

ALCOHOL AND DRUG SERVICES

## *Variations Summary:*

*Variations from current National policy and clinical practice guidelines*

# Tasmanian Opioid Pharmacotherapy Policy and Clinical Practice Standards

Draft 2011



## Introduction

The Tasmanian Opioid Pharmacotherapy Policy and Clinical Practice Standards, 2011 (TOPP) have been developed based on contemporary evidence and national and jurisdictional clinical policies and guidelines for the use of methadone, buprenorphine and naltrexone in the treatment of opioid dependence.

In developing the draft Tasmanian Opioid Pharmacotherapy Policy and Clinical Practice Standards, 2011 the Alcohol and Drug Service has directly drawn or adapted information from other national and state guidelines from which some material. These include:

- Department of Health and Ageing, National Clinical Guidelines and Procedures for the Use of Buprenorphine/Methadone in the Treatment of Opioid Dependence;
- Department of Health and Ageing, (1997). National Methadone Policy.
- Department of Health and Ageing, (2001). National Buprenorphine Policy.
- Department of Health and Ageing (2007). National Pharmacotherapy Policy for People Dependent on Opioids. National Drug Strategy.
- Queensland Health (2008). Queensland Opioid Treatment Program Clinical Guidelines.
- Department of Human Health, Victoria (2006). Policy for Maintenance Pharmacotherapy for Opioid Dependence.
- Department of Health, Western Australia (2007). Clinical Policies and Procedures for the use of methadone and buprenorphine in the treatment of opioid dependence.

The TOPP's development has also taken into account the local circumstances and needs of Tasmania including: epidemiological data; the patterns and types of opioid drug use in Tasmania; identified and documented public health and clinical safety issues; legislative, regulatory; and administrative requirements.

The TOPP has an emphasis on the identification and management of clinical risks and as a result the clinical and policy approach of the TOPP is necessarily conservative. This will ensure that individuals and their families, affected by opioid dependence, receive high quality, contemporary, safe and effective treatment.

In ensuring that these issues and local needs are met there are some variations from the current national policies and clinical guidelines. This document has been developed to provide summary information about these variations.

# Variations

### Focus on Prescription Opiates

Multiple data sources indicate that use of heroin in Tasmania is relatively uncommon, whilst use of pharmaceutical opioids is more widely reported. The TOPP's development has taken into account the nature of drug use in Tasmania, and as a result, the document has a focus on pharmaceutical opioids.

While much of the information regarding diagnosis and treatment of heroin and pharmaceutical opioids overlap, The Tasmanian Opioid Pharmacotherapy Policy and Clinical Practice Standards vary from current available national and jurisdictional policies and clinical guidelines in this regard.

#### Further discussion of this issue can be found in:

SECTION 1: Epidemiology of Opioid Use in Tasmania

### Emphasis on clinical risk management

A number of significant public health and clinical safety issues have been identified in Tasmania over the last 5 years. These relate to increased rates of prescription medicine use and misuse. Of particular concern is the number of opioid-related deaths in Tasmania. In 2007, the PSB identified 33 deaths associated with opioid use or misuse, in a State with a population of 500,000 this is a high rate of opioid related deaths per capita, when compared with international data. As a consequence of these public and clinical safety issues the clinical and policy approach of the TOPP is necessarily conservative.

This means that there are aspects of the TOPP that are more conservative than what is presented in the current national policy and clinical guidelines. Further to existing national and state guidelines the TOPP identifies specific clinical practice standards relating to requirements for ongoing review; access to unsupervised dosing; polydrug use particularly in relation to concurrent opioid and other CNS depressant medications; client attendance for medical reviews and case management appointments; and regular random urine drug screens. These standards relate specifically to identified clinical risks and are required to ensure effective risk mitigation.

#### Further discussion of this issue can be found in:

SECTION 1: Epidemiology of Opioid Use in Tasmania;

SECTION 2: Clinical Features of Opioid Dependence;

SECTION 3: Policy Framework;

SECTION 4: Clinical Pharmacology; and

SECTION 5: Assessment for Entry into the Opioid Pharmacotherapy Program

### Emphasis on the Assessment and management of risk and protective factors

In implementing a clinical risk management the TOPP has adopted and extended a risk assessment framework that includes the identification of both risk and protective factors.

This framework draws from existing literature in the area of risk and protective factors and applies this to all aspects of clinical care including assessment, treatment planning, ongoing review, prescription and medication management.

Current national and jurisdictional policies and clinical guidelines pay particular attention to clinical risks, risk assessment and management but do not describe or emphasise protective factors. In addition the TOPP draws on strengths based and contingency management approaches to emphasise protective factors. This approach has value in actively engaging the client in the identification and reduction of risks and the enhancement of protective factors.

