# The Ethical Use of Psychosocially Assisted Pharmacological Treatments for Opioid Dependence

**Adrian Carter**
**Queensland Brain Institute, University of Queensland,**
**St Lucia, QLD 4072 Australia**

**Wayne Hall**
**School of Population Health, University of Queensland**
**Herston, QLD 4066 Australia**

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## EXECUTIVE SUMMARY

The ethical delivery of psychosocially-assisted pharmacological treatment of opioid dependence is achieved by respecting the following ten basic principles:

*1: Human rights of opioid dependent individuals should be respected*

*2: Treatment decisions should be based on the best available evidence*

*3: Treatment decisions should be based on standard principles of medical care ethics*

*4: Equitable access should be provided to treatment and psychosocial support that best meets the needs of the individual patient*

*5: Treatment should respect and validate the autonomy of the individual*

*6: Patients should be fully informed about the risks and benefits of treatment choices*

*7: Programs should create supportive environments and treatment relationships to facilitate treatment*

*8: There should be co-ordinated treatment of comorbid mental and physical disorders and social factors*

*9: Programs should include participation of community and other stakeholders*

*10: The use of legal coercion into treatment for opioid dependence should respect basic ethical and legal principles*

Our analysis of the practical application of these basic principles suggests that the ethical delivery of psychosocially-assisted treatment of opioid dependence treatment should meet a series of minimum requirements. These are:

1) The provision of initial treatment aimed at the stabilisation of the client from the cycle of withdrawal and intoxication to increase their capacity to make major decisions about treatment. The provision of information and requirement of consent to treatment should be limited at this stage until the client is stabilised and their decision making capacity has improved.
2) The use of procedures to ensure the safety of individual clients, e.g. reducing their overdose risk by close monitoring during induction onto opioid agonist maintenance treatments; close supervision of dosing; and in abstinence based treatment, providing clear information about the risks of overdose if they return to drug use.
3) Provision of enough information to give an understanding of the rationale behind treatment, including the risks and benefits of treatment in the short to long term, and information on other treatment options.
4) Ensuring there is a good understanding by staff and patients of treatment aims that serve the ends of both personal and public health.
5) Education of treatment staff about the effectiveness of different treatment strategies, and emphasis on the importance of a co-operative and trusting relationship with clients.
6) Availability of a range of treatment options that best achieve goals of the client.
7) A defensible drug testing program (e.g. urinalysis) with a rationale that is understood by clients and staff.
8) Adequate dosing that aims to substantially reduce if not eliminate the use of illicit opioids.
9) Supportive treatment that includes regulatory measures that reward compliance with successful treatment, and the use of punitive measures only to protect society, not punish the client. This includes the use of additional counselling in dealing with breaches of regulations.
10) A treatment system with a choice of settings suited to the patients' needs and situation e.g. specialist clinic vs. primary physicians.

11) An appropriate balance between supervised drug consumption and take-away doses for stable clients.
12) An appropriate balance between over-regulation and lack of regulation of clinics that aims to treat as many people as possible, while still providing effective treatment.
13) Flexibility to adjust treatment as the situation of the client changes, including the setting, regulations (e.g. drug testing, take home doses) and other social services (e.g. education, housing, employment, and social skills).
14) The protection of privacy and confidentiality of information provided by clients, as for other medical records, that is kept securely and separate and is not accessible to the criminal justice system.
15) The reliance on due process when treating clients under legal coercion and providing clients with a choice from a full range of treatment approaches.
16) A range of treatment options made readily available to those entering prison.
17) The co-ordinated treatment of comorbid psychiatric disorders and subclinical symptoms.
18) The availability of social support when required, including employment, housing, education, and social skills.
19) Adequate funding of treatment programs in order to meet the above requirements.

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## OVERVIEW

The treatment of opioid dependence has been highly contentious in ways that raise important ethical issues. Our analysis of these issues is broken up into 4 sections. We begin with a broad discussion of generally accepted ethical principles and basic human rights that govern how individuals who are opioid dependent should be treated. We then provide a more practical discussion of how particular pharmacological treatments for opioid dependence may be delivered in specific circumstances in an ethically sound manner. In Section 1, we provide a brief history of drug treatments and policies for opioid dependence, and outline the rationales for the major pharmacological treatment approaches currently being used. We summarise the evidence base for psychosocially-assisted pharmacological treatments for opioid dependence. We conclude this section by setting out some minimum conditions for the ethical treatment of opioid dependence derived from basic ethical principles and human rights.

In Section 2, we use this ethical framework to explore the major ethical issues that arise in the treatment of opioid dependence and the unique social and political climate within which it is often provided. This section discusses the nature of opioid dependence, how it affects both the individual and society, and what the rights and obligations of opioid dependent people are. We discuss four major ethical issues that arise in the pharmacological treatment of opioid dependence: (1) the degree of personal autonomy that opioid dependent persons have and its implications for their capacity to consent to different forms of pharmacological treatment; (2) the ethical issues that arise from the fact that many opioid dependent persons enter treatment under some form of legal coercion (that is, either being compelled to undergo treatment by the courts or offered treatment as an alternative to imprisonment); (3) the ethical implications of potential conflicts between the goals of treatment programs that aim to both benefit individual participants and justify public funding of treatment by serving public goods, such as reducing blood borne virus (BBV) transmission and the criminal activities in which some opioid dependent persons engage; and (4) how to balance the rights and responsibilities involved in treating opioid dependence so that there is a fair distribution of the costs and benefits of drug policy and treatment.

In Section 3, we apply the ethical principles from Section 2 to develop some practical guidelines for delivering ethical and effective treatment for opioid dependence in a way that protects the rights of both the opioid dependent individual and society. We detail appropriate methods for providing each of the various modes of opioid dependence treatment, including dosing, distribution and regulation of medication, testing for compliance with treatment, as well as suggestions for providing treatment in different settings and to particular vulnerable groups.

Finally, we conclude by synthesising the results of preceding analyses into a set of minimum ethical requirements for psychosocially assisted pharmacological treatment of opioid dependence (Section 4).

# SECTION 1: INTRODUCTION TO OPIOID DEPENDENCE AND THE ETHICS OF MEDICAL TREATMENT

## History of the Treatment of Opioid Dependence

Illicit opioids, such as heroin and morphine, are used by a very small minority of the population, with approximately 1-2% of the population in developed countries such as Australia, Europe and Northern America reporting heroin use at some point during their lives (Australian Institute of Health and Welfare, 1999; European Monitoring Centre for Drugs and Drug Addiction, 2001; SAMHSA, 2002). Opioid abuse is nonetheless a significant contributor to mortality and morbidity (Hall et al., 2006). Opioids cause significant harm to those who use them: around 1 in 4 of those who report using heroin become dependent on it (Anthony et al., 1994), and in developed countries, dependent heroin users have a mortality rate that is 13 times higher than the rest of the population (Hulse et al., 1999). The increased risk of premature death arises from drug overdoses (Darke and Zador, 1996), violence and suicide (Darke and Ross, 2002; Goldstein and Herrera, 1995; Vlahov et al., 2004) and human immunodeficiency virus (HIV) infection and the acquired immune deficiency syndrome (AIDS) (Darke and Zador, 1996; Degenhardt et al., 2004).

Historically, most attempts to reduce or eliminate opioid use have involved the use of social and legal control measures that aim to reduce the availability of opioid drugs and penal sanctions that aim to discourage opioid use (National Research Council, 2001). In the USA this began with the 1914 Harrison Narcotics Act that effectively removed the treatment of opioid addiction from the medical profession (Ling and Compton, 2005). Globally, opioid addiction came to be seen as a social evil that was best remedied through criminal prosecution of users and suppliers in an effort to raise heroin price, reduce availability, punish those caught using the drug, and strengthen social disapproval of heroin use (Ling and Compton, 2005). While these measures have reduced opioid use, they have been at the expense of increasing harm to the minority of the population who use opioids despite prohibition by encouraging: the use of injection to maximise opioid effects, unsafe injecting practices (sharing needles and poor injecting technique), the use of impure forms of drug of uncertain strength,

and increased incarceration for committing crimes to fund the use of an expensive illicit drug (Hall et al., 2006).

These punitive policies have assumed that opioid use is a matter of individual choice, that is, that those who use and abuse opioids do so knowingly and of their own free will. In the last few decades, there has been a gradual shift in our understanding of opioid dependence, and addiction in general. An increase in opioid addiction after the second world war in many developed countries, and the failure of tough laws to reduce opioid dependence, have led to the re-emergence of a disease model of heroin addiction analogous to that advocated by Alcoholics Anonymous for alcoholism in the late 1930s (Joint Committee of the ABA and the AMA on Narcotic Drugs, 1961). The credibility of a disease model of opioid dependence has been enhanced by the development of effective pharmacotherapies for opioid dependence and neuroscience research into heroin and other forms of drug dependence (Hall et al., 2004).

The modern era in pharmacotherapy for opioid dependence began in the mid 1960s with the development of methadone maintenance (Dole and Nyswander, 1965). Since then, advances in genetics and neuroscience have greatly improved our understanding of the biological basis of opioid dependence in particular, and addiction in general (Volkow and Li, 2004). Research into opioid addiction has identified some of the biological and social factors that make some individuals more vulnerable to opioid dependence than others including: psychological and genetic vulnerabilities and social factors, such as family history, socio-economic background, and opportunities to use heroin (Volkow and Li, 2004).

Recent research on the neurobiology of heroin addiction has added weight to the idea that opioid dependence is a neurobiological entity that requires some form of pharmacological treatment. There has been increased research into new and effective pharmacotherapies for opioid dependence, such as buprenorphine, and into depot forms of opioid agonists and antagonists, such as naltrexone. The increased choice of pharmacotherapies for opioid dependence promises to broaden the acceptance of pharmacological approaches to its treatment by physicians and patients. While this research has softened punitive social attitudes towards opioid dependent individuals,

suspicion and mistrust of heroin dependent people is still widespread within the health care system and society more broadly.

The resurgence of the view that opioid dependence is a disease requiring medical treatment is not without its own set of concerns (Hall, 2006a; Hall, 2006b). Someone who is less responsible for their behaviour is also less capable of changing it. This raises the possibility that the community will make greater use of coercive treatment to reduce addiction. The use of pharmacological treatments under coercion raises ethical issues that need to be addressed. As will become apparent, many of these problems arise from the tension between the competing and co-existing medical and legal models of opioid addiction.

## Pharmacological Treatment Options for Opioid Dependence[1]

Pharmacological treatment approaches to opioid dependence programs can be divided into three broad categories: detoxification, relapse prevention, and maintenance treatment programs. Those who staff these programs often have different understandings of the causes and treatment of opioid dependence, and about what constitutes successful treatment and how best to achieve this. Much of the tension arises from a difference between two broad approaches to the treatment of opioid dependence, and drug dependence in general: (1) approaches that aim at achieving abstinence in the short to medium term, and (2) harm minimisation approaches which see abstinence as a long term goal and are prepared in the short to medium term to encourage less harmful forms of drug use in the interests of reducing harm to users and the community. While these two approaches are sometimes characterised as mutually exclusive by some of their proponents, they can be seen as lying on a continuum of treatment options. Many of the ethical issues in treatment of opioid dependence arise from this difference in approach. How individuals align themselves within this debate is often driven by their understanding of the nature of opioid

[1] For a systematic review of the effectiveness of pharmacological treatments of opioid dependence, refer to Gonzalez G, Oliveto A, Kosten TR (2004) Combating opiate dependence: a comparison among the available pharmacological options. *Expert Opinion on Pharmacotherapy*, **5**: 713-725, Lingford-Hughes AR, Welch S, Nutt DJ (2004) Evidence-based guidelines for the pharmacological management of substance misuse, addiction and comorbidity: recommendations from the British Association for Psychopharmacology. *Journal of Psychopharmacology*, **18**: 293-335.

dependence and by assumptions about the degree of autonomy and responsibility that opioid dependent individuals have over their conduct.

*Pharmacologically Assisted Detoxification*

Detoxification programs involve supervised withdrawal from opioids. Although this goal may be accomplished with psychosocial support in the absence of drugs, it most often involves using drugs to minimise or suppress opioid withdrawal symptoms (Mattick and Hall, 1996). This might be accomplished by the use of tapered doses of methadone (Amato et al., 2005a) or buprenorphine, a partial opioid agonist (Gowing et al., 2006a), or by masking withdrawal symptoms using α2-adrenergic agonists, such as clonidine or lofexidine (Gowing et al., 2004). It is also possible to accelerate the withdrawal process by using opioid antagonists such as naltrexone, usually in combination with other drugs (e.g. α2-adrenergic agonists, benzodiazepines, and buprenorphine) to suppress the shortened but intensified withdrawal symptoms (Hall and Mattick, 2000). This also includes the controversial method of ultra rapid opioid detoxification (UROD) in which accelerated withdrawal is accomplished under general anaesthetic within 24 hours (Hall and Mattick, 2000).[2]

Detoxification programs are usually a prelude to treatment that aims to assist opioid dependent individuals become and remain abstinent from opioids thereafter (Mattick and Hall, 1996). In the absence of any other treatment following detoxification, rates of relapse to opioid use are very high (Mattick and Hall, 1996). Treatments that aim at abstinence from opioids therefore have typically followed opioid detoxification with various forms of psychosocial support for abstinence. These have included spending time in a residential therapeutic community, providing outpatient supportive counselling or attending 12-step self-help groups, such as Narcotics Anonymous.

All of these treatment approaches share a commitment to achieving abstinence from all opioid and other illicit drugs; they do not substitute other opioid drugs for heroin. Instead, they use group and psychological interventions to assist dependent heroin users to remain abstinent. TCs (therapeutic communities) and DC (drug counselling)

[2] We provide a more detailed analysis of the dangers and controversy of UROD in Section 3.

are usually provided via specialist addiction or mental health services. The former are residential and the latter are usually provided on an outpatient basis.

There have been no randomised-controlled trials for TCs or outpatient DC. Most of the evidence on the effectiveness of TC and DC programs comes from observational studies such as the Drug Abuse Reporting Program (Simpson and Sells, 1982), the Treatment Outcome Prospective Study in the USA (Hubbard, 1989) and the National Treatment Outcome Study in the UK (Gossop, 1997; Gossop, 1998). In these studies TCs and DC were less successful than methadone maintenance treatment in attracting and retaining dependent heroin users in treatment. They nonetheless substantially reduced heroin use and crime in those who remained in treatment for at least three months (Gerstein and Harwood, 1990; Gossop, 1997; Gossop, 1998). There was some evidence that TCs may be more effective if they are used in combination with legal coercion to ensure that heroin users are retained in treatment long enough to benefit from it (Gerstein and Harwood, 1990).

Self-help groups, such as Narcotics Anonymous, are run by recovering drug users using the 12-step philosophy of Alcoholics Anonymous. Some individuals use these groups as their sole form of support for abstinence whereas for others they provide an adjunctive support for abstinence in addition to professional assistance. Self-help groups particularly complement TCs which are often based on the same principles of abstinence-oriented treatment. Such groups are usually not open to people who are in involved in opioid substitution treatment.

The most extensive research on self-help has been in the treatment of alcohol dependence where participation in AA has been found to be associated with higher rates of abstinence from alcohol (Tonigan et al., 2003; Tonigan et al., 1996). The major threat to the validity of this finding has been the effects of self-selection. Because participants are not randomly assigned to participation in AA groups the good outcome of those who attend AA meetings may reflect self-selection of more motivated participants into self-help groups. If this were true, then AA attendance would be an indicator of greater commitment to abstinence as a goal rather than a contributory cause of sustained abstinence. More recent studies have attempted to

control for this possibility using sophisticated statistical methods to correct for self-selection bias. The results of these analyses have been mixed, with some showing persistence of an effect of self-help after correction (Tonigan et al., 2003) while others have not (Fortney et al., 1998).

