician	88	1.00	2.00	1.95	2	0.21
Consult with the prescriber (mins): pharmacist	116	.50	9.00	2.79	2	2.11
Consult with the prescriber (mins): dispensing technician	8	1.00	1.00	1.00	1	0.00
Consult with someone other than the prescriber (mins): pharmacist	153	.50	7.00	2.00	1	1.55
Consult with someone other than the prescriber (mins): dispensing technician	1	2.00	2.00	2.00	2	.

Table 26 Time taken for each component task of dispensing in instalments

Item	N	Minimum	Maximum	Mean	Std. Deviation
Dispense & set up (mins): pharmacist	2015	.00	15.00	0.55	1.42
Dispense & set up (mins): dispensing technician	2015	.00	5.00	0.15	0.61
Supply an instalment (mins): pharmacist	2015	.00	8.00	2.23	1.41
Supply an instalment (mins): dispensing technician	2015	.00	3.00	0.18	0.65
Deliver an instalment (mins): pharmacist	2015	.00	7.00	0.17	0.56
Deliver an instalment (mins): dispensing technician	2015	.00	2.00	0.09	0.40
Consult with the prescriber (mins): pharmacist	2015	.00	9.00	0.16	0.82
Consult with the prescriber (mins): dispensing technician	2015	.00	1.00	<0.01	0.06
Consult with someone other than the prescriber (mins): pharmacist	2015	.00	7.00	<0.01	0.68
Consult with someone other than the prescriber (mins): dispensing technician	2015	.00	2.00	<0.01	0.04
Total time for instalment: pharmacist	2015	.00	24.00	3.23	2.55
Total time for instalment: dispensing technician	2015	.00	6.00	0.42	1.24
Total time for instalment	2015	.00	27.00	3.68	2.79
Total time for instalment (excluding dispensing): pharmacist	2015	.00	14.00	2.71	1.91
Total time for instalment (excluding dispensing): dispensing technician	2015	.00	5.00	0.27	1.02
Total time for instalment (excluding dispensing)	2015	.00	14.00	2.98	1.91

Table 27 Time taken for each component task of dispensing in instalments (zeros included)

Large proportions of missing values representing legitimate null data occurred in the questions relating to activities that did not occur with every instalment, including dispensing (Tables 16 and 17), delivery (Tables 20 and 21) and consultation (Tables 22-25). When these null values are converted to the zero values that they actually represent, the effect is that when mean times are calculated, the time devoted to these intermittent activities is distributed across all instalment events. Table 27 summarises the times taken for each task in all 2015 reported instalments, including all the zero times when a particular component task was not performed. Total times (with and without the dispensing component) have also been calculated for each instalment. It can be seen that the mean of each total is the sum of the means of its individual components. The means in this table can be meaningfully added in this way because the total time reported in the trial for each component task has in effect been uniformly spread (“amortised”) across all 2015 instalments.

The mean of the total time excluding dispensing is the most crucial for determining the labour cost of DII, because the pharmacy is already remunerated for the dispensing component. The dominant component is the pharmacist supplying an instalment, since this component is present in most instances.

Reference will be made to this table when calculating an appropriate level of remuneration for DII.

Type of container		Frequency	Percent	Valid Percent
Valid	Own container	712	35.3	35.8
	Capped container	462	22.9	23.2
	Disposable pack	490	24.3	24.6
	Disposable dosing aid	85	4.2	4.3
	Reusable dosing aid	113	5.6	5.7
	No container - consumed in pharmacy	126	6.3	6.3
	Total	1988	98.7	100.0
Missing	System	27	1.3	
Total		2015	100.0	

Table 28 Type of container

In 67.9% of cases the pharmacy supplied the clients with containers. Reference will be made to this table when calculating an appropriate level of remuneration for DII.

Mode of supply		Frequency	Percent	Valid Percent
Valid	Consumed in pharmacy	140	6.9	7.0
	Collected by the consumer	1578	78.3	79.5
	Collected by consumer (consumed first dose)	128	6.4	6.4
	Collected by an agent	49	2.4	2.5
	Delivered	91	4.5	4.6
	Total	1986	98.6	100.0
Missing	System	29	1.4	
Total		2015	100.0	

Table 29 Mode of supply

In the vast majority of cases the consumer collected their own drugs

7.3.3 Limitations of trial data

Data collected in the trial is subject to a number of limitations and potential sources of bias. These include the non-random nature of the sample of participating pharmacies, the reliance on self-reported data, the approximate nature of time estimates (recorded to the nearest minute) and the fact that there were gaps (non-responses) in the data recorded for dispensings and instalments.

The first three of these limitations were inherent in the agreed trial methodology and were accepted on the grounds of feasibility and compliance.

With regard to “missing data”, a distinction must be drawn between incomplete data due to failure to answer relevant questions on the form, and null data - blanks occurring because particular items of data were not applicable in particular circumstances. The first of these is a potential source of bias; the second is not.

Incomplete data occurred predominantly in relatively peripheral questions in the header of the recording form; the highest proportion was 29% of cases, regarding private prescriptions (see Table 5). In such a case, the non-responses may predominantly represent implicit “no” responses.

7.4 Trial pharmacy interviews

The tables below detail the responses from the pharmacists and technician who were interviewed at the completion of the trial. Appendix A21 shows the questionnaire that was asked of the pharmacists and technician. At least one pharmacist from each pharmacy included in the trial was interviewed by the chief investigator at the completion of the data collection phase. In one case a dispensing technician was also interviewed. The results were as follows.

Proprietor	Other Pharmacist	Technician	Total
7	1	1	9
78%	11%	11%	100%

Table 30 Type of respondent

As seen above eight out of the nine interviews were with pharmacists. The one technician that was interviewed had very different responses to the questions, typically answering that the processes were in place before commencement of the job. For questions 1, 2, 4, 5 and 6, the response was “Not Applicable”. For this reason the technician’s responses were excluded from the following analysis.

Q1) Decision Tree for Reporting Anomalies (DT-01)

	Strongly agree	Agree	Neutral/ Uncertain	Disagree	Strongly Disagree	Not Applicable	Total
Represents best practice	1	4	2		1		8
	13%	50%	25%	0%	13%	0%	100%
Is understandable & easy to use	1	4	1	1	1		8
	13%	50%	13%	13%	13%	0%	100%

Table 31 Decision tree for reporting anomalies

In both questions five of the eight respondents felt the Decision Tree for Reporting Anomalies represented best practice and was easily understandable.

Q2) Decision Tree for the Best Practice Model for Dispensing in Instalments (DT-02)

	Strongly agree	Agree	Neutral/ Uncertain	Disagree	Strongly Disagree	Not Applicable	Total
Represents best practice	2	5			1		8
	25%	63%	0%	0%	13%	0%	100%
Is understandable & easy to use	2	5				1	8
	25%	63%	0%	0%	0%	13%	100%

Table 32 Decision tree for best practice model

In both questions seven of the eight respondents felt the Decision Tree for Best Practice Model represented best practice and was easily understandable.

Q3) Trial protocols 1-7

	Strongly agree	Agree	Neutral/ Uncertain	Disagree	Strongly Disagree	Not Applicable	Total
Represents best practice	2	5	1			0	8
	25%	63%	13%	0%	0%	0%	100%
Is understandable & easy to use	3	2	1	1		1	8
	38%	25%	13%	13%	0%	13%	100%

Table 33 Trial protocols

Seven of the eight respondents felt that the Trial Protocols represented best practice. However, only five felt they were easily understandable.

Q4) Prescriber Register (RF-05)

	Strongly agree	Agree	Neutral/ Uncertain	Disagree	Strongly Disagree	Not Applicable	Total
Represents best practice	2	3	1		1	1	8
	25%	38%	13%	0%	13%	13%	100%
Is understandable & easy to use	3	3			1	1	8
	38%	38%	0%	0%	13%	13%	100%

Table 34 Prescriber register

Five respondents felt that the Prescriber Register represented best practice and six felt it was easily understandable.

Q5) Dispensing in Small Quantities Record Sheet (RF-01)

	Strongly agree	Agree	Neutral/ Uncertain	Disagree	Strongly Disagree	Not Applicable	Total
Represents best practice	3	1				4	8
	38%	13%	0%	0%	0%	50%	100%
Is understandable & easy to use	3		1			4	8
	38%	0%	13%	0%	0%	50%	100%

Table 35 Dispensing in small quantities

Only four of the eight respondents had used the Dispensing in Small Quantities record sheet. All four felt that it represented best practice. However, one was uncertain about its ease of use.

Q6) Consumer Register (RF-02)

	Strongly agree	Agree	Neutral/ Uncertain	Disagree	Strongly Disagree	Not Applicable	Total
Represents best practice	1	3	2		2		8
	13%	38%	25%	0%	25%	0%	100%
Is understandable & easy to use	2	3		1	1	1	8
	25%	38%	0%	13%	13%	13%	100%
Were the “reasons for dispensing” adequate?		6	1	1			8
	0%	75%	13%	13%	0%	0%	100%

Table 36 Consumer register

Four respondents felt that the Consumer Register represented best practice and five felt it was easily understandable. Six respondents thought the reasons for dispensing included on the form were adequate.

Q7) Dispensing in Instalments Record Form (RF-03)

	Strongly agree	Agree	Neutral/ Uncertain	Disagree	Strongly Disagree	Not Applicable	Total
Represents best practice	3	4		1			8
	38%	50%	0%	13%	0%	0%	100%
Is understandable & easy to use	3	2	1	1	1		8
	38%	25%	13%	13%	13%	0%	100%
Extra: Were the times captured adequately	1	4	1		2		8
	13%	50%	13%	0%	25%	0%	100%

Table 37 Dispensing in instalment record form

Seven respondents felt that the Dispensing in Instalments record form represented best practice and five felt it was easily understandable.

Q8) Cost of the instalment containers

Capped container	Disposable pack	Disposable dispensing aid	Re-usable dosing aid
\$ 0.02	\$ 0.21		
\$ 0.05	\$ 0.50		
\$ 0.07			
\$ 0.07			
\$ 0.15			
\$ 0.22			
\$ 0.24			

Table 38 Cost of instalment container

Respondents all charged a variety of amounts for capped containers, and two charged for disposable packs. No pharmacies charged for the other two containers.

Q10) If a package of decision trees, protocols, consumer register (or perhaps individual consumer cover sheet), and Dispensing by Instalments Record Form (RF-03) with the time recording aspect removed, were distributed by the Guild, would you use it?

Yes	Probably	Maybe	Probably not	No	Total
5		1	2		8
63%	0%	13%	25%	0%	

Table 39 Would you use a pack?

Five respondents said they would use a best practice model pack if it were available.

It should be noted that those respondents who answered negatively did not generally disagree with the need for protocols or with the content of the proposed protocols. In most cases they regarded the protocols and recording forms used in the trial as duplication of existing procedures and of data collected and recorded in their computer systems.

7.5 Consumers

Pharmacists in the trial pharmacies were requested to recruit volunteer consumers for post-trial interviews. The intention was for potential interviewees to be selected by the trial pharmacies from their client base trying to ensure a broad cross section of consumers from the project target groups:

- Consumers who have a drug dependency (illicit or prescription) who have a therapeutic need for a drug with dependency properties.
- Consumers who have a psychiatric condition who may misuse the medication.
- Consumers who have a cognitive deficit which may be caused by a psychiatric condition, intellectual disability, or ageing.

Consent was to be gained from these clients.

Of the clients selected it was intended that pharmacists would make a confidential approach to selected consumers who they considered may be capable of participating in an interview to evaluate the trial protocols. The aim was that each pharmacy should attempt to recruit three potential interviewees from among the trial consumers; if possible, one from each of the target groups.

However, in practice recruiting clients for an interview was problematic for the pharmacies due to general reluctance to become involved and the erratic behaviour of many of the consumers.

Appointments were made with a sample of consumers, however all but one failed to keep their appointments.

Very little information can be deduced from an analysis of this single interview with a consumer. The consumer was uninterested in the process.

7.6 General pharmacy survey

A questionnaire (see Appendix A21) was designed in consultation with key informants and was approved by both the Steering Committee and the Pharmacy Guild. On the advice of the Guild, the form was limited to two pages in length to encourage pharmacists to complete it. The questionnaire was distributed via the Guild newsletter to some 4000 Guild members. Four hundred and seven responses were received by the deadline date of January 31, 2006. Advice from the Guild was that a response rate of 5% could be expected, and so the response rate of 10%, whilst low by general survey standards, was encouraging.

7.6.1 Limitations of the survey of pharmacists

An anonymous self-completion fax-back methodology was used to survey pharmacists for reasons of privacy and feasibility. It must be stressed that the group of pharmacists who responded to the survey of pharmacists does not constitute a random sample. The statistical inferences made in this report are predicated on the assumption that the survey respondents were a representative sample (equivalent to a random sample) of the whole population of pharmacists. However, because of the voluntary nature of the survey and the low response rate, there is a strong possibility that the validity of the interpretations and conclusions might be undermined to some degree by self-selection bias; i.e. there may be important differences between the characteristics, practices, attitudes and opinions of pharmacists with whom contact was made and who chose to respond, and those who were either not contacted, or who declined to participate. Hence the sample data might not be representative of the population of pharmacists as a whole. This is an inherent risk in self-completion surveys of this kind.

Further, there is always potential conflict between providing background information to establish relevance and encourage participation in a survey and minimising the risk of bias due to responses being tailored to achieve particular outcomes. The wording of the covering letter, which was determined in consultation with the Steering Committee and the Guild, was regarded as striking an appropriate balance with regard to these competing objectives.

7.6.2 Analysis of survey responses

State		Frequency	Percent	Valid Percent
Valid	NT	1	.2	.2
	NSW & ACT	147	36.1	36.2
	VIC	101	24.8	24.9
	QLD	70	17.2	17.2
	SA	42	10.3	10.3
	WA	25	6.1	6.2
	TAS	20	4.9	4.9
	Total	406	99.8	100.0
Missing	System	1	.2	
Total		407	100.0	

Table 40 Geographical Distribution by State

The total responses to the survey were 407 with the majority of responses coming from NSW (36.2%) followed by Victoria (24.9%); the response profile was broadly proportional to the state populations.

			Geographical location		Total
			Capital city	Regional/rural	
State	NT	Count	0	1	1
		% within State	0.0	100.0	100.0
	NSW & ACT	Count	59	87	146
		% within State	40.4	59.6	100.0
	Vic	Count	48	52	100
		% within State	48.0	52.0	100.0
	Qld	Count	26	44	70
		% within State	37.1	62.9	100.0
	SA	Count	25	17	42
		% within State	59.5	40.5	100.0
	WA	Count	18	7	25
		% within State	72.0	28.0	100.0
	TAS	Count	6	13	19
		% within State	31.6	68.4	100.0
Total		Count	182	221	403
		% within State	45.2	54.8	100.0

Table 41 Geographical Distribution within States

Table 41, which is based on an analysis of postcodes, shows that within each state and territory except NT, both capital cities and regional/rural areas were well represented within the survey sample, though the proportions varied, particularly in the less populous states. Overall, just under half of the responding pharmacies were in capital cities. By comparison, of the six trial pharmacies, three were in Sydney, one in Darwin, and two in regional Victoria (Table 2).

Number of S4&S8 OTMB clients per week		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Less than 10	141	34.6	37.5	37.5
	10-19	39	9.6	10.4	47.9
	20-29	30	7.4	8.0	55.9
	30-39	19	4.7	5.1	60.9
	40-49	7	1.7	1.9	62.8
	50-99	19	4.7	5.1	67.8
	100-199	16	3.9	4.3	72.1
	200-499	32	7.9	8.5	80.6
	500-999	48	11.8	12.8	93.4
	1000+	25	6.1	6.6	100.0
	Total	376	92.4	100.0	
Missing	System	31	7.6		
Total		407	100.0		

N	Minimum	Maximum	Mean	Median	Std. Deviation
376	.0	2000.0	213.75	20	375.96

Table 42 Number of clients per week DII or SD dispensed to

It should be noted that the profile in this and a number of the following tables is positively skewed; the majority cluster toward the lower end of the scale with a minority forming a long tail of larger values. This is not immediately obvious in the tables because the range of the categories has been progressively increased to compensate for the progressive sparseness of the data values.

Out of the total sample 37.5% of respondents reported seeing less than 10 S4 & S8 OTMB clients per week. At the other end of the scale 25 respondents (6.1%) said they see 1000+ S4 & S8 OTMB clients. As a result of the widely divergent responses the mean is 213.75 but with a very large standard deviation.

No. per week requiring DII or SD		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	None	67	16.5	17.0	17.0
	Up to 1	71	17.4	18.1	35.1
	1.1 - 2	61	15.0	15.5	50.6
	2.1 - 3	51	12.5	13.0	63.6
	3.1 - 4	23	5.7	5.9	69.5
	4.1 - 5	26	6.4	6.6	76.1
	5.1 - 10	53	13.0	13.5	89.6
	10.1 - 20	22	5.4	5.6	95.2
	20.1 - 50	10	2.5	2.5	97.7
	>50	9	2.2	2.3	100.0
	Total	393	96.6	100.0	
Missing	System	14	3.4		
Total		407	100.0		

N	Minimum	Maximum	Mean	Median	Std. Deviation
393	.0	650.0	8.72	2	42.25

Table 43 Number per week requiring DII or SD

A small proportion of respondents gave a numerical range, in which case the midpoint was used. This resulted in a small number of fractional values – hence the numerical ranges in the table.

Sixty seven or 17% of respondents said that they do not use DII or SD for their S4 & S8 clients; a further 285 or 72.6% said they service less than or equal to 10 S4 & S8 clients requiring DII or SD. Only 10.4% service greater than 10 S4 & S8 clients requiring DII or SD per week. The mean of the data is 8.72 reflecting the great number of responses less than or equal to 10. With a large positive skew the standard deviation is quite large – 42.25.

Contacts per week involved in DII or SD for S4 & S8 clients		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	None	64	15.7	16.6	16.6
	Up to 1	55	13.5	14.2	30.8
	1.1 - 2	34	8.4	8.8	39.6
	2.1 - 3	24	5.9	6.2	45.9
	3.1 - 4	27	6.6	7.0	52.8
	4.1 - 5	16	3.9	4.1	57.0
	5.1 - 10	81	19.9	21.0	78.0
	10.1 - 20	47	11.5	12.2	90.2
	20.1 - 50	28	6.9	7.3	97.4
	>50	10	2.5	2.6	100.0
	Total	386	94.8	100.0	
Missing	System	21	5.2		
Total		407	100.0		

N	Minimum	Maximum	Mean	Median	Std. Deviation
386	.0	600.0	9.98	4	32.67

Table 44 Contacts per week involving DII or SD

A small proportion of respondents gave a numerical range, in which case the midpoint was used. This resulted in a small number of fractional values – hence the numerical ranges in the table.

Respondents indicated that in 78% of cases they had less than 10 contacts per week requiring DII or SD; with a further 12.2% having between 10.1 and 20 contacts per week requiring DII or SD. The mean in this instance is 9.98 but with a large positive skew causing the standard deviation to be quite large – 32.67.

Comparison with Table 12 reveals that the six pharmacies involved in the DII trials fell towards the high end of this distribution. Average contacts per week ranged from 6.6 to 42.0, and the overall trial average was 19.0 contacts per pharmacy per week, which is around the 90th percentile of the survey distribution. This is not surprising, since pharmacies engaged for the trial were required to have substantial levels of DII activity.

No. per week private prescriptions		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	None	141	34.6	41.6	41.6
	Up to 5	99	24.3	29.2	70.8
	5.1 - 10	43	10.6	12.7	83.5
	10.1 - 20	26	6.4	7.7	91.2
	20.1 - 50	17	4.2	5.0	96.2
	>50	13	3.2	3.8	100.0
	Total	339	83.3	100.0	
Missing	System	68	16.7		
Total		407	100.0		

N	Minimum	Maximum	Mean	Median	Std. Deviation
339	.0	350.0	9.44	1	27.18

Table 45 Number per week PBS scripts written as private

A small proportion of respondents gave a numerical range, in which case the midpoint was used. This resulted in a small number of fractional values – hence the numerical ranges in the table.

Pharmacists responded that in 41.6% of cases private prescriptions were not received; a further 49.6% had between 1 and less than or equal to 20 private prescriptions per week. The large maximum value has skewed the data somewhat with the mean being 9.44 and the standard deviation quite large at 27.18.

FTE Pharmacists		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	None	16	3.9	4.3	4.3
	One	164	40.3	43.6	47.9
	1.1 - 2.0	119	29.2	31.6	79.5
	2.1 - 3.0	59	14.5	15.7	95.2
	More than 3.0	18	4.4	4.8	100.0
	Total	376	92.4	100.0	
Missing	System	31	7.6		
Total		407	100.0		

N	Minimum	Maximum	Mean	Median	Std. Deviation
376	.00	30.00	1.76	1.35	1.77

Table 46 EFT pharmacists on staff

The zeros and many of the missing values may represent sole traders who do not classify themselves as being on-staff. Also a few of the missing values were from respondents who did not understand the term “FTE”. If we assume the zeros and missing values were sole

owner traders and include them in the 1 FTE category; then 47.9% of respondents are single pharmacist pharmacies. The mean value for FTE pharmacists is 1.77 per pharmacy.

% DII from single prescription		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	0	56	13.8	17.2	17.2
	0.01 - 25	41	10.1	12.6	29.8
	26 - 50	61	15.0	18.8	48.6
	51 - 75	20	4.9	6.2	54.8
	76 - 99.99	40	9.8	12.3	67.1
	100	107	26.3	32.9	100.0
	Total	325	79.9	100.0	
Missing	System	82	20.1		
Total		407	100.0		

	N	Minimum	Maximum	Mean	Median	Std. Deviation
Single prescription supplied by DII	325	.00	100.00	57.88	60	39.81
Multiple repeat prescriptions supplied by DII	325	.00	100.00	41.87	40	39.83

Table 47 Percentage of DII arising from single prescription

The percentage of DII arising from single prescriptions (as opposed to multiple repeat prescriptions) is fairly evenly spread across the full range from zero (17.2% of case) to 100% (32.9% of cases).

The mean value for the percentage of DII arising from single prescriptions is 57.88% with a very wide standard deviation of 39.81%. From the opposite perspective, the mean value for the percentage of DII arising from multi-repeat prescriptions is 41.87% with a standard deviation of 39.83%.

% DII where instalment much smaller than script		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	0	22	5.4	6.8	6.8
	1 - 25	14	3.4	4.3	11.2
	26 - 50	18	4.4	5.6	16.8
	51 - 75	7	1.7	2.2	18.9
	76 - 99	48	11.8	14.9	33.9
	100	213	52.3	66.1	100.0
	Total	322	79.1	100.0	
Missing	System	85	20.9		
Total		407	100.0		

	N	Minimum	Maximum	Mean	Median	Std. Deviation
Instalment is similar in size to prescription quantity	322	.00	100.00	15.15	0	30.58
Instalment is much smaller in size than prescription quantity	322	.00	100.00	84.13	100	31.41

Table 48 Percentage of DII where instalment size is much smaller than prescription quantity

Respondents were asked in what percentage of DII was the instalment much smaller in size than the prescription quantity. For the great majority of respondents, instalments are much smaller in size than the prescription quantity, either in all cases (67% of respondents) or in more than 75% of cases (a further 15% of respondents).

The mean value for the percentage of instalments which are much smaller in size than prescription quantity is 84.13%. This supports the expectation that DII is done to limit the take home amount of a drug a client is given.

Use of containers	Rarely/Never		Sometimes		Often		Total	
	Count	%	Count	%	Count	%	Count	%
Consumer's own container	278	79.7	50	14.3	21	6.0	349	100
Capped container	86	23.5	99	27.0	181	49.5	366	100
Disposable pack	145	43.4	88	26.3	101	30.2	334	100
Disposable dispensing aid	205	62.3	70	21.3	54	16.4	329	100
Re-usable dosing aid	210	64.6	70	21.5	45	13.8	325	100

Table 49 Use of instalment containers

The great majority of pharmacists (79.7%) reported rarely or never using the consumer's own container. It is most likely that a capped container (often 49.5%; sometimes 27.0%) or disposable pack (often 30.2%; sometimes 26.3%) would be used.

