A national funding model for pharmacotherapy treatment for opioid dependence in community pharmacy

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The Pharmacy Guild of Australia manages the Fourth Community Pharmacy Agreement Research & Development which supports research and development in the area of pharmacy practice. The funded projects are undertaken by independent researchers and therefore, the views, hypotheses and subsequent findings of the research are not necessarily those of the Pharmacy Guild.
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Sarah Lord – Australian Injecting and Illicit Drug Users League
## Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Explanation</th>
</tr>
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<tbody>
<tr>
<td>ACT</td>
<td>Australian Capital Territory</td>
</tr>
<tr>
<td>BTOM-C</td>
<td>Brief Treatment Outcome Measure – Concise</td>
</tr>
<tr>
<td>Guild</td>
<td>Pharmacy Guild of Australia</td>
</tr>
<tr>
<td>NDARC</td>
<td>National Drug and Alcohol Research Centre</td>
</tr>
<tr>
<td>NSW</td>
<td>New South Wales</td>
</tr>
<tr>
<td>NT</td>
<td>Northern Territory</td>
</tr>
<tr>
<td>PhARIA</td>
<td>Pharmacy Access/Remoteness Index of Australia</td>
</tr>
<tr>
<td>PwC</td>
<td>PricewaterhouseCoopers</td>
</tr>
<tr>
<td>QLD</td>
<td>Queensland</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomised Controlled Trial</td>
</tr>
<tr>
<td>SA</td>
<td>South Australia</td>
</tr>
<tr>
<td>TAS</td>
<td>Tasmania</td>
</tr>
<tr>
<td>VIC</td>
<td>Victoria</td>
</tr>
<tr>
<td>WA</td>
<td>Western Australia</td>
</tr>
<tr>
<td>WHOQoL-8</td>
<td>World Health Organisation Quality of Life-8 scale</td>
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1. Background and purpose of the research

Since Methadone was introduced as a substitution treatment for opioid dependence, studies have shown that opioid users reduce their illicit opioid use and improve their health and social wellbeing while maintained on Methadone (Hall & Wodak, 1999; Mattick, Breen, Kimber, & Davoli, 2004, 2008; Mattick, Kimber, Breen, & Davoli, 2004; Ward, Hall, & Mattick, 1999; Ward, Mattick, & Hall, 1992; Ward, Mattick, & Hall, 1998). In addition, the physical health and wellbeing of clients improves and there is evidence of markedly reduced mortality (Caplehorn, Dalton, Cluff, & Petrenas, 1994; Caplehorn, Dalton, Halder, Petrenas, & Nisbet, 1996; Darke, Degenhardt, & Mattick, 2007). There is also very substantially reduced crime (Lind, Chen, Weatherburn, & Mattick, 2005), resulting in a cost-benefit of being in treatment from reduced crime and other cost-offsets (P. G. Barnett & Hui, 2000; P.G. Barnett, Zaric, & Brandeau, 2001; Harwood et al., 2002; Shanahan, Hetherington, Mattick, & Weatherburn, 2007).

Maximising the health benefits from the treatment of opioid dependence is reliant on a number of factors to do with the effectiveness of the pharmacotherapy used, its accessibility and its attractiveness to the target group. The ability to retain these clients in treatment and provide long-term care depends on a number of factors, including the affordability of the treatment. A number of studies have shown that the reduction and elimination of fees for pharmacotherapy treatment increases retention and improves outcomes (Rosenbaum, Irwin, & Murphy, 1988; Rosenbaum, Ulrwin, & Murphy, 1987; Breen et al., 2003; Maddux et al., 1994). The central construct underpinning the thinking behind subsidised treatment is that such arrangements increase affordability and through that, improve access and retention. On the other hand, the evidence base regarding the extent of the impact of fees on retention is not unambiguous, particularly in regards to whether fees encourage clients to leave treatment earlier than they otherwise would (Ritter & Chalmers 2009).

In Australia, it is generally accepted that the cost of treatment fees is $5 to $6 per day, or $30 to $40 per week. The Australian Government funds the provision of pharmacotherapies via pharmaceutical benefits arrangements, through clinics and pharmacies approved by state and territory governments; however the costs associated with providing pharmacotherapy treatment are not funded. State/Territory governments also subsidise service providers in some instances. Funding in Victoria (VIC) for those aged less than 19 and juvenile justice individuals is fully funded by the state government. For individuals post prison release, fees are fully paid directly to the pharmacy for four weeks post release. Other States and Territories may provide limited funding, to some extent, to compensate the pharmacists providing the service, however they vary in their respective models. Often this funding is for the pharmacist only to incentivise providing pharmacotherapy; none of this funding reduces the cost for the client. Only in the Australian Capital Territory (ACT) is the client payment subsidised by the ACT Government, where $20 is paid by ACT health directly to the pharmacy.

The differing funding models for pharmacotherapy treatment across the states and territories (including those with zero funding) lead to a lack of consistency in the cost of treatment for the clients and level of incentives for the pharmacist. This is exacerbated by the fact that pharmacies within each jurisdiction may be charging clients different daily / weekly fees and implement their own policies (eg the provision of credit).

The community pharmacy sector has taken on a large and central role in the administration of pharmacotherapy treatment. The inability of public clinic systems to provide the accessibility and hours of operation achieved by community pharmacies makes the involvement of this sector critical to the effective reach of treatment in Australia. In addition, community pharmacies are seen as a normal environment by pharmacotherapy clients for receiving their doses. A recent estimation of the number of clients, in Australia, who are on pharmacotherapies for opioid dependence is 41,347 (Australian Institute of Health and Welfare, 2008), with the largest proportion of clients (42.0%) seen in New South Wales (NSW). Eighty-six percent (86.0%) of dosing points (ie where pharmacotherapy treatment is supplied to a client), are in the community pharmacy setting, whilst the remaining 14.0% are in public, state or private clinics.

Recent research suggests that the community pharmacy sector has the capacity to increase pharmacotherapy treatment client numbers. However, the disinclination of community pharmacists to be involved in pharmacotherapy treatment has been noted (Matheson, Bond, & Mollison, 1999). As mentioned previously, a number of jurisdictions have differing funding models to try and incentivise pharmacies to deliver the service and overcome some of the negatives associated with offering the service in the
pharmacy. A survey conducted in 2002 by the Pharmacy Guild of Australia (the Guild) found that the arrangement with the ACT Government was effective and of benefit to the clients and subsequently the pharmacy. The $15 subsidy was found to assist the client's finances and positively impact their treatment; and the funding was found to be beneficial for the pharmacies delivering the program by increasing their overall satisfaction in providing this service in their pharmacy.

The need for robust empirical evidence to support “best practice funding options” for the provision of pharmacotherapy treatment in community pharmacies is well recognised. A recent study commissioned by the Guild, reported information on the efficiency, effectiveness and sustainability of the funding models and consumer outcomes (Healthcare Management Advisors, 2006). The study examined funding model options for supplying pharmacotherapies for opioid dependence in community pharmacy and reported findings which indicated consumer improvement in the areas of health, wellbeing, social, treatment and economic outcomes, along with improved consumer satisfaction with the treatment. From a pharmacy perspective, the study reported improved service and economic outcomes, as well as improved relationships and communication between pharmacists/staff and consumers. Although the study provided insight into many of the important dimensions, it was hampered by the small sample size and short duration of the trial, amongst other things. However it did show that further investment in investigating the funding models and client outcomes was warranted.

The complete literature review can be found in Appendix C of the Full Final Report.

1.1. Rationale for the present research

The differing funding models for pharmacotherapy treatment across the states and territories (including those with zero funding) lead to a lack of consistency in the variable:

- cost of treatment for the clients
- levels of incentives for the pharmacist.

While the efficacy of pharmacotherapy treatment is well demonstrated, accessibility and attractiveness to the target group and the ability to retain these clients in treatment to provide long-term care, depends on a number of factors. Affordability of the treatment is thought to be key in this regard.

The role of community pharmacy in providing access to pharmacotherapy treatment has been significant, and the potential to grow their role in this area has been identified. The Guild reported that 80% of consumers receiving treatment in public clinics have indicated that they would prefer to receive their treatment in community pharmacies\(^1\). There is currently no national system in place to support community pharmacies for their role in the treatment of this client group.

Given these factors, the Guild commissioned PricewaterhouseCoopers (PwC) and the National Drug and Alcohol Research Centre (NDARC) to undertake a research project to trial and evaluate the impact of a funding model as part of pharmacotherapy treatment for opioid dependence through community pharmacy.

\(^1\) The Pharmacy Guild of Australia, NSW Branch http://www.guild.org.au/nsw/content.asp?id=1081 (last accessed 28/03/08)
1.2. Objectives of the study

The focus of the research project was to consider key elements of a national funding model for pharmacotherapy treatment in community pharmacy. Specifically, the study focused on two key objectives:

1. To evaluate the benefits of the implementation of a nationally consistent client subsidy and to consider the impacts of this arrangement on the following key outcomes:
   - client retention rates in the program
   - client compliance / adherence with doses
   - client health and social outcomes
   - the use of illicit opioids.

