



HEALTHCARE MANAGEMENT ADVISORS

Funding Model Options for Dispensing of Pharmacotherapies for Opioid Dependence in Community Pharmacy

Final Report

This project was funded by the Australian Government Department of Health and Ageing as part of the Third Community Pharmacy Agreement through the Third Community Pharmacy Agreement Research and Development Grants Program and managed by The Pharmacy Guild of Australia

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We also appreciated the ongoing advice from the Expert Advisory Group (EAG) that was responsible for approving each stage of the project comprising:

- Australian Injecting and Illicit Drug Users' League, Annie Madden,
- Intergovernmental Committee on Drugs, Keith Moyle
- The Pharmacy Guild of Australia, Denis Leahy, Khin Win May
- Pharmaceutical Society of Australia, Irvine Newton
- Department of Health and Ageing, Dr John Primrose, Tracey Cook, Klaus Klaucke, Louise Butkus and Heather Cocks.

We also wish to thank the Research and Development Program staff: Simone Jones and Erica Vowles.

Abbreviations

AACP	Australian Association of Consultant Pharmacy
ADP	Alcohol and Drug Program
AIVL	Australian Injecting and Illicit Drug Users' League
BTOM	Brief Treatment Outcome Measure
BTOM-C	Brief Treatment Outcome Measure – Concise
CAS	Clinical Advisory Service
CPOP	Community Program for Opioid Pharmacotherapy
DAO	Drug and Alcohol Office
DASSA	Drug and Alcohol Services of South Australia
DHHS	Department of Health and Human Services
DHS	Department of Human Services
EAG	Expert Advisory Group
GP	General Practitioner
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
NDARC	National Drug and Alcohol Research Centre
NDSF	National Drug Strategic Framework
NEPOD	National Evaluation of Pharmacotherapies for Opioid Dependence
NHS	National Health Service
ORPACS	Opioid Replacement Pharmacotherapies Advice and Complaints Service
PAMS	Pharmacotherapies Advocacy, Mediation and Support Service
PBS	Pharmaceutical Benefits Scheme
PDDA	Poisons and Dangerous Drugs Act
PHARMAC	NZ Pharmaceutical Management Agency
PIN	Personal Identification Number
PSA	Pharmaceutical Society of Australia
PSA Vic	Pharmaceutical Society of Australia, Victorian Branch
QCPP	Quality Care Pharmacy Program

Executive summary

The Pharmacy Guild of Australia (the Guild) appointed Healthcare Management Advisors (HMA), in collaboration with the Victorian College of Pharmacy, to conduct a study to:

“assess funding model options for dispensing pharmacotherapies for opioid dependence in community pharmacy”.

The study had the following main objectives:

- to develop options for a best practice funding model for the subsidisation of pharmacotherapy dispensing costs within the community pharmacy setting that achieves optimal health outcomes for clients;
- trial and evaluate the options in a range of community pharmacies; and
- develop a plan for evaluating the model(s) including parameters for assessing efficiency and effectiveness (including health outcome indicators).

The project was funded by the Australian Government Department of Health and Ageing as part of the Third Community Pharmacy Agreement through the Third Community Pharmacy Agreement Research and Development Grants Program and managed by The Pharmacy Guild of Australia.

The key objective was to collect a wide range of data that could be used to investigate the health, social and economic benefits of best practice funding model options for the provision of methadone and buprenorphine. Three models were trialled and evaluated in six pharmacies based in New South Wales, Victoria and South Australia. The trials were conducted in two pharmacies (one regional and one metropolitan) in each of these states over a 12 week period.

PROJECT METHODOLOGY

The key stages of the project methodology are outlined below.

- (1) **Detailed project planning.** In consultation with the Guild’s Project Manager and the Expert Advisory Group (EAG), HMA developed a detailed project plan which was agreed by the EAG in November 2004.
- (2) **Situation analysis.** The situation analysis incorporated a review of the policy and environmental context for the dispensing of pharmacotherapies for opioid dependence, a literature review and stakeholder consultation. The Situation Analysis document was presented to the Guild’s Project Manager in April 2005.
- (3) **Baseline data collection (scoping studies).** The purpose of the scoping studies was to collect baseline data about current community pharmacy practice and the clients who use the pharmacotherapy dispensing services. Ten sites (pharmacies) were involved and four consumer groups were interviewed. The data collected included time and financial data which was used to estimate the cost and financial return per dose for dispensing methadone and buprenorphine. This enabled comparisons across states, client numbers and pharmacy locations.
- (4) **Preparation of funding options discussion paper.** Based on the results of the scoping study a summary paper was prepared that synthesised the investigations that had been undertaken to this point, including the situation analysis, the literature review and the scoping studies. The paper identified options for

funding pharmacotherapy. The paper was presented to the EAG in November 2005 and has been incorporated into this report.

- (5) **Design trial evaluation methodology and evaluation framework.** The baseline analysis from the scoping study, the findings of the literature review and the situation analysis were drawn on to design the trial methodology and the evaluation framework
- (6) **Establishment of trials.** Following ethics approval, trials across six pharmacies were established. The trials were based on the trial methodology and associated management strategy that included collecting baseline data from the pharmacy staff and the consumers currently using pharmacotherapy services.
- (7) **Trials.** The trial operated in each of the six pharmacies for a period of three months from March 20th 2006 until June 11th 2006. Three funding models were trialled and initially involved 96 clients.
- (8) **Post trial data collection.** On completion of the trial in June 2006 interviews were conducted with participating pharmacists (and their staff) as well as the clients.
- (9) **Report of outcomes.** A comprehensive report of the project was prepared (this document).

ENVIRONMENTAL SCAN

The objective of this project was to identify funding model options for community pharmacy, which support the provision of pharmacotherapy treatments, and to evaluate the efficacy of each of these models. A situation analysis was undertaken that identified a range of community pharmacy related funding issues which could potentially impact upon Australian, state and territory health jurisdictions, community-based service providers and consumers alike. The key issues requiring consideration included:

- (1) **Determining an equitable charging base to clients.** It was evident that a large proportion of consumers experience a financial burden in receiving pharmacotherapy treatments. Furthermore, the charges to clients for dispensing methadone and buprenorphine vary considerably both within and between States and Territories.
- (2) **Determining funding model options.** It was apparent that there was no single funding model which was likely to address and resolve the problems associated with the provision of pharmacotherapy services. However, it was important to recognise that funding models have the potential to act as a major influence on both client and practitioner behaviour. As part of the stakeholder interview process a number of potential funding models were identified including:
 - consumer co-payment model;
 - incentive model for dispensing pharmacotherapy treatments;
 - shared care model (similar to the one implemented in Glasgow);
 - subsidy to consumers (eg for dispensing of methadone/buprenorphine, limited period treatment subsidy and travel subsidy);
 - nationally funding practice allowance for pharmacists; and
 - PBS Funding Model

These options have been considered and adapted for the trial associated with this project.

THE SCOPING STUDIES

Scoping studies were undertaken to provide information that would develop an understanding and the knowledge about current community pharmacy practice in respect of pharmacotherapy dispensing. Twelve scoping study sites (pharmacies) were identified, although ultimately only ten participated fully. Four consumer groups were also interviewed. The data collected included time and financial data that was used to estimate the cost per dose of methadone and buprenorphine. A description of existing services and funding models was generated.

The scoping study confirmed that current Australian practice relating to opioid pharmacotherapy in community pharmacy was extremely varied not only at a state level, but also at an individual practice level.

In general, average financial returns from participation in the program were modest and 40% of pharmacies did not cover the cost of providing the service. In those states where state health jurisdictions provided some level of subsidy support, they appeared to derive a modest financial return for the services being provided, but the subsidy was not found to be a major driver of financial viability of the programs for most pharmacies. Clients are contributing substantially greater amounts than from other sources of funding, such as subsidies.

The variability of service models and implications for financial viability was found to exist despite the provision in many jurisdictions of standards for program delivery. Even within states or territories there can be substantial variation of practice which reflects the complexity surrounding the service provision, and individual pharmacies motivation for participation and service ethos.

Based on these potential options, three models for subsidising methadone and buprenorphine dosing were designed that were based on the options above. The subsidy amount paid was based on the data gathered on the cost of providing methadone and buprenorphine dosing as determined by the scoping studies.

These scoping studies were designed to provide baseline data for comparison with the trial pharmacy sites. This methodology was chosen due to the difficulty of gaining ethics approval to run the trial using a control group of clients from the trial pharmacies. The six trial pharmacies were selected from a different group than the ten scoping study sites in order to provide as broad a range of comparative data as possible. Whilst HMA recognises that the lack of a client control group placed limitations on the study, the use of pre- and post- trial observations enabled important comparisons to be made.

THE TRIAL

The three models that were developed for trial were as follows:

- (1) **Model 1.** This was Fee-for-Service Model, Version 1 and included a dispensing fee per dose to the pharmacy, which was \$4.40, coupled with a \$2.50 consumer incentive. There was no change to the current pharmacy service model. Prior to the trial clients were paying in the range of \$5 to \$6.67 per dose, depending

on the individual pharmacy, so the consumer incentive represented around 50% of the normal client co-payment. This model was trialled in two pharmacies in Victoria.

- (2) **Model 2.** This was Fee-for-Service Model, Version 2 and included a dispensing fee per dose to the pharmacy, which was \$1.90, coupled with a consumer incentive, whereby the client paid nothing for each dose (meaning the pharmacy received the client subsidy of \$4-\$5 per dose). There was no change to the current pharmacy service model. Model 2 was therefore designed to specifically assess the impact on key client outcomes of eliminating the client payment altogether. This model was trialled in two pharmacies in South Australia.
- (3) **Model 3.** This was an Enhanced Care Model and included a \$2.50 consumer incentive (which meant the client paid about half of the normal client co-payment), a dispensing fee per dose (as per Model 1) and a lump sum pharmacy incentive payment (\$50 per consenting client) who elected to receive enhanced care.

The enhanced care model was developed in consultation with the representative of the Australian Injecting and Illicit Drug Users' League (AIVL) and pharmacists with expertise in pharmacotherapy practice. The aim of the enhanced care component was to develop a tool and associated process that sought to deliver client and pharmacy focussed enhanced care.

A total of 92 clients from six participating pharmacies commenced the trial.

OUTCOMES OF THE TRIAL

Evaluation of these funding models was undertaken using a structured approach that covered an assessment of efficiency and effectiveness (including health outcome indicators). In this context the findings below have been grouped accordingly:

Efficiency

The project investigated:

- the level of satisfaction of pharmacists and consumers with the funding models including the remuneration/subsidies paid;
- the evidence of improved retention rates with the pharmacotherapy program;
- any changes in the number of doses missed; and
- any factors that impacted on the client's ability to continue their pharmacotherapy treatment.

Findings were that:

- clients and pharmacists reported being satisfied with the trial funding models. Further statistical modelling did not reveal any statistically significant differences in satisfaction between the three funding models;
- pharmacists reported that the funding models trialled had a strong positive impact on service delivery. This was mainly related to improved relationships with clients due to reduced concerns about money and chasing of bad debts associated with pharmacotherapy;
- clients expressed satisfaction with the trial arrangements with 91.4% stating that treatment arrangements were better during the trial than before it;

- the impact of the enhanced care component of the model trialled in New South Wales appeared to have been minimal. It should be noted, however, that only 14 of a possible 19 clients had the enhanced care form completed and, for most of these, it was not completed until late in the trial thus eliminating the opportunity to fully trial this option. Participating clients did not believe they had received an improved level of service;
- there was no evidence that retention rates in treatment changed as a result of the trial;
- overall, the satisfaction of clients with the cost of dosing improved significantly during the trial from an average 25% satisfied pre-trial to an average 85.1% satisfied post trial;
- while clients believed that the trial had no impact on their ability to stay on the pharmacotherapy program, pharmacy staff believed that there had been a positive impact. This was particularly related to the financial aspects of treatment; and
- most clients believed that the trial had little or no impact on whether they missed doses. However, in South Australia, where clients received full subsidisation, 53.8% of them believed the trial had a positive impact on whether they missed doses.

Effectiveness and sustainability of the funding models

The project investigated:

- any identifiable differences to the cost effectiveness of services delivered through the three funding models;
- the extent to which the funding models were sustainable;
- whether the funding models provided for an improvement in the level of unrecoverable costs as a result of the funding model trialled;
- how the pharmacy benefited from other cost savings due to the implementation of the trial funding model;
- whether the pharmacy realised other efficiency benefits as a result of implementing the trial funding model; and
- any improvements to the funding model that could improve sustainability of service delivery.

Findings were that:

- Consumers identified a number of issues that impacted on their access to pharmacotherapy:
 - pharmacy opening hours not long enough;
 - long waiting times to receive doses;
 - travel time to get to the pharmacy and cost of petrol;
 - lack of takeaway doses, especially for those who were employed and had to take time off each day to go to the pharmacy; and
 - inappropriate dosing area (lack of privacy).
- clients were satisfied with the helpfulness and attitudes of pharmacy staff and this level of satisfaction improved during the trial;
- pharmacists confirmed that there had been an improvement in the level of previously unrecoverable debts as a result of the funding model trialled; and
- improvements in relationships with clients;
- pharmacies realised other efficiency benefits as a result of implementing the trial funding model;

- there was a reduction in client bad debts during the trial; and
- improved service and time management.

Due to the considerable variations in the financial outcomes for the trial pharmacies it was difficult to develop a conclusive view about specific improvements that could be applied to the funding model. All funding models trialled indicated greater financial returns for the pharmacies. In addition, it was apparent that both clients and pharmacists' viewed some form of subsidy as effective in improving health and financial outcomes for clients and improving effectiveness and financial viability for pharmacists.

Client outcomes

The project investigated:

- the change in the level of consumer health status as a result of trialling the funding model;
- whether there had been an improvement in family relationships due to the implementation of the trial funding model;
- evidence of improved financial management as a result of implementing the trial funding model;
- whether the funding model trialled contributed to a decrease in the use of opioid for participating clients;
- whether the trialled funding model impacted upon social productivity and employability;
- any other social functioning changes that had occurred as a consequence of the funding model trialled; and
- whether drug use behaviour had changed as a result of the trial.

Findings were that:

- there were improvements identified to client well-being, social, and health status and 60% of clients attributed these improvements to the availability of more money due to the reduced cost of their pharmacotherapy. Areas of improvement included:
 - only 9.5% of participants reported their health as being poor post trial compared with 20.7% pre trial, and 39.3% reported their health as good compared with 28.3% pre trial;
 - participants indicated that they had reduced conflict with their partners and relatives post trial mainly due to fewer arguments about money.
 - pharmacy staff reported that clients' financial management and debt management had improved;
 - there had been a decrease in the use of both alcohol and illicit drugs during the trial period, although it is unknown whether this was attributable to the trial, as it may be a trend related to the ongoing participation of the client in the pharmacotherapy treatment rather than the trial;
 - during the trial period there was a significant reduction in the number of participants who had injected a drug in the previous three months (reduced from 31.1% to 18.1%), but again it is not possible to be definitive as to whether this is a direct effect of the trial or if it is a result of the normal processes of participation in pharmacotherapy treatment.

Conclusions regarding trials

The project considered the hypothesis “*the cost of treatment affects client treatment outcomes*”. Analysis of the data collected using the BTOM-C instrument demonstrated statistically significant differences were found that indicated client improvement in the areas of health, wellbeing, social, treatment and economics. Particularly, evidence supported greater improvements in the client group trialling the fully subsidised funding model (Model 2-South Australian clients) compared with the client groups trialling the half subsidised models (Model 1- Victorian and Model 3- New South Wales clients). In New South Wales, pharmacists did not take full advantage of the enhanced care option so the project was unable to form a conclusive view about the value of that program.

From a pharmacy perspective, comparing the each trial pharmacies’ average cost per dose for each pharmacotherapy revealed the sensitivity of estimates and the variation across pharmacies. This was particularly the case at two pharmacies which were identified as outliers to the data. Nevertheless, in evaluation of the hypothesis; “How do the funding models affect pharmacies?” the trial and proposed modelling demonstrated continuing financial viability, and improved service delivery for the trial pharmacies. The financial outcomes indicated an increased financial return, and pharmacy staff reported more satisfaction and less stress as they did not have to pursue clients for outstanding payments.

From a client perspective the project has established considerable support that subsidised dosing of methadone and buprenorphine leads to improved satisfaction with service and improved social, health and economic outcomes. From a pharmacy perspective the trials indicated improved service and economic outcomes for pharmacies and their staff as well as improved relationships and communication between pharmacists/staff and clients.

Notwithstanding the limitations of the project related to the small number of sites, associated clients as well as the short duration of the trials it was apparent that these benefits were measurable. **It is therefore recommended that:**

R1 Clients participating in pharmacotherapy treatment through community pharmacies be subsidised according to the following:

- Option 1 to be full subsidisation based on an agreed maximum; or
- Option 2 to be partial subsidisation based on an agreed maximum.

R2 The level of subsidisation be higher for buprenorphine to recognise the higher cost of dispensing.

CONCLUSIONS REGARDING SUBSIDY LEVELS

Based on assessment of the views of participants, using the BTOM-C instrument pre- and post- trial, it was apparent that the health and financial outcomes for clients had improved. In addition, pharmacists and their staff were pleased with the outcome of the trial in that they had fewer problems with client payments. Statistical analysis did not demonstrate any substantial differences between the models from a financial perspective. Coupled with the limited cost data available (as only six pharmacies were included) means that additional work may be required to establish an appropriate level of subsidy that is linked to the cost of service provision as well as reflective of the variations that may be inherent across over 5,000 pharmacies.

If partial subsidy is considered it is recommended that:

- R3 The level of subsidy initially be set at \$2.50/dose for methadone treatment and \$3.50/dose for buprenorphine treatment and that the level be reviewed and adjusted annually with consideration to be given to inflationary effects and future practice and available evidence.**

The project collected significant amounts of cost data during the scoping study as well as revenue/charges (see Chapter 3), but only from a small number of sites. The trial subsidy levels were chosen as a practical balance between project budget allowance and the costs/charges (some pharmacies were identified as making a positive return while others were identified as making a negative return on the pharmacotherapy service). The suggested \$2.50/\$3.50 was identified as a reasonable mid-point but may be subject to adjustment based on policy decisions. Nevertheless a more detailed analysis of costs would provide more robust information. As a consequence **it is recommended that:**

- R4 A project be initiated to undertake a financial impact analysis of delivering a pharmacotherapy treatment program through community pharmacies. The project should be of sufficient size to ensure the appropriate analysis of pharmacy site, pharmacotherapy clients and geographic location characteristics.**

OTHER ISSUES

Due to the length of the trial period and the resulting low take up of the enhanced care option in NSW the project was unable to make definitive conclusions regarding the impact of this option. As a consequence it is recommended that:

- R5 Further investigation of the impact of incorporating enhanced care into routine pharmacotherapy treatment be undertaken (including consideration of the outcomes of an evaluation of the New South Wales Pharmacy Incentive Program which encompasses the provision of integrated care options to clients).**

1

Introduction

The Pharmacy Guild of Australia (the Guild) appointed Healthcare Management Advisors (HMA), in collaboration with the Victorian College of Pharmacy, to conduct a study to:

“assess funding model options for dispensing pharmacotherapies for opioid dependence in community pharmacy”.

The purpose of this project was to establish whether providing clients with a subsidy which effectively reduced the cost of methadone and buprenorphine dosing would lead to:

- (1) improved compliance with the dosing regime;
- (2) increased client and pharmacist satisfaction with the pharmacotherapy treatment program; and
- (3) to assess which of the three options trialled had the best outcomes for both clients and pharmacists.

The study had the following main objectives:

- (1) to develop options for a best practice funding model for the subsidisation of pharmacotherapy dispensing costs within the community pharmacy setting that achieves optimal health outcomes for clients;
- (2) trial and evaluate the options in a range of community pharmacies; and
- (3) develop a plan for evaluating the model(s) including parameters for assessing efficiency and effectiveness (including health outcome indicators).

The project was funded by the Pharmacy Guild under the Third Pharmacy Agreement.

1.1 PROJECT BACKGROUND

The project provided an important opportunity to obtain quantitative and qualitative data that could be used to fully understand pharmacotherapies from the perspective of both community pharmacy providers and consumers, the costs of service provision, resource utilisation and provider satisfaction in providing opioid substitution as it related to funding arrangements.

The key objective was to collect a wide range of data that could be used to investigate the health, social and economic benefits of best practice funding model options for the provision of methadone and buprenorphine. These models were trialled and evaluated from the perspective of the role of community pharmacists in the provision of these treatments and the cost effectiveness of including community pharmacists in the development of a strategic approach to the delivery of these models.

1.2 METHODOLOGY

The key stages of the project methodology are outlined below.

- (1) **Detailed project planning.** In consultation with the Guild's Project Manager and the Expert Advisory Group (EAG), HMA developed a detailed project plan which was agreed by the EAG in November 2004.
- (2) **Situation analysis.** The situation analysis incorporated a review of the policy and environmental context for the dispensing of pharmacotherapies for opioid dependence, a literature review and stakeholder consultation. The Situation Analysis document was presented to the Guild's Project Manager in April 2005.
- (3) **Baseline data collection (scoping studies).** The purpose of the scoping studies was to collect baseline data about current community pharmacy practice and the clients who use the pharmacotherapy dispensing services. Ten sites (pharmacies) were involved and four consumer groups were interviewed. The data collected included time and financial data which was used to estimate the cost and financial return per dose for dispensing methadone and buprenorphine. This enabled comparisons across states, client numbers and pharmacy locations.
- (4) **Preparation of funding options discussion paper.** Based on the results of the scoping study a summary paper was prepared that synthesised the investigations that had been undertaken to this point, including the situation analysis, the literature review and the scoping studies. The paper identified options for funding pharmacotherapy. The paper was presented to the EAG in November 2005 and has been incorporated into this report.
- (5) **Design trial evaluation methodology and evaluation framework.** The baseline analysis from the scoping study, the findings of the literature review and the situation analysis were drawn on to design the trial methodology and the evaluation framework
- (6) **Establishment of trials.** Following ethics approval, trials across six pharmacies were established. The trials were based on the trial methodology and associated management strategy that included collecting baseline data from the pharmacy staff and the consumers currently using pharmacotherapy services.
- (7) **Trials.** The trial operated in each of the six pharmacies for a period of three months from March 20th 2006 until June 11th 2006. Three funding models were trialled and initially involved 96 clients.
- (8) **Post trial data collection.** On completion of the trial in June 2006 interviews were conducted with participating pharmacists (and their staff) as well as the clients.
- (9) **Report of outcomes.** A comprehensive report of the project was prepared (this document).

1.3 METHODOLOGY FOR EVALUATION OF TRIAL OUTCOMES

The methodology for evaluating the outcomes of the trial were as follows:

- (1) **Analysis of BTOM-C data.** The BTOM-C instrument was used pre- and post-trial to assess client outcomes from the trial and was analysed according to the Score Summary Sheet Guidelines for the BTOM-C.

- (2) **Analysis of other qualitative and semi-quantitative client data.** Results from qualitative questions were classified according to common theme and pattern that were identified during the analysis.
- (3) **Analysis of other qualitative and semi-quantitative post trial client data.** Relevant satisfaction measures were repeated in the post trial interview, and results compared to baseline satisfaction scores. Qualitative themes around the trialled models were summarised, including assessment of the positive and negative features of the trialled model, and suggestions for enhancement of the trialled models.

1.4 TERMINOLOGY

In preparing this report a number of terms were used that warrant clarification. The term **enhanced care** was used to describe the process whereby pharmacotherapy clients were able to receive additional support and information from pharmacists beyond the routine pharmacotherapy dosing treatment. More specifically (and as described in Section 4.3) the enhanced care model was based on addressing specific individual (client) needs consisting of one or more of the following features:

- regular structured communication between the pharmacist and prescriber (especially in relation to attendance for dosing, state of health, suitability for take-away doses and dose changes);
- development of a client care plan;
- conducting multidisciplinary case conferencing; and
- liaising with local agencies and associated support services to establish appropriate referral points for clients (where appropriate).

The term **dispensing fee** (or similar) refers to the payment by clients for pharmacotherapy dosing. As pharmacotherapy services provided by pharmacists are NOT funded under the Pharmaceutical Benefits Scheme (PBS) the use of this term does NOT imply PBS funding.

The term **pilot** is used to refer to the initial study (based on 12 sites) to determine the cost of pharmacotherapy treatment and determine the models of funding to be tested through the **trials** which were based at six sites across three states (a different funding model was trialled in each state).

1.5 PROJECT MANAGEMENT

The Guild was a principal contact point for HMA during the project. The project also had access to advice from the Guild's Expert Advisory Group (EAG) that was responsible for approving each stage of the project. This group was comprised of:

- Australian Injecting and Illicit Drug Users' League, Annie Madden,
- Intergovernmental Committee on Drugs, Keith Moyle
- The Pharmacy Guild of Australia, Denis Leahy, Khin Win May
- Pharmaceutical Society of Australia, Irvine Newton
- Department of Health and Ageing, Dr John Primrose, Tracey Cook, Klaus Klauke, Louise Butkus and Heather Cocks
- Research and Development Program staff, Simone Jones and Erica Vowles.

1.6 PROJECT LIMITATIONS

The project sought to develop a methodology that satisfied the Project's Terms of Reference and provide the sector with options for the future funding of pharmacotherapy treatment in community pharmacies. At the outset HMA, in conjunction with the EAG, recognised that there would be limitations with the outcomes as follows:

- (1) **Need for ethics approval.** Ethics approval was required (and granted) to undertake the project. Relevant stipulations included that, within an individual pharmacy, ALL clients had to be invited to participate in the trial. Whilst this meant that it was not possible to identify and study a control group of clients within a single pharmacy during the trial, the use of a pre- and post-observational trial at each pharmacy provided an important insight into the benefits of the trials.
- (2) **Project budget limitations.** The project was required to operate within the agreed budget. Based on the agreed funding models (and resultant patient subsidies) this limited the number of clients to around 117 across six pharmacies.
- (3) **Limitations on pharmacy numbers.** Consistent with the limitations on the project budget and total patient numbers, the desire to test three alternate models meant that there would be two pharmacies and these would be in each of three states (each state testing one of the three alternate funding models).

Whilst these limitations did not impact on the ability to undertake the trials, the project has sought to maximise the value of the data collected. This has included comparison of the trial data with the results of the scoping study (pre-trial).

1.7 STRUCTURE OF FINAL REPORT

The remainder of this report is presented in seven chapters:

- (1) Chapter 2 presents the findings from the literature review and describes the environmental context in which pharmacotherapy is provided.
- (2) Chapter 3 describes the findings from the scoping studies undertaken to inform the trial methodology.
- (3) Chapter 4 describes the design and implementation processes for the trial and associated funding models.
- (4) Chapter 5 presents the analyses of the trial findings.
- (5) Chapter 6 synthesises the findings to draw conclusions and associated recommendations

2

Environmental Context

In seeking to understand the environmental context for the trials, the project sought to examine the existing operational and funding arrangements (nationally and in each state and territory) and identify how these models have impacted on a range of issues including accessibility, efficiency, effectiveness and quality of service provision of pharmacotherapy treatments (ie methadone and buprenorphine) in relation to community pharmacies.

The intent of this work was to provide an evidence base and guide for the identification of a number of preferred funding model options to be trialled and evaluated. The focus was on the role of community pharmacists' in the provision of pharmacotherapy treatments, and the cost effectiveness of including community pharmacists in the development of a strategic approach to the delivery of these models. This chapter is based on:

- a synthesis of stakeholder consultations with representatives from Pharmacy User Groups, Drug and Alcohol Agencies, Australian and state/territory government funding authorities, the Pharmacy Guild of Australia and Pharmacy Society of Australia;
- evidence from the literature review on current Australian practice and international practice with similar funding models.

2.1 OVERVIEW OF PHARMACOTHERAPY

There is considerable evidence that the effectiveness of the implementation of harm minimisation programs is enhanced by the involvement of community pharmacists. The aims of methadone treatment are to:

- reduce or eliminate illicit heroin and other drug use by those in treatment;
- improve the health and well-being of those in treatment;
- facilitate the social rehabilitation of those in treatment;
- reduce the spread of blood borne diseases associated with injecting opioid use;
- reduce the risk of mortality and morbidity associated with opioid use; and
- reduce the level of crime associated with opioid use.

It is widely accepted in numerous countries that methadone treatment is effective in reducing the intake of opiates, minimising social dysfunction and reduces the risk of infection with blood borne viruses including HIV and Hepatitis B and C.^{1,2} There are numerous models of methadone treatment that have been implemented, leading to a dramatic increase in demand since the inception of treatment services, and significant expansion in Australia from 1985. In Australia the prevailing form of treatment for opiate dependence has progressively emerged over the past 35 years to the point in Australia methadone treatment is the largest specialty practice in pharmacy.³ The Australian Association of Consultant Pharmacy's (AACP) report indicated that client retention in methadone treatment involving community pharmacies was higher than in

clinic-based programs and that the costs of both private and public clinic based programs were higher than in the community pharmacy sector.

2.1.1 Management of Pharmacotherapy Treatment Programs

Responsibility for the management of pharmacotherapy treatment programs in Australia lies with individual State and Territory governments and covers:

- authorisation of prescribers and clients; and
- determination of models of service delivery for private and public administration of pharmacotherapies.

The most commonly accessed source for pharmacotherapies for clients receiving opioid substitution doses are the community pharmacies representing approximately 70% of total clients with the remaining 30% receiving doses from public, state or private clinics.

2.1.2 Issues Impacting on Engagement and Retention in Treatment Programs

Findings from a number of drug outcome studies undertaken in UK and the USA have identified that the engagement and retention of service users in methadone treatment programs (as well as other forms of intervention) for a sufficient time period are key indicators for improved outcomes.⁴ The literature findings indicate that:

- (1) Methadone is prescribed in many ways: as a short- and long-term treatment and as a short- and long-term detoxification treatment. Evidence suggests that the more severe the dependence, the higher the dosage should be and the longer the treatment should last. Engagement and higher retention rates are achieved by ensuring consumers have effective treatment doses (typically greater than 60mg/day), access to counselling, and the availability of takeaway doses.
- (2) Many drug dependent people who start treatment are required to deal with a multitude of problems and needs including:
 - attending a pharmacy (for an initial period) on a daily basis;
 - establishing normal daily living with respect to accommodation, family, food and clothing; and
 - availability of sufficient financial resources to pay for the medical and pharmacy costs of treatment.

Studies have also shown that one of the most prevalent reasons why many drug dependent people do not access methadone substitute therapies or drop off their methadone treatments is due to the lack of available financial resources to pay for these treatments.⁵ This is because the consumers are often financially disadvantaged and living on low incomes. Research by the Guild indicated that the dispensing fees charged by community pharmacists ranged from \$3.00 to \$7.00 per day and the \$21.00 to \$35.00 per week payment can represent a significant financial burden to individuals, many of whom are already socially and economically disadvantaged.⁶

- (3) Pharmacist providers have argued that the existing fees for dispensing of opioid substitution pharmacotherapies (derived by patient payments) do not provide sufficient returns to justify their involvement in this activity. For example, in their submission to the “Inquiry into Substance Abuse in Australian Communities,” the Guild, recommended that an Australian Government subsidy be paid to pharmacists dispensing and supervising methadone doses.⁷

- (4) The inquiry also found there was great need for more social support and counselling for people requiring pharmacotherapies for opioid dependence. In this context the committee recommended that the Australian, State and Territory governments provide sufficient funding for the provision of comprehensive support to opioid dependent people receiving pharmacotherapies. It was considered essential that the cost of pharmacotherapies be affordable for those wishing to avail themselves of this treatment.⁸
- (5) People in some rural areas continue to have difficulty gaining access to methadone programs. These difficulties can be in part attributed to problems in recruitment and retention of medical practitioners and pharmacists to the rural sector.

2.2 IMPACT OF PHARMACOTHERAPY

2.2.1 *Impact of substance and opioid dependence*

Drug dependence is a condition characterised by a strong desire to continue using a particular substance despite health, interpersonal and legal problems. Pharmacotherapy treatment options for opioid dependent individuals across Australia are currently provided in the form of methadone and buprenorphine.

The American Psychiatric Association described substance dependence as *‘a cluster of cognitive, behavioural and physiological symptoms indicating that the individual continues use of the substance despite significant substance-related problems...a pattern of repeated self-administration that usually results in tolerance, withdrawal, and compulsive drug-taking behaviour.’*⁹

It has been stated that *“although tolerance and withdrawal are characteristics of substance dependence, neither is necessary for a diagnosis of substance dependence.”*¹⁰

Also relevant was that the American Psychiatric Association defined opioid dependence as *“a disorder which has similar criteria as substance dependence and includes physical tolerance of, and dependence on, opioids, as well as the compulsive use of opioids despite harm.”*

Opioid dependent people frequently experience serious health and social problems and are at high risk from premature death from accidental drug overdose, drug-related accidents and violence. Re-using needles and syringes and other drug-taking equipment also places them at high risk of acquiring Hepatitis C virus (HCV) and/or other blood-borne pathogens. These problems may also be compounded by multiple substance use, as well as by factors such as poverty, homelessness and a range of mental health disorders. In addition, people with drug dependencies have often experienced a long history of stigma social exclusion, poor service delivery and for some, incarceration, which reinforces their sense of alienation and isolation.

2.2.2 *Pharmacotherapy treatment programs*

Although other forms of treatment for opioid dependence continue to be explored in Australia and overseas, the use of methadone and buprenorphine remains the most widely used form of treatment for people who are dependent on opioids.¹¹

- (1) **Methadone.** Methadone is an opioid receptor agonist with similar pharmacological actions to morphine and has been used to treat opioid dependence in Australia since 1969. Until 2000, it was the only available pharmacotherapy treatment. For nearly three decades methadone has been the primary means of treating opiate addiction.¹²
- (2) **Buprenorphine.** Buprenorphine is a partial opioid receptor agonist, which gives an opioid effect whilst also reducing the effects of additional opioid use. This medication was registered in Australia as Subutex® in October 2000 for the treatment of opioid dependence, including detoxification and treatment.¹³ In August 2001 buprenorphine became available as an additional treatment option for opioid dependence.

Methadone and buprenorphine treatments are considered to be effective opioid substitution treatments for most opioid-dependent people wanting to minimise harm associated with their illicit opioid use. These pharmacotherapy treatments aim to minimise withdrawal symptoms, reduce opioid drug craving and reduce euphoric effects of injected episodes. For some, pharmacotherapy treatment provides an opportunity to reduce or cease illicit drug use.¹⁴ In 2006 a combination of buprenorphine and naloxone, an opioid receptor antagonist (Suboxone®), was introduced in Australia. The inclusion of naloxone with buprenorphine reduces the likelihood that doses will be diverted for illicit injection.

2.2.3 Role of the Australian and state/territory governments in pharmacotherapy treatment

The role of the Australian government is to facilitate access to pharmacotherapy treatment by funding both the wholesale cost of methadone and buprenorphine (under Section 100 of the Pharmaceutical Benefits Scheme (PBS)) and the costs associated with medical consultation and urinalysis relating to methadone services (through the Medicare Benefits Schedule).

Each state and territory government has the responsibility for managing the delivery of pharmacotherapy within their own jurisdictions. This includes the authorisation of prescribers, pharmacists and clients, as well as determining the service delivery pattern for public and private administration of pharmacotherapies.

Methadone and buprenorphine are currently administered through a variety of service delivery and funding models. This process requires ongoing and effective collaboration between all levels of government, health professionals, peak bodies and client groups. Although pharmacotherapies are provided through a range of dispensing agents, the most commonly accessed source is the community pharmacy. In January 2004 it was estimated that, of 34,213 clients receiving pharmacotherapy nationally, 24,091 (70%) clients received their doses from community pharmacies, with the remaining 10,122 (30%) clients receiving their doses from public, state or private clinics.

Table 2.1 demonstrates the breakdown of the numbers of clients in each state receiving pharmacotherapy through a community pharmacy.