Charge for containers	Rarely/Never		Sometimes		Often		Total	
	Count	%	Count	%	Count	%	Count	%
Capped container	283	82.3	34	9.9	27	7.8	344	100
Disposable pack	272	88.3	15	4.9	21	6.8	308	100
Disposable dispensing aid	232	77.9	16	5.4	50	16.8	298	100
Re-usable dosing aid	246	83.4	24	8.1	25	8.5	295	100

Table 50 Charge for instalment container

The majority of pharmacies (greater than 80%) responded for all types of containers that they rarely charged for the container.

7.6.3 Charge for capped container

Whilst the survey question was framed in terms of a charge per unit, a number of respondents charge on a weekly basis (and in one case on a monthly basis). Hence two sets of tables have been produced – per container and per week.

Charge (\$) per instalment		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	.20	1	.2	1.6	1.6
	.25	1	.2	1.6	3.2
	.30	2	.5	3.2	6.3
	.45	1	.2	1.6	7.9
	.50	16	3.9	25.4	33.3
	.60	1	.2	1.6	34.9
	1.00	25	6.1	39.7	74.6
	1.10	1	.2	1.6	76.2
	1.20	1	.2	1.6	77.8
	1.75	1	.2	1.6	79.4
	2.00	12	2.9	19.0	98.4
	5.00	1	.2	1.6	100.0
	Total	63	15.5	100.0	
Missing	System	344	84.5		
Total		407	100.0		

N	Minimum	Maximum	Mean	Median	Std. Deviation
63	.20	5.00	1.08	1	.75

Table 51 Charge for capped instalment container

Container charges ranged between \$0.20 and \$5 with the vast majority of pharmacies charging \$0.50 (25.4%) and \$1 (39.7%). The mean value was \$1.08.

Weekly charge (\$)		Frequency	Percent	Valid Percent
Valid	5.00	1	.2	100.0
Missing	System	406	99.8	
Total		407	100.0	

Table 52 Weekly charge for capped instalment containers

Only one respondent charged \$5 weekly for a capped container.

Charge for disposable pack (\$)		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	.50	2	.5	5.6	5.6
	.60	2	.5	5.6	11.1
	1.00	8	2.0	22.2	33.3
	1.50	1	.2	2.8	36.1
	2.00	7	1.7	19.4	55.6
	2.50	2	.5	5.6	61.1
	3.00	4	1.0	11.1	72.2
	3.50	2	.5	5.6	77.8
	3.80	2	.5	5.6	83.3
	4.00	3	.7	8.3	91.7
	5.00	2	.5	5.6	97.2
	5.50	1	.2	2.8	100.0
	Total	36	8.8	100.0	
Missing	System	371	91.2		
Total		407	100.0		

N	Minimum	Maximum	Mean	Median	Std. Deviation
36	.50	5.50	2.36	2	1.41

Table 53 Charge for disposable pack

The price of disposable packs ranged from \$0.50 to \$5.50 with the majority charging \$1 (22.2%) and \$2 (19.4%). The mean charge is \$2.36.

Weekly charge (\$ for disposable pack		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	3.00	1	.2	25.0	25.0
	4.00	1	.2	25.0	50.0
	5.00	1	.2	25.0	75.0
	5.50	1	.2	25.0	100.0
	Total	4	1.0	100.0	
Missing	System	403	99.0		
Total		407	100.0		

N	Minimum	Maximum	Mean	Median	Std. Deviation
4	3.00	5.50	4.38	4.5	1.11

Table 54 Weekly charge for disposable packs

Only four respondents charged between \$3 and \$5.50 per week for a disposable pack. The mean charge was \$4.38.

Charge (\$) for disposable dispensing aid		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	.60	1	.2	1.7	1.7
	1.00	5	1.2	8.5	10.2
	2.00	6	1.5	10.2	20.3
	2.50	6	1.5	10.2	30.5
	2.60	1	.2	1.7	32.2
	2.75	1	.2	1.7	33.9
	3.00	18	4.4	30.5	64.4
	3.80	2	.5	3.4	67.8
	4.00	7	1.7	11.9	79.7
	4.40	1	.2	1.7	81.4
	4.50	1	.2	1.7	83.1
	4.70	2	.5	3.4	86.4
	5.00	5	1.2	8.5	94.9
	5.50	3	.7	5.1	100.0
	Total	59	14.5	100.0	
Missing	System	348	85.5		
Total		407	100.0		

N	Minimum	Maximum	Mean	Median	Std. Deviation
59	.60	5.50	3.18	3	1.24

Table 55 Charge for disposable dispensing aid

The price of disposable dispensing aids ranged from \$0.60 to \$5.50 with the majority charging \$3 (30.5%). The mean charge was \$3.18.

Weekly disposable dispensing aid charge (\$)		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	2.50	1	.2	7.1	7.1
	3.00	6	1.5	42.9	50.0
	3.30	1	.2	7.1	57.1
	3.50	1	.2	7.1	64.3
	4.00	3	.7	21.4	85.7
	4.50	1	.2	7.1	92.9
	5.00	1	.2	7.1	100.0
	Total	14	3.4	100.0	
Missing	System	393	96.6		
Total		407	100.0		

N	Minimum	Maximum	Mean	Median	Std. Deviation
14	2.50	5.00	3.49	3.15	.71

Table 56 Weekly charge for disposable dispensing aids

Only 14 respondents charged weekly for disposable dispensing aids ranging in price from \$2.50 to \$5.00. The majority charged \$3 (42.9%) with the mean charge \$3.49.

Charge (\$) for re-usable dosing aid		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	.50	1	.2	2.6	2.6
	1.00	3	.7	7.9	10.5
	2.00	6	1.5	15.8	26.3
	2.50	4	1.0	10.5	36.8
	2.60	1	.2	2.6	39.5
	2.75	1	.2	2.6	42.1
	3.00	1	.2	2.6	44.7
	3.50	4	1.0	10.5	55.3
	4.00	4	1.0	10.5	65.8
	4.50	1	.2	2.6	68.4
	4.70	2	.5	5.3	73.7
	5.00	1	.2	2.6	76.3
	8.00	1	.2	2.6	78.9
	10.00	1	.2	2.6	81.6
	10.95	1	.2	2.6	84.2
	20.00	1	.2	2.6	86.8
	22.00	1	.2	2.6	89.5
	28.00	1	.2	2.6	92.1
	33.00	1	.2	2.6	94.7
	40.00	2	.5	5.3	100.0
	Total	38	9.3	100.0	
Missing	System	369	90.7		
Total		407	100.0		

N	Minimum	Maximum	Mean	Median	Std. Deviation
38	.50	40.00	7.76	3.5	10.70

Table 57 Charge for re-usable dosing aid

38 respondents charge for re-usable dosing aids ranging in price from \$0.50 to \$40. The majority charged \$2 (15.8%). There is a large variation in the responses to this question – possibly due to the variety and cost of these packs to the pharmacy. The mean charge is \$7.76 but with a large standard deviation.

Additional charge for DII		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Rarely/Never	294	72.2	78.2	78.2
	Sometimes	27	6.6	7.2	85.4
	Often	55	13.5	14.6	100.0
	Total	376	92.4	100.0	
Missing	System	31	7.6		
Total		407	100.0		

Table 58 Extent of charging an additional fee

Except for rare occasions, a DII fee is charged by only 22% of the 376 respondents who answered this question.

The following question was framed in terms of a charge per instalment or per prescription, and respondents were invited to nominate any other basis. Twenty nine respondents charge on a weekly basis, and five reported charging a fee per day, though it is not clear how that differs from a fee per instalment. Hence four tables have been produced.

Fee (\$) per Instalment		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	.00	1	.2	1.9	1.9
	.50	1	.2	1.9	3.7
	.60	2	.5	3.7	7.4
	.70	1	.2	1.9	9.3
	1.00	16	3.9	29.6	38.9
	2.00	10	2.5	18.5	57.4
	2.50	3	.7	5.6	63.0
	2.60	1	.2	1.9	64.8
	3.00	4	1.0	7.4	72.2
	3.75	1	.2	1.9	74.1
	4.00	4	1.0	7.4	81.5
	4.70	3	.7	5.6	87.0
	5.00	6	1.5	11.1	98.1
	7.50	1	.2	1.9	100.0
	Total	54	13.3	100.0	
Missing	System	353	86.7		
Total		407	100.0		

N	Minimum	Maximum	Mean	Median	Std. Deviation
54	.00	7.50	2.44	2	1.67

Table 59 Fee per instalment

There is a wide range charged per instalment but the mean is \$2.44 with a standard deviation of \$1.67.

Fee (\$) per script		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	2.00	2	.5	20.0	20.0
	4.70	1	.2	10.0	30.0
	5.00	5	1.2	50.0	80.0
	10.00	2	.5	20.0	100.0
	Total	10	2.5	100.0	
Missing	System	397	97.5		
Total		407	100.0		

N	Minimum	Maximum	Mean	Median	Std. Deviation
10	2.00	10.00	5.37	5	2.72

Table 60 Fee per prescription

There is a wide range charged per script but the mean is \$5.37 with a standard deviation of \$2.72.

Fee (\$) per day		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	.70	1	.2	20.0	20.0
	2.00	2	.5	40.0	60.0
	2.50	1	.2	20.0	80.0
	4.00	1	.2	20.0	100.0
	Total	5	1.2	100.0	
Missing	System	402	98.8		
Total		407	100.0		

N	Minimum	Maximum	Mean	Median	Std. Deviation
5	.70	4.00	2.24	2	1.19

Table 61 Fee per day

There is a range charged per day has a mean of \$2.24 with a standard deviation of \$1.19.

Fee (\$) per week		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	.25	1	.2	3.4	3.4
	1.00	1	.2	3.4	6.9
	2.50	2	.5	6.9	13.8
	2.60	1	.2	3.4	17.2
	2.70	1	.2	3.4	20.7
	3.00	3	.7	10.3	31.0
	3.20	1	.2	3.4	34.5
	3.50	1	.2	3.4	37.9
	4.00	2	.5	6.9	44.8
	5.00	9	2.2	31.0	75.9
	7.00	1	.2	3.4	79.3
	10.00	1	.2	3.4	82.8
	20.00	1	.2	3.4	86.2
	21.00	1	.2	3.4	89.7
	25.00	2	.5	6.9	96.6
	35.00	1	.2	3.4	100.0
	Total	29	7.1	100.0	
Missing	System	378	92.9		
Total		407	100.0		

N	Minimum	Maximum	Mean	Median	Std. Deviation
29	.25	35.00	7.70	5	8.62

Table 62 Fee per week

There is a wide range in the amount being charged per week. The mean is \$7.70 with a large standard deviation of \$8.62.

	N	Minimum	Maximum	Mean	Median	Std. Deviation
Dispense and set up (mins): pharmacist	333	1.00	120.00	9.02	5	11.24
Dispense and set up (mins): dispensing technician	103	1.00	240.00	9.93	5	24.09
Supply a DII instalment (mins): pharmacist	318	1.00	30.00	4.27	3	4.22
Supply a DII instalment (mins): dispensing technician	71	1.00	120.00	6.96	5	14.27
Supply a SD instalment (mins): pharmacist	178	.50	60.00	4.48	3	5.96
Supply a SD instalment (mins): dispensing technician	37	1.00	15.00	4.92	5	3.47
Deliver an instalment (mins): pharmacist	144	.50	60.00	6.09	3	8.25
Deliver an instalment (mins): dispensing technician	54	1.00	120.00	15.02	10	17.88
Prescriber consultation (mins): pharmacist	273	.20	30.00	5.70	5	4.24
Prescriber consultation (mins): dispensing technician	25	1.00	60.00	8.44	5	11.51
Other DII consultation (mins): pharmacist	187	1.00	60.00	5.35	5	5.88
Other DII consultation (mins): dispensing technician	21	1.00	30.00	8.33	5	7.21

Table 63 Component task statistical summary

Table 63 summarises the estimated times for each component task and shows the number of respondents who provided an estimate for each component. The means in this table represent the average estimated time for each task.

Some of the distributions of responses are very positively skewed, with the majority of times clustered toward the lower end of the scale and a minority forming a long tail of larger values. With such data, the median, which represents the middle value when the data are sorted in order of magnitude, is more indicative of a typical value than the mean. The skew is in part due to the presence of a small number of very high estimates in the survey data. The influence of such extreme values is reflected in the differences between the mean and median values, which are generally larger than is the case in the trial data. The issue here is very different from that discussed in the context of the trial data. In the trial, the “cases” were actual instances of instalments, and the most extreme values which occurred were just as valid as any other. However in the survey context, the “cases” are the estimates made by each pharmacist, and the question arises as to whether extreme divergent estimates should be accorded the same credence as more consistent estimates. Hence there is some justification for using the medians of the estimates rather than means of the estimates in this case.

It is not possible to calculate an estimated time for a typical instalment by simply adding the mean or median times for each task because the tasks are not all performed in every case.

However, the trial data could be used to estimate the proportion of occasions on which each component is performed, and a sum of mean or median times, weighted according to these proportions, could be calculated. Because pharmacies are already remunerated for the dispensing component, it is appropriate to exclude this component from an assessment of the labour cost of DII. The dominant component is the pharmacist supplying an instalment, since the trial data shows that this component is present in most instances.

Clearly, the survey-based estimates of the time required for this and some of the other components are considerably greater than the trial-based estimates. This is in part due to a small number of very high estimates in the survey data, as discussed above. However, this does not completely account for the discrepancy between the survey data and the trial data. There is a broad tendency for the survey-based estimates to be higher than the trial-based observations. In the view of the research team, more credence should be given to the trial data because it is based on the recorded evidence of actual occurrences (albeit self-reported in a limited number of pharmacies), whereas the survey-based data consists of generalized estimates.

	Yes		No		Total	
	Count	%	Count	%	Count	%
Dispensing S4/S8 OTMB drugs in instalments	279	73.8	99	26.2	378	100.0
Supervised dosing for S4/S8 OTMB drugs	246	67.4	119	32.6	365	100.0

Table 64 Would standard procedures and remuneration increase these practices?

Around 75% and 70% respectively say yes.

	Rarely/Never		Sometimes		Often		Total	
	Count	%	Count	%	Count	%	Count	%
Dispensing S4/S8 OTMB drugs in instalments	51	13.2	190	49.2	145	37.6	386	100
Supervised dosing for S4/S8 OTMB drugs	78	24.1	118	36.4	128	39.5	324	100

Table 65 Communication between pharmacist and medical practitioner

In both cases, around 40% of pharmacists report communicating often with the medical practitioner. At the other extreme 13% and 24% respectively report rarely or never.

	Rarely/Never		Sometimes		Often		Total	
	Count	%	Count	%	Count	%	Count	%
Telephone	24	6.4	111	29.7	239	63.9	374	100
Email	245	92.5	13	4.9	7	2.6	265	100
Fax	91	28.5	159	49.8	69	21.6	319	100
Post	156	54.5	98	34.3	32	11.2	286	100
Other	1	11.1	3	33.3	5	55.6	9	100

Table 66 Methods of communication

In this question, missing values (blanks) probably represent “rarely/never”, and so the true “rarely/never” proportions are probably even higher than those shown in the table. Clearly, phone is the preferred medium, with email being used by an extremely small proportion of pharmacists.

	Count	% of Responses	% of Cases
Weekly	50	9.1	13.4
Monthly	90	16.3	24.2
Less than once a month	65	11.8	17.5
At prescription commencement	167	30.3	44.9
At prescription expiry	98	17.8	26.3
Other	82	14.9	22
Total Responses	552	100	148.4
Total Cases	372		

Table 67 Frequency of communication with medical practitioner

This was a multiple response item; respondents could select more than one response, so the percentages of respondents (cases) selecting each response add up to more than 100%.

The most common basis of communication with the medical practitioner is at commencement of the prescription, reported by 45% of the 372 respondents who answered this question.

In the majority of cases where “other” was the response a comment was added to the effect that they rang as required or requested by the doctor.

	Count	% of Responses	% of Cases
Medical practitioner unavailable after hours	143	37.3	62.2
Medical practitioner unavailable for other reasons	134	35	58.3
Messages not delivered in a timely manner	80	20.9	34.8
Other	26	6.8	11.3
Total responses	383	100	166.5
Total cases	230		

Table 68 Issues and difficulties with providing feedback to medical practitioners

Again, this was a multiple response item; respondents could select more than one response, so the percentages of respondents (cases) selecting each response add up to more than 100%.

Of the 230 respondents who reported issues or difficulties with providing feedback to medical practitioners, over half reported unavailability of the medical practitioner, either after hours (62%) or for other reasons (58%).

Where the respondent added a comment or selected the “other” response most of the comments related to the difficulties in contacting prescribers who were locums, hospital based and sessional workers.

7.6.4 Consumer concerns with DII and/or SD?

188 responses to this question were received. The data are extremely difficult to interpret. INVIVO was used to search the comments for common threads. These varied in nature and are listed below. They are not prioritised nor an exhaustive list:

- Concerns over the cost of DII and SD dispensing and the fact these clients often cannot afford to pay for the scripts.
- The consumers are seen as difficult, abusive and unreliable and erratic with little understanding of the legal restraints on the pharmacist.
- These clients take up considerable amount of time and are often non-compliant.
- Clients often assume because they are having a drug dispensed in instalments that the pharmacist will organise repeats and new scripts with the GP. Problems are encountered with client expectation of how much drug will be dispensed per prescription which can lead to aggressive behaviour.
- Clients find the system inconvenient. However, on the flip side, others want less drugs given because they are stolen from them.

7.6.5 What strategies used with this client group

225 responses to this question were received. The data are extremely difficult to interpret. INVIVO was used to search the comments for common threads. These varied in nature and are listed below. They are not prioritised nor an exhaustive list:

- Communication
 - Rules spelt out to the consumer to ensure they know the expectations the pharmacy has for the consumer.
 - Always warned when script running out and when they need to see the doctor for further prescriptions
 - Working closely with the doctors so that the client receives the same story.
 - Running sheet signed by the consumer so they are aware of number of tablets left to be dispensed. In some cases a calendar format was used.
 - Be fair but firm.
- Private rooms and dosing booths to segregate the consumer from the rest of their clients.
- Preparation of the scripts in advance to reduce waiting time for the consumer. The consumer is also expected to come in at the same time each day to avoid waiting times.
- Supervision of the consumer when they are on the premises.
- Charge for initial bottle but if re-used no further charging for containers.
- Scripts and dispensing done in a separate area of the dispensary.

7.6.6 Other comments

190 responses to this question were received. The data are extremely difficult to interpret. INVIVO was used to search the comments for common threads. These varied in nature and are listed below. They are not prioritised nor an exhaustive list:

- Costly expense for the pharmacy with no remuneration. Often dispensing multiple times for one dispensing fee. Many responses alluded to the need for a consistent fee being charged however, the

consumer is also unable to pay. Suggestion that the fee should be paid by a government agency – e.g. PBS, Centrelink or DVA.

- Concerns re the legality of dispensing in instalments
- Time consuming and costly therefore consumers discouraged from using their pharmacy.
- Consumer violence and abuse a major problem.
- Need for guidelines as the current system is unsatisfactory.

8. Cost Calculations

8.1 Labour costs

The minimum Award rate for a "pharmacist after first year of experience" is \$784.80 per 38-hour week (<http://www.wagenet.gov.au/WageNet/Search/view.asp?docid=268851&page=15&quickview=Y>, accessed March 2006). According to the Australian Government *jobsearch* website the average salary for community pharmacists (all ages) is \$1100 per 38-hour week. (<http://jobsearch.gov.au/joboutlook/default.aspx?pagelid=KeyInfo2&AscoCode=2382> accessed March 2006).

However, data from the Pharmacy Post-Registration Graduate Destination Survey, April 2005 (<http://www.vcp.monash.edu.au/news/postregistration-report2005.pdf> accessed March, 2006) indicate that the average salaries paid in community pharmacies are considerably higher than these figures. The median annual salary reported by males working in community pharmacies in their first year post-registration was \$73,000 for a 44-hour week, and by females was \$60,000 for a 40 hour week. It is considered that these figures provide a more realistic benchmark for staff cost calculations.

Assuming a 46-week year (4 weeks annual leave, 2 weeks public holidays) these figures equate to averages of \$1586.96 per 44-hour week or \$36.01 per hour for males, and \$1304.35 per 40-hour week or \$32.61 per hour for females. Whilst the overall median salary for males and females was not reported, the sample sizes for males and females in the graduate survey were 63 and 162 respectively. Weighting the average hourly rates for males and females in these proportions, results in an estimated average salary cost of \$33.56 per hour. Assuming salary on-costs of 25.47%¹, this represents a cost to the pharmacy of \$42.11 per hour. Addition of a 25% profit margin² results in a total labour cost component of \$52.64 per hour, or \$0.88 per minute. The average profit margin as reported by the participating pharmacies was 25%.

In estimating the labour cost per instalment, dispensing time has been excluded because pharmacies are already remunerated by the PBS for dispensing.

8.1.1 Trial data

From the trial data, the mean value of the total time per instalment (excluding dispensing) was 2.98 minutes (see Table 27). Of this, 2.71 minutes (91%) was the pharmacist's time. The accuracy of these means is limited by the fact that times were generally recorded to the nearest minute. Considering this, and given that the percentage of the time attributable to the pharmacist is so high, we can for simplicity cost the total time at the pharmacist rate without substantially affecting the accuracy of the estimate.

This results in an estimated mean cost in the order of $0.88 \times 2.98 = \$2.61$ per instalment.

8.1.2 Survey data

From the survey data, the mean estimated time for supply of an instalment by a pharmacist was 4.27 minutes (see Table 63).

¹ This figure was supplied by the The Pharmacy Guild of Australia.

² The average profit margin as reported by the participating pharmacies.

Estimates were also made for the times for the other components. However because of the intermittent nature of these components, the estimated times cannot simply be added. Instead the following indirect procedure is employed.

In the trial, mean total time per instalment was the 2.98 minutes, of which 2.23 minutes was the mean time for the pharmacist to actually supply an instalment. This represented 75% of the total time of 2.98 minutes. The remaining 25% was made up of small contributions for consultation and delivery by pharmacists, and for the time of dispensing technicians.

If we suppose that the survey mean time of 4.27 minutes for supply of an instalment by the pharmacist represents the same proportion (75%) of the total time per instalment, then this implies a mean total time of 5.69 minutes.

Again assuming that this is predominantly pharmacist time, this results in an estimated mean cost in the order of $0.88 \times 5.69 = \$5.01$ per instalment.

Clearly, the survey-based estimate of the time required, and hence the estimated cost, are considerably greater than the trial-based estimates. This is in part due to a small number of very high estimates in the survey data, as discussed above. However, this does not completely account for the discrepancy between the survey data and the trial data. There is a broad tendency for the survey-based estimates to be higher than the trial-based observations. In the view of the research team, whilst both of the remuneration figures should be interpreted with caution because of the potential biases in both trial and survey methodologies, more credence should be given to the trial data because it is based on the evidence of actual occurrences (albeit self reported, recorded only approximately, and recorded in a limited number of pharmacies), whereas the survey-based data consists of generalized estimates which may well be worst-case or high-end estimates. Hence a remuneration figure closer to \$2.61 would be more justifiable than one closer to \$5.01.

8.2 Container costs

The mean container cost per instalment is estimated by combining information about charges made for containers from the survey (see Table 50) and information about frequency of supplying containers from the trial (see Table 9). Each unit charge is weighted (multiplied) by the proportion of instalments in which the container is supplied, and the resulting figures added (see Table 69). This of course assumes that the charges made represent cost recovery for the containers.

On this basis the mean container cost is estimated to be \$1.41 per instalment.

A dominant component in this estimate is the relatively high cost of re-useable dosing aids. If these are excluded (on the basis that payment by the consumer is feasible and appropriate for these items), then the mean cost of the other types of container is estimated to be \$0.97 per instalment.

Type of container	Percent of instalments: trial (a)	Mean unit charge (\$): survey (b)	Weighted contribution (\$) a×b/100
Own container	35.8		
Capped container	23.2	1.08	0.25
Disposable pack	24.6	2.36	0.58
Disposable dosing aid	4.3	3.18	0.14
Reusable dosing aid	5.7	7.76	0.44
No container - consumed in pharmacy	6.3		
Total	100.0		\$1.41
Total excluding re-useable dosing aids			\$0.97

Table 69 Combined container costing

8.3 Total costs

Using the estimated costs per instalment calculated above, the total annual costs of a remuneration scheme are estimated in Table 70.

