Provision of opioid substitution therapy services in Australian pharmacies

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REVIEW

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Abstract

Opioid dependence, despite being the subject of significant public funding, remains a costly burden to Australian society in human and economic terms. The most cost-effective public health strategy for managing opioid dependence is opioid substitution therapy (OST), primarily through the use of methadone or buprenorphine. Supervised dispensing of OST from specialist clinics and community pharmacies plays a crucial role in enhancing compliance, monitoring treatment and reducing diversion. Australia, compared with other countries in the world, ranks very high in illicit opioid use; hence there is a great demand for OST.

The utilisation of community pharmacies for stable patients has many advantages. For public clinics, patient transfer to community pharmacies relieves workload and costs, and increases capacity for new OST patients. From a patient's perspective, dosing at a pharmacy is more flexible and generally more preferable. Pharmacists stand to gain clientele, profit and receive small incentives from state governments in Australia, for their services. Yet, many "unmet needs" exist and there is a high demand for more involvement in OST service provision in community pharmacy in Australia.

In the UK there has been a steady increase in community pharmacy provision of OST, and pharmacists appear ready to provide further healthcare services to these patients.

The role of pharmacy in some countries in Europe, such as Germany, is less prominent due to their approach to harm minimisation and the complex, variable nature of OST provision across the European Union (EU). The provision of OST by pharmacists in the USA on the other hand is of lesser frequency as the healthcare system in the USA encourages detoxification clinics to handle cases of illicit drug addiction.

At a time when harm minimisation strategies constitute a topic of considerable political and public interest, it is important to understand the scope and variability of pharmacy involvement in drug policy in Australia. Hence, this review highlights the role of pharmacists in OST and explores the scope for expanding this role in the future.

Key Words
Opioid Substitution Therapy services, Australian pharmacies.

Background

The health, social and economic costs of heroin and other illicit opioid use are significant for individuals and society in general. The costs of heroin dependence are not only in terms of procurement, but include a wide range of risk of adverse outcomes such as overdose (and possible death), spread of infectious diseases (particularly HIV/AIDS, hepatitis B and C), other medical and psychological complications, social and family disruption, harm to the welfare of children, violence and drug-related crime and problems associated with corruption.[1]

Providing a range of accessible and effective treatments for heroin and other illicit opioid use such as methadone or buprenorphine treatment, known as opioid substitution therapies (OST) can reduce the demand for illicit drugs and minimise the adverse consequences.[1] Extensive clinical research in Australia and overseas has demonstrated that OST is effective in reducing heroin use, in reducing the risk of death by overdose, in freeing people to engage in normal activities, and in reducing crime associated with drug use.[2,3] OST is now widely recognised as the most effective treatment for heroin

dependence worldwide[4,5]. Other treatments, such as naltrexone, are available but less effective and associated with significant mortality and morbidity.[3,6–7] The benefits of opioid treatment are optimised when programmes are readily accessible, entry into treatment is prompt and retention in treatment is high. Outcomes improve as time in treatment increases. Patients are encouraged to remain in treatment for at least 12 months to achieve enduring lifestyle changes. People who drop out of treatment, particularly in the first year, are highly likely to return to opioid use, criminal activity and social dysfunction.[1,5]

Scope of the problem

In Australia there are over 39, 000 people receiving OST, more than two-thirds of whom reside in the states of New South Wales (NSW) and Victoria (VIC).[8] Community pharmacies are a major point of OST delivery in Australia, as is the case in many countries, such as the UK, France, and New Zealand[9–10]. The number of patients per pharmacy varies from less than 5 up to 50. In many rural areas, community pharmacies are the only dosing points available[1]. According to Berbatis et al (2003) the relatively high rates of methadone and buprenorphine dispensing reflect the continued success of community pharmacies in primary care-based OST programmes in Australia.[11] Reviews of international data corroborated the large and effective roles played by community pharmacies in the prevention and management of drug misuse. [12–14]

Consequently, in response to high demand, the involvement of pharmacists in providing OST has been rapidly expanding not only in Australia but many other countries, including Ireland, New Zealand, Canada, the UK and other European countries such as Belgium, France, Spain, Germany, Sweden, Italy, Switzerland and Portugal.[14–18] The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) reportedly considers OST a topic widely discussed and of "considerable political and public interest", but not all OST services in European countries are provided by pharmacists. This is due to the complex nature and regional variations of historical developments in adopting OST across the EU, as well as substantial differences in the organisation of health and social services in different countries of the EU.[15]

