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NSW Community Pharmacy Survey
SWAT Report 2

NDARC Technical Report No. 297

NEW SOUTH WALES COMMUNITY PHARMACY PRACTICE SURVEY SWAT REPORT 2

Adam Winstock, Toby Lea and Jill Molan

Technical Report Number 297

Funded by Mental Health and Drug & Alcohol Office, NSW Department of Health
Administered through Drug Health Services, Sydney South West Area Health Service

ISBN: 978 0 7334 2695 7

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Abbreviations

AGPN	Australian General Practice Network (formerly ADGP)
AHS	Area Health Service
AIVL	Australian Injecting and Illicit Drug Users' League
GP	General Practitioner
HMR	Home Medicines Review
IDU	Injecting drug user(s)
MHDAO	Mental Health and Drug & Alcohol Office, NSW Health (formerly Centre for Drug and Alcohol)
NSP	Needle and Syringe Program
NSW	New South Wales
NUAA	NSW Users and AIDS Association
NUM	Nursing Unit Manager
OTP	Opioid Treatment Program
PIS	Pharmacy Incentive Scheme
PSA	Pharmaceutical Society of Australia
PSB	Pharmaceutical Services Branch, NSW Health
SD	Standard deviation
SWAT	State-Wide Advisory Team: Drug Health Streamed Shared Care
TGA	Therapeutic Goods Administration

NSW Area Health Services

GSAHS	Greater Southern Area Health Service
GWAHS	Greater Western Area Health Service
NCAHS	North Coast Area Health Service
NSCCAHS	Northern Sydney/Central Coast Area Health Service
HNEAHS	Hunter/New England Area Health Service
SESIAHS	South Eastern Sydney/Illawarra Area Health Service
SSWAHS	Sydney South West Area Health Service
SWAHS	Sydney West Area Health Service

Acknowledgements

We would like to thank the following people for their assistance throughout the various stages of this project:

- Si Banks, President, Pharmacy Guild of Australia (NSW Branch)
- Nicky Bath, Manager, Alcohol and Other Drugs Program, AIDS Council of NSW (ACON)
- Denis Leahy, Vice President, Pharmacy Guild of Australia (NSW Branch)
- Annie Madden, Executive Officer, Australian Injecting and Illicit Drug Users' League (AIVL)
- Janelle Quinn, Pharmacy Liaison Officer, Pharmacy Guild of Australia (NSW Branch)
- Associate Professor Janie Sheridan, School of Pharmacy, Faculty of Medical and Health Sciences, University of Auckland

Finally, thank you to the community pharmacists throughout NSW who took the time to participate in the survey.

Summary

The State-Wide Advisory Team (SWAT): Drug Health Streamed Shared Care was established in 2005 by Drug Health Services, Sydney South West Area Health Service and NSW Department of Health for the purpose of mapping, consulting and supporting opioid pharmacotherapy services, including treatment provision at community pharmacies across New South Wales (NSW). Specifically, SWAT had the objective of building capacity within existing specialist and community resources for the management of those with drug and alcohol problems, initially for those with opioid dependence.

This report presents the findings of the *NSW Community Pharmacy Practice Survey* conducted by SWAT during 2006. This survey was the first of its kind conducted in NSW in that it explored not only practical issues of treatment delivery, but also identified barriers to treatment expansion and problems experienced with both prescribers and clients.

Consultations with Area Health Services (AHS) and the NSW Pharmacy Guild revealed wide variation in the availability of community pharmacy dosing places across metropolitan, regional and rural NSW. Public clinics also varied widely in their practice regarding the transfer of clients from public clinic to community pharmacy dosing. Initial work by the SWAT project (*Pharmacy Capacity Survey*, SWAT, 2006) identified a large number of unfilled community pharmacy dosing places across NSW. Their under-utilisation in many cases was in part explained by a lack of referred clients.

After discussion with NSW Health and the NSW Pharmacy Guild, it was decided to undertake a study to explore factors that would encourage pharmacies to take on more clients, as well as explore their current work practices (with an emphasis on supervised dosing and medication diversion), including the range and frequency of problems experienced with both clients and prescribers.

A questionnaire was sent to all community pharmacies participating in the NSW Opioid Treatment Program. Responses were received from 407 pharmacies after three mailouts (response rate=69%). Where appropriate, results have been used to develop recommendations for clinical practice. A full list of the recommendations is provided in the following section.

Pharmacy client capacity and activity

Participating community pharmacies had been providing opioid treatment for a mean of 8.87 years, with 31% participating in the program for five years or less. The mean number of clients receiving treatment at each pharmacy was 13.61. Eighty-nine percent of clients at the community pharmacies were on methadone treatment. The mean number of methadone clients was 12.37; the mean number of buprenorphine clients was 2.6. Almost every pharmacy provided methadone (98%). Ninety-one percent provided Methadone Syrup®, 35% provided Biodone Forte®, and 29% provided both formulations. Fifty-nine percent of pharmacies provided buprenorphine and 5% provided buprenorphine-naloxone. Overall, 53% of pharmacies reported providing injecting equipment, with 39% reporting participation in the Pharmacy Guild Needle and Syringe Program (NSP), and 42% reporting selling injecting equipment to injecting drug users (IDU). Eighty percent of pharmacies reported providing access to a Home Medicines Review (HMR) service.

Available capacity

More than half of the pharmacies (59%) reported that they had current vacancies for dosing additional clients. The mean number of current vacancies reported at pharmacies with current vacancies was 7.95 (range: 1-48). There were a total of 1,907 vacancies reported by the 407 participating pharmacies. Extrapolating this data to all community pharmacies providing dosing in NSW suggested that there are approximately 2,800 unfilled dosing places across NSW. Of note, 5% of pharmacies providing methadone and 19% of pharmacies providing buprenorphine reported having no clients currently on that medication type.

The factors that pharmacies reported would provide them with the strongest encouragement to dose additional clients on opioid treatment were: 'increased confidence that referred clients are stable'; 'ability to return unstable clients to a public clinic immediately'; and 'increased financial return per client'.

Takeaway doses

Almost all pharmacies provided takeaway doses of methadone. Thirty-seven percent of pharmacies dispensed methadone takeaways within current NSW guidelines: maximum of two consecutive takeaways and no more than four takeaways per week (NSW Department of Health, 2006). The remaining 63% of pharmacies dispensed methadone takeaways to at least some clients outside of these guidelines. Thirty-six percent provided a maximum three consecutive takeaways,

and 27% provided four or more consecutive takeaways. Subsequent analysis suggested that remoteness and difficulty of access to the pharmacy were not major contributing factors associated with these pharmacies dispensing takeaway methadone doses outside of NSW guidelines.

Dispensing fees, credit and provision of buprenorphine-naloxone

For methadone, the majority of pharmacies (92%) charged a flat weekly dispensing fee (mean=$31.90) regardless of the number of takeaway doses provided. For buprenorphine, 75% of pharmacies charged a flat weekly dispensing fee regardless of the dosing schedule (mean=$31.00). The 25% of pharmacies not charging a flat fee for buprenorphine charged a mean weekly fee of $34.81 to clients on daily dosing, $20.50 to clients on alternate day dosing, and $15.68 to clients on thrice weekly dosing. Intended dispensing fees for buprenorphine-naloxone suggested that most pharmacies would not be offering a reduction in dispensing fees when a script indicates that no supervised doses are to be provided. A reduction in dispensing fees for buprenorphine-naloxone was only seen for clients in receipt of fortnightly takeaways and no supervised doses (mean=$38.37 per fortnight).

Seventy-one percent of pharmacies reported that they provided credit to clients, with approximately one-quarter of pharmacies stating they currently had clients in debt. The proposed termination of the Pharmacy Incentive Scheme by NSW Health (which provides $100 every six months per client for up to a maximum of 20 clients) may lead to some community pharmacies increasing their dispensing fees to compensate for any shortfall in remuneration. The impact upon existing community pharmacy clients and the ability to transfer stable public clinic clients to community pharmacy dosing may be significant should there be any increase in dispensing fees charged.

Refusal to dose and termination of treatment

Overall, 74% of pharmacies had refused to dose a client for any reason in the preceding 12 months, and 32% had refused to dose a client for any reason in the preceding month. The most common reasons for termination were: expired prescription; missing three or more doses; accumulated debt; intoxication; and aggression. The vast majority of pharmacies indicated that they always notified the prescriber/public clinic if a dose had been refused. Almost half the pharmacies (47%) had terminated a client's treatment in the preceding 12 months, and 11% had terminated a client's treatment in the preceding month. Based on available information, it is

estimated that between 240 and 820 clients had their treatment terminated at the community pharmacies surveyed in the preceding 12-month period. The most common reasons for termination were client behaviour and non-payment of dispensing fees.

Administration and supervision of buprenorphine

The most commonly reported preparation of buprenorphine administered was tablets broken into two to six pieces, reported by 50% of pharmacies. Whole tablets were most commonly administered at 32% of pharmacies, and crushed tablets at 14% of pharmacies. There was wide variation between pharmacies in the level of supervision provided during buprenorphine dosing, which appears to reflect a variation in the perceived need for supervision of different clients.

Diversion of methadone and buprenorphine

Among pharmacies providing methadone, 37% had seen a client divert or attempt to divert a supervised methadone dose in the preceding 12 months, and 9% in the preceding month. Twenty-nine percent of pharmacies providing buprenorphine had seen a client divert or attempt to divert a supervised buprenorphine dose in the preceding 12 months, and 7% in the preceding month. There was a demonstrable lack of consistency between different pharmacists over what behaviours were considered to represent buprenorphine diversion.

Problems with prescribers

The most commonly reported problems experienced by community pharmacists in both the preceding 12 months and preceding month were difficulty contacting prescribing doctors, followed by pharmacy concerns over the prescribing of takeaway doses for clients considered unstable by the pharmacist.

Recommendations

Recommendation 1.1
It is recommended that all dosing community pharmacies provide access to methadone, buprenorphine, and buprenorphine-naloxone. Where pharmacies are currently providing only methadone, it is recommended that they be encouraged to register with the Pharmaceutical Services Branch (PSB) to provide buprenorphine and buprenorphine-naloxone.

Recommendation 1.2
In cases where dosing community pharmacies are reluctant to provide buprenorphine, it is recommended that a Pharmacy Guild representative or local specialist clinician offer to discuss any concerns.

Recommendation 2
That there is a consistent and regularly updated database of all community pharmacies participating in the program. This database should be held between both PSB and the NSW Pharmacy Guild to provide data back-up in case of a natural disaster or other information loss.

Recommendation 3
All community pharmacies that are registered providers of methadone and/or buprenorphine but who currently have no clients should be specifically approached by public clinics, prescribers, and local drug and alcohol services. There may be some utility in public clinics providing the details of dosing community pharmacies to local general practitioner (GP) prescribers so that GPs may be more proactive in placing stable clients appropriately in the community.

Recommendation 4
Direct induction of low-risk clients (following full medical assessment) onto both methadone and buprenorphine should be considered as one potential future response to reducing access block and utilising available community pharmacy capacity.

Recommendation 5.1
All public clinics should adopt as the first goal of public clinic treatment the attainment of sufficient stability to permit transfer to a community pharmacy. All public clinics should, where possible, ensure that clients are selected for transfer to community pharmacies only when they are stable. All clients should be notified at the start of treatment that public clinic clients, once

stable, will be expected to transfer to a community pharmacy for dosing. This would typically occur over a three to 12 month period for most clients.

Recommendation 5.2

All public clinics should introduce a 'no-questions-asked return' policy for all clients transferred to community pharmacy dosing. The pharmacy should be assured that if the client were to become unstable, the clinic will take him/her back immediately.

Recommendation 5.3

For all clients transferred to community pharmacies from public clinics, explicit, consistent, and reiterated communication should occur between the clinic, pharmacy, and client with regard to the processes and policies involved in the transfer. These include the assessment undertaken by the clinic prior to referral, the identification of stable clients for transfer, and ongoing support available from the clinic.

Recommendation 6

In light of the recent release of the *NSW Opioid Treatment Program Clinical Guidelines for Methadone and Buprenorphine Treatment of Opioid Dependence* (NSW Department of Health, 2006), it is recommended that systems be developed for the monitoring of takeaway prescribing.

Recommendation 7

It is recommended that pharmacies be encouraged to reconsider their intended fee structure for buprenorphine-naloxone to take into account the relative reduction in labour that weekly dispensing with no supervised doses allows. Providing pharmacies with more information on the process of client selection and any changes that buprenorphine-naloxone may lead to in required administration may support a more equitable fee structure.

Recommendation 8

It is recommended that NSW Health consider requesting a change in policy to permit the exclusion of buprenorphine-naloxone clients in receipt of unsupervised doses from the current limit of 50 clients imposed upon dosing community pharmacies in NSW.

Recommendation 9.1

Pharmacists and clients should be given advice on how to minimise debt being accumulated at community pharmacies. Information available from the Pharmacy Guild on how to link Centrelink payments to pharmacy dispensing fees could be more widely disseminated.

Recommendation 9.2

Non-payment of pharmacy dispensing fees should be one of the routine review questions that prescribers or other clinicians enquire about when contacting a pharmacist in relation to conducting a clinical review.

Recommendation 9.3

Consideration should be given by NSW Health to increase AHS funding to allow the subsidisation of pharmacy dispensing fees. This may be done on a transitional payment basis (i.e., supporting dispensing fees for the first three months) or on a means tested basis (i.e., full remuneration for those in receipt of Centrelink payments).

Recommendation 10.1

It is recommended that referral pathways are developed to increase the uptake and appropriate use of Home Medicines Reviews (HMRs) by both GPs and community pharmacies involved in the delivery of opioid treatment.

Recommendation 10.2

Information about the number of HMRs completed for clients on opioid treatment over specified time periods is required. It is recommended that a monitoring system be established.

Recommendation 11

Refusing to dose a client may be a difficult decision for pharmacists and is likely to result in client distress, regardless of the reason. It is suggested that all clients are made aware at the commencement of community pharmacy treatment the circumstances under which they will be refused a dose. This information should be provided verbally and in written form. Pharmacists and their staff should be provided with access to educational resources that will provide them with skills in managing threatening behaviour.

Recommendation 12

Training should be developed and made available to all community pharmacists regarding the identification of and appropriate responses to intoxication and withdrawal for all psychoactive substances (particularly opioids and other central nervous system depressants). This is especially important for community pharmacists providing methadone and buprenorphine treatment. Such training should be video-based to be most effective. NSW Health should liaise with the Pharmacy Guild and Pharmaceutical Society of Australia (PSA) in developing such a resource and formulating effective strategies for disseminating this information to pharmacists. Consideration should be given to providing this training to undergraduate pharmacy students.

Recommendation 13

Prior to the renewal of any script, the pharmacist should be contacted by the prescriber or public clinic and asked to provide clinically relevant information on the client's progress. This feedback may be formalised utilising written *Pharmacy Feedback Forms*.

Recommendation 14

Public clinics should monitor the proportion and number of transferred clients that remain without incident at community pharmacies.

Recommendation 15

Clarity as to what constitutes an episode of buprenorphine diversion is required. SWAT proposes the following definition be adopted: 'a client removing or attempting to remove a supervised buprenorphine dose from the dosing site before the dose has been fully absorbed by the client'.

Recommendation 16

It is recommended that a consistent, therapeutically orientated response to suspected episodes of diversion be developed and implemented within dosing community pharmacies. Such responses should be consistent with those adopted at local public clinics. Suspected episodes should be followed by a first and second (final) warning and be accompanied by notification to the prescriber and/or public clinic with request for an early clinical review of the client.

Recommendation 17

It is recommended that 8mg buprenorphine tablets are broken in half or into four to six pieces. Tablets should be broken in the blister pack prior to administration. 2mg tablets should be administered as whole tablets.

Recommendation 18

Once administered, buprenorphine should be sighted by the pharmacist as being under the tongue and the client requested to remain within view of the pharmacist until all the medication is absorbed. Clients should have clear expectations of what is required of them during the supervised period.

Recommendation 19

All dosing community pharmacies should be provided with the contact details and hours of availability of public clinics and prescribers whose clients are dosed at the pharmacy. This information should be provided as part of the arrangements undertaken when any clients are accepted for dosing at the pharmacy.

1. Introduction

Community pharmacies in Australia have been supporting the management of opioid dependence through the provision of methadone, and more recently buprenorphine (Subutex®), for 30 years, with this role further being developed with the addition of Needle and Syringe Programs (NSP) in the 1980s. With the rapid expansion of opioid pharmacotherapy treatment places in many states including New South Wales (NSW) in the 1980s and early 1990s, the demand for community pharmacy dosing places increased, particularly in regional and rural areas. Fortunately, there has been a steady increase in the number of participating community pharmacies and available dosing places across NSW. According to the Pharmacy Guild of Australia (NSW Branch), there were 381 community pharmacies participating in the NSW Opioid Treatment Program (OTP) in July 2000, providing dosing to over 4,700 clients. By October 2006, the number of dosing pharmacies had increased to 631, providing dosing to over 7,000 clients (NSW Pharmacy Guild, unpublished data, March, 2007). However, according to the Pharmaceutical Services Branch (PSB) of NSW Health, there were 678 dosing community pharmacies in December 2006 (PSB, unpublished data, December 2006)[1]. According to statistics provided to NSW Health by the PSB, community pharmacies currently provide treatment for approximately 43% of the more than 16,000 clients on opioid treatment in NSW (NSW Health, unpublished data, December, 2006).

