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A review of the evidence-base for harm reduction approaches to drug use

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FORWARD THINKING ON DRUGS

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Acknowledgement - The findings regarding heroin prescribing are abridged from Stimson G and Metrebian M (forthcoming 2003) Prescribing heroin – what is the evidence? Joseph Rowntree Foundation.

1 Introduction

'Harm reduction' is a term that is used to refer both to a set of general principles used to underpin policies concerning the way that societies respond to drug problems and, simultaneously, to some specific types of intervention, such as needle and syringe programmes and methadone treatment, which are often seen as being synonymous with 'harm reduction'.

This overview addresses both understandings of harm reduction and summarises its key principles before going on to consider the strength and nature of the evidence of the effectiveness of various forms of 'harm reduction' intervention. In doing so, some consideration is also given to criticisms of harm reduction that are occasionally encountered.

2 What is harm reduction?

In essence, harm reduction refers to policies and programmes that aim to reduce the harms associated with the use of drugs. A defining feature is their focus on the prevention of drug-related harm rather than the prevention of drug use *per se*. One widely-cited conception of harm reduction distinguishes harm at different levels - individual, community and societal - and of different types - health, social and economic (Newcombe 1992). These distinctions give a good indication of the breadth of focus and concern within harm reduction.

When considering a definition of harm reduction, it is notable that several terms are used somewhat interchangeably; these include 'risk reduction', 'harm reduction' and 'harm minimisation'. In distinguishing these, Strang (1993) clarifies that it is harm that should be our target and, consequently, support for different proposals based on an appraisal of their impact on harm. Nevertheless, risk - the likelihood that an event causing harm may occur – is sometimes used as a surrogate for harm, as harm is not always directly or easily measurable. He discusses harm minimisation as an overall goal or endpoint of policy and, by contrast, a harm reduction policy or programme as "something that is essentially operational". By convention, it is 'harm reduction' that has become the generally preferred term and, given the largely operational focus of this overview, this is the term that will be used throughout this document.

Rather unhelpfully, no definitive definition of ‘harm reduction’ exists. A number of definitions have nevertheless been offered (for example Newcombe 1992; CCSA 1996; Lenton and Single 1998; Hamilton, Kellehear & Rumbold, 1998).

The term came into use at least as long ago as 1987 (Newcombe 1987) and its principles can be traced back much farther in publications such as that of the Rolleston Report (1926), which adopted an approach to opiate dependence that included the possibility of medically maintaining the addict: a principle which underpinned the *British System* for some 50 years or so (Stimson and Oppenheimer 1982; Strang and Gossop 1996).

As its name suggests, harm reduction is concerned with reducing the *harms* that can accompany drug use and is sometimes contrasted with approaches that prioritise prevention of drug *use* and a rigid ‘zero tolerance’ enforcement of drug prohibition; sometimes characterised as the ‘war on drugs’ approach (Lenton and Single 1996; Drugs and Crime Prevention Committee, Parliament of Victoria 1999).

In practice there is more convergence between countries that are associated with harm reduction and those that are more associated with a ‘war on drugs’ than is often acknowledged. Globally, drug prohibition is universal, but with differences in the way that it is implemented (see section 3.4 Depenalisation). Similarly, primary prevention efforts to discourage the use of drugs by young people have remained a feature of the drug policy of countries that have been most strongly associated with the harm reduction approach such as The Netherlands, Australia, Canada, Germany, Switzerland and the United Kingdom. Conversely, treatments such as methadone maintenance that are firmly located within a harm reduction framework are widely available within the USA, which nevertheless continues to oppose needle and syringe programmes at the federal level.

Historically, the main stimulus to the development of harm reduction policies and programmes was the identification of the role of injecting drug use and the sharing of needles and syringes in the transmission of HIV/AIDS. More or less in parallel, a number of countries re-examined the tension between policies that prioritised the reduction of drug *use* and those primarily concerned with reducing *harm*, drawing conclusions similar to that of the *Advisory Council on the Misuse of Drugs* (1988), which advised the British government that the:

'threat to individual and public health posed by HIV and AIDS was much greater than the threat posed by drug misuse'

and led to the conclusion that a hierarchy of goals should be pursued as follows:

1. *Reduce the incidence of sharing injecting equipment*
2. *Reduce the incidence of injecting*
3. *Reduce the use of street drugs*
4. *Reduce the use of prescribed drugs*
5. *Increase abstinence from all drug use.*

As the quotation above suggests, it is an approach that is grounded within public health and around this time, a number of countries introduced needle exchange schemes and developed or extended their methadone treatment programmes, subsequently leading to claims that these policies have been successful in averting or reversing the epidemic spread of HIV/AIDS (Stimson 1996; Des Jarlais 1998; Des Jarlais 1999; Commonwealth Department of Health and Ageing 2002)

Since the 1980s, people espousing harm reduction policies have gathered within a social movement, which was given impetus by the first *Conference on the Reduction of Drug Related Harm* in Liverpool, 1990. *The International Harm Reduction Association* (IHRA) was subsequently formed as an interdisciplinary, membership organisation to advance harm reduction policies around the world (www.ihra.net). Its membership includes public health and other health and social care practitioners, academics, policy-makers and – notably - drug users, who are encouraged to participate fully within collaborative efforts to reduce drug related harm. However, although for most practical purposes there is a good deal of consensus about what harm reduction is amongst its adherents, even the IHRA has no formally adopted definition. It nevertheless suggests that the term harm reduction should be understood to mean:

"policies and programs which attempt primarily to reduce the adverse health, social and economic consequences of mood altering substances to individuals drug users, their families and their communities".

(IHRA 2002)

2.1 Harm reduction principles

Harm reduction is partly defined by a range of principles in which policies and programmes are grounded. The Canadian Centre on Substance Abuse (CCSA 1996) offers the following:

1. ***Pragmatism: Harm reduction*** *accepts that some use of mind-altering substances is a common feature of human experience. It acknowledges that, while carrying risks, drug use also provides the user with benefits that must be taken into account if drug using behaviour is to be understood. From a community perspective, containment and amelioration of drug-related* ***harms*** *may be a more pragmatic or feasible option than efforts to eliminate drug use entirely.*

2. ***Humanistic Values:*** *The drug user's decision to use drugs is accepted as fact. This doesn't mean that one approves of drug use. No moralistic judgment is made either to condemn or to support use of drugs, regardless of level of use or mode of intake. The dignity and rights of the drug user are respected.*

3. ***Focus on Harms:*** *The fact or extent of a person's drug use per se is of secondary importance to the risk of* ***harms*** *consequent to use. The* ***harms*** *addressed can be related to health, social, economic or a multitude of other factors, affecting the individual, the community and society as a whole. Therefore, the first priority is to decrease the negative consequences of drug use to the user and to others, as opposed to focusing on decreasing the drug use itself.* ***Harm reduction*** *neither excludes nor presumes the long-term treatment goal of abstinence. In some cases,* ***reduction*** *of level of use may be one of the most effective forms of* ***harm reduction****. In others, alteration to the mode of use may be more effective.*

4. ***Balancing Costs and Benefits:*** *Some pragmatic process of identifying, measuring, and assessing the relative importance of drug-related problems, their associated* ***harms****, and costs/benefits of intervention is carried out in order to focus resources on priority issues. The framework of analysis extends beyond the immediate interests of users to include broader community and societal interests. Because of this rational approach,* ***harm reduction*** *approaches theoretically lend themselves to evaluation of impacts in comparison to some other, or no, intervention. In practice, however, such evaluations are complicated because of the number of variables to be examined in both the short and long term.*

5. ***Priority of Immediate Goals:*** *Most* ***harm-reduction*** *programs have a hierarchy of goals, with the immediate focus on proactively engaging individuals, target groups, and communities to address their most pressing needs. Achieving the most immediate and realistic goals is usually viewed as first steps toward risk-free use, or, if appropriate, abstinence.*

Overlapping these, Lenton and Single (1998) have suggested that a policy, programme or intervention can be construed as harm reduction if:

> *a) the primary goal is the reduction of drug-related harm rather than drug use per se;*
> *b) where abstinence orientated strategies are included, strategies are also in place to reduce the harm for those who continue to use drugs; and,*
> *c) strategies are in place to demonstrate that, on the balance of probabilities, a net reduction in drug related harm is likely to occur.*

And that the harm reduction approach:

- *avoids exacerbating the harm caused by the misuse of drugs;*
- *treats drug users with dignity and as normal human beings;*
- *maximises the intervention options;*
- (is) based on the) pr*ioritising of achievable goals;*
- (is) *neutral regarding legalisation or decriminalisation; and,*
- *distinct from a war on drugs.*

Harm reduction principles such as pragmatism, with its focus on immediate, achievable goals are routinely applied to many causes of harm. In this sense the harm reduction approach is no different to the way that risks are routinely managed in many different realms of human activity.

Despite the injuries, environmental impact, pollution and death toll associated with motoring, its elimination is not seen as realistic because people depend on their vehicles and, realistically, will not relinquish them. Speed limits, emission controls, seat belt and crash helmet laws can all be understood as harm reduction strategies to reduce the risks and harms of motoring.

Harm reductionists hold the view that the use of drugs has been an enduring feature of human societies and that, however desirable it may be, a drug free world is an unrealistic objective, the exclusive pursuit of which can impede practical, achievable measures that reduce the burden of harms such as the disease and premature death that sometimes accompany drug use.

Where it seems the most feasible way to reduce harm, harm reductionists view abstinence as a valid and legitimate goal and interventions to promote abstinence are generally thought of as “a special subset of harm reduction” (IHRA 2002). Little

distinction is made between drugs that are currently legal in most parts of the world from those that are largely illegal. The International Harm Reduction Association proposes that “harm reduction should be understood to encompass alcohol, tobacco, prescribed and illicit drugs and volatile substances” (IHRA 2002). In this sense, programmes that result in both abstinence and more controlled drinking each have a place within harm reduction (Heather 1993: 180) as do measures such as drink driving campaigns, guidance as to safer levels of consumption and regulations requiring labelling that displays the volume of alcohol contained in alcoholic beverages. Similarly, measures that aim to reduce tar inhalation associated with nicotine dependence and tobacco smoking e.g. low tar cigarettes or nicotine replacement patches or gum, can also be understood as harm reduction measures.

Despite the universal way in which harm reduction principles can be applied to legal and illegal drugs, the focus within this overview primarily concerns those drugs that are prohibited by national legislation developed to comply with the Single Convention on Narcotic Drugs (1961), the Convention on Psychotropic Substances (1971) and the United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988).

2.2 Drug-related harms

The United Nations Office for Drug Control and Crime Prevention estimate that about 185 million people consume illicit drugs (annual prevalence 1998-2000) including 147million cannabis users, 33 million amphetamine users, 13 million cocaine users, 7 million ecstasy users and 13 million opiate users, of whom about 9 million use heroin (UNODCCP 2002). Harm reduction is overwhelmingly concerned with the deployment of effective interventions relating to all harms associated with this use. There is little evidence that effective interventions exist, which can exert a primary prevention effect on illicit drug use (WHO 2002). Consequently, although many harm reductionists would regard primary prevention as a compatible goal, there is generally an emphasis on more immediate, achievable goals relating to the many harms associated with drug use, of which some of the more important are listed here.

HIV/AIDS

It is estimated that 42 million people are currently living with HIV/AIDS of whom 5 million became newly infected in 2002. Over 3 million people died of AIDS in 2002 (UNAIDS/WHO 2002). Injecting occurs in something like 135 countries and it is estimated that there are nearly 3 million injecting drug users with HIV infection i.e. 5-

10% of all infections globally, many of which are attributable to sharing injecting equipment (Kroll 2002). Alongside transmission of HIV through shared needles and syringes, sexual transmission probably plays a significant role people who inject (Kral et al 2001; Strathdee et al 20021). Within this overall picture, substantial HIV epidemics are occurring among populations of injecting drug users such as those within China, India, Nepal, Myanmar, Indonesia, the Russian Federation and many of the Central Asian Republics. The widespread sharing of needles and syringes among people who inject also favours the rapid spread of HIV within other populations where prevalence has historically been lower, such as within Bangladesh, Vietnam and the Balkans. In Latin America, the spread of HIV through the sharing of injecting drug equipment is of growing concern in several countries, notably Argentina, Brazil, Chile, Paraguay and Uruguay, the northern parts of Mexico, Bermuda and Puerto Rico. Against this bleak background, a noteworthy success is the vigorous prevention programme in Brazil, which has led to a reversal of the spread of HIV among IDUs (UNAIDS/WHO 2002; UNAIDS 2002) and embraces harm reduction principles.

Viral Hepatitis

Other than HIV, many other blood-borne viruses can be transmitted through sharing injecting equipment. Hepatitis B and C are currently regarded as the most important of these because of their widespread prevalence and impact on health. Globally, about 170 million people are estimated to have hepatitis C (WHO 1999). In developed countries about 90% of people infected with C are former or current injecting drug users (WHO 2000). Between 50-90% of people who become infected fail to clear the virus and develop a chronic infection, with a consequent risk of developing liver cirrhosis and liver cancer and the corresponding social and economic costs . By contrast, only about 5% of people infected with Hepatitis B develop chronic liver disease, although the consequences are equally serious for those who do. Unlike hepatitis C, which is not commonly transmitted sexually, hepatitis B is readily spread through sexual contact. People with hepatitis B are also at risk of co-infection with hepatitis D, which cannot be acquired independently. In general, co-infection with different viruses and re-infection with different strains or sub-types of the same virus worsen the person's outlook.