**Further discussion of this issue can be found in:**

SECTION 5: Assessment for Entry into the Opioid Pharmacotherapy Program;

SECTION 6: Safe Treatment Induction;

SECTION 7: Maintenance Treatment;

SECTION 10: Psychosocial interventions in opioid pharmacotherapy; and

SECTION 12: Managing Complex Presentations

### **Harm Reduction**

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. This definition and approach is consistent with current national and state opioid pharmacotherapy policy and clinical guidelines.

In the TOPP however, the term harm reduction is 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. In this instance harm reduction does not exclude the reduction or cessation of use of drugs of concern as a potential outcome of therapeutic strategies.

In addition, 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.

In some sections of the TOPP the emphasis on the management of clinical risks may be construed by some readers as the adoption of an abstinence model in the treatment of opioid dependence. However, this emphasis on risk management does not negate harm reduction as the fundamental construct that underpins the TOPP.

## VARIATIONS SUMMARY

### Further discussion of this issue can be found in:

SECTION 2: Clinical Features of Opioid Dependence; and

SECTION 3: Policy Framework;

### Shared Care

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.

The TOPP extends beyond other national and jurisdictional policies and guidelines by adopting a shared care model of opioid pharmacotherapy in Tasmania. This means that the Tasmanian Alcohol and Drug Service (ADS) will facilitate the development and support the implementation of the shared care model of opioid pharmacotherapy.

In operationalising this model the TOPP describes the ‘specialist- primary care interface’ by setting out the roles and responsibilities for both the specialist and primary care setting. As part of this approach the policy requires the ADS to provide support and supervision for primary care physicians currently providing, or demonstrating potential to provide, pharmacotherapy services.

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.

### Further discussion of this issue can be found in:

SECTION 3: Policy Framework; and

SECTION 15: Prescriber Training and Authorisation

### Pharmacotherapy agents and preparations

A great deal has changed in Tasmania since 2000 when the Tasmanian Methadone Policy 2000 was published, there is a large body of evidence to guide the delivery of treatment for opioid dependence. The introduction of buprenorphine has expanded the range of opioid pharmacotherapy treatment options available and treatment has evolved in relation to the way in which it can most safely and efficaciously be delivered. Consistent with national policy and clinical guidelines the TOPP focuses on both methadone and buprenorphine pharmacotherapies.

In contrast to the national and some jurisdictions approaches the TOPP adopts a Gateway Model. This model identifies buprenorphine as the preferred agent of choice for induction onto the Opioid Pharmacotherapy Program in view of its superior safety profile and the limited access to seven day pharmacy dispensing options in Tasmania and at a time when takeaway doses are very likely to be misused.

In addition following the release of the Suboxone® sublingual film formulation in September 2011, the TOPP includes product information and guidelines for the use and dispensing of sublingual film. This information is not currently available in existing state and national guidelines.

**Further discussion of this issue can be found in:**

SECTION 4: Clinical Pharmacology;

SECTION 7: Maintenance Treatment; and

SECTION 16: Pharmacy Instructions

### **Assessment and Ongoing Review Requirements**

Further to existing national and state guidelines the TOPP identifies specific clinical practice standards relating to required timeframes for review; client attendance for medical reviews and case management appointments and regular random urine drug screens. These standards relate specifically to identified clinical risks and are required to ensure effective risk mitigation.

**Further discussion of this issue can be found in:**

SECTION 5: Assessment for Entry into the Opioid Pharmacotherapy Program;

SECTION 6: Safe Treatment Induction;

SECTION 7: Maintenance Treatment;

SECTION 10: Psychosocial interventions in opioid pharmacotherapy; and

SECTION 12: Managing Complex Presentations

### **Unsupervised Dosing: Takeaway Doses**

Further to existing national and state guidelines the TOPP identifies specific clinical practice standards relating to timeframes and demonstrated clinical stability required prior to the provision of unsupervised dosing. This includes a stepped approach to access to takeaway doses.

In contrast to the other current state and national guidelines the TOPP:

- Requires 3 months demonstrated continuous clinical stability before being eligible for any unsupervised dosing (takeaway doses)
- Restricts unsupervised dosing to two methadone takeaway doses ( the National guidelines allows 3)
- Restricts takeaway doses for buprenorphine to daily dosing clients who are unsuitable for double dosing in view of the advantages of double and triple day dosing available to patients treated with buprenorphine.