While the primary role of community pharmacies in the treatment of opioid dependence is in the supervised administration of methadone and buprenorphine, it is clear there are many other useful roles pharmacists can play to enhance the health of this population. They can provide injecting equipment, feedback to other clinicians, health promotion and information (Sheridan, Carson, & Aggleton, 2003; Sheridan, Wheeler, & Walters, 2005) and can enhance compliance

[1] The discrepancy between Pharmacy Guild and PSB data can be explained by the different primary data sources that each organisation uses. The PSB database is derived from the number of approvals it provides to pharmacies wishing to participate in the program. The NSW Pharmacy Guild use as its source the number of pharmacies who apply for enhancements and this may mean that those pharmacies dosing only a few clients may not qualify or take the time to apply for this remuneration. The PSB database, although based on approvals provided to registered pharmacies, may be out of date since some pharmacies change hands or move location and the necessary notifications to the PSB may not be provided in a timely fashion. The number of clients that are dosed at community pharmacies, both as an absolute number and as a proportion of all those in treatment in NSW, is also potentially inaccurate and may vary depending upon the primary data source.

with other medications (Wu et al., 2006). These additional roles may be especially important in instances where the pharmacist is the health care professional with whom the client has the most frequent contact and where access to other health care professionals is limited (e.g., in rural areas).

The rewards for pharmacists who become involved in the management of opioid dependence are twofold. The first is the opportunity to extend their clinical role and become an important source of support and feedback for both client and prescriber. Secondly, there are financial incentives for the pharmacist. A dispensing fee is paid by the client for treatment received at the pharmacy. This is typically in the region of $30-40 per week (Madden, Lea, Bath, & Winstock, 2007, in press). In addition, the Pharmacy Incentive Scheme (PIS) was in place at the time of the survey, consisting of an incentive payment of $100 paid to community pharmacies by NSW Health in each six month period for each client receiving treatment, for up to a maximum 20 clients (maximum $4,000/year per pharmacy). However, NSW Health has recently made a decision to terminate the PIS at the end of 2007. A replacement scheme is currently under development (M. Anns, NSW Health, personal communication, June, 2007).

Pharmacists thus have a dual relationship with clients on opioid treatment: as a health care provider and as a commercial proprietor. The former requires them to develop a positive therapeutic relationship with the client, which includes duty of care responsibilities such as ensuring an intoxicated person is not dosed or provided with takeaways. The latter requires pharmacists to ensure a commercially viable business relationship with the client. While the remuneration received may be a motivator for many pharmacists, others may not consider the level of remuneration sufficient to provide this service. For example, a considerable amount of time is needed to prepare doses for supervised or unsupervised consumption, and additional time to complete the documentation required for Schedule 8 medications. Potential problems that some pharmacists may perceive as being commonplace with this group of clients such as non-payment of fees or inappropriate behaviours (e.g., aggression, intoxication, or shoplifting) may be a disincentive for some pharmacists to participate in the program, particularly where there is actual or perceived loss of income at the pharmacy.

With the current limitations upon the capacity of many public clinics to provide places for new-to-treatment, non-priority clients (see *Survey of NSW Opioid Treatment Program Public Clinics*)

(SWAT, 2007a) and the recognition that many public clinic dosing places are occupied by long-term, relatively stable clients (NSW Health Department, 2000), the State-Wide Advisory Team (SWAT): Drug Health Streamed Shared Care, in discussion with the NSW Pharmacy Guild, decided to conduct a study to address these issues. It was determined that there was a need to assess the current availability and utilisation of community pharmacy dosing places and to explore barriers to increasing the number of opioid treatment clients dosed in the community. There was also a need to address the common concerns of pharmacies such as dose diversion, inappropriate client behaviour, supervision of dosing, payment of fees, and access to prescribers.

This report presents the findings of the *NSW Community Pharmacy Practice Survey*, and incorporates feedback from meetings with NSW Pharmacy Guild representatives and from several hundred community pharmacists who have attended a range of training sessions developed and delivered by the SWAT project during 2006. This study builds on the *Pharmacy Capacity Survey* (SWAT, 2006) undertaken in April 2006, which assessed the capacity of community pharmacies to take on additional opioid treatment clients. Of note, both the *Pharmacy Capacity Survey* and the current survey were conducted prior to the release of the new *NSW Opioid Treatment Program Clinical Guidelines for Methadone and Buprenorphine Treatment of Opioid Dependence* (NSW Department of Health, 2006), which includes a revision of the NSW policy regarding the provision of takeaway doses of methadone and buprenorphine.

2. Method

A self-complete questionnaire was mailed to every dosing community pharmacy in NSW (n=593) between July and September 2006 accompanied by a cover letter from the NSW Pharmacy Guild and a reply paid envelope. The list of dosing pharmacies was obtained from the NSW Pharmacy Guild and was current at July 2006. A unique identifying number was printed on each questionnaire to allow co-ordination of subsequent mailouts to non-responding pharmacies. As an incentive to participate in the survey, pharmacies who returned their questionnaires within one week of the first mailout were offered entry into a draw to win a $500 department store gift voucher. Two additional mailouts were sent to non-responding pharmacies. Pharmacies responding to the second or third mailout were placed into a draw to win a $300 department store gift voucher. A response rate of 69% (n=407) was achieved after three mailouts, ranging from 56% and 77% between Area Health Services (AHS). Fifty-one percent of pharmacies responded to the first mailout, 13% to the second mailout, and 5% to the third mailout. The number of respondents in each AHS is presented in Table 1.

Table 1. Community pharmacies participating in the survey according to AHS

Area Health Service	Total OTP pharmacies[a]	Participating pharmacies
Greater Southern Area Health Service (GSAHS)	48	35
Greater Western Area Health Service (GWAHS)	25	16
Hunter/New England Area Health Service (HNEAHS)	93	70
North Coast Area Health Service (NCAHS)	74	57
Northern Sydney/Central Coast Area Health Service (NSCCAHS)	86	62
South Eastern Sydney/Illawarra Area Health Service (SESIAHS)	106	59
Sydney South West Area Health Service (SSWAHS)	113	70
Sydney West Area Health Service (SWAHS)	64	38

[a]According to NSW Pharmacy Guild database (n=609), September, 2006

The questionnaire was designed specifically for the purposes of this project and was developed following discussion with treatment providers at public clinics, researchers specialising in community pharmacy drug health, the Australian Injecting and Illicit Drug Users' League (AIVL), and the NSW Pharmacy Guild. The questionnaire was adapted from an earlier version piloted on 50 community pharmacists whose opioid treatment clients participated in a consumer satisfaction survey of opioid treatment at community pharmacies in NSW (Winstock & Lea, unpublished data, 2005). The questionnaire was reviewed after receiving feedback from these pharmacies and revised into its current form. The questionnaire was subsequently approved by the Pharmacy

Guild of Australia (Survey No.623) with an AAA rating, the highest survey approval rating offered by the Pharmacy Guild. Please refer to Appendix A for a copy of the questionnaire.

The questionnaire explored the following areas of opioid treatment delivery at community pharmacies:

1. The number of clients dosed at community pharmacies and the number of unfilled dosing places. This was undertaken to confirm the findings from the *Pharmacy Capacity Survey* (SWAT, 2006).
2. Factors that would encourage community pharmacies to increase the number of clients they currently dose.
3. Pharmacy dispensing fees for administering a dose, for dispensing takeaway methadone doses, and for clients on different buprenorphine dosing schedules. Intended pharmacy dispensing fees for buprenorphine-naloxone (Suboxone®), recently introduced in Australia, were also explored for a range of dispensing schedules.
4. Reasons pharmacies have refused to dose a client, and their frequency.
5. Reasons pharmacies have terminated a client's treatment, and the frequency of termination.
6. The range of problems, and their frequency, that pharmacies have experienced with prescribing doctors, including a number of issues surrounding communication with the prescribing doctor.
7. Pharmacy practice in the preparation, administration, and supervision of buprenorphine treatment, including rationales for these practices at individual pharmacies.
8. The proportion of pharmacies reporting at least one episode of actual or suspected methadone or buprenorphine diversion at the pharmacy during supervised dosing, including individual pharmacy responses to such episodes.
9. The range of behaviours pharmacies considered to be indicative of buprenorphine diversion and responses to such instances.

The questions included in this survey aimed to canvass issues to provide a general overview of current pharmacy practice in the delivery of opioid treatment. This was intended to identify areas worthy of more detailed exploration in future studies including issues around dose diversion, barriers to increasing capacity, and the major concerns that pharmacists experience with clients

and prescribers. As such, there are deficiencies in some of the data that limits the range of analyses that can be conducted.

3. Results and recommendations

3.1 Pharmacy characteristics and services provided

3.1.1 Years providing service and days open

Q6. How long has this pharmacy been dispensing methadone and/or buprenorphine?

Participating community pharmacies had been providing opioid treatment as part of the NSW OTP for a mean of 8.87 years (SD=6.18), ranging from six months to 30 years at individual pharmacies. Thirty-one percent of pharmacies (n=126) had been providing opioid treatment for five years or less, 29% (n=119) for five to 10 years, 19% (n=79) for 10 to 20 years, and the remainder (20%, n=83) for 20 to 30 years (see Figure 1).

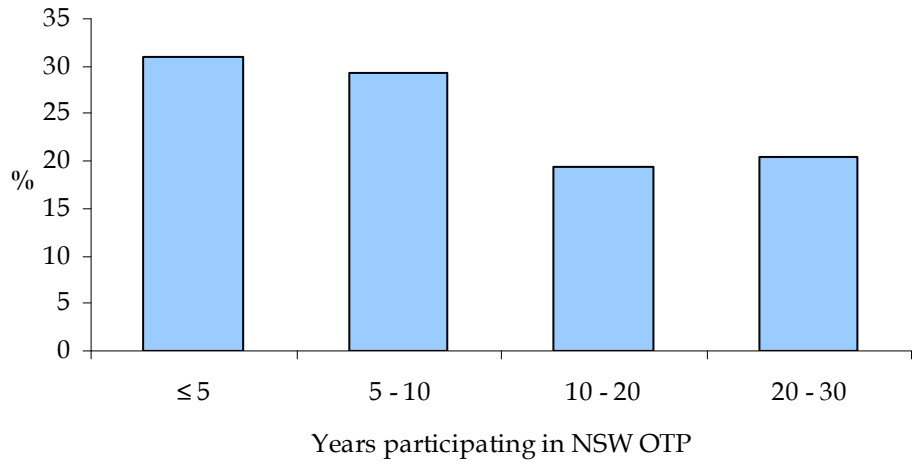

Figure 1. Number of years community pharmacies had been participating in the NSW OTP

Q17. How many days a week is this pharmacy open?

Pharmacies were open a median of six days each week (range: 5-7 days). Forty-one percent of pharmacies (n=168) were open seven days each week, 57% (n=230) six days each week, and 2% (n=9) five days each week.

3.1.2 Pharmacotherapies

3.1.2.1 Dispensed pharmacotherapies

Q7. Which pharmacotherapies does this pharmacy dispense?

Almost every pharmacy reported that they provided methadone (98%, n=397). Ninety-one percent (n=372) provided Methadone Syrup®, 35% (n=142) provided Biodone Forte®, and 29% (n=117) provided both preparations of methadone. Fifty-nine percent of pharmacies (n=242) provided buprenorphine (Subutex®) and 5% (n=21) provided buprenorphine-naloxone (Suboxone®).

Recommendation 1.1

It is recommended that all dosing community pharmacies provide access to methadone, buprenorphine, and buprenorphine-naloxone. Where pharmacies are currently providing only methadone, it is recommended that they be encouraged to register with the Pharmaceutical Services Branch (PSB) to provide buprenorphine and buprenorphine-naloxone.

Rationale

As part of the process for community pharmacies to be registered to provide methadone and buprenorphine treatment, the Pharmacy Guild is notified by PSB of the pharmacy's registration. The initial process for a pharmacy to be registered as a provider is for the pharmacist to contact PSB and inform them of its desire to participate in the program. PSB sends information outlining the obligatory responsibilities and regulatory requirements for the dispensing of methadone or buprenorphine as part of a treatment program. The pharmacist then accepts these regulations and confirms that he/she is able to fulfil the necessary requirements. PSB registers the pharmacy to participate in the program and at the same time notifies the drug manufacturers that this pharmacy is now able to receive the appropriate medications. Subsequently, the Pharmacy Guild makes telephone contact with the pharmacist to offer support and ensure he/she is able to provide methadone and buprenorphine treatment in the community pharmacy setting.

Recommendation 1.2

In cases where dosing community pharmacies are reluctant to provide buprenorphine, it is recommended that a Pharmacy Guild representative or local specialist clinician offer to discuss any concerns.

Rationale

There are only two medications available for the treatment of opioid dependence in Australia. Further restricting this choice as a result of medication availability at a particular dosing site is inappropriate. In some instances, an otherwise stable buprenorphine client suitable for pharmacy transfer would not be able to cease public clinic dosing because the identified pharmacy does not provide buprenorphine. Pharmacists who are capable of providing methadone are also capable of providing buprenorphine.

3.1.2.2 Current clients

Q8. How many clients does this pharmacy currently dose?

The total number of clients receiving their doses at the participating community pharmacies was 5,539. This represents 79% of all clients on opioid treatment at community pharmacies in NSW (NSW Health, unpublished data, December, 2006).

The mean number of clients receiving their doses at each community pharmacy was 13.61 (SD=13.13, range: 0-111). The mean number of methadone clients dosed at pharmacies providing methadone was 12.37 (SD=12.14, range: 0-110). The mean number of buprenorphine clients dosed at pharmacies providing buprenorphine was 2.6 (SD=3.17, range: 0-25).

Three pharmacies exceeded the maximum 50 clients permitted to be dosed at a single pharmacy. These pharmacies dosed 51, 55, and 111 clients, respectively. The pharmacy with 111 clients reported that it had been dosing this many clients before the 50 client cap was set and was provided with an exemption from complying with the cap. Figure 2 presents the participating community pharmacies according to the number of clients for whom treatment is currently provided.

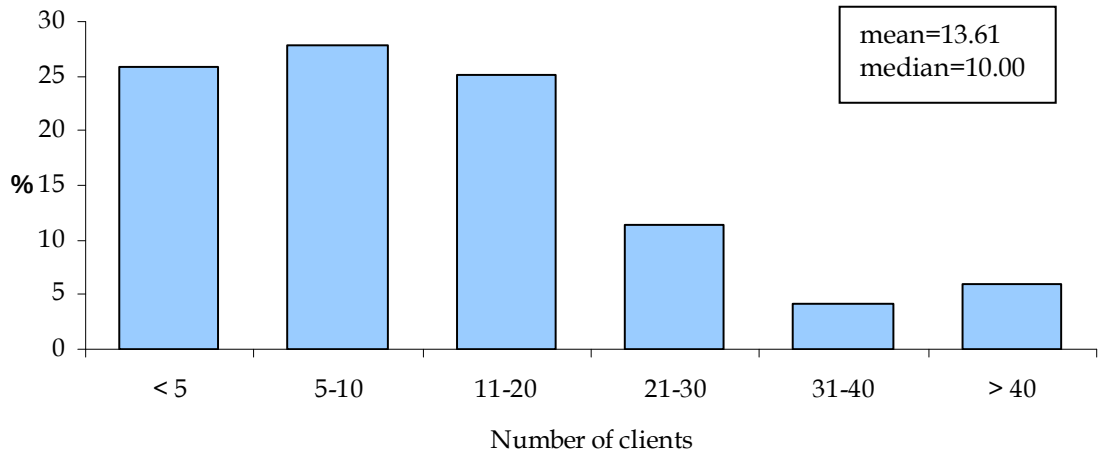

Figure 2. Number of OTP clients for whom treatment is provided at community pharmacies

The total number of clients receiving their doses at the participating pharmacies compared across pharmacotherapy type is presented in Figure 3, and shows 89% of clients on methadone treatment and 11% on buprenorphine treatment. The proportion of clients on methadone and

buprenorphine in our sample is similar to state-wide statistics from June 2006 which report that the majority (84%) of OTP clients in NSW are on methadone while 16% are on buprenorphine (NSW Health, unpublished data, December, 2006). The recent SWAT survey of NSW public clinics identified 81% of clients managed at public clinics were on methadone and 19% were on buprenorphine (see *Survey of NSW Opioid Treatment Program Public Clinics*) (SWAT, 2007a).

Of note, a number of pharmacies reported that they currently had no methadone and/or buprenorphine clients. This consisted of 5% of pharmacies providing methadone (n=21) and almost one in five pharmacies providing buprenorphine (19%, n=46).

These figures may serve as a useful baseline assessment of current activity among dosing community pharmacies. It may be useful to repeat this assessment in subsequent years to determine if the mean number of clients dosed at each pharmacy has increased. Such an increase may act as a proxy measure for increased utilisation of availability pharmacy capacity and may be paralleled by a reduction in available capacity at these sites. These measures, however, are only useful if there is a consistent and regularly updated database of all community pharmacies participating in the program.