Local and systemic bacterial infections

Besides blood-borne viruses such as HIV, hepatitis B and hepatitis C, bacterial infections are also common among injecting drug users due to poor injecting hygiene or the use of contaminated drugs. Local infections such as abscesses and cellulitis

are common especially among populations with poor access to sanitation, such as the homeless. Endocarditis, septicaemia and outbreaks of botulism, tetanus and other clostridial infections also are also known among IDUs (see section 3.7).

Overdose

Among young adults, overdose is among the leading causes of premature death in many countries. Within the European Union, death rates more than doubled between 1985 and 2000 and currently 7-8000 acute drug related deaths occur annually (EMCDDA 2002b). In 1999, 958 deaths in Australia were attributed to opioid overdose and estimates indicate between 12,000 – 21,000 non-fatal overdoses occur in Australia every year (Ministerial Council on Drug Strategy 2001). The use of cocaine, ecstasy, methamphetamine and other amphetamine-type-stimulants can all precipitate life threatening, and sometimes fatal, emergencies.

Dependence

Heroin dependence is increasing in many countries. By 2000, 76% of countries and territories reported to the UN that they had problems with heroin use. Heroin dependence is a major public health problem with an elevated risk of illness and of death, and has high social and criminal costs. Heroin is the most frequently used drug among people seeking treatment for drug problems in Europe, Asia, and Australia, and is second to cocaine in North America (UNDCP 2000). Heroin use is increasing in East Europe, Central Asia and Africa (UNODCCP 2002). Cocaine use has decreased in the USA, but is increasing in South America, Africa and Europe (UNODCCP 2002).

Other physical and mental health problems

Drug dependence and infections associated with injecting contribute to general physical debilitation and lowered immunity, which in turn increases vulnerability to infections such as pneumonia and tuberculosis, with respiratory problems particularly affecting people who inhale their drugs e.g. crack smokers and heroin users who ‘chase the dragon’. Cocaine and amphetamine type stimulants are associated with drug-induced psychosis (Connell 1958; Ellison et al 1996).

Accidents and aggression

Driving while intoxicated – ‘drug-driving’ - is increasingly recognised as a problem within developed countries, and intoxication can contribute to other accidents, aggression and injuries. Although, at present, it is unlikely that any illegal drug comes close to producing the burden of harm that alcohol does in this regard.

Public nuisance
At the community level, drug use can cause nuisance as a result of people discarding drug related litter such as used needles and syringes. Open drug scenes can affect the real and perceived safety of people who do not use drugs - as well as drug users themselves. High levels of drug use and drug dealing can contribute more generally to problems in neighbourhoods and communities with little cultural capital and high levels of poverty.

Crime
Reducing the acquisitive and other crime that is largely associated with dependent drug use has long been a secondary objective of treatment programmes such as those pioneered by Dole and Nyswander (1965; 1967). In some countries such as the UK and Netherlands there are signs that the emphasis on this aspect of drug-related harm has been increasing in recent years, as indicated by the introduction of compulsory and quasi-compulsory treatment programmes such as SOV in the Netherlands and Drug Treatment and Testing Orders in the UK.

Harms caused by criminalisation
Conversely, harm reductionists also focus on the harms that arise out of the legal framework for drug control and the consequences of criminalisation, such as disenfranchisement and exclusion from housing and education and the health and social impact of imprisonment.

2.3 Criticisms of harm reduction
Harm reduction is not without its critics. Despite the fact that it is an approach grounded within public health, for which a considerable evidence base now exists, there remain people with reservations about a) its effectiveness, b) its effects and c) its intentions.

2.3.1 Harm reduction does not work
In terms of harm reduction's effectiveness, the rest of this document provides an overview of this. It is necessarily brief and selective, due to the constraints of space, but it highlights the main features of the present evidence-base and should identify the main or most important evidence in each area that is considered. It identifies some areas where this is strong, others where it is weaker or equivocal, and draws attention to several areas where further research is desirable. This constitutes the argument about its effectiveness. It will be for the reader to judge what this says about whether, or in what ways, harm reduction works. The main limitations of the current evidence are also clearly laid out.

2.3.2 Harm reduction keeps addicts 'stuck'

Concerns regarding harm reduction's effects include the anxiety that deploying a harm reduction approach may 'enable' drug use and keep people stuck within a pattern of addiction from which they would otherwise escape, perhaps after hitting a 'rock bottom' from which harm reduction protects them. This is probably best evaluated with reference to the literature regarding methadone maintenance treatment (discussed in more detail within section 3.2). Methadone maintenance treatment has been evaluated against various drug free alternative treatments including placebo medication, offers of drug-free treatment, detoxification and waiting-list control. It consistently performs better at retaining people in treatment and reducing heroin use: to which critics might respond 'And so it should, if drug users are being given drugs'. However, there is also evidence that it prevents HIV infection, reduces mortality, reduces crime and is cost-effective: outcomes that are rarely demonstrable from other treatments within a field where, regrettably, little is as effective as one would like.

2.3.3 It encourages drug use

Another possible effect is that, somehow, harm reduction encourages drug use. The rationale behind this argument appears to be that, by assisting people who are already using drugs to remain healthier, avoid problems and stay alive, people who do not use drugs will regard drugs as safe and decide to start using drugs themselves. Harm reduction is thought to 'send out the wrong signal' and undermines primary prevention efforts. The area where this has best been tested probably concerns needle and syringe programmes (see section 3.1). Several study have investigated the hypothesis that their introduction increases drug use and found no evidence that they do (Watters et al 1994; Normand et al 1995; Paone et al 1995). However, a problem with any research into this question is that drug use is itself a dynamic phenomenon, that will independently increase and decline over time. Attributing causation or disproving it is difficult for both its critics and advocates.

Nevertheless, the view that harm reduction may encourage drug use seems to underestimate the complexity of the factors that shape people's decisions to use drugs (for example see Barnard and McKeganey 1994). The implication is that, by holding a discourse with people who are using drugs about how they might limit harm and reduce their exposure to risk, non-users may learn of this, or see harm reduction services and be encouraged to try drugs. This seems to ignore the fact that a

fundamental feature of the harm reduction discourse is its emphasis on harm. Whilst harm reductionists believe that this can be reduced in various ways, they would rarely claim that it can be completely avoided – as our experience globally with legal drugs makes abundantly clear. Thus, the basic harm reduction message is that all drug use is potentially harmful, but that the harms can, to some extent, be constrained.

2.3.4 Harm reduction is a 'Trojan horse' for drug law reform

Finally, some people consider that harm reduction's underlying intention is to achieve drug law reform and promote the legalization of drugs. It is an undeniable fact that some advocates of harm reduction are also advocates of drug law reform and the creation of some form of legal, regulated market, for some or all drugs that are currently proscribed and, effectively, unregulated. Equally, many harm reductionists would oppose such developments. Yet others would reject dealing with drugs within the criminal law but retain civil penalties for drug use. There is no consensus on this issue among harm reductionists.

Some harm reductionists would, and do, argue that public policy regarding drugs - including the prevailing system of drug prohibition - should be subject to a utilitarian appraisal that evaluates the costs and benefits of prohibition and bases policy upon the evidence of what works best. This somewhat glosses over the considerable difficulties of generating good evidence in this area; although there is a developing and instructive evidence base concerning depenalisation policies, primarily with reference to cannabis, which is summarised in section 3.4.

However, some of the most prominent statements of harm reduction's principles are explicit about harm reduction's neutrality regarding legalisation or decriminalisation (CCSA 1996; Lenton and Single 1998). The critic might construe these as 'weasel words' that disguise harm reductionists' true intentions. However, a different interpretation can be derived by looking at the origins of the harm reduction movement, which emerged as a response to a global crisis of HIV infection among people who inject.

Harm reduction retains this overall priority within a world in which a number of epidemics of HIV infection are simultaneously evolving in Asia, North and South America, Africa, Oceania and Europe. Part of any high quality response to this

ongoing health crisis is for a broad coalition of people from across different disciplines to collaborate effectively. This collaboration therefore encompasses a range of people including – crucially - drug users along with public health specialists, drug treatment workers, doctors, nurses, social workers, teachers, community activists, youth workers, politicians, parents, academic researchers, civil servants (as well as drug law reformers), who try to work together to reduce the harms that arise when people use drugs.

3 Harm reduction interventions

3.1 Needle and syringe programmes

Arguably, programmes for needle and syringe exchange are more readily associated with the harm reduction approach than any other type of intervention. The role of 'needle sharing' in the transmission of blood-borne viral infections such as hepatitis B among injecting drug users (IDUs) had been known since at least the 1970s (Howard and Borges 1971). However, it was the spread of HIV/AIDS within populations of injecting drug users in the 1980s that prompted the widespread introduction of needle and syringe programmes (NSPs) - commonly referred to as needle exchanges or syringe exchange schemes - within a number of industrialised countries across Europe, Australia and in parts of North America (Gibson et al 2001) and, more latterly, within a number of developing and transitional countries (Ball et al 1998; Bastos et al 2000; Commonwealth Department of Health and Ageing 2002).

Early HIV epidemiology identified the crucial role of needle and syringe sharing for viral transmission between IDUs (for example Chaisson et al 1987; van den Hoek 1988). This almost certainly remains the single most important risk factor for transmitting blood borne-viruses. When illicit drugs are prepared for injection they are typically mixed in powdered form with water before being cooked up in a 'cooker' or spoon. Often they will be filtered through a 'cotton' or cigarette filter before being drawn up for injection. The sharing of such paraphernalia has been identified as a further potential risk factor for viral transmission (Koester, Booth and Wiebel 1990). Consequently, some programmes also distribute other equipment, such as sterile wipes, 'cookers', filters and sterile water to discourage their re-use. Furthermore, some practices used to divide drugs between two or more people ('frontloading' or 'backloading') may also be implicated in the spread of blood-borne viruses as they enable infections to be passed from one syringe to another (Grund et al 1991; Jose

et al 1993; Hagan et al 2001). NSPs provide a point of contact that enable these practices and a wide range of other health matters to be discussed.

The primary goal of NSPs is therefore to prevent the transmission of HIV/AIDS and other blood-borne viral infections that are spread between IDUs through the sharing of injecting equipment. Additionally, NSPs aim to limit sexual transmission of HIV between IDUs as well as to the wider, non-injecting population (Moss 1987). The core services provided by exchanges aim to increase the number of syringes in circulation, and encourage their return and safe disposal, so that each syringe is used fewer times, thereby reducing the chances of viral transmission. Alongside the distribution of needles and syringes, NSPs also use contacts with IDUs to increase their impact by:

- communicating with IDUs to provide information and education – such as how best to disinfect used syringes/needles;
- providing easier access to addiction treatment, health and social services; and,
- using outreach methods to make contact with hidden populations. (World Health Organisation 1998)

NSPs have many different forms, and are shaped by the local and national context in which they occur. For example, a national survey of NSPs in the UK identified the following types, often coexisting and complementing each other within a given locality: pharmacy exchange schemes, 'dedicated' (i.e. stand-alone) syringe exchanges, exchanges attached to specialist drug services, community outreach schemes and mobile services. Besides these many localities had supplementary distribution points in accident and emergency departments, genito-urinary clinics and primary care settings (Parsons et al 2002). A review by Coffin (2000) identifies a further range of modalities for preventing HIV by ensuring good availability of sterile equipment including: pharmacy sales, injector-specific packs, mass distribution, and vending machines. The varying provision of NSPs, often integrated alongside other drug treatment services, poses some challenges in identifying their specific impact and in commenting upon the generalisability of findings from one context to another, but also suggests how flexibly they can be tailored to local conditions.

3.1.1 Specific populations

The majority of NSPs are provided within community settings and are available to the general population of IDUs. Nevertheless, certain populations warrant particular consideration - notably prisoners and people working within the sex industry.

Prisoners

Relative to the general population, prisoners have high lifetime levels of injecting. For example, a national survey within the UK found the following rates: adult male (24%), female (29%) and young offenders (4%) and indicated that 6% of injectors in prison began injecting while incarcerated (Weild et al. 2000). It is probable that many injectors stop injecting temporarily while they are in prison, though for those that continue to inject, the risks can be greatly enhanced (Martin et al. 1998).

