

Opioid Replacement

Therapies

Supporting Evidence

This document provides further Supporting Evidence for the [UnitingCare ReGen \(ReGen\) Position Statement](#) on the therapeutic and social value of Opioid Replacement Therapies.

Understanding Opioid Dependence

Opioid dependence is a complex condition that occurs in individuals after a period of regular opioid use. The length of time required to develop an opioid dependence is highly variable, depending upon a wide range of factors relating to the individual user, the substances used and external environmental factors. The World Health Organisation considers that:

Opioid dependence is not just a heavy use of opioids, but a complex health condition that has social, psychological and biological determinants and consequences, including changes in the brain. It is not a weakness of character or will. (WHO, 2004: p7)

Opioid dependent individuals face a variety of associated harms, including:

- Poor health – transmission of blood-borne viruses (such as HIV or Hepatitis B and C), local infections and vein damage for people who inject, along with malnutrition, dental complications and reduced mental health;
- Risk of overdose, with the potential for permanent injury or death – due to taking combinations of respiratory depressants, changes in individuals' tolerance (for example, following withdrawal), the variable availability and purity of opioids used (reducing individuals' capacity to maintain a 'standard dose');
- Poverty – due to the high cost of illicit opioids and the impact of dependence on people's capacity to maintain employment;
- Engagement in criminal activity – in addition to the purchase and possession of illicit substances, crimes committed whilst substance affected and/or to finance further use;
- Social isolation and vulnerability – stress on relationships, stigmatisation and homelessness.

Globally, the mortality rate for dependent opioid users (either from overdose or other causes) is between six and 20 times higher than for the general population, depending on age and gender (WHO, 2004).

In addition to the individual harms associated with opioid dependence, families and the broader community bear the social and economic costs associated with:

- Increased demand for health services – affecting service funding and accessibility;

- Increased law enforcement costs – police investigations, court proceedings, imprisonment and supervision of community-based orders;
- Social isolation and vulnerability of family members – emotional trauma, reduced capacity to maintain employment, stigmatisation and shame, impaired physical, social and emotional development of affected children.

In Australia, public perceptions of opioid dependence have generally focused on illicit heroin use, associated criminal behaviour (such as drug importation and dealing, property crime by dependent users and drug related violence) and deaths from overdose. However, in recent years, there has been growing concern at the marked growth in the problematic use of prescription opioids, either as a supplement to existing heroin dependence or as a result of individuals becoming reliant on opioid-based pain medication (Ling et al, 2011; Lloyd, 2011). This pattern is in keeping with international experience (Kim-Katz & Anderson, 2011)

What are Opioid Replacement Therapies?

The World Health Organisation recognises that:

Opioid dependence is a complex condition that often requires long-term treatment and care. No single treatment modality is effective for all people with opioid dependence. Adequate access to a wide range of treatment options should be offered to respond to the varying needs of people with opioid dependence. (WHO p32, 2004)

Opioid Replacement Therapies (ORT) are a group of medications used in the treatment of opioid dependence. They are also known under a variety of descriptions including: opioid substitution treatment, opioid pharmacotherapies, opioid agonist medication or opioid maintenance program. While there are other possible medications which could be considered here, the three primary ones that are currently used in Australia are:

- Methadone
- Buprenorphine (Subutex®)
- Buprenorphine and naloxone combination (Suboxone®)

As with other pharmacotherapies used in the treatment of chronic medical conditions such as diabetes, heart disease and hypertension, ORT enable people to stabilise their condition while they adopt behavioural changes to reduce associated future risks.

In Victoria, ORT medications are listed as 'Schedule 8' and 'Schedule 11' drugs of dependence under the Drugs, Poisons and Controlled Substances Act (1981). This classification imposes significant barriers to their prescription and distribution that make them more difficult to access than other pharmacotherapies.

How do they work?

ORT are opioid agonists that operate by occupying opioid receptors in the brain and producing most of the effects associated with opioid use, without the accompanying sense of euphoria.

Antagonists (such as naloxone, or the longer acting variant naltrexone) create a barrier that blocks the effect of opioids on the brain. The introduction of antagonists when opioids are present will displace them from opioid receptors and place an individual into immediate withdrawal. It is important to note that opioid antagonists are used for a variety of purposes (such as in response to overdose), but they do

not constitute replacement therapy and are not generally associated with the long term therapeutic benefits of ORT.

