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The Use of Methadone or Naltrexone for Treatment of Opiate Dependence: An Ethical Approach

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Abstract

The policy of Harm Reduction was adapted and implemented by the Australian health establishment in response to a rising epidemic of opiate use, dependency and death from overdose and fears of the spread of AIDs and Hepatitis C throughout the intravenous drug-using population in the 1980s. The Harm Reduction movement provided funding for the methadone treatment program, needle exchanges, education about safe use of drugs, a harm reduction approach by police, a safe injecting room in Sydney and the call for drug trials of heroin for maintenance purposes. This is despite the lack of evidence that these measures result in disease prevention, reductions in drug use and/or criminality, or that health is significantly improved. On the other hand, naltrexone has been shown to be non-toxic, safe with no significant side-effects, highly effective in providing high rates of detoxification, and helpful in improving long term drug free status. Being drug free significantly reduces all risks associated with drug addiction. In Australia, since the year 2000, recent major reductions in the numbers of individuals using opiates and dying of overdose indicate that the enforcement of legal penalties and reduction in supply, has resulted in a reduction in demand and a greatly reduced rate of mortality. It seems these policies need to be part of a broad-based and coherent policy on preventing harm from drug use. This also applies to abstinence-based treatment approaches. Opiate dependent people have a right to the best form of treatment available and the right to choose to be drug-free and that includes naltrexone treatment incorporating those components which maximise effectiveness and safety..

Introduction

In recent years, a philosophy and policy of Harm Reduction has been adopted and implemented by the Australian health establishment in response to a rising epidemic of opiate use, dependency, and death from overdose. This change follows the liberalisation of laws relating to contraception and abortion, and a shift in emphasis toward individual civil rights in opposition to concepts of for some people, social engineering and for others, community values and rights. In the early 1980's the spread of HIV/AIDS was primarily among the gay communities of inner city suburbs. In the face of a morally prejudicial call for homosexual men to forego sexual relationships to manage the spread of the disease, a program of harm minimisation was initiated, which recognised this group's right to freely express their sexuality. It was based on education and prevention measures and research into and implementation of treatment to minimise and prevent harm to this group. Overseas studies also indicated that the other major risk group for contracting the disease was that group of people who used drugs, particularly opiates and amphetamines intravenously, and who often shared needles (Drucker & Clear, 1999; Day, 2003). Harm minimisation was then applied to allay the fears of the spread of AIDs and Hepatitis C throughout the intravenous drug-using population and then among the general population they interacted with (Drucker & Clear, 1999).

In the 1980s, the Labor Government in Australia at the time adapted the Harm Reduction approach for this group and provided funding for the methadone treatment program, needle exchanges, education about safe use of drugs, and a harm reduction approach by police that minimised harassment of drug users on the streets and emphasised health interventions to save lives (Wodak & Lurie, 1996). More recently, the introduction of a safe injecting room in Sydney and the call for trials of heroin for addicts was initiated (Wodak & Lurie, 1996). The fundamental belief was that just as gay men had a right to form sexual relationships and to be free from harms associated with this activity, so intravenous drug-users had a similar right to practice drug use free from harms. (Hathaway, 2002). These harms included criminal charges and police harassment, contraction of communicable diseases (dealt with by providing clean needles and information on sterilisation of needles and safe injecting practices), and risk of overdose and death (Hathaway, 2002). The fact that there is a significant overlap between these

groups has given added impetus to this push toward harm minimisation. This emphasis on human rights was made clearly by the Chief Minister in the ACT, Mr Jon Stanhope. In response to a request that the Government consider supporting trials of naltrexone implants in the ACT, his argument was that such a measure would infringe on the rights of drug-users and that it would entail some form of "enforced abstinence", which was unacceptable (Stanhope, 2002, personal correspondence). The fundamental right here was the prevention of harm, especially from HIV/AIDS and the obligation on society to protect people who chose to use drugs recreationally; the liberal provision of methadone was a major plank in this policy.