Total costs	Labour	Containers	Containers (excluding re-useable dosing aids)
	\$	\$	\$
Mean cost per instalment	2.61	1.41	0.97
Mean instalments/pharmacy/week (Table 43)	9.98	9.98	9.98
Mean cost/pharmacy/week	26.05	14.07	9.68
Mean cost/pharmacy/year	1,354.49	731.73	503.39
Number of pharmacies (Guild membership)	4,000	4,000	4,000
Total cost/year	5,417,942	2,926,934	2,013,565

Table 70 Estimates of total cost of a remuneration scheme

9. Discussion

The Collaborative Centre for eHealth carried out this project to determine a best practice model for dispensing and monitoring of schedule 4 and schedule 8 drugs. The project commenced with a literature review and consultation with key informants to assist in determining best practice. This research enabled the project team to design a best practice model for dispensing S4 and S8 drugs using a dosing in instalments regime. The best practice model included appropriate dispensing and counselling protocols. This model was trialled in six pharmacies, in Ballarat, Sydney and Darwin, for five months. During the trial, data were collected on all S4 and S8 drugs dispensed using a “supervised dosing” regime, but consumer groups affected were limited to those who manage their own medication. Data collected in the trial data also enabled development of an appropriate fee for unit dose medication.

At the end of the trial, pharmacists across Australia were surveyed to ascertain their supervised dosing practices and experiences, and to provide additional data about aspects of the best practice model. In addition, at least one pharmacist from each pharmacy included in the trial was interviewed at the completion of the data collection phase. In one case a dispensing technician was also interviewed. Pharmacists in the trial pharmacies were also requested to recruit volunteer consumers for post-trial interviews. However, in practice recruiting clients for an interview was problematic for the pharmacies due to general reluctance to become involved and the erratic behaviour of many of the consumers. Only one consumer interview was completed. To promote increased participation of consumers and feeling of being valued in future projects, it is worth considering some form of remuneration.

The data collected during the trial and the survey of pharmacists, along with the literature review and in-depth interviews formed the basis of the recommendations in this final report.

The survey-based estimates of the time required for dispensing and hence the estimated costs are considerably greater than the trial-based estimates. This is in part due to a small number of very high estimates in the survey data. However, this does not completely account for the discrepancy between the survey data and the trial data. In the view of the research team, more credence should be given to the trial data because it is based on the evidence of actual occurrences (albeit recorded only approximately, and recorded in a limited number of pharmacies), whereas the survey-based data consists of generalized estimates which may well be worst-case or high-end estimates.

Thus, a labour remuneration figure of \$2.61 and a container remuneration figure of \$0.97 are recommended for containers other than re-useable dosing aids, which it is assumed are generally purchased by the consumer.

There is clear evidence from the study that diazepam and oxycodone are currently the drugs which have the highest risk of dependency and/or diversion. However, it is acknowledged that the nature of the class of drugs could change and that other drugs of a similar nature may present as a high risk for dependency and/or diversion in the future that could be suitable for inclusion in the category for dosing by instalment as routine practice.

Several of the medications administered as DII during the study are used for the treatment of psychoses and do not have dependence-inducing potential. Therefore dispensing by instalments is useful not only for preventing substance abuse but also for poorly compliant patients, usually due to mental illness.

The forms used during the trial should be simplified to make them less research focused and more operationally oriented.

The Consumer Register (RF-02), Prescriber Register (RF-05) and the consent forms are not required.

For the Dispensing in Instalments Record Form (RF-03):

- the Consumer Code field should be deleted and the client name and identifying criteria added to the header so that a single A4 sheet could be used.
- the Prescriber Code field should be deleted and a field for the doctor's name should be added.
- a coded field for the reason for dispensing in instalments could be added although this is not essential.
- the sections relating to time taken for the dispensing, instalment and consultations should be removed; these were included on the trial form to enable costs to be calculated.
- the initial dispensing quantity, the instalment quantity supplied and held and the client /pharmacist signatures need to be retained.

During the trial it was stipulated that a new Dispensing in Instalments Record Form should be used for each prescription dispensed. This would not be necessary if the data were purely for internal pharmacy use.

The key findings from this project are:

- *the need to establish appropriate remuneration for this service;*
- *the need to identify an efficient communication mechanism between general practitioners and pharmacists;*
- *the need for appropriate recording and monitoring of dispensing in instalments;*
- *the need to facilitate appropriate communication between consumers and pharmacists;*
- *there were concerns raised by pharmacists regarding legal and PBS regulations in relation to the storage of drugs that are dispensed in instalments; and*
- Diazepam and oxycodone are drugs with a high risk of dependency and diversion.

10. Conclusion

The project team conducted the project to determine the best practice model. This was informed by a literature review and consultation with specialists. The best practice model was trialled in community pharmacies in Ballarat, Sydney and Darwin. Over 4000 members of the Pharmacy Guild were surveyed by means of a paper based survey to ascertain their views to the best practice model. The information gathered from the trial and the survey led the project team to determine appropriate remuneration costs for dispensing and provision of containers. The project team has put forward six recommendations for action by the Guild.

It is concluded that there is a clear need to use dispensing and counselling protocols for unit dose medication to patients who may be at risk from drugs with dependency properties (Schedule 4 and Schedule 8) and that this service needs to be appropriately remunerated.

11. Recommendations

The objective of the project was to develop a best practice model for the dispensing of S4 and S8 drugs in instalments. The following recommendations are made by the project team to the Pharmacy Guild for action:

Based on the key finding that there is a *need to establish appropriate remuneration for this service as justified by a combination of survey and trial evidence*, it is recommended that:

An appropriate remuneration package should consist of a labour figure of \$2.61 per instalment and a container remuneration figure of \$0.97 per instalment. (Recommendation 1)

Based on the key finding that there is a *need to identify an efficient communication mechanism between general practitioners and pharmacists*, it is recommended that:

A sustainable system to support the communication process (e.g. computer software) should be provided to support referral systems and medication continuance programs. (Recommendation 2.1)

An education package for GPs should be developed and distributed using the general practice network prior to the rollout of the best-practice model to pharmacies nationally. (Recommendation 2.2)

Based on the key finding that there is a *need for appropriate recording and monitoring of dispensing in instalments*, it is recommended that:

The forms used during the trial should form the basis of this practice with some modifications to make them more operationally oriented. (Recommendation 3)

Based on the key finding that there is a *need to facilitate appropriate communication between consumers and pharmacists*, it is recommended that:

Pharmacies providing the service of dispensing in instalments should have a designated private area in the pharmacy where appropriate consultation between pharmacist and consumer can take place. (Recommendation 4)

Based on the key finding that there were *concerns raised by pharmacists regarding legal and PBS regulations in relation to the storage of drugs that are dispensed in instalments*, it is recommended that:

The current state and territory legislations regarding dispensing and storage may require amendment to allow for dispensing in instalments, where drugs are still kept on the pharmacy premises after initial dispensing until all instalments are distributed. (Recommendation 5.1)

The issue of incomplete supply and legal requirements for storage should be further investigated. (Recommendation 5.2)

The procedures for dispensing in instalments should be incorporated into all community pharmacy dispensing computer systems to facilitate electronic claiming. (Recommendation 5.3)

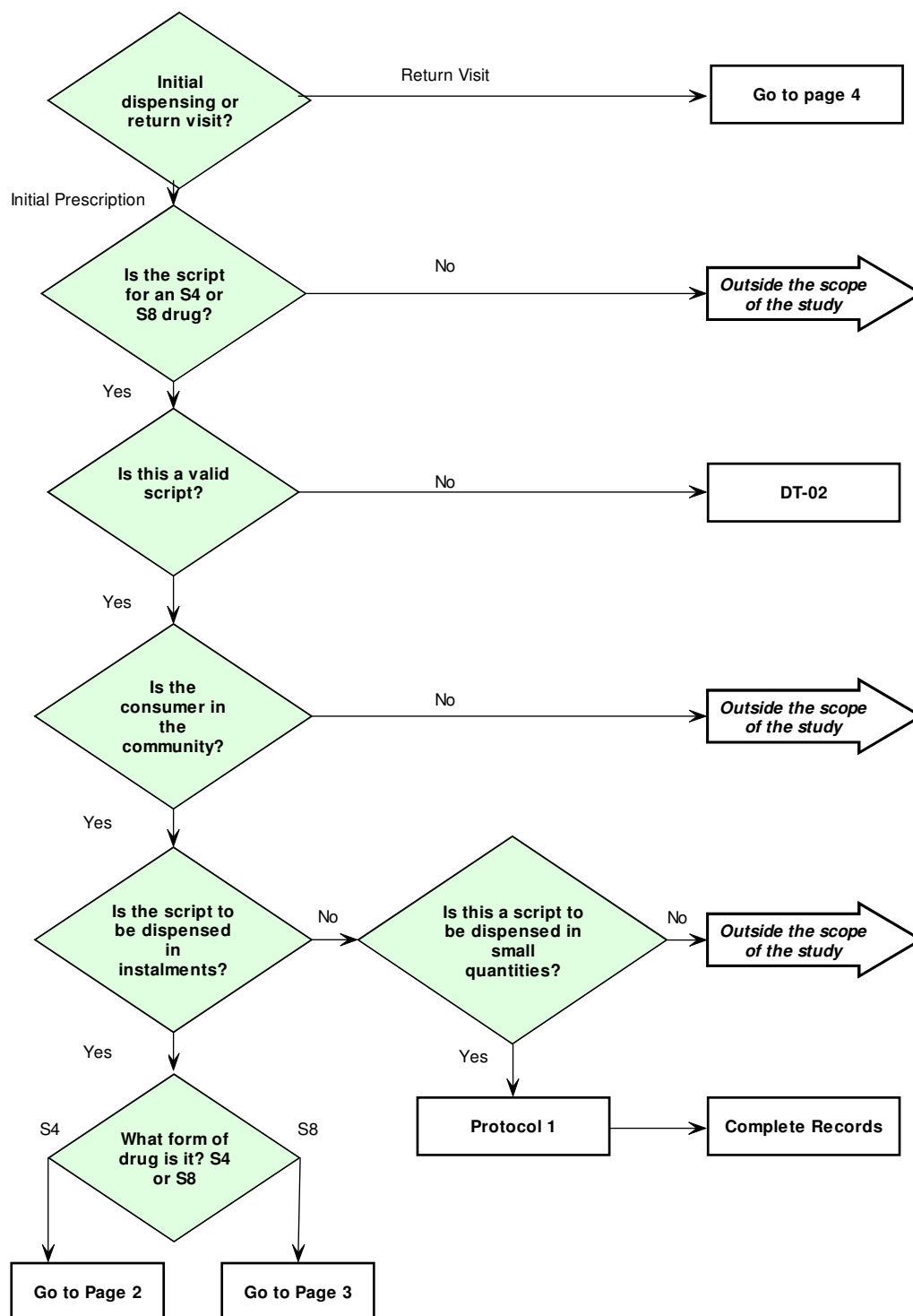
The system should require the prescriber to clearly endorse the prescription that is to be dispensed in instalments, as this is required by Medicare Australia for pharmacy reimbursement. (Recommendation 5.4)

Based on the key finding that diazepam and oxycodone are currently the drugs which have the highest risk of dependency and/or diversion it is recommended that:

Diazepam and oxycodone should be included in the category for dosing by instalments as a routine practice as per Quality Use of Medicines Principles. (Recommendation 6)

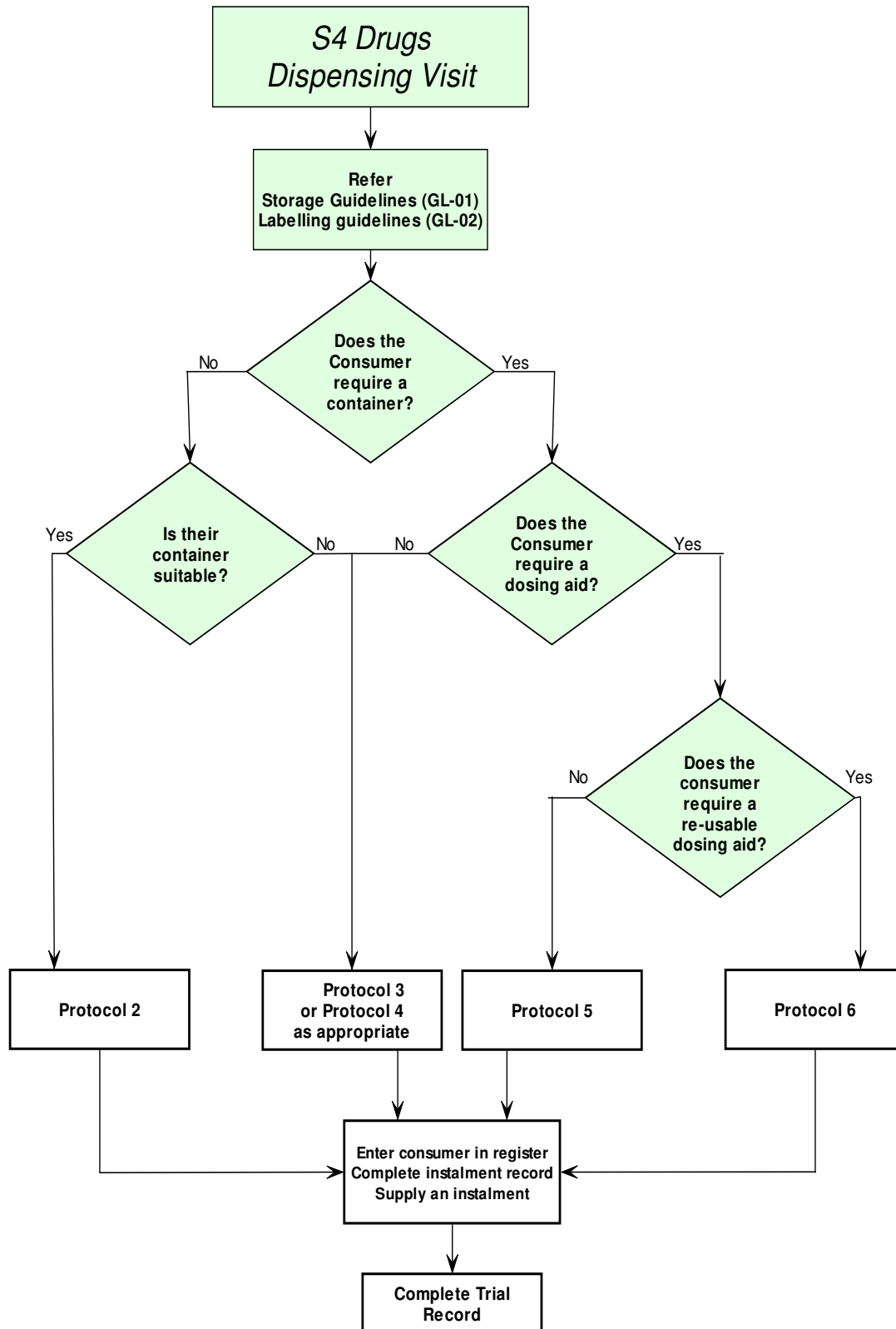
13. Appendices

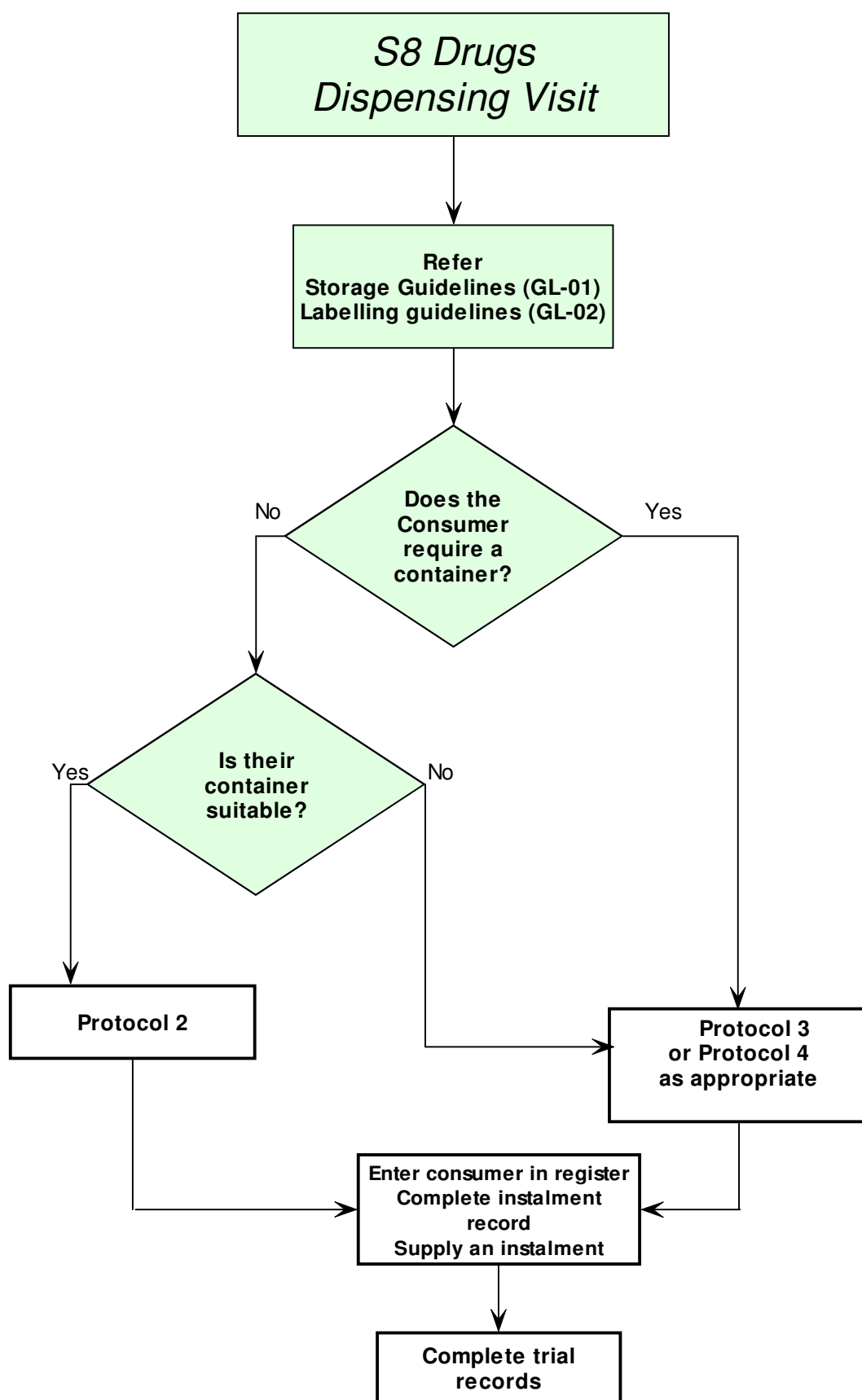
12.1 Appendix 1: Decision Tree for best practice model

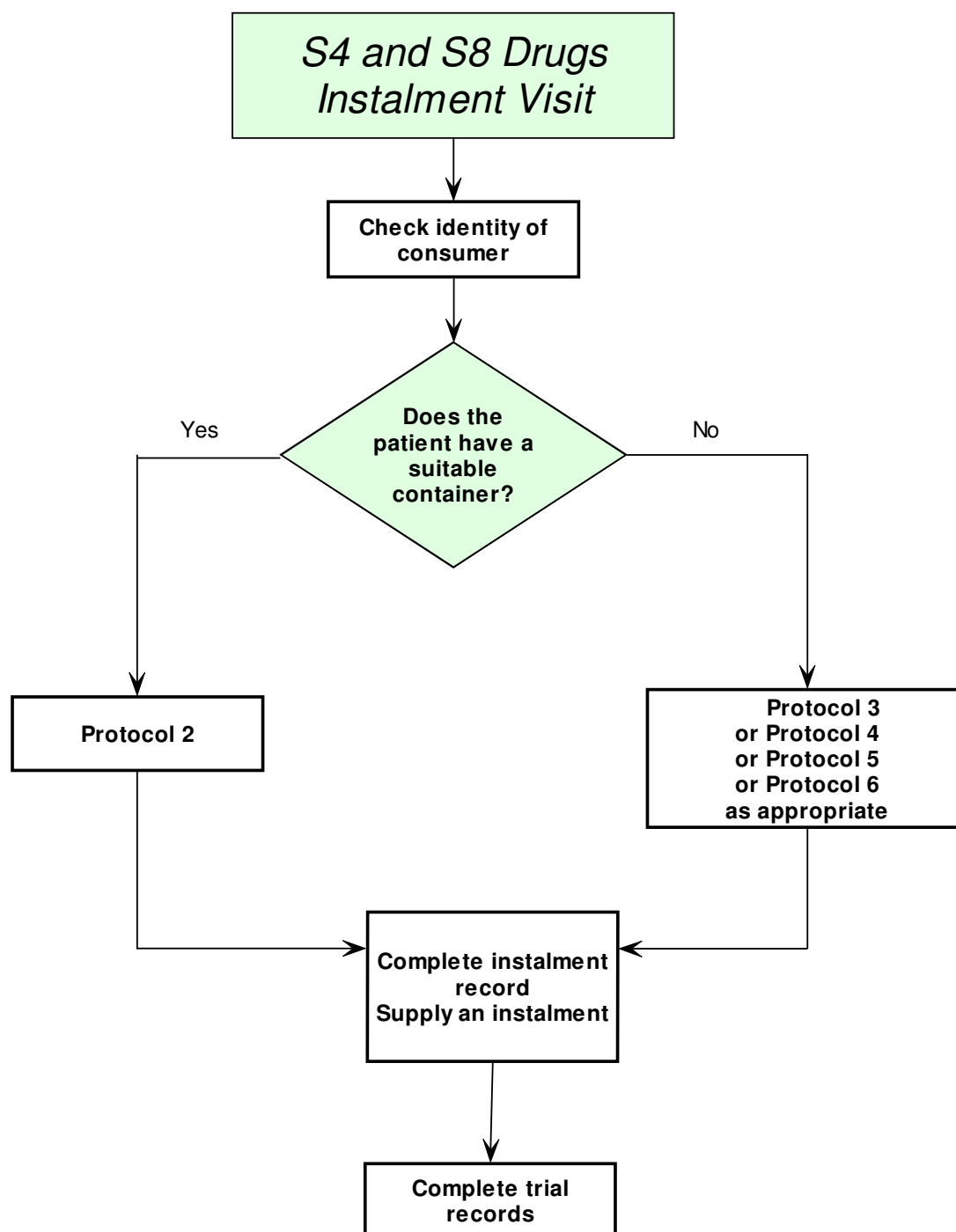


Legend

- Protocol 1: Dispensing in small quantities
- Protocol 2: Own Container
- Protocol 3: Capped Container
- Protocol 4: Disposable pack (e.g. Medicopack)
- Protocol 5: Disposable Dosing Aid
- Protocol 6: Reusable Dosing Aid (e.g. Webster pack)