The provision of OST services in pharmacy

Publicly-funded specialist clinics that provide OST to patients without co-payment are in general more costly to run than pharmacy-based services, where the patient is charged a co-payment for the dispensing service. Many specialist clinics have reached operational capacity, have long waiting lists of candidate patients and/or are geographically distant from patients' home base. At present it is estimated only about 50% of heroin users are in treatment. The availability of OST is limited by capacity within both public specialist clinics and the availability of community pharmacies providing the service.[5, 9] It is becoming ever more important that more pharmacists are needed to participate in the delivery of OST services to the public, especially in rural and other areas where access to clinics may be limited.

Most studies exploring OST services in pharmacy are survey based.[14] In the UK, the National Addiction Centre was the first to conduct systematic national research of harm reduction activities performed in community pharmacies from the late 1980s.[12,19–20] Sheridan et al (2007) found an increase in the proportion of pharmacies providing OST from 51% in 1995 to 63% in 2005.[21] Similarly, in Scotland, Matheson et al[17] conducted a series of survey studies and found an increase in the proportion of pharmacies providing OST services of 26% over a decade.

In Australia the first comprehensive surveys and cost analyses of methadone programmes involving community pharmacies were first performed in 1996 by Victoria's Turning Point group.[22] In 1999 and 2000, a national evaluation conducted by researchers at Curtin University (WA) reported pharmacists were well regarded by OST patients, the price of methadone dosing in pharmacies was lower or competitive with private clinics, and the retention of patients in OST programmes with pharmacies was higher than in hospital-based methadone programmes[23]. The study reported a prevalence of 34.6% and 10.8% of Australia's pharmacies involved in methadone and buprenorphine dosing, respectively, in 2002, which was a marked increase from the 31% of Australia's pharmacies in May 2000 registered to provide methadone for opioid-dependent patients.[23] This does signify quite clearly however, that less than half the pharmacies in Australia are engaged in provision of OST services to the public.

In 2007, Berbatis et al identified a number of facilitators and predictors for enhanced services such as OST, to be provided in pharmacy. These included issues such as access to patients' clinical notes, more opportunities to study and accreditation. Pharmacies with high turnovers and younger owners or managers were also found to be more likely to conduct such services.[24]

Problems identified with OST services in community pharmacies

The provision of OST services to the community does not come without some challenges. Some researchers have explored problems encountered with OST provision in

general; others have explored those related to pharmacy-based OST services in particular.

For example, a recent study conducted by Fraser et al,[5] focused on the provision of "takeaways" (doses of methadone or buprenorphine which the patient is allowed to take home for various reasons, for ingestion without supervision) and the problem of "diversion" i.e. the use of methadone or buprenorphine doses-intended for takeaway-for purposes other than treatment, such as selling on the black market-a common problem encountered in this field of practice. [25–27] This expansive, in-depth study identified a number of concerns relating to methadone maintenance in both NSW and VIC, some of which related to OST service providers, including pharmacists. Point Seven in the key findings and recommendations of this study stated:

"Clients and service providers identified a significant *unmet demand for treatment* in both New South Wales and Victoria, and suggested that this affected quality of care. Where clients have difficulty accessing the programme and have limited choice of service provider, they are especially poorly placed to negotiate treatment on an equal footing...This serious issue points to an immediate *need for increased funding for treatment* in both states." [5(p2)]

The study further identified some resources "*urgently*" needed for service providers, including:

- Further education, training and mentoring of service providers (clinic staff, doctors and community pharmacists) in the assessment of clients and meeting client needs.
- Further training and support for service providers in reading and using the clinical guidelines. This includes 'refresher' courses through the life of existing policies.
- A framework to monitor quality of treatment standards.
- A robust and independent feedback and complaints management process.