Programmes distributing and promoting the use of bleach are one way by which people have sought to reduce these risks (Dolan et al 1999). In recent years, NSPs within prisons have also been increasingly developed. The first of these was piloted in Switzerland in 1992 and evaluations of this and subsequent programmes have documented reductions in sharing rates, no new acquisitions of HIV, HBV or HCV and no serious unintended consequences (Dolan et al 2003). NSPs are currently available within prisons in Switzerland, Germany and Spain - where the national policy is now for all prisons to offer needle exchange. It is of note that Spain had policies based on abstinence until the early 1990s and the highest rate of HIV infection among IDUs in Europe (Rinken and Romero-Vallecillos 2002). Large scale harm reduction policies from 1992-1994 and have produced significant reductions in HIV (Hernandez-Aguado et al., 1999). HIV prevalence among Spanish prisoners has declined from 23% in 1996 to 17% in 2001. Though this is more likely to be attributable to the earlier introduction of methadone programmes along with education, counselling and condom distribution (UNAIDS 2002)

Commercial sex workers

People who inject drugs and work in the sex industry are, potentially, doubly exposed to risk, which may also occur at elevated rates. For example, a study of women in five US cities found that, compared to other women who inject, they reported higher rates of needle sharing and unprotected sex with their primary partners (Paone et al 1999). Whilst condom distribution is a common feature of many NSPs, some localities with high levels of prostitution have developed services that target female and male commercial sex workers. In this way it is possible to provide a more accessible service that is likely to be more effective and better adapted to the specific needs of this doubly marginalized population (Crosby 1997).

3.1.2 Effectiveness of needle and syringe programmes

Since the 1980s, there have been many investigations concerning the impact of NSPs on risk behaviours and the viral status of people who use them. A variety of practical, methodological and ethical problems surround any attempt to undertake randomised, controlled trials with hidden populations of people involved in illegal, highly stigmatised activities within community settings. Nevertheless, many other research designs have proven feasible including:

- prospective studies that compare the incidence of HIV infection and related risk behaviours in needle exchange attenders and non-attenders over time (Oliver et al 1994; Des Jarlais et al 1996; Schoenbaum et al 1996; van Haastrecht 1996; Bruneau et al 1997; Hagan et al 1999; Schechter et al 1999);
- multiple cross-sectional studies examining the correlations between use of NSPs and risk behaviours for HIV (Des Jarlais et al 1994; Singer et al 1997; Bluethenthal et al 1998; Broadhead et al 1999);
- case-control studies comparing people who acquired HIV with a matched sample from the same population who did not become infected (van Ameijden 1992; Hagan et al 1994; Hagan et al 1995; Bruneau et al 1997; Patrick et al 1997);
- observational studies comparing NSP attenders with non-attenders (Hartgers et al 1989; Klee et al 1991; Donoghoe et al 1993; Frischer and Elliott 1993; Hartgers et al 1993; Keene et al 1993; van Ameijden et al 1994; Watters et al 1994; Klee and Morris 1995; Bruneau et al 1997; Strathdee et al 1997; Bluethenthal et al 1998; van Ameijden and Coutinho 1998);
- longitudinal studies of the clients of NSPs, which looked for reductions in risk behaviours - usually without comparison groups (Donoghoe et al 1989; Oliver et al 1994; Hagan et al 1995; Vlahov et al 1997)
- observational studies of NSP clients that compare people according to the length of time they have used the NSP or according to the proportion of syringes they obtain from the NSP (Paone et al 1995; Guydish et al 1995; Guydish et al 1998);
- multiple cross-sectional designs without pre and post comparisons (Peak et al 1995);
- ecological studies comparing cities with high and low prevalence of HIV or examining the characteristics of cities that have averted HIV spread (Ljungberg et

al 1991; Des Jarlais et al 1995; Stimson 1995; Groseclose et al 1996; Hurley et al 1997; Lamden et al 1998); and,

- modelling studies looking at the circulation time of syringes and the proportion of HIV-infected returned syringes (Heimer et al 1993; Kaplan and O'Keefe 1993; Kaplan and Heimer 1994; Kaplan et al 1994; Kaplan and Heimer 1995).

All of these have been appraised within a recent review by Gibson et al. (2001) to address the question – are needle and syringe programmes effective at reducing HIV risk behaviours and HIV infection among injecting drug users? Of the 42 studies (some used more than one design within the same the same study) 28 found positive effects and 14 found either no association or a combination of positive and negative effects. Overall, this provides extremely strong evidence of the positive impact of NSPs on HIV risk behaviour and HIV infection and gives good justification for their implementation. It is nevertheless useful to try to understand the two exceptions in which negative results occurred.

The two negative associations occurred within designs making comparisons between non-attenders and attenders of NSPs within community samples, in which 12 further studies found positive results and there were null effects in 11. The eight studies within NSP clients all found positive results, as did five of the six ecological studies and the five modelling studies.

In trying to explain the counter-intuitive negative results in their own research, Strathdee et al (1997) suggest that NSPs on their own may not be sufficient. However, more plausible explanations seem to be a combination of selection effects and dilution.

Selection effects arise when people who elect to use NSPs have higher rates of risk taking and infection and where 'higher risk' attenders are less likely to drop out (Schoenbaum et al 1996; Hahn et al 1998; Schechter et al 1999; Hagan et al 2000). For example, in one study, there was a higher preponderance of cocaine users among NSP users, which is relevant because cocaine users are known to have a greater frequency of injecting and associated injecting and sexual risk than heroin users (Hagan et al 2000). Similarly, Hahn et al (1998) noted that syringe exchange attenders "tended more often to be homeless, to inject more frequently, and to be a more chaotic and destitute population than non-attenders".

The other main source of bias within community samples is 'dilution'. Where IDUs have access to clean needles and syringes through other sources within the community, such as by purchasing them at pharmacies, any measurable impact of the NSPs may be reduced. Support for this comes from the fact that, within the community studies, Gibson et al found that having needle/syringe availability from community pharmacies was significant associated with negative/null results within the studies in their review. There is also evidence that the discretion that pharmacists have about who they serve may mean that they do not sell them to people they believe to be drug users whereas more socially integrated drug users may be served (Vlahov 2000).

These factors suggest that the exceptional cases where negative effects are found are best accounted for by confounding processes rather than being a negative consequence of the NSPs themselves. Indeed, the fact that the large majority of evaluations are positive despite such potential confounds suggests that, if anything, these studies may underestimate the health impact of NSPs.

In light of this, and when evaluating the evidence overall, Gibson et al (2001) conclude that "there is substantial evidence that syringe exchange programs are effective in preventing HIV risk behavior and HIV sero-conversion among IDU(s)".

3.1.3 Criticisms of NSPs

A number of further studies have sought to establish whether various hypothesised negative consequences occur after the introduction of NSPs; such as the possibility that they facilitate injecting and increase its prevalence and frequency. These suggest that NSPs do not:

- increase drug use (Watters et al 1994; Normand et al 1995; Paone et al 1995)
- hinder uptake of treatment (Wolk et al 1990; Hagan et al 1993; Heimer and Lopes 1994; Heimer et al 1994; Paone et al 1996; Heimer et al 1996; Brooner et al 1998); or,
- increase rates of equipment in the street (Oliver et al 1992; Lurie and Reingold 1993; Normand et al 1995; Doherty et al 1997; Macalino et al. 1998.

These concerns have been investigated by leading US scientists and been judged unfounded (NIH 1997; Shalala 2000). Furthermore, following the closure of a NSP due to claims that it was causing the city's drug problem and contributing to

discarded needles in public areas, it was found that discarded needles and syringes and drug injecting debris did not decrease after it closed, while both the frequency of reusing needles and the reliance on needles from an unreliable source increased i.e. public nuisance was unaffected but HIV risk taking increased (Broadhead et al 1999).

3.1.4 Community–based outreach

Closely allied to NSPs are community-based outreach programmes, with which they are sometimes linked. Without necessarily distributing needles and syringes, these aim to obtain face-to-face contact with IDUs, provide literature about HIV risk reduction, distribute condoms and bleach for disinfection of needles and syringes (especially where NSPs are not operating), promote teaching and modelling of HIV risk reduction by network leaders, referral to services, improve access to risk assessment and HIV testing, provide counselling and support community organising. A review of 36 publications examined the following outcomes (proportion of studies reporting positive findings are shown in brackets): cessation of injecting (10/11), reduced injecting frequency (17/18), stopped/reduced reuse of needles and syringes (16/20), reuse of other paraphernalia for injecting (8/12), reduction/cessation of crack use (7/7), needle disinfection (10/16), drug treatment entry (6/7) and increased condom use/reduction in unprotected sex (16/17) (Coyle et al 1999). This suggests that community-based outreach can be an important component of the overall response.

3.1.5 Costs and cost effectiveness

Given the strength of evidence that NSPs are effective a further question concerns their cost effectiveness. Several studies have attempted to quantify the costs and cost effectiveness of NSPs using a range of different methodologies (Gold et al 1997; Lurie and Drucker 1997; Holtgrave et al 1998; Laufner 2001). In each case NSPs were shown to be cost effective. An independent national review in New Zealand has calculated that each $NZ spent on NSPs yields a $NZ20 saving in lifetime treatment costs (The Centre for Harm Reduction 2002) and an Australian study concludes that “NSPs are effective in reducing the incidence of both diseases and that they represent an effective financial investment by government” (Commonwealth Dept of Health and Ageing 2002).

3.1.6 Other impacts

As has been noted, harm reduction programmes address a range of negative consequences from drug use beyond HIV/AIDS; many of which are specific to

injecting as a form of drug use - such as abscesses or collapsed veins, or greatly exacerbated by it - such as the risk of overdose. NSPs and community outreach programmes frequently attend to these additional issues within broader efforts to engage IDUs in drug treatment and increase their social inclusion. As illustration, a national review of services within the UK discusses the role of NSPs as being to:

- *offer sterile syringe and needle distribution*
- *offer safe syringe and needle disposal, usually by return*
- *offer advice and counselling on HIV, hepatitis and drug problems*
- *offer advice and counselling on other health, social and welfare problems*
- *provide referral to other treatment services*
- *provide easy access and a user-friendly service for all injecting drug misusers*
- *collect routine information.*

(Department of Health 1996)

An implication of this is that any appraisal of NSPs purely in terms of their affect on HIV/AIDS is likely to under-estimate their overall impact because of the wider opportunities they present to reduce risk and enhance the health and well-being of IDUs and other community members. For example, there is a growing focus on preventing overdose deaths using information campaigns to prevent overdose, along with interventions to enhance overdose management as an adjunct to NSPs and community outreach programmes (see Advisory Council on the Misuse of Drugs 2001; Ministerial Council on Drug Strategy 2001). The potential additional impact of NSPs in this area is largely unevaluated, as rather less attention has been paid to these outcomes until recently. Similarly, there is some limited evidence that NSPs may be able to reduce the incidence of injecting within programmes that focus on influencing the route of drug administration, rather than drug use per se (Casriel et al 1990; Hunt et al 1998; Hunt et al 1999). However, one area that has begun to receive more systematic attention is their impact on the spread of hepatitis C.

Hepatitis C is far more prevalent than HIV among IDUs. Studies of occupational transmission of HCV among healthcare workers suggest that the chance of becoming infected with HCV from an infected needlestick is around 2 to 3%, compared to about 0.3% for HIV (Centers for Disease Control and Prevention 2001). Furthermore, around 60 to 85% of those infected with HCV go on to develop chronic infection and remain infectious (National Institutes of Health 2002).

Although the hepatitis C virus was only identified in 1989,(Choo et al 1989; Kuo et al 1989) results from an epidemiological study in the UK suggests that it has been present in injecting populations since well before the introduction of NSPs (Balogun et al 2002). Probably for this combination of reasons, evidence of an impact of NSPs on hepatitis C has been slower to emerge as, by the time of their introduction, hepatitis C was virtually endemic among injecting drug users and it is also more easily acquired. So, rather than averting an epidemic, in most populations the task has been to reverse one, which is far harder and probably requires higher levels of NSP coverage and risk reduction. Indeed, it initially seemed uncertain whether NSPs could have any impact on HCV prevalence as the evidence suggested that measures which are adequate to avert HIV are not necessarily sufficient for hepatitis C (Van Beek et al 1998; Crofts et al 1999; Judd et al 1999; Hagan et al 2000; Brunton et al 2000).

However, there are now some early indications that, from a generally high baseline, NSPs may be having an impact even though the HCV incidence rate and levels of viraemia remains unacceptably high (Smyth et al 1999; Taylor et al 2000; Commonwealth Dept of Health and Ageing 2002; Parsons et al 2002). A contemporary and comprehensive review of NSPs in the UK suggests that, despite their widespread availability, needle exchange coverage should be further improved (Parsons et al 2002) and more proactive measures ought to be deployed within NSPs for their impact on hepatitis C to be maximised (Ashton 2003).

Against this uncertainty regarding what the optimum effectiveness of NSPs might become with regard to HCV, both of the recent cost-effectiveness assessments within New Zealand and Australia, favourably indicate the additional value that may accrue from NSPs with regard to HCV prevention (The Centre for Harm Reduction 2002; Commonwealth Dept of Health and Ageing 2002): findings which are consistent with an earlier attempt to model the cost-effectiveness of NSPs in prevention hepatitis C (Pollack 2001)

3.1.7 Summary

In summary, there is substantial evidence that NSPs are effective at preventing HIV and reducing risk behaviours that can transmit this and other blood-borne viruses such as hepatitis B and C. Initial, hypothesised risks of introducing NSPs do not arise and NSPs are a cost effective intervention for preventing HIV. Alone or in

combination with community outreach programmes they can be tailored to meet the needs of more marginalized or vulnerable groups such as people working within the sex industry and prisoners. Their eventual capacity to produce outcomes in other area - notably reducing overdose deaths and preventing hepatitis C - is less certain but probably already adds to the current cost effectiveness of NSPs. There are some evident opportunities to improve existing practice and further enhance outcomes.

