Pharmaceutical Benefits Scheme

Post-market Review
of
PBS Opioid Dependence Treatment Program medicines

Report to the Pharmaceutical Benefits Advisory Committee

March 2023

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Terminology and Abbreviations

Terminology

The report uses the term “consumer” rather than “client” or “individual” to mean people with opioid dependence in the context of opioid dependence treatment programs. The term “patient” is used in contexts that are medical in nature.

Varying terms (and their acronyms) are often used to describe treatment of opioid dependence with medicines, including opioid agonist treatment (OAT), opioid substitution therapy (OST), opioid maintenance treatment (OMT), opioid replacement therapy (ORT) and medication assisted treatment for opioid dependence (MATOD). In this report we use **‘opioid dependence treatment (ODT) medicines’ to refer to the pharmacotherapy (or medicines) used for the treatment of opioid dependence listed on the Pharmaceutical Benefits Scheme (PBS),** although all terms have limitations.

The term ‘**ODT programs’ is used to describe the broader treatment of opioid dependence provided by individual jurisdictional programs.**

The abbreviation **‘PBS ODTP’ is used to identify the Australian Government’s Section 100 (S100) PBS Opiate Dependence Treatment Program specifically**.

The abbreviation ‘ODTP PMR’ is used to identify the Post-market Review of Opiate Dependence Treatment Program medicines. The term ‘the Review’ is also used.

The term buprenorphine + naloxone is used to describe the buprenorphine with naloxone combination. Where referred to together, the term buprenorphine +/- naloxone is used to describe both buprenorphine without naloxone and the buprenorphine with naloxone combination.

Abbreviations

Abbreviation	Full Name / Wording
7CPA	Seventh Community Pharmacy Agreement
ACCHO	Aboriginal Community Controlled Health Organisations
ADS	Alcohol and Drug Service
AEMP	Approved Ex-manufacturer Price
CAMH	Centre for Addiction and Mental Health
CHO	Chief Health Officer
CTG	Closing the Gap
Department	Department of Health and Aged Care
EFC	Efficient Funding of Chemotherapy Program
Forum	Stakeholder Forum
GP	General Practitioner
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HSD	Highly Specialised Drugs Program
LAIB	Long-acting injectable buprenorphine (or modified release buprenorphine)
Legislation Register	Federal Register of Legislation
MATOD	Medication Assisted Treatment for Opioid Dependence
MBS	Medicare Benefits Schedule
National Guidelines	National Guidelines for Medication-Assisted Treatment of Opioid Dependence 2014
NDARC	National Drug and Alcohol Research Centre
NH Act	*National Health Act 1953*
NICE	National Institute for Health Care Excellence
NOPSAD	National Opioid Pharmacotherapy Statistics Annual Data
ODT	Opioid Dependence Treatment
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PBS ODTP	Australian Government's PBS Section 100 (S100) Opiate Dependence Treatment Program
PMR	Post-market Review
PSA	Pharmaceutical Society of Australia
RCT	Randomised Control Trials

S100	Section 100 of the *National Health Act 1953*
S85	Section 85 of the *National Health Act 1953* (also known as the general schedule)
TGA	Therapeutic Goods Administration
THN	Take Home Naloxone
TOR	Term(s) of Reference
TSQM	Treatment Satisfaction Questionnaire for Medication
WHO	World Health Organization

Acknowledgements

The report was prepared by the Australian Government Department of Health and Aged Care (the Department). The Department is grateful to the broad range of stakeholders including consumers, prescribers, service providers, pharmacists, peer-based organisations and state and territory governments who contributed to the Review and participated in the consultation processes.

The Department would like to acknowledge the Traditional Owners and Custodians of the lands of the Ngunnawal people on which the report was written as well as the lands on which the report is read. The Department would like to pay its respect to Elders past, present, and emerging.

The Department would also like to acknowledge the contributions of:

National Drug and Alcohol Research Centre, UNSW Sydney

Australian Injecting and Illicit Drug Users League

NPS MedicineWise

Members of the Reference Group (Refer Appendix 1- capacity of appointments)

Report Structure

This report is presented in several parts, as outlined below. The report has been structured in this way to address the Terms of Reference (TOR) for the Review.

For each TOR, the report summarises the key findings for each TOR and outlines stakeholder views. The latter part of each chapter presents the findings from the literature review as well as other analyses or evidence used to inform the Review.

Each TOR is intended to build upon the evidence and discussion presented in the previous chapter.

Part 1 – Background: Provides context for the topic of Opioid Dependence Treatment (ODT) in Australia and is divided into two parts:

- Part 1A provides context for the Review, including a description of the Post-market review (PMR) program, the reasons for reviewing the Pharmaceutical Benefits Scheme (PBS) ODTP, and an outline of the Review methodology and main data sources.
- Part 1B introduces the medicines available under the PBS ODTP and their current listing arrangements, the current structure of the PBS ODTP and its funding arrangements.

Part 2 – TOR 1: This chapter discusses the current elements of ODT in Australia including the characteristics of people accessing ODT, existing treatment guidelines and compares these with international models of countries with similar health systems to Australia.

Part 3 – TOR 2: This chapter first presents key findings from specific consumer consultation undertaken to inform this review and then literature on the barriers and facilitators of ODT from the point of view of consumers, prescribers, and pharmacists.

Part 4 – TOR 3: This chapter first reviews literature on the benefits of each ODT medicine and their cost to patients, prescribers, pharmacies, and governments. This is followed by an analysis of trends in expenditure and medicine utilisation from Commonwealth PBS ODTP expenditure data.

Part 5 – TOR 4: This chapter brings together the evidence and analyses presented in the previous TOR to examine and propose improvements to existing jurisdictional ODT service delivery models (including access to ODT medicines under the PBS) to best support consumers and service providers in a way that is cost-effective for the Australian Government.

Part 6 –Review Outcomes: This chapter brings together the stakeholder input and evidence presented in the TOR and puts forward matters for Pharmaceutical Benefits Advisory Committee (PBAC) consideration and response.

Part 1: Background

The purpose of this chapter is to provide background information on the Post-market Review (PMR) of Opiate Dependence Treatment Program (ODTP) medicines.

The Background chapter can be divided into two sub-Parts: Pharmaceutical Benefits Scheme (PBS) PMR and Opioid Dependence Treatment (ODT).

The sections on PMRs include an overview of the PBS post-market monitoring program, the context for conducting the ODTP PMR as well as describing the process that was undertaken and the methods used to inform the Review.

The sections on ODT include a brief history of the Commonwealth and state and territory government programs, the medicines used to treat opioid dependence and the listing of these medicines on the PBS.

Part 1A: PBS Post-market Reviews

1.1. Post-market monitoring

The PMR program is a systematic approach to monitoring medicines subsidised by the PBS. PMRs were initiated under the 2011-12 Budget measure 'Improving sustainability of the PBS through enhanced post-market surveillance.' PMRs are established under the quality use of medicines objective of the National Medicines Policy framework; promoting the safe and effective use of medicines, with the aim to improve health outcomes for all Australians.

The PMR program contributes to the following:

- improved patient safety through better understanding of adverse events and medicine-related harms, including hospitalisations
- a more sustainable PBS through better targeting of medicines, and avoidance of preventable wastage, or inappropriate prescribing
- a better knowledge base to understand medicines utilisation, to validate the intended clinical benefit which will inform medicines evaluation processes, and
- a strengthened approach to medicine pricing management, including through better management of clinical and economic uncertainty.

A PMR can be initiated when concerns related to the quality use of a medicine, cost-effectiveness, clinical effectiveness, higher than predicted utilisation and/or international differences are raised. A full PMR will only proceed following agreement by the independent Pharmaceutical Benefits Advisory Committee (PBAC) and Ministerial approval.

While recommendations vary from review to review, examples of reviews outcomes include PBS restriction changes, actions to address gaps in prescriber education and research to promote improved awareness of the safety profile of in-scope medicines and changes to price following a review of cost effectiveness.

The PMR Framework outlines the usual approach to medicines reviews. A review usually takes two to three years depending on its complexity.

1.2. Context to the Review

There are currently three drugs available on the PBS ODTP: methadone hydrochloride (liquid form), buprenorphine (in tablet and modified-release injection forms) and buprenorphine + naloxone (film).

In the financial year for 2021-2022[1]:

- there were 47,563 people in Australia (excluding data for Queensland) were receiving treatment for their opioid dependence
- there were 2,485 state and territory approved dosing point sites nationally (excluding data for Queensland) and 9 in 10 sites (89% or 2,200 sites) were pharmacies
- there were 2,673 state and territory authorised prescribers of ODT medicines in Australia (excluding Queensland)
- Australian Government expenditure on medicines for ODT was approximately $108 million in 2021-22, an increase of 20 per cent from 2020-21 (approximately $90 million).

Work to register a legislative instrument for the PBS ODTP on the Federal Register of Legislation (Legislation Register) originally commenced in August 2019. This action was, in part, to address a commitment made to the Office of the Australian Information Commissioner to progress registration of this instrument on the Legislation Register. In doing this, significant concerns about the existing administration arrangements, governed by states and territories, were raised through the public consultation process on a draft legislative instrument (which occurred from 30 November to 18 December 2020). Stakeholders raised several issues with access to ODT medicines under the PBS including patient access and affordability, remuneration for pharmacies and consistency in service and program delivery across each jurisdiction.

The post-market review was approved by the former Minister for Health and Aged Care, the Hon Greg Hunt, and announced on 24 March 2021 to consider stakeholder concerns about access and affordability of medicines for opioid dependence.

1.3. Terms of Reference for the ODTP PMR

Term of Reference 1

1. Describe and compare essential elements of models of service delivery for ODT in Australia (and internationally) including best practice guidelines and current models (including models developed in response to the COVID-19 pandemic) that support timely access to ODT medicines through both pharmacy and non-pharmacy settings*.

   *Non-pharmacy settings include a range of service settings where ODT medicines are delivered in Australia including, but not limited to, correctional facilities, hospitals, public and private clinics, Aboriginal Community Controlled Health Organisations (ACCHOs), general practices and specialist clinics.

Term of Reference 2

2. Examine the consumer experience, focussing on equity of access, geographical barriers to access, cultural safety, and affordability of ODT medicines across the different models of service delivery. This will include consideration of access to ODT for at risk population groups including people living in rural and remote areas, Aboriginal and Torres Strait Islander peoples and other populations who may have limited access to health care services, including ODT.

Term of Reference 3

3. Explore the utilisation of PBS subsidised ODT medicines in Australia, including funding, benefits (health system and societal) and costs incurred in the supply and dispensing of ODT medicines in pharmacy and non-pharmacy settings. This will include examination of current PBS restriction criteria and the impact of the listing of modified release buprenorphine injections on the PBS ODTP.

Term of Reference 4

4. Propose improved service delivery arrangements for access to ODT medicines, with an aim of identifying an ODTP that is equitable, timely, reliable, and affordable for consumers and stakeholders involved in the supply and delivery of ODT medicines and cost-effective for the Australian Government.

1.4. Review Process

The Review has the overall aim of reviewing the current PBS ODTP arrangements to ensure that Australians who have an opioid dependency continue to have access to medicines to help treat their opioid dependence. The Terms of Reference (TOR) for the ODTP PMR are provided in Section 1.3.

1.4.1. Development of the Terms of Reference

The draft TOR for the Review were open to public consultation from 28 May 2021 to 30 June 2021. A total of 28 responses were received from a cross-section of peak bodies, research institutes and individuals. Except where requested otherwise, public comments were published on the Review's website, available at www.pbs.gov.au/info/browse/reviews.

In August 2021, the PBAC considered the draft TOR and comments from stakeholders. The former Minister for Health and Aged Care approved the final TOR for the ODTP PMR on 13 August 2021 (refer Section 1.3).

1.4.2. Reference Group

In line with the PMR Framework, a Reference Group was formed to assist in the review of the evidence and information for each of the Review's TOR, and to ensure that the perspectives of stakeholders are considered in its preparation of the Review Report to the PBAC. Members of the Reference Group are appointed as either individuals or organisational representatives. The Reference Group membership for this Review includes:

- addiction medicine specialist, GP, and nurse practitioner representation with expertise in providing ODT to marginalised and at-risk populations
- consumer representation from several groups including those representing injecting and illicit drug users and First Nations people
- pharmacy representation
- leaders in the field of drug and alcohol research.

The Reference Group for the ODTP PMR was appointed on 22 September 2021. Refer Appendix 1.

The separate consultation processes are outlined in the following sections.

1.4.3. Stakeholder contributions to the Review

As part of the PMR Framework there are a number of opportunities for stakeholders to contribute their experiences and evidence to inform the Review. Stakeholders include but are not limited to, the pharmaceutical industry, state and territory governments, medical practitioners, service providers as well as consumers and supporting organisations. The key opportunities include public consultation on the draft TOR, a public submission process to address the final TOR, and the Stakeholder Forum. The information and evidence gathered through these consultation processes forms an important part of the Review Report.

1.4.4. Public Submissions

Public submissions addressing the final TOR for this Review were open from 17 August 2021 to 1 October 2021. This process provided stakeholders with an opportunity to identify relevant issues, evidence or data that may inform the Review and to provide comment against each of the TOR.

Submissions were received from 35 stakeholder including peak bodies, pharmaceutical companies, state and territory governments, health professionals and individuals and highlighted the complexity of considerations when viewed from different stakeholder perspectives. Except where requested otherwise, public submissions were published on the ODTP PMR website, available at www.pbs.gov.au/info/browse/reviews.

The content of the public submissions was considered in the development of the report and incorporated into the Review where appropriate. Overall, the evidence provided in the public submissions was consistent with those identified in the literature review addressing each TOR.

1.4.5. Stakeholder Forum

A Stakeholder Forum (Forum) for the ODTP PMR was held by the Department via webinar on 24 February 2022. Stakeholders with an interest in ODT were invited to participate in the Forum, including industry, peak bodies, consumers (and consumer advocacy organisations), prescribers, pharmacists, and state and territory government representatives.

Of the 87 external participants attending the Forum, the highest proportion of participants were nurses or nurse practitioners (16%), followed by pharmacists (13%), other health professionals (13%), and organisations representing health professionals (13%). The Forum was also attended by consumers of ODT.

The discussion from the Form is summarised in the key finding for each TOR. Issues raised by stakeholders in the Forum were broadly consistent with the evidence provided in the public submissions and literature review. A full version of the Forum Summary is published on the ODTP PMR website, available at www.pbs.gov.au/info/browse/reviews.

1.4.6. Targeted consumer consultation

In line with the PMR Framework, the Reference Group provided guidance on the stakeholder input to the Review and advised the Department to undertake specific consumer consultation in addition to the usual consultation processes. It was considered particularly important for the ODTP PMR to seek input directly from people who use medicines for the treatment of opioid dependence regarding their experiences and treatment journey including how they access their medicines. Consumers also had an opportunity to attend the broader Forum.

Coordinated by the Australian Injecting and Illicit Drug Users League, consumer consultation activities were undertaken in each jurisdiction consisting of multiple focus groups and individual interviews which sought insight into consumer experiences relating to ODT with a particular focus on barriers and facilitators for populations with specific needs. The full report summarising the outcomes of the targeted consumer consultation is available at Appendix 3.

1.5. Review methodology

1.5.1. Literature review

Systematic literature reviews of both qualitative and qualitative data were undertaken and summarised by the National Drug and Alcohol Research Centre (NDARC).

Relevant studies were searched through MEDLINE, Embase, and PsycINFO databases, following which they were screened by multiple reviewers for inclusion in the review. Key findings and methodologies were then extracted from included studies and meta-analysed where appropriate. This process was conducted both when reviewing qualitative and quantitative studies.

Additionally, to review clinical guidelines across countries to address TOR 1 of the PMR, a methodical search for grey literature was undertaken. Australian Government, state and territory government, provincial and non-government websites were searched to identify guidelines that outline the clinical management of opioid dependence in Australia, Canada, and the United Kingdom. Where this information wasn't available, stakeholders were contacted to obtain the relevant information.

For TOR 3, the literature review also drew from an ongoing systematic review of buprenorphine studies, being conducted by NDARC, which includes oral methadone as a comparator.

1.5.2. Primary data sources

Commonwealth PBS ODTP expenditure data

The Australian Government receives monthly data from PBS ODTP medicine suppliers on the number of medicine packs supplied, the costs of these and the locations to which these have been delivered.

The Department does not hold individual patient level dispensing data for these medicines. Dosing points order medicines directly from the pharmaceutical companies at no cost, and the Commonwealth pays the full cost of the medicines directly to the pharmaceutical companies.

Australian National Opioid Pharmacotherapy Statistics Annual Data

The National Opioid Pharmacotherapy Statistics Annual Data (NOPSAD) collection by the Australian Institute of Health and Welfare comprises data collected by state and territory health departments about opioid pharmacotherapy consumers, prescribers, and dosing points. Each jurisdiction uses different methods to collect data about the pharmacotherapy (i.e. ODT medicines) used to treat those with opioid dependence. The data are a mix of survey and administrative data. Data between 2016 and 2021 are summarised in the current report. Further information can be found in the annual NOPSAD Report[1].

It should be noted that data for Queensland for the 2021 NOPSAD collection was not available for inclusion in the data report, meaning comparison with other data are likely to be underestimated and caution should be taken when comparing 2021 data with previous years.

Additionally, data for buprenorphine for NSW is grouped into a single category, while other jurisdictions have three separate categories for sublingual buprenorphine tablets,

buprenorphine + naloxone films and long-acting injectable buprenorphine (LAIB). This causes a systematic underestimation of consumers being treated with LAIB and buprenorphine + naloxone films, and an over estimation of consumers being treated with sublingual buprenorphine tablets in country-wide estimates.

CoLAB: Community Studies of LAIB

This program of research, funded by Indivior (manufacturer of Sublocade®), included:

- a pre-implementation survey of 400 people regularly using opioids, conducted prior to availability of LAIB in Australia, which evaluated willingness to receive the new formulation[2], costs borne by consumers for receiving ODT medicines[3, 4], and barriers and facilitators to treatment (manuscript in preparation);
- a single arm implementation trial of LAIB in 100 people recruited from 6 specialist and primary care clinics in NSW, VIC, and SA[5, 6];
- in-depth qualitative research interviews with consumers, providers and policymakers exploring barriers and facilitators to treatment (Lancaster et al., under review; Treloar et al., under review); and
- costing of treatment delivery at the 6 sites involved in the implementation trial (manuscript in preparation).

ETHOS Engage: Enhancing Treatment of Hepatitis C in Opioid Substitution Settings

ETHOS Engage is an observational cohort study evaluating testing, treatment, and hepatitis C prevalence among people attending drug treatment clinics and needle syringe programs (17 sites in NSW)[7]. Eligible participants are people with a history of injecting drug use, either in the last 6 months, or currently receiving opioid agonist therapy. At enrolment, participants were invited to complete a questionnaire, providing information on drug use, drug treatment, and hepatitis C testing and treatment. The first wave of ETHOS Engage enrolment was May 2018 – September 2019 and the second wave of recruitment was November 2019 and June 2021.

PREFER

PREFER is a cross-sectional cohort study evaluating consumer preferences for ODT medicines in Australia among people attending drug and alcohol treatment clinics[8, 9]. Eligible participants were people who have current opioid dependence (defined as having used opioids in 21 of the past 28 days). At enrolment, participants were contacted over the phone or videoconference and invited to complete an interviewer-administered questionnaire, providing information on consumer preferences for ODT medicines, demographics, drug and alcohol use, and drug treatment uptake. Participants were enrolled between October 2020 and April 2021.

MedicineInsight

MedicineInsight is a large-scale primary care data set of longitudinal de-identified electronic health records in Australia. It uses third-party data extraction tools to extract, de-identify, encrypt, and securely transmit whole-of-practice data from the clinical information systems of general practices. Patient level data are de-identified ‘at source’ meaning patients’ personal identifiers such as name, date of birth and address are not extracted by the tool. However, each patient is assigned a unique number which allows all the records (clinical,

prescription, referral etc) held in the database to be linked to the associated patient number. The process of collecting patient data achieves a data collection that meets the definition of non-identified data in the NHMRC National Statement on Ethical Conduct in Human Research.

As of June 2021, 5,082 active GPs were participating in the MedicineInsight program, representing 14% of the national GP workforce. MedicineInsight has national coverage across all states and territories and remoteness areas. Practices in South Australia are underrepresented and practices in Tasmania are overrepresented, but otherwise the distribution of MedicineInsight practices in each state is similar to the distribution of all practices in each state or territory. Compared to Medicare Benefits Schedule (MBS) data, patients in MedicineInsight are representative of the Australian patient population in terms of age and gender. Of the patients in the MedicineInsight cohort, 3.0% identified as First Nations people, similar to the 2.8% rate reported in 2016 national population census.

Part 1B: Treatment of opioid dependence

1.6. Medicines for the treatment of opioid dependence

1.6.1. What is opioid dependence

Opioid dependence is defined by the International Statistical Classification of Diseases and Related Health Problems, 11th edition as:

"a disorder of regulation of opioid use arising from repeated or continuous use of opioids. The characteristic feature is a strong internal drive to use opioids, which is manifested by impaired ability to control use, increasing priority given to use over other activities and persistence of use despite harm or negative consequences. These experiences are often accompanied by a subjective sensation of urge or craving to use opioids. Physiological features of dependence may also be present, including tolerance to the effects of opioids, withdrawal symptoms following cessation or reduction in use of opioids, or repeated use of opioids or pharmacologically similar substances to prevent or alleviate withdrawal symptoms."[10].

Opioid dependence has been characterised as a chronic, relapsing condition with periods of active use, abstinence, and relapse which can occur over many years[11]. Estimates from the Global Burden of Diseases, Injuries and Risk Factors Study suggest that in 2019 the Australian prevalence of opioid dependence was 0.5%; this is higher than the global prevalence of 0.29%[12] and represents a 19.8% increase since 2010.

Opioid dependence is associated with high rates of morbidity and mortality. These are often due to the route of administration of opioid use, with injection of opioids associated with the spread of blood borne infections such as human immunodeficiency virus (HIV) and hepatitis C virus (HCV). Opioid dependence is also associated with reduced quality of life, mental health problems, and increased criminal activity. People with opioid dependence are at greatly increased risk of death,[13] particularly from overdose.

1.6.2. Overview of Treatment Guidelines for ODT

ODT medicines are one of the main treatments used for opioid dependence and involves use of a prescribed pharmacotherapy, usually a longer-lasting opioid agonist or partial agonist, to replace an individual's opioid use. The aim of maintenance treatment is to reduce exposure to risk behaviours and stabilise health and social functioning, while also managing the physical dimension of dependence.

Many people may view ODT as consisting of ODT medicines alone. ODT medicines, while important, are but one element of ODT. Holistic treatment for opioid dependence is a combination of ODT medication and psychosocial support which includes addressing the often-complex components of psychological and physical health, as well as the social environment of a person with opioid dependence. The additional support required may vary by person and over time and should be adapted to the patient's changing needs.

The World Health Organization (WHO) international guidelines for ODT medicines were published in 2009[14] and given developments in the field require updating. However, these guidelines indicate that a range of other services be provided in addition to ODT medicines to address the psychological health and social problems that can be associated with opioid use.

These may include other medical care, mental health services, vocational and other assistance, and provision of naloxone.

The National Guidelines for Medication Assisted Treatment of Opioid Dependence 2014[15] (National Guidelines) provide a broad policy context and framework for Australian state and territory policies and guidelines concerned with delivering ODT medicines (Table 4). However, jurisdictions vary in their requirements for ODT medicine services, prescribers, and consumers. There is also variation between jurisdictions in the funding models, subsidy schemes for associated costs to service providers, and dispensing fees for consumers. The National Guidelines have not been updated to incorporate the use of LAIB to date.

In Australia, medicines registered for use as ODT include methadone and buprenorphine (with or without naloxone), both of which are listed by the WHO as essential medicines for opioid dependence[14]. These medicines can help to reduce drug cravings and withdrawal symptoms; improve health, social functioning and economic participation; and reduce crime[13, 16, 17].

Treatment guidelines including an overview of key ODT medicine characteristics in each jurisdiction as well as comparisons between methadone and buprenorphine are discussed in further detail in TOR 1 (Part 2). Methadone and buprenorphine +/- naloxone both are considered effective in the treatment of opioid dependence and are considered first-line treatment options.

Methadone

Methadone is the most established medicine used as ODT. Being a synthetic opioid agonist, methadone is cross-tolerant with other opioid drugs and is administered orally. As a medicine for use as ODT, methadone is available as an oral liquid and has a half-life of around 24-48 hours. As a full mu opioid receptor agonist, methadone is considered to have a stronger opioid effect, but has more side effects, risks, and drug-drug interactions.

Buprenorphine

Buprenorphine is considered to have a reduced risk of over-sedation, respiratory depression, and overdose. Unlike methadone and heroin, buprenorphine is a synthetic partial opioid agonist with high receptor affinity and slow receptor dissociation. When combined with naloxone, buprenorphine may also block euphoric effects if the medication is injected rather than taken as intended as a sublingual dose[15]. Additionally, maintenance buprenorphine reduces the effects of co-administered opioids. Buprenorphine is available as a sublingual tablet (buprenorphine without naloxone), in a film preparation (buprenorphine + naloxone combination), or as a subcutaneous injection (long-acting buprenorphine without naloxone). LAIB are administered subcutaneously by a healthcare provider and release buprenorphine at a controlled rate over the dosing interval (weekly or monthly).

1.6.3. Current PBS listing of medicines for the treatment of opioid dependence

The PMR focusses on medicines recommended for agonist maintenance that are listed on the PBS (Table 1). Although methadone and buprenorphine +/- naloxone have different pharmacological profiles, both are considered safe and effective in the treatment of opioid dependence and the choice of medicine should be based on the individual needs of the

consumer. Both methadone and buprenorphine +/- naloxone are considered first-line treatment options.

Other medicines that could be used for the treatment of opioid dependence that are not currently listed on the PBS have been raised through the consultation process however only ODT medicines currently listed on the PBS were included in the Review. Consideration of emerging pharmacotherapies that are not currently subsidised under the PBS or registered on the Australian Register of Therapeutic Goods for treatment of opioid dependence should follow the standard procedure guidance for listing medicines on the PBS.

Access to these PBS subsidised medicines through state and territory ODT programs is described below in Section 1.7.

The ODT medicines currently listed on the PBS and their corresponding criteria for availability are shown in Table 1.

Table 1. PBS ODT medicine listings and criteria for availability*

ODT medicine	PBS item codes	PBS criteria for availability†
Buprenorphine sublingual tablets (Subutex®)	6307Y 6308B 6309C	• Opiate dependence • Treatment Phase: Maintenance and detoxification (withdrawal) • The treatment must be within a framework of medical, social, and psychological treatment
Buprenorphine injection (Buvidal® and Sublocade®)	11754P 11759X 11766G 11767H 11768J 11773P 11774Q 11987X 11990C 12981F	• Opiate dependence • Must be treated by a health care professional • The treatment must be within a framework of medical, social, and psychological treatment • For monthly injections: Patient must be stabilised on one of the following prior to commencing treatment with this drug for this condition: (i) weekly prolonged release buprenorphine (Buvidal Weekly) (ii) sublingual buprenorphine (iii) buprenorphine/naloxone
Buprenorphine + naloxone sublingual film (Suboxone®)	9749D 9750E	• Opiate dependence • The treatment must be within a framework of medical, social, and psychological treatment
Methadone liquid (Aspen Methadone Syrup ® and Biodone Forte®)	6171T 6172W	• Opiate dependence

*For more information, see www.pbs.gov.au.

†Care must be taken to comply with the provisions of State/Territory law when prescribing these medicines.

1.7. The PBS Opiate Dependence Treatment Program

1.7.1. A brief history of the PBS ODTP

Originally (pre-1974) methadone treatment was only available on the PBS in tablet form which was prescribed by doctors and dispensed at a pharmacy to take home. It was noted at the time that this was problematic because patients could take the methadone tablets home, crush and then intravenously inject them.

In 1973 the Commonwealth Health Department sent a letter to all states and territories asking them to consider a proposal for clinics approved in each jurisdiction to be supplied with an oral liquid preparation of methadone (instead of the tablet form) for use in the narcotic management programs based on methadone maintenance. When the ODTP was first implemented in 1974, methadone liquid for maintenance treatment was only available from state run detoxification clinics and public hospitals. This, then agreed, partnership delivery model ensured that methadone was provided at no cost via the Commonwealth S100 PBS program and the daily administration to consumers was provided at no cost to consumers via state and territory operated service providers.

The arrangements at this time were that state and territory health departments would approve dispensing outlets, order methadone directly from the drug company who would deliver to the place of dispensing and then invoice the Commonwealth directly.

ODT has developed from a small methadone maintenance treatment program run through state hospitals to a significantly larger program run through a broad range of state and territory authorised dosing point sites including hospitals, public clinics, private clinics, ACCHOs and community pharmacies. There is also a large proportion of drugs for ODT dispensed throughout Australia within correctional facilities.

1.7.2. Opioid dependence treatment programs now

The PBS (including access to ODT medicines) is available to all Australia residents who hold a current Medicare card. However, ODT programs are run by state and territory governments. This means a person needs to be enrolled or authorised to receive ODT medicines under the relevant state and territory program and ODT medicines must be prescribed by a state and territory approved prescriber even though it is funded by the PBS. The current PBS subsidy arrangements for ODT medicines are discussed in subsection 1.7.3.

States and territory programs have progressively moved to involve community pharmacies in the delivery of their ODT programs and in the dispensing of these medicines, with these arrangements varying between jurisdictions. The Commonwealth has no role in approving community pharmacists for dispensing under jurisdictional programs.

The operation of ODT programs continues to be managed by state and territory governments in line with their program policies and regulations. Around 9 out of 10 dosing sites are in community pharmacies[1] and today there is less reliance on treatment through public clinics. These private pharmacies charge consumers daily dose administration fees (in some cases, e.g. ACT, NSW and Tasmania, state and territory governments provide a partial subsidy or targeted incentives to community pharmacies in recognition of the cessation of the previously free public sector programs).

State and territory governments are responsible for the delivery of ODT programs to patients in their respective jurisdictions and for determining the following matters:

- patient eligibility for the relevant state or territory ODT program
- prescriber eligibility for the program (that is, medical practitioners and nurse practitioners that can prescribe in a general practice or clinic setting)
- dosing sites which is inclusive of pharmacy and non-pharmacy settings. In this context, states programs manage arrangements with dosing sites as to the number of patients that can receive ODT medicines at a particular dosing site. Pharmacy participation in state ODT programs is voluntary so not all pharmacies participate in the supply of ODT medicines
- training, accreditation requirements and administrative processes for prescribers and suppliers/dosing sites
- dosing arrangements, including criteria for access to takeaway dosing
- applicable charges, including fees charged to patients for dispensing these medicines (noting that pharmacies may charge a private administration fee in line with state and territory program arrangements and that some jurisdictions provide pharmacies partial subsidies or incentive payments for participation in ODT programs).

ODT medicines are controlled drugs, which are listed under Schedule 8 of the *Poisons Standard* (made under Section 52D(2) of the *Therapeutic Goods Act 1989* (Commonwealth)). Each jurisdiction gives legal effect to the specific requirements for their handling, storage, prescription and dispensing through relevant legislation.

1.7.3. Current PBS subsidy arrangements for the PBS ODTP

The PBS is designed to provide timely, reliable, and affordable access to essential medicines to all Australians who hold a current Medicare card. Governed by the *National Health Act 1953* (NH Act), most pharmaceutical benefits or medicines listed on the PBS form part of the general schedule and are subsidised under S85 of the NH Act. Most of the listed medicines are dispensed by pharmacists and used by patients at home. This is different to the current PBS subsidy arrangements for medicines for opioid dependence treatment

In addition to the drugs and medicinal preparations available under normal PBS arrangements listed in the general schedule, some drugs are also available as pharmaceutical benefits but are distributed under alternative arrangements where these are considered more appropriate. These alternative arrangements are provided for under S100 of the NH Act. Several programs exist to support provision of S100 medicines, including the PBS ODTP, each with their own unique arrangements. Examples of other S100 programs include the Highly Specialised Drugs (HSD) Program which provides PBS subsidised access to specialised medicines, usually affiliated with hospitals, that have restrictions on where they can be prescribed and supplied, and the Efficient Funding of Chemotherapy (EFC) Program that provides for chemotherapy medicines used for the treatment of cancer that are administered through infusion or injection at public or private hospitals. Another example is the Growth Hormone Program which provides subsidised access to growth hormone medicines for eligible paediatric and adult patients and has clinically complex restriction criteria for dosing.

To enable access to methadone and buprenorphine +/- naloxone by eligible patients who are enrolled in state and territory ODT programs, the Commonwealth pays the full cost of the medicines through direct payments to pharmaceutical companies at the approved ex-manufacturer price through a S100 arrangement (dosing sites do not outlay the cost of medicines).

A unique feature of the PBS ODTP is that, as the pharmacist is supplied these medicines at no cost, a PBS claim is not submitted to Services Australia by the pharmacist and accordingly no other fees or payments are payable by the Commonwealth. Similarly, patients are not required to make a PBS contribution for the cost of the medicine, as the total cost of the medicine is paid for by the Commonwealth which means a PBS co-payment to access these medicines is not necessary. As a result, the amount that contributes to a patient's PBS Safety Net is zero.

Payment to pharmaceutical sponsors for medicines on the PBS ODTP is paid based on the quantity of products supplied to state and territory authorised dosing sites (including community pharmacies), not the quantity of medicine dispensed to a patient. Consequently, any wastage, expiration, diversion, theft, or damaged stock is not considered.

The literature review found that dispensing of methadone and sublingual buprenorphine +/- naloxone can occur daily or several times a week (depending on the number of takeaway doses) which falls outside of how the general PBS usually operates at community pharmacies. These medicines are consumed by the patient in the presence of an approved dispenser (referred to as supervised dosing) except when a takeaway dose is dispensed. The mix of supervised dosing and preparation of takeaway doses do not align with how medicines are usually dispensed and claimed at a community pharmacy under PBS arrangements, however community pharmacies have practices in place to support the delivery of ODT. Pooled estimates of the proportion of consumers receiving takeaway doses available in Table 15.

Other PBS medicines that are provided in instalments can be eligible for the Staged Supply Program. The Staged Supply Program is funded through the Seventh Community Pharmacy Agreement (7CPA) and is designed to assist patients who are *at risk* of drug dependency or who are otherwise unable to manage their medicines safely. The eligibility criteria for the Staged Supply Program targets medicine groups most likely to be associated with of accidental or intentional misuse, non-medical use or diversion of prescribed medicines. Opioid substitution medicines supplied under the PBS ODTP for treatment of *established* opioid dependence are not eligible under the Staged Supply Program. Pharmacies are not eligible to claim the 7CPA staged supply payment for patients accessing pharmacotherapy for the treatment of opioid dependence.

Take home naloxone

A complementary program to ODT programs is the National Take Home Naloxone (THN) Program that makes naloxone (a medicine that temporarily reverses the effects of opioids, including heroin) available for free to people who may experience, or witness, an opioid overdose. Specifically, people who use illicit drugs and people who use prescription opioid medication, including ODT medicines, as well as their carers, friends, family and community members. Through this program naloxone is available nationally from participating community and hospital pharmacies as well as other sites such as alcohol and other drug treatment centres, custodial release programs and needle and syringe programs. While THN does not specifically fall within the TOR, many states and territories also include access to naloxone for patients in ODT programs.

Part 2: TOR 1: Essential elements of models of service delivery of ODT

TOR 1: Describe and compare essential elements of models of service delivery for opioid dependence treatment (ODT) in Australia (and internationally) including best practice guidelines and current models (including models developed in response to the COVID-19 pandemic) that support timely access to ODT medicines through both pharmacy and non-pharmacy settings*

*Non-pharmacy settings include a range of service settings where ODT medicines are delivered in Australia including, but not limited to, correctional facilities, hospitals, public and private clinics, ACCHOs, general practices and specialist clinics.