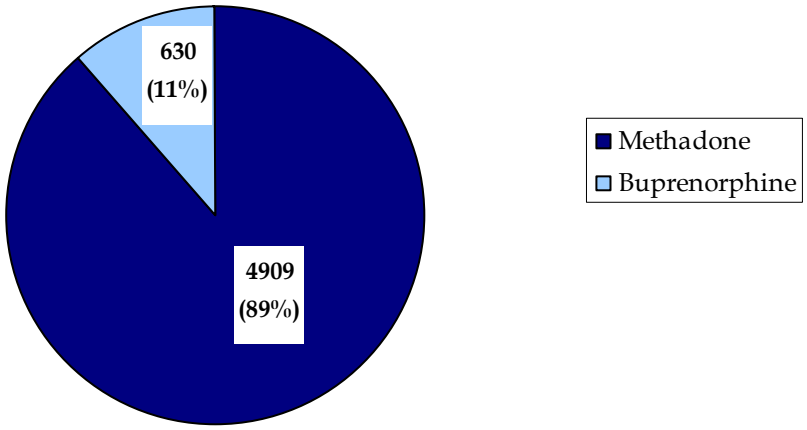

Figure 3. Proportion of clients on methadone and buprenorphine treatment at community pharmacies

Recommendation 2

That there is a consistent and regularly updated database of all community pharmacies participating in the program. This database should be held between both PSB and the NSW Pharmacy Guild to provide data back-up in case of a natural disaster or other information loss.

Rationale

Baseline measures of capacity and efforts at monitoring future growth are only useful where a consistent and regularly updated list of participating pharmacies is available. In addition, should circulars be required to be sent informing pharmacists of changes to practices or regulations, then a complete list of current participating pharmacies is essential. NSW Health (through PSB) should provide current and regularly updated lists of all registered OTP community pharmacies in NSW to all public clinics. Public clinics may choose to update and locally maintain a list of dosing pharmacies in their areas. Although this will place an additional load on the public clinic, it does ensure regular contact between public clinics and community pharmacies.

Recommendation 3

All community pharmacies that are registered providers of methadone and/or buprenorphine but who currently have no clients should be specifically approached by public clinics, prescribers, and local drug and alcohol services. There may be some utility in public clinics providing the details of dosing community pharmacies to local GP prescribers so that GPs may be more proactive in placing stable clients appropriately in the community.

Rationale

Failure to utilise registered pharmacies through a lack of referrals may lead to diminished interest and the possible withdrawal of active involvement of some pharmacies in delivering treatment.

3.1.2.3 Client capacity

Q9. How many current vacancies do you have for dosing?

Community pharmacies were asked how many vacancies they currently had for dosing additional clients. More than half of pharmacies (59%, n=240) reported having current vacancies. Close to one-third of pharmacies (32%, n=132) reported having no current vacancies. Nine percent of pharmacies (n=35) did not respond to this question. The mean number of current vacancies reported by pharmacies with vacancies was 7.95 (SD=8.13, range: 1-48). Pharmacies who currently dosed more than 20 clients had a mean additional capacity of 7.16 clients. Pharmacies dosing between 11 and 20 clients had a mean additional capacity of 4.78 clients, and those dosing up to 10 clients had a mean additional capacity of 4.44 clients. The total number of vacancies reported across the pharmacies was 1907. Pharmacies were asked only to report whether they had available dosing places, and not whether these dosing places referred to vacancies for methadone clients, buprenorphine clients, or both.

Discussion

Accepting that our sample is representative of all NSW community pharmacies registered to provide methadone and/or buprenorphine treatment (which is reasonable given a 69% response rate and that the responding pharmacies provided treatment to 79% of NSW pharmacy clients), we can extrapolate data on current vacancies to non-responding pharmacies. We therefore estimate that there are approximately 2,800 currently unfilled pharmacy dosing places across NSW. This was calculated as follows:

> Reported vacancies (1,907) ÷ Responding pharmacies (407) x Registered pharmacies (593) = Total NSW vacancies (2,779)

However, the estimated capacity reported is considerably lower than the estimate obtained by the *Pharmacy Capacity Survey* in April 2006, which identified 2,700 additional places from 374 community pharmacies (SWAT, 2006). This figure, if extrapolated to the whole of NSW, provided an estimate of between 4,000 and 5,000 additional treatment places at community pharmacies. It is unclear why discrepancies between the two surveys exist, but may reflect sampling differences as well as changes in actual capacity over time.

Taking into consideration the results of both the *Pharmacy Capacity Survey* and the current survey, there is clearly an under-utilisation of community pharmacy dosing places with the majority of pharmacies reporting current vacancies. However, the large number of available dosing places at community pharmacies should not be seen as a panacea to the current problems facing many public clinics in NSW in terms of limited ability to take on non-priority new-to-treatment clients. Based on local consultation and feedback from public clinic Nursing Unit Managers (NUMs), it is clear that, in many instances, available community pharmacy dosing places are not always located where they are most needed. All AHS have already been provided with the contact details of community pharmacies in their areas that have available dosing places.

However, in some areas where community pharmacy dosing places are readily available, it may be that public clinics are not making the best use of pharmacies in their area. Public clinics may benefit from reviewing referral pathways that relate to the transfer of stable clients to a community pharmacy. In some instances, in order to make better use of available pharmacy places, public clinics, with the support of senior clinical and managerial staff may need to reorientate themselves to transferring stable clients from public clinic dosing. In areas where limited pharmacy places are available, public clinics should take note of Recommendations 5 and

14 in this report which discuss approaches for optimising available pharmacy capacity. The reader is also referred to *Survey of NSW Opioid Treatment Program Public Clinics* (SWAT, 2007a).

Recommendation 4

Direct induction of low risk clients (following full medical assessment) onto both methadone and buprenorphine should be considered as one potential future response to reducing access block and utilising available community pharmacy capacity.

Rationale

Given that there is dosing availability at the majority of community pharmacies and accepting that many public clinics are unable to take on non-priority cases, it seems appropriate to consider the direct induction of low-risk clients at community pharmacies. While at present the practice in NSW is, wherever possible, to commence dosing at a specialist clinic, in regional and rural areas of NSW, clients are often inducted on treatment at a community pharmacy. Although this may be associated with greater risks among some client groups, in Victoria and elsewhere such as the United Kingdom, the routine induction of clients at community pharmacies is commonplace and appears to be quite safe for many clients (Gossop & Grant, 1991; Nielsen et al., 2007). Although this suggestion may appear to be in direct contrast to the current strategy and clinical pathways outlined by NSW Health (NSW Department of Health, 2006), given access at public clinics is limited, all avenues for increasing rapid access to treatment must be explored. Many clients (often non-priority) could safely be engaged in treatment through this process.

3.1.2.4 Factors encouraging community pharmacies to increase client capacity

Q10. To what extent would the following encourage you to increase your capacity for dosing methadone and/or buprenorphine clients?
(Strongly encourage / Somewhat encourage / Not encourage)

- More support from local Drug & Alcohol Services
- Increased confidence that referred clients are stable
- Ability to return unstable clients to a public clinic immediately
- A copy of your clients' care plans
- Easier recording systems
- More integration with other health care professionals involved in clients' care
- Increased financial return per client
- More referrals to pharmacy
- Other that would strongly encourage (specify)

In the *Pharmacy Capacity Survey* (SWAT, 2006), pharmacies were asked to identify issues that prevented them from taking on additional OTP clients. The three most commonly cited issues were:

1. 'too busy to supervise additional clients' (38%);
2. 'the potential impact on other customers' (38%); and,
3. 'a lack of clients being referred' (31%).

In the current survey, pharmacies were asked whether each of a number of factors would encourage them to increase their client capacity. Pharmacies responded to each item on a three-point scale indicating the extent to which each of the eight factors would encourage them to dose additional clients (1=strongly encourage; 2=somewhat encourage; 3=not encourage). These questions were completed by all pharmacies regardless of whether they had or did not have current vacancies for dosing. The factors that provided pharmacies with the strongest encouragement to dose additional clients were:

1. 'increased confidence that referred clients are stable';
2. 'ability to return unstable clients to a public clinic immediately'; and,
3. 'increased financial return per client'.

More detailed results are presented in Figure 4.

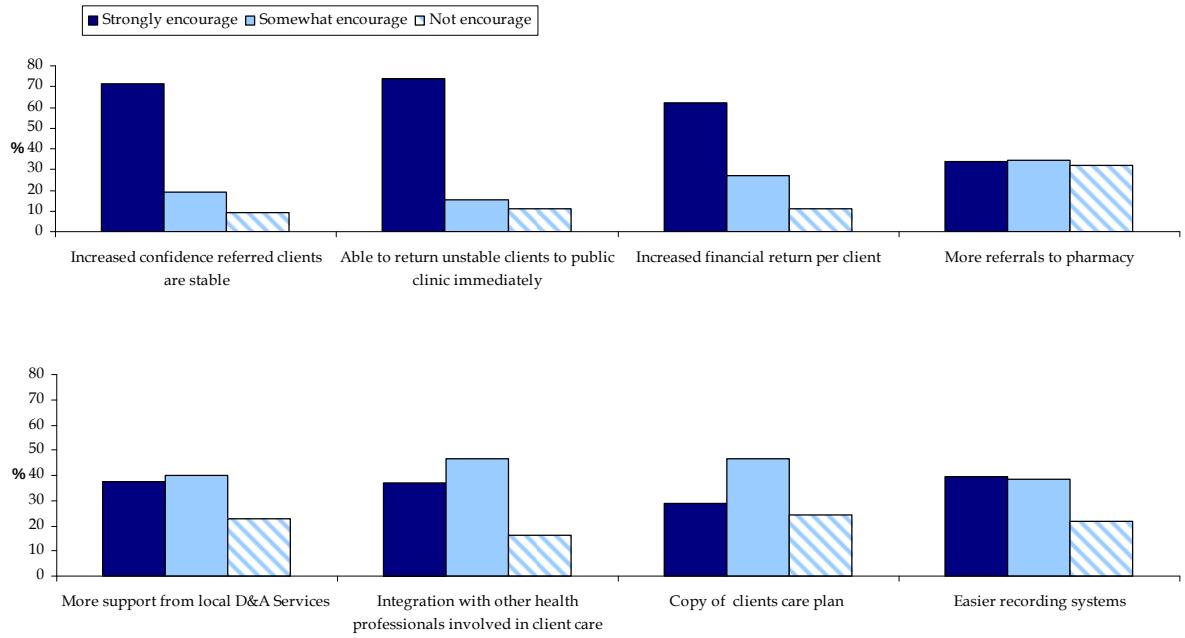

Figure 4. Extent to which various factors would encourage community pharmacies to increase their capacity for dosing clients on opioid treatment

Discussion

Public clinics need to maintain a focus on induction and stabilisation. Stable clients are least in need of daily supervision and intensive clinical support and are most appropriate for transfer to community dosing. These clients can be considered as the group who pose the lowest level of risk to themselves as well as to the community. Refocusing clinical assessments and reviews to identify risk and instability may increase the likelihood that only stable clients are transferred. This selection process will help both client and pharmacist obtain the best outcome. These aims may be supported by assessment and transfer tools such as the *SWAT Stability Assessment Flowchart* (Appendix B). Please also refer to the *Survey of NSW Opioid Treatment Program Public Clinics* (SWAT, 2007a). Clients with chronic mental illness, alcohol dependence, and other risky patterns of substance use, or those who exhibit severely antisocial behaviours may be better managed within the public clinic setting. Pregnant women may also benefit from enhanced supervision when there are concerns over engagement with antenatal services or risk of domestic violence.

It is envisaged that, under these circumstances, the rate of transfer of clients from public clinics to community pharmacies (defined as the proportion of publicly dosed clients moved out to community pharmacy dosing each month) in most areas will be slow. It is likely that the proportion of clients transferred from public clinics to community pharmacies each month will be between 3% and 15%. For an example of how an assessment of clinic throughput can be monitored, please refer to Appendix C.

Recommendation 5.1

All public clinics should adopt as the first goal of public clinic treatment the attainment of sufficient stability to permit transfer to a community pharmacy. All public clinics should where possible ensure that clients are selected for transfer to community pharmacies only when they are stable. All clients should be notified at the start of treatment that public clinic clients, once stable, will be expected to transfer to a community pharmacy for dosing. This would typically occur over a three to 12 month period for most clients.

Recommendation 5.2

All public clinics should introduce a 'no-questions-asked return' policy for all clients transferred to community pharmacy dosing. The pharmacy should be assured that if the client were to become unstable, the clinic will take him/her back immediately.

Recommendation 5.3

For all clients transferred to community pharmacies from public clinics, explicit, consistent, and reiterated communication should occur between the clinic, pharmacy, and client with regard to the processes and policies involved in the transfer. These include the assessment undertaken by the clinic prior to referral, the identification of stable clients for transfer, and ongoing support available from the clinic.

Rationale

Some public clinics have expressed concern over providing an assurance that unstable clients will be taken back immediately from community pharmacies. Clinics have suggested that a guarantee cannot always be made that space will be available to take back clients once new clients have commenced treatment at the clinic. The SWAT project's view is that if clients are selected using appropriate stability criteria, the rate of return (defined as the proportion of transferred clients returning to public clinic dosing each month) will be very low. This assumption is confirmed by data presented in Section 3.2.4 of this report that demonstrates a relatively low rate of treatment termination at community pharmacies due to clinical concerns. It may be useful for some public clinics to ensure that their monthly capacity for new clients incorporates one or two places for clients returning from a community pharmacy.

Special note.

Given that increasing financial remuneration was identified as a potentially important incentive for taking on more clients by the majority of pharmacies, it is unfortunate that at the time of writing NSW Health has recently terminated the existing PIS. This is likely to have a significant negative impact upon the goals of the SWAT project. Reducing financial remuneration to participating pharmacies may have the following consequences:

1. Participating pharmacies may withdraw from the program.
2. The possibility of service expansion may be damaged since it is only within the community pharmacy sector that this opportunity exists.
3. The reduced level of pharmacy involvement may jeopardise the ability of general practitioners (GPs) to manage clients in the community because of reduced dosing places.
4. Participating pharmacies may increase their dispensing fees.
5. If pharmacy dispensing fees were to increase, public clinic clients may be less likely to accept transfer to a community pharmacy if financial concerns are a barrier to transfer.
6. Some community pharmacy clients may request a return to public clinic dosing if they are unable to afford higher dispensing fees.
7. Client debt may increase and is less likely to be tolerated with the possibility of clients being terminated at their dosing site.

8. The goodwill of a professional group who is the mainstay of treatment delivery (dosing > 40% of clients) may be lost.
9. Pharmacies may be less likely to expand their involvement such as providing buprenorphine-naloxone and supporting GPs requests for Home Medicines Reviews (HMR).

In addition, the loss of the PIS is likely to have a significant impact upon the accuracy of the data the PSB currently uses to describe the location of clients dosed at community pharmacies. In the absence of the PIS, it is likely that the information provided by community pharmacies to PSB will revert to the situation that existed prior to the PIS which was associated with significant levels of under-reporting of community pharmacy dosing.

3.1.2.5 Supervised dosing area

Q11. Regarding the supervised dosing area, is there a separate area where clients are given their dose? If yes, is this area: In full view of other customers/In partial view of other customers/Private, not in view of other customers If no, are doses administered: Over the counter/Other (specify)

Two-thirds of pharmacies (n=268) reported that they have a separate area in the pharmacy for the dispensing and supervised dosing of methadone and buprenorphine. Among these pharmacies, 16% (n=41) reported that the dosing area was in full view of other customers, 61% (n=161) reported that it was in partial view of other customers, and 23% (n=62) reported that it was private and not in view of other customers. Some pharmacies that did not have a private dosing area indicated that they tried to dose clients as discreetly as possible, and when other customers were not in the pharmacy.

Discussion

Confidentiality and privacy have been well documented as issues of significant concern for clients in opioid treatment, in particular among clients dosed at community pharmacies, and those receiving treatment in regional or rural areas (Donnermeyer, Barclay, & Jobes, 2002; Kumar & Rajwal, 2006; Luger, Bathia, Alcorn, & Power, 2000; Stone & Fletcher, 2003; Treloar, Fraser, & Valentine, 2007; Madden et al., 2007, in press). However, it is recognised that for many pharmacies space limitations and prohibitive cost will preclude the creation of a more private space.

3.1.2.6 Takeaway doses

Q19. Does this pharmacy provide takeaway doses of buprenorphine?

Forty-three percent of pharmacies providing buprenorphine (n=105) reported that they dispense takeaway doses of buprenorphine. However, the *NSW Policy for the Use of Buprenorphine in the Treatment of Opioid Dependence* (NSW Health Department, 2001), current at the time of the survey, indicated that takeaway doses of buprenorphine generally should not be provided unless in exceptional circumstances such as when a client cannot tolerate less than daily dosing, in emergencies, and in rural and remote areas. The provision of takeaway doses of buprenorphine at community pharmacies was least commonly reported in SSWAHS and most commonly reported in NSCCAHS (see Table 2).