2. To consider the perspective of the community pharmacists who supply pharmacotherapy, within a nationally consistent subsidised environment, and to consider the impact of this arrangement in terms of:
   - the pharmacists’ satisfaction with the trialled funding arrangements
   - the way in which pharmacists deliver the service
   - the costs associated with the delivery of the service.
2. Research project and trial design

2.1. Design of the research project

The research project consisted of five stages, as illustrated in Figure 1. The research project commenced in August 2008 and concluded in April 2010. To provide an intervention period of six months, the trial was implemented over an elapsed period of eleven months from February 2009 to January 2010 based on the staggered commencement of three cohorts selected to fill the sampling framework for the trial. Further detail on the design of the research project can be found in Section 3 of the Full Final Report.

Figure 1: Research project outline

<table>
<thead>
<tr>
<th>Stage 1: Project initiation (5 weeks)</th>
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<tbody>
<tr>
<td>Stage 2: Trial design (3 months)</td>
</tr>
<tr>
<td>Stage 3: Trial implementation (11 months)</td>
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<tr>
<td>Stage 4: Analyse trial results (2 months)</td>
</tr>
<tr>
<td>Stage 5: Final report (2 months)</td>
</tr>
</tbody>
</table>

- **Initial consultations and literature review**
- **Trial design**
- **Ethics approval**
- **Recruitment of pharmacies**
- **Recruitment of clients and treatment allocation (2:1)**
- **Pharmacy level data collection**
  - Pharmacy demographics
  - Client payment per dose
  - Satisfaction (baseline & 6 month)
  - Activity based costing study
- **Client level data collection**
  - Monthly dosing data (provided by pharmacist)
  - Client survey (baseline & 6 month)
- **Analysis of trial results**
- **Final report and key findings**

2.2. Features of the trial design and methodology

Key features of the trial design and methodology are discussed below. A full description of the trial design and methodology can be found in Section 3 and Section 4 of the Full Final Report.

**Project governance**

The Advisory Panel for the project provided a representative group of key stakeholders to oversee the design and implementation of the trial, endorse and guide the project and review key aspects of the project. Membership of the Advisory Panel comprised the Guild, Department of Health and Ageing, Pharmaceutical Society of Australia, the Intergovernmental Committee on Drugs, community pharmacists and consumer representative organisations.

A Reference Group was established to convene a representative group of local practising community pharmacists, who provide pharmacotherapy treatment, to provide practical/operational advice for the project.
**Randomised controlled trial approach**

Randomised controlled trials (RCT) are the methodology of choice in healthcare research as they provide the highest level of evidence for treatment efficacy; they are an invaluable support to the development of evidence based policy. RCTs involve the random allocation of participants in treatment to different intervention groups. The most important advantage of proper randomisation is that it eliminates selection bias, balancing both known and unknown prognostic (ie outcome influencing) factors, in the assignment of participants to different treatment groups. The methodology for achieving appropriate and statistically robust randomisation is well documented and was used in this study.

Randomisation to the intervention and control groups was based on pharmacy rather than the client. Randomisation occurred at a 2:1 ratio, intervention: control. Statistical robustness was a key consideration in the methodological approach. To achieve 80% power of detecting a small difference (effect size = 0.25), between the intervention and control groups, a total sample size of around 700 clients was required to actively participate in the trial. Further detail on the RCT approach is outlined in Section 4.4 of the Full Final Report.

**Design of the funding model for the trial**

The trial tested a specified funding model nationally. The funding model was collaboratively developed and agreed by the Guild, the Advisory Panel and the research team at the outset of the trial. The funding model comprised two components, a client subsidy and a pharmacy incentive, as outlined in Table 1.

**Table 1: Trial funding model**

<table>
<thead>
<tr>
<th></th>
<th>Intervention group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists</td>
<td>• Pharmacists received an incentive of $15 per consented client per week:</td>
<td>• Pharmacists received an incentive of $50 per month for the provision of</td>
</tr>
<tr>
<td></td>
<td>- to subsidise the service</td>
<td>monthly data for the research.</td>
</tr>
<tr>
<td></td>
<td>- for the provision of monthly client dosing data for the research.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Pharmacists received an additional $15 per consented client per week:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- to subsidise the client payment by $15 per week</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- pharmacists signed a declaration stating that the subsidy would be passed on to</td>
<td></td>
</tr>
<tr>
<td></td>
<td>the client</td>
<td></td>
</tr>
<tr>
<td>Clients</td>
<td>• Clients received a reduction of $15 per week in their payments.</td>
<td>• Clients received no reduction in their payments and received usual care.</td>
</tr>
<tr>
<td></td>
<td>• The trial aimed to maintain a co-payment focus; where the client was to pay a</td>
<td></td>
</tr>
<tr>
<td></td>
<td>minimum of $5 per week.</td>
<td></td>
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</tbody>
</table>

Further detail on the design of the funding model is discussed in Section 3.2 of the Full Final Report.
Development of a nationally representative sampling framework

The aim of the sampling framework was to identify a nationally representative sample of pharmacies and clients across all jurisdictions (except the ACT\(^2\)). In order to be eligible to participate in the trial, pharmacies needed to be currently providing pharmacotherapy services.

As described previously, a total sample of approximately 700 clients who were actively participating in the trial was required to achieve statistical robustness. In order to avoid creating tension between clients in a particular pharmacy, it was deemed advisable that all pharmacotherapy clients in a pharmacy should be invited to participate. The only exclusion criterion for pharmacies to participate was based on the size of their client group. Those pharmacies with more than 50 clients participating in the pharmacotherapy program were excluded from participating, in order to prevent any single pharmacy from contributing too great a proportion of the overall sample. Stratification was based on Pharmacy Access/Remoteness Index of Australia (PhARIA) category (an index to provide specific measurement of remoteness of any pharmacy within Australia) and client bands (pharmacies with one to 20 clients and those with 21 to 50 clients) for each jurisdiction. The sampling framework is outlined in Appendix A.

Recruitment of pharmacies and clients

Pharmacies were recruited to the trial through an expression of interest process; all pharmacies supplying pharmacotherapy treatment were invited to participate. Those pharmacies that expressed interest were randomly selected to meet the sampling framework (Appendix A). Selected pharmacies where then consented to the trial.

As part of the trial design, pharmacies were recommended to approach all clients who were on the pharmacotherapy program to participate in the trial. To be considered eligible for the trial, a client had to be prescribed Methadone, Subutex or Suboxone, which was provided by a participating community pharmacy. In addition, they had to be aged 18 years and over. Pharmacists obtained informed consent from their clients who wanted to participate in the trial. The process for the recruitment of pharmacies and clients is described in full in Section 4.3 of the Full Final Report.

Following the recruitment of all pharmacies and clients, allocation to the control and intervention group was undertaken based on pharmacy. In other words, when participating pharmacies and clients consented to participate in the trial, they were unaware of the group (control or intervention) to which they would be allocated. The process for allocation to the control and intervention groups is described in Section 4.4 of the Full Final Report.

Pharmacy and client data collection

A summary of the approach to the collection of data from pharmacists and clients is described in Appendix B. A full description of the data collection process is outlined in Section 4.5 and Section 4.6 of the Full Final Report. In brief there were three broad streams of data collection:

1. **Data collected directly from clients:** the aim of this stream was to obtain information about the experience and outcome of the clients participating in the trial. Information was collected about health, wellbeing and their experience using a telephone survey methodology and standardised survey components. They survey components are described in brief below. Clients participating in the trial provided this information at the beginning and at the end of the trial.

\(^2\) The ACT was excluded from the trial because their funding model already subsidises the client by $15 week.
### Survey component

<table>
<thead>
<tr>
<th>Type of information measured</th>
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<tbody>
<tr>
<td><strong>Brief Treatment Outcome Measure – Concise (BTOM-C)</strong></td>
</tr>
<tr>
<td>• Client demographics</td>
</tr>
<tr>
<td>• Information on the clients recent drug and alcohol use and risk behaviours</td>
</tr>
<tr>
<td>• Information on the social aspects of the clients life and their perception of their health</td>
</tr>
<tr>
<td>• Information about the clients current and previous drug and alcohol treatment</td>
</tr>
<tr>
<td><strong>World Health Organisation Quality of Life-8 scale (WHOQoL-8)</strong></td>
</tr>
<tr>
<td>• How the clients feels about their quality of life, health, relationships, financial situation and other areas of life</td>
</tr>
<tr>
<td><strong>Satisfaction questions</strong></td>
</tr>
<tr>
<td>• The clients satisfaction with the costs associated with the program and the program in general.</td>
</tr>
<tr>
<td><strong>Financial strain questions</strong></td>
</tr>
<tr>
<td>• The financial impact (if any) on the lives of the client, resulting from the fees associated with participating in the pharmacotherapy program</td>
</tr>
</tbody>
</table>

### Data collected from the pharmacists

The aim of this stream of data collection was to obtain information about the experience of pharmacists participating in the trial to obtain objective evidence about the participation in treatment of their clients.