To address this TOR, the sections in this Part discuss the current elements of ODT in Australia including the characteristics of people accessing ODT, existing treatment guidelines and compares these with international models of countries with similar health systems to Australia. These comparisons with existing models of service delivery, along with stakeholder contributions and other evidence on elements for best practice are used to draw out the essential elements of models of service delivery.

2.4. TOR 1 Key findings

On a snapshot day in 2021, 47,563 people in Australia (excluding data for Queensland) were receiving treatment for their opioid dependence.[1] Most people received methadone (58%), the median age was 44 years and over two-thirds were male. It is estimated that most consumers were unemployed and lived in a major city, approximately 8% were homeless and an estimated 71% had been incarcerated previously.[7]

MedicineInsight data indicates ODT medicines were mostly prescribed by a private health practitioner with approximately 10% of prescribers responsible for 80% of the prescribing of ODT medicines. ODT medicines were mainly dispensed in pharmacies (around 68%). Prior to the COVID-19 pandemic, 32% of people had received takeaway doses, which increased to 47% during the pandemic.[7] However, access to takeaway doses may have since reduced in some jurisdictions, e.g. in NSW the amendment to policy guidance that allowed for consideration of higher numbers of takeaway doses during the COVID-19 pandemic was rolled-back to pre-pandemic ODT policies.[18]

Examination of treatment guidelines and current models of ODT service delivery demonstrate significant variability in how ODT has been implemented across different jurisdictions. While a direct comparison of individual features is challenging, a range of elements across both international and domestic ODT service delivery models were identified as being essential for improved ODT service delivery (refer Section 2.6). These findings are also consistent with the essential elements raised by stakeholders.

Affordability for people accessing ODT programs, especially ODT medicines, was identified as a key issue throughout the Review. Most consumers are charged private, unregulated fees particularly when accessing ODT medicines through community pharmacies. Approaches to address the affordability of ODT for consumers across jurisdictional ODT programs are variable. While some jurisdictions, such as ACT, NSW and Tasmania, provide a subsidy or targeted incentives for community pharmacy participation in ODT programs, most other

jurisdictions have not adopted this approach. The ACT ODT program has a framework in place that sets a cap on the amount that pharmacies can charge through private fees thereby ensuring consistent (and capped) fees for consumers. In some jurisdictions, such as Victoria, fees associated with the dispensing of ODT medicines are only subsidised for priority population groups, such as young people or newly released prisoners. In most cases, dosing at public clinics, where available, is free but stakeholder input to the review suggests places are limited.

In addition, the Review found that the continued growth in the demand for access to ODT is constrained by a reliance on public clinics to assist with the initiation of pharmacotherapy, affordability of treatment, workforce challenges, access to specialist review, and prescriber caps in many jurisdictions compared with other countries with less rigid supervision and prescriber restrictions.

The Review also found that ODT consumer access to equitable and affordable medicines for the treatment of opioid dependence could be improved to align with other medicines for chronic conditions listed on the PBS, including the provision for consumers to be able to access the Safety Net threshold for their ODT medicines.

The literature review found that community pharmacy dosing is considered appropriate for: consumers already stabilised on treatment, consumers who do not require the high levels of supervision and monitoring provided by private or public ODT clinics, or where clinic dosing is unavailable (e.g., consumers are unable to geographically access clinics due to mobility or transport issues).

Although research evidence suggests LAIB is an attractive cost-saving option for some consumers due to reduced dosing fees, it is important to note that many people who are opioid dependent would not choose LAIB. It is noteworthy that a significant proportion of consumers have been on methadone treatment for extended periods (decades in some cases). The importance of consumer choice in treatment formulation, and potential erosion of this choice, is a recurring concern reported across LAIB studies.

The Review also found that ODT medicines, while important, are but one element of ODT. Holistic treatment for opioid dependence is a combination of ODT medication and psychosocial support which includes addressing the often-complex components of mental and physical health, as well as the social environment of a person with opioid dependence. The additional support required may vary by person and over time and should be adapted to the patient's changing needs.

2.4.1 Stakeholder views for TOR 1

Stakeholder views were broadly consistent with the matters outlined in literature review and presented in Section 2.6. Submissions to the review and other consultation reports are publicly available through the ODTP PMR website (www.pbs.gov.au/info/browse/reviews).

2.5. Overview of stakeholder views for TOR 1

Stakeholders compared the current arrangements for access to ODT to various international models and overall considered revision of ODT programs could be guided by overseas experiences, by programs for other medicines within Australia (such as opioids prescribed for other indications) and by listings for other medicines on the PBS.

Stakeholders considered the affordability of medicines for consumers and remuneration for pharmacists to be key aspects of ODT service delivery. Specifically, stakeholders considered consumer choice in their treatment important to strengthen and maintain, including choice of medicine, formulation, and provider.

Stakeholders also considered many lessons can be learned from changes to treatment models during COVID-19 restrictions, which demonstrated that changes to the way medicines are dispensed, delivered, and managed are possible.

Stakeholders suggested the range of public and private organisations that provide services under the PBS ODTP be considered and ensure that access is maintained across the spectrum of dosing points.

Additional elements of ODT service delivery raised by stakeholders include:

- Consumer-focussed and flexible ODT
- National consistency across jurisdictional programs and normalising of ODT
- Culturally safe ODT service delivery for First Nations people
- A holistic multi-disciplinary approach that provides consumers with the full range of wrap around support services to ensure the best possible outcome and engages practitioners to their full scope of practice
- A sustainable and knowledgeable professional workforce.

2.6. Literature Review - Characteristics of ODT consumers across Australia

The PMR looked at several data sources to understand the characteristics of people who receive ODT medicines.

According to NOPSAD, on a snapshot day in 2021, 47,563 people in Australia (excluding data for Queensland) were receiving treatment for their opioid dependence.[1] Most people received methadone (58%), the median age was 44 years and over two-thirds were male. ODT medicines were mostly prescribed by a private health practitioner, dosing was mainly dispensed in pharmacies, and the primary drug of concern for the majority was heroin.

Further consumer and prescriber characteristics from NOPSAD can be seen in Table 2.

Data from the ETHOS Engage study was used to further characterise potential participants of ODT medicines. Most (92%; n=693) of the cohort were unemployed and 84% (n=635) lived in a major city. It was determined that 8% of participants receiving ODT medicines were homeless, 71% had been incarcerated previously and 37% recently incarcerated, and nearly half had injected recently.[7]

Prior to the COVID-19 pandemic, 32% had received takeaway doses.[7] This increased to 47% during the pandemic. However, access to takeaway doses may have since reduced in some

jurisdictions, e.g. in NSW the amendment to policy guidance that allowed for consideration of higher numbers of takeaway doses during the COVID-19 pandemic was rolled-back to pre-pandemic ODT policies.[18]

Data from MedicineInsight provided further detail on ODT consumer and prescriber characteristics. More than half of patients prescribed ODT medicines also have a record of a mental disorder, and patients prescribed an ODT medicine were more than twice as likely to have a record of chronic pain. The proportion of patients prescribed ODT medicines were more than 5 times as likely to have a record of alcohol disorder or liver disease, than patients who were not prescribed an ODT medicine. This data gives insight to the broader mental and physical health issues experienced by ODT consumers and supports other Review findings that treatment for opioid dependence should be considered holistically in the context of a person's broader environment and wellbeing.

According to MedicineInsight, approximately 10% of prescribers (fewer than 10 practices) were responsible for 80% of the prescribing of ODT medicines. The final 20% of prescribing was done by approximately 89-95% of prescribing practices. This means it is likely there is only a small number of prescribers servicing the bulk of population accessing ODT which is consistent with comments arising from other inputs to the review.

Table 2. Description of people receiving ODT medicines in Australia, 2021 [19]

	N (%)
Number of people receiving ODT medicines	
Methadone	27,732 (58%)
Buprenorphine (all formulations)	19,831 (42%)
Age, median [IQR][20]	44 [N/A]
Age category[21]	
Under 30 years	3,824 (8%)
30-39 years	11,479 (24%)
40-49 years	16,963 (36%)
50-59 years	10,276 (22%)
60 and over	5,020 (11%)
Sex[22]	
Women	14,934 (31%)
Men	32,576 (69%)
Aboriginal and/or Torres Strait Islander[23]	
No	39,110 (82%)
Yes	5,715 (12%)
Not stated	2,738 (6%)
Prescriber type[24]	
Public prescriber	11,752 (25%)
Private prescriber	30,678 (65%)
Public/private prescriber	121 (<1%)
Correctional facility	5,012 (10%)
Opioid drug of dependence[25]	
Heroin	21,058 (44%)
Morphine	1,263 (3%)
Methadone	1,582 (3%)
Buprenorphine	2,024 (4%)
Codeine	1,131 (2%)
Oxycodone	2,228 (5%)
Other pharmaceutical opioids	1,740 (4%)
Not stated/not reported	16,537 (35%)

Source: Australian Institute of Health and Welfare. National Opioid Pharmacotherapy Statistics Annual Data (NOPSAD) collection. Cat. no. PHE 266. Canberra: AIHW, 2021.[1]

Table 3. Other characteristics of ETHOS Engage participants receiving ODT medicines in Australia (N = 753)

n (%)	
Employed*	60 (8%)
Lives in a major city*	635 (84%)
Proportion (95%CI)	
Homeless	0.08 (0.07, 0.09)
Incarceration history	
Recent (< 6 months)	0.37 (0.37, 0.38)
Ever	0.71 (0.69, 0.74)
Received takeaway doses	
Pre-COVID	0.32 (0.29, 0.36)
During COVID	0.47 (0.44, 0.51)
Median [95%CI]	
Median daily dose	
Methadone (mg)	75 (47, 75)
Buprenorphine sublingual- (mg)	13 (13, 61)

*The ETHOS cohort is a sample of people with a history of injecting drug use, recruited from public and private drug treatment clinics, high case-load GPs, and NSPs.[7]

2.7. Literature Review – Australia and international guidelines

The literature review outlined existing Australian state-based and national treatment guidelines including the impact of COVID on service delivery. The literature review then compared ODT medicine service delivery across Australian jurisdictions and internationally in countries with similar national drug policy and health systems to the Australian context with the view to drawing out the essential elements.

2.7.1 Australian state-based and national treatment guidelines

As shown in Table 4, there are several guidelines across Australia pertaining to the use of pharmacological treatment of opioid dependence, many of which are based on the National Guidelines.

Table 4. Key Australian opioid dependence treatment guidelines

Jurisdiction	Year	Guideline
National	2014	National Guidelines for Medication-Assisted Treatment of Opioid Dependence
Victoria	2016	Policy for maintenance pharmacotherapy for opioid dependence
NSW	2018 2019	NSW Clinical Guidelines: Treatment of Opioid Dependence – 2018 Clinical guidelines for use of depot buprenorphine in the treatment of opioid dependence
QLD	2018-2019	Queensland Medication-Assisted Treatment of Opioid Dependence: Clinical Guidelines 2018 Long-Acting Injection Buprenorphine in the Treatment of Opioid Dependence Queensland Clinical Guidelines: 2019
TAS	2014	Tasmanian Opioid Pharmacotherapy Program Policy and Clinical Practice Standards
ACT	2018	Opioid Maintenance Treatment in the ACT: Local Policies and Procedures
WA	2014	Western Australian Community Program for Opioid Pharmacotherapy. Clinical Policies and Procedures for the Use of Methadone and Buprenorphine in the Treatment of Opioid Dependence
SA	2016	Guidelines for South Australian Pharmacists Dispensing Medication Assisted Treatment for Opioid Dependence (MATOD) Interim Brief Clinical guidelines for use of long-acting buprenorphine (Buvidal® and Sublocade®) in the treatment of opioid dependence For South Australian Community MATOD prescribers
NT	2012	Schedule 8 and Restricted Schedule 4 Substances Policy and Clinical Practice Guidelines

The National Guidelines[15] emphasise that medication-assisted treatment of opioid dependence relies on a combination of pharmacological treatment (e.g., methadone, buprenorphine +/- naloxone, and others) and psychological support. While pharmacological treatments work on reducing symptoms of withdrawal and craving, psychosocial support services aim to improve an individual's psychological health and social environment to improve quality and duration of life.

In line with WHO recommendations,[26] the National Guidelines[15] emphasise that pharmacological treatment should be accessible to all those in need, regardless of the setting that care is provided (primary care, hospitals, prisons and other closed settings). Integration of treatment into primary care is viewed as a primary mechanism of increasing accessibility and coverage of treatment. Comprehensive PBS subsidy is therefore central in ensuring equitable and affordable access to key pharmacological treatments for opioid dependence.

The literature review found that a stepped care approach to treatment delivery is preferred, using less restrictive treatment approaches for those with low severity dependence (e.g., detoxification, counselling), with more intensive treatment options (e.g., ODT medicines, residential rehabilitation facilities) reserved for those with more severe and complex health and social problems where necessary,[15] while maintaining patient autonomy and appropriate clinical care.

2.7.2 Pharmacological management of detoxification/management of withdrawal

Medicines and treatment approaches recommended for the management of opioid withdrawal include.[15]

- abrupt cessation of opioid use and symptom amelioration using non-opioid medicines:
  - clonidine + benzodiazepines, non-steroidal anti-inflammatory drugs, antiemetics, antispasmodic drugs
- short course (less than 1 month) of reducing doses of buprenorphine
- reducing doses of methadone
- induction of withdrawal using opioid antagonists (naltrexone or naloxone) via rapid detoxification.

Of these approaches, the first two are generally the most common and preferred in Australia and are well supported by evidence. Overall, the use of buprenorphine is associated with significantly better amelioration of withdrawal symptoms than clonidine and supplementary medicines. It is also deemed to be the most flexible. In addition to low rebound withdrawal symptoms upon cessation, it enables transfer to other necessary treatments - naltrexone for relapse prevention treatment or maintenance treatment if the detoxification attempt is not successful.

Supportive medicines, such as benzodiazepines for sleep disturbance and anxiety, anti-emetics, anti-diarrhoeal, muscle relaxants and non-opioid analgesics, are often used with either approach to provide additional symptomatic management.

2.7.3 Pharmacological management of opioid dependence (agonist maintenance)

The aim of maintenance treatment is to reduce exposure to risk behaviours and stabilise health and social functioning, while also managing the physical dimension of dependence.

Medicines recommended for agonist maintenance:

- Methadone
- Buprenorphine
- Buprenorphine and naloxone.

Although methadone and buprenorphine +/- naloxone have different pharmacological profiles, both are considered effective in the treatment of opioid dependence and the choice of medicine should be based on the individual needs of the consumer. Both are considered first-line treatment options.

The general characteristics and differences between methadone and buprenorphine are summarised in Table 5 below.

Table 5. Key differences in the characteristics between methadone and buprenorphine for the treatment of opioid dependence

Methadone	Buprenorphine
Full mu opioid agonist	Partial mu opioid agonist
24-36 hour half-life	36-48 hour half-life
Daily dose frequency	Range of dose frequencies
Oral (liquid) administration	Sublingual and long-acting administration
More misuse potential –supervised doses preferred	Less misuse potential – better option if takeaway doses are needed
No protective overdose factors, more risks during treatment induction	Ceiling effect limits overdose risk, safer during treatment induction
More effective for severe dependence	More suited to mild-moderate dependence
Generally associated with a high level of stigma (towards both patients and the treatment itself)	Less stigma associated with use

As a full mu opioid receptor agonist, methadone is considered to have a stronger opioid effect, but has more side effects, risks, and drug-drug interactions. Buprenorphine is considered safer than methadone largely due to having a reduced risk of over-sedation, respiratory depression, and overdose.

The nature of methadone treatment has remained largely unchanged over time, with newer treatment alternatives focused on modifications to the delivery of buprenorphine. First, there was the combined buprenorphine + naloxone sublingual formulation as a means of reducing diversion, and more recently, the introduction of the long-acting formulation of buprenorphine as a means of providing a more convenient treatment option to both consumers and care providers, while at the same time reducing diversion and encouraging adherence. Although the use of LAIB is not currently integrated into the National Guidelines,[15] several jurisdictions[27-29] have prepared local guidelines to support clinicians in using this formulation as a treatment option, bearing in mind that some modifications to delivery of treatment services are required to accommodate the reduced dosing interval (i.e. weekly, monthly).

2.7.4 Impact of COVID on service delivery of ODT

The recent CHOICE study[30] collected data on the impact of COVID on service organisation and delivery through in-depth interviews with providers. The key findings are described below.

Physical setting, risk environments and dosing points as COVID-19 "hotspot"

Delivering ODT medicines can involve frequent contact with large concentrations of consumers. Recognising this, providers assessed ODT consumers' risk environments at the clinic and made rapid adaptations to reduce the chances of consumers contracting COVID-19 while accessing treatment. However, some adaptations to ODT medicine access made consumers feel like the pharmacy was prioritising the interests of the public over those of the ODT consumer. For example, when pharmacies chose to remove their ODT medicine dosing cubicles to allow for physical distancing, some ODT consumers felt their privacy had diminished.

LAIB

In response to the COVID-19 pandemic, policies encouraging the use of LAIB were introduced by state and territory governments as a strategy to reduce footfall at dosing points, due to the weekly or monthly schedule of injections (rather than often daily dosing of oral and sublingual ODT medicines). ODT consumers receiving LAIB described a multitude of benefits from this ODT medicine formulation, however some concerns were also observed.

Increased access to ODT medicine takeaways and treatment adherence

New state and territory policies that scaled-up access to takeaways in response to the COVID-19 pandemic raised concerns among providers that there would be an increase in treatment diversion and adverse effects. However, to date no published data have demonstrated an increase in adverse events – although such data may be delayed in being collated and reported. Treatment providers highlighted the need for state-level evaluation to assess the impact on ODT medicine-related overdose during COVID-19, before maintaining increased access to takeaways (some of these initiatives are now being rolled back to pre-pandemic ODT policies in some jurisdictions). ODT medicine consumers reported that increased takeaways were more convenient, supported flexible dosing, improved treatment adherence, and instilled a sense of empowerment in the consumer.

2.7.5 Comparison across Australian jurisdictions

In April 2021, the Department summarised the ODT medicine guidelines and policies across all Australian jurisdictions.[31] The table was updated during the literature review and is current as at March 2022 (see Table 6).

Patient fees charged at community pharmacies

The most common dispensing service for ODT medicine across all states and territories is through community pharmacies. There is usually a dispensing cost to the consumer. Pharmacies can independently set the dispensing fee, with costs averaging $35 per week but known to range between $21 to $90 per week.[32] Government subsidy or targeted incentives for ODT medicines is available for community pharmacies in the ACT, NSW, and Tasmania. While the full detail of the subsidy provided by the ACT government to pharmacists is commercial-in-confidence, the private dispensing fee able to be charged to consumers is capped at $15 per week. NSW provides a $1,000 one-off payment to pharmacies for enrolment into the treatment program per pharmacy, with an additional $100 per consumer, twice a year (capped at 20 consumers and consumers must be dosed continuously for 2 months). Consumers in WA can be referred to financial assistance services such as Centrelink. However, in practice, if a WA consumer cannot afford to pay for pharmacy dosing, then they cannot receive ODT medicines dispensed by pharmacies.

Patient fees at public clinics and correctional services

Public clinics are available in ACT, NSW, SA, NT, and Tasmania, and provide ODT medicines with no fees for varying durations. Victoria has no public clinics but covers the treatment fees for consumers on Youth Justice community orders and for consumers released from prison, up to the first 30 days. Queensland does not cover all costs of ODT medicines in its public clinics or corrective services.

Table 6. ODT medicine guidelines and policies across Australian Jurisdictions[31]

	ACT	NSW	Qld	WA	SA	Tas	NT	Vic
Government subsidy for community pharmacies (incl. incentive payments)	Y	Y	N	N*	N	Y (Tiered)	N	N†
Cap consumer fee (pharmacies)	Y	N	N	N	N	N	N	N
Capped amount for consumer at pharmacy	$15/wk.	N	N	N	N	N	N	N
Subsidy amount to pharmacists for services relating to supply of ODT medicines	Not disclosed	$1000/pharmacy, once $100/consumer, twice a year (capped 20 consumers)	N	N	N	Depends on drug and number of days/wk. attending	N	N
Services largely delivered via	Community pharmacy‡ (72%)	Community pharmacy‡ (52%)	Community pharmacy‡ (68%)	Community pharmacy‡ (91%)	Community pharmacy‡ (90%)	Community pharmacy‡ (88%)	Community pharmacy‡ (93%)	Community pharmacy‡ (92%)
Public funded clinics	Y	Y	Y	Y	Y	Y	Y	N‡
ODT medication provided for free from public clinic (largely)	Y	Y	N§	-	Y (6 weeks)	Y	Y	N
No consumer fee at correctional facilities	Y	Y	N§	-*	Y	Y	Y	Y#
ODT medicine Budget approved	-	$306M AOD, not meds alone (2020-21)	-	-	-	-	-	$315MAOD, not meds alone (2020-21)
Prescriber approval required for full suite of ODT medicines (legislated)	Y (5+ consumers)	Y	Y	Y	Y	Y	Y	Y**
Consumer cap per prescriber	Y (endorsed: no limit, non-end.: 5)	Y (accredited: 200+, non-accredit.: 30)	Y††	Y (metro 50, rural 25)	Y (non-accredit: 10)	Y (20)	N	Y (non-accredit.: 30)
Prescriber training	Y (refresh 5 yrs)	Y	Y	Y	Y	Y	Y	Y
Specific approval required by community pharmacies to supply ODT medicines	Y (regs)	Y (policy)	N (broader Sch8)	Y (regs)	N (Broader Sch8)	Y (act)	N	Y‡‡ (policy)
Consumer cap per dosing site	N	Y (65)	-	Y (50)	N	N	N	Y (85)
Pharmacist training	Y (refresh 5 yrs)	-	-§§	Y	Y	Y	N	Y
Local engagement with stakeholders	Y	Y	Y	N	Y	Y	Y	Y

Note: Table 6 is based on a summary of guidelines and policies compiled by the Department of Health in 2021 and has been updated based on more recent sources (policy documents, AIHW 2021, National Opioid Pharmacotherapy Statistics Annual Data collection 2020, input from jurisdictions) where applicable. Evidently, policy and practice related to ODT medicine delivery varies considerably between jurisdictions

*Consumers can be referred to financial assistance services such as Centrelink. However, in practice if a consumer cannot afford to pay for pharmacy dosing, they cannot engage in ODT medicines. (Source: WA response HO template, 2021);

†The VIC Department of Health pays pharmacy service fees for consumers under 19 years of age and consumers on Youth Justice community orders. The Department of Justice and Community Safety pays pharmacy service fees for consumers for up to 30 days post-release from prison. For all other consumers, the consumer is responsible for ensuring payment of all pharmacy fees. In cases of severe financial hardship, consumers may contact the Pharmacotherapy Advocacy Mediation service for information and advice. 2016. *Policy for maintenance pharmacotherapy for opioid dependence*, Victoria State Government, page 22;

‡AIHW 2021, *National Opioid Pharmacotherapy Statistics Annual Data collection 2020;*

§Hospital and Health Services that provide ODT medicines through public pharmacies and correctional centres can charge between $25-$35 per week at the discretion of the Hospital and Health Services. (Source: QLD response HO template, 2021).

#The VIC Department of Health pays pharmacy service fees for consumers on Youth Justice community orders. The Department of Justice and Community Safety pays pharmacy service fees for consumers for up to 30 days post-release from prison. 2016. *Policy for maintenance pharmacotherapy for opioid dependence,* Victoria State Government, page 22;

**For methadone and for >10 buprenorphine consumers (policy);

††A consumer cap exists for the buprenorphine + naloxone only prescriber type. There are no caps for other prescriber types (full, interim, shared care);

‡‡*Policy for maintenance pharmacotherapy for opioid dependence*, Victoria State Government;

§§Queensland Health's state-wide alcohol and other drug training and workforce development service, Insight, provides free self-paced publicly accessible online training about opioids and the Queensland Opioid Treatment (non-prescribers) which pharmacists may access if they choose.

State and Territory prescribing and dispensing regulations

Australia has no central body to regulate the handling of S8 or controlled drugs, including ODT medicines. Although the Therapeutic Good Administration (TGA) is the national body for the regulation of medicines, each state and territory self-regulate under the general principles established by the TGA and has its own medicines and poisons legislation that regulates controlled drugs, resulting in varied requirements. An added challenge for travelling consumers is that a prescription for a controlled drug in one state or territory may not be legal in another.[33] In these circumstances, dispensing pharmacists need to contact the medical practitioner in the consumer's home state or territory. Prior to consumers travelling, prescribers are required to check for up-to-date information on interstate requirements for ODT medicine prescriptions and contact details for interstate regulatory groups for assistance with temporary interstate transfers. This is intended to avoid delays in consumers accessing treatment by attempting to obtain a local prescription from a medical practitioner in the state the consumer is visiting however consumer input to the review indicated this remains a significant challenge. Alternatively, consumers can apply to their home jurisdiction in advance to arrange take-away doses for the duration of their travel, a process which can be onerous and intrusive for consumers to coordinate and do not easily accommodate emergency travel.

Table 7 summarises the prescriber training and case load restrictions across Australia. In all states and territories there are no caps on the number of prescribers that can participate in ODT programs but there are rules on the number of patients per prescriber, and this can vary by state and territory, and treatment type. All states and territories require their prescribers to apply for an authorisation to prescribe ODT medicines as methadone and buprenorphine are both controlled drugs. Most states and territories require and provide prescriber training; however, the rules differ based on initiation of treatment, treatment type and case load. Different terminology is used to describe this training across states and territories; the ACT uses the term endorsement whereas NSW, South Australia and Victoria refer to this training as an accreditation. The Northern Territory does not appear to provide official training for prescribers.

Pharmacists play a key role in delivering opioid dependence treatment services. The literature review found that community pharmacy dosing is considered appropriate for: consumers already stabilised on treatment, consumers who do not require the high levels of supervision and monitoring provided by private or public ODT clinics, or where clinic dosing is unavailable (e.g., consumers are unable to geographically access clinics due to mobility or transport issues). Community dispensing offers flexibility and convenience for consumers to be dosed near where they live or work. However, community dispensing has its challenges. Issues for consumers include limited pharmacy options and opening hours, lack of privacy and confidentiality with dosing in a smaller community pharmacy, expense associated with travel for dosing and pharmacy fees, difficulties with the time required to travel to collect medication, and concern about the impact this can have on employment.[34]

Some ODT programs have a maximum number of consumers for supervised dosing of ODT medicines (methadone and buprenorphine combined) at any one community pharmacy. In WA the cap is 50 consumers, in NSW a pharmacy can dispense to 65 consumers, and 85 in

Victoria. In most jurisdictions accredited training for pharmacists in the delivery of ODT medicine services is not mandatory, although a review of processes around ODT medicine service delivery forms part of the Pharmacy Guild of Australia's Quality Care Pharmacy Program accreditation process. As such, pharmacists are encouraged to participate in training regarding ODT medicines. In the ACT and WA, a community pharmacist must ensure that all pharmacists dispensing treatment have successfully completed the required training. In Tasmania, accreditation to undertake opioid pharmacotherapy dosing requires each pharmacist to undertake a short professional development program and complete a short exam. It is suggested that all pharmacists complete their accreditation to dose ODT medicines during their intern year.

Table 7. Prescriber regulations across Australian jurisdictions

State\territory	Prescriber regulations
New South Wales	Prescribers must be accredited to prescribe opioids to up to 200 consumers who dose in community pharmacies or private clinics, or up to 300 consumers who dose in public clinics. To become accredited, prescribers are required to complete the Opioid Treatment Accreditation Course; pass a course examination; and complete a workplace assessment (a 2–3-hour clinical placement). Unaccredited prescribers may apply for an authority to initiate consumers with buprenorphine or buprenorphine + naloxone but are not allowed to initiate a consumer onto methadone. Unaccredited prescribers may be authorised to prescribe for up to 20 buprenorphine or buprenorphine + naloxone consumers and 10 methadone consumers.
Victoria	Training involves two modules; the first is completed online; followed by a 1-day workshop. Initial permission to prescribe all pharmacotherapies is limited to treatment for up to five consumers (unless under the close supervision of an established pharmacotherapy prescriber). Since the COVID-19 pandemic buprenorphine/naloxone can be prescribed for up to 30 consumers without completing Module 2. Completing Module 2 is essential for medical and nurse practitioners who want to increase buprenorphine/ naloxone consumer numbers or prescribe methadone or buprenorphine (without naloxone).
Queensland	There are multiple prescriber types: level 1 can prescribe the full suite of pharmacotherapy; level 2 is an interim prescriber, typically on hospital rotation and can prescribe the full suite of pharmacotherapy for 3 months under supervision; a buprenorphine + naloxone only prescriber type has a consumer cap of 20; and lastly a community shared care prescriber who can provide the full suite of pharmacotherapy under an approved share-care arrangement with an approved prescriber. There are no caps for other prescriber types.
Western Australia	A metro prescriber is permitted to prescribe for a maximum of 50 active pharmacotherapy consumers. A regional prescriber is limited to a maximum of 25 pharmacotherapy consumers. The risk to continuity of care is particularly high where the prescriber is a sole practitioner and/or is in a regional area. Other prescribers may not be available to continue treatment if a prescriber withdraws from the program. Each prescriber is required to complete a 6-hour face to face training session and take-home assessment package for all approved forms of pharmacotherapy. An online program is currently being developed.
South Australia	A prescriber must become accredited if they wish to prescribe buprenorphine/naloxone film for more than ten consumers at one time or prescribe: methadone liquid, buprenorphine as a single agent (Subutex®), or long-acting buprenorphine. Prescriber training involves completing an online course followed by a 3-hour skills development component involving consumers. Unaccredited medical practitioners can still prescribe buprenorphine with naloxone in film form (Suboxone®) for up to 10 consumers for opioid dependence.
Tasmania	To become an authorised prescriber, an application to the Alcohol and Drug Service (ADS) Clinical Director must be made and complete training in opioid dependence and pharmacotherapy with an ADS Addiction Medicine Specialist. Prescribers will also be invited to observe a pharmacotherapy practice during a clinic; they must pass a multi question exam. A prescriber in a full-time general practice can prescribe methadone or buprenorphine to a maximum of 20 consumers. Practitioners with clinical skills and an interest in this area can apply to increase this number.
Australian Capital Territory	A prescriber must hold an endorsement to treat drug-dependency if they wish to initiate consumers onto treatment or to prescribe for more than five stable consumers at a time unless the prescriber is working at a defined ACT institution. An endorsed prescriber has no limits to the number of consumers. To become endorsed, prescribers must have successfully completed a designated training program with short examination and a practical placement. To maintain endorsement prescribers are required to undertake refresher training every five years.
Northern Territory	A prescriber must apply to the NT Chief Health Officer (CHO) for an authorisation to prescribe to each consumer. The CHO decides in relation to each individual application whether the prescriber is competent. Each prescriber is allowed 10 buprenorphine, buprenorphine/naloxone and methadone authorisations and may apply in writing for an increase.

Information has been drawn from relevant policy documents. All states and territories require and provide some prescriber training, though the nature of this training differs in each jurisdiction. Restrictions on prescribing (e.g., consumer caps before and after training) also differ by jurisdiction.

2.7.6 Comparison of Australian and international treatment guidelines

ODT medicine guideline documents commonly include elements relating to program delivery which include (but are not limited to) eligibility criteria for receiving ODT medicines, dosing requirements, restrictions on prescribers, pharmacists, and consumers, consumer fees and subsidies from government entities. Additionally, guidelines also cover other elements related to treatment including unsupervised dosing, and urine drug screening. The literature review extracted details from guideline and policy documents from Australia, the United Kingdom, England, Scotland, Wales, and Canada. Comparator countries were selected due to similarities in the healthcare systems in each of these countries to Australia.

Eligibility criteria for ODT medicines

Eligibility criteria across ODT medicine guidelines from Australia largely omitted information regarding the minimum age for treatment entry. However, the province of Ontario in Canada did mention a minimum age of 16 years and federal guidelines suggest that individuals under 18 are eligible for ODT medicines if they fulfill the criteria for opioid dependence. Like Australian guidelines, most jurisdictions mention the requirement of an opioid dependence diagnosis for an individual to be eligible to receive ODT medicines. Guidelines from the province of Alberta, where injectable diacetylmorphine or hydromorphone are available as ODT medicines, state that individuals require a diagnosis of opioid use disorder, current or previous intravenous drug use, and previous attempts using oral forms of ODT medicines.[36]

Guidelines regarding daily doses prescribed

The National Institute for Health and Care Excellence (NICE) guidelines in the United Kingdom provide information on the initial daily dose recommended for methadone and buprenorphine. For methadone, the initial daily dose range is between 10-30mg, lowered to 10-20mg if the opioid tolerance is unknown. For buprenorphine, the initial daily dose range is 4-8mg, increasing to a maintenance dose in the range of 12-16mg[37]. Guidelines for methadone in Ontario and Alberta state an initial daily dose of 10-30mg,[36,38] while the range increases in British Columbia from 5-30mg.[39] For Quebec, methadone dosing is individualised and determined by the care provider.[40] Centre for Addiction and Mental Health (CAMH) guidelines are followed for buprenorphine dosing and apply across Ontario, Quebec, Alberta, and British Columbia. Initial dose is between 2-4mg, with doses increased by increments of 2-4mg to a maximum of 8-16mg/day.[41]

Data from two global systematic reviews suggests that optimal dosing for methadone is ≥60mg for methadone and ≥8 mg for buprenorphine.[42,43] Data from routine clinical practice in the United Kingdom found that the mean dose of methadone prescribed ranged from 48-65 mg, with only 43% of people receiving a dose of over 60 mg.[44] In Canada, the median dose of methadone ranged from 75-89.5mg with over half receiving a dose greater than 80mg. Buprenorphine dose data from routine clinical practice was only available for the United Kingdom, and the mean doses of buprenorphine were 7.5-9mg. Only 21% of people receiving buprenorphine received over a threshold dose of 12mg.[44]

Prescriber and pharmacist restrictions

In Canada, most provinces have no cap on the number of prescribers, nor is there a consumer cap per prescriber. In all Canadian provinces, prescribers are required to obtain a specific exemption to prescribe methadone. Further requirements vary by Canadian province, such as a one-day clinical observership in Ontario,[38] an online education program in Quebec and British Columbia,[39,40] or a relationship with an experienced buprenorphine prescriber for prescribers without experience treating opioid dependence. For prescription of methadone and buprenorphine, little detail was available regarding prescriber restrictions or requirements for any country in the United Kingdom.

In Canada, provinces do not have a consumer cap per dosing site. Pharmacists in Alberta and British Colombia require pharmacist training to dispense methadone,[36,39] however, Quebec and Prince Edward Island do not have such a requirement for pharmacists,[38,40] Pharmacist training is also required to dispense methadone and buprenorphine in the United Kingdom.[37]

Consumer restrictions and fees

Quebec and British Columbia's provincial guidelines state that there is a government subsidy for community pharmacies.[39,40] For Prince Edward Island, there is no subsidy for community pharmacy dispensing.[38] This information was not included from Alberta's and Ontario's guidelines, nor was there information regarding a capped consumer fee and payments to pharmacies for services relating to supply of ODT medicines. There is no cap on consumer fees outlined in Quebec, British Columbia, or Prince Edward Island's guidelines.[38-40]

Guidelines for England, Scotland and Wales do not include information on capped amounts for consumers, subsidies provided to community pharmacies for ODT medicine service provision, consumer cap per prescriber or prescriber training requirements for either methadone or buprenorphine. In Scotland, pharmacists are paid £2.16 for every dose of methadone dispensed and £1.34 (2018-19) for supervising consumption.[45] There is no dispensing fee charged to consumers in Scotland.

There is no mention of subsidies for community pharmacies in guidelines for England and Wales. Both England and Wales have a single activity fee of £1.29 and £2.50 for oral methadone plus an additional "packaged dose fee" of £0.55.[46]

No information was available pertaining to ODT medicine consumer fees in correctional facilities in England, Wales, or Scotland. In Canada, there is no fee charged in correctional facilities in British Columbia or Prince Edward Island.[38,39] A fee is charged in correctional facilities in Quebec,[40] and no information was available for Ontario or Alberta.