### *Pharmacologically-Assisted Relapse Prevention*

In the past decade, the poor retention in psychosocial abstinence-oriented treatment programs has prompted the search for pharmacological ways of reducing relapse to drug use after detoxification. The philosophy of abstinence-oriented treatment has typically meant that opioid agonists – drugs that produce similar effects to heroin – have been unacceptable. The only pharmacological approach that has been acceptable within abstinence oriented treatment programs has been the use of opioid antagonists, such as naltrexone, that produce no opioid-effects and solely block the effects of heroin and other opioid agonists by occupying opioid receptor sites in the brain. These drugs are typically used to reduce the risk of relapse to regular opioid use after withdrawal, particularly during the first few months after withdrawal from heroin when addicts appear to be especially likely to relapse.

#### *Opioid Antagonist Maintenance Treatment*

Opioid antagonists can also be used in the longer term as a form of antagonist maintenance. The major problems with oral naltrexone maintenance have been poor patient compliance, and an increased risk of opioid overdose in the majority of patients who relapse to heroin use with zero opioid tolerance. Poor patient compliance with oral antagonists has generally meant that opioid antagonists have been more often used for the purposes of relapse prevention than for long term maintenance. These poor outcomes have prompted the recent development and trial of naltrexone implants and depot injections to increase compliance (Comer et al., 2002). These sustained release formulations may be particularly attractive in situations where opioid dependent patients are treated under legal coercion (Harwood and Myers, 2004; Marlowe, 2006).

#### *Opioid Agonist Maintenance Treatment*

Opioid agonist maintenance programs use methadone or buprenorphine to stabilise and maintain opioid dependent people on an oral, long-acting drug to replace the short-acting injectable heroin. This treatment approach acknowledges that opioid dependence is a chronic, relapsing disorder, and that for some patients, abstinence from all opioids is an unrealistic goal in the short- to medium-term. The aim of these programs is to reduce illicit opioid use and the harms associated with the injection of illicit heroin. Maintenance programs have the dual advantage of reducing the risks of opioid dependence for the opioid dependent individual, (e.g. by reducing their risk of overdose death, BBV infection and incarceration) and the adverse societal effects of opioid dependence (public drug use, drug-related crime and emergency health care costs e.g. responding to overdoses).

The oldest and most widely prescribed form of maintenance has been methadone maintenance treatment (MMT) but more recently the partial agonist-antagonist buprenorphine has gained in popularity because of its greater safety in overdose, its longer action allowing less frequent dosing, the greater ease of withdrawal, and the likelihood that it can be more safely prescribed by primary care physicians than methadone.

Opioid agonist maintenance can also be achieved by the prescription of injectable opioids, either heroin or methadone. This approach has been successfully trialed in Switzerland and the Netherlands (Central Committee on the Treatment of Heroin Addicts, 2002; Perneger et al., 1998; Rehm et al., 2001). These programs are usually treatments of last resort that are reserved for opioid dependent patients who have tried and failed to respond to several trials of oral agonist maintenance. The aim of these programs is the same as that for oral agonist maintenance, namely, to reduce illicit heroin use and the associated crime, overdose risk, and BBV transmission from unsupervised injecting, as well as other negative consequences of risky behaviours associated with heroin use. These programs have been controversial because they maintain addicts on their drug of choice – heroin. They have also proven to be an expensive form of opioid agonist maintenance because of the need for additional security in drug supply and the need for staff to supervise daily injections to minimise the risk of diversion to the black market (Amato et al., 2005b; Hall et al., 2006).

## Ethical Analysis and the Minimum Conditions for the Ethical Treatment of Opioid Dependence

We believe that the treatment for opioid dependence should observe the minimum requirements for ethicality of any form of medical or psychosocial treatment that have been expressed in four influential ethical principles, namely, respecting the personal *autonomy* of persons who are treated, avoiding harm (*non-maleficence*), doing good (*beneficence*), and providing a fair distribution (*distributive justice*) of costs and benefits of treatment and policy.[3]

These ethical principles could be taken to imply the following requirements:

1) There should be rigorous evidence of the safety and effectiveness of the treatment that is provided.
2) Effective treatment should be provided safely in well-structured, well-resourced and well-managed treatment programs.
3) Treatment staff should observe the ethical principles of: respecting patients' autonomy by ensuring that they give free and informed consent to participate in treatment, protecting their privacy and the confidentiality of information provided to treatment personnel, and delivering treatment in a way that maximises its effectiveness for each individual by matching patients to the treatment that meets their individual needs and situation.
4) Treatment programs should ensure that opioid dependent persons have equitable access to treatment and that they do not bear a disproportionate social burden in accepting treatment.
5) It is important that pharmacological treatment is not used to compensate for poor social policies that lead some to opioid use and addiction, or inappropriate drug policies that may be involved in the negative impact of opioid use.

[3] A detailed analysis of the history and derivation of these principles is beyond the scope of this report. We therefore refer those interested in a deeper understanding of the foundations of these ethical principles to some useful references Beauchamp TL, Childress JF (2001) *Principles of biomedical ethics*. Oxford University Press, New York, MacIntyre A (1998) *A short history of ethics: a history of moral philosophy from the Homeric Age to the twentieth century*. University of Notre Dame Press, Notre Dame, IN, Rachels J (1999) *The elements of moral philosophy*. McGraw-Hill College, Boston.

These four ethical principles also form the basis of important statements of human rights, such as the World Medical Association's Declaration of Helsinki (1964) and similar statements by United Nations organisations (Brody, 1998). The Universal Declaration of Human Rights (UDHR) sets out an international set of human rights to be honoured by all signatory nations (United Nations General Assembly, 1948). The UDHR recognised that all people have rights by virtue of being human. It aims to treat all people as equal, irrespective of who they are or where they come from, and to promote and protect the right to life, liberty and security of person (International Federation of Red Cross and Red Crescent Societies and Francois-Xavier Bagnoud Center for Health and Human Rights, 1999; Mann, 1999). This also includes "negative rights" such as the rights not to be enslaved or kept in servitude, not be to be tortured or subject to cruel, inhuman and degrading treatment or punishment, including the denial of basic medical treatment. It also obliges signatory states to afford people equal treatment before the law and the equal protection of the law, without discrimination by requiring that everyone charged with a penal offence should be presumed innocent until proved guilty according to law in a public trial with access to "all the guarantees necessary for his defense" (United Nations General Assembly, 1948).

Ethical principles provide guidance to individuals, such as physicians, carers, researchers and patients in ethically sound ways of providing a particular treatment program (Mann, 1997). In contrast, acceptance of the principles of human rights obliges governments and the state to promote, respect and protect the rights of their citizens. Human rights are most relevant to the way in which treatments and interventions are used to treat and prevent addiction. Respect for human rights informs how the state and society as a whole responds to individuals with opioid dependence, e.g. by introducing policies and laws to deal with people who are addicted to opioids. Treatment of opioid dependence often requires the use of the coercive powers of the state and other forms of denial of liberty and autonomy, as well as access to different treatment options. Treatment of opioid dependence therefore requires careful justification and balancing of treatment and policy decisions (Gostin and Mann, 1999). For ease of comprehension we will consider human rights to be encompassed within ethical analysis, and will use these terms interchangeably.

Before discussing the major ethical considerations in the treatment of opioid dependence, we describe how the ethical principles described above should be applied. Broadly speaking, the ethical imperatives described above are largely uncontroversial.[4] Most reasonable people would agree that individuals should be respected and treated fairly but consensus often proves elusive in the case of treatment of opioid dependence because of disagreements about what is considered ethical treatment; what these ethical imperatives require us to do; and where the balance of effort and responsibility lies. These disagreements are often largely driven by different answers to the following questions:

- What is the nature of addiction?
- How does opioid addiction affect those who suffer with it? What sort of person is an opioid dependent individual? What are they capable of and responsible for?
- How does opioid addiction impact on society?
- What are the respective rights and responsibilities of society and opioid dependent individuals?

While ethical imperatives are substantiated by a long history of ethical debate of fairness and goodness, how these imperatives are achieved depends largely on empirical evidence relevant to what addiction is, the impact that addiction has on the individual and society, and the benefits and harms of different drug treatments and policies, for both individual and society. Accordingly, in specifying what constitutes ethical treatment for opioid dependence, we use empirical evidence (biological, sociological and psychological) to better understand addiction and the appropriateness of different treatment strategies.

Our approach to ethical analysis is a pluralist one. We use a set of broadly accepted ethical principles that constrain an empirically driven, utilitarian approach to balancing harms and benefits. This involves a dialectical process analogous to that described by Rawls as seeking *reflective equilibrium* (Rawls, 1971). Our

[4] We acknowledge that there are a variety of different ethical theories (e.g. consequentialist, deontological, rights based, feminist etc) that would provide very different justifications for, and very different priorities to, these principles.

understanding of addiction and drug treatment and policy derived from empirical research is combined with general ethical principles and applied to specific situations to specify the conditions for ethically sound treatment of opioid dependence. The empirical evidence is not being used to *validate* or prove a *prima facie* ethical perspective. Rather the ethical principles were derived from ethical theories and the empirical evidence has been used to determine the best way of achieving these ethical goals. This is akin to the distinction between instrumental and final reasoning (Casebeer, 2003). The ethical principles outlined above were derived from final reasoning: what sorts of goals is it desirable to set in order to achieve ethical ends? The empirical approach is used as part of an instrumental reasoning: a study of the best means of attaining the final goals, in this case ethical treatment of opioid dependence.

## SECTION 2: GENERAL ETHICAL CONSIDERATIONS IN THE PHARMACOLOGICAL TREATMENT OF OPIOID DEPENDENCE

In this section we focus on the major ethical issues raised in providing different forms of pharmacologically assisted treatment to opioid dependent persons. We assume for the purposes of this discussion that safe and effective forms of these treatments are provided in an efficient way, and that there are no additional cultural or political impediments to treatment. We acknowledge that a persistent challenge in the treatment of opioid dependence, even in wealthy developed societies, has been ensuring that treatment services have sufficient human and material resources to provide safe and effective treatment. We also acknowledge that there are cultural and political pressures that can limit the effectiveness and availability of treatment in different countries.[5]

As outlined previously, our ethical analysis will make use of the four main principles of medical treatment: autonomy, non-maleficence, beneficence and distributive justice (Beauchamp and Childress, 2001). While most would argue that these principles are ethically desirable, there is much disagreement about what respecting these principles might entail, or how it would be achieved. There is a gap between these broad principles and the statement of practical ethical guidelines for the treatment of opioid dependence that this chapter aims to fill.

The nature of addiction, and how it affects (or doesn't affect) individual ability to control drug use, is central to all subsequent discussions of what ethical treatment of opioid dependence involves. How much autonomy do opioid dependent persons have? To what extent are they able to make decisions about their drug use, consent to enter treatment, choose not to use drugs, be involved in decisions regarding their treatment, and take responsibility for their actions?

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[5] While we believe that the ethical principles outlined in Section 1 apply to all situations, we acknowledge that cultural, social and economic peculiarities of some regions will affect how these principles are best achieved.

Answers to these questions depend upon what sort of condition opioid dependence is. Whether we believe it is a disease or wilful bad behaviour influences the degree to which the societal response is medical or judicial or some combination of the two. It also affects how responsible we hold those who use opioids to be for their actions, and how much of the burden of treating the condition should be borne by the individual and how much by society.

The two other ethical principles of non-maleficence and beneficence are largely uncontroversial in the treatment of opioid dependence in the sense that everyone agrees that we should aim to benefit and avoid doing harm to those who seek treatment for opioid dependence. There is nonetheless disagreement about the harms and benefits of the different treatment approaches, the evidence for which is discussed in Section 3.

Ethical concerns about the autonomy of opioid dependent persons involve an evaluation of two related claims: (1) that addicts are by virtue of their addiction are incapable of freely consenting to receive treatment that involves being maintained on a drug of dependence; and (2) that their autonomy may be impaired if they are forced to enter treatment as a result of legal coercion e.g. being coerced into entering treatment to avoid prosecution in the criminal justice system. We also discuss the potentially adverse effect that legally coerced treatment may have on patient privacy and the confidentiality of information obtained in the course of treatment.

In the remainder of this report we consider each of these issues as they arise in pharmacologically-assisted detoxification, relapse prevention, and maintenance treatment. We conclude with a brief discussion of the distributive justice issues that arise in treatment provision and the challenges in managing conflicts between the treatment goals of assisting opioid dependent persons and serving the public good by reducing the public health and order consequences of opioid dependence.

## Autonomy and the Opioid Dependent Individual

For much of the 20$^{th}$ century, opioid dependent persons were seen as autonomous, self governing individuals who wilfully, knowingly, and voluntarily engaged in criminal

and immoral behaviour (Dalrymple, 2006; Szasz, 1997). The presumed autonomy and responsibility of such individuals has been called into question by recent genetic and neuroscientific research on addiction conducted primarily at the US National Institutes on Drug Abuse (NIDA) (Leshner, 1997; Volkow and Li, 2004). In 1997, Leshner described addiction as a "chronic, relapsing brain disease" (Leshner, 1997), a view recently supported by the current directors of NIDA and the National Institute for Alcoholism and Alcohol Abuse (NIAAA). They argue that addiction is caused by chronic self-administration of drugs that produces enduring changes in brain neurotransmitter systems that leave addicts vulnerable to relapse after abstinence has been achieved (Volkow and Li, 2005b). In the same way that cardiovascular disease is a result of abnormal heart tissue, the chronic brain disease model of addiction holds that addiction is the result of abnormal neural tissue (Volkow and Li, 2004).

The bran disease model challenges the traditional belief that drug use is always a voluntary choice. Studies have shown that prolonged drug use results in long-lasting changes in brain structure and function that undermine voluntary control (Leshner, 1997; Volkow and Li, 2004). Studies of the effects of repeated drug use on brain function, combined with knowledge of how environmental, genetic, and developmental factors can influence vulnerability to addiction, increases our ability to treat and, more speculatively, to prevent addictive disorders (Cami and Farre, 2003; Leshner, 1997; National Academy of Sciences, 1996). Neuroscience and genetic research, it has also been argued, may also change the way in which we think about addiction, and the social policies that we adopt to deal with it (Dackis and O'Brien, 2005; Leshner, 1997; Volkow and Li, 2004).

Neuroimaging studies of the last 5-10 years have identified changes in brain regions involved in the cognitive processes of salience, motivation, memory and conditioned learning, and inhibitory control. Studies have shown that chronic drug use produces a significant decrease in dopaminergic activity that is involved in the disruption of limbic and prefrontal regions (Volkow and Li, 2005a). Adaptations in limbic regions emphasize the rewarding effects of drugs and make addicted individuals less sensitive to the rewarding effects of natural reinforcers (everyday stimuli such as food, work and relationships). Disruption of functioning in the prefrontal regions focuses addicts' attention on drug use and impairs their ability to control impulses to use drugs

(Volkow and Fowler, 2000; Volkow et al., 2003). These neuroadaptations can persist for months after abstinence (Volkow and Li, 2004). Neurocognitive studies have also shown that addicted individuals display cognitive deficits in decision-making tasks (Bechara, 2005; Bechara et al., 2001). Neuroimaging of decision-making has identified differences in brain function that underlie these decision-making deficits (Bechara, 2005).

These results are beginning to produce a neurophysiological picture of how addictive drugs can subvert endogenous reward circuits that are essential to survival, thereby giving drug use an over-riding motivational salience that works to the detriment of all other goal directed activities (Dackis and O'Brien, 2005). According to its proponents, it also explains why addicts continue to use drugs despite tolerance to their pleasurable effects and the serious aversive consequences that they cause.

The problem with the disease model of addiction, and any of the 'lifestyle diseases" such as obesity and diabetes, is that nearly any kind of behaviour is going to be accompanied by biological changes in the brain that can be detected if researchers look hard enough. Finding such differences does not indicate a disease of biological origin, as possessing a biological correlate is a necessary but not sufficient condition for being a disease. This point has often been overlooked in simplistic disease models of addiction. By contrast, those who claim that addiction is a self-serving excuse for willful and bad behaviour (Dalrymple, 2006; Szasz, 1997) ignore the biological correlates of addiction. The nature of addiction is actually a much more complex phenomenon than either perspective allows. Disease models need to acknowledge that people with an opioid dependence still maintain some autonomy in making decisions about their drug use. Sceptics need to acknowledge the role of brain neurobiology in impairing the ability of drug dependent people to make decisions about their drug use.