At the same time, traditional approaches to treatment, such as home or medicated detoxification, followed by rehabilitation programs such as therapeutic communities based on 12 step models, were falling out of favour among the advocates of harm minimisation (Drucker & Clear, 1999). These traditional treatment programs tended to see drug-use as problematic, often seemingly, from a moral perspective with condemnation of the drug user as a morally flawed person and with abstinence as the primary, or only, goal of treatment (Drucker & Clear, 1999). The new order saw this as an attack on the lifestyle choice of the drug user, an attack on their civil liberties and their right to be free of preventable harms associated with drug use. Instead of confronting the 'denial' or 'rationalisation' of the drug user for continuing the habit, some in the harm minimisation group adapted a counselling style, which sought to legitimise the drug users' choice and to empower them as an oppressed group, to defend their right to freely use whatever drugs they chose, licit or illicit (Goodfellow, 2004; Madden, 2004). A post-modern position underpinned this movement with the belief that no one has any objective knowledge of the rights and wrongs of these issues, and that the risk associated with drug use is socially constructed and not a matter of correct or rational knowledge and are culturally created and political in essence (Southgate, Day, Kimber, Weatherall, MacDonald, Woolcock, Mc Guckin & Dolan, 2003). This was accompanied by the adaptation of Narrative Therapy to treat drug dependency (Campbell, 1999). In this paper, Campbell says: "Narrative Therapy is concerned with the repressive role of dominant discourses…. and potentially pathologising therapeutic discourses. In the drug and alcohol field, they may emerge as dependency stories or narratives" (p. 3). Moreover, this group advocated the idea that we were a 'drug using society' and that anything from coffee and aspros

to heroin and ecstasy, were all drugs, the only difference being that some were arbitrarily declared to be legal and some were not, leading to a loss of free choice and the persecution of those who chose one drug as opposed to another. People who held this view often failed to differentiate between the relative harm of different drugs and the social factors affecting the way different drugs are used.

The same group also declared that the "War on Drugs' had failed and that we, as a society, should reduce our efforts to interdict supply; minimise our focus on the prosecution of drug suppliers and the deterrence and/or punishment of those who seek to use drugs; and divert the funds into treatment approaches, most notably the Methadone Maintenance Program (Wodak, 1997, Dillon, 1999; Goodfellow, 2004). The success of this program's major aim of preventing the spread of HIV/AIDS and Hepatitis C is not clear. While rates of HIV/AIDS transmission in the injecting drug user population is low in Australia, rates of Hep C infection among this group is very high, despite the harm minimisation policies of the last 25 years. It seems that harm minimization has a discordant effect on HIV and Hepatitis C, and therefore it is most likely that harm minimization strategies are not responsible for either effect: the effect on HIV seems to provide some evidence that harm minimization works well, whilst the effect on Hep C suggests that it is ineffectual. Hence, the most likely explanation is that it is not the prime mover of these disparate trends. (Caplehorn, McNeil & Kleinbaum, 1993; Southgate, Day, Kimber, Weatherall, MacDonald, Woolcock, Mc Guckin & Dolan, 2003; Wodak & Lurie, 1996).

Methadone v. Naltrexone

Despite the lack of evidence to indicate that disease prevention has been affected by the implementation of methadone maintenance, or that the perceived benefits in drug use, criminality and health are significantly improved (Caplehorn, McNeil & Kleinbaum, 1993; Reno & Aiken 1993; Mattick, Been, Kimber & Davoli, 2009), this same group tends to advocate strongly for the use of methadone as the preferred or Golden Standard treatment for opiate dependence (Wodak, 1997; Byrne, 1995; Byrne, 2004). This form of treatment was developed in New York in the 1960's as a substitute for more intensive and expensive interventions, especially among the city's African-American and Hispanic populations: to curtail crime, to reduce health costs, and to control the addict by requiring