Table 2.1: Pharmacies dispensing pharmacotherapy treatment by State/Territory, June 2006

Jurisdiction	Registered pharmacotherapy clients	Number receiving pharmacotherapy from pharmacies	Number of pharmacies	Pharmacies dispensing pharmacotherapy
New South Wales	16,364	7,066	1,709	634 (37 %)
Victoria	10,790	10,113	1,166	459 (39%)
Queensland	4,539	3,280	963	272 (28%)
Western Australia	2,888	2,569	502	241 (48%)
South Australia	2,943	1,649	399	190 (48%)
Tasmania	547	488	131	40 (31%)
Aust Capital Territory	790	507	58	27 (47%)
Northern Territory	114	96	27	9 (33%)
Australia	38,975	25,768	4,955	1,872 (38%)

Source: The Pharmacy Guild of Australia

2.3 AUSTRALIAN POLICY AND ADMINISTRATIVE FRAMEWORK

There are a number of national and state initiatives relating to opioid substitution therapies relevant to considering funding model options. This section provides an overview of the policy arrangements that have been implemented in Australia.

2.3.1 The National Illicit Drug Strategy

In Australia the *National Drug Strategic Framework* (NDSF) was established in 1997. This policy currently forms the basis for Australia's approach to management of the impact of illicit drug usage. The NDSF identified specific strategies focused on issues surrounding the availability and use of illicit drugs known and are included in the *National Illicit Drug Strategy*. A key strength of the national policy framework is its effect in encouraging a cooperative and consistent response throughout Australia, while remaining sufficiently flexible to enable appropriate action to be taken at the state/territory level.

The current *National Drug Strategy 2004-2009* is a policy framework that provides a coordinated and integrated approach to preventing and reducing the harm caused by drug use in the Australian community. The strategy guides government and non-government organisations in the development and delivery of programs and initiatives aimed at preventing and reducing harmful drug use.¹⁵

Within this framework individual health jurisdictions and non-government organisations are responsible for the development of plans and strategies that reflect the key elements of this strategy. They are required to report annually on implementation of programs, activities and initiatives. The current NDSF has five key elements:

- (1) **Harm minimisation:** An approach that aims to reduce the adverse health, social and economic consequences from the misuse of alcohol and other drugs, by minimising or limiting the harms and hazards of drug use for both the community and the individual, without necessarily eliminating use.
- (2) **Drug control:** A broad spectrum of control measures is required, ranging from legislative provisions to controls on the access, availability and use of drugs for certain groups or in certain situations.
- (3) **Intersectoral approach:** Alcohol and drug problems need to be addressed in an integrated manner across a broad range of sectors.

- (4) **International cooperation:** Drug abuse is an international concern. Treaties, conventions and global action plans have been formulated to address drug-related issues in a concerted and cooperative manner. Australia is an active participant.
- (5) **Evaluation and accountability:** A commitment to the application of needs-based planning and evaluation activities to ensure the effectiveness and efficiency of strategies to minimise drug-related harm.¹⁶

Since the inception of this strategy there have been a range of initiatives that have been implemented around monitoring and evaluation. For example, the National Evaluation of Pharmacotherapies for Opioid Dependence (NEPOD) was a comparative evaluation of the outcomes of a range of trials of opioid detoxification and pharmacotherapy treatments that was conducted by various states and territories. The NEPOD project was completed in 2001 and evaluated 13 treatment outcome studies comprising a total of 1,500 trial participants. The evaluated pharmacotherapies included buprenorphine, methadone, levo acetyl methadol and naltrexone.¹⁷

At the completion of the NEPOD project, funding was provided to develop a nationally coordinated dissemination and implementation strategy. This sought to ensure that accurate information about the nature, costs and effectiveness of the evaluated pharmacotherapies was made available. The strategy included the development of the following resources:

- a guide for opioid users and their families/carers;
- a resource for distribution to frontline workers; and
- a CD-ROM/overhead presentation package that presented NEPOD's findings.

The general conclusion of the NEPOD study was that methadone appeared to be the most cost-effective treatment currently available, and that treatment in GP (shared-care) settings appeared more cost effective than in specialist clinics.¹⁸

2.3.2 Strategic policy/guidelines for use of opioid substitution pharmacotherapies

Since 1985, Australia has had national guidelines for methadone treatment, while in 1993 these guidelines took the form of a national policy on methadone treatment. A National Methadone Committee was established as a standing committee of the National Drug Strategy Committee in 1994. This committee developed a strategic plan to address training, service quality, alternative pharmacotherapies and monitoring procedures.¹⁹ Further work on developing national standards for methadone prescriber competencies in terms of core knowledge, attitudes and skills, methodologies for assessing competencies and providing training to attain competencies has also been undertaken.

State health jurisdictions have also developed drug and alcohol strategies and guidelines to assist medical practitioners and pharmacists in the safe and effective use of methadone to treat opioid dependence. These guidelines address a range of policy issues relating to methadone treatment including prescribing, dispensing and monitoring.

2.3.3 *Quality Care Pharmacy Program*

The Quality Care Pharmacy Program (QCPP) is a community pharmacy quality assurance program developed in 1998 by the Guild with the assistance of industry stakeholders.²⁰ The objectives of this program are to:

- establish standards for the delivery of pharmacy professional services and management, thereby improving the quality of pharmacy services and management across the industry;
- improve the quality and consistency of services to the consumer, and for that to translate to the quality use of medicines and improved health outcomes for consumers; and
- ensure the services are delivered in a cost-effective manner.²¹

Under the Third Community Pharmacy Agreement, funding was allocated to encourage community pharmacies to embrace the QCPP and achieve accreditation. Financial incentives have been offered to pharmacies to:

- register for the Program and purchase all of the Program materials; and
- achieve accreditation.²²

The program seeks to promote the enhanced involvement of community pharmacy in the delivery of quality and cost effective services and includes the development of standards to assist pharmacists and staff to:

- understand and accept the need for a standard in a particular area;
- integrate the necessary actions into everyday routines; and
- continue to meet the national standards on a consistent basis.²³

2.4 PHARMACOTHERAPY TREATMENT ARRANGEMENTS/FUTURE DIRECTIONS IN AUSTRALIA

This section provides a description of the current operational and funding arrangements that have been implemented by each Australian State and Territory and the views of stakeholders (see Appendix 1) on the various programs as elicited in the interviews with them.

2.4.1 *New South Wales*

The Pharmacy Incentive Program is a drug treatment program administered by the New South Wales Health Department under the statutory requirements of the New South Wales *Poisons and Therapeutic Goods Act, 1966* and associated *Regulations*. The program was established following recommendations from the New South Wales Drug Summit in May 1999 which highlighted the need for:

- additional funding for an expansion in methadone treatment and related counselling services both in the public sector and in community-based services through the use of pharmacists and general practitioners;
- development of training programs in substitution therapies in consultation with the Pharmacy Guild; and
- appointment of drug dependency case managers in Area Health Services to work with the public and private sector, the community sector and non-government organisations in implementing ‘shared care’ arrangements.²⁴

This publication committed over \$54 million to the expansion and improvement of the quality of methadone treatment services in New South Wales.

The New South Wales model for delivering the methadone/buprenorphine pharmacotherapy program includes three main components:

- prescribing the drug;
- administering or dispensing the drug; and
- ongoing case management, counselling and support.

These components are provided within the public and private sectors. The current means of service delivery varies throughout the State and is largely determined by the availability of public resources; geographical access issues; and the size of the potential treatment population. As reported in the New South Wales Drug Services Treatment Plan, pharmacotherapy treatments are provided across a range of treatment settings, as follows:

- corrections settings;
- private clinics;
- public clinics or hospitals;
- community pharmacies;
- treatment received from private medical practitioners (less than 1% of GPs being involved in the program); and
- community pharmacies.²⁵

Table 2.2 shows the registered clients in the New South Wales Methadone/Buprenorphine Program by region of treatment and sex for the five year period 2000 to 2004.

Table 2.2: New South Wales Methadone/Buprenorphine Program by region of treatment and sex, 2000-2004

Treatment Region		2000	2001	2002	2003	2004	% Change 5 years
Urban	Males	6,196	6,488	6,593	6,776	6,985	
	Females	3,622	3,886	4,056	4,095	4,110	
	Total	9,818	10,374	10,649	10,871	11,095	13%
Rural	Males	1,418	1,422	1,372	1,555	1,707	
	Females	1,009	996	1,003	1,105	1,155	
	Total	2,427	2,418	2,375	2,660	2,862	18%
Justice Health	Males	847	1,098	1,104	1,242	1,316	
	Females	161	235	250	230	250	
	Total	1,008	1,333	1,354	1,472	1,566	55%
Total	Males	8,461	9,008	9,069	9,573	10,008	
	Females	4,792	5,117	5,309	5,430	5,515	
	Total	13,253	14,125	14,378	15,003	15,523	17%

Source: New South Wales Health²⁶

Table 2.2 also shows that since the Year 2000, the number of participants in the New South Wales Methadone/Buprenorphine Program has progressively increased from 13,253 to 15,523 (17%). In 2004, there were a total of 15,523 clients registered on the program, 64% being males and 36% females, and 71% of these clients received treatment in urban areas, with 18% in rural areas and 10% in the correctional system.

Since 1986 the number of clients on the methadone program has increased almost six-fold.

Current service model. The New South Wales model of pharmacological service delivery aims to provide treatments to:

- increase the proportion of heroin dependent individuals in treatment to 40-45%;
- improve retention in treatment; and
- improve treatment outcomes such as improved health and social functioning, and reduced crime.

There are 13 private and 32 public clinics that provide access to treatment, stabilising patients, managing complex and difficult patients who require specialist acute care and also support in maintaining patients. General practitioners in conjunction with community pharmacies are responsible for the ongoing treatment of stable patients. It is proposed that the model of service delivery recognise the specialist roles of clinics and the community sector (community pharmacists and general practitioners). The roles of these specialist services are formalised through agreements and established partnerships between sectors and a commitment to patient case management including the delivery of supportive strategies to assist treatment withdrawal.

Current funding arrangements. The New South Wales Health Department funds a Pharmacy Incentive Scheme, which is administered by the Guild (New South Wales Branch). The Guild provides the following support for pharmacists dispensing pharmacotherapy treatments for opioid dependent patients:

- on-site and distance professional support;
- links with Area Health Service Drug and Alcohol Departments;
- methadone and buprenorphine quality assurance resource kit;
- subsidiary registers for methadone and buprenorphine;
- pharmacotherapy workshops for pharmacists;
- administration of incentive payments for new and existing pharmacies;
- advocacy with New South Wales and the Australian Government; and
- recruitment of pharmacists to provide pharmacotherapies.²⁷

Financial incentive payments are provided to new participating pharmacies to establish a pharmacotherapy program in their pharmacy with the payment of a once-only incentive fee of \$1,000. This incentive payment is conditional on the pharmacy establishing quality care standards for methadone or buprenorphine dispensing and dosing of at least one patient for a period of at least two months.²⁸

Pharmacies providing pharmacotherapies are also paid an additional fee of \$100 every six months for each patient they dose at their pharmacy. This patient fee is conditional on the patient being dosed at the pharmacy for two months prior to 30th April and 31st October each year. The conditions of payment of the pharmacy dispensing fees are capped to a total of 20 patients. All claims for payment are processed by the New South Wales Branch of the Guild.²⁹

Stakeholder feedback. During the consultation a number of issues were identified as impacting on the effectiveness of the New South Wales program as follows:

- (1) **Diversion problems.** The New South Wales Health Department indicated there was an ongoing need to minimise the diversion of pharmacotherapies from the program. Takeaway doses (methadone doses consumed at home rather than at

clinic or pharmacy premises) are highly valued by clients because they allow clients to develop or resume a lifestyle that does not revolve around the delivery of medication. However, concerns about the potential negative effects of takeaway dosing, including the diversion of methadone to street sale (which has in turn been linked to accidental fatal overdose) are areas of ongoing concern. To address this issue, strategies had been established to monitor and ensure compliance with its current policy which strictly limits the number of takeaway doses available to recent admissions while giving stable, long-term patients access to takeaway privileges.

- (2) **Effectiveness of the current funding arrangements.** At the commencement of this project in 2004 there was a view expressed by the New South Wales Health Department regarding the ability of the current incentive program to increase the involvement of additional pharmacies. It was noted that the original estimates of expected pharmacy recruitment had not been initially observed. This had led to internal views that a subsidy scheme, on its own, was not likely to achieve further increases in pharmacy numbers. Nevertheless, it appears that in the intervening period there was significant increases in the number of clients being dosed by community pharmacies (estimated increase of 2,000 to 6,800). Similarly, there are now an additional 170 community pharmacies providing pharmacotherapy. Significantly it is estimated that there are around 3,500 unfilled spaces for potential pharmacotherapy patients.
- (3) **Issues impacting on community pharmacies.** From a community pharmacy perspective there were a number operational issues identified that required further consideration in the development of equitable funding model options, including:
 - the management of the bad debts incurred by pharmacies due to non-paying clients and loss of revenue;
 - the time required to complete required documentation and providing a quality service to clients;
 - improving the support provided to pharmacies particularly in dealing with difficult clients;
 - compensation for loss in trade due to the community stigmatisation concerning the methadone/buprenorphine program and its clientele; and
 - public clinics providing free pharmacotherapy services indefinitely have impeded the spread of patients in community pharmacies.

During the discussions with stakeholders regarding the future directions for the New South Wales methadone/buprenorphine program the following issues were identified:

- (1) **Future program funding.** The New South Wales Health Department plans to continue funding the incentive payment scheme for pharmacists to participate in dispensing pharmacotherapy treatment. The New South Wales Health Department is currently renegotiating the way the funding is administered in order to identify opportunities for achieving improved efficiencies and costs savings.
- (2) **Pharmacy Liaison Officers.** The New South Wales Health Department expressed a view, based on interstate experiences (eg Victoria), that an alternative service model warranted consideration, which involved the increased use of Pharmacy Liaison Officers within the program to support pharmacists in dealing with difficult patients as well as assist in the recruitment of more

community pharmacies into the program. It was considered that this service model would generate improved outcomes for both pharmacies and consumers in New South Wales. The Guild suggested that these positions need to be focused on the achievement of predetermined outcomes and appropriate reporting mechanisms to monitor progress. Since 2004 there has been little progress on the recruitment of Pharmacy Liaison Officers in NSW with only two currently being employed. Positions were originally funded and managed by the NSW Health through the Area Health Services. Individual Area Health Services were responsible for recruitment and allocation of tasks for pharmacy liaison officers.

- (3) **Improving relationships with GPs.** The New South Wales Health Department advised that there was a need to consider alternative strategies that would establish stronger relationships between GPs and community pharmacists that would increase consumer participation in the methadone/buprenorphine program and achieve improved outcomes.
- (4) **Alternative funding model options.** The Department supported the consideration of other funding model options. However, it was stated that there would be insufficient resources available to fund a model which had both incentive and cost subsidisation components. There were a number of other funding model options suggested including:
 - payment of a travel subsidy to consumers living in rural and remote areas;
 - limited period subsidisation of treatment for consumers; and
 - an incentive payment system to support a shared care service model with GPs and pharmacists.
- (5) **National funded pharmacotherapy model.** From a pharmacy perspective it was considered that a national funded scheme which incorporates a pharmacy practice allowance warranted consideration. HMA were advised that a practice allowance arrangement had previously been paid by the Australian Government for specific initiatives (ie Rural Pharmacy Maintenance Allowance, Practice Incentives Program) and a similar arrangement would enable the additional financial burden of providing pharmacotherapies to be addressed and could also be linked to the better outcomes quality program.

2.4.2 Victoria

Methadone treatment was introduced in Victoria in 1972.³⁰ Initially, services were funded and provided by government clinics and hospitals. In 1993 the Victorian Drug Strategy adopted a five-year strategic plan as part of the National Drug Strategy. In 1994, large institutions were closed and the first phase of redevelopment of the service network was undertaken. Methadone treatment places expanded and an emphasis was placed on delivering methadone services in a community-based setting, rather than in a large clinic or institutional setting. Since 1985, the proportion of Victorian clients attending for community-based methadone treatment accounts for approximately 95% of all clients on methadone programs.³¹ In 1996, in response to the Premier's Drug Advisory Council report, the Victorian Government announced a substantial range of new initiatives in the development of alcohol and drug services in Victoria under the title *Turning the Tide* which included strengthening community-based treatment services.^{32, 33}

Current service model. The Department of Human Services (DHS) in Victoria has adopted a 'harm minimisation' strategy in respect of the use of illicit drugs. The aim

of this strategy is to reduce the harm to both drug users and the general community and in particular to:

- minimise or limit the harms and hazards of drug use for both the community and the individual without necessarily eliminating use;
- recognise that there is a broad spectrum of levels of drug use and associated risks;
- prevent anticipated harm and reduce actual harm;
- put in place strategies focused on preventing and reducing harm to individual drug users, their families, workplaces and the wider community; and
- utilise a range of measures to prevent and reduce drug related harm, including law enforcement, early intervention, special treatment, supply control, safer drug use and abstinence.³⁴

The Victorian pharmacotherapy service model is distinctive for its generalist and community-based approach, with access to specialist services, where required, for complex or difficult cases. The jurisdictional policy was extensively revised in 2006 to provide advice to practitioners on the legal, safe and effective delivery of pharmacotherapy services. The policy adopts the National Clinical Guidelines for both methadone and buprenorphine, and provides for the introduction of buprenorphine/naloxone combination treatments. The introduction of this new treatment has allowed for the provision of regular take-away doses of a buprenorphine-based therapy. This is expected to have the effect of improving treatment flexibility, and to increase access and retention in treatment.

Pharmacotherapy treatment, in most cases, occurs as part of a generalist health service, with particular emphasis on GPs who are provided training and support, and by specialist and institutional services where necessary. Most dosing is provided in community pharmacy settings. This allows for a large low profile, widely distributed, program in community-based health settings, which is believed to be more conducive to re-integration. Under this model the GP is clinically responsible for the client, and specialist counselling is optionally available. Generally, government-funded drug treatment services in Victoria are based on a purchaser-provider model, where the government purchases a range of drug treatment services from agencies on behalf of the community including:

- counselling and support services;
- drug withdrawal services;
- methadone and other pharmacotherapies;
- rehabilitation and post withdrawal services;
- services for families;
- services for young people; and
- services for Koori communities.

The DHS has also implemented a number of other initiatives as part of the community-based treatment arrangements including:

- (1) **GP Training and Authorisation:** DHS contracts suitable agencies to develop and deliver training programs for GPs to become authorised pharmacotherapy prescribers. In 2006 the current contractor, Turning Point Alcohol and Drug Inc., in conjunction with RACGP, developed an on-line module to support the pre-workshop reading and preparation for trainees. Funding was also provided for trainees to participate in a mentoring process with an experienced prescriber following completion of the training workshop.

- (2) **Provider forums:** Funding is provided through the training contract to deliver a series of provider forums. Authorised prescribers and pharmacists can attend regular forums where topics relevant to the practice of pharmacotherapy are presented. These forums facilitate networking between community based service providers.
- (3) **Pharmacotherapy Support Program:** DHS funds the payment of pharmacy dosing fees for all clients under 19 years of age, and for Juvenile Justice clients. Pharmacies are advised when they accept an eligible client and submit invoices for processing to DHS.
- (4) **The Pharmacotherapy Advocacy and Mediation Service (PAMS):** DHS funds a dispute resolution service. PAMS is a client run program delivered by VIVAIDS, the Victorian Drug Users Group. The service is available to clients, prescribers and pharmacists to deal with problems in service delivery, and to mediate successful solutions. PAMS deals with around 30 individual matters per month.
- (5) **The Pharmacotherapy Development Program:** DHS maintains a full time team of officers dedicated to support of the community based system and capacity building activities. Development Officers visit GPs and pharmacies to recruit new participants to the system. A number of pharmacotherapy capacity building projects are run jointly with DHS Regions. Much of this work supports the integration of private medical services with other state funded programs such as Community Health Centres.

Pharmacotherapy Development also provides planning and policy support for the Victorian system. Jurisdictional policy development, such as the major revision of the state's pharmacotherapy policy in 2006, and contributions to inter-jurisdictional initiatives such as national policy and guideline development are conducted through this group.

Data provided by the DHS demonstrates that there has been a consistent increase of 10-15% in the number of clients participating in pharmacotherapy with almost all of the expansion occurring in private practitioner programs and pharmacotherapy dispensing in community pharmacies.

Table 2.3 presents the number of patients receiving methadone and buprenorphine treatment for the period from 2000-01 to 2005-06.

Table 2.3: Victorian Pharmacotherapy Program, Participation, 2000-2004

Year	Methadone		Buprenorphine		Total
	n	%	N	%	
2000-01	7,264	96.6%	258	3.4%	7,522
2001-02	4,877	63.4%	2,811	36.6%	7,688
2002-03	4,795	53.2%	3,890	44.8%	8,685
2003-04	5,483	54.9%	4,524	45.2%	10,007
2004-05	6,148	57.2%	4,605	42.8%	10,753
2005-06	6,395	59.6%	2,881 (bup) 1,460 (bup/nal)	40.4%	10,736

Current funding arrangements. The funding for pharmacotherapy treatment in Victoria is shared between the Australian and state governments, where:

- the Australian Government (through the Department of Health and Ageing) funds pharmacotherapy drugs (\$6.75m); and
- the Australian Government (through Medicare Australia) funds medical services and urine drugs screens (funding unable to be quantified); and
- the DHS provides funding for GP training in pharmacotherapy, Pharmacotherapy Support Program, PAMS, Specialist Pharmacotherapy Services, and Pharmacotherapy Development. DHS also provides resources to support various pharmacotherapy initiatives through Regions, including some pharmacotherapy outreach workers.

Other than the Pharmacotherapy Support Program, there are no other government financial incentives offered to pharmacies for participating in Victorian pharmacotherapy provision. The Victorian model consists of methadone and buprenorphine being dispensed mainly by privately owned community pharmacies which charge a dispensing fee for their service. The dispensing fee is generally paid for by the consumer and is approximately \$30 per week (approximately \$1,560 per year) and there is currently no mechanism for consumer subsidisation of dispensing fees. It has been estimated that the total cost paid by consumers for dosing is \$18m.³⁵

Stakeholder feedback. The following is a summary of issues that were identified by stakeholders consulted in Victoria:

- (1) **Financial burden for pharmacotherapy treatments.** In Victoria, an estimated one third of methadone clients are working or studying, therefore approximately two thirds of methadone clients are unemployed. Almost half have not completed education beyond Year 10, and over one quarter have a correctional order.³⁶ As a result, the majority of methadone clients rely on social security payments as their income. Surveys conducted by Turning Point Drug and Alcohol Centre and the Pharmacotherapy Advocacy and Mediation Service (PAMS), as well the consultation with relevant stakeholders in Victoria, indicated that dispensing fees are a considerable financial burden to those on methadone and buprenorphine treatment.³⁷ Pharmacists have estimated that approximately 45% of all treatment terminations were due to financial difficulties.³⁸ Costs to pharmacies were commensurate with fees charged in 1996 and methadone fees have effectively remained at their current level since the 1980s.³⁹
- (2) **Other issues.** There were a number of other key issues that were raised by stakeholders consulted, including:
 - dispensing fees paid by clients in opioid substitution treatment were considered to be high (\$1,500-\$2,000 per client per annum) in comparison to the costs paid for subsidised medicines by all other patient groups, and do not fall under the PBS safety net;
 - clients who cannot pay their dispensing fees are denied effective treatment;
 - diversion of pharmacotherapy treatments was an ongoing concern;
 - Victorian pharmacists dilute takeaway doses of methadone into 200 ml of cordial, trying to reduce the risk of clients injecting the methadone;
 - pharmacists have not increased dispensing fee rates since the 1980s and are carrying bad debts for failure of clients to pay for dosing;
 - it was considered that linkages between GPs and community pharmacists involved in pharmacotherapy should be strengthened;

- there is a need to extend training to pharmacists in the dispensing of pharmacotherapy as not all pharmacists are adequately trained;
- there are negative community attitudes about pharmacotherapy (eg pharmacists, staff and members of the community). It was felt with adequate training this could be altered; and
- it was noted that for those pharmacies that provided pharmacotherapy to 25-30 clients on a daily basis, this would provide the necessary economies of scale. However, it was considered that pharmacies dispensing to small numbers of clients could potentially incur an additional cost.

In respect of the future direction of the pharmacotherapy:

- (1) **Future Departmental funding arrangements.** The DHS plans to continue the current operational arrangements and there were no plans to introduce a pharmacy incentive scheme or subsidised dispensing fee. The Departmental view was that more information was required regarding the effectiveness of program incentives and subsidisation in terms of improving health outcomes.
- (2) **Alternative funding model option.** Currently methadone and buprenorphine are not included under the PBS arrangements. An alternative funding model option was for the Australian Government to subsidise methadone as part of the PBS for those eligible for concession/pensioner benefits, which would reduce the cost to this group of methadone clients.

2.4.3 Queensland

Methadone treatment for opioid dependence was established in Queensland by a small number of private psychiatrists in the early 1970's. The first public methadone program was implemented at a Brisbane Psychiatric Outpatient Clinic in approximately 1975.⁴⁰

Current service model. As shown in Table 2.4 it was reported that at 12 April 2005, there were a total of 4,573 clients in Queensland participating in the opioid treatment program (3,533 public and 1,040 private) and since 1 July 2004 there was an increase of 493 clients representing an overall increase of approximately 12% (approximately 3% in the public sector and 64% in the private sector).

Table 2.4: Number of clients registered as at the end of the year*

Location	2003-04	2004-05*
Public	3,446	3,533
Correctional centre and/or government medical officer	29	34
Private	634	1,040
Total	4,080	4,573

* Up to 12th April 2005 for 2004-05

As shown in Table 2.5, for the 2003-04 financial year there were 250 community pharmacies and four private dosing centres involved in dispensing methadone and buprenorphine throughout Queensland.

Table 2.5: Number of dispensers at stated locations, 2003-04 and 2004-05

Location of Dispensing	2003-04	2004-05*
Community pharmacy	250	264
Private dosing centre	4	4
Total Pharmacies	254	268
ATODS Clinic	8	7
Total Public Clinics	8	7
Doctors	2	1
Government department	3	1
Hospitals	36	37
Institution	3	1
Total Other	44	40
Total	306	315

* Up to 12th April 2005

Table 2.6 indicates that there were 83 doctors treating methadone and buprenorphine opioid dependent clients in 2003-04 and there was approximately a 4% reduction in the number of doctors treating these clients in 2004-05. These data also show approximately 18% and 22% of the authorised prescribers did not provide any form of pharmacotherapy treatment in 2003-04 and 2004-05 respectively.

Table 2.6: Number of treating doctors and authorised prescribers, Queensland, 2003-04, 2004-05

Number of Doctors	2003-04			2004-05*		
	Public	Private	Total	Public	Private	Total
Authorised prescribers	21	80	101	22	81	103
Doctors treating clients	20	63	83	20	60	80

* Up to 12th April 2005

The Queensland Department of Health (Alcohol, Tobacco and Other Drug Services Branch) employs an environmental health officer who is responsible for liaising with community pharmacies regarding the dispensing of methadone and buprenorphine. The Department also promulgates a number of guidelines to pharmacists, including:

- sample of the written instructions for use by pharmacists;
- Queensland Methadone Program Policy, Procedures and Treatment Manual 1995; and
- Clinical Guidelines and Procedures for the Use of Buprenorphine in the treatment of Heroin Dependence.⁴¹

Queensland Health stipulates that pharmacists with no experience in supply of methadone or buprenorphine should be encouraged to start dispensing pharmacotherapy treatment on a trial basis with a small number of clients, namely a maximum of four patients for 2-3 months. No more than 25 patients should be dosed at one pharmacy without first seeking approval.⁴²

Queensland Health recommends that a contract outlining expectations between the supplier and client be available in the interests of best treatment for the client and developing a good rapport. The schedule for dosing and conditions, upon which the supplier will continue to provide a service for the patient, should be included in the contract.⁴³

Current funding arrangements. The Queensland government provides no financial incentives to pharmacists that dispense pharmacotherapy treatment. Pharmacists in Queensland charge a dispensing fee to patients that varies from \$5 to \$7 per day.

Some pharmacists charge differential rates for dispensing methadone and buprenorphine.⁴⁴

Stakeholder feedback. The primary issue raised by Queensland stakeholders related to the need to increase the participation of community pharmacies in the pharmacotherapy treatment program. HMA were advised that only 25% of pharmacists in Queensland participate in the dispensing of pharmacotherapy treatments, which means that participating pharmacies carry large numbers of clients.

Queensland stakeholders propose to continue to work with community pharmacies and the Guild to try and support the pharmacies currently providing community dispensing, with the aim of increasing the proportion of community pharmacies providing this important service.

2.4.4 South Australia

The methadone program began in South Australia in 1973 at Hillcrest Hospital. In the late 1970s a Royal Commission finding resulted in the establishment of Warinilla which is the state government funded drug treatment centre. In the early 1980's Warinilla had approximately 40 patients and by 1994, it was treating approximately 1,000 patients. The increasing number of clients resulted in the involvement of community pharmacies in the dispensing of pharmacotherapy treatments, which commenced in 1994.⁴⁵ South Australia now has approximately 200 pharmacies (40%) that dispense methadone and buprenorphine.

Current service model. The methadone/buprenorphine program is part of the South Australian harm minimisation program developed by the Drug and Alcohol Services of South Australia (DASSA). DASSA have developed policies and guidelines to support the involvement of community pharmacies, including:

- policy for non supervised methadone and buprenorphine dosing;
- policy for split doses in drug treatment programs; and
- guidelines for action to be taken in response to serious breaches of drug treatment programs.

Current Funding Arrangement. The South Australian government currently has no financial incentive scheme or financial subsidy provided to the community pharmacies or the general consumer. However, some qualifying patients do receive pharmacotherapy treatments free for the first six weeks on the program that is provided by:

- DASSA;
- Adelaide Central Community Health Service;
- Drug Court Program; or
- Prison Opioid program.

A drug summit held in South Australia in June 2002 resulted in the implementation of 21 priority initiatives aimed at addressing the complex issues relating to drug misuse. An important outcome was a recommendation that the lack of a financial subsidy needed to be investigated to give more incentive for community pharmacies to be involved in dispensing methadone and buprenorphine.⁴⁶

Stakeholder feedback. Based on consultation with key stakeholders the following issues have impacted on the pharmacotherapy program:

- (1) **Decrease bad debts.** There was a need to address the loss in revenue for pharmacists that incur significant bad debts due to client's inability to pay for dosing. Some pharmacists have adopted the CentrePay system, which deducts the dispensing fee from the client's Centrelink payment prior to the client receiving their benefit. This has helped to reduce the level of bad debts.
- (2) **Increase participation of community pharmacies.** Although there is a need to increase the participation of community pharmacies in the dispensing of pharmacotherapy treatments, not all pharmacies have the appropriate environment to dispense methadone and buprenorphine. Some pharmacists would need to undertake a major remodelling of the pharmacy in order to allow for appropriate privacy and security (eg monitored alarm system, video surveillance) and this would have a significant cost implication.
- (3) **Increase program promotion.** There was a view that not all pharmacists and pharmacy staff agreed with the methadone program and this had resulted in negative attitudes towards clients. It was also suggested that additional initiatives could be introduced that would facilitate improved promotion of the program.
- (4) **Diversion of pharmacotherapy treatments.** There are ongoing concerns regarding the diversion of treatments including the volume of takeaway doses.

The following is a summary of the future program initiatives identified by stakeholders in South Australia:

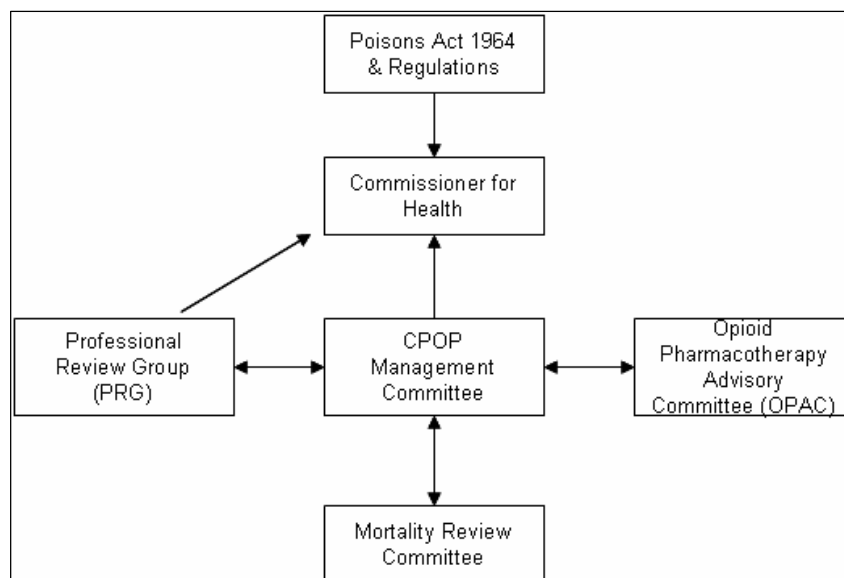
- (1) **Alternative funding model option.** HMA were advised that consideration should be given to the inclusion of methadone and buprenorphine under the PBS arrangements, which would mean that pharmacotherapies be classified as other pharmaceuticals.
- (2) **Costs of dispensing.** Interviewed Pharmacists considered that there is a need to understand the cost of dispensing pharmacotherapy treatments so that a more equitable funding basis could be developed.
- (3) **Lack of resources.** Best practice methadone programs should be comprehensive and involve ongoing counselling, health education, and dose monitoring. However, due to resource constraints, many of the services currently provided are focused on dispensing rather than providing the support services required to meet client needs.

2.4.5 Western Australia

The Department of Health, Western Australia established the Australian *Community Based Methadone Program* in 1997, which was renamed the *Community Program for Opioid Pharmacotherapy* (CPOP) when buprenorphine became available for the treatment of opioid dependence in 2001.

Current service model. Management of the CPOP was restructured in 2003-04, with the current structure shown in Figure 2.1.

Figure 2.1: Management Structure of CPOP



The *Poisons Act, 1964* provides for the decision making authority to rest with the Commissioner of Health. A number of committees, (see Figure 2.1) serve various advisory and management functions of the program. Responsibilities are as follows:

- the CPOP Management Committee has responsibility to ensure effective and efficient delivery of the program, provide strategic direction and ensure development of appropriate policies, procedures and guidelines for pharmacological treatment, training and assessment of treatment providers;
- the Professional Review Group has responsibility for establishing competencies for prescribers and dispensers and advising the Commissioner of Health on the suitability of individual prescribers and dispensers to provide pharmacological treatment, provide advice to CPOP Management Committee on the establishment of clinical governance and quality assurance, and provide a forum to hear patient appeals concerning the application of the guidelines;
- the Opioid Pharmacotherapy Advisory Committee provides an opportunity for key stakeholders to provide feedback and advice to the CPOP Management Committee on matters affecting the delivery of pharmacological treatment for opioid dependent people; and
- the Mortality Review Committee reviews mortality associated with opioid related pharmacotherapies and advises the CPOP Management Committee on its findings and recommendations for further action.

Prescribers and dispensers are required to attend a training and assessment program in order to obtain authorisation. The Drug and Alcohol Office (DAO) provides training for prescribers, while the Pharmaceutical Council of Western Australia provides training for dispensers. Training for dispensers is now incorporated into the tertiary training for pharmacists so recent graduate pharmacists no longer require further training. The Commissioner of Health issues authorisation to prescribe and dispense upon notification of successful completion of the training and assessment requirements.

Pharmacies wishing to dispense opioid pharmacotherapies are subject to limits on numbers of clients per pharmacy they can manage. However, allowances are made to pharmacies that are able to accommodate more clients. There are currently 314 authorised dispensers but only 212 are currently dispensing pharmacotherapy treatment.

The Opioid Replacement Pharmacotherapy Advocacy & Complaints Service (ORPACS) is a service of the Western Australian Substance Users' Association (WASUA). WASUA is the peer-based drug user's organisation in WA. ORPACS provides advocacy and mediation, information/education, counselling/support and referral for people who access the CPOP and/or use opioids illicitly. ORPACS extends its services to other CPOP service providers (eg prescribers, dispensers etc) and key stakeholders and offer consultation, information/education, liaison and community development services. ORPACS represents consumer interests on a number of committees and regularly consults with consumers. The purpose of the ORPACS is to improve consumer satisfaction, service delivery, treatment options, retention rates and continuity of care as well as to increase consumer representation and advocacy for people who access CPOP and/or who use opioids illicitly.