The ability, or lack thereof, of the opioid dependent individual to have control over their drug use is central to ethical debates regarding the treatment of opioid dependence. These arguments hinge on whether these individuals are *compelled* to use drugs. While arguments for compelled behaviour can stem from both biological and social causes, arguments for compulsive behaviour are made most often for

biological causes. Genetic and neurophysiological explanations of compulsive drug use are much more compelling and have the appearance of material fact. The presence of "addictive genes" and pictures of "addicted brains" possess the allure of truth, and are easily misrepresented or misunderstood. These results are often used to portray the opioid addict as someone who is "internally coerced by an *irresistible* force" and therefore lacks autonomy with regard to drug use (Foddy and Savulescu, 2006). In the words of the then director of the National Institute of Drug Addiction, the brains of addicts have been "*hijacked"* by their drug of dependence (Leshner, 1997). We explore the issue of autonomy in opioid addicts by evaluating arguments that have questioned the ability of opioid dependent persons to consent to either treatment or research that involves the offer of opioid drugs.

*Capacity to Consent to Agonist Maintenance*

Recently, some ethicists have been prompted by this emerging neurobiological conception of addiction to question the capacity of opioid dependent individuals to make free and informed choices about some forms of treatment for their dependence (Charland, 2002; Cohen, 2002). According to these ethicists, heroin addicts are, by definition, unable to make rational decisions about whether to accept an offer of heroin either in the setting of a research study (Cohen, 2002), or a clinical trial of heroin maintenance treatment (Charland, 2002). In the case of heroin maintenance, if a treatment can only be offered to patients if there is evidence of its safety and efficacy provided by a randomised controlled trial, then accepting Charland's argument would prevent the completion of the randomised controlled trials required to assess its safety and efficacy, and hence would preclude its clinical use. If these arguments were accepted, they would raise the same doubts about any treatment that involved offering opioid dependent persons maintenance on an agonist drug, such as methadone and buprenorphine, arguably two of the most effective pharmacological treatments currently available (Gowing et al., 2006a; Mattick et al., 2003).

Cohen (2002) argues that:

> *"the nature and pathology of untreated substance dependence make the condition inherently incompatible with a rational, internally uncoerced and*

> *informed consent on the part of those volunteering to receive addictive drugs in a non-therapeutic research setting" (p 74).*

According to Cohen, only those who enter treatment display enough rational capacity to consent to participate in research. Using the terminology of the US National Bioethics Advisory Committee, untreated heroin addicts offered their drug of dependence are "vulnerable subjects", which means that they cannot serve as experimental subjects in such studies, or they can only do so if consent is given on their behalf by others (National Bioethics Advisory Commission, 1999).

Charland (2002) has used a similar argument to arrive at the conclusion that heroin addicts are unable to give free and informed consent to participate in heroin prescription trials. Heroin addicts, he argues, based on the testimony of one former heroin addict, are incapable of saying "no" to the offer of free heroin. Citing statements by senior neuroscience researchers, Charland argues that opioid dependent individuals are so altered by the drug, that they are unable to consider the risks of taking it. By using drugs, addicts' behaviour has been "hijacked" by the drug – *"[t]heir decision is not truly theirs"* (Charland, 2002, p43). According to Charland, opioid addicts are therefore unable to consent to participate in trials of injectable heroin.[6]

There is no clear distinction between research and treatment in the case of opioid dependence and it cannot be assumed, as Charland and Cohen have done, that the act of entering treatment displays decision making capacity. Cohen argues that by virtue of entering into treatment, addicts demonstrate the capacity to control drug use: by entering treatment, addicts "display a minimal degree of concern for their own well-being" and by continuing to take drugs they demonstrate a lack of competence (Cohen, 2002). However, it does not follow that only healthy choices are competent choices. Many people make choices that are unhealthy, but we would not argue that by being unhealthy, they are incompetent choices (e.g. rock climbing, drink driving).

[6] Heroin trials refer to studies in Switzerland, but also in the Netherlands, that examined the effectiveness of providing treatment refractory heroin users with free injectable heroin under strict medical supervision and legal regulation.

It does not follow that addicts lack self-preservation or concern for their own well being.

Charland's claim that heroin users are unable to say "no" to an offer of heroin is empirically false because the Swiss heroin trials were not inundated with untreated heroin addicts seeking "free heroin". This was clearest in a randomised controlled trial of immediate vs. delayed entry to heroin maintenance (with the delayed entry group given access to usual treatment, methadone maintenance or abstinence) (Perneger et al., 1998). The researchers intended to recruit 40 patients in each group but only recruited 24 and 27 patients, respectively. Moreover, when those who were allocated to delayed entry to heroin treatment were offered the choice at the end of six months, two thirds of the group decided against receiving heroin (Perneger et al., 1998). Severely dependent treatment refractory Swiss heroin addicts were thus capable of saying "no" to an offer of heroin prescription.

The arguments of Charland and Cohen interpret the DSM-IV criteria that describe loss of control and compulsive behaviour in absolute terms, as reflecting an incapacity to control drug use rather than as describing varying degrees of impaired control over drug use in varying situations. The DSM-IV criteria that they rely on are simply descriptive terms, and in themselves do not constitute proof or evidence. Many addicts, for example, are able to control their drug use in particular settings when experiencing serious difficulties. They may, and often do, stop using drugs without assistance for varying periods, either to reduce their tolerance or to take time out from the rigours of their life style. The fact that many opioid addicts stop using in response to changes in life situation, such as a birth of a child or input from friends, family and colleagues indicates that addictive behaviour is more than a simple neurochemical drive (Dalrymple, 2006).

In order for 'addiction' to plausibly deny any autonomy to individuals with an opioid dependence, the forces, internal and external, must be demonstrably irresistible and absolute. It is clear from behavioural and observational studies that this is not the case. Also, the evidence some ethicists cite from the neuroscience literature is less compelling than they might think. A closer reading of articles by leading neuroscientists about "hijacked" brains would suggest that certain expressions were

meant to be understood metaphorically for the explicit purpose of obtaining more humane treatment for addicts. They were not intended to be taken literally and used in their strictest sense; such an interpretation is not supported by a close reading of the neuroscience. The idea of "compulsion" in neuroscience terms derives from animal studies which have an uncertain application to the contexts in which humans use drugs. Also, neuroimaging studies of the "addicted brain" produce highly constructed and manipulated images that generally only demonstrate group differences in brain function that are not found in all addicts. In particular, the neurocognitive deficits that are said to typify addiction are not seen in all addicts, while some non-addicted persons do display these cognitive deficits (Bechara, 2005; Bechara et al., 2001). In summary, neuroscience research on addiction does not prove that addicts lack autonomy: addicts retain some degree of control over their drug use and some degree of autonomy.

The autonomy of opioid addicts in making choices about their drug use is undoubtedly impaired in certain situations, e.g. when they are acutely intoxicated or experiencing severe opioid withdrawal symptoms. A commonly held (and we believe) reasonable view among addiction researchers has been that drug dependent people are able to give free and informed consent so long as they are not intoxicated or suffering acute withdrawal symptoms (Adler, 1995; Gorelick et al., 1999). Since many addicts enter treatment while intoxicated or in withdrawal, entering into detailed treatment contracts should be delayed, and not required on admission to treatment programs. The worst drug withdrawal symptoms should be reduced by medication (or withdrawal symptoms should have abated), and patients be given time to consider their treatment options before they are required to make long-term or far-reaching decisions implied by signing a treatment contract.

Addiction may therefore affect addicts' ability to consent to treatment in the short term and their capacity to choose a specific treatment from the types available. We should nonetheless assume that addicts possess decision making capacity and attempt to engage them as much as possible to make their own decisions rather than make decisions for them, or over-ride their wishes by coercing them into treatment. This is the presumption that is made by the courts in holding addicts responsible for their actions (rather than exculpating on the grounds of their addiction). It seems

reasonable to make the same assumptions in the treatment setting when seeking consent to treatment.

### *Capacity to Consent to Abstinence Oriented Treatment*

Concerns about capacity to consent have often been selectively raised in the context of pharmacological maintenance treatment. Critics such as Cohen and Charland, for example, seem to implicitly assume that the only free and informed decision that an addict is capable of making is the decision to enter abstinence-oriented treatment. But, by the same type of reasoning, there are grounds for doubting that all decisions in favour of this treatment type would be truly free or informed. Many addicts enter abstinence-oriented treatment under some form of coercion, such as the threat of criminal prosecution, or the loss of employment or a relationship. Heroin addicts who enter such treatment without coercion may overestimate their capacity to achieve abstinence, underestimate the difficulties of remaining abstinent, and may not appreciate the risks (e.g. increased risk of a fatal overdose on relapse to heroin use). Abstinence-oriented treatment programs, no less than agonist maintenance treatment, must therefore meet ethical obligations to inform patients of the low success rate of their treatment, and the increased risk of fatal overdose that they assume in entering abstinence-oriented treatment.

### *Implications*

In dealing with heroin addicts in desperate physical and mental states, treatment services must be informed by acknowledgement of the very real neurobiological changes that affect addicts' ability to control their drug use and to make decisions about themselves while intoxicated or in acute withdrawal. These facts can be acknowledged while recognising that opioid dependent persons who are not in these states still possess some capacity to make decisions about their treatment. This capacity should be nurtured and developed so that they can play an active role in their treatment and recovery. This means that treatment services must operate in a manner that allows addicts to stabilise before making commitments to further treatment and that they should provide accurate information about the likely success and the risks and benefits of the different treatment options available to them.

## Coerced Treatment of Addiction

There is reasonable evidence that those who enter agonist maintenance treatment for heroin abuse will benefit from the treatment, and the longer they remain in treatment, the better off they will be (Gerstein and Harwood, 1990; Ward et al., 1998b). The same is broadly true of abstinence oriented treatment but with lower rates of success; fewer are attracted into this form of treatment and rates of treatment retention are generally poorer than agonist maintenance treatment (Gerstein and Harwood, 1990). The fact that many opioid dependent persons do not wish to enter abstinence oriented treatment has led to the use of various forms of coercion to encourage opioid dependent people to enter and remain in treatment. Can legal coercion be used ethically and effectively in the treatment of opioid dependence? If so, under what conditions is it ethical to do so?

There are various forms of coerced treatment for opioid dependence that vary in the amount of force used, and therefore in the degree to which they contravene an individual's liberty, freedom and autonomy. Mild informal coercion includes social pressure from friends and family to enter treatment (Maddux, 1988). More formal (but not involving criminal proceedings) coercion may come from employers and government agencies who make it a condition of continued employment to undergo treatment (Weisner, 1990). Legally enforced forms of coercion involve the use of the criminal justice system to enforce entry to treatment on pain of imprisonment (Klag et al., 2005).

Evidence has shown that social coercion is an effective motivation for addicts to enter and complete treatment (Hasin, 1994; Room et al., 1991; Wild et al., 1998). Addiction puts an enormous emotional and financial burden on families, and it is not surprising that pressure from loved ones (e.g. highlighting the destructive impact of a person's drug use or threatening to end a relationship if they continue to use drugs), can motivate those who still have strong social ties to seek treatment. Many addicts do not appreciate the impact that their drug use has on themselves or their friends and families; pressure from friends and family to cease their drug use often provides an external indication that their drug use is problematic.

Unfortunately, for some long-term opioid abusers, such important social ties have lost either influence or significance in their lives, and treatment often requires more coercive forms of intervention. Formal non-criminal coercion by employers and other nongovernmental agencies, such as Employment Assistance Programs (EAP), are negotiated between agencies or employers and the individual. The ethical guidelines for how these programs operate are codified in the appropriate laws (e.g. industrial relations).

While informal social coercion and formal non-criminal coercion represent very important motives for entering treatment, they arguably raise fewer ethical issues in the treatment of opioid dependence than legally coerced treatment. In both these cases, the opioid dependent person is *relatively* free to agree to treatment or suffer the threatened consequence (such as loss of employment or relationship). The coercive pressure in these situations arguably does not deprive them of their liberty or deny their autonomy. The form of coercion that raises more ethical concerns is court sanctioned coercion in which the threat of imprisonment is used to motivate entry into, or compliance with, addiction treatment.

### *The Case for Legally Coerced Treatment*

One of the major justifications for the use of legally coerced treatment is that treating offenders' drug dependence will reduce the likelihood of their re-offending (Gerstein and Harwood, 1990; Inciardi and McBride, 1991). Studies from both the US and Australia have shown quite convincingly that treatment for heroin dependence significantly reduces criminal and violent behaviour while addicts remain in treatment (Bell et al., 1992; Gerstein and Harwood, 1990; Hubbard et al., 1988; Ward et al., 1992). The use of drug treatment programs as an alternative to incarceration has also been motivated by the failure of prison terms to reduce drug use and drug-related crime and the over-representation of drug dependent people in prisons (Hall, 1997; Pedic, 1990; Stathis, 1991; Stathis et al., 1991).

Medical models of addiction highlight the causal role that heroin addiction plays in leading to imprisonment and the high rates of relapse to heroin use after release (Gerstein and Harwood, 1990). The advent of HIV/AIDS has provided an additional argument for treating heroin addiction (Dolan et al., 1996). By keeping injecting

heroin users out of prison, there is likely to be a reduction in the transmission of infectious diseases such as HIV and hepatitis C virus (HCV). The ethical, correctional and public health arguments for drug treatment under coercion are reinforced by the economic argument that it is less costly to treat offenders who are drug dependent in the community than it is to imprison them (Gerstein and Harwood, 1990).

Legal coercion covers a wide range of strategies for getting individuals into treatment programs. The most coercive is compulsory treatment programs, such as civil commitment programs in the US and Sweden where individuals are sentenced by the court to enforced addiction treatment in a secure facility for an extended period of time (Farabee and Leukefeld, 2001; Weisner, 1990). While such treatment strategies were used frequently in the past, the difficulty in ethically justifying such deprivation of liberty, and evidence suggesting that newer legal options for coerced treatment are more effective, have seen these civil commitment programs fall out of favour in the US (Wild, 1999).[7]

The form of legal coercion that has become increasingly popular within the criminal justice system is the use of diversionary programs that offer opioid dependent persons treatment as an alternative to imprisonment at various stages in the criminal justice process. In the first instance, treatment may be offered as an alternative to being prosecuted with an offence prior to being charged by police. This is not an ideal method of coercion as it falls outside judicial oversight. It is possible that relying on the discretion of police may open the way for individuals being coerced into treatment for reasons other than criminal behaviour, such as odd or unconventional behaviour or being a member of an ethnic minority (Hall, 1997).

Legally coerced treatment is most often advocated for persons charged with or convicted of an offence to which their drug dependence has contributed. It is generally offered as an alternative to imprisonment in order to have legal sanctions deferred, reduced or lifted, or as a condition of parole (Klag et al., 2005; Rotgers,

[7] While civil commitment statutes were created throughout the 1960s in the US, no state is currently committing significant numbers for drug treatment Gostin LO (1993) Compulsory treatment for drug-dependent persons: justifications for a public health approach to drug dependency. In Bayer R, Oppenheimer GM (eds.), *Drug policy: illicit drugs in a free society*. Cambridge University Press, Cambridge, UK.

1992). Suspension of legal sanctions is usually made conditional upon successful completion of a treatment program, with the threat of imprisonment if the person fails to comply with treatment (Hall, 1997; Spooner et al., 2001). Each of these forms of legally coerced treatment have different legal and social consequences for the offenders subjected to them, requiring varying degrees of deprivation of liberty, restraint and hardship. The ethical validity of the use of these forms of coercion will be outlined below.

### *When Is Coerced Treatment Ethical?*

Careful consideration of ethical issues is critical when the state uses the threat of imprisonment to encourage opioid dependent persons to seek treatment. Coerced treatment of heroin addiction must operate within a constitutional and legal framework which protects the civil liberties of the people being coerced into treatment (Klag et al., 2005). It is important that treatment does not over-ride an individual's basic human or civil rights in order to achieve broader social goals (Anderer, 1992; Bersoff, 1992; Kleinig, 2004; Wexler, 1993). Under what circumstances, if any, is society justified in restricting the liberty of heroin addicts?

