

Policy Framework

In this section you will...

- *Gain an understanding of harm minimisation, biopsychosocial approaches and evidence based practices as they relate to opioid pharmacotherapy treatment;*
- *Understand the rationale for and the aim of opioid pharmacotherapy treatment;*
- *Discover who will be given priority access to treatment; and*
- *Acquire an insight into how opioid pharmacotherapy treatment is provided in Tasmania.*

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3.1 Principles of Harm Minimisation

Harm minimisation is the fundamental concept underpinning the management of people with alcohol, tobacco and other drug problems in Australia. The concept was central in Australia's National Campaign Against Drug Abuse (NCADA), first launched in 1986, and has remained a core principle of the current National Drug Strategy (2010 - 2015).

The harm minimisation approach aims to reduce the harm associated with substance use by providing an overarching framework that supports a range of interventions. It recognises the impact of substance use on the individual, their immediate family and social networks, and the community as a whole, while at the same time acknowledging that the eradication of psychoactive substance use is not possible (see also Hamilton & Rumbold, 2004).

Harm minimisation is a core principle driving the Australian National Drug Strategy and the Tasmanian Opioid Pharmacotherapy Program

The aim is to reduce harms associated with substance use by providing an overarching framework that supports a range of interventions

The term 'harm minimisation' is regularly used in conjunction with, or interchanged with, the term harm reduction. While the exact definitions of the two terms vary widely, Room (2004) observes that the term 'harm reduction' is often used when referring to specific interventions or strategies used for influencing drug related harm, for example, needle exchange programs and supervised injecting rooms. The core feature of these harm reduction strategies is that they do not necessarily advocate abstinence from drug use.

Hence, for this document, the term harm reduction will be used when referring to specific strategies for reducing drug related harm, particularly for individual patients of the Tasmanian Opioid Pharmacotherapy Program (OPP), or patients receiving prescription opioids from their physicians. Therefore, potential outcomes of the therapeutic strategies may range from reduction to cessation of the drug/s of concern. This would be consistent with the goal of the program; that is to reduce the harm associated with inappropriate use of prescription opioids (or heroin) by replacing them with appropriate use of a controlled and less harmful substance.

Finally, clinicians have a duty of care to address and manage identified risks and clinical safety issues for their patients' substance use. If reducing or abstaining from substance use is identified as an achievable and appropriate goal, then this should be explored by the clinician and patient as a potential treatment goal, along with other harm reduction strategies. This is particularly important if it facilitates the patient's retention in opioid pharmacotherapy treatment.

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For a more detailed discussion on harm minimisation and harm reduction, see Room, 2004.

3.2 Biopsychosocial approach

A number of factors can influence both the aetiology of substance abuse and the effectiveness of subsequent treatment. In Tasmania, Alcohol and Drug Services (ADS) provide a range of treatment programs that are informed by the biopsychosocial approach.

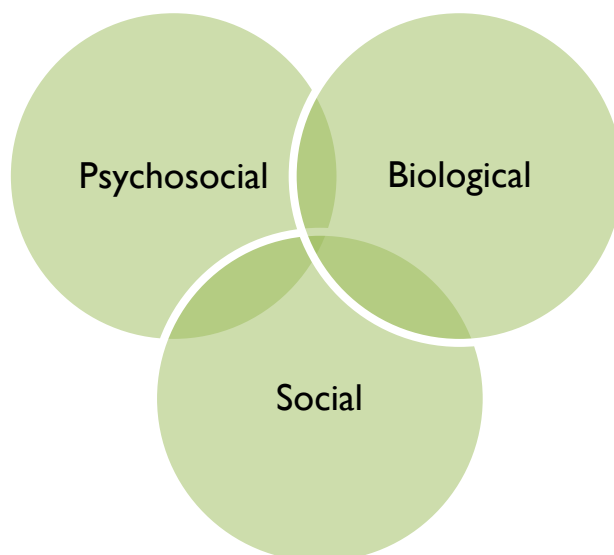


Figure 3.1: Biopsychosocial Theoretical Model

(Engel, 1977)

The biopsychosocial model, as represented in Figure 3.1, is commonly adopted by health services as a guide to service delivery (Engel, 1977 & 1980). This holistic approach specifies that three main factors contribute to an individual's overall functioning and health outcomes: biological, psychological, and social factors.

In applying this model to the treatment of alcohol and other drug use issues, factors influencing substance use, abuse and dependence can be further specified as follows:

- psychological (e.g. mental health, grief and loss issues, stress);
- social (e.g. family relationships, peer groups, social support, socio-economic factors, geographical location, education, lifestyle, health beliefs, cultural influences); and
- biological (e.g. physical health, blood-borne viruses, predisposition to dependence, neuroadaptation).