Information collected included the characteristics of their practice and satisfaction with the funding arrangements for the pharmacotherapy program and the trial. Pharmacies were also asked to provide data to the trial on the attendance and compliance rates of the individual clients that were recruited into the trial through the provision of dosing data on a monthly basis.

### Data collected as part of the activity based costing study

The aim of this stream of data collection was to obtain a comprehensive snapshot of the way in which pharmacists deliver the service and the costs associated with the delivery of the service.

Data were collected via an observational study undertaken in a mix of 20 pharmacies across three states. Pharmacies were selected for the observation study based on a random sample of 20 pharmacies already consented to the trial from the east coast states of Australia (NSW, VIC and QLD), to represent both PhARIA and client numbers per pharmacy in a similar fashion to that represented in the overall trial.

The principle data were obtained through systematic observational sessions in each pharmacy lasting two to three hours, using standardised observational capture tools, during and around peak supply times over a three day period. The observational data collection tool was developed to ensure that the researchers were recording information in a consistent manner. The tool was piloted and refined based on observations in two volunteer pharmacies who were not participating in the trial.

A research team member observed every pharmacotherapy treatment client who presented for treatment during the three observation periods in the pharmacy. The researcher recorded the time for activities directly associated with each client who attended for treatment. At the end of each observational period, other activities (either having taken place before observation or to take place after observation) relating to each client who had presented during the period, were also recorded through self report of the pharmacist. Those activities not directly associated with an individual client, but relating to the overall delivery of the pharmacotherapy program (eg ordering, storage) were also obtained by self report from the pharmacist. Similarly estimates for the costs of infrastructure and consumables relating to the program were obtained by self-report from the pharmacist.
3. Who participated in the trial

A total of 79 pharmacies were consented to the trial. Of these pharmacies, 74 actively participated in the trial (that is, recruited clients and provided data to the trial) and 72 pharmacies completed the trial.

There were 25 pharmacies in the control group and 49 in the intervention group at the outset of the trial, with 24 control and 48 intervention pharmacies completing the trial. Figure 2 illustrates recruitment and retention of pharmacies.

Data capture from participating pharmacies approached 100%.

Figure 2: Recruitment and retention of pharmacies

A total of 749 clients were recruited to the trial, of which 259 were allocated to the control group and 490 to the intervention group.

A total of 639 clients remained in the trial at six-months. A total of 110 clients had dropped out of the trial at six-months; 44 (18.3%) were control clients and 66 (14.0%) were intervention clients. Of the 110 clients who dropped out, follow-up data was obtained on 83 (75.0%).

From the follow-up data it was identified that of the clients who had dropped out of the trial, 15 (14.6%) had successfully come off the program over the six-month period and 49 (47.6%) were identified has having transferred to another pharmacy. This indicates that of the 749 clients who started in the trial, 703 (93.9%) remained in treatment at the end of the trial.

It was identified that 37 clients had insufficient data at baseline to be included in the analysis of trial data. This resulted in 712 (95.0%) clients being included in the trial for analysis purposes (240 in the control group and 472 in the intervention group).

Figure 3 illustrates the recruitment and retention of clients during the trial period.
Figure 3: Recruitment and retention of clients

749 clients consented

- 259 clients in control group
- 490 clients in intervention group
- 37 clients had insufficient baseline data to be included in trial analysis

712 clients (for analysis purposes)

- 240 control clients
- 196 control clients remained at month 6
- 44 clients dropped out (18%)

- 472 intervention clients
- 406 intervention clients remained at month 6
- 66 clients dropped out (14%)

A full description of recruitment and retention of pharmacies and clients is outlined in Section 6.1 of the Final Full Report.

Client demographics are outlined in Section 5.2 and pharmacy demographics in Section 6.2 of the Full Final Report.
4. What are the benefits of a nationally consistent client subsidy for pharmacotherapy clients?

Maximising the health benefits from treatment of opioid dependence is reliant on a number of factors to do with the effectiveness of the pharmacotherapy used, its accessibility and its attractiveness to the target group. A key factor in the ability to retain these clients in treatment, provide long-term care and achieve health benefits is the affordability of the treatment. Affordability of treatment is one of the most discussed issues for pharmacotherapy programs in Australia.

In community pharmacies across Australia, clients are required to self-fund the cost of treatment to varying degrees. The inability of this client group to pay is well documented, particularly for those who are low income earners. Moreover, low income earners dominate this client group. Among opioid users entering treatment in Australia, the literature states that only one in six (17.0%) listed a wage as their main source of income, most existing on social security payments (Ross et al., 2005).

The focus of the present study was to consider key elements of a national funding model for pharmacotherapy treatment in community pharmacy. A key plank of the funding model was to improve affordability for the client group, through a nationally consistent subsidy of the treatment cost for clients (details of the funding model are outlined in Table 1). A primary objective of this study was to evaluate the benefits of the client subsidy in terms of impacts on key client outcomes, alongside a better understanding of the costs and service provided by the pharmacy.

4.1. What are the costs of participating in pharmacotherapy treatment for clients in the community pharmacy setting?

As a starting point for understanding the inputs to a national funding model, this study collected information about the current cost of pharmacotherapy treatment, from the perspective of clients, of obtaining treatment in community pharmacy settings around Australia.

In line with previous reports, income for the cohort participating in the trial was modest. The main source of income for approximately half the cohort was a pension (52.5%) and 21.6% were in some form of employment. Approximately 40.0% of all clients earned between $250 and $399 per week and 20.6% between $150 and $249 per week.

Information was obtained at the outset of the study from all participating pharmacies about the fees that were charged to their clients, per day, for participating in the program at their pharmacy. These data were collected prior to the recruitment of clients to the trial and therefore do not include the client subsidy.

The fees which pharmacists reported their clients were being charged per day varied considerably within the three types of pharmacotherapies (Methadone, Subutex and Suboxone). The costs ranged from $1.43 to $10 per dose. There was little variation in cost across the type of pharmacotherapy and the variation by jurisdiction did not appear to be particularly systematic. The overall median cost per day to the client ranged from $4.65 to $5.00 across Methadone, Subutex and Suboxone.

Intervention pharmacies were asked to provide detail on what they charged their clients per week (on average), after the $15 per week client subsidy had been applied. All pharmacies had been informed at baseline that their clients should be charged a minimum of $5 per week. Three pharmacies reported that they did not charge their clients anything for their doses; the three pharmacies had a total of six clients participating in the trial. These pharmacies tended to be located in rural and remote areas. Table 2 outlines the average cost to the client per week for the supply of their pharmacotherapies, after the client subsidy had been applied.
Table 2: Average cost per week of client payments for intervention clients – after the application of the $15 per week client subsidy

<table>
<thead>
<tr>
<th>State</th>
<th>Pharmacies (N)</th>
<th>Mean</th>
<th>Std deviation</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>New south Wales (NSW)</td>
<td>15</td>
<td>$16.27</td>
<td>$6.81</td>
<td>$0</td>
<td>$27</td>
</tr>
<tr>
<td>Northern Territory (NT)</td>
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<td>$15</td>
<td>$15</td>
</tr>
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<td>$9.39</td>
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<td>$20</td>
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<tr>
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<td>$4.83</td>
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<tr>
<td>Western Australia (WA)</td>
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<td>$10</td>
<td>$35</td>
</tr>
<tr>
<td>South Australia (SA)</td>
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<td>$0.00</td>
<td>.</td>
<td>$0</td>
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</tr>
<tr>
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<td>$3.66</td>
<td>$7.75</td>
<td>$0</td>
<td>$35</td>
</tr>
</tbody>
</table>

It is widely acknowledged that there are significant differences in the level of fees paid by clients, both across and within jurisdictions. The variation is due to both differences in state and territory regulations and structures, along with the credit and payment policies set within individual pharmacies. The data obtained in this study corroborates previous findings of variation in cost and the low income status of a large proportion of the client group. Further detail on the findings relating to the costs to client can be found in Section 5.9 of the Full Final Report.

4.2. The impact of the implementation of the nationally consistent client subsidy for clients

Evaluation of the impact of the nationally consistent client subsidy trialled in this study was undertaken through a comparison of the experience of the intervention group, who received the subsidy, and the control group who did not receive the subsidy. The evaluation approach capitalised on the strength of the RCT methodology, which randomly allocates, all but the key treatment variable (in this instance the client subsidy), across both groups.

Four key client health outcome areas were measured: retention in treatment; compliance with the treatment regimen; ongoing harmful health related behaviours such as drug and alcohol use; and self reported health and social outcomes. In addition, client satisfaction with the subsidised arrangement was considered a key outcome, and as such was also evaluated.

Impact on retention in treatment

Retention in treatment is the major variable used by all commentators to assess the effects of pharmacotherapy treatment, as it is the best single predictor of treatment success.