Coerced treatment for heroin addiction may be justified by appealing to either of two ethical principles: paternalism or the public good. Heroin addiction is a harmful behaviour in which to engage; it impacts negatively on an individual's health and social welfare, with a significantly increased mortality and morbidity (Hall et al., 2006). Coerced treatment of heroin addiction could therefore be justified for *paternalistic* reasons: that is, on the grounds that it is in the best interests of the individual. This would involve coerced treatment for the addict's "own good".

Two forms of paternalism can be distinguished on the basis of the degree of coercion involved. Treatment that is provided against an individual's wishes, where the individual is deemed competent in making this decision is referred to as *hard paternalism*. When an individual is deemed incapable of making a competent decision, treatment is imposed because it is argued that their condition prevents them from making informed decisions on their own behalf. This form of coerced treatment is referred to as *soft paternalism*. It is soft paternalism that is most likely to be used to justify coerced treatment in the case of addiction.

In many countries, people with serious mental illnesses can be compelled to accept treatment under certain circumstances, but this is usually after some form of judicial or quasi-judicial review. We do not, however, generally treat people suffering from other medical conditions against their will, unless the individual lacks the capacity to give free and informed consent to treatment, as in minimally conscious patients.[8] While there is a strong beneficent justification for providing treatment, respect for an individual's liberty to make their own decisions about treatment generally over-rides the beneficent drive to intervene (Childress et al., 2002; Dworkin, 1972). This would prevent the use of coerced treatment under hard paternalistic justification.

The use of paternalistically coerced treatment could be justified if heroin addicts were seen to suffer from a brain disease that robbed them of their autonomy and impaired their capacity to consent to treatment, as is argued by some (Charland, 2002; Cohen, 2002; Dackis and O'Brien, 2005). This justification would be similar to the forced treatment of minimally conscious patients or children, or mentally ill adults where consent to treat is required from a surrogate, usually the next of kin. However, as argued above, we believe this soft paternalist rationale for coerced addiction treatment would be based on a misrepresentation of the neurobiology of addiction. While addicts' decision-making is impaired, they retain some degree of control over their drug use which undermines the soft paternalistic justification of coerced treatment.

The second principle that can be used to justify coerced treatment of opioid dependence is to protect the social welfare or the *public good*. The public good claim for the use of coerced treatment depends upon the negative impact of opioid dependent users on society (e.g. via drug dealing and other criminal activity to finance their drug use). The ethical justification of coerced treatment in order to protect the public good therefore becomes a distributive justice issue: that is, providing a fair distribution of the costs and benefits of drug use and drug treatment. This analysis arguably creates an obligation on society to provide treatment, and an analogous obligation on opioid dependent individuals to accept treatment under certain

[8] Our analysis assumes that addiction treatment falls under the auspices of medicine. It is commonly agreed that addiction is a disease, and the use of psychopharmacology is only justified if it is being administered as a medical treatment.

circumstances. This is the most commonly used justification for coerced treatment of addiction (Hall, 1997). The question is: when or under what circumstances is coerced treatment justified in order to protect the public good?

Some authors reject any form of treatment under coercion for heroin (or any other form of drug) dependence. Radical libertarians such as Thomas Szasz and Theodore Dalrymple deny that drug dependence exists, arguing that all drug use is always voluntary (Dalrymple, 2006; Szasz, 1997). According to Szasz, the law should not prohibit adults from using any drug, and any drug user who commits a criminal offence should be punished. The punitive policy consequences of Szasz's libertarianism enjoy more public support in developed countries than the proposal to legalise the use of all currently illegal drugs.

Others, such as Newman, accept that drug dependence exists but oppose compulsory drug treatment on the grounds that it does not work (Newman, 1974). If treatment under coercion were ineffective (as Newman claims), then there would be no ethical justification for providing it. Of course, even if treatment under coercion is effective, it does not follow that it should be provided. For example, the community might place a higher value on punishing than rehabilitating offenders (Hall, 1997).

A consensus view on drug treatment under coercion prepared for the World Health Organization (Porter et al., 1986) concluded that coerced treatment was legally and ethically justified if and only if: (1) the rights of the individuals were protected by "due process" (in accordance with human rights principles), and (2) if effective and humane treatment was provided. Due process would require some form of judicial oversight of the coerced treatment process. In the absence of such due process, coerced treatment could become *de facto* imprisonment without judicial oversight. In the absence of humane care and effectiveness, coerced "drug treatment" would not meet the WHO ethico-legal standard.

The uncertain benefits of coerced treatment have led some proponents to argue that offenders should be allowed two "constrained choices" (Fox, 1992). The first constrained choice would be whether they participate in drug treatment or not. If they declined to be treated, they would be dealt with by the criminal justice system in the

same way as anyone charged with the same offence. The second constrained choice would be given to those who agreed to participate in drug treatment: this would be a choice of the type of treatment that they received. There is some empirical support for these recommendations in that there is better evidence for the effectiveness of coerced treatment that requires some degree of "voluntary interest" by the offender (Gerstein and Harwood, 1990).

*Implications*

The constrained choice condition has three implications. First, pharmacological treatments options, including agonist maintenance, should be included in the range of options that are offered to coerced addicts. There has been a tendency for coerced treatment programs to only offer "drug-free" abstinence-oriented treatments which prevents coerced addicts from accessing the forms of treatment that are most likely to benefit them (Hall, 1997). Second, pharmacological treatment options should not be the only options available; there should be a range of drug-free treatment options available for those who do not wish to use pharmacological treatment. Third, the safety, effectiveness and cost-effectiveness of whatever forms of treatment are offered should be rigorously evaluated (National Research Council, 2001).

*Is compulsory addiction treatment ethically acceptable?*

Compulsory treatment – unconditional, enforced entry to addiction treatment – does not offer an opioid dependent individual any choice. This type of coerced treatment involves an extreme violation of an individual's autonomy and liberty. Mandatory treatment has generally involved the confinement of individuals in specialised drug-treatment facilities, or prison hospitals, usually with the goal of attaining abstinence from heroin (Farabee and Leukefeld, 2001; Gostin, 1993; Klag et al., 2005; Weisner, 1990). [9] Upon successful completion of an abstinence program, individuals may be released from the facility into some sort of intensely supervised outpatient facility. Failure to comply with any condition of the program usually results in being readmitted to a secure inpatient facility (Gostin, 1993).

[9] Antagonist treatments such as naltrexone detoxification or maintenance are the favoured pharmacological treatment methods in such situations. The advent of sustained release formulations of naltrexone or opioid vaccines may be particularly attractive to proponents of compulsory treatment regimes. The ethics of these forms of treatment will be discussed below.

Because compulsory treatment involves a maximal deprivation of liberty, it a correspondingly requires a greater ethical and legal justification than coerced forms of treatment. Arguably this includes stronger evidence that this form of treatment is effective and that the consequences of not treating the person are large and extremely likely to occur (Aronowitz, 1967; Childress et al., 2002). Given the evidence presented above, it is hard to justify the use of compulsory treatment regimes, for either paternalistic or public good reasons (Leukefeld and Tims, 1988). Importantly, compulsory treatment programs completely abolish the autonomy of the individual, and arguably constitute a violation of civil liberties in a manner that contravenes the UN bill of human rights. Coercive diversion strategies, by contrast, are less restrictive, because they involve constrained choices. They are accordingly less ethically objectionable than compulsory treatment. A choice not to enter treatment would leave the person to face the judicial system, but with their civil and human rights intact.

Another concern with the use of compulsory treatment is the effect that this has on the ability for those seeking treatment to find it. It makes little sense if treatment places for compulsory treatment reduce places for those voluntarily seeking it (Hall, 1997; National Institute on Drug Abuse, 1983). Also, compulsory treatment programs can increase the burden on programs that are effective, well funded and well resourced. It can also affect staff morale and have a negative impact on what might otherwise be successful treatment centres (Hall, 1997).

### *Ethical Issues in Providing Coerced Addiction Treatment*

Ethical issues in coerced addiction treatment also arise from the interaction between the correctional and drug treatment systems (Platt et al., 1988; Reynolds, 1992; Rotgers, 1992; Sheldon, 1987; Skene, 1987). A major problem is the conflicting expectations of correctional and treatment personnel about the effectiveness of drug treatment and their understanding of each other's roles and responsibilities.

Treatment staff usually regard the drug offender as a client: someone who should be involved in treatment decisions and the confidence of whose personal information should be respected. Treatment staff also expect that their clients will have relapses to drug use which should be dealt with therapeutically rather than punitively.

Correctional and judicial personnel, by contrast, often expect treatment to produce enduring abstinence. They see treatment as something directed by the court, and hence regard drug use in treatment as a breach of a court order that treatment staff are legally obliged to report. When these expectations of treatment effectiveness are not met, and there is little communication between courts and treatment services, judges and magistrates may become sceptical about the value of coerced treatment and reduce their use of it (Baldwin, 1979; Skene, 1987).

The effective and ethical use of coerced drug treatment accordingly requires a shared understanding of the likely benefits of treatment, and a clear statement of the roles of correctional and treatment staff. The latter should include agreement upon their respective responsibilities for monitoring and reporting upon an offender's progress in drug treatment. These issues should be addressed in written protocols that govern interactions between courts and treatment personnel. We explore this tension between the often conflicting aims of treatment in greater detail next.

## Personal Health and the Public Good in Opioid Dependence Treatment

The treatment of opioid dependence is complicated by two additional issues. First, many opioid addicts who seek treatment are involved in the criminal justice system because they have been arrested for offences committed to fund their drug use. They may be coerced into treatment to reduce the adverse effects that their behaviour has on society. Second, many opioid dependent persons are not able to pay the costs of their treatment. In many developed countries, this usually means that opioid treatment is provided either by charitable non-government organisations (NGOs) or by governments, with a small private sector catering to wealthy addicts. The NGO sector has traditionally provided drug-free forms of treatment such as residential rehabilitation programs, self-help groups and outpatient counselling. Government programs have more often provided pharmacologically based treatments such as agonist maintenance treatment. These programs have often been funded on the grounds that they provide a cost-effective form of treatment, with the largest cost savings arising from the fact that these programs substantially reduce crime among opioid dependent persons (Hall et al., 2006; Ward et al., 1998b).

The fact that pharmacological treatment of opioid dependence serves mixed personal, public health and public order goals complicates the provision of treatment. As noted above, it often involves interactions between the health and criminal justice systems, in which conflicts can arise between different professions (e.g. law enforcement, clinical staff, and public health) with different ethics and approaches to health care. The same can be true for conflicts between public health and personal medical care professionals who have different aims, methods of acting, and guiding ethical values. The use of pharmacological treatments means that maintenance treatment falls under the umbrella of medicine as these drugs are prescribed by physicians. Yet, as noted, the justification for public funding of maintenance treatment for opioid dependence often depends upon the public health and public order benefits (via reduced criminal activity) that they produce (Hall, 2006a).

Clinical or personal medicine "focuses on the treatment and cure of individual patients" while public health medicine "aims to understand and ameliorate the causes of disease and disability in a population" (Childress et al., 2002, p 170). While "the physician-patient relationship is at the centre of medicine", public health involves "interactions and relationships among many professional and members of the community as well as agencies of government" (Childress et al., 2002, p 170). The involvement of the criminal justice system in coercing patients into treatment amplifies the opportunities for conflict between the goals of opioid dependence treatment. The tensions between these competing goals must be managed by all forms of treatment, including abstinence-oriented treatment but they present special issues for programs that provide pharmacological treatment of opioid dependence.

Public ambivalence about the ethical acceptability of maintaining addicts on opioids often leads to the imposition of restrictive rules and regulations on pharmacological treatment. Some regulations are intended to minimise the risk of non-addicted persons entering treatment (e.g. by demanding evidence of an extensive history of dependence and documented failure at abstinence treatment). Other regulations aim to prevent the diversion of pharmaceutical opioids to the black market where they may be used inappropriately and result in overdose deaths and addiction. Some programs specify the frequency of urine testing and require patients to be excluded from programs if

they provide three "dirty" urine samples. Some programs place time limits on treatment or insist upon a goal of abstinence from all opioids being achieved within some arbitrary period (e.g. one or two years). The unintended effects of these types of regulations may include: discouraging opioid dependent persons from seeking treatment until their condition is chronic, decreasing program retention because of the onerous requirements made of patients, and forcing stable patients to withdraw from treatment and return to illicit opioid use (Ward et al., 1992).

Ethically acceptable and effective agonist maintenance treatment of opioid dependence requires program rules and regulations that balance patient and community safety while permitting patients to remain in and benefit from treatment. Ethical and effective treatment must be a multifaceted strategy that addresses *all* of the needs of the individual. It is important that treatment is not limited by the ideological viewpoints of the staff that operate the treatment programs. Individuals who receive support and counselling must have access to appropriate pharmacological drugs if required, while those in maintenance and relapse prevention programs should not be limited to just pharmacological strategies. Treatment must also recognise the changing circumstances of the patient as treatment progresses, and be flexible enough to meet these needs.

## Distributive Justice and Drug Policy: Balancing the Burden of Disease and Treatment

The justification of the public funding for opioid dependence treatment programs in terms of the public benefits that it brings is important in obtaining support but there is a danger that public policies that are beneficial to the majority may impose unfair burdens on a vulnerable minority. An important aspect of ethical analysis of opioid dependence treatment is ensuring that public policies do not *unfairly* burden or discriminate against a vulnerable minority in order to serve the public good.[10]

[10] Such a public policy would be justified on most utilitarian analyses but as outlined in Section 1, this is not an approach that we support. We believe that there are important ethical principles that need to respected and balanced against the greater good.

Distributive justice is a difficult and emotively charged issue in the case of addiction because drug use and drug policy have negative impacts on both society and the dependent individual. This raises important questions about where the burden of responsibility lies for society and the addicted individual in dealing with opioid dependence. For treatment to be ethical, we need to show that it is effective in reducing negative outcomes for both society and the individual, and that the social and political forces that lead to addiction do not unfairly burden the minority who become addicted. It would be arguably unethical to use pharmacological treatment of opioid dependence as a form of compensation for inappropriate social policies or the neglect of vulnerable populations, no matter how effective the treatment was in improving the *status quo*.

Those who receive treatment, particularly when it is publicly funded and subsidised, also arguably have a reciprocal responsibility to engage in a reasonable treatment program, to meet its aims and to avoid behaviour that adversely affects society. For the rest of this section, we will analyse this issue by focussing on (1) the impact that society and social policy has on drug use, the responsibility of society to reduce this impact and the ethics of providing pharmacological treatment to a vulnerable population, and (2) the responsibility of opioid addicts to engage and comply with treatment, and what measures society may reasonably take to ensure compliance with this obligation.

*The ethics of pharmacological treatment of vulnerable populations*

Few public issues have produced a global consensus in the way that prohibition of the recreational use of opioids has. While there is disagreement around the margins, such as exactly which opioids should be illegal, and how to treat those that use and become dependent on illicit opioids, most nation states have enacted laws that prohibit or restrict their use. These restrictive policies are designed to protect the majority of society who do not use opioids for recreational purposes and discourage their recreational use. These policies are effective in reducing rates of recreational opioid use but this is achieved at the cost of significant problems for the small minority who continue to use illicit opioids. A discussion of the fairness of pharmacological treatment of opioid dependence needs to acknowledge and consider the impact that the illegality of these drugs has on those who use them. Are we justified in ignoring

their suffering in the interests of serving the greater good by reducing opioid use, as many utilitarian would argue?

The view of opioids as a banal drug that only creates harm because of its illegality is occasionally advanced by some commentators (e.g. Carnwath and Smith, 2002)). Given the fact that recreational opioid use has been illegal in most countries for over half a century, there is limited empirical evidence to evaluate this claim. There is nonetheless, some evidence from experience with opioid dependence among medical practitioners that even pharmaceutically pure opioids used by well educated and informed people carry a significant level of risk in terms of addiction and fatal overdose (Cadman and Bell, 1998). These risks arise from the pharmacokinetic properties of opioids when injected. As tolerance to the rewarding effects of opioids increases, the dose required to achieve these effects increases and the window between the dose required to achieve euphoria and a fatal overdose narrows, making it more difficult for even educated users to use pure forms of the drug safely (White and Irvine, 1999). They are also at additional risk of suicide, motor vehicle accidents, and work related accidents, which may also impact on their patients (Strang et al., 1998). These properties provide an argument for some form of regulation of opioids, although the form that the regulation should take is more controversial.