Table 2. Provision of buprenorphine takeaways at community pharmacies according to AHS

Area Health Service	Provide buprenorphine		Provide buprenorphine takeaways	
	n	%[a]	n	%[b]
GSAHS	25	71	12	48
GWAHS	9	56	5	56
HNEAHS	44	63	16	36
NCAHS	34	60	12	35
NSCCAHS	39	63	25	64
SESIAHS	33	56	14	42
SSWAHS	44	63	14	32
SWAHS	14	37	7	50

[a] % of participating pharmacies; [b] % of participating pharmacies providing buprenorphine

Q18. Does this pharmacy provide takeaway doses of methadone?

If yes, what is the maximum number of consecutive takeaways you currently dispense to one client at one time?

Almost all pharmacies providing methadone treatment reported dispensing takeaway doses of methadone (99%, n=394). The mean maximum number of consecutive takeaway methadone doses dispensed to one client at one time was 3.14 (SD=1.26) ranging from one to seven. The *NSW Methadone Maintenance Treatment Clinical Practice Guidelines* (NSW Health Department, 1999), current at the time of the survey, stated that no more than two consecutive methadone takeaway doses were to be dispensed to one client at any one time, with a maximum of four takeaways able to be dispensed each week. These takeaway guidelines are maintained in the new *NSW Opioid Treatment Program Clinical Guidelines for Methadone and Buprenorphine Treatment of Opioid Dependence* (NSW Department of Health, 2006).

Thirty-seven percent of pharmacies (n=144) dispensed methadone takeaways within these parameters, with the remaining 63% dispensing takeaways outside the guidelines. Thirty-six percent (n=136) provided a maximum three consecutive takeaways, and 27% (n=102) provided four or more consecutive takeaways. It may be that community pharmacies providing a maximum of three consecutive takeaways were including those who received additional takeaways for public holidays. Pharmacies in rural areas were no more likely to dispense four or more takeaways at one time than pharmacies located in metropolitan or regional areas (see Table 3).

Table 3. Provision of methadone takeaways at community pharmacies according to AHS

Area Health Service	Provide methadone takeaways	Provide ≥ 4 consecutive methadone takeaways	
	n	n	%[a]
GSAHS	34	4	12
GWAHS	16	2	13
HNEAHS	66	11	17
NCAHS	57	21	37
NSCCAHS	62	19	31
SESIAHS	58	15	26
SSWAHS	67	21	31
SWAHS	34	9	26

[a] % of pharmacies providing methadone takeaways

In an attempt to confirm whether pharmacies providing four or more consecutive takeaways were doing so according to the exceptional circumstances described in the NSW guidelines (NSW Department of Health, 2006; NSW Health Department, 1999) (i.e., exceptions were related to reasons of geographic inaccessibility in rural and remote areas), the Accessibility/Remoteness Index of Australia (ARIA+) index was used to estimate the remoteness of the pharmacies by their street addresses (Population Health Division, 2004). Thirty-two of the 102 pharmacies providing four or more consecutive methadone takeaways were located in metropolitan areas. Of the remaining 70 pharmacies, 59 were in areas classified as 'inner regional', to which geographic inaccessibility would not normally apply. Eleven were located in an area classified as less than 10% 'outer regional'. This analysis suggests that remoteness and difficulty of access to the pharmacy would not be the main reason for these pharmacies dispensing takeaway methadone doses outside the guidelines. Pharmacy dispensing practices reflect prescribing practices, and it is suggested that this data is an indication of prescribers providing takeaways outside the NSW guidelines. Further investigation of this is needed.

Discussion

The provision of methadone takeaway doses has been associated with increased treatment compliance, and improved treatment retention (Pani & Pirastu, 2000; Pani, Pirastu, Ricci, & Gessa, 1996; Rhoades, Creson, Elk, Schmitz, & Grabowski, 1998). Clients in methadone treatment report many benefits of being in receipt of regular takeaway doses, including increased flexibility, less travel time and travel costs, and less restrictions on maintaining employment (Treloar et al., 2007). Access to takeaway doses has been cited by methadone clients receiving treatment at a public clinic as one of the things they would most like to change about their

treatment (Madden et al., 2007, in press). None of the public clinics where these clients received treatment routinely provided takeaway doses. However, the provision of takeaways can be associated with community harm when takeaways are diverted to someone other than the person they were prescribed to. The majority of black-market methadone in NSW comes from diverted takeaway doses (Lintzeris, Lenne, & Ritter, 1999; O'Brien et al., 2007; Ritter & Di Natale, 2005), and methadone-related fatalities have been reported particularly when methadone is taken concomitantly with other central nervous system depressants, by those who have only recently been inducted on treatment, and by those not on methadone treatment (Caplehorn & Drummer, 2002; Sunjic & Zador, 1999; Zador & Sunjic, 2000; Zador & Sunjic, 2002). While the new NSW guidelines strongly encourage the thoughtful, documented and appropriate prescribing of takeaways (NSW Department of Health, 2006), previous reports suggest that some prescribers may be inappropriately generous in this regard (Hailstone, Indig, Lawrance, Gill, & Anns, 2004). It is hoped that the Australasian Chapter of Addiction Medicine *Clinical Guidelines Assessing Suitability for Unsupervised Medication Doses in the Treatment of Opioid Dependency* (Winstock & Bell, 2006) and the accompanying training package will support prescribers in making more appropriate clinical decisions. Monitoring the provision of takeaways at community pharmacies may provide an early warning system for undesirable changes in prescribing practice.

Recommendation 6

In light of the recent release of the *NSW Opioid Treatment Program Clinical Guidelines for Methadone and Buprenorphine Treatment of Opioid Dependence* (NSW Department of Health, 2006), it is recommended that systems be developed for the monitoring of takeaway prescribing.

Rationale

File audits of prescribers identified as prescribing a large number of takeaways to a large number of clients may be conducted to determine the level of documented assessment and whether the documented assessment is supportive of the provision of takeaway doses. Community pharmacies would appear to be in an ideal position to identify potentially high-risk prescribers. See *Survey of NSW Opioid Treatment Program Public Clinics* (SWAT, 2007a) for recommendations on public clinics conducting audits on clients receiving two or more takeaways per week.

3.1.2.7 Pharmacy dispensing fees

Q20. Is a flat fee charged for methadone dosing regardless of whether clients receive takeaways or not?

If yes, what is the flat weekly fee for methadone clients?

If no, what is the weekly fee for those receiving: One or two takeaways per week
Three or four takeaways per week

For the provision of methadone, the majority of pharmacies (92%) charged a flat weekly dispensing fee (mean=$31.90) regardless of the number of takeaway doses provided. The 8% of pharmacies not charging a flat fee charged according to the number of takeaways provided each week, although there was little difference between schedules in terms of final cost. For example, methadone clients receiving one or two takeaways each week were charged a mean weekly fee of $31.25, while clients receiving three or four takeaways each week were charged a mean weekly fee of $32.57 (see Table 4).

Table 4. Methadone dispensing fees according to number of takeaway doses provided each week

Fee schedule	n	Mean ± SD; range
Flat weekly fee regardless of number of takeaways	366	$31.90 ± 6.18; 10-70
One or two takeaways per week	31	$31.25 ± 7.18; 15-42
Three or four takeaways per week	31	$32.57 ± 11.10; 9-60

Q21. Is a flat fee charged for buprenorphine dosing regardless of whether clients are dosed daily or less than daily?

If yes, what is the flat weekly fee for buprenorphine clients?

If no, what is the weekly fee for buprenorphine clients who are dosed:
Daily
Every second day
Three times a week

For the provision of buprenorphine, 75% of pharmacies charged a weekly flat fee regardless of dosing schedule (mean=$31.00). The 25% of pharmacies not charging a flat fee charged a mean weekly fee of $34.81 to clients on daily dosing, $20.50 to clients on alternate day dosing, and $15.68 to clients on thrice weekly dosing (see Table 5).

Table 5. Buprenorphine dispensing fees according to dosing schedule

Fee schedule	n	Mean ± SD; range
Flat fee regardless of dosing schedule	181	$31.00 ± 6.77; 10-50
Daily dosing	61	$34.81 ± 8.23; 14-58
Alternate dosing	61	$20.50 ± 5.53; 8-35
Thrice weekly dosing	61	$15.68 ± 4.34; 6-30

In summary, it would appear that the majority of pharmacies charged a flat fee for both methadone and buprenorphine with no reduction in charge associated with less frequent supervised dosing. Pharmacies providing buprenorphine that did adjust for the frequency of supervised dosing had lower dispensing fees associated with less than daily dosing regimes.

3.1.2.8 Pharmacy dispensing fees for buprenorphine-naloxone

Q26. If this pharmacy plans to dispense Suboxone® what fee would you charge for:

- Supervised dose on Monday with two takeaways. Supervised dose on Thursday with three takeaways
- Supervised dose on Monday with six takeaways
- No supervised doses and weekly pick-up of takeaways
- No supervised doses and fortnightly pick-up of takeaways
- Flat fee regardless of number of supervised doses and takeaways

Pharmacies currently providing buprenorphine treatment (n=242) were asked whether they intended to provide buprenorphine-naloxone. Thirty-eight percent (n=93) reported an intention to provide buprenorphine-naloxone, 31% (n=74) were unsure, 8% (n=19) did not intend to provide buprenorphine-naloxone, and 9% (n=21) already had buprenorphine-naloxone clients. The remainder (14%, n=35) were unaware of the introduction of buprenorphine-naloxone.

Table 6 displays pharmacy dispensing fees for buprenorphine-naloxone charged by pharmacies currently providing buprenorphine-naloxone treatment, according to different dosing schedules. Table 7 displays dispensing fees pharmacies currently providing buprenorphine reported that they intended to charge for the provision of buprenorphine-naloxone according to different dosing schedules (Winstock, Lea, & Ritter, 2007).

Table 6. Fees charged by pharmacies currently dispensing buprenorphine-naloxone

Dosing schedule	n	Mean ± SD; median; range
Two supervised doses / Five takeaways per week	12	$29.04 ± 9.99; 30; 20-56
One supervised dose / Six takeaways per week	13	$27.62 ± 11.66; 30; 10-56
No supervised doses / Weekly takeaways	11	$24.64 ± 13.94; 25; 8-56
No supervised doses / Fortnightly takeaways	11	$42.73 ± 31.96; 25; 12-112
Flat fee regardless of number of supervised doses and takeaways	14	$28.79 ± 11.11; 30; 10-56

Table 7. Intended dispensing fees for buprenorphine-naloxone by pharmacies not currently dispensing buprenorphine-naloxone

Dosing schedule	n	Mean ± SD; median; range
Two supervised doses / Five takeaways per week	80	$30.76 ± 8.75; 30; 10-60
One supervised dose / Six takeaways per week	73	$27.97 ± 10.30; 30; 6-60
No supervised doses / Weekly takeaways	64	$27.13 ± 10.90; 30; 5-60
No supervised doses / Fortnightly takeaways	59	$38.37 ± 20.99; 35; 5-80
Flat fee regardless of number of supervised doses and takeaways	90	$30.88 ± 8.14; 30; 5-60

Recommendation 7

It is recommended that pharmacies be encouraged to reconsider their intended fee structure for buprenorphine-naloxone to take into account the relative reduction in labour that weekly dispensing with no supervised doses allows. Providing pharmacies with more information on the process of client selection and any changes that buprenorphine-naloxone may lead to in required administration may support a more equitable fee structure.

Rationale

The absence of any cost reduction for stable clients who are no longer attending for daily supervised dosing seems inequitable. The present situation may have significant ramifications upon the appropriate roll out and best use of the opportunities that being able to provide extended periods of unsupervised dosing permits (Winstock, Lea, & Ritter, 2007). Reduced dispensing fees for clients receiving increased levels of unsupervised dosing with buprenorphine-naloxone has the potential to save considerable amounts of money for these clients, many of whom would have been on a supervised treatment program for a long period of time. Many community pharmacists have reported that buprenorphine clients dosed less than daily object to paying the same weekly fee as those on daily dosing and that this creates tension between the

client and pharmacist (Nielsen et al., 2007). This will continue to be a problem if buprenorphine-naloxone clients are charged the same dispensing fee regardless of the number of supervised and unsupervised doses received each week. However, it is important to note that the majority of pharmacists were reporting intended fee structures, not actual fee structures. Regardless, there was considerable overlap between intended fees and actual fees charged by the small number of pharmacies already dispensing buprenorphine-naloxone. These fees were comparable to the average weekly dispensing fees charged for buprenorphine and methadone. A reduction in buprenorphine-naloxone dispensing fees was evident only for clients in receipt of fortnightly takeaways with no supervised doses.

A considerable proportion of pharmacies currently dispensing buprenorphine were undecided as to whether they intended to provide buprenorphine-naloxone. It would be clinically inappropriate and potentially detrimental to the expansion of opioid treatment delivery to withhold unsupervised dose provision to stable clients on buprenorphine because their dosing pharmacy had chosen not to dispense buprenorphine-naloxone. Concerns that may underlie the ambivalence of some pharmacists in providing buprenorphine-naloxone should be addressed through education and information provision as to processes that have been put in place to support the appropriate selection of clients suitable for unsupervised dosing.

Recommendation 8

It is recommended that NSW Health consider requesting a change in policy to permit the exclusion of buprenorphine-naloxone clients in receipt of unsupervised doses from the current limit of 50 clients imposed upon dosing community pharmacies in NSW.

Rationale

If this recommendation is not supported, community pharmacists charging lower fees for unsupervised dosing with buprenorphine-naloxone will face a loss of income when a client is transferred from buprenorphine to buprenorphine-naloxone. This may act as a barrier to transferring stable clients from buprenorphine to buprenorphine-naloxone.

3.1.2.9 Credit

Q22. Do you provide credit when methadone/buprenorphine clients cannot pay?

If yes, how much (maximum)?

Q23. How many clients are currently not paid up to date?

Seventy-one percent of pharmacies (n=285) reported that they provide credit to clients when they cannot pay. The mean maximum amount of credit pharmacies permitted clients to accumulate was $64.14 (SD=85.2, range: 5-1000). This figure broadly equates to two weeks of dispensing fees. The mean proportion of clients currently in debt to their pharmacies was 22% (SD=25.55, range: 0-100).

Discussion

In a recent consumer survey of 508 clients receiving opioid treatment at 50 NSW community pharmacies, almost one-quarter of participants (23%, n=113) reported that they were currently in debt to their dosing pharmacies. The mean amount of current debt was $71.75 (SD=67.06), ranging from $2 to $400 (Madden et al., 2007, in press).

Among 448 clients receiving treatment at nine public clinics in NSW, the median weekly amount clients were willing to pay to be dosed at a pharmacy was $10.00 (mean=$13.93, SD=13.57) (Madden et al., 2007, in press). One-third reported that they could not afford to pay anything to be dosed at a pharmacy.

Recommendation 9.1

Pharmacists and clients should be given advice on how to minimise debt being accumulated at community pharmacies. Information available from the Pharmacy Guild on how to link Centrelink payments to pharmacy dispensing fees could be more widely disseminated.

Rationale

The Centrelink deduction process does not appear to be widely in use and if adopted would ensure that the pharmacy receives its fees through an automatic deduction from the client's Centrelink payment. Although this process may assist some clients in budgeting activities, for others the absence of any flexibility on payment arrangements may be overly restrictive and therefore the option of direct deductions should be done only after thoughtful discussion between pharmacist and client. There is a need for education and support to be made available to pharmacists (e.g., from the NSW Pharmacy Guild) on how to limit credit availability and on managing late payment issues. We are reluctant to recommend that under no circumstances should credit be given since clearly on occasion the availability of credit will be a beneficial intervention for clients. However, long-term accumulation of debt will be beneficial to neither clients nor community pharmacists.

Recommendation 9.2

Non-payment of pharmacy dispensing fees should be one of the routine review questions that prescribers or other clinicians enquire about when contacting a pharmacist in relation to conducting a clinical review.

Rationale

In some instances, non-payment of dispensing fees will be a marker for destabilisation and may indicate the need to return to public clinic dosing. The early identification of non-payment of dispensing fees may allow for intervention before accumulated debt or associated problems escalate to the point where a client's treatment is terminated at the pharmacy. In all cases where budgeting remains an issue, the clinic should offer direct support or referral to an appropriate financial agency to support improved budgeting control. Addressing tobacco smoking may free up significant funds for many clients and also improve their general health. The provision of nicotine replacement therapy patches through public clinics prior to pharmacy transfer may be one useful approach.

Recommendation 9.3

Consideration should be given by NSW Health to increase AHS funding to allow the subsidisation of pharmacy dispensing fees. This may be done on a transitional payment basis (i.e., supporting dispensing fees for the first three months) or on a means tested basis (i.e., full remuneration for those in receipt of Centrelink payments).

Rationale

While the majority of clients appear willing to pay at least something toward pharmacy dosing, many clients have expressed concerns to public clinic staff about the costs associated with pharmacy dosing. Less than 20% of public clinic clients report that they are in a position to pay $30 or more a week for dispensing fees (Madden et al., 2007, in press). In light of this, it may be useful to consider alternative funding. Within existing budgets, many AHS would not be in a position to support this additional cost, especially in rural and regional settings. Given that it is cheaper to provide treatment at community pharmacies than public clinics, subsiding pharmacy dispensing fees may be a sensible economic approach to both reducing costs and building client capacity in NSW. Another approach that could be adopted is that used in the Australian Capital Territory (ACT) where clients pay 50% of the dispensing fee ($15 per week) with the remainder subsidised by the government.