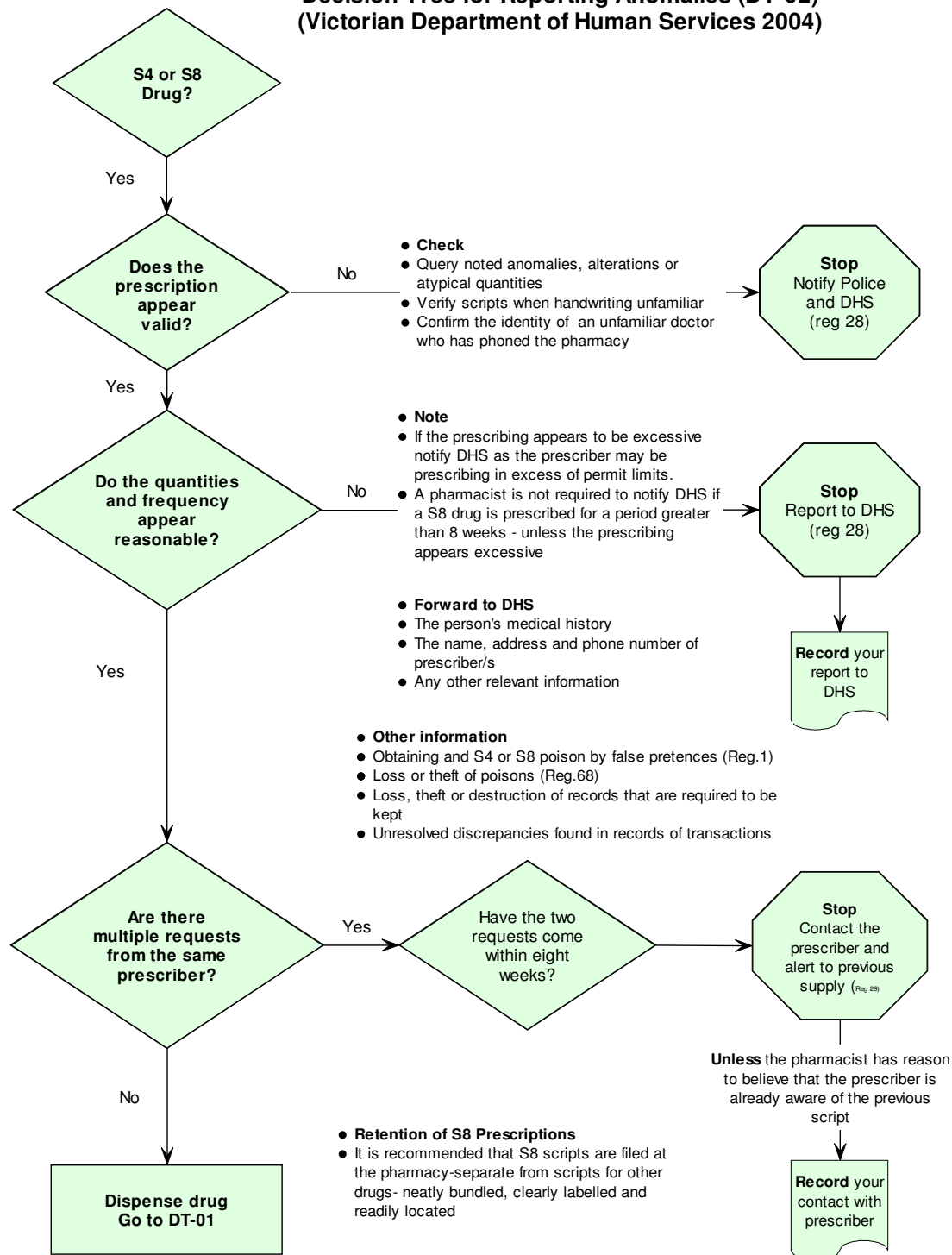






12.2 Appendix 2: Decision tree for anomalies (DT-02)

Decision Tree for Reporting Anomalies (DT-02) (Victorian Department of Human Services 2004)



12.3 Appendix 3: Dispensing in instalments trial protocols

Collaborative Centre for eHealth, University of Ballarat

Dispensing and monitoring of schedule 4 and schedule 8 drugs (with dependency properties)

Dispensing in Instalments Trial Protocols

Dispensing in Instalments Protocol (instructions)	Supporting Documents	Records to Complete
<i>Protocol 1</i>		
<i>Dispensing a full prescription when a SMALL QUANTITY is requested</i>		
• Step 1 Check to determine if prescription for the S4 or S8 drug is valid according to the state regulations		
• Step 2 Dispense drug as per usual pharmacy practice.		
• Step 3 Complete RF-02 to allocate a consumer code.		<i>RF-02</i> <i>Consumer Register</i>
• Step 4 Complete a line in the RF-05 to allocate a GP code		<i>RF-05</i> <i>GP Register</i>
• Step 5 Complete a line in the RF-01 form indicating a small quantity has been dispensed		<i>RF-01</i> <i>Dispensing in Small Quantities record sheet</i>

Protocol 2		
<i>Dispense full prescription but supply in instalments (daily, 2-3 daily or weekly) to the consumer IN THEIR OWN CONTAINER</i>		
• Step 1 Check to determine if prescription for the S4 or S8 drug is valid according to the state regulations		
• Step 2 Dispense drug as per usual pharmacy practice.		
• Step 3 Complete RF-02 to allocate a consumer code.		RF-02 Consumer Register
• Step 4 Complete a line in the RF-05 to allocate a GP code		RF-05 GP Register
• Step 5 Complete header information in RF-03 in preparation for first instalment.		RF-03 Dispensing in Instalments record sheet
• Step 6 Store all S4 tablets that have not been supplied in the dispensing area		
• Step 7 Store all S8 tablets that have not been supplied in a locked cabinet suitable for controlled drugs, as per storage guidelines	GL-01 Storage Guidelines	
• Step 8 When consumer arrives to collect instalment check if container is clean. If clean supply counted tablets into own container. If not clean, supply a new labelled container as per protocol 3.	GL-02 Labelling guidelines	

<p>• Step 9</p> <p>Complete a line in the RF-03 form indicating a quantity of the drug has been supplied.</p>		<p><i>RF-03</i></p> <p><i>Dispensing in Instalments record sheet</i></p>
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Protocol 3		
Dispense full prescription but supply in instalments (daily, 2-3 daily or weekly) to the consumer IN NEW CONTAINER Option 1 - CAPPED CONTAINER		
• Step 1 Check to determine if prescription for the S4 or S8 drug is valid according to the state regulations	<i>DT-02</i> <i>Decision Tree for reporting anomalies</i>	
• Step 2 Dispense drug as per usual pharmacy practice. .		
• Step 3 Complete RF-02 to allocate a consumer code		RF-02 Consumer Register
• Step 4 Complete a line in the RF-05 to allocate a GP code		RF-05 GP Register
• Step 5 Complete header information in RF-03 in preparation for first instalment.		RF-03 Dispensing in Instalments record sheet
• Step 6 Store all S4 tablets that have not been supplied in the dispensing area		
• Step 7 Store all S8 tablets that have not been supplied in a locked cabinet suitable for controlled drugs, as per storage guidelines	<i>GL-01</i> <i>Storage Guidelines</i>	

<p>• Step 8</p> <p>Each day the consumer is expected to attend the pharmacy to collect their supply, fill a new container with the consumer's drugs (1 week's supply).</p>		
<p>• Step 9</p> <p>Attach a label to the new container (child proof capping) according to the labelling guidelines.</p>	<p><i>GL-02</i></p> <p><i>Labelling guidelines</i></p>	
<p>• Step 10</p> <p>Store prepared medication behind the dispensary for S4 drugs, or in a locked drugs cupboard for S8 drugs until the consumer arrives to collect the medication.</p>		
<p>• Step 11</p> <p>Complete a line in the RF-03 form indicating a quantity of the drug has been supplied.</p>		<p>RF-03</p> <p><i>Dispensing in Instalments record sheet</i></p>

Protocol 4		
Dispense full prescription but supply in instalments (daily, 2-3 daily or weekly) to the consumer IN NEW CONTAINER Option 2 - MEDIPACK		
Step 1 Check to determine if prescription for the S4 or S8 drug is valid according to the state regulations	<i>DT-02</i> <i>Decision Tree for reporting anomalies</i>	
• Step 2 Dispense drug as per usual pharmacy practice. .		
• Step 3 Complete RF-02 to allocate a consumer code		RF-02 Consumer Register
• Step 4 Complete a line in the RF-05 to allocate a GP code		RF-05 GP Register
• Step 5 Complete header information in RF-02 in preparation for first instalment.		RF-03 Dispensing in Instalments record sheet
• Step 6 Store all S4 tablets that have not been supplied in the dispensing area		
• Step 7 Store all S8 tablets that have not been supplied in a locked cabinet suitable for controlled drugs, as per storage guidelines	<i>GL-01</i> <i>Storage Guidelines</i>	
• Step 8 Once a week, fill a MediPack dosing aid with the consumer's drugs (1 week's supply).		

<p>• Step 9</p> <p>Labels are required to be attached to each segment of the MediPack the consumer will be allocated (a label per day for daily pickup, a label per 2-3 days for a 2-3 daily pickup, or a label for a week's supply when a week's supply is required)</p>	<p><i>GL-02</i> <i>Labelling guidelines</i></p>	
<p>• Step 10</p> <p>When the consumer collects the daily or 2-3 daily supply, the pharmacist tears the required number of day's medication from the MediPack (with perforations), and supplies to the consumer. The remaining medication in the MediPack is to be stored on a shelf behind the dispensary (S4) or in a locked drug cupboard (S8).</p>		
<p>• Step 11</p> <p>Complete a line in the RF-03 form indicating a quantity of the drug has been supplied.</p>		<p><i>RF-03</i> <i>Dispensing in Instalments record sheet</i></p>

Protocol 5		
Dispense full prescription but supply in instalments (weekly) to the consumer IN NEW CONTAINER Option 3 - DISPOSABLE DOSING AID		
Step 1 Check to determine if prescription for the S4 or S8 drug is valid according to the state regulations	DT-02 Decision Tree for reporting anomalies	
• Step 2 Dispense drug as per usual pharmacy practice. .		
• Step 3 Complete RF-02 to allocate a consumer code		RF-02 Consumer Register
• Step 4 Complete a line in the RF-05 to allocate a GP code		RF-05 GP Register
• Step 5 For the first instalment, complete header information in RF-03.		RF-03 Dispensing in Instalments record sheet
• Step 6 Store all S4 tablets that have not been supplied in the dispensing area		
• Step 7 Store all S8 tablets that have not been supplied in a locked cabinet suitable for controlled drugs, as per storage guidelines.	GL-01 Storage Guidelines	
• Step 8 Once a week, fill a dosing aid with the consumer's drugs (1 week's supply).		

<p>• Step 9</p> <p>Ensure there is a current label attached to the dosing aid, according to the labelling guidelines.</p>	<p><i>GL-02</i></p> <p><i>Labelling guidelines</i></p>	
<p>• Step 10</p> <p>Complete a line in the RF-03 form indicating a quantity of the drug has been supplied.</p>		<p><i>RF-03</i></p> <p><i>Dispensing in Instalments record sheet</i></p>

Protocol 6		
Dispense full prescription but supply in instalments (weekly) to the consumer in RE-USABLE DOSING AID		
Step 1 Check to determine if prescription for the S4 or S8 drug is valid according to the state regulations	DT-02 <i>Decision Tree for reporting anomalies</i>	
• Step 2 Dispense drug as per usual pharmacy practice. .		
• Step 3 Complete RF-02 to allocate a consumer code		RF-02 Consumer Register
• Step 4 Complete a line in the RF-05 to allocate a GP code		RF-05 GP Register
• Step 5 Complete header information in RF-02 in preparation for first instalment.		RF-03 Dispensing in Instalments record sheet
• Step 6 Store all S4 tablets that have not been supplied in the dispensing area		
• Step 7 Store all S8 tablets that have not been supplied in a locked cabinet suitable for controlled drugs, as per storage guidelines	GL-01 <i>Storage Guidelines</i>	
• Step 8 Once a week, fill the consumer's spare re-usable dosing aid with the consumer's drugs (1 week's supply).		
• Step 9 Ensure there is a current label attached to the dosing aid, according to the labelling guidelines.	GL-02 <i>Labelling guidelines</i>	

<p>• Step 10</p> <p>Complete a line in the RF-03 form indicating a quantity of the drug has been supplied.</p>		<p><i>RF-03</i></p> <p><i>Dispensing in Instalments</i></p> <p><i>record sheet</i></p>
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<i>Protocol 7</i>		
<i>Data Transmission</i>		
<p>• Step 1</p> <p>1 At the end of each month, photocopy all forms, which have entries for the month (make sure you cover consumer identifying information - consumer name and signature on the <u>RF-03 Dispensing in instalments record sheet</u>) and fax or mail to:</p> <p><u>Project Leader</u></p> <p><u>Dispensing and monitoring of schedule 4 and schedule 8 drugs (with dependency properties)</u></p> <p><u>Suite 15, Greenhill Enterprise Centre</u></p> <p><u>University Drive, Mt Helen Vic 3350</u></p> <p><u>Fax: 03 5327 9307</u></p>		

Affix Pharmacy Stamp here

12.4 Appendix 4: Dispensing in small quantities record sheet (RF-01)

Dispensing in Small Quantities Record Sheet (RF-01)

Date dispensed	Prescriber Code	Consumer code	Drug Name	Number of tablets in standard script	Quantity supplied

Form to be used for recording all instances where the prescription is a small quantity rather than dosing in instalments

Dispensing in Instalments Record Form (RF-03 Side B)

DO NOT FAX
THIS SIDE

Fold here →|

Consumer's name:		
Drug Name:		
Date	Signature of consumer agent or courier	Signature of Pharmacist or D Tech

Affix Pharmacy Stamp here

12.6 Appendix 6: Prescriber Register

Prescriber Register (RF-05)

G General Practitioner P Psychiatrist D Dentist O Other



Prescriber Code	Prescriber type	Date	Prescriber Name	Prescriber Address
001				
002				
003				
004				
005				
006				
007				
008				
009				
010				
011				
012				
013				
014				
015				

016				
017				
018				
019				
020				

12.7 Appendix 7: Storage Guidelines

Collaborative Centre for eHealth, University of Ballarat

Dispensing and monitoring of schedule 4 and schedule 8 drugs (with dependency properties)

STORAGE GUIDELINES (GL-01)

These regulations are an extract of the Victorian Government Regulations (Victorian Government, 1995).

Division 4—Storage

31. Application of regulations in this Division

- (1) In this Division, regulations 32, 33, 34 and 36 apply to—
 - (a) a person authorised under section 13(1) of the Act; and
 - (b) a person holding a licence, permit or warrant to manufacture, sell, supply, purchase or otherwise obtain, possess, administer or use a Schedule 4 poison, Schedule 8 poison or Schedule 9 poison; and
 - (c) a person, other than the holder of a licence, permit or warrant, who is authorised by these Regulations to possess, use or administer a Schedule 4 poison, Schedule 8 poison or Schedule 9 poison in the provision of health services.
- (2) In this Division, regulations 32, 35 and 36 apply to a person referred to in Part 2 of the table in regulation 5 to have in his or her possession a Schedule 4 poison or Schedule 8 poison.

32. General security requirement—Schedule 4 poisons

- (1) A person to whom this regulation applies must store any Schedule 4 poisons in his or her possession in a lockable storage facility.

Penalty: 100 penalty units.

- (2) Despite sub-regulation (1) and regulation 34, a pharmacist may store Schedule 4 poisons in—
 - (a) the dispensing area of a pharmacy, pharmacy department or premises referred to in an approval under section 27(1)(b) of the **Pharmacists Act 1974** (as the case may be); or
 - (b) in an area separated from the remainder of the premises and to which only a pharmacist has access.

33. Secure storage

- (1) A person to whom this regulation applies must store any Schedule 8 poisons or Schedule 9 poisons in his or her possession in a lockable storage facility that provides not less security than a storage facility that is—
- (a) constructed of mild steel plate of 10 millimetres thickness; and
 - (b) constructed with continuous welding of all edges; and
 - (c) fitted with a door constructed of mild steel plate of 10 millimetres thickness, swung on hinges welded to the door and body of the cabinet, the door being flush fitting with a clearance around the door of not more than 1.5 millimetres; and
 - (d) fitted with a fixed locking bar, welded to the inside face of the door near the hinge edge, which engages in a rebate when the door is closed; and
 - (e) fitted with a 6 lever lock securely affixed to the rear face of the door; and
 - (f) securely attached to a wall or floor in such a manner that it will resist attack by hand tools for 30 minutes or power tools for 5 minutes.

Penalty: 100 penalty units.

- (2) A person to whom this regulation applies must take all reasonable steps to ensure that the storage facility referred to in sub-regulation (1) is used only for the storage of Schedule 8 poisons, Schedule 9 poisons and drugs of dependence.

Penalty: 100 penalty units.

- (3) A person to whom this regulation applies must keep any Schedule 8 poisons or Schedule 9 poisons in his or her possession which are being transported for use in another place in a locked storage facility which is secured to prevent unauthorised access to those poisons.

Penalty: 100 penalty units.

34. Facility to be secured at all times

A person to whom this regulation applies must take all reasonable steps to ensure that the storage facility for Schedule 4 poisons, Schedule 8 poisons or Schedule 9 poisons remains locked and secured to prevent access by an unauthorised person at all times, except when it is necessary to open it to carry out an essential operation in connection with the poisons stored in it.

Penalty: 100 penalty units.

35. Storage requirements—authorised persons

A person to whom this regulation applies must—

- (a) store any Schedule 8 poison in his or her possession in a lockable storage facility which is firmly fixed to a floor or wall; and
- (b) take all reasonable steps to ensure that the storage facilities for Schedule 4 poisons and Schedule 8 poisons remain locked and secured to prevent access by an unauthorised person at all times, except when it is necessary to open them to carry out an essential operation in connection with the poisons stored in them.

Penalty: 100 penalty units.

36. Additional security provisions required in certain circumstances

(1) Despite regulations 32 and 33, the Secretary after having regard to—

- (a) the nature and quantity of the poisons or controlled substances being stored; and
- (b) the location, layout and construction of the facility and the premises; and
- (c) the warning devices and detectors with which the facility and premises are equipped; and
- (d) the number and frequency of transactions; and
- (e) the number of persons requiring access; and
- (f) any other factors the Secretary considers relevant in the circumstances—

Reg. 36(1)
amended by
S.R. No.
150/2004
reg. 28(2)(b).

Reg. 36(1)(f)
amended by
S.R. No.
150/2004
reg. 28(2)(b).

may direct a person to whom this regulation applies to provide more secure storage for Schedule 4 poisons, Schedule 8 poisons or Schedule 9 poisons than that described in regulations 32, 33 and 35.

(2) A person who is directed by the Secretary to provide more secure storage under sub-regulation (1) must provide that secure storage.

Penalty: 100 penalty units.

Reg. 36(2)
amended by
S.R. No.
150/2004
reg. 28(2)(b).

Victorian Government. (1995). *Poisons and Controlled Substances Regulations 1995*. Office of the Chief Parliamentary Counsel. Retrieved Feb, 2005, from the World Wide Web: http://www.dms.dpc.vic.gov.au/Domino/Web_Notes/LDMS/PubLawToday.nsf?OpenDatabase

12.8 Appendix 8: Labeling Guidelines

Collaborative Centre for eHealth, University of Ballarat

Dispensing and monitoring of schedule 4 and schedule 8 drugs (with dependency properties)

Extracted from A Guide to Labelling Drugs and Poisons in Accordance with the Standard for the Uniform Scheduling of Drugs and Poisons (TGA, 2000).

Schedule 4 Requirements

Label contents Legal requirements

PRESCRIPTION ONLY MEDICINE

or

PRESCRIPTION ANIMAL REMEDY

Bold sanserif capital letters, uniform thickness;
Height, half that of largest letter or numeral on the label (minimum 1.5mm, maximum 6mm on containers of 2 litres or less or 15mm on larger containers);
First line on label.

KEEP OUT OF REACH OF CHILDREN

Bold sanserif capital letters, uniform thickness;
Four tenths height of "PRESCRIPTION ONLY MEDICINE" with minimum height of 1.5mm;
Second line of label.

FOR ANIMAL TREATMENT ONLY

Bold sanserif capital letters, uniform thickness;
On main label.
(Only on products for animal treatment).

TRADE NAME OF PRODUCT

No specifications.

NAME AND STRENGTH OR PROPORTION OF ALL ACTIVE INGREDIENTS

If for human therapeutic use, see *Therapeutic Goods order No 48- General requirement for labels of Drug Products*.

NAME AND ADDRESS OF MANUFACTURER OR DISTRIBUTOR

Must be an Australian address;
Must be a street address NOT a post office box.

NETT CONTENTS

Required by consumer legislation.
If for human therapeutic use, see *Therapeutic Goods order No 48- General requirements*

for labels of Drug Products.

DIRECTIONS FOR USE

If for human therapeutic use, see *Therapeutic Goods order No 48- General requirements for labels of Drug Products*

WARNING STATEMENTS

Some poisons require warning statements.
These are to be placed immediately before the directions for use.
All other writing required on label Minimum height 1.5mm measured on capital letters or lower case letters with ascenders or descenders (e.g. d, b, g, p).

EXAMPLE LAY OUT

For human therapeutic use

PRESCRIPTION ONLY MEDICINE

KEEP OUT OF REACH OF CHILDREN

PRODUCT NAME

Each tablet contains:(name of poison) mg
quantity

Name and address

For the treatment of animals

PRESCRIPTION ANIMAL REMEDY

KEEP OUT OF REACH OF CHILDREN

FOR ANIMAL TREATMENT ONLY

PRODUCT NAME

Each tablet contains:(name of poison) mg
quantity

Name and address

Schedule 8 Requirements –

Label contents Legal requirements

CONTROLLED DRUG

Bold sanserif capital letters, uniform thickness;
Height, half that of largest letter or numeral on the label (minimum 1.5mm, maximum 6mm on containers of 2 litres or less or 15mm on larger containers);
First line on label.

POSSESSION WITHOUT AUTHORITY ILLEGAL

Bold sanserif capital letters, uniform thickness;
Four tenths height of "CONTROLLED DRUG" with a minimum height of 1.5mm;
line on label.

KEEP OUT OF REACH OF CHILDREN

Nothing else on same line.
Bold sanserif capital letters, uniform thickness;
Four tenths height of "CONTROLLED DRUG" with a minimum height of 1.5mm;
Third line of label.

FOR ANIMAL TREATMENT ONLY

Bold sanserif capital letters, uniform thickness;
On main label.
(Only on products for animal treatment).

TRADE NAME OF PRODUCT

No specifications.

NAME AND STRENGTH OR PROPORTION OF ALL ACTIVE INGREDIENTS

If for human therapeutic use, see *Therapeutic Goods Order No for labels of Drug Products*.

NAME AND ADDRESS OF MANUFACTURER OR DISTRIBUTOR

Must be an Australian address;
Must be a street address NOT a post office box.

NETT CONTENTS

Required by consumer legislation.
If for human therapeutic use, see *Therapeutic Goods Order No 48- General requirements for labels of Drug Products*.

DIRECTIONS FOR USE

If for human therapeutic use, see *Therapeutic Goods Order No 48- General requirements*

for labels of Drug Products

WARNING STATEMENTS

Some poisons require warning statements.
These are to be placed immediately before the
directions for use.

All other writing required on label Minimum height 1.5mm
measured on capital
letters or lower case letters with ascenders or
descenders (e.g. d, b, g, p).

EXAMPLE LAY OUT

CONTROLLED DRUG
POSSESSION WITHOUT AUTHORITY ILLEGAL
KEEP OUT OF REACH OF CHILDREN
PRODUCT NAME
Contains: (NAME OF POISON) g/L, mL/L, g/kg, mL/kg
Quantity
Name and address

TGA. (2000). *A Guide to Labelling Drugs and Poisons in Accordance with the Standard for the Uniform Scheduling of Drugs and Poisons*. Commonwealth Department of Health and Aged Care. Retrieved May, 2005, from the World Wide Web: <http://www.tga.gov.au/ndpsc/gldap.htm>

12.9 Appendix 9: Covering letter S4 S8 information pack

4th July 2005

To whom it may concern

Dispensing and monitoring of schedule 4 and schedule 8 drugs (with dependency properties) project

The Collaborative Centre of eHealth seeks to recruit three pharmacies in Sydney to participate in a five to six month trial for the project Dispensing and monitoring of schedule 4 and schedule 8 drugs (with dependency properties).

To explain this project I have enclosed some explanatory documents.

The enclosed documents are:

- Collaborative Centre for eHealth – Who are we?
- Project Information for Pharmacists and Dispensing Technicians
- Expectations of pharmacists and dispensing technicians participating.
- Invitation to participate.

Pharmacies will be reimbursed for their participation.

If your pharmacy is interested in participating in the trial, please complete and return the fax back sheet attached to “Invitation to participate”.

Yours sincerely,

Chris Lynton-Moll
Collaborative Centre for eHealth
Greenhill Enterprise Centre
University of Ballarat
Ph: +61 3 5327 9311
Fax: +61 3 5327 9307
Email: cceh@ballarat.edu.au

12.10 Appendix 10: Expectations pharmacists and dispensing technicians participating in the trial

Collaborative Centre for eHealth, University of Ballarat

Dispensing and monitoring of schedule 4 and schedule 8 drugs (with dependency properties)

Expectations of pharmacists and dispensing technicians participating in the trial

Pharmacists who agree to be involved in this trial they will be expected to:

- Be involved in a trial of new prescribing protocols for S4 and S8 drugs of addiction (with dependency properties) of between five and six months duration.
- Change their current prescribing regime for S4 and S8 drugs of addiction (with dependency properties) when dispensing in instalments using the protocols provided by the project team.
- Collect and record a variety of activities. The recording of these activities is in addition to current recording requirements. This includes the following recording sheets:
 - Time and activity records
 - Dispensing in instalments recording sheet
 - Dispensing in small quantities recording sheet
 - Consumer register
- Follow the legislative guidelines that will be provided. These include:
 - Storage guidelines
 - Labeling guidelines
- Forward completed and de-identified activity sheets to the project leader of the S4 and S8 drugs of addiction (with dependency properties) project on a monthly basis.
- Recruit suitable consumers for and in-depth interview at the end of the trial to assess the impact of the new protocols.
- Participate in an in-depth interview at the end of the trial of approximately one hour's duration.