A complete analysis of the arguments for and against the prohibition of opioids is beyond the scope of this report. While acknowledging that this is an important issue, we will in the remainder of the paper accept the current legal status of opioids in the majority of WHO members states.[11] This acknowledges the reality that the global policy of prohibiting recreational opioid use is not likely to change and it ensures that our arguments have the potential to affect the ethical provision of treatment for opioid dependence under current legal regimes.

Policies that govern the treatment of opioid dependence need to acknowledge the social, biological and psychological factors that can lead to addiction. While it is

[11] The prohibition of recreational opioid use is a complex issue that cannot be dealt with adequately in the space that we have available. More detailed analyses of the ethical validity of drug prohibition have been provided by: Husak DN (1992) *Drugs and rights*. Cambridge University Press, Cambridge, UK, Husak DN (2004) The moral relevance of addiction. *Substance Use & Misuse*, **39**: 399-436.

important that drug treatment programs are available, it is also important to ensure that pharmacological treatment does not become a surrogate for social policies that neglect certain populations. This is particularly pertinent given the strong association between social disadvantage, family history of violence and drug use and the presence of comorbid psychiatric disorders, and emerging evidence of genetic and neuropsychological vulnerabilities to opioid addiction (Hall et al., 2006). While social differentials in addiction risk do not exculpate the actions of those who use opioids, they do create an onus on social policy makers to be mindful of these social differentials and work to reduce them, in the interests of ethical drug policy and in order to reduce the incidence of opioid dependence. Social policies should provide more humane and less punitive treatment for those who become opioid dependent and use interventions that aim to reduce the social disadvantage and adversity that increases the likelihood of addiction. This may include ensuring a fairer distribution of wealth and opportunities amongst members of society via public investments in education, family education and support, and social welfare (Spooner and Hall, 2002).

*Reciprocal obligations for individuals receiving treatment*

Those with an addiction still have some choices, as argued above, and therefore have some obligations regarding their actions in treatment. Society is justified in expecting that drug dependent individuals who engage in treatment adhere to treatment and not act in ways that adversely affect society. For example, while MMT has been shown to be relatively safe and effective in reducing opioid use, it can lead to overdose if methadone is diverted to opioid-naïve users. In the UK during the 1990s, poorly regulated methadone programs lead to the diversion of methadone onto the black market resulting in fatal methadone overdoses involving persons not in treatment (Hall, 1998). This risk highlights the importance of delivering treatments in ways that protect both the person receiving it and the broader society. It indicates the need for regulations, procedures and treatment requirements in the provision of methadone treatment to protect users and the community.

Treatment responses and regulations used to ensure that those who enter treatment meet their obligations must be informed by a broad set of ethical principles, as detailed in the section that follows. In order to be ethical, they must: (1) not unduly violate privacy and autonomy of individuals; (2) scale responses to individual lapses

to their relative importance in achieving overall treatment goals; (3) be mindful and consistent with the ability of individuals to meet their obligations (including actively helping individuals to do so); and (4) be sensitive to the situation of the individual, with regard to both internal (neurophysiology and neuropsychology) and external (social) circumstances. A discussion of how this may be best achieved follows.

## SECTION 3: PRACTICAL ETHICAL ISSUES IN DELIVERING PHARMACOLOGICAL TREATMENT OF OPIOID DEPENDENCE

Based on ethical analyses in the preceding section, we now outline a set of broad ethical principles that we believe should motivate the provision of pharmacological treatment for opioid dependent persons.[12]

First, opioid dependent persons should have equitable access to safe and effective forms of treatment. That is, they should not be discriminated against by virtue of their condition nor should the illegal status of their actions prevent them from access to safe and effective treatment.

Second, there should be rigorous evidence that the treatment is safe and effective. New pharmacological treatments for opioid dependence need to have their safety and efficacy rigorously assessed before they are widely used.

Third, treatment should ideally be individualised to the patient. Opioid addicts differ in many ways and addiction is a dynamic process so the needs of different individuals will vary and may change over time and circumstances. It is accordingly important that treatment flexibly meets patients' changing needs.

Fourth, treatment staff need to emphasize the importance of the client-carer relationship in providing ethically adequate treatment that respects the autonomy of patients, their privacy and the confidentiality of information that they provide.

Fifth, ideally treatment that accords with the ethics of personal medical care is also the most successful in meeting the aims of a public health care program because good

[12] These principles and requirements of treatment reflect the goals of treatment outlined in other WHO publications World Health Organization (2004) *Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention: position paper*. WHO, Geneva.

individual treatment will ensure good program retention and maximize the benefits to the individual and the community that funds his or her treatment.

Sixth, good relationships between clients and staff are important in successful treatment. Attitudes of staff towards clients and their relationship with clients have been found to be the critical factors in determining the success of methadone maintenance treatment (Ball and Ross, 1991; Bell, 1998). This involves: affirmation and validation of the client; the building of trust over time; and flexibility in treatment delivery to meet an individual client's needs.

It is important that the treatment of opioid dependence be governed by the primary aim of treating the opioid addict. Most of the obstacles to effective treatment are the result of different understandings of the nature of opioid addiction and confusion over the aims of treatment (Bell, 1998). Often the regulations and policies that guide treatment are aimed at controlling, and even punishing an individual. Not only are such approaches ethically unsound – in that they violate the individual's right to safe and effective treatment – they are also ineffective from the utilitarian ethical perspective that often motivates the provision of treatment for opioid dependence. Treatment that aims to produce a therapeutic benefit for the individual is more effective if it engages the patient in treatment (Bell et al., 1995).

## Entering Treatment and the Role of Informed Consent

When opioid dependent individuals enter treatment, they are often in a desperate state, physically, emotionally, socially, or in any combination thereof. They may be willing to agree to almost anything in order to get into treatment (e.g. to end their withdrawal symptoms or avoid the negative social consequences of their addiction). For these reasons, individuals in this situation should not be asked to provide detailed consent to a treatment program, apart from indicating their acceptance of the immediate offer of assistance.

A client can only begin to think about treatment after they have either been stabilised on a longer acting opioid, or they have completed supervised opioid withdrawal. When choosing what sort of treatment to enter, it is important that the client

understand the likely effectiveness of the treatment, the benefits and risks of completing treatment, and the requirements of the program. The treatment that is chosen should reflect the aims of the individual rather than those of the staff or the wider community. The staff member's responsibility is to ensure that the client is well informed about the treatment options that are available, their goals, risks and benefits, and what the expectations are of them in entering the program. This will include discussions about the pros and cons of abstinence vs. maintenance treatment goals, as well as an honest appraisal of the risks and the likelihood of benefiting from both types of treatment.

Obtaining informed consent is not solely a requirement of pharmacological treatment programs. Abstinence, self-help and psychotherapeutic treatment programs also have a responsibility to obtain free and *fully informed* consent. This is particularly salient in the treatment of heroin addiction where the likelihood of relapse is high and there is a significant increased risk of overdose due to opioid naïveté after withdrawal. As for pharmacological based treatment programs, psychotherapeutic treatment programs have an obligation to inform an individual of risks and benefits of abstinence, as well of other options available, including pharmacological treatment programs, and the relevant evidence on the pros and cons of each of these options.

In many developed countries it is generally a legal obligation in medical and psychiatric treatment to obtain a signed treatment "consent form" during intake. The process of gaining consent is important not only to satisfy legal and ethical requirements; it plays a crucial role at the beginning of treatment. Obtaining consent should be motivated by a respect for autonomy as much as the desire to do good for the patient. Little attention has been given to investigating what is required for informed consent to treatment for opioid dependence and how this is best obtained (Sugarman et al., 1999). More research is needed on this topic. Also, studies of attitudes and understanding of the issue of consent by physicians and providers is often poor (Forman et al., 2002). Therefore, better training of staff is desirable, not just to meet legal requirements or provide the minimum of rights, but to facilitate better treatment.

The minimum requirements for acquiring free and fully informed consent, adapted from Walker (2005), are:

1) Providing information to clients about clinical characteristics and diagnosis
2) Treatment recommendations
3) Risks and benefits of treatment
4) Costs of treatment
5) Program rules – rights and obligations
6) Alternative services and interventions
7) Freedom to choose and refuse treatment

We now consider the practical issues specific to each of the different treatment approaches.

*Detoxification*

When entering a detoxification program, clients should be aware of the risks of relapse after successfully completing withdrawal if they do not engage in any further treatment. It is important that clients are aware of this as they may have over-inflated expectations of what the treatment will be able to achieve. This is particularly important in opioid detoxification because of the high likelihood of relapse and the risks of overdose on return to drug use. As part of a successful detoxification, patients lose their tolerance to opioids, making them effectively opioid naïve. This increases the risk of a fatal overdose if the individual relapses to heroin or other opioid use and uses the accustomed amount of heroin. It is important that patients understand this when entering into a detoxification program, both in terms of being fully informed, and in reducing the chances of an overdose in the event of relapse.

Those who enter detoxification with an abstinence treatment goal also need an honest evaluation of the likelihood of their success. Many addicts enter abstinence-oriented treatment under some form of coercion; either the threat of criminal prosecution, or the loss of employment or a relationship. Heroin addicts who enter such treatment may overestimate their capacity to achieve abstinence, underestimate the difficulties of remaining abstinent, and may not appreciate the risks of attempting abstinence (e.g. of fatal overdose on relapse to heroin use).

*Ultra Rapid Opioid Detoxification (UROD)*

A controversial procedure that gained popularity during the 1990s was the use of the antagonist naltrexone to accelerate opioid detoxification under general anaesthesia or heavy sedation (Gold et al., 1999; Loimer et al., 1990; Loimer et al., 1988; O'Connor and Kosten, 1998; Scherbaum et al., 1998). The procedure accomplished opioid withdrawal within 24 hours but at the cost of requiring an intensive care bed, intubation and artificial ventilation, specialist nursing, and an anaesthetist, making UROD an extremely expensive procedure (Gonzalez et al., 2004; Hall and Mattick, 2000). UROD also entailed a small known risk of mortality from anaesthesia, with several deaths recorded (Badenoch, 2002; Gold et al., 1999; Hamilton et al., 2002; Mayor, 1997). This risk is difficult to justify given that untreated opioid withdrawal is generally not life threatening and that withdrawal can be safely achieved in other ways with a minimum of discomfort (Gonzalez et al., 2004).

Studies of the effectiveness of UROD have been limited, and most have had methodological flaws, such as a lack of comparison or control group, and a high degree of selection bias. A recent systematic review of UROD has shown that naltrexone detoxification under heavy sedation is no more effective than under light sedation, making it difficult to justify the risks and costs of UROD (Gowing et al., 2006b).

The prohibitive cost and risks of UROD make it difficult to justify public funding of this form of detoxification even in wealthy developed countries. UROD might be an attractive option to highly motivated individuals (e.g. professionals under some form of social or professional coercion, such as doctors) who do not have the time to go through a protracted detoxification process (Gonzalez et al., 2004). As such, UROD could be made available to those who wish to privately fund such a procedure. The major concern with the private provision of this treatment is that UROD has been portrayed in the media, and by the companies offering it, as a quick and simple (if expensive) “cure” for this disorder (Hall, 2000). These claims exploit the desperate families of addicts who may incur large debts to fund an ineffective treatment. Regulatory authorities need to ensure that the standards of evidence that are required of effective treatment of AIDS, cancer or heart disease are not waived in the treatment of addiction (Hall and Mattick, 2000).

*Methadone maintenance treatment*

Patients entering methadone programs need to understand their rationale clearly and not do so under the mistaken belief that it is a short term option or a more protracted form of withdrawal. They also need to be made aware of the risks of methadone overdose. The lethal dose of methadone for an opioid-naïve adult is estimated at between 25 to 50 mg – 2 to 4 times less than what some individuals in MMT consume (Ghodse et al., 2004; Humeniuk et al., 1999). Methadone overdose is of particular concern during the initial titration onto a stabilised dose for low level users who may have overestimated their opioid consumption in order to obtain entry to a program, or for polydrug users who continue to use other central nervous system (CNS) drugs, such as alcohol and benzodiazepines. Prescribers have a duty of care to warn about these risks and to monitor patients during induction to ensure that patients are safely inducted into treatment.

For this reason various constraints or measures have been put in place in dispensing methadone to avoid overdose. This is particularly important in opioid addicts who may be feeling desperate, act compulsively, and have difficulty in controlling their drug use. The use of regulations is justified on both paternalistic and public health grounds – protecting the patient from overdose and protecting society from negative consequences of the provision of prescribed methadone that may be diverted to the black market. It is nonetheless important to ensure that these regulations are not used punitively or in ways that reduce patient entry to retention in treatment.

The need for strict supervision of methadone dosing in the early stages of treatment is seen in the outcomes of unsupervised methadone provision in the UK where in the 1990s MMT was often provided via a large number of take-away doses from pharmacies. Restrictions were increased after a large number of methadone overdose deaths were documented, including deaths of people who were not enrolled in programs (Hall, 1998). It is unethical to provide unsafe treatment to individuals with reduced capacity to consent or who enter treatment under legal coercion. It not only fails to meet the ethical requirement of a paternalistic health program in benefiting the client; it also fails the public health goal of reducing opioid overdose deaths.

*Privacy and Confidentiality*

In order to provide effective treatment of opioid dependence, providers are required to collect a significant amount of personal information. This may, but not always, include personal information such as address, familial and personal relationships, history of drug use and criminal activity, results of urine tests, the presence of a comorbid psychiatric condition and criminal history. It may also contain information about next of kin, or an agreed person of contact. This information is used for several reasons: it is critical in the provision of safe and effective treatment and in monitoring treatment progression, it is useful for reviewing the effectiveness of the treatment program, and it assists in identifying changes that need to be made to provide better treatment. This information might also be used to follow up effectiveness of treatment success, or to locate someone who has dropped out of treatment (Scott and White, 2005).

Information should only be collected from people who knowingly and freely consent to their personal information being taken (Ostini et al., 1993). This means that participants understand what information will be collected, why it is being collected, who will have access to it, how it will be stored, and most importantly, under what circumstances it will be shared (National Health and Medical Research Council, 1991; Ostini et al., 1993). Information should only be collected for the specific purposes directly connected with the aims of the treatment program, and as outlined to the participant (National Health and Medical Research Council, 1985; Veatch, 1981). This information could potentially be used by third parties to identify participants as illegal drug users or by police to press criminal charges. It is therefore important that participants' information is not disclosed for these purposes and that rules of confidentiality are communicated effectively to potential participants. Providing information and reassurance on this point increases the likelihood that individuals will enter treatment. The provision of accurate information also makes it more likely that they will receive effective treatment and build a trusting and effective therapeutic relationship. Clinical records of individuals held by treatment programs should be kept by sufficiently secure means, as are personal records in other registers of sensitive information (e.g. records held by physicians, psychiatrists, the courts or other public authorities). This system should also be separate from other government agencies, particularly law enforcement.

In many developed countries there are central registers of persons who enter maintenance forms of treatment for opioid dependence. This is usually justified as a way of preventing clients from "double dosing", that is, obtaining a maintenance drug from more than one program. This is important to protect the safety of individuals on methadone programs and to prevent methadone being diverted to the illicit market. A central register also has other benefits, such as the ability to ensure the effectiveness and safety of treatment by enabling patients to move between services, particularly in other states, while providing continuity of service. It also enables the performance of programs to be monitored in terms of patient retention and it can be used for public health surveillance purposes in monitoring trends in opioid dependence (Carise et al., 1999).