3.1.3 Needle and Syringe Programs (NSP)

Q2. Does this pharmacy participate in the Pharmacy Guild needle exchange scheme?

Q3. Does this pharmacy sell needles, syringes, and other injecting equipment to injecting drug users?

Thirty-nine percent of pharmacies (n=160) reported that they participate in the NSW Pharmacy Guild NSP, providing free injecting equipment to injecting drug users (IDU). Forty-two percent (n=172) reported that they sell needles, syringes, and other injecting equipment to IDU. When these figures are combined, over half of community pharmacies providing OTP make needles, syringes, and other injecting equipment available to IDU (53%, n=217). With respect to access to injecting equipment, rural areas fare less well than metropolitan areas, as they do in regard to all specialist drug and alcohol services. In particular, GWAHS and SWAHS appear to have limited access to the Pharmacy Guild NSP or pharmacies that sell injecting equipment. A breakdown of these services by AHS is presented in Table 8.

Table 8. Provision of NSP and selling injecting equipment to IDU at community pharmacies by AHS

Area Health Service	Provide NSP		Sell injecting equipment		Provide either service	
	n	%	n	%	n	%
GSAHS	10	29	17	49	22	63
GWAHS	2	13	6	38	6	38
HNEAHS	41	59	39	56	51	73
NCAHS	28	49	29	51	37	65
NSCCAHS	21	34	24	39	29	47
SESIAHS	19	32	22	37	26	44
SSWAHS	30	43	25	36	36	51
SWAHS	9	24	10	26	10	26

3.1.4 Home Medicines Review (HMR)[2]

Q1. Does this pharmacy provide a Home Medicines Review (HMR) service?

If yes, is this provided by: pharmacy owner or proprietor; employee pharmacist; contract pharmacist

Eighty-percent of community pharmacies (n=323) reported providing an HMR service. Among those pharmacies, the majority reported that HMR was provided by a contracted pharmacist

[2] Also known as Domiciliary Medication Management Review (DMMR)

(58%, n=188), while 31% (n=101) reported that the pharmacy owner or proprietor provided HMR, and 17% of pharmacies (n=56) provided HMR through an employee pharmacist.

Discussion

As they are medicines with a narrow therapeutic threshold, clients in methadone and buprenorphine treatment qualify for HMR. The findings of this study suggest that most clients dosed at a community pharmacy will have ready access to an HMR assessor once a referral from a GP is made. The HMR may, when used as part of comprehensive assessment, provide a client's GP with additional information that can contribute to the GP care plan (see *Patient Journey Kit 1*, available online) (SWAT, 2007b). In some cases where the dosing pharmacist is also HMR accredited, additional information may be available to the GP regarding client stability and use of other prescribed or over the counter medications.

The GP/pharmacist should determine the most appropriate location to conduct the HMR in discussion with the client. It is not mandatory that the interview be done in the client's home, as long as it is in a location in which the client and the pharmacist are both comfortable, and the client's privacy is protected. In part, a suitable location will be determined by factors such as convenience and client preference. In cases where the pharmacist is considering conducting such a review in the client's home, a risk assessment should be undertaken by the pharmacist regarding such factors as the presence in the home of persons with a history of violence, and pets, particularly dogs, in the home. Also, any child protection issues that arise must be appropriately addressed.

HMRs are a useful additional source of clinical information that provide important information about the client to the GP, and provide additional remuneration for both the GP and the pharmacist. HMRs may support ongoing provision of treatment to this client group by both professions who, as a result of adopting this process, may not only provide better coordinated care but may also be better remunerated.

Recommendation 10.1

It is recommended that referral pathways are developed to increase the uptake and appropriate use of HMRs by both GPs and community pharmacies involved in the delivery of opioid treatment.

Recommendation 10.2

Information about the number of HMRs completed for clients on opioid treatment over specified time periods is required. It is recommended that a monitoring system be established.

Rationale

Within the context of a combined care and business plan (see *Patient Journey Kits*) (SWAT, 2007b), HMRs probably represent an under-utilised resource for OTP clients and their prescribers. At present, pharmacies are not required to record details of HMRs undertaken. As a result, there is no way of recording the current level of HMR utilisation by OTP clients. The NSW Pharmacy Guild in collaboration with the Alliance of NSW Divisions of General Practice and the Australian General Practice Network (AGPN, formerly Australian Divisions of General Practice (ADGP)) should be encouraged to co-ordinate the promotion of HMRs in the management of clients on opioid treatment programs. The *Patient Journey Kits* will support this process.

3.2 Problems pharmacists experienced with clients

3.2.1 Refusal to dose

Q12. Have you refused to administer a supervised dose of methadone or buprenorphine to clients at this pharmacy for any of the following reasons:

- They were intoxicated
- They were behaving aggressively
- They had missed three or more doses
- They were in debt to the pharmacy
- Their script had expired
- Other (Specify)

Pharmacies were asked whether they had refused to dose a client in the preceding month and in the preceding 12 months for a variety of specified reasons including client intoxication, aggressive behaviour, three or more missed doses, expired prescription and debt to the pharmacy for non-payment of pharmacy dispensing fees. Overall, 74% (n=302) of pharmacies had refused to dose a client for any reason in the preceding 12 months, and 32% (n=129) had refused to dose a client for any reason in the preceding month.

The most commonly reported reason for refusal to provide a dose was an expired prescription, reported among 62% (n=246) of pharmacies in the preceding 12 months, and 23% (n=91) of pharmacies in the preceding month. Almost half of pharmacies (48%, n=189) had refused to dose a client in the preceding 12 months because he/she had missed three or more doses. One in 10 pharmacies (10%, n=41) had refused to dose a client in the preceding month because he/she was in debt to the pharmacy. Detailed results are presented in Figure 5.

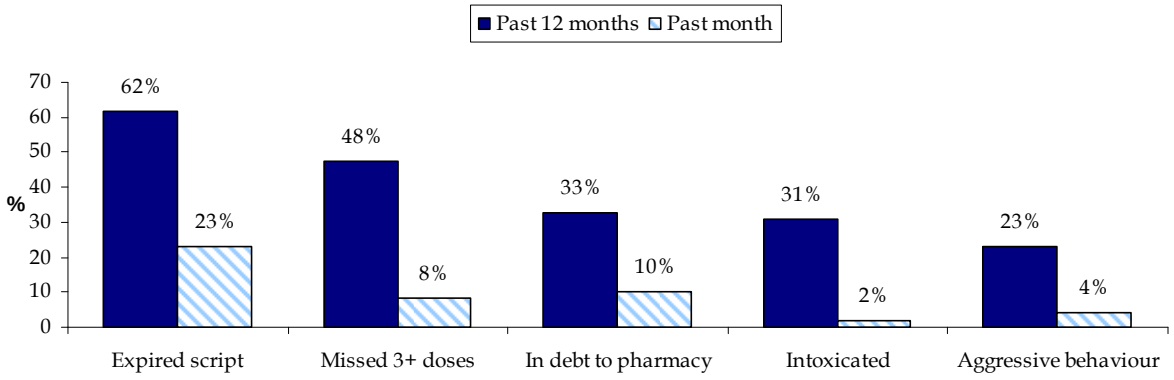

Figure 5. Proportion of community pharmacies that had refused to dose a client in the preceding month and the preceding 12 months

The utility of these findings is somewhat limited since information regarding the number of clients actually refused a dose was not requested, the results being limited to the number of pharmacies who had refused to dose at least one client in the given time periods. This does not give any indication of pharmacy policies or standards of practice. We do not know how many pharmacists dosed on expired prescriptions, or how many dosed a client after three doses were missed, so results should be interpreted with some degree of caution.

Recommendation 11

Refusing to dose a client may be a difficult decision for pharmacists and is likely to result in client distress, regardless of the reason. It is suggested that all clients are made aware at the commencement of community pharmacy treatment the circumstances under which they will be refused a dose. This information should be provided verbally and in written form. Pharmacists and their staff should be provided with access to educational resources that will provide them with skills in managing threatening behaviour.

3.2.2 Identification of opioid toxicity and opioid withdrawal

Q16. How competent would you feel in identifying opioid toxicity and opioid withdrawal in methadone and/or buprenorphine clients at your pharmacy?

(Very competent/Somewhat competent/Not competent)

Regarding the self-assessed competence of pharmacists in identifying opioid toxicity and opioid withdrawal in clients on methadone and buprenorphine treatment, the majority of pharmacists reported that they were 'somewhat competent' in identifying opioid toxicity and opioid withdrawal, with a minority reporting that they were 'very competent' or 'not competent' (see Figure 6).

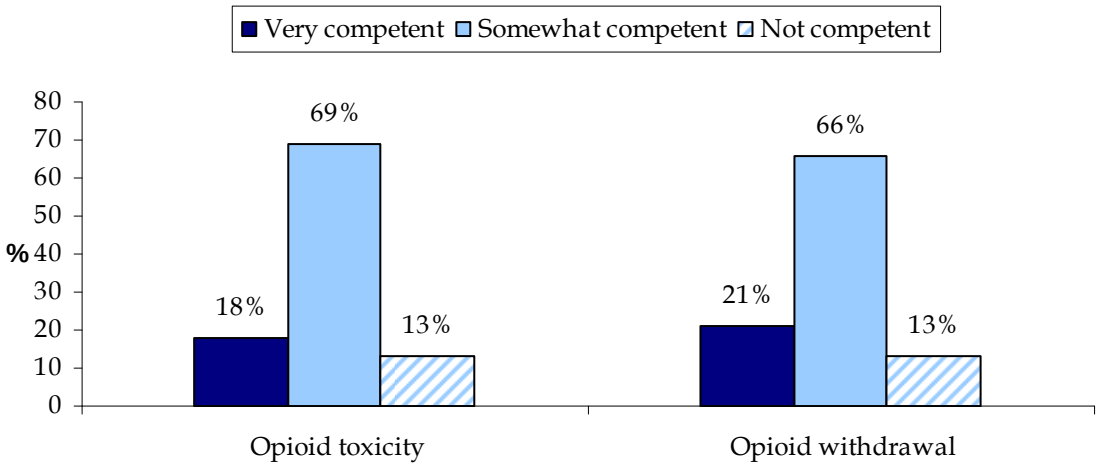

Figure 6. Pharmacists' self-reported competence in assessing opioid toxicity and opioid withdrawal in clients on methadone and buprenorphine treatment

Discussion

While the results reflect a reasonable level of self-reported competence in the identification of opioid intoxication and opioid withdrawal by the majority of community pharmacists, it is of some concern that almost one in eight pharmacists identified themselves as 'not competent' in these important skills which are necessary to ensure the safety of clients. It is also a concern that only a small proportion of pharmacists rated themselves as 'very competent' in identifying opioid toxicity and opioid withdrawal.

That this issue is of clinical importance is confirmed by findings of a survey of community pharmacists providing methadone treatment in Melbourne (Koutroulis et al., 2000). They reported that 32% of pharmacists would provide clients with their prescribed methadone dose if they presented intoxicated. However, 56% of pharmacists reported that they would notify a client's prescriber at the time if the client presented for dosing intoxicated (Koutroulis et al., 2000). In the current survey, almost one-third of pharmacies had refused to dose a client in the preceding 12 months due to intoxication. However, contrary to the findings of Koutroulis et al,

most pharmacists in the current survey reported that they would notify the prescriber or public clinic if they refused to dose a client, irrespective of the reason (see Section 3.2.3 below).

Dosing pharmacists need to be confident in their ability to assess intoxication and sedation over the counter to avoid providing medication to a person for whom its consumption may lead to an adverse outcome, including precipitated withdrawal in those on buprenorphine (Walsh & Eissenberg, 2003). Pharmacists have a duty of care not to provide a dose to a client in such instances. They should be supported in making these decisions by having adequate education to be confident in identifying such occasions. Since community pharmacists also play an important role in supporting dose reduction in stable clients, it may be helpful to provide education on being able to assess both subjective and objective signs of withdrawal to assist in accurate feedback to both clients and prescribers which may guide any changes in dosing.

Recommendation 12

Training should be developed and made available to all community pharmacists regarding the identification of and appropriate responses to intoxication and withdrawal for all psychoactive substances (particularly opioids and other central nervous system depressants). This is especially important for community pharmacists providing methadone and buprenorphine treatment. Such training should be video-based to be most effective. NSW Health should liaise with the Pharmacy Guild and Pharmaceutical Society of Australia (PSA) in developing such a resource and formulating effective strategies for disseminating this information to pharmacists. Consideration should be given to providing this training to undergraduate pharmacy students.

Rationale

Given the risk of fatal overdose associated with methadone, particularly among those recently commenced on methadone treatment (Caplehorn & Drummer, 2002; Sunjic & Zador, 1999; Zador & Sunjic, 2000; Zador & Sunjic, 2002), the training of pharmacists who provide methadone to become more competent in the identification of opioid toxicity and opioid withdrawal may help to reduce the incidence of methadone overdose and methadone-related deaths. Visual examples of the important physical signs and symptoms of opioid withdrawal and opioid toxicity will be most helpful to pharmacists in learning to recognise these in their own clients. Pharmacy students are likely to be particularly receptive to such training, and have ready access to training sources.

3.2.3 Notification of refusal to dose and missed doses

Q13. Do you notify their prescriber/clinic if you have refused to dose a client?
Q14. Do you notify their prescriber/clinic if a client misses three or more consecutive doses?

The majority of pharmacies (85%, n=334) reported that they notify a client's prescriber or public clinic in all cases where a client is refused a dose. Thirteen percent (n=49) reported that they sometimes notify the prescriber or public clinic, and 2% (n=9) do not notify the prescriber or public clinic in these situations. It was not determined whether pharmacies were more or less likely to notify the prescriber or public clinic depending on the reason why a client was refused a dose.

Regarding notifying a client's prescriber or public clinic if three or more consecutive doses are missed, almost all pharmacies (95%, n=372) reported that they notify the prescriber or clinic in all cases of this situation arising, while 3% (n=11) sometimes notify, and 2% (n=8) do not notify the prescriber or clinic.

Recommendation 13

Prior to the renewal of any script, the pharmacist should be contacted by the prescriber or public clinic and asked to provide clinically relevant information on the client's progress. This feedback may be formalised utilising written *Pharmacy Feedback Forms* (Appendix D).

Rationale

Community pharmacists are to be commended on their prompt and appropriate action in notifying prescribers or clinics when clients miss doses or are refused a dose. Early notification by pharmacists of behaviours suggestive of destabilisation may allow pre-emptive action to be taken by the public clinic or prescriber to prevent the client from disengaging with treatment. The use of *Pharmacy Feedback Forms* (see Appendix D) may be one way to ensure the regular exchange of information concerning a client's progress at community pharmacies.

Ideally the *Pharmacy Feedback Form* would be completed by the pharmacist and returned to the prescriber and public clinic (if applicable) a few days before the next review appointment. The co-ordination of this may be difficult and places additional administrative burden upon the pharmacist. It is therefore suggested that the prescriber or public clinic case manager contact the pharmacy and obtain the information required for a *Pharmacy Feedback Form* to be completed prior to the client's next prescriber review. Since this takes only one or two minutes to complete, it can

easily be done while the client is in the consultation room or waiting room. This process permits timely and efficient feedback with minimal additional burden on the pharmacist. Documentation that such information has been obtained by the prescriber is also useful should there ever be a need to justify clinical decisions. An additional benefit of the prescriber contacting the pharmacist during a patient consultation is the explicit demonstration of information exchange between different service providers. At the very least, prescribers should ask the dosing pharmacist the following questions before providing their patient with a prescription:

1. Have they missed any doses?
2. Have you refused to provide any doses?
3. Have they presented for dosing intoxicated?
4. Do you have any other concerns?

Community pharmacists have considerably more contact with clients on opioid treatment than prescribers and are thus an essential source of information on client progress. Findings from this study also support the notion that, as a group, pharmacists would like to be more involved in the care of these clients. Ensuring that prescribers have access to information on client behaviour and compliance with treatment will assist prescribers in their clinical decisions, particularly regarding the provision of takeaways and changes to dose. In addition, many pharmacists have indicated that greater integration with other health care professionals involved in the delivery of care for OTP clients would encourage greater participation in overall treatment provision (see Figure 4).

3.2.4 Termination of treatment

Q15. Have you terminated treatment for a client at your pharmacy in the past 12 months / past month?

If yes, how many clients have you terminated in the past year? (Less than five/five to 10/More than 10)

What was the most common reason you terminated a client's treatment?

Almost half of the pharmacies (47%, n=191) had terminated a client's treatment in the preceding 12 months, and 11% (n=43) had terminated a client's treatment in the preceding month. Among these pharmacies, the majority (94%, n=180) had terminated treatment for less than five clients in the preceding 12 months. Pharmacies were not asked to identify the specific number of clients whose treatment they had terminated; they were provided with a range to select from. As such,

only a broad estimate of the number of clients who may have had their treatment terminated at a pharmacy can be provided. Based on available information, we estimate that between 240 and 820 clients had their treatment terminated at the community pharmacies surveyed in the preceding 12-month period. This represents between 3% and 12% of the total treatment population at community pharmacies in NSW (NSW Health, unpublished data, December, 2006).