3.2 Methadone and other replacement therapies

Methadone is the most widely used and researched opioid[1] replacement therapy (Hall et al 1998:1-2). It is used as part of the treatment for people whose use of heroin or other opiates dominates their life pathologically or becomes maladaptive, leading to a diagnosis of 'substance dependence' (American Psychiatric Association 1994) or 'dependence syndrome' (WHO 1992). This section considers the evidence for the use of methadone and other replacement treatments, with the exception of heroin prescribing, which is considered separately (see section 3.3).

Hall et al describe opioid replacement therapy as a form of treatment that:

> "involves the administration of a long-acting opioid drug to an opioid dependent person, usually by a non-parenteral route of administration, for the therapeutic purposes of preventing or substantially reducing the injection of illicit opioids, such as heroin. Its goal is to improve the health status and psychological and social well-being of the opiate-dependent person."

The origins of methadone maintenance treatment (MMT) can substantially be traced back to two doctors in the USA - Dole and Nyswander (1965; 1967), who considered that opiate dependence produced a metabolic disorder that was best managed by replacement with an orally administered alternative drug. Methadone was chosen because it prevents withdrawal symptoms, does not produce the characteristic, euphoric 'high' of heroin and has a long action (24-36 hours) and therefore only requires daily administration. These features enable people with opioid dependence to participate in rehabilitation programmes. Its beneficial effect on both heroin use and crime led to its rapid adoption across the USA and beyond, and has been further

[1] Opioid is the collective term for all 'opiates' (drugs derived from the opium poppy) but also includes synthetic narcotic analgesics (such as methadone) that exert a similar effect to the opiates.

stimulated by indications of its potential importance as a component within the global response to HIV/AIDS among people who inject drugs.

Although the analogy is imperfect, substitution treatment is sometimes compared to the use of other drugs that are effective in treating serious chronic conditions such as hypertension and diabetes. Opiate dependence resembles these conditions, insofar as they are chronic, require daily treatment, and have a high risk of adverse effects if treatment is stopped.

3.2.1 The aims of opioid substitution treatment

The aims of substitution treatment can be summarised as being to:

- Assist the patient to remain healthy, until, with the appropriate care and support, they can achieve a life free of illegal drugs;
- Reduce the use of illicit or non-prescribed drugs by the individual;
- Deal with problems related to drug misuse;
- Reduce the dangers associated with drug misuse, particularly the risk of death by overdose and of HIV, hepatitis B & C, and other blood-borne infections from injecting and sharing injecting paraphernalia;
- Reduce the duration of episodes of drug misuse;
- Reduce the chances of future relapse to drug misuse;
- Reduce the need for criminal activity to finance drug misuse;
- Stabilise the patient where appropriate on a substitute medication to alleviate withdrawal symptoms;
- Improve participation in other medical care; and,
- Improve overall personal, social and family functioning.

3.2.2 How methadone and other substitution treatments work

Methadone is a ‘synthetic opioid agonist’ that can be substituted for heroin or other opioids to provide a more controllable form of addiction. An ‘agonist’ is a compound that binds to a receptor within the nervous system and produce a full

pharmacological response. Using a long-acting agonist alleviates many of the withdrawal symptoms that are experienced by people who are dependent on opioids.

Another medication that is increasingly prescribed for opiate dependence is buprenorphine. Buprenorphine is not a pure agonist, but a mixed agonist - antagonist. An antagonist is a blocking agent that occupies the same receptor sites in the brain as the drug(s) on which someone is dependent and does not provoke a pharmacological response - thus denying access for the drug. When someone is taking an opioid antagonist, such as naltrexone, the effects of heroin are blocked because the heroin cannot act on the brain. The antagonist has no mood-altering properties.

Pure antagonists, such as naltrexone, that prevent opioids from having any effect, are used less frequently but can be given to reduce the risk of relapse when people stop being maintained on drug substitutes or leave detoxification or drug-free treatment programs.

3.2.3 Abstinence v maintenance as treatment goal

People often ask why maintenance might be contemplated rather than abstinence. This dichotomy is rarely as clear cut as the question implies. Within replacement therapy, abstinence is not ordinarily excluded as a long-term possibility. Nevertheless, it will often be a subordinate and longer term objective due to the following factors summarised by Farrell et al (1994):

- clinics based on maintenance treatment have better outcomes than those with abstinence as their primary treatment goal (Ball and Ross 1991);
- longer stays in methadone maintenance treatment are associated with better outcomes (Dole and Joseph 1978; Stimmel et al1978; Simpson 1979; Cushman 1981; MacGlothlin and Anglin 1981; Simpson 1981; Simpson and Sells 1982; Hubbard et al 1989);
- patients whose treatment ends with staff approval do better than those who leave for other reasons (Cushman 1978; Dole and Joseph 1978; Stimmel et al1978; Cushman 1981; Des Jarlais et al 1981; Simpson 1981; Simpson 1982; Milby 1988); and,
- earlier curtailment of methadone treatment produces poorer outcomes after treatment (McGlothlin and Anglin 1981; Rosenbaum 1981; Anglin et al 1989).

For some, the idea of prescribing one opioid drug in the treatment of another arouses ethical and/or moral objections. Hall et al (1998; 7-11) discuss this at greater length than is possible here, and they are worth reading in full on this issue. However, in summary, the first response they suggest is a utilitarian assessment of the costs and benefits of treatment. If the benefits are shown to outweigh the harms, treatment may then be regarded as ethical. As has already been suggested (see section 2.3), an objection that is sometimes raised is that it simply "replaces one drug of dependence with another". To this they suggest that the philosopher Kant's proposition that "showing that a moral obligation (to be drug free) is empirically impossible, or at least extremely difficult to meet (as it is for many people with opioid dependence who, therefore repeatedly relapse), provides a good reason for modifying it". They put this further in context by examining other potential reasons for this opposition to methadone, and questioning whether opponents of maintenance therapy believe that:

- Use of all opiates is wrong, which would mean that opiates used for analgesia post-operatively and in childbirth would also be wrong; or,
- Long term opioid dependence is wrong, which would preclude their use in the management of chronic, intractable pain or palliative care.

Finally, they ask whether this view arises because the dependent person was not 'ill' when they started using opioids or is responsible for their condition; the logic of which would preclude treatment for a range of conditions that are transmitted sexually or arise from the misuse of alcohol, tobacco or dietary fats and sugars.

3.2.4 Clinical effectiveness of methadone maintenance treatment

Methadone has been in use for approaching 40 years and its efficacy as a maintenance treatment compared to other forms of therapy, has been investigated extensively, leading to claims that it is the most researched of the available treatments (Farrell et al 1994). Studies have examined its impact on a range of different outcomes including:

- Use of illicit drugs (Dole 1969; Dole and Joseph 1978; Stimmel et al 1978; Newman 1979; Simpson 1979; Cushman 1981; Gunne 1981; McGlothlin and Anglin 1981; Simpson 1981; Simpson and Sells 1982; Hubbard et al 1989; Ball and Ross 1991; Vanichseni 1991; Yancovitz 1991; Bell et al 1992; Strain 1993);

- Participation, compliance and retention in treatment (Newman 1979; Vanichseni 1991; Yancovitz 1991; Strain 1993);
- Vocational outcomes (Dole 1969; Gunne 1981);
- Criminal activity and imprisonment (Dole 1969; Dole and Joseph 1978; Stimmel et al 1978; Newman 1979; Simpson 1979; Cushman 1981; Gunne 1981; Simpson and Sells 1982; Hubbard et al 1989; Ball and Ross 1991);
- Mortality (Newman 1979; Gunne 1981);
- Health (Gunne 1981);
- HIV infection (Abdul-Quader et al 1987; Marmor et al 1987; Schoenbaum et al 1989; Novick et al 1990; Chaisson et al 1991); and,
- Risky injecting and the sharing of injecting equipment (Abdul-Quader et al 1987; Selwyn et al 1987; Darke et al 1990; Ball and Ross 1991; Klee et al 1991).

Six of these were randomised controlled trials (RCTs), which is regarded as the strongest possible single research design (Dole 1969; Gunne 1981; Newman 1979; Vanichseni 1991; Yancovitz 1991; Strain 1993). The remainder are mainly observational studies, either comparing self-selected MMT participants with people receiving other treatments or using pre and post-testing within the same population as they progress through treatment. Such a large body of work is most easily appraised through systematic reviews that have summarised the findings and augmented them using meta-analytic methods.

Several reviews have systematically examined these - and allied studies - to evaluate the conclusions that can reasonably be drawn. These include two major academic textbooks (Ball and Ross 1991; Ward et al 1998), two reports from authoritative bodies (Gerstein and Harwood 1990; Advisory Council on the Misuse of Drugs 1993) and two reviews published in peer-reviewed journals (Farrell et al 1994; Marsch 1998). All of these conclude that methadone treatment is beneficial and effective. The emphasis and focus within each review varies, with later studies widening their focus to include HIV prevention. Methadone maintenance treatment emerges as a treatment that is effective at reducing heroin use, crime and HIV risk behaviours.

Beyond this, an even more powerful way of evaluating the evidence from randomised controlled trials is to combine studies that use similar measures in order to undertake a meta-analysis, which derives greater power and precision from the inclusion of a larger sample. The Cochrane Library is an international scientific collaboration that

promotes the conduct and dissemination of such systematic reviews and includes a review of methadone maintenance treatment (Mattick et al 2003), as well as several other replacement therapies discussed below.

The rigorous requirements that must be met for meta-analytic procedures, such as having comparable outcome measures, mean that many studies may be ineligible for inclusion. Nevertheless, Mattick et al found six RCTs that were eligible for inclusion in their review (Dole 1969; Gunne 1981; Newman 1979; Vanichseni 1991; Yancovitz 1991; Strain 1993) generating a sample of 954 participants from "a range of geographic regions including USA, Sweden, Hong Kong, Thailand..largely typical of heroin dependant individuals, in terms of age and gender". Despite the fact that the studies included contained relatively small samples for this procedure, they confirmed that that methadone maintenance treatment is an effective intervention for the management of heroin dependence, that methadone is superior to the drug-free alternatives (placebo medication, offer of drug-free treatment, detoxification, or waiting-list control) for retaining patients in treatment and that it reduces heroin use. Results on criminal activity from three studies (n=363) were consistent with the findings on heroin use but did not achieve statistical significance. Similarly the evidence concerning methadone's ability to prevent death was in a favourable direction but did not achieve statistical significance within the meta-analysis. They conclude that "methadone should be supported as a maintenance treatment for heroin dependence".

3.2.5 Other factors that influence outcome

A consistent observation across the studies of opioid replacement therapy are that programmes vary in their organisation and delivery. That positive outcomes are found so reliably across different conditions adds to the confidence that can be had in their validity and generalisability. However, several specific factors have been examined for their effect on outcomes and are useful to consider:

- Dose[2], which is consistently related to retention and illicit opioid use with low dose predictive of drop out (Goldstein and Judson 1973; Handal and Lander 1976; Ling et al 1976; Slassi et al 1977; McGlothlin and Anglin 1981; Ball and Ross 1991; Capelhorn and Bell 1991; Joe et al 1991; Johnson et al 1992; Capelhorn et al 1993; Strain 1993);

[2] For an extended analysis and discussion of the issues concerning dosing and patient self-regulation see Ashton (2002)

- By contrast, and as has already been noted, programmes that enforce withdrawal from methadone appear to be ineffective (McGlothlin and Anglin 1981; Rosenbaum et al 1988; Anglin et al 1989; Capelhorn 1994; Gossop et al 2001a); and,
- The amount and quality of support services affects treatment outcome, with higher support and better quality services enhancing outcome, but diminishing returns with very high intensity programmes (McLellan et al 1988; Ball and Ross 1991; Joe et al 1991; Condelli and Dunteman 1993; McLellan et al 1993; D'Ippoliti et al 1998; Magura et al 1998; Strain et al 1999).

This suggests that caution is advisable where any divergence is contemplated from Dole and Nyswander's (1967) original programme, which was based on a relatively high average dose and well resourced psychotherapeutic and rehabilitative services.

3.2.6 Methadone treatment in prisons

As has been noted in section 3.1.1, drug users inject in prison and are exposed to similar risks as IDUs living within the general community, leading to the question of whether they should have access to the same opioid replacement therapies. Although there is little research on opioid replacement therapy within prisons, what evidence there is suggests that drug use and injecting risk behaviours are reduced (Dolan et al 1998; Vegue-Gonzalez et al 1998). The arguments for providing such treatment and the concerns and criticisms have been further examined by Dolan et al (1998) who conclude that, in line with these results, there is reason believe that they should confer broadly similar benefits. However, they also argue that there is a need for well-designed, prospective, randomised controlled trials to better clarify their impact.