There should be strict controls over who has access to the register to ensure that patients have confidence in the confidentiality of the information. This should include rules against access by employers, or by law enforcement without either strict application of due process (eg., by subpoena), or the consent of participants. The use of such information for research purposes should be in accordance with ethical procedures as required for any other epidemiological study: data used should be stripped of personal information that might identify a person, and individuals must not be identifiable in any published results (National Health and Medical Research Council, 1985; National Health and Medical Research Council, 1991; Veatch, 1981).

*Buprenorphine Maintenance*

Given the safety issues associated with methadone, and the difficulty of completing withdrawal, there has been an interest in providing alternative forms of opioid maintenance using the partial agonist buprenorphine. Buprenorphine is a partial agonist that has a much lower risk of causing respiratory depression and is protective against overdose on relapse to heroin use (Davids and Gastpar, 2004). The greater safety of buprenorphine means that it may have less potential for abuse and diversion and may be more amenable to use in primary care settings, allowing more flexible delivery of treatment. The ceiling effect of the partial agonist means that buprenorphine can also be given in greater doses, thus requiring fewer visits to treatment centres (several times a week instead of once a day), also increasing

flexibility. Depot formulations are also under development for even less frequent dosing.

More studies are needed to establish the comparative strengths and weaknesses of buprenorphine and methadone maintenance. It may be that buprenorphine is less effective in stabilising opioid addicts and maintaining individuals free from illicit opioid use in the long term. Its reduced agonist effects appear to be less useful in maintenance and in medicating the emotional problems of opioid dependent persons (Lingford-Hughes et al., 2004). It is a cost-effective form of opioid maintenance treatment (Doran et al., 2003), but its cost is four times that of methadone, which is no longer on patent.

*Setting and program structure*

The type of setting in which maintenance treatment is provided is important in providing a service that meets the needs of the client while minimising any adverse consequences for the client and the community. The type of setting and the structure of the program will depend in part on the pharmacological action of the treatment being offered (i.e., duration of action, and overdose risk). Drugs like methadone that act for 24 hours will require daily dose dispensation unless take-away doses are allowed. Longer-acting partial agonists like buprenorphine may allow alternate day supervised dosing or once-weekly dosing with take-aways. The challenge for treatment staff is in striking a balance between the convenience of less frequent dosing and risks of diversion of take way doses for stable patients. Take-away dosing is a valuable tool for positively reinforcing stabilised and compliant patients; it also reduces pressure on treatment clients, program costs, and demands on staff, and encourages retention in treatment. However, take-away doses can lead to increased diversion and fatal overdoses if not monitored carefully.

Large treatment clinics provide an economy of scale in the delivery of opioid maintenance treatment but they may be expensive to run and they have a number of other problems associated with them. These include: client loitering in the vicinity of the program, increasing its visibility and creating minor social nuisance to neighbours; the congregation of drug users in a community; low staff morale and a high staff turnover; and less personalised treatment of individuals in the interests of the public

health values of the program. Such programs also need to be highly structured to operate efficiently. This may be an advantage for newcomers to treatment but their inflexibility may be a major disincentive for more stable patients to remain in treatment.

To reduce the impact of the regimentation and strict regulation of large clinics alternative methods of delivery need to be found. This may include the provision of methadone in a primary care setting by a general practitioner to a selected population of stabilised and more socially integrated methadone clients. This has been shown to work effectively, with no increased risk to society (Fiellin et al., 2001; Keen et al., 2002; Merrill et al., 2005). It is also cost-effective provided that physicians are given the necessary training and expert support to deal with crises that may arise. This approach has the following advantages: it enables the client to develop a therapeutic relationship with one physician, reduces stigma, increases program flexibility, and enables the client to achieve greater social reintegration because of the reduced interference of treatment demands with everyday life.

*Maintenance Dosage*

Research has repeatedly shown that an adequate dose of methadone is one of the most important factors in determining treatment retention and success (Hargreaves, 1983; Ward et al., 1998b). It has been estimated that methadone doses accounts for 40% of variance in heroin use (Trafton et al., 2006). The dose needs to be high enough to both prevent opioid withdrawal symptoms from developing and to attenuate the rewarding effects of any heroin or other illicit opioids that are used.

Dosage can be difficult to set because it varies from person to person. Selecting a desired dose may also be a point of contention between recipient, dispenser and program. While methadone is less harmful than faster-acting opioids such as morphine and heroin, it can lead to overdose during stabilisation. A greater concern is maintaining an adequate dose during the maintenance phase of treatment. Research has shown that doses of methadone of 60 mg and over assist addicts to stabilise their lives by reducing the cycle of withdrawal and intoxication, and attenuating the emotional disturbances that are common in opioid dependence. This form of

treatment has been shown to be effective in reducing heroin use and crime, and maintaining patients in treatment.

Some clients don't want high doses of methadone because this prevents them from deriving pleasure from injecting illicit opioids or forces them to use larger doses of illicit opioids to achieve these effects. Doses should be based on the needs of the individual to achieve the aims of their treatment program (i.e. maintenance or detoxification), and based on best scientific evidence. The dose should be selected in consultation with the patient, and be flexible to meet their changing needs. Dose reductions or increases should not be a tool for punishing or controlling individuals in treatment because this undermines treatment and it is counterproductive in keeping people in treatment, and developing therapeutic relationships.

*The role of urinalysis in agonist maintenance treatment*

Urinalysis is the screening of urine samples for small quantities of various drugs or drug metabolites. It has become a familiar part of most opioid replacement treatment programs, with many clinical and administrative decisions based on the results of urine drug tests (Trellis et al., 1975). Urinalysis is helpful both in managing a patient's treatment and in evaluating the effectiveness of the program (Ward et al., 1998a). These tests can be used to ensure that a client is taking their methadone, that their dose is adequate, and to measure the consumption of other drugs (e.g. cannabis, heroin, amphetamines, or cocaine).

The way in which information from urine tests is used is often dictated by the treatment philosophy of the program. A positive test may be seen as an indication of lack of treatment, and therefore result in an increased methadone dose or additional counselling sessions to address the use of illicit substances. While urinalysis can be an effective tool in guiding treatment, its results can also be used to punish patients for failing to maintain abstinence from illicit opioids. In these situations, a positive urine sample usually results in negative or punitive contingency measures, such as loss of take-home privileges, a decrease in methadone dose, and possibly expulsion from the treatment program.

Urinalysis can be an intrusive process if it involves directly observing the patient urinating.[13] This is a significant intrusion and undermines what little control someone suffering from heroin addiction has over one of the most private activities. In addition to being humiliating, urinalysis also promotes distrust between clients and staff that can undermine the effectiveness of the treatment program. Therefore the intrusion on privacy entailed by urinalysis needs to be justified by showing that the test results are accurate, and that regular urine testing is effective and cost-effective in reducing illicit opioid use (Childress et al., 2002).

There is some uncertainty over whether urinalysis can effectively and accurately detect illicit drug use (Ward et al., 1998a). The half-lives of the most common illicit drugs abused by opioid addicts (e.g. heroin and cocaine) are extremely short. Therefore, to accurately detect illicit drug use, tests need to be given on a daily basis, as was originally done by Dole and colleagues (Dole and Nyswander, 1965). Because the costs of daily testing are unmanageable for most programs, and the intrusion into patients' lives enormous, urine tests are often performed intermittently, thereby undermining their ability to detect illicit drug use..

Studies have shown that urinalysis does not decrease or control drug use (Goldstein and Judson, 1974; Grevert and Weinberg, 1973; Hall, 1983) and that programs with more frequent urinalyses have a higher drop-out rate. The use of contingency management – making rewards contingent upon clean urines – has been shown to improve the effectiveness of programs (Iguchi et al., 1988) but punitive responses to dirty urines significantly increases program drop-out and hence poor patient outcomes (Stitzer et al., 1993; Stitzer et al., 1986).

There is also a question of how necessary urinalysis is. Most assume that urinalysis is required as self-report is an invalid measure of heroin use, particularly when honesty may lead to expulsion from the program. However, this may have more to do with the punitive response of abstinence-oriented treatment programs to self-reported drug use. Studies have shown that in the absence of punitive responses to drug use, self-

[13] Given that urinalysis often results in punitive responses for positive tests, it is not surprising that clients attempt to tamper with a sample if they fear that it may be positive. Therefore, it is generally agreed that for urinalysis to be effective, urination must be directly observed.

reports were as effective, or nearly so, as urinalysis in determining illicit drug use (Magura et al., 1987; Magura and Lipton, 1988). If the treatment environment was oriented towards developing more cooperative relationships with patients, then the patient would be able to be honest about their drug use without fearing punishment, and in the end, more amenable to change (Ward et al., 1998a).

Urine tests may nonetheless be required to maintain public support for MMT programs, by demonstrating to the community that heroin addicts in MMT are heroin free and that they are punished for failing to remain abstinent. If this is the case, then, urinalysis needs to be done in an efficient way. There is certainly little point in regularly testing someone who is doing well within a program. If testing is done, it is probably better to have different testing schedules for different stages of treatment. For those entering treatment, testing may be frequent for the first few weeks while they become stabilised. At this time objective measures of illicit opioid use are useful in guiding clinical decisions (e.g. in setting dose). However, as individuals become stabilised and develop more stable lifestyles, the frequency of testing could be reduced or testing only conducted if there was reason to suspect illicit opioid use.

### *Depot, Sustained Release Drugs and Drug Vaccines*

An active area of investigation is in the development of long acting depot formulations of partial agonists, such as buprenorphine, to reduce the frequency of dosing, and in the case of antagonists like naltrexone, to improve poor patient compliance with oral forms of the drug (Harwood and Myers, 2004). Drug vaccines have been under investigation for relapse prevention in nicotine and cocaine dependence (Kosten and Owens, 2005), but the same procedure could also be used to develop a vaccine against morphine. Evidence of the safety and effectiveness of these approaches will be required before they are used to treat opioid dependence (Harwood and Myers, 2004). The following brief discussion of potential ethical issues that may be raised by their use assumes that such evidence will eventually become available.

A number of ethical issues would arise in using vaccines or depot formulations to treat opioid dependent people who voluntarily seek treatment, that is, who freely and willingly decided to enter treatment in the absence of any legal duress. The first

ethical issue would be to ensure that patients freely consented to the vaccine in full knowledge of its effects and any risks that its use entails (Hall and Carter, 2004).

The second ethical issue arises if a vaccine or depot formulation is registered for therapeutic use, namely, who would have access to the vaccine? Access will depend upon how much it costs and who pays for the vaccine or drug (e.g. the patient, a third party such as the government or health insurer, or some combination of patient and third party). If these approaches prove to be costly treatments for which patients must pay, then indigent and poor patients would be denied access to its benefits (Hall and Carter, 2004).

Long acting depot formulations and drug vaccines may be attractive options for treatment under legal coercion (Harwood and Myers, 2004). On the analysis provided above, an ethically defensible use of a vaccines or depot formulations under legal coercion would involve the offenders being given a choice of whether they accept treatment or not, and, if they do, being offered a vaccine or depot formulation among the range of treatments from which they can choose. If vaccines and depot formulations were used in this way, their safety, effectiveness and cost-effectiveness would need to be rigorously evaluated (Harwood and Myers, 2004). We would also need realistic expectations about their efficacy since both can be subverted by increasing drug doses or using other illicit drugs (Fox, 1997; Kosten et al., 2002). Any coerced use of these long acting agents should accordingly be implemented cautiously and rigorously evaluated. This would probably only be done after considerable experience had shown it to be safe and effective in treating voluntary patients.

## Special Issues in the Treatment of Opioid Dependence

### *Psychiatric Comorbidity*

Many opioid dependent persons also suffer from comorbid psychiatric disorders, such as depression, anxiety and personality disorders. While some of these disorders are the result of a stressful and abusive lifestyle, for many opioid abuse is an attempt to self-medicate other underlying psychological problems (Bell, 1998; Gelkopf et al.,

2002; Khantzian, 1985). It is accordingly important that addiction treatment services diagnose and properly treat these disorders. This may be easiest to do once a client has been stabilised. It is important to do so for both ethical and practical reasons. It is ethically necessary to ensure that opioid dependent people with mental disorders have the same access to treatment for these disorders as non-opioid dependent people; it is also important for good addiction treatment outcomes to treat these other mental or social issues.

### *Treatment in Prisons*

Given the high rates of imprisonment among opioid dependent persons more should be made of the opportunity to offer them treatment while in prison. At a minimum, we should avoid the current practice in many prison systems of compulsory unassisted detoxification. Basic human rights include access to good pharmacological management of withdrawal symptoms on prison entry. A good case can also be made for providing methadone maintenance in a prison setting with the aims of both benefiting opioid dependent prisoners and contributing to the good management of prisons (Hall et al., 1993). This may also reduce BBV transmission within prison and reduce BBV transmission and relapse to heroin use post release (Dolan et al., 1996).

## SECTION 4: BASIC ETHICAL PRINCIPLES IN THE TREATMENT OF OPIOID DEPENDENCE

Based on the preceding discussion, we outline a series of principles for ethical treatment of opioid dependence. In each case we provide a brief description of the principle and why it is required, list its key elements and suggest how it might be achieved. These principles describe how the ethical justifications may be applied, and are essential in developing effective social policies towards behaviours or conditions that are stigmatised and have a negative social impact. They aim to describe how pharmacological treatment of opioid dependence can be provided ethically and in accordance with principles of basic human rights, in ways that have the best chance of success for treated individuals, and in reducing the social burden of opioid dependence. This approach was adapted from a recent report published by the World Health Organization on the treatment of HIV/AIDS in intravenous drug using populations and reflects continuity in ethical requirements for the provision of medical treatment to vulnerable and stigmatised populations (World Health Organization, 2005).

### Principle 1: Human rights of opioid dependent individuals should be respected

The human rights of people who are dependent on opioids should be respected by ensuring that they have access to appropriate and effective medical treatment and psychosocial support. This is the core ethical principle that broadly informs all strategies and approaches to treating people suffering from opioid dependence. Individuals should not be stigmatised or discriminated against by virtue of their condition, nor should the legal status, gender, age, lifestyle, race, political, religious or other beliefs, social, financial, sexual, criminal or other status, or physical of mental capabilities, bar them from accessing safe and effective treatment.

### Principle 2: Treatment decisions should be based on best evidence

To ensure that treatment is safe and effective, rigorous evidence should be used to guide treatment decisions. With new pharmacological treatments for opioid dependence emerging (such as vaccines and long acting agonists and antagonists), there is a need to ensure that their safety and efficacy are rigorously assessed before they are widely used. Existing treatment programs must operate in accordance with the obligation to evaluate treatment safety, effectiveness and acceptability to their clients and patients.

### Principle 3: Treatment decisions should be based on medical care ethics

It is important that treatment decisions be based on objective measures of what will provide the most effective medical care and the best health care outcomes. Treatment that accords with the ethics of personal medical care should also be the most successful in meeting the aims of a public health care program because good individual treatment will ensure good program retention and maximum benefits to the individual and the community that funds his or her treatment. Treatment programs should be separate from law enforcement agencies.

### Principle 4: Equitable access should be provided to treatment and psychosocial support that best meets the needs of the individual patient

Treatment should be individualised to the patient. Opioid addicts differ in many ways: addiction is a dynamic process where the needs and circumstances of different individuals will vary and change over time. It is accordingly important that treatment is flexibly provided to meet patients' changing needs. Patients should be able to choose from a variety of forms of treatment that are shown to be safe and effective, including detoxification, relapse prevention and maintenance programs with good quality psychosocial care to address the many personal and social problems experienced by opioid dependent individuals.

## Principle 5: Respect and validate the autonomy of the individual

Treatment staff and programs need to respect and validate the autonomy of the opioid dependent individuals by involving them in the process and evolution of the treatment. Programs should emphasise the importance of the client-carer relationship in providing ethically adequate treatment that respects the autonomy of patients, and protects their privacy and the confidentiality of information that they provide. When autonomy is impaired, the goal should be to enhance the autonomy of the individual by increasing their ownership and control over treatment. The primary goal of treatment, both pharmacological and psychotherapeutic, should be to increase the autonomy of individuals by facilitating improvements in decision-making abilities. This may be either by breaking the cycle of intoxication and withdrawal by stabilising on medication, or by providing the skills and support to make decisions not to use drugs and confront the situations that lead to drug use. Respecting autonomy also includes respecting a decision not to receive treatment.