them to appear at a Government controlled dosing centre each day for treatment (Drucker & Clear, 1999). Despite this policy, the spread of HIV/AIDS among this injecting drug group in the United States is very high and the policy has failed to prevent the spread of this disease or Hepatitus C (Wodak & Lurie, 1996). The best evidence, following a Cochrane review of methadone compared to no treatment, shows that there is an increase in retention in treatment (which is not surprising given the addictive nature of methadone), but no significant improvement in criminality or mortality (Mattick, Been, Kimber & Davoli, 2009). Others would dispute this and claim that mortality is reduced significantly, by 20-40%, for those who cease injecting drug use, and remain in treatment on methadone (Drucker & Clear, 1999). They would claim that substitution treatment benefits users by reducing injection (Ward, Mattick & Hall, 1997). However, methadone is associated with continued injection of heroin and other drugs, as the overall median duration of injecting is longer for those who start methadone compared to those who don't. For those who do not start methadone treatment, the medium time of injecting is 5 years (with nearly 30% ceasing within a year) compared to a prolongation of opiate use, and injecting for 20 years for those who do start substitution treatment (Kimber, Copeland, Hickman, Macleod, McKensie, De Angelis & Robertson, 2010). This means that if the risk that applies for injecting drugs is 4 times as long, then there is an overall increase in mortality for methadone when considered over the longer term. Many of the papers justifying methadone are done over only 6-12 months and up to 5 years, often with small samples (Drucker & Clear, 1999; Davoli, Bargagli, Perucci, Schifano, Belleudi, Hickman, et al, 2007; Hubbard, Craddock & Anderson, 2003; Gossop, Marsden, Stewart & Kidd, 2003; Darke, Ross, Teesson, Ali, Cooke, Ritter, et al, 2005). This is neither relevant nor informative, as many people stay on methadone for 20 to 40 years. This group's major criticism of antagonist treatment (naltrexone) for opiate dependency was the short retention times in treatment, and overdose due to reduced tolerance (Wodak, 1997; Bartu, Freeman, Gawthorne, Allsop and Quigley, 2002).

Therein lies an ethical dilemma as advocates of naltrexone treatment and abstinence face the problem of the practical application of treatment and whether those who attain abstinence can maintain it, given the high incidence of co-morbidity. Research and clinical knowledge indicates that there is a group who have been dependent on opiate, who tend to relapse at very high rates and that relapse for

someone whose tolerance for the drug has been reduced, are prone to overdose and death (Fellowes-Smith, 2011). This was the case for oral naltrexone as people often ceased using it prematurely and succumbed to early relapse. However, this problem is common to anyone whose tolerance has been reduced. For example, those leaving prison when tolerance is lowered, die at much higher rates from opiate overdose (2,6% within 28 days of leaving prison) than those who are using heroin regularly (Larney, 2010). Treatment approaches that involved a support person to administer the medication each day minimised the problem, however, it placed an often unwanted burden on carergivers and left vulnerable those who did not have a reliable support person. Slow release naltrexone implants were seen as a vast improvement on compliance rates. An editorial in the Drug and Alcohol Review (2001), confidently predicted that: “Implants are a logical method of attempting to ensure that the benefits of naltrexone are not undermined by poor compliance rates” (p. 349) and this has been borne out by recent research. Notwithstanding, some risk remains even after prolonged periods of abstinence.

One of the strongest arguments for methadone as a treatment is that the addict’s tolerance is maintained at a high level by maintaining or increasing the daily dose to a level where the craving for other opiates is reduced or eliminated (Byrne, 1995; Byrne, 2004). Consequently use of heroin, even after a period of being ‘clean’, is not as likely to result in an overdose. Notwithstanding, there are a number of people who die each year with methadone being implicated in their death. Recent estimates put this at 0.7% per annum, (Fellows-Smith, 2011), and for those leaving prison rates of 1.6% have been found for those who are being dosed with methadone (Larney, 2010), often as a consequence of concurrent use of other CNS depressants and that those on methadone tend to stay on the drug for many years (Kimber et al. 2010; Caplehorn, Dalton, Haldar, Petranus and Nisbet, 1996).