The key feature of ORT is that they provide a regular, consistent and long-acting dose of opioids that allows people the opportunity to break the chaotic cycle of behaviours associated with obtaining and using short-acting illicit opioids. By removing the drivers for much of the problematic behaviour associated with opioid dependence, ORT provide people with an opportunity to establish behavioural and lifestyle changes that will support sustainable change. ORT are, therefore, an effective support to other therapeutic approaches (including withdrawal, counselling and rehabilitation) and the achievement of goals that are recognised as being indicative of sustained change: improved family relationships, community engagement and participation in study/training or employment (Ritter & Chalmers, 2009; Stotts et al, 2009).

ORT have proven value in supporting the achievement of a variety of treatment goals, from reducing the level of opioid use through to complete abstinence. The current National Pharmacotherapy Policy for People Dependent on Opioids states that:

Pharmacotherapies for opioid dependence should be part of a comprehensive treatment program, with access to counselling and other ancillary services available to all individuals. (ICD, 2007, p7)

ReGen recommends that all people participating in treatment for opioid dependence include ORT as part of a holistic approach.

What is the difference between the different therapies?

Methadone

Methadone is a synthetic opioid that is taken orally in liquid form. It is the most common form of ORT used in Australia and internationally. With adequate dosage, it can suppress withdrawal symptoms and opioid cravings for at least 24 hours and is the medication most commonly associated with opioid maintenance (the long-term use of a consistent high dose). The extent of research evidence supporting the effectiveness of methadone in reducing heroin use, criminal activity, overdose fatalities and behaviours associated with a high risk of HIV transmission, along with improving health and social functioning (Ritter & Chalmers, 2009) has established it as the 'gold standard' in the treatment of opioid dependence for over 30 years (Lum & Tulskey, 2006).

Australian and international research has indicated significant improvements amongst those retained in methadone treatment for one year, with higher doses of methadone generally associated with greater reductions in heroin use than moderate or low doses (DoHA, 2007).

Approximately 75% of people commencing ORT have been found to respond well to methadone, with few side effects (WHO, 2004). However, there remains a significant proportion of people who, for various reasons, will be better served by alternative medications.

Buprenorphine

Available in Australia under the name Subutex®, buprenorphine acts in a similar fashion to methadone, but can be longer lasting, only needing to be taken every two to three days, depending on dosage. The strong binding of the buprenorphine molecule to the receptor makes it difficult for other opiates to attach, thereby blocking their ability to act. As a partial agonist, it produces a weaker opioid effect than methadone, poses a lower risk of overdose (even when taken together with other opioids) and is associated with a less painful experience of withdrawal. The product is a pill that is crushed to a powder and administered sublingually (absorbed under the tongue) or, more recently, a fast dissolving film.

These properties make buprenorphine an important alternative to methadone. Its effectiveness has been shown to be similar to methadone in supporting reduced illicit opioid use and improved psychosocial functioning, but may be associated with lower rates of retention in treatment (Lintzeris, et al, 2006).

Buprenorphine-naloxone

Available in Australia under the name Suboxone®, the combination of buprenorphine and naloxone (also known, in its injectable form as Narcan®, the drug administered by paramedics to treat opioid overdoses) serves to decrease the injection potential of the product. If taken sublingually, the buprenorphine's effectiveness is unchanged and the product achieves the same therapeutic result as Subutex®. However, if injected, the naloxone is activated to block opioid receptors and precipitates opioid withdrawal. This feature reduces the likelihood of buprenorphine-naloxone being diverted to non-prescribed users and makes it the preferred option for 'take-away' doses (DoHA, 2007)

As a further measure to increase ease of administration and reduce opportunities for diversion, the pill form of the product is currently being phased out of production in favour of a 'film' version which is more easily absorbed sublingually.

Opioid Replacement Therapies in Australia

ORT have been available in Australia since 1969, with the introduction of methadone. ReGen was one of the first authorised methadone providers when a Victorian program was established in 1972. Methadone remained the only ORT medication available in Australia until the introduction of buprenorphine in 2000. Buprenorphine-naloxone was introduced in 2005.

In the early 1990s, Victoria established a 'community-based' ORT program, which focussed on prescription by General Practitioners and supervised dispensing by community pharmacies. This was part of a strategy to de-stigmatise opioid dependence and increase the accessibility of ORT as a treatment option. Specialist services were also introduced to work with people with the most complex needs and support community-based ORT providers.