Current Funding Arrangements. The Western Australian Department of Health (DOH) funds the administration of the CPOP, including:

- management, policy and clerical staff positions within the DAO and DOH, Poisons Branch to meet the regulatory requirements and support the management structure;
- initial assessment and referral of clients through the Alcohol and Drug Information Service (24 hr service);
- provision of training and assessment of prescribers through the GP Project; and
- provision of a clinical advisory service (24 hour service) to provide ongoing support of prescribers (including medical consultancy), dispensers and client management services (eg facilitating patient transfers). The clinical advisory service also performs a key role in the patient authorisation process and makes recommendations regarding clinical decisions for complex clients.

The Western Australian government does not provide direct financial assistance to prescribers or dispensers. Pharmacies charge approximately \$4 to \$6 per day for dispensing methadone and \$4 to \$10 per day for buprenorphine.⁴⁷

Stakeholder feedback. Stakeholders identified a number of issues impacting upon the provision of pharmacotherapy treatments in Western Australia, including:

- the large geographic dispersion means some clients experience difficulty in accessing methadone services;
- there is a lack of skill development offered, which could assist pharmacists in being able to deal with difficult clients;
- shoplifting issues for pharmacists who dispense pharmacotherapy treatment which detracts from other pharmacists becoming involved in dispensing methadone and buprenorphine;
- there have been some problems with diversion of pharmacotherapy treatments, and the recommendation to crush buprenorphine tablets caused confusion amongst pharmacist, and increased supervision time, resulting in some pharmacists not wishing to dispense buprenorphine;
- there is a need to employ a pharmacy liaison officer who could address many of the community pharmacy issues; and

- the current service model requires additional resources to provide a more effective support infrastructure to community pharmacies.

The Department of Health Western Australia highlighted the following future initiatives:

- (1) **Revision of policy regulations.** Western Australian Drug and Alcohol services are currently re-drafting policy regulations relating to pharmacotherapy.
- (2) **Alternative funding model options.** The Department of Health, Western Australia has indicated that due to problems in retaining pharmacies in the pharmacotherapy program there is a need to consider incentive payment options. An alternative funding option proposed was for the provision of an incentive payment through the Health Insurance Commission's Pharmacy Agreement for pharmacies that dispense treatments for drug dependence.

2.4.6 Tasmania

The Tasmanian state-wide Methadone Maintenance Program commenced in December 1992 in Hobart as a pilot program.⁴⁸ Methadone was dispensed through an alcohol and drug centre, funded by the government, which consisted of detoxification and rehabilitation units as well as an outpatient clinic. In 1995, the Department of Health and Human Services (DHHS) adopted a policy to implement a community-based pharmacotherapy treatment model to increase access to clients in need of treatment outside of central Hobart.⁴⁹ Pharmacists were accorded a financial incentive to dispense methadone and patients dispensing fees were subsidised so that patients were only paying approximately \$1 per treatment.

Current service model. The Pharmaceutical Services Branch of the DHHS is responsible for issuing authorities to prescribe methadone in Tasmania pursuant to Section 22 of the *Alcohol and Drug Dependency Act, 1969*, and the Alcohol and Drug Services of the same Department provides related clinical training and manages the methadone program. In February 2005, the DHHS reported there were 506 clients receiving methadone and 80 receiving buprenorphine. Around 160 patients are in the public system, meaning they are bulk billed by the GPs or receive a free medical service. There were also 47 community pharmacies participating in the methadone program and 26 prescribers. The program is guided by the *Tasmanian Methadone Policy, 2000*.

Current funding arrangements. The DHHS provides incentive payments to pharmacies that dispense pharmacotherapies. The incentive payments are provided on a sliding scale based on the number of clients that the pharmacy services (Table 2.7).

Table 2.7: Incentive payment made to Pharmacies by Tasmanian State Government

No. of Clients	Quarterly Incentive
1-5	\$144.38
6-10	\$288.75
11-15	\$360.94
16-20	\$866.25
21-25	\$1,443.75
26-30	\$2,165.63
31-35	\$2,887.50
36-59	\$3,465.00
60+	\$6,930.00

Source: Alcohol & Drug Service Pharmacotherapy program Incentives WEF 1 July 2004

All clients receiving pharmacotherapy treatment are charged a dispensing fee by pharmacies. The Guild (Tasmania) has a recommended dispensing fee; however pharmacists are able to set their own individual dispensing fees. Buprenorphine dispensing fees are generally higher than methadone dispensing fees as this drug takes longer to dissolve and therefore requires more time from the pharmacist.

Stakeholder feedback. It was reported there is increasing evidence that the (primarily) non-specialist, community-based program was becoming unsustainable due to inadequate numbers of prescribers and pharmacists and a general view that the service providers felt unsupported. In response, an internal Departmental review of the Program, undertaken in 2003, resulted in a number of recommendations for program improvement.

In essence, these recommendations suggested a full shared-care model of service delivery with the public role being one of a specialist, supporting service taking and stabilising the more difficult clients and providing more help and support to community pharmacists and prescribers. The Department has accepted these recommendations and a funding cycle for enhancement of the program has commenced.

The following issues were raised for further consideration:

- (1) **Alternate funding model option.** The Department of Health and Human Services (DHHS) considered that methadone and buprenorphine should be a general PBS item instead of a Schedule 100 item.
- (2) **Support for community pharmacies.** The Department was currently examining public dispensing of methadone in Hobart, especially for clients that have behavioural issues, which would provide additional support to community pharmacies.

2.4.7 Australian Capital Territory

The first official methadone program in the Australian Capital Territory commenced in 1979 at the Woden Valley Hospital. Prior to this a number of private practitioners were involved in methadone treatment of private clients, but not in a regulated or co-ordinated program.⁵⁰

The methadone treatment program has undergone rapid change and expansion in recent years which was precipitated by:

- the strong methadone consumer lobby group which exists in the Australian Capital Territory; and
- the 1992 Australian Capital Territory Legislative Assembly Select Committee on Drugs report *Methadone Treatment Services* recommended a number of changes to the existing methadone program.

Current service model. The Australian Capital Territory government implemented the *ACT Alcohol and other Drug Strategy* in December 2003, which outlined the actions that the Government would, in partnership with the community and non-government organisations, work to implement over the four-year period 2004 to 2008. It covers key areas of harm minimisation: supply reduction, demand reduction and harm reduction. One of these actions was the creation of 100 additional subsidised places in the methadone and buprenorphine program. The Australian Capital

Territory pharmacotherapy program includes the use of methadone and buprenorphine and there is an intention to introduce naltrexone for withdrawal.⁵¹

Current Funding Arrangements. The Australian Capital Territory is the only jurisdiction in Australia that provides a subsidised methadone dispensing fee. In the Australian Capital Territory, people wanting to start on methadone/buprenorphine treatment are assessed by an Alcohol and Drug Program (ADP) medical officer to determine their suitability. This involves taking a patient history and conducting a physical examination. Suitable clients commence an induction process, usually on the day of medical assessment and clients continue to be reviewed by a medical officer during treatment. Pharmacotherapy prescriptions are reviewed every three months.⁵²

Pharmacotherapy treatment services are delivered to clients through several treatment 'tiers' combining both public and community provision as outlined below.

- (1) **Tier I.** Methadone is prescribed by Australian Capital Territory Community Health's Medical Officers and dispensed by the Australian Capital Territory Community Health's ADP. Methadone is free for six months and thereafter all consumers pay \$15 per week.
- (2) **Tier II.** Methadone is prescribed by Australian Capital Territory Community Health's Medical Officers and dispensed by a community pharmacy. The client pays \$15 to the pharmacist per week with the ADP paying the pharmacy a \$15 weekly subsidy.
- (3) **Tier III.** Methadone is prescribed by a community prescriber and dispensed by a community pharmacy. Client's pay \$30 per week to the community pharmacy.
- (4) **Tier VI.** This tier is used for interstate transfers and the client pays \$35 per week to ACT Health.⁵³

Stakeholder feedback. The main issues raised were limited resource availability, constraints in being able to increase pharmacy participation in the pharmacotherapy treatment due to funding limitations. Consideration that dosing become an Australian Government rather than a state/territory responsibility is needed. It was also suggested that an alternative model for funding of pharmacotherapy services to be based on the PBS Safety Net Model.

2.4.8 Northern Territory

A methadone program was established in Darwin in the 1970s but due to abuse of the program and dose diversion, the program was disbanded in 1978.⁵⁴ In 1993, the Northern Territory Methadone Policy was developed based on the 1987 National Methadone Guidelines outlining the role of methadone and core operational procedures.⁵⁵

Current service model. The current model is largely based on the Queensland model for pharmacotherapy treatment. Amendments to the Northern Territory *Poisons and Dangerous Drugs Act* (PDDA) were introduced in April 2003 following the Drug Taskforce findings delivered in 2002. The model is a mix of public and private services and has a community-based approach to provide greater access and availability to clients. In addition, there is a specialised clinic that provides services for complex and difficult clients. In 1999, a Darwin-based GP drug clinic was established by the Alcohol and Other Drugs Services to provide an opiate withdrawal and management program. The Department of Health and Community Services also

employed a medical officer in July 2002 to provide an expert referral and support service to the primary care sector in the alcohol and drugs field.

Methadone was initially only prescribed on a 12 week dose reduction schedule for withdrawal treatment. However, it is now used for pharmacotherapy and withdrawal treatment by daily dosing from the Drug and Alcohol Service itself or by community pharmacies. The prescribing and dispensing of methadone and buprenorphine is tightly regulated in the Northern Territory due to the lack of doctors skilled in the management of opioid dependency.

Current funding arrangements. There are currently 80 patients receiving methadone treatment in the Northern Territory. Northern Territory pharmacies were eligible for an incentive payment if they agreed to: participate in the program for a minimum of 12 months; dispense both methadone and buprenorphine; and dispense to a minimum number of patients (dependent on local demand). However, the Drug and Alcohol Services Association in Alice Springs advised that there is currently no incentive scheme for pharmacists to dispense methadone or buprenorphine. Only one pharmacy in Alice Springs currently dispenses pharmacotherapy treatments for opioid dependence. Current methadone/ buprenorphine clients pay a dispensing fee to the pharmacist and this averages about \$5 per dose. However, the Northern Territory Government pays the dispensing fee for mothers and pregnant women.

Northern Territory pharmacists are only able to dispense Schedule 8 substances (methadone and buprenorphine) if prescribers are registered and practicing in the Northern Territory. Takeaway doses are not allowed in this jurisdiction.

Stakeholder feedback. Similarly to the Australian Capital Territory, it was indicated that the ability to increase the availability of pharmacotherapy treatment in the Northern Territory is limited by the availability of funding for treatment places.

2.4.9 Summary of State/Territory arrangements

Table 2.8 below provides a summary of the current pharmacotherapy treatment funding arrangements for the dispensing of methadone and buprenorphine in the community-based sector across Australian States and Territories.

Table 2.8: Summary of Pharmacotherapy Treatment Funding Arrangements

Issue	NSW	VIC	QLD	SA	WA	TAS	ACT	NT
Pharmacy incentive payment	✓					✓		
Capped pharmacy patient volume fee	✓							
Subsidised dispensing fee							✓	
Payment of dispensing fee for mothers and pregnant women								✓
Limited period funding				✓				
No incentive or subsidisation payment		✓	✓	✓	✓			
Methadone outreach program		✓						
Pharmacotherapy Support Program for clients under 19 yrs		✓						

This table shows that New South Wales, Tasmania, the Northern Territory and the Australian Capital Territory are the only States/Territories that have implemented funding arrangements for the dispensing or subsidisation of pharmacotherapy treatments, while South Australia provides initial free treatment to a selected group of clients. Table 2.9 below provides a summary of the key future pharmacotherapy program initiatives that were identified across Australia.

Table 2.9: Future Pharmacotherapy Program Initiatives

Issue	NSW	VIC	QLD	SA	WA	TAS	ACT	NT
Employment of Pharmacy Liaison Officers	✓*							
Implementation of a shared care model with GPs and Pharmacists	✓							
Travel subsidy for consumers living in rural areas	✓							
Limited period subsidy for consumers	✓							
Nationally funded Practice Allowance	✓				✓			
PBS Funded Model		✓		✓			✓	
Increased support for participating pharmacies	✓	✓	✓	✓	✓	✓		✓
More equitable funding for dispensing of treatments				✓				
<i>Improve service model to include counselling, health education and dose monitoring</i>				✓				

* Only 2 of the 8 Area Health Services have Pharmacy Liaison Officers

2.5 CONSULTATION FINDINGS

This section considers issues relevant to the funding models as identified by community pharmacies and consumers.

2.5.1 Specific issues identified by community pharmacies

Issues identified by community pharmacies were as follows:

- (1) **Standards for Community Pharmacists.** Standards for pharmacist management of illicit opioids in Australia are set down in State and National regulations and guidelines.^{56,57,58} Harm reduction in pharmacies in Australia now encompasses a range of activities including:
 - participation in needle syringe programs;
 - programs involving methadone, buprenorphine and other therapies (or activities for treating drug or agent dependence);
 - providing information for reducing harm from the misuse of drugs;
 - distributing condoms for the purpose of reducing sexually transmitted diseases; and
 - measures to identify and prevent drug or agent misuse in individuals.^{59,60}
- (2) **Treatment agreements.** Pharmacists who dispense opioid pharmacotherapy are encouraged by most state/territory health jurisdictions (through the promulgation of pharmacotherapy treatment guidelines) to have a treatment

agreement between themselves and the client. This agreement is to ensure that all clients receiving methadone/buprenorphine have a clear understanding of their responsibilities and obligations as partners in the treatment process. The agreement is signed by all clients prior to receiving their first dose. Generally, the conditions of agreement should address:

- expected conduct and behaviour of clients;
- takeaway doses;
- contact arrangements with the doctor;
- attendance requirements; and
- payment arrangements for doses (fees and charges).

The types and details of contracts vary between community pharmacies and across States and Territories.

(3) **Operational and cost related issues.** During the consultation with pharmacists there were a number of operational and cost related factors raised for consideration in the development of future funding model options, including:

- recognition that there were many clients who experienced financial hardship and, as a consequence, client payment for doses was problematic and resulted in bad debt issues that often were not recouped. This was estimated by some pharmacists as up to 5% of their total revenue;
- additional costs had also been expended by pharmacies in the initial program set up costs (eg dispensing pumps, which were approximately \$300 each). Some pharmacies had upgraded security systems in line with general trends in pharmacy practice;
- the additional time involved in supervising dosing to avoid diversion of doses was also a cost factor;
- the time required to maintain the required documentation as specified by health agencies needed to be accounted for in future funding models;
- problems were experienced in recruiting pharmacists and pharmacy assistants willing to dispense due to the continuing stigmatisation of drug users in the community;
- it was considered that the current service model essentially focused dose dispensing and there was insufficient time devoted to provide support and counselling to meet client needs;
- problems in providing services to complex and difficult clients (whilst only a small number) caused significant problems;
- additional training and support was required for pharmacists to encourage increased participation in the program; and
- some pharmacists indicated that where there were high volumes of clients (ie >50), the current price structure is likely to cover the operating costs due to increased throughput. However, this was not the case where fewer patients were serviced.

2.5.2 Consumer issues and pharmacotherapy funding

Consultation was undertaken with a number of consumer representatives to identify views regarding the effectiveness of the pharmacotherapy treatment program in meeting their needs. There were a number of issues related to the cost of receiving pharmacotherapy treatment that were identified by consumers:

- (1) There was inconsistency in what consumers pay for pharmacotherapy treatments such as the additional charge incurred for takeaway doses in some pharmacies, additional cost for doses on public holidays and paying the same dispensing fee regardless of whether the person was being dosed each day or were on alternate day dosing;
- (2) The current dispensing fee payment model places pressure on both the consumer and pharmacist to ensure payment for dosing, which often leads to consumers being taken off the program and causes additional stress on consumers.
 - consumers indicated that the CentrePay payment option has considerable merit; and
 - there was a strong view that methadone treatment should be part of the PBS, like other pharmaceuticals.

The lack of flexibility in how and where methadone and buprenorphine are dispensed is one of the most important issues for consumers on the program. For the most part clients are required to attend a community pharmacy to be dosed. This creates considerable restrictions on daily living as well as imposing additional costs. In particular:

- (1) Travel costs can be significant. Some clients needed to travel up to 100 km per day to have access to the pharmacotherapy program and these travel costs have a significant financial impact, particularly if the client is not employed;
- (2) The opening and closing times of pharmacies may impact on peoples' ability to both work and attend for their doses. Consumers that work full time are not always able to access community pharmacies easily, as most pharmacies do not open until after 8.30am and close by 5-6pm. Some pharmacies also have specific times for dosing further restricting flexibility for working clients.
- (3) Consumers were aware that the policy on takeaway doses varied across Australia, with some clients having access to 2-3 takeaway doses per week, whereas clients in other states/territories unable to have access to takeaway doses even after being on the program for 10 years. Some pharmacies charge extra for takeaway doses compared to a dose in the pharmacy. Charging extra for takeaway doses also means that some consumers such as people with young children who are living on benefits and people working irregular hours cannot always afford to pay the extra cost for takeaway doses.
- (4) Consumers also highlighted that there seemed to be little or no recognition of the problems that general or chronic illness can cause for pharmacotherapy clients. Unless their illness happened to coincide with a scheduled takeaway dose, clients are expected to attend the pharmacy as usual even if they are quite ill. Clients without transport either have to go without their dose or perhaps use a taxi to get to the pharmacy which once again increases the total cost of the dose to the consumer. This can become a significant problem if the illness is a chronic or ongoing condition.

2.5.3 Social Issues

Consumer representatives indicated the need for a more sophisticated approach to pharmacotherapy treatment to take into account the complex health, social and legal issues associated with providing drug dependency treatment including:

- ensuring a better ‘fit’ between the program and clients – the current program was described by some consumers as a ‘medical model managing a social issue’;
- developing a program that is more responsive to individual need and accounts more for the individual motivations for entering and continuing treatment such as whether someone is seeking to stop or simply better manage their drug use;
- recognising that while the provision of a ‘substitute’ medication is very important, it should not be the only treatment experience and that drug dependency needs to be understood and addressed within a broader social and cultural context;
- improving the attitudes of pharmacists, pharmacy staff and the general community towards people on pharmacotherapy programs - consumers mentioned that it was often distressing when confronted with negative attitudes such as having to wait while all other customers are served before being dosed, and blaming only pharmacotherapy clients for shoplifting that occurs within the pharmacy; and
- implementing an improved social support structure within pharmacotherapy treatment in order to meet the specific needs of consumers, including:
 - ensuring pharmacotherapy consumers are treated equally to other people with equivalent complex conditions (eg chronic diseases like diabetes); and
 - ensuring access to quality support and counselling services.

2.5.4 Need for systems to manage payment issues and debts

Consumers reported that some pharmacies allow some people, to accumulate medium to large amounts of debt for dispensing fees which inevitably results in conflict between consumers and pharmacists. People have on occasions been removed from the program after conflict over debt or just being unable to repay debt which then escalates the potential health and social problems for those consumers.

Consumers believe that there is a need for clear systems to be developed to ‘manage’ debts within the context of pharmacotherapy dosing. Such a system should include repayment planning systems and a way to ensure that people are not refused dosing or removed from the program due to accumulated debts. Table 2.10 below provides a summary of the key issues impacting of the provision of pharmacotherapy treatment services across Australia. It indicates there is a high degree of commonality of issues being experienced across Australia.

Table 2.10: Current Issues Identified through the Consultation Process

Issue	NSW	VIC	QLD	SA	WA	TAS	ACT	NT	Comm. Pharm	Consumers
Diversion problems	✓	✓		✓	✓					✓
Effectiveness of current funding model	✓				✓		✓	✓		✓
Financial burden to pharmacies (eg bad debts, set up costs, security)	✓	✓		✓	✓				✓	
Consumer costs		✓							✓	✓
Continued stigmatisation of program	✓	✓		✓					✓	
Strengthening of GP/ Pharmacist linkage		✓								✓
Additional training		✓			✓				✓	
Need to increase participation of pharmacists			✓	✓	✓					✓
Additional support for consumers (eg counselling)									✓	✓
Recognition of time involved in program by pharmacists	✓				✓				✓	

2.6 OVERSEAS PHARMACOTHERAPY TREATMENT FUNDING ARRANGEMENTS

This section provides an overview of the pharmacotherapy treatment funding arrangements that have been implemented in the United Kingdom, Canada and New Zealand.

2.6.1 United Kingdom pharmacotherapy

In the United Kingdom, methadone dispensing is fully funded under the National Health Service (NHS). In most of the UK the dispensing of methadone and buprenorphine is undertaken by all pharmacies when they are presented with NHS prescriptions requesting the products. A standard dispensing fee is paid for these products and an additional controlled drug fee is paid to reflect the extra work required in completing and maintaining documentation as specified by the *Misuse of Drugs Act*.

Most areas now have supervision schemes for methadone, whereas supervision of buprenorphine is less widespread, but is becoming more commonplace as the prescribing of buprenorphine increases. These schemes are negotiated and organised at a local level, with varying fees payable.

As part of the new national community pharmacy contract, the UK is developing standardised 'enhanced' services which will include a supervision service and this was due for release by mid-2005. These services aim to have standard service specifications and benchmark pricing to guide local negotiations. For now, they will continue to be commissioned and negotiated by the NHS at a local level.

In Glasgow, the Health Board provides an additional fee to pharmacists for supervising dosing.⁶¹ It was considered that this initiative may encourage more pharmacists to provide what can be a time-consuming service.⁶²

In 1995, due to the increasing workload of Glasgow pharmacists, the health authority began paying a small annual fee to community pharmacists who agreed to provide supervision, report every month on all methadone dispensing, undertake training, and participate in audits. The fee was paid on a sliding scale according to the number of days a week that supervision was provided and the number of supervisions in a month. The annual fee ranged from £200 (\$A320) for a five day service and up to 250 supervisions per month to £1,400 (\$A2,240) for a seven day service and over 500 supervisions per month. These amounts were later negotiated to reflect better the work entailed.⁶³ Currently, when pharmacies are applying for funding for a locally agreed supervision service, additional funding is also available in some areas for supervision booths and security measures. The core elements included:

- set up costs (one-off fee per pharmacy);
- annual administration fee (per pharmacy);
- supervision fee (per administration or per client);
- training costs; and
- audit and report costs (a set cost/hour for a pharmacy contractor and used the time involved to calculate fees).

The incentive scheme also has associated additional training, education and support. This may explain why a high proportion of Glasgow pharmacists participate in dispensing of methadone and buprenorphine.⁶⁴ The Glasgow scheme also recognises the importance of effective non-medical support so regular counselling and social support are a condition of participation in the scheme. This is an integrated service model that provides a framework within which general practitioners and their staff, community pharmacists, and drug counsellors can cooperate to ensure that methadone and buprenorphine is used safely and patients are given the opportunity to improve their physical, emotional and social well being.

During the stakeholder consultation process, a number of informants indicated that the funding model implemented in Glasgow represented a best practice model that warranted further consideration.

2.6.2 Canadian pharmacotherapy treatment model

Since the mid 1990s there have been significant changes with administration of methadone treatment in Canada. In the Canadian service model, physicians wishing to prescribe or administer methadone are required to obtain authorisation from Health Canada. It is the responsibility of the pharmacists to ensure that the practitioner is authorised to prescribe methadone prior to dispensing it to any patients. Community pharmacies that dispense methadone must keep records and submit reports along with the regular narcotic and controlled substances sales reports.⁶⁵

Recently, Canadian provinces have begun to take over some responsibility for administering methadone pharmacotherapy treatment programs. British Columbia, Ontario, Quebec and Saskatchewan have developed their own provincial guidelines for practitioners and pharmacists prescribing methadone.⁶⁶ In 2001, the British Columbia Pharmacy Association implemented a new methadone treatment payment. Pharmacies that chose to participate in the new payment program were reimbursed for the following:

- drug cost reimbursement will be set at the actual acquisition cost to a maximum of \$0.02/ml;

- the usual dispensing fee will be paid (\$10.49, equivalent to approximately \$A10.74); and
- a \$7.70 interaction fee will be paid for each dose of methadone dispensed. The interaction fee is payable to enrolled pharmacies only.⁶⁷

Reimbursement is provided by personal identification numbers (PINs) that each pharmacy submits to Pharmacare.⁶⁸ In return for the compensation, participating pharmacies are not allowed to bill patients more than the amounts compensated by Pharmacare. Pharmacists must also agree not to offer cash or incentives of any kind to methadone patients. Pharmacists who elect not to participate in the new payment program will not receive the interaction fee but are still eligible for the dispensing fee and drug cost reimbursement. Pharmacists who dispense methadone but do not have direct interaction with patients (including methadone provided to incarcerated patients, patients in pre trial facilities or to physicians for administration to patients) are also not entitled to the interaction fee.

The Provincial Health Plan 2004-2008 for the New Brunswick (Fredericton) province begun funding for methadone pharmacotherapy programs in January 2005 in four provincial centres: Saint John, Moncton, Fredericton and Miramichi. This funding comes from the Department of Health and Wellness and operated through the Regional Health Authority where the treatment centre is located. The development of a provincial Methadone Maintenance Program Framework reflects evidence-based 'best practices' that will cover administration, compliance monitoring, counselling and long-term follow-up.⁶⁹

2.6.3 New Zealand methadone pharmacotherapy treatment model

There are an estimated 13,500-26,000 people with opioid dependence in New Zealand, a number predicted to grow 15% per year for the foreseeable future. The New Zealand model for methadone pharmacotherapy treatment services is currently based on a relatively specialised, centralised approach compared with service models operating in Australia and Britain.⁷⁰ Pharmacists provide an important function in supporting community-based management of people on opioid substitution treatment. The community pharmacists work alongside the specialist services and general practitioner. Pharmacists administer doses both under observation and takeaway doses.

The cost of pharmaceuticals in New Zealand is negotiated by the Pharmaceutical Management Agency (PHARMAC) which was established under the *New Zealand Public Health and Disability Act, 2000*. Currently there are no private methadone treatment services in New Zealand. All fully funded controlled substances such as methadone are available to patients at no cost. The State pays for both the cost of the medication and the dispensing fee. Methadone is the only pharmacotherapy available for opioid substitution in New Zealand.⁷¹

2.6.4 Summary of findings

Table 2.11 below provides a summary of the current pharmacotherapy treatment funding arrangements for the dispensing of methadone and buprenorphine in the community-based sector overseas.

Table 2.11: Summary of International Pharmacotherapy Treatment Funding Arrangements

Issue	United Kingdom	Canada	New Zealand
Fully Funded National dispensing fee including payment of a drug control fee for maintaining required documentation as specified by legislation	✓		✓
Methadone Maintenance Payment Model that funds pharmacies for drug cost, dispensing fee and an interaction fee		✓	

2.7 REVIEW OF LITERATURE

The following section summarises the methodology, study and findings from the literature review.

2.7.1 Methodology

As well as considering policy documents and government publications as described in the previous sections, a review of the learned literature was undertaken in order to fully understand the issues relating to the delivery of substitutable pharmacotherapy treatment models in the Australian and international community pharmacy settings.

HMA conducted a review of national and international literature which sought to identify articles that provided an analysis of the funding models described above. The literature search encompassed both peer-reviewed journals and other published literature. The literature search methodology incorporated the following elements:

- (1) **Electronic database searches.** Subject and text words were used in searching databases for relevant research concerning barriers to consumer access to prescription medicines with English language limits and a publication date from 1990 to present (2006) being applied from PubMed, Informit, CINAHL, Social Sciences Index, and Wellness database and The Cochrane Library.
- (2) **Internet searches.** A search was made of internet resources in Australia and internationally using search criteria, such as *opioid addiction, pharmacotherapy, funding models*.
- (3) **Scanning of reference lists.** Reference lists of publications (primary studies and reviews) found through database searches were scanned to identify further studies for consideration.
- (4) **Grey literature and conference proceedings.** The internet was also searched for examples of recent conference proceedings that discussed the topic.
- (5) **Documenting the search.** The unfiltered searches were retained in their entirety for future potential reanalysis.

The search strategy involved a detailed examination of the material that had been identified as part of the search strategy. In this stage, the literature was excluded if the subject matter was insufficiently described and therefore the documentation did not contribute important information to the project. For example, longitudinal studies are likely to be a particularly valuable resource as they facilitate the testing of relationships between early events or characteristics and later outcomes, which enable the construction of theoretical models, which can then be validated in future research. In addition cross-sectional studies, which use large samples and methodological research designs, are also valuable.

In undertaking the literature review, consideration was given to a number of key issues in reviewing the research outcomes including the:

- assessment of the validity of research;
- nature of correlational research;
- measurement of influencing variables; and
- comparability of cross-cultural findings.

These key issues are discussed below.

An assessment of the validity of the research studies that have been identified was undertaken using the protocol suggested in the Cochrane Handbook⁷². This involved an assessment of each paper, which was rated according to criteria of low, moderate, or high risk of bias as outlined in Table 2.12 below.

Table 2.12: Protocol for Assessing the Validity of Studies

Risk Bias	Relationship to individual criteria	Definition
Low Risk	Plausible bias unlikely to seriously alter the results	All criteria is met
Moderate Risk	Plausible bias that raises some concerns about the results	One or more criteria partly met
High Risk	Plausible bias that seriously weakens confidence in the results	One or more criteria not met

The methodological cut-off point for inclusion of all types of studies in this review considered the overall quality of the literature retrieved and therefore a flexible approach was adopted

2.7.2 Literature review findings

Only a small number of articles were identified that provided an analysis of funding models and found that there were no Cochrane reviews on this topic. A small number of studies were identified that had investigated the effect of dispensing fees on methadone and buprenorphine treatment and showed that retention rates were sensitive to changes in treatment fees. All of the studies were conducted in the United States.

A study by Maddux *et al.* suggested the demand for treatment is quite elastic in response to changes in the price of treatment. In a controlled study, 152 illicit opioid users admitted to methadone treatment were randomly allocated to a fee or no-fee status. The no-fee subjects paid nothing for treatment and the fee subjects were required to pay a fee of \$2.50 per day. It was found that when fees were eliminated, retention significantly increased. Of the fee and no-fee subjects, 34% and 54% were retained respectively in one year of methadone treatment. In this study the removal of treatment fees led to an increase in program retention of 20%.⁷³

Des Jarlais reported a marked difference in retention rates between New York publicly funded free methadone programs and private fee methadone programs. For the years 1975 and 1976 the publicly funded free methadone programs had retention rates of 59% and 58%, respectively. For the same years, the rates in the private fee methadone programs were 37% and 38% respectively.⁷⁴

Public methadone programs in the United States began charging treatment fees in the 1980s. There was a belief that treatment fees improve the effectiveness of treatment. For example, payment of a fee has been assumed to improve the effectiveness of

counselling. The person who pays a fee is thought to invest more in the process than one who does not pay.⁷⁵

Building on this rationale Bishai et al investigated what was the optimal subsidy for drug rehabilitation. They found that the fee was the most important predictor of the probability of client enrolment in a program with a price elasticity of -39. These writers found that clients will pay more for higher rates of treatment success and for the presence of case management.

Therefore, they drew the conclusion that there is a need to subsidise treatment in order to ensure continued attendance by the client but that some clients are influenced more by cost than others and therefore subsidies should be tailored to the needs of the client. Furthermore, clients who lived with parents or a sexual partner, and who had a high psychiatric severity scale, appeared to also have a higher willingness to pay and that an improvement in psychiatric condition was correlated with a reduced willingness to pay. This may indicate that in order to maintain client participation in the program co-payments should reduce over time as the client recovers.⁷⁶

Dispensing fees are not the only cost associated with being on methadone and buprenorphine treatment. People receiving these treatments also incur costs for treatment in the form of travel expenses and time. A study by Goodman and Borisova attempted to estimate the time cost for a methadone dose. This study emphasised that travel and waiting times represented a significant cost to the patient and suggested that policies aimed at reducing the time involved in obtaining treatment - particularly travel times would lead to greater rates of treatment initiation and retention.⁷⁷

Barnett and Hui found that in the states of the US where Medicaid does not cover payment for methadone treatments, failure to pay is an important reason why treatment is discontinued. They investigated whether methadone pharmacotherapy treatment should be offered as a benefit in health care plans, given that methadone treatment is cost effective, since access to methadone reduces other health and social problems suffered by addicts.⁷⁸

Clyde et al, in their study conducted in Florida, also found cost to be amongst the most important reasons for drug addicts not seeking health care especially because those with the worst health problems did not have health insurance.⁷⁹

In many countries, one of the reasons why methadone treatment is not subsidised or provided through mainstream health funding is because politicians have believed that the community is unwilling to contribute towards pharmacotherapy for drug addicts. Cartwright and Solano suggest that this is a rather short-sighted view in that these financial arrangements are inconsistent with rational budgeting theory and lead to less than optimal organisation and management of drug abuse treatment.⁸⁰ This view is also presented by Zaric et al when considering the cost of HIV infection to the community and the utility of its prevention through reducing injecting drug use. They found that there would be considerable saving to the community by funding methadone programs adequately and thus averting the spread of HIV.⁸¹

Zarkin et al conducted a study of two different population cohorts of in the United States where they investigated the communities' willingness to pay for treatment of drug users and to what level. They used a contingent valuation method where participants were asked to estimate the price they were willing to pay towards a drug treatment program after they had been given information about the impact of drug abuse on their community. These researchers concluded that the study participants

would be willing to contribute to the cost of drug treatment programs within their communities up to an amount of \$37 each.⁸²

From this limited review of the literature the following conclusions can be drawn:

- (1) In economic terms the demand for treatment for opioid addiction is quite elastic in relation to fees charged. A lower fee results in increased retention in the program.
- (2) Conversely, co-payment of a fee may increase the clients valuing of the program and thus retention in it.
- (3) Due to the elasticity of demand based on price it may be appropriate to tailor fees to the individual needs and expectations of the clients.
- (4) Other costs associated with attendance for treatment (such as travel costs) may act as a disincentive and need to be considered when developing policies around funding of pharmacotherapy programs.
- (5) In economic terms the cost to government of providing subsidised methadone treatment is far less than the cost of providing alternative health services to injecting drug users.
- (6) Community members are willing to subsidise pharmacotherapies for drug addicts if they understand the consequences of not doing so.

2.8 KEY ELEMENTS OF EVIDENCE BASED BEST PRACTICE MODELS

Based on the review of policies and processes, the literature review and the stakeholder and consumer consultations presented in this chapter, there are a number of key features of pharmacotherapy that are linked to improved client outcomes. The review indicates that effective pharmacotherapy treatment involves the development of client focused service models that involve a spectrum of care, from counselling and detoxification, to prescribed medication and aftercare and these depend on the needs of a particular client. Prescribing medication is an important element of many drug treatment programs. It is also evident that the cost of the therapy to the client is quite elastic in economic terms and that price can provide a strong disincentive for the continuation of treatment. Key factors are summarised below.

2.8.1 Retention in treatment

Numerous studies have demonstrated a link between retention in pharmacotherapy treatment and other positive treatment outcomes such as reductions in criminal behaviour and also increased socially productive behaviour (eg employment). There is also a need to ensure that future service delivery and funding model options include strategies that facilitate retention in the program. Evidence indicates that the cost of the service to the client is a strong indicator for retention in treatment.

2.8.2 Client-centred service models

There has been a growing emphasis on how best to meet the needs of the individual clients. Our findings are that identification and meeting of client treatment needs is a program characteristic that is associated with treatment success. A client-centred service model needs to take into account the needs of specific groups of clients such as those located in rural and remote regions.