As highlighted throughout this document, all aspects of opioid pharmacotherapy in Tasmania, including assessment and risk management, treatment delivery, and recommendations regarding psychosocial interventions, will be informed by the biopsychosocial model of health.

3.3 Evidence based practice

The current guidelines are based on evidence based practice (EBP). EBP is a decision making model designed to assist clinicians in making the most appropriate recommendations for their patients. EBP involves three components: best available evidence, clinical expertise, and patient values and preferences (Sackett, et al., 2000). According to this model, clinicians need to be up-to-date with the best available, most current and relevant research evidence.

However, decisions cannot be based on research evidence alone. While evidence may suggest that a particular therapy or treatment is suitable for most patients; the evidence based intervention cannot always be applied uniformly. Therefore, clinicians need to also be aware of the patient's circumstances, preferences, and values. Finally, while patients may indicate preferences, their choices may not always be the most clinically appropriate. Therefore, clinical expertise and specialist knowledge is required to make decisions, with consideration of clinical risk and safety issues. According to EBP, none of these components can operate in isolation. It is also important to highlight that EBP does not always imply that the most cost effective treatments are best practice. Rather, the fit between the evidence, patient values, and clinical judgment will indicate which treatment is most suitable for each patient.

Current evidence from national and international research will be cited throughout this document. Furthermore, guidelines for how to make the most appropriate decision for each patient are also included: for example, Section 5 outlines how to assess a patient's opioid use and their suitability for opioid pharmacotherapy.

3.4 Rationale for opioid pharmacotherapy

Opioid dependence is characterised by a cluster of symptoms (as discussed in Section 2), including increased preoccupation with, and time spent, obtaining and using the drug. Furthermore, impairment of control over use of the drug is a key clinical feature of dependence (see Section 2 for the full diagnostic criteria). Other potential consequences of opioid use and/or dependence include fatal and non-fatal overdose, transmission of blood-borne viruses, negative impacts on a range of aspects of social functioning, including family relationships, housing, crime and family disruptions (Chalmers, et al., 2009). In addition, many opioid dependent people who attempt to withdraw rapidly often relapse to opioid use or dependence, particularly if unsupported in their attempts to withdraw (Kenny, et al., 2009). Thus, opioid dependence can negatively impact on a range of biopsychosocial health factors.

Hence, for opioid dependent people, replacing heroin or other unsanctioned opioid use with maintenance therapies, such as methadone and buprenorphine treatment, is recommended (Mattick, et al., 2009; National Pharmacotherapy Policy, 2007). Clinical research in Australia and internationally indicates a range of benefits of these treatments, resulting in overall improved biopsychosocial functioning for individuals. Specifically, placing opioid dependent people on supervised oral pharmacotherapy has been shown to:

- reduce the risks associated with unsanctioned opioid use and dependence, including reduced risk of premature death;
- reduce rates of spread of blood borne viruses from intravenous administration;

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- reduce crime rates; and
- decreased use of unsanctioned opioids

(Gowing et al., 2008; Mattick, et al., 2001; Teesson et al., 2008).

The benefits of pharmacotherapy treatments are associated with the pharmacological properties of the maintenance drugs (see Section 4 for further information). In brief, both methadone and buprenorphine are long acting oral medications and, when taken daily, blood levels of the medications remain constant after an initial stabilisation phase. Hence, patients become tolerant to the effects, and are less likely to display symptoms of opioid intoxication and withdrawal and experience an overall reduction in drug seeking behaviours, than when using heroin or other unsanctioned opioids (Mattick, et al., 2001). This increases the likelihood that individuals will be able to focus on improving various other aspects of their health, as well as maintaining stable employment, and re-engaging in social activities.

Furthermore, engagement in treatment programs often results in increased and improved access to various health, welfare and support services for an often marginalised group of individuals. These benefits have been shown to be improved over longer periods of treatment (Simpson & Sells, 1982).

3.5 Aims of opioid pharmacotherapy treatment

The overall aims of opioid pharmacotherapy treatment are to:

- assist opioid dependent individuals to reduce or cease the use of illicit or unsanctioned opioids by replacing them with safer maintenance medication;
- improve the biopsychosocial health and overall functioning of the opioid dependent individual; and
- reduce the risks and harms associated with illicit and unsanctioned opioid use to the individual, his or her family and social network, and the community as a whole.