Although the aim of the ORT program in Victoria was to increase access and to normalise drug treatment in community settings, the reality is somewhat different. Access is constrained because less than 10% of medical practitioners are registered to prescribe them, and less than 40% of pharmacies are able and willing to dispense the various medications. Research on the issue has consistently identified concerns about the accessibility of ORT, particularly for people in rural and regional areas. Clients of community programs also often report that they feel stigmatised and experience service discrimination (King, Ritter & Berends, 2011). The ongoing cost of the medications has also been noted as a barrier for those amongst the most vulnerable in our community (Ritter & Chalmers, 2009). The Victorian Government acknowledges these problems and has recently increased program funding and introduced changes to suboxone policy in an attempt to increase GP participation and client access (Department of Health 2012).

The benefits of ORT

40 years' worth of consistent research evidence demonstrating the effectiveness of ORT in supporting the achievement of a wide range of benefits.

Reduces risk

ORT has been shown to reduce the risks to individuals associated with:

- Opioid and other drug use (lapse/relapse);
- Unplanned exit from AOD treatment;
- Overdose;
- Blood-borne virus transmission;
- Criminal activity (Stotts et al, 2009; Teesson et al, 2006; DHS, 2006).

Improves health

By providing a platform of stability to support behavioural changes, ORT has also been demonstrated to contribute to:

- Improved health e.g. nutrition, liver and vein care;
- Improve social functioning e.g. family relationships, engagement with community, employability (Stotts et al, 2009; Teesson et al, 2006; WHO, 2004).

Supports change

People participating in AOD treatment often leave prematurely due to relapse. Retention in treatment is consistently associated with improved individual outcomes as it provides an extended period during which people can address a range of contributing factors to their AOD use. ORT are most effective when combined with other interventions to enable people to achieved sustainable behavioural changes (National Drug Strategy, 2007)

Cost effective

The cost of providing ORT has been repeatedly demonstrated (both in Australia and internationally) to be significantly outweighed by the consequent savings across a range of fields, including justice, law enforcement, health and welfare (Ritter & Chalmers, 2009). A failure to provide adequate levels of ORT is costly for government-funded services and the community (WHO, 2004).

Respects human rights

Individuals who use drugs do not forfeit their human rights. These include the right to the highest attainable standard of physical and mental health (including access to treatment, services and care), the right not to be tortured or arbitrarily detained, and the right not to be arbitrarily deprived of their life. Too often, drug users suffer discrimination, are forced to accept treatment, are marginalized and often harmed by approaches which over-emphasize criminalization and punishment while underemphasizing harm reduction and respect for human rights. United Nations High Commissioner for Human Rights (Pillay, 2009)

ORT are provided within a Harm Minimisation approach: the overarching model for Australia's policy framework for reducing the supply of, demand for and harms caused by AOD (MCDS, 2011). Harm Minimisation accepts that, despite all efforts to prevent AOD use, people will continue to have access to licit and illicit substances and use them in a way that poses risks for themselves and the community. ORT help reduce immediate risks while supporting longer-term changes.

Common Arguments Against ORT

People should be able to just stop using

There is a general misunderstanding of the reality of opioid (or any other substance) dependence within the broader community. AOD dependence is a chronic, relapsing condition and is associated with physical changes in the brain, which mean that overcoming opioid dependence is a complex process that relies on more than just 'willpower' to succeed (Ritter & Chalmers, 2009). ORT reduce the occurrence of relapses, thereby helping people remain engaged in treatment long enough for their brain to readapt, to embed new thought patterns and behaviour (Mattick et al, 2003).

Sends the 'wrong message'

This is a common response (particularly by politicians and media commentators) to harm reduction practices and is based on the general public's misunderstanding of AOD dependence. Part of the misunderstanding is the belief that there is a simple solution to the problems posed by AOD dependence. It is a complex issue and, for those affected, there is a wide range of interrelated factors that play a role in any efforts to make sustainable life changes. The use of ORT does not condone opioid use, but provides an evidence based response that has been consistently demonstrated to be effective.

As there is no one 'message' that will resolve all issues associated with AOD use, there is no single panacea for opioid dependence. ORT can play an important role in enabling sustainable change and personal development, but is unlikely to be successful in isolation.