2.8.3 *Integrated comprehensive services*

The preceding review of the literature (including national policy) has highlighted that the optimal management of a person with drug dependence involves access to comprehensive and multidimensional services and pharmacotherapy should be closely integrated with a wide variety of treatment elements and support services that is broader than just the pharmacotherapy treatment. Moreover, since recovery can often be a long and complex process, service providers must be able to continually assess and adjust the client's treatment and service to ensure that it is appropriate to the individual's changing needs. In addition to behavioural and pharmacological therapies, the client may need other medical services, family support services, financial management and other social and legal services. The potential elements of an integrated service model for the management of drug dependency include:

- shared care responsibilities between GPs and pharmacists;
- case management;
- counselling;
- mental health services;
- health promotion, disease prevention and education;
- a range of ancillary support services; and
- other health services as required.

Our situation analysis has indicated that, in Australia and internationally, there is wide variation in the extent to which pharmacotherapy clients have access to ancillary supports and services. These services are critical in addressing the major social and medical problems associated with opioid dependence.

2.9 FUNDING MODEL IMPLICATIONS

The objective of this project was to identify funding model options for community pharmacy, which support the provision of pharmacotherapy treatments, and to evaluate the efficacy of each of these models. The findings of the situation analysis identified a range of community pharmacy related funding issues which can potentially impact upon Australian, state and territory health jurisdictions, community-based service providers and consumers alike. The key issues requiring consideration included:

- (1) **Determining an equitable charging base to clients.** As discussed in this chapter, it was evident that a large proportion of consumers experience a financial burden in receiving pharmacotherapy treatments. Furthermore, the charges to clients for dispensing of methadone vary considerably both within and between States and Territories.
- (2) **Determining funding model options.** Based on the literature review findings, it was apparent that there was no single funding model which was likely to address and resolve the problems associated with the provision of pharmacotherapy services. However, it was important to recognise that funding models have the potential to act as a major influence on both client and practitioner behaviour. As part of the stakeholder interview process a number of potential funding models were identified including:
 - consumer co-payment model;
 - incentive model for dispensing pharmacotherapy treatments;

- shared care model (similar to the one implemented in Glasgow);
- subsidy to consumers (eg for dispensing of methadone/buprenorphine, limited period treatment subsidy and travel subsidy);
- nationally funding practice allowance for pharmacists; and
- PBS Funding Model

These options have been considered in the following chapter and adapted for the trial associated with this project.

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3

Scoping Studies

In order to further contribute to the development of the funding model options, an important component of the project involved working with a number of community pharmacies to understand the costs of the pharmacotherapy service. These were referred to as scoping studies and this chapter summarises that component of the project.

3.1 METHODOLOGY FOR THE SCOPING STUDIES

Twelve pharmacies were selected to participate in the scoping studies, although two sites subsequently withdrew (one was due to a reluctance to disclose the detailed financial information required and the other was due to significant health problems being experienced by the pharmacist). In addition, State/territory based client user groups were identified in New South Wales, Victoria, South Australia and the Australian Capital Territory, and contacted to obtain their views regarding key issues relevant to developing the funding model options.

Data relating to time and cost of providing the pharmacotherapy service was collected from each site and this enabled estimates to be derived for the cost and financial return per dose of methadone and buprenorphine. To maintain confidentiality, the participating pharmacies have not been identified in describing the results.

3.1.1 Community pharmacies - site selection, participation and site visits

Potential sites for the scoping surveys were selected in consultation with members of the EAG represented organisations and state/territory branches of the Guild. Participation was invited and background information provided to pharmacies.

Each scoping study involved a site visit to the participating pharmacies by a member of the project team who met with pharmacists and other relevant personnel; observed the pharmacotherapy dispensing process; and collected data on costs and time spent as outlined in the following section.

3.1.2 Community pharmacies - data analysis, cost estimation and model descriptions

Key features of the methodology for the scoping study were as follows:

- (1) **Data collection.** Quantitative and qualitative data were collected with respect to the pharmacotherapy service including the costs of service provision, cost utilisation profiles, and data relating to the appropriateness of the current funding model arrangements (see Appendix 2 for the pharmacy data collection form). In particular, there was an emphasis on understanding variations in dispensing practices (and associated costs), drivers for (and barriers to) enhancing existing funding systems and opportunities for improving the current funding arrangements.

- (2) **Service and funding model descriptions.** Analysis of the scoping study findings was used as input into the analysis of the various service models and funding arrangements that existed.
- (3) **Activity based cost estimation and model development.** Data collected from the pharmacies was used to develop an activity based costing model for each pharmacy. A bottom-up activity based costing approach was applied which measured the time taken to perform designated activities to allocate costs against each activity. The following data were collected:
 - **Client activity and dosing data.** For both methadone and buprenorphine clients;
 - **Pharmacy activity data.** The time taken by pharmacies to undertake a full range of specific tasks for the dispensing of pharmacotherapy services to clients. This measured the time taken for preparation and dispensing, record keeping, and counselling and brief interventions) ; and
 - **Financial data** - relating to the operating costs (inclusive of overheads) of the pharmacy.
- (4) **Cost reconciliation and verification.** The preliminary costing models were reviewed by pharmacies to establish face validity of the results.
- (5) **Assessment of variations.** An assessment of significant variations in the component costs between pharmacies was analysed to identify key factors driving cost variations.
- (6) **Estimation of unit costs.** The findings from the scoping studies were extrapolated to provide an estimate of the unit level and total cost for community pharmacies dispensing pharmacotherapies in Australia.

3.2 KEY FINDINGS FROM SCOPING STUDIES

Two pharmacies participated in each of New South Wales, South Australia, the Australian Capital Territory, Victoria and Tasmania. The pharmacies were located in one regional and one metropolitan area in each state. However, in the Australian Capital Territory they were both metropolitan.

3.2.1 Client Management

Table 3.1 presents key findings for dimensions related to client service provision.

Table 3.1: Pharmacotherapy service provision, findings from scoping study

Dimensions analysed	Main findings	Commentary
Commencement on program	<ul style="list-style-type: none"> one pharmacy 1980s; seven pharmacies 1990s; and remainder 2000s. 	<ul style="list-style-type: none"> some variation, but most active for more than 5 years.
Clients in program 2003-04	<ul style="list-style-type: none"> average 51 clients per pharmacy; and range 15-113 clients. 	<ul style="list-style-type: none"> significant variation in size of programs by pharmacy.
Dispensing method	<p>Methadone:</p> <ul style="list-style-type: none"> one pharmacy used computerised dispensing; and remainder used manual pumps. <p>Buprenorphine:</p> <ul style="list-style-type: none"> usually given as crushed dose unless otherwise specified by doctor; two pharmacies prepared doses before clients arrived; and remainder prepare when client presents. 	<ul style="list-style-type: none"> some variation in dispensing methods.
Client movement	<ul style="list-style-type: none"> majority of clients leave due to change of address, completion of program or discontinue from dissatisfaction with program; and few clients asked to leave due to contract/agreement breach. 	<ul style="list-style-type: none"> some variation - client turnover generally low in proportion to the number of clients at pharmacy.
Dosing limitations	<ul style="list-style-type: none"> NSW reports maximum clients to be 50 per pharmacy; and some pharmacies reported being at physical limits. 	<ul style="list-style-type: none"> some variation - physical space for dosing was the main factor determining dosing limitations.
Doses dispensed 2003-04	<ul style="list-style-type: none"> doses dispensed as expected approximately proportional with number of clients. 	<ul style="list-style-type: none"> expected variation by client numbers.
Difficult client management and discontinuation of clients	<ul style="list-style-type: none"> major difficulty reported was inability (or sometimes unwillingness) to pay pharmacy charges; generally pharmacies reported difficult client management not often a problem. 	<ul style="list-style-type: none"> some variation- contracts/ agreements facilitate client management.
Diversion of therapies	<ul style="list-style-type: none"> identified as a time consuming element of dosing; systems in place to minimise in most pharmacies. 	<ul style="list-style-type: none"> some variation – dual use of systems and individualised client management generally needed.

3.2.2 Pharmacy Management

Table 3.2 presents key findings across the ten sites for a range of dimensions including general pharmacy management, opioid pharmacotherapy information management, and pharmacy support and training.

Table 3.2: Pharmacy management findings from scoping survey

Dimensions analysed	Main findings	Commentary
GENERAL PHARMACY MANAGEMENT		
Operating times	<ul style="list-style-type: none"> closing times: 5:30pm-midnight; seven pharmacies open 7 days; three open 6 days; five pharmacies no restrictions on dosing times; and five short period restrictions after opening and prior to closing. 	<ul style="list-style-type: none"> primarily different business models.
Initial set up adjustments and costs	Range of set-up adjustments including: <ul style="list-style-type: none"> purchase computer and program specific software; installation or reconfiguration of video surveillance; purchase of filing equipment to store the records; and installation of a water cooler. 	<ul style="list-style-type: none"> anticipated variation reflecting differing capital infrastructure and program specific needs at time of set-up.
INFORMATION MANAGEMENT		
Information management systems	<ul style="list-style-type: none"> three pharmacies use Methadose software; seven use manual records for dosing. 	<ul style="list-style-type: none"> some variation – manual recording still predominating; differing reporting requirements due to state regulations.
State reporting requirements	<ul style="list-style-type: none"> monthly reporting predominates (ACT, NSW, SA, TAS) VIC reports quarterly 	<ul style="list-style-type: none"> some variation – reflecting state based legislation/ regulations.
Pharmacy Guild reporting requirements	<ul style="list-style-type: none"> no pharmacies reported requirements to submit data to the Guild on the program 	<ul style="list-style-type: none"> no variation in practice.
PHARMACY SUPPORT AND TRAINING		
Program participation strategies	<ul style="list-style-type: none"> NSW: Guild liaison officer supports pharmacies; TAS: DHHS provides training to pharmacists starting the program; Vic: Dedicated pharmacotherapy development staff program within DHS. Focus on capacity building, recruitment and support of authorised dosing pharmacies. 	<ul style="list-style-type: none"> some variation – reflecting differing levels of program support provided at state/territory level.
Training opportunities and support provisions and requirements	<ul style="list-style-type: none"> training available in some form in all jurisdictions but considerable variation on how, by whom and to whom delivered; some pharmacies report difficulties in finding locums. 	<ul style="list-style-type: none"> significant variation in administration and degree of satisfying training needs – probably reflecting diversity in training needs; flexibility of training and increased program support required.

3.2.3 Integration with GP's and other service providers

Table 3.3 presents current practices in respect of service interaction and integration as reported by the ten scoping study sites.

Table 3.3: Integration findings from scoping surveys

Dimensions analysed	Main findings
Pharmacy interaction with GPs	<ul style="list-style-type: none"> great variation in quality and satisfaction of professional interaction with GPs.
Some areas need more GPs providing programmatic support.	<ul style="list-style-type: none"> significant variation – reflecting differing knowledge, skills and attitudes of providers providing a specialised service.
Pharmacy interaction with other service providers	<ul style="list-style-type: none"> generally limited interaction with other service providers, despite an apparent need for increased social support and case management services; consistently limited interaction in current practice.

3.2.4 Costs of service delivery and resource utilisation

The scoping surveys provided for the collection and analysis of detailed cost information from a range of community pharmacies across. Table 3.4 summarises key findings that were relevant to the development of detailed cost models for service provision.

Table 3.4: Factors impacting on cost models for service provision

Dimensions analysed	Main findings
Dispensing fees	<ul style="list-style-type: none"> vary from \$2.10/day (\$15/week) to \$5.20/day (\$36.40/week) for buprenorphine; some pharmacies offer discounts of order of magnitude of \$5 week for pre-payment, or discounts for weekly payments
Penalty fees (increased daily cost) for prolonged failure to pay	<ul style="list-style-type: none"> significant variation – reflecting differing subsidy arrangements in jurisdictions and payment contract conditions set at an individual practice level.
Subsidies paid	<ul style="list-style-type: none"> ACT: territory pays \$20/week for subsidised places on program, \$15/week client contribution
NSW and TAS: pharmacy incentive payment based on numbers of clients	<ul style="list-style-type: none"> significant variation – reflecting differing levels of program support provided at state/territory level.
Dosing payment arrangements	<ul style="list-style-type: none"> range of approaches decided at the pharmacy level from no pay, no dose, to limited credit, to advance payments; significant variation – payment conditions set at an individual practice level.
Financial viability in the program	<ul style="list-style-type: none"> participation: ranges from social altruism to business strategy
Perceptions of “viable” client thresholds vary from 10 to 30-40 clients	<ul style="list-style-type: none"> significant variation – reflecting the interaction of individual pharmacists within varying business models in different communities.
Bad debt management	<ul style="list-style-type: none"> most report some level of bad debts, but not to a degree that threatens ongoing participation
Bad debt management improves with experience	<ul style="list-style-type: none"> some variation – reflecting local practice and experience.

In developing the dosing costs for methadone and buprenorphine per dose, the major cost components for the analysis included:

- (1) **Salaries and wages and on-costs.** The costs of salaries and wages, superannuation and other salary on-costs were allocated based on the daily time spent on the program for methadone and buprenorphine.
- (2) **Consumables costs.** The costs of consumables used in the dispensing of pharmacotherapies were recorded.
- (3) **Overhead costs.** The funding methodology included an estimation of the overhead cost component that was attributed to the provision of methadone and buprenorphine dosing. Staff attributable costs were apportioned to the program based on the program time allocation (derived from the time data collected). Other overhead allocation was based on the proportion of the floor space allocated to dosing activities relative to the total pharmacy floor space.

The average cost per dose of methadone and buprenorphine was subsequently calculated by summing the total allocated costs for each drug and dividing by the total number of doses. Table 3.5 summarises the average costs for major component costs to derive an estimated average cost per dose for dispensing opioid pharmacotherapies. It is noted that methadone and buprenorphine had similar average costs per dispensed dose. We do note, however, the significant variation in the range of costs observed (both at the individual component cost and overall levels). Such variation is not uncommon where there is significant variation in the characteristics of pharmacies involved in a project of this nature (eg size of pharmacy, number of pharmacotherapy clients, geographic location and so on) as well as small numbers of observations (eight for buprenorphine and ten for methadone). Nevertheless for the purposes of the scoping study the derived averages were sufficiently robust to enable the identification of a suitable level of reimbursement for the trials.

Table 3.5: Details of average costs by pharmacy and average cost per dose

	Methadone Average cost by pharmacy (range) N=10 pharmacies	Buprenorphine Average cost by pharmacy (range) N=8 pharmacies	Total Average cost by pharmacy (range) for all study sites
Total doses	13,096 (3,294 – 26,196)	6,910 (2,196-13,780)	18,624 (5,490-39,100)
Consumables	\$2,278 (\$519 [#] -\$6,518)	\$318 (\$158 [#] -\$655)	\$2,533 (\$695 [#] -\$7,033)
Salaries and wages	\$28,034 (\$3,369-\$63,662)	\$18,525 (\$5,496-\$54,798)	\$42,854 (\$7,031-\$100,200)
Overhead costs*	\$12,561 (\$2,289-\$55,301)	\$3,908 (\$833-\$5,942)	\$15,688 (\$2,775-\$60,773)
Total program costs	\$42,873 (\$7,685-\$119,749)	\$22,752 (\$8,203-\$60,899)	\$61,075 (\$11,125-\$140,945)
Average cost per dose [^]	\$3.27 (\$1.61-\$7.37)	\$3.29 (\$1.03-\$8.18)	\$3.28 (\$1.41-\$7.37)

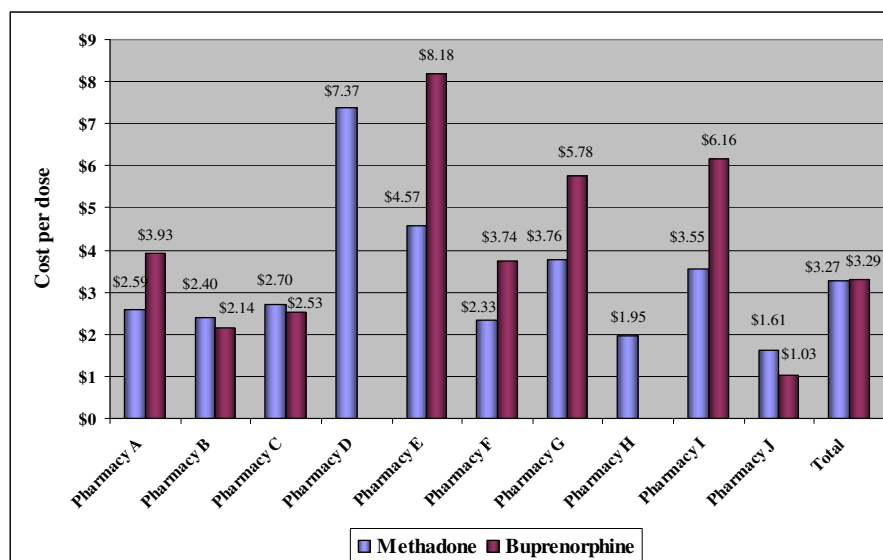
* Apportioned based on number of doses

[#] One pharmacy reported government paid for consumables, so next lowest cost entered for minimum bound of range

[^] average cost per dose is calculated by dividing the aggregate total program costs for all pharmacies for methadone, buprenorphine and combined, and dividing by the total doses dispensed by all pharmacies

Figure 3.1 depicts the comparative cost per dose of methadone and buprenorphine by pharmacy (unidentified), indicating substantial variation between pharmacies, and within some pharmacies for type of opioid pharmacotherapy dispensed.

Figure 3.1: Cost per dose of methadone or buprenorphine by pharmacy



In respect to the cost per methadone dose the following observations were made:

- less than half (40%, 4/10) had a cost greater than the average cost (\$3.27) with costs ranging from \$1.61 to \$7.37;
- the median cost per dose was \$2.65;
- the major variation between pharmacy D and pharmacy J appeared to be due to differences in the daily time devoted to the program, as pharmacy D reported they spent 32.7% of daily time on the program compared to 13.9% at pharmacy J, where the 10.2% was the average and 7.9% was the median time spent on the program across the pharmacies; and

In respect to the cost per dose of buprenorphine (eight pharmacies):

- in contrast to methadone, over half (62.5%, 5/8) of the pharmacies had costs greater than the average cost of \$3.29 per dose with a range from \$1.03 to \$8.18 per dose;
- the median cost per dose was \$3.83;
- the major variation between pharmacy E and pharmacy J appears to be predominantly due to differences in the relative salary and wages expense between the pharmacies (pharmacy E had 20 full-time equivalent (FTE) staff, whereas pharmacy J had 1.5 FTEs, and pharmacy E only reported 1.7% of its time on the buprenorphine program); and
- pharmacy E also appeared to have an unusually high proportion of the pharmacy floor space dedicated to the dosing area, as this pharmacy reported 18.5% of floor space dedicated to dosing, whereas 7% was the average and 4.7% was the median pharmacy floor space for the dosing area across the pharmacies.

3.2.5 Financial return from the opioid pharmacotherapy programs in community pharmacy

The average financial return/dose of methadone and buprenorphine was estimated by revenue/dose minus cost/dose. From Table 3.6, it is evident that methadone dosing provided, on average, a better financial return compared to buprenorphine (\$1.00 compared with \$0.42 respectively), resulting in an average financial return of \$0.83

per dose. Furthermore, the median financial return for methadone was \$1.22, \$0.70 for buprenorphine and \$1.02 overall. Since average costs were similar for the alternate therapies, it was apparent that average and median revenues per dose for methadone are higher than that for buprenorphine.

Again, there is significant variation between and within pharmacies for aspects of the program, with some pharmacies effectively making losses for some activities. These variations are graphically represented in the following sections, and the likely reasons for major variability are reviewed.

Table 3.6: Details of average revenue per dose

	Methadone average revenue by pharmacy (range) N =10 pharmacies	Buprenorphine Average revenue by pharmacy (range) N=8 pharmacies	Total Average revenue by pharmacy (range) for all study sites
Total doses	13,096 (3,294 – 26,196)	6,910 (2,196-13,780)	18,624 (5,490-39,100)
Clients	\$47,885 (\$8,316-\$108,713)	\$23,832 (\$5,544-\$53,489)	\$66,950 (\$13,860-\$123,186)
Other subsidies	\$16,237* (\$3,093-\$32,759)	\$2,862* (\$1,107-\$7,392)	\$9,459 (\$4,200-\$36,000)
Total program revenue	\$56,003 (\$19,415-\$141,472)	\$25,620 (\$12,936-\$53,489)	\$76,500 (\$32,341-\$158,191)
<i>Average revenue per dose</i>	<i>\$4.28</i> <i>(\$2.63-\$7.01)</i>	<i>\$3.71</i> <i>(\$2.63-\$6.45)</i>	<i>\$4.11</i> <i>(\$2.63-\$7.01)</i>
Average cost per dose	\$3.27 (\$1.61-\$7.37)	\$3.29 (\$1.03-\$8.18)	\$3.28 (\$1.41-\$7.37)
Total program financial return	\$13,130 (-\$22,536-\$35,515)	\$2,869 (-\$32,819-\$27,645)	\$15,424 (-\$44,474-\$59,530)
<i>Average financial return per dose</i>	<i>\$1.00</i> <i>(-\$2.37-\$5.06)</i>	<i>\$0.42</i> <i>(-\$3.32-\$2.29)</i>	<i>\$0.83</i> <i>(-\$2.37-\$5.06)</i>

*Average for "Other subsidies" calculated with N=5 (only pharmacies eligible to receive subsidies)

^ Average cost per dose is calculated by dividing the aggregate total program costs for all pharmacies for methadone, buprenorphine and combined, and dividing by the total doses dispensed by all pharmacies

Based on the costing and estimated revenues, some practices are essentially losing money from providing the opioid pharmacotherapy program. Figure 3.2 depicts the cost, revenue and financial return across the scoping study sites and indicates that one practice made a negative financial return of over \$40,000 (site I) while the maximum positive return was in the order of \$60,000 (site B). Eight of the ten pharmacies were making some positive financial return with the average return per pharmacy being \$15,424. Furthermore, the median financial return across pharmacies (\$16,850) was similar to the average.

Figure 3.2: Estimated total program costs, revenue and financial return by pharmacy

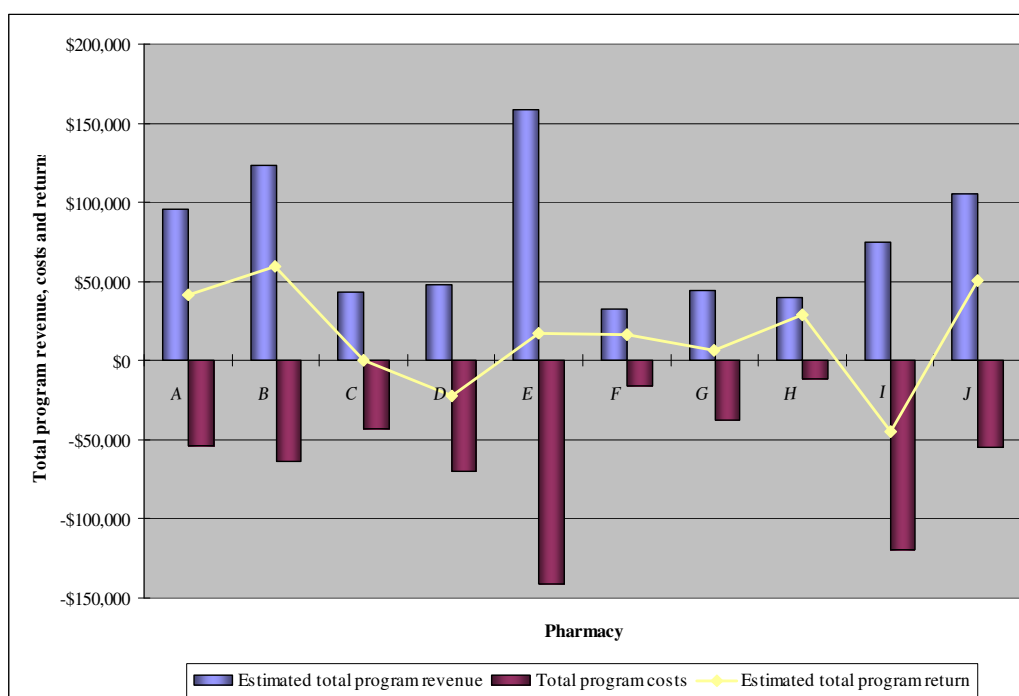


Figure 3.3 depicts the financial return for the ten scoping study sites for methadone doses only. It can be seen that over half (60%, 6/10) of the pharmacies made a financial return greater than the average (\$1.00) while three of the pharmacies recorded a negative financial return on methadone dosing. The financial return per dose ranged from -\$2.37 to \$5.06. Furthermore, the median financial return across pharmacies (\$1.22) was slightly higher than the average return for methadone. Examination of observed variation revealed:

- pharmacies H and F had high relative revenues per dose of methadone that contributed to greater financial returns (pharmacy H \$7.01 per dose, pharmacy F \$5.89 per dose);
- for the pharmacy (pharmacy D), there was a high proportion of pharmacy time spent on this aspect of the program (32.7%), driving a high cost per dose not covered by a revenue of approximately \$5 per dose; and
- pharmacy I reported the next highest negative financial return per methadone dose, and this appears to be predominantly due to low revenue per dose relative to other pharmacies (\$2.84).

Figure 3.3: Financial return per methadone dose

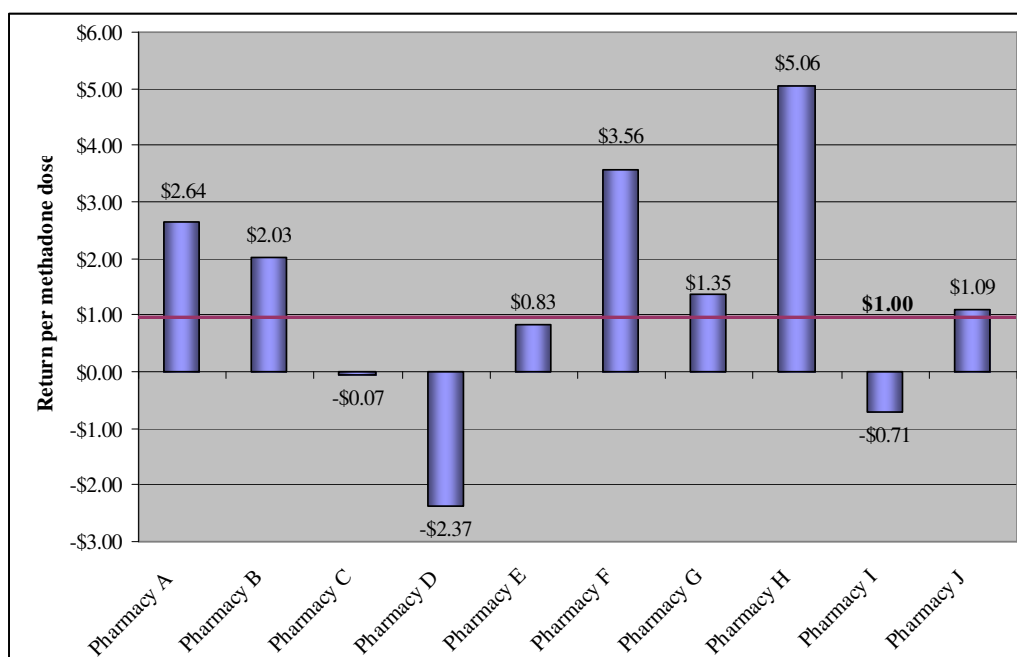


Figure 3.4 depicts the financial return per dose of buprenorphine. Half of the pharmacies (50%, 4/8) recorded a financial return above the average (\$0.42/dose) while three recorded a financial return below the average. The financial return ranged from -\$3.32 to \$2.29 per dose. Furthermore, the median financial return across pharmacies (\$0.70) was higher than the average return for buprenorphine.

Examination of observed variation revealed that:

- the pharmacy with the highest financial return per dose (pharmacy B, \$2.29 per dose), had relatively low costs per buprenorphine dose (related to moderate time expenditure and a high total number of doses administered);
- the pharmacy with the lowest financial return per dose was pharmacy I (-\$3.32 per dose) and this appeared to be related to a low revenue per dose (\$2.84), and a relatively high time spent on buprenorphine dosing;
- 9.8% of pharmacy time was devoted to buprenorphine dosing compared to 8.1% of time for methadone (with approximately 40% of total doses administered as buprenorphine); and
- the other pharmacy with a negative financial return (pharmacy E, -\$1.73 per dose) had high costs per dose. These appear to be related to a large proportion of the pharmacy time devoted to dosing (~19%) and high salary and wages expense of the practice.

Figure 3.4: Financial return per buprenorphine dose

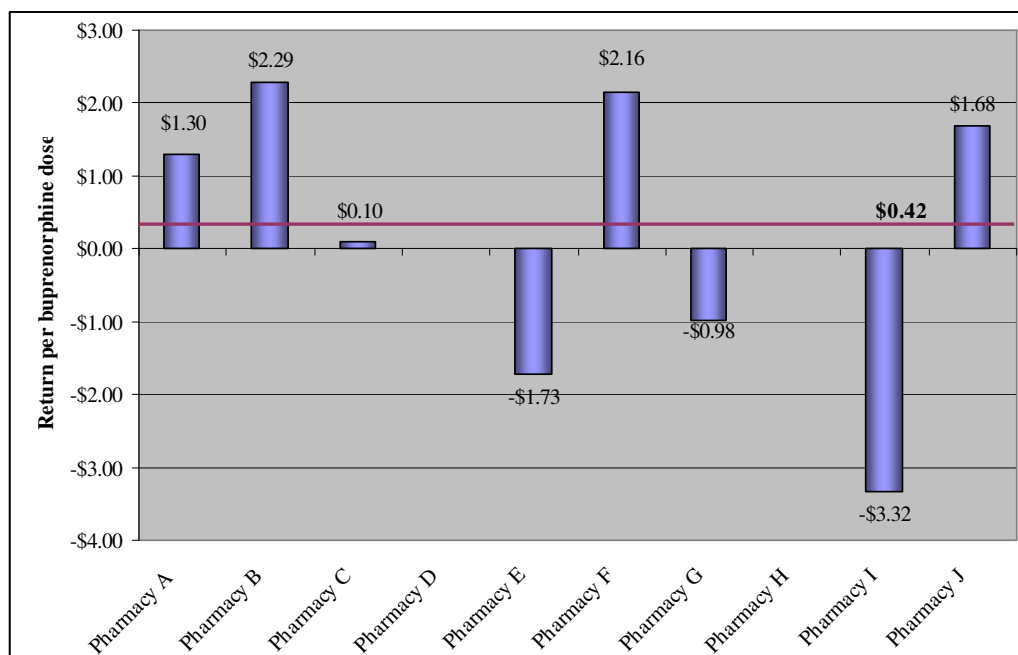
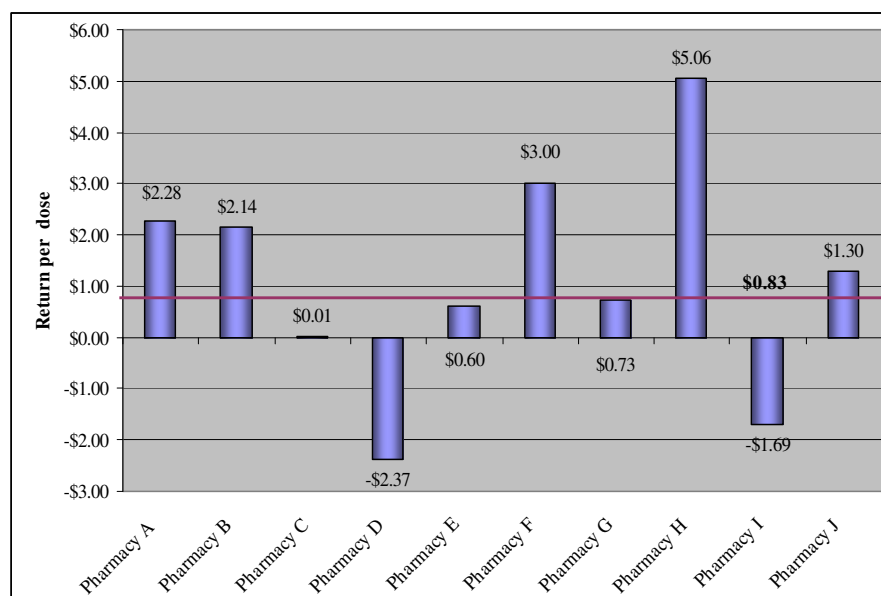


Figure 3.5 depicts the overall financial return per pharmacotherapy dose (combining methadone and buprenorphine) by pharmacy. Of the ten pharmacies, two pharmacies reported negative financial returns, with a further three pharmacies reporting financial returns below the average (\$0.83 per dose). The financial return ranged from \$5.06 to -\$2.37 per dose of opioid pharmacotherapy dispensed. The median financial return across pharmacies (\$1.02) was slightly higher than the average return. Many aspects of major variation have been analysed in the previous figures, but in summary:

- pharmacy H – highest overall financial return per dose had high revenues per dose, no subsidy support;
- pharmacy F – pharmacy with next highest financial return and had balanced revenue and costs and some subsidy support;
- pharmacy I – highest overall negative financial return per dose, had low revenues per dose and higher time allocated to program driving higher costs; and
- pharmacy D – second highest negative financial return per dose, had high costs associated with higher proportion of time dedicated to the program.

Figure 3.5: Financial return per dose of opioid pharmacotherapies* by pharmacy



* Incorporating buprenorphine as well if dispensed by pharmacy (in addition to methadone)

It should be noted that the variation between estimates of costs and returns per dose for each pharmacy indicates the sensitivity of the estimates.

3.2.6 Current best practice, role in harm minimisation and negative program aspects

Visits to the scoping study sites provided the opportunity to consider current operational aspects and Table 3.7 presents general conclusions about the current community pharmacy opioid pharmacotherapy service and funding models.

Table 3.7: Pharmacy general operational issues from scoping survey

Dimensions analysed	Main findings	Commentary
OPERATIONAL ISSUES		
Current model best practice	<ul style="list-style-type: none"> strong theme of belief of the power of the community pharmacy program model to make important social contribution to communities and individuals; awareness of negative impact of level of costs for client retention in program; and one site emphasised the importance of retaining some degree of client co-payment to facilitate ownership and program retention. 	<ul style="list-style-type: none"> generally there was consensus on the value of the program, and the importance of financial burden on program success.
Applicability to harm minimisation strategy	<ul style="list-style-type: none"> generally reports emphasise that the pharmacy programs make an important contribution to harm minimisation; and benefit could be enhanced by greater number of pharmacies participating and responsible service providers facilitating review of outcomes and exit strategies from the program. 	<ul style="list-style-type: none"> responses emphasised the benefit of the model and the need for ongoing collaboration with other service providers to focus on longer term outcomes.
Negative aspects of the program	<ul style="list-style-type: none"> a range of negatives include: bad debt and its management; management of clients behaviour; and lack of after hours support and collaboration between responsible service providers. 	<ul style="list-style-type: none"> varied responses reflected the complexity of the issues.

3.2.7 Opportunities for improvement of current funding arrangements

The major opportunities to improve current arrangements focused on the need for additional pharmacy subsidy (effectively representing a client subsidy administered to pharmacy) and the need to increase pharmacies participating in the program (to improve accessibility and service provision to clients). Issues highlighted by the pharmacists in the scoping studies were as follows:

- efficiency improvements such as better dosing equipment, or record keeping and report generation would be of benefit;
- improved training is needed for pharmacists as part of undergraduate training or continuing practice education;
- accreditation for pharmacotherapy programs. This may play a role in improving programs, especially in the context of promoting quality programs;
- improved after hours support for pharmacists and staff is needed;
- improved communication with and from GPs. It was identified that incentives for increased interactions may result in better client outcomes;
- greater focus on program outcomes by Australian and state governments should more actively focus on strategies to manage and improve outcomes (especially successful exiting from the program);
- improved access to ongoing case management services. Pharmacists sometimes feel they are left to be the main service provider for clients, who are facing complex social and health related issues; and
- greater clarity of take home dosing guidelines for methadone and buprenorphine in some jurisdictions.

3.3 KEY IMPLICATIONS FROM THE PHARMACY SCOPING STUDY

The scoping study confirmed that current Australian practice relating to opioid pharmacotherapy in community pharmacy is extremely varied not only at a state level, but also at an individual practice level.