Clients reported at the outset of the trial how long they had been in their current treatment (Table 3). Approximately 30.0% of the cohort had been in treatment between one to three years, while 23.94% of clients had been in treatment between five to ten years and 21.7% of clients had been in treatment for more than 10 years. This indicates that clients in the trial were relatively stable in terms of their treatment, with only a small proportion having been in treatment for less than a year.
### Table 3 Number of years client's had been in their current treatment

<table>
<thead>
<tr>
<th>Number of years in current treatment</th>
<th>All clients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N*</td>
</tr>
<tr>
<td>Less than 1 year</td>
<td>34</td>
</tr>
<tr>
<td>1 to 3 years</td>
<td>147</td>
</tr>
<tr>
<td>3 to 5 years</td>
<td>87</td>
</tr>
<tr>
<td>5 to 10 years</td>
<td>118</td>
</tr>
<tr>
<td>10 to 15 years</td>
<td>57</td>
</tr>
<tr>
<td>15 to 20 years</td>
<td>33</td>
</tr>
<tr>
<td>More than 20 years</td>
<td>17</td>
</tr>
</tbody>
</table>

*Missing = 219

In the trial, client retention was measured using the monthly client dosing data provided by pharmacists, which was substantiated by the drop-out data provided by the jurisdictions. The study showed that retention of clients in pharmacotherapy treatment was high for the entire cohort participating in the trial. In all, 86.0% of intervention clients and 81.7% of control clients remained in treatment over the duration of the trial. There was a clear trend towards higher retention in the intervention group, although this did not reach statistical significance.

In fact, retention in treatment was potentially higher than the rate reported above. The main reason for clients leaving the trial (from either group) was transferring to another pharmacy or program. Moreover, fifteen clients were identified as having finished the program successfully over the six-month trial period. The client subsidy trialled did not significantly influence the high retention levels of the clients in the study. The study did find that age was found to be significantly associated with retention (p=0.0020), indicating that the older the client, the more likely they were to stay in treatment. Further detail on the findings relating to client retention can be found in Section 5.3 of the Full Final Report.

**Impact on compliance with treatment regimen**

Client compliance with their treatment regimen is another important and often cited measure of treatment impact. The effectiveness of pharmacotherapy treatment is critically dependent on staying in and complying with treatment on a long-term basis. Compliance with the treatment regimen was measured using the monthly client dosing data provided by pharmacists and examined the frequency of doses provided by the pharmacy, from which a missed dose could be identified. The study found that compliance for both groups was very high, with small increases observed in both groups, over the six-months of the trial:

- **Control group:** compliance with doses was 94.3% at month one and 97.6% at month six.
- **Intervention group:** compliance with doses was 94.5% at month one and 96.7% at month six.

The client subsidy did not significantly influence compliance with doses, in that there were no statistically significant differences found between the intervention and control groups, either at the outset of the trial or over time.

However, these findings do indicate that they were a stable cohort in terms of their compliance and had a low risk of becoming unstable. As described previously, a large proportion of clients had been in long-term treatment and this stability in treatment may have resulted in a cohort of high functioning clients. Further detail on the findings relating to client compliance can be found in Section 5.4 of the Full Final Report.
Impact on drug and alcohol use and related behaviours

An important impact of effective treatment for opioid addiction is the reduction in other harmful health related behaviours. Evidence which has accumulated from randomised controlled trials shows that while on pharmacotherapy treatment there is a marked and sustained reduction in injecting opioid use by clients (Mattick, Breen et al., 2004, 2008). Client drug and alcohol use and related behaviours were measured in the trial using the BTOM-C which formed part of the client survey, administered at baseline and six-months. The key findings relating to drug and alcohol use and related behaviours were:

- At baseline, both groups reported:
  - for the overwhelming majority of clients in the trial, heroin was the drug which had led them to seek treatment and injecting was the main method of taking the drug
  - similar and reasonably low levels of harmful behaviour, such as injecting, overdosing, drug using days and polydrug use were evident
  - both groups reported consistent use of non-illicit drugs, with clients in both groups reporting smoking reasonably heavily and drinking alcohol beyond recommended levels on most days.

- At the end of the trial:
  - the low levels of harmful behaviour reported at baseline were maintained across the trial period, with few differences between groups
  - alcohol consumption did not change for either group.

Overall, there was little influence of the client subsidy on drug and alcohol and related behaviours across the period of the trial. At the same time, it must be acknowledged that both groups were functioning at high levels on many of the key measures used – that is drug related behaviours – and particularly so in the context of this client group. Further detail on the findings relating to drug and alcohol use and related behaviours can be found in Section 5.5 of the Full Final Report.

Impact on health and social outcomes

As already discussed, pharmacotherapy treatment has proven to be a highly effective means of treating illicit opioid drug dependence. Over 20 years of research have demonstrated that pharmacotherapy treatment reduces illicit opioid use, reduces criminal behaviour, improves health and improves psychosocial functioning. The impact of the client subsidy on such outcomes was, therefore, a focus of the trial.

Client health and social outcomes were measured in the trial using the BTOM-C and the WHOQoL-8, which formed part of the client survey administered at baseline and the six-month follow-up. The key results relating to health and social outcomes were:

- At the outset of the trial, both intervention and control clients reported reasonably high levels of health and social functioning.

- A minority of clients in each group reported that financial problems or conflict problems with relatives or others were common for them.

- The vast majority of clients reported that they were not living with other drug users and that they had no arrests in the last three months.

- Overall, there were no significant differences in social functioning over time, or between the control and intervention groups - social functioning remained high for both groups.

- At the outset of the trial 40.3% of the control group and 40.9% of the intervention group described their overall quality of life as being ‘good’. There were no significant differences in quality of life over time.
between the control and intervention groups, with quality of life remaining reasonability high for both groups.

Overall, there was a high level of functioning in the study cohort at the outset of the trial, and this remained the case at the end of the trial, with no differences between the groups. The client subsidy did not significantly influence these outcomes. On the other hand, it is plausible to suggest that high levels of functioning, reflecting retention in an effective treatment regimen, created something of a ‘ceiling effect’. Further gains in global outcomes – such as quality of life for example – become more difficult to achieve from the already high levels observed at baseline. Further detail on the findings relating to health and social outcomes can be found in Section 5.6 of the Full Final Report.

Impact on client satisfaction

As discussed, the very clearly demonstrated benefits to be gained from pharmacotherapy treatment for opioid dependence rely very critically on the ability to retain these clients in treatment and provide long-term care. It was of interest in this trial to understand the impact of the client subsidy on their perceptions of treatment. Another relevant proxy measure for the attractiveness of the pharmacotherapy program was client satisfaction overall with the program and with the payments that are required of them to remain in treatment.

At baseline, the majority of clients in both groups (59.2% of control clients and 53.9% of intervention clients) reported being ‘dissatisfied’ or ‘very dissatisfied’ with the fees they were charged for their doses. Just under one third of clients (27.2% control and 31.9% intervention clients) reported being ‘satisfied’ or ‘very satisfied’ with the fees.

At the six-month follow-up, there was a dramatic change in the reported levels of satisfaction with the payments required for treatment. As at baseline, about a third of control clients (30.9%) reported that they were ‘satisfied’ or ‘very satisfied’ with the fees at the end of the trial. In contrast, over a half of intervention clients (53.1%) reported that they were ‘satisfied’ or ‘very satisfied’ with the fees. Satisfaction levels with client payments was significantly higher, having nearly doubled, for those clients receiving the subsidy ($p=<.0001).

The level of client subsidy trialled had a significant impact on overall satisfaction with the program. While satisfaction is only a proxy measure for the treatment attractiveness, the finding does raise the potential influence of the subsidy on the client’s decision to remain in treatment. Remembering that the sample participating in the trial had already made the decision to pay the fee, it is worth positing that those opioid users not already in stable treatment might also be positively influenced to enter/remain in treatment if the co-payment system were in place. Further detail on the findings relating to client satisfaction can be found in Section 5.8 of the Full Final Report.

4.3. What is the impact of affordability for clients?

As previously discussed, income data generally indicate that most illicit opioid users are poorly placed to pay any significant amounts towards the costs of their treatment. The trial was designed on the premise of a nationally consistent client subsidy for those in community pharmacy pharmacotherapy programs, based on the strength of the debate which argues that a client subsidy improves affordability of treatment.

To a large extent the premise of the trial, a nationally consistent client subsidy to improve affordability, is difficult to implement in the current Australian context. As previously discussed, the fees paid by clients participating in pharmacotherapy treatment in a community pharmacy setting are highly variable – by jurisdiction and by pharmacy. Accordingly, a uniform client subsidy ($15 per week for each client) has a highly variable offsetting impact in line with the variable level of cost to individual clients. The impact of the client subsidy on affordability, therefore, is likely to be inconsistent due to the variable cost borne by the client to remain in treatment.

In order to further analyse the question of affordability, even though it was not a key focus of the trial, the absolute level of client payments borne by the cohort was considered, regardless of whether a client subsidy was received or not. Using the information provided by the pharmacists, it was possible to re-configure the
trial participants into a single cohort, ranked by the costs that their pharmacist reported charging for the program, with the assumption that each client is charged similarly within the same pharmacy. This analysis provided a way to systematically differentiate clients based on the client fees.