Taxpayers shouldn't be paying for people to use drugs

By providing ORT, governments are making substantial cost savings by reducing future burdens on the law enforcement, justice, health and welfare systems. The aim of public funding for ORT programs is not to subsidise individual's patterns of substance use but to reduce harms in the short term and provide suitable conditions for sustainable behavioural change. As with all public funding for medications in Australia, inclusion of ORT within the Pharmaceutical Benefits Scheme has been based on their capacity to provide quality healthcare that is cost-effective and responsive to individual people's needs (DoHA, 2000).

People participating in ORT also contribute significantly to the cost of their treatment (Muhleisen et al, 2005). Financial barriers (such as pharmacists' dispensing fees) have long been recognised as a limitation on the potential effectiveness of ORT (King, Ritter & Berends, 2011; Chalmers et al, 2009).

Just replacing one drug with another

This argument has much in common with the previous two, in that it assumes that the main purpose of ORT is to subsidise people's AOD use, without requiring any significant changes in their behaviour. Again, this relies on community misconceptions about the experience of AOD dependence. It also ignores the possibility of change in the context of ongoing efforts to overcome opioid dependence. However, where this argument differs from the first is that it is sometimes made by the people directly affected.

For many people, the concept of ongoing ORT maintenance, simply represents 'changing the witch for the bitch' or a set of 'chemical handcuffs' which will, instead of supporting change, simply further entrench their opioid dependence. This perception is strengthened by the difficulty many people experience in reducing (or ceasing) their use of ORT, particularly methadone.

ReGen would stress that, while ongoing ORT maintenance may not be the primary objective for all opioid dependent people, it can provide an essential support to achieving stepped treatment goals. Due to the prevalence of relapse amongst opioid dependent people and the overdose risks associated with recent reductions in opioid use (for example, following withdrawal), ReGen strongly recommends

against rapid changes in people's patterns of opioid use. ORT reduction/cessation needs to be a carefully planned process that is undertaken over a suitable period to support sustainable behavioural change.

Not a 'safe alternative'

Due to their psychoactive properties and the nature of illicit drug markets, there is always the potential for ORT doses (as with other prescribed medications) to be diverted from their intended recipient and passed on (or sold) to others (Neilsen et al, 2007). In the context of supervised dosing, this means that diverted ORT is commonly contaminated after being removed from an individual's mouth. The introduced bacteria can pose a serious infection risk to the end user, particularly if they are injecting the diverted medication. The non-prescribed use of ORT, can contribute to overdoses, particularly when they are combined with other sedatives such as alcohol and benzodiazepines (DHS, 2006).

The provision of 'take-away doses' (a supply of self-administered doses to cover a set period, as is the standard practice with most other medications), has been suggested as representing an increased risk of diversion and of potential overdose (DHS, 2006). There has been at least one case in Victoria of an overdose fatality that has been attributable to the presence of 'take-away' ORT doses in a family home (Lowe, 2011).

While the diversion of ORT does present clear risks to individuals and the community, they are significantly outweighed by their benefits, as outlined above. As with any medication, ORT should be consumed responsibly and with consideration of their interactions with other medication or non-prescribed substances. As with any medication ORT should be treated with suitable precautions in the home, particularly where children are present.

Summary

Opioid Replacement Therapies are an evidence based, efficient and, most importantly, effective response to opioid dependence. They enable the achievement of mutually reinforcing improvements in peoples' lives provide an important support to the long term process of making sustainable behavioural change. This process is a complex one that requires therapeutic interventions that can be adapted to the various contributing factors and individual goals.

In combination with other complementary therapeutic interventions, ORT produce powerful social benefits but their role is not well articulated within the general community. There is much that can be done to expand the positive impacts of ORT on individuals, families and communities in Victoria. There is also a need for a more informed public understanding of key issues relating to AOD use and the process of overcoming opioid dependence.

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About ReGen

Our purpose is to promote health and reduce alcohol and other drug related harm.

ReGen is the lead Alcohol and Other Drugs (AOD) treatment and education agency of UnitingCare Victoria and Tasmania. ReGen is a not-for-profit agency, which has over 40 years experience delivering a comprehensive range of AOD treatment and education services to the community.

These services include Counselling and Support, Assessment and Intake, Community Outpatient, Home-based and Residential Withdrawal for adults and youth, Supported Accommodation, Drug Diversion programs, Youth and Family Services, an Intensive Playgroup, Alcohol Community Rehabilitation Program and AOD services at Port Phillip Prison. ReGen also delivers Education and Training programs nationally.

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