In order to provide comprehensive and holistic care to the individual in treatment, a range of ancillary services, such as counselling, employment support, care coordination, and housing support, should be accessible. In Tasmania, treating teams will facilitate access to such services when appropriate, particularly if limited resources prevent these services from being directly provided by the opioid pharmacotherapy treating team.

Finally, since patient outcomes are improved over longer periods of treatment, the provision of opioid pharmacotherapy should not be time limited.

Opioid pharmacotherapy is suitable for opioid dependent individuals.

Opioid pharmacotherapy should not be time limited.

3.6 Priority access

Opioid pharmacotherapy should be accessible to all patients seeking treatment for opioid dependence. When there is a delay in access to treatment, patients most at risk of deterioration in health outcomes if treatment is not available should be provided with priority access to the Tasmanian (OPP). These include:

- pregnant women and their opioid dependent partners;
- people with HIV and carriers of Hepatitis B and their opioid dependent partners; and
- opioid dependent people recently released from prison (and consequently at a high risk of overdose).

Priority access to pharmacotherapy treatment should be provided to:

- *pregnant women and their opioid dependent partners;*
- *people with HIV and carriers of Hepatitis B and their opioid dependent partners; and*
- *opioid dependent people recently released from prison.*

These factors should be taken into consideration during the assessment phase. Clinical judgment will guide the allocation of priority services.

3.7 Evidence for effectiveness of various opioid pharmacotherapies

The effectiveness of opioid replacement therapies have been widely researched and documented over many years (Ward, Mattick and Hall, 1998). In 2001, the Australian National Council on Drugs (ANCD) released a report rating the evidence for the effectiveness of methadone as strong, and moderate for buprenorphine. This report also noted that the evidence for the efficacy of naltrexone in relapse prevention treatment is limited (Gowing et al., 2001, Tucker, et al, 2004).

The National Evaluation of Pharmacotherapies for Opioid Dependence (NEPOD) study was a multi-centre, randomised clinical trial that compared the clinical effectiveness, clinical safety, and cost effectiveness of a range of opioid pharmacotherapies. In a comparison of methadone, buprenorphine, and naltrexone, the authors found that methadone maintenance was the most cost effective treatment for opioid dependence in Australia (Mattick et al., 2001). They also found that retention rates in treatment – a highly important indicator of treatment success - at six months was 44% in the groups treated with methadone and buprenorphine, in comparison to a retention rate of 4% for those treated with naltrexone. As a result of the findings from the NEPOD study, the Commonwealth government was prompted to fund a wider range of opioid pharmacotherapy treatment options.

Since evidence indicates that methadone and buprenorphine pharmacotherapy treatments are current best practice in the treatment of opioid dependence, they will be the focus of

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these TOPP guidelines. However, while methadone remains the most cost effective treatment for opioid dependence in Australia, the pharmacological properties of buprenorphine (outlined in Section 4) indicate that it is a clinically safer medication than methadone. This decision for clinicians between the safer medication and the most cost effective medication remains challenging (see Mattick et al., 2008 and Gray, 2007 for discussions on this topic).

This document will provide information and guidelines for medical practitioners and pharmacotherapy treatment teams for identifying the most appropriate medication for each individual patient.

3.8 Key principles for effective treatment

This section describes the qualities required for an 'ideal' opioid pharmacotherapy treatment setting. When developing a service, or providing opioid pharmacotherapy, clinical safety for the patient and clinicians, as well as public safety, are the most important considerations in decision making. Furthermore, constraints and limitations on resources will affect the viability of providing all the recommended components of an ideal pharmacotherapy service.

The key principles for effective pharmacotherapy treatment include:

- Availability - where a need for opioid treatment services exists, these services should be made available;
- Accessibility - services should be located at appropriate sites, affordable to patients, and open during hours that optimise service utilisation;
- Acceptability - the operation of opioid treatment services should be acceptable to major stakeholders including patients, service providers and the local community;
- Equity - treatment services should be planned and operated to reduce inequities between target groups in terms of access to and quality of services;
- Quality of Care - treatment services should be of a high standard. Doses should be provided to suppress opioid withdrawal and adjusted in accordance with a continuous assessment of clinical safety;
- Accountability to key stakeholders should be maintained through ongoing review processes of clinical practices and treatment outcomes;
- Length of time in treatment - opioid pharmacotherapy should not be time limited. Current evidence indicates that post-treatment outcomes are improved with increased time in pharmacotherapy (Simpson & Bracy, 1982), and that people who drop out of treatment within the first year are much more likely to relapse than those who remain in treatment for longer than one year (Teesson, et al., 2008; Greenfield & Fountain, 2000);
- Voluntary - all patients must be receiving opioid pharmacotherapy treatment voluntarily. In Tasmania, patients referred via Court Mandated Diversion still have a choice in whether they participate in the pharmacotherapy treatment program under the clinical recommendations of staff in the program;