If you require clarification please contact:

Collaborative Centre for eHealth

Greenhill Enterprise Centre

University of Ballarat

Ph: +61 3 5327 9311

Fax: +61 3 5327 9307

Email: cceh@ballarat.edu.au

12.11 Appendix 11: Informed consent for pharmacists and dispensing technicians

Collaborative Centre for eHealth, University of Ballarat

Dispensing and monitoring of schedule 4 and schedule 8 drugs (with dependency properties)

Informed Consent for Pharmacists and Dispensing Technicians

Consent (fill out below)

I

of

.....

hereby consent to participate as a subject in the research study titled Dispensing and Monitoring of Schedule 4 and Schedule 8 (with dependency properties) drugs.

The research program in which I am being asked to participate has been explained fully to me, verbally and in writing, and any matters on which I have sought information have been answered to my satisfaction.

I understand that:

- all information I provide (including questionnaires) will be treated with the strictest confidence and data will be stored separately from any listing that includes my name and address
- aggregated results will be used for research purposes and may be reported in scientific and academic journals
- any quotes from my interview will be de-identified
- I am free to withdraw my consent at any time during the study with my participation in the research ceasing immediately and any information obtained from it will not be used. However, once information has been aggregated it is unable to be identified, and therefore from this point on it is not possible to withdraw consent to participate

SIGNATURE: **DATE:**

12.12 Appendix 12: Project information for consumers

Collaborative Centre for eHealth, University of Ballarat

Dispensing and monitoring of schedule 4 and schedule 8 drugs (with potential dependency properties)

Project Information for Consumers

Background

The Collaborative Centre for eHealth, University of Ballarat (UB) is undertaking a project which seeks to develop a best-practice model for *Dispensing and Monitoring of Schedule 4 and Schedule 8 drugs*.

Procedure

The participating pharmacists will be required to implement a set of standard procedures for dispensing S4 and S8 drugs in instalments. These best practice protocols include standards and procedures for storage, security, record keeping, counselling and feedback to General Practitioners.

Confidentiality

All data, including your personal information, will be de-identified, treated as confidential and only made available to members of the research team on a need to know basis.

Benefits to consumer

The direct benefits to those involved will be the opportunity to use a dispensing in instalments model which will be based on best practice principals.

Thank you for taking part in this research. If you have any queries please call the University of Ballarat on the number below. Further information about this research is available on the Pharmacy Guild web site www.guild.org.au

Yours sincerely

*Chris Lynton-Moll
Collaborative Centre for eHealth
Greenhill Enterprise Centre
University of Ballarat
Ph: +61 3 5327 9311
Fax: +61 3 5327 9307*

12.13 Appendix 13: Informed consent for consumers

Dispensing and monitoring of schedule 4 and schedule 8 drugs (with dependency properties)

Informed Consent for Consumers

Consent (fill out below)

I

of

.....

hereby consent to participate as a subject in the research study titled *Dispensing and Monitoring of Schedule 4 and Schedule 8 (with dependency properties) drugs*.

The research program in which I am being asked to participate has been explained fully to me, verbally and in writing, and any matters on which I have sought information have been answered to my satisfaction.

I understand that:

- my role in the research study is to be interviewed by a researcher from the University of Ballarat (UB) about dispensing in instalments:
- all information I provide (including questionnaires) will be treated with the strictest confidence and data will be stored separately from any listing that includes my name and address:
- aggregated results will be used for research purposes and may be reported in scientific and academic journals:
- any quotes from my interview will be de-identified:
- I am free to withdraw my consent at any time during the study with my participation in the research ceasing immediately and any information obtained from it will not be used. However, once information has been aggregated it is unable to be identified, and therefore from this point on it is not possible to withdraw consent to participate.

Signature: **Date:**

CONTACT DETAILS

Name:

Street Address:

Suburb or Town:

Postcode:

Telephone:

12.14 Appendix 14: Consumer Register**Consumer Register (RF-02)**

Tear here →

**FAX THIS
PART ONLY**

Affix Pharmacy Stamp here

Consumer Code	Consumer Name	Consumer Code	Date registered	Reason for Dispensing in Instalment Regime (Tick appropriate box or boxes)					
				Dependency	Psychiatric Condition	Intellectual Disability	Cognitive problem	Other (Specify if known)	Not Known
001		001		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
002		002		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
003		003		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
004		004		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
005		005		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
006		006		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
007		007		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
008		008		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
009		009		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
010		010		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
011		011		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
012		012		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
013		013		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
014		014		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
015		015		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Dispensing and Monitoring of S4 & S8 Drugs

016		016		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
017		017		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
018		018		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
019		019		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
020		020		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

12.15 Appendix 15: Protocols for pharmacists to recruit consumers

Collaborative Centre for eHealth, University of Ballarat

Dispensing and monitoring of schedule 4 and schedule 8 drugs (with dependency properties)

Protocols for pharmacists to recruit consumers for post-trial interviews

At the end of the trial, it is proposed to conduct in depth interviews with consumers to evaluate the new trial protocols that have been implemented and the impact they have had on consumers in managing their S4 and S8 drugs of addiction (with dependency properties).

To recruit consumers certain protocols must be followed. These are:

Select

Each pharmacy should attempt to recruit three potential interviewees from among consumers in the trial. If possible, include one from each of the target groups:

- Consumers who have a drug dependency (illicit or prescription) who have a therapeutic need for a drug with dependency properties.
Consumers who have a psychiatric condition who may misuse the medication.
Consumers who have a cognitive deficit which may be caused by a psychiatric condition, intellectual disability, or ageing.

Approach

Make a confidential approach to selected consumers who you consider may be interested in participating in an interview to evaluate the trial protocols. Outline the project and discuss with consumers what their participation in an interview will require:

- Provide the information sheet
Provide the consumer with time to think about their participation in the trial
Provide the consumer with the consumer consent form

Invite

Invite the consumer to participate. Be non-coercive. Ensure the consumer has signed the consent form, given their contact details and then collect the consumer consent form. Forward this information to the S4 and S8 drugs (with dependency properties) project leader .

If you require clarification please contact:

Collaborative Centre for eHealth

Greenhill Enterprise Centre

University of Ballarat

Ph: +61 3 5327 9311

Fax: +61 3 5327 9307

Email: cceh@ballarat.edu.au

12.16 Appendix 16: Human Research Ethics submission and response

Human Research Ethics Committee (HREC)

HUMAN RESEARCH ETHICS COMMITTEE (HREC)

PROJECT APPLICATION

Application	Committee	Tick box
Humans (<i>attach Schedule A</i>) Humans (<i>attach Schedule A</i>) Teaching Project (<i>attach Schedule B</i>)	Executive Committee (<i>original + 3 copies</i>) REC Full Committee (<i>original + 1 copy</i>)	<input checked="" type="checkbox"/>
Teaching Project (<i>attach Schedule B</i>)	HREC Executive Committee (<i>original + 3 copies</i>)	

PROJECT DETAILS

Title of Research Project:

Dispensing in instalments of S4 S8 Drugs with dependency properties: evaluation of trial protocols & survey of pharmacists

Person (s) Making Submission:	Telephone Number	Email
Jack Harvey	53 279065	j.harvey@ballarat.edu.au

School: Information Technology & Mathematical Sciences - Collaborative Centre for eHealth (CCeH)

Application Is Made For	Name	Tick box
Research by a member of UB staff	Chris Lynton-Moll Jack Harvey	<input checked="" type="checkbox"/>
Research by a postgraduate student		
Research by an honours student		
Research by an undergraduate student		
Teaching Project for class use		

Application Date: 31/10/05.....

Proposed Commencement Date: 21/11/05.....

Proposed Completion Date: 30/4/06..... ...

PROJECT DESCRIPTION

1. Aims/research question(s) and background of the project.

This is the second ethics submission in relation to this project. The overall project description and aims are reiterated here.

Background

Under the *Drugs, Poisons & Controlled Substances Act 1981* and the *Drugs, Poisons and Controlled Substances Regulations 1995* potentially toxic substances are categorised into eight schedules. The most highly regulated medicines are listed on either Schedule 4 (*prescription-only medicines*) or Schedule 8 (labelled *controlled drug*). Some drugs on Schedules 4 and 8 have dependency properties. In order to minimise diversion and abuse of such drugs, community pharmacists currently provide “unit dose medication” or “dispensing by instalments” (DBI) for consumers considered to be at risk, when requested to do so by GPs. This service involves supplying the drug from a single prescription in small quantities (or even individual doses) on a regular basis over a period of time. Whilst procedures for handling drugs up to the point of initial dispensing are highly regulated, the practice of dispensing by instalment, and the attendant issues of storage, security and record keeping, are managed in an ad hoc and unregulated manner. Furthermore, the pharmacists are not financially compensated for this or for the associated counselling services, beyond the standard single dispensing fee.

Aims

The project being undertaken by the UB Collaborative Centre for eHealth (CCeH) is examining the role, effectiveness and the cost for the pharmacist within this drug management strategy. It will develop, trial and evaluate dispensing and counselling protocols, and is seeking to identify and recommend an appropriate fee structure for unit dose medication to patients who may be at risk from drugs with dependency properties.

The specific aims of this project are:

1. to identify the scope of the practice of dispensing by instalments, with respect to:
 - the range of S4 and S8 drugs involved
 - the categories of patient at risk
 - the prevalence of the practice in selected pharmacies in three test regions
2. to identify the key elements of the process
3. to formulate protocols for dispensing, packaging, storage, supply, security, record keeping, and provision of feedback to GPs
4. to trial the protocols in a sample of community pharmacies
5. to maintain “activity records” throughout the trial for evaluation purposes.
6. to further evaluate the trial on the basis of interviews with participating pharmacists, dispensing technicians and consumers, and the analysis of “activity records” maintained throughout the trial.
7. to survey a wider group of pharmacy proprietors in order to further quantify current practices and to elicit information about costs against which data from the trials can be compared.

Aims 2 and 3, and to a large degree Aim 1, have been addressed through a literature review and consultation with key informants in an Expert Advisory Group (EAG) and in partner organisations. The EAG includes representatives of the Pharmacy Guild of Australia (PGA), which is the sponsoring organisation, and other key stakeholders including the Pharmaceutical Society of Australia (PSA) and the Australian Government Department of Health and Ageing. The partner organisations include the School of Pharmacy at the University of Tasmania, Ballarat and District Pharmacy Alliance (BDPA),

local members of PGA and PSA, and Ballarat and District Division of General Practice (BDDGP).

The first UBHREC approval (A05-073 Meeting 4/05) pertained mainly to the trial protocols (Aim 4) and the activity monitoring (Aim 5).

This application pertains to Aim 6 (interviews) and Aim 7 (survey). However, for reasons of timing, all aspects of recruitment and informed consent of pharmacists, dispensing technicians and consumers pertaining to Aim 6 were included in the previous application and approved at that time.

Hence this application pertains to:

- A. the process and content of the evaluation interviews, and**
- B. the wider survey of pharmacy proprietors**

- 2. Participants.** Provide a brief description of the **participants/subjects**, the sample size, the source of participants, and the means by which they will be recruited/collected.

A. Evaluation Interviews

Potential participants (and anticipated sample sizes) are:

- Operators/managers/proprietors of participating pharmacies (7 - 3 In Ballarat, 3 in Sydney & 1 in Darwin).
- Other pharmacists employed in participating pharmacies who are involved in DBI (up to 30).
- Other pharmacy staff involved in DBI – dispensing technicians (up to 30).
- Consumers (up to 200).
- Agents of consumers (parents, carers) who pick up medication from pharmacies (up to 50).

It is considered that the first three groups are participants in the trial. These participants have been fully informed and have signed informed consent forms previously approved. The information and consent pertains not only to the trial itself, but also to the post-trial interviews. All seven operators/managers/proprietors of participating pharmacies, and samples of seven employed pharmacists and seven dispensing technicians (one of each from each participating pharmacy – chosen randomly from available staff) will be interviewed.

Consumers are indirect passive participants in the trials, in the sense that the protocols under which their S4 and S8 drugs are supplied are the subject of the trial, and that records about their purchase and use of these drugs are being collected and analysed as part of the trial. Approval was granted to incorporate data about them in the trial without their consent. Approval was also granted for pharmacists to recruit consumers and obtain informed consent for participation in post-trial evaluation interviews. The target sample to be interviewed is 14 consumers (two from each participating pharmacy to be selected by pharmacists on the basis of assessed ability to provide informative feedback).

Agents (parents, carers, friends) who pick up medication from pharmacies on behalf of consumers are similarly involved only peripherally. Note that consumers in institutions such as nursing homes and hostels have been excluded from the trial, so that agents are limited to family, friends etc. of community-based consumers. Approval was also granted not to seek informed consent of agents. Agents will not be interviewed as part of the evaluation.

B. Survey of pharmacy operators/managers/proprietors

The Pharmacy Guild will distribute the survey form and a covering letter (Attachments 4 & 5) to all of its 5000 members (pharmacy proprietors) throughout Australia. The anticipated response rate is 10-15%, resulting in a sample size of 500-750.

- 3. Procedure.** In the case of **human** subjects, please provide a description of what participants will be asked to do, materials or equipment that will be used, who will collect the data, and where data collection will take place. If a questionnaire will be used, attach a copy to your application.

A. Evaluation interviews

The selected operators/managers/proprietors, employed pharmacists, dispensing staff and consumers will be interviewed in accordance with the attached interview forms (see Attachments 2 & 3). Interviews will be conducted face-to-face by a member of the research team, in a private office space at each pharmacy. The interviewer will complete the form. No video or audio recordings will be made.

B. Survey of pharmacy operators/managers/proprietors

The survey form and a covering letter (Attachments 4 & 5) have been developed in consultation with the EAG, and will be pilot tested in a small sample of Ballarat pharmacies who are not involved in the trials. The PGA will distribute the form and letter to all of its members (pharmacy proprietors) throughout Australia. Respondents will be awarded Quality Care Pharmacy Program (QCPP) points by the Guild for completing the survey form. For this purpose, a Guild membership number will be required, but the research team will be blinded to the identity of the respondents, although the data will be potentially identifiable. Completed forms will be returned to the PGA by reply paid mail or fax. Return of a completed form will be taken to imply informed consent.

PPROVALS/PREREQUISITE READING

Declaration/s: I/We, the undersigned

- **accept** responsibility for the conduct of the research outlined in this application in accordance with the ethical principles specified by the Human Research Ethics Committee of the University of Ballarat and the information provided in this application.
- **advise** that all relevant reading has occurred as per details provided below. (Refer: **Reserve Desk, Library** and/or Research & Graduate Studies Office. Refer UB homepage for Ethical Principles document)

Research Involving Human Subjects

√ box

Ethical Principles in Human Experimentation: Information for Students (Univ. of Ballarat)



NHMRC Statement on Human Experimentation (*Mandatory*)



(*Where necessary*) Supplementary note 2 (research on children, mentally ill)

Guidelines on ethical matters in Aboriginal and Torres Strait Islander research

	Signatures	Print Name in Full	Date
Student Applicant(s)
Staff Applicant(s)
Staff Applicant(s)
Staff Applicant(s)
Staff Applicant(s)
Staff Supervisor

RHDE Co-ordinator to sign (if not available or if the Co-ordinator is the Principal Researcher then the Head of School may sign):

The research outlined in this application is soundly based; the academic staff responsible for undertaking or supervising the research are appropriately qualified.

School :	_____	Date :	_____
Signed :	_____	Print Name	_____

SCHEDULE A

1. PROTECTION OF PARTICIPANTS

- (a) Identify any procedures that might leave a participant open to risks of emotional or physical harm greater than or additional to risks encountered in the participant's normal lifestyle. Some such risks could follow from disclosure of the names or data about participants. If there are such risks, identify steps you will take to minimise them and steps you will take if participants become distressed.

Whilst it is considered that there is nothing in the content of the interview questions that should cause a consumer distress, there is a risk that consumers in some categories may be particularly susceptible to distress, and may become distressed during an interview. In selecting consumers to be recruited for interviews, pharmacists have been requested to select clients who they know and who they consider will have the capacity to be interviewed productively and without distress. Consumer interviews will take place in a private space on the pharmacy premises. The pharmacist who recruited the consumer will be close at hand, and if any distress occurs the interview will be immediately terminated.

- (b) Will any invasive procedures be involved? Will participants come into contact with any equipment which uses an electrical supply in any form e.g., audiometer, biofeedback, electrical stimulation, etc.? If "YES", please outline below what safety precautions will be used.

No

- (c) If the research is being undertaken by an undergraduate or postgraduate student under supervision, what steps will be taken by the supervisor to ensure that the student is sufficiently competent to undertake the procedures involved in data collection and will conduct the research in accord with the procedures approved by the Human Research Ethics Committee?

Not applicable

2. CONFIDENTIALITY

EITHER outline the procedures you will follow to ensure the confidentiality of the information participants provide **OR** provide a justification for not protecting the confidentiality of the information participants provide. If you anticipate any secondary use for the data, please provide details. If any person with access to the data has another relationship with any of the participants (eg. family member, employer/employee, therapist/client, instructor/student), please identify the steps that will be taken to preserve the anonymity of participants.

- All primary data will be de-identified and treated as confidential and only made available to members of the research team on a need to know basis.

- Information linking participant names to participant codes will only be accessed by the Chief Investigators.
- Only aggregated data and statistical summaries will be presented in reports to the PGA or publicly released reports.

3. SECURITY OF DATA

How will security of data be maintained **(a)** during the study and **(b)** following completion of the study? (A period of five years, with the data held by Principal Researcher in the School, is standard).

Note: The keeping of audiotapes used for transcription is optional; if the tapes are kept they should be preserved with the same level of confidentiality as the transcribed data.

(a) *During the study*

Data entry will be carried out under the supervision of the Principal Researchers, and will be stored on password-protected laptop computers of the researchers on a need to know basis. Paper records will be stored in a locked filing cabinet in a secure room in the CCeH.

(b) *Following the completion of the study*

Paper records will be stored for at least 5 years in a locked filing cabinet designated for the purpose within the CCeH. The electronic data files will be held in the user domains of the Principal Researchers on a secure UB file server, and archived for at least 5 years on UB file system backups.

4. OTHER ETHICAL ISSUES

Identify and comment on any ethical issues that are inherent in the research and the procedures to be employed (see **Attachment 2** for checklist - eg. researcher(s)' use of deception requiring debriefing of participants; provision of counsellors for participants experiencing stress; minority and cultural sensitivities which may impact on the individual, etc.).

The following (reiterated from our previous application) pertains to the research as a whole, including the recruitment of individuals to be interviewed.

Special relationship between the recruiter, or any investigator, and the participants

- An employer-employee relationship exists between the recruited pharmacy managers and the recruited pharmacists and dispensing technicians. To assist in the recruitment process, information sessions will be held with all pharmacists within any pharmacies that are interested in participating in this study. The nature of the information sessions will be to inform potential participants of the trial protocols they will be asked to implement, and also the wider implications of the study and potential long term benefits to their profession as a whole. Pharmacist managers will be asked to discuss the study with their staff prior to agreeing to participation. If most pharmacists and dispensing technicians within a pharmacy are interested and prepared to participate in the study, and are each prepared to sign individual consent forms, the trial will proceed in that pharmacy.

According to the industry experts associated with this study, pharmacies generally use the same locum pharmacists on a regular basis. To ensure locum pharmacists are also prepared to participate in the study, they will be invited to the preliminary information sessions and will be encouraged to participate in any discussions the pharmacy manager has with staff about possible participation in the study. In addition an information kit will be provided to participating pharmacies that can be used to train any new staff or locum staff joining the pharmacy during the trial period.

The trial protocols will not require all pharmacists and dispensing technicians within a participating pharmacy to participate in the trial, although it will obviously be more convenient for all concerned if that is the case.

- A supplier-consumer relationship exists between participating pharmacists and consumers who they recruit for post-trial evaluation interviews. Recruitment protocols include a clear statement that participation is voluntary, and that no adverse consequences regarding future health care will follow from declining to participate.

Attachments

No.	Document
1	Ethical issues checklist
	Evaluation interview protocols
2	Pharmacists and dispensing technicians
3	Consumers
	Survey of pharmacies
4	Covering letter
5	Survey form

ATTACHMENT 1

(Must be attached to every application involving human subjects)

ETHICAL ISSUES

Please indicate (*by X as appropriate*) what in your view are the ethical issues involved in this research. The following is a checklist of possible ethical issues.

	YES	NO
(a) Does the research involve external funding?	<input checked="" type="checkbox"/>	
(b) Is deception to be used? Please state below how disclosure and confidentiality are to be dealt with		<input checked="" type="checkbox"/>
(c) Does the data collection process involve access to confidential participant data without the prior consent of subjects? For the project as a whole – yes. This was dealt with in the previous application. Not for the aspect of the data collection covered by this application.		<input checked="" type="checkbox"/>
(d) Will subjects have pictures taken of them, e.g., photographs, video recordings? If "YES", please explain below how you intend to retain confidentiality and ultimately dispose of the material.		<input checked="" type="checkbox"/>
(e) If interviews are to be conducted, will they be tape-recorded? If "Yes", please explain below how you intend to retain confidentiality and ultimately dispose of the material.		<input checked="" type="checkbox"/>
(f) Will participants come into contact with any equipment which uses an electrical supply in any form e.g., audiometer, biofeedback, electrical stimulation, sharp objects, etc.? If "YES", please outline below what safety precautions will be used.		<input checked="" type="checkbox"/>
(g) Will participants be asked to commit any acts, or disclosure of information which might diminish self esteem or cause them to experience embarrassment or regret?		<input checked="" type="checkbox"/>
(h) Will any treatment be used with potentially unpleasant or harmful side effects e.g. drugs or other substances? Not as part of the research per se		<input checked="" type="checkbox"/>
(i) Does the research involve any stimuli, tasks, investigations or procedures which may be experienced by subjects as stressful, noxious, aversive or unpleasant during or after the research procedures?		<input checked="" type="checkbox"/>
(j) Will the research involve the use of no-treatment or placebo control conditions?		<input checked="" type="checkbox"/>
(k) Will any samples of body fluid or body tissue be required specifically for the research which would not be required in the case of ordinary treatment?		<input checked="" type="checkbox"/>
(l) Is there any special relationship between the recruiter, or any investigator, and the participants? If so, what steps will be taken to minimise coercive, inducive and/or deceptive influences on subjects?	<input checked="" type="checkbox"/>	

Dispensing and Monitoring of S4 & S8 Drugs

- (m) Are there any social, cultural, linguistic, religious or other sensitivities that have been taken into account in the design of the study? ☒
- (n) In your opinion, are there any other ethical issues involved in the research? ☒

NOTE: If the answer to any of the above questions is "yes", please explain your response in Question 4: **Other Ethical Issues**, of either Schedule A or Schedule B.

Response from Ethics Committee

HUMAN RESEARCH ETHICS PROVISIONAL APPROVAL FORM

Principal Researcher/Supervisor: J Harvey

Associate/Student Researcher/s:

School: ITMS / Collaborative Centre for eHealth (CCeH)

Ethics Provisional Approval has been granted for the following project:

Project Number: A05-156

Project Title: Dispensing in instalments of S4 S8 drugs with dependency properties: Evaluation of trial protocols & survey of pharmacists

Full approval is subject to the following special conditions being met, as stipulated by the Human Research Ethics Committee:

- Letter to participants – Please remove the sentence 'we need your assistance'. Participants must be invited to participate.

Please quote the Project No. in all correspondence regarding this application.

BEFORE BEGINNING THIS PROJECT

You **MUST** provide the Executive Officer with a letter or memo detailing how the above issues have been addressed. Hard copies of any changed documents (eg. Plain Language Statements or notices) to be provided to the Executive Officer. **You may not begin this project until full approval has been granted.**

Timeline – evidence of how the above provisions have been addressed is to be provided to the Executive Officer by the 10 December 2005.