However, naltrexone, a potent opiate antagonist, has been shown to have valuable properties for the treatment of addiction to opiates, such as heroin and methadone. The most important property is its ability to completely block the effects of heroin and methadone (Tennant, Rawson, Cohen, & Mann, 1984), making relapse to regular opiate use almost impossible while it is being taken or being released as an implant. Research has shown that a dose of 50-100mg of oral naltrexone provides effective protection against heroin for 2-3 days, and with chronic dosing, no accumulation of naltrexone or its

metabolites have been observed (Meyer, Straugn, Lo, Schary, & Whitney, 1984). Naltrexone implants have been shown to effectively block the effects of opiates for between 180 and 240 days, thus allowing an extended drug free period to deal with social and psychological problems that would otherwise lead to early relapse and risk of overdose (Hulse, et la., 2009; Colquhoun, Tan & Hull, 2005). Moreover, naltrexone is non-toxic (Volavka, Resnick, Kestenbaum, & Freedman, 1976; Meyer et al., 1984, Colquhoun, 2003a) and produces no clinically important side-effects (Volavka et al., 1976; Meyer et al., 1984; King, Volpicelli, Gunduz, O'Brien, & Kreek, 1997; Perez & Wall, 1980). Naltrexone use offers no (immediate) reinforcement and the discontinuation of naltrexone use produces no adverse effects or withdrawal symptoms. This contrasts with heroin and methadone use, which offers strong reinforcement immediately after use, and adverse effects, withdrawals, if use is discontinued (Comer, Collin, Kleber, Nuwayser, Kerrigan and Fischman, 2002). Naltrexone has been shown to be highly effective in providing high rates of detoxification (Colquhoun, 2010) and improving long term drug free status (Kunøe, et al., 2009, Hulse, et la., 2009; Colquhoun, Tan & Hull, 2005). Being drug free significantly reduces all risks associated with drug addiction (Kimber et al., 2010). Since around the year 2000 in Australia, the numbers of individuals using opiates indicate that the enforcement of legal penalties and reduction in supply has resulted in less demand and a substantial decrease in mortality due to overdose (O'Brien, et al., 2007).

The Argument for Harm Minimisation

With the coming to power of the Liberal Government, there was a shift in policy direction from Harm Reduction to Harm Minimisation. This policy placed less emphasis on harm reduction, ie., the rights of those who want to use illicit drugs, and more importance on minimising harm to those who are yet to experiment with drugs and the rights of the wider community who do not use illicit drugs. Hence greater emphasis has been given to supply reduction and interdiction, prevention, mainly through education and deterrence, diversion programs, and treatment, with abstinence as the ultimate goal (House of Representatives Inquiry, 2007; Road to Recovery, 2003).

Those who advocate for continuation of Harm Reduction policies fall into two broad and overlapping camps: those who argue for the rights of drug users to be able to choose to use illicit drugs because

they enjoy it (Madden, 2004; Hathaway, 2002) and those who argue that those who use illicit drugs are often the most marginalised groups who are alienated from the main stream and suffer mental health problems which they medicate using these drugs (Goodfellow, 2004). In both cases, they see the shift to Harm Minimisation, with an emphasis on deterrence and treatment, as persecution of these groups and as an infringement on their civil liberties. For Madden (2004) the recent report, "The Road to Recovery" (2003), spelt out the new, upcoming National Drug Strategy incorporating "harm prevention" to replace the harm minimisation approach. For her, Harm Prevention is seen as a two pronged approach including: prevention of all illicit drug use in the first place via supply and demand reduction strategies; and the promotion of drug treatment that sees abstinence from all drug use as the ultimate outcome.