- Quality of the therapeutic relationship - attitudes of the treating team can influence the quality of opioid treatment programs. Evidence shows that when patients have a good relationship with at least one treatment team member, program effectiveness is positively influenced (Gjersing, et al., 2010). A non-judgmental attitude among clinicians is important in fostering good clinical relationships;
- Holistic care - patients should have access to a range of ancillary services to help improve all aspects of their biopsychosocial health, including psychosocial interventions such as counselling services (McLellan et al., 1993; Drummond & Perryman (2007)). If such services are not immediately available, referrals should be made when appropriate. (For more details regarding psychosocial interventions and case management, see Section 10);
- High staff morale - the maintenance of high staff morale is critical to the delivery of effective opioid pharmacotherapy services. Staff should be appropriately trained to deliver pharmacotherapy services, and require ongoing workforce development and training, recognition and acknowledgment of skilful clinical practice, as well as support in managing complex patients;
- Staff and clinical safety and risk management - staff and other patients must feel safe at all times and appropriate security measures should be available. Decisions regarding patient care should be made with awareness and attention to clinical risk factors above all other considerations. This includes close supervision of consumption of liquid and tablet medications to reduce the risk of overdose, accidental poisoning, and diversion.

3.9 How opioid pharmacotherapy is provided in Tasmania

The delivery of opioid pharmacotherapy in Tasmania provides many challenges to both public specialist services and other non-specialist community based services. Although many services often experience funding restrictions, the delivery of Tasmania's specialist drug services is further limited by geographical accessibility. That is, 48.7% of Tasmania's population lives in rural and remote areas (Australian Bureau of Statistics, 2001), with little or no access to public transport. Hence, managing the requirements of accessibility to services while maintaining high standards for the management of clinical and other risks can often create competing demands on policy.

Opioid pharmacotherapy in Tasmania is currently provided through either public opioid treatment clinics, that is, specialist Alcohol or Drug Services (ADS), or community based medical practitioners. The specialist public clinics are staffed by prescribing doctors, specialist nurse case managers, pharmacists (Hobart ADS only) and allied health professionals, who provide a range of services (e.g. counselling, psychotherapy, and access to medical care, psychiatric treatment, social services). Case management is undertaken by designated opioid pharmacotherapy program staff or (in the private sector) by the patient's prescribing doctor.

During the induction phase into pharmacotherapy treatment, dosing usually occurs onsite at the Specialist Pharmacotherapy Pharmacy in the South, and community dispensing pharmacies in the North and North West. Once patients are stabilised, they can be dosed at a convenient community or hospital pharmacy.

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Community based medical practitioners (usually general practitioners and sometimes specialist medical practitioners) also provide opioid pharmacotherapy treatment, as well as performing a case management role with their patients. These patients usually attend community pharmacies to receive their methadone or buprenorphine.

Hospital pharmacies are an important avenue for delivering opioid pharmacotherapy in Tasmania. In some rural settings, the community health care centre or hospital pharmacy may be the only available options for dispensing.

Difficulties are experienced in both types of service delivery models. The combination of the location of the specialist clinics, funding restrictions, limitations on outreach work, and safety considerations, may contribute to specialist services being less accessible to some patients. In addition, specialist clinics can, at times, experience difficulty meeting the demand for their services, primarily due to periodic increases in demand from consumers for these services and an ongoing shortfall in the number of specialist clinicians in these services.

Conversely, community based medical practitioners and community pharmacies can often be overwhelmed by the complexity of opioid dependent patients, can feel unsupported in the management of these patients, and may lack specialist knowledge in this area. Safety concerns are also a limitation for providing opioid pharmacotherapy in many smaller medical clinics.

In order to improve the availability and quality of opioid pharmacotherapy services in Tasmania, a model of service delivery that supports close collaboration between primary care (i.e. community based medical practitioners) and specialty care (specialist drug services) services is required. Therefore, Tasmania will adopt and develop a shared care model of service delivery for its opioid pharmacotherapy program.

3.10 Shared Care Model

Shared care models of care have been adopted in many countries for the management of chronic health conditions. Models of shared care vary widely from formalised referral and discharge pathways to regular contact and collaboration between treating services in the ongoing management of patients (Keene, et al., 2004).

For the current document, the shared care model will be broadly defined as a structured system in which primary and specialty clinicians collaborate over an extended period in order to provide high quality care to patients with chronic disease (p. 214, Smith et al., 2008).