Pharmacies were asked to report the most common reason they had terminated a client's treatment in the preceding 12 months. This question was asked in an open-response format and responses were coded by one researcher. The most common reasons for termination of treatment initiated by community pharmacists are presented in Table 9; these were inappropriate client behaviour and non-payment of dispensing fees.

The third most common reason for termination, cited by 25 pharmacists, was transfer from the community pharmacy not initiated by the pharmacist. This included clients transferring their treatment to a different pharmacy, returning to a public clinic, or leaving the treatment program. While the questions regarding termination of pharmacy treatment were directed at termination initiated by the pharmacist, it is clear from these responses that some pharmacies included any client who ceased treatment at their pharmacy in their definition of termination. The proportion of pharmacies that had actively terminated a client's treatment on the grounds of problematic issues may therefore be lower than reported. The minimum and maximum number of potential terminations in the preceding 12 months should also be interpreted with caution.

Table 9. Most common reasons for pharmacist initiated termination of treatment at a community pharmacy in the preceding 12 months

Reason for termination	**Number of pharmacies**
Behaviour (aggressive/offensive/intoxication)	64
Non-payment of dispensing fees	29
Diversion/selling dose or takeaways	17
Noncompliance/missed doses	23
Shoplifting from pharmacy	7
Unstable client	11
Pharmacy had > 50 clients	1

Discussion

The most common reasons for pharmacist-initiated termination can all be considered as markers of instability. That between 240 and 820 clients had their treatment terminated at a participating pharmacy in the preceding 12 months for potentially preventable reasons is a major cause of concern and should remain a focus for treatment providers. The selection of more stable clients for transfer may reduce the number of early clinic returns. Early detection of destabilisation among community pharmacy clients may provide an opportunity for early intervention (e.g., reviews by case manager and prescriber). Detecting and responding early to such signs may reduce the number of clients whose pharmacy treatment is terminated, improving client outcomes and reducing the requirements of public clinics to take back unstable clients.

At the outset of treatment, unacceptable behaviours and conditions which may lead to refusal of a dose should be made clear to clients by the pharmacist, and may be supported by contracts. It should also be determined at the start of treatment the process for script renewals, dose refusal, reminders of appointment dates, and consequences of non-attendance at prescriber reviews. This can be reiterated at regular intervals throughout treatment. Given that non-payment of dispensing fees and accumulated debt are common reasons for treatment termination at a community pharmacy, subsidisation of dispensing fees may be considered by NSW Health as one approach to enhance retention in treatment (see Recommendation 9.3). This is particularly important given the financial hardships often experienced by clients on methadone and buprenorphine treatment (Gossop, Marsden, Stewart, & Kidd, 2003; Mattick et al., 2001; Ross et al., 2005).

All dosing pharmacists should be reminded that they are not legally permitted to provide a drug of addiction to a client without a valid prescription. If a pharmacist provides doses of methadone or buprenorphine to a client whose script has expired, or provides takeaway doses when not indicated, they will be contravening the *Poisons and Therapeutic Goods Regulation 2002 (NSW)* made under the *Poisons and Therapeutic Goods Act 1966 (NSW)*. Pharmacists should also be aware that prescribers are not obligated to provide retrospective prescriptions for dispensed medications.

Ultimately, expired prescriptions should remain the responsibility of clients, although friendly and timely reminders from the dosing pharmacist one to two weeks before the expiry date may be helpful. It may be that better co-ordination between public clinics, prescribers and pharmacies may reduce the incidence of expired scripts. However, when due to non-attendance for script review, the refusal to dose may be clinically indicated since the ongoing provision of a

prescription without a prescriber review may place both the patient and prescriber at risk. The introduction of computerised prescriptions may help automate this process.

It may also be useful for public clinics to monitor the proportion and number of transferred clients that remain without incident at community pharmacies. If stability assessment processes are consistently implemented in the selection of clients identified as suitable for community pharmacy dosing and review processes between prescriber, public clinic and pharmacy adopted, the number of pharmacist initiated terminations may be reduced (see *Stability Assessment Flowchart,* Appendix B; *Pharmacy Feedback Forms,* Appendix D). Regardless of how well an assessment is conducted, sometimes clinical judgement will not accurately reflect a client's situation. Ongoing assessment and review is required to monitor changes in client progress following transfer to a community pharmacy. This ensures that changes in a client's circumstances and behaviour are identified early and that appropriate changes to care plans can be implemented.

Recommendation 14

Public clinics should monitor the proportion and number of transferred clients that remain without incident at community pharmacies.

Rationale

The period of transfer between dosing sites may represent a high-risk time for client destabilisation. Thus there is a requirement for a planned, negotiated and mutually agreed timeframe for each individual to ensure that the transfer does not result in poor client outcomes. Selection of stable clients, based on definitions and processes shared between clinic and client should support the most optimal outcome – ongoing effective retention in treatment.

The tracking of client movement between dosing sites may have an additional benefit in exploring whether there is any particular pattern (e.g., clients transferred to a particular pharmacy or selected by a specific clinician), or risk factors for clients destabilising at community pharmacies and having their pharmacy treatment terminated. Identification of any patterns may permit effective responses to enhance treatment retention. For example, it may be that the period during which clients are most likely to be terminated because of non-payment or aggression is during the first few months following transfer. In this instance, the schedule for script reviews and nature of feedback from the pharmacist to the prescriber and public clinic could be adapted to ensure closer monitoring and support during high risk times. It may be useful for public clinics to track clients for at least the first six to 12 months after transfer. It is possible that a low rate of return to clinic following transfer to a pharmacy may indicate that the appropriate selection of

stable clients has occurred prior to transfer. Data collected through the PSB may be used to track retention in treatment following transfer of dosing location within an AHS. State-wide data broken down by AHS has been requested as part of the *SWAT Clinical Mapping Activity Dataset* and local data will be made available to each AHS. Different levels of local data collection may be required to assist individual clinics to monitor their own client retention following transfer.

3.2.5 Diversion of methadone and buprenorphine

Q32. Have you seen a client divert/attempt to divert his/her methadone at this pharmacy in the past 12 months/past month?

Q33. Have you seen a client divert/attempt to divert his/her buprenorphine at this pharmacy in the past 12 months/past month?

Q36. Thinking of the last person you considered to have diverted/attempted to divert their medication, what action did you take?

- Nothing
- Refused to provide further treatment
- Notified prescriber/clinic
- Changed dispensing practice
- Confronted client about diversion
- Returned client to clinic
- Other (Specify)

Diversion, for purposes of this report, is defined as 'a client removing or attempting to remove a supervised methadone or buprenorphine dose from the pharmacy before the dose has been fully absorbed by the client'. Pharmacies were provided with this definition in the questionnaire.

Among pharmacies providing methadone, 37% (n=129) had seen at least one client divert or attempt to divert a supervised methadone dose in the preceding 12 months, and 9% (n=30) had seen diversion or attempted diversion of supervised methadone in the preceding month. Among pharmacies providing buprenorphine, 29% (n=67) had seen at least one client divert or attempt to divert a supervised buprenorphine dose in the preceding 12 months, and 7% (n=16) had seen diversion or attempted diversion of supervised buprenorphine in the preceding month.

Pharmacists who had seen diversion of methadone or buprenorphine at the pharmacy in the preceding 12 months (n=154) were asked to report which of a number of possible treatment responses they performed in response to the most recent episode of diversion at the pharmacy. Pharmacists could select more than one response from a list provided. Results are presented in Table 10.

Table 10. Pharmacist responses to most recent episode of methadone or buprenorphine diversion

Response	n	%[a]
Notified prescriber / public clinic	105	68
Confronted client about diversion	115	75
Changed dispensing practice	50	32
Refused to provide further treatment	40	26
Returned client to public clinic	30	19
Gave warning would be terminated	5	3
Increased supervision	1	1
Did nothing	1	1

[a] % of pharmacists who had seen diversion or attempted diversion in the preceding 12 months

Discussion

A variety of motivations for dose diversion have been reported including saving the dose for later, recent or planned heroin use, pressure from others to divert, ambivalence over treatment, wanting to inject the dose, or wanting to sell the dose (Fountain, Strang, Gossop, Farrel, & Griffiths, 2000; Winstock, Lea, & Jackson, 2008, in press). In its various guises, diversion can be regarded first and foremost as a marker of problems within the therapeutic relationship. As such, the first response must be one that attempts to re-engage the client into an effective treatment relationship as opposed to a punitive response from treatment providers. An inconsistent response by pharmacists to different clients may lead to problems at individual dosing sites and may result in unnecessary conflict and possible termination of treatment. In addition, having a structured, therapeutically orientated response to diversion may result in a potentially divisive episode being used as a window of opportunity to proactively address any underlying problems related to treatment.

The majority of diverted methadone comes from diverted methadone takeaways (Lintzeris et al., 1999; O'Brien et al., 2007; Ritter & Di Natale, 2005). However, findings from this study indicate that attempted diversion of a supervised methadone dose occurs, with almost one in 10 pharmacists reporting at least one incident in the preceding month. It appears that there is an over-representation of buprenorphine diversion compared to methadone diversion, as there are more than seven times as many clients on methadone than buprenorphine in NSW. In the current study, the detection of at least one episode of diversion in the preceding month and preceding 12 months was broadly similar between the two pharmacotherapies. However, comparison of observed diversion for supervised buprenorphine and methadone is not

straightforward. Since the majority of methadone clients would have been in receipt of regular takeaway doses, the necessity for diverting a supervised dose may be reduced. Secondly, the process of administration of methadone gives only a short window in which an attempt at diversion may be made compared to the several minutes available to clients dosed with buprenorphine. Further, diverting a sublingual tablet would appear easier than diverting a supervised oral liquid dose, as the tablet can be secreted in the mouth (Winstock, Lea, & Sheridan, 2008). Taken together, these differences suggest that it may be easier to identify the diversion of supervised methadone than supervised buprenorphine. This may explain the high rate of detection of diversion of supervised methadone.

3.2.5.1 Buprenorphine diversion

Q31. Which of the following buprenorphine preparations do you think is associated with the highest rate of diversion?

(Whole tablets/Broken into two to six pieces/Coarse granules/Fine powder)

Q30. Which of the following do you consider are examples of buprenorphine diversion:

- Spit dose onto floor/into bin
- Swallow dose
- Attempt to remove dose from mouth into hand/clothing
- Obscure dose in mouth (identified by mouth inspection before leaving pharmacy)
- Moving tablets around mouth during absorption
- Particular interactions with others inside or outside the pharmacy
- Attempt to leave pharmacy before having mouth inspected
- Attempt to move out of view while being observed
- Swallow dose after being approached by staff
- Other (Specify)

Additional questions were asked about buprenorphine diversion because of the relative ambiguity of the act when applied to the diversion of a sublingual tablet. These questions were not asked about oral methadone as there was assumed to be less ambiguity regarding non-compliance with the ingestion of an oral liquid. In retrospect this was an unfortunate omission.

The majority of pharmacies providing buprenorphine treatment (91%, n=204) considered that whole tablets were associated with the highest rate of buprenorphine diversion. A minority reported that tablets crushed to a fine powder (4%, n=10), and tablets broken into two to six pieces (4%, n=9) were associated with the highest rate of diversion.

Pharmacies were provided with a list of nine behaviours that may be considered to be indicative of an episode of buprenorphine diversion during supervised dosing. The behaviours that the majority of pharmacies considered to be examples of buprenorphine diversion were clients attempting to remove the dose from their mouths into a hand or clothing; attempting to move out of view while being observed during absorption; attempting to leave the pharmacy before having their mouths inspected; and, obscuring the dose in their mouths as identified by a mouth inspection. Detailed results are presented in Table 11.

Table 11. Behaviours considered as examples of buprenorphine diversion among pharmacies providing buprenorphine treatment

Behaviour	**n**	***%***
Attempt to remove dose from mouth into hand/clothing	211	87
Attempt to move out of view while being observed	193	80
Attempt to leave pharmacy before having mouth inspected	193	80
Obscure dose in mouth (identified by mouth inspection)	177	73
Particular interactions with others inside/outside pharmacy	120	50
Spit dose onto floor/into bin	101	42
Swallow dose after being approached by staff	97	40
Moving tablets around mouth during absorption	58	24
Swallow dose	56	23

Discussion

The diversion of buprenorphine from community pharmacies is a significant issue for a number of reasons. First, there are significant risks associated with use of diverted buprenorphine. The injection of sublingual buprenorphine tablets has been associated with serious injection-related complications (Cazorla et al., 2005; Feeney & Fairweather, 2003; Jenkinson, Clark, Fry, & Dobbin, 2005; Loo, Yam, Tan, Peng, & Teoh, 2005), and has been implicated in a series of buprenorphine-related deaths (Kintz, 2001 & 2002). The proportion of pharmacies reporting buprenorphine diversion in the current study was high: almost one-third in the preceding 12 months and one in 14 pharmacies in the preceding month. Finally, there was wide variation in what behaviours were considered to be buprenorphine diversion. This is of particular concern given that some pharmacies responded to suspected diversion by terminating the client's treatment at the pharmacy.

This study has identified diversion to be a poorly defined concept when applied to the supervised administration of buprenorphine. Community pharmacists providing buprenorphine treatment

should be provided with a clear definition of what behaviours can confidently be identified as episodes of attempted or actual buprenorphine diversion. The inconsistent identification of diversion within community pharmacies places both clients and pharmacists at risk of potentially avoidable adverse outcomes. Behaviours that were not actually diversion may have resulted in termination of pharmacy treatment for some clients.

In cases of suspected diversion, it is suggested that the pharmacist provide feedback to clients that continued non-adherence to dosing instructions may jeopardise future treatment provision at the pharmacy. The client's prescriber and/or case manager should also be notified and a clinical review scheduled. To avoid arguments, false accusations, or the possibility that clients are unaware that particular actions may be interpreted as diversion, there must be consistent and unambiguous recommendations about how buprenorphine is to be administered and optimally absorbed. In addition, it is important that the expectations of clients be explained in an unambiguous way by the pharmacist. These expectations should be determined at the outset of treatment, be reiterated throughout the first few weeks at a new dosing site and be supported by written information in the form of a contract (see Appendix E – *Is buprenorphine the right drug for you?*).

Recommendation 15

Clarity as to what constitutes an episode of buprenorphine diversion is required. SWAT proposes the following definition be adopted: "a client removing or attempting to remove a supervised buprenorphine dose from the dosing site before the dose has been fully absorbed by the client".

Recommendation 16

It is recommended that a consistent, therapeutically orientated response to suspected episodes of diversion be developed and implemented within dosing community pharmacies. Such responses should be consistent with those adopted at local public clinics. Suspected episodes should be followed by a first and second (final) warning and be accompanied by notification to the prescriber and/or public clinic with request for an early clinical review for the client.

3.3 Buprenorphine

3.3.1 Buprenorphine practice

Q27. How does this pharmacy most often prepare buprenorphine for supervised dosing?

(Whole tablets/Crushed to granules/Crushed to fine powder/Tablets broken into two to six pieces/Other)

Q28. What is the main reason this pharmacy most often prepares buprenorphine in this way?

- To reduce diversion
- To speed up dissolving
- To increase absorption
- Client request
- Script instructions
- Other (Specify)

Pharmacies administering buprenorphine were asked to report how they most often prepared buprenorphine for supervised dosing. The most commonly reported preparation was tablets broken into two to six pieces, reported by half of pharmacies, followed by whole tablets reported by one-third of pharmacies, and crushed tablets reported by 14% of pharmacies (see Figure 7).

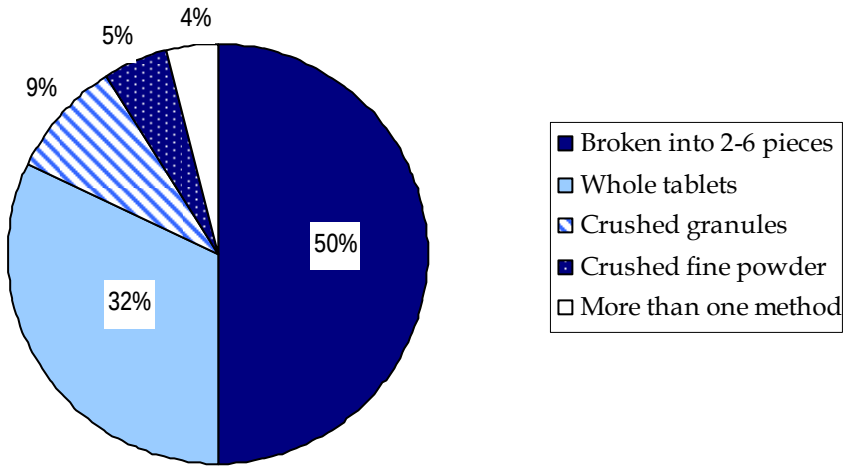

Figure 7. Most common method of preparation of buprenorphine for supervised administration reported by community pharmacies

Pharmacies were asked to report the main reason why the pharmacy most often prepares buprenorphine in this way. Results were compiled separately for pharmacies depending on the way they most often prepared buprenorphine. The most commonly selected reason that pharmacies prepared buprenorphine broken into two to six pieces was 'to speed up dissolving'.