Addiction diminishes but does not extinguish autonomy. The primary initial aim of such treatment, aside from quickly stabilising lifestyle, should be to increase an opioid dependent individual's autonomy and their ability to exercise it. Opioid maintenance treatment aims to reduce the cycle of withdrawal and intoxication, and create the freedom to deal and think about things other than procuring and using drugs, thereby increasing an individual's ability to make free and informed decisions. Increased autonomy is a common goal for both pharmacological and psychosocial treatment.

## Principle 6: Patients should be fully informed about treatment

Following on from the principle of respect for autonomy, clients should be fully informed of the risks, benefits, likely outcomes, costs, requirements and punishments associated with the treatment program in which they are participating. Individuals should also be informed of other treatment options and their relative risks and benefits.

Potential opioid dependent patients need to understand the rationale, risks and benefits of the treatments from which they must choose. The risks include: fatal overdose (post-detoxification in those aiming at abstinence, and during induction in the case of

methadone); the low chance of achieving abstinence in the short to medium term; and the high likelihood of relapse after detoxification in the absence of other pharmacological or psychosocial treatments that support abstinence. These issues are especially important if clients enter treatment under legal coercion. Patients entering maintenance treatment need to understand its rationale, its expected duration, and the consequences of ending treatment early or against medical advice. They need to understand the rules and regulations within which the treatment will be provided and the reasons for them.

Enough information should be provided to clients to allow an informed choice of treatment and its safe and effective delivery. The information required will vary with the stage of treatment. The initial focus may be on the most immediate needs of a person in crisis and limited to what they are able to take in. The need for greater information will evolve as the client's autonomy increases and their needs change in the light of treatment progress. It should become easier as a therapeutic relationship of trust develops and the client engages more in treatment and other support programs. The guiding principle must be to increase client autonomy by increasing their understanding of their situation and motivating them to improve.

### Principle 7: Creation of supportive environments and treatment relationships to facilitate treatment

Punitive policies and attitudes towards individuals in treatment represent a failure to provide ethical treatment and an impediment to successful treatment outcome. Good relationships between clients and staff are important factors in successful treatment outcome. Attitudes of staff towards clients and their relationship with clients are especially critical factors in determining the success of methadone maintenance treatment. This involves: affirmation and validation of the client; building trust over time; and ensuring flexibility in treatment delivery to meet individuals' needs.

### Principle 8: Co-ordinated treatment of comorbid disorders and social factors

Many people who seek or require treatment for opioid dependence also suffer from an underlying psychiatric disorder. They may also have a number of concomitant social and personal difficulties (e.g. with housing, employment, children and family relationships). Treatment services for mental and substance abuse are often separate, with many people requiring treatment for mental disorders required to have substance abuse treatment before receiving mental health treatment or vice versa. More effort needs to be made to co-ordinate efforts to ensure good outcomes for opioid dependent individuals with mental disorders. The same broad principle applies to the need to address concomitant social impediments to good treatment outcomes.

### Principle 9: Participation of community and other stakeholders

Garnering community support for and involvement in the treatment of opioid dependence is vital in preventing the cycles of drug use within vulnerable populations. A complete understanding of the causes and outcomes of drug use and treatment programs is important in overcoming stigmatised views of people suffering from opioid addiction, and preventing the discriminatory attitudes and policies that hinder adequate and effective treatment and the reintegration of treated addicts into the community. Broader community support for education and employment programs are also needed.

### Principle 10: Ethical use of legal coercion into treatment for opioid dependence

Coerced treatment is ethically justified if and only if: (1) the rights of the individuals are protected by "due process" (in accordance with human rights principles), and (2) effective and humane treatment is provided. Drug dependent offenders should be allowed two "constrained choices": (1) whether they participate in drug treatment or not; and (2) if they agree to participate in drug treatment, a choice of the type of treatment that they receive. Pharmacological and non-pharmacological treatment approaches should be in the range of options from which they choose. Clear protocols need to be established to govern the interactions between treatment staff and the

judicial system to avoid conflicts about confidentiality and to address very different expectations of treatment between the therapeutic and judicial systems.

## REFERENCES


Adler MW (1995) Human subject issues in drug-abuse research. *Drug and Alcohol Dependence*, **37**: 167-175

Amato L, Davoli M, Minozzi S, et al. (2005a) Methadone at tapered doses for the management of opioid withdrawal. *Cochrane Database of Systematic Reviews*, **3**: CD003409

Amato L, Davoli M, Perucci CA, et al. (2005b) An overview of systematic reviews of the effectiveness of opiate maintenance therapies: available evidence to inform clinical practice and research. *Journal of Substance Abuse Treatment*, **28**: 321-329

Anderer SJ (1992) Introduction to the symposium: integrating legal and psychological perspectives on the right to personal autonomy. *Villanova Law Review*, **37**: 1536-1568

Anthony JC, Warner LA, Kessler RC (1994) Comparative epidemiology of dependence on tobacco, alcohol, controlled substances, and inhalants: basic findings from the National Comorbidity Survey. *Experimental and Clinical Psychopharmacology*, **2**: 244-268

Aronowitz D (1967) Civil commitment of narcotics addicts. *Columbia Law Review*, **67**: 405-429

Australian Institute of Health and Welfare (1999) 1998 National Drug Strategy household survey: first results. AIHW, Canberra

Badenoch J (2002) A death following ultra-rapid opiate detoxification: the General Medical Council adjudicates on a commercialized detoxification. *Addiction*, **97**: 475-477

Baldwin R (1979) Proposals for drug and alcohol court assessment programme. *NSW DAA Internal Paper*New South Wales Drug and Alcohol Authority, Sydney

Ball JC, Ross A (1991) *The effectiveness of methadone maintenance treatment: patients, programs, services, and outcome*. Springer-Verlag, New York

Beauchamp TL, Childress JF (2001) *Principles of biomedical ethics*. Oxford University Press, New York

Bechara A (2005) Decision making, impulse control and loss of willpower to resist drugs: a neurocognitive perspective. *Nature Neuroscience*, **8**: 1458-1463

Bechara A, Dolan S, Denburg N, et al. (2001) Decision-making deficits, linked to a dysfunctional ventromedial prefrontal cortex, revealed in alcohol and stimulant abusers. *Neuropsychologia*, **39**: 376-389

Bell J (1998) Delivering effective methadone treatment. In Ward P, Mattick RP, Hall W (eds.), *Methadone maintenance treatment and other opioid replacement therapies*. Harwood Academic Press, Sydney

Bell J, Chan J, Kuk A (1995) Investigating the effect of treatment philosophy on outcome of methadone maintenance. *Addiction*, **90**: 823-830

Bell J, Hall WD, Byth K (1992) Changes in criminal activity after entering methadone maintenance. *British Journal of Addiction*, **87**: 251-258

Bersoff DN (1992) Autonomy for vulnerable populations: the Supreme Court's reckless disregard for self-determination and social science. *Villanova Law Review*, **37**: 1569-1605

Brody BA (1998) *The ethics of biomedical research: an international perspective*. Oxford University Press, New York

Cadman M, Bell J (1998) Doctors detected self-administering opioids in New South Wales, 1985-1994: characteristics and outcomes. *Medical Journal of Australia*, **169**: 419-421

Cami J, Farre M (2003) Drug addiction. *New England Journal of Medicine*, **349**: 975-986

Carise D, McLellan AT, Gifford LS, et al. (1999) Developing a national addiction treatment information system. An introduction to the Drug Evaluation Network System. *Journal of Substance Abuse Treatment*, **17**: 67-77

Carnwath T, Smith I (2002) *Heroin century*. New York, London

Casebeer WD (2003) *Natural ethical facts: evolution, connectionism, and moral cognition*. MIT Press, Cambridge, MA

Central Committee on the Treatment of Heroin Addicts (2002) *Medical co-prescription of heroin: two randomized controlled trials*. Central Committee on the Treatment of Heroin Addicts, Utrecht

Charland LC (2002) Cynthia's dilemma: consenting to heroin prescription. *American Journal of Bioethics*, **2**: 37-47

Childress JF, Faden RR, Gaare RD, et al. (2002) Public health ethics: mapping the terrain. *Journal of Law Medicine & Ethics*, **30**: 170-+

Cohen PJ (2002) Untreated addiction imposes an ethical bar to recruiting addicts for non-therapeutic studies of addictive drugs. *Journal of Law Medicine & Ethics*, **30**: 73-81

Comer SD, Collins ED, Kleber HD, et al. (2002) Depot naltrexone: long-lasting antagonism of the effects of heroin in humans. *Psychopharmacology*, **159**: 351-360

Dackis C, O'Brien C (2005) Neurobiology of addiction: treatment and public policy ramifications. *Nature Neuroscience*, **8**: 1431-1436

Dalrymple T (2006) *Romancing opiates: pharmacological lies and the addiction bureaucracy*. Encounter Books, New York

Darke S, Ross J (2002) Suicide among heroin users: rates, risk factors and methods. *Addiction*, **97**: 1383-1394

Darke S, Zador D (1996) Fatal heroin 'overdose': a review. *Addiction*, **91**: 1765-1772

Davids E, Gastpar M (2004) Buprenorphine in the treatment of opioid dependence. *European Neuropsychopharmacology*, **14**: 209-216

Degenhardt L, Hall WD, Warner-Smith M, et al. (2004) Illicit drug use. In Ezzati M, Lopez A, Rodgers A, Murray C (eds.), *Comparative quantification of health risks: global and regional burden of disease attributable to selected major risk factors*. World Health Organization, Geneva, pp. 1109-1176

Dolan K, Wodak A, Hall WD, et al. (1996) HIV risk behaviour of injecting drug users before, during and after imprisonment in New South Wales. *Addictive Research*, **4**: 151-160

Dole VP, Nyswander M (1965) A medical treatment for diacetylmorphine (heroin) addiction - a clinical trial with methadone hydrochloride. *Journal of the American Medical Association*, **193**: 646

Doran CM, Shanahan M, Mattick RP, et al. (2003) Buprenorphine versus methadone maintenance: a cost-effectiveness analysis. *Drug and Alcohol Dependence*, **71**: 295-302

Dworkin G (1972) Paternalism. *Monist*, **56**: 64-84

European Monitoring Centre for Drugs and Drug Addiction (2001) Annual report on the state of the drugs problem in the European Union 2001. Office for Official Publications of the European Communities, Luxembourg

Farabee D, Leukefeld CG (2001) Recovery and the criminal justice system. In Frank MT, Leukefeld CG, Platt JJ (eds.), *Relapse and recovery in addiction*. Yale University Press, London

Fiellin DA, O'Connor PG, Chawarski M, et al. (2001) Methadone maintenance in primary care: a randomized controlled trial. *JAMA*, **286**: 1724-1731

Foddy B, Savulescu J (2006) Addiction and autonomy: Can addicted people consent to the prescription of their drug of addiction? *Bioethics*, **20**: 1-15

Forman RF, Bovasso G, Woody G, et al. (2002) Staff beliefs about drug abuse clinical trials. *Journal of Substance Abuse Treatment*, **23**: 55-60

Fortney J, Booth B, Zhang M, et al. (1998) Controlling for selection bias in the evaluation of Alcoholics Anonymous as aftercare treatment. *Journal of Studies on Alcohol*, **59**: 690-697

Fox BS (1997) Development of a therapeutic vaccine for the treatment of cocaine addiction. *Drug and Alcohol Dependence*, **48**: 153-158.

Fox RG (1992) The compulsion of voluntary treatment in sentencing. *Criminal Law Journal*, **16**: 37-54

Gelkopf M, Levitt S, Bleich A (2002) An integration of three approaches to addiction and methadone maintenance treatment: the self-medication hypothesis, the disease model and social criticism. *Israel Journal of Psychiatry and Related Sciences*, **39**: 140-151

Gerstein DR, Harwood HJ (1990) *Treating drug problems. Volume 1: a study of the evolution, effectiveness and financing of public and private drug treatment options*. Institute of Medicine, National Academy Press, Washington DC

Ghodse H, Schizfano F, Oyefeso A, et al. (2004) *Drug-related deaths as reported by participating procurator fiscal and coroners*. St George's Hospital Medical School, London

Gold CG, Cullen DJ, Gonzales S, et al. (1999) Rapid opioid detoxification during general anesthesia - A review of 20 patients. *Anesthesiology*, **91**: 1639-1647

Goldstein A, Herrera J (1995) Heroin addicts and methadone treatment in Albuquerque: A 22-year follow-up. *Drug and Alcohol Dependence*, **40**: 139-150

Goldstein A, Judson B (1974) Three critical issues in the management of methadone programs. In Bourne PG (ed.), *Addiction*. Academic Press, New York, pp. 129-148

Gonzalez G, Oliveto A, Kosten TR (2004) Combating opiate dependence: a comparison among the available pharmacological options. *Expert Opinion on Pharmacotherapy*, **5**: 713-725

Gorelick D, Pickens RW, Benkovsky FO (1999) Clinical research in substance abuse: human subjects issues. In Pinchus HA, Lieberman JA, Ferris S (eds.), *Ethics in psychiatric research: a resource manual for human subjects protection*. American Psychiatric Association, Washington, DC

Gossop M (1997) The National Treatment outcome research study in the United Kingdom: six month follow-up outcomes. *Psychology of Addictive Behaviors*, **11**: 324-337

Gossop M (1998) *NTORS at one year: changes in substance use, health, and criminal behaviour one year after intake*. Department of Health, London

Gostin LO (1993) Compulsory treatment for drug-dependent persons: justifications for a public health approach to drug dependency. In Bayer R, Oppenheimer GM (eds.), *Drug policy: illicit drugs in a free society*. Cambridge University Press, Cambridge, UK

Gostin LO, Mann JM (1999) Toward a development of a human rights impact assume for the formulation and evaluation of public health policies. In Mann JM (ed.), *Health and human rights: a reader*. Routledge, London

Gowing L, Ali R, White J (2006a) Buprenorphine for the management of opioid withdrawal. *Cochrane Database of Systematic Reviews*, **2**: CD002025

Gowing L, Ali R, White J (2006b) Opioid antagonists with minimal sedation for opioid withdrawal. *Cochrane Database of Systematic Reviews*, **1**: CD002021

Gowing L, Farrell M, Ali R, et al. (2004) Alpha2 adrenergic agonists for the management of opioid withdrawal. *Cochrane Database of Systematic Reviews*, **4**: CD002024

Grevert P, Weinberg A (1973) A controlled study of the clinical effectiveness of urine test results in a methadone maintenance program. *Proceedings of the National Conference on Methadone Treatment*, **2**: 1052-1059

Hall S (1983) Methadone treatment: a review of the research findings. In Cooper J, Altman F, Brown B, Czechowicz D (eds.), *Research on the treatment of narcotic addiction: state of the art*. National Indicate of Drug Abuse, Rockville, MD

Hall WD (1998) The search for an elixir of abstinence. *Australian Family Physician*, **27**: S1-S2

Hall WD (2000) UROD: an antipodean therapeutic enthusiasm. *Addiction*, **95**: 1765-1766

Hall WD (2006a) Avoiding potential misuses of addiction brain science. *Addiction*, **101**: 1529-1532

Hall WD (2006b) Stereotactic neurosurgical treatment of addiction: minimizing the chances of another 'great and desperate cure'. *Addiction*, **101**: 1-3

Hall WD, Bell J, Carless J (1993) Crime and drug use among applicants for methadone maintenance. *Drug and Alcohol Dependence*, **31**: 123-129

Hall WD, Carter L (2004) Ethical issues in using a cocaine vaccine to treat and prevent cocaine abuse and dependence. *Journal of Medical Ethics*, **30**: 337-340

Hall WD, Carter L, Morley KI (2004) Neuroscience research on the addictions: A prospectus for future ethical and policy analysis. *Addictive Behaviors*, **29**: 1481-1495

Hall WD, Mattick RP (2000) Is ultra-rapid opioid detoxification a viable option in the treatment of opioid dependence? *CNS Drugs*, **14**: 251-255

Hall WD (1997) The role of legal coercion in the treatment of offenders with alcohol and heroin problems. *Australian and New Zealand Journal of Criminology*, **30**: 103-120

Hall WD, Doran C, Degenhardt L, et al. (2006) Illicit opioid dependence. In Jamison D, Evans D, Alleyne G (eds.), *Disease control priorities in developing countries*. Oxford University Press for the World Bank, New York, 2nd ed.