Compliance was re-analysed by cost of pharmacotherapies based on the total average cost of methadone, suboxone and subutex per pharmacy, per week (calculated and categorised into three groups based on tertiles of cost, excluding the $15 per week client subsidy provided to the intervention clients):

<table>
<thead>
<tr>
<th>Cost group</th>
<th>Tertile of cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low cost group</td>
<td>Up to $29.80 per week</td>
</tr>
<tr>
<td>Medium cost group</td>
<td>Between $29.81 to $42.50 per week</td>
</tr>
<tr>
<td>High cost group</td>
<td>Greater than $42.50 per week</td>
</tr>
</tbody>
</table>

By considering the compliance data as a function of absolute level of client payments, a significant difference was found between the low cost group and high cost group (p=0.005) for compliance with doses.

Specifically, the level of costs associated with client fees was found to have a significant impact on a client's compliance with their doses. Those clients who were paying less than an average of $29.80 per week were more likely to be compliant than those who were paying more than $42.50 per week in fees, regardless of whether they were in the intervention or control group.

This finding indicates three things very clearly:

- First, a nationally consistent client subsidy, like that implemented in the trial, was unlikely to have had a uniform impact on affordability for all clients.
- Second, the specific level of client subsidy may not have been sufficient to improve compliance among clients at the higher end of the cost spectrum.
- Third, the cost actually incurred by clients participating in the trial, quite apart from whether they were in the intervention or control group, had a significant impact on their compliance with treatment, which is in line with previous research.

Taken together, these three findings point to the importance of addressing the cost and affordability of treatment on the client as part of a national funding model.

4.4. Summary

The focus of the present study was to consider key elements of a national funding model for pharmacotherapy treatment. A key plank of the funding model was improved affordability for the client group, through a nationally consistent subsidy of the treatment cost. The benefits of the implementation of a nationally consistent client subsidy, in terms of impacts on key client outcomes, need to be considered against the background of the variable cost of participating in the pharmacotherapy program in community pharmacies in Australia.

Overall, the findings of this national trial lend weight to the impact of affordability as a determinant of treatment outcome. A clinically non-trivial improvement in retention (around 5% improvement) was observed as a consequence of receiving the client subsidy. The trend towards improved retention was corroborated by significantly higher satisfaction with the program among intervention clients, compared with control clients. The level of cost associated with client payments for treatment had a significant impact on client compliance with their dosing regime. Taken together, the findings indicate that not all clients can afford the costs associated with pharmacotherapy treatment, and that a subsidised arrangement as part of a national funding model is likely to reap greater benefits from the program.
5. The role of and the cost to community pharmacies in the provision of pharmacotherapy treatment

5.1. The role of community pharmacies in the provision of pharmacotherapy treatment

As described previously, the community pharmacy sector has taken a prominent role in the provision of pharmacotherapy treatment over the past 20 years. Service provision through community pharmacies has become a critical part of the successful reach of treatment, with the capacity to increase client numbers.

On the other hand, the challenges to realising the available capacity of the sector to participate in service provision have been well documented. In Australia, research has shown that there is a high rate of bad debt amongst consumers (A. Winstock, Lea, & Molan, 2008), with over 70.0% of pharmacies reporting that they provide credit to clients and one-quarter of the 407 community pharmacies responding to the survey indicating that they had clients in debt. Additional problems associated with behavioural disinhibition and aggression among clients, shop-lifting and general dislike of the clientele also reduce pharmacists’ enthusiasm for involvement in the pharmacotherapy program. The participation of community pharmacy in the provision of pharmacotherapy treatment undoubtedly reflects a range of motivations, including client care and community service, but also for a fee for the provision of the service.

The trial implemented a two-pronged nationally consistent subsidised environment – a subsidy for client payments and an incentive for the pharmacists in the intervention group (as outlined in Table 1). A central objective of the study was to consider the impact of the implemented subsidised and incentivised environment on participating pharmacists, and to consider this impact against the background of understanding the provision of pharmacotherapy treatment in the community pharmacy setting.

The starting point for understanding the impact of the subsidised and incentivised environment on pharmacists was an observational study. The observational study collected data about the way in which pharmacotherapy services are delivered and the costs associated with the delivery of the services.

The process map in Figure 4 (page 18) provides an overview, in general terms, of the way in which pharmacotherapy treatment was found to be delivered across the observed 20 pharmacies. The process map demonstrates the diversity of the service that the community pharmacist provides and highlights that the service is user driven and there is a need for flexibility on the part of the pharmacist.

While there were variations in the way in which the activities outlined in Figure 4 were undertaken, it was clear that it was possible to identify broad categories of activities: (1) those involving direct client interaction; (2) those that were client related but not direct face-to-face interactions; and (3) business related back-end and administration activities that varied depending on the pharmacy’s business model.

From Figure 4, it can be seen that back-end business related activities included things like ordering, storage, record keeping and the like. Direct client interaction activities included pre-screening of the client to assess their eligibility for treatment on the day, or perhaps counselling the client. Indirect client related activities included pre-preparation of doses, inducting new clients and communication with other service providers. Perhaps most obviously from the process map, it can be seen that the process has a large number of variable steps and therefore the clinical judgement of the pharmacist is a key determinant of the interaction with the patient on any given occasion.

The process map in Figure 4, was also the basis of the design of the observational data capture tool used for the observational study.
For the purposes of data collection, analysis and reporting, the schema in the process map was classified into eight basic categories, all but one of the categories, administration, are client related activities:

- preparation of doses
- pre-screening the client
- recording of the doses
- dosing the client
- processing payments
- counselling / talking with the client
- administration activities
- other activities eg inducting new clients, communication with other providers etc

As already described in Section 2.2, 20 pharmacies across NSW, QLD and VIC participated in the observational study. Three observation periods, of approximately three hours each, were undertaken in each pharmacy and all activities associated with each client presenting in that time were timed and recorded. A total of 218 client presentations were observed in the study. Further detail on the observed time spent on each of the eight categorised activities, per client, are described in Section 6.4.2 of the Full Final Report.

On average, the greatest proportion of pharmacist time was devoted to clinical care delivery associated with the treatment. Approximately one fifth of the pharmacists' time was spent interacting and conversing with the client during the pre-screening of the client and the provision of counselling to the client. In total clinical activities - those relating to the delivery of the treatment pharmacotherapy (preparation of the dose, dosing the client) - together with counselling and pre-screening, accounted for around three quarters of the time spent by pharmacists in delivering the service.

The single most time consuming activity from the observational study was the ‘other activities’ category, reflecting the ad hoc nature of the needs of the clients that pharmacists are required to respond to in the community pharmacy setting. This finding is well corroborated anecdotally by pharmacists who report essential activities, which may unpredictably require additional time when a client has a crisis (eg coordinating with other healthcare and social welfare providers on behalf of the client).

The significant variability evident in both the process map and the time recorded in the observational study demonstrates an imperative need for flexibility in the provision of the pharmacotherapy program. The time spent by the pharmacist engaging with, supporting and interacting with this client group is key to retaining these clients on the program and a fundamental part of the service offered by community pharmacists participating in pharmacotherapy treatment. Variation due to changing client needs is an inherent part of the service delivery model.

The results of the observational study demonstrate that the time/cost drivers for the delivery of pharmacotherapy treatment in the community pharmacy setting are comprised of two separate variables that would need to be part of a national funding model - 'service delivery models' and 'levels of complexity' – both of which are driven by the needs of the client:

1. Service delivery models: six service delivery models were identified, reflecting three models of care which were underpinned by pharmacy business models (these are described in Section 5.2).

2. Levels of complexity: it was also identified that there was an unpredictable variation in the time per client interaction, related to the variable and unpredictable time that pharmacists need for counselling the client and coordinating with other healthcare and social welfare providers. We have called this a 'level of complexity' because it is analogous to the urgency/complexity features that characterise Emergency Care classification systems.

The data document that the time spent by the pharmacist engaging with, supporting and interacting with this client group is a fundamental part of the service offered by community pharmacists.