The most common reason pharmacies administered whole buprenorphine tablets was due to 'client request', while the main reason pharmacies administered crushed buprenorphine tablets was 'to reduce diversion'. Results are presented in Figure 8.

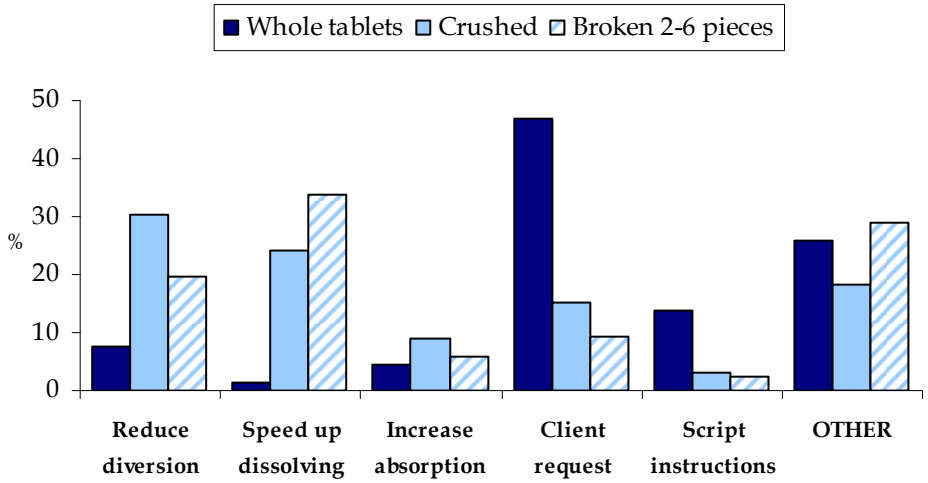

Figure 8. Most important reason community pharmacies prepare buprenorphine according to different methods of buprenorphine preparation

Discussion

This study has confirmed the widespread variation in administered preparations of buprenorphine at community pharmacies. Although approval of buprenorphine by the Therapeutic Goods Administration (TGA) was based on clinical trials that investigated sublingual tablets administered as whole tablets, the most common methods of buprenorphine administration in the current study involved manipulation of the tablet. Whether or not these practices have any utility in addressing the dual aims of speeding up dissolution and reducing diversion is unclear. The sublingual bioavailability of different buprenorphine preparations must be assessed in a crossover study that also examines different doses before any recommendation can be made regarding the optimal mode of administration of sublingual buprenorphine. At present there are varied opinions on the consequences of crushing tablets (Muhleisen, Spence, & Nielsen, 2003; Nielsen et al., 2007; Winstock et al., 2008). While smaller particles provide a larger surface area for absorption and possibly quicker dissolution, the provision of crushed powder may also lead to a particulate solution being formed that may promote premature swallowing. In addition, a crushed powder may be more difficult to physically keep under the tongue. While whole tablets are generally considered more susceptible to diversion and take longer to dissolve, they may be more easily kept under the tongue and the slower dissolution may provide more time for the buprenorphine to be absorbed increasing overall bioavailability. However, at the present

time there is a lack of evidence to ascertain the bioavailability of different preparations of buprenorphine and the relative risk of diversion of different preparations.

Recommendation 17

It is recommended that 8mg buprenorphine tablets are broken in half or into four to six pieces. Tablets should be broken in the blister pack prior to administration. 2mg tablets should be administered as whole tablets.

Rationale

This recommendation is based on a large amount of observational work, discussion with staff and clients, and a review of the limited available evidence. In terms of optimal preparation, breaking the tablet in the blister pack before administration is a simple, sterile approach that does not require the use of tablet cutters or crushers. The broken tablets then can be placed in a cup and given to clients with instructions that the cup is to be emptied under the tongue and returned to the dispenser. Clients should be asked to remain in the dosing area until the entire dose is absorbed. During stabilisation on buprenorphine, it may be worthwhile to adopt a 'supportive supervised observation' approach which emphasises supervision and observation as being helpful in providing feedback to the client on optimal absorption strategies (e.g., tipping head forward, swallowing saliva, not swallowing the tablet).

A summary recommendation on the administration and supervision of buprenorphine has recently been prepared by NSW Health based on SWAT recommendations. Please refer to Appendix F – *Dispensing buprenorphine (Subutex®, Suboxone®) to achieve optimal absorption.*

3.3.2 Supervision of buprenorphine dosing

Q29. Please indicate how often you perform the following when administering buprenorphine at this pharmacy:

(Never/Sometimes with some clients/Always with some clients/Always with all clients)

- Before administering, do you check that the client's mouth is empty?
- After administering the dose, do you check that the dose has been placed under the client's tongue?
- Do you require that clients remain in the pharmacy while they are absorbing their dose?
- Do you observe clients while they are absorbing their dose?
- Do you check that the dose is still under their tongues while it is absorbing? (midway check)
- Do you check that the all their dose has been absorbed before clients leave the pharmacy?

Pharmacies providing buprenorphine were asked about their practices regarding the supervision of buprenorphine dosing. Pharmacists were asked to report the degree of supervision they provided for a number of supervision practices on a four-point scale. Results for each practice are presented in Figure 9.

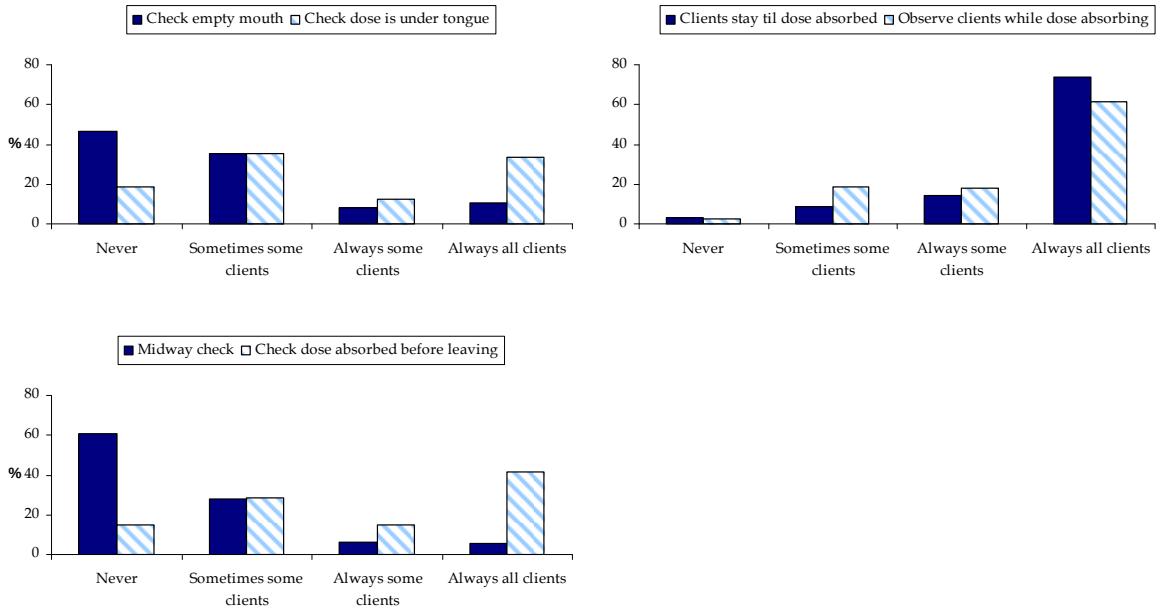

Figure 9. Frequency of supervision of buprenorphine administration and absorption

Discussion

It is likely that the wide variation in supervision provided during buprenorphine dosing reflects the variation in perceived need for supervision among pharmacists dosing different clients. Central to the question 'what level of supervision is sufficient?' is what the purpose of supervision is, and how well it achieves these goals. In the first instance, supervision is in place to reduce diversion. Secondly, supervision allows regular contact with a health care professional and especially early on in treatment may permit the opportunity for educational feedback on optimising absorption. It could be argued that for clients who have been stable on treatment with no evidence of diversion or instability, high levels of observation may not be required. Indeed, it will be this group of clients who will be deemed suitable for transfer onto buprenorphine-naloxone. In such instances, many clients may not be in receipt of any supervised doses at all.

Recommendation 18

Once administered, buprenorphine should be sighted by the pharmacist as being under the tongue and the client requested to remain within view of the pharmacist until all the medication is absorbed. Clients should have clear expectations of what is required of them during the supervised period.

3.4 Problems experienced with prescribing doctors

Q38. Have you experienced any of the following problems with doctors prescribing methadone/buprenorphine in the past 12 months/past month?

- Difficulty contacting prescribing doctors
- Inadequate information provided by doctor about other health needs of individual clients
- Poor communication between doctor and pharmacy regarding changes to treatment
- Illegible scripts
- Unclear dosing instructions
- The provision of takeaways to clients you considered unstable

Pharmacies were asked to report if they had experienced any of a number of problems in relation to their clients' methadone and buprenorphine prescribers in the preceding 12 months and in the preceding month.

The most commonly reported problems experienced in both the preceding 12 months and preceding month were difficulty contacting prescribing doctors and the prescribing of takeaway doses for clients considered unstable by the pharmacist. Results are presented in Figure 10.

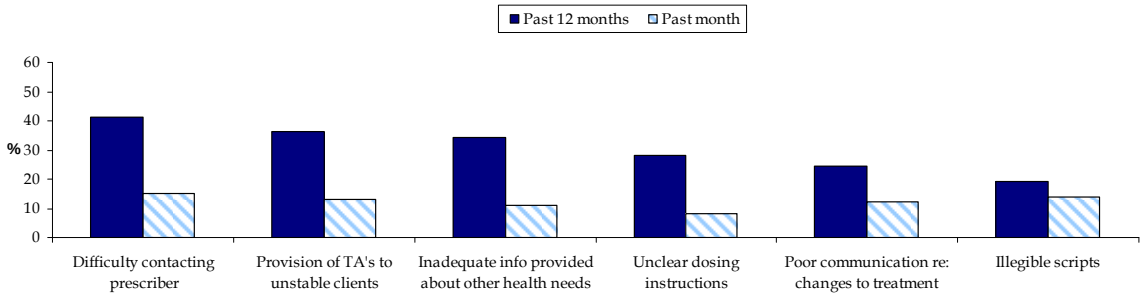

Figure 10. Proportion of community pharmacies experiencing problems with methadone and buprenorphine prescribers

Discussion

Over the course of 12 months it appears that many community pharmacists experienced problems with methadone and buprenorphine prescribers. The issues of concern cited above are clinically important, and improved communication exchange between pharmacists and prescribers may help in providing better care to clients. Improved access to prescribers by pharmacists may become less of an issue if the prescriber or public clinic makes regular contact with the pharmacist (e.g., prior to renewing a client's prescription). Please also refer to the *Pharmacy Feedback Forms* (Appendix D). Prescribers should consider feedback provided by dosing

pharmacists in their decision to prescribe takeaway doses. This is especially the case where the prescriber is providing the maximum permitted number of takeaway doses.

Recommendation 19

All dosing community pharmacies should be provided with the contact details and hours of availability of public clinics and prescribers whose clients are dosed at the pharmacy. This information should be provided as part of the arrangements undertaken when any clients are accepted for dosing at the pharmacy.

4. Conclusions

This study provides an important insight into the current practices of community pharmacies providing methadone and buprenorphine treatment for opioid dependence across NSW. A major finding was the significant under-utilisation of available capacity for pharmacotherapy clients at community pharmacies, with the potential to further increase this capacity by the adoption of simple communication and streamed shared care practices such as transferring clients to community pharmacy dosing only when stability has been demonstrated. Other key findings include a high level of pharmacy adherence to recommended guidelines on refusal to dose and prescriber notification. Problems experienced by community pharmacists with prescribing doctors are not uncommon, with many of these amenable to simple improvement in communication and information exchanges. Finally, there was considerable variation in the level of supervision of buprenorphine dosing provided at different pharmacies as well as ambiguity over what constitutes an episode of buprenorphine diversion. This highlights the need for clear, evidence-based guidelines on the optimal process for the administration and supervision of buprenorphine.

It is strongly recommended that NSW Health maintain a long-term commitment to supporting the appropriate transfer of clients from public clinic to community pharmacy dosing. Locally relevant initiatives are required to address the variations in practice, resources and culture across NSW.

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6. Appendices

Appendix A. Pharmacy Practice Questionnaire

Appendix B. Stability Assessment Flowchart

Appendix C. Method of calculating public clinic throughput to community dosing

Appendix D. Pharmacy Feedback Forms

Appendix E. Is buprenorphine the right drug for you?

Appendix F. Dispensing buprenorphine (Subutex®, Suboxone®) to achieve optimal absorption

Appendix A. Pharmacy Practice Questionnaire

OPIOID TREATMENT PROGRAM PHARMACY PRACTICE SURVEY

This survey has been endorsed by the Pharmacy Guild of Australia (AAA rating; Survey no. 623)

Your Pharmacy

1. Does this pharmacy provide a home medication review (HMR) service? O Yes O No

   If yes, is this provided by: O pharmacy owner / proprietor O employee pharmacist O contract pharmacist

2. Does this pharmacy participate in the Pharmacy Guild needle exchange scheme? O Yes O No

3. Does this pharmacy sell needles, syringes, and other injecting equipment to injecting drug users? O Yes O No

4. When commencing methadone / buprenorphine at this pharmacy, do clients sign a contract? O Yes O No

5. Do you inform clients of the potential impact of driving under the influence of methadone / buprenorphine?

   O Never O Sometimes O Often O Mostly O Always

6. How long has this pharmacy been dispensing methadone and/or buprenorphine? ……..…..years O Don't know

7. Which of the following does this pharmacy dispense? O Methadone O Biodone O Buprenorphine

8. How many clients does this pharmacy currently dose? Methadone (incl. Biodone): …… Buprenorphine: ……

9. How many current vacancies do you have for dosing? ……

10. To what extent would the following encourage you to increase your capacity for dosing methadone and/or buprenorphine clients?

		Strongly encourage	Somewhat encourage	Not encourage
i.	More support from local Drug & Alcohol Services	O	O	O
ii.	Increased confidence that referred clients are stable	O	O	O
iii.	Ability to return unstable clients to public clinic immediately	O	O	O
iv.	A copy of your clients care plan	O	O	O
v.	Easier recording systems	O	O	O
vi.	More integration with other health care professionals involved in clients care	O	O	O
vii.	Increased financial return per client	O	O	O
viii.	More referrals to pharmacy	O	O	O
ix.	Other that would strongly encourage:……			

Treatment Delivery

11. Regarding the supervised dosing area, is there a separate area where clients are given their dose? O Yes O No

    If yes, is this area: O In full view of other customers O In partial view of other customers O Private, not in view of other customers

    If no, are doses administered: O Over the counter O Other (specify): ……

12. Have you refused to administer a supervised dose of methadone or buprenorphine for any of the following reasons at this pharmacy:

		In the past year?	In the past month?
i.	They were intoxicated	○ Yes ○ No	○ Yes ○ No
ii.	They were behaving aggressively	○ Yes ○ No	○ Yes ○ No
iii.	They had missed three or more doses	○ Yes ○ No	○ Yes ○ No
iv.	They were in debt to the pharmacy	○ Yes ○ No	○ Yes ○ No
v.	Their script had expired	○ Yes ○ No	○ Yes ○ No
vi.	Other (please specify): ……	○ Yes ○ No	○ Yes ○ No

13. Do you notify their prescriber / clinic if you have refused to dose a client? ○ Yes ○ No ○ Sometimes

14. Do you notify their prescriber / clinic if a client misses three or more consecutive doses? ○ Yes ○ No ○ Sometimes

		In the past year?	In the past month?
15.	Have you terminated treatment for a client at your pharmacy:	○ Yes ○ No	○ Yes ○ No

If yes, how many clients have you terminated in the past year? ○ Less than 5 ○ 5 - 10 ○ more than 10

What was the most common reason you terminated a client's treatment? ……

……

16. How competent would you feel in identifying the following in methadone and/or buprenorphine clients at your pharmacy?

		Very competent	Somewhat competent	Not competent
i.	Opioid toxicity	○	○	○
ii.	Opioid withdrawal	○	○	○

Pharmacy Fees and Take Away Doses

17. How many days a week is this pharmacy open? ……

18. Does this pharmacy provide takeaway doses of methadone? ○ Yes ○ No

If yes, what is the maximum number of consecutive takeaways you currently dispense to one client at one time? ……

19. Does this pharmacy provide takeaway doses of buprenorphine? ○ Yes ○ No ○ N/A

20. Is a flat fee charged for methadone dosing regardless of whether clients receive takeaways or not? ○ Yes ○ No

If yes, what is the flat **weekly** fee for methadone clients? $.....

If no, what is the **weekly** fee for those receiving: 1 or 2 takeaways per week? $.....

3 or 4 takeaways per week? $.....

21. Is a flat fee charged for buprenorphine dosing regardless of whether clients are dosed daily or less than daily? ○ Yes ○ No ○ N/A

If yes, what is the flat **weekly** fee for buprenorphine clients? $.....

If no, what is the **weekly** fee for buprenorphine clients who are dosed:

Daily? $..... Every second day? $..... 3 times a week? $.....