In general, average financial returns from participation in the program were modest and 40% of pharmacies were estimated to be making some degree of loss on the program and such low financial returns may impact on the ability to provide a service model that reflects best practice. Key dimensions of the service model include the provision of client centred service models (with a focus on retaining clients on the program) and integrating with a wider range of third party support services. Specifically, to be more likely to run a program with reasonable financial returns, a pharmacy may need to increase client contributions per dose or reduce the time providing service. Both of these changes however may be associated with sub-optimal client outcomes.

Jurisdictions with some level of subsidy support appear to derive a modest benefit, but this is not a major driver of financial viability of the programs for most pharmacies. Clients are contributing substantially greater amounts than from other sources of funding, such as subsidies.

The variability of service models and implications for financial viability exists despite the provision in many jurisdictions of standards for program delivery. Even within states or territories there can be substantial variation of practice which reflects the

complexity surrounding the service provision, and individual pharmacies motivation for participation and service ethos.

3.4 KEY FINDINGS FROM CLIENT USER GROUP SURVEYS

Consumer groups in four states were consulted during the course of the scoping study and this section describes the characteristics of the clients normally serviced by the pharmacotherapy program and their views of the program. The data collection form used for this process is included as Appendix 3.

3.4.1 Clientele profiles

The major reasons for initial and ongoing program participation were identified as normally being related to the financial, social and health problems associated with heroin addiction. An additional, ongoing reason for participation was the development of methadone dependence, which for some clients becomes an alternate addiction associated with its own problems.

The major reasons for discontinuation of the program were program dissatisfaction (summarised in the following sections) and financial burden associated with participation (which is varied between jurisdictions).

3.4.2 User group assessments of pharmacy service models

Once clients were able to access community pharmacy dispensing of opioid pharmacotherapies, it was generally acknowledged that the model provided an important and useful service that was needed by clients. However, it is clear that the system is not seen to be ideal by the majority of clients.

Individual clients' experiences with particular pharmacies (and the systems established in those pharmacies), lead to great variability in client satisfaction and feelings of support. Whilst times to access dosing and the use of contracts/agreements were usually viewed fairly positively, the costs of accessing dosing and the time commitments (such as travelling to pharmacies and waiting for doses) were generally viewed negatively.

3.4.3 Integration with GP's and other service providers

Generally it was felt that there was poor communication and integration between service providers with the exception of support provided by case managers. However, ongoing case management of the clients care (beyond simply the management of pharmacotherapy treatment but also referral to other health professionals such as counselling) was not provided in most jurisdictions once clients are on pharmacotherapy treatment. Generally clients suggested that their general practitioners were too busy and not trained adequately to provide case management support to clients.

3.4.4 Client satisfaction and opportunities for improvement

In general, the existence of pharmacotherapy programs was seen as a positive compared to the disruption and stress of active heroin use. The availability of buprenorphine as an additional treatment option was seen by some clients as a positive development. These clients found buprenorphine to have seemingly fewer

side effects than methadone and left people feeling more alert and better able to function normally.

In contrast, the majority of clients were dissatisfied with some aspect of the current program with these being identified as:

- initial accessibility onto the program (there are often significant waiting times);
- stigmatisation through program participation (pharmacies and other service provider environments are not always supportive and non-threatening to clients);
- client costs; (seen as high);
- lack of focus on client outcomes; and
- lack of case management support.

Opportunities to change the existing service model to better address consumer needs and improve outcomes included:

- (1) **The need to reduce delays to program access.** In some areas there are waiting times to access the program, and there has been resistance to allowing private practitioners initiating people onto the program;
- (2) **The need to improve service providers' attitudes to clients.** Some clients feel stigmatised at times, and better education and training is needed for service providers including pharmacy staff; and
- (3) **Case management access should be a priority.** There is currently inadequate communication and integration between service providers and there is a low priority given to trying to improve health and program outcomes.

3.4.5 Key implications of client feedback

Consultation with client user groups emphasised the current service and funding model of opioid pharmacotherapies through community pharmacy is only partially addressing best practice service dimensions. The best practice dimensions focus strongly on the positive effects on clients through retention on treatment and the provision of client centred services that are integrated across the range of relevant services.

The cost to clients and inconvenience of program participation appear to impact on some people's capacity to remain on these programs, although there appears to be more of a burden in some jurisdictions than others. Individual client experience on the program varies significantly across jurisdictions and at the individual pharmacy level, but almost universally it appears that there is a perception of a lack of integrated services and support. Support appears to be best provided through ongoing case management, and such case management should be focussed on improved health outcomes for clients as well as management of the client and development of a plan to completely exit from methadone/buprenorphine treatment).

Improving the flexibility and responsiveness of pharmacotherapy programs remains one of the major challenges facing the program from the client perspective. Program models need to be developed to ensure that the stated program goal of 'normalising people's lives' is supported by the way the program operates in practice. Potential strategies may include providing more dispensing points, longer and more flexible dispensing hours, access to unsupervised dosing arrangements based on clear criteria and individual assessment, affordable dosing arrangements, non-judgmental service provision and better access to social support services.

4

Designing Funding Model Options and Trialling

Based on the findings from the literature and environmental research (Chapter 2) coupled with the results of the scoping studies (Chapter 3) a number of potential funding models were developed and are presented in this chapter. First, a brief summary of the key factors impacting on the models is given.

4.1 SERVICE ISSUES IMPACTING ON FUNDING MODELS

Effective pharmacotherapy treatment was found to involve the development of client focused service models that include a spectrum of care depending on the needs of a particular client. Key program factors that are linked to improved client outcomes were as follows:

- (1) **Retention in treatment.** There is a need to ensure that future service delivery and funding model options include strategies that facilitate retention in the program. Research has shown that longer retention in treatment is associated with improved post-treatment outcomes. In addition, many studies confirmed that a longer length of time in treatment reduces criminal behaviour and also increases socially productive behaviour (such as employment).
- (2) **Client-centred service models.** There is a growing focus on how best to meet the needs of the individual clients. The literature review found that identifying and meeting client treatment needs is a program characteristic associated with treatment success. A client-centred service model includes taking into account the needs of the individual.
- (3) **Integrated comprehensive services.** As highlighted in the literature review (including the National Illicit Drug Strategy) the best treatment programs are comprehensive and multidimensional, with the evidence indicating that the most effective pharmacotherapy treatment programs are closely integrated with a wide variety of treatment elements and support services beyond just pharmacotherapy treatment. The potential elements of an integrated comprehensive service model for the provision of pharmacotherapy treatment include:
 - shared care responsibilities between GPs and pharmacists;
 - case management;
 - counselling;
 - mental health services;
 - health promotion, disease prevention and education; and
 - a range of ancillary support services.

4.2 FUNDING MODEL OPTIONS

This section discusses the funding models implemented in the trial and the methodology used to evaluate them.

4.2.1 Conceptual framework for enhanced models

Conceptually, (as summarised in Table 4.1) funding models can be laid out in a simple matrix taking account of the following dimensions:

- extent of client and/or pharmacy subsidies; and
- activities linked to reimbursement, which may range from simple dispensing to multi-activity payments or shared care payments.

Table 4.1: Conceptual framework for enhanced funding models

Consumer subsidy	Pharmacy subsidy	Pharmacy subsidy	Level of activity
Consumer co-payment Partial payment of client payments	Special treatment dispensing fee Such as a fee per dose or for 7 doses weekly	PBS funding model Such as dispensing fee per script	<i>Payment only for dispensing</i>
Consumer co-payment and subsidy Such as extra subsidy as contribution to travel expenses	Nationally funded practice allowance For provision of the dimensions of a quality pharmacotherapy program	Incentive model for dispensing pharmacotherapy treatments Practice subsidies linked to program outcomes	<i>Multi-activity payment</i> Such as a dispensing, and quality care program
		Glasgow shared care model or other shared care Incorporating relevant areas of case management	<i>Shared care/ integrated service models</i>

The following were considered as funding models:

- (1) **Consumer co-payment model.** Consumers receive a co-payment for their doses, but continue to pay a smaller nominal fee for doses (with or without additional consumer subsidy for other expenses such as travel).
- (2) **Consumer payment model.** Consumers do not pay anything for doses (with or without additional consumer subsidy for other expenses such as travel).
- (3) **Pharmacy subsidy for dispensing fee** (fee-for-service model - with or without consumer co-payment or payment). The range of options for ongoing pharmacy subsidy included:
 - PBS dispensing fee;
 - special unit dose per day payment;
 - pharmacy subsidy as a practice allowance;
 - single payment for setting up program;
 - payment with multiple dimensions around activities (such as start-up payment, ongoing client dispensing payments); and
 - payments can be service provision based, or incentive based (outcome focussed).
- (4) **Pharmacy shared care model** – an additional subsidy above multi-activity payments for provision of value added client focussed supervision or care (such

as adherence to program, or other prescribed medication use) within the context of integrated care (communication with other service providers).

4.2.2 Evaluation of potential models against best practice service elements

Within the conceptual framework identified in the previous section, Table 4.2 presents a matrix reconciling the list of potential models for evaluation against identified best practice service criteria.

Table 4.2: Degree of consistency of options with best practice service dimensions

Potential model	Expected impact on retention in treatment	Client-centred service models	Integrated comprehensive services
CONSUMER CO-PAYMENT MODEL⁸³			
Without additional consumer subsidy			
With additional consumer subsidy ⁸⁴			
CONSUMER PAYMENT MODEL⁸⁵			
Without additional consumer subsidy			
With additional consumer subsidy			
PHARMACY SUBSIDY FOR DISPENSING FEE			
PBS funding model ⁸⁶			
Special unit dose per day payment ⁸⁷			
PHARMACY SUBSIDY AS A PRACTICE ALLOWANCE			
Single payment ⁸⁸ – service provision based			
Multi-activity payment – service provision based ⁸⁹			
Multi-activity payment – service and outcome (incentive) based ⁹⁰			
PHARMACY SHARED CARE			
Multi-activity payment – service provision based ⁹¹			
Multi-activity payment – service and outcome (incentive) based ⁹²			


































Legend: Degree of consistency with best practice criteria: High Medium Low




Using this framework, it was concluded, from a best practice perspective, the most effective model of care is where the pharmacist provides shared care with other health care providers, and is paid an incentive for improved service outcomes.

4.2.3 Evaluation of potential models against major stakeholder criteria

The proposed models were next examined according to major dimensions of stakeholder criteria for enhanced service and funding models as identified in the prior consultation and analysis phases of the project. Table 4.3 demonstrates how funding or payment options impact on client service requirements and client outcomes.

Table 4.3: Degree of consistency of options with client users dimensions

Potential model	Acceptability	Positive impact on service to clients	Positive impact on outcomes to clients
CONSUMER CO-PAYMENT MODEL			
Without additional consumer subsidy			
With additional consumer subsidy			
CONSUMER PAYMENT MODEL			
Without additional consumer subsidy			
With additional consumer subsidy			
PHARMACY SUBSIDY FOR DISPENSING FEE			
PBS funding model			
Special unit dose per day payment			
PHARMACY SUBSIDY AS A PRACTICE ALLOWANCE			
Single payment – service provision based			
Multi-activity payment – service provision based			
Multi-activity payment – service and outcome (incentive) based			
PHARMACY SHARED CARE			
Multi-activity payment – service provision based			
Multi-activity payment – service and outcome (incentive) based			

Legend: Degree of consistency with client user issues:  High  Medium  Low

Again, consideration of Table 4.3 demonstrates that payment of an incentive to the pharmacist to provide a shared care approach to the client can be expected to have the most positive impact on services provided to the client and on client outcomes.

As presented in Table 4.4, each model was also assessed against pharmacy focussed dimensions. Using this evaluation framework it was apparent that the most financially viable and effective models of care included an incentive payment to the pharmacist to provide a shared care approach and that the pharmacists were not necessarily concerned about client subsidies.

Table 4.4: Degree of consistency of options with pharmacy focused dimensions

Potential model	Acceptability / feasibility	Financial viability of program	Positive impact on outcomes to clients
CONSUMER CO-PAYMENT MODEL⁹³			
Without additional consumer subsidy ⁹⁴			
With additional consumer subsidy			
CONSUMER PAYMENT MODEL			
Without additional consumer subsidy			
With additional consumer subsidy			
PHARMACY SUBSIDY FOR DISPENSING FEE			
PBS funding model			
Special unit dose per day payment ⁹⁵			
PHARMACY SUBSIDY AS A PRACTICE ALLOWANCE			
Single payment – service provision based			
Multi-activity payment – service provision based			
Multi-activity payment – service and outcome (incentive) based			
PHARMACY SHARED CARE			
Multi-activity payment – service provision based			
Multi-activity payment – service and outcome (incentive) based			

Legend: Degree of consistency with pharmacy issues: High Medium Low

4.3 THE TRIAL

Data from the scoping studies, detailed in Chapter 3, and the evaluation of candidate funding models, summarised in the previous section, were used to develop three potential funding models for subsidising methadone and buprenorphine dosing. These three funding model options emerged as appropriate for the trial following the submission of the “Funding Options Discussion Paper” to the EAG in October 2005. As described below these three models allowed the investigation of the hypotheses; “*That the cost of treatment affects client treatment outcomes?*” in regards to client outcomes, and to answer the following question “*How do funding models affect the pharmacies?*”

4.3.1 Candidate funding models

The three models that were developed for trial were as follows:

- (1) **Model 1.** This was Fee-for-Service Model, Version 1 and included a dispensing fee per dose to the pharmacy, which was \$4.40, coupled with a \$2.50 consumer incentive. There was no change to the current pharmacy service model. Prior to the trial clients were paying in the range of \$5 to \$6.67 per dose, depending on the individual pharmacy, so the consumer incentive represented around 50% of the normal client co-payment. This model was trialled in two pharmacies in Victoria.

- (2) **Model 2.** This was Fee-for-Service Model, Version 2 and included a dispensing fee per dose to the pharmacy, which was \$1.90, coupled with a consumer incentive, whereby the client paid nothing for each dose (meaning the pharmacy received the client subsidy of \$4-\$5 per dose). There was no change to the current pharmacy service model. Model 2 was therefore designed to specifically assess the impact on key client outcomes of eliminating the client payment altogether. This model was trialled in two pharmacies in South Australia.
- (3) **Model 3.** This was an Enhanced Care Model and included a \$2.50 consumer incentive (which meant the client paid about half of the normal client co-payment), a dispensing fee per dose (as per Model 1) and a lump sum pharmacy incentive payment (\$50 per consenting client) who elected to receive enhanced care.

The enhanced care model was developed in consultation with the representative of the Australian Injecting and Illicit Drug Users' League and pharmacists with expertise in pharmacotherapy practice. The aim of the enhanced care component was to develop a tool and associated process that sought to deliver client and pharmacy focussed enhanced care.

The main tool for assessing the clients views of the enhanced care model also was the BTOM-C v1 interview form. Therefore, the same information was collected for all clients regardless of funding model they were involved in. However, to assess the impact of the enhanced care model additional questions were added to the Part B section of the BTOM-C v1 to be asked in post trial interviews for all clients committing to the enhanced care model.

Additionally, the "Client Issues Identification and Support Form" included as Appendix 4 was the main tool for assessing the pharmacist's interaction with each client involved in the enhanced care model. This form was completed and signed jointly by the client and pharmacist and retained by the pharmacy as a confidential record of issues/support required. For the trial, pharmacists completing the client issues form were paid \$50, which was an average allocation for the estimated time to complete the form and subsequent actioning of any identified issues. Pharmacist's normal duty of care to clients continued to operate during the period of the trial. This model was trialled in two pharmacies in New South Wales. Table 4.5 presents a summary of the payments made under each model.

Table 4.5: Incentive payments for the three models

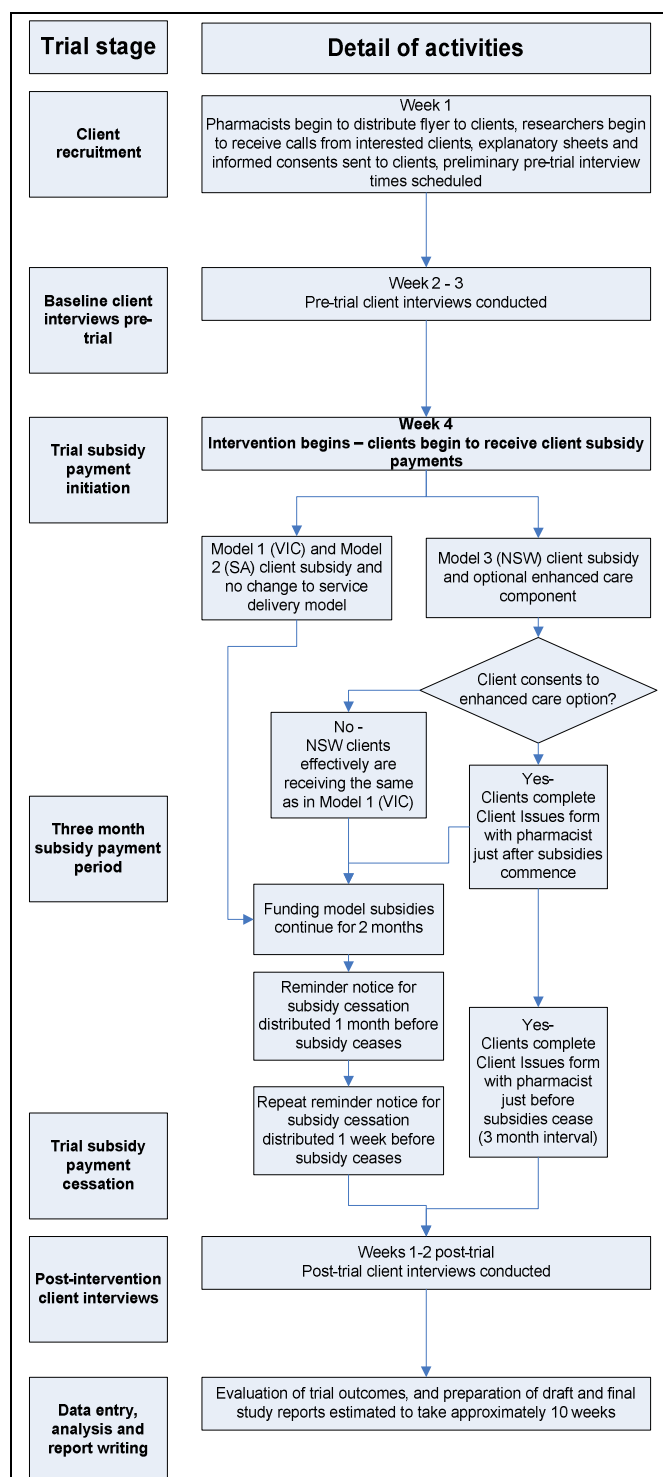
Payment Component	Model 1	Model 2	Model 3
Consumer co-payment (ongoing)*	\$2.50	\$0.00	\$2.50
Consumer incentive paid by trial*	\$2.50	\$5.00	\$2.50
Pharmacy incentive per dose paid by trial	\$4.40	\$1.90	\$4.40
Total payment to pharmacy per dose (excluding enhanced care payment)	\$9.40	\$6.90	\$9.40
Enhanced care payment/client for consenting clients			\$50.00

**Slight variation across pharmacies depending on individual arrangements*

The trial extended over approximately four months with the first month required for client recruitment, initial client interviews and distribution of trial materials. All three funding models operated for a three month period.

Figure 4.1 is a schematic representation of the trial processes and these are further discussed in the following sections.

Figure 4.1: Trial process flow and associated procedures



4.3.2 *Ethical Issues*

Prior to commencing the trial ethics approval was sought and granted from the Monash University Standing Committee on Ethics in Research Involving Humans. The issues considered included:

- methods for recruitment of participating clients and the need to ensure that there was no coercion of clients to participate;
- methods for explaining the trial process to participating clients;
- methods to maintain confidentiality, security and appropriate disposal of data;
- the need to ensure privacy for clients participating in the interviews;
- the method for selecting participating pharmacies;
- methods to maintain anonymity of participating clients; and
- how participating clients would be informed about the method for making a complaint.

4.3.3 *Pharmacy selection*

The pharmacies involved in the scoping studies were deemed to have too large a number of clients to be able to be accommodated within the trial itself. Therefore, six pharmacies were identified in conjunction with the EAG to include approximately 117 clients in total. These pharmacies were selected to be trial sites, with one metropolitan and one regional community pharmacy in each of the three states of New South Wales, Victoria and South Australia. Ultimately only 92 clients across the pharmacies chose to participate.

4.3.4 *Methods for client recruitment and consent*

In the interests of equity to participants, all regular clients that were currently being dosed at the trial pharmacies (at the initiation of the trial) were able to participate in the trial. The process of recruitment involved the following:

- (1) **Criteria for client participation.** As there was the potential for the pharmacy to be faced with an influx of “regular” clients to the pharmacy when clients in the area learned about the trial, the following procedures were followed to determine client eligibility to participate in the trial:
 - clients were nominated as regular clients of pharmacy by the participating pharmacy and provided with a numbered flyer from the pharmacy before the trial;
 - clients that met the criteria above, contacted researchers, and made themselves available for the baseline client interview prior to the trial commencing were included (baseline client interviews occurred two weeks prior to trial initiation);
 - clients were not able to be admitted to the trial if the pre trial interviews were unable to be completed, except if exceptional circumstances led to an inability to schedule interviews earlier; and
 - regular clients could only be nominated by the pharmacy prior to the initiation of the trial, after which no new regular clients could be admitted to the trial.
- (2) **Client recruitment.** To reduce the potential for perceptions of coercion if pharmacists approached clients for participation, the following occurred:

- Each pharmacy provided each regular client with the numbered leaflet (in Appendix 5) at the time of regular dosing, approximately three weeks prior to the commencement of the trial;
 - the flyer provided details to the regular client on how to contact the researcher if they were interested in participating in the trial and to seek any additional information about the trial;
 - on receipt of the phone call to register the regular client's interest in participating, the researcher :
 - confirmed the client was a regular client of the pharmacy, then discussed the trial and answered any questions;
 - discussed the involvement of the client in the research study including provisional scheduling of the first interview dates/time and location;
 - forwarded confirmation of the discussion together with the explanatory letter to each client that had registered an interest in participating (see Appendix 5 for a sample confirmation of appointment letter and for the explanatory letter for each state). The package also included the informed consent forms (see Appendix 5, for the consent form for each state); and
 - clients were advised that the informed consent form could be signed and provided to the researcher at the time of the first interview (or signed at the start of the first interview if the client had any last minute questions around consent prior to final consent being granted).
- (3) **Follow-up client recruitment.** One week after the initial client contact, researchers followed-up via telephone to:
- determine the client's continued willingness to participate in the trial;
 - answer any further questions they may have; and
 - finalise the date and location for the pre trial interview.
- (4) **Consent procedures.** The consent forms were provided to clients along with the explanatory letter to ensure clients had the opportunity to review the consent form and ask any questions related to consent when the follow-up recruitment call was made. A further opportunity to seek additional information was also accorded at the start of the initial client interview. Different consent forms were required for the New South Wales (enhanced care) trial.
- (5) **Client participation information.** The following information was included in the explanatory letter to clients:
- project title;
 - information on the sponsors for the trial (the Pharmacy Guild) and the contracted researchers;
 - information on the research investigators, including contact details;
 - project description;
 - commencement date and duration of the trial;
 - statement emphasising that post trial dosing fees and activities revert back to the pre trial arrangements;
 - major trial client related activities (commencement interview, post trial interview, enhanced care option if New South Wales participant);
 - benefits from trial participation;
 - client subsidies per dose of methadone/buprenorphine for all options trialled, with some variation by model;
 - other benefits.

- summary information about any additional pharmacy payments made during the trial (varied by funding option trialled);
- information about any additional actions required by clients or pharmacy staff related to the funding model option being trialled (such as reporting activities by pharmacy for the shared/enhanced care model option);
- other information which included:
 - criteria for consumer participation;
 - confidentiality provisions;
 - guarantees of voluntary participation and withdrawal;
 - feedback arrangements for trial results;
 - interpreting arrangements for persons with limited English;
 - complaints procedures;
 - procedures for registering interest in the project; and
 - consent procedures.

It should be noted the self-selection client recruitment process is a potential source of bias in the client related data. It may be worthwhile to consider clients higher financial problems may be more inclined to be involved in the trial, due to the financial incentives.

4.3.5 Pre trial client interviews and pharmacy data collection

Prior to commencing on the trial, each client participated in a structured interview with a researcher. Each interview took approximately one hour. The interview included the use of the BTOM-C instrument (Appendix 6), which incorporated a range of questions about the interviewee's drug taking habits, social health and well being, and treatment that they have undergone for their drug taking problems (including type of treatment). Additional questions were also included to understand the services provided by their community pharmacy and their satisfaction with the current payment arrangements (see Appendix 6).

Site visits were conducted at each of the participating pharmacies to inform the pharmacists and their staff about the implementation of the trial and this also included data collection from pharmacies relating to the cost of providing the pharmacotherapy service (identical data to that collected during the scoping studies was sought) (see Appendix 7).

4.3.6 Trial implementation

The trial was conducted over 12 weeks from March 20th 2006 until June 5th 2006. A total of 92 clients from six participating pharmacies commenced as identified in Table 4.6.

Table 4.6: Participating pharmacies and commencing clients

Town/city and state	Number of clients commencing trial
Metropolitan/Victoria	18
Regional/Victoria	12
Metropolitan/South Australia	13
Regional/South Australia	30
Metropolitan/New South Wales	14
Regional/New South Wales	5
Total	92

The three different models were implemented as described, and clients continued to receive their medications as normal in each of the sites, with the only difference being the payment.

In Victoria they paid \$2.50 less per dose, compared with \$5-\$6.67 under usual arrangements. South Australian clients paid nothing, compared to \$4-\$5 under usual arrangements. In New South Wales, clients paid \$2.50 less per dose compared with \$5-\$6 under usual arrangements. The enhanced care model (model 3) was implemented in New South Wales with 14 of the 19 clients participating.

4.3.7 Transition back to normal client payment arrangements

Reminder notices were provided to clients one month and again at one week before the trial period ended and subsidies ceased (Appendix 5). To transition clients back to normal payments a reduced subsidy was provided. Clients were encouraged to discuss with their pharmacists the transition back to normal arrangements well in advance of the ending of subsidies. There were no reported difficulties for clients.

4.3.8 Post trial data collection

During the final week of the trial all of the clients who had participated in the trial were contacted and invited to attend an interview with an HMA researcher. They were initially contacted by telephone or through messages left with the pharmacies. Specific appointments were made with them by telephone and then they were sent a follow up letter confirming the date, place and time of the interview (Appendix 5).

Eight of the commencing client group did not attend the post-trial interview (one client had moved, one was away on holiday, two had ceased treatment, one refused to attend the interview, and three failed to attend an interview-no reason given).

With the exception of regional Victoria, each location was visited twice (if necessary) in an attempt to interview all clients (ie clients unavailable on the first visit, were contacted again for an appointment on the second visit).

Table 4.7 illustrates the number of clients from each pharmacy who attended the post trial interview.

Table 4.7: Participating pharmacies and completing clients

Town/city and state	Total Clients	Number of clients completing
Metropolitan/Victoria	18	17
Regional/Victoria	12	9
Metropolitan/South Australia	13	11
Regional/South Australia	30	29
Metropolitan/New South Wales	14	13
Regional/New South Wales	5	5
Total	92	84

Data was again collected using the BTOM-C with additional questions relating to the clients' perceptions about the impact of the funding model trialled on their health and social functioning. The interviews were conducted in a private space, either on the pharmacy premises or in medical clinic rooms nearby. Each interview took approximately half an hour.

Data was also collected from the pharmacies about the impact of the trial on their work and on their relationships with the clients. They were also asked to provide a subjective assessment of any changes they had noted in the clients' health or social functioning. These data were collected both through a paper based survey and also through on site structured interviews with pharmacists and their staff.

Each participating pharmacist was posted enough questionnaires for themselves and each of their staff with the expectation that these could be answered anonymously. (See Appendix 6 for survey). Nine of these questionnaires were returned. Six were completed by the pharmacists and three were completed by pharmacy assistants.

Structured interviews were conducted by HMA researchers with ten pharmacists and five pharmacy staff. These interviews were conducted either at the pharmacy or in a medical clinic close by. Each interview took approximately half an hour. (See Appendix 6 for consultation questions).

⁸³ Consumer continues to make a reduced client contribution

⁸⁴ Additional subsidy for client support apart from dispensing, such as travel reimbursement

⁸⁵ Full client payment for reimbursement, no client contribution

⁸⁶ PBS dispensing fee for opioid pharmacotherapy scripts

⁸⁷ New initiative for unit dose per day payment through PBS or new funding model (precedent home medicine reviews)

⁸⁸ Single payment for pharmacy to commence provision of opioid pharmacotherapy

⁸⁹ Multi-dimensional payment based on service provision – such as start-up payment, 6 monthly payment for clients treated

⁹⁰ Multi-dimensional payment with additional outcome incentive measures – such as clients successfully exiting program

⁹¹ Additional payment for value added client focused supervision or care – such as reporting adherence to program to doctor

⁹² Additional payment for value added client focused supervision or care with outcome incentive measures – such as reduced other prescribed medication use

⁹³ Assumes client subsidy payments are able to be accessed directly by pharmacy and not direct payments to clients

⁹⁴ Assumes partial consumer subsidy payments

⁹⁵ Assumes payment per dose partially covering full activity based cost of dose and program delivery

5

Trial Data Analysis

Chapter 4 has described the methodology used for the trial and the tools used to measure outcomes for both the clients and the pharmacies. This chapter describes the data collected and presents the analyses. The analysis of outcomes encompassed considerable statistical analyses that were undertaken with the assistance of the Statistics Department of the University of Adelaide.

5.1 OVERVIEW OF DATA COLLECTION

Considerable qualitative and quantitative data was collected during the course of the trial. The aim was to assess the impact of the change in funding arrangements on the pharmacies and clients from the three months and whether there was any differences observed between the three funding models.

For clients, comparisons have been made based on comparing the data collected using the BTOM-C (Appendix 6) at the pre and post trial interviews with clients. Qualitative information was also sought about changes in client behaviour or outcomes which had occurred as a direct result of the trial.

From a pharmacy perspective, each pharmacist was asked to collect data about the time taken to dispense pharmacotherapies prior to and at the conclusion of the trials (see Appendix 7). Qualitative views about the impact of the trial were also sought (see Appendix 8).

5.2 CLIENT DATA

This section provides basic demographic data about the clients participating in the trial and those who left the trial without completing it.

5.2.1 *Client demographic data*

Ninety two clients commenced the trial and eighty four completed the trial (completion was defined as participating in the post trial interview). Their locations are shown in Table 5.1.

Table 5.1: Location and number of trial participants

Town/city and state	Number of clients commencing	Number of clients completing
Metropolitan/Victoria	18	17
Regional/Victoria	12	9
Metropolitan/South Australia	13	11
Regional/South Australia	30	29
Metropolitan/New South Wales	14	13
Regional/New South Wales	5	5
Total	92	84

The data collected at both the pre trial and post trial phases included basic demographic data about the clients' age, gender and living arrangements. These data

were analysed by region to determine whether there were any patterns in the demographic profiles of those clients who failed to complete the trial.

Of the eighty four clients who completed the trial, two were aged less than 25, fifteen were aged 26-30, thirty nine five aged 31-40 years and thirty two were aged more than 40. The mean age was 37 years.

Other demographic data included:

- 64% (54) were female and 36% (30) were male;
- 21.7% (18) lived alone, 30.1% (25) lived with parents, relatives or friends, 8.4% (7) lived with a partner, 19.3% (16) lived alone with child(ren), 13.3% (11) lived with a partner and child(ren), and the remaining 7.2% (6) lived with either friend(s)/relative(s)/parent(s) and child(ren), or other people;
- 73.9% (62) of the clients' main source of income was from a pension or temporary benefit, 10.7% (9) from fulltime employment, 9.5% (8) from part time employment and 5.9% (5) student allowance or dependent on others; and
- 65.5% (55) of the clients lived in a rented house or flat, 28.6% (24) lived in a privately owned house or flat, and the remaining 5.9% (5) lived in sheltered accommodation or a boarding house.

Table 5.2 below provides the demographic profile for the trial participants and the eight clients who did not complete the post trial interview.

Table 5.2: Age, gender, living arrangements and employment status of clients

Characteristic	Classification	Participants completing trial		Clients not completing trial
		#	%	#
Gender	Male	56	66.7%	3
	Female	28	33.3%	5
Age (Banded)	<26	5	6.0%	3
	26 - 30	13	15.5%	
	31 - 40	33	39.3%	4
	>40	33	39.3%	1
Main source of income	Pension or temporary benefit	62	73.9%	7
	Other	22	26.1%	1
Living arrangements	Rented house or flat	55	65.5%	6
	Privately owned house or flat	24	28.6%	1
	Sheltered accommodation or boarding house	5	5.9%	1

These data suggest that there is no specific group of clients who did not participate in the final data collection as the number of clients who failed to complete was small and largely mirrored the overall client demographic profiles.

The reasons given for clients leaving the trial early or not participating in the final interview were:

- one client had moved;
- one was away on holiday;
- two had ceased treatment;
- one refused to attend for the interview; and
- three failed to attend for interview (no reason given).

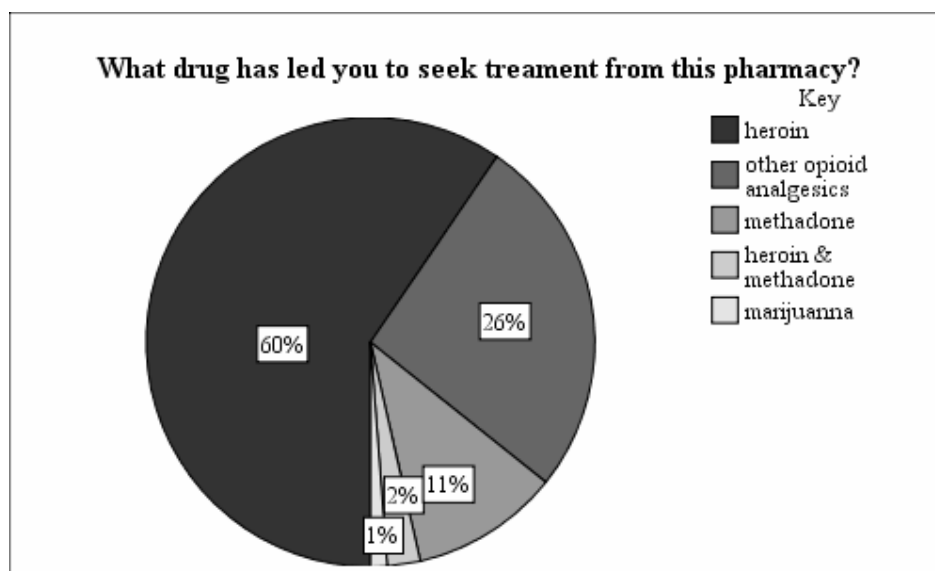
5.2.2 Client drug and alcohol use before and after the trial

Clients were asked about their use of both licit and illicit drugs pre and post trial to identify whether the trial had any impact on their drug and alcohol use. The data collected for the 84 clients who completed the trial have been analysed based on the BTOM–C Score Summary Sheet Guidelines (see Appendix 6).

Pre trial client's responses are depicted in Figure 5.1 and were as follows:

- 59.5% (50) had been using heroin prior to treatment;
- 26% (22) had been using other opioid analgesics such as morphine and pethidine;
- 11% (9) had been using street or diverted methadone; and
- 3% (3) had been using a combination of heroin and methadone or marijuana.