If you do not provide the Executive Officer with this evidence by this date, the provisional approval will lapse and a resubmission will be required.

Signed:.....

Date: **10 November 2005**

(Executive Officer, HREC)



Human Research Ethics Committee (HREC)

Research & Graduate Studies Office

HUMAN RESEARCH ETHICS APPROVAL FORM

Principal Researcher/Supervisor: J Harvey
Associate/Student Researcher/s: C Lynton-Moll
School: ITMS / Collaborative Centre for eHealth (CCeH)

Ethics approval has been granted for the following project:

Project Number: A05-156

Project Title: Dispensing in instalments of S4 S8 drugs with dependency properties: Evaluation of trial protocols & survey of pharmacists

For the period: 16/11/2005 **to** 30/04/2006

Please quote the Project No. in all correspondence regarding this application.

PLEASE NOTE: Within one month of the conclusion of the project, researchers are required to complete a Final Report Form and submit it to the HREC Executive Officer. Therefore, a final report on this project is due on the **30 May 2006.**

If the project continues for more than one year, researchers are required to complete an Annual Progress Report Form and submit it to the HREC Executive Officer within one month of the anniversary date of the ethics approval.

Signed:.....
(Executive Officer, HREC)

Date: **16 November 2005**

12.17 Appendix 17: Questionnaires and surveys

S4 & S8 Drugs: Dispensing in Instalments Survey



This questionnaire concerns dispensing of S4 and S8 drugs **other than methadone and buprenorphine**, in instalments and including the use of unit dose packaging containers that could dispense benzodiazepines, narcotics and stimulant drugs.

Definitions: In this questionnaire, the terms

- **S4/S8 OTMB** is used as a short hand for S4 and S8 drugs **other than methadone and buprenorphine**.
- **Dispensing in instalments (DII)** is the practice of dispensing a single prescription in multiple instalments.
- **Supervised dosing (SD)** is the practice of supplying a single dose of a medicine and observing the consumer take the dose. DII includes SD.

Please enter information in the spaces provided.

1) Postcode of your pharmacy.	
2) How many clients per week does your pharmacy dispense S4/S8 OTMB to?	
3) How many of these per week require DII or SD?	
4) How many contacts per week do DII and SD of S4/S8 OTMB involve?	
5) How many of PBS listed items per week are written as private prescriptions?	
6) How many FTE pharmacists do you have on staff?	
7) What percentage of your DII programs would you describe as follows?	

A single prescription supplied by DII	%
Multiple repeat prescriptions supplied by DII	%
Total	100 %
Instalment is similar in size to prescription quantity	%
Instalment is much smaller in size than prescription quantity	%
Total	100 %

8) How often do you use the following instalment containers?

	Rarely/Never	Sometimes	Often
Consumer's Own Container	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Capped container	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Disposable pack	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Disposable dispensing aid	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Re-usable dosing aid	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9) Do you charge for instalment containers? If so, how much?

	Rarely/Never	Sometimes	Often	Charge
Capped container	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	\$ _____
Disposable pack	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	\$ _____

Dispensing and Monitoring of S4 & S8 Drugs

Disposable dispensing aid ☐ ☐ ☐ \$ _____
 Re-usable dosing aid ☐ ☐ ☐ \$ _____

10) Do you currently charge an additional fee for DII (over and above any container fee)?

Rarely/Never ☐ Sometimes ☐ Often ☐

If so, how much? \$ _____ per instalment

OR \$ _____ per prescription

OR some other basis \$ _____ Specify basis _____

11) Regardless of whether or not you charge, how much time do you estimate each of the following DII activities takes you and/or your staff?

	Pharmacist	Dispensing tech.
Dispense and set up	minutes	minutes
Supply a DII instalment	minutes	minutes
Supply a SD instalment	minutes	minutes
Deliver an instalment	minutes	minutes
Prescriber consultation	minutes	minutes
Other DII consultation	minutes	minutes

12) If there were standard procedures and remuneration for these practices, would it increase the use of:

	Yes	No
Dispensing S4/S8 OTMB drugs in instalments?	<input type="checkbox"/>	<input type="checkbox"/>
Supervised dosing for S4/S8 OTMB drugs?	<input type="checkbox"/>	<input type="checkbox"/>

13) Does communication/feedback occur between you and the medical practitioner when a request made for:

	Rarely/Never	Sometimes	Usually
Dispensing S4/S8 OTMB drugs in instalments?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Supervised dosing for S4/S8 OTMB drugs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

14) How does the communication occur?

	Rarely/Never	Sometimes	Often
Telephone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Email	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fax	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Post	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

15) On average, how often do you communicate with the medical practitioner about each DII consumer?

Weekly	<input type="checkbox"/>
Monthly	<input type="checkbox"/>
Less than once a month	<input type="checkbox"/>
At prescription commencement	<input type="checkbox"/>
At prescription expiry	<input type="checkbox"/>
Other	<input type="checkbox"/> Specify _____

15) On average, how often do you communicate with the medical practitioner about each DII consumer?

Weekly ☐

Monthly	<input type="checkbox"/>	
Less than once a month	<input type="checkbox"/>	
At prescription commencement	<input type="checkbox"/>	
At prescription expiry	<input type="checkbox"/>	
Other	<input type="checkbox"/>	Specify _____
16a) Do you have any issues/difficulties with providing feedback to medical practitioners?	Yes	No
	<input type="checkbox"/>	<input type="checkbox"/>
16b) If YES, what are some of the issues/ difficulties with providing feedback to medical practitioners?		
Medical practitioner unavailable after hours	<input type="checkbox"/>	
Medical practitioner unavailable for other reasons	<input type="checkbox"/>	
Messages not delivered in a timely manner	<input type="checkbox"/>	
Other (specify below)	<input type="checkbox"/>	

17) Are you aware of any concerns consumers may have with DII or SD for S4/S8 OTMB drugs?

18) What strategies have you used to assist in the management of DII and/or SD with this client group?

Please comment on any other aspect of dosing in instalments or supervised dosing for S4 and S8

Thank you for taking the time to participate in this survey.

Please refer to the covering letter for details of how to mail or fax back to CCeH on 03 5327 9307 by January 31, 2006.

Consumer Interview

S4 & S8 Drugs: Dispensing in Instalments – Consumer Interview

Italicized text is for the information of the interviewer.

Go through the following information in a conversational manner.

Introduction

As you know, this pharmacy, and you yourself, have been involved in a trial of a best practice model for the dispensing in instalments of S4 and S8 drugs. The purpose of this interview is to get a consumer point of view on the procedures involved in the best practice model.

Procedure

I have just a few questions to ask. You are welcome to make additional comments at any time. I will record your opinions and note your comments. If you don't think a particular question is applicable to you, or if you have no opinion about it, feel free to say so. You are welcome to view my notes at any time, or after the interview.

1) How often do you attend your pharmacy to pick up your medication?

2) Do you get a single dose of your medication at a time? Yes No N/A

☐ ☐ ☐

3) **If NO to Q2** What sort of container do you use? **Ask conversationally, and fill in the following.**

	Rarely/Never	Sometimes	Often
Consumer's Own Container	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Capped container	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Disposable pack	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Disposable dispensing aid	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Re-usable dosing aid	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4) Were you getting medication in this way before the best practice trial began? Yes No DK

☐ ☐ ☐

5) **If YES to Q5** Have you noticed any changes since the trial began? Yes No DK

☐ ☐ ☐

If YES, what changes have you noticed?

Are these changes for the better or worse?

6) Would you say you are happy with the procedure for getting your medication?

Yes No

☐ ☐

If NO, what are you not happy/satisfied about

6) Has Dosing in Instalments **or** Supervised Dosing (***as applicable***) increased your costs?

Yes	No	DK
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

That is all of my questions

8) Would you like to make any other comments about any aspects of the trial?

Thank you for taking the time to participate in this research

Trial Pharmacies Post Interview

S4 & S8 Drugs: Dispensing in Instalments – Trial Pharmacies Interview

Pharmacy						
Interviewee	Name _____	Signature _____	Date _____			
Interviewer	Name _____	Signature _____	Date _____			
Type of respondent	<input type="checkbox"/> Proprietor/manager <input type="checkbox"/> Other pharmacist <input type="checkbox"/> Dispensing Technician					

Italicized text is for the information of the interviewer.

Get the interviewee to sign off that they understand the instructions prior to filling out the questionnaire

Go through the following information in a conversational manner.

Introduction

As you know, this pharmacy (and you yourself) has been involved in a trial of a best practice model for the dispensing in instalments of S4 and S8 drugs **other than methadone and buprenorphine**. The purpose of this interview is to find out three things:

- how well you think the trial worked,
- whether you think any aspects of the best practice model need to be altered, and
- whether you feel that the various documents adequately captured the relevant information and adequately represented the workload involved in the dispensing in instalments.

Firstly, just to clarify the terminology:

- The term **S4 & S8 drugs** is used as a shorthand for S4 and S8 drugs **other than methadone and buprenorphine**.
- **Dosing in instalments** is the practice of dispensing a single prescription in multiple instalments.
- **Supervised dosing** is the practice of dispensing a single dose of a medicine and observing the consumer take the dose. DII includes SD.

Preamble

The trial protocols involved a number of **documents**. There were two aspects to these documents.

1) If the protocols are ultimately adopted as standard professional practice (by the Pharmacy Guild or some regulatory authority), **these documents will form the basis of future standard procedures**. For this purpose we need to know:

- whether the document **adequately represents best practice**.
- Whether the document is **easy to use**.

2) However, some of the documents also had **extra aspects which only applied to the trial**. These included:

- the **reversing and folding** of documents which consumers had to sign, which was to preserve consumer anonymity by keeping consumers' names hidden from us (the researchers) and
- the recording of the **time spent on each task**, which was to enable us to estimate the workload involved and hence recommend an appropriate remuneration level for this work.

I am going to ask you about each document in turn. Most questions are about the first aspect i.e. **whether the document represents best practice** and **whether the document would work in practice**. In answering these questions, I want you to try to **disregard** any aspects of the document which only applied to the trial itself.

Two questions are about the second aspect i.e. whether the trial really did gather the **relevant information about workloads**.

Procedure

In most cases, I will first ask you for an opinion on a 5 point scale from strongly positive to strongly negative, and then invite you to make a comment or make any suggestions for improvements if you wish to.

I will record your opinions and take notes of your comments. If you don't think a particular question is applicable to you, or if you have no opinion about it, feel free to say so. You are welcome to view my notes at any time, or after the interview.

1) Decision Tree for Reporting Anomalies (DT-01)

	Strongly agree	Agree	Neutral/ Uncertain	Disagree	Strongly Disagree	Not Applicable
Represents best practice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is understandable & easy to use	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments/suggestions	<hr/>					
	<hr/>					
	<hr/>					
	<hr/>					

2) Decision Tree for the Best Practice Model for Dispensing in Instalments (DT-02)

	Strongly agree	Agree	Neutral/ Uncertain	Disagree	Strongly Disagree	Not Applicable
Represents best practice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is understandable & easy to use	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments/suggestions	<hr/>					
	<hr/>					
	<hr/>					
	<hr/>					

3) Trial protocols 1-7

	Strongly agree	Agree	Neutral/ Uncertain	Disagree	Strongly Disagree	Not Applicable
Represents best practice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is understandable & easy to use	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments/suggestions

4) Prescriber Register” (RF-05)

	Strongly agree	Agree	Neutral/ Uncertain	Disagree	Strongly Disagree	Not Applicable
Represents best practice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is understandable & easy to use	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments/suggestions

5) Dispensing in Small Quantities Record Sheet (RF-01)

	Strongly agree	Agree	Neutral/ Uncertain	Disagree	Strongly Disagree	Not Applicable
Represents best practice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is understandable & easy to use	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments/suggestions

6) Consumer Register (RF-02)

	Strongly agree	Agree	Neutral/ Uncertain	Disagree	Strongly Disagree	Not Applicable
Represents best practice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is understandable & easy to use	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Extra: Were the “reasons for dispensing” adequate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments/suggestions

7) Dispensing in Instalments Record Form (RF-03)

	Strongly agree	Agree	Neutral/ Uncertain	Disagree	Strongly Disagree	Not Applicable
Represents best practice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is understandable & easy to use	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Extra: Were the times captured adequately	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments/suggestions

Other pharmacists and dispensing technicians go straight to Q11.

Questions for proprietor/manager only.

In the trial we collected data about staff time and numbers of instalment containers used. This was to enable us to work out adequate remuneration levels for DII and SD. For this purpose, the Pharmacy Guild has provided us with data about hourly rates for pharmacists and dispensing technicians.

8) Can you tell me the cost of the instalment containers you use?

Capped container \$ _____

Disposable pack \$ _____

Disposable dispensing aid \$ _____

Re-usable dosing aid \$ _____

9) Are there any other costs that we should factor in to remuneration estimates?

- 10) If a package of decision trees, protocols, consumer register (or perhaps individual consumer cover sheet), and Dispensing by Instalments Record Form (RF-03) with the time recording aspect removed, were distributed by the Guild, would you use it?

Yes	Probably	Maybe	Probably not	No
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If NO or PROBABLY NOT, what would change your opinion

That is all of my questions

- 11) Do you want to make any other comments about any aspects of the trial?

Thank you for taking the time to participate in this research

12.18 Literature Review

Introduction

Background

The role of the community pharmacist in managing consumers with dependency issues has been expanding, particularly since the 1980s (Anderson & Berridge, 2003). Services provided by pharmacists to assist with this problem, from an international perspective include: needle exchange; methadone dispensing; notification of addicts; treatment services such as monitoring and feedback to the prescriber; and advice to consumers (Berbatis, Sunderland & Bulsar, 2003a).

Another potential role for the community pharmacist in managing consumers with dependency issues was identified from the National Pharmacy Database Project (Berbatis, Sunderland, Mills & Bulsara, 2003b): An Analysis of Pharmacy Practices in Australia. One of the outcomes of this work, recommendation 13, highlighted a need to investigate the practices of dispensing using 'supervised dosing' for drugs other than methadone and buprenorphine and to develop a model of practice which included appropriate remuneration. This recommendation stated that:

High percentages of Australia's community pharmacies reported the weekly provision of dose administration aids and supervised dosing without charging ... National bodies of pharmacy should organise and publicise the cost-effectiveness evaluations of the provision of dose administration aids and supervised dosing by pharmacies in order to establish acceptable remuneration for these services. University departments of pharmacy should emphasise the benefits and procedures of dose administration aids and supervised dosing in the routine teaching of pharmacy practice (p. 11).

Berbatis et al., (2003b) discriminate between supervised dosing for methadone and buprenorphine programs, and supervised dosing for drugs other than those used in opioid substitution programs, however they do not explicitly investigate the practice of dosing in daily, two to three daily or weekly instalments. Preliminary discussions with pharmacists who currently use the process dispensing in instalments (commonly referred to as daily dosing)³, reinforced the need for this issue to be investigated. They highlighted the potential benefits to consumers and the health system, and warned of the current risk that the practice will cease due to the problems currently being experienced by pharmacists.

The Pharmacy Guild of Australia and the Australian Government Department of Health and Ageing through the Dispensing and monitoring of schedule 4 and schedule 8 drugs (with dependency properties) project, wish to develop dispensing and counselling protocols, including the development of an appropriate fee for unit dose medication to patients who may be at risk from drugs with dependency properties. They wish to examine the role, effectiveness and cost for the pharmacist within this drug management strategy and make recommendations, including remuneration and dispensing protocols, to all parties concerned.

This literature review provides background to this project including a problem definition, project scope and the aims of the project. This is followed by a review of Australian and international literature that relates to the practice of dispensing in instalments. The results of interviews with industry experts and the issues arising from these will be included in the next revision of this report (mid-term).

Supervised dosing of methadone and buprenorphine have been excluded from this work as there is a concurrent project investigating issues surrounding these medications.

³ In the literature, the term used to describe this practice is 'dosing or dispensing in instalments'. As the term commonly used within Australia for this practice is 'daily dosing' even when the dosing is weekly or biweekly, the term dispensing in instalments will be used from this point forward.

Reasons for dispensing in instalments

According to interviews with industry experts, a number of consumers if given a full prescription of drugs with addictive properties may take too many of the drugs at one time, run out of their supply before they are due for their next prescription, forget to take their medication on a regular basis, divert the drugs (sell or swap the drugs for illicit drugs) or induce self harm by over dosing.

One strategy for dealing with these problems is for a prescriber to prescribe a drug of addiction in a small quantity. Another strategy is to prescribe a full dose, but request the pharmacist to control the supply of the drug. The drug may be dispensed in small quantities at more frequent intervals (prescription written for the total quantity, but dispensed in portions, weekly or biweekly) (Gardner-Nix, 2003).

The expected benefits of instalment dispensing include:

- supporting consumers who have complex social needs (SERFLFC, 2004);
- ensuring consumers have regular contact with a health professional (SERFLFC, 2004);
- aiding in compliance (SERFLFC, 2004);
- assisting in the prevention of suicide (PSNC, 2003);
- prevention of diversion (PSNC, 2003; Tebbutt, 2004);
- managing benzodiazepine levels following a withdrawal program (PSNC, 2003);
- reducing benzodiazepine prescribing (Routledge, 2002).

Consumers who may benefit from dosing in instalments

Three groups of consumers have been identified who may benefit from the use of dispensing in instalments. These groups may include (but are not limited to):

- consumers who are drug dependent, and have a therapeutic need for a schedule 8 (controlled drug) or schedule 4 (restricted drug) drug which has addictive properties;
- consumers who have a psychiatric illness who have difficulty managing their medications. Remaining on their medication will assist in the management of their disorder. Failing to manage their medication is likely to result in re-admission to acute psychiatric services, resulting in additional trauma to the consumer and his/her family, and an additional cost to the public health system; and
- a third but smaller group of consumers who may benefit from this process, are consumers who have a disability which prevents them from managing their medication. One example given by a pharmacy expert was a woman with an intellectual disability who took medication for epilepsy. Failure to take the medication would result in a reoccurrence of her epilepsy, whereas assistance with the management of her epilepsy allows her to remain in the community.

Issues surrounding the practice of dispensing in instalments

Although pharmacists within Australia dispense in instalments, the pharmacist experts interviewed for this project stated that pharmacists are increasingly choosing not to offer the service of daily dosing and that there is a risk that the potential benefits of this practice will be lost unless a model of service delivery, including appropriate remuneration, is developed and rolled out across Australia. The frustrations experienced by pharmacists identified by these initial interviews include:

- a lack of remuneration for the additional time required for prescribing a prescription in multiple instalments. One pharmacist indicated that he has up to 30 people on daily dosing at any one time, a service which costs the pharmacy time and resources, with no remuneration;
- the consumer population take a significant amount of time and are a difficult group to deal with;
- the practice is not regulated (limited legislation about how this practice should be handled), and so the processes used by pharmacies are ad hoc.

Aims of project

The project will examine the role, effectiveness and the cost for the pharmacist within this drug management strategy. It will develop, trial and evaluate dispensing and counselling protocols, and will

seek to identify and recommend an appropriate fee structure for unit dose medication to patients who may be at risk from drugs with dependency properties.

The specific aims of this project are:

1. to identify the scope of the practice of dispensing by instalments, with respect to:
 - the range of S8 and S4 drugs involved
 - the categories of patient at risk
 - the prevalence of the practice in seven pharmacies in three test regions
2. to identify the key elements of the process
3. to formulate protocols for dispensing, packaging, storage, supply, security, record keeping, and provision of feedback to medical practitioners
4. to trial the protocols in a sample of community pharmacies
5. to maintain “activity records” throughout the trial for evaluation purposes.
6. to further evaluate and analyse the trial on the basis of interviews with participating pharmacists, dispensing staff, medical practitioners and consumers
7. to survey a wider group of pharmacists in order to further quantify current practices and to elicit their reactions to the outcomes of the trial and to provisional recommendations.

Project Scope

The groups involved in the process of dispensing in instalments include interactions between the State regulation authorities, prescribers, dispensers, consumers and their support networks. The literature review, the interviews with industry experts, and discussion surrounding the best practice model will include the role of each of these four groups, as indicated in Figure 0-1.

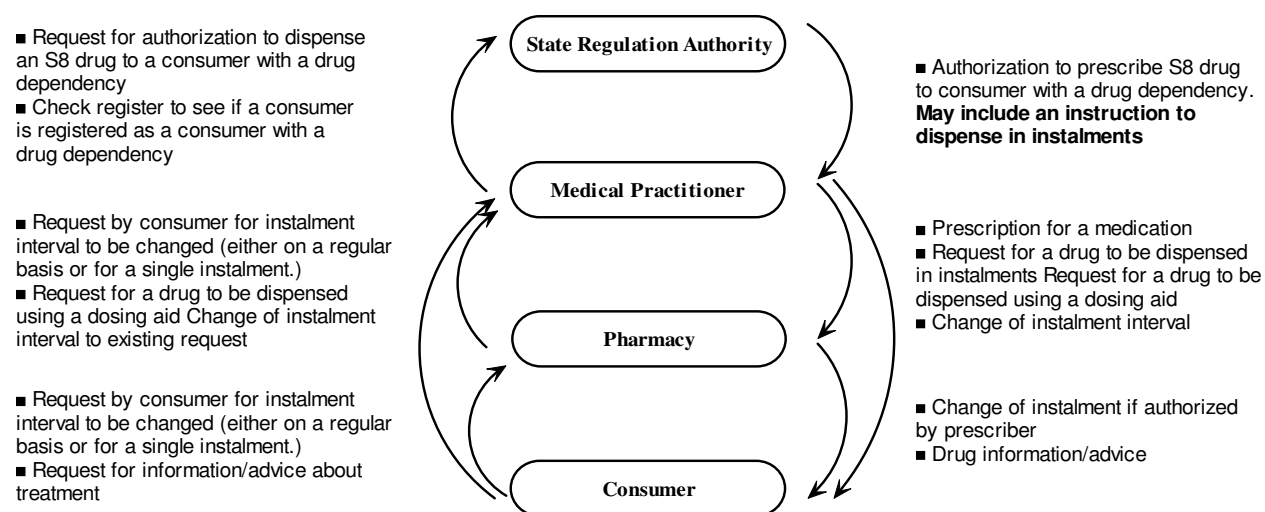


Figure 0-1 Dispensing in instalment information flows

The trial of the best practice model will be limited to the role of the dispensing pharmacy and pharmacy staff, as indicated in **Figure 0-2**. Data can be gathered about the communication between from the medical practitioner to the pharmacist, and from the consumer to the pharmacist, however as the medical practitioners and consumers have not been recruited as research participants, it will not be possible to implement best practice guidelines for these groups to follow.

To include protocols that include communication from the medical practitioner to the pharmacist, medical practitioner/pharmacist pairs would need to be recruited, rather than pharmacists only. Also, informed consent would need to be obtained from the medical practitioners as well as the pharmacists. This would increase the complexity of the study, which is broader than what was specified within the original tender documentation.

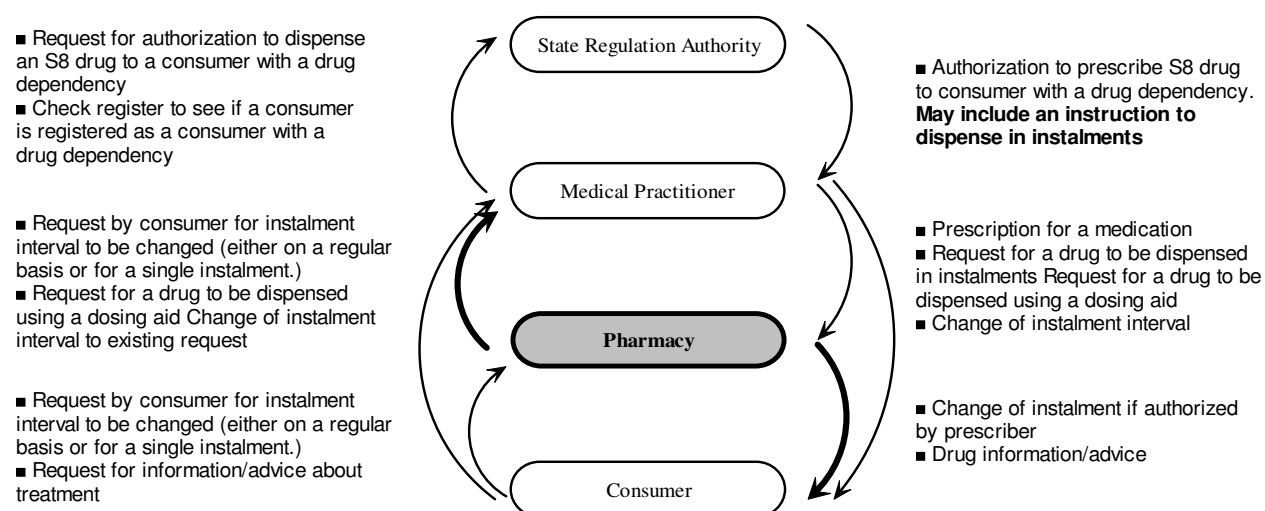


Figure 0-2 Information flows included in the Best Practice Model trial

The project scope includes:

- the practice of dispensing schedule 4 (S4) and schedule 8 (S8) drugs (with dependency properties), in daily, two to three daily or weekly instalments;
- the three consumer groups described in section 1.2.1;
- consumers in community settings only.