Unsupervised dosing and urine drug screening

Supervised dosing in the United Kingdom is required for the first three months of treatment, which can then be relaxed subject to the perceived status of the consumer and once an assurance of compliance is made.[37] Provincial Canadian guidelines on supervised dosing differ on the treatment that is being administered. For methadone, both Quebec and Alberta require supervised dosing for the first three months,[36,40] while British Columbia guidelines stipulate supervised dosing for one month once a stable dose has been reached and 12 weeks of negative urine screening.[39] Ontario requires two months of supervised dosing and at least

one week without problematic substance use.[38] The impact of COVID-19 on increased access to ODT medicines is discussed in section 2.4.4.

Urine drug screening was recommended to be based on the current status of the consumer in UK guidelines, stipulating it should be carried out at least twice per year. There was a contradiction between the NICE 2017 Guidelines and the National Health Service Prescribing Guidelines that recommend urine drug screening to be carried out every three months.[37,47] Canadian provincial guidelines vary on the treatment prescribed. For methadone, urine drug screening is based on where the consumer is at in their treatment with more frequent screening occurring in the initiation and titration phase (ranging from weekly to fortnightly).[38] Drug screening lessens as the stabilisation and maintenance phases are reached (once per week to once every three months).[38] For buprenorphine, recommendations for urine drug screening range from before treatment has begun in Ontario and Alberta,[36,38] at each consumer appointment in Quebec and at least monthly during induction and titration in British Columbia.[39] In Australia, the National Guidelines state urine drug screening can be an important tool and the frequency is primarily based on the judgement of the prescribing doctor. However, the National Guidelines note that directly observed urine samples are intrusive and impact negatively on therapeutic engagement.

2.8. Literature Review - Changes arising from the PBS listing of LAIB

The LAIB formulations are expected to have an ongoing significant impact on the ODT medicines landscape. Therefore, the literature review examined changes that have occurred to date in ODT medicine provision because of the PBS listing of LAIB for prescribers, dispensing/administration sites, and patients.

It is acknowledged that the available evidence may be somewhat limited given the recent introduction of these products and may be subject to change as further studies are published. However, it was considered important for the Review to consider the available evidence on the impact of LAIB formulations as preliminary guidance to assist in possible future policy considerations.

2.8.1 Overview of LAIB

The recent introduction of LAIB provides an opportunity to potentially address some ODT medication barriers and facilitate ODT medication scale-up where clinically appropriate and while respecting consumer autonomy and treatment choice. LAIB is administered by subcutaneous injection of a buprenorphine suspension slowly releasing buprenorphine over periods up to a month. LAIB administered via weekly or monthly subcutaneous injections eliminates the need for frequent dosing, potentially offering some patients benefits such as treatment efficacy through improved treatment exposure. However, despite the potential benefits, research evidence and stakeholders have also raised concerns regarding the use of LAIB and its uptake in Australia, particularly the need to ensure consumers understand how LAIB works and that treatment options continue to be made available.

Two LAIB brands are registered for use in Australia. Buvidal®, a monthly or weekly injection became available on the PBS from 1 September 2019. Sublocade® is a monthly injection and became available on the PBS from 1 May 2020. The TGA recommended an initial restriction

in distribution to hospital and specialist alcohol and drug services. This would enable a robust post marketing study during the first six months for accurate adverse events reporting and to make decision on further expanding the access. These conditions have since been completed and removed from each LAIB product.

The literature review found the potential benefits of LAIB include improved treatment retention, greater choice/flexibility, and reduced pharmacy/clinic attendance in settings where this is a typical feature of ODT.[48-50] Two randomised controlled trials of LAIB[51,52] informed Australian regulatory approval; single-arm studies also exist.[6] Study limitations include the absence of appropriate comparator arms, limited long-term follow-up, and lack of cost-effectiveness analyses. Particularly in the COVID era, LAIB is being increasingly used as an ODT medication given reduced need for clinic attendance and greater flexibility.

It is important to note that many people who are opioid dependent would not choose LAIB.[2] Concerns include being unable to control medication doses or stop treatment easily, potential side effects, and reduced choice.[49,50] There are concerns that LAIB may perversely reduce consumer choices if clinicians or ODT program policies insist on this ODT medication in place of others (sublingual buprenorphine or methadone).

The section below summarises the changes that have occurred in practice and service delivery because of the introduction of LAIB, and the benefits and drawbacks of LAIB as perceived by consumers, and preferences for this versus other available ODT medicines.

2.8.2 Uptake of LAIB

Available data reveals increasing uptake of LAIB since approval of the two products, particularly in correctional facilities. Refer TOR 3 (Part 4) for further detail regarding the utilisation of PBS ODTP products.

Evidence indicates an increase in use of LAIB appears to have been accelerated as a strategy to decrease interaction with consumers and help adhere with density limits and social distancing rules during the COVID-19 pandemic as well as a possible shift in state and territory government policies regarding the use of LAIB in correctional facilities. One such model was a rapid-access clinic in metropolitan Melbourne dedicated to LAIB.[53] Multiple referral pathways including self-referral, a triage process performed by drug and alcohol nurses, review of available history (such as permits, Safescript dispensing history), and subsequent telehealth specialist consultation to assess suitability, if required, were core components of the model. Whilst pathology was not performed prior to treatment initiation unless clinically indicated, other services provided included vaccination, blood borne virus testing and treatment, and THN. At the time of conducting the literature review evaluation of consumer outcomes and acceptability of the model is pending.

Both formulations of LAIB were introduced in all Australian states and territories ahead of many other countries, with only 22% of health providers from high income countries reporting availability in one survey conducted in May 2020.[54] Appendix 2 Table 2.1 describes the variation in jurisdictional policy regarding who can prescribe and administer LAIB, and in which settings. In addition, the Pharmaceutical Society of Australia's (PSA) Summary of legal authority for pharmacist administration of medicines by injection (September 2022) is available from the PSA website at www.psa.org.au.

The CoLAB single-arm cohort of LAIB (n=100) documented the early experience and issues encountered by clinics during implementation of monthly LAIB as a new treatment modality (Table 8). Key practical considerations included the need for staff training, procedures for handling of a cold-chain product in compliance with state S8 requirements, and the need for regular contact and follow up with consumers between monthly clinic visits.

More broadly, for many providers the implementation of LAIB occurred in the context of the COVID-19 pandemic and was often accelerated as a strategy to decrease frequency of consumer attendance and therefore reduce COVID-19 infection risk for consumers and staff. Challenges reported include development of protocols and procedures to minimise the risk of COVID-19 transmission when administering long-acting injections, and how to provide treatment to consumers who are in quarantine or self-isolation. Guidance material to support patients transferral from methadone treatment to LAIB, remains poorly documented or evaluated.[55] Most patients are currently established on sublingual buprenorphine prior to commencing LAIB.

Table 8. Challenges experienced and strategies used at the CoLAB study sites in SA, VIC and NSW during a study examining use of long acting buprenorphine, May 2019 to November 2020 (n=100)[5]

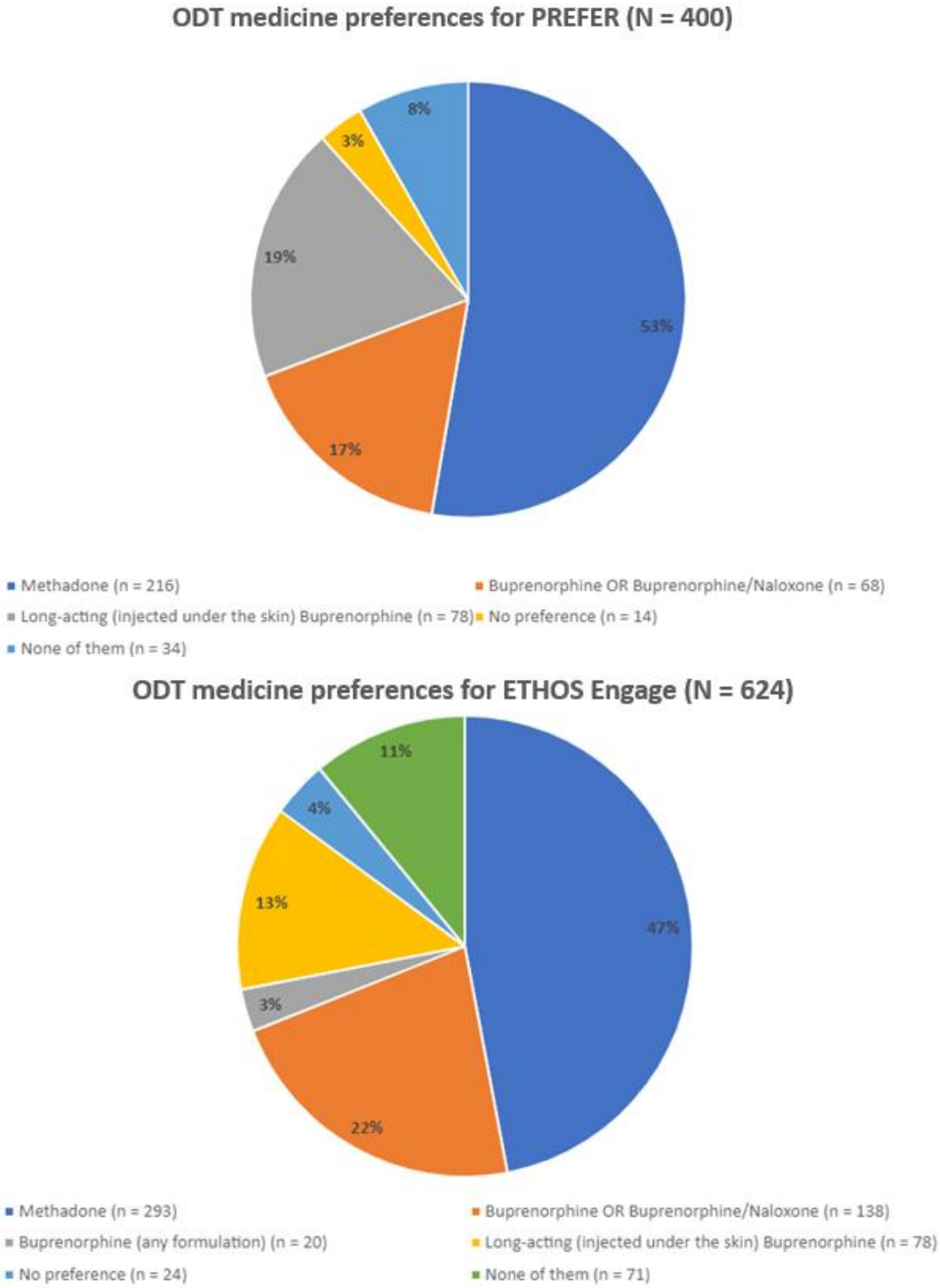
Issue category	Description	Strategies
Consumer engagement and retention	• Uptake not an issue, for this small sample size (assisted by increasing consumer awareness, pre-PBS listing)	• Advertising and clinic flyers/posters used in some clinics • Clinic check-up calls to consumers several days before next injection due to gauge dose (especially dose 3 involving switch from 300mg to 100mg Sublocade®) • Text reminders • Financial incentives (research interview reimbursement of $50 per month) • Word of mouth (some sites experienced in long-acting buprenorphine through previous trial) • Trial participants advocating BUP-XR among their peers
Prescription	• Diversity of practitioners (specialist vs General Practitioner vs Nurse Practitioner) • local authorisation to prescribe • Consumer permits	• Nurse Practitioners (with specialist oversight), opportunity for workforce development
Clinic schedule management	• Appointment booking and management for initial and subsequent visits • Staff allocation and clinic structure • The need to operate parallel clinics for long acting and sublingual consumers	• Dedicated clinics vs integrated or ad hoc, flexible clinics
Staff resourcing	• Study drug management (for more frequent deliveries) • Utilisation of freed up resources	• Distribution of tasks among teams • Allocation of dedicated tasks to certain personnel
Drug supply chain, storage, and management	• Delivery schedule • Drug storage location, S8 compliance • Waste management and destruction • Accountability	• Community pharmacy, hospital pharmacy, on-site clinic storage models • Coordination between distributor, storage location and clinic site (including intra-service movements) • Fridge vs safe, and impact on clinic schedule, recruitment, retention, product wastage
Managing consumer expectations and concerns:	• Lump • Pain • Withdrawal	• Speed of injection • Application of ice pack at the injection site • Counselling • Sublingual top-up
Staff training requirements	• Treatment administration, range of qualifications (General Practitioners, specialists, Nurse Practitioners)	• Study-specific training (including company product information) • Regular follow up and contact • Monthly newsletters and monthly conference calls
Managing adverse events	• Loss of frequent contact with consumers • Resources involved in managing AEs	• Follow up contact between visits • Consumer card

2.8.3 Consumer treatment preferences

In a survey of 400 people with opioid dependence, conducted prior to access to LAIB in Australia, 68% of people thought that LAIB (hypothetically) would be a good treatment option for them.[2] Those who thought this were more likely to be younger, women, have less than 10 years of education, and report past month heroin and methamphetamine use. Fifty-four percent reported no preference for weekly versus monthly injections, whilst 7% preferred weekly and 39% preferred monthly. Of people currently receiving ODT medicines, those with shorter treatment episodes, fewer unsupervised doses, and longer travel distance were more likely to perceive that LAIB would be a good option for them. This is consistent with other surveys and qualitative research demonstrating positive perceptions and potential benefits of LAIB.[48-50] However, people have also noted important concerns about LAIB, including reduced choice and control.[49,50]

Two recent studies, PREFER and ETHOS Engage, examined consumer preferences for LAIB versus the sublingual formulation or methadone (Figure 1). The ETHOS Engage study assessed people who reported prescribed or non-prescribed opioid use in the preceding six months or had received ODT medicines in the preceding six-month period. Almost half of respondents reported a preference for methadone (47%), whilst 13% preferred LAIB. This is consistent with the PREFER survey (53% preferred methadone), although more people stated a preference for LAIB (19%).

Figure 1. Consumer preferences for ODT medications in the ETHOS (top) and PREFER* (bottom) studies



*Question on any formulation of buprenorphine was added after the PREFER study was completed.

2.8.4 Consumer treatment satisfaction

Studies generally reported high consumer satisfaction with LAIB in the Australian context. In an open-label, randomised, clinical trial of 119 participants, the mean Treatment Satisfaction Questionnaire for Medication (TSQM) global score was significantly higher in the group receiving LAIB (Buvidal®) than in the group receiving sublingual buprenorphine at week 24 (mean score 82.5 vs 74.3).[56]

This is consistent with the CoLAB single arm cohort of LAIB (Sublocade®, n=100) which observed high rates of treatment satisfaction and an increase of 15% in mean treatment satisfaction (measured by the TSQM) at week 12, after 3 months of LAIB compared with baseline treatment satisfaction scores (following sublingual buprenorphine treatment but prior to the first long-acting injection).[5] Similarly, among a small sample (n=15) of people receiving either weekly or monthly long-acting in an England and Wales study, 81% reported overall satisfaction,[57] 81% convenient and 77% treatment effectiveness.

2.8.5 Qualitative studies of the benefits of LAIB

Of a sample of 30 consumers receiving monthly LAIB (mostly through a clinical trial) located in metropolitan Sydney, regional NSW and metropolitan Melbourne and interviewed from February 2019 to March 2020, reported advantages of LAIB included a reduction in exposure to stigma and opportunity to think of themself in new or less stigmatising ways; a new sense of freedom from 'liquid handcuffs', with time freed up which afforded the opportunity to engage in other activities, including travel (particularly for those in regional areas); and a new sense of normalcy and reimagining the potential for a different future life.[58,59]

Many viewed LAIB as cost saving through avoidance of pharmacy fees. Others reported perceived benefits to include the slow-release formulation's ability to maintain a "level" or "normal" throughout the day for many days at a time, and the view that long-acting is the least stigmatising treatment modality available.[49] Especially for those with long treatment histories, LAIB has been reported as an opportunity to avoid being identified as being on ODT medication, allowing participants to "pass as normal" and avoid stigma, and to consequently reshape their self-identities.[60]

The reduced contact with pharmacies and drug treatment services may be viewed more positively amongst those with extensive treatment histories. Willingness to receive LAIB was greater amongst those with a goal of drug use abstinence, where flexibility and choice around dose and dosing frequency is offered, and depending on who administers the injection, with the option of self-administration viewed positively (if the option was to become available, noting currently patients are not able to handle LAIB directly).[50]

2.8.6 *Concerns about long-acting buprenorphine*

Reported drawbacks for consumers receiving LAIB in NSW and VIC include loss of social connection; erosion of the daily routine and structure (which had also acted as support to control substance use); less control over medication dosing; and the inability to sell takeaway buprenorphine doses for income.[58,59] The stated benefits of LAIB are echoed in consumer samples based in London, with people noting important concerns with LAIB treatment such as being unable to control the medication dose or stop treatment easily once started, having something foreign inside of them, potential side effects, potential reduced social interactions, and reduced choice and control.[49,50] Consumers are concerned about the dose not 'holding them' for the dosing interval, and desire for choice of injection site. The importance of consumer choice in treatment formulation, including dosing frequency and dose of LAIB, and potential erosion of choice, is a recurring concern reported across the studies.

2.9. Essential elements of ODT service delivery models

In addressing the various aspects of TOR 1, the following overarching principles could be used to guide the future design and delivery of ODT medicines specifically:

- person-centred care (autonomy and shared-decision making)
- equitable and affordable access
- high-quality treatment (both ODT medicines and psychosocial support services)
- safety (clinically as well as psychologically and culturally)
- inclusivity and de-stigmatisation
- choice.

Overall, the Review found the essential elements of ODT service delivery are:

- a holistic approach inclusive of access to pharmacological treatment e.g., methadone, buprenorphine +/- naloxone as well as psychosocial support services
- access to different treatment options (including ODT medicines) through both the public and private sector (e.g., a stepped care approach with low/moderate needs treated in community settings and if necessary, ODT medicine initiation and complex/high needs referred to the specialist treatment sector)
- additional treatment considerations for population groups with specifics needs and priority e.g., for First Nations people and people from Culturally and Linguistically Diverse backgrounds, women (including pregnant/breastfeeding), people living in rural/remote communities and people with co-existing issues (e.g., comorbid mental health conditions, homelessness)
- a standardised patient contribution and pharmacy remuneration model that is nationally consistent, and equitable for patients
- treatment supported by up-to-date evidence, practice, guidelines, and regulation
- a broad geographic distribution of dosing sites through community pharmacy and non-pharmacy sites including implementation of innovative approaches for rural and remote areas
- care coordination and management of continuity of access to ODT medicines for consumers initiating treatment and transferring from custodial to community settings, travelling interstate and between different care settings
- support for the prescriber workforce to increase participation and retention
- flexibility and access to takeaway doses
- education and training on available treatment options for consumers, prescribers, pharmacists, and service providers to reduce stigma and discrimination
- access to take home naloxone
- a partnership model between the Australian Government and state and territory governments
- a framework for data collection, monitoring, reporting and system improvement.

Part 3: TOR 2: Consumer experience of ODT

TOR 2: Examine the consumer experience, focussing on equity of access, geographical barriers to access, cultural safety, and affordability of ODT medicines across the different models of service delivery. This will include consideration of access to ODT for at risk population groups including people living in rural and remote areas, Aboriginal and Torres Strait Islander peoples and other populations who may have limited access to health care services, including ODT.

This chapter first presents key findings from specific consumer consultation undertaken to inform this review and then literature on the barriers and facilitators of ODT from the point of view of consumers, prescribers, and pharmacists. The perspectives of consumers on facilitators and barriers to accessing ODT is important in considering the design of future models of service delivery (discussed later in TOR).

3.1 TOR 2 Key findings

Though both domestic and international studies, as well as stakeholder input to the review, a range of factors were identified as facilitators and barriers to initiation and ongoing access to treatment for people with opioid dependence. Facilitators include shared decision making in treatment, flexibility of supervised dosing schedules and access to takeaways; and staff that act with discretion and treat consumers equitably. Barriers include stigma and discrimination (against both participants and the program itself), community and clinician belief that the program doesn't treat addiction, cost of private, unregulated fees associated with accessing ODT medicines and accompanying costs such as transport, time, rigidity of dosing hours and location, particularly when consumers need to travel interstate.

Prescribers, pharmacists, and other health care workers have identified a range of common facilitators to engage health care workers in providing ODT medicines. These include financial incentives, interdisciplinary support and collaboration, and additional dispensing pharmacies to share the ODT medicine dispensing workload. Common barriers to providing ODT reported by health care workers include lack of financial remuneration for the workload associated with supply of ODT medicines, and among prescribers and pharmacists a lack of education, knowledge, and training around drug dependence and ODT, as well as belief that ODT is not a valid treatment. These barriers contribute to ongoing stigma and discrimination experienced by consumers who access ODT.

Although experienced by many ODT consumers, people in rural areas in particular commonly reported that their access or retention to ODT was impeded by time consuming, costly, and restrictive daily medication collection; and the lack of privacy at dosing sites, leading to a fear of identification, stigma and discrimination. Accordingly, in addition to affordability, the most reported facilitators to treatment by ODT consumers in rural settings were access to takeaway doses to alleviate issues with travel and time constraints, and the establishment of separate dosing areas in pharmacies to offer privacy to ODT consumers.

In Australia, the affordability for consumers due to the high cost of private, unregulated fees associated with dispensing of ODT medicines was consistently identified as a barrier for both consumer access to treatment and for the provision of ODT through prescribers and pharmacists and was also the most common theme arising from stakeholder submissions to

the Review. Addressing the matter of private fees associated with accessing ODT medicines should therefore be a priority in reformed ODT programs.

3.1.1 Stakeholder views for TOR 2

The review considered the views of stakeholders across the breadth of opioid dependence treatment stakeholders including service delivery providers such as prescribers and pharmacists. In addition, targeted consumer views were sought directly from specific consumer populations with specific needs through externally facilitated focus groups. Stakeholder views were broadly consistent with the matters outlined in literature review. Submissions to the review and other consultation reports are publicly available through the ODTP PMR website (www.pbs.gov.au/info/browse/reviews). The full report summarising the outcomes of the targeted consumer consultation is available at Appendix 3.

3.2 Overview of stakeholder views for TOR 2

Stakeholders felt access and consumer out-of-pocket costs when accessing their medicines from dosing sites are critical issues. Stakeholders consider ODT medicines provide treatment for the chronic condition of opioid dependence and should therefore be provided at the same or similar costs to the consumer as other PBS medicines for other chronic conditions. Stakeholders suggest ODT consumers accessing medicines on the PBS should have equitable access to the PBS Safety Net, as they would for any other chronic condition.

Stakeholders also were of the opinion the jurisdictional requirements for supervised dosing should be reviewed, particularly for buprenorphine products.

Stakeholders stated the cost and complexity of the program for pharmacists is a significant barrier. They felt that participation in ODT is not financially viable for many pharmacists, and the Australian Government covering the cost of the medicine alone through the PBS does not improve consumer access or quality use of medicines.

In addition, stakeholders commented the lack of an adequate funding model for prescribers (particularly GPs) was a significant barrier to prescriber participation in the program.

Relating to access to culturally safe ODT for First Nations people, stakeholders noted that despite examples of successful integration of ODT medicine services into ACCHOs, it appears there are few ACCHOs that provide ODT services in Australia. Stakeholders commented that ACCHOs are not usually resourced or funded for ODT, possibly due to competing priorities however were of a view that it is important to ensure access to culturally secure treatment from both ACCHOs and mainstream ODT dosing sites. Stakeholders also noted there are opportunities for the comprehensive role ACCHOs could play in providing holistic treatment for opioid dependence beyond ODT medicines alone.

3.3 Literature Review – Barriers and facilitators from a range of perspectives

Table 9 is drawn from the 69 eligible studies identified in the systematic review of published qualitative literature.

Table 9. Barriers and facilitators to ODT medicine entry, delivery, and retention from a range of perspectives

Perspective	Facilitators to treatment	Barriers to treatment
People with opioid dependence	• Flexible dosing site hours and flexibility with payment of dispensing fees • Autonomy and shared decision making in treatment • Non-judgemental and equitable treatment from ODT medicine service staff • Staff that act with discretion • Receiving holistic support in one facility	• Stigma • Restrictive dosing hours • Lack of privacy • Time consuming nature of supervised dosing; rigidity of treatment programs, particularly with takeaways • Feelings of continuing to be a "drug user" while on an ODT medicine program • Consistent staff turnover that prevents formation of a therapeutic alliance between prescriber / dispenser
Prescribers	• Interdisciplinary support and collaboration • Recognition of ODT medicines as a necessary treatment • Education • Financial incentives	• Stigma and related doubts about the validity of ODT medicines • Time consumed as part of prescribing ODT medicines • Lack of knowledge regarding ODT medicines • Behaviour of ODT medicine consumers • Poor financial remuneration
Dispensing pharmacists	• Financial incentives • Positive attitudes towards ODT medicine consumers • Increasing the number of dispensing sites to evenly distribute the workload • Feeling a sense of professional or community satisfaction from providing ODT medicines	• Lack of financial or general support • The expectation that aggressive consumer behaviour would lead to theft, violence, or deterrence of other customers • Increased workload • Unpaid dispensing bills creating duty of care dilemmas and straining the consumer-dispenser relationship • A lack of education
Other healthcare workers	• Supervised dosing as a means of providing stability and enhancing the formation of a therapeutic relationship • Flexible attendance policies • Non-punitive stance toward drug use	• Lack of pharmacy providers • Demanding workloads preventing relationship forming with consumers • Complex medical needs of ODT consumers • Stigma associated with working in addiction medicine

3.3.1 Perspectives on facilitators and barriers from people with opioid dependence

Facilitators and barriers to accessing and being retained on treatment were identified in 47 studies from the perspective of people with opioid use disorder (Table 9). One study was from Wales, two studies were from Scotland, 13 from England, 19 from Canada and 12 from Australia.

Facilitators to accessing or being retained in treatment can be grouped into three categories – flexibility in dispensing - dispensing sites working hours and dispensers who are flexible with dispensing fees; autonomy in treatment – treatment programs that are reflective of the

consumer and the ability to engage in shared decision making, and discretion - both from the physical setting of the pharmacy allowing ODT medicine consumers to be indistinguishable from other pharmacy consumers and on behalf of the dispensing pharmacists.

Barriers to accessing treatment can be grouped in seven categories – stigma on behalf of prescribers and dispensers toward ODT medicine consumers; logistical barriers such as inconveniently located prescribers, inconvenience of travelling to a pharmacy to be dosed and the time involved for supervision; restrictive and inflexible dosing schedules often resulting in doses being missed and also incompatibility with traditional working hours; a lack of knowledge about ODT medicines on behalf of the consumer, prescriber, and dispenser; high staff turnover or inconsistencies with staff (both prescribers and dispensers) preventing the formation of a therapeutic relationship; a lack of discretion and privacy when dispensers are providing or discussing a consumers dose at a dispensing site and dosing sites, and queues at marketplaces to buy and sell drugs as well as reencountering people that could provoke relapse or reengagement in criminal activity.

The barriers identified by ODT consumers receiving LAIB can be grouped into three categories – a lack of control including lack of control over the dosage, negative side effects and treatment as an implant or injection; a loss of social support and connection from monthly or weekly administration; and fear of premature "weaning off".

Barriers and facilitators to ODT medicines: The CoLAB community survey

The CoLAB community survey, a survey of 400 people regularly using opioids in NSW, VIC, and TAS, collected detailed information on the barriers and facilitators of ODT medicine services in 2018. Participants in the sample regularly used illicit opioids and just less than three-quarters of the sample (71%) was receiving ODT medicines at the time of the survey. The majority (90%) had lifetime experience with one or more form of ODT medicine (90%).

All participants were asked about a range of potential barriers or facilitators regarding treatment entry. Each participant responded with how likely or unlikely each factor would help or prevent them from entering treatment with ODT medicines. Figure 2 displays the responses for each factor.

The financial costs of treatment were a clear barrier to treatment for participants, and free treatment was also noted as a facilitator. Respectful staff that understand the situation of the consumer was also noted as a treatment facilitator, as well as the ability to re-enter treatment easily if they dropped out. Improvement of personal life factors, including physical & mental well-being, as well as relationships were also facilitators to entering treatment. Relationships were also noted as a potential barrier, if a treatment required disclosure to friends and family. Accessibility of treatment factors, such as a higher number of locations, lower travel costs, and immediate start were also noted as potential facilitators.

Participants in the CoLAB study with a history of receiving ODT medicines shared their main goal prior to receiving ODT medicines. The main goal of most participants was to stop or reduce opioid use (69%). Specifically, the most common treatment goal was to stop using all opioids, including ODT medicines (31%), followed by stopping use of only illicit opioids (20%),

and reducing or controlling opioid use (18%). Less commonly reported treatment goals included regaining control over one's life (10%), improving physical health (6%), reducing opioid cravings (3%), improving relationships (3%), and improving mental health and wellbeing (2%). Figure 3 displays the common treatment goals among the sample.

Figure 2. Perceived facilitators and barriers for entering treatment with ODT medicines

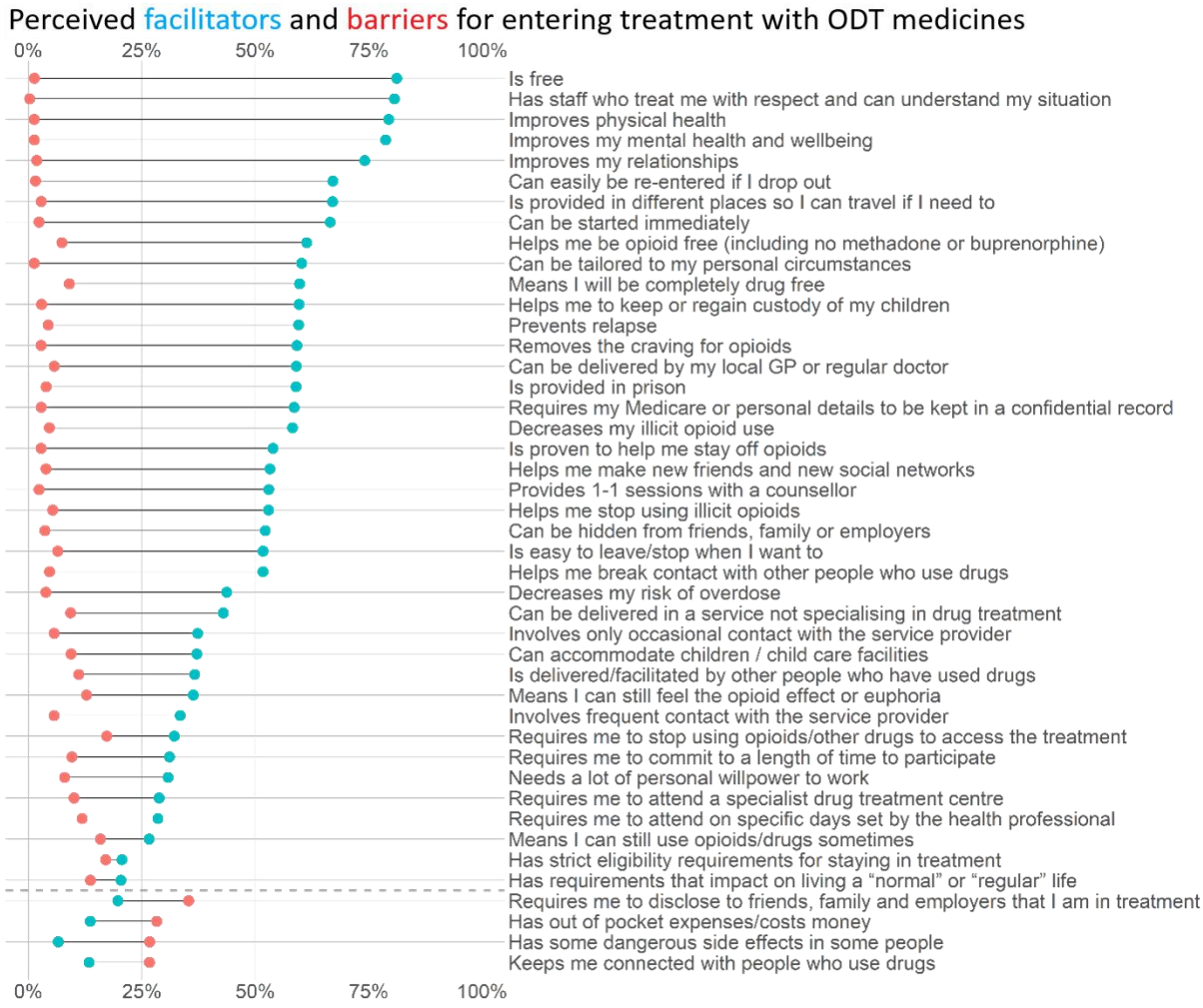
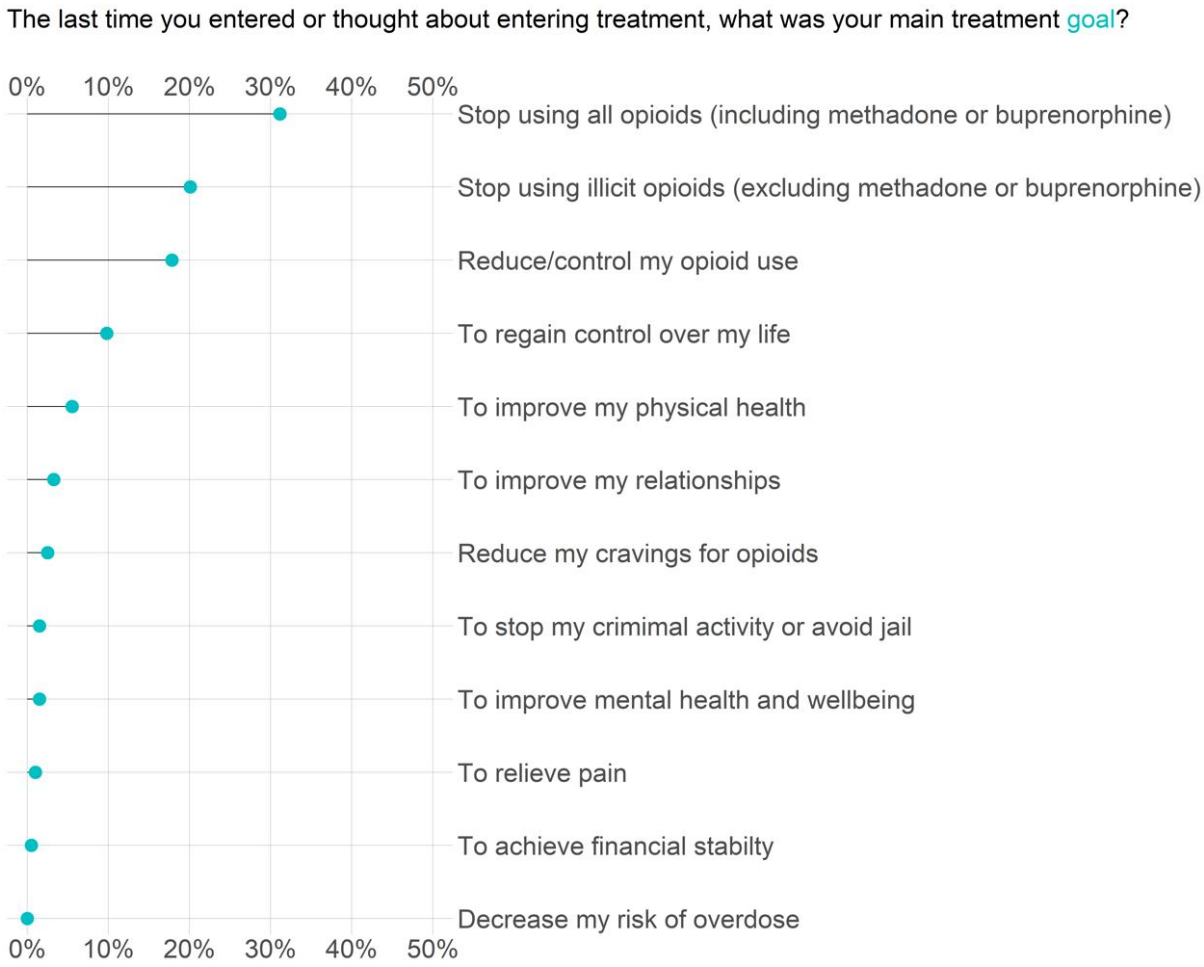


Figure 3. Main treatment goal in ODT medicines reported by participants of the CoLAB study (n=400)

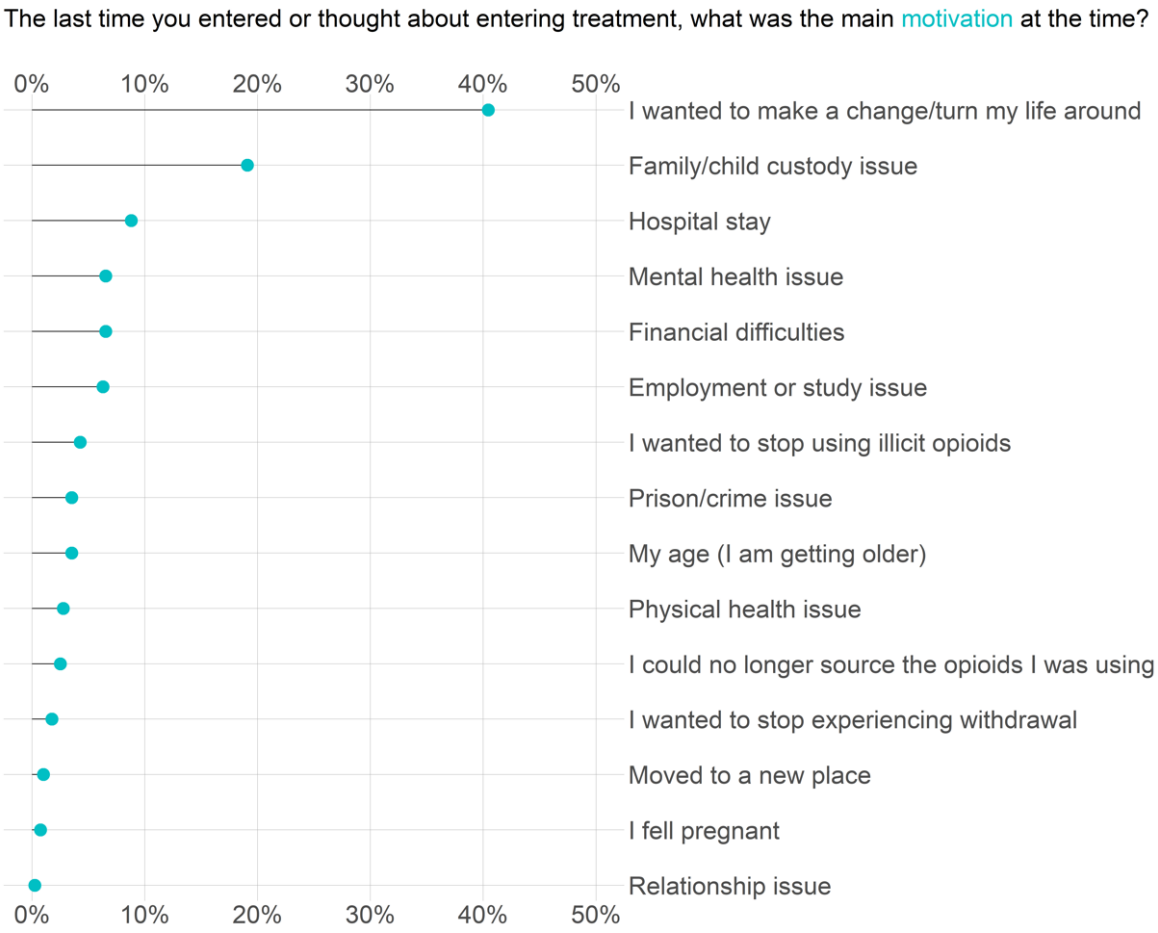


Participants also shared their main motivation prior to receiving ODT medicines (Figure 4). The most common motivation for participants was to change their life or 'turn their life around' (41%). Family or custody issues were also a main motivation for one in five participants (19%). Other main motivations for entering treatment included a hospital stay (9%) and issues with mental health (7%), money (7%), and employment or study (6%).