A robust national funding model, one that explains the variation in time spent / cost to deliver a pharmacotherapy service, will need to be an algorithm comprised of both a 'service delivery model' component and 'level of complexity' component.
Figure 4 Overview of the way in which pharmacotherapy treatment is delivered in the community pharmacy

- **Call jurisdiction to find out if client is registered**
- **Call pharmacy clinic the client was last dosed at to establish dosage**
- **Conduct client induction interview (phone and/or face-to-face)**
- **Update client records**
- **Call prescriber to discuss issue and update prescription**
- **Check script to ensure script is current and check dose**
- **Preparation of on-site dose**
- **Dose client**
- **Prepare TIA doses**
- **Hand over TIA doses**
- **Administration activities (checking payment schedules)**
- **Update daily drug register and client file and/or dosing sheet to record dose**
- **Processing payment**
- **Does the client require further counselling?**
- **Converse with client to discuss issues/problems with program, payment, or general wellbeing**

**Pharmacist tasks and end of day preparation**

- **Tally dispensary register**
- **Store away book**
- **Is client the last client of the day?**

**Client**

- **Induction of new client**
- **Is client under the influence of other drugs or medications? (Pre-screening)**
- **Delay until appropriate to resume process**

**Pharmacist activities directly related to the client**

- **Create new client file**
- **Check client script received in person by client or faxed by prescriber**
- **Is the client new to the pharmacy?**
- **Discussion with GP required?**
- **End**

**Notes**

- *Denotes observed variability in this process between pharmacies*
- TIA = Take away dose
5.2. **What are the costs associated with the provision of the pharmacotherapy program in community pharmacies?**

A key purpose of the observational study was to obtain robust estimates of the costs associated with providing the pharmacotherapy program in community pharmacies, though costing: (a) the provision of an occasion of service by the pharmacy (ie each client interaction); and (b) consumables and investments made specific to the program. The costs obtained in the study are based on the following factors:

- the amount of time involved in specific activities directly related to each client interaction
- the hourly cost of the pharmacist
- investments made and ongoing costs in delivering the program.

**Service delivery models**

From the observational study it was apparent that the fundamental processes between each pharmacy did not greatly differ. However two main dimensions resulted in systematic variation in the processes. These variations occurred regularly within individual pharmacies, rather than systematically varying by pharmacy.

The first dimension driving variation of process was clearly based on client health need, ie based on the type of treatment required. These can be best thought of as different treatment ‘models of care’, analogous for instance to home dialysis vs hospital dialysis. The data from the observational study revealed that there were three such discernable models of care for the delivery of pharmacotherapy treatment to clients in the community pharmacy. These models of care were based on whether:

- the client’s dose was taken in the pharmacy
- the client’s dose was a take-away
- the client had had a dose in the pharmacy and also received a take away dose.

These models of care were underpinned by the second dimension driving variation of process, the pharmacist driven business model, ie whether the doses were pre-prepared or not. While a range of other occasional variations were observed in business processes, these were not consistently observed across the pharmacies and therefore are not included in this analysis. For example: the use of a syringe or manually measuring doses, whether medication was stored back in the safe after each dosing event, or whether the client signed individual dosing sheets to record each dose. Figure 5 shows that the combination of models of care with business models resulted in six possible service delivery models, which together capture the observational data in a form suitable for cost analysis.

**Figure 5: Observed models of care, business models and resulting service delivery models**
Hourly costs

During the observational study, it became apparent that in most pharmacies the Pharmacist in Charge was responsible for the regular activities that were observed in the costing study. This is unsurprising, given the sensitive clinical nature of the pharmacotherapy program. The implication for the current analysis is that the rate used for the calculation of costs was based on the average base hourly rates for the Pharmacist in Charge level (Association of Professional Engineers, Scientists & Managers, Australia, 2009). The rate used was $47.53 per hour which included 25% on-costs to cover annual holidays, public holidays, sick leave, long-service leave and superannuation contributions.

The time spent on the service delivery models

Table 4 provides an overview of the average time spent by pharmacists in the delivery of each service delivery model. The models include the supply of all three types of pharmacotherapies: Methadone, Suboxone and Subutex.

Of the six models, Model 3 was not observed as part of the study. While not all the models were observed in all the pharmacies, when they did occur, they did not systematically vary by pharmacy. In other words, all models could potentially occur in all pharmacies participating in the observational study, and the same client could receive their dose in several different ways depending on the point at which their treatment was observed.

Moreover, data from the observational study indicates that quantum’s of time are logically and systematically associated with different care and business models. That is not to say that the time associated with service delivery models is invariant, or even similar across or within pharmacies. As outlined in Table 4, substantial variation was evident. However logical patterns of time to undertake different service delivery models are clear. For example, on average, models involving a combination of take away and in-pharmacy doses were the most time consuming. This is as expected, given the multiplicative clinical and administrative effort. Similarly, it would be expected that a model involving pre-preparation of doses would result in less time spent than a model involving preparation at the time of service; but that total time would be a function of the business approach in combination with the model of care required by the client at the time of service. These expectations are confirmed in the observations reported in Table 4. For example, Model 6, the service delivery model including an intensive model of care (in-pharmacy) and an intensive business model (take-away dose that was not pre-prepared), was the most time consuming model observed.

The observational study found that there are discernable service delivery models for delivery of pharmacotherapy treatment in community pharmacy. The implication of this finding is central. The data indicate that it is possible to descriptively classify systematic service delivery models in community pharmacies participating in the pharmacotherapy program. Understanding service delivery functions in this way is central to developing a nationally consistent funding model and provides a platform for associating systematic variation in delivery with a costing. The observational study demonstrates the complexity that will be required for a robust national funding model, ie there is wide variation between the costs associated with service delivery models.
Table 4: Average time spent by pharmacists in the delivery of each service delivery model, per occasion of service - based on time observed from the observational study

<table>
<thead>
<tr>
<th>Service delivery model</th>
<th>Number of pharmacies in which the model was observed</th>
<th>Number of observations on which this model was based*</th>
<th>Average time per client / occasion of service (mins)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Mean</td>
</tr>
<tr>
<td>Model 1</td>
<td>6</td>
<td>9</td>
<td>5.32</td>
</tr>
<tr>
<td>Model 2</td>
<td>19</td>
<td>99</td>
<td>14.57</td>
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<tr>
<td>Model 3</td>
<td>Model not observed</td>
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<td>7.25</td>
</tr>
<tr>
<td>Model 5</td>
<td>6</td>
<td>34</td>
<td>12.87</td>
</tr>
<tr>
<td>Model 6</td>
<td>11</td>
<td>65</td>
<td>19.86</td>
</tr>
</tbody>
</table>

* Four observations were excluded from the analysis

The cost of the service delivery models

Table 5 provides the average cost for each of the service delivery models. The cost of each service delivery model was calculated using the observed time spent on the regularly recurring activities (see Section 6.4.2 of the Full Final Report) and the average base hourly rates outlined earlier in this section.

The cost of each service delivery model clearly parallels the observed time, given that none of the service delivery models involves devolution of the activities to different staff, and is therefore a multiple of senior pharmacist time. The greatest average cost was associated with Model 6 at $16.60 per client/observation and Model 1 was the least expensive, which was on average, $4.21 per client/observation (see Section 6.4.3 of the Full Final Report).

On further investigation of the characteristics of the pharmacies who provided Model 1 and Model 2, which provided similar models of care - the only difference being whether the doses are pre-prepared or not, yet there was a substantial difference in cost – it was found that there were no key differences in the characteristics of these pharmacies (eg numbers of clients, PhARIA, State, pharmacotherapy type etc).

Table 5: Average cost, per client, of the provision of each service delivery model per occasion of service – based on time observed in the observational study and average base hourly rates for Pharmacist-in-Charge

<table>
<thead>
<tr>
<th>Service delivery models</th>
<th>Number of pharmacies in which the model was observed</th>
<th>Number of observations on which this model was based*</th>
<th>Average cost per client per occasion of service ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Mean</td>
</tr>
<tr>
<td>Model 1</td>
<td>6</td>
<td>9</td>
<td>4.21</td>
</tr>
<tr>
<td>Model 2</td>
<td>19</td>
<td>99</td>
<td>11.81</td>
</tr>
<tr>
<td>Model 3</td>
<td>Model not observed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Model 4</td>
<td>4</td>
<td>7</td>
<td>5.74</td>
</tr>
<tr>
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<td>34</td>
<td>10.20</td>
</tr>
<tr>
<td>Model 6</td>
<td>11</td>
<td>65</td>
<td>16.60</td>
</tr>
</tbody>
</table>

* Four observations were excluded from the analysis
The cost of consumables for the pharmacotherapy program

Table 6 provides an overview of the average cost, per client, for consumables for the provision of the pharmacotherapy program, as reported by the pharmacists who participated in the activity based costing study and identifies the cost of consumables, per client, for the provision of a dose. For the purposes of building the cost of consumables in the costing, it has been assumed that on average, a client will have five dosing points or occasions of service per week (with two take-away doses). Overall, the average total cost of consumables per client was $0.62 per occasion of service. Again the cost of consumables varied widely.

Table 6: Average cost, per client, of consumables per occasion of service – based on pharmacist self-reported data

<table>
<thead>
<tr>
<th>Consumable</th>
<th>Pharmacies (N)</th>
<th>Average cost, per client, of consumables per occasion of service ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bottles</td>
<td>18</td>
<td>Mean 0.31 Minimum 0.028 Maximum 0.6</td>
</tr>
<tr>
<td>Labels</td>
<td>20</td>
<td>Mean 0.092 Minimum 0.002 Maximum 0.708</td>
</tr>
<tr>
<td>Mugs</td>
<td>18</td>
<td>Mean 0.052 Minimum 0.01 Maximum 0.14</td>
</tr>
<tr>
<td>Cordial</td>
<td>8</td>
<td>Mean 0.03 Minimum 0.002 Maximum 0.066</td>
</tr>
<tr>
<td>Others</td>
<td>20</td>
<td>Mean 0.082 Minimum 0.002 Maximum 0.462</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>Mean 0.618 Minimum 0.098 Maximum 1.462</td>
</tr>
</tbody>
</table>

The total cost of the service delivery models based on pharmacist time and the cost of consumables

Table 7 provides the total average cost, per client, for each of the service delivery models including the cost of consumables. The costs presented in Table 7 are based on the average cost, per client, of the delivery each service delivery model plus the average cost of consumables per client.