## VARIATIONS SUMMARY

### Further discussion of this issue can be found in:

- SECTION 5: Assessment for Entry into the Opioid Pharmacotherapy Program;
- SECTION 6: Safe Treatment Induction; and
- SECTION 7: Maintenance Treatment

### Concurrent Drug Use

- Requirement for benzodiazepines reduction programs/regimens to be undertaken in preparation for/and as part of ongoing opioid pharmacotherapy

### Further discussion of this issue can be found in:

- SECTION 5: Assessment for Entry into the Opioid Pharmacotherapy Program;
- SECTION 6: Safe Treatment Induction;
- SECTION 7: Maintenance Treatment
- SECTION 10: Psychosocial interventions in opioid pharmacotherapy; and
- SECTION 12: Managing Complex Presentations

### Transfers

Recent health reforms at a national level have led to a proposed agreement that allows prescriptions written by nationally registered medical practitioners to be recognised in other states. For clinical and public safety reasons, Tasmania has chosen not to support this agreement and therefore the legislation and regulations of the Tasmanian jurisdiction should be observed. Consequently, in Tasmania, prescriptions for opioid pharmacotherapy from other jurisdictions (states and territories) will not be recognised.

While it is accepted that prescriptions written by nationally registered medical practitioners are recognised in some states, the TOPP does not recommend continued prescribing by Tasmanian prescribers for either temporary or permanent interstate transfers, once again for clinical and public safety reasons.

The TOPP specifies that transfers to the Tasmanian OPP will be managed by the ADS opioid pharmacotherapy program. This includes transfers to Tasmania from other states or countries. The public program has the capacity to manage the administrative tasks associated with a transfer through their case management systems. They can also provide information to interstate prescribers and clients about the Tasmanian program requirements, and assess, review and monitor new clients during the vulnerable transition period following transfer.

In contrast to current national and state guidelines the TOPP clinical practice standards specify:

- Transfers to the Tasmanian public opioid pharmacotherapy program cannot be guaranteed.
- A temporary or permanent transfer request must be received 4 weeks prior to the transfer date.

- The transferring clinician will need to ensure that the client has read and signed the Tasmanian opioid pharmacotherapy program treatment agreement.
- Temporary transfer to or from the Tasmanian opioid pharmacotherapy program is generally for a period of no more than 4 weeks.
- Unsanctioned transfers will not be accepted, clients will be advised to return to their opioid treatment provider.
- There are restrictions on access to unsupervised dosing for inter-state transfer and a requirement of 3 months demonstrated continuous clinical stability (regardless of previous interstate arrangements).

**Further discussion of this issue can be found in:**

**SECTION 13: Transfers**

### **Psychosocial Interventions for Opioid Pharmacotherapy**

Providing pharmacotherapy alone does not address the holistic needs of the client. A range of factors can have an impact on a client's engagement and compliance with the pharmacotherapy program. That is, psychosocial factors (psychological and social factors) can have a direct effect on the success of treatment.

In early 2009, the World Health Organisation (WHO) recognised the need to address psychosocial factors when providing opioid pharmacotherapy treatment in Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence (2009). Similarly, the American Psychiatric Association's Practice Guidelines for the Treatment of Psychiatric Disorders: Compendium (2006) and the National Pharmacotherapy Policy for People Dependent on Opioids (2007) also support the inclusion of psychosocial interventions as a key component of opioid pharmacotherapy treatment programs.

Therefore, the TOPP (unlike current national policies and guidelines) has a deliberate focus on the biopsychosocial approach and emphasises access to psychosocial interventions to support and enhance treatment outcomes. This approach also supports the adoption of the risk and protective framework with the TOPP.

Tasmanian ADS will ensure that pharmacotherapy and psychosocial intervention programs are well integrated, and that private practitioners are aware of agencies or health professionals that are able to provide psychosocial interventions. In addition the ADS will provide case management for clients registered for treatment for the ADS.

**Further discussion of this issue can be found in:**

**SECTION 5: Assessment for Entry into the Opioid Pharmacotherapy Program;**

**SECTION 6: Safe Treatment Induction;**

**SECTION 7: Maintenance Treatment;**

**SECTION 10: Psychosocial interventions in opioid pharmacotherapy; and**

**SECTION 12: Managing Complex Presentations**

### **Prescriber Training**

## VARIATIONS SUMMARY

Current national policies and guidelines do not specify the training requirements or accreditation processes required in order to prescribe opioid pharmacotherapy.

The TOPP clinical practice standards specify that medical practitioners who prescribe buprenorphine and methadone for the treatment of opioid dependence must be authorised by the Clinical Director, Alcohol and Drug Services, Department of Health and Human Services.

To become an authorised prescriber, a medical practitioner must:

- Make an application to the ADS Clinical Director, DHHS;
- Undertake training in opioid dependence and pharmacotherapy with an ADS medical officer. Prescribers will also be invited to attend ADS and observe pharmacotherapy practice during a clinic;
- Complete and return a multi question exam (and achieve a passing grade); and
- Agree in writing to prescribe in accordance with the policies and clinical practice standards described in the Tasmanian Opioid Pharmacotherapy Program: Policies and Clinical Practice Standards (TOPP, 2011).

In addition and unlike other jurisdictions, ongoing authorisation requires annual renewal, which involves the completion of a refresher program.

**Further discussion of this issue can be found in:**

**SECTION 15: Prescriber Training and Authorisation.**