Consumer perspectives on the potential facilitators of LAIB are summarised as follows: allows less frequent attendance to treatment services (76%), allows more time to do other things (69%), allows travel for work or holidays (66%), prevents cravings for opioids (64%), greater control of treatment (63%), suppresses withdrawal symptoms (62%), avoid regular contact with other people in drug treatment (59%), blocks the effects of other opioids (54%), reduces the need for willpower to stay in treatment and/or avoid using other opioids (54%), decreases risk of overdose (safety) (52%).

Consumer perspectives on the potential barriers of LAIB are summarised as follows: might not hold people for the whole period between doses (40%), blocks the effects of other opioids (26%), less treatment flexibility (17%), feel less in control of treatment (16%), dislike of having the drug/long-acting release profile (16%).

Figure 4. Main motivation for entering treatment with ODT medicines reported by participants of the CoLAB study (n=400)



3.3.2 First Nations people

While the participants of many studies included First Nation Australians, the literature review did not discover any qualitative studies that focused exclusively on describing the barriers and facilitators to ODT medicines from this perspective. Considering that First Nations people are overrepresented in the ODT medicines population (see Table 2), and that this population may face a distinct set of barriers and facilitators accessing and being retained on ODT medicines, there is a need for research in this area.

3.3.3 Prescribers of ODT medicines

The facilitators and barriers experienced by prescribers of ODT medicines were identified in 16 studies. Four studies were from Australia, one from Scotland, two from England and nine from Canada.

The six categories for facilitators for prescribers of ODT medicines are interdisciplinary support and collaboration, including continuity of care; view of ODT medication as a necessary treatment and a duty to provide harm reduction; access to information about prescribing protocols, opioid dependence, and ODT medicines; financial incentives; access to ongoing educational opportunities; and ODT medication as a point of entry into addressing other areas of consumer's health.

The barriers identified for prescribers of ODT medicines can be grouped in to six categories – negative previous experiences with ODT consumers; poor financial remuneration; not viewing ODT medication as a valid treatment; perception that the health needs of ODT consumers are too complex to address; previous behaviour of ODT consumers and the potential for the risk of violence; a lack of education and training surrounding drug use and treatment and lack of fellow prescribers with whom to ask advice and support.

3.3.4 Pharmacists dispensing ODT medicines

There were seven papers identified in the qualitative review describing the facilitators and barriers experienced by ODT dispensing pharmacists. Four papers were from Australia, two of which were from the perspective of rural pharmacists, one from Scotland, one from Canada and one from England.

Facilitators for dispensing ODT medicines can be grouped into four categories – financial incentives to increase the uptake of ODT medication dispensing sites; distribution of the workload by more pharmacies, and other sites such as hospitals, dispensing ODT medicines; constant contact with consumers receiving ODT medicines allowing pharmacists to be better able to monitor their progress; and viewing ODT medication as a service to the community by providing harm reduction methods.

Barriers can be grouped into five categories – inadequate financial remuneration or ability to recoup dispensing fees and associated costs with dispensing; stigma toward ODT consumers and concerns about ODT provision deterring non-ODT consumers; lack of knowledge and training on ODT medication programs; managing the difficult behaviour of consumers; and time commitment and workload associated with dispensing ODT medicines that can detract from other pharmacy work.

3.3.5 *ODT medicines in rural settings*

The TOR specifically highlighted geographical barriers to access which have been specifically considered below.

Table 10. Barriers and facilitators to ODT medicines for rural and remote communities

Perspective	Facilitators to treatment	Barriers to treatment
People with opioid use disorder	• The establishment of private dosing areas to reduce the chances of identification and stigma from members of the community • Takeaway dosing to enable travel and reduce the amount of time and money spent collecting medicine	• A lack of privacy in the dosing process, leading to fears of being identified and stigmatised as an ODT consumer by those in the community • Daily dosing as a requirement that restricts the freedom to travel to other areas for employment or holiday • The time or financial cost associated with travelling to treatment
Dispensing pharmacists	• Additional dosing sites to share the ODT medicine dispensing workload in rural areas more evenly • The perception that as the only pharmacist in the area, dispensers have no choice but to provide ODT medicines • A sense of contributing to the community through harm reduction	• Difficulty finding staff trained in ODT to assist with the increased workload that is borne by pharmacists providing the treatment • A lack of allied health service availability due to remoteness and a subsequent lack of holistic support for ODT consumers • Additional freight fees for the delivery of medication to some rural areas

People who are opioid dependent

The literature review identified four studies that reported barriers and facilitators for access to ODT medicines for people who are opioid dependent in rural areas (Table 10). Three studies were from Australia, and one was from England.

The most reported facilitators to treatment were the establishment of separate dosing areas in pharmacies to provide privacy, and takeaway dosing to remove the costly, time consuming and restrictive issues associated with daily medication collection.

Barriers to accessing ODT medicines for consumers in rural settings included a lack of privacy in the dosing process which resulted in fears of being identified as someone who engages in ODT. People with opioid dependence in rural areas considered the money and time spent travelling to treatment for the purposes of supervised dosing, in addition to the cost of treatment, as a barrier. Additionally, daily dosing regimens were reported as a barrier to treatment due to the restrictions they placed on consumers that wished to travel for work or holiday.

Dispensing pharmacists

The literature review identified four studies that reported barriers and facilitators to providing ODT medicines for dispensing pharmacists in rural areas. Three studies were from Australia, and one was from Canada.

A common barrier reported by rural pharmacists was the difficulty of finding staff trained in ODT medicine provision to assist with the increased workload that is borne by pharmacists

providing the treatment. According to rural pharmacists, the remoteness of their communities also resulted in a lack of allied health and service availability, such that ODT medicine consumers were unable to access holistic support. Rural pharmacists also reported that the additional freight fees associated with the delivery of medication to some rural areas were a barrier to providing treatment.

Several studies reported that a facilitator to ODT medicine service provision for rural pharmacists was an increase in the amount of dosing sites, which allowed the workload of dispensing ODT medicines to be spread more evenly across the area. Some rural pharmacists reported that they provided ODT medicines because they believed that as the only pharmacist in the area, they had no choice. On the other hand, other rural pharmacists said a facilitator to ODT medicine provision was the feeling that they had contributed to harm reduction in the community.

Part 4: TOR 3: Medicine Utilisation

TOR 3: Explore the utilisation of PBS subsidised ODT medicines in Australia, including funding, benefits (health system and societal) and costs incurred in the supply and dispensing of ODTP medicines in pharmacy and non-pharmacy settings. This will include examination of current PBS restriction criteria and the impact of the listing of modified release buprenorphine injections on the PBS ODTP.

This chapter presents literature review findings on the benefits of each ODT medicine and their cost to patients, prescribers, pharmacies, and governments. This will be followed by an analysis of Commonwealth expenditure data, discussing trends in government expenditure on ODT medicines and number of doses supplied over the past 5 years, as well as looking at differences in medicine supply between jurisdictions and different sites where medicines are delivered.

4.1 TOR 3 Key findings

There is strong evidence for a wide range of health and social benefits for people with opioid dependence associated with ODT medicines. Being in a methadone/buprenorphine program reduces injecting risk behaviour, the risk of HIV/Hepatitis C virus acquisition, criminal activity and overdose deaths and increases quality of life including mental and physical health. In terms of societal costs, ODT is also highly cost-effective, and actually cost-saving when costs of crime are included.[61] Addressing cost barriers to treatment entry and retention (through the PBS and with states and territories) has the potential to improve a wide range of health and other outcomes for people with opioid dependence.

By and large, there are few clear differences between methadone and sublingual buprenorphine +/- naloxone in terms of impacts on a wide range of primary and secondary outcomes (e.g., drug use, mental health); one clear exception identified through the literature review is that people are retained better on methadone than on sublingual buprenorphine +/- naloxone.

LAIB presents potential cost savings in terms of monthly dosing staff costs compared to other more frequent dosing treatments and consumer travel costs. Preliminary data indicates high retention rates associated with LAIB treatment, but this requires further study given the very small evidence base to date. A recent yet to be published study of LAIB found the adjusted mean days in treatment was longer for the LAIB group compared to the combined methadone and sublingual buprenorphine group as was the time to first stopping treatment.[62,63] Further, not all consumers feel that LAIB is a suitable treatment choice for them personally.

Approximately half of all consumers on oral and sublingual ODT medicines receive any takeaway doses as estimated in the quantitative systematic review undertaken as part of the ODTP PMR, with slightly more consumers on sublingual buprenorphine +/- naloxone receiving takeaways compared to methadone.

There are limited clinical and research data, and no population-based data on individual-level ODT medicine doses and dosing patterns in Australia, a limitation of the current funding model particularly for methadone where one bottle can be shared among multiple patients.

Such data, including daily dose variability and frequency of dispensing where possible, are very important to consider real-world patterns of ODT medicine use.

Commonwealth expenditure on the PBS ODTP has been steadily increasing over the years. In 5 years, expenditure has doubled from the 2016-17 financial year ($51.5 million) to 2021-22 ($108.6 million) and has grown by 20% from the 2020-21 financial year alone ($90.3 million).

PBS ODTP expenditure growth was mostly steady before the introduction of LAIB in September 2019. In 2021-22 approximately half of all expenditure on the PBS ODTP was for LAIB products. The listing of this new medicine was followed by a sharp increase in overall expenditure growth, as well as a decrease in growth across other ODT medicines. Further analysis of PBS ODTP expenditure data indicates that the acceleration of program expenditure growth is likely due to a growth in patient numbers due to LAIB facilitating the removal of both logistical and cost-based barriers to ODT medicines, as well as potentially due to improved retention rates. It is important to note the uptake of LAIB is also likely as a result of implementation of new state and territory ODT policies and guidelines, particularly in correctional facilities.

Costs borne by consumers, especially pharmacy-charged private dosing fees to consumers, create burdensome expenditures for consumers, especially those on fixed or limited incomes, thereby creating barriers to treatment entry and retention with flow-on impacts to social, mental and physical health more broadly. Dosing fees vary widely across states and territories because pharmacies set their own fees based on their own cost assessments. Costs to patients through private, unregulated fees typically range from $5-8 per day[64] (and can be higher). Input to the Review suggests remuneration for pharmacies (through alternative funding sources rather than being borne by patients) may help maintain or improve their involvement in ODT, and/or for dosing fees charged to consumers to be standardised, reduced, or eliminated.

Through analysis of Commonwealth expenditure data, approximately 80% of oral and sublingual PBS ODTP medicines are supplied through community pharmacies. In contrast, LAIB is supplied across a wider range of dosing points, with 29% going through community pharmacies. Notably, 18% of LAIB is supplied through correctional facilities, while only 3% of oral and sublingual PBS ODTP doses are supplied directly to these sites.

4.2 Overview of stakeholder views for TOR 3

Stakeholders strongly believed that ODT medicines provide significant societal benefits including reduction of drug-related hospitalisation and mortality, reduced crime, and overall improvement in the quality of life for patients.

Stakeholders commented that, although the Commonwealth Government funds the full cost of ODT medicines, this funding is insufficient as it does not cover additional costs associated with the supply and administration of ODT medicines or other elements of ODT. These additional costs are then usually passed on to the customer. Stakeholders suggested that a funding model for ODT consider remuneration for pharmacists and other medical staff who administer ODT medicines.

Additionally, stakeholders suggested patient costs to receive ODT medicines be made consistent with those for other PBS listed medicines, where patients pay the standard PBS co-payment which also counts towards the patient's PBS Safety Net threshold. However, stakeholders also acknowledged that a standard S85 PBS listing has limitations and may not be suitable for the delivery of all ODT medicines, as medicines listed under S85 are largely dispensed from community pharmacies only.

Stakeholders believed that the introduction of LAIB has had many advantages. LAIB improves access to ODT medicines due to the lack of a requirement for daily dosing and has allowed for improved provision of ODT medicines outside of the community pharmacy setting, such as in correctional facilities. Additionally, stakeholders reported high treatment satisfaction for LAIB patients. However, stakeholders emphasised that there is no one medication or delivery system that will suit all patients at all times and felt that patient choice should be a core feature of ODT medication service delivery.

4.3 Literature review – Evidence of impacts of opioid agonist treatment

The literature review found that, compared to those not in treatment, people receiving ODT medicines had lower rates of adverse outcomes (e.g., criminal activity, all-cause mortality), and higher rates of positive outcomes (e.g., HIV viral suppression, quality of life) across the board. ODT medicines reduce injecting risk behaviour[65] and risk of HIV and HCV acquisition,[6667] increases engagement in the HIV and HCV cascade of care,[68] reduces criminal activity[16,69] and reduces all-cause and overdose mortality.[70] There is weaker evidence that it may reduce suicide and accidental injuries. In terms of societal costs, ODT medicines are also highly cost-effective, and actually cost-saving when costs of crime are included.[71]

The protective effect on mortality is marked in people who are opioid dependent who experience incarceration, especially during the highest risk periods; that being in the first month of incarceration, time in prison and in the first 4 weeks post-incarceration. Modelling shows that scaling-up ODT medication service delivery in prisons and the community could avert between 23.9% and 75.0% more deaths over 20 years than only scaling-up in the community. This suggests that interruptions in ODT medication access during incarceration may limit its population benefits and overall impact.

4.3.1 Comparisons between buprenorphine and methadone

Previous reviews suggest retention is higher for people on higher doses of methadone (>80mg daily) than lower methadone doses (<60mg daily).[72] Retention is also higher among people on methadone compared with buprenorphine. It is worth noting retention on buprenorphine compared with methadone has significantly improved over time since its introduction in 2001 in NSW.[73]

Evidence on the impact of ODT medication type on extra-medical opioid use and other illicit drug use is mixed, with randomised controlled trials and observational studies reporting varying effects depending on how these measures have been collected and assessed.

Comparisons of physiological and functional measures most often favoured buprenorphine over methadone. In observational studies, validated measures of craving, severity/intensity, mean treatment satisfaction, depressive symptoms, as well as cardiac functioning, sexual

dysfunction and all-cause adverse events are improved on buprenorphine compared to methadone. Methadone is favoured only for the outcome of global functioning in observational studies and for validated measures of craving in randomised controlled trials (RCTs).

In the first 4 weeks of treatment, rates of all-cause mortality and drug-related poisoning among people on methadone were almost double the rates during the remainder of ODT with medicines but not for buprenorphine.[70] Two studies have found lower risk of mortality during induction onto sublingual buprenorphine versus methadone.[74,75] Among opioid dependent women who are pregnant, neonatal outcomes may be superior for women maintained on buprenorphine.[76]

Higher doses of methadone and buprenorphine increase retention in treatment.[42] There is low quality evidence that supervised dosing (i.e., doses provided as directly observed doses by a pharmacist or other clinical worker) does not impact on retention.[77] There is insufficient evidence to assess the effectiveness of urine drug screening during ODT with medicines upon retention.[77,78] Guidelines developed by the WHO for quality provision of ODT with medicines is based on evidence more than a decade old; these guidelines would likely benefit from updating to reflect developments in the evidence base since its publication.

There is no evidence to suggest dosages taken as prescribed, dosing visits missed (in randomised controlled trials), or treatment adherence (in observational studies) varied by medication type.

4.3.2 Comparisons of sublingual versus LAIB formulations

There are few data on effectiveness and no independent studies of effectiveness or cost-effectiveness of LAIB formulations in the Australian setting. Two US RCTs of the two LAIB therapies have been published. One RCT was a placebo-controlled study of the Sublocade® product.[51] No study has compared Sublocade® to sublingual buprenorphine. The other RCT compared LAIB (Buvidal® product) to daily sublingual buprenorphine.[52] LAIB was superior to placebo; and non-inferior to sublingual buprenorphine, in reducing illicit opioid use. LAIB retention at 24 weeks was 67%[51] for Sublocade® and 73%[52] for Buvidal®.

A small (n=119) company-sponsored RCT comparing one product (Buvidal®) to sublingual buprenorphine in public ODT clinics has been completed.[56] This study was underpowered to demonstrate equivalence; the paper focused on consumer satisfaction and found that those who received LAIB reported higher satisfaction with treatment than those who received sublingual buprenorphine.[56]

4.3.3 Costs to consumers

Out-of-pocket costs for ODT constitute a barrier to treatment entry and retention. The percentage of consumers in ODT medicines who are receiving some form of social security payments may be as high as 90%.[79] In a cross-sectional survey of 402 people with opioid use disorder in NSW, Victoria, and Tasmania, 87% of consumers receiving ODT medicines paid out-of-pocket costs, with travel costs to attend for dosing (52%) and dispensing fees (44%) comprising the majority of these costs.[3] The mean monthly total out-of-pocket costs (in 2018

Australian dollars) were $135 for public clinics, $161 to $214 for community pharmacies and $355 for private clinics.

Travel costs (including dispensing travel costs and ODT medicine-related appointment travel costs) accounted for more than half the costs (52%), followed by dispensing fees (44%) and ODT medicine-related appointment costs (4%). Compared to participants in NSW private clinics, those at public clinics paid one third the total out-of-pocket costs and those attending NSW, Tasmanian, and Victorian pharmacies paid approximately half the costs.

Further, total out-of-pocket costs disproportionately affects those who are newer in treatment and receiving fewer unsupervised doses. People receiving ODT medicines for more than a year paid half the total out-of-pocket costs, compared with those receiving ODT medicines less than a year. Higher total out-of-pocket cost were associated with consumers who were men, no history of incarceration, travel distance of more than 5km to the dosing location, and treatment with buprenorphine compared with methadone treatment.

Consumers reported that they spent one-eighth of their income on out-of-pocket costs associated, with the financial burden higher for those attending private clinics compared with public clinics or pharmacies, which often involves unsupervised dosing. Some people face a higher burden of treatment: 23% of participants paid fees comprising 10% to <20% of their monthly income, and 7% of participants paid fees comprising 20% or more of their monthly income.[4] Among those that had ever been received ODT medicines, 72% experienced difficulties in paying treatment costs; 36% left treatment earlier than intended and 25% had been excluded due to payment difficulties.

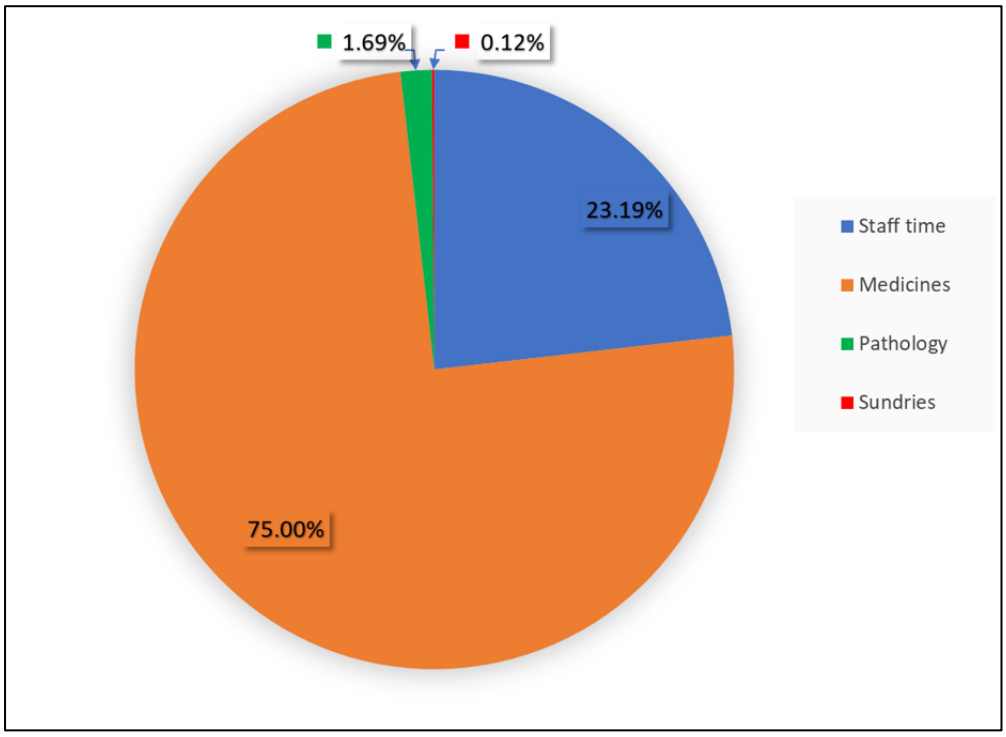
This often had a detrimental impact on people's social, physical, and mental well-being and resulted in a range of strategies to gain income to support treatment continuation. The most common strategies reported were to borrow money from family and/or friends (36%), reduce food intake (17%), theft/fraud/dealing (12%), failure to pay household bills (phone, electricity, gas, etc) (10%), reduction of drug/alcohol use (9%) and incurring at least one form of debt (38%). Consequently, cost savings as a result of avoiding pharmacy fees from previous daily dosing regimens requirements is a key motivator for transitioning to and staying on the reduced dosing schedule required for LAIB.[58]

4.3.4 Costs to governments

Costs of ODT medicines in community-based treatment settings

Bottom-up costing using the ingredients approach (meaning the costing of the different clinical components in the local sites were collected) conducted as part of the CoLAB cohort showed that the majority (75%) of the total annual treatment cost for consumers receiving LAIB was drug costs paid by the Australian Government, with less than a quarter attributed to state-funded staff time involved in treatment administration (Figure 5).

Figure 5. Resource use as a percentage of total annual costs for delivery of 12 months of LAIB treatment



Source: CoLAB study, unpublished

Costs of ODT medication provision in custodial settings

The cost of ODT medication provision in NSW correctional facilities,[80] estimated by a bottom-up approach as part of an open-label, non-randomised study (*the 'UNLOC-T' study, ACTRN12618000942257*) revealed potential savings in the cost of medication administration for LAIB compared with the sublingual formulation and with oral methadone. The monthly costs of treatment administration (in 2019 Australian dollars), funded by the NSW government (both Corrective Services NSW and the Justice Health and Forensic Mental Health Network), and the costs of the actual medication, paid for by the Commonwealth government are summarised in Table 11. As in the community, the costs of the actual medication comprised the bulk of the total cost for LAIB.

Table 11. Costs of ODT medicines in NSW correctional facilities[80]

Medicine	Monthly cost of treatment administration	Monthly cost of medication
LAIB	$151	$434
Sublingual buprenorphine	$1,529	$525
Oral methadone	$379	$80

Costs are in 2019 Australian dollars

A simulated scenario of long-acting scale-up in which 5% of consumers on ODT medicines were transferred to LAIB each month revealed potential for cost savings related to treatment administration. If consumers transferring from oral methadone received two weekly LAIB

doses before dosing frequency was reduced to monthly, whereas those transferring from sublingual buprenorphine to LAIB were initiated immediately on monthly dosing, the monthly per consumer cost for LAIB treatment administration was $178 after month one. This fell to $92 after 12 months, whereas the per consumer monthly administration cost of sublingual buprenorphine increased to $2,162 and methadone costs increased to $530.

4.3.5 Costs to prescribers

A cost-effectiveness analysis of an RCT comparing methadone and buprenorphine[81] found the average per consumer annual cost of treatment with methadone estimated in 1998 Australian dollars was $2,830. This consisted of: staff costs ($492), diagnostic procedures ($368), medications ($74), and other facility level costs ($1,894).[81] The study estimated the annual consumer costs of treatment with sublingual buprenorphine at $3,458, constituting: staff time ($698), diagnostic procedures ($202), medications ($918), and other facility level costs ($1,534).

In 2015, the average annual per consumer costs of treatment with supervised buprenorphine + naloxone were estimated at $8,552 (95% confidence interval $6,852 –$10,248) (costing year 2015). This constitutes 13.1% staff costs, 23.2% medicines, 17.5% dosing and dispensing, 9.4% diagnostics and 41.1% other health facility costs.[82]

The CoLAB study showed that for healthcare services providing supervised daily dosing of ODT medicines, there is the opportunity for substantial staff cost savings with LAIB compared to oral and sublingual opioid dependence treatments (CoLAB study, unpublished data). The annual average cost of providing 12 months of treatment with LAIB, estimated through bottom-up costing from a healthcare provider perspective using prospective resource data collection by CoLAB study sites, was $6,425 ($5,811–$7,793). The bulk of the cost was administering the medication (medications and staff time involved) ($5,071 per year), and the Australian Government funded medicine costs constituted 95% of this cost with the remaining 5% making up the state cost for staff time and sundries. The average annual costs for other activities were clinical assessment ($405), clinic administration ($241), medicines storage and handling ($246), screening (initial assessment and medical history) ($282), case management and psychosocial services ($99), and adverse events management ($67). The type of staff who provided services for the different activities varied by study site, which included five specialist clinics and one primary care clinic (Table 12). The main cost driver of care was the actual delivery of treatment (administering the medication), accounting for 79% of the annual average participant cost, followed by clinical assessment (6%). Administration, drug storage and handling and screening each accounted for approximately 4% of the average cost while case management and adverse events management accounted for approximately 1% of costs.

Although the study found that staff and other costs were a much smaller quantum of the total cost of providing treatment with LAIB compared to the cost of medicines, overheads and other indirect health costs were excluded, as were costs borne by the consumers.

Table 12. Staff type and time use for the delivery of the different activities in treatment using LAIB

	SOUTH AUSTRALIA	NEW SOUTH WALES			VICTORIA		
Activity	**Specialist Drug & Alcohol Clinic #1**	**Specialist Drug & Alcohol Clinic #1**	**Specialist Drug & Alcohol Clinic #2**	**Specialist Drug & Alcohol Clinic #3**	**General practice**	**Specialist Drug & Alcohol Clinic #1**	**Average time per person per visit in minutes (range)**
Screening (Initial assessment and medical history)	Medical Officer, Nurse	Medical Officer, Nurse	Medical Officer, Nurse	Medical Officer	GP	Medical Officer, Nurse Practitioner	165 (60 – 180)
Administering the medication	Nurse, Medical Officer	Nurse	Nurse	Nurse, Medical officer	Nurse, GP	Nurse practitioner	16 (10 – 30)
Clinical Assessment	Nurse	Nurse	Nurse	Medical Officer	GP	Nurse	25 (15 – 45)
Case management and psychosocial services	Nurse, Social worker	Nurse	Medical Officer	Nurse, Psychologist	GP	Nurse	44 (15 – 75)
Clinic Administration	Administrator	Nurse	Nurse	Administrator	Nurse	Administrator	23 (12 – 40)
Adverse events management	Nurse	Nurse	Nurse	Nurse	Nurse	Nurse	9 (5 – 15)
Medicines storage and logistics	Pharmacist	Pharmacist	Nurse with pharmacist	Nurse with Pharmacist	Pharmacist	Nurse	65 (15 – 120)

Note: Data from two sites in New South Wales that were under the same management (an outreach community clinic and a specialist drug and alcohol treatment clinic) were combined.

4.3.6 Costs to pharmacies

A key motivator to pharmacies in providing ODT medicines reported in the literature is financial reward, with provision contingent on perceived favourable risk-benefit profile of including ODT medicine provision in the business model.[83] Reported risks include financial and interpersonal challenges involved in managing consumers unable to pay dispensing co-payments in the form of daily or weekly dosing fees. Dosing fees vary widely across states and territories because pharmacies set their own fees based on their own cost assessments. Costs charged to patients typically range from $5-$8 per day[64] (and can be higher). Therefore, the average cost consumers are required to pay pharmacies for 12 months of treatment is likely to be as high as $2,920. This compares differently from treatment of other chronic conditions where the per monthly script fee for someone with a healthcare card is $6.80 (capped at $326.40 annually in 2022). Hence, any changes to the funding structure of ODT medicines need to consider the direct impact on pharmacies.

4.3.7 Economic evaluation studies

From 2007 to date there are only five Australian studies on economic evaluations of ODT medicines. These studies, summarised below, investigated oral methadone and/or sublingual buprenorphine compared to no pharmacotherapy treatment, ODT medicines compared to no pharmacotherapy treatment, observed compared to unobserved sublingual buprenorphine, sublingual buprenorphine + naloxone compared to no pharmacological treatment and oral methadone compared to sublingual buprenorphine and buprenorphine + naloxone. There are currently no published studies comparing LAIB to other ODT medicines.

Methadone and/or sublingual buprenorphine compared to no pharmacotherapy treatment

Using data from the observational Australian Treatment Outcome Study, and from a societal perspective, Moore et al (2009)[84] evaluated the cost-effectiveness of oral methadone or sublingual buprenorphine compared to no pharmacotherapy (prison or residential rehabilitation) for consumers seeking treatment for heroin dependence in a community setting in Australia. Pharmacotherapy was more cost-effective at $2,002 per year compared to $52,000 for prison.

ODT medicines compared to no pharmacotherapy treatment

ODT medication dominated no pharmacotherapy in an observational cohort of recently released opioid dependent people from prison in Australia in an analysis of the cost-effectiveness of ODT medicines in reducing mortality risk post-release from incarceration. The study conducted from the perspective of the treatment provider and criminal justice system estimated ODT medicines to be cost-effective with 97% certainty at a willingness-to-pay threshold of $500 per life year saved (2012 Australian dollars).[85] Indeed, it was estimated to be cost saving.

Observed compared to unobserved dosing of sublingual buprenorphine

Using a health system perspective primarily and including consumer travel costs, Bell et al. 2007[82] assessed the cost-effectiveness of observed compared to unobserved dosing of buprenorphine among people who use heroin in a clinical trial. The results showed no significant differences between groups in terms of days of heroin use, quality of life and psychological state.

Sublingual buprenorphine + naloxone compared to no pharmacological treatment

An Australian RCT study estimated the cost-effectiveness of sublingual buprenorphine + naloxone compared to no clinical intervention among people with heroin dependence from both a healthcare perspective and a healthcare plus criminal justice perspective. Excluding crime, incremental cost per heroin-free-day gained from treatment was $18.24 (2009 Australian dollars) (95% confidence interval $4.50 - $28.49). Including crime costs, a net saving of $5,722 over 12 weeks (95% confidence interval $3,299 - $8,154) in favour of sublingual buprenorphine + naloxone treatment was observed.[86]

Methadone compared to sublingual buprenorphine and buprenorphine + naloxone

Previously, Doran et al. 2005[87] estimated the cost-effectiveness of methadone, low dose buprenorphine, high dose buprenorphine and buprenorphine + naloxone in the maintenance of heroin dependence using a provider perspective in public ODT clinics in Australia. Oral methadone dominated low-dose sublingual buprenorphine. However, the results for oral methadone compared to high dose sublingual buprenorphine and methadone compared to sublingual buprenorphine + naloxone were not statistically significantly different, with confidence intervals of -$2,068 - $2,916 around a point estimate of $906 (methadone compared to high dose buprenorphine) and -$1,520 - $2,367 around a point estimate of $357. Costs are in 1999 AUD.

4.3.8 ODT medication doses

Mean doses prescribed

Individual ODT medicine consumers are treated with a range of medicine dosages, depending on their unique circumstances, such as phase of treatment (i.e., initiating treatment or stable), their level of addiction or their tolerance to opioids. For this reason, unlike most other PBS listed medicines, a pack or bottle of ODT medicines will contain a different number of doses depending on individual requirements. In addition, different countries have different guidelines for ODT medicines, which may include differences in recommended dosages (refer Section 2.4.6). To better understand national medicine utilisation trends, it is important to have an idea of what a typical dose is for each medicine for ODT patients in Australia, as will be further discussed in Sections 4.4.2 and 4.4.3.

The mean daily dose of methadone in Australia estimated from the quantitative systematic review is 75mg (Table 12). This is considerably higher than the mean dose prescribed in the UK which is 48mg/day. For sublingual buprenorphine, the mean dose is again higher in Australia, with a mean dose of 16mg/day (Table 13) compared to 9.2mg/day in the UK and lower doses in Canada.