Literature Review

Introduction

A review has been conducted of literature that relates to the practice of dispensing in instalments, within Australia and internationally. This includes a discussion of legislation, regulations and guidelines as well as published research.

Terminology

A number of industry terms and classification are used within this document. These have been defined below.

Australian standards for uniform scheduling of drugs and poisons throughout Australia

The scope of this project includes drugs of dependence, that are either schedule 8 (S8) drugs (controlled drugs) or a subset of schedule 4 (S4) drugs (restricted drugs) which have dependency properties. Schedule 8 and schedule 4 drug classifications vary between States and Territories within Australia. To assist in obtaining some consistency between States and Territories, a document, "Standard for the uniform scheduling of drugs and poisons (SUSDP)" (TGA, 2005) has been developed by the Commonwealth Government Department of Health and Ageing, to promoting uniform scheduling of substances and uniform labelling and packaging requirements throughout Australia. This document describes:

The Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) and its Amendments contain the decisions of the National Drugs and Poisons Schedule Committee (NDPSC), regarding the classification of drugs and poisons into Schedules for inclusion in the relevant legislation of the States and Territories. The SUSDP also includes model provisions about containers and labels, a list of products recommended to be exempt from those provisions, and recommendations about other controls on drugs and poisons (p.1)

At this stage, however, there remains variation in drug scheduling between the States and Territories of Australia.

Schedule 8, schedule 4 and drugs of dependence

The following definitions, from the Victorian Government health legislation (DHS, 2004b), are used within the remainder of this document.

Schedule 8 poisons (*labelled Controlled Drug*) are drugs with more strict legislative controls, eg. morphine (Kapanol, MS-Contin), pethidine, oxycodone (Oxycontin, Endone), methadone (Physeptone), hydromorphone (Dilaudid), flunitrazepam (Hypnodorm), fentanyl (Durogesic, Sublimaze), codeine phosphate (alone).

A permit might be required before prescribing S8 poisons.

Schedule 4 poisons (*labelled Prescription Only Medicine*) include all other drugs for which prescriptions are required, eg. diuretics, contraceptives, antibiotics, some compound analgesics (Panadeine Forte) and many others.

The term “**drugs of dependence**” is used to describe **all** S8 poisons **plus** those S4 poisons that are more subject to misuse and trafficking, eg. benzodiazepines, dextropropoxyphene (Doloxene, Digesic), anorectic drugs (Tenuate Dospan, Duromine,) and anabolic steroids (p.1)

Supervised dosing

‘Supervised dosing’ is the practice of dispensing a single dose of a medicine, and observing the consumer take the medication to minimise the risk of drug diversion. This practice is used extensively in opioid substitution programs, and according to the National Pharmacy Dispensing Project (Berbatis et al., 2003b), is also used with drugs such as analgesics, benzodiazepines, and other psychotropics.

Dispensing in instalments

The term ‘dispensing in instalments’ has two distinct contexts. In Australia ‘dispensing in instalments’ describes the practice of dispensing a single prescription in multiple instalments (e.g. daily, biweekly, or weekly). This concept is also referred to informally as ‘daily dosing’. In the United Kingdom, the term ‘dispensing in instalments’ is used in the above context, but also to describe the practice of prescribing in larger than single prescription quantities (such as a six-month supply), and then dispensing in six, single monthly instalments (equivalent to a single prescription). This process is referred to ‘repeat dispensing’, described below in section 2.3.8.1 (“Repeat Dispensing Will Merge with ETP and Medicines Management,” 2003).

For the purposes of this work ‘dispensing in instalments’ refers to the former definition, dispensing multiple instalments from a single prescription.

Daily dosing

Within this document, the term ‘daily dosing’ is used to refer to the informal name health professionals use to describe dispensing in daily, two to three daily, or weekly instalments. This is also referred to as ‘controlled dispensing’.

The term ‘daily dosing’ is also a unit of measurement used to describe the average daily consumption of a drug. This term has been developed in an attempt to overcome the difficulties in units of measurement between countries (Cosentino, Leoni, Banfi, Lecchini & Frigo, 2000). This is not the definition being used in this work.

Dose administration aids

Dose administration aids (DAAs) are devices used to aid the administration of medications (Berbatis et al., 2003b). According to the National Pharmacy Dispensing Project, these aids assist in monitoring and enhancing consumer compliance with therapeutic recommendations. They have also been found to reduce error rates during medication administration, however they increase pharmacy workloads (Roughead, Semple & Gilbert, 2003).

A group from Queensland University conducted a study investigating the effectiveness and cost effectiveness of dose administration aids (Roberts, Lentile, Lewis, Stokes, Doran, Hendry & Jensen, 2004) define dosing aids as:

- ...devices or packaging systems where doses of one or more solid oral medications (tablets or capsules) can be organised according to the time of administration. DAAs offer a number of potential advantages over taking medicines packaged in their original manufacturer's packs. For a person who must take a number of different solid oral medications each day, at a number of different times per day, using medications packed in original packs would involve:
- remembering that a dose time is due;
 - correctly retrieving the packs for each of the medications to be taken;
 - opening each pack and taking out the required number of tablets or capsules prescribed for a particular dose time. This might also involve different numbers of the same tablets at different times of day (e.g. one in the morning and two at night), and;
 - repeating the above for each dose time in a day (pp 4-5).

Dose administration aids in community settings also require the practice of dispensing a full prescription and supplying in weekly multiple instalments. Dose Administration Aids will therefore be included in the scope of this work for the previously defined consumer groups (see 1.2.2), who manage their own medication in the community setting (under consideration by the Expert Advisory Group).

Current Practices

As stated previously, there are no guidelines, legislation or regulations within Australia for the practice of dispensing in instalments. There are, however, regulations, legislation and guidelines for managing controlled drugs. These practices can be used when deriving a best practice model for dispensing in instalments. This section reviews the legislation, regulations and guidelines in Australia, and then reviews the current practices internationally that have been reported in publications.

Legislation and Guidelines in Australia

Medical practitioners and pharmacists are required to follow legislative guidelines surrounding the prescribing and dispensing of controlled and restricted drugs. This legislation varies between States and Territories within Australia.

Prescribing and Dispensing

The Drugs and Poisons Unit for each State and Territory have developed guidelines for medical practitioners and pharmacists based on their own legislation (Australian Capital Territory Government, 1993; Government of Western Australia, 1964; Northern Territory Government, 2005; NSW Government, 2002; Queensland Government, 1996; South Australian Government, 1996; Tasmanian Government, 2002; Victorian Government, 1995). An example is the Drugs and Poisons in Victoria: Information for health professionals web site, which provides guidelines for medical practitioners and pharmacists (DHS, 2004a). These guidelines are based on the Drugs, Poisons and Controlled Substances Act 1981 and Drugs, Poisons and Controlled Substances Regulations 1995. These acts are available on the Victorian Legislation and Parliamentary Documents Website (Victorian Government, 1995).

These guidelines provide information about:

- ensuring there is a valid therapeutic need;
- determining if the consumer has a drug dependency;
- reporting if a consumer is drug dependent;
- holding a permit to prescribe S8 drugs for more than eight weeks;
- holding a warrant to prescribe an oral retinoid, ovulatory stimulant or prostaglandin;
- prescribing S8 and S4 drugs for consumers with a history of drug addiction;
- prevention illegal use of controlled drugs;
- record keeping in relation to sale or supply of drugs of addiction;
- storage of controlled drugs;
- disposal of controlled drugs.

A flowchart outlining the prescribing requirements for medical practitioners can be found in Appendix A, and the notification requirements for pharmacists can be found in Appendix B.

Some individual variations between States and Territories include:

- In South Australia and Tasmania there is an additional guideline stating that a drug of dependence is restricted to two day's supply (South Australian Government, 1996; Tasmanian Government, 2002) unless the person is known to the pharmacist, the pharmacist recognises the signature of the prescriber, or has verified the prescriber's identity.
- In the Northern Territory, S8 drugs are separated into two categories, restricted and non-restricted. A medical practitioner can only prescribe S8 drugs for a limited number of consumers at any time (Northern Territory Government).

There are many guidelines to specifically address issues surrounding opioids substitution programs, and the practice of 'supervised dosing' of methadone and/or buprenorphine, however no specific guidelines have been found within the Australian literature for dispensing drugs of addiction to a person with a drug dependency, in instalments.

A best practice model for dispensing in instalments will need to accommodate the variations in legislation and regulations between each State and Territory.

Reporting Labelling and Storage,

Recording, Labelling and Storage

For each of these protocols there are regulations pertaining to controlled and restricted drugs, but not specifically in relation to dispensing in instalments. Each of the following sections will outline the regulated practices in Victoria for these protocols, and comment on any significant State or Territory variation, with a discussion about how these regulations can be applied to develop a best practice model for dispensing in instalments.

Recording

For controlled drugs dispensed in Victoria, the following records must be kept (Victorian Government, 1995):

- A person to whom this Division applies must, as soon as practicable after completing a transaction, record—
- (a) the date of each transaction; and
 - (b) the name, form, strength and quantity of the poison or controlled substance; and
 - (c) in the case of a transaction involving supply on a prescription, the name of the prescriber, and the directions for use as set out on the prescription; and

- (d) the name and address or location of persons to whom the poison or controlled substance is transferred, supplied, administered or otherwise disposed of (pp. 37-38);

Based on the regulations above, records that need to be maintained each time an instalment is made include:

- Full details of the prescription as would be required for any other dispensing of a controlled drug;
- The date of each instalment;
- The quantity of tablets supplied and the quantity remaining on the premises;
- The name of the person supplying the drugs
- Labelling on the container the medication is supplied to the consumer indicating the name of the prescriber, and directions for use as set out on the prescription

Labelling

The Therapeutics Goods Administration (TGA) of Australia has developed some guidelines for labelling therapeutic goods. These guidelines make recommendations about labelling prescription medications when they are dispensed in a full prescription quantity, but do not specify labelling guidelines for supply in instalments (TGA, 2000). As these guidelines are extensive and very specific, they have been included in Appendix C.

Reinforcing the need for clear labels, a Quality Use of Medicines document outlining consumer Perspectives on managing multiple medications States that, “Labels are a vital source of information and they are critical in enabling consumers to manage their medications on a day-to-day basis” (p. 12, (PHARM Committee, 2001)). A recommendation from this report is to ensure “consistent labels on inner containers as well as any outer packaging if the two could become separated” (p.21 (PHARM Committee, 2001))

The implication for dispensing in instalments is that the labelling guidelines be implemented for each instalment, i.e. each instalment, whether in a container or a segment of a dosing aid should be labelled according to the regulations.

In the Australian Capital Territory legislation, it is required that a substance may not be supplied in any container without the explicit warning and safety directions attached (Australian Capital Territory Government, 1993). In Western Australia, leaving poisons unlabelled is an offence (Government of Western Australia, 1964)

Storage

Schedule 4 drugs

According to the Victorian government guidelines (Victorian Government, 1995), S4 drugs can only be stored:

- in the dispensing area of a pharmacy;
- in an area separated from the remainder of the premises and to which only a pharmacist has access;

Schedule 8 drugs

According to the Victorian government guidelines (Victorian Government, 1995), S8 drugs must be stored in:

- (a) a lockable storage facility that provides not less security than storage facility that is—
constructed of mild steel plate of 10 millimetres thickness; and

- (b) constructed with continuous welding of all edges; and
- (c) fitted with a door constructed of mild steel plate of 10 millimetres thickness, swung on hinges welded to the door and body of the cabinet, the door being flush fitting with a clearance around the door of not more than 1.5 millimetres; and
- (d) fitted with a fixed locking bar, welded to the inside face of the door near the hinge edge, which engages in a rebate when the door is closed; and
- (e) fitted with a 6 lever lock securely affixed to the rear face of the door; and
- (f) securely attached to a wall or floor in such a manner that it will resist attack by hand tools for 30 minutes or power tools for 5 minutes (pp33-34).

This locked cabinet, where possible, is to be dedicated to the storage of S8 and S9 poisons only. Any person responsible for transportation of S8 drugs must keep either the drugs and/or the key to a locked cabinet in his/her possession to prevent unauthorised access.

It can be assumed that when dispensing S8 and S4 drugs in instalments, once a prescription has been dispensed, but before it has been fully supplied to a consumer, that the above regulations for storage continue to apply to S8 and S4 drugs.

Privacy

Dosing in instalments requires cooperation between the consumer, the prescriber and the pharmacist. When there is health information exchange between health providers, consideration of privacy issues is required.

According to the Victorian Health Records Act (2001) (Victorian Government, 2001),

An organisation may use or disclose health information about an individual for the primary purpose for which the information was collected in accordance with HPP 1.1. (p.128)

And when all of the following apply

- (i) the organisation is a health service provider providing a health service to the individual; and
- (ii) the use is for the purpose of the provision of further health services to the individual by the organisation; and
- (iii) the organisation reasonably believes that the use is necessary to ensure that the further health services are provided safely and effectively; and
- (iv) the information is used in accordance with guidelines, if any, issued or approved by the Health Services Commissioner under section 22 for the purposes of this paragraph; (pp 128-129)

Communication between medical practitioners and pharmacists in relation to issues surrounding a dosing in instalments program for a consumer appears to be within the privacy laws of Victoria, without explicit consumer consent, as long as the communication "is necessary to ensure the further health services are provided safely and effectively" (p.129).

Current systems for prescribing and dispensing in instalments

The practice of dispensing in instalments is discussed within the international literature. Although daily and two to three day instalment prescribing and dispensing to assist with has been recommended by a number of organizations (Routledge, 2002; Tebbutt, 2004), the only location it has been implemented is in the Republic of Ireland.

Recommendations to use dispensing in instalments that have not been implemented

The National Services Framework for Mental Health (PSNC, 2003), discussed the need to promote safer prescribing of antidepressants to consumers who are at risk of self harm. One strategy they suggest is to prescribe small doses, with a recommendation to consider dosing in instalments, although they highlight the fact that there is no current provision in England for prescribing in instalments for this class of drugs.

There is no problem giving weekly prescriptions to patients who are exempt from paying prescription charges, but for patients who are not this may act as a deterrent to treatment, particularly at a time when they may be experiencing side effects, but as yet deriving little benefit from the drug. Under the current system in England it is not possible to prescribe antidepressants or antipsychotics in instalments on FP10. Instalment dispensing has been identified as an appropriate contribution that community pharmacists can make to the care of people with mental illness (p.24).

Guidelines (British National Formulary, 2004) and a prescription form for prescribing in instalments, is available in England; the FP10MDA prescription form (NHS, 2005b). However, this form is used to order controlled drugs specifically for the treatment of addiction, and equivalent program to the methadone and buprenorphine programs in Australia. A copy of this form is in Appendix C.

A Canadian paper suggesting strategies for the management of pain in non-cancer consumers, recommends the use of dispensing in instalments (Gardner-Nix, 2003) to assist in the prevention of diversion for this population.

If there is a past history or strong family history of substance abuse, the patient can still be treated with opioids but within certain boundaries: opioid medication may be dispensed from the pharmacy in small quantities at more frequent intervals (prescriptions can be written for a total quantity to be dispensed in portions, specified, at weekly or biweekly intervals), and the patient treated with only sustained-release or long-acting opioids (no short-acting opioids, which are often given for activity pain or pain exacerbations). Patients in this situation should be asked to sign a written contract with the physician (p.1).

Although this practice has been recommended, no legislation, regulations or guidelines have been located to describe the implementation of this practice.

Dispensing in instalments implementation

The Republic of Ireland has a dispensing in instalments system, which although designed specifically for opioid substitution programs, can also be used for prescribing other drugs.

Although this process is specifically for consumers who have an addiction, this process is also available to doctors for prescribing other controlled drugs (Pharmaceutical Society of Northern Ireland, 2004). The regulation accompanying this prescribing form relates specifically to the supply of a drug for the purposes of treating an addiction. The extract below is from the Statutory Instrument 2004 No. 627. The National Health Service (Personal Medical Services Agreements) Regulations 2004 (Crown (Republic of Ireland), 2004).

Where a prescriber orders the drug buprenorphine or a drug specified in Schedule 2 to the Misuse of Drugs Regulations 2001 (controlled drugs to which regulations 14, 15, 16, 18, 19, 20, 21, 23, 26 and 27 of those Regulations apply) for supply by instalments for treating addiction to any drug specified in that Schedule, he shall –

- (a) use only the prescription form provided specially for the purposes of supply by instalments;

- (b) specify the number of instalments to be dispensed and the interval between each instalment; and
- (c) order only such quantity of the drug as will provide treatment for a period not exceeding 14 days (Part 3 Sect 38).

The regulations surrounding this practice do not appear to be significantly different from the dispensing in instalments processes and procedures in the United Kingdom, they are just applied to instalments less than a week, rather than the monthly instalments in the repeat dispensing scheme in England.

Frequency of dispensing in instalments in Australia

As discussed, dispensing in instalments is a practice that is informally used within Australia. According to (Berbatis et al., 2003b) up to 50% of community pharmacists performed supervised dosing in at least one of the five categories of drugs included in their survey each week. A total of 46.7% of pharmacies were reported to be supervising dosing of methadone and/or buprenorphine more than once a week. The following table (Table 2-1), from the National Pharmacy Database, indicates the % and the number of times a supervised dose occurs per seven days supervised dosing occurs. As can be seen from this table (below), the supervised dosing has been reported for drugs other than buprenorphine and methadone. No literature, however, has been found on the practice of supervised dispensing for drugs other than opioid substitution programs. It is likely, therefore, that these authors have included the practice of dispensing in instalments within these figures, although it is not clear from the reporting of this data.

Drugs	% active pharmacies (>0 per week)	% pharmacies (>1 per week)	Pharmacy per seven days (LCI)	National estimate per seven days
Analgesics	21.4	17.3	0.82	3,956
Benzodiazepines	35.9	26.9	1.09	5,258
Buprenorphine	12.5	11.1	0.56	2,701
Methadone	38.1	35.6	2.48	11,963
Other psychotropics	12.6	9.6	0.42	2,026
Other agents	5.0	3.8	NA	NA

Table 2-1. Australia's community pharmacies by drugs and patients with supervised dosing per typical seven days in pharmacy (Berbatis et al., 2003b)

At this stage it is not known how frequently dispensing in instalments currently occurs in Australia, and the frequency it is likely to occur if pharmacists were remunerated and the practice was regulated.

Medical practitioner dispensing

According to the Pharmaceutical Society of Australia (Pharmaceutical Society of Australia, 2001) a small but increasing number of medical practitioners are prescribing and dispensing medications. They agree that there may be a need for a medical practitioner to dispense medications in emergency situations and where pharmaceutical services may not be available. They state that separation of the roles provides a second level of monitoring and reviewing which assists in the prevention of errors and assists in optimal therapeutic outcomes due to the counselling and monitoring role traditionally played by pharmacists.

The Medical Board of Victoria also agree that there is a valid reason for the roles of dispensing and prescribing, and state that it is good practice to separate these roles (Medical Board of Victoria, 2005).

The differentiation of responsibilities between pharmacists and doctors, who work collaboratively in the best interests of patients, has evolved for very good reasons and should be maintained. The division between prescribing and dispensing responsibilities provides essential checks and balances to safeguard patients. The role of the pharmacist in this process of monitoring

medications is recognised by law and in regulations regarding record keeping, labelling and dispensing. Inspectors from the Pharmacy Board closely monitor adherence to the standards demanded by these regulations (p.1).

In other countries, where this practice is more common, ensuring the prescribing and dispensing tasks are separated is also viewed as being important in managing controlled drugs. One example is the National Prescribing Centre, England (NPC, 2004) recommendation that:

...the person prescribing the CD (controlled drug) should not also personally undertake all of the following tasks: preparation, dispensing, transportation and administration of the CD. For safety reasons it is always good practice to ensure that another appropriate individual is involved in and thus can reflect on, the process (p.37).

A recommendation for a best practice model is that the practices of prescribing and dispensing of controlled and regulated drugs be separated where practical to ensure a second level of monitoring and safety.

Diversion

Diversion can occur anywhere from the purchase of ingredients by drug manufacturers through to the prescribers, dispensers and at the level of the consumers. Although the primary focus of this work is on the prevention of diversion at the consumer end, a brief discussion of diversion in other sectors of the supply flow have been included to highlight the need to be aware of these other sources of diversion.

According to the Drug Enforcement Administration (DEA) in Washington DC (Leonhard, 2004), “the number of Americans aged 12 or older who have engaged in illicit (nonmedical) use of pain relievers during their lifetime has arisen to more than 31 million” (p. 67172). They state that “a proportion of this type of drug abuse is directly facilitated by a small number of physicians who dispense controlled substances for other than legitimate medical purposes and then fraudulently claim that the drugs were dispensed for the treatment of pain” (p. 67172).

Some additional examples provided by the DEA are:

- the physician warned the patient to fill prescriptions at different drug stores;
- the physician issued prescriptions to a patient known to be delivering the drugs to others;
- there was no logical relationship between the drugs prescribed and treatment of the condition allegedly existing;
- the physician wrote more than one prescription on occasions in order to spread them out (p.1).

Another kind of diversion involves fraudulent prescriptions (*A Pharmacist's Guide to Prescription Fraud*, 2000). Some examples include:

- legitimate prescription pads are stolen from physicians' offices and prescriptions are written for fictitious patients;
- some patients, in an effort to obtain additional amounts of legitimately prescribed drugs, alter the physician's prescription;
- some drug abusers will have prescription pads from a legitimate doctor printed with a different call back number that is answered by an accomplice to verify the prescription;
- some drug abusers will call in their own prescriptions and give their own telephone number as a call back confirmation;

- computers are often used to create prescriptions for nonexistent doctors or to copy legitimate doctors' prescriptions (p.1).

Health professionals can also develop addictions to drugs. According to the Office of Diversion Control (*Drug Addiction in Health Care Professionals*, 2000), the maintenance of security measures surrounding controlled drugs to prevent unauthorised access, whilst ensuring consumers can access the drugs they need at the time they need them.

A best practice model for dispensing in instalments needs to ensure security of these drugs at all stages of the prescribing and dispensing processes.

Minimising the risk of diversion

A number of strategies have been suggested for the minimization of diversion:

Medical Practitioners (DHS, 2004d)

- ensure there is a valid therapeutic need;
- report consumers suspected of having a drug dependency;
- apply for permits as required by the state authority;
- for new consumers requesting S8 or S4 drugs with dependency properties, verify medical history prior to prescribing full prescription quantity. If unable to verify, supply small quantity until history has been verified;
- check state authority register for consumers who they suspect of diversion, to determine if they have been registered;
- ensure security measures for prescription pads are implemented as per state guidelines.

Pharmacists (DHS, 2004c)

- ensure security measures for controlled and restricted drugs are implemented as per the state regulation;
- ensure identity of consumer is ascertained prior to supply of the medication;
- ensure the prescription is valid;
- if the request for the controlled or regulated drugs appears inappropriate question it at the level of the state authority;
- if a consumer presents a prescription for controlled or regulated drugs from different prescribers, alert the prescribers;
- ensure pharmacy staff supply S8 and S4 drugs with addictive properties.

A best practice model for dispensing in instalments should ensure security of schedule 4 and schedule 8 (with dependency properties) drugs at all stages of the prescribing and dispensing processes.