These costs represent what it actually costs the pharmacist to deliver the service to clients in the community pharmacy (based on time spent by the pharmacist and the cost of consumables) and would need to be factoored into any future national funding model. Overall, the total average costs outlined in Table 7 indicate that the pharmacist incentive trialled in this study, of $15 per client per week, does not cover the costs of providing any one of the service delivery models, on a weekly basis.
### Table 7: Total average cost, per client, of the service delivery models and consumables per occasion of service – based on time observed in the observational study, average base hourly rates for Pharmacist-in-Charge and the average cost of consumables per dose

<table>
<thead>
<tr>
<th>Service delivery model</th>
<th>Number of pharmacies in which the model was observed</th>
<th>Number of observations on which this model was based</th>
<th>Average cost per client of service delivery model and consumable, per occasion of service ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model 1</td>
<td>6</td>
<td>9</td>
<td>Mean: 5.94 Std deviation: 6.75 Minimum: 1.87 Maximum: 18.04 Mean: 4.00</td>
</tr>
<tr>
<td>Model 2</td>
<td>19</td>
<td>92</td>
<td>Mean: 15.19 Std deviation: 10.41 Minimum: 2.87 Maximum: 32.62 Mean: 13.12</td>
</tr>
<tr>
<td>Model 3</td>
<td>Model not observed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Model 5</td>
<td>6</td>
<td>34</td>
<td>Mean: 13.49 Std deviation: 8.52 Minimum: 2.87 Maximum: 24.73 Mean: 14.61</td>
</tr>
<tr>
<td>Model 6</td>
<td>11</td>
<td>59</td>
<td>Mean: 20.48 Std deviation: 17.32 Minimum: 2.87 Maximum: 64.12 Mean: 18.62</td>
</tr>
</tbody>
</table>

*Four observations were excluded from the analysis*

### The cost of investments for the pharmacotherapy program

As part of the activity based costing study, pharmacists reported on the investments directly related to the delivery of the pharmacotherapy program that had been made in their pharmacy. These costs included, for example, a shop fit-out, equipment, software, security etc. They are noted for interest, although their place in a nationally consistent funding model is unclear and would need to be considered further. Pharmacists reported that:

- 50% had made investment costs of <$500
- 25% had made investment costs of $500-$2,000
- 25% had made investment costs of >$2,000.

### 5.3. What was the impact of trial for pharmacists?

As already discussed, community pharmacy plays a significant and critical role in the provision of pharmacotherapy treatment in Australia. While uptake has been impressive, unmet need for the services and untapped capacity in the sector have both been identified. An important part of a nationally consistent funding model needs to include consideration of any incentive from the perspective of the community pharmacy, in terms of meeting their needs. Accordingly, all participating pharmacists provided their views on the subsidised environment and incentive implemented as part of the trial. The views of pharmacists in the intervention group, where both the pharmacy incentive and the client subsidy were part of the funding model, were compared with those of the control pharmacies.

At baseline, there were no substantive differences between the control and intervention pharmacists, with both groups reporting low levels of satisfaction with the program overall and the financial arrangements in particular, although most reported good relationships with their clients.
In sharp contrast at the end of the trial, satisfaction levels among the pharmacists in the intervention group differed dramatically from those reported by the control group. At the end of the trial, intervention pharmacists reported:

- significantly greater overall satisfaction with the pharmacotherapy program: 92.5% of intervention pharmacies, compared with 55% of control pharmacies, reported that they were ‘satisfied’ or ‘very satisfied’ (p=0.0002)

- significantly greater satisfaction with the funding arrangements for the pharmacotherapy program: 92.9% of intervention pharmacies, compared with 40% of control pharmacies, reported that they were ‘satisfied’ or ‘very satisfied’ (p=0.0001)

- significantly greater satisfaction with the client contribution / co-payment: 83.3% of intervention pharmacies, compared to 45% of intervention pharmacies, reported that they were ‘satisfied’ or ‘very satisfied’ (p=0.0026).

The findings of the study indicate very clearly that the level of subsidy and incentive arrangements provided in the trial to participating intervention pharmacies and clients, significantly improved the satisfaction of pharmacists in relation to participation in the program. Further detail on the findings relating to pharmacy satisfaction can be found in Section 6.3 of the Full Final Report.

5.4. Summary

A key objective of this trial was to collect data about the way in which pharmacotherapy services are delivered, the costs associated with the delivery of the service and the satisfaction of community pharmacists with a nationally consistent subsidised environment. In the first instance, it was seen as desirable to develop an understanding of the service as delivered by community pharmacists, along with the true costs of the service provision.

First and foremost, the observational study indicated that the nationally consistent pharmacy incentive implemented for the trial, $15 per consented client per week, was unlikely to meet the costs of the provision of the service, even at its least costly estimate. Once the cost of consumables and investment in infrastructure was factored in, the likely shortfall of the implemented incentive was further highlighted.

The other key implication from the observational study is the ability to identify and describe relatively invariant service delivery models within community pharmacies participating in the pharmacotherapy program. These service delivery models varied by their nature, rather than by pharmacy habit. Gaining an understanding that service delivery functions in this way is central to developing a nationally consistent funding model. In addition, it was identified that there was unpredictable variation in the time taken per client interaction, which was a result of the responsiveness of the pharmacist to the needs of the client on any given day. This adds a level of complexity to the service which is analogous to the urgency/complexity features that characterise Emergency Care classification systems.

The findings from the observational study contribute significantly to the key considerations for a future funding model. Fundamentally, the observational study highlights the extent and the flexibility of client care delivered by community pharmacy, in terms of responsiveness to client need, client interaction and engagement. The high levels of retention and treatment compliance demonstrated in the trial attests to the value brought to the treatment environment, for this cohort, by community pharmacy.

Perhaps most importantly for consideration in a funding model is the impact on satisfaction of the subsidised and incentivised environment. Despite the fact that the pharmacy incentive provided in the trial was shown to be unlikely to cover the costs of providing the service, the satisfaction of pharmacists in the intervention group improved dramatically. One interpretation of this finding might be that, in the first instance, the positive impact on the dynamic of the care setting provided by the subsidised and incentivised environment (for example improved affordability), was in fact a key positive result.
6. **Key elements of a national funding model for pharmacotherapy treatment in community pharmacy: Implications of the national trial**

The present study trialled a nationally consistent funding model for the provision of pharmacotherapy treatment in community pharmacy. The funding model reflected two fundamental elements: improved affordability for clients through a subsidy of their treatment costs and improved incentives for pharmacists. The trial yielded three areas of findings central to providing recommendations concerning the key elements of a national funding model.

6.1. **Implementation of a nationally consistent funding model**

Contrary to previous research, the present study found that a reduction in client payments, through the nationally consistent subsidy of the treatment cost, did not result in a statistically significantly improvement in compliance with the treatment regimen, retention in treatment or broader health outcomes. The data showed that there was a high level of compliance and retention overall (a ‘ceiling effect’).

The study also found that the fees paid by clients participating in the pharmacotherapy program in a community pharmacy setting are highly variable – by jurisdiction and by pharmacy. Accordingly, a uniform client subsidy ($15 per week for each client in this instance) had a highly variable offsetting impact - in line with the variable level of cost to individual clients (‘affordability’).

Thus, a key finding of the study was the inherent difficulty of implementing a nationally consistent funding model in the Australian context. Given that context, the impact of any nationally consistent client subsidy on affordability is likely to be inconsistent because of the variable cost borne by the client to remain in treatment. The findings suggest that a key element of any future national funding model should be a client subsidy that takes into account the base cost of client payments, in order to achieve equitable financial impact across the client group.

6.2. **Subsidisation of client payments: the impact on affordability for treatment for clients**

The efficacy of pharmacotherapy treatment is very well documented and was not the primary focus of the present study. The primary focus was harnessing the full benefits of what is clearly a very effective treatment regimen. It is well accepted that the foundation of good treatment outcomes in pharmacotherapy treatment is the ability to retain clients in treatment and provide long-term care. The central construct underpinning the thinking behind subsidised treatment is that such arrangements increase affordability, and through that, increase access to and improve retention in treatment.

The study found that affordability is an important determinant of treatment outcome. While the uniform client subsidy did not significantly impact client outcome, the absolute level of client payments borne by the client did significantly impact outcome. The net weekly treatment cost (prior to the provision of the client subsidy) provided a way of differentiating clients based on the cost of treatment borne by them at an individual level. The level of cost associated with client payments for treatment had a significant impact on client compliance with their dosing regime, with higher cost being associated with significantly poorer compliance.