Table 13. Medication type and dose used in the community – data pooled from recent Australian cohort studies

	Methadone		Buprenorphine		Long-acting Buprenorphine	
	Pooled Estimate (95% CI)	**Sources**	**Pooled Estimate (95% CI)**	**Sources**	**Pooled Estimate (95% CI)**	**Sources**
Proportion of ODT consumers on medication	0.55 (0.54, 0.55)	2, 7, 73, 79, 89-95	0.44 (0.44, 0.45)	2, 7, 73, 79, 88-94, 96	0.11 (0.09, 0.13)	7, 91
Mean dose (mg/day)	74.06 (69.44, 78.69)	7, 95	16.00 (14.39, 17.61)	7		
Median dose (mg/day)	75 (47, 75)	2, 7, 79, 90, 97	13 (13, 16)	2, 7, 79, 90, 96, 97		

Where applicable $I^2 = 0.0$.

The distribution of doses in a small sample drawn from the ETHOS ENGAGE cohort shows that most consumers receiving LAIB report dosing monthly rather than weekly (Table 14).

Table 14. Dose distribution for LAIB formulations

ETHOS Engage (N=49)[7]					
Buvidal® (N=46, 94%)				**Sublocade® (N=3, 6%)**	
Buvidal® Weekly (N=11, 22%)		**Buvidal® Monthly (N=35, 71%)**			
16mg	2 (18%)	**64mg**	9 (26%)	**100mg**	2 (67%)
24mg	4 (36%)	**96mg**	7 (20%)	**300mg**	1 (33%)
32mg	3 (27%)	**128mg**	12 (34%)		
Unknown	2 (18%)	**Unknown**	7 (20%)		

Source: Data from ETHOS Engage samples people with a history of injecting drug use enrolled from sites including ODT clinics and NSPs in NSW, QLD, SA, and WA in 2018-2019.

Takeaway doses

Dosing arrangements, including takeaway or unsupervised dosing are determined by individual jurisdictions for their ODT programs. There are broadly three types of takeaway dosing: primary supervised (except perhaps for single occasion), partially supervised (combination of supervised and takeaway doses) and unsupervised (less than weekly supervision) dosing, although arrangements between jurisdictions varies.

Approximately half of all consumers on ODT medicines receive any takeaway doses as estimated in the quantitative systematic review, with slightly more consumers on buprenorphine receiving takeaways compared to methadone (Table 15). This represents a considerably larger proportion with access to takeaway doses compared with the period before the COVID-19 pandemic, when only a third of consumers on ODT medicines received takeaways. In general, the number of takeaway doses is higher for consumers on buprenorphine compared to methadone. There is limited evidence of the impact of increasing

frequency and number of takeaway doses. There is strong support and advocacy from people in ODT programs and stakeholders for greater flexibility in take away doses. One cautionary aspect of increasing takeaway doses particularly of methadone is the risk of increased death rates. A 2010 study in England and Scotland reported a reduction in mortality related to increased rates of supervision of methadone, after a period with little to no supervision of dosing in those countries.

Table 15. Pooled estimates of the proportion of consumers receiving takeaway doses

	Overall ODT medicines		Methadone		Buprenorphine	
	Pooled Estimate (95%CI)	**Sources**	**Pooled Estimate (95%CI)**	**Sources**	**Pooled Estimate (95%CI)**	**Sources**
Pre-COVID						
Proportion with takeaway doses	0.32 (0.29, 0.36)	[2, 91, 96]	0.20 (0.16, 0.26)	[91]	0.30 (0.23, 0.37)	[2, 91]
During COVID						
Proportion with takeaway doses	0.47 (0.44, 0.51)	[7, 91]	0.51 (0.47, 0.55)	[91]	0.55 (0.49, 0.61)	[91]

Where applicable, I^2=0.0.

4.4 Commonwealth expenditure data – PBS ODTP medicine utilisation trends

4.4.1 Commonwealth expenditure trends across PBS ODTP medicines

Commonwealth Government expenditure on the PBS ODTP has been steadily increasing over the years. Expenditure has doubled from the 2016-17 financial year ($51.5 million) to 2021-2022 ($108.6 million).

Notably, growth has accelerated significantly since the 2019-2020 financial year (see Tables 16-17). This increase coincides with the listing of LAIB formulations in September 2019. Table 17 demonstrates that LAIB are the only medicine form for which growth in expenditure has been observed following this increase.

In 2021-22, LAIB overtook buprenorphine + naloxone films as the medicine with the highest expenditure ($54.4 million and $44.0 million respectively), while for methadone and buprenorphine tablets the Commonwealth expenditure is significantly lower ($5.1 million each).

Although Table 16 provides a broad understanding of the Commonwealth expenses related to each medicine, these figures do not consider patient numbers thereby making cost-effectiveness analyses challenging. It is important to note that the analysis of expenditure alone does not provide an accurate picture of the number of doses of each medicine supplied each year or the number of customers accessing ODT medicines. For example, while methadone sales are only a small fraction of overall PBS ODTP costs, NOPSAD indicates it is the most common medicine being supplied to patients. On the other hand, the opposite is true for buprenorphine formulations, particularly buprenorphine + naloxone and LAIB, which together account for 90% of expenditure but account for less than half of doses supplied to patients.[1]

This inconsistency is due to large variation in the costs of individual doses for each medicine, as will be discussed in the following section.

Table 16. Annual expenditure of medicines for opioid dependence treatment by financial year

	Financial Year					
Drug	**2016-17**	**2017-18**	**2018-19**	**2019-20**	**2020-21**	**2021-22**
Buprenorphine tablet	$4.8 M	$5.0 M	$5.2M	$5.2 M	$5.2 M	$5.1 M
Buprenorphine LAI	-	-	-	$7.9 M	$32.3 M	$54.4 M
Buprenorphine + naloxone	$41.2 M	$45.5 M	$49.9 M	$52.0 M	$47.4 M	$44.0 M
Methadone	$5.5 M	$5.5 M	$5.4M	$5.4 M	$5.3 M	$5.1 M
Total	**$51.5 M**	**$56.0 M**	**$60.5 M**	**$70.4 M**	**$90.3 M**	**$108.6 M**

Source: PBS ODTP expenditure data.
Note: Based on published expenditure excluding GST.

Table 17. Annual expenditure growth of medicines for opioid dependence treatment by FY

Drug	**2016-17 to 2017-18**	**2017-18 to 2018-19**	**2018-19 to 2019-20**	**2019-20 to 2020-21**	**2020-21 to 2021-22**
Buprenorphine tablet	4%	4%	10%	0%	-2%
Buprenorphine LAI	-	-	-	311%	68%
Buprenorphine + naloxone	10%	10%	4%	-9%	-7%
Methadone	<1%	-2%	1%	-2%	-5%
Total	**9%**	**8%**	**16%**	**28%**	**20%**

Source: PBS ODTP expenditure data.

4.4.2 Cost of medicines per dose

Expenditure figures alone do not provide a complete picture of how many doses of each medicine are supplied to patients. Additionally, to fully understand the real cost of each medicine to the Commonwealth, it is useful to understand how expensive it is, on average, to treat individual patients with each medicine.

An estimate for the average cost of each medicine per daily dose was calculated using average daily doses from the literature review (Table 13) and the average ex-manufacturer price (AEMP) for each medicine formulation. These costs per dose are summarised in Table 18. It should be noted these estimates reflect the direct cost of the medicines funded by the Commonwealth only. It does not, for example, consider additional private costs currently borne by consumers or service providers.

Daily doses for each patient can vary significantly at an individual level, due to patients being in different phases of treatment, having different tolerance levels and due to varying responses to ODT medicines, for example. However, in the absence of detailed information on the distribution of dosages across the ODT population, average dose estimates are useful to obtain approximate population-wide estimates of how many doses are provided for each medicine.

Table 18 demonstrates the large differences in the cost per average dose for each medicine. Most notably, methadone is significantly cheaper than all buprenorphine formulations, for instance being twenty times cheaper than buprenorphine + naloxone films on a per daily dose basis. Buprenorphine formulations however, are similarly priced compared to each other,

with some slight variations: buprenorphine + naloxone films are slightly more expensive compared to same doses of buprenorphine tablets, due to the addition of naloxone, while LAIB have an additional premium based on additional benefits of reduced diversion, misuse, improved retention, reduction in service fees and reduced issues related to stigma for consumers.[98]

Table 18. Cost per average daily dose of each PBS ODTP medicine

Medicine form	Cost per daily dose
Buprenorphine + Naloxone	$9.99
Methadone	$0.51
Buprenorphine LAI	$13.20
Buprenorphine tablet	$9.16

4.4.3 PBS ODTP medicine utilisation by supplied daily doses

Annual estimates of average daily doses supplied were calculated for each medicine from expenditure data, based off the costs per average dose in Table 18, to provide a suitable metric to analyse yearly trends in medicine utilisation.

Figure 6 shows the trend for approximate all daily ODT medicine doses supplied over time (black dashed line), and a breakdown by medicine for each year.

Oral methadone has consistently been the most commonly supplied ODT medicine throughout the years, making up approximately 52% of supplied ODT medicine doses supplied in 2021-22. The remaining 48% of doses in 2021-22 are made up of the various buprenorphine formulations, with LAIB and sublingual buprenorphine + naloxone films making up an almost equal fraction of supplied doses (22% and 23% respectively), and sublingual buprenorphine tablets being the least common medicine supplied (3% of doses).

Although oral methadone represents a large fraction of supplied doses, methadone expenditure is approximately 5% of total PBS ODTP expenditure in 2021-22 ($5.1 million out of $108.6 million). This is due to the significantly smaller cost per dose of oral methadone compared to other ODT medicines (Table 18).

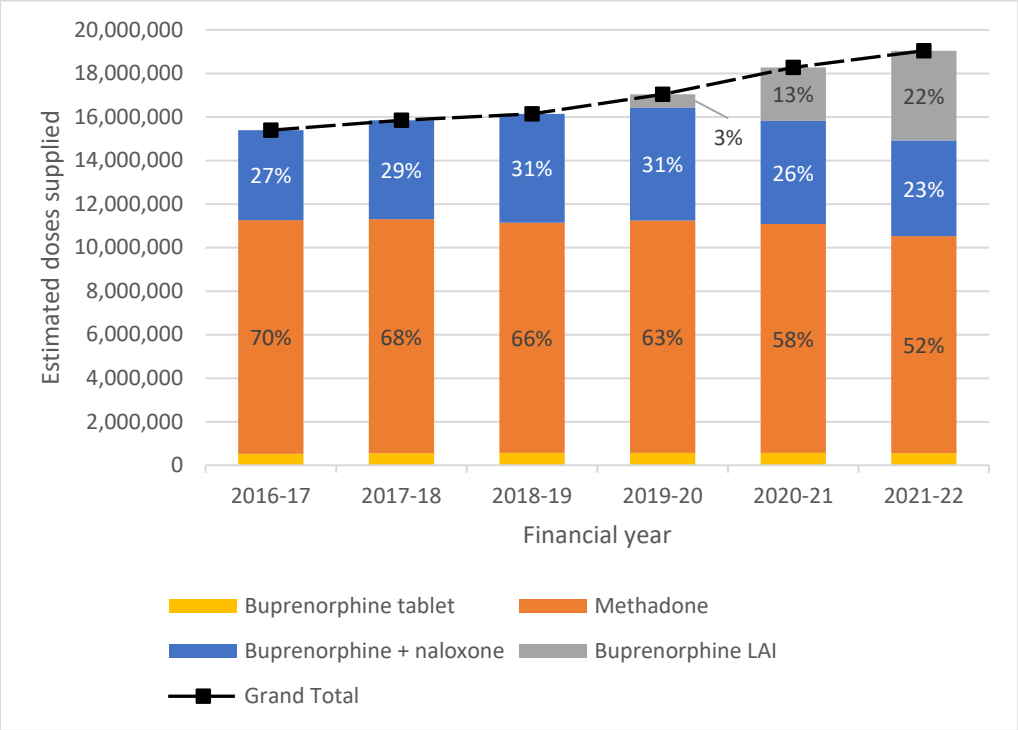
Representing ODTP expenditure data in terms of approximate daily doses supplied can also provide further intuition on the possible underlying reasons for the increased growth in PBS ODTP expenditure since the listing of LAIB in September 2019 (see Table 17 and Section 4.4.1).

To some degree, this increase in expenditure can be explained by LAIB replacing other treatment types, especially buprenorphine + naloxone (see Figure 6). Since LAIB is more expensive than buprenorphine + naloxone on a cost per dose basis ($13.20 vs $9.99 respectively), it follows that treatment substitution towards LAIB contributes a slight increase to the overall expenditure of the program.

More importantly however, Figure 6 demonstrates an increase in growth in the estimated total doses supplied following the listing of LAIB in 2019. With utilisation of other ODT medicines either remaining largely stable, or decreasing in the case of buprenorphine + naloxone, this suggests the introduction of LAIB was followed by a growth in the overall

number of PBS ODTP consumers and an expansion of the population able to access ODT medicines due to the listing of LAIB. This could be due to preliminary evidence suggesting LAIB treatment has better patient retention compared to other medicines,[98] or due to the removal of barriers to access enabled by the LAIB formulation, such as consumers not having to attend a dosing point each day and possibly lower financial burden due to paying a single monthly fee rather than multiple daily fees.

Figure 6. Approximate number of supplied ODT daily doses per financial year, broken down by medicine type.



Note: percentages for buprenorphine tablets omitted due to space constraints. Buprenorphine tablets account for approximately 3% of doses each year, with very little variation between years.

4.4.4 Commonwealth expenditure across PBS ODTP medicines by jurisdiction

With regards to total expenditure by jurisdiction in 2021-22 (Table 19), most Commonwealth expenditure was for ODT medicine supplies in NSW ($42 million, 39% of all expenditure), followed by Victoria ($28 million, 26% of all expenditure) and Queensland ($20 million, 19% of all expenditure), with remaining jurisdictions accounting for less than 10% of expenditure each.

This pattern does not significantly change when looking at expenditure broken down by individual medicines, with the one exception being buprenorphine tablets, for which Queensland accounts for 49% of national expenditure ($2.5 million out of $5.1 million).

The largest proportion of expenditure in most jurisdictions is LAIB, except in Queensland, SA and Tasmania where supplies of buprenorphine + naloxone films are the greater proportion.

Table 19. Breakdown of total PBS ODTP expenditure by drug and state and territory (GST exclusive, 2021-22 FY)*

	Buprenorphine + Naloxone (sublingual film)	Methadone	Long-acting injectable buprenorphine	Buprenorphine (sublingual tablet)	Total	Expenditure (%)
ACT	*$635 K*	*$114 K*	$1 M	*$21 K*	**$2 M**	2
NSW	$14 M	$2 M	$24 M	$1 M	**$42 M**	39
NT	*$228 K*	*$9 K*	*$315 K*	*$72 K*	***$624 K***	1
QLD	$9 M	*$519 K*	$8 M	$3 M	**$20 M**	19
SA	$4 M	*$251 K*	$3 M	*$76 K*	**$8 M**	7
TAS	*$929 K*	*$47 K*	*$654 K*	*$163 K*	**$2 M**	2
VIC	$12 M	$1 M	$14 M	*$640 K*	**$28 M**	26
WA	$2 M	*$266 K*	$3 M	*$97 K*	**$5 M**	5
Total	**$44 M**	**$5 M**	**$54 M**	**$5 M**	**$108 M**	

*M – million, *K – thousand*

4.4.5 Supply of medicines by dosing point

With the current PBS ODTP arrangements, sites from which ODT medicines are dispensed and/or administered order medicines directly from their manufacturers and the medicines are then paid for by the Commonwealth. Commonwealth PBS ODTP expenditure data can be used to determine how many medicines are supplied through each type of site (Table 20). While the data reflects current trends in the supply of medicines if the PBS listings of ODTP medicines were to change following PBAC recommendations from the PMR there would likely be changes to the distribution patterns of medicines.

It should be noted that PBS ODTP expenditure data is limited to where medicines are supplied to, and therefore does not account for internal arrangements between dosing sites where supplies may be delivered to a subsequent location following their initial delivery.

According to Table 20, most daily medicine formulations (oral/sublingual) are supplied through pharmacies (80% of all doses).

The distribution of LAIB is more spread out across dosing points, with only 29% of supplies being delivered to pharmacies. The remaining doses are largely supplied through public hospitals (19%), health services (18%) and correctional facilities (18%).

By comparison, only 3% of oral and sublingual ODT medicines are supplied to correctional facilities, suggesting that LAIB has advantages over other medicines in facilitating provision of ODT medicines to detainees.

Overall, 69% of medicines are supplied through community pharmacies. This is consistent with NOPSAD estimates, which state 2 in 3 consumers receive ODT medicines from community pharmacies.[1]

Table 20. Estimated percentage of PBS ODTP medicine doses supplied to each type of dosing point by medicine form

	Buprenorphine + Naloxone (sublingual film)	Methadone	Long-acting injectable buprenorphine	Buprenorphine (sublingual tablet)	Oral/sublingual PBS ODTP medicines	All PBS ODTP medicines
Alcohol/Drug Treatment Centre	4%	10%	6%	7%	**8%**	**7%**
Correctional facility	>1%	4%	18%	0%	**3%**	**6%**
Health service	1%	2%	18%	0%	**1%**	**5%**
Medical centre	1%	1%	5%	5%	**1%**	**2%**
Community Pharmacy	87%	77%	29%	78%	**80%**	**69%**
Private Hospital	1%	3%	4%	>1%	**2%**	**3%**
Public hospital	5%	3%	19%	5%	**4%**	**7%**
Rehabilitation centre	1%	>1%	>1%	4%	**1%**	**>1%**

Note: Breakdown by dosing point was not available for 2021-22. Fraction for all ODTP medicines in the 2021-22 FY was estimated by applying fractions for individual medicines from the 2020-21 FY to 2021-22 FY expenditure data, to account for changes in fractional market share between medicines. Estimates for total doses across all medicines were made based off an average cost per dose for each form, calculated using the costs per average dose in Table 18.

4.5 Review of current PBS restriction eligibility criteria

The literature review examined current jurisdictional-based, national guidelines/policies and existing treatment algorithms (refer Section 2.4.1) to compare with current PBS restriction eligibility criteria and identify if restrictions are up to date with current clinical advice and practice.

4.5.1 ODT medicine PBS listing criteria

The ODT medicines currently listed on the PBS and their corresponding criteria for availability are shown in Table 1. The criteria for availability align closely with recommended treatments for agonist maintenance. Most medicines available for symptomatic relief are available on the general PBS schedule.

On 1 May 2022 the restriction criteria were updated in line with the PBAC recommendation to remove the requirement for stabilisation on sublingual buprenorphine or sublingual buprenorphine +/- naloxone prior to commencing treatment with weekly prolonged release buprenorphine, consistent with the recent amendment to the TGA indication.

Part 5: TOR 4: Proposed improvements to service delivery of ODT

TOR 4: Propose improved service delivery arrangements for access to ODT medicines, with an aim of identifying an ODTP that is equitable, timely, reliable, and affordable for consumers and stakeholders involved in the supply and delivery of ODT medicines and cost-effective for the Australian Government.

This chapter bring together the evidence and analyses presented in the previous TOR to examine and propose improvements to existing jurisdictional ODT service delivery models (including access to ODT medicines under the PBS) to best support consumers and service providers in a way that is cost-effective for the Australian Government.

5.1 TOR 4 Key findings

The essential elements of ODT service delivery outlined in Section 2.6 could serve as guiding principles for collaborative efforts by Commonwealth and jurisdictions toward improved ODT service delivery arrangements.

Addressing the affordability of access to ODT medicines for consumers due to the high cost of private, unregulated fees is a primary issue raised throughout the Review. This issue is closely intertwined with remuneration for pharmacists as one cannot be resolved without the other. In addition, solving for affordability of access to ODT medicines may also need to consider management and implications of daily dosing requirements, clinical aspects regarding models of service delivery and considerations regarding Commonwealth and jurisdictional responsibility for ODT programs. Close engagement between the Commonwealth and jurisdictions will likely be required to resolve ODT service delivery issues raised throughout the Review.

Currently dispensed ODT medicines do not attract PBS co-payments and consequently there is no annual limit of dispensing charges to the consumer. PBS listings of ODT medicines with PBS co-payments from consumers would mean these payments contribute to the Safety Net threshold as well as providing remuneration for PBS approved suppliers like pharmacists, like other medicines for chronic conditions on the PBS. This means pharmacists would not be able to (and would not need to) charge private fees on top of the PBS co-payment as with other medicines on the PBS. However, it is important to note that PBS remuneration for pharmacist dispensing activities associated with ODT medicines may need to consider whether separate fees are required for supervised dosing/dose management, and if so, consider options for how these could be implemented including whether they could be supported within the PBS framework.

Improved support for delivery of jurisdictional ODT programs through ACCHOs may assist in improving accessibility to culturally safe treatment for First Nations for people wishing to access ODT medicines through these settings. Under the PBS, the Closing the Gap (CTG) Co-payment measure aims to improve access to affordable PBS medicines for First Nations people living with, or at risk of, chronic disease. Similarly, the eligibility of the CTG program could be extended to ODT medicines listed on the PBS, ensuring access to culturally secure treatment from both ACCHOs and mainstream ODT dosing sites. Stakeholders suggest this could occur though specific programs to enhance uptake and provide support for ACCHOs.

Possible programs could include specific prescriber training (and clinical staff such as Aboriginal Health Practitioner and ACCHO nurse), support for on-site dosing and funding for ODT medicine provision within ACCHOs, and prison in-reach services.

To provide guidance towards consistency in jurisdictional policy the Review highlighted the importance of updating the *National Guidelines for Medication-Assisted Treatment of Opioid Dependence 2014* (National Guidelines) to incorporate and revise clinical evidence regarding treatment pathways since the introduction of LAIB to the ODT medicines landscape. This could also include considerations regarding updated evidence with regards to improved flexibility of supervised dosing and reviewing prescriber accreditation requirements to encourage and support greater prescriber participation in ODT programs.

Aspects of the current ODT service delivery model can pose significant barriers to ongoing treatment for consumers, especially some more populations with specific needs. For example, in the context of daily dosing, consumers who live in regional, rural and remote areas and consumers with no permanent address face challenges in attending dosing points regularly. Changes to ODT policies by state and territory governments due to the COVID-19 pandemic demonstrate the adaptability of the service model to support unsupervised dosing, primarily through an increase in takeaway doses (despite these initiatives now being rolled back to pre-pandemic ODT policies in some jurisdictions).

Evidence suggests that a small number of prescribers are caring for a high concentration of ODT consumers. Stakeholder input indicated that typically, these prescribers are elderly and nearing retirement age which represents a significant risk to the program. This risk is also present for the Addiction Medicine Specialty where less than 20% of fellows are under the age of 50 years and more than half of them are older than 60 years. Many health professionals participate in prescribing ODT medicines under state and territory programs for only short periods. There is a need to identify and respond to the reasons for this. It is critical to put in place strategies to increase retention of prescribers and broaden the base of health professionals involved in the delivery of ODT.

While system complexities, multiple stakeholders, and a lack of data availability across domains mean that the consequences of any changes to the current PBS listing of ODT medications are difficult to predict, stakeholders are of a view that a revised PBS listing arrangement for ODT medicines that provided equitable and affordable access would significantly improve patient health and societal outcomes. Regular reviews of consumer and provider responses should be monitored following any changes to the treatment listing.

The Review identified ongoing access to the breadth of ODT medicines is important to support improved patient outcomes.

Medicines with daily dosing requirements

For oral methadone and sublingual buprenorphine, more frequent dispensing may be required related to the often daily preparation and supervision of doses. Remuneration for these activities needs to be considered if access to ODT medicines is to be made affordable for consumers. It is also important to note supervised dosing policy for ODT medicines is determined by state and territory governments and is also a decision made by the patient's prescriber.

Stakeholders are of a view that one option to address community pharmacy remuneration for dispensing ODT medicines would be to enable pharmacies to claim the 7CPA staged supply payment for patients accessing OPD medicines or to use this program as a model for a similar program for ODT medicines. As noted in Section 1.7.3, the Staged Supply Program is designed to assist patients who are at risk of drug dependency or who are otherwise unable to manage their medicines safely and the program rules state that pharmacies can claim payments for the provision of Staged Supply Services for up to 15 eligible patients.

Medicines with a prolonged duration

By nature of their longer duration, LAIB align more closely with the usual pattern of use of PBS medicines where the quantity dispensed is often a month's supply. Although LAIB may be considered as an attractive, and potentially cost-saving option for some consumers due to sometimes reduced private dosing fees, some consumers prefer sublingual buprenorphine or oral methadone, and the importance of patient choice of medicine has been consistently noted in this review; there are no cost-effectiveness data comparing these treatments directly. It is suggested future research focus on comparing new and existing formulations in relation to essential elements of care, including modes of delivery and costs to both the consumer, treatment provider, and health system.

Stakeholders are of the view that on-site pharmacist administration of LAIB may develop further in future, noting pilot programs have commenced in some jurisdictional ODT programs. As treatment with LAIB evolves, additional consideration could be given to the option of remuneration for on-site pharmacist administration as this is not covered by current PBS arrangements.

5.1.1 Stakeholder views for TOR 4

Stakeholder views received throughout the Review are consistent with the findings of the literature review. Stakeholders suggested improved arrangements for ODT programs strive towards optimising the essential elements of ODT service delivery that were put forward in TOR 1 (Part 2).

The primary concerns for stakeholders are the affordability of ODT medicines for consumers, renumeration for pharmacists and normalising access to ODT medicines in line with other chronic conditions. Several stakeholders have put forward submissions on how ODT medicines could be listed on the PBS as a mechanism by which the affordability of these medicines might be addressed which have also been considered as part of the Review.

In addition, stakeholders supported improved policy consistency across jurisdictional ODT programs and the importance of a broad model of care that provides supporting services beyond access to ODT medicines alone. Improved support for populations with specific needs and for people transitioning between care settings was also considered an important aspect of improved ODT service delivery, particularly First Nations people and people in correctional facilities (in whom First Nations people are overrepresented). Stakeholders also supported improved access to prescribers through innovative models of care particularly for rural and remote communities.

5.2 Literature Review – Proposed improvements to service delivery of ODT

5.2.1 Commonwealth and jurisdictional responsibility

The challenge of federal and jurisdictional responsibility is reflected in many countries including the United States of America, Canada, Germany, Spain, among others. There is no gold standard, or one model of excellence identified in the literature for delivery and most models reflect the organisation and systems of funding health care and social care. Also, the approaches to links between health care and criminal justice systems strongly influence the actual delivery and continuity of treatment across the system.

The complexity of the organisation of ODT in Australia is exemplified by the mix of Commonwealth and jurisdictional input and funding into the program and the considerable variation across jurisdictions. The shared responsibility has resulted in very marked variation in the models of service delivery across different jurisdictions. The variation in expenditure by state has also shaped the variation in models of service delivery. Overarching principles of care, equity and high-quality accessible treatment should guide the future design and delivery of ODT programs.

Treatment coverage in Australia is comparably good by international standards[99] and the level of provision within the criminal justice system is much higher than many other countries. However, there are still major gaps in both the provision and the continuity of treatment and much variation across jurisdictions. Future moves towards provision of LAIB in state and territory justice settings will likely require more active planning both within prisons and on discharge to communities to ensure full coverage.

5.2.2 Improving the affordability of ODT medicines for consumers

Research evidence, stakeholder input, consumer consultation and Reference Group members suggests solving for the core issue of affordability is the number one priority area for change that will result in the most positive impact on the lives of people in ODT. Recognising the challenge for consumers around cost and affordability requires a design of broader community services that are funded through both Commonwealth and jurisdictional resources that avoids cost shifting and ensures a high-quality treatment service where the private sector is relied upon for delivery of treatment. Examples in England, Wales and Scotland, Ireland, Canada, and France demonstrate that costs to people in ODT programs can be minimised in a manner that reduces barriers to access to care. Up-front costs to service users are critical barriers to care.

PBS listings of ODT medicines with PBS co-payments from consumers would mean these payments contribute to the Safety Net threshold as well as providing remuneration for PBS approved suppliers like pharmacists, like other medicines for chronic conditions on the PBS. This means pharmacists would not be able to (and would not need to) charge private fees on top of the PBS co-payment as with other medicines on the PBS. However, it is important to note that PBS remuneration for pharmacist dispensing activities associated with ODT medicines may need to consider whether separate fees are required for supervised dosing/dose management, and if so, options for how these could be implemented.

While stakeholders suggested the Commonwealth introduce new MBS items specifically for ODT service delivery, noting the Strengthening Medicare Taskforce currently underway,

consideration of matters raised in relation to the MBS were not considered in detail as part of the TOR for this review. The Strengthening Medicare Taskforce Report published in February 2023 recommends significant changes to how primary care is funded and delivered to enable high quality, integrated and person-centred care for all Australians.

In addition, opioids and non-medical use of pharmaceuticals are included as key areas of focus under Australia's National Drug Strategy. Through the Strategy, all Australian governments have identified a range of evidence-based approaches to minimise harm associated with these substances. This includes clinical assessment and support provided through primary care and clinical care settings, the provision of specific drug and alcohol treatment and support services, access to naloxone and opioid maintenance pharmacotherapies, as well as state and territory-run programs such as medically supervised injection centres.

The support for addiction specialists and practitioners including nurse practitioners and GPs is critical to the overall organisational support and development of high coverage and well-organised ODT at both a Commonwealth and jurisdictional level.

Research regarding barriers and facilitators to ODT for First Nations people will be important to inform future policy and programs. In addition, focussed support for ACCHOs participating in state and territory ODT programs would assist in addressing key health gaps and systemic responses.

5.2.3 Professional engagement

While much of the data are patchy, there is consistent information that for the full range of professionals involved across all jurisdictions the bulk of work is carried by an ageing population of professionals who have been engaged and committed to this program for decades. Many of these are approaching retirement age. There is a need to recruit a cadre of young professionals to replace those retiring over the next five to ten years.

Evidence suggests there are critical workforce issues to be addressed if the future workforce is to be properly trained and professional standards of the multidisciplinary teams are part of an ongoing support and development approach. This would likely involve broader training and needs to be adequately remunerated with incentives to promote high quality and equitable practice. Ideally, there should also be a continuity of approach with respect to the inclusion of values clarification, role obligation and evidence into practice for ODT that would promote universal access. Making this assessable and part of curriculum for undergraduate teaching, postgraduate training (for all health professionals but especially General Practice) through to Continuing Professional Development activities would embed it as part of core practice. The role that stigma and discrimination play in limiting provider and service engagement cannot be underplayed and must be addressed.

The use of new technologies, including telehealth, are integral to improve remote and regional health care. Supported development and training to diversity prescribing options will assist to broaden rural and remote access. Practitioners should be adequately supported to ensure they are not isolated and overwhelmed.

5.2.4 *Number of participating pharmacies/dosing sites*

Internationally the challenge of ensuring broad geographic distribution of dosing sites has been met using community pharmacists and this remains the key option to use to increase and maximise ODT medication provision and access. The organisation of approaches to new buprenorphine formulations would likely benefit from a broader and more radical consideration particularly for rural and remote settings where innovative models may address some of the critical challenges of achieving adequate coverage in such settings. Innovation approaches could include negotiating the inclusion of access to ODT into the next National Community Pharmacy agreement between the Commonwealth Government and the Pharmacy Guild of Australia, nurse or pharmacy or allied health professional prescription, and delivery or other technology and telehealth forms of mobile remote delivery and monitoring of treatment. New forms of team organisation of treatment using hub and spoke models.

NOPSAD explores ODT medicine dosing point sites across Australia by Statistical Areas Level 2 regions (SA2).[1] There is a clear difference in the distribution in the number of dosing point sites per SA2 across the country, with notably fewer sites in the centre and western regions of Australia.

5.2.5 *The importance of the involvement of people who use drugs*

There is a strong international movement to mobilise a broad range of peer support and networks of people who use drugs. Australia was originally a cutting-edge force in such developments and there is a long and successful history of partnership between the established peer-led drug user organisations and governments in Australia. Therefore, peer-led organisations have a central role to play in the planning, delivery, and quality improvement of ODT in Australia.

5.2.6 *Future monitoring, evaluation, and other activity*

Future Electronic Medical Record Systems and Real Time Prescribing Monitoring Services if efficiently designed afford the opportunity to put in place sophisticated Outcome Monitoring Systems (although stakeholders raise privacy and confidentiality concerns regarding their use). This, along with future Economic Costing and Modelling approaches, could be used to ensure that future high-quality, cost-effective, accessible, and user-friendly services are enabled. The additional challenge given the high levels of social, physical health, and mental health problems among people with opioid dependence requires careful integration of ODT service delivery with a broader range of health and social services.

This review highlights that there are major gaps in information and data for ODT programs. Future consideration could be given to large-scale monitoring and costing and modelling of different models of treatment delivery which could provide data to optimise models of program delivery. Uses of economic costing and modelling and the development of National Outcome Monitoring approaches would be a wise future investment. In addition, further revision of the current National Guidelines and the opportunity to ensure that new and emerging technologies are fully harnessed to maximise treatment impact and outcomes is suggested.

5.2.7 *Impact of COVID-19 upon accessing ODT medicines*

The experience of COVID also requires reflection and consideration. Both nationally and internationally there were significant changes in approaches to dosing frequency with a shift to greater takeaway doses for both methadone and buprenorphine, although in some jurisdictions these measures have since been rolled back. The consumer feedback on such changes was uniformly positive. A shift to a more flexible and less frequent attendance model needs full consideration. Possible negative impacts include potential for higher methadone-related deaths, medication diversion and consequent negative community views on treatment programs. However, the PMR did not have access to published data about any possible adverse events – such data may be delayed in being collated and reported.

As described in Section 2.5.2, the literature review found an increase in the use of LAIB appears to have been accelerated by state and territory ODT programs as a strategy to decrease interaction with consumers, help adhere with density limits and social distancing rules during the COVID-19 pandemic. ODT consumers receiving LAIB described a multitude of benefits from this ODT medicine formulation, however some concerns were also observed.

5.3 Literature Review – Considerations regarding PBS listings

It is critical to understand the impact (benefits and challenges) when considering how ODT medicines could be funded and how the medicines are listed as pharmaceutical benefits. While system complexities, multiple stakeholders, and a lack of data availability across domains mean that the consequences of any changes to the current PBS listing of ODT medications are difficult to predict, stakeholders are of a view that a revised PBS listing arrangement for ODT medicines that provides equitable and affordable access would significantly improve patient health and societal outcomes. In considering the design of possible listing changes it will be important to give due consideration to any shifts in medicine utilisation trends, issues with supply of medicines to specific settings that have not been accounted for in new listings and guidelines, or any unintended changes in numbers of prescribers and dosing points. It is also important to keep in mind that regardless of how ODT medicines might be listed on the PBS, jurisdictions operate and manage the broader aspects of ODT programs including approvals, eligibility, accreditation and supervised dosing requirements as well as regulation of controlled substances which occur independent of the Commonwealth.

Many stakeholders throughout the Review proposed ODT medicines could be either considered for listing on S85 alone or to duplicate the medicine listings across both S100 and S85 as a way of addressing the affordability for consumers and remuneration for pharmacists. Below is an overarching exploration of these options.

5.3.1 *To continue with the status quo*

The impetus to conduct this review relating to issues identified herein around access, affordability and equity of access to ODT medicines mean that it is important to explore whether any changes to the PBS funding of ODT medicines could address these issues.

5.3.2 To switch the listing of ODT medicines to S85 entirely

In line with the functions and operations of the general PBS schedule, this would involve consumers being dispensed S85 medicines from PBS approved suppliers and paying a PBS co-payment depending on their beneficiary status. This confers both potential financial and societal benefits; consumers would be eligible for PBS Safety Net benefits and ODT medicine dispensing would be aligned with medicines used to treat other health conditions under the PBS. It also allows medicine use dispensing claims data to be monitored on an individual level, allowing for improved modelling of treatment utilisation and needs at a policy level.