Prescriber Consumer Contracts

One strategy used to assist in the management of opioids for chronic pain is to use a contract between a prescriber and consumer. The contract used by the College of Physicians and Surgeons of Alberta, Canada (College of Physicians and Surgeons of Alberta, 2004) has been included in Appendix D.

The aim of the contract is to explicitly inform the consumer of his/her rights and responsibilities if they choose to take opioids to manage chronic pain, and to provide a consequence for diversion. A contract on its own is unlikely to prevent diversion, as a breach of contract could presumably result in a consumer approaching another doctor. This, in combination with a State authority reporting scheme, or a procedure that a medical practitioner cannot prescribe these drugs without written (or at least direct verbal) discussion with the previous prescriber, so that the consequences of a breached contract are more severe than cessation of the drug with a specific prescriber.

Communication between medical practitioners, pharmacists and Consumers

This section will be further informed by the analysis of the in-depth industry expert interviews. The industry experts consulted for this work indicated that communication between medical practitioners, pharmacists and consumers for the informal practice of dispensing in instalments included, but was not limited to:

- request for dispensing in instalments;
- clarification of instalment frequencies (over time);
- pharmacist monitoring of consumer and feedback back to prescriber;
- pharmacist monitoring and counselling of consumer;
- pharmacist reminder to consumer that prescription will need renewal;
- consumer request to medical practitioner for prescription renewal;
- pharmacist request to medical practitioner for prescription renewal;
- medical practitioner request that medication schedule be altered.

A full list of interactions and the time taken for each of these interactions will need to be documented and measured in order to develop a remuneration package for dispensing in instalments. This list will be formulated throughout the trial.

Factors important to consumers

Consumers are the recipients and therefore important in the development of a dispensing in instalments model. Implementing a best practice model that enables consumers to better manage their medication is a key element to the effective success of dispensing in instalments.

One study in Aberdeen and Glasgow, investigated consumer views of pharmacies that provide services to drug users. The results of the study demonstrated that the majority of pharmacy customers are supportive of drug misuse services, provided there is adequate privacy in the pharmacy (Lawrie, Matheson, Bond & Roberts, 2004). Although dispensing in instalments is a practice that can be used for populations other than those with a drug dependence, prevention of drug misuse is one component. The provision of a separate area for pharmacists to provide a dispensing in instalment service may be important in assisting pharmacy consumers acceptance of this practice.

Strategies that can be borrowed from prescribing and dispensing practices

There are a number of prescribing and dispensing practices used internationally that although are not specifically related to the practice of dispensing in instalments, offer some ideas for a best practice model for this practice.

Repeat dispensing

Repeat dispensing is a system that has been used in Australia for a number of years, but has recently been considered in the United Kingdom.

One pilot study conducted in the United Kingdom involved a single pharmacy (Polak, 2002). The target consumer group were those who were dispensed more than five drugs at a time. A consumer can choose to be registered for the program. Once registered, the consumers sign a form to give the pharmacist permission to order medications on their behalf; the pharmacist then conducts an initial review to identify any known adverse drug reactions, contraindications or additional problems with their medications. The aim was that each of these people were reviewed with the pharmacist by their medical practitioner every six months, the prescription cycle is for twenty eight days, and so each consumer comes into the pharmacy once every twenty eight days for their medications, without having to visit the medical practitioner each time.

The benefits of this system to the consumer are that; collection of medications is convenient; only medication needed is collected, and the stockpile of medications is reduced. The benefits to the pharmacist are an improved relationship with the medical practitioner, and a more consistent workload.

This system has not been evaluated, and the pharmacist involved in this pilot study said he had received significant criticism from his colleagues for providing this service without remuneration. He said that setting up each consumer is very time consuming, however the establishment of an effective service, and the ability to predict his workload were enough benefits to continue the practice.

One variation to this system is that some consumers are on a one week cycle rather than a twenty eight day cycle. The one week cycle is a similar practice to the concept of 'daily dispensing' used in Australia.

The trials of repeat dispensing have been developed further and are about to be rolled out throughout the UK. At this stage, repeat dispensing does not include the dispensing of the UK schedule 2 and schedule 3 controlled drugs have been excluded (NHS, 2005a). The scheduling classifications used within the UK are as follows (British National Formulary, 1971):

Schedule 1 includes drugs such as cannabis and lysergide which are not used medicinally.

Possession and supply are prohibited except in accordance with Home Office authority.

Schedule 2 includes drugs such as diamorphine (heroin), morphine, remifentanyl, pethidine, secobarbital, glutethimide, amphetamine, and cocaine and are subject to the full controlled drug requirements relating to prescriptions, safe custody (except for secobarbital), the need to keep registers, etc. (unless exempted in schedule 5).

Schedule 3 includes the barbiturates (except secobarbital, now schedule 2), buprenorphine, diethylpropion, mazindol, meprobamate, pentazocine, phentermine, and temazepam. They are subject to the special prescription requirements (except for phenobarbital and temazepam, see [Controlled Drugs and Drug Dependence](#)) but not to the safe custody requirements (except for buprenorphine, diethylpropion, and temazepam) nor to the need to keep registers (although there are requirements for the retention of invoices for 2 years).

In Australia, repeat dispensing is not allowed for controlled drugs. In the United Kingdom, they have implemented the same restriction (NHS, 2005a).

One variation between the system that is about to be implemented in the United Kingdom, is that the instalment time in Australia is the length of a full prescription. The system in the United Kingdom has provision for the repeat dispensing instalment cycle to be as short as a week.

The processes and procedures used within the repeat dispensing procedure could be extended to include daily and two to three daily instalments.

Triplicate prescriptions

In America and Canada, triplicate prescriptions are used as a method of tracking controlled drugs. This process assists in the process of auditing controlled drugs at any stage.

In 1981, the Texas Legislature passed a law which requires doctors to write all prescriptions for Schedule II drugs on a special three-part or triplicate form. When your doctor issues a prescription for a Schedule II drug, he/she keeps one copy of the prescription for his/her records, and gives you two copies. Both copies must be taken to your pharmacy when you have the prescription filled. You have seven days from the date the prescription is written to have it filled. After the seven days, the prescription is no longer valid and may not be filled.

The pharmacist keeps one copy for the pharmacy's files and mails one copy to the Texas Department of Public Safety (DPS). DPS enters the prescription information into a central computer at the DPS. It is important to note that triplicate prescription information is not public information and the information is only released to authorized agencies for investigative purposes. The information is used by licensing boards to identify doctors, dentists, and/or

pharmacists who may be inappropriately prescribing or dispensing these highly abusable drugs. The triplicate prescription program has been very effective in reducing abuse, misuse, and diversion of Schedule II drugs in Texas. (p. 1, TSBP, 2002)

In Victoria, controlled drug data is recorded and stored on the pharmacy premises for three years (Victorian Government, 1995). This information must be produced on demand by an authorised officer. The process of triplicate prescriptions would assist with minimizing diversion as the data is stored centrally rather than in discrete pharmacies.

A Clozaril National Registry using controlled dispensing

A program was developed in the United States of America with the aim of “preventing consumers from developing potentially fatal agranulocytosis secondary to treatment with the antipsychotic medicine clozapine” (Honigfeld, Arellano, Sethi, Bianchini & Schein, 1998) (p.3). This program involved pharmacists, medical practitioners and a quality assurance chair person. The program involved monitoring for signs of agranulocytosis and restricting medication dispensing to seven days at a time. This served the purpose of ensuring the consumer came in regularly for monitoring and a secondary outcome was increased compliance with medications.

The authors state that despite the additional logistic requirements based on the pharmacists and medical practitioners, the outcomes of this study were that the system substantially reduced potentially fatal outcomes, and increased treatment systems and consumer compliance.

It may be useful to consider regular case meetings (possibly six monthly)

Summary of dispensing in instalments literature and implications for best practice model

A number of components of a best practice model for dispensing S8 and S4 drugs with dependency properties have been identified from the literature. These have been summarised below:

Record keeping

- Full details of the prescription as would be required for any other dispensing of a controlled drug;
- The date of each instalment;
- The quantity of tablets supplied and the quantity remaining on the premises;
- The name of the person supplying the drugs
- Labelling on the container the medication is supplied to the consumer indicating the name of the prescriber, and directions for use as set out on the prescription

Labelling

- Ensure each instalment has a full label as outlined in Appendix C

Storage

For drugs that have been dispensed but before they have been supplied:

- Ensure S8 drug as stored as per legislation
- Ensure S4 drugs are stored in the dispensary in an area that only the pharmacist has access

Dedicated prescription pad

Consider the development of a dedicated prescription pad for the practice of prescribing controlled drugs to be dispensed in instalments. The advantages may be:

- Clear processes and procedures
- Clear identification of instalment request to pharmacist
- Ensuring all required information about the dispensing in instalment request is conveyed from the prescriber to the dispenser

Medical practitioner dispensing

Recommend that medical practitioners only conduct dispensing in instalment practices in emergency situations or when there are no pharmacy services available such as in rural and remote locations.

Minimising Diversion

The medical practitioner requirements:

- ensure there is a valid therapeutic need;
- report consumers suspected of having a drug dependency;
- apply for permits as required by the state authority;
- for new consumers requesting S8 or S4 drugs with dependency properties, verify medical history prior to prescribing full prescription quantity. If unable to verify, supply small quantity until history has been verified;
- check state authority register for consumers who they suspect of diversion, to determine if they have been registered;
- ensure security measures for prescription pads are implemented as per state guidelines.

The pharmacist requirements:

- ensure security measures for controlled and restricted drugs are implemented as per the state regulation;
- ensure identity of consumer is ascertained prior to supply of the medication;
- ensure the prescription is valid;
- if the request for the controlled or regulated drugs appears inappropriate question it at the level of the state authority;
- if a consumer presents a prescription for controlled or regulated drugs from different prescribers, alert the prescribers;
- ensure pharmacy staff supply S8 and S4 drugs with addictive properties.

Triplicate prescriptions

Consider the implementation of a triplicate prescription system for controlled drugs to ensure controlled drugs can be accounted for and audited with minimal delay.

Consumer, Pharmacist, Medical Practitioner communication

This section will be further informed following the analysis of the in-depth industry expert interviews

- Consider the need for a separate section in the dispensary for dispensing in instalments to assist in maintenance of consumer privacy;
- Consider trialling case conferences to initiate a dispensing in instalments program. The case conference would include the pharmacist, medical practitioner, consumer and consumer support (i.e. advocate, family member, family friend, case manager)

Conclusion

The role of the community pharmacist can be expanded to include an acknowledged, regulated and remunerated practice of dispensing in instalments. It is anticipated that the groups who would use this service include: consumers with a drug dependency who have a therapeutic need for a drug with dependency properties; consumers with a psychiatric condition who may be at risk of self harm intentionally or accidentally; and consumers who have a condition which includes a cognitive impairment which results in an inability to manage medication.

The review of Australian and international literature has revealed that the practice of dispensing in instalments is unregulated in Australia. There are two systems currently in existence, one in the Republic of Ireland and one in the United Kingdom that are based predominantly on a dedicated prescription form, and processes surrounding the use of that form.

Many elements of a best practice model can and have been derived from current practices surrounding the management of controlled and restricted drugs. These will be incorporated into a best practice model that will be trialled in seven pharmacies around Australia in the next phase of this work.

Medical practitioner reporting requirements

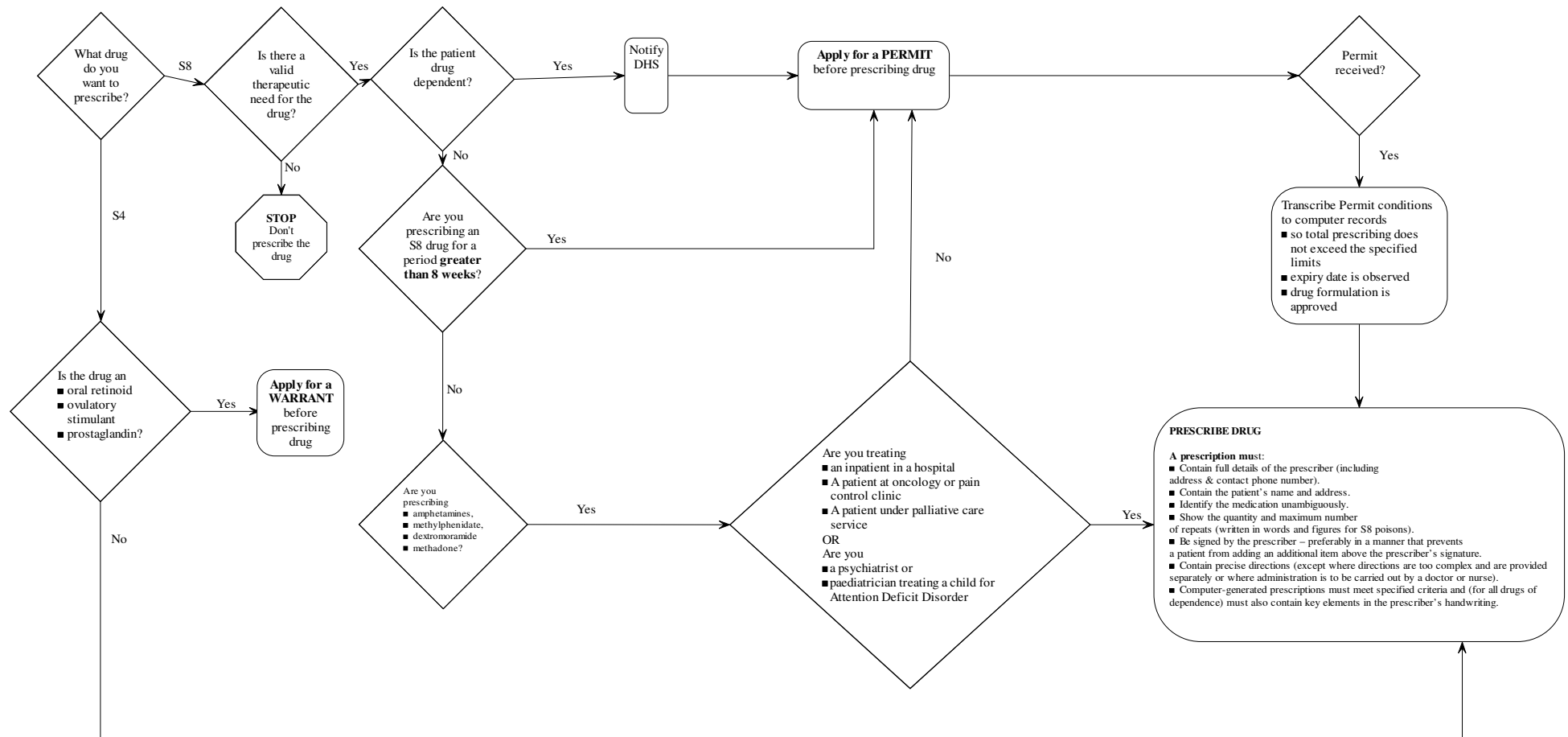


Figure 0-3 Prescribing Requirements for Medical Practitioners Decision Tree Based on (DHS, 2004d)

Pharmacist notification requirements

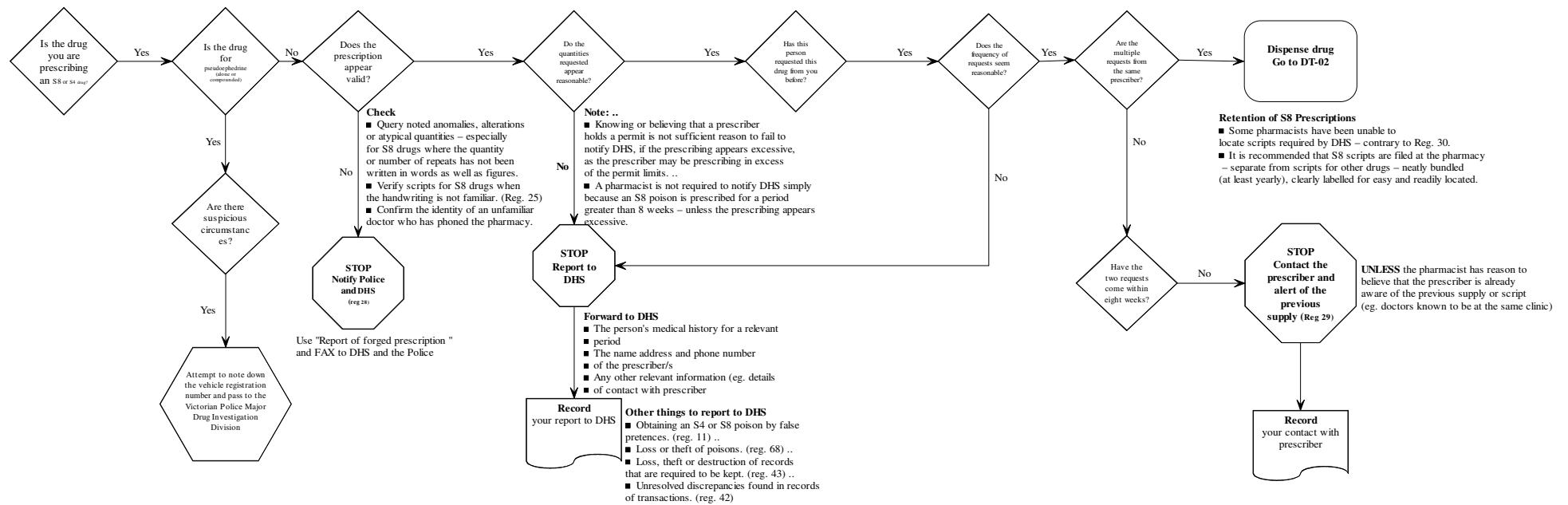


Figure 0-4 Notification Requirements for Pharmacists Based on (DHS, 2004c)

Labelling Guidelines

Extracted from A Guide to Labelling Drugs and Poisons in Accordance with the Standard for the Uniform Scheduling of Drugs and Poisons (TGA, 2000).

Schedule 4 Requirements

Label contents Legal requirements

PRESCRIPTION ONLY MEDICINE

or

PRESCRIPTION ANIMAL REMEDY

Bold sanserif capital letters, uniform thickness;
Height, half that of largest letter or numeral on the label (minimum 1.5mm, maximum 6mm on containers of 2 litres or less or 15mm on larger containers);
First line on label.

KEEP OUT OF REACH OF CHILDREN

Bold sanserif capital letters, uniform thickness;
Four tenths height of "PRESCRIPTION ONLY MEDICINE" with minimum height of 1.5mm;
Second line of label.

FOR ANIMAL TREATMENT ONLY

Bold sanserif capital letters, uniform thickness;
On main label.
(Only on products for animal treatment).

TRADE NAME OF PRODUCT

No specifications.

NAME AND STRENGTH OR PROPORTION OF ALL ACTIVE INGREDIENTS

If for human therapeutic use, see *Therapeutic Goods order No 48- General requirement for labels of Drug Products*.

NAME AND ADDRESS OF MANUFACTURER OR DISTRIBUTOR

Must be an Australian address;
Must be a street address NOT a post office box.

NETT CONTENTS

Required by consumer legislation.
If for human therapeutic use, see *Therapeutic Goods order No 48- General requirements for labels of Drug Products*.

DIRECTIONS FOR USE

If for human therapeutic use, see *Therapeutic Goods order No 48- General requirements for labels of Drug Products*

WARNING STATEMENTS

Some poisons require warning Statements.

These are to be placed immediately before the directions for use.

All other writing required on label Minimum height 1.5mm measured on capital

letters or lower case letters with ascenders or descenders (e.g. d, b, g, p).

EXAMPLE LAY OUT

For human therapeutic use

PRESCRIPTION ONLY MEDICINE

KEEP OUT OF REACH OF CHILDREN

PRODUCT NAME

Each tablet contains:(name of poison) mg
quantity

Name and address

For the treatment of animals

PRESCRIPTION ANIMAL REMEDY

KEEP OUT OF REACH OF CHILDREN

FOR ANIMAL TREATMENT ONLY

PRODUCT NAME

Each tablet contains:(name of poison) mg
quantity

Name and address

Schedule 8 Requirements –

Label contents Legal requirements

CONTROLLED DRUG	Bold sanserif capital letters, uniform thickness; Height, half that of largest letter or numeral on the label (minimum 1.5mm, maximum 6mm on containers of 2 litres or less or 15mm on larger containers); First line on label.
POSSESSION WITHOUT AUTHORITY ILLEGAL	Bold sanserif capital letters, uniform thickness; Four tenths height of "CONTROLLED DRUG" with a minimum height of 1.5mm; line on label. Nothing else on same line.
KEEP OUT OF REACH OF CHILDREN	Bold sanserif capital letters, uniform thickness; Four tenths height of "CONTROLLED DRUG" with a minimum height of 1.5mm; Third line of label.
FOR ANIMAL TREATMENT ONLY	Bold sanserif capital letters, uniform thickness; On main label. (Only on products for animal treatment).
TRADE NAME OF PRODUCT	No specifications.
NAME AND STRENGTH OR PROPORTION OF ALL ACTIVE INGREDIENTS	If for human therapeutic use, see <i>Therapeutic Goods Order No for labels of Drug Products</i> .
NAME AND ADDRESS OF MANUFACTURER OR DISTRIBUTOR	Must be an Australian address; Must be a street address NOT a post office box.
NETT CONTENTS	Required by consumer legislation. If for human therapeutic use, see <i>Therapeutic Goods Order No 48- General requirements for labels of Drug Products</i> .
DIRECTIONS FOR USE	If for human therapeutic use, see <i>Therapeutic Goods Order No 48- General requirements</i>

for labels of Drug Products

WARNING STATEMENTS

Some poisons require warning Statements.
These are to be placed immediately before the
directions for use.

All other writing required on label Minimum height 1.5mm
measured on capital
letters or lower case letters with ascenders or
descenders (e.g. d, b, g, p).

EXAMPLE LAY OUT

CONTROLLED DRUG
POSSESSION WITHOUT AUTHORITY ILLEGAL
KEEP OUT OF REACH OF CHILDREN
PRODUCT NAME
Contains: (NAME OF POISON) g/L, mL/L, g/kg, mL/kg
Quantity
Name and address

Sample Contract



900 Manulife Place, 10180-101 Street
Edmonton, Alberta, Canada T5J 4P8

Chronic Opioid Therapy in Non-Malignant Pain

Sample Patient Contract

For use with patients (1) at higher risk of addiction; (2) who have had compliance problems with medication in the past.

Letter of Understanding

This letter of understanding is being undertaken between _____ (the patient), and Dr. _____ (the doctor), to define the responsibilities of the patient regarding treatment of a chronic pain problem, using opioid analgesics.

1. The patient hereby agrees that this trial of treatment has been explained to him/her in terms of the purpose, the side effects of the medication and the risks of this treatment.
2. In particular, the patient understands that using opioids to treat chronic pain will result in the development of a physical dependence on this medication, and that sudden decreases or discontinuation of the medication will lead to the symptoms of opioid withdrawal. The patient understands that opioid withdrawal is uncomfortable but not a physically life-threatening process.
3. The patient agrees not to change the dose or the frequency of taking their medication without first consulting the doctor, and to follow-up with the doctor as an outpatient, on a prescribed basis, for monitoring of the treatment.
4. The patient agrees to keep the prescribed medication in a safe and secure place and that lost, damaged, or stolen medication will not be replaced until the next regularly scheduled visit.
5. The patient agrees not to give, sell, lend, or in any way provide his/her medication to any other person, nor to obtain medication from anyone but a licensed pharmacist.
6. The patient agrees not to seek, obtain, nor use ANY pain medication or mood-modifying medication from ANY other physician, without first discussing this with the doctor.
7. In patients taking chronic opioid therapy, there is a small but definite risk that opioid addiction can occur. Almost always, this occurs in patients with a history of other substance abuse. Therefore, the patient agrees to refrain from the use of ALL other mood-modifying drugs, including alcohol, with the exception of nicotine and caffeine, unless prescribed by a physician and agreed to by the undersigned doctor. The patient agrees to submit to random urine and/or blood testing at the doctor's request to verify this.
8. As part of this treatment program, the patient agrees to attend and participate fully in other chronic pain treatment modalities which may be recommended by the doctor.

The patient understands that ANY deviation from the above conditions can be grounds for Dr.

_____ to discontinue this form of treatment.

Signed at _____ on _____, 20____.

(patient)

(witness)

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