3.2.7 Cost-effectiveness of methadone maintenance treatment

Given the weight of evidence that MMT is effective across a range of outcomes, it is useful to ask whether it is cost-effective. The health-economic research regarding MMT is less well developed than that regarding its clinical and other outcomes. Nevertheless, Ward and Sutton (1998) identify three investigations of its cost effectiveness (Goldschmidt 1976; Harwood et al 1988, Gerstein et al 1994 - the CALDATA study). Within the current limits of this discipline, they conclude that the "research to date suggests that the provision of methadone treatment is cost-beneficial, at least from a taxpayer's perspective, because of the substantial

reductions in crime and drug use that occur. Furthermore, methadone compares favourably with alternative interventions with opioid dependent individuals".

A recent study in the UK has examined aspects of the cost effectiveness of different programmes, within which MMT was one of the core treatments (Gossop et al 2001b). This concluded that "for every extra £1 spent on drug misuse there is a return of £3 in the cost savings associated with lower levels of victim costs of crime and reduced demands on the criminal justice system. These cost savings are only one part of the benefit from treatment, and also only indicate immediate rather than longer term benefits…As may be expected, the ratio of costs to benefits is likely to change. For example, treatment could be expected to reduce the number of premature deaths among drug users. Only a few averted deaths would add substantially to the calculated social cost savings".

Other studies have addressed more specific questions concerning the impact of MMT on HIV transmission (Zaric et al 2000) and on the optimal configuration and resourcing of MMT programmes (Kraft et al 1997; Avants et al 1999). Zaric et al estimated the costs of programme expansion in low and high HIV prevalence communities and concluded that as the cost-effectiveness was below a $33,000 per QUALY threshold (derived from other research), MMT was cost-effective for HIV prevention. Avants et al assessed the cost-effectiveness of providing MMT within an intensive day treatment programme compared with 'enhanced standard care'. Both had good outcomes but these were not significantly higher for the day programme, which was more than twice as expensive. Kraft et al compared MMT programmes with low, intermediate and high levels of support. These cost $16,485, $9,804, and $11,818 per abstinent client respectively, yet outcomes at 6 months follow up found corresponding abstinence rates of 27% (low), 47% (intermediate) and 49% (high), suggesting that programmes with moderate levels of support are almost equally effective as high support programmes but provide substantially better value for money.

3.2.8 Buprenorphine

Increasingly, the mixed opioid agonist/antagonist buprenorphine is being used within opioid replacement therapy. Within Europe, it has been licensed for use within a growing number of countries since 1996 and is now available in Austria, Denmark, Finland, France, Italy, Luxemburg and the UK. In October 2002 it was licensed for

use within the USA[3]. Although lacking the breadth of evidence that underpins methadone, a growing number of studies have investigated its efficacy and three systematic reviews have been undertaken including one by Mattick and colleagues within the Cochrane Library (West et al 2000; Barnett et al 2001; Mattick et al 2003).

A potential advantage of buprenorphine is that its operation as a partial agonist appears to make buprenorphine safer in overdose. It may also have an easier withdrawal phase and, because of the longer duration of action, the option of alternate day dosing (Mattick et al 2003).

Mattick et al reviewed buprenorphine performance in comparison to placebo and methadone. Their conclusions are similar to those within the other two systematic reviews that have been undertaken:

> *"The implication of the results of the meta-analytic review conducted and reported herein are clear for clinical practice. Buprenorphine is an effective treatment for heroin use in a maintenance therapy approach compared with placebo. However, methadone maintenance treatment at high dose is associated with higher rates of retention in treatment and better suppression of heroin than buprenorphine maintenance treatment. Buprenorphine maintenance should be supported as a maintenance treatment, only where higher doses of methadone cannot be administered. The reasons for not applying the best available treatment should be investigated rather than promoting less effective treatment approaches.*
>
> *Given buprenorphine's different pharmacological properties, it may have advantages in some settings and under some policies where its relative safety and alternate-day administration are useful clinically compared to methadone."*

3.2.9 LAAM

Levo-Alpha Acetyl Methadol (LAAM) is a long acting opiate agonist with a similar action to methadone, but a longer half life, which means that it needs to be administered no more frequently than every 2 days. It has been associated with a series of life threatening cardiac arrhythmias, with the result that it is no longer licensed for the treatment of dependence in Europe. However, it is still used with caution in some other parts of the world. Its clinical efficacy is broadly similar to that of methadone. A Cochrane review of studies comparing LAAM and methadone

[3] US Medicine, November 2002.

maintenance concluded that for people for whom methadone and buprenorphine is ineffective, LAAM provides an alternative treatment to consider and suggest that the risks of LAAM should be weighed against the risk of continued heroin use (Clark et al 2003).

3.2.10 Naltrexone

Although not a maintenance treatment in the sense that methadone and buprenorphine are, the opioid antagonist naltrexone is sometimes used within relapse prevention to assist people to maintain an opioid free state after they have completed withdrawal. By competing for opiate receptors it prevents heroin and other opioids from exerting any effect and temporarily nullifies any reason to take the drug(s).

Kirchmayer et al (2003) have reviewed its efficacy in a systemic review within the Cochrane Library. As yet, they conclude that the evidence is not adequate to make a final evaluation of this treatment, although a trend in favour of its use was noted and it may have some merit with highly motivated patients.

3.2.11 Substitution for non-opiate drug dependence

Some countries, such as the UK, Sweden and Japan, have or have had substantial populations of amphetamine injectors (Klee 1997). Some pilot level research has been undertaken to investigate the feasibility and potential benefit of amphetamine prescribing (Klee et all 2001; Shearer et al 2001). A larger study of dexamphetamine prescribing, funded by its Department of Health is currently underway within the UK. Given the fact that the strongest rise in drug use globally is within amphetamine type stimulants (ATS) it will be important to monitor whether larger studies suggest that this approach can confer any benefits.

3.2.12 Summary

Methadone maintenance treatment is the most researched treatment currently available for people who are dependent on opioids. Its use is supported by an evidence-base developed over almost 40 years and from across many different countries. It retains patients in treatment for longer than any alternative, non-replacement therapy, and has a superior effect on the reduction of heroin use and crime associated with opioid dependence. It is effective at reducing HIV risk behaviours and there is evidence that it also reduces the risk of mortality from opioid

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http://www.usmedicine.com/article.cfm?articleID=537&issueID=44 Accessed 24/2/03

use. Increasingly, buprenorphine is used and appears to have merit as a second line treatment. It may offer benefits under certain circumstances, but methadone treatment prescribed at an adequate dose and with suitable psychotherapeutic and social support is currently the first treatment that should be considered and the most effective.

3.3 Heroin prescribing

Providing a medical prescription for pharmaceutical heroin (diamorphine) to heroin addicts has been seen in some countries as a way of helping to solve the 'heroin problem', with potential benefit to the individual addict and society.

As has been noted, the most common substitution drug for heroin is methadone. However, despite the benefits of oral methadone documented in section 3.2, there are people who do not want it or benefit from it. They are not attracted into drug treatment, or if receiving treatment, do not significantly change their behaviours. Therefore it has been suggested that pharmaceutical heroin might be prescribed as a substitute drug for illicit heroin. This proposal is controversial.

Arguments for and against prescribing heroin

For:

- Current treatments – mainly methadone – are insufficiently attractive or effective for some heroin addicts. Heroin might attract more people into treatment and retain them in treatment. More heroin users would get help and there would be fewer untreated heroin users in the community;
- It may help some people to stop or reduce their illicit drug use; this undercuts the illicit market in heroin; and it ensures that they can use a drug of known quality and strength;
- It may improve or safeguard health (such as the avoidance of overdose and unsafe injecting practices that can lead to HIV and hepatitis);
- It may lead to less acquisitive crime to support a drug habit and improved social functioning (work and family life);
- It is a first step that may facilitate a gradual change from heroin to methadone, and from injecting to oral use; and,

- Individual patients would benefit – and so would society by having less drug related crime, lower criminal justice and prison costs, fewer or less visible drug markets, lower aggregate health care costs, and lower social welfare costs.

Against:

- It might maintain the condition of addiction by removing the motivation to stop using drugs or inject them. It might prolong the time a patient is dependent and injecting drugs;
- Individuals might suffer adverse health consequences as a result of continued injecting including risk of overdose, infections, abscesses and of blood-borne viruses e.g. HIV and HCV;
- Society might have more heroin users and an increasing burden of ill-health.
- An accumulating population of patients receiving heroin prevents others from getting treatment;
- Pharmaceutical heroin is more expensive than methadone. Society has finite resources so needs to allocate them equitably;
- Patients would come to expect heroin and might not accept alternatives such as oral methadone;
- There would be potential for diversion of heroin onto the illicit market, with the danger that new heroin users would be created; and,
- It is better to use treatments of known effectiveness such as methadone.

3.3.1 Which countries allow the prescription of heroin to addicts?

Heroin is prescribed in the treatment of addiction in only a few countries.

- The UK is exceptional internationally because heroin has been prescribed to treat addicts since the 1920s. It was originally adopted to help addicted people lead normal lives. More recently the government has proposed limited expansion of heroin prescribing because of its potential impact on reducing crime as well as improving the health of patients. About 450 patients get heroin on prescription from about 46 licensed doctors (Metrebian et al 2002).

- Scientific trials of heroin treatment have been completed in Switzerland (Uchtenhagen et al 1999) and the Netherlands (van den Brink et al 2002). Switzerland has now authorised the prescription of heroin for opiate dependence. Since 1998, heroin can be prescribed in the Netherlands for research purposes.

- Scientific trials are planned or are taking place in Germany, France, Belgium, Spain, and Canada. In 1992 Australia undertook research studies on the feasibility of prescribing heroin but the proposed trial was not sanctioned by the Australian government.

3.3.2 How is heroin prescribed and dispensed?

In the Swiss and Dutch trials heroin was dispensed and consumption supervised at the clinic as part of research studies.

- In Holland patients attended the drug clinic three times a day, seven days a week, and were provided with a measured dose of the drug. Patients sat in a glass walled room under staff supervision from outside. A cabin with negative air pressure was provided for those smoking heroin. The mean daily dose was 550 mg for injectable and smokeable heroin.

- In Switzerland heroin was dispensed three times a day, seven days a week, from selected drug clinics for supervised injection on-site in designated injecting rooms. The mean daily dose was 500 mg for injectable heroin and 1000 – 1850 mg for smokeable heroin.

In the UK heroin is prescribed by a drug dependency clinic doctor and dispensed from a community or hospital pharmacy for unsupervised injection at home, as part of clinical practice.

- Most doctors prescribe heroin in freeze-dried ampoules, to be mixed with sterile water for injection. The mean daily dose was 200mg (range between 5 and 1500). There is little consensus among doctors about who is eligible to receive heroin. Most agree that it is a treatment for entrenched heroin injectors who have failed in other treatments (Metrebian et al 2002).

3.3.3 The evidence base for effectiveness

The evidence base for the effectiveness of heroin as a treatment is rather scanty - four small scale studies in the UK (Hartnoll et al 1980; Stimson and Oppenheimer 1982; McCusker and Davies 1996; Metrebian et al 1998), one large trial with multiple components undertaken in Switzerland and two large trials conducted in the Netherlands. There have been four randomised controlled trials – one in the UK (Hartnoll et al 1980), one in Switzerland (Perneger et al 1998), and two large trials to assess both injectable and smokeable heroin treatment in Holland (Van den Brink et al 2002). One reason for the lack of research is that heroin is prohibited for use in the treatment of opiate dependence in many countries, and pressure brought to bear from the International Narcotics Control Board against countries wanting to conduct research trials. Another is the cost of trials. The Canadian trial is expected to cost $CAN 8.1m. (G V Stimson personal communication)

3.3.4 What does the research indicate about the effects of heroin prescribing?

Prescribing heroin is practical in specialist treatment settings

Practical considerations include drug storage and security, dispensing and supervision of consumption of heroin ampoules and powder for smoking. Studies conducted in the UK have not involved supervised consumption, however, they suggest that the storage and control and dispensing of heroin is practical. Studies in the Netherlands (van den Brink et al 2002) and Switzerland (Uchtenhagen et al 1999) where the prescription was supervised have found the prescribing of heroin to be practical in specially established drug treatment clinics.

The drug is as safe for patients as comparable treatments with injectable drugs

No serious side effects were reported in toxicology studies in Switzerland. Fewer mild side effects were reported by patients receiving injectable or oral heroin compared to those receiving methadone or morphine (Uchtenhagen et al 1999). The Dutch trial found that the incidence of serious side effects was comparable to patients receiving oral methadone (van den Brink et al 2002).

Prescribing is safe for clinic staff

Incidents of negative behaviour from patients to staff (disputes, aggression, violence) appear no different to other treatments (Uchtenhagen et al 1999; van den Brink 2002).

Prescribing heroin does not pose problems for the community

Neither the Dutch or Swiss trials experienced any serious public order or safety problems in the surrounding neighbourhood (Uchtenhagen et al 1999; van den Brink 2002). Studies in the UK found little or no public order problems. A few patients were found to be injecting their drugs in the local vicinity and were then given the opportunity to inject at the clinic (Metrebian et al 2001).