The fact that there may be problems associated with OST services is a significant issue which has the potential to impact on patient outcomes, as a large body of research indicates that longer treatment duration is associated with better long-term outcomes and that treatment retention has become a surrogate marker for treatment success[28]. Retention of patients in OST is however, considered surprisingly low in many programmes around the world; some claiming up to a 50% drop-out rate within six months, with patients relapsing to illicit drug use rather than participating in planned tapered withdrawal. On the other hand, there is also an increasing number of OST patients who remain in treatment for many years, considered "stuck" in the treatment programme.[28]

The pharmacist must accommodate for all these variations, with little support and often little communication or information about the patient and their needs. Researchers, Winstock and Sheridan (2010), found that some of the problems experienced in community pharmacies providing OST services may be related to the number of OST patients/clients the pharmacy serves and communication problems with prescribers.[9]

There have also been findings in the literature indicating certain tendencies to stigmatised attitudes and discrimination amongst some pharmacists in the UK, both providers and non-providers of OST services.[29] It was found that pharmacists showed "clear behavioural discrimination" towards people with opioid dependence, attributing this to pharmacy managers who refuse to dispense methadone, which is a discretionary service in the UK, as is the case in Australia. There may be a number of reasons for this, which may include negative attitudes towards drug users, fear of aggression/increased rates of shoplifting, and the impact that providing OST services may have upon other customers and pharmacy staff.[30–32] This aspect of attitudinal behaviour has yet to be fully studied in Australian pharmacists.

The aforementioned recent study conducted in Australia by Fraser et al (2007) noted that OST patients perceived that providers generally treated them in a manner more resembling characteristics of "criminal justice" rather than healthcare providers, stressing that this issue needs to be investigated further with more qualitative social research in the area.[5] Reasons for pharmacists' attitudes in this domain will be of importance to the profession, which has to date enjoyed a good reputation in society, for decades ranking high in polls and regarded as one of the top five most trusted professions.[33]

From a consumer perspective, one study identified "considerable unmet needs", seen to be within the ambit of primary healthcare providers such as pharmacists who provide OST services.[34] OST patients in the study expressed their need for more help with health issues such as dental problems, constipation, sweating and sexual enjoyment. Those on more than 100mg of methadone daily were also more likely to need help with excessive sedation. The study concluded that treatment providers should consider improving detection and

response to common health problems experienced by patients on OST.[34]

In another study investigating consumer perspectives, researchers Sheridan and Winstock (2008), observed that in general consumers expressed high levels of satisfaction with OST services in pharmacies in NSW, but that there was less satisfaction with the quality of privacy afforded them, and the fact that OST patients claimed to be made to wait longer than other patients or clients in the pharmacy, perceiving they were "treated differently".[35] Interestingly, 23% of the participants in this study were in debt to the pharmacy for their dispensing fees.[35]

Dispensing fees have been identified as an important barrier for patients accessing community pharmacy-based OST. Many OST patients have few financial resources and are reliant on government benefits, for example, almost half of the participants in a large longitudinal study of heroin treatment seekers in Australia reported government benefits as their main source of income.[36]. Dispensing fees are not subsidised for OST patients and fees are typically $31 per week.[37] Although a seemingly modest cost, this equates to large proportion of income. A Victorian report into the impact of dispensing fees on OST patients reported a number of dire circumstances for patients with limited capacity pay; these included prioritising dispensing fees over other necessities, reliance on emergency relief services, and in some cases engagement in sex work or acquisitive crime in order to make the payment.[38] Indeed dispensing fees were identified as a primary reason for treatment discontinuation. The report identified that patients' difficulties in paying the dispensing fees was a key contributor for breakdowns in the patient-pharmacist relationship. Subsidisation was a key recommendation of the report which argued that this would benefit both patients and pharmacists. The author of the report, Rowe (2008), argued that dispensing subsidised by the Commonwealth-regulated Schedule of Pharmaceutical Benefits would potentially increase the number of pharmacists willing to dispense OST as the risk of bad debt associated with the programme would be reduced.[38]

Other cost-saving opportunities arise with new OST regimens, such as the new buprenorphine-naloxone regimen which involves a larger number of unsupervised and take-away doses. Yet despite this, Winstock and colleagues (2007) found that in NSW pharmacies, OST dispensing charges differed little across the different regimens and with little difference between daily methadone dosing and buprenorphine–naloxone dosing. The study reported on the limited guidance pharmacists were given on pricing structures for the new regimens. The important message from this work, as pointed out by the authors, was the lack of clear policy and education to pharmacists following the introduction of new OST regimens. [37]

