CANADIAN HIV·AIDS LEGAL NETWORK | RÉSEAU JURIDIQUE CANADIEN VIH·SIDA

Injection Drug Use and HIV/AIDS:

Legal and Ethical Issues

BACKGROUND PAPERS

Health Canada Santé Canada

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Table of Contents

The Project

Two major reports released in 1997 concluded that the legal status of drugs in Canada contributes to the difficulties encountered in addressing HIV among injection drug users. As a follow-up to these reports, and in light of their recommendations, Health Canada funded the Canadian HIV/AIDS Legal Network to examine further the legal and ethical issues surrounding HIV/AIDS and injection drug use; and to identify possible solutions to some of the legal and ethical dilemmas raised (1) in providing care, treatment, and support to injection drug users with HIV/AIDS; and (2) by efforts to reduce the harms of drug use. To this end, the Network, in three national workshops held between November 1997 and March 1999, brought together fifty individuals from across Canada with knowledge and experience in matters related to HIV/AIDS and injection drug use to

1. identify legal and ethical issues pertaining to (a) the care, treatment, and support of drug users with HIV/AIDS; and (b) measures to reduce the harms of drug use;
2. undertake an analysis of a number of priority issues designated by workshop participants; and
3. propose recommendations on the priority issues.

Seven priority issues have been analyzed:

1. What is the impact of the current legal status of drugs and drug use on HIV/AIDS care, treatment, and support of drug users? What are alternatives to the current legal regime on drugs and drug use? What legal and ethical issues are raised?

2. What legal and ethical issues arise in circumstances in which drug use is permitted or tolerated in the course of providing health care and social services – primary health care, community clinics, pharmacy services, residential care, palliative care, housing services – to drug users?
3. Is it legal and ethical to make cessation of drug use a condition for treatment of a drug user? Is it legal and ethical to withhold antiretroviral drugs from HIV-positive drug users?
4. What legal and ethical issues arise in the context of prescribing opiates and controlled stimulants to drug users in Canada?
5. What legal and ethical issues are raised by (a) the absence of clinical trials on the impact of illicit recreational drugs on the immune system; (b) the absence of trials on the interactions between HIV/AIDS drugs and illicit recreational drugs; (c) the exclusion of drug users from clinical trials involving drugs for HIV/AIDS?
6. What are the legal and ethical grounds for ensuring that health-care providers, drug users, and the general public have accurate and complete information on illicit recreational drugs and their effects?
7. What legal and ethical considerations should be taken into account when implementing syringe exchange and methadone maintenance programs directed at reducing the harms from drug use?

Three experts were contracted to prepare papers on these issues, based on their particular perspective and expertise: Dr Diane Riley, International Harm Reduction Association and Canadian Foundation for Drug Policy, on drug policy; Mr Eugene Oscapella, Canadian Foundation for Drug Policy, on legal issues; and Dr David J Roy, Director, Centre for Bioethics, Clinical Research Institute of Montréal, on ethical issues. Their draft papers were discussed and reviewed by participants at the national workshops organized by the Project. After the workshops, they revised the papers in light of the discussion and information provided at the workshop. Finally, the papers underwent peer review and were finalized taking that review into account. Richard Elliott, Director of Policy & Research of the Legal Network, undertook the final rewrite of the background paper on legal issues together with Eugene Oscapella.

This volume contains the final version of the three background papers. It should be read together with *HIV/AIDS and Injection Drug Use: Legal and Ethical Issues*,[1] the Report on Phases I and II of the Project, which contains a summary of the analysis of the seven priority issues, and the recommendations developed by the workshop participants. The Report is based on the background papers in this volume and the comments made by workshop participants at the three workshops held between November 1997 and March 1999. However, for the Report, further research was undertaken on each of the seven issues.

With the release of the Report and this volume of background papers, the Project is not completed. Work will be undertaken by the Network in different areas. The focus will be directed to the implementation of the recommendations in the Report, as well as to the dissemination of the contents of the Report and the background papers to various audiences.

[1] R Bessner. Montréal: Canadian HIV/AIDS Legal Network, 1999.