Heroin is not diverted to the illicit market

In the UK heroin is prescribed for take-home consumption. There is little evidence that current prescribed heroin is diverted onto the illicit market but historically this was significant. With unsupervised consumption diversion might become a problem if more people were prescribed heroin. In Switzerland and Holland consumption is supervised and diversion not an issue.

Patients can be maintained on a stable dose of heroin

It appears that many patients can be maintained on a stable non-increasing dose. The Swiss trial showed that after the first few months doses were more likely to decrease than increase and that patients were stabilised on between 500 – 600 mg a day. In the UK (Metrebian et al 1998) and in the Dutch and Swiss trials additional oral methadone was prescribed to stop night-time withdrawal and reduce the number of times patients needed to inject heroin.

Attraction and retention of target group

It is uncertain whether is attracts more drug users into treatment

There has been no research to examine whether prescribing heroin attracts patients into treatment. Metrebian et al (1998, 2000) found that offered the choice of receiving injectable methadone or heroin, one third of patients chose methadone, indicating that heroin is not always the drug of choice. This study and one of the Swiss trials also took some time to recruit patients suggesting that there was no ‘honey-pot’ effect.

It does not appear to discourage patients from accepting oral methadone treatment

Metrebian et al (1998, 2000) found that offered the choice between receiving injectable methadone or heroin, one third of patients chose methadone, indicating that heroin is not always the drug of choice. Research from Switzerland found that 30 per cent of those receiving heroin changed to receive oral methadone after one year, two-thirds by the end of five years and 60 per cent by the end of seven years (Uchtenhagen et al 2001).

Patients are retained in treatment equal to or better than methadone

UK research indicates that heroin retains more drug users in treatment than oral methadone treatment. In a randomised controlled trial, Hartnoll et al (1980) found a lower drop-out rate among the heroin than the methadone group (74% on heroin compared to 26% on methadone were retained in treatment at 12 months). In Metrebian et al's study, those on heroin were better retained in treatment at 12 months than those on injectable methadone (59% vs 48%). The retention rate was higher than that reported by the National Treatment Outcome Research Study of oral methadone maintenance programmes at 12 months (59% vs 38%).

The Swiss heroin trial found that 70% were retained in treatment at 12 months, but there was no comparison with oral methadone treatment (Uchtenhagen et al 1999).

The Dutch heroin trial found that those prescribed injectable heroin were only marginally better retained in treatment than the methadone group and those in the inhalable heroin group were less well retained in treatment than the methadone group. However, many of those not retained in the heroin groups had received therapeutic discharges (van den Brink 2002).

Effectiveness – at an individual level

Illicit use of heroin and other drugs decreases

All studies found that illicit drug use reduces compared to before treatment and (where available) to controls, but were not eliminated in all patients. Both Hartnoll et al (1980) and Metrebian et al (1998) found that illicit drug use was reduced but not eliminated. The Swiss trial showed significant reductions in illicit drug use amongst those still in treatment but there was no control group to assess whether similar

findings would have been found with oral methadone. However, the RCT conducted in Switzerland (Perneger 1998) found that at six months none of the study patients receiving heroin were using illicit heroin on a daily basis, compared to nearly half of those on the waiting list (many of whom were receiving oral methadone). The Dutch trial (van den Brink 2002) found similar results, at 12 month follow-up only half the study participants receiving heroin were using illicit drugs

Health improves

Studies have measured physical health symptoms, mental health, overdose, and risk of infection with blood borne viruses (HIV, HBV. HCV). Most find health improvements but the lack of controls makes definitive conclusions difficult. Metrebian et al (1998) found significant improvements in health but the lack of a control group makes it impossible to know whether similar gains would have been made had study participants been receiving oral methadone. Hartnoll et al (1980) found no evidence of improved health with heroin prescribing, although HIV was not an issue at the time. The Swiss study found improved health but again had no control group receiving oral methadone (Uchtenhagen et al 1999). At 12 months, the Dutch trials found health had improved significantly more in the heroin group than in the methadone group (van den Brink et al 2002).

Social functioning improves

Findings from the Swiss trial showed that, at 18 months, patients' accommodation situation had improved, the number of patients achieving permanent employment nearly doubled, and there was a decrease in the numbers of patients regularly in contact with drug users (Uchtenhagen et al 1999). The Dutch trial and studies in the UK found similar results. However, substantial numbers of patients remained unemployed (van den Brink et al 2002; Metrebian et al 1998).

Patients commit less crime than before being prescribed heroin

Hartnoll et al (1980) and Metrebian et al (1998) found that crime reduced but was not eliminated. The Swiss trial (Uchtenhagen et al 1999) showed that self-reported criminal activity progressively reduced and 12 months after entering treatment the majority of patients had no convictions. The Dutch trial found similar results, at 12 month follow-up only half the study participants receiving heroin were involved in crime (van den Brink et al 2002). Again, those in the heroin group had reduced their criminal behaviour, while criminal behaviour remained high among the control group.

All studies found crime had reduced compared to levels at entry to treatment and, where available, to controls.

Patients tend not to switch to methadone or oral routes of administration

There is little evidence to suggest that prescribing heroin will help change drug users route of administration from injectable to oral routes. Hartnoll et al (1980) found that the majority of the heroin group continued to receive an injectable prescription. Similarly, Metrebian et al (1998) found only a few patients moved to oral methadone. Other UK research found that one third of a sample of drug users prescribed heroin from the early London drug clinics were still receiving a prescription for heroin six years later (Thorley et al 1977). These UK studies suggest that prescribing heroin without regular supervised injection might reduce the motivation to stop using heroin. However, research from Switzerland and the Netherlands where there is daily supervision of prescribed heroin found 30 per cent moved on to other treatments at the end of one year.

It is not clear who does best on the treatment

The research evidence comes from patients with long injecting careers who have previously tried and failed oral methadone treatment. It is not known who of these would most benefit. Most studies have not been designed in a way that can answer this question.

Effectiveness – at a community level

At current levels of prescribing heroin probably does not undercut the illicit markets in drugs and reduce drug scenes

Studies have only used individual measures of illicit drug use and have shown that prescribing heroin reduces illicit drug use, therefore there is a potential impact on drug markets and drug scenes. However there have been no studies measuring the impact of heroin prescribing at a community level.

Costs and cost effectiveness

Prescribing heroin is more expensive that methadone

Assuming other services remain the same, for example that a person on heroin needs the same amount of staff time and other resources as a patient on methadone, then the main costs that vary are those of the drug itself, and extra costs for the supervision of injecting or smoking the drug. Current information suggests a price range for prescribing methadone of from £1320 to £3550 a year for developed countries.

In the Swiss trial the annual patient cost for a patient receiving heroin was £8030, and in Holland between £9775 and £17109. These costs included labour, medical material, substitute drugs, laboratory costs, rent, maintenance, energy and administration, including depreciation. This is substantially higher than for methadone, but the trials were resource intensive with daily visits by patients for supervised consumption and, high levels of psychosocial support.

In the Dutch heroin trial the main costs were for nurses (around 30% of costs). Nurses were required to be present to supervise the self-administration of heroin by the patients. The costs of heroin itself were relatively low, at €1,800 per person per year.

It is cost effective

The Swiss trial suggests that the benefits far outweigh the treatment costs. For every franc invested there was a benefit of CHF 1.75. However, as costs were largely accounted for but benefits were often estimated, they consider that the programme might have a higher cost benefit ratio of between 3 and 5. The cost of prescribing heroin has savings for the health sector (decrease in medical and hospital costs), criminal justice and employment sectors.

It is uncertain if it is more cost-effective than methadone

There are no data on comparative cost - effectiveness.

Conclusions of the WHO appointed international panel on the Swiss trial

The Swiss trial:

- provided evidence that if an injectable substance is to be used for substitution therapy, the prescription of injectable heroin is feasible;
- demonstrated that clients can be maintained on a stable dose of heroin;

- showed that a heroin treatment programme can be delivered at treatment centres providing methadone maintenance with some modifications, and where very high levels of services are provided;
- showed that a heroin treatment programme achieved reasonable retention levels;
- showed self-reported improvements in the individuals' physical and mental health, social functioning (employment*)*, and reported drug use and criminal behaviour;
- few problems occurred at any site;
- the majority of those receiving heroin were maintained on stable dosages of heroin, or heroin and methadone, or other opiate substitute;
- there was no evidence of substantial problems with dose determination, induction and stabilisation onto the injectable programme;
- most of the benefits identified following entry into treatment were accrued in the initial six months of treatment. These benefits occurred in terms of health and social well-being;
- the retention rates were 89% at six months and 66% at eighteen months;
- the Swiss studies were not able to examine whether improvements in health status or social functioning in the individuals treated were causally related to heroin prescription per se or a result of the impact of the overall treatment programme.

Ali et al (1999)

3.3.5 Summary

The evidence base for heroin prescribing is weak – with few studies, and only four with control groups. Therefore no more than cautious conclusions can be drawn about the merits of prescribing heroin.

That said, it appears that there are health and social gains when this treatment is offered to long term injectors and smokers for whom other treatments have failed.

- Prescribing heroin is feasible in specialist clinical settings;
- It is not known whether heroin attracts more people into treatment;
- Patients receiving heroin are well retained in treatment, and generally better retained than those receiving methadone;
- It is possible to maintain patients on a stable dose of heroin;

- Patients improve in most areas – physical and mental health, illicit drug use, crime, and employment;
- It costs more than methadone but has been shown to be cost effective;
- It is not known whether it is more cost effective than methadone;
- It is not known who would most benefit from this treatment.

The potential indicated by the studies that have been conducted so far indicates that there should be a cautious expansion of this form of treatment accompanied by further evaluation.

3.4 Depenalisation and the harms associated with criminal penalties for drug use

Depenalisation or decriminalisation entails 'removal of penal controls and criminal sanctions in relation to an activity, which however remains prohibited and subject to non-penal regulations and sanctions (e.g. administrative sanctions such as the removal of driving licence)'(United Nations Office for Drug Control and Crime Prevention (UNDCP) 2000: 18). Depenalisation can be 'dejure', involving changes to the legal statutes themselves, or 'defacto', where the laws remain unchanged but the way the law is enforced by police is altered by administrative instructions. Dejure depenalisation can include *prohibition with civil penalties*, and *partial prohibition*. Under the former, possession and use remain illegal but civil rather than criminal penalties apply and more severe sanctions are maintained for larger scale possession supply offences. Such a system applies to cannabis use in 11 U.S. states (Oregon, Maine, Colorado, California, Minnesota, Ohio, Mississippi, New York, N. Carolina, and Nebraska since the 1970's; and in Nevada since 2001) and 3 Australian jurisdictions - South Australia (1987), The Australian Capital Territory (1992) and Northern Territory (1996). Under *partial prohibition* personal use activities are legal, but commercial activities are illegal. Examples exist in Columbia (Lenton et al 2000a), Spain (where possession is only considered punishable if it is for consumption in public places (Dorn and Jamieson 2001)) and Switzerland (Anonymous 2002). *Defacto* depenalisation can include *prohibition with cautioning and/or diversion* schemes (examples of which operate for a range of drugs in Italy, Portugal and Australia (Council of Australian Governments (COAG), unpublished; EMCDDA 2003)) and *prohibition with an expediency principle.* Under the latter, all-drug related activities are illegal, however, cases involving defined small quantities

are not investigated or prosecuted by police. Examples of this system operate for cannabis in Belgium, Germany, Denmark and the Netherlands (EMCDDA 2003).

3.4.1 Impact of a criminal penalty on individuals

Most research on the impact of criminal penalties on drug offenders has been done on cannabis users. Studies of the gatekeepers of social systems such as employers, school administrators and others have found that where 'pseudo' job applicants' prior cannabis charges were known to the employer, they were less likely to get a job offer than those without an offending record (Schwartz and Skolnick 1962; Palys 1976; Erickson and Goodstadt 1979). Studies of apprehended cannabis users with short follow up periods (up to 12 months) failed to find that employment problems could be attributed to a cannabis arrest (Erickson and Murray 1986; Erickson 1980). However, more recent research which asked offenders about impacts up to 10 years post apprehension has shown that a conviction for a minor cannabis offence can: adversely affect employment, both in terms of loss of job and difficulty getting future jobs; result in further trouble with the law; and problems with relationships, accommodation and travel (Lenton et al 1999; Lenton and Heale 2000). Furthermore, a comparison of the social impacts of a conviction under *strict prohibition with criminal penalties* with that of *prohibition with civil penalties* scheme showed that the latter was no worse than the former at deterring cannabis use among those apprehended, but the adverse social impacts on individuals were far less (Lenton et al 2000b). That is, depenalisation did not result in increased rates of cannabis use but did substantially reduce the adverse social costs on apprehended individuals.