However, this option under current policy would exclude many critical dispensing points currently providing ODT medicines, such as both private and public clinics, and correctional facilities. It would also impact ODT programs in public hospitals and clinics which currently rely on the S100 arrangements to fund the supply of medicines. The usual supply arrangements for most S85 medicines for chronic conditions represent a month's treatment. There may be limitations to applying the existing S85 legislative and administrative claiming structure to ODT medicines which have individualised dosing schedules given oral methadone and sublingual buprenorphine require more frequent dispensing activities associated with the often daily preparation and supervision of doses. S85 PBS arrangements are not well suited to ODT medicines (i.e., methadone and sublingual buprenorphine) that require daily dosing.

As a prescription for LAIB can be dispensed on a per pack basis for a specific patient, these products could be considered for listing on the PBS under S85 supporting access through pharmacies. In this situation a S100 arrangement may still be needed to facilitate access to LAIB for consumers accessing treatment through private and public clinics, and receiving treatment in correctional facilities.

There is also potential for considerable wastage as S85 medicines are dispensed on an individual patient basis. For methadone, one bottle would be dispensed to a consumer who may not use the entire bottle, in contrast to the current S100 arrangement in which multiple consumers can be dosed from the same bottle.

While this option would potentially contribute, in part, to achieving more mainstream PBS arrangements for access to ODT medicines through community pharmacy dosing sites it would not address access through broader, non-pharmacy settings for ODT programs.

5.3.3 To list ODT medicines as duplicates on both S85 and S100 schedules

This option would potentially allow consumers to access their ODT medicines from a community pharmacy in the same way as they currently access other PBS subsidised medicines for other medicines (e.g. under s85 with the PBS Safety Net entitlement) while potentially also allowing other non-community pharmacy dispensing points to continue to have PBS subsidised access to the medicines as occurs now (under s100).

Stakeholders and members of the Reference Group have raised there is some precedence for this; hepatitis C medications can be obtained both through S85 and S100 schemes. These medicines differ however, in that under the s100 arrangements there is still an individual patient supply which is captured through a PBS claim made by a PBS approved supplier which does not occur for ODT medicines (where, under s100 payments are made direct to pharmaceutical companies for the drugs without any individual patient claim).

Having 2 separate reimbursement schemes for ODT medicines through both S85 and S100, is likely to contribute to increasing complexity within the health system by introducing duplicative processes. Pharmacy remuneration also needs to be considered in such an option to ensure fees for daily dosing are commensurate to the activities undertaken and time required to dispense ODT medicines and so patients are not charged ongoing out-of-pocket costs for pharmacy daily dosing fees.

5.3.4 Revised S100 schedule

The current S100 arrangements for ODT medicines (i.e. the PBS ODTP) could be amended to incorporate elements similar to other PBS medicines in which reimbursement to pharmacists occurs at the time of dispensing on a per-patient basis and there is a PBS patient contribution (instead of private, unregulated pharmacy dosing fees). A revised S100 arrangement could also provide for access to ODT medicines from a range of settings, not just community pharmacy.

Stakeholder input to the PMR noted that it is not unusual for medicines with specific dosing and dispensing requirements to be listed on the PBS under S100 programs that accommodate alternative supply arrangements such as the HSD, EFC or Growth Hormone Programs. Possible improvements suggested by stakeholders include retrospective dispensing, flexible dispensing intervals and developing algorithms that consider frequent and variable dosing.

While existing S100 PBS fees for dispensing medicines go some way towards remunerating pharmacies, it is acknowledged these fees may not adequately compensate pharmacies for the time taken to observe the patient taking their doses within their premises and/or to prepare and provide takeaway doses. This is despite the review finding that approximately half of all consumers of ODT medicines receive some takeaway doses. Therefore, this option would require consideration of both a PBS patient contribution and a remuneration approach for pharmacies to ensure patient affordability is fully addressed.

This option has the potential to achieve more mainstream arrangements and improved affordability of dispensing and supply of ODT medicines for consumers however there remains the need to ensure work is undertaken with state and territory governments on ensuring access to affordable and equitable treatment options from a range of settings in addition to community pharmacy including from correctional facilities and public treatment choices.

5.4 Pathways of service delivery for ODT medicines

As identified in the literature review, all ODT medicines (except for the monthly injections) are considered first-line treatment options. ODT medicines that require more frequent dispensing are short acting and can be subject to variable arrangements around dose, frequency and supervision requirements depending on assessment of the consumer on presentation. More frequent reviews (e.g., every week) usually occur early in treatment, during periods of instability, or during withdrawal attempts. Patients who are stable in long-term treatment may be reviewed less frequently (for example on a monthly or longer basis).

Although subject to jurisdictional guidelines, there are broadly three types of takeaway dosing: primarily supervised (except perhaps for single occasion), partially supervised

(combination of supervised and takeaway doses) and unsupervised (less than weekly supervision) dosing. The aspects discussed above make considerations for a more standard PBS listing of these daily dosed ODT medicines challenging.

To be prescribed the monthly LAIB, a consumer is required to be stabilised on the shorter acting buprenorphine formulations due to the modified release formulation making dose-adjustment more difficult.

It is the clinical decision of the prescriber (in discussion with the patient) to determine the most suitable approach to ODT, including which ODT medicine to prescribe (noting there are pharmacological differences between ODT medicines and formulations which result in different clinical responses and therefore may suit patients differently) and the level, if any, of supporting services required.

Part 6: Review Outcomes

This chapter brings together the stakeholder input and evidence presented in the TOR and puts forward matters for PBAC consideration and response.

6.1 Outline of matters arising from the PMR

In addressing the ODTP PMR TOR and proposing improved service delivery arrangements for access to ODT medicines the PBAC may wish to consider the following summary of key matters arising from the PMR.

Research evidence, stakeholder input, consumer consultation and Reference Group members suggests solving for the core issue of affordability is the number one priority area for change that will result in the most positive impact on the lives of people in ODT. The review found there is a significant opportunity cost that could be improved through universal and equitable access to these medicines facilitated through the implementation of revised PBS listing arrangements for ODT medicines that address the high out of pocket costs currently paid by consumers through a PBS co-payment arrangement and PBS Safety-Net provisions.

The review also highlighted broader concerns about access for people participating in state and territory ODT programs, particularly the low number of prescribers engaging in ODT, that present a significant challenge and need a collaborative Commonwealth and state and territory government response. The review also highlighted the importance of updating the National Guidelines for Medication-Assisted Treatment of Opioid Dependence 2014 to reflect current clinical evidence and practice, including for LAIB which was PBS listed under the ODTP subsequent to the development of these guidelines.

In line with the PMR Framework, the PBAC may wish to respond to matters concerning the operation of the PBS and also provide advice to Government on broader matters impacting consumers access to ODT medicines.

As with any PBS medicines undergoing a change in the PBS listing, alteration to the circumstances under which medicines for opioid dependence are available on the PBS would need to consider the impact to the net cost to the PBS and importantly on consumer access. Given state and territory governments manage ODT services in accordance with relevant state and territory policy, program guidelines and drugs and poisons legislation, any changes to PBS listings or remuneration arrangements will need to consider ongoing consultation with state and territories to ensure there are no unintended consequences that may affect patient choice of treatment, the number of patients able to access treatment or potential impacts to the number of participating prescribers and pharmacies.

6.1.1 Affordability

Affordability is the primary concern raised throughout the review. Most consumers (80%) access their PBS listed oral or sublingual ODT medicines through community pharmacies where costs to consumers through private, unregulated fees typically range from $5-8 per day (and can be higher). Conservatively, this means consumers may pay an estimated $120 million per year in out-of-pocket costs for medicines to treat their opioid dependence. The consumer consultation report at Appendix 3 presents a powerful insight into the lives of people accessing ODT medicines and the significant impact of the out of pocket costs.

The review found that mechanisms for access to ODT medicines that directly address the issue of private, unregulated patient fees is the primary priority for the sector. Improving affordability and ensuring equitable access to ODT medicines has broader societal benefits. Research evidence demonstrates that participating in ODT programs increases quality of life including mental and physical health, and reduces injecting risk behaviour, the risk of HIV/Hepatitis C virus acquisition, criminal activity, and overdose deaths. In terms of societal costs, ODT is also highly cost-effective, and actually cost-saving when costs of crime are included.

Addressing cost barriers to treatment entry and retention (through the PBS and with state and territory governments) has the potential to significantly improve a wide range of health and other outcomes for people with opioid dependence. Throughout the review stakeholders, including consumers participating in ODT programs and Reference Group members strongly considered that the high financial cost of private fees was the most important barrier to treatment initiation, adherence and retention.

The review found, strongly supported by stakeholders and Reference Group members, that a response to address affordability and equity of access issues could be addressed through a revised S100 ODTP program that introduces a PBS co-payment and Safety Net provisions for consumers thereby ensuring that some of the most vulnerable people in the Australian community are receiving equitable and affordable access to medications that can save their lives.

6.1.2 Summary of other matters arising from the PMR

In conducting the PMR, the Department heard a broad range of concerns that are likely beyond the PBS alone to address (refer Section 2.6). These often relate to policies and regulations for ODT programs that are managed at a state and territory government level and includes suggestions to review the processes and requirements for the approval of patients, prescribers and dosing sites, and supervised dosing arrangements as well as public treatment options for those who cannot manage treatment through private health services (i.e., through GP practice/community pharmacy).

The Commonwealth and state and territory governments would need to work in partnership to address the broad range of issues with current service delivery arrangements identified through the PMR.

In addition to considering how the affordability of treatment through community pharmacies is addressed and ensuring equity of access for population groups at greater risk, stakeholders have identified the lack of prescriber participation in ODT as an important issue and suggest improved support for GPs, ODT specialists, nurse practitioners and First Nations prescribers to encourage participation and reduce the burden on existing prescribers. The insufficient number of prescribers and voluntary participation of dosing sites results in long waiting lists and delays in commencing treatment which can mean consumers continue to use opioids while waiting for a place. The lack of consistency in ODT service delivery across jurisdictions also complicates access to ODT for consumers.

Relying entirely on the community pharmacy sector for dispensing ODT medicines also presents very significant service delivery issues. While many patients can access treatment as

private patients, this is not an area of treatment which can be exclusively provided by the private sector (i.e., by GP practice/community pharmacy). Stakeholders suggest the issues of equity of access and affordability could be addressed to a large extent through a revised PBS listing. In addition, to ensure patients with specific needs for whom GP charges and PBS co-payments may still put treatment out of reach, the review highlights the need for treatment to be available in a range of settings including the need for an ongoing state and territory public treatment option. The review notes that this includes supporting First Nations people to access ODT services through their preferred setting, including through ACCHOs, in a culturally safe manner. Research evidence and stakeholders also indicate that supporting transitions to and from correctional facilities and between other settings is an important aspect of improved ODT service delivery, particularly for First Nations people who are greatly overrepresented in custodial settings.

Stakeholder views also suggested the focus on ODT services as simply relating to medication access is a narrow and a suboptimal conceptualisation of health care for many people with opioid dependence. The review also raised the importance of coordinated social, mental and other health services being made available as options to support best possible outcomes beyond ODT medicines alone. The review found that while moving access to ODT medicines into primary care increases accessibility and coverage of treatment, a stepped care approach to opioid dependence treatment delivery should continue to be provided. That is, using less restrictive treatment approaches for those with low severity dependence and more intensive treatment options reserved for people initiating treatment and/or people more severe and complex health and social problems where necessary, while maintaining patient autonomy and appropriate clinical care.

6.2 Review outcomes for PBAC consideration

6.2.1 Solving for affordability and equity of access

Opioid dependence has been characterised as a chronic, relapsing condition with periods of active use, abstinence, and relapse which can occur over many years. As noted in the National Guidelines, the chronic relapsing nature of drug dependence links opioid dependence with other chronic medical conditions such as asthma, hypertension and diabetes. Stakeholders consider that, given ODT medicines provide treatment for the chronic condition of opioid dependence, they should therefore be provided at the same or similar costs to the consumer as other PBS medicines for other chronic conditions.

Research evidence and the stakeholder consensus response to the primary issue of affordability is for consumers accessing ODT medicines on the PBS to have equitable access to the PBS co-payment and PBS Safety Net, as they would for any other PBS listed medicine, as well as remuneration for community pharmacies which would replace all private, unregulated dispensing and dosing fees. This would allow greater flexibility for variable dosing arrangements and provide national consistency and universal access through the PBS to these medicines for patients who dose at community pharmacies regardless of jurisdiction, type and formulation of drug, or supervision requirements.

The review acknowledges the unique nature of methadone and sublingual buprenorphine medicines due to their more frequent (often daily) dosing requirements which a) often does

not align with the usual pattern of use of other S85 PBS medicines where people are dispensed a full script quantity to take home and b) require more frequent activities to be performed by the pharmacist associated with the often-daily preparation, dispensing and supervision of doses. However, stakeholder input to the PMR also notes that it is not unusual for medicines with specific dosing and dispensing requirements to be listed on the PBS under S100 programs that accommodate alternative supply arrangements such as the HSD or EFC Programs.

This suggests there is a need to consider how ODT medicines can be listed differently on the PBS to align it more closely with some elements of PBS practice (i.e. PBS co-payment and Safety Net provisions) while at the same time acknowledging the features that are unique and may require an exception to the usual operation of the PBS. These include elements such as more frequent dispensing requirements and the need for access to ODT medicines from a range of settings, not just community pharmacy.

Therefore, in order to solve for the primary issue of affordability in a nationally consistent manner, an option before the PBAC is to consider revised listings of ODT medicines through the PBS under a revised S100 program to accommodate the unique features of most ODT medicines.

It is important to keep in mind that regardless of how ODT medicines might be listed on the PBS, jurisdictions operate and manage the broader aspects of ODT programs including approvals, eligibility, accreditation and supervised dosing requirements as well as regulation of controlled substances which occur independent of the Commonwealth. In exploring an S100 model, it will be important this is done in consultation and collaboration with jurisdictions to ensure the S100 model alignment with their policy and regulations. This means the Commonwealth and state and territory governments will need to work collaboratively to solve for the issues of affordability as well as equity of access.

While the majority of ODT medicines supplies occur through community pharmacies, access to ODT medicines also occurs through a range of other settings including alcohol and drug treatment centres, correctional facilities and medical centres. The Department acknowledges the importance of ongoing engagement with state and territory governments to ensure continued patient access to ODT medicines provided outside of PBS approved suppliers, for example to correctional facilities and that an option is that this could continue to be supported under a revised S100 model.

The PBAC may wish to respond to the issues of affordability that could be solved through a PBS S100 arrangement for all ODT medicines (methadone, buprenorphine tablets and injections, buprenorphine with naloxone film) that provides affordable and equitable access to ODT medicines in a nationally consistent manner in line with the following principles:

- **Acknowledges the unique dosing frequency requirements of ODT medicines**
- **Patients no longer pay unregulated private fees to access medicines for ODT**
- **Patients instead pay a PBS contribution amount that counts towards their Safety Net threshold when accessing treatment from a community pharmacy**

- **Aligns with usual aspects of the PBS such that pharmacists dispense a prescription quantity and receive remuneration for supply and managing in-pharmacy and take-away dosing**
- **Similar to other PBS medicines, pharmacists cannot seek additional payment from patients (other than PBS-related e.g. co-payment)**
- **Considers improved access for First Nations people through expansion of the CTG program**
- **Considers continued support for ODT medicines that are supplied through non-pharmacy settings such as correctional facilities**
- **Acknowledges the importance of ongoing engagement with state and territory governments.**

6.3 Other advice the PBAC may wish to consider providing to Government

In addition to the primary issue of affordability (and equity of access) discussed above, the review highlights additional areas of improvement across ODT service delivery more broadly. The PBAC may also wish to consider providing advice to Government on these matters.

6.3.1 Issues arising from the PMR relating to state and territory policy

In addition to changes to the PBS to better support affordable and equitable access to ODT medicines, research evidence and stakeholder input are of the view improvements should be made in program delivery aspects that are managed by state and territory governments i.e.:

- changing policy to allow for greater access to and more flexible unsupervised dosing for stable consumers
- changing policy to support consistent ODT program rules across states and territories while maintaining and/or improving autonomy and equity of access for consumers
- loosening of accreditation requirements for prescribers and increasing support for the prescriber workforce more broadly (e.g. to encourage the participation of GPs/nurse practitioners/nurses) with more proactive triage of initiating/complex vs stable consumers, case management support and assistance with facilitating referral pathways for social/mental health workers and other support services (e.g., housing)
- encourage participation of community pharmacies in ODT programs
- investment in ongoing jurisdictional treatment options (e.g. public clinics), to provide additional choices for patients, particularly those initiating treatment and/or patients with more specific and complex needs, who may benefit from jurisdictional support
- more effective care coordination and management of continuity of access to ODT medicines for patients when transferring from custody to community settings, when travelling interstate and between care settings (i.e., hospital and community)
- improved access to culturally safe ODT for First Nations people through ACCHOs, including within custodial settings
- improved ODT data collection – i.e., improved reporting and categorisations of medicines for the NOPSAD collection.

Stakeholders acknowledge solving for these matters will likely require collaborative engagement across different levels of government and have provided their views on possible

solutions presented within the report to inform future discussions. Holistic reform of ODT will require the Commonwealth and state and territory governments to work together on strategies to best support people with opioid dependence to access equitable and affordable treatment services when required, of which ODT medicines are an important, but not necessarily the sole, element.

The PBAC may wish to respond to matters relating to the varying nature and models of service delivery used to provide ODT, jurisdictional dosing policies and access to treatment through jurisdictional public treatment options with advice to Government to progress discussions with state and territory governments.

6.3.2 Update of opioid dependence treatment guidelines

There is no formal partnership agreement between the Commonwealth and jurisdictions for opioid dependence treatment. Each state and territory government manages individual treatment programs which are reflected in jurisdictional clinical and policy guidance documents. Complimentary to jurisdictional regulatory, policy and governance frameworks for opioid dependence treatment are the National Guidelines, intended to assist decision makers across various Australian jurisdictions in establishing a consistent framework for opioid dependence treatment.

Through the PMR, stakeholders and members of the review Reference Group have emphasised the importance of updating these guidelines to reflect current treatment pathways, standards, and practice. Published in 2014, there is a significant gap in the National Guidelines as they do not include clinical guidance for LAIB. During the COVID-19 pandemic changes were made to the delivery of ODT programs at a jurisdictional level, particularly regarding takeaways and as such this section of the guidelines warrants specific review.

The PBAC may wish to endorse an update of the overarching National Guidelines to reflect current evidence regarding pathways of care and service delivery of ODT, including for LAIB.

6.3.3 Prescriber workforce issues

Throughout the review research evidence, stakeholder input and Reference Group members have identified that there is a shortage of prescribers who participate in ODT programs, particularly in regional and remote areas. This negatively impacts access to ODT medicines, additional support and further contributes to stigmatisation of people with opioid dependence, and the financial impacts of accessing ODT for consumers. The review identified recruitment and retention of GPs as a primary barrier to access and suggests there needs to be innovative solutions that include greater use of MBS telehealth items, case management support, assessable and ongoing undergraduate and postgraduate training (for all health professionals) as well as jurisdictional level solutions.

Stakeholders are of a view that support to encourage increased participation and retention of addiction specialists, GPs and in particular nurse practitioners is critical to ODT at both a Commonwealth and jurisdictional level and could consider funding and/or incentive payments that acknowledge the case complexity of many ODT patients, with one option possibly being MBS items that give specific consideration to supporting ODT patients and their prescribers.

Currently, to support services to patients, there are several service items and payment available under the MBS which include time-tiered general attendance items with general practitioners, addiction medicine specialist attendance items (for assessment and treatment) as well as chronic disease management and mental health items. Noting the Strengthening Medicare Taskforce currently underway, consideration of matters raised in relation to the MBS was not considered in detail as part of the TOR for this review.

The PBAC may wish to respond to prescriber workforce issues with advice for Government consideration and progression of discussions with state and territory governments on options for ensuring people have equitable and affordable access to treatment programs for opioid dependence.

6.3.4 Access to LAIB administration in community pharmacies

Evidence and stakeholder input to the review suggests that the use of LAIB is anticipated to continue to grow and for some patients the injections have the potential benefits of eliminating the need for daily supervised and/or takeaway dosing with methadone or sublingual buprenorphine (where this is their choice and preferred treatment) and improving accessibility of treatment, particularly where clinic dosing is unavailable (e.g., consumers are unable to geographically access clinics due to mobility or transport).

Separate to the PBS, the PBAC may wish to consider a mechanism to support remuneration for on-site pharmacist administration of LAIB an option to further improve the accessibility of treatment. It may also ease pressure on the prescriber workforce and on patients that find it difficult to find an appointment with a GP or who find it difficult to regularly visit a GP practice for administration of the injection.

The PBAC may wish to endorse an option for consideration by Government for community pharmacies to administer LAIB injections.

6.3.5 Access to ODT for First Nations People

The Review highlighted specific patient populations such as First Nations people and people either within or recently released from custodial settings (in which First Nations people are greatly overrepresented) experience disproportionate barriers to access and will need specific consideration in any service delivery arrangements for access to ODT medicines.

Approaches raised by stakeholders during the review include:

1. improved access to culturally safe care through ACCHOs and other settings (including correctional facilities)
2. strategies to increase the First Nations workforce in the delivery of ODT (e.g. Aboriginal Health Practitioners and ACCHO nurses)
3. extension of the PBS CTG program to include PBS listed medicines for opioid dependence treatment.

The PBAC may wish to respond to matters relating to access to ODT medicines and services for First Nations and other populations with specific needs progressed with advice for Government consideration and discussion with state and territory governments.

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Appendix 1: ODTP PMR Reference Group Membership

Name	Organisation	Capacity of Appointment
Dr Elizabeth Marles	General Practitioner Member of the Pharmaceutical Benefits Advisory Committee	Chair
Professor Kirsten Howard	Member of the PBAC Chair of the Economics Sub-Committee (ESC) of the PBAC Professor of Health Economics, School of Public Health, University of Sydney	Deputy Chair
Associate Professor Robert Ali	Discipline of Pharmacology, School of Biomedicine, Faculty of Health and Medical Sciences, The University of Adelaide	Technical Expert
Renae Beardmore	Pharmaceutical Society of Australia	Organisational representative
Dr Jonathan Brett	Staff specialist in clinical pharmacology, toxicology, and addiction medicine at St. Vincent's Hospital Clinical lecturer at the University of NSW and University of Sydney	Technical Expert
Dr Dawn Casey	Deputy CEO, National Aboriginal Community Controlled Health Organisation	Organisational representative
Professor Diana Egerton-Warburton OAM	Emergency Medicine physician	Technical Expert
Chris Gough	Executive Director, Canberra Alliance for Harm Minimisation and Advocacy and The Connection Health Service	Organisational representative and consumer advocate
Jason Harrison	National Secretary, Australian College of Nurse Practitioners Drug and alcohol Nurse Practitioner	Technical Expert
Dr Cameron Loy	General Practitioner Principle Medical Officer, Justice Health, Department of Justice and Regulation, Victoria	Technical Expert
Dr Annie Madden	Executive Director, Harm Reduction Australia	Organisational representative and consumer advocate
John Ryan	CEO, Pennington Institute	Technical Expert
Dr Hester Wilson	General Practitioner/Addiction Medicine Specialist Chair of the RACGP GP Specific Interests Addiction Medicine Group	Technical Expert

Appendix 2: State and territory policy on administration of long-acting (depot) buprenorphine*

STATE	Where can depot be accessed? i.e., clinic or GPs or pharmacies.	What is the cost to access depot?	Who can prescribe depot?	Who can administer depot?	Comments
NSW[100]	GP practices, public clinics, private hospitals or private clinics, dispensing clinics, pharmacy	Public clinics and bulk billing GPs- free of charge. Private, non-bulk billing GPs and pharmacies can charge what they wish. Pharmacists can charge what they wish to handle and administer.	Any medical practitioners who are not accredited OTP prescribers can manage up to 20 patients using depot buprenorphine	Any medical practitioner or nurse practitioner who is an accredited Opioid Treatment Program (OTP) prescriber can administer depot buprenorphine. RN's (or ENs) may administer Depot BPN in a community setting provided it is within their scope of practice Pharmacists can administer a controlled drug by injection when dispensed on a prescription lawfully issued by a medical practitioner, dentist, or nurse practitioner. "Injections should only be by an Australian Health Practitioner Regulation Agency (AHPRA) registered healthcare professional who has injection of schedule 8 medications within their scope of practice."	"Any medical practitioner or nurse practitioner who is an accredited Opioid Treatment Program (OTP) prescriber may prescribe depot buprenorphine as part of their patient limit of 200." Any pharmacy and "registered medical practitioner can obtain depot BPN from a licensed wholesaler on a signed and dated order (on the letterhead) of the medical practitioner. Provision is also made to order stock electronically or by telephone from a licensed wholesaler, providing that a signed confirmation of order and receipt of order is returned to the licensed wholesaler after delivery of the stock."

STATE	Where can depot be accessed? i.e., clinic or GPs or pharmacies.	What is the cost to access depot?	Who can prescribe depot?	Who can administer depot?	Comments
Victoria[101]	GP practices, public clinics, private hospitals or private clinics, pharmacy	Public clinics and bulk billing GPs are free of charge. Private, non-bulk billing GPs and pharmacies can charge what they wish. Pharmacists can charge what they wish to handle and administer.	Medical or nurse practitioners (patient limits outlined in comments column)	Medical or nurse practitioners, registered nurses, or pharmacists. In addition to required competencies, pharmacists must administer an initial LAIB injection under the supervision of a medical or nurse practitioner.	Practitioners (medical or nurse) can prescribe buprenorphine (SL or LAIB) for up to 10 patients without completing MATOD training, those who have completed MATOD training can prescribe to an unlimited number of patients.
SA[102]	GP practices, public clinics and private hospitals or private clinics	Public clinics and bulk billing GPs are free of charge. Private, non-bulk billing GPs can charge what they wish. Pharmacists can charge to handle. Pharmacists cannot administer. "A fee structure and method of payment by the patient for any cost for the supply of the medication will need to be determined and communicated with the patient as part of the treatment planning. Currently most patients are charged a dispensing fee and payment is made prior to dosing."	Accredited Drug and Alcohol Services SA (DASSA) prescribers for DASSA clients; medical and nurse practitioners who have completed the required MATOD and depot specific training.	Registered health professional only.	Medical and nurse practitioners can prescribe and administer depot Buprenorphine, after completing the DDU approved training: 'Theory - Depot Buprenorphine - SA' (This module has been included in the Theory component of the MATOD Prescriber Training Course - South Australia since April 2020. Those who completed training prior to this are required to do it separately.)

STATE	Where can depot be accessed? i.e., clinic or GPs or pharmacies.	What is the cost to access depot?	Who can prescribe depot?	Who can administer depot?	Comments
WA[28, 103]	GP practices, public clinics, private hospitals, or private clinics	One public clinic and bulkbilling GPs are free of charge. Private, non-bulk billing GPs can charge what they wish. Pharmacists can charge to handle. Some public clinics order through a retail pharmacy so there is usually a charge to the patient "A fee structure and method of payment by the patient for any cost for the supply of the medication will need to be determined with the pharmacy and communicated with the patient as part of the treatment plan. Most patients will be charged a service and delivery fee with payment made prior to dosing."	Medical practitioners that have undertaken training to become an authorised prescriber. Must be authorised by the Department of Health CEO and endorsed by the Director of Clinical Services at Next Step	Only pharmacies approved by the WA Health Department may dispense depot buprenorphine. Medical clinics are not permitted to order directly from the wholesaler.	Prescribers are subject to limits on the number of patients they can prescribe to at any time. Pharmacists cannot administer.
TAS	Correctional facilities, public clinics and aboriginal health providers and GP practices	Public clinics are free of charge.	Authorised prescribers. Completed buprenorphine training, Tasmanian Opioid Pharmacotherapy Program and depot buprenorphine training and have obtained a	GP's and nurses.	

STATE	Where can depot be accessed? i.e., clinic or GPs or pharmacies.	What is the cost to access depot?	Who can prescribe depot?	Who can administer depot?	Comments
			permit with Pharmaceutical Services Branch		
QLD[104, 105]	Public opioid treatment services, operated by Hospitals and Health Services (including correctional facilities), private opioid treatment prescribers and community settings	Public clinics and bulk billing GPs are free of charge. Private, non-bulk billing GPs and pharmacies can charge what they wish to handle.	Medical practitioners or nurse practitioners can be prescribers. Prescribers are required to complete training and obtain approval from Queensland Health before being able to prescribe.	Pharmacists can administer approved opioids by injection on a prescription. Currently the only approved injectable opioid is long-acting injectable buprenorphine. Depot buprenorphine can only be administered by Australian Health Practitioner Regulatory Agency (AHPRA) registered healthcare professional who has injection of schedule 8 medications within their scope of practice.	Pharmacists can dispense depot buprenorphine from an approved prescriber or sell depot buprenorphine on compliant purchase order to an approved prescriber.
ACT	GP practices, public clinics, private hospitals or private clinics, pharmacy	Public clinics and bulk billing GPs are free of charge. Private, non-bulk billing GPs and pharmacies can charge what they wish. Pharmacists can charge to handle.	Only prescribers in hospital and specialist drug rehabilitation clinics who have reviewed education materials may prescribe Depot BPN	For prescription-only medicines, pharmacists should administer medicines by injection under a collaborative arrangement with the prescriber, pharmacist, and consumer as per the PSA	Prescribers are required to obtain a Chief Health Officer approval prior to prescribing. Prescribers are required by ACT Health to obtain an endorsement to prescribe to more than 5 patients.

STATE	Where can depot be accessed? i.e., clinic or GPs or pharmacies.	What is the cost to access depot?	Who can prescribe depot?	Who can administer depot?	Comments
				Guidelines for administering medicines by injection	
NT[106]	Pharmacies (community and hospital), correctional services health centres; GP clinics, health centres, hospitals, Top End Health Services and Central Australian Health Service.	Public clinics free of charge	Any Accredited MP (see comments)	Any pharmacy and public clinic. LAIB must be administered by registered health practitioners.	Prescribers may apply to the CHO for limited authority to prescribe buprenorphine/naloxone, including buprenorphine injectable depot formulations) for opioid substitution therapy for treatment of addiction. Under this authorisation, Prescriber's may prescribe for up to FIVE (5) patients with buprenorphine/naloxone, including buprenorphine injectable depot formulations) preparations within a shared care framework with a CHO approved Alcohol and Other Drugs service.

* Literature review table updated in November 2022 to include PSA Summary of legal authority for pharmacist Administration of medicines by injection

Appendix 3: Report on consultation with people participating in opioid dependence treatment programs

Biotext

Creating great content

Post-market review of the Opiate Dependence Treatment Program

Consumer focus groups and interview report

6 December 2022

Contents

Summary

The Australian Government Department of Health and Aged Care is conducting a post-market review of the Pharmaceutical Benefits Scheme (PBS) medicines used to treat opioid dependence under the Opiate Dependence Treatment Program (ODTP).

A total of 106 clients of state and territory opioid dependence treatment programs shared their pharmacotherapy treatment journeys and experiences through focus groups and one-on-one interviews.

This report provides a summary of participants' perspectives, including what they found works well, what does not work well and what changes could improve the program.

Key findings

Experiences varied greatly between topics of discussion, but people's individual journeys through the program are rarely smooth.

Although the program has enabled many people to stabilise their lives, and to study or maintain a job – accessing it is difficult, and it is expensive, restrictive and complicated.

The treatment is most participants' top priority, over everything else, but managing its demanding logistics complicates many aspects of their lives. As one participant said:

> Managing your dependency is a full-time job.

Access

Access was a major issue for many participants:

- A shortage of state and territory approved pharmacotherapy prescribers means that some people have trouble getting timely appointments for their prescriptions or have to travel long distances. The expansion of telehealth has helped to some degree.
- A shortage of dispensers means that there are long waiting lists, and dispensers can decline to take on clients.
- Restricted access hours set by dispensers and the long distances some participants must travel to their dispenser affect personal relationships and employment opportunities.

Cost

Cost was a major issue for most participants:

- Few prescribers bulk bill and dispensing fees vary, so the cost of treatment takes up a large proportion of many participants' income.
- Although public clinics provide free treatment, they are often not a viable option for participants, because of distance and restricted opening hours.
- Participants prioritise paying for their treatment over everything else, because they struggle to function without it. This sometimes means they forego food or other critical medicines, or they get behind on rent and utilities payments.

Many participants said they wanted medicines on the program to be treated like any other prescription medicine, with a cap on pricing, a safety net threshold, and the ability to collect from any pharmacy at any time.

Treatment frequency

Frequent attendance during restricted hours and limited numbers of takeaway doses caused significant disruption in people's lives – many worked reduced hours or had to turn down job opportunities as a result.

In general, people with fewer interactions with prescribers and dispensers (those who had longer intervals between prescriptions, more takeaway doses, or monthly injections) had a more positive experience.

Autonomy and choice

Participants stressed the importance of having the choice of medicine type, and autonomy to manage their own medicines, because their experiences on different medicines varied greatly. But many had no choice in the type of medicine they received or felt pressured to switch medicine.

Impact on access to other medicines

Being registered on a pharmacotherapy program means that people cannot access other medicines when they need them, even for significant pain. Several participants had experienced major issues as a result.

Transfers

Participants found the process for transferring between states and territories to be complicated and stressful, and too often go wrong. Some participants miss out on travel or work opportunities to avoid going through it. Many called for a national system or better use of technology to simplify transfers.

Parallel support

Very few people have been referred to other support services, such as counselling, through the program. Many were afraid to seek other support for fear of punitive measures.

Stigma and relationships with prescribers and dispensers

The service provided by different prescribers and dispensers varied vastly. The relationships that participants have with their prescriber and dispenser make a huge difference to their experience of the program.

All participants who discussed the topic had experienced stigma and discrimination from members of the public, pharmacy staff and health practitioners, and many had faced privacy issues:

- At some dispensers, even if they are the first to arrive, participants often wait for their dose in full view of other customers for long periods until all other customers have been served.
- Participants felt they were seen as one-dimensional 'drug addicts/junkies' rather than people with health concerns. Needing other medicine is often seen as drug-seeking behaviour rather than a genuine need, and other health issues are sometimes not investigated or diagnosed.
- Some participants raised urine testing as being humiliating, stigmatising and punitive.
- Many participants felt that health practitioners and other staff needed more education about their circumstances.

Background

The review

The Australian Government Department of Health and Aged Care is conducting a post-market review of the PBS medicines used to treat opioid dependence under the ODTP.

The 3 medicines provided by the program are:

- buprenorphine (sublingual tablets, Subutex®, and modified-release injections, Buvidal® and Sublocade®)
- buprenorphine with naloxone (sublingual films, Subutex®)
- methadone (oral liquid, Aspen Methadone Syrup® and Biodone Forte®).

The Australian Government pays the full cost of ODTP medicines. State and territory governments are responsible for program regulation and administration, including:

- approving prescribers and dispensing sites
- enrolling clients
- regulating the prescribing, supply and supervised dosing of the medicines.

People in opioid dependence treatment programs do not pay a PBS co-payment, and there is no Australian Government subsidy for dispensing and dose management activities. Dispensers charge clients a private dosing fee, which can vary and does not count towards the client's PBS safety net threshold.

The majority of clients access their medicines from community pharmacies, but other dosing sites include public and private clinics, correctional facilities and other health services.

Read more about the review.

The focus groups and interviews

As part of the post-market review, the department commissioned the Australian Injecting and Illicit Drug Users League to coordinate focus groups and in-depth one-on-one interviews with clients of state and territory opioid dependence treatment programs from all states and territories. A total of 106 current and former clients took part.

The interviews, which took place in November 2022, aimed to understand the participants' experiences and treatment journeys, and get feedback on how the program has worked for them.