A study involving 50 randomly selected South Australian pharmacists delivering OST provided insights in to the attitudes of and issues faced by this group. A high level of satisfaction was identified, but the study also highlighted a desire for increased communication between prescriber and pharmacist.[39] Greater communication and a more inter-professional "shared-care" approach to community OST delivery is likely to have benefits for all parties including the patients, but a move to formalising this or at least practically facilitating it at a policy level is yet to be achieved. Indeed, overall, the literature suggests that community pharmacists are often sidelined in the OST policy issues, despite being the largest provider of OST services. Engaging more community pharmacists in the drug policy debate, planning and education processes may be one way of addressing this issue.

The aforementioned South Australian study identified high levels of support for provision of OST by community pharmacists involved in the programme and almost all (98%) pharmacists surveyed intended to continue to provide OST services.[39] Argumentative behaviour was the most commonly identified issue to have occurred in the past three months and only by half the pharmacists surveyed. Aggression and theft were reported to have "never" occurred in the last three months by 62% of pharmacists and 70% of pharmacists reported that diversion had "never" been an issue in the preceding three months. This is contrast to a Victorian study that found diversion was the most commonly reported negative aspect of buprenorphine dispensing.[40] The study found that the rate of diversion was estimated to be 33 times per 100 OST patients per month and that diversion reports were associated with larger programmes of 10 or more patients.[40] This corroborates other studies' findings, which have suggested an inverse relationship between the quality of outcomes of the service and the number of OST patients per pharmacy.[9]

An important aspect of community pharmacies' provision of OST is the impact it has on other pharmacy (i.e. non-OST) customers. The South Australian study described above reported that only 20% of pharmacists surveyed reported complaints from other customers as a problem associated with the provision of OST, and that of these 12% reported this to occur "rarely" and only 8% "occasionally". Lawrie and colleagues (2004) examined this issue in the UK. Customers in high drug use areas were interviewed about their attitudes to community pharmacies providing such services to drug users. The

pharmacies selected were from a range of geographic locations (rural, suburban and city) and involved a high, medium or low level of drug user services. Overall, the findings suggest that customers are supportive of the provision of drug user services, although their knowledge of OST specifically was generally limited.[41] The main caveat on the provision of services was that adequate privacy is needed. Although this kind of study has not been replicated in Australia, it is unlikely the results would be markedly different as there is generally good public support for harm reduction services such as needle and syringe exchange.[42]

Conclusion

Opioid dependence, despite being the subject of significant public funding, remains a costly burden to Australian society in human and economic terms. The most successful and cost-effective public health strategy for managing opioid dependence is OST, primarily involving the use of methadone or buprenorphine. Supervised dispensing and administration of OST in community pharmacies play a crucial role in enhancing compliance, treatment monitoring and minimising diversion.

Community pharmacies are conveniently located within local communities and provide an ideal opportunity for treatment delivery outside potentially more stigmatised specialist drug treatment clinics, whilst also relieving the burden of long waiting lists for treatment at clinics already at full capacity. Consumers of OST services at pharmacies are generally well satisfied with the OST services provided, indicating more health needs could be addressed at the pharmacy. However, community pharmacies do not always embrace providing OST services and may choose not to provide drug treatment services.

Given the high demand and potential for good outcomes for all stakeholders in the provision of OST to the public through community pharmacies, it would be worthwhile to further investigate OST services in pharmacy in Australia. Factors which impact on the uptake and quality of OST service provision in community pharmacy are yet to be fully explored. Research is needed to better understand these factors and to inform policies and effective strategies for optimising the outcomes derived from community pharmacy OST services, as well as increase the number of pharmacies participating in the programme.

Overall, there appears to be a higher demand of OST service provision in pharmacy than there currently is provided through pharmacies. This often overlooked, under-rated service provision by pharmacists is a vital service to the Australian community and places pharmacy in a worthy, well-respected position in society and amongst the healthcare provider fraternity. Obstacles to further expansion of this service may be remedied with awareness, government support, more involvement in decision making and most importantly, dedication to the profession's core values and raison d'être.

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CONFLICTS OF INTEREST

The authors declare that they have no competing interests.