22. Do you provide credit when methadone/buprenorphine clients can't pay? ○ Yes ○ No If yes, how much (maximum)? $.....

23. How many clients are currently not paid up to date?……

24. Are you aware of the introduction of buprenorphine-naloxone (Suboxone®)? ○ Yes ○ No

25. If yes, is this pharmacy planning on dispensing Suboxone®? ○ Yes ○ No ○ Not sure ○ Currently dispensing

26. If this pharmacy plans to dispense Suboxone® what fee would you charge for:

i.	Supervised dose on Monday with 2 takeaways. Supervised dose on Thursday with 3 takeaways	$...../ week	○ Not sure
ii.	Supervised dose on Monday with 6 takeaways	$...../ week	○ Not sure
iii.	No supervised doses and weekly pick-up of takeaways	$...../ week	○ Not sure
iv.	No supervised doses and fortnightly pick-up of takeaways	$...../ 2 weeks	○ Not sure
v.	Flat fee regardless of number of supervised doses and takeaways	$...../ week	○ Not sure

Buprenorphine *Please complete this section if this pharmacy dispenses buprenorphine*

27. How does this pharmacy most often prepare buprenorphine for supervised dosing? (please tick ONE only):

○Whole tablets ○Crushed to granules ○Crushed to fine powder

○Tablets broken into 2-6 pieces ○Other (specify): .....

28. What is the main reason this pharmacy most often prepares buprenorphine in this way? (please tick ONE only):

○To reduce diversion ○To speed up dissolving ○To increase absorption

○Client request ○Script instructions ○Other (specify):……

29. Please indicate how often you perform the following when administering buprenorphine at this pharmacy:

		Never	Sometimes (with SOME clients)	Always (with SOME clients)	Always (with ALL clients)
i.	Before administering, do you check that the client's mouth is empty?	○	○	○	○
ii.	After administering the dose, do you check that the dose has been placed under the client's tongue?	○	○	○	○
iii.	Do you require that clients remain in the pharmacy while they are absorbing their dose?	○	○	○	○
iv.	Do you observe clients while they are absorbing their dose?	○	○	○	○
v.	Do you check that the dose is still under their tongue while it is absorbing? (midway check)	○	○	○	○
vi.	Do you check that the all their dose has been absorbed before clients leave the pharmacy?	○	○	○	○

30. Which of the following do you consider are examples of buprenorphine diversion:

i.	Spit dose onto floor / into bin	○ Yes	○ No	○ Not sure
ii.	Swallow dose	○ Yes	○ No	○ Not sure
iii.	Attempt to remove dose from mouth into hand / clothing	○ Yes	○ No	○ Not sure
iv.	Obscure dose in mouth (identified by mouth inspection before leaving pharmacy)	○ Yes	○ No	○ Not sure
v.	Moving tablets around mouth during absorption	○ Yes	○ No	○ Not sure
vi.	Particular interactions with others inside or outside the pharmacy	○ Yes	○ No	○ Not sure
vii.	Attempt to leave pharmacy before having mouth inspected	○ Yes	○ No	○ Not sure
viii.	Attempt to move out of view while being observed	○ Yes	○ No	○ Not sure
ix.	Swallow dose after being approached by staff	○ Yes	○ No	○ Not sure
x.	Other (specify): ……	○ Yes	○ No	○ Not sure

Pharmacotherapy Diversion

Diversion for the purpose of the following questions is defined as a "client removing or attempting to remove a supervised methadone or buprenorphine dose from the pharmacy before the dose has been fully absorbed by the client"

31. Which of the following buprenorphine preparations do you think is associated with the highest rate of diversion? (please tick ONE only)

O Whole tablets O Broken into two to six pieces O Coarse granules O Fine powder

		In the past year?	In the past month?
32.	Have you seen a client divert/attempt to divert their methadone at this pharmacy:	O Yes O No	O Yes O No
33.	Have you seen a client divert/attempt to their divert their buprenorphine at this pharmacy:	O Yes O No	O Yes O No

34. Thinking of the last person you considered to have diverted/attempted to divert their medication, please answer the following:

35. Which medication did the client divert or attempt to divert? O Methadone O Buprenorphine

36. What action did you take? (please tick ALL that apply): O Nothing O Refused to provide further treatment

O Notified prescriber / clinic O Changed dispensing practice O Confronted client about diversion

O Returned client to clinic O Other (specify): ……..

37. What do you think is the most common reason clients divert their methadone/buprenorphine? ……

.....

Prescribing Doctors

38. Have you experienced any of the following problems with doctors prescribing methadone / buprenorphine?

		In the past year?	In the past month?
i.	Difficulty contacting prescribing doctors	O Yes O No	O Yes O No
ii.	Inadequate information provided by doctor about other health needs of individual clients	O Yes O No	O Yes O No
iii.	Poor communication between doctor & pharmacy regarding changes to treatment	O Yes O No	O Yes O No
iv.	Illegible scripts	O Yes O No	O Yes O No
v.	Unclear dosing instructions	O Yes O No	O Yes O No
vi.	The provision of takeaways to clients you considered unstable	O Yes O No	O Yes O No

About You

39. Your gender: O Male O Female

40. Your age: ……..

41. How long have you been a qualified pharmacist? ……

42. How long have you been working at this pharmacy? ……

43. Pharmacy postcode: | | | | |

Thankyou for taking the time to complete this questionnaire.
The results will be fed back to pharmacists in the Pharmacy Guild Bulletin.

Appendix B. Stability Assessment Flowchart

State-Wide Advisory Team (SWAT): Drug Health Streamed Shared Care

SYDNEY SOUTH WEST AREA HEALTH SERVICE
NSW HEALTH

Assessment of stability – identifying parameters for transfer to community pharmacy

(Please note this algorithm is a guide to clinical practice and judgement, it does not replace clinical judgement).

The transfer to pharmacy dosing has many advantages for clients.

The vast majority of clients would prefer to be dosed at a pharmacy
More normal existence
Freedom to be dosed at times that suit them
Access to takeaways
Easier for work/study/family
Not having to come to a clinic

- Clients should not normally be considered for transfer to pharmacy until they have been on supervised methadone for at least three months and buprenorphine for one month.

- Clients who move to pharmacy need to be considered stable (see below).

- Stable means that they have been on the same dose of medication for several weeks and that this keeps them comfortable and free from any side effects; that they attend daily and are not routinely missing doses or are refused them. There should also be evidence of no or significantly reduced illicit drug use (through examination/urines) and there should be no concerns regarding overdose, self harm or child protection.

- When transferring clients **clinicians should also consider the possible disadvantages of pharmacy transfer such as any possible deterioration due to lower levels of monitoring** and access to support (e.g. among those with acute mental health issues or those regular polydrug users presenting with high risk intoxication).

- Stable clients are the ones who are most likely to do well in the less supported environment of the community pharmacy. They should be in possession of the necessary social and behavioural skills to engage in such a therapeutic relationship since these are the clients that pharmacies will be most comfortable in accepting.

- Pharmacists are able to supervise clients daily and may be able to identify deterioration or improvement in clients and should be contacted routinely after transfer especially around the time of new prescriptions to ensure things are going well. They may sometimes be able to supervise other medications if required.

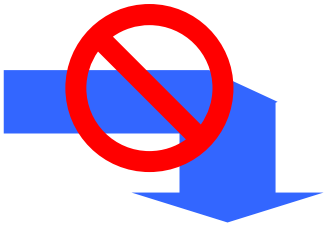
- Positive feedback should be provided to your client explaining why they are being considered appropriately stable for transfer to a community pharmacy.

- Please use the box over the page to help you and your client identify if they are suitable for transfer to a community pharmacy. Any barriers to moving can then be dealt with in revised care plan and addressed in further clinical review meetings.

Stability Assessment Flowchart

Contraindications to transfer to community pharmacy: (behaviour last four to eight weeks)
Any of these should be seen as a potential contraindication to community transfer.

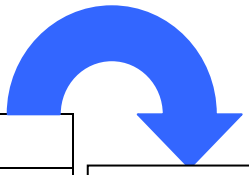
Parameter	*Y/N*	*Comment*
Withdrawal between doses		
Peak dose sedation after dosing		
Still craving for heroin		
Regular and problematic injecting drug use		
Risky substance use/overdose risk		
Urine drug screen results showing continued illicit drug use		
Irregular attendance for dosing		
Episodes of refused dosing/presenting intoxicated/threatening behaviour		
Recent diversion		
Acute significant mental health problems/risk of self harm		
Child risk / protection issues		
Unstable accommodation		



The client should remain at the clinic and in discussion with his/her case manager/prescriber causes for current instability should be identified and addressed in a revised care plan. Transfer should be revisited in eight weeks.

If no contraindications then consider for transfer

Indications to support transfer

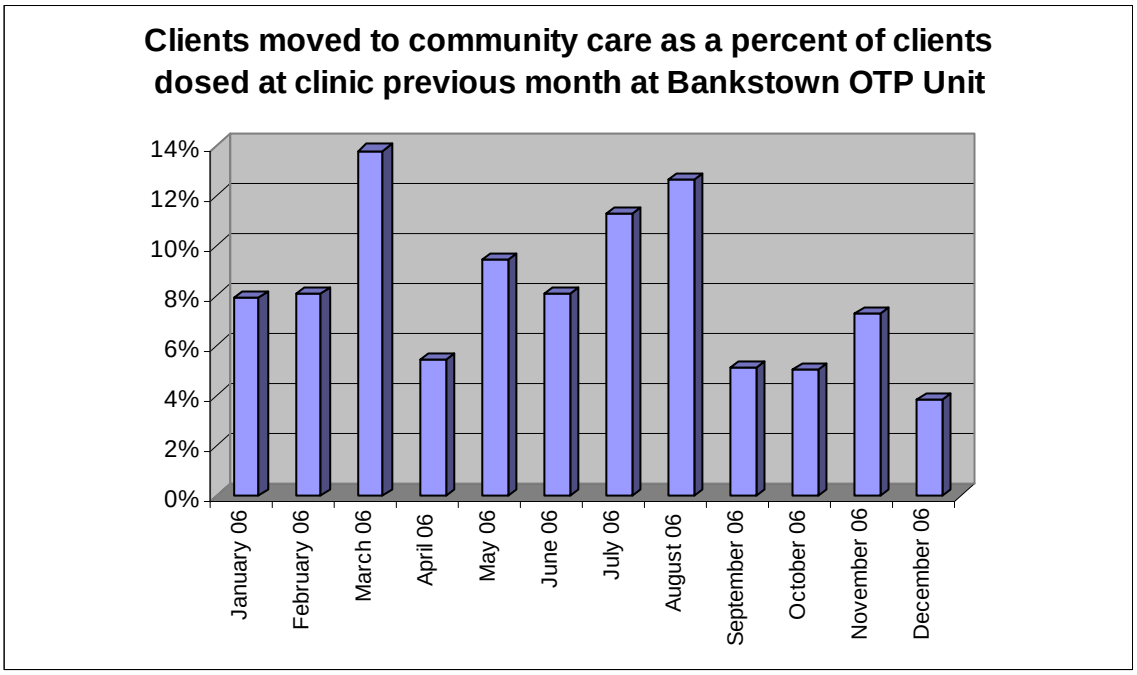


Parameter	*Y/N*	*Comment*
Medication stability		
No risky substance use/overdose risk		
Urines and examination support significantly reduced/nil injecting use		
Attends regularly/good presentation		
No recent refused doses/diverted doses		
No current acute mental health problems/risk of self harm		
No child risk issues		
Stable accommodation/stable social and financial situation		

Find pharmacy.
Arrange prescriber review.
Arrange transfer.
Remind re safe storage of medications.

Maximum of four week scripts for first three months.
No or very limited takeaways.
Regular feedback/contact with dosing pharmacy.

Appendix C. Method of calculating public clinic throughput to community dosing



Numerator = Number of clients moved from the public clinic (public and private prescriber) to a community pharmacy over a calendar month

Denominator = Total number of clients dosed at the public clinic (public and private prescriber) at the end of the previous calendar month

(e.g., A clinic transfers 10 clients to community dosing between April 1 and April 30. The clinic was providing dosing for 100 clients on March 31. Therefore the percentage throughput from clinic to pharmacy is 10% for this clinic in April).

Source: Drug Health Services, Sydney South West Area Health Service, 2007

Appendix D. Pharmacy Feedback forms

Monitoring stability in community dosed OTP clients by pharmacists

Client name …… Dosing period ……

Pharmacy name ……

Factor	Outcome	Comment
Number of missed doses (insert number)*		
Erratic/threatening behaviour (Y or N)*		
Payment (up to date or $ debt)*		
Episodes of refused dosing/presenting intoxicated*		
Recent diversion attempts*		
Concerns over client stability*		
Last dose and reported medication stability		
Dose changes (up, down, the same)		
Pathology requests for urine screen provided to client by pharmacy (number, no, or N/A)		
Child risk or protection issues		

* any of these may lead you to request an early clinic/prescriber review

Please answer the following questions:

Are you happy to continue to provide dosing for this client?	Yes	No
Do you think they are doing well?	Yes	No
Do you think the number of takeaways provided is appropriate?	Yes	No
Do you have any concerns at all about this client?	Yes	No
Would you like someone from the clinic to contact you?	Yes	No

Any other comments? ……

……

……

Signed: …… Pharmacist …….. Client

…… Date …….. Date

PHARMACY STAMP or LABEL

CONFIDENTIAL **The PHARMACY GUILD OF AUSTRALIA NSW BRANCH**

PATIENT REVIEW FORM

COMMUNITY PHARMACY BUPRENORPHINE/METHADONE TREATMENT

Date : _____

PATIENT'S NAME: _____ **DOB:** _____ **ADDRESS:** _____ _____	**PRESCRIBER'S NAME:** _____ **PHARMACIST'S NAME:** _____ **CASE MANAGER'S NAME:** _____

Treatment with:
Methadone ❒ Buprenorphine (sublingual technique checked) ❒

Current dose: _____ T/A per week_____
Client is aware of the correct storage of T/A doses **Yes** ❒ **No** ❒
Current medications which may interact with or affect the metabolism of methadone or buprenorphine:

_____

Number of occasions the patient presented intoxicated in last month: _____

Does the pharmacist or staff have concerns about patient behaviour: _____

Number of missed doses in last month: _____

Has the patient presented with any of the following Clinical symptoms?
(Indicate by circling symptom)
sleep disturbance, aches, pains, teeth/dental problems, reduced libido, lethargy, excessive sweating

Any known problems with illicit drug use? **Yes** ❒ **No** ❒

Any recent symptoms or issues relating to the patient which may be relevant to their treatment eg health, social, financial, family or emotional problems **Yes** ❒ **No** ❒

Would you like the prescriber to contact you? **Yes** ❒ **No** ❒

Pharmacist's telephone number: _____

PHARMACIST's SIGNATURE:_____

Appendix E. Is buprenorphine the right drug for you?

- I understand why the staff had concerns about how I was taking my buprenorphine.
- I have been given a chance to discuss any things I am not clear about.
- I understand how I need to take my buprenorphine so that staff will not think that I am diverting my dose.
- I understand now what things in the future may lead staff to think that I am diverting my dose.
- I have had a chance to discuss any changes in treatment I would like or any other problems that could be addressed to remove the need/wish for future behaviours that will be considered as diversion.
- I understand that the clinic cannot give a drug to a person that they think is not taking it as directed. I understand that should I be considered by the staff (based on the information that has just been provided to me) to have diverted my dose that I will be offered either a two-week detoxification or a transfer to methadone.

Client name …… Staff member name ……

Signed …… Signed ……..

Date…….

Date……

Appendix F. Dispensing buprenorphine (Subutex®, Suboxone®) to achieve optimal absorption

Data on the bioavailability of buprenorphine has all been produced using whole tablets of the product, administered sublingually. The TGA approval for the release of buprenorphine relates to whole tablets. It is of interest that many patients receive their buprenorphine dose as tablets which have been broken, crumbled to pieces the size of 2-3 mm in diameter or crushed into a powder form. These observations have been confirmed by the recent SWAT evaluation of dispensing practices in pharmacies in NSW.

The rationale for breaking the tablets into smaller sizes has been:

- it decreases the ease of diverting the dose;
- it facilitates dissolution of the tablet thus;
- it decreases the time needed for observation after dosing; and
- the above means patients spend less time in the dosing room.

The crushing of tablets is a problem for the following reasons:

- there are no good data to show that this improves dose absorption;
- patients on doses >12 mg end up with a slurry of tablet and saliva in their mouth which is often swallowed in the belief that the tablet has now dissolved. This may lead to inadequate absorption, suboptimal dosing and treatment failure;
- diversion is not prevented by this approach although crushing into a powder does hinder this process; and
- it is not reasonable to believe that by crushing the tablets, time can be saved in the dosing process. Patients allowed to leave after three to four minutes will be able to salvage powder from the saliva and divert this for street use. This has significant consequences including the risk of fungal infections in those injecting the diverted, contaminated product.

Recommendation:

That all crushing of buprenorphine tablets at dosing points in the NSW OTP cease.

If tablets are to be broken to facilitate sublingual placement then breaking the tablet into four to six pieces or crumbling to a size of 2-3 mm in diameter is acceptable, BUT dosing staff must ensure that patients are advised repeatedly that swallowing the slurry of tablet and saliva will result in inadequate drug levels.