The overwhelming weight of criminological research concludes that penalty severity has little impact on deterrence, especially in regard to private behaviours such as drug use where the likelihood of apprehension is relatively low (MacCoun 1993). However, research summarised above shows that impacts on those who do get apprehended can be considerable. Given this, it is interesting to consider the likely social impacts of measures taken in many states in the US which aim to make drug use less attractive by increasing the social costs of being convicted of a drug offence. These include: eviction from public housing, being made ineligible for welfare benefits and financial aid for study. In fourteen states those convicted of drug offences and other felonies can be preventing from voting for life (Drug Policy Foundation 2003a). In 1986 the US Congress enacted minimum mandatory sentences. From 1986 to 1996 the average federal drug sentence for African

American s rose from 11% to 49% higher than that for whites. Over the same period the number of women in prison for drugs increased 421% (Drug Policy Foundation, 2003b). Under mandatory minimum sentences and provisions which allow the state to 'terminate parental rights' once they have been separated from their parents for a period of 15 of the last 22 months, many women sentenced to custody for drug related offences are now losing custody of their children (Levi et al., unpublished). Such strategies are likely to greatly increase adverse social impacts and marginalisation, but, on the basis of published research are unlikely to be any better than civil penalties at deterring drug use.

3.4.2 Policy impact studies of depenalisation

There are a handful of policy impact studies done on 'natural experiments' where minor cannabis offences have been depenalised. Taken as a whole, this research finds that removing criminal penalties for cannabis possession and use does not result in higher rates of cannabis use in the general community. Eleven US States depenalised cannabis during the 1970's (although Alaska recriminalised it in 1990. Four controlled studies conducted on these provide strong evidence for the view that those states which removed criminal penalties did not experience greater increases in cannabis use among adults or adolescents, nor more favourable attitudes towards the drug, than those states which maintained strict prohibition against cannabis possession and use (Single 1989; Theis and Register, 1993; Single et al 2000). The research on the impact of the South Australian Cannabis Expiation Notice system concluded that rates of recent (weekly) use, and use among young adults and school students had not increased at a greater rate in South Australia compared to other states which had not changed their laws (Donnelly, Hall & Christie 2000; Donnelly, Hall & Christie 1999).

A cross-national comparison between the Netherlands, other European states and the USA, shows that despite the introduction of cannabis *coffeeshops* the Dutch do not have higher rates of cannabis use than these other countries (MacCoun and Reuter 1997). Reductions in criminal penalties in the Netherlands from 1976 to 1992 have had not resulted in increasing rates of cannabis use in the community. However, there is suggestive evidence that an increase in commercial access to cannabis, associated with the growth in numbers of cannabis *coffeeshops* from 1992 to 1996, may have resulted in growth in the cannabis using population, including young people (MacCoun and Reuter 1997; MacCoun and Reuter 2001a; MacCoun

and Reuter 2001b) but this growth has put the rates of cannabis use no higher than that in the USA (MacCoun and Reuter 1997). Despite these concerns, the Dutch have shown that a system of cannabis supply can be established which effectively separates the cannabis market from that for other illicit and potentially more harmful substances. While the system operating in the Netherlands is in apparent conflict with the spirit of international conventions, which expressly prohibit commercial sale and supply of cannabis, the Dutch do in fact maintain a legislative prohibition.

3.4.3 Fine tuning depenalisation

While there are different types of depenalisation, each with it's own strengths and weaknesses, the effectiveness of each example will also depend on how it is implemented in any one location, recognising that what works well in one socio-cultural context might not work well in others. For example, the Dutch approach of formalising inconsistency between the provisions of legislation and its implementation might work in the Netherlands but be less acceptable in other countries where it could be as seen as conveying confusing messages to the community.

Similarly the effectiveness of *prohibition with civil penalties* schemes depends to a great extent on the detail of how they are implemented. The South Australian scheme has been shown to have a low rate (45%) of people paying their fines by the due date (Christie and Ali 2000). Furthermore, the ease at which notices could be issued by police lead to a significant increase in the number of people issued notices. This so called net-widening, increased the numbers at risk of criminal sanction for non-payment of fines, which can particularly disadvantage those of limited financial means (Christie and Ali 2000). However, such problems can be addressed. Payment rates can be improved by having modest fines, requiring proof of identification to be eligible for an infringement notice, and allowing offenders to attend a specified education session in lieu of a fine. Such features have been introduced in a new scheme which will be before the West Australian Parliament in April 2003 (Prior et al 2002). Despite, having some problems, research demonstrates that neither the South Australia general public, nor police and the judiciary wanted to return to a criminal penalty scheme (Heale et al 2000; Sutton and McMillan 2000).

3.4.4 Summary

Overall, the evidence suggests that depenalisation schemes are no worse than strict prohibition at deterring drug use, and the adverse social costs on individuals are significantly reduced. Existing research largely focuses on cannabis and it will be

important to understand how lessons from this body of work might apply to other drugs. Recent policy changes within several European countries provide opportunities for investigating this.

3.5 Information, Education and Communication

The World Health Organisation (1998) describes information, education and communication (IEC) approaches as an essential component of the response to HIV infection among injecting drug users. IEC principles are also employed to address many other forms of drug related harm, such as the risk of heatstroke incurred by ecstasy users, or overdose among opiate users. Materials such as leaflets, videos and web-based materials are produced and used extensively by organisations specialising in harm reduction work with drug users[4] and are widely used to complement other programmes such as needle exchange and community based outreach (see section 3.1).

The WHO (1995) describe IEC in the following terms:

> *IEC is a broad term comprising a range of approaches, activities and outputs. Although the most visible component of IEC is frequently the materials produced and used, such as posters hanging on clinic walls, materials are only one component. Effective IEC makes use of a full range of approaches and activities.*
>
> *Approaches may range from the use of mass media to inform or establish positive norms among the general population to the use of targeted, interpersonal communication to help those at particular risk evaluate their own behaviour and develop new personal skills. IEC activities may include designing and providing training in communication skills, carrying out research on audiences to determine what information is needed and the most effective way of delivering it, as well as designing and producing the materials to support activities.*
>
> *Overall, IEC must be integrated with all existing HIV/AIDS prevention and care programmes as well as with on-going training services. For example, promotion of condom use or STD treatment among individuals with high-risk behaviour will be*

[4] Such as: Better World Advertising http://www.socialmarketing.com/ Crystal neon http://www.crystalneon.org/ Dancesafe http://www.dancesafe.org/ Exchange http://www.saferinjecting.org/ Harm Reduction Coalition (whose website hosts a leaflet exchange service) http://www.harmreduction.org/pamphlets/brochure_exchange.html HIT http://www.hit.org.uk/ Lifeline http://www.lifeline.org.uk/ Monkey http://www.sid.u-net.com/monkey/ The Chicago Recovery Alliance http://www.anypositivechange.org/menu.html

effective only if condoms are also made accessible and STD treatment services are available and non-stigmatizing.

Similarly a positive social environment without discrimination and stigmatization will facilitate behavioural change.

Different media are widely used within IEC programmes. They may be the only communication between health and care social agencies and many hard-to-reach, hard to engage or hidden groups. The can potentially fulfil a wide range of functions such as:

- Advertising services and attracting people into treatment;
- Providing harm reduction information to reduce risk-taking and enhance self-protection;
- Improving lay care and management of medical crises such as overdose; and,
- Shaping sub-cultural norms (for example, see Monkey magazine's feature on discarded sharps http://www.sid.u-net.com/monkey/i7a9.htm).

Despite their widespread use, there is relatively little research on their effectiveness. This may partially be explained because they are generally integrated into wider programmes, which are evaluated in their entirety, and from which it would be difficult to disaggregate their effects (For example, see Coyle et al 1999). Nevertheless, some narrowcast interventions, drawing directly on social marketing principles, have been subject to evaluations, which primarily focus on their development and process. These are rarely published in peer-reviewed journals and exist mainly in the grey literature (for an illustrative, and entirely Anglocentric selection, see Linnell 1993; Henderson 1994; Henderson 1998; Henderson 2000; Henderson 2002). Such materials frequently attain high levels of cultural acceptability and approval among the target populations, with impacts on knowledge and attitudes and reported or planned behaviour. However, evaluations of their impact on end outcomes are largely absent from the literature.

3.5.1 Summary

Information, education and communication interventions are widely used to try to reduce the risks and harm associated with drug use. Process evaluations suggest their efficacy. However, given the widespread use of IEC, there are few of these and there is a need to understand their outcomes and the factors that produce or impede these better.

3.6 Safer injecting and other 'drug consumption rooms'

There is no internationally agreed terminology but 'drug consumption rooms' (EMCDDA 2002a: 3), 'safer injection rooms' (Nadelmann et al 1999) or 'medically supervised injecting centres' (Mattick et al. 2001) are all terms used to describe environments that are deliberately provided for drug use in order to reduce the associated harms. Because some of these facilities are provided for people who smoke, rather than inject, their drugs the term 'consumption rooms' is used here.

3.6.1 Rationale

Consumption rooms aim to reduce harm both for the drug user and the wider community. A number of potential outcomes have been suggested. Among these the benefits to drug users include:

- Reducing overdose;
- Preventing infection with HIV, HBV and HCV;
- Reduced venous damage;
- Facilitating access to treatment; and,
- Providing social support and social reintegration.

Community level benefits include reductions in:

- discarded needles and syringes and other drug related litter; and,
- open drug scenes and public injecting.

Drug consumption rooms are available in Australia (Mattick et al 2001), Germany, Switzerland and the Netherlands (Nadelmann et al 1999; Kimber at al 2002), Spain (Kimber et al 2002) and are being contemplated in Canada (MacPherson 2001: 63; Parliament of Canada 2002;). A survey conducted during 1999-2000 identified 39 'supervised injecting centres' within the Netherlands, Switzerland, Germany and Spain (Kimber et al. 2002). Facilities are planned within Portugal and Luxembourg and have been contemplated, but rejected, in Norway and Denmark (EMCDDA 2002b:35).

The organisation of consumption rooms and the emphasis within their objectives varies according to the setting in which they are provided. In Australia the Medically Supervised Injecting Centre in Sydney was introduced against a context of high levels of heroin overdose and is provided within a relatively clinical environment with injecting cubicles and resuscitation equipment to hand and nursing staff in

attendance. In the Netherlands, where rates of injecting and overdose are comparatively low, there is a greater emphasis on reducing the nuisance from street drug use and providing social support within a more informal setting. Perhaps reflecting this, a study across three cities in the Netherlands, Germany and Austria found substantial variation regarding users and potential users of consumption rooms and with regard to key features such as whether people inject or smoke their drugs, with only 23% of people injecting in Rotterdam, but 69% and 64% in Hamburg and Innsbruck respectively (Zurhold et al 2001)

3.6.2 The effectiveness of consumption rooms

A review by Nadelmann et al (1999) summarises evidence, which suggests that consumption rooms may be effective for:

- Contacting hard to reach or vulnerable drug users including people with HIV, HCV, the homeless and foreign nationals;
- Promoting safer injecting;
- Reducing overdose risks;
- Preventing HIV infection;
- Decreasing discarded needles and syringes in public areas;
- Reducing crime; and,
- Reducing public drug use.

The evidence base at the time was not well developed but, based on their demographic data, it is probably reasonable to accept that consumption rooms can be effective at attracting vulnerable and marginalized drug users such as homeless drug users and foreign nationals.

However, there are a number of limitations to the evidence of their impact. The first consumption room opened in Frankfurt in 1994 and Nadelmann et al suggest that it may have contributed to falling overdose rates in that city between 1991 and 1997 while those in the rest of Germany remain steady. This is acknowledged as the consequence of an ‘integrated harm reduction strategy’ and it is unclear to what extent consumption rooms contributed to this reduction.

In part, lowered levels of risk taking observed among people attending consumption rooms might be attributable to selection effects, whereby more health conscious drug users attend consumption rooms. Furthermore, in the absence of controls, it is

always possible that observed reductions in risk status and improvements in health may also be caused in part by maturation or, alternatively, history effects arising from external factors such as changes within drug markets, rather than the impact of consumption rooms themselves. Similarly, factors such as changes to local policing strategy may confound impacts on crime.

Although it is probably unduly conservative to attribute all impacts to these factors, it is difficult to assess the true impact of the consumption rooms considered at the time of Nadelmann et al's review.

A subsequent paper by Dolan et al. (2000) has elaborated many points within Nadelmann et al's review and usefully provides more detailed descriptive accounts of consumption rooms across Europe. They note the feasibility of their operation, when developed in consultation with the local community, police and local government and highlight probable successes in reducing the visibility and public nuisance of the drug scenes in Switzerland and Germany along with improvements in access to health and other services. The limitations to our ability to evaluate their impact on overdose and blood-borne viral transmission are again noted. However, low rates of non-fatal overdose to injections and the fact that consumption room staff intervene when people overdose suggest that some impact on overdose deaths rates occurs. Similarly, they point to reductions in needle sharing and increased condom usage as indicative of some impact on risk behaviours for the acquisition of blood-borne viruses.

In terms of understanding the impact of consumption rooms, the most significant development to date may prove to be the setting up of the 'medically supervised injecting room' in Sydney, Australia, which opened in May 2001. This is currently subject to extensive evaluation[5]. Preliminary results indicate that during the first six months over 1500 people have registered to use the facility and it received 11,237 visits lasting an average of 30 minutes. About 1 out of every 18 visits has led to the provision of further assistance including drug dependence treatment (42%), primary health care (33%) and social welfare services 925%). 87 drug related incidents have required medical intervention including 50 overdoses, 42 of which were managed by the administration of oxygen and 28 cases involving cocaine (Mattick et al 2001).