Madden (2004) says that it carries the message that "people who use illicit drugs have "self-inflicted" problems and therefore do not deserve protection in terms of their health and human rights, do not deserve to be treated with dignity and respect, should at best be viewed as "sick" and as "victims" and should only be given two choices: don't use drugs in the first place or stop using; or, if you can't stop – "go into drug treatment but you must have life-long abstinence as your only goal." (p.2)

Alternatively, the views of Goodfellow and colleagues that present drug addicts as victims, and suggest that the reasons why some people use and ultimately become dependent upon certain drugs are largely social and environmental and that genetic factors often predispose some people to addiction (Goodfellow, 2004). Some of the risk factors impacting upon young people that are associated with drug dependence in later life include:

- depression, suicidal behaviour, exposure to crime, risk of homelessness;
- extreme economic deprivation, family conflict, low literacy/limited education, social isolation, and;
- a lack of appropriate community education about drug use and harm reduction (Hawkins, Catalano & Miller, 2000).

Opiate dependency is seen as a ‘chronic relapsing condition or disease’, which entails changes to the person’s nervous system, which may or may not be permanent. The harm minimisation position is that the addict is unable , for at least a short time (5 years) and sometimes never, to be cured, despite their best intentions and the help of well-intentioned help of others (Barnett, 1999. This mimics the Alcoholic Anonymous position of the chronic alcoholic who can never drink again, as it will inevitably lead to relapse to alcohol dependency. In this disease model of addiction, alcoholics are seen as different at a biological level compared to those who can drink socially and not become addicted. Or alcoholics had personality (or moral) flaws, which the rest of us were free of, which predisposed them to alcoholism and was incurable. In the present case though, advocates of harm minimisation suggest that the addict be maintained on their drug forever, either methadone, or preferably morphine or heroin (Barnett, 1999). Despite the arguments which stress the ‘lifestyle choice’ and human rights of the addict, this concept of difference, of being fatally flawed, persists. In this scenario, addicts are treated with disregard for their dignity, or their rights, often by health professionals, including those working in methadone clinics

Advocates of Harm Reduction suggest that a ‘zero tolerance’ policy, which the National Drug Strategy enshrines, tends to neglect the needs of those caught up in addiction, especially those with social or psychological problem, and deterrence can manifest as persecution of these vulnerable groups. This approach tends to neglect the need to protect young people from easy access to addictive drugs and the harms associated with them.

The cries that the “War on Drugs” is not winnable and we should abandon the fight (Wodak, 2002; Madden, 2004) is like suggesting that deterrence of drunk driving is not winnable and infringes on these people’s rights; so we should give up and allow them to create death and mayhem on our roads. Or that seatbelt use in Australia should not be enforced as ‘it harms no-one else’. Despite the suggestion that the ‘War on Drugs” is not reducing drug use, recent reductions since around the year 2000 in Australia in the numbers using opiates and dying of overdose, indicate that the enforcement of legal penalties and reduction in supply has resulted in a reduction in demand. In the period from 1999 to 2003. it was estimated that $5 billion in ham was avoided by Australia’s adoption of a “’Tough on

Drugs ‘ policy (House of Representatives Inquiry, 2007). Perhaps these policies need to be part of a broad-based and coherent policy on preventing harm from drug use. Just as a reduction in harm is associated with reduction in supply, there also seems to be benefits arising from abstinence-based treatments for those who want them. For this reason, methadone should be seen as a temporary harm minimisation approach for a small group of highly dependent and unmotivated addicts and not as a permanent or long-term treatment for the vast majority of this group. Methadone, when used in this way, is a form of social control that removes the person’s opportunity to be drug-free and removes their dignity and capacity for choice.

The Right to Choose to be Drug Free

The overwhelming evidence is that most people who become addicted to a drug, including opiates, at some point become drug-free and go onto live ‘normal’ lives. Most people do this spontaneously without or with minimal intervention. (Kaufman, 1994; Robins, Helzer & Davis, 1975; Robins, Helzer, Hesselbrock & Wish, 1980; Donath, 2004). People who experience spontaneous remission from substance misuse often do so because of one or more of the following factors: increasingly negative outcomes such as health, accident or legal problems; the gradual worsening of important aspects of life such as personal relationships, financial problems; or positive life events such as marriage, work and children. These are all responses of individuals to the problems posed by addiction. Perhaps the overriding factor in the rate of dependency, and similarly, spontaneous recovery, is the access and availability of the substance to those who are addicted to it (Hall, Ross, Lynskey, Law & Degenhardt, 2000). Clearly, policies which emphasise the potential harm associated with drug use and the role of deterrents will have a major impact on rates of addiction and the time frame for remission (Kaufman, 1994). However, in an environment where there is a tendency to minimize harm or the consequences of drug use, an acceptance of illicit drug use is viewed as a right, and where the drug is cheaply and readily available, then intervention is more likely to be needed to attain abstinence. While there still is a need to more fully explore the optimal techniques for the safe use of naltrexone, and how counselling can best help addicts and their families break free from heroin and methadone dependence, they have a right to choose to be drug-free. Naltrexone detoxification and