Figure 5.1: Drug use lead to seeking treatment



It was found that the majority of users (80.7%) had injected their drug of choice. Additionally, besides the drug of addiction that prompted the client to seek treatment, a range of other drugs had caused them concern, as listed below:

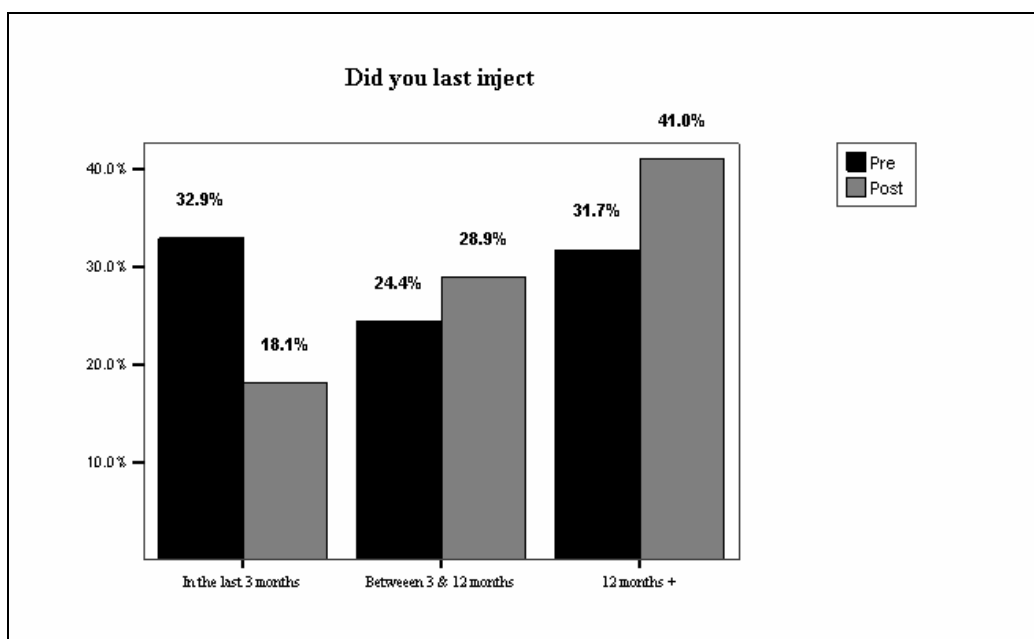
- amphetamines;
- cannabis;
- alcohol;
- other opioid analgesics;
- benzodiazepines;
- stimulants and hallucinogens; and
- barbiturates.

Clients were also asked both pre and post trial when they had last injected any drug and 12% indicated they had never injected. Of the remaining 88%, 32.9% had injected in the three months prior to commencement of the trial and 18.1% had injected during the three months of the trial.

Figure 5.2 depicts when trial participants had last injected. It is apparent that the trial may have impacted on the extent of injection in the last three months, as there were overall changes in the clients' injecting drug use behaviour. Pre trial 33.9% of participants had injected in the last three months, whereas post trial only 18.1% had

injected in the last three months (the period of the trial). A paired samples T test showed an overall statistically significant difference between pre and post trial responses to this question ($P = 0.000$). However, the Kruskal-Wallis test was used to assess whether the three groups differed from one another. This test found the three groups of clients did not differ from one another for pre and post trial responses. Hence, irrespective of the funding model clients' trialled, a decrease in injecting drug use behaviour was reported after three months.

Figure 5.2: Injecting behaviour



Consideration of other data collected found:

- across all clients there was no significant change in the use of shared needles and equipment;
- at both the pre and post trial interviews only one participant admitted to having overdosed in the past three months;
- analysis of participant responses about use of other drugs pre and post trial, (specifically about the use of heroin, other opioid based drugs, cannabis, cocaine, amphetamines and tranquilisers) found that there was significant ongoing use of amphetamines, tranquilisers and cannabis but no statistically significant change in drug use during the term of the trial. However, there was a slight decrease in the use of other opiates between pre and post trial interviews (P -value = 0.040 in a paired samples T test).

The types of treatment clients had undergone, the settings in which treatment had been delivered, the prescriber of the treatment and the dispenser of the medication were also investigated. Of the 84 clients who responded:

- 73.8% were currently being treated with methadone and 26.2% with buprenorphine;
- 100% of clients received their doses through the community pharmacy;
- the three main previous treatment types were counselling (16.5%), methadone (13.8%) and withdrawal management (10.3%);

- counselling (18%), other pharmacotherapies (9.8%) and outpatient consultations (9.3%) were the main three concurrent treatments;
- 25.8% of clients reported that methadone/buprenorphine was the only current treatment they were receiving;
- the main three sources of referral to the methadone/buprenorphine program were by a general practitioner (40.8%), closely followed by self referral (38.2%), then referral by a family member/friend (7.9%); and
- 100% of participants were provided with prescriptions through a doctor.

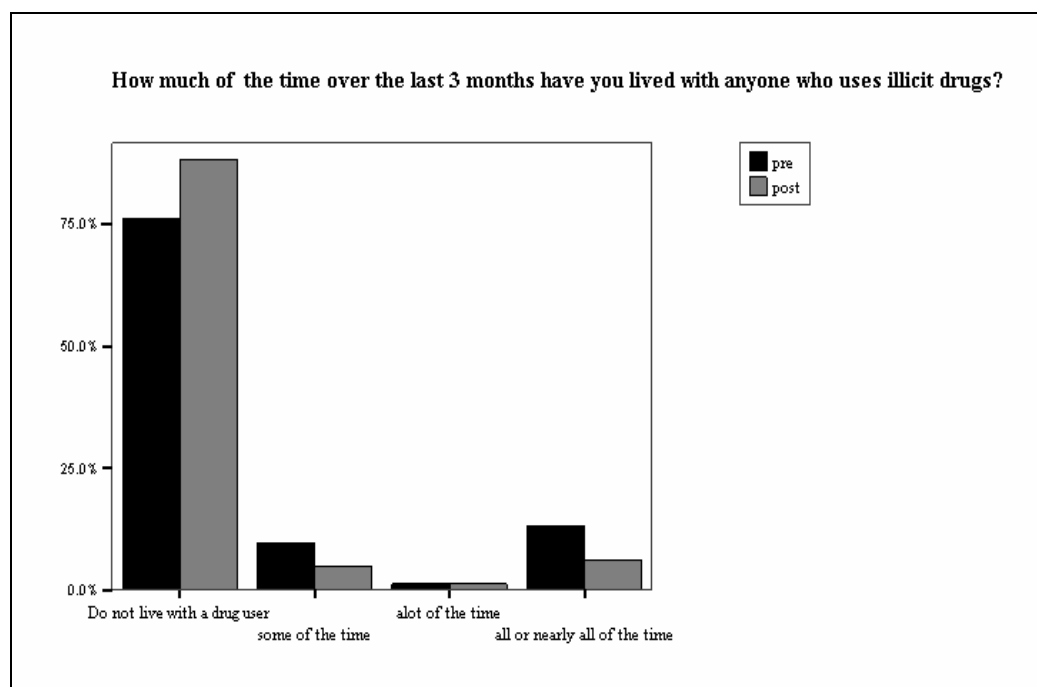
The majority of participants (63.1% to 60.2% in pre and post trial measurements respectively) said that they would definitely recommend the community pharmacy program to a friend who needed it.

5.2.3 Client health and well being pre and post trial data

Both pre and post trial participants were asked a range of questions regarding their general health and well being. Analysis demonstrated that some changes had occurred in the clients' perceptions of their own health and well being and suggested that these could be attributed to the availability of more money to spend (due to the trial subsidies).

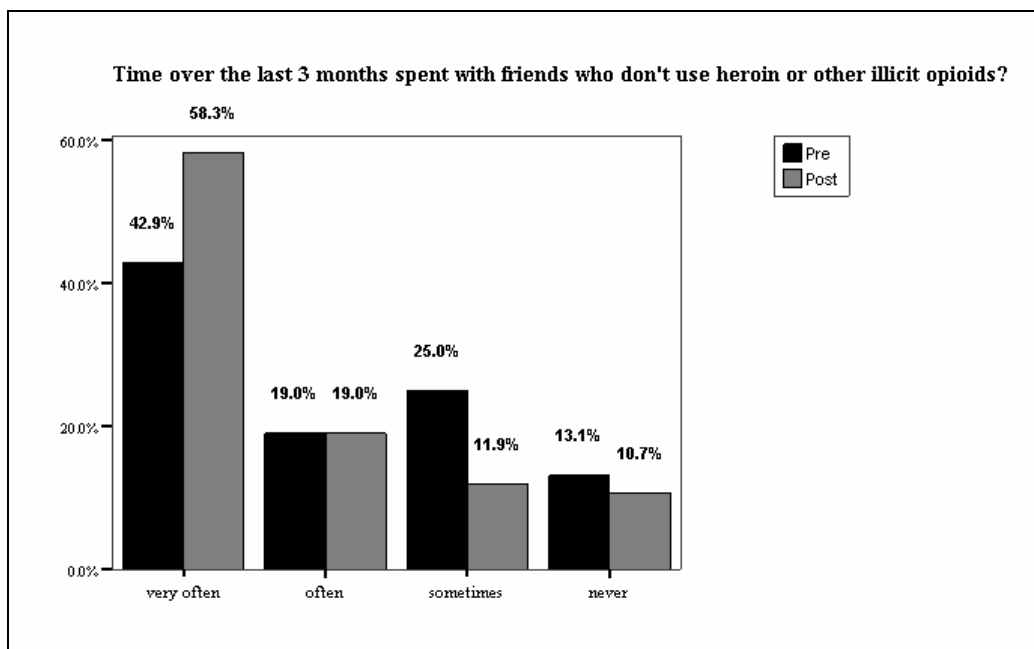
Using a paired samples T test, a statistically significant decrease in amount of time participants spent living with another drug user was found between pre and post trial interviews. This changed from 76.2% of pre trial to 88.1% of post trial respondents not living with a drug user, as illustrated in Figure 5.3. The statistical significance of this outcome had a P-value = 0.024. Following this finding, a Kruskal-Wallis test was used to assess whether the three groups of clients differed from one another for pre and post trial responses. This test found that responses from the pre trial interviews differed to some degree, but this difference was not statistically significant (P = 0.060).

Figure 5.3: Frequency of time respondent spent with illicit drug users



Using a paired samples T test, a statistically significant increase in amount of time participants spent with friends who don't use heroin and other illicit opioids was found between pre and post trial interviews. The decrease in the number of participants who did not spend time with drug users was from 42.9% of pre trial to 58.3% of post trial respondents not spending time drug users, as illustrated in Figure 5.4. The statistical significance of this outcome had a P-value = 0.027. Following this finding, a Kruskal-Wallis test was used to assess whether the three groups of clients differed from one another for pre and post trial responses. This test found that responses from both interviews for all groups did not differ.

Figure 5.4: Frequency of time spent with non-drug using friends over the last three months

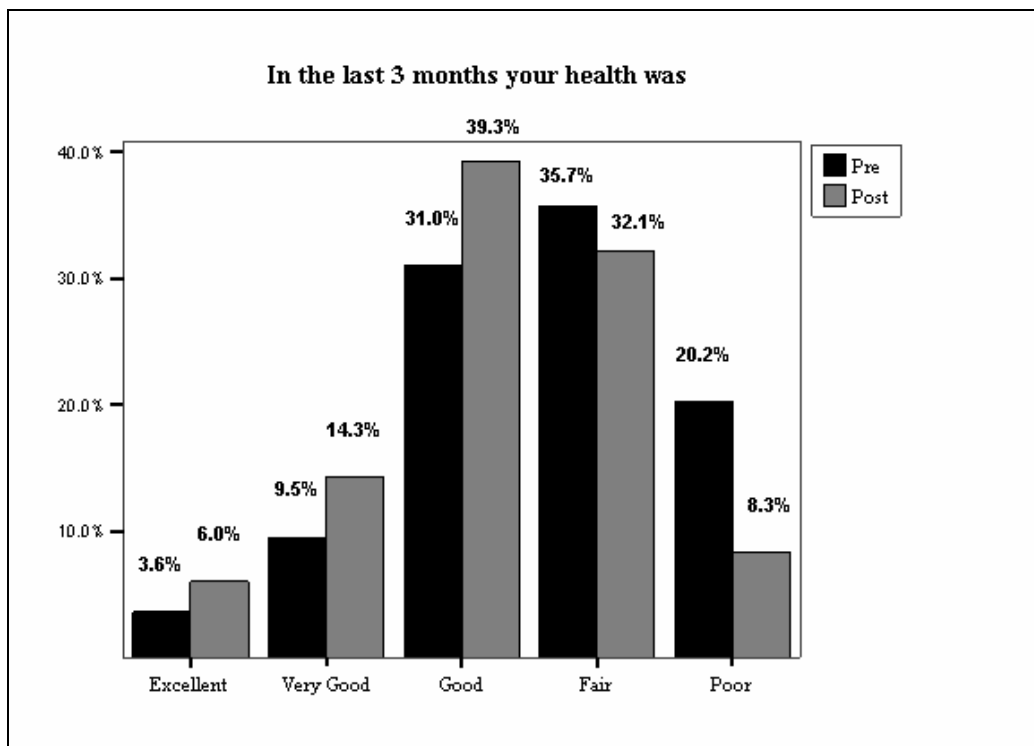


The BTOM-C Score Summary Sheet was also used to calculate any changes in client drug usage during the trial and tested illicit drugs as well as alcohol and tobacco. The paired samples T-test (95% confidence interval) identified a high statistically significant decrease between pre and post interviews in polydrug use of illicit drugs (P-value = 0.006). Therefore, mean illicit drug use decreased over the 6 month period for all respondents. Further analysis using a Kruskal-Wallis test was used to assess whether the three groups of clients differed from one another in their pre and post trial responses. This test found that responses from the pre trial interviews did not differ, but they did for participants' responses in post trial interviews (P= 0.030).

For alcohol and tobacco use there was no statistically significant changes in usage demonstrated, although raw data shows the mean total alcohol consumed to have reduced from 64 to 33 standard drinks per month.

Clients were also asked how they viewed their health status over the last three months at both interviews. Using a Paired Sample T-test (P-value = 0.001), a high statistically significant improvement for all clients was perceived in the health status between interviews as depicted in Figure 5.5. Further analysis using a Kruskal-Wallis test was used to assess whether the three groups of clients differed from one another in their pre and post trial responses. This test found that responses from the both interviews did not differ between the three groups.

Figure 5.5: Self reported health score for pre and post trial



Analysis of other aspects of the pre and post trial client data collection revealed that:

- respondents reported less conflict with their partner or spouse during the trial than previously. A paired samples T test confirmed the drop in conflict with their partner or spouse, but this was not a statistically significant change. A Kruskal-Wallis test found there was no difference between the three groups of clients with respect to their response to this question.
- respondents reported that they had less conflict with their relatives during the period of the trial. Again, a paired samples T test confirmed the drop in conflict with their partner or spouse was not a statistically significant change. A Kruskal-Wallis test was also used to find there was no difference between the three groups of clients with respect to their response to this question.
- change in the level of conflict with the client's employer over the past three months was not appropriate to consider as only 17/84 respondents were employed;
- participants were asked whether they had been arrested in the past three months at both the pre and post trial interviews, and there was a change as nine respondents had been arrested three months before the trial and only five clients had been arrested during the trial period; and
- none of the participants had involvement with child protection services during the period of the trial.

Social functioning questions (25 -30 in the BTOM-C, see Appendix 6) are designed to measure over the past three months: the client's levels of financial hardship; conflict in relationships with spouses/partners, other relatives and employers/school staff and students; time spent living with a drug user and time spent with non-drug users. Data from these questions were scored using the BTOM-C Score Summary Sheet Guidelines. The social functioning score is out of 18, where a low score may indicate a high level of social functioning.⁹⁶ These data were analysed using a Paired Samples

T-test, which resulted in identifying significant differences between pre and post trial interviews. The P-value of 0.000 indicates high statistical significance, where a difference between responses provided in the pre and post trial interviews was found. The mean social functioning score decreased between interviews as the mean indicates along with the other test results presented in Table 5.3.

Table 5.3: Paired Samples T-test Analyses of the social functioning scores

Paired Samples Test								
Pair: Social Functioning Scale post trial & Social Functioning Scale pre trial	Paired Differences					t	df	Signif (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
	-1.3917	3.2704	.3568	-2.1014	-.6819	-3.900	83	.000

Further analysis using a Hypothesis Test for the difference between the pre and post trial scores of the social functioning scores found that there was a significant decrease after the trial in both South Australia and Victoria. Therefore, social functioning improved most significantly in South Australia, but also improved in Victoria, yet did not statistically show improvement in New South Wales. Table 5.4 shows the differences between pre and post trial responses for each state. This indicates a comparison of three funding models, namely where in South Australia a full subsidy resulted in the most improvement in the social functioning of respondents. Also, the half subsidy group in Victoria also showed some improvements in social functioning, yet this was a less statistically significant difference.

Table 5.4: Social functioning pre and post trial differences

State	Mean of Differences	Standard Deviation of Diffs	Wilcoxon Statistic	Wilcoxon P- value
South Australia	-2.1625	3.932096	124	0.003095
New South Wales	-0.22222	2.237003	39	0.673953
Victoria	-1.01538	2.429764	48	0.034761

5.2.4 Client satisfaction with the pharmacy services

Questions were asked both pre and post trial about client satisfaction with:

- the services they received from the pharmacy;
- the opening hours;
- their relationships with the pharmacy staff;
- the dosing environment;
- timeliness of dosing;
- communication by the pharmacy with their doctor; and
- the appropriateness of the services they receive.

The quantitative data analysed for these questions demonstrated little differences pre and post trial. Responses were, however, of interest:

- (1) Clients who attended two of the regional pharmacies were either very dissatisfied or dissatisfied with the dosing environments that are in open areas (37.9% and 44.4% at each pharmacy). Around 31% of all clients were either very dissatisfied or dissatisfied with the pharmacy opening hours, but the majority were satisfied (59.5%).
- (2) Most respondents expressed satisfaction with the approachability, attentiveness and understanding of the pharmacy staff with a total of 77.2% saying they were either satisfied or very satisfied pre trial. It was noted 29.6% of clients in one SA pharmacy were either very dissatisfied or dissatisfied with this aspect of the service pre trial but the number of clients expressing dissatisfaction dropped to 7.7% post trial.
- (3) Regarding timeliness of dosing pre trial, the overall satisfaction level was 63.1% before the trial and 68.7% after the trial. However, there were high levels of dissatisfaction at two regional pharmacies during pre-trial interviews. That is, 41.3% and 33.3% either very dissatisfied or dissatisfied pre trial but the level of satisfaction improved at those pharmacies so that, post trial, only 28.5% of clients were dissatisfied or very dissatisfied and 0% at the other pharmacy respectively.
- (4) A majority of clients (>70%) was satisfied with the communication between the pharmacy and their doctor at both pre and post trial stages. This is in contrast to the findings from the scoping studies-see Chapter 3-where clients had indicated that they were generally dissatisfied with the ability of their GP to “case manage” their care.
- (5) Very few of the trial participants had a case manager other than their GP, but those that did were generally satisfied with the communication between the pharmacy and their case manager.
- (6) Most clients also expressed satisfaction with the pharmacist’s referral to other services with little difference being shown in the pre and post trial data. Interestingly in New South Wales, where the enhanced care model was trialled, with the aim of increasing referrals to other services, there was a slight drop in satisfaction between pre and post trial interviews.
- (7) The overall view of clients was that treatment arrangements were much better during the trial than before it started with 91.4% of respondents answering positively to this question.

5.2.5 Client satisfaction with cost of dosing

Pre trial only 23.8% of clients said they were either satisfied or very satisfied with the cost of dosing but post trial 85.1% were either satisfied or very satisfied. Pre trial, 26.1% of respondents were very dissatisfied compared to post trial in which only a minority were very dissatisfied (5.4%). In South Australia, where doses normally cost the least, 22.5% were either satisfied or very satisfied pre trial but this rose to 76.7% post trial, following a full subsidy being provided. The greatest change in satisfaction with cost was in New South Wales where only 16.7% were satisfied or very satisfied pre trial but 83.3% of respondents were either satisfied or very satisfied post trial. None of the respondents interviewed post trial said that they were very dissatisfied with the cost during the trial. These changes in satisfaction with treatment cost are illustrated in Table 5.5.

Table 5.5: Levels of satisfaction with treatment cost over pre and post trial responses by state

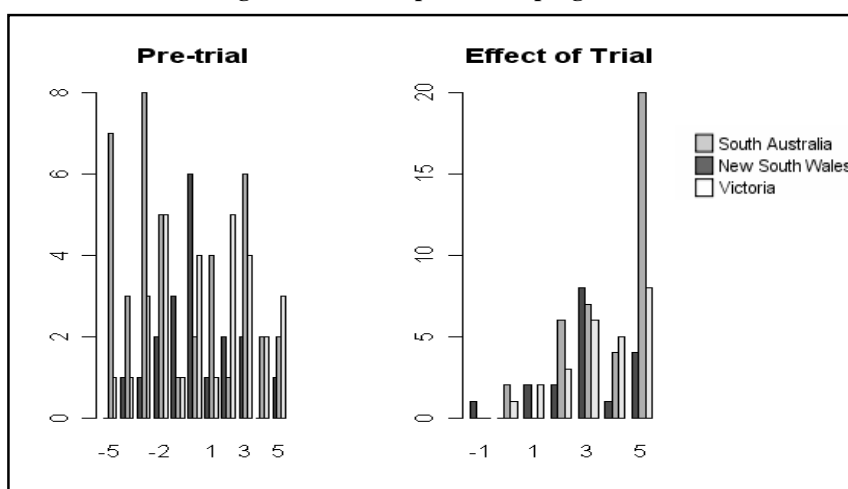
State	Pre trial		Post trial	
	Dissatisfied/ Very dissatisfied	Satisfied/ Very satisfied	Dissatisfied/ Very dissatisfied	Satisfied/ Very satisfied
South Australia	70.0%	22.5%	6.7%	76.7%
New South Wales	66.7%	16.7%	5.6%	83.3%
Victoria	50.0%	30.8%	3.8%	96.2%
Total	63.1%	23.8%	5.4%	85.1%

Additional comments about cost of doses included that:

- “it is cheaper to obtain other medications through the PBS”;
- “pricing is not standard across all pharmacies”;
- “costs should depend on income level”; and
- “cost is too high for low income earners”.

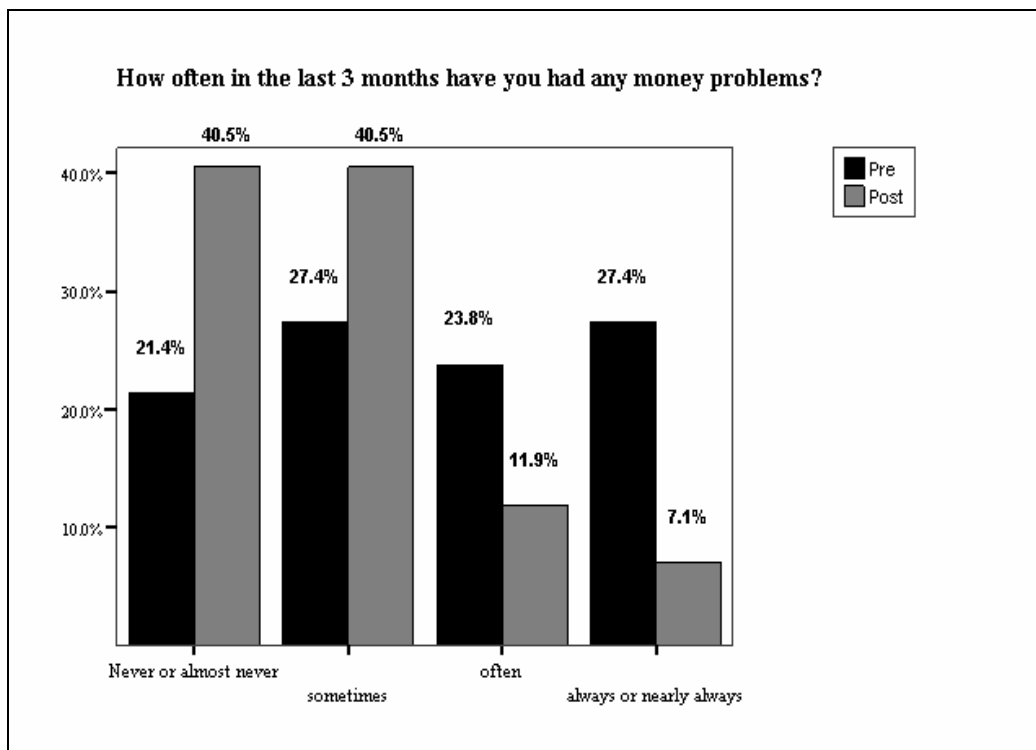
In addition, prior to the trial, participants were neutral regarding the impact of the program on their finances, whereas after the trial the responses in all states were very positive. As Figure 5.6 shows, a skewed normal distribution in pre trial responses changed to a linear curve in post trial responses.

Figure 5.6: The impact of the program on clients' finances



The BTOM-C also asked about financial issues over the last three months. In particular, one of the social functioning questions, asked about the client's money problems over the last three months. Using a paired samples T test, a high statistically significant decrease in money problems was reported by participants between pre and post trial interviews ($P=0.000$). There change in the number of participants reporting they did not have money problems over the last three months nearly doubled, as it increased from 21.4% in the pre trial interview to 40.5% in the post trial responses. The distribution of all responses to this question is illustrated in Figure 5.7.

Figure 5.7: Frequency of money problems in the last three months



Further analysis of the frequency of consumer money problems was carried out using a Hypothesis Test to test the difference between the pre and post trial responses for each funding model. The difference was highly significant in South Australia and Victoria as indicated in Table 5.6. Therefore, although there was a decrease in the frequency of money problems for all participants, the change in responses were highly statistically significant for both South Australia ($P=0.00001$) and Victoria ($P=0.007$). Hence, consumers in the state trialling the full subsidy funding model reported the most improvement with money problems.

Table 5.6: Pre and post trial differences between how often in the last 3 months the client had money problems

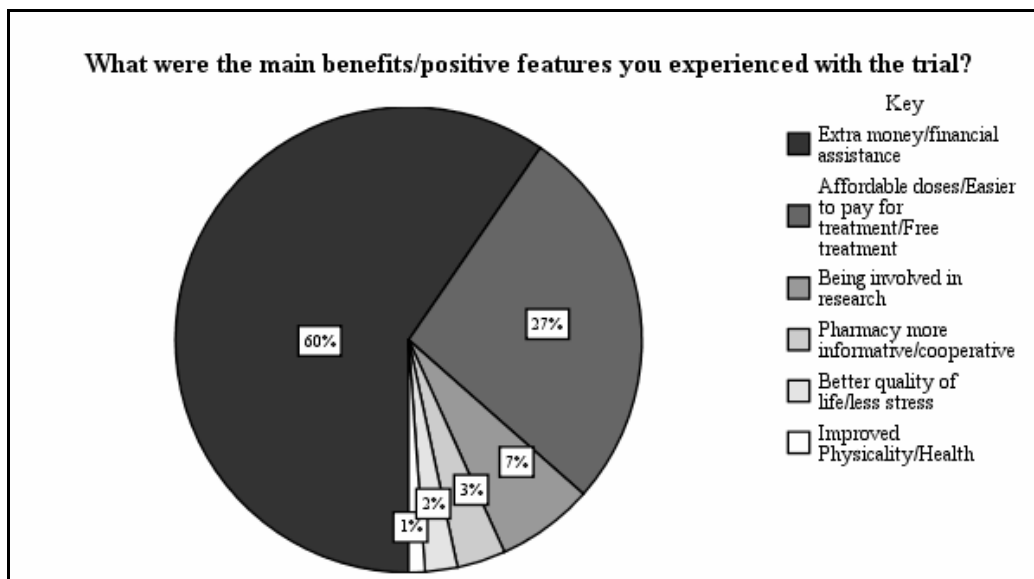
State	More often	Less often	No Change	P-value
South Australia	1 (2.5%)	21 (52.5%)	18 (45%)	0.00001
New South Wales	3 (16.7%)	7 (38.9%)	8 (44.4%)	0.35
Victoria	2 (7.7%)	13 (50%)	11 (42.3%)	0.007

5.2.6 Impact of the trial for clients

As well as using the BTOM-C to assess whether social functioning, health status and drug use had changed during the three months of the trial, additional questions were added and were used to assess client satisfaction with the trial and any impacts of the trial on the participants (see Appendix 6 for Part B of the questionnaire). The questionnaire also sought to assess the enhanced care component for relevant New South Wales clients. Clients overwhelmingly identified the main benefit of the trial

as “having more money” and “more affordable doses” as is demonstrated by Figure 5.8 below.

Figure 5.8: Client identified positive features of the trial



When asked specifically about the impact of the trial on their finances, frequent client statements included that they had been able to “save money”, “spend more money on food”, “pay off their debt at the pharmacy”, and buy clothes. Ninety five per cent of clients indicated that the trial had a positive impact on their finances.

Clients were asked whether the trial had impacted on their ability to stay on the pharmacotherapy program. These responses were recorded on a Likert scale graded from -5 to +5. For the majority (56%), the trial had no impact on their ability to stay on their medication and that this was most noticeable in New South Wales where 72.2% of respondents stated that it had no impact. Comments included that “they needed the medication anyway” and that the “doses were affordable”.

When asked whether the trial had an impact on whether they missed doses of buprenorphine or methadone, 70% said it had not, with 100% of New South Wales respondents stating this. However, in South Australia, the response was lower with 53.8% indicating that the trial had a positive impact. Comments included that they either “never miss doses,” or miss doses due to financial or work constraints.

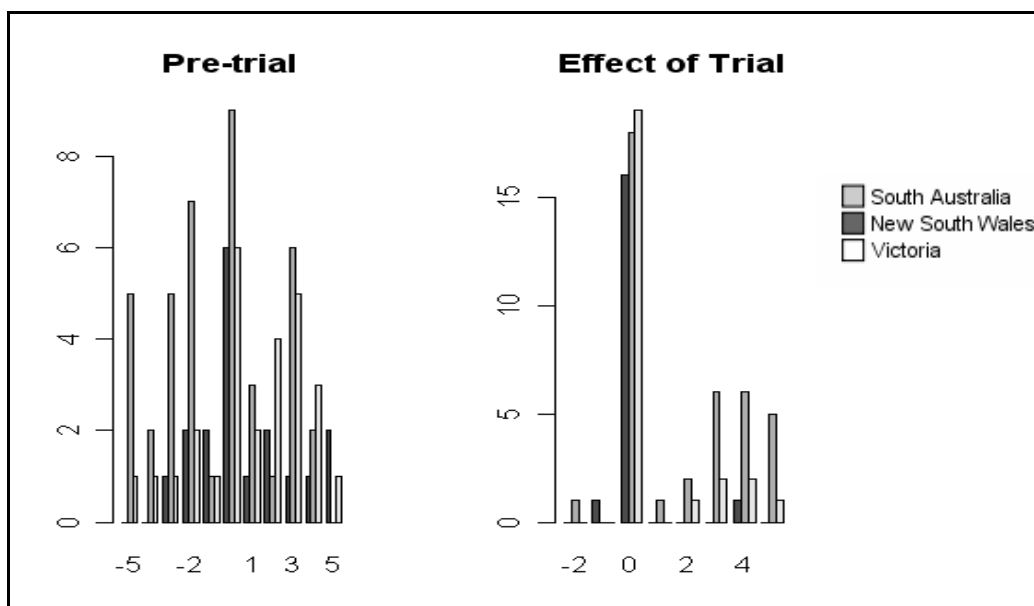
Overall, client feedback seemed to demonstrate that the trial had no impact on their overall quality of life, but it had a positive impact on their social life, due to the availability of more money.

During interviews clients were also asked about the impact the program and the trial had to their quality of life. Prior to the trial, participants seemed quite positive regarding the impact of the program on their quality of life. After the trial, the response of Victorian and New South Wales participants was less positive, but the response of South Australian participants was more positive in this regard.

Both before and after the trial, New South Wales and Victorian participants seemed neutral regarding the impact of the program on their social life. For South Australian participants, although pre-trial responses were also neutral (the zero value in Figure 5.9), their post-trial responses were somewhat more positive. Figure 5.9 shows the

distribution of the pre and post trial responses, where pre trial responses show an approximate normal distribution, and the post trial responses, show a linear distribution.

Figure 5.9: The impact of the program on clients' social life



Overall, the pre and post trial responses suggest that whilst the perceived impact of the program on New South Wales and Victorian participants was fairly neutral in most aspects of the program, the perceived impact of the program on South Australian participants was noticeably positive.

5.3 PHARMACY DATA

In evaluating the trial outcomes, staff from each of the six pharmacies were involved in interviews with research staff. They were asked questions about their perceptions of the trial's impact on both the pharmacy in which they work, and the clients whom they serve. They were also invited to complete a survey.

5.3.1 Impact of the trial for clients

In addition, to the client interviews, the responses gained from the pharmacy staff interviews and survey further supplement the evaluation of the funding models trialled.

Information gathered from all six pharmacies demonstrated agreement that the trial had a high positive impact on the clients. Along the Likert scale graded from -5 to +5, the mean response, was +3. Using a One Sample test, this was found to be a statistically significant result (P-value = 0.000) and Figure 5.10 illustrates the distribution of scores. Further analysis using a Kruskal-Wallis test found that regardless of funding model, staff agreed the trial had a positive impact on clients. In support of this, the pharmacy staff indicated how the trial had impacted on clients with 50% indicating that clients benefited from financial support and improved debt management, as illustrated in Figure 5.10. This supports benefits reported by clients as discussed in Section 5.2.6.