[5] The evaluation protocol is available from http://notes.med.unsw.edu.au/ndarc.nsf/website/Research.current.cp16

3.6.3 Summary

In conclusion, there is good evidence that, when developed in consultation with the wider community, a range of operational models for drug consumption rooms is possible, and these can serve differing populations and local needs. Data concerning the number of visits they receive provides evidence of the amount of injecting that is transferred to a safer environment, probably decreasing nuisance and in which skilled personnel with access to emergency equipment are in attendance. In line with their objectives, consumption rooms have demonstrated an ability to attract more marginalized and vulnerable drug users. There are indications that they are likely to have an impact on overdose deaths and may reduce risk behaviours for blood-borne viruses. However, these cannot yet be well-quantified. Beyond this, they can provide access to a range of drug treatment, health and social care services. As yet, the cost-effectiveness of consumption rooms is uncertain. Whilst they show some promise, further research is required to clarify their overall impact and value for money.

This overview has been unable to include much of the most recent European literature published in Dutch, German, French and Spanish. An international review of the evidence regarding consumption rooms is currently being undertaken by the European Monitoring Centre on Drugs and Drug Addiction (EMCDDA 2002a) and is expected to report shortly. This should provide the most comprehensive review of the available evidence to date.

3.7 Pill testing and allied warning systems

Whereas the production of regulated drugs and foodstuffs products has to adhere to strict production standards with regular inspection of manufacturing and distribution facilities; illegal drugs are subject to few such controls – with the partial exception of pharmaceutical products diverted into illicit markets, for which the manufacture is controlled but not storage and distribution.

In consequence, illicit markets have long been associated with harms arising from poor product safety. Production of alcohol during periods of prohibition such as in the USA during the early 20th century was sometimes contaminated with the more toxic form of alcohol – methanol (Edwards et al 1994:6) and more recently illegally distilled alcohol has been associated with lead poisoning (Ellis and Lacy 1998).

Harm can be associated with unregulated, illicit drug production in several ways:

- Contamination – residues from the production process or contaminants that are unintentionally incorporated during the production or distribution process may cause poisoning;
- Adulteration – diluents (bulking/cutting agents) and other substances deliberately added during the manufacturing or distribution process can result in poisoning;
- Dosing/purity errors – uncertainty about the strength/purity of illicit drugs means that dose estimation is uncertain and – especially when drugs of unexpected purity become available - can result in unintentional overdose.

Although the intentional adulteration of drugs with hazardous substances is probably rare (Coomber 1997a; Coomber 1997b), various harms are associated with the contamination and adulteration of illicit drugs. These have included MPTP induced Parkinsonism among heroin users (US Center For Disease Control 1984; Opeskin and Anderson 1997), scopolamine poisoning (Hamilton et al 2000), fatalities caused by PMA within 'ecstasy' tablets (Byard et al, 1998) and clostridium infections such as botulism (Werner et al. 2000), tetanus and within an outbreak of clostridium novyi in the UK (McGuigan et al. 2002). In recent years, particular attention has focused on the range of substances found within 'ecstasy' which, beside the potentially fatal drug PMA , have been found to include amphetamine, methamphetamine, ketamine and drugs allied to ecstasy (MDMA) such as MDEA (Sherlock et al 1999). Heroin overdose is also sometimes attributed to the circulation of batches with higher purity than expected (Gossop et al 1996) although this may not be as common an explanation of fatal overdose as is sometimes thought (Hall 1996).

Harm reduction responses to these hazards include *early warning systems and pill testing.*

A wide variety of ***Early warning systems*** exist (Griffiths et al. 2000). They are primarily established to operate as sentinel systems regarding changes in drug consumption patterns. However, when necessary, these can be linked to targeted information campaigns through governmental and other health and social care agencies to alert drug users to hazards due to contaminated or adulterated drugs, such as those of the US Center for Disease Control (1984) regarding MPTP contaminated heroin and the European Infection Warning System (Christie 2000), which issued alerts concerning clostridium infections. Additionally, there is a growing

focus on new synthetic drugs through initiatives such as the European Early Warning System on New Synthetic Drugs (EMCDDA 2002c), which allow alerts to be issued regarding contaminated 'ecstasy' pills such those found to contain PMA (see above). The impact of such systems on the knowledge and health of drug users when specific hazards are present within drug markets is largely unevaluated. Logically, they should work. However, there is a need to further investigate how the effectiveness and efficiency of such systems for identifying, and reacting to new hazards can be optimised and, closely linked to questions concerning information, education and communication interventions, how relevant messages can best be communicated to the target populations in ways that promote behavioural change.

Pill testing is increasingly used in clubs and festivals within which 'ecstasy' is used and is available to some degree in various European countries including the Netherlands, Austria, Belgium, Germany, Spain and France, Switzerland although it is only comprises part of the official drug policy in the Netherlands (EMCDDA 2001). The sophistication of the tests used is highly variable (Winstock et al 2001). Depending on which test is used, pill testing is one way in which early warning systems can be alerted to the circulation of batches of high strength or contaminated pills. Conversely, services providing pill testing are a way by which information about hazardous substances can potentially be disseminated to drug users.

The evidence base surrounding 'pill testing' is not very well developed and at present it is difficult to appraise its overall impact on health. Whilst it appears to have merits for facilitating contact with ecstasy users and gathering and providing a certain amount of information, its efficacy is influenced by the specificity of the tests used and their ability to quantify the substance. These range from highly sophisticated and more expensive tests that are able to provide a qualitative and quantitative appraisal of the drug such as chromatography, through to the use of far more limited tests using simple reagents such as the Marquis test that are not very specific, cannot identify contaminants and do not provide an accurate quantification of the drug. Consequently, the utility of pill testing has been questioned by some commentators (Winstock et al 2001).

Nevertheless, in the most comprehensive review of pill testing that has yet been undertaken, the European Monitoring Centre on Drugs and Drug Addiction (EMCDDA 2002) has concluded that currently:

- *Pill testing interventions are important measures to enter into contact with hard to reach populations and to raise their interest in preventive and harm reduction messages.*
- *On-site pill testing interventions should closely be linked to information provision with preventive and "safer use" messages, through a wide range of information supports.*
- *Despite the lack of empirical data, for health systems in general and information and prevention projects in particular, it is crucial to know about new substances and consumption trends, otherwise there is a high risk of losing credibility with well-informed users of psychoactive substances. Pill-testing projects can be an important source of information on new substances and consumption trends as they are in closest possible contact with the relevant scenes, more so than other organisations within the prevention system. Furthermore, they have an insight into most of the substances that are actually being consumed and know by whom, where, how and why these substances are being consumed.*
- *By using the information from on-site pill testing interventions, a national warning system could deepen its data pool in terms of social contexts: who are the people consuming these substances, how, where and why are they consuming these substances in this and that particular way and which information can be passed on to potential consumers in a meaningful and successful manner?*
- *Due to the lack and difficulties of evaluation, on the one hand there is still no strict scientific proof for the protective impact of on-site pill-testing interventions but on the other hand, there is also no scientific evidence to conclude that such interventions rather promote drug use or might be used by dealers for marketing purposes.*
- *There is a need for more research and evaluation studies on the whole range of effects of on-site pill-testing interventions. This appears to be a prerequisite in policy-making when completing the range of strategies to respond to drug issues in recreational settings.*

This effectively summarises our present understanding of pill testing and the related research agenda.

3.8 Motivational interviewing

As has been noted, a feature of harm reduction is the prioritising of immediate, achievable goals. Furthermore, the delivery and organisation of harm reduction services emphasises 'user-friendliness' and 'low-threshold services' such as needle exchange and outreach that generate contact between drug users and drug workers.

A purpose of this contact is to serve as an opportunity for promoting change. Without face-to-face contact, there is no opportunity for services to promote health behaviour change. Motivational interviewing is a useful reference point regarding the way that talk/counselling is structured between drug users and practitioners and is sometimes drawn upon explicitly within harm reduction work. For example, 'motivational training' is central to the World Health Organisation's (1998) conception of the 'information, communication and education' component within efforts to prevent HIV infection among drug users.

Motivational Interviewing is defined as "a client-centred, directive method for enhancing intrinsic motivation to change by exploring and resolving ambivalence" (Miller and Rollnick, 2002). In essence it is a way of talking with clients about changing aspects of their behaviour in a way that minimises resistance and increases the probability that some change will occur. It embodies an approach and philosophy that sits in opposition to more confrontational and authoritarian interventions with drug users (Rollnick and Miller 1995). For many clinicians this gives motivational interviewing an intuitive appeal and face validity. In addition to working with clients to change their addictive behaviour it has influenced the development of brief health behaviour change interventions (Rollnick, Mason and Butler 1999). These have direct relevance to the aims and objectives of harm reduction services, in particular facilitating changes in drug user's injecting practice and sexual behaviour.

The efficacy of Motivational Interviewing as a pure counselling approach has not been addressed in the research literature. However, there is a significant body of research investigating brief interventions that claim to use the principles and techniques of motivational interviewing. There are three reviews of this research; Noonan and Moyers (1997), Dunn DeRoo and Rivara (2001) and Burke, Arkowitz and Dunn (2002). Each of these supports the efficacy of adapted Motivational Interviewing particularly in relation to changing substance use. It is effective in engaging and retaining clients in treatment and effects are sustained at follow up. It has also been demonstrated that these adaptations of Motivational Interviewing have an effect after a short time period (1 to 4 sessions). Burke, Arkowitz and Dunn (2002) conclude that Motivational Interviewing is more effective than no treatment but not significantly different from credible alternatives such as cognitive behavioural treatment.

Regarding HIV risk behaviours, the effectiveness of these adaptations of Motivational Interviewing is less clear. Two Australian papers have reported results from an adaptation of motivational interviewing in changing injecting and sexual risk behaviour (Baker, Heather, Wodak, Dixon and Holt 1993; Baker, Kochan, Dixon, Heather and Wodak 1994). The results from these studies are inconclusive as both the treatment and control groups showed reduced risk behaviour. Resnicow, DiIorio, Soet, Borrelli, Ernst, Hecht and Thevos (2002) review three studies that have aimed to increase HIV sexual risk reduction strategies amongst women using motivational interviewing principles. These studies indicate some behaviour changes consistent with reducing HIV sexual risk compared to control groups.

3.8.1 Summary

Motivational interviewing provides a theoretical framework that is broadly consistent with the values underpinning the way many harm reductionists engage with drug users. It gives a widely researched set of principles and techniques that can be drawn upon by low-threshold services such as NSPs and community-based outreach, and within methadone and other replacement therapies as part of efforts to promote behaviour change and reduce drug related harm. From a clinical perspective, motivational interviewing is an important frame of reference for people working with drug users and provides a clear theoretical rationale to a humane and client-centred approach. However, the limited number of studies that have tried to evaluate the distinct contribution of motivational interviewing on HIV risk behaviours is largely inconclusive. Further research is highly desirable to clarify ways in which this or other approaches can augment the impact of contacts generated within harm reduction services with people who are otherwise ‘hard-to-reach’.

4 Conclusions

The HIV/AIDS epidemic provided the need and momentum for the consolidation, refocusing and reinvigoration of a number of existing interventions as well as the development of new ones. The harm reduction movement has provided an important vehicle for this response and has matured to encompass the breadth of drug related harms such as overdose, viral hepatitis, the impact of drug use on communities and the impact of criminalisation on drug users. It has allowed a diverse group of disciplines to collaborate on the basis of broadly shared values and principles to find and disseminate effective responses to the numerous harms associated with legal and illicit drugs and the contexts within which they are used. Among these principles, and perhaps better reflected within the membership of the harm reduction movement

and its organisation than within the academic literature, is a commitment to genuine and valid drug user involvement and empowerment within the systems and responses that affect the lives of both people who use drugs and those who don't.

Despite the fact that the bulk of its development has occurred in just 20 years or so, there is an extensive and rapidly developing literature on interventions that can be situated within a harm reduction perspective. This evidence base reveals that there are interventions that:

- definitely work – such as methadone and other replacement therapies, or needle and syringe programmes. These should be considered for adoption in regions where they are currently unavailable;
- show promise and require cautious expansion with evaluation in ways that are adapted to local settings e.g. heroin prescribing, depenalisation, the use of drug consumption rooms and pill testing;
- are widely used yet under-researched - notably information, education and communication programmes and motivational interviewing approaches to conventional harm reduction targets such as the prevention of HIV, hepatitis C, hepatitis B and overdose.

Just as the evidence-base in other fields such as oncology, the treatment of diarrhoeal disorders or in the treatment of schizophrenia continues to develop, so does that of harm reduction. It is a project that is incomplete, just like other programmes concerning health and social care and public policy. Harm reductionists would argue strongly that harm reduction is an empirically-based approach (Lenton and Single 1998) and that the best response to this is to better develop the evidence, in order to discard approaches that do not work and develop and disseminate those that do.

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