the use of slow-release naltrexone implants provide this opportunity. (Colquhoun,2010; Hulse, Morris, Arnold-Reed, & Tait, 2009; Kunoe, et al., 2009; Colquhoun, Tan & Hull, 2005; Comer, Collins, Kleber, Nuwayser, Kerrigan, & Fischman, 2002).

Opiate dependent people have a right to the best form of treatment available and that includes naltrexone treatment incorporating those components which maximise effectiveness and safety. (Kimber et al. 2010). Naltrexone has now been shown to be highly effective in providing high rates of detoxification (Loimer, Lenz, Schmid & Presslich, 1991; Mattick, Diguisto, Doran, O'Brien, Shanahan, Kimber, J. et al., 2001; Colquhoun, 2010) and with the use of slow release implants, retention in treatment is much higher and long-term abstinence is achievable. Moreover, there is a demonstrated reduction of mental health problems, overall improvements in physical health, dramatic reductions in crime, morbidity and mortality, and a chance to contribute to society in a meaningful way once more (Latt, Jurd, Houseman & Wutzke,2002; Comer, Collins, Kleber, Nuwayser, Kerrigan, & Fischman, 2002; Kunøe, et al., 2009, Hulse, et la., 2009, Colquhoun, Tan & Hull, 2005).

Therefore, the major argument in favour of naltrexone treatment is based on evidence of its safety and efficacy, but also on the ethical issue, and ultimately on the argument in favour of the human rights of the dependent person to be free from dependency.

Author Information:

Dr Ross Colquhoun is a Clinical Health Psychologist working in private clinical practice since 1996. He specialises in the treatment of addictions and is a leader in the treatment of substance dependency, especially opioid dependency and in the neuroscience of addiction. He is principally responsible for the psychological assessment and treatment planning for substance dependent patients entering the program, which has a focus on concurrent treatment of co-morbid conditions. These include mental health problems, brain injury and chronic pain. He also has expertise in the prevention and treatment of psychological problems, especially burnout among health professionals, rehabilitation and couples and family counselling, and medico-legal reports. The practice employs two other psychologists/ psychotherapists and intern psychologists as well as nurses and doctors part-time. Information can be found at www.addictiontreatment.com.au

Dr. Colquhoun developed the concept of Mindcheck Wellness Centres to provide diagnosis and treatment planning for people with dementia and to support their families. As there is a three year delay between onset and diagnosis of dementia, he developed an on-line screening test for people who are concerned about their cognitive performance, as early intervention can significantly impact the progress of the disease, quality of life and functioning, and allows people a say in their care before it is too late. This can be found at www.mindcheck.com.au.

He has had two books published, "The Use of Naltrexone in the Treatment of Opiate Dependence", (Lambert Academic, Germany), based on his doctoral thesis and "Is Dementia a Bigger Word than Cancer?" (Xlibris, USA). This book aims to encourage people to seek early assessment and to prepare people for dementia. It clearly explains what you might expect and what you can do in terms of prevention and treatment.

Conflict of Interest Statement:

I declare that I have no proprietary, financial, professional or other personal interest of any nature or kind in any product, service and/or company that could be construed as influencing the position presented in, or the review of, the manuscript entitled except for the following: I am the clinical director of Addiction Treatment and Psychology Services in Sydney, Australia which provides treatment services to people who are drug or alcohol dependent using naltrexone implants among other things.

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