Figure 5.10: Staff reported impact of the trial on clients

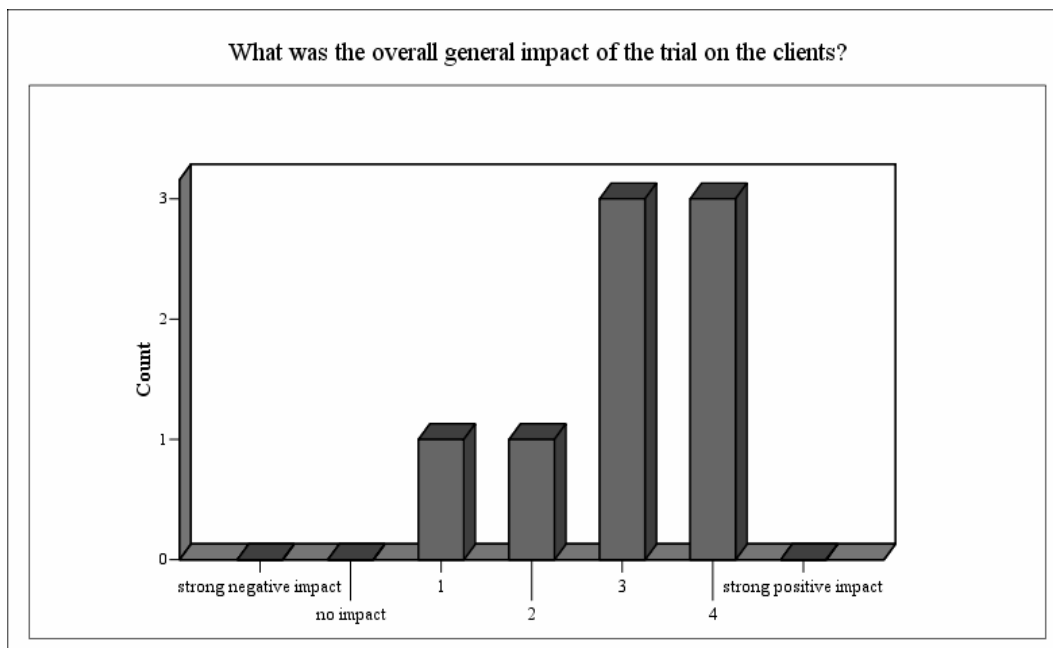
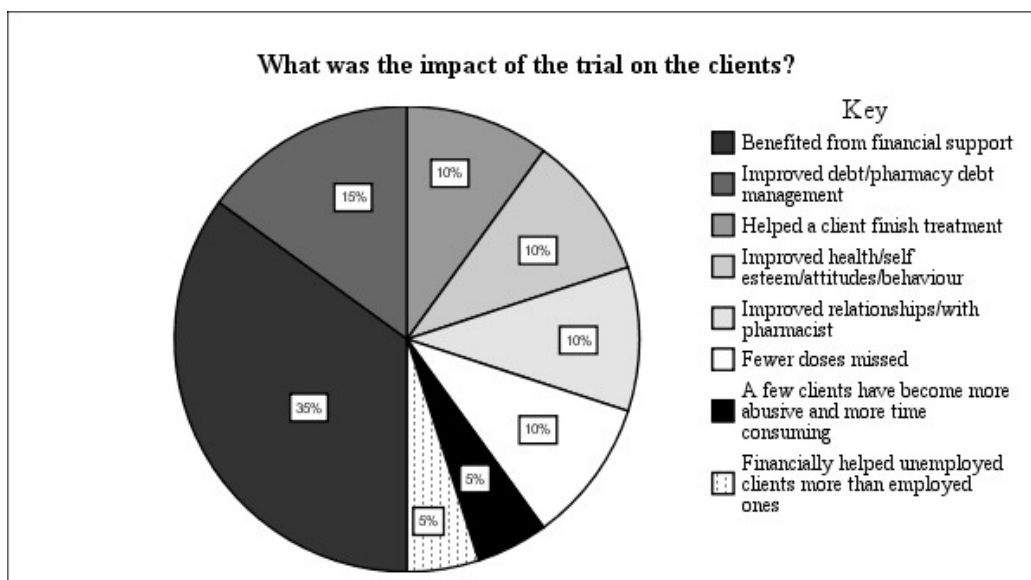


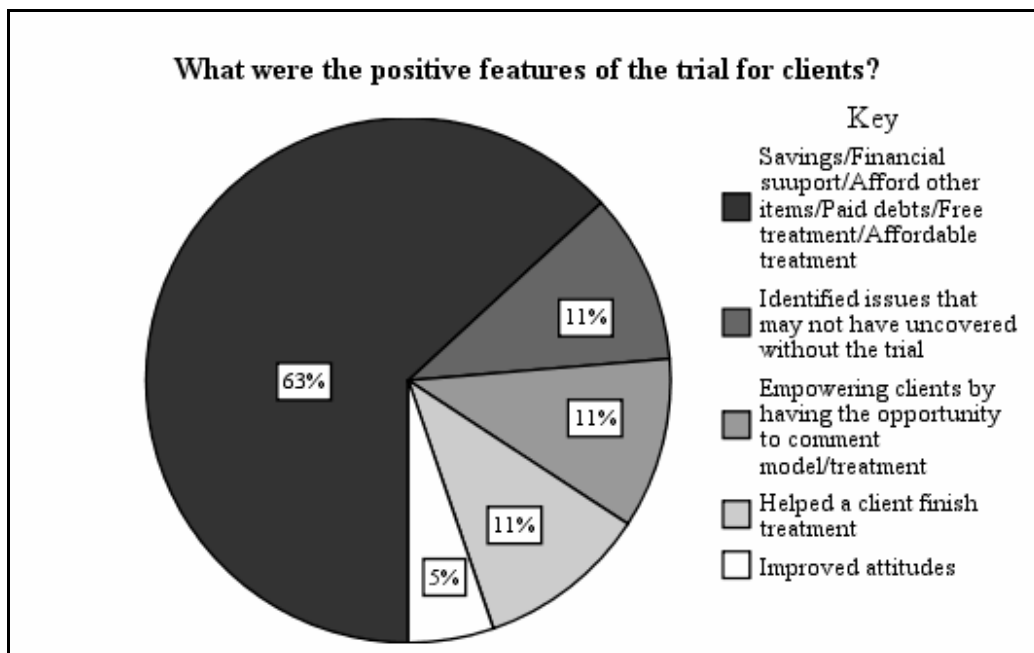
Figure 5.11 illustrates the impacts on the clients as reported by pharmacy staff.

Figure 5.11: Staff comments on the trial impact on clients



Sixty three percent of staff reported that the benefits to clients were financial assistance and ability to afford treatment. Eleven percent indicated the trial gave pharmacies an opportunity to discuss social issues with clients, and in the case of the metropolitan South Australian pharmacy, the trial had helped a client finish treatment. These trial benefits for clients are illustrated in Figure 5.12.

Figure 5.12: Staff comments on the trial benefits for clients

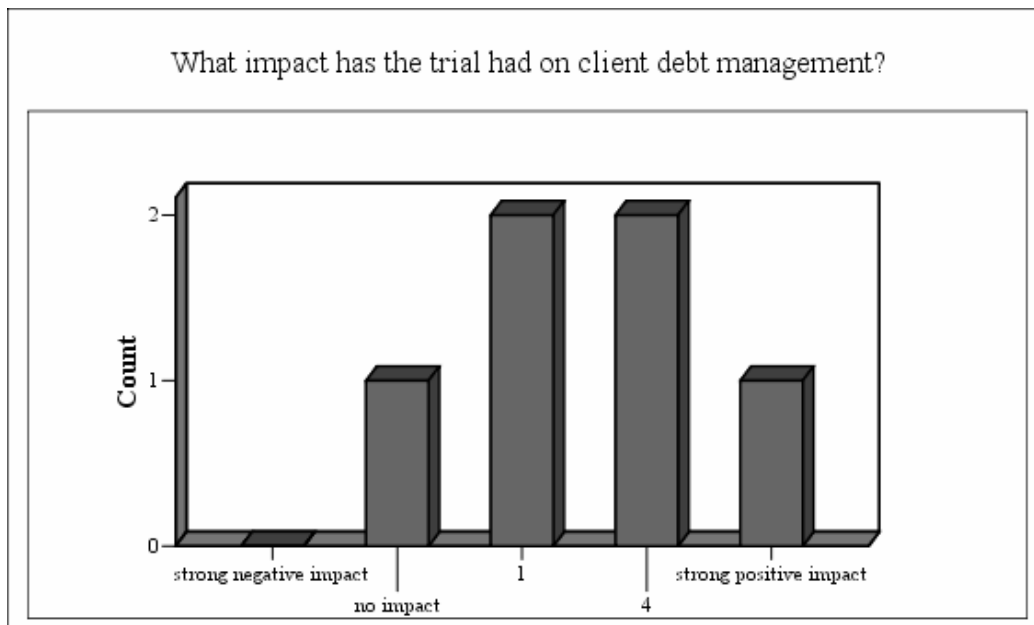


The only negative responses, associated with the trial for clients indicated that the enhanced care option was not perceived as beneficial to clients in the New South Wales pharmacies.

Another significant comment was that the metropolitan South Australian pharmacy also reported more missed doses by clients. However, a One Samples Test indicated that the trial did not impact on the overall proportion of clients missing doses.

In evaluating the impact of the funding model on clients, pharmacies reported that the trial had impacted positively on the clients' debt management. On the Likert scale graded from -5 to +5, the mean response, was +2.5. Using a One Sample test, this was found to be a statistically significant result (P-value = 0.032). Additionally, further analysis using a Kruskal-Wallis test found no differences between the pharmacies trialling different funding models. Therefore, regardless of funding model, the trial positively impacted on the clients' debt management within the pharmacies. This supports both client identified benefits in Section 5.2.6, and the benefits identified by pharmacy staff above. Figure 5.13 illustrates the frequency of responses to this question results.

Figure 5.13: Staff reported impact on client debt management



The trial was also judged to have made a positive impact on the clients' ability to stay in treatment. On the Likert scale from -5 to 5, the mean response was +1, indicating a small positive impact, but a statistically significant one as found in the One Sample test, giving a P-value = 0.018. Additionally, further analysis using a Kruskal-Wallis test found no differences between the participants trialling different funding models. Thus the results show a link between treatment cost and commitment to treatment. This contradicted comments made by some pharmacists who indicated dose cost does not affect a client's commitment to treatment.

5.3.2 Impact of the trial for pharmacies

In evaluating the impact of the trial on pharmacies, staff indicated that the trial had impacted on the pharmacy. On the Likert scale graded from -5 to +5, the mean response, was +1.75. Figure 5.14 illustrates the distribution of scores reported. Using a One Sample test, this was found to be a highly statistically significant result (P-value = 0.004). Further analysis using a Kruskal-Wallis test found no differences between the participants trialling different funding models. Therefore, regardless of funding model, the trial positively impacted on each pharmacy.

Other positive impacts reported by pharmacy staff were that relationships had improved between staff and clients (33%), and 22% indicating that staff "didn't have to deal with payment issues with clients" which aided relationships and enabled focusing on clinical care and improved time management of staff and service.

Figure 5.14: Staff reported trial impact on the pharmacy

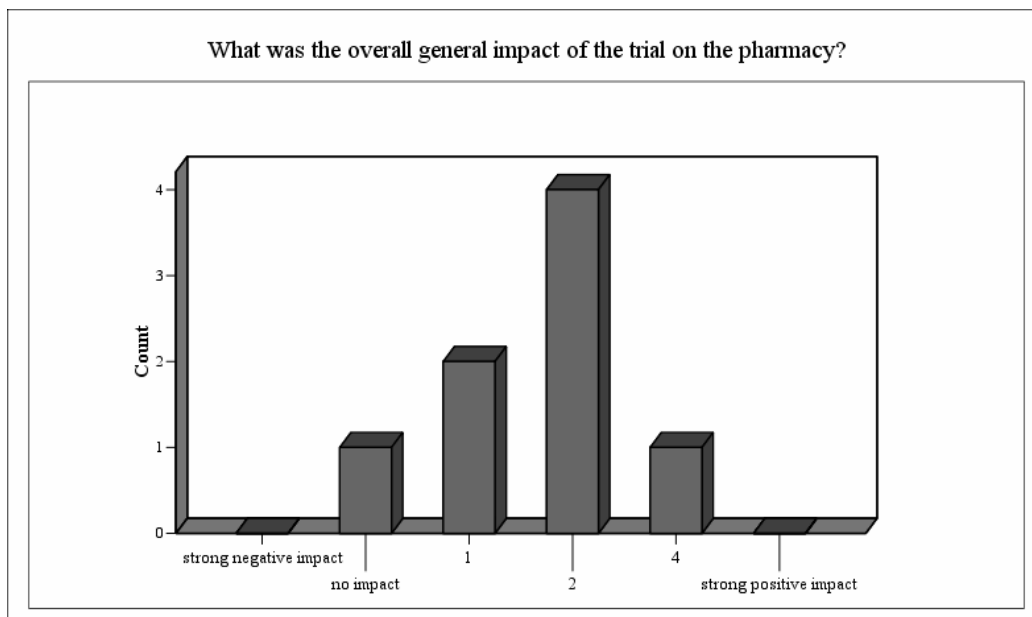
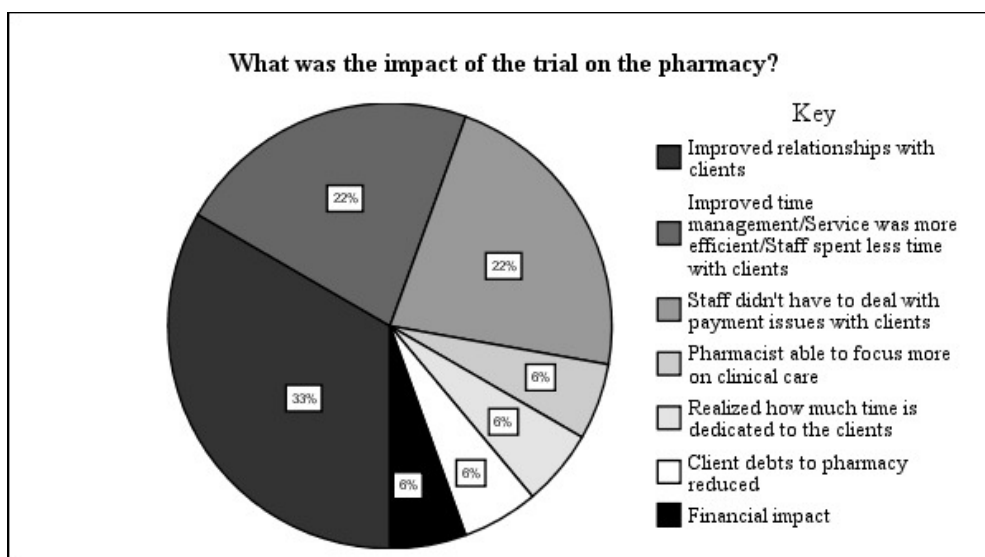


Figure 5.15 illustrates the range of comments made about the impact of the trial on the pharmacy. Again staff commented that the trial positives were the improved client relations and less focus on financial issues (45%), and that client pharmacy debts reduced (15%), along with 15% indicating the financial pharmacy incentive recognised the value of the staff resources allocated to pharmacotherapy dosing.

Staff commented that the only trial negatives for the pharmacy were increased paperwork (57%). This was however, considered less time consuming than arguing with clients about payment. Additionally, in New South Wales, the enhanced care form was considered time consuming for already stretched staff resources.

Figure 5.15: Staff comments on the trial impact on the pharmacy

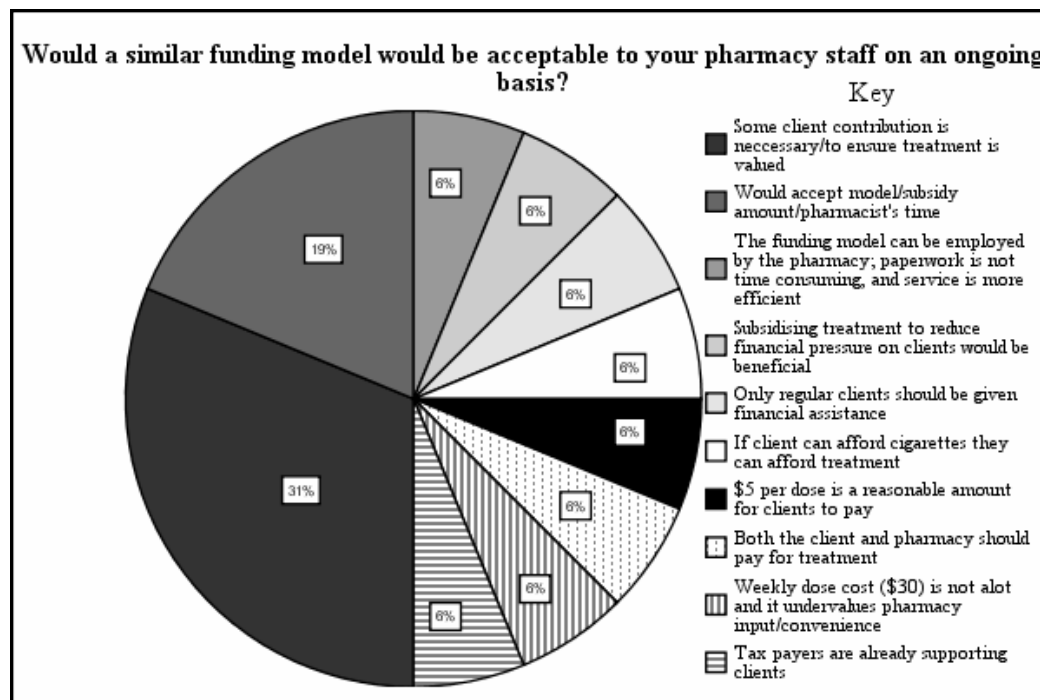


In evaluating the feasibility of the model in pharmacies, all locations indicated that the model trialled would be feasible in the long term. Additionally, in evaluating the acceptability of the funding model to staff, all except one of the 14 staff who were

interviewed or responded to the questionnaire said they would accept the model. One pharmacy assistant stated that they believed that clients should pay full price for the doses as subsidisation was an imposition on taxpayers.

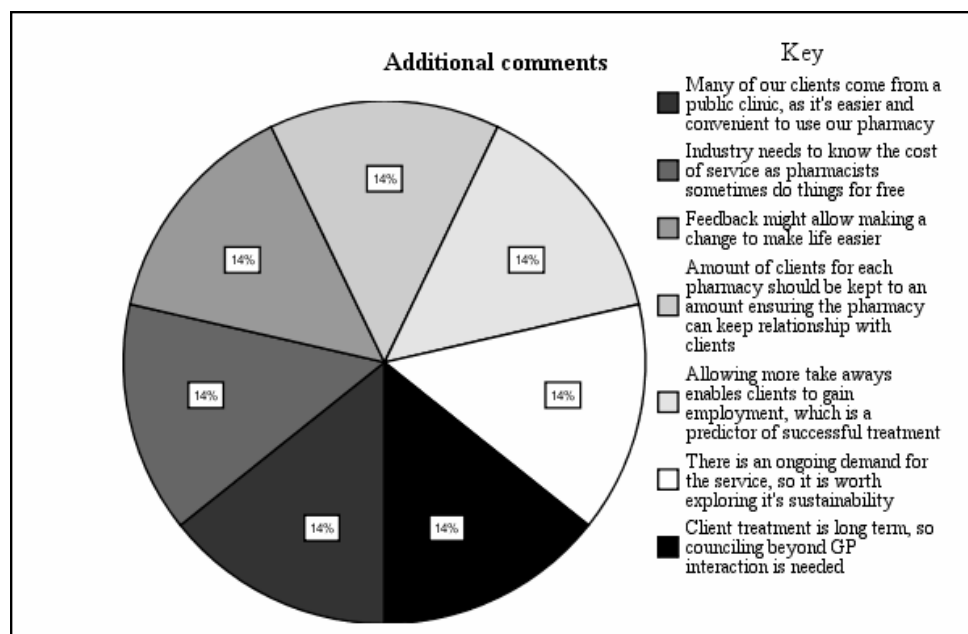
Comments made on the acceptability of the funding model are illustrated in Figure 5.16. Thirty one percent of those interviewed indicated that for treatment to be valued, some level of client payment was necessary. Twenty Five percent indicated that they would accept the model and incentive payment, where at least one respondent from each state said they would accept the funding model trialled in their pharmacy.

Figure 5.16: Staff comments on the acceptability of the funding model



Key indicators staff identified that could lead to service improvement, are illustrated in Figure 5.17.

Figure 5.17: Staff comments on community pharmacy pharmacotherapies for opioid dependence treatment program



5.4 FUNDING MODEL OUTCOME ANALYSIS

In analysing the financial outcomes for the six pharmacies involved in the trial, the costs of dosing for both buprenorphine and methadone, and the subsequent financial return made by each pharmacy was considered both before and during the trial. These results were then compared with the results obtained from the ten pharmacies included in the scoping studies. To reiterate the models as described on page 63:

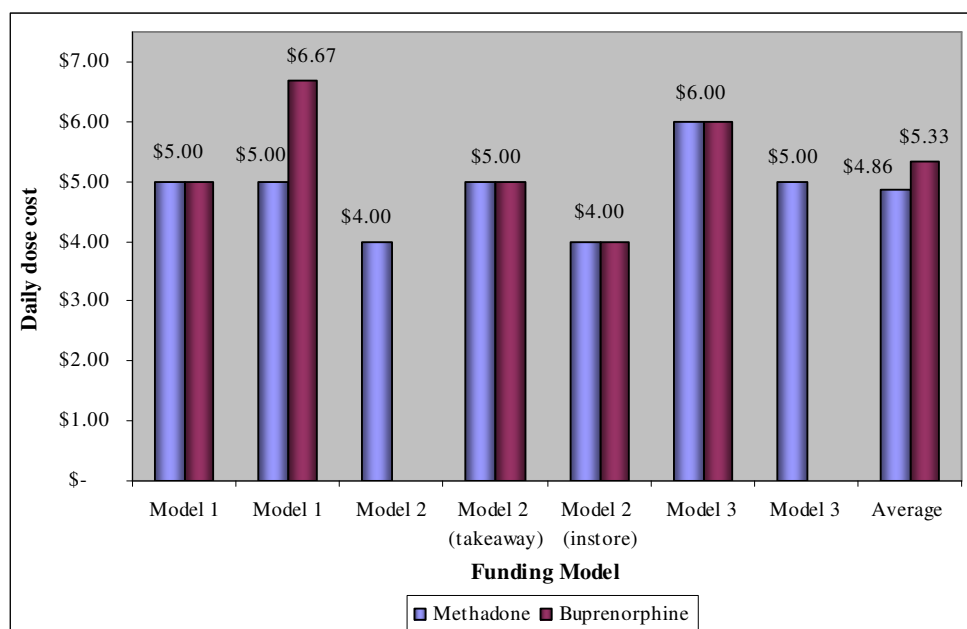
- (1) Model 1 was the Fee-for-Service Model in which the pharmacies were paid a \$4.40 dispensing fee per dose plus a \$2.50 consumer incentive. There was no change to the current pharmacy service model. The consumer incentive represented around 50% of the normal client co-payment (\$2.50 per dose). This model was trialled in two pharmacies in Victoria;
- (2) Model 2 was the other Fee-for-Service Model in which the pharmacies were paid a \$1.90 dispensing fee per dose plus a consumer incentive covering the client's dosing cost (between \$4-\$5 per dose). There was no change to the current pharmacy service model. This model was trialled in two pharmacies in South Australia; and
- (3) Model 3 was the Enhanced Care Model in which the pharmacies were paid a \$4.40 dispensing fee per dose plus a \$2.50 consumer incentive (as per Model 1). The consumer incentive represented around 50% of the normal client co-payment (\$2.50 per dose). Also the pharmacies were paid \$50 per consenting client who elected to receive enhanced care.

5.4.1 Cost of dosing in trial pharmacies

The average dispensing fee per dose paid by clients before receiving a subsidy is illustrated in Figure 5.18. It shows the average dispensing fee for buprenorphine and

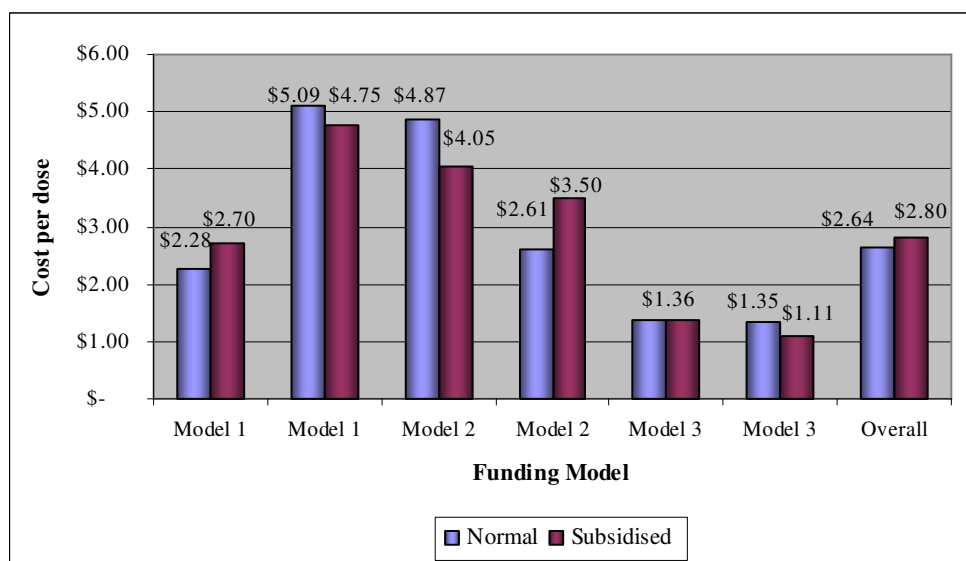
methadone was around \$5 each, and the collection of pharmacies in each model charged approximately the same amount for doses.

Figure 5.18: Client cost per dose of treatment



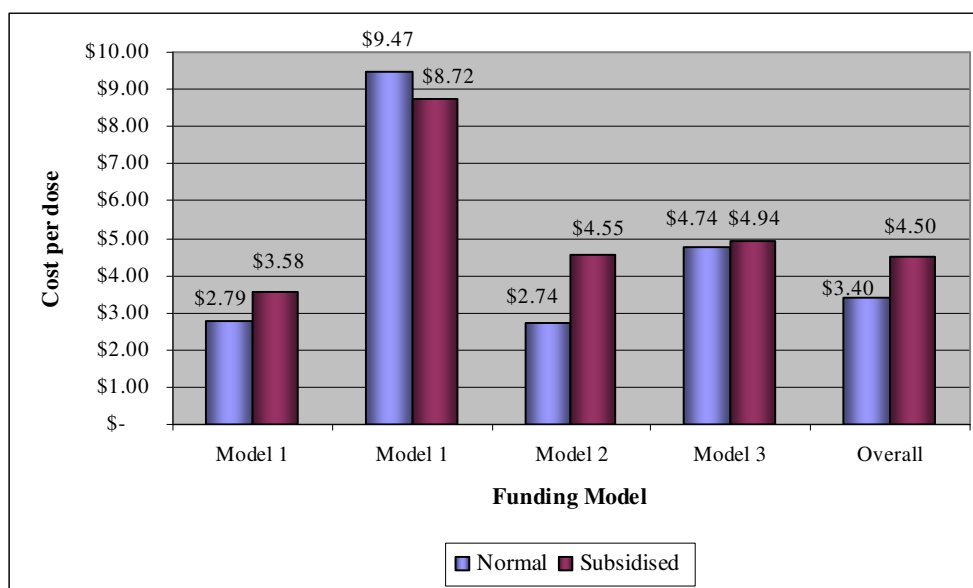
The average cost per dose of methadone was calculated both before the trial commenced (normal) and during the last month of the trial (subsidised). The difference in costs for each pharmacy is due to the time activity variation. The variance is minor and the average cost per dose changed only slightly during the trial. The average cost per methadone dose over all pharmacies was estimated at \$2.64 pre trial and \$2.80 during the trial and the variation across trial pharmacies is depicted in Figure 5.19. The difference between the 'normal' and 'subsidised' estimates is that the first measurement uses client payments only, and the second factors pharmacy incentive and consumer subsidy payments made over the trial. It is evident the cost of providing doses slightly increased for most pharmacies during the trial, which may be an effect of the additional trial management process pharmacy staff dedicated to the implementing the funding model. Nevertheless, the higher costs per dose should be noted for the second pharmacy trialling model 1 and the first pharmacy trialling model 2, as these estimates affect the other estimates dependent on these values.

Figure 5.19: Average pharmacy cost per dose of methadone



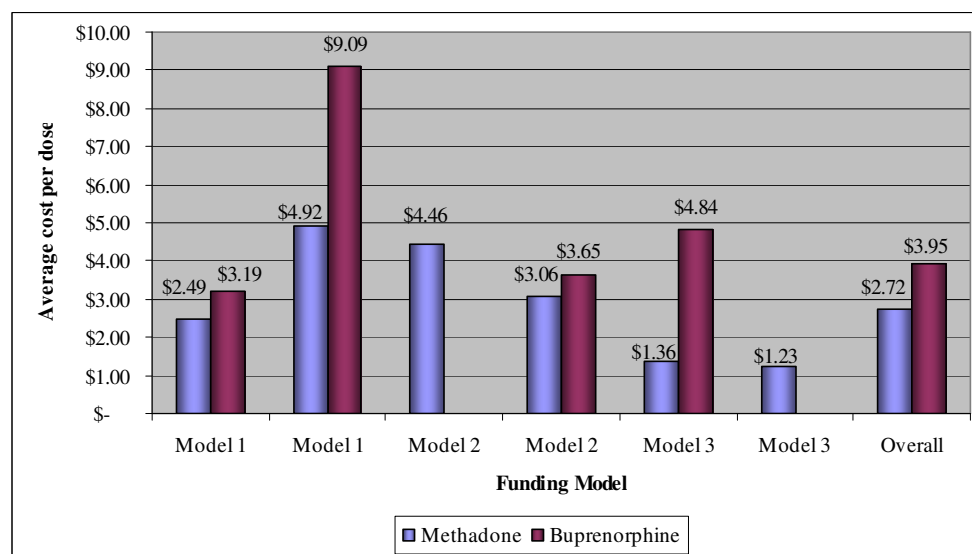
Similarly, the average cost per dose of buprenorphine (only four pharmacies dispensed) was calculated for each round of activity data that was collected. Figure 5.20 illustrates the estimates found. The average cost per dose of buprenorphine changed marginally during the trial (compared to pre trial) and it costs the pharmacies more to dispense than methadone. The average cost per buprenorphine dose was found to be \$3.40 pre trial and \$4.50 during the trial. The higher cost reflected the greater amount of time staff reported as being necessary to prepare and supervise the doses, particularly at a pharmacy trialling model 1. This is most likely because buprenorphine is provided as a sublingual tablet and staff spend more time with clients, as they watch the client until it is dissolved. This measure is a means to prevent diversions, whereas methadone is presented as a liquid which is swallowed immediately by the client. Again, it is evident the cost of providing doses slightly increased for most pharmacies during the trial, which may be an effect of the additional trial management process pharmacy staff dedicated to the implementing the funding model. Furthermore, the estimate of cost per dose at the second pharmacy trialling model 1, which affects other estimates dependent on this value.

Figure 5.20: Average pharmacy cost per dose buprenorphine



The average cost per dose was calculated for each pharmacotherapy and pharmacy based on the two rounds of time activity data to produce an average. Figure 5.21 depicts these average costs for each pharmacy, and the overall average cost for methadone and buprenorphine as \$2.72 and \$3.95 respectively. The average cost for buprenorphine at one of the pharmacies trialling model 1 was significantly higher than all other pharmacies, and should be noted as an outlier to the data.

Figure 5.21: Average cost per dose for each pharmacotherapy by trial model

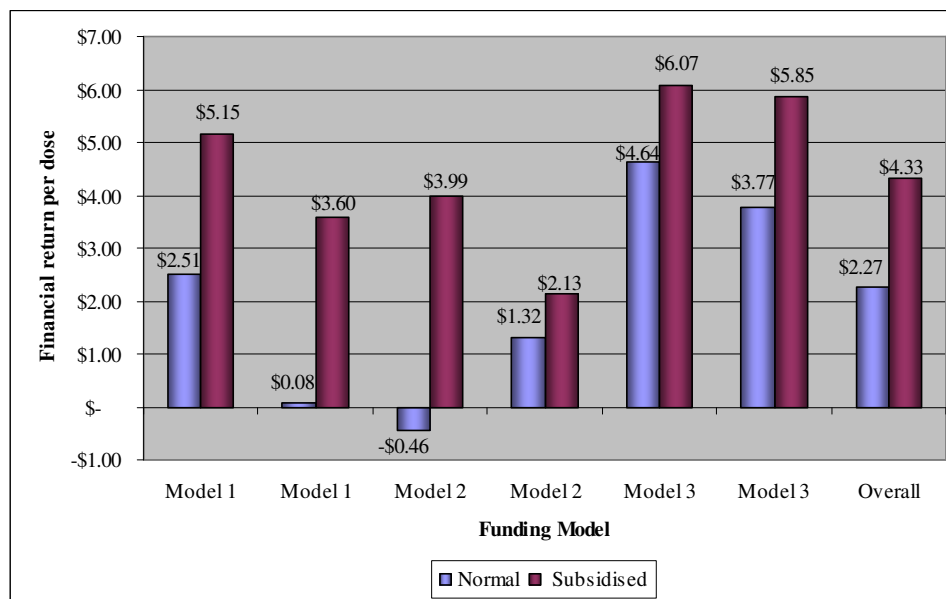


5.4.2 Financial return per dose

Using each pharmacy's average dose cost as derived above, the financial return per dose was then calculated. This allowed direct comparison of before and during trial returns for each treatment and pharmacy as illustrated in Figure 5.22 and Figure 5.23.

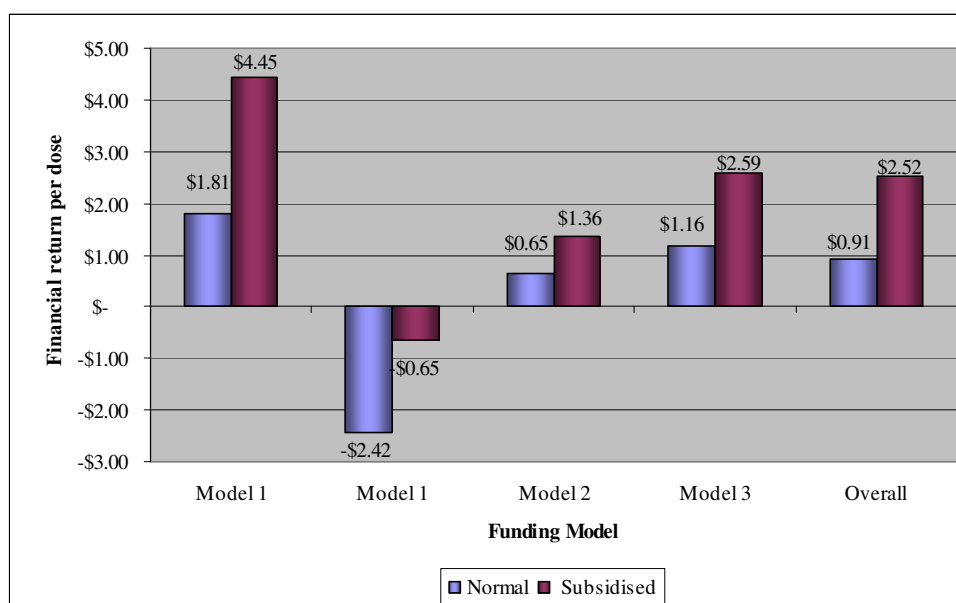
As Figure 5.22 shows, all pharmacies made a greater financial return per methadone dose during subsidisation, including the pharmacy that was making a loss per methadone dose normally. The average financial return increased from \$2.27 normally to \$4.33 subsidised.

Figure 5.22: Average financial return per methadone dose by trial model



Similarly to methadone, the financial return per dose for buprenorphine was calculated using each pharmacies and pharmacotherapies' average cost per dose for normal and subsidised revenue. As Figure 5.23 shows, all pharmacies made a greater financial return (or less of a loss in the case of one of the pharmacies trialling model 1) through subsidisation. Overall, the financial return made for each buprenorphine dose increased from an average of \$0.91 from normal revenue to \$2.52 from subsidised revenue.

Figure 5.23: Average financial return per buprenorphine dose by trial model



5.4.3 Trial pharmacy costs compared with scoping study pharmacies

During the scoping studies, the costs and financial returns from ten pharmacies were evaluated using the same methodology as was used for the pharmacies participating in the trial. This provided a useful data set with which to compare the financial viability of the pharmacies trialling the funding models with those that were not, and a means to measure the typicality of the trial pharmacies.

The average cost per methadone dose in the scoping study was found to be \$3.27 and the average cost per buprenorphine dose to be \$3.29. This compares with the trial pharmacies overall cost per dose of methadone of \$2.72 and \$3.95 for buprenorphine.

Furthermore, the scoping studies average financial return per dose of methadone was \$1.00, which was comparable with the normal trial pharmacies financial return of \$2.27. Similarly, the scoping studies average financial return per dose of buprenorphine was \$0.42, which was comparable with the normal trial pharmacies financial return of \$0.91.

These comparisons and the average subsidised financial return for each methadone and buprenorphine dose are illustrated in Figure 5.24 **Error! Reference source not found.** and Figure 5.25 respectively.