While there are numerous documents outlining, describing, and evaluating the benefits and challenges of shared care arrangements, the availability of high quality randomised control studies (RCT) is limited. For example, in a review of over 4,000 documents on shared care, Smith and colleagues (2008) found that only 20 studies met the criteria for inclusion in a systematic review. The authors found positive results for the benefits of shared care in improving mental health, improving quality of life and wellbeing, reducing functional impairment, reducing hospital admissions and inpatient days, and improving appropriateness of prescribing practices (Smith et al., 2008).

Various other investigations specific to opioid treatment programs have found that well defined shared care models can assist in maintaining prescribing practices within specified

guidelines, allow drug users to feel normalised by accessing help through the primary care setting, and provide a holistic approach to patient care (Felice & Kouimtsidis, 2008; Smith & Mistral, 2003). Furthermore, shared care models are more likely to attract the participation of primary care providers if they feel well supported, for example, through the support of their specialist colleagues or a liaison officer (Dey et al., 2002; Felice & Kouimtsidis, 2008; Keene et al., 2004).

Finally, there are indicators that the outcomes of opioid pharmacotherapy – specifically, buprenorphine – are equivalent when provided by either specialist services or well supported specialist primary physicians (Gibson, et al., 2003). All these indicators, combined with the limitations of the current opioid pharmacotherapy program in Tasmania, indicate that a shared care model will be both beneficial for patients, as well as progress the quality and accessibility of services.

3.1.1 Tasmanian Shared Care Model

The Tasmanian ADS will facilitate the development and support the implementation of the shared care model of opioid pharmacotherapy in Tasmania. The ADS recognises the need to provide support and supervision for primary care physicians currently providing, or demonstrating potential to provide, pharmacotherapy services. As the capacity of the specialist services improves, increased opportunity for support, education and professional development will be established. Despite current service limitations, if a primary care physician cannot provide a safe treatment service within the current guidelines, then no opioid treatment should be provided.

If safe treatment cannot be provided, then no treatment should be provided.

The Tasmanian shared care model will have the following characteristics:

3.1.1.1 Specialist services

The Tasmanian ADS Opioid Pharmacotherapy Program (OPP) will:

- be responsible for the initial assessment of a large proportion of Tasmanian patients for their suitability for registration on the opioid pharmacotherapy program (excluding patients with access to authorised GPs, see 3.1.1.2);
- induct patients into the OPP;
- oversee the dosing of patients;
- provide or facilitate access to other services as required;
- transfer patient care to a community based general practitioner if:
 - (a) a suitable practitioner is available;
 - (b) the practitioner agrees to take the patient; and
 - (c) the patient is stable and safely managed in a primary care services.

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In addition, the Tasmanian ADS will also:

- manage the care of complex, non-compliant or moderate to high risk patients;
- provide care for patients who have begun to display behaviours of increased risk including non-compliant or moderate to high risk while being managed in primary care services;
- provide support for primary care physicians;
- provide case management services; and
- provide access to multidisciplinary reviews for integrated care planning and specialist intervention.

3.11.2 Primary care services

Primary care physicians may assess, induct, and stabilise opioid pharmacotherapy patients if:

- they are experienced in providing opioid pharmacotherapy;
- the treatment provided is consistent with the current Tasmanian Opioid Pharmacotherapy guidelines;
- the patient is generally compliant and low risk;
- the offer or provision of services does not place the patient, the community, or clinicians at risk; and
- they are authorised to do so by the Clinical Director, ADS, in conjunction with the Chief Pharmacist, Pharmaceutical Services Branch.

Primary care services practitioners roles also include:

- providing generalist medical services to all opioid pharmacotherapy patients, including the management of blood borne viruses;
- providing referrals to external health services when appropriate; and
- consulting with or referring to ADS when pharmacotherapy clients they are managing become either non-compliant or increase from low to medium or high risk.

3.11.3 Specialist-primary care interface

To improve the quality of opioid pharmacotherapy services provided to Tasmanian patients, ADS will engage in the following strategies.

- ADS will provide to primary care physicians involved in the provision of opioid pharmacotherapy services:
 - teaching;
 - clinical supervision;
 - clinical mentoring; and
 - consultation and liaison services.

- ADS will improve strategies for:
 - increasing the number of medical practitioners able to provide opioid pharmacotherapy, particularly in remote communities;
 - ensuring efficient referral pathways and communications with specialist services;
 - engaging primary care physicians in generalist care of opioid pharmacotherapy patients prior to discharge from specialist services;
 - consulting with primary care clinicians and
 - PSB (DHHS) in further developing Tasmania's shared care model of opioid pharmacotherapy.

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