Participants represented various age groups (20 to 69 years) and genders (male, female and non-binary), as well as various population groups, including:

- First Nations people
- non-Indigenous Australians
- LGBTQIA+ people
- people living in metropolitan, regional, rural and remote regions of Australia

- people experiencing homelessness
- people experiencing chronic pain
- people recently released from prison or custodial settings
- people who had transitioned in and out of different settings (including the community, hospitals, prisons) and geographical locations
- people at different stages of their treatment journey, such as those who
  - had been in the program for a long time (some for more than 30 years)
  - had been in and out of the program many times
  - had successfully exited the program.

Appendix 1 provides a breakdown of participant demographics and characteristics.

Appendix 2 provides the questions and prompts used during the interviews.

The report

This report will be included as an appendix to the *Post-market review of the PBS Opioid Dependence Treatment Program medicines: report to the Pharmaceutical Benefits Advisory Committee*, which will help inform discussions about future options for the ODTP. It outlines the views and concerns expressed during one-on-one interviews and focus groups with 106 clients of state and territory opioid dependence treatment programs, including what they found works well, what does not work and what changes would improve their experience.

We have included many direct quotes from participants, because these most powerfully illustrate their experiences in their own words. To maintain the privacy of participants' and the services they use, we have removed any identifying information, such as names and locations.

We thank all the people who took the time to share their experiences and treatment journeys.

Constraints

The program involves 2 levels of government and has complex legislative requirements. Additionally, some participants access different types of health care and support from various health practitioners. Inevitably, given this complexity, some participants had limited understanding of how the program works, what level of government is responsible for what part, and what their dispensing fees paid for. The phrasing of some questions also led to some confusion, which is reflected in some of the responses. For example:

- many answered the 'supervised/unsupervised' question in terms of whether the pharmacists watched and timed them as they took their dose (to make sure they had taken it), rather than in terms of taking onsite or takeaway doses
- many answered the question about what would make the program more affordable with 'if it was cheaper/free', without expanding further.

Interview responses

Overall perceptions of the program

• What works well

Participants reported some positive aspects of the program, but these positives were often restricted by difficulties. For many, pharmacotherapy treatment provides:

- some stability in their lives, which enables them to work or study – although restrictions on dispensing hours and travel time can create barriers
- flexibility to choose a dispenser – although this was greatly limited by the number and availability of dispensers participating in the program
- flexibility to choose a medicine (and its associated frequency of administration) that suits individual needs – but many could not get the option they wanted.

> I went straight onto methadone, and it saved my life. Best thing ever. No problems with it. I took to it really good, and it's the best thing that happened to me. I dose every day. I haven't missed a day, ever. It's a routine for me. I've got nothing but praise for it. Life changer.
>
> It was a life saver for me, after getting a heroin habit and working 2 jobs just to support it.
>
> It's helped me stabilise, it's helped [me] get back into study. It's changed my life.

• What does not work well

Although there were some variations between states and territories, participants consistently raised common issues, including the:

- insufficient number of prescribers and dispensers and long waiting lists, resulting in participants either continuing to use opioids while waiting for a place, or spending a lot of time and money (for petrol or other transport) travelling long distances
- high and variable prescribing and dispensing fees – the only exception was the Australian Capital Territory, where the dispensing fee is capped and subsidised by the territory government
- requirement for frequent prescriptions and dosing during restricted opening hours, with no or very few takeaway doses allowed
- lack of national consistency, making transfers and travel extremely complicated, and often leading to missed doses
- lack of autonomy and flexibility for people to choose and manage their own medicine
- stigmatisation, discrimination and lack of understanding from health practitioners, as well as a power imbalance where participants felt doses are used as reward or punishment
- lack of privacy in many clinics and pharmacies
- pressure to switch medicine, and lack of information about what to expect when switching
- inability to access other medicines as a result of being a registered opioid user.

> We know people who have given up on the program because it's too hard, and it's sad because it shouldn't be like that.

Treatment access

Most participants first entered the program through a doctor and received their medicine through a community pharmacy. A smaller number attended public or private clinics.

In general, although more expensive than public clinics, pharmacies were the most convenient options.

> [Pharmacies] are generally easy to access. They're in your local community, often … A lot of pharmacies are open … decent hours, long hours, so you've got a bit of flexibility in how and when you collect your dose. You can establish a relationship with the person or people providing your medication. And that normalisation aspect of just getting medication from a pharmacy, like every other person in the world, so there's an element of … less stigma.

Public clinics were often not viable options because of distance or restricted access hours, or because of the poor quality of service provided.

> There is no [public] clinic either in [location removed] or in rural areas. Considering we've just had a new hospital built … that's a big issue for this community.

Participants appreciated the notion of being able to choose a prescriber and dispenser, but access experiences varied. Although some participants had been able to find a prescriber and dispenser without any trouble, many faced significant difficulties.

The fact that access to medicines on the program is managed differently from access to other medicines was seen as stigmatising and unfair.

> At the end of the day, it's a medication, and anybody can go and get their own medication, so why should this be any different. It shouldn't be, and we shouldn't have a limit on how many people can be dosed.

• Availability of prescribers and dispensers

Participants reported that dispensers often have long waiting lists, can decline to take on a client for any reason, or might require an interview to decide whether they will take on a client. Some participants also found it hard to make timely appointments with their doctor for their prescription. Those who lived in rural and regional areas, in particular, had faced access difficulties.

> At the moment, we have, I think, around half-a-dozen prescribers in the whole state and 2 public places where you can be prescribed … and a waiting list of up to 12 months. It's crazy.

> I'd have to take whatever pharmacist was willing to have a place for me.

> It's not a simple choice. I can choose as long as there's availability and it's in close proximity, and that's not always the case. There are some chemists unwilling to do it.

> It's this constant feeling of anxiety, I think, like what if this doctor stops prescribing or doesn't want to do it anymore, what am I going to do?

These issues meant that some participants:

- could not see the prescriber or dispenser they would have liked
- had to travel further that they would have liked, which cost them time and extra money
- continued to use opioids while waiting for a place in the program, despite wanting to stop using.

> Where I lived when I first started getting dosed, they only have certain capacity of people that they would take on, and that doesn't work. There's a lot of people in the community who have drug problems, and if you can't get dosed in [location removed] then you have to travel to [location removed], and when you don't have a licence or a way to get there, it makes it very difficult.

> I have to go all the way to [capital city] to get my monthly injection, because it's too booked up here. It's about 2 hours because I can't get any treatment here … they said that I'd have to wait 8 months … I couldn't wait that long.

> I wish there was a shorter waiting list. When people are waiting to get treatment, they need to get treated straight away, you know, not tomorrow, not in 6 weeks. But there is obviously not enough staff, not enough people treating it.

> You really need the support when you are in the mental state to want it. You often end up failing and falling hard before you can even get on the program.

> I'd like to see more places being made available, I'd like to see more places that dispense the drugs, more clinics being opened up. I'd like to see GPs being encouraged to take on people for pharmacotherapy treatment programs.

Many people have dropped out of the program, or were kicked out, and faced waiting lists to get back on again.

> I've been kicked off before, and I've been with a private doctor who kicked me off really quickly because I refused to do a urine or didn't do a urine in time, and so I was forced to go to [a public clinic] … Upon intake they told me there would be up to a 6-week wait, which made me bawl my eyes out, because I needed the treatment then and there … I had to use in that time to stop myself from hanging out … I actually overdosed after they kicked me off, for the first time in my life … I overdosed twice.

All participants who mentioned telehealth said that having the option to have phone consultations had made getting prescriptions much easier and, for some, had reduced travel costs.

> I've been on it 20 years, nothing's changing [in my treatment], it's so much easier [to have a phone consultation].

Opening hours

Access hours for pharmacotherapy clients varied greatly between dispensers.

Some participants said that their dispensers had long or flexible opening hours, which helped them maintain employment or study and generally manage their lives.

But many dispensers restrict the times when program participants can access their medicine. These windows are often when people work or take their children to school – such as after 9 am – which participants found very stressful. This caused significant disruption to people's daily lives.

> It's difficult trying to get there on time, especially if your life is unmanageable a lot of the time, like mine is. And having to go there every day... I have a car, but otherwise it's 50 minutes by public transport, so it adds up.

> At the public hospital, you've got to be before 10 [am], and in the afternoon, 1.30 to 3 [pm]. It's hard for work.

> The hospital pharmacy is a particular nightmare, because they're only open for half an hour and you've got to be there in that half hour.

For some participants, their dispenser's allocated dosing window had prevented them from accepting or keeping a job, while for others it meant working shorter hours than they would have liked.

> There's particular times... We're not allowed to come in after 5.30 [pm], and [location removed] open at 8 [am], but you're not allowed to go in until 9 [am]. I've had to quit jobs before, because you just can't get in to dose.

These restricted hours also affected participant personal relationships, especially for those who wanted to keep their treatment confidential.

> Unless your family knows you're on methadone, you've got no way of getting them to understand why you're late every time or why you can't show up until later in the afternoon. And often they take it personally and think you're just not willing to make an effort for the sake of your family, and then that fractures the family bonds which you're trying to maintain.

> The public clinic would make you go in on a public holiday. How are you meant to maintain family relationships when you're trekking in – it's 50 minutes on a regular day, how bad is it going to be on a public holiday on public transport? It's the whole day.

Eligibility limitations

Participants felt that signing up to the program should be quicker and easier, because when people are ready to seek help, they are often not in a state of mind that can cope with complicated processes.

> When you start, they make you jump through so many hoops, and at that time you're not a stable person to be able to jump through them hoops. I knew a girl who died of an overdose waiting to get on the program because of them hoops.

> I detoxed before attempting to start treatment, so I had no opiates in my system when I was first urine tested … I was told I had to have drugs in my system to be even allowed into the program. So I had to go back and use, and then wait another 6 weeks before the program would start, so I had 6 weeks of intravenous using until I was then starting on the program again. That was pretty disheartening to go through that withdrawal in that couple of weeks … and then be told, 'actually come back to us with some drugs in your system'. It was a really horrible way to go about it.

Relationship with prescribers and dispensers

Participants reported vastly different experiences with their prescribers and dispensers – some received caring support, while others reported being treated as second-class citizens.

The level of care and the relationship that participants had with their prescriber and dispenser made all the difference to their experience of the program. Several participants reported seeing a prescriber or dispenser that was not the most convenient simply to be treated with respect.

> I actually go to a chemist that's a bit further away from my house because they're nicer there. And I've stayed with that chemist for that reason … I had some bad experience in the past with chemists. They don't treat you very nicely when you're dosing. But this one does, so I like to go there.

> If you find a good pharmacy, you stick with them.
>
> I've got a lovely chemist, actually. They will see me pretty much straight away, and if they're going to be a while, they'll ask me to come back, which is fine, I'll come back. I've been going to them 9 years.
>
> It works great with the GP, because he understands me and I've been seeing him for over 10 years. So we have a really good relationship, and he knows what medications don't work well for me. I have to see him every 3 months to get my script … He was just very busy; being able to get in to see him was very difficult.
>
> This is a great little service … I think it's unreal … it feels good to come here, and that's the first [time], you know, of not worrying about being judged and all that.

Some participants said that the good relationship they had built with their prescriber or dispenser had resulted in added support and flexibility – for example, with opening hours, switching treatment or transferring interstate.

> All of them are really nice ... They've been really good with work. I can get [my doctor] to email across if I need to pick up early because of work. Because they open at 8 am and I start work at 8.30 am, so it's kind hard, so they've been really good in accommodating this.

Some felt that handling pharmacotherapy treatment in the same way as any other medicine and providing health practitioners more training and support would help address shortages, reduce waiting lists and improve quality of care.

Impact of COVID-19

COVID-19 infections, quarantine and lockdowns caused a lot of anxiety among participants, and the approach varied significantly between jurisdictions.

Some were able to access extra takeaway doses, while others were not.

> I get 5 takeaway doses a week. I was stuck at 3 for years and years and years, and they only gave me my fourth one because of COVID. Then I've been offered the fifth takeaway just recently.
>
> Through most of COVID, they just gave me a box of subbie strips for the month. I just rocked in once a month and it's how it should be. Stupidly enough, they can snap their fingers and, all of a sudden, I can pick up once, like a normal med … I didn't have to be late for work or run the risk of being late for work. Instead of having to wait half an hour, I could just go in there and get my box and go. It was funny how it just changed overnight, and then it changed back overnight, and now I'm back to normal.
>
> This changed with COVID. They were 2 months for a long time, then the doctor started giving me 3 months. It's better.
>
> And if they did [offer more takeaways during COVID], it would have been great, because my dad was dying and I felt really bad going to the chemist all the time, because I was bringing 'flus home. It was terrible.

Some had their doses delivered, while others had to organise other ways to collect their doses, which created privacy issues for those who wanted to keep their treatment confidential.

> I was in quarantine, and I had to get my brother to get it, but I didn't want my brother to know.

> I had COVID and I had to get somebody to go there with a licence to pick up my dose and take it to me. If I didn't have a mate that was kind enough and do it with a licence, which was hard to find... I had to pay him money. [I missed] 2 doses at the start, because I couldn't find anybody.

All participants agreed that the increased availability of telehealth appointments was one of the good things to come out of the COVID-19 pandemic, though not all participants have had access to such appointments.

End of treatment

Most participants had been part of the program for some years – some as many as 30 years – and many saw it as a lifetime treatment. Some said they appreciated not being under pressure to come off the program, as they did not think they could ever go without their medicine. Several people reported having been under pressure to exit the program before they were ready.

> I'm on a high dose, stable, very happy. I think I'll be on it for the rest of my life, but let's see.

> I don't think I know anybody that's actually ever gotten off it, which is a good thing, because it saves them from using, it saves them from crime, it saves them from a whole bunch of things.

> Some people aim to get clean, some people expect to stay on the rest of their lives.

Several participants said they had 'fallen off the wagon' at various stages to use opioids again, and they appreciated being able to return to the program, though many had to re-join a waiting list.

Others had gradually reduced their dose until they were able to stop treatment altogether. These participants would have liked to have this achievement acknowledged in some way and reflected in their medical records.

> An official congratulations at the end of the program – it shows the same as if you drop out … it's not listed differently in your records than if you spend 2 years reducing your dose and coming off it.

Treatment cost

The high and ongoing cost of the treatment was a significant issue for most participants. The only jurisdiction where participants did not feel this financial pressure was the Australian Capital Territory, where dispensing fees are subsidised by the territory government and capped at $14.70.

For many, the cost of treatment represented a significant proportion of their income, and, in some cases, was the reason they dropped out of the program. For others, their inability to pay led to punitive measures from their prescriber or dispenser, such as being taken off the program.

> [The cost is] huge at the moment, especially not being able to work long hours because you've got to get to the chemist 4 times a week. It's really, really, really difficult. It's a huge cost. I get $300 a week and $60 goes to my methadone. It's a big chunk.

> The cost impacts my life very much. I pay $50 … and when you've got $250 to see you for a fortnight, $100 taken out of that is quite a big chunk. And because it is your methadone, you have to pay, you can't cope if you don't. It's an absolute necessity.
>
> When I lived in boarding houses in Melbourne, by the time I had paid my rent, paid my travel to the chemist every day, and paid the dispensing fee, I had $15 left for the fortnight for food. Similarly, when I was in Sydney, because I was working, I had to get on a private clinic there … it was like $80 a week and that's a substantial amount of money every week to pay.
>
> Getting out to the chemist every single day is actually quite costly for me, because I've got to get petrol money, and my sister's car uses a lot of petrol. I can't just give her $5, that's only 3 litres of petrol. There is no buses here that go there.
>
> It is a struggle, absolutely. I've had to borrow from family to pay that. I'm only on a pension, so $40 a week is a fair sum. Obviously, the best outcome would be for it to be on the PBS for people to pay for it as a normal script.
>
> I know of others who wouldn't go and pick up their medication because they didn't have the $5, and that's not good enough. They shouldn't be not allowed to dose because they didn't have money.
>
> I've seen with friends and other community members that the financial impact, the cost of opioid treatment is a reason why they stop dosing, and they fall behind. They can't afford to pay for their dose. It gets too much. And so people end up coming off the program because of the cost.

Some participants acknowledged that pharmacotherapy treatment was much cheaper than illicit drugs. But many stressed it is not comparable, as the treatment is about getting their lives in order and paying for rent, utilities, food and other medication, and the added financial burden of the treatment could be demoralising.

> That $140+ a fortnight [for 2 people] was absolutely noticeable … It made times even tougher, it was really stressful, an added stressor … Bills accumulate … Being in active addiction, I wasn't very good with money, so there were some things owing, so the added stress of trying to get on track, you seem to always be just behind.
>
> When I first got on the program it was lifesaving, because I was spending I don't even want to tell you how much a day on morphine. So I was saving money, but then eventually, you get a normal lifestyle, where you're paying your rent again, you're paying your power again. [Previously] I was squatting in my own flat. I had no power, I never ate food, I had to do other things to try and get income in that weren't necessarily legal … When I was on the program, I got those freedoms back, because I was only paying $6 a day … When I got behind in the pharmacy, the pharmacist said to me, 'why can you not afford this when you would have spent way more money on drugs'. I was so shocked because 1. it's treatment, 2. now I can live a normal life. I can pay my bills again, I can go shopping, do normal stuff … I was only working part time. I couldn't believe someone said that to me. Would you rather I go back … to doing all kinds of other things to make it work?
>
> [They say,] 'how much did you use to spend on heroin?' Well if you could afford that, you can afford the $60 a week. The whole point of this is so we can change our lives, not so we still have to break and enter into people's houses and cars … That's how they judge the success of these, is by getting people out of crime … $60 a week for somebody on Newstart, you're not getting them out of crime … and if you're getting them out of crime, you're getting them into starvation, and that's not any better.

> It is a legitimate drug, it's a need. I'm 61, so I'm looking on being on the old age pension. It's going to really affect me then, because I won't be working at all. And I'm only working casually now. So, I do worry about it in the future.

Several participants said they would like medicines for opioid dependence treatment to be available free from pharmacies. Although public clinics offer free dispensing, they are often not a viable option. Many wanted the medicines to be treated like any other medicine on the PBS, with a cap on pricing, a safety net threshold, and the ability to pick them up at any time during opening hours.

> I definitely believe it should be on the PBS, because the people that are on it … we're coming from struggles. We're not coming from money. We're coming from the bottom of the rack. We're fighting from day dot. Then when we're trying to do the right thing, we're getting slugged with this huge amount of money taken off us.

> I don't really understand how methadone is any different to any other long-term prescribing drug. Our methadone is not counted [towards the PBS safety net threshold], even though it's $50 a week. So why is that not counted? We've always been told that methadone is given to the pharmacies for free. I do understand that they have to dispense it, so the bottles, the labelling, the time. I do appreciate that it is important that the pharmacies get compensated for providing the service, but I think that the government should offer some subsidies to make it more affordable.

> Prices of everything's going up … We can't survive paying rent, we can't survive buying food and everything else. It's a big problem when someone's trying to better their life and they have this problem of not being able to dose because they don't have the money … It should be like any other medication, any other script that you get, a cost of $6.80 … and that's all we should be paying for that.

> We're accessing a health service. You have a brain injury, you see the neurologist. You have a heart problem, you go to see that heart doctor. We're getting medication to treat a disease.

> At bare minimum, it should be part of the cap. It's a needed medication. It's like saying to someone with a with epilepsy, 'oh look, we're not going to cap your medication'.

> I've got a concession card. If I could pay like I do my antidepressants or any other, like $6.80 or whatever it is a month. But instead I'm paying $120 a month. I'm not even paying for the drug. It's funded by the government.

> If I could get a monthly script of $6.80, that would be brilliant!

> When I was on methadone, it would have been amazing to just be able to treat it like any other medication and [not have it] feel like a penalty … almost as though we're such a burden to the pharmacy that they've got to charge about 10 times what they would charge for any other drug.

> Under Closing the Gap, I get all my medication for free, but they wouldn't put that under Closing the Gap. It's like a service fee.

Cost of prescribers

Many participants could not access bulk-billing prescribers, so had to pay to see their prescriber each time they needed to renew their prescription – the timeframe between appointments varied greatly between participants, from every 2 weeks to every 3 months.

> Because I go to a private prescriber, that also costs me money once a month. No one bulk bills down here anymore, so I have to have at least $100 a month in my account to pay my doctor just to get a prescription once a month. So that's added on top of methadone.

The increased access to telehealth as a result of the COVID-19 pandemic had been beneficial to those who had accessed it.

Cost of dispensers

Dispensing fees varied between pharmacies. Some charge more for takeaway doses than for those taken at the pharmacy, and others charge a dispensing fee for each day, even when participants picked up takeaway doses only twice a week.

> If you miss a day [of dosing], they still charge you the $5 to 'keep your place'.

> You go in and get your takeaways, and you get charged for 5 days of dispensing fees, but they only dispense once. That's my pet peeve – don't charge us for days we haven't come in.

> I'm in a regional area, and it's a 90-kilometre round trip, and with the price of fuel, it's ridiculous. And then it's $10 a day [dispensing fee]. I only get a couple of takeaway doses. How they come up with that $10 for 5 minutes, I don't know... Nobody else has to pay for dispensing. I don't understand what we're paying for when the actual drug is free.

> It's just unbelievable to me that there is no cap on how much a pharmacy can charge... There should at least be a cap and it should be the same as any other prescription that you're paying for.

The consequences of cost

Participants said they prioritised paying for their treatment over everything else, because not having it made them sick and they struggled to function without it. This sometimes meant they had to forego food or other critical medicines, or get behind on rent and utilities payments.

> I go without my other medication. I make my 2 other medications last twice as long as they need to, just so I can have the one that's most important, so that I don't miss doses, so I don't start feeling sick. I don't get the full range of medication that I need, because one of them is so expensive that it stops me being able to afford the other ones.

> I buy less food, and I don't buy any luxuries, none, not even a packet of biscuits.

> Sometimes, it's like food or methadone. And it's obviously got to be methadone first.

> I do work, but only part time, and I'm on a low income... I have to have that medication, because [without it] I can't work, and if I can't work, I can't get paid, I lose my job, it's a round circle, and I've gone without other medications, because this is the one that affects me day-to-day the most, it has the most physical effects … If I miss my other medications, I'm in trouble too, but this is the most noticeable. I've gone without food, I've been late on my rent, I've gone without power … because [with it] I can function. If I have to deal with everything else on top of the fact that I'm in withdrawals, then it all becomes too much.

> I've struggled to pay for my dose each week and pay for food sometimes.
>
> It's the first thing I pay before I buy anything. My rent comes out of my pay, so what's in my account is mine, so I go straight to the pharmacy and pay my bill.

For others, the cost means that they do not follow a regular treatment schedule as prescribed by their doctor.

> I can't afford to dose the way they want me to. So one of the ways that I've found is by switching to alternate days and then asking for a higher dose. I pay less money, because it doesn't matter the amount you're on, the cost of the dose is the same. I cut my squares really small and I take one every 6 hours.

Dosing frequency

The vast majority of participants said daily attendance during specific times of day restricted their freedom greatly, affecting their ability to work, study or travel or to take their children to school. Many called it the 'liquid handcuffs' or the 'ball and the chain'. They preferred the relative freedom of takeaway doses or monthly injections, but not everyone has these options, and many felt that takeaway doses are used as a form of control.

> I was offered a wonderful job, but I can't do it because it's working away 4 days a week, which really sucks, because you only get 3 takeaways a week, and you can't have them consecutively. In the country, it makes it so hard, and I've missed out on so many opportunities, and it's a big reason why I'm still on the dole.
>
> I just couldn't keep making these appointments with the fishing as a job, so I had to let it go ... Do I keep my job or do I lose my job and stay on the program? So it was a predicament to be in.
>
> It's so hard to tell your employer, I've got to go to the chemist, I've got to get an hour off to get me dose.
>
> I understand where they're coming from with giving you just 3 [takeaway doses] a week, but when you're working, you need those couple of extra ones so that you can just get up, dose, go to work, get up, dose, go to work.
>
> Dosing [with takeaway doses] every 2 weeks would make a big difference to my life. My aim is to get down to 30 to be able to get on the Sublocade. My partner being on it, he works away a bit, and he can just pack up and go. He's only got to worry once a month to have his injection. If they did that with the methadone as well, that would be awesome. Even once a week would help.
>
> I like to go bush. I like to get out of town, go camping, take the dogs and the kids fishing. You just can't do that when you're on the program, you're trapped in town.
>
> They don't give you credit for the progress you've made.

For some, the daily attendance is a reminder of their situation and hinders their progress, which can have flow-on impacts. Many said that not having to attend so frequently helped to change their mindset and to remove themselves from detrimental situations and people.

> When you've got to go every day, it's hard to get that out of your lifestyle. The drug taking is still huge part of your life. You can't develop a more normal life, you know, around other things, around work, around anything else.

> The thing about going to the clinic every day – it reminded me every day that I was in treatment for a drug addiction. It reinforced that. Now you can forget about it… Being able to devote the time to [dealing with my trauma]. I'm not stuck on that 9 and 11 timeframe.
>
> Some people don't want a reminder that they have to dose every day. So they prefer the jab [long-acting buprenorphine injection].
>
> It helps get your head out of the whole illicit drug mindset. I have to go to [name removed] every 3 months and walk under that sign where it mentions addiction, and for that day, I'm a drug addict again. Luckily, that only happens once every 3 months. The minimal supervision regime has freed me from this whole mindset. I don't see people with drug problems by chance at the chemist anymore. If you go every day, that part of your life remains active.
>
> With contact with the clinic, I'd rather as little as possible … only because … when you're trying to get away from that lifestyle, and you're standing in line at the clinic, and all you can hear is, '… you got any pills, or you got any Xan, do you know anyone who's got takeaways, do you know where to get heroin from?'
>
> When I didn't get any takeaways, it was so hard to separate yourself from the drug-using culture mentality, because you're spending every day with other drug users and you can't get away from that.

Daily attendance can also cause major issues in cases where dispensers close unexpectedly.

> During the floods … the pharmacy was closed for 3 full days and there were people who were in the methadone and the subbie program sitting out in front of this pharmacy waiting. They waited 3 whole days. They came back in the morning, they came back at night... these poor people were withdrawing for 3 whole days. During that storm, nobody contacted them to let them know what was happening with their dose, nobody [cared], and it was so heartbreaking to me, because I could see how sick they were … I couldn't believe that that was allowed to happen.

In general, those with fewer interactions had a more positive experience of the program.

> I was at a public clinic for a really long time going every day, and when I switched to a chemist and I was only going in once a week, it was a massive difference, a massive weight off my shoulders to not have to worry about getting to the clinic before closing time each day, and a lot more freedom.
>
> With takeaways, I'm able to study. I'm doing some courses part time, and there'd be no way I'd be able to attend the classes if I had to go and pick up. It's a kind of freedom to live your life and live freely for a day or 2.
>
> It's a lot more convenient with the takeaways for work. Because I'd have to stop [work], and then drive across town and drive all the way back, and there's 2 hours.
>
> I've got my life back [with the monthly injection]. I can like do things like spontaneously go away for the weekend. I don't have to worry about having to come cap in hand for takeaways.
>
> Not going to the clinic on a daily basis, that allows me to do other things, specifically volunteer my time and work on aspects of drug law reform. I like the fact that even though it's a 28-day injection, I can play around with that day – a couple of days beforehand or afterwards, I'm not going to go straight into withdrawals and the clinic so far has had no issue with me going in late.

> I'm on a monthly injection. It allows me to do other things. Being able to do those other things has raised my self-esteem somewhat. And by raising my self-esteem, it has encouraged within myself to start going to the dentist a little bit more, to take care of my arthritic hip, to look at getting some treatment for the chronic pain and back injuries I've been carrying for 15 years – self-care.
>
> When you're not going to the clinic every single day, suddenly you've got a bit of time. So, you've got time to go to the dentist.
>
> I'm on the minimal supervision regime so it is quite easy for me. I see the doctor every 3 months, and I fill the script every month, like a normal medication … I couldn't imagine going back to the old way. I'd probably be more likely to go off it, to be honest. It's really the reason I'm still on buprenorphine. It's half price, so I pay $60 a month. When I moved onto this, it became very easy. I just wake up every morning and have my dose … It really is as simple as pie.

Participants felt that once they have been on the program without any issues for a specified period, they should be allowed more takeaway doses if they wanted them.

> If you're actually not abusing it, and they know, because they see you every day … If he's been on the program for 10 years, he's never [messed] up, you should be allowed to have takeaways … I know a lot of people on it, and they're restricted in going … anywhere. They're handcuffed to their central location, and if they want to go anywhere it's a … hassle, you know, like just to go away for 4 days, they can't do it.

A small number of participants did prefer supervised dosing because it provides a routine and some accountability and prevents problems.

> For a long time, I wasn't using methadone properly. I was skipping days – that was when I was at a private chemist. So it was good to have the option to have the [daily] dose … now I'm at a public clinic and I'm consistent. I go there every day, and that's like extra stability … It stops me getting in trouble with myself.
>
> It took me years to be stable, and to go to the chemist every day, it's my routine, it's my outing. Supervised dosing helps you do the right thing. It's hard to do the right thing.

Many participants said that reducing the frequency of prescription renewals would also be helpful, to save on the cost of consultations and, in some cases, travel as well as time.

> We went from 6-monthly check-ups with our prescribing doctor to 3 months, and I think that should be on individual cases. Because someone like me who just cruises along, nothing really changes. I'm quite stable, so I don't see why I have to go in every 3 months. And it's all a bit like, 'hi, how are you going', and it's done. But I understand there are other people who are different.

Treatment choice and changes

Reactions to different treatments

Physiological reactions varied when switching medicine, or even when using different brands of the same medicine (such as the different types of methadone), with participants:

- finding some treatments to be ineffective
- experiencing significant side effects from some treatments
- finding the experience to be difficult and unpleasant.

> I went from methadone to the bup strips. I just had to miss one day of dosing. Within the hour of having it … I had a bit of energy. I could do things. Then tried the Buvidal shots. I went from weekly to the monthly, but it didn't hold me. It just didn't work … I told my doctor, 'I want to go back' … she did it straight away, no problems.
>
> I was on Suboxone for years … I got such bad anxiety … and I ended up going back onto methadone, and my anxiety went, but my depression came back … I can't quite figure out, is it better to have anxiety or is it better to have depression?
>
> I tried Suboxone and didn't like it. It didn't carry me. I found I'd have to go too high. I was on 18, and that should be enough for anybody. But it wasn't holding me.
>
> I went from methadone to Suboxone strips, and I found it quite hard. I don't think I could have done it without quite a few Xanax. I wasn't sleeping at all. They ended up putting my dose down … then was able to get a bit of sleep. It was not pleasant.
>
> I initially got put on Subutex. That was giving me mouth ulcers. So they put me on the methadone.
>
> I tried bup, but it sent me straight into precipitated withdrawals. My body just couldn't deal. So I jumped back on methadone.
>
> It felt to me like the effect of bup was stopping my native endorphins from working. I just felt like I was living with no endorphins in my system.
>
> [Switching was] horrific – they changed me from methadone to buprenorphine, and I had to come down to 30 milligrams of methadone from 65, to then jump off that onto bup, which put me in precipitated withdrawal, and it never left me. I was so sick for 3 months and went right down to point 2, but then I started using again and they put be straight back on methadone.
>
> When buprenorphine began to be prescribed, I was more happy to go on that, because methadone doesn't agree with me very well. It has a much worse effect on me than heroin.
>
> Even preferences between the 2 types of methadone – one will hold one person and not the other, and vice versa. That's why choice is so important.

Choice of treatment

Participants stressed the importance of having a variety of pharmacotherapy treatment options and allowing people to choose the treatment that worked for them, because not all treatments suited everyone.

But many participants had not had a say in their treatment. The types of medicines and doses that health practitioners choose to prescribe vary between jurisdictions and practitioners, and some settings (such as prisons) have only a single option.

> People wanting to get onto methadone up here are not able to. They have to go to [location removed]. I do know people very close to me who have tried, and even though their habit was out of control, [the clinic] said, 'no, you have to go onto the strips', and that doesn't work for everybody.
>
> Their desire to have everybody on bup or Suboxone could be changed. Methadone is a great treatment. It works for a lot of people. They could be a little bit more liberal about prescribing it instead of arguing with the patient. It's supposed to be the patient's choice. If you ask for methadone, it's an argument.
>
> In terms of going up and down in dosage, they make that very difficult too. It's taken me years and years to reduce as it is, and any time they would think there was the slightest hiccup, they would put me back up. I'd go through months of reducing, and then they just put me back up.
>
> When you say you've got side effects, [you need] options as well. When you say this is the issue … all you're told is, 'you haven't got any other options, so suck it up'. I don't want to suck it up anymore.

Several people said they had felt pressured to switch medicine – particularly to the monthly injection – whether they wanted to or not, and they did not feel like they could say no. Some participants felt that there was a push to eliminate methadone from the program.

> Our local AOD [alcohol and drug service] is the only prescriber, and you have to fight to stay on methadone there. They want you on subbies, and then once you're on subbies, they want everybody to be on the injection.
>
> My GP was putting me under a bit of pressure to switch over to the monthly injection … [inaudible] 3 times to switch over. All 3 times I left … It just wasn't for me.
>
> I was on Subutex originally, and then they wanted to put me on Suboxone, I was like '… no', because that's another one that punishes you when you stuff up, and I'm totally against that. I find that reprehensible that the government is making people take something that can possibly make them incredibly sick … as a punitive measure.
>
> I don't want to have to fight for it. I don't have the fight – especially with that authoritative figure and that different power dynamic – to fight for my rights and stay on what I want.
>
> It's really hard to stand up, because they're holding your life in their hands. You argue with them and it's not going to end well.
>
> They harass me to get this injection that I don't want. And everyone who's tried it says it doesn't work, and they're back after a week. I just want to be left alone. I don't do the wrong thing. The whole point of this is to get away from needles.

> People don't have time to be sick and go through that – they have kids, they have jobs. If they're happy with what they're on, they should be left alone. I want to be left alone.
>
> [Public clinic] wanted me off methadone on Suboxone, and because of my prior experience in detox – even after 48 hours being off methadone I would go into precipitated withdrawal – they had actually written on my chart not to give this patient Suboxone, but they refused to hear me out on that. They want me off methadone for whatever reasons. I have no idea.
>
> There is a real push to get rid of methadone, you can feel it wherever you go. But people don't want a blocker, which is going to muck up your surgery when you're in hospital.
>
> I've never tried those other medications, but I'm scared. The way it's going is that people are getting forced or very firmly encouraged to be on the long-acting injectables or Suboxone, and it's really distressing.

Several participants said they were reluctant to try other treatments, because they were worried about the side effects and that they would not be able to go back to their original treatment if the new one did not work for them. The monthly injection was a particularly difficult leap for people, because its effectiveness varied greatly.

> It's a game changer, these injections.
>
> Since moving to the injection, it's easy, once a month, and even if you go 2 weeks past, up to 6 weeks, you don't feel like you're withdrawing, it's very subtle. You don't have to go right on 4 weeks.
>
> Injections sound like a good idea [for travel]. But I wouldn't want to take something that I can't get out of my body if I don't like it, because I had that bad experience with naltrexone, and I thought thank god I didn't take the implant. It was horrible. It was like an exorcism.
>
> Coming off methadone is the worst out of all, so I don't want to be on methadone again. With the monthly injections, they were quite good … maybe at first. By the fourth week … you might feel it a bit, but the more you've been on it, then it just doesn't work at all.

On the other hand, some who did want to switch to the injection – because of the cost saving or freedom from daily doses – could not do so because of other medicines (such as gabapentin) they were taking, or because their daily doses were so low.

Moving between treatment settings

Participants had vastly different experiences the various treatment settings they used.

> I found the environment of a lot of dosing clinics, the look and the feel and the vibe of them to be horrible, stigmatising places, cold and clinical. You can tell that there's not a lot of money being invested into it, no effort into keeping them looking even half decent. Some of the dosing clinics that I've dosed at have been kind of just horrible cold rooms, really dirty wall. It feels horrible, all plastic chairs with broken legs and rips in the seats. The physical environment can really impact how you feel about yourself.
>
> [Going from a public clinic to a private clinic] was like being free from having been in shackles. I went from getting one takeaway a week to coming in one day a week. And plus, they're much nicer too, they help you out more.
>
> Even going to public pharmacies from the clinic. I found there were issues with procedures. At the clinic, you can go in and go, 'I'm on 60 a day, I'm finding it a bit much, and I want to go

> down to 55', and they go, 'sure'. Try doing that at the pharmacy, and they go, 'you've got to go see a doctor and get your script changed if you want to go down 5 mil'.
>
> Some pharmacists and some pharmacy staff are very, very stigmatising. And they will make you wait for your dose even if they haven't got anything else to do, they'll make me wait as a matter of course. At the public clinic you don't get that.