Figure 5.24: Comparison of scoping studies and trial pharmacies costs and financial return for methadone dispensing

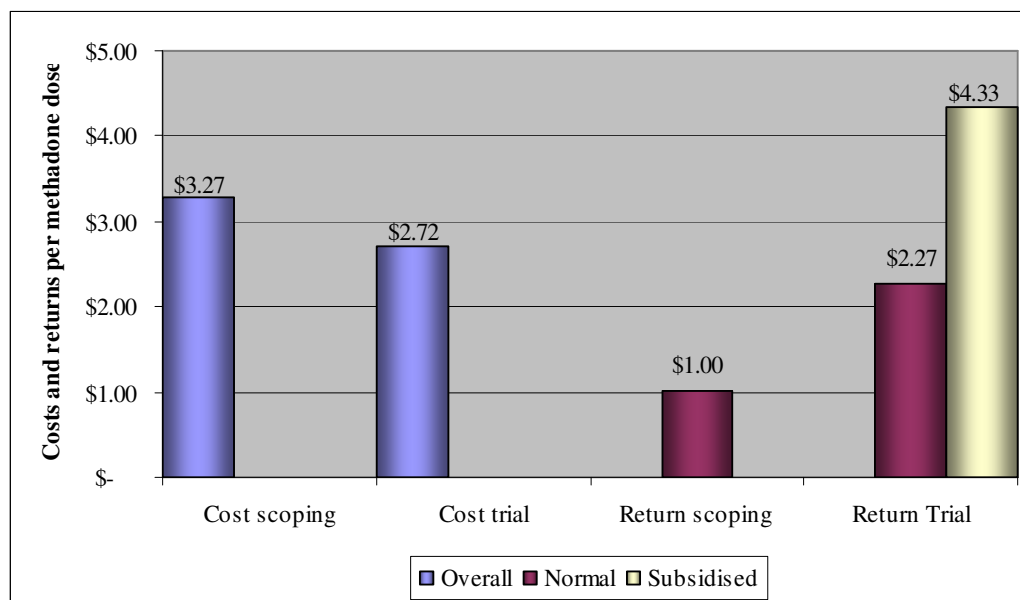
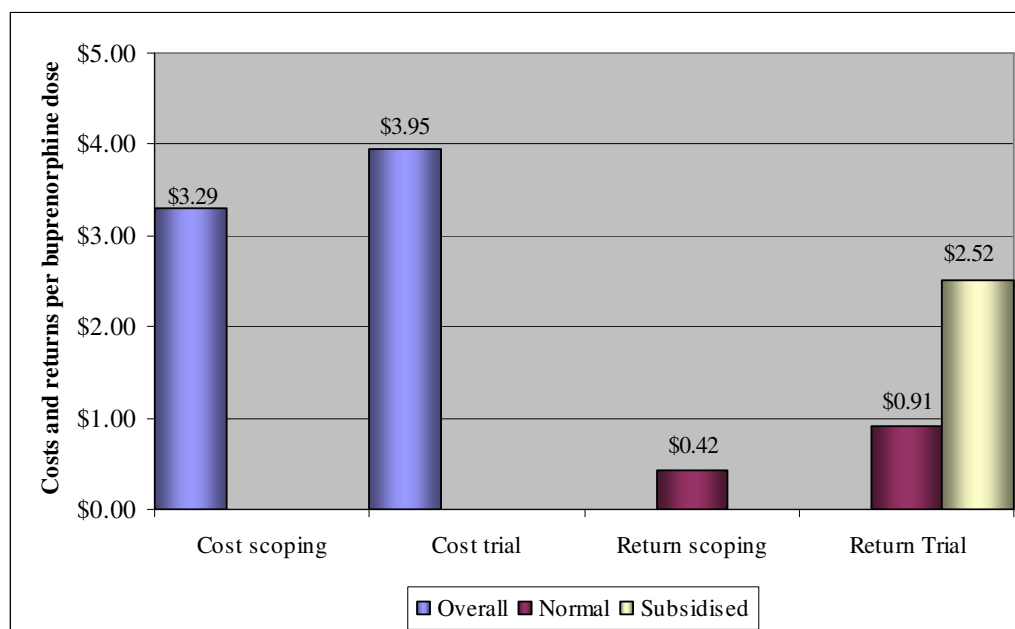


Figure 5.25: Comparison of overall scoping studies and trial pharmacies costs and financial return for buprenorphine dispensing

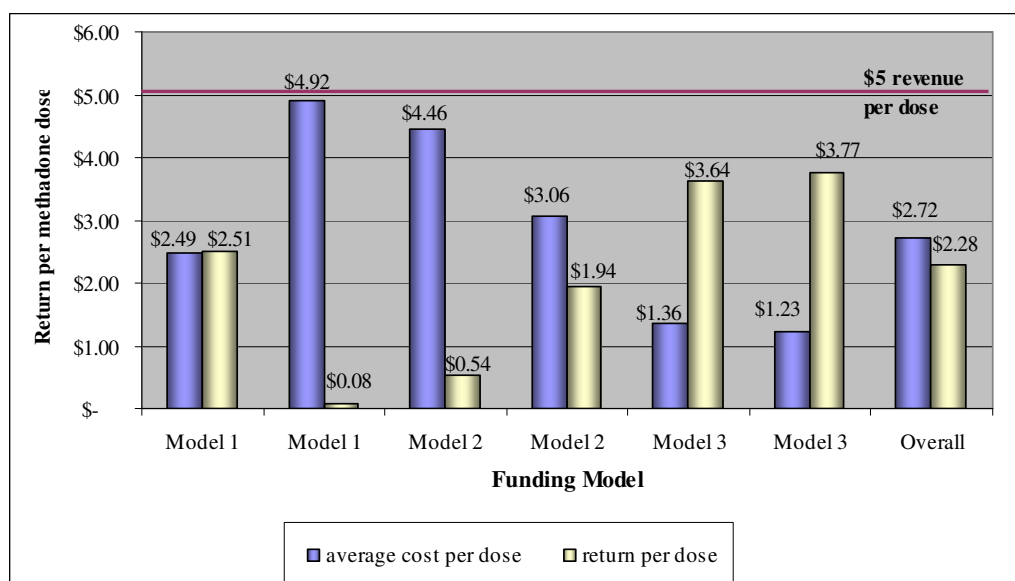


5.4.4 Modelling of proposed subsidy/revenue amounts

To evaluate feasible levels of subsidy/revenue for pharmacies dispensing methadone and buprenorphine, a model of the expected financial return was developed based on the costs per dose found over the trial period for trial pharmacies. As analyses have shown, the cost of providing buprenorphine compared to methadone, is approximately \$1 more per dose, therefore differential subsidisation may be required for each drug. Therefore, this model bases pharmacy revenue at \$5 per dose for methadone and \$6 per dose for buprenorphine. This model maps the financial returns for both a fully subsidised funding option and the possibility of a \$2.50 client payment per dose for each drug, with a \$2.50 per dose subsidy provided for methadone and a \$3.50 subsidy provided for buprenorphine. This approach was taken to ensure there are no disincentives for either the client or the pharmacy when choosing between methadone and buprenorphine.

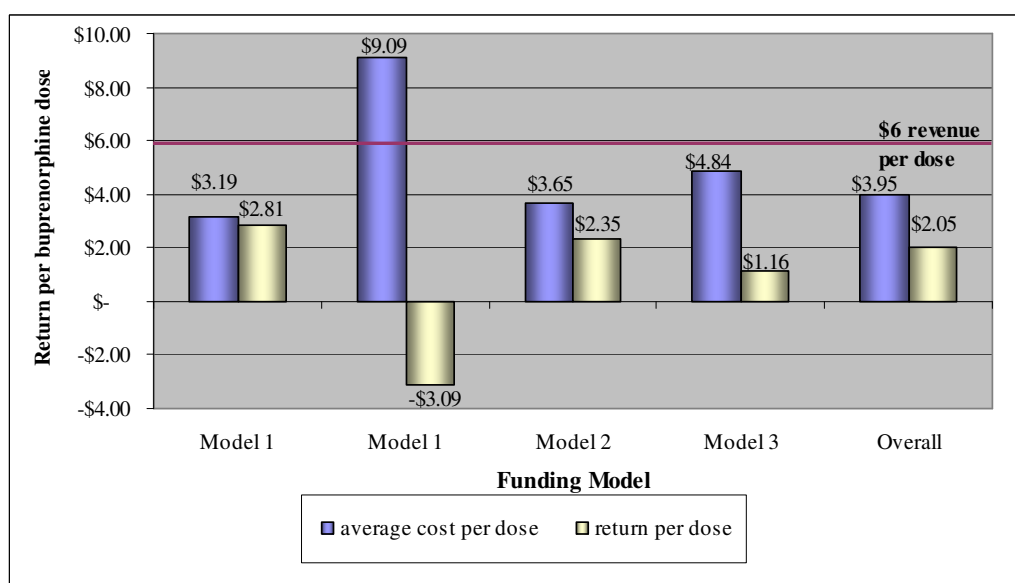
Figure 5.26 maps this average cost for each pharmacy (as illustrated in Figure 5.21) compared with the expected financial return per dose for methadone with client payments of \$2.50 and a subsidy of \$2.50. The overall financial return per dose is \$2.28. Again, the higher cost found at the second pharmacy trialling model 1 (\$4.92) and the first pharmacy trialling model 2 (\$4.46) reduces the financial returns for those pharmacies and lowers the overall estimates for cost and return per dose.

Figure 5.26: Modelled financial return per dose of methadone



Additionally, Figure 5.27 maps the average cost for each pharmacy (as illustrated in Figure 5.21) compared with the expected financial return per dose for buprenorphine with client payments of \$2.50 and a subsidy of \$3.50. The overall financial return per dose is \$2.05. Comparing the overall financial return made from methadone and buprenorphine, indicates that similar financial returns for each drug arise through this modelling, which therefore justifies the greater revenue received per dose for buprenorphine. As noted earlier, the high average cost per dose for the second pharmacy trialling model 1 (\$9.09) is an outlier to the data and gives a loss and lowers the average return across all pharmacies.

Figure 5.27: Modelled financial return per dose of buprenorphine

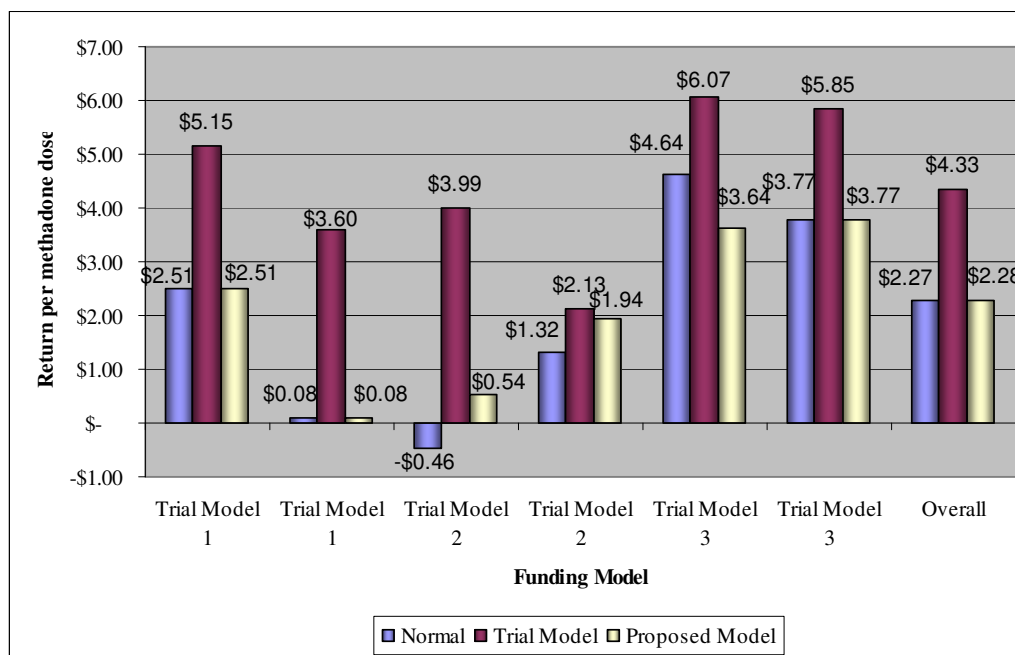


Furthermore, comparison for each funding model for each pharmacy and pharmacotherapy has been developed. Hence, Figure 5.28 and Figure 5.29 compare for each pharmacy the normal return, the return measured whilst implementing the

trial model and the mapping of the proposed model of a \$5 or \$6 revenue per dose for methadone and buprenorphine respectively.

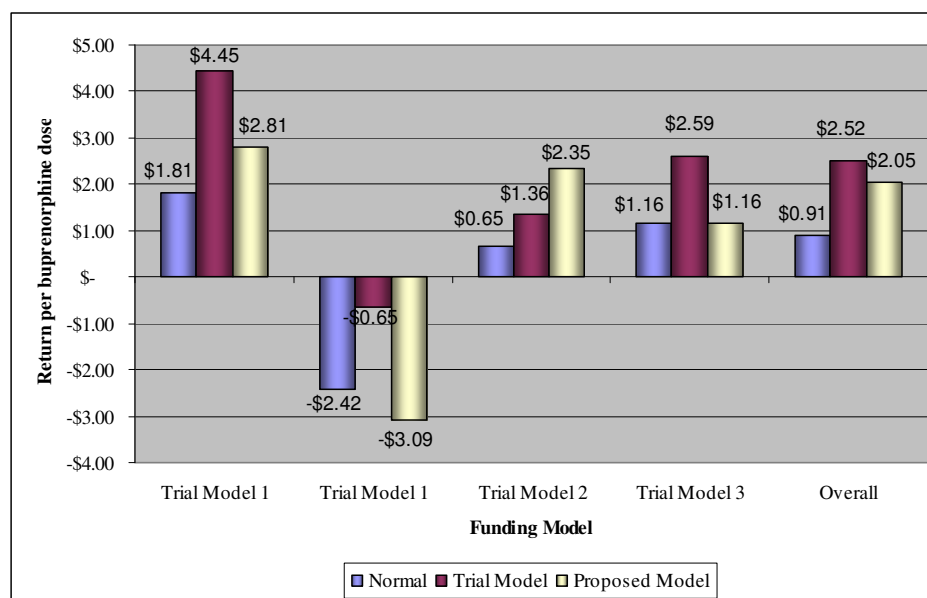
In Figure 5.28 the pharmacies trialling model 1 show identical returns between normal revenue and the proposed model as the revenue amount remains constant for both funding models (ie \$5 per dose). Furthermore, \$5 capping found a return of \$2.28 per dose of methadone. Again, it should be noted that the outliers identified earlier, namely the higher cost found at the second pharmacy trialling model 1 and the first pharmacy trialling model 2 reduce the return for all pharmacies.

Figure 5.28: Financial return per methadone dose for each funding model by funding model



Similarly, in Figure 5.29 the pharmacy that trialled model 3 also shows identical returns between normal revenue and the proposed model as the revenue amount remains constant for both funding models (ie \$6 per dose). Nevertheless, the figures illustrate the application of the proposed funding model to all pharmacies involved in trialling the funding model options. Furthermore, \$6 capping found a return of \$2.05 per dose of buprenorphine, which is comparable to the average found from the trial models. Again, the outlier identified earlier should be noted; the average cost per dose for the second pharmacy trialling model 1 was much higher than the other pharmacies, as it produces a loss in all funding models and lowers the average return across pharmacies.

Figure 5.29: Financial return per buprenorphine dose for each funding model by funding model



5.5 CONCLUSIONS

5.5.1 Client Outcomes

To summarise the statistically significant findings from data collected from clients and pharmacy staff participating in the funding model trials, outcomes found in health, wellbeing, social, treatment and economic areas follow.

Health Outcomes. The statistical analysis of data collected throughout the trial period found health outcomes in these areas:

- Analysis of the clients' injecting behaviour found a highly statistically significant decrease between pre and post trial interviews for all clients;
- Analysis of the clients' illicit drug use found a highly statistically significant decrease between pre and post trial interviews for all clients, and post trial responses differed for at least one group;
- Analysis of the clients' illicit drug use found a statistically significant decrease between post trial responses for at least one of the three client groups; and
- Analysis of the client's self-perception of health status found a highly statistically significant improvement between pre and post trial interviews for all clients.

Social Outcomes. The statistical analysis of data collected throughout the trial period found social outcomes in these areas:

- Analysis of the clients' responses found a highly statistically significant decrease in time spent with illicit opioid users between pre and post trial interviews for all clients; and
- Analysis of the clients' social functioning score found a highly statistically significant decrease between pre and post trial interviews for all clients, which may indicate improved client social functioning; and
- Analysis of the clients' social functioning score found a highly statistically significant decrease for South Australian/fully subsidised clients and a statistically

significant decrease for Victorian /half subsidised clients, which provides support that the fully subsidised model (Model 2) improved client social functioning more so than the half subsidised models (Model 1 and 3).

Wellbeing Outcomes. The statistical analysis of data collected throughout the trial period found client well being outcomes in this area. Analysis of the pharmacists' responses about client outcomes found the trial had a highly statistically significant positive impact on all clients. Pharmacy staff identified positive client outcomes in finances, pharmacy debt management, treatment retention, behaviour, and in relationships with pharmacy staff.

Treatment Outcomes. The statistical analysis of data collected throughout the trial period found client treatment outcomes in this area. Analysis of the pharmacists' responses about client retention in pharmacotherapy treatment found the trial had a statistically significant positive impact for all clients.

Economic Outcomes. The statistical analysis of data collected throughout the trial period found economic outcomes in these areas:

- Analysis of the clients' responses found a highly statistically significant decrease in clients' problems with money between pre and post trial interviews for all clients;
- Analysis of the clients' responses found the highest statistically significant decrease in clients' problems with money for South Australian/fully subsidised clients but a highly statistically significant decrease was also found for Victorian /half subsidised clients, which provides support that the fully subsidised model (Model 2) improved client financial situation more so than the half subsidised models (Model 1 and 3);

In evaluating the hypothesis that "*the cost of treatment affects client treatment outcomes?*" it was found that there was client improvement in the areas of health, wellbeing, social, treatment and economics. Particularly, evidence supported greater improvements in the client group trialling the fully subsidised funding model (Model 2-South Australian clients) compared with the client groups trialling the half subsidised models (Model 1- Victorian and Model 3- New South Wales clients).

5.5.2 Pharmacy and Funding Model Outcomes

Pharmacy Outcomes. To summarise the statistically significant outcomes derived from data collected from pharmacy staff participating in the funding model trials outcomes were found in the following areas.

- Analysis of the pharmacists' responses found the trial had a statistically significant positive impact on decreasing the levels of client bad debts for all pharmacies; and
- Analysis of the pharmacists' responses found the trial had a highly statistically significant positive impact on all pharmacies. Pharmacy staff identified positive pharmacy outcomes in improving relationships with and care for clients, improving time management, efficiency, and less financial issues with clients and pharmacy bad debts.

Therefore, in evaluation of the question of "*How do the funding models affect pharmacies?*" it was found:

- the financial viability of each trial pharmacy improved;
- bad debt levels decreased;

- client retention improved; and
- the trial arrangements positively impacted on all pharmacies.

Furthermore, all pharmacies reported they would accept the model trialled in their pharmacy.

Funding Model Outcomes.

The average cost per methadone dose over all pharmacies was estimated at \$2.64 pre trial, \$2.80 during the trial, giving a \$2.72 average. Higher costs per dose were noted for the second pharmacy trialling model 1 and the first pharmacy trialling model 2, which affected other estimates. Each pharmacy's average dose cost was derived based on the two rounds of activity data to calculate the financial return per dose normally and during subsidisation. All pharmacies made a greater financial return per methadone dose during the trial. Comparison of the average cost per methadone dose found from the scoping study pharmacies was found to be comparable to trial pharmacies costs per dose. As was the scoping studies pharmacies' average financial return per dose of methadone to the normal trial pharmacies' financial return. Furthermore, a \$5 revenue model found a return of \$2.28 per dose of methadone. Again, the outliers identified reduced the financial returns for those pharmacies and lowers the overall estimates for cost and return per dose, regardless of funding model. Nevertheless, comparing the overall financial returns made from methadone between trialled and proposed funding models indicated similar financial returns.

The average cost per buprenorphine dose was estimated at \$3.40 pre trial, \$4.50 during the trial, giving a \$3.95 average. The higher cost reflected the greater amount of time staff reported as being necessary to prepare and supervise the doses, particularly at a pharmacy trialling model 1. Furthermore, the estimate of cost per dose at this, affected other estimates dependent on this value. All pharmacies made a greater financial return (or less of a loss in the case of one of the pharmacies trialling model 1) through subsidisation. Comparison of the average cost per buprenorphine dose found from the scoping study pharmacies was found to be comparable to trial pharmacies costs per dose, as was the scoping studies pharmacies' average financial return per dose of buprenorphine to the normal trial pharmacies' financial return. Furthermore, a \$6 revenue model found a return of \$2.05 per dose of buprenorphine. As identified earlier, the high average cost per dose for the second pharmacy trialling model 1 was an outlier to the data and gave a loss and lowered the average return across all pharmacies. Nevertheless, comparing the overall financial returns made from buprenorphine between trialled and proposed funding models indicated similar financial returns.

In conclusion, comparing the each trial pharmacies' average cost per dose for each pharmacotherapy reveals the sensitivity of the estimates and the variation across pharmacies. This finding was also evident for estimates found from the scoping studies pharmacies. The sensitivities were particularly evident for estimates for two pharmacies; these were identified as outliers to the data. Nevertheless, in evaluation of the proposed hypothesis; "How do the funding models affect pharmacies?" the trial and proposed modelling demonstrated continuing financial viability, and improved service delivery for the trial pharmacies.

⁹⁶ NSW Health Department 2004, *BTOM-C User's Guide, March*, p18

6

Synthesis of Findings and Future Directions

6.1 INTRODUCTION

The project sought to identify best practice funding models for the provision of pharmacotherapy opioid dependence treatments based in community pharmacies. The project identified three different funding models that were subsequently trialled:

- (1) **The model trialled in South Australia** provided a full subsidy to the clients for each drug dose (\$5.00 per dose) with an additional payment made to the pharmacy (\$1.90 per dose).
- (2) **The model trialled in Victoria** provided a subsidy of \$2.50 to the clients for each dose (thus halving the cost of their therapy) with an additional payment made to the pharmacy (\$4.40 per dose to the pharmacist).
- (3) **The model trialled in New South Wales** was identical to the Victorian model in that clients received a \$2.50 subsidy for each dose and the pharmacist received \$4.40 per dose. Each pharmacist was also entitled to a \$50 payment per client by providing the client with “enhanced care”.

Chapter 5 presented the analysis of the impacts of these three funding models and this chapter synthesises the project’s findings, presents the conclusions and formulates recommendations.

6.2 FINDINGS RELATING TO THE MODELS

Evaluation of these funding models was undertaken using a structured approach that covered an assessment of efficiency and effectiveness (including health outcome indicators). The study involved trialling three concurrent models with clients involved in long term pharmacotherapy treatment (to avoid positive changes being potentially attributed to the benefits for new entry into such treatment programs). Of trial participants, 100% of New South Wales clients, 76.9% of Victorian clients and 57.5% of South Australian clients had been treated for more than 12 months. Comparison was by way of assessing pre- and post- trial change in client feedback and outcomes. In this context the findings below have been grouped accordingly:

6.2.1 *Efficiency*

The project investigated:

- the level of satisfaction of pharmacists and consumers with the funding models including the remuneration/subsidies paid;
- the evidence of improved retention rates with the pharmacotherapy program;
- any changes in the number of doses missed; and
- any factors that impacted on the clients’ ability to continue their pharmacotherapy treatment.

Findings were that:

- clients also expressed satisfaction with the trial arrangements with 91.4% stating that treatment arrangements were better during the trial than before it;
- clients and pharmacists reported being satisfied with the trial funding models. Further statistical modelling did not reveal any statistically significant differences in satisfaction between the three funding models;
- pharmacists reported that the funding models trialled had a strong positive impact on service delivery. This was mainly related to improved relationships with clients due to reduced concerns about money and chasing of bad debts;
- the impact of the enhanced care component of the model trialled in New South Wales appears to have been minimal. It should be noted, however, that only 14 of a possible 19 clients had the enhanced care form completed and, for most of these, it was not completed until late in the trial thus eliminating the opportunity to fully trial this option. Participating clients did not believe they had received an improved level of service;
- there was no evidence that retention rates in treatment changed as a result of the trial;
- overall, the satisfaction of clients with the cost of dosing improved significantly during the trial from an average 25% satisfied pre-trial to an average 85.1% satisfied post trial;
- while clients believed that the trial had no impact on their ability to stay on the pharmacotherapy program, pharmacy staff believed that there had been a positive impact. This was particularly related to the financial aspects of treatment; and
- most clients believed that the trial had little or no impact on whether they missed doses. However, in South Australia, where clients received full subsidisation, 53.8% of them believed the trial had a positive impact on whether they missed doses.

6.2.2 Effectiveness and sustainability of the funding models

The project investigated:

- any identifiable differences to the cost effectiveness of services delivered through the three funding models;
- the extent to which the funding models were sustainable;
- whether the funding models provided for an improvement in the level of unrecoverable costs as a result of the funding model trialled;
- how the pharmacy benefited from other cost savings due to the implementation of the trial funding model;
- whether the pharmacy realised other efficiency benefits as a result of implementing the trial funding model; and
- any improvements to the funding model that could improve sustainability of service delivery.

Findings were that:

- Consumers identified a number of issues that impacted on their access to pharmacotherapy. They included:
 - pharmacy opening hours not long enough;
 - long waiting times to receive doses;
 - travel time to get to the pharmacy and cost of petrol;

- lack of takeaway doses, especially for those who were employed and had to take time off each day to go to the pharmacy; and
- inappropriate dosing area (lack of privacy).
- clients were satisfied with the helpfulness and attitudes of pharmacy staff and this level of satisfaction improved during the trial;
- pharmacists confirmed that there had been an improvement in the level of previously unrecoverable costs as a result of the funding model trialled; and
- improvements in relationships with clients;
- pharmacies realised other efficiency benefits as a result of implementing the trial funding model;
- there was a reduction in client bad debts during the trial; and
- improved service and time management.

Due to the considerable variations in the financial outcomes for the trial pharmacies it was difficult to develop a conclusive view about specific improvements that could be applied to the funding model. All funding models trialled indicated greater financial returns for the pharmacies. In addition, it was apparent that both clients and pharmacists' viewed some form of subsidy as effective in improving health and financial outcomes for clients and improving effectiveness and financial viability for pharmacists.

6.2.3 *Client outcomes*

The project investigated:

- any change in the level of consumer health status as a result of trial funding model;
- whether there had been an improvement in family relationships due to the implementation of the trial funding model;
- evidence of improved financial management as a result of implementing the trial funding model;
- whether the funding model trialled contributed to a decrease in the use of opioid for participating clients;
- whether the trialled funding model impacted upon social productivity and employability;
- any other social functioning changes that had occurred as a consequence of the funding model trialled; and
- whether drug use behaviour had changed as a result of the trial.

Findings were that:

- there were improvements identified to client well-being, social, and health status and 60% of clients attributed these improvements to the availability of more money due to the reduced cost of their drugs. Areas of improvement included:
 - only 9.5% of participants reported their health as being poor post trial compared with 20.7% pre trial, and 39.3% reported their health as good compared with 28.3% pre trial;
 - participants indicated that they had reduced conflict with their partners and relatives post trial mainly due to fewer arguments about money.
 - pharmacy staff reported that clients' financial management and debt management had improved;
 - there had been a decrease in the use of both alcohol and illicit drugs during the trial period, although it is unknown whether this was attributable to the trial, as

it may be a trend related to the ongoing participation of the client in the pharmacotherapy treatment rather than the trial; and

- during the trial period there was a significant reduction in the number of participants who had injected a drug in the previous three months (reduced from 31.1% to 18.1%), but again it is not possible to be definitive as to whether this is a direct effect of the trial or if it is a result of the normal processes of participation in pharmacotherapy treatment.

6.2.4 Conclusions and recommendations

Based on the outcomes discussed in chapter 5 the proposed hypothesis “*the cost of treatment affect client treatment outcomes*” was evaluated. Analysis of the data collected using the BTOM-C instrument demonstrated statistically significant differences were found that indicated client improvement in the areas of health, wellbeing, social, treatment and economics. Particularly, evidence supported greater improvements in the client group trialling the fully subsidised funding model (Model 2-South Australian clients) compared with the client groups trialling the half subsidised models (Model 1- Victorian and Model 3- New South Wales clients). It should be noted in New South Wales, pharmacists did not take full advantage of the enhanced care option so the project was unable to form a conclusive view about the value of that program.

Furthermore, from a pharmacy perspective, comparing the each trial pharmacies’ average cost per dose for each pharmacotherapy revealed the sensitivity of estimates and the variation across pharmacies. This was particularly the case at two pharmacies which were identified as outliers to the data. Nevertheless, in evaluation of the hypothesis; “How do the funding models affect pharmacies?” the trial and proposed modelling demonstrated continuing financial viability, and improved service delivery for the trial pharmacies. The financial outcomes indicated an increased financial return, and pharmacy staff reported more satisfaction and less stress as they did not have to pursue clients for outstanding payments.

Therefore, the project established considerable support that subsidised dosing of methadone and buprenorphine leads to improved satisfaction with service and improved social, health and economic outcomes for clients and improved service and economic outcomes for pharmacies and their staff.

It is therefore recommended that:

- R1 Clients participating in pharmacotherapy treatment through community pharmacies be subsidised according to the following:**
 - Option 1 to be full subsidisation based on an agreed maximum; or
 - Option 2 to be partial subsidisation based on an agreed maximum.
- R2 The level of subsidisation be higher for buprenorphine to recognise the higher cost of dispensing.**

6.3 OPTIONS FOR LEVEL OF SUBSIDY

Based on assessment of the views of participants, using the BTOM-C instrument pre- and post- trial, it was apparent that the health and financial outcomes for clients had improved. In addition, pharmacists and their staff were pleased with the outcome of the trial in that they had fewer problems with client payments. Statistical analysis did

not demonstrate any substantial differences between the models from a financial perspective (although qualitative feedback suggested that the enhanced care component of the New South Wales model did not produce any significant benefits)

A number of options for providing an ongoing subsidy to clients prescribed methadone or buprenorphine pharmacotherapy based on the models trialled follows. The financial implications for subsidising dosing in the range of \$1-\$3 per dose, has been explored, as well as the implications of allowing clients to access the PBS Safety Net for their methadone and buprenorphine doses.

These calculations are based on the estimated 24,000 clients receiving pharmacotherapy who receive seven doses per week, although it is known that not all clients receive seven doses per week for various reasons.

If partial subsidy is considered it is recommended that:

R3 The level of subsidy initially be set at \$2.50/dose for methadone treatment and \$3.50/dose for buprenorphine treatment and that the level be reviewed and adjusted annually with consideration to be given to inflationary effects and future practice and available evidence.

The project collected significant amounts of cost data during the scoping study as well as revenue/charges (see Chapter 3), but only from a small number of sites. The trial subsidy levels were chosen as a practical balance between project budget allowance and the costs/charges (some pharmacies were identified as making a positive return while others were identified as making a negative return on the pharmacotherapy service). The suggested \$2.50/\$3.50 was identified as a reasonable mid-point but may be subject to adjustment based on policy decisions. Nevertheless a more detailed analysis of costs would provide more robust information. As a consequence **it is recommended that:**

R4 A project be initiated to undertake a financial impact analysis of delivering a pharmacotherapy treatment program through community pharmacies. The project should be of sufficient size to ensure the appropriate analysis of pharmacy site, pharmacotherapy clients and geographic location characteristics.

6.3.1 Modelling the cost of subsidised dosing

Table 6.1 shows the cost of subsidising dosing for 24,000 clients for estimates in the range of \$1.00 and \$3.00 per dose. Whilst there is no definitive rationale for determining a level of subsidy, it was apparent that most clients felt comfortable with paying some contribution to their doses, and pharmacists and other stakeholders as well as the literature supported the view that some client co-payment is appropriate. However, modelling of pharmacy financial returns based on this level of subsidy showed greater financial viability for pharmacy involvement in the pharmacotherapy for opioid dependence service delivery. As such, estimating a subsidy of around \$2.50 per dose is reasonable (representing around 50% of the current client co-payment as increasing the amount (eg to a full subsidy as in the South Australian trial), which had some measurable impact on their social outcomes, but not on their level of satisfaction and health. Subsidising doses at \$2.50 would have a financial implication of around \$21 million nationally.

Table 6.1: The cost of subsidised dosing

Subsidy Amount per dose \$	Amount paid to pharmacist by client \$	Total amount to pharmacist per dose \$	Total subsidy amount paid by funder \$
1.00	3.00-5.00	4.00 – 6.00	8,736,000
1.50	2.50-4.50	4.00 – 6.00	13,104,000
2.00	2.00-4.00	4.00 – 6.00	16,752,000
2.50	1.50-3.50	4.00 – 6.00	20,940,000
3.00	1.00-3.00	4.00 – 6.00	26,208,000

6.3.2 The PBS Safety Net option

A number of stakeholders highlighted the option to utilise the PBS structure (and associated safety net provisions) to provide clients with the subsidy. In considering this option it is relevant to note that the majority of pharmacotherapy clients (75%) reported that they were a government beneficiary of some type. The following information represents a brief overview of the PBS safety net provisions:⁹⁷

“There are two categories of Pharmaceutical Benefits Scheme (PBS) access – general and concessional. These are based broadly on individuals’ ability to pay and benefits entitlements (determined by Centrelink). Each category has its own patient co-payment amount per prescription and corresponding safety net amount.

Pharmaceutical benefit co-payments increased with effect from 1 January 2006. The concessional patient co-payment is now \$4.70 and the general patient co-payment is \$29.50. The safety net thresholds are \$253.80 (for concession card holders) and \$960.10 (for all other patients). The same general or concessional safety net threshold is applied to a family unit regardless of whether the unit consists of an individual, a couple or a family with dependent children.

After reaching the safety net threshold, general patients pay for further PBS prescriptions at the concessional co-payment rate and concession card holders are dispensed PBS prescriptions at no further charge for the remainder of that calendar year. In order to access the safety net arrangements, people need to maintain records of their PBS expenditure on a Prescription Record Form. These are available from all pharmacies.

All pensioners, (including part pensioners, Veterans Affairs beneficiaries, sickness allowees and other older long term allowees, including parenting allowees over 60 years and receiving income support for at least 9 months), continue to receive a pharmaceutical allowance of \$2.90 per week payable fortnightly, or \$150.80 per year, to help defray their out-of-pocket pharmaceutical expenses.”

The cost of applying the PBS Safety Net to all participants in the Australian pharmacotherapy dispensing program through community pharmacies was estimated on the basis that clients usually take one dose per day, although this may gradually reduce over months or years.

This project has shown that clients, attending a community pharmacy, are charged by the dose at a cost of around \$5.00 or \$35.00 per week. Therefore, based on clients paying the dispensing fees under the PBS schedule, government benefit recipients

would take just over 50 doses or 7-8 weeks to reach the safety net threshold. It is assumed that non concessional clients would also pay the \$35 per week, but they would take longer, 27-28 weeks, to reach the safety net threshold, as Table 6.2 shows.

Based on the estimated 24,000 people participating in the community pharmacy pharmacotherapy programs, it would be expected that the percentage of government benefit recipients or health care card holders would be similar to the sample included in the trial (ie 75%). Therefore, around 18,000 (75%) of people participating in the pharmacotherapy program would be eligible to take advantage of the PBS Safety Net within eight weeks of the beginning of each calendar year. The remaining 25% (6,000 clients) would be eligible within 27 weeks.

This should be considered a maximum amount of time as many of these people also take other prescribed drugs, the cost of which would be also added to their safety net total. Table 6.2 demonstrates the cost to government of applying the PBS Safety Net to pharmacy clients receiving methadone and buprenorphine doses. It shows the annual cost as \$32,970,000.

Table 6.2: Cost of PBS Safety Net

Clients	Cost per week	No of weeks	Cost per annum (\$)
18,000	\$35.00	44	27,720,000
6,000	\$35.00	24	5,250,000
Total			32,970,000

It is apparent that the option of providing subsidised dosing to clients through their community pharmacy is considerably less costly, but there would be significant administration costs involved in setting up and managing a new system of payment both for the pharmacies and for the funder.

The advantage of using the PBS Safety Net approach would be that it is already in place and is understood by both pharmacist and clients alike. It is also a mainstream system and is not likely to stigmatise clients in the same way that a special subsidy system would. In addition, using the PBS Safety Net would provide equity to clients as it has been found that different pharmacies charge different rates and in some cases the same pharmacy charges clients at different rates for doses. Some clients are aware of this variation and a number of those interviewed commented on the lack of fairness, equity and transparency within the current system.

6.3.3 Other Issues

Due to the length of the trial period and the resulting low take up of the enhanced care option in NSW the project was unable to make definitive conclusions regarding the impact of this option. As a consequence it is recommended that:

R5 Further investigation of the impact of incorporating enhanced care into routine pharmacotherapy treatment be undertaken (including consideration of the outcomes of an evaluation of the New South Wales Pharmacy Incentive Program which encompasses the provision of integrated care options to clients).

⁹⁷ Department of Health and Ageing, "Pharmaceutical Benefits Safety Net Arrangements," www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pbs-general-pbs-phbensna.htm, accessed 11/7/06