While the study did not set out to specifically examine the impact of treatment affordability on client outcomes, the tipping point for net cost of treatment to have an impact, was evident in the findings. Those clients who were paying less than an average of $29.80 per week were significantly more likely to be compliant with the treatment regimen than those who were paying more than $42.50 per week in fees.

Taken together, the findings indicate that affordability significantly impacts the ability of clients to maintain their treatment regimen in the pharmacotherapy program and that a subsidised arrangement, as part of a national funding model, is likely to reap greater benefits from the program. More specifically, the findings
suggest that a key element of a national funding model would be to consider the real impact of any flat client subsidy and/or possibly the case for means testing low income earners. The present results suggest that those in the top two thirds of the cost spectrum, that is where cost is greater than $29.80, are at increased risk of being unable to maintain treatment.

6.3. Reimbursement of pharmacies: how the service is delivered and the associated costs

The observational study identified relatively invariant service delivery models in community pharmacies participating in the pharmacotherapy program. In all, six service delivery models were identified, with two main dimensions driving the precise characteristics of the service delivery model.

The first dimension reflected client health need, based on the type of treatment required. These can be best thought of as different treatment ‘models of care’, based on whether the treatment regimen required in-pharmacy, take-away or some combination of treatment approaches. These models of care were found to be underpinned by a core component of the pharmacist driven business model, namely whether the doses were pre-prepared or not. The combination of models of care with business models resulted in six possible service delivery models. Moreover, data from the observational study indicated that the quantum of time for service delivery was logically and systematically associated with different care and business models.

A second key finding of the observational study was the extent and the flexibility of client care delivered by community pharmacy in terms of responsiveness to client need, client interaction and engagement. In particular, it was identified that there was unpredictable variation in the time taken per client interaction, which was a result of the responsiveness of the pharmacist to the needs of the client on any given day. This adds a level of complexity to the service which is analogous to the urgency/complexity features that characterise Emergency Care classification systems. The high levels of retention and treatment compliance obtained attests to the value brought to the treatment environment, for this cohort, by community pharmacy. The observational study corroborated much anecdotal evidence concerning the need for flexibility in practice to meet the needs of this high need client group.

Gaining an understanding that service delivery functions this way (i.e. there are both service delivery models and levels of complexity) is central to developing a national funding model. The data indicate that it is possible to descriptively classify systematic service delivery models in community pharmacies participating in the pharmacotherapy program. These data provide a platform for associating systematic variation in service delivery with a costing, analogous to more or less complex procedures, as the basis for costing as in other areas of healthcare delivery, e.g. emergency care. The observational study demonstrated the complexity that will be required for a robust national funding model. That is, there is wide variation between the time/costs associated with the service delivery models and the complexity of the client group across the sector, which will need to be considered further.

The observational study also suggests that the pharmacy incentive implemented in the trial, $15 per consented client per week, was unlikely to meet the costs of the provision of the service, even at its least costly estimate. Once the cost of consumables, and investment in infrastructure was factored in, the likely shortfall of the implemented incentive was further highlighted.

A premise for the present study was that a national funding model needs to incorporate some level of incentive for pharmacists as a key element, to retain existing service providers and to attract new pharmacies into the program. Despite the fact that the incentive provided in the trial was shown to be unlikely to cover the costs of providing the service, the satisfaction of pharmacists in the intervention group improved dramatically. From a national funding model’s perspective, this suggests that incentives for participating pharmacies do not entirely depend on precise reimbursement, and that the improved environment under the subsided and incentivised arrangements may also contribute to service provider satisfaction.
6.4. Strengths and limitations of the Study

The great strength of this study was its design and the successful implementation of that design. The randomised controlled trial methodology provides the gold standard in health care research because of the ability to attribute influence specifically to the study factors – in this instance the impact of being in the intervention or the control group. The strength of the study design was supported by extremely complete data being collected from all participating pharmacies and clients.

The main limitations of the study emanate from the observational study. While the study was entirely robust within the parameters of the data collected, the sampling of observations was potentially incomplete. A decision, in collaboration with the Advisory Group, was taken to include three observation periods in each pharmacy at peak supply periods. The impact on pharmacy practice of different times of the day, different days of the week and simply having more observation periods are all unknown. However, the likely impact of these limitations relate to the distribution of different service delivery models: Which are most common? When are they most common? These and similar questions would be answered by more complete sampling. From the perspective of the study objectives however, to evaluate key elements of a national funding model for pharmacotherapy treatment, the findings remain robust. They demonstrate that several discernable and systematic service delivery models are in place to provide the service and that differing levels of pharmacy effort and cost are associated with the different models.

6.5. Recommendations for key elements of a national funding model

This study has reported new data that are critical to the design of a national funding methodology for the provision of pharmacotherapy treatment in the community pharmacy. It has identified the key elements of a national funding model, as outlined below.

Client subsidy element

- Affordability is a significant determinant of treatment outcome and a subsidised arrangement, as part of a national funding model, is likely to reap greater benefits from the program.

- The precise level of the client subsidy will need to consider ‘real’ financial impact, given the variability between jurisdictions in client payment costs.

- The high frequency of financial disadvantage in this client cohort suggests a case for some sort of means testing for low income earners.

- The study results suggested that net treatment costs greater than $29.80 are associated with increased risk of being unable to maintain treatment.

Pharmacist service incentive element

- The funding model needs to incorporate some level of incentive for pharmacists, to improve their satisfaction with the program and attract new pharmacies into the program.

- In developing the service incentive, the ‘true’ costs of the delivery of the pharmacotherapy program in the community pharmacy needs to be factored in, recognising that discernable service delivery models exist and that these have systematically varying costs associated with them.

- In developing the service incentive, the flexibility and variable time commitment required to meet the complexity of and health needs of the pharmacotherapy consumer population needs to be factored in.

Pharmacy consumables reimbursement element

- Consumables were found to be an important cost element in providing the service and should be factored into a national funding model.
References


## Appendix A: Trial sampling framework

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<th>VIC</th>
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<td>2</td>
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<td>Pharmacies &lt;20 clients</td>
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<td>164</td>
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<td>83</td>
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<td>Pharmacies &gt;20 clients</td>
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<td>132</td>
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<td>134</td>
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<td>64</td>
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<tr>
<td><strong>Total</strong></td>
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Appendix B: Pharmacy and client data collection methods
## Data collection method

<table>
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<tr>
<th>Data collection method</th>
<th>Description</th>
<th>Timing</th>
<th>Response rate</th>
</tr>
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<tbody>
<tr>
<td><strong>Pharmacy level data</strong></td>
<td><strong>Pharmacy information form</strong></td>
<td>The pharmacy information form collected core information on pharmacies such as: type of pharmacy (eg banner, independent etc); pharmacy location; number of clients the pharmacy is authorised to supply to; number of clients on the program; and client fees charged.</td>
<td>Baseline</td>
</tr>
<tr>
<td></td>
<td><strong>Pharmacy satisfaction survey</strong></td>
<td>The pharmacy satisfaction survey was designed to ascertain the pharmacist’s satisfaction with the pharmacotherapy program and the trial in relation to: financial arrangements; client contribution; interactions with clients; trial subsidy; and trial participation.</td>
<td>Baseline</td>
</tr>
<tr>
<td></td>
<td><strong>Activity based costing study</strong></td>
<td>The key component of the activity based costing study was an observational component undertaken in a mix of 20 pharmacies across NSW, QLD and VIC. Time was recorded for activities directly associated with each client who presented for dosing and those activities not directly associated with an individual client, but relevant to the overall delivery of the program (eg ordering, storage). It also included the collection of data on the cost of consumables and infrastructure specifically related to the delivery of the program. Further information on the study is in Appendix B.</td>
<td>Mid trial</td>
</tr>
<tr>
<td><strong>Client level data</strong></td>
<td><strong>Client survey</strong></td>
<td>The client survey was based on the Brief Treatment Outcome Measure – Concise (BTOM-C) and included the World Health Organisation Quality of Life-8 scale (WHOQoL-8), financial strain and satisfaction questions. The survey was administered at baseline and end of trial to clients via a telephone survey, which was undertaken by Roy Morgan Research.</td>
<td>Baseline</td>
</tr>
<tr>
<td></td>
<td><strong>Client dosing data</strong></td>
<td>Pharmacies were required to provide client dosing data on a monthly basis and included the following information: number of days in a month; whether the client was provided with a regular dose, takeaway dose, double/triple dose or missed their dose; and dosage strength.</td>
<td>Monthly</td>
</tr>
<tr>
<td></td>
<td><strong>Client drop-out data</strong></td>
<td>Clients were able to be identified as a drop-out from the trial from the monthly dosing data. There were three methods utilised for following up client drop-outs: (1) Pharmacists were asked to provide a reason for trial drop-out, if known; (2) clients who participated in the end of trial survey were asked why they were no longer on the program; and (3) data was requested from the jurisdictional health authorities to identify whether the client had moved pharmacy or had left the program.</td>
<td>Point of drop-out</td>
</tr>
</tbody>
</table>