The experiences of participants who transferred from one setting to another – such as community, prison or hospital – varied greatly. Some participants had a very smooth transition, but most faced some issues, and many missed some doses until resolved.

> I've been released from jail twice to [hospital name removed]. The first time, they didn't want to dose me, they carried on. I got dosed the next day. The next time I got out, I had [jurisdictional agency] there the next day to make sure I got dosed, and everything went smoothly.
>
> I've been to jail and just had to detox. When I went to prison, I was on the program, but hadn't dosed for 3 weeks, so I got kicked off the program and just had to detox … They could have put [me] back on the program there, but they didn't.
>
> I went in hospital, and they were pretty helpful. They got onto it straight away. And it was good actually, because I didn't have to pay for it.
>
> I think the hospitals are getting better at saying, 'okay, this person is on methadone, we need to get that sorted now'. The day I leave hospital, the hospital usually dose me, then the next day, I just start back at my pharmacy.

Although the process seems generally smoother going from the community into hospital or prison than going back into the community from those settings, it often meant switching dispenser or treatment type, which is a difficult process.

> When you go to jail they put you straight back on methadone, because they don't do suboxone in jail anymore, and when you get out, you have to switch back again. It was annoying because methadone is not a good substance … it's a lot harder to get off. I had to go into the detox unit to do that, because every time I've tried to do it on my own, I can't last that period of time. I'm too scared of rapid withdrawal, then you start using again.
>
> In [jurisdiction], if you transition from the community to the hospital, it's mandatory, your script gets transferred to [the public clinic] and we have a lot of people who aren't at the [clinic], because they've had issues with them before. And so they're forced to go back to this service where they've had problems with, and it always goes downhill.

Travel and transfers

Participants raised the lack of consistency and coordination between jurisdictions as a major issue, with many calling for a coherent national system or better use of technology to enable smoother transfers so that people can continue their treatment uninterrupted.

> Wouldn't it be fantastic if they used the technology, and [you] could walk into any methadone-dispensing chemist and they jiggle the keys, pull up the database, 'oh I see you're dosed here'? They've got this script program that makes sure that we're not doctor shopping. How about using that for someone's benefit?
>
> You could have a card with a barcode on it, and if you go to a chemist, they scan your card, and it tells the pharmacist your dosing details, so that you can be dosed and be on your way.

There is really, in this day and age, no reason why it shouldn't be a smooth process.

A national dosing database could be helpful, a completely linked-up system where it doesn't matter where I am in the country, I can rock up to a dosing pharmacy … and get my dose from that pharmacy … there's a list of pharmacies that I can access online that I know dose and I can go to wherever I am in the country … and they log it on the system and they have all the information they need about me – photos, identification, amount of dose that I'm on, my personal details, when I last dosed … and then that's registered in the system that I've dosed for the day. I might be in a different town on another day, but it doesn't matter, because we have a nationally linked system. That would be my ideal.

Consistency across jurisdictions, and the federal government should be leading on this. They have retina scanners, but they're not leveraging this to make it easy for consumers.

[To travel,] I have to make a physical appointment with my doctor, and go in and have my script altered. It's just another appointment. But I think you have to prove you're going. Sometimes they might want to see plane tickets. It's red tape you have to do every time you want to travel.

When I moved to [location removed], I had to start again at [the public clinic] for about 6 weeks to establish my credentials. They said you're going to have to go to the [clinic] first [to dose] to prove that you're a stable client. It was the bus from [location removed] to [location removed]. It would take a couple of hours; it wasn't particularly convenient, but you didn't have a choice.

It is a jurisdictional thing. But the idea that, when you come in from another jurisdiction – even though you might have 10 years on the program, and even though a doctor in [this jurisdiction] could just pick up and talk to your doctor to find out if you're stable or not – you have to go to this public clinic … and prove yourself. Now what other health service do you have to prove yourself at?

The process to transfer between dispensers, especially when travelling interstate or overseas, was described as lengthy, complicated and rigid, and is an extra administrative burden for health practitioners. It was rarely smooth, though experiences did vary, depending on the support provider by health practitioners.

It's half an hour of phone calls and waiting for them to bring me back because I won't get through. They'll take a message, then they'll bring me back, and depending on if I'm at work and talking to people, well, I can't grab the phones. I'm going to have to play phone tag just to organise something stupid like 2 days' worth of dosing.

[Original doctor] had to fill out an amazing number of paperwork. He was up doing it at 8 o'clock at night for me … They buggered up my dose too, and I didn't realise. I was on 3, and now I think I'm on 6. So now I'm on a higher dose than I was back home ... I think they just stuffed up.

I couldn't see the reason why my doctor over there had to go through so much crap … why his qualifications and his 50 years of being a doctor with so many letters after his name [wasn't enough]. It was us and them, like another country. To simplify that part of it really needs to happen … It shouldn't have been that hard.

I wanted to go to Sydney where my family was, and I wanted 2 weeks for a big family reunion down there … they wouldn't give me more than 4 takeaways. They don't know you from a bar of soap, they don't know your story. And they have the control to tell you you can't see your family at Christmas time.

> I often travel for work, and I've got to be right on top of it, because it takes a week or so to get all this stuff arranged, and then it's all absolutely locked in. I can't change days.

> I went from a private doctor to [a private clinic] because I had to for work, because I was working out of town everywhere, and the doctor got sick of doing my script transfers. It was a lot easier, a lot more convenient. It was just a phone call for them, whereas when I was doing it through a private doctor, I had to take a letter from me employer.

It seems common that paperwork from the exiting dispenser in one jurisdiction does not go through to the new dispenser in the other jurisdiction in time for the next dose.

> The number of times that we find that there is some issue. The pharmacist hasn't been notified, and you think you've got everything sorted out, and you rock up to the pharmacy and they've got no paperwork and no idea, and it's a Saturday morning.

> I'd have to land, and find a way to the chemist that same day, and then to be told … we haven't received the form from the health department yet. When we do, we'll let you know, but come back around 6 or 7 o'clock just before we close, and there was that gap, and then you won't get dosed today.

Quickly finding the right pharmacy on the first day within opening hours in an unfamiliar place is another stressor, especially for those who don't have a car. It also causes privacy issues for people who want to keep their participation in the program confidential.

> You're in a new city, and if you don't have your own car, you have to explain to your friend, 'guess what, while I'm staying with you, can you please just drive me to the chemist every morning about 9 o'clock and then drive me back. And it has to be this particular chemist, not the one closest to your house.'

> When I was at the public clinic … they'd transfer me, and I'd have to – in that new city – I'd have to try to find that chemist and try to make sure I got there, and that was a hassle. Since I went to a private prescriber … I haven't had any trouble getting takeaways.

> It shouldn't be state by state. It should be national. Going to Darwin, they had to exit me off the public clinic – totally out – and then get to Darwin and enter their system. And it's really scary, because you're travelling interstate and you're not on a program anywhere, and it's like, what's going to happen when you get there?

> I didn't let my friend know I was on it, and then when went up to her place and then had to drive her car, because I went by train and then her chemist knew.

> I had some friends who wanted to travel around Australia, and their family didn't know, and they had to organise a schedule of chemists and plan every stop and sneak off.

While takeaway doses can help with interstate travel, their maximum number is limited, not everyone is eligible for them, and participants commented that methadone bottles can leak or break during air travel, because of air pressure changes.

> I usually organise my travel to start on the day that I pick up my takeaway doses and get back in time for my next dose at the pharmacy.

Several people mentioned they just did not travel, as the process was too hard.

> I have passed up opportunities to go away for a week or 2, because of the hassle of it.

In some cases, people had to find other solutions so they could travel or keep jobs that required interstate travelling.

> I was on methadone, and because of that job that was taking me interstate, it wasn't a situation where I would know that I would be in Queensland for 2 weeks or New South Wales for 2 weeks, it could be ad hoc, so I couldn't organise a pharmacy to go to. So I asked for as many takeaways I could get, which was 3, and I filled up a bottle with water, and I detoxed myself by just having a swig every now and again when I was feeling uncomfortable, and made it stretch. So I'd go the next few weeks detoxed myself by having a swig at the bottle. I would push myself to the limit before I would get to the bottle swig stage. I had to suck it up, princess.

Need for support and information

Many participants felt unprepared, uninformed and unsupported during their treatment journey.

Some said they had not understood that the treatment would be long term, and potentially lifelong, or that methadone was, for some people, harder to withdraw from than heroin.

> I [was] looking for anything to help me. I didn't actually know that methadone was something, when I first went on it – this was 30 years ago – that it was for life, essentially. It seems really naïve now, but I was not really part of the drug community. This was a big issue for me, and in some ways it still is. I've got a bit of anger about that. I thought it was something to help you get off … I didn't realise it was just to maintain.
>
> I've been on it 20 years. I thought I was going to be on for a year, maybe, get it under control, and then I could drift off [inaudible]. They don't tell you.
>
> At the old clinic, someone had scratched on the doorway, 'methadone: life sentence'.
>
> To transfer over onto something that's legal and subscribed, the doctors and nurses need to be a bit more explanatory towards the patient on how long their recovery is going to be … and the shortest term possible for them to come off it and be normal and not need methadone.

Some participants said they had never been told important information, such as how to store takeaway doses or the fact that people who are adjusting to new doses are not allowed to drive.

> When I did my switch, I was driving in every single day, and that was the worst bit because I was … hanging out. It was stressful as well. Getting the bus and the train would have been way worse, though.
>
> There is all this assumed knowledge that they expect you to have.
>
> I always feel like we're supposed to know [things] we don't know.

The need for information and ongoing medical support was highlighted as being critical to achieving long-term health goals, to successfully switching medicines or reducing doses, or to working towards exiting the program. Many had never been told how to do so.

> I've never been given a care plan, and that's something that should be a must.
>
> Focusing on your 5-year plan, I think, is a good thing.

> I think I could have probably gotten off methadone a long time ago if they had helped support me more in terms of reducing [my dose] and having faith in me.

> I went on the bup when they first brought it in. I had been on methadone for 10 years. It was very odd at first. It was a bit uncomfortable. Wasn't really doing much. I tried to stick it out. I spoke to the doctor and he said, 'you have to get used to it, you're feeling normality for the first time'. After about a month, 6 weeks, I went into the doctor and I said this thing isn't holding me, I'm uncomfortable, I feel like I'm on dirty speed, I'm edgy, I'm tense. I know a lot of people who have had this. But the doctor kept going, 'oh we'll put you on a higher dose', then I'd go back in a fortnight and say the higher dose isn't working, and he'd say, 'oh, we'll try you on a lower dose'. I kept going, 'please this is really uncomfortable'. After 6 to 8 months, I just stopped. I had to go into the clinic and say I need some methadone or I'm going to throw myself off the roof. It was shocking.

> It's an important, an integral part of the changeover. You need to be listening to what the person is saying, because that person knows their body better than anybody else, doctors included.

> Moving from one treatment to another is very difficult … especially methadone to buprenorphine. People who have been abstinent from drug use for years, and the changeover has been so rugged, in terms of they've gone into precipitated withdrawal when the doctor has said that they won't, then the doctor is unavailable, and you need them right then and there. If you take that Suboxone tablet and things are starting to go bad, you need to go, you need access to the doctor, and in a lot of cases, the doctors aren't available. And, actually, we've seen a lot of cases where the person has ended up back on heroin because the transfer has been so difficult.

> If you are going to transfer someone from one medication to another … it's really difficult, and you need medical help, you need access in a timely fashion during that period, and that's almost impossible.

> If you have a good doctor, like I had, that made the world of difference of how I coped on the program … wanting to stay on it, and wanting to do better. He's always encouraging me … and I think that's worth 1,000 words, just that consultation.

> When I was given information about switching over, it was all glory stories … so simple. And when it wasn't simple for me, the staff were saying you're obviously not committed, you don't care. That was frustrating. A little bit more patience from the staff to understand that some people will try, but it may not be the right thing for them to do.

This was not the case for everyone. Some participants had a smooth transition and felt well supported, which highlights the importance of people's relationships with their health practitioner.

> Everyone that I have been associated with in the whole methadone, Suboxone, Sublocade process has been wonderful. I couldn't have asked for a more seamless transition for me, especially being so afraid of coming off the methadone.

Many participants said that having more peer workers with lived or living experience involved in the process would help ensure they had access to realistic information they could trust.

> They're missing peer workers … people who have actually had addictions, instead of people with degrees talking to you and telling you everything. A person with actual lived experience would be awesome.

> People can't explain what they haven't gone through.

> I would feel much more comfortable ringing up and talking to a peer worker, rather than a doctor.

> I always wanted to know when I was talking to someone, did they know from experience? I could get the precipitated withdrawal on an academic level, but I wish someone had told me, 'hey, what it's going to feel like is: third-day withdrawal [inaudible] cold turkey, but in a couple of hours, you'll be fine' … it would have prepared me better.

Parallel support

A few participants – mostly in New South Wales – had been referred to counselling, dental care and other health practitioners to treat other health issues. This seemed highly dependent on the participant's health practitioner. For some, the referrals led to further assistance, including help accessing income support, education support or housing.

> The doctors at the clinic, you get to talk to them about other things as well as the program itself and how you're going on that. They have given me support… Dr [name removed] went to bat for me when I was refused … for housing when I had bowel cancer … He was so outraged, and he got on the phone and rang the [name removed] office and spoke to the person who was the author of the letter; it was almost embarrassing to sit opposite while he tore strips off them. And by the end of that phone call, they changed their mind and I've been given a place to live.

> They've seen that I've been struggling with psychological issues and they put me in contact with the psychologist that works next door.

> I was at a public clinic, and referred to … infectious disease care for hepatitis C at [the] hospital. That was in the dark old days, my life quickly fell apart, and other services became involved all through the hospital. So in a roundabout way, that referral to the hospital got me access a whole lot of other things like a psychiatrist, which got to the bottom of my PTSD and depression.

The vast majority of participants, however, had never been referred to other support services as a result of their participation in the program, or had just been given resources to find their own support.

Some who accessed the program through their GP said they were able to discuss any issues during those consultations, while for others, it was not an option. Most people accessing the program through clinics said their consultation was solely about accessing their pharmacotherapy treatment.

> Our current doctor just says, 'I don't do anything else. I will not talk to you about your heart, I'll not talk to you about your mental health, I will not talk to you about your physical health, I will not give you a script for antibiotics. If you've got the flu, I don't want to know. I'm just here to do your script and that's it'.

> [Following cancer treatment and complications causing pain] Not one person came to my aid and said, 'this is what we think you should do'. No one would measure my pain, no one offered me any assistance … I have to buy my pain killers off the street. But they've got me on Biodone, they're not offering me else but Biodone, and I know [the clinic] are part of the pain specialists, but no one's done anything for me. And I still have the radiation ulcer.

> They just pass on the information, basically. [They didn't contact anyone] on my behalf, but they could give me a list of resources, which isn't very effective when you're severely depressed, because that's often the hardest time to reach out.

> I think it would be good for all services to work from a harm reduction framework, to be more compassionate, to focus on building a therapeutic relationship with the person that's in front of them.

Lack of autonomy

Many participants wanted more autonomy to manage their own treatment just as they would with other prescription medicines. This included having longer periods between prescriptions, having access to more takeaway doses, and being able to manage their own dosing.

> Letting people have more takeaways and have more control over their own medication. We need this medication, we're not going to go without it. There's so many jobs that people could be doing if they weren't in liquid handcuffs.

> [I'd like to see] less policing on it, not having to jump through so many hula hoops so you can get takeaways, and more trust on their end.

> They can monitor any medications that you get through doctors... They have absolute records of you not abusing medications. They can see that you're not abusing any other substances, you're giving clean urines. They should allow you more freedoms, more support and encouragement.

> Giving people more control of their own medication and their own health would be better, and to be more flexible with people's jobs, just more flexibility. I've missed out on overseas trips and all things I would love to do, but I can't; what would be the option? I'd have to go down the road and find some heroin, and that ruins your holiday.

> Let's just make it more flexible and give people more control over how they dose, when they dose, especially if you've been on it 20 years.

> It's just the control, and I think taking control away from people who are trying to get control back over their lives does not help them in their efforts to rehabilitate themselves.

> Just treating us as the adult humans that we are. Treating it as a medical condition, which it is, and [stopping] this over-regulating of takeaways.

> They wouldn't do the things they do to opioid users – they wouldn't do that to any other illness. They think this is something totally different, this isn't like any other illness … the morality shouldn't come into it, but it does over and over again.

> They need to stop this 'one size fits all' when it comes to the program.

Several participants had been prescribed inadequate doses that did not meet their needs or pushed out of the program before they were ready, which led some to relapse.

> They didn't put you on a high enough dose early on.

> Everyone was still looking for how to boost their dose.

> I basically got told, 'you've been on long enough' – which I think they decided was 3 months – 'we're weaning you, and see you later'. And they were quite confident that I'd be fine ... I started using again quite quickly, and went through that whole thing again.

> The public [clinics] were pretty bad. They didn't have any takeaways, they tried to get people off as quickly as possible. They would quite obviously prematurely throw people off who would then just end up using again … They'd say, 'well, you've really been on long enough.

> It's time for you to start weaning … It shouldn't really be a thing that you're on long term … you think some of those people probably went on to overdose and could have died through that idiotic decision. You know, taking the decision away from the consumer … Private clinics … basically let you decide when you're ready to go off.

Many felt that prescribers and dispensers were in a position of power and used their dosing and supply of takeaway doses as control measures.

> It's just extremely difficult in terms of the way they kind of control you and [use] punitive practices and punishments … for using. It's not effective.

> If you're sick, you have difficulties in your life, you have mental health issues. You miss an appointment and there's one strike against your record.

> The time when my mother died. She had cancer, and I went to Dr [name removed], and I said mum's been put into hospital and she's not expected to make it beyond the next couple of days. I've got to go down south now, and Dr [name removed] laughed in my face and said, 'oh no it's far too soon [for takeaway doses]', and my mother died that night.

Fear of punitive measures

Many participants mentioned the use of punitive measures, such as removing takeaway doses or kicking people off the program for being unable to pay, for what dispensers saw as unacceptable behaviour, or because they saw them as a difficult client. This was seen as counterproductive and damaging, and often meant participants were afraid to discuss issues or seek support.

> There was at the time when I was kicked off the program because I missed 3 appointments … I've struggled with PTSD and agoraphobia. They knew, and I had called them to cancel the appointments, but it's this whole punishment thing.

> There's been a couple of times where I've felt all right and haven't gone in. But you can only do that 1 day, because if you do it 2 days, you get cut off. So you can't really see how you can go without it.

> If you miss 3 days of getting your dose, you're cut off and you've got to go through the process again. I understand they keep that there so that people go to the chemist, but you don't know someone's situation. They may not be able to get to the chemist, they might not have family support and they're trying their best. And then if they don't go, they're cut off and then they're sick. And then they relapse.

> I would like to tell them a few things, but I'm afraid I'll end up back at the hospital. So I keep my mouth shut, where I could have been getting help from them.

> If we could chat more to doctors about what's going on in our lives without fear of punitive responses. You know, if opioid treatment prescribing was provided with a whole bunch of other wraparound services, that might support people more.

> They're caught between seeing it as a medical issue and still seeing it as an ethical issue … Any other illness you've got, any other problem you've got, if your medicine isn't working, you might give them more. You wouldn't stop it. You wouldn't just give punitive measures just because their medicine isn't working, and it's seen as an ethical lapse.

> The lack of cooperation is horrible, the lack of trust and the punitive, coercive way that services are delivered, and the fact that they're not delivered in a harm-reduction focused way. If you end up using a little bit whilst you're on the program, and, you know, you often experience things like being reduced off your methadone rather than having a discussion

about, ‘can we support you to use less? Should we increase your dose?’ It’s often like, ‘oh the person is using, we better kick them off the program because they’re not supposed to be using while they’re on the program’. So it’s not delivered in a very harm-reduction focused way, and often the decisions that are made around that type of stuff increase harms for people.

I should be able to tell my doctor, ‘the dose hasn’t been holding me, so as a result, I have been using’, and not have any punitive measures thrown at me, you know, say, ‘well, we’ll just have to stop your takeaways or have to do this’. It should be, ‘let’s see what’s wrong with you, let’s adjust your dose’, like you would do if you were seeing a psychiatrist or anything else you had … But it’s seen as your weakness, your failing if the dose isn’t working.

This power imbalance and use of punitive measures seemed to be most pronounced in public clinics, and this often resulted in people having to attend private clinics at a much higher cost, whether they could afford it or not.

I’m not into being punished for having a stuff up. We’re all going to have a stuff up, a hiccup. At the public clinic, they like to punish you for that. They’ll either give you a half dose, or if you [have been] allowed to get takeaways for the weekend, you’re not allowed to get them anymore.

[The public clinic] was just so punitive. They had a policy that if you only filled your urine cup halfway, you only got half a dose ... It was just an excuse to punish you. Then you did your urine, and you’d have to drop your pants to your ankles and lift your shirt up … it was horrific.

I’d love to see the government really work on the public clinics. There is so much they can do there. People shouldn’t be in private clinics because the public clinics are just so awful. They are so awful that people will pay these crazy amounts of money – unemployed people on Newstart paying $60 a week – and they’re doing that because the public clinics are so awful. The government can fix that … and they should be.

Stigma and discrimination

Most participants had, at some stage, faced judgement and stigmatisation from pharmacy staff, health practitioners and members of the public. This varied greatly between prescribers and dispensers, and even between people within a dispensing service.

You’re automatically not trusted because we’re addicts. I really think the stigma needs to shift. We are addicts, but we’re addicts reaching out for help and support. We need to be shown that we can be trusted.

They don’t treat you the same as they treat every other customer.

You don’t feel like a customer, you feel like a scumbag. They treat you like the J word.

The pharmacy that I dosed at when I was on the strips, even if I was the first person in the shop, I would be the last one to be served.

I’ve been kept waiting and been late for things that are really important to me to attend – such as work, study, collecting my children – because the pharmacist has waited so long to actually dose me while [serving] other people in front of me.

Eventually I started at the chemist. I find them to be a respectful service. Different chemists have different codes, and some will keep you waiting even if other people come after you. You’re a customer, you should be treated with the same respect as any other.

> One of the main reasons why I do stay at the particular chemist I've been going to is because they do treat me quite fairly, and you are served in line with other customers, and so many other chemists won't do that. You have to wait until all the other people are served, and that can really impact you when you've got to go to work. Just because you're on methadone doesn't mean you've got all day to sit around and wait for it.
>
> My pharmacy and my doctor, they're doing the best they can, I feel. They're very good, very polite. I think they do a fantastic job.
>
> I've had some chemists who have been really, really unhelpful and made me dread going in there, and other times I've had some chemists who have been really supportive of me.
>
> I'm a patient looking for help and we're not seen that way, we're seen as a drug addict … I used to have to pick mine up in a … lockbox because I've got children. Do you know how embarrassing it is, walking into a pharmacy with this big box, plonking it on the desk, unlocking it. It's got my … name, my phone number. It's so obvious that you're not like everyone else … the whole process is so demoralising … I've already got PTSD and that's further traumatising. It's punishing me for trying to do the right thing. How does that help, and how does it help my children seeing me do this, because it's this odd thing happening. Mummy's different. Why is mummy different?
>
> I've been with them for years, and it doesn't make any difference how long you've been there. One little mistake, one missed appointment, it's always day 1. You can't build faith... It doesn't matter what you do right, you can't do enough for them. They just invent new hoops.

Participants stressed that the stigma and discrimination can have a significant impact on people's self-esteem, and can lead people to leave the program.

> It can be very depressing, if you have to go somewhere every day, and you feel like you're not good enough all the time, you start to believe it after a while.
>
> Sometimes the chemist and the pharmacies and even the doctors, their reactions affect you and then you might not come back, and then you're in a really unsafe situation.
>
> You definitely can't have anyone … being really judgemental to any drug addicts or alcoholics or whatever. That'll send them back to use … they already feel bad enough about themselves to have even gone out to ask … they're defeated people. They really need to be looked after, not to be judged.
>
> If you treat people with respect and dignity, you get it back in spades.

In some cases, judgement and stigmatisation has resulted in a lower level of privacy, and poorer service and health care. Some had unrelated health issues ignored or missed, or were unable to access other important medicines they needed, because the first reaction they encountered was suspicion.

> You're seen as an addict. You're not a person with addiction that has comorbidity or other factors in their life.
>
> [In hospital for pancreatitis], I was treated very differently by staff as soon as they learned that I was on methadone – I was no longer a person with health issues, I was a drug addict, that's who I was to them, and everything I did from that moment was drug-seeking behaviour... It was kind of traumatic, actually.

> When I finished the program, I made the decision to go into detox. And then when I got into detox they were apprehensive in allowing me to have Valium in increments which was titrated over the week. Coming off buprenorphine I was sick for months, it was disgusting.

Several participants found testing of urine samples to be humiliating and stigmatising, and felt it was used as a form of control.

> I'd love to get rid of the stigmatising thing of urines, where your takeaways are used as a mode of punishment or reward.

Need for staff and health practitioner education

Many participants felt that health practitioners and other staff needed more education and training about addiction and trauma, to increase understanding and empathy.

> A great thing would be education for the people who dispense, so they understand we're not there to rip them off, we're not doing anything wrong, we are trying to help ourselves. I think they think we're just there to get free drugs.

Privacy concerns

The lack of privacy in some clinics and pharmacies was also raised as an issue. Arrangements vary greatly – some dispensers have separate rooms for dosing, others have separate counters, and some dispense doses at the general prescription counter. Many participants want to keep their treatment confidential, but the set-up makes it impossible.

> A lot of the time you don't have privacy, so you're dosing in front of the entire pharmacy. The pharmacies I've been to are quite small, so anyone in the pharmacy can see me. Having somewhere a little bit more discreet to be dosed, or even to wait – there is a specific waiting area, everyone knows what that waiting area is for, so just by waiting for your dose, it's obvious why you're actually in the pharmacy.

> You feel like you're put on display whilst you're already in a vulnerable state. I know that I get rather sick before receiving my dose, so the last thing you want to feel is even more vulnerable.

> I remember being all dressed up to go to school, as a schoolteacher, and I had to go inside the building, and there'd be a big line-up of people... Any of the clinics, I've always had a privacy issue. The system made it very difficult for me. I could not be seen by the general public. It could have been a student that saw me, or a parent, and I just couldn't risk that. Going into a chemist is far more acceptable to me.

> There was no separate section for dosing. [There were] people I know, parents of the kids that go to the school.

> I've run into people that I don't want to run into that don't know I'm on the program, and I've been publicly outed that way.

> I go to a chemist in a different town deliberately, so that I don't have people wagging their tongues about me.

> Sometimes when you're with your family you don't want to run off and go to the pharmacy. Some of my family members, I didn't want them to know I was on methadone.

Privacy is also a concern for those having to organise a transfer for interstate travel.

> I don't want my family knowing about it. I've managed to keep it under wraps all these years, so for me to turn around and tell them I've got to go see the chemist before it shuts, they'll begin asking questions. And even though I let [the pharmacy] know that's the problem, and why I'm reluctant to go down that [transfer] path, it still doesn't get you any extra takeaways.

Impact of being registered on pharmacotherapy treatment

Being registered on a pharmacotherapy treatment program can create issues for participants, especially when needing pain relief, even in cases of major injuries or surgeries.

> I got a script from my methadone-prescribing doctor for Panadeine Forte … very short-term situation … my chemist looked at it, 'you don't need that, you're on methadone'. They think we walk around in a cloud of numb.

> My sister and myself had the same operation; we had our thyroids removed … all they gave me was Panadol and then she gets morphine. And it's the same operation of the neck … Because I'm known to use and she's not an opiate user, I am, she gets morphine and I get Panadol.

> I had my jaw broken and had to have it wired up … because I told them … I had used occasionally, no pre-meds. No nothing. Where everyone else is all drowsy.

> I got cancer 6 years ago, and I started using, because having that on your file that you're an opioid user, they don't tend to help you out with medication. So I started using to help get me through the pain of the cancer.

> You go to the hospital with a broken arm, and because you're a registered user, you're lucky to get Panadol for your broken arm. That black mark does obviously have a huge impact on medical treatment at times.

> I've done my left knee and my doctor said, 'stop reducing [your methadone]', because we can't get anything else for pain.

Participants who had exited the program successfully felt that there should be a time limit on their medical records showing they had been through the program.

> It will follow you for the rest of your life. It doesn't matter how long you've been off the program for, it's always going to be on your record. There should be a time limit … so that it doesn't come up when you need a certain medication or in a medical situation. It shouldn't be on your record for the rest of your life.

> I'm waiting for my ADHD prescription. My GP keeps applying for it, and because of my transparency with my substance abuse background, it keeps being rejected. I went to rehab for 7.5 months, I did the program for 3 years. I finished the program. I went through all of these steps. But it still follows you... I'm studying at university, I can't concentrate because I have ADHD, but I can't be prescribed ADHD medication because of past medication that doesn't affect me anymore. It's classed as drug-seeking behaviour.

Supporting health practitioners to improve quality of care

Some participants raised that tackling the shortage of health practitioners involved in the program would go further than just reducing waiting lists. It would also improve quality of care and support, and help ensure people receive holistic care that addresses more than just their addiction.

> The only thing I think that's going to improve it is if the whole area of opioid treatment is better funded and there's more services, and we work really hard to continue to reduce the stigma, so that we attract more doctors and more nurse practitioners and workers in the field – people who really want to do this work.
>
> If we had more doctors, perhaps the doctors that we have would have more time to do some of that more holistic health care and to support people with navigating the health system a bit better.
>
> I think the processes for health professionals are really hard. I think there's a lot of admin costs, and there's a huge administrative burden for doctors when taking on people on the program, and that puts a lot of doctors off. So, we have to reduce some of those challenges for medical professionals, as well, because I think that will encourage more doctors to want to do this work. There's not enough training and support for doctors who do want to come into this field.
>
> And then, doctors, once they're in the field, if they do make it, they get burdened really quickly with high numbers of clients, because everyone has more demand than the sector can ever meet. So, doctors may end up taking more patients … than allows them to provide quality health care, so they get burnt out and stop providing good quality health care.
>
> They're just such outcast services that seem to exist outside of mainstream health, and I think that's part of the problem as well.
>
> I'd be really supportive of nurse practitioner-type models, and I would be even open to pharmacy provision … we need to come up with innovative models, and I think the pharmacist is obviously one of them.

Participant suggestions for improvements

Participant suggestions on how the program could be improved included:

- reducing the cost of the treatment by treating pharmacotherapy prescriptions the same as any other PBS-subsidised prescription medicine, or by subsidising and setting a cap on dispensing fees
- increasing the number of approved public and private prescribers and dispensers – or addressing barriers to increase the number of doctors and pharmacists who prescribe and dispense pharmacotherapy treatments – to reduce waiting lists, costs and the need for travel
- creating a national system or using technology to enable participants to travel interstate, change dispensers and move between treatment settings without red tape, paperwork and the risk of missing doses
- allowing people to pick up their treatment whenever the dispenser is open, rather than at specific times of day
- giving people more autonomy and choice over their treatment – as is afforded for any other prescription medicine – by allowing people to choose their medicine type without pressure, allowing longer periods between prescriptions and providing more takeaway doses
- involving more people with lived or living experience in the process, to help provide realistic information to participants and to support and advocate for them
- providing education to health workers and pharmacy staff, to reduce stigma and judgement
- placing a time limit on medical records for people who have successfully exited the program
- providing more parallel support for those who want it, such as counselling, education and training to improve employment prospects.

> I'm just really glad that you're doing this, and I really, really hope that there can be some changes made to the current program, and hopefully one day it will be on the PBS.

Appendix 1: Participant characteristics

Characteristics	Number
Gender	
Male	54
Female	51
Non-binary	1
Age group	
20–29 years	7
30–39 years	18
40–49 years	35
50–59 years	29
60–69 years	17
First Nations person	12
Regional/remote	22
Experiencing homelessness	4
Recently released from prison	4
Culturally and linguistically diverse	1
LGBTQIA+	9
Living with chronic pain	25
Total number of participants	**106**

Appendix 2: Interview prompts

The Department of Health and Aged Care provided the following prompts to interviewers. This was a discussion guide only, and interviewers were free to diverge from it and ask any other question they felt was relevant to the discussion. No quantitative data has been collected from these questions.

When you **first started treatment** on a methadone and/or buprenorphine program for opioid dependence:

a. Who was your prescriber? Doctor ☐ Nurse ☐ Other
b. Where did you receive your methadone and/or buprenorphine dose – eg a free public clinic, an alcohol and drug service, a community pharmacy or through another service?
c. What drug were you prescribed?
    i. Methadone
    ii. Buprenorphine tablet
    iii. Buprenorphine film
    iv. Buprenorphine injection

2. Where do you **currently receive** your methadone and/or buprenorphine dose?
    a. a free public clinic, an alcohol and drug service, a community pharmacy or through another service?
    b. If from a community pharmacy, can you choose which community pharmacy you get your methadone and/or buprenorphine dose from?
    c. If from a community pharmacy, what works well and what
        i. What works well?
        ii. What can be improved?

3. In general, what has been your experience of the methadone and/or buprenorphine program services or service providers?
    a. What worked well?
    b. What did you find difficult?
    c. What could be improved?
    d. Were you ever given a referral to a specialist or other support services – If so, what worked well and what could be improved?

4. When on a methadone and/or buprenorphine program do you also receive other treatment or support services such as counselling/mental health services, social/welfare/case management?
    a. No, Im on a methadone and/or buprenorphine program and don't receive any other treatment/support
    b. If yes, what treatment or support are you receiving?
        i. What worked well?
        ii. What can be improved?

Demographics

Gender: Male ☐ Female ☐ Other ☐

Age group:

Under 20 ☐ , 20-29 ☐ , 30-39 ☐, 40-49 ☐

50-59 ☐, 60-69 ☐, 70-79 ☐, 80+ ☐

State:

Treatment stage

Starting treatment (3 months or less) ☐

Continuing treatment (3 months or more)

Recently restarted treatment ☐

Tick the following that apply:

Living in rural and remote region ☐

First Nations person ☐

Homeless person ☐

Pregnant woman ☐

Recently released from prison or custody ☐

Culturally and linguistically diverse ☐

LGBTIQA+ ☐

Person living with chronic pain ☐

Person part of the elderly population ☐

5. Have you switched medicines for opioid dependence treatment before, for example to the buprenorphine injection? How did you find the process of switching over to another medicine? How could this be improved?

6. We understand that ODT can be costly for many people.
    a. How does the financial cost of ODT impact your life?
    b. What would make treatment affordable to you?

7. What has been your experience (if any) transitioning between treatment settings (e.g. hospital to community, public clinic to community pharmacy, prison to community)?
    a. What worked well
    b. What did you find difficult?
    c. What could be improved?

8. With COVID-19, we have seen the increase in take-away doses being provided to people.
    a. How many takeaway doses do you get in a week? None, 1, 2, 3, 4, 5, 6, 7
    b. do you have a preference for supervised or unsupervised (take-away) doses? (We know that some people prefer the flexibility and convenience of take-away doses, but others like to have regular contact with their pharmacist or clinic)
    c. Have you ever been on longer-term takeaway doses (over weeks), due to **interstate** travel?
        i. What worked well
        ii. What did you find difficult?
        iii. What could be improved?

9. Do you have any other suggestions on how methadone and/or buprenorphine programs can be improved to make it easier for you to access treatment, make treatment more affordable and stay on the program?
    a. What changes to methadone and/or buprenorphine programs would make a difference to you?