Hamilton RJ, Olmedo RE, Shah S, et al. (2002) Complications of ultrarapid opioid detoxification with subcutaneous naltrexone pellets. *Academic Emergency Medicine*, **9**: 63-68

Hargreaves WA (1983) Methadone dosage and duration for maintenance treatment. In Cooper J, Altman F, Brown B, Czechowicz D (eds.), *Research on the treatment of narcotic addiction: state of the art*. National Institute on Drug Abuse, Rockville, MD

Harwood HJ, Myers TG (2004) *New treatments for addiction: behavioral, ethical, legal, and social questions*. National Academies Press, Washington, DC

Hasin DS (1994) Treatment/self-help for alcohol-related problems: relationship to social pressure and alcohol dependence. *Journal of Studies on Alcohol*, **55**: 660-666

Hubbard RL (1989) *Drug abuse treatment: a national study of effectiveness*. University of North Carolina Press, Chapel Hill

Hubbard RL, Collins JJ, Rachal JH, et al. (1988) The criminal justice client in drug abuse treatment. In Leukefeld C, Tims FM (eds.), *Compulsory treatment of drug abuse: Research and clinical practice*. NIDA, Rockville, MD

Hulse GK, English DR, Milne E, et al. (1999) The quantification of mortality resulting from the regular use of illicit opiates. *Addiction*, **94**: 221-229

Humeniuk H, Ali R, White J, et al. (1999) Proceedings of expert workshop on the induction and stabilisation of patients onto methadone. *National Drug Strategy Monograph* 39. Adelaide, South Australia

Husak DN (1992) *Drugs and rights*. Cambridge University Press, Cambridge, UK

Husak DN (2004) The moral relevance of addiction. *Substance Use & Misuse*, **39**: 399-436

Iguchi MY, Stitzer ML, Bigelow GE, et al. (1988) Contingency management in methadone maintenance: effects of reinforcing and aversive consequences on illicit polydrug use. *Drug and Alcohol Dependence*, **22**: 1-7

Inciardi JA, McBride DC (1991) *Treatment alternatives to street crime: history, experiences and issues*. National Institute of Drug Abuse, Rockville, MD

International Federation of Red Cross and Red Crescent Societies, Francois-Xavier Bagnoud Center for Health and Human Rights (1999) Human rights: an introduction. In Mann JM (ed.), *Health and human rights: a reader*. Routledge, London, pp. 21-28

Joint Committee of the ABA and the AMA on Narcotic Drugs (1961) *Drug addiction: crime or disease? Intirim and final reports of the Joint Committee of the American Bar Association and the American Medical Association on Narcotic Drugs,*. Indiana Press, Bloomington, IN

Keen J, Oliver P, Mathers N (2002) Methadone maintenance treatment can be provided in a primary care setting without increasing methadone-related mortality: the Sheffield experience 1997-2000. *British Journal of General Practice*, **52**: 387-389

Khantzian EJ (1985) The self-medication hypothesis of addictive disorders: focus on heroin and cocaine dependence. *American Journal of Psychiatry*, **142**: 1259-1264

Klag S, O'Callaghan F, Creed P (2005) The use of legal coercion in the treatment of substance abusers: An overview and critical analysis of thirty years of research. *Substance Use & Misuse*, **40**: 1777-1795

Kleinig J (2004) Ethical issues in substance use intervention. *Substance Use & Misuse*, **39**: 369-398

Kosten T, Owens SM (2005) Immunotherapy for the treatment of drug abuse. *Pharmacology & Therapeutics*, **108**: 76-85

Kosten TR, Rosen M, Bond J, et al. (2002) Human therapeutic cocaine vaccine: safety and immunogenicity. *Vaccine*, **20**: 1196-1204

Leshner AI (1997) Addiction is a brain disease, and it matters. *Science*, **278**: 45-47

Leukefeld CG, Tims FM (1988) *Compulsory treatment of drug abuse: research and clinical practice*. National Institute on Drug Abuse, Rockville, MD

Ling W, Compton P (2005) Recent advances in the treatment of opiate addiction. *Clinical Neuroscience Research*, **5**: 161-167

Lingford-Hughes AR, Welch S, Nutt DJ (2004) Evidence-based guidelines for the pharmacological management of substance misuse, addiction and comorbidity: recommendations from the British Association for Psychopharmacology. *Journal of Psychopharmacology*, **18**: 293-335

Loimer N, Schmid R, Lenz K, et al. (1990) Acute blocking of naloxone-precipitated opiate withdrawal symptoms by methohexitone. *British Journal of Psychiatry*, **157**: 748-752

Loimer N, Schmid R, Presslich O, et al. (1988) Naloxone treatment for opiate withdrawal syndrome. *British Journal of Psychiatry*, **153**: 851-852

MacIntyre A (1998) *A short history of ethics: a history of moral philosophy from the Homeric Age to the twentieth century*. University of Notre Dame Press, Notre Dame, IN

Maddux J (1988) Clinical experience with civil commitment. In Leukefeld CG, Tims FM (eds.), *Compulsory treatment of drug abuse: research and clinical experience*. National Institute on Drug Abuse, Rockville, MD, pp. 35-56

Magura S, Goldsmith D, Casriel C, et al. (1987) The validity of methadone clients' self-reported drug-use. *International Journal of the Addictions*, **22**: 727-749

Magura S, Lipton DS (1988) The accuracy of drug-use monitoring in methadone treatment. *Journal of Drug Issues*, **18**: 317-326

Mann JM (1997) Medicine and public health, ethics and human rights. *Hastings Center Report*, **27**: 6-13

Mann JM (1999) Health and human rights. In Mann JM (ed.), *Health and human rights: a reader*. Routledge, London

Marlowe DB (2006) Depot naltrexone in lieu of incarceration: a behavioral analysis of coerced treatment for addicted offenders. *Journal of Substance Abuse Treatment*, **31**: 131-139

Mattick RP, Breen C, Kimber J, et al. (2003) Methadone maintenance therapy versus no opioid replacement therapy for opioid dependence. *Cochrane Database of Systematic Reviews*, **2**: CD002209

Mattick RP, Hall WD (1996) Are detoxification programmes effective? *Lancet*, **347**: 97-100

Mayor S (1997) Specialists criticise treatment for heroin addiction. *British Medical Journal*, **314**: 1365-1365

Merrill JO, Jackson TR, Schulman BA, et al. (2005) Methadone medical maintenance in primary care. An implementation evaluation. *Journal of General Internal Medicine*, **20**: 344-349

National Academy of Sciences (1996) *Pathways of addiction: opportunities in drug abuse research*. National Academy Press, Washington, DC

National Bioethics Advisory Commission (1999) *Research involving persons with mental disorders that may affect decision-making capacity*. National Bioethics Advisory Commission, Rockville, MD

National Health and Medical Research Council (1985) *Report on ethics in epidemiological research.* Australian Government Publishing Services, Canberra

National Health and Medical Research Council (1991) Guidelines for the protection of privacy in the conduct of medical research. *Commonwealth of Australia Gazette P19*: 1 July, p. 1

National Institute on Drug Abuse (1983) *Consensus statement: research panel on comes treatment and drug abuse*. NIDA, Rockville, MD

National Research Council (2001) *Informing America's policy on illegal drugs: what we don't know keeps hurting us*. National Academy Press, Washington, DC

Newman R (1974) Involuntary treatment of drug addiction. In Bourne PG (ed.), *Addiction*. Academic Press, New York

O'Connor PG, Kosten TR (1998) Rapid and ultrarapid opioid detoxification techniques. *Journal of the American Medical Association*, **279**: 229-234

Ostini R, Bammer G, Dance PR, et al. (1993) The ethics of experimental heroin maintenance. *Journal of Medical Ethics*, **19**: 175-182

Pedic F (1990) *Drug use in prisons: data collection procedures. A review and recommendations*. National Drug and Alcohol Research Centre, Sydney

Perneger TV, Giner F, del Rio M, et al. (1998) Randomised trial of heroin maintenance programme for addicts who fail in conventional drug treatments. *BMJ*, **317**: 13-18

Platt JJ, Buhringer G, Kaplan CD, et al. (1988) The prospects and limitations of compulsory treatment for drug addiction. *Journal of Drug Issues*, **18**: 505-525

Porter L, Arif A, Curran WJ (1986) *The law and the treatment of drug- and alcohol-dependent persons: a comparative study of existing legislation*. WHO, Geneva

Rachels J (1999) *The elements of moral philosophy*. McGraw-Hill College, Boston

Rawls J (1971) *A theory of justice*. Belknap Press of the Harvard University Press, Cambridge, MA

Rehm J, Gschwend P, Steffen T, et al. (2001) Feasibility, safety, and efficacy of injectable heroin prescription for refractory opioid addicts: a follow-up study. *Lancet*, **358**: 1417-1423

Reynolds A (1992) Interface between health and law. Paper presented at: *Winter School in the Sun Conference (Alcohol and Drug Foundation Queensland)*. ADFQ, Brisbane

Room R, Greenfield T, Weisner C (1991) People who might have liked you to drink less: changing responses to drinking by US family members and friends. *Contemporary Drug Problems*, **18**: 573-595

Rotgers F (1992) Coercion in addictions treatment. In Langenbucher JW, Mccrady BS, Frankenstein W, Nathan PE (eds.), *Annual review of addictions research and treatment*. Pergamon, New York, pp. 403-416

SAMHSA (2002) Results from the 2001 household survey on drug abuse, vol. 1. Office of Applied Statistics, SAMHSA

Scherbaum N, Klein S, Kaube H, et al. (1998) Alternative strategies of opiate detoxification: Evaluation of the so-called ultra-rapid detoxification. *Pharmacopsychiatry*, **31**: 205-209

Scott CK, White WL (2005) Ethical issues in the conduct of longitudinal studies of addiction treatment. *Journal of Substance Abuse Treatment*, **28**: S91-S101

Sheldon J (1987) Legal and ethical issues in the behavioural treatment of juvenile and adult offenders. In Morris E, Braukmann C (eds.), *Behavioural approaches to crime and delinquency*. New South Wales Drug and Alcohol Authority, Sydney

Simpson D, Sells S (1982) Effectiveness of treatment for drug abuse: An overview of the DARP research program. *Advances in Alcohol and Substance Abuse*, **2**: 7-29

Skene L (1987) An evaluation of a Victorian scheme for diversion of alcoholic and drug dependent offenders. *Australian and New Zealand Journal of Criminology*, **20**: 247-268

Spooner C, Hall WD (2002) Public policy and the prevention of substance-use disorders. *Current Opinion in Psychiatry*, **15**: 235-239

Spooner C, Hall WD, Mattick RP (2001) An overview of diversion strategies for Australian drug-related offenders. *Drug and Alcohol Review*, **20**: 281-294

Stathis H (1991) Drug use among offenders: a literature review. New South Wales Department of Corrective Services, Sydney

Stathis H, Bertram S, Eyland S (1991) Patterns of drug use amongst NSW prison receptions. *Research Publication* 23. Research and Statistics Division, New South Wales Department of Corrective Services, Sydney

Stitzer M, Iguchi M, Kidorf M, et al. (1993) Contingency management in methadone treatment: the case for positive incentives. In Onken L, Blaine J, Boren J (eds.), *Behavioral treatments for drug abuse and dependence*. National Indicate of Drug Abuse, Rockville, MD

Stitzer ML, Bickel WK, Bigelow GE, et al. (1986) Effect of methadone dose contingencies on urinalysis test results of polydrug-abusing methadone-maintenance patients. *Drug and Alcohol Dependence*, **18**: 341-348

Strang J, Wilks M, Wells B, et al. (1998) Missed problems and missed opportunities for addicted doctors. *British Medical Journal*, **316**: 405-406

Sugarman J, McCrory DC, Powell D, et al. (1999) Empirical research on informed consent - an annotated bibliography. *Hastings Center Report*, **29**: S1

Szasz T (1997) *Ceremonial chemistry: the ritual persecution of drugs, addicts and pushers*. Learning Publications, Holmes Beach, FL

Tonigan J, Connors G, Miller W (2003) Participation and Involvement in Alcoholics Anonymous. In Babor T, Del Boca F (eds.), *Treatment in matching alcoholism*. Cambridge University Press, Cambridge, UK

Tonigan JS, Toscova R, Miller WR (1996) Meta-analysis of the literature on Alcoholics Anonymous: sample and study characteristics moderate findings. *Journal of Studies on Alcohol*, **57**: 65-72

Trafton JA, Minkel J, Humphreys K (2006) Determining effective methadone doses for individual opioid-dependent patients. *PLoS Medicine*, **3**: e80

Trellis ES, Smith FF, Alston DC, et al. (1975) The pitfalls of urine surveillance: the role of research in evaluation and remedy. *Addictive Behaviors*, **1**: 83-88

United Nations General Assembly (1948) Universal Declaration of Human Rights. United Nations, New York. http://www.un.org/depts/dhl/humanrights/

Veatch RM (1981) *A theory of medical ethics*. Basic Books, New York

Vlahov D, Wang CL, Galai N, et al. (2004) Mortality risk among new onset injection drug users. *Addiction*, **99**: 946-954

Volkow N, Li TK (2005a) The neuroscience of addiction. *Nature Neuroscience*, **8**: 1429-1430

Volkow ND, Fowler JS (2000) Addiction, a disease of compulsion and drive: involvement of the orbitofrontal cortex. *Cerebral Cortex*, **10**: 318-325

Volkow ND, Fowler JS, Wang GJ (2003) The addicted human brain: insights from imaging studies. *Journal of Clinical Investigation*, **111**: 1444-1451

Volkow ND, Li TK (2004) Drug addiction: the neurobiology of behaviour gone awry. *Nature Reviews Neuroscience*, **5**: 963-970

Volkow ND, Li TK (2005b) Drugs and alcohol: treating and preventing abuse, addiction and their medical consequences. *Pharmacology & Therapeutics*, **108**: 3-17

Walker R, Logan TK, Clark JJ, et al. (2005) Informed consent to undergo treatment for substance abuse: a recommended approach. *Journal of Substance Abuse Treatment*, **29**: 241-251

Ward J, Mattick RP, Hall WD (1992) *Key issues in methadone maintenance treatment*. New South Wales University Press, Kensington, NSW

Ward J, Mattick RP, Hall WD (1998a) The use of urinalysis during opioid replacement therapy. In Ward J, Mattick RP, Hall WD (eds.), *Methadone maintenance treatment and other Opioid replacement therapies*. Harwood Academic Press, Sydney

Ward P, Mattick RP, Hall WD (1998b) *Methadone maintenance treatment and other opioid replacement therapies*. Harwood Academic Press, Sydney

Weisner C (1990) Coercion in alcohol treatment. In Institue of Medicine (ed.), *Broadening the base of treatment for alcohol problems*. National Academy Press, Washington, DC

Wexler D (1993) Therapeutic jurisprudence and changing conceptions of legal scholarship. *Behavioural Science and Law*, **11**: 17-29

White JM, Irvine RJ (1999) Mechanisms of fatal opioid overdose. *Addiction*, **94**: 961-972

Wild TC (1999) Compulsory substance-user treatment and harm reduction: a critical analysis. *Substance Use & Misuse*, **34**: 83-102

Wild TC, Newton-Taylor B, Alletto R (1998) Perceived coercion among clients entering substance abuse treatment: structural and psychological determinants. *Addict Behav*, **23**: 81-95

World Health Organization (2004) *Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention: position paper*. WHO, Geneva

World Health Organization (2005) *Basic principles for treatment and psychosocial support of drug dependent people living with HIV/AIDS*. WHO, Geneva

World Medical Association (1964) Declaration of Helsinki. World Medical Assembly, Helsinki. http://www.fda.gov/oc/health/helsinki89.html