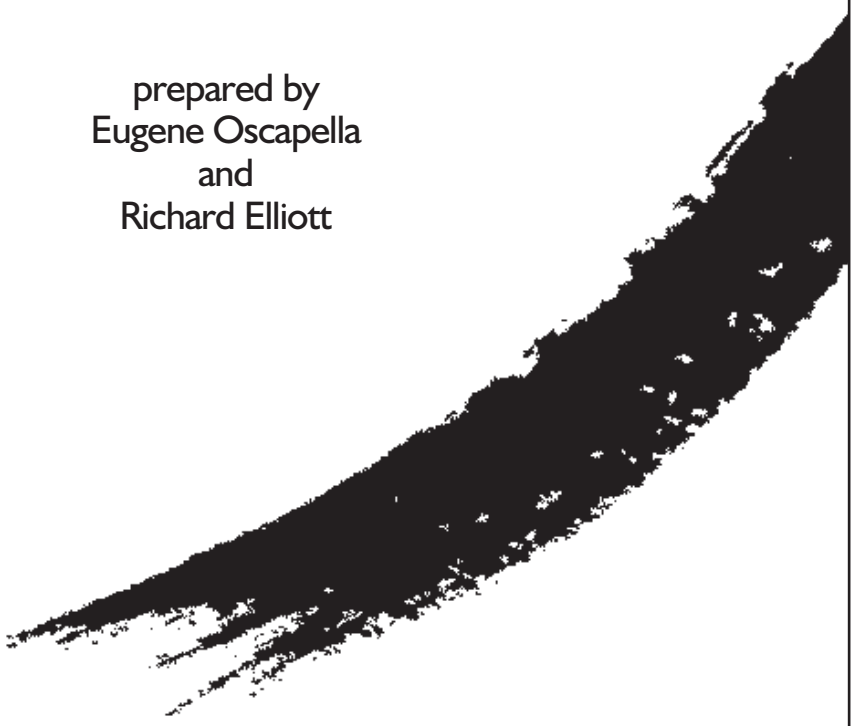
Info sheets summarizing the main results will be prepared to make the information in the Report and background papers more accessible, articles on the Project will be published in the *Canadian HIV/AIDS Policy & Law Newsletter* and other publications, and other follow-up activities will be undertaken.

CANADIAN HIV·AIDS LEGAL NETWORK | RÉSEAU JURIDIQUE CANADIEN VIH·SIDA

Injection Drug Use and HIV/AIDS:

A Legal Analysis of Priority Issues

prepared by
Eugene Oscapella
and
Richard Elliott



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Eugene Oscapella is a Barrister and Solicitor in Ottawa, and a founding member of the Canadian Foundation for Drug Policy. Richard Elliott is Director, Policy & Research, of the Canadian HIV/AIDS Legal Network.

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CAVEAT
This paper does not constitute legal advice, nor should it be relied upon as such. Readers with specific questions about the legality or legal consequences of certain activities should seek legal counsel familiar with laws and policies regarding controlled substances.

Table of Contents

Introduction

This paper considers some legal aspects of seven priority issues related to HIV prevention for injection drug users, and of the access of HIV-positive injection drug users to care, treatment, and support. The companion papers provide a similar exploration of the same issues from an ethical and policy perspective respectively. The issues addressed from each of these perspectives are as follows.

Issue 1: Current Legal Status of Drugs and Drug Use

What is the impact of the current legal status of drugs and drug use on HIV/AIDS care, treatment, and support of drug users? What legal issues are raised by possible alternatives to the current legal status? What issues should be considered in moving toward alternatives?

Issue 2: Drug Use and Provision of Health and Social Services
What legal issues must be considered in allowing or tolerating drug use in the course of providing health care or social services (primary health care, community clinics, pharmacy services, residential care, palliative care, housing services)?

Issue 3: Treatment
Is it legal to make cessation of drug use a condition for treatment for a drug user? Is it legal to withhold antiretroviral drugs (particularly current triple or quadruple combinations of drugs) from HIV-positive drug users?

Issue 4: Prescription of Opiates and Controlled Stimulants
What legal issues must be considered in prescribing opiates and controlled stimulants to drug users in Canada?

Issue 5: Drug Users and Studies of HIV/AIDS Drugs and Street Drugs
What legal issues relate to the absence of studies of the impact of street drugs on the immune system; the absence of studies of interactions between HIV/AIDS drugs and street drugs; and the exclusion of drug users from studies of HIV/AIDS drugs?

Issue 6: Information about the Use and Effects of Street Drugs
What legal mechanisms exist for ensuring that health-care providers, drug users, and the general public have accurate and complete information about the use and effects of street drugs?

Issue 7: Syringe Exchange and Methadone Maintenance Treatment
What are the legal regulations governing syringe-exchange programs and methadone maintenance treatment programs?

The "Law"

The "law" dealing with HIV/AIDS and injection drug use is not a single, straightforward, entity. It is a complex hierarchy of rules that emanate from various levels of government, and includes:

- international law, including conventions protecting human rights (the right to health being one of them) and conventions dealing with illicit drugs;
- the *Canadian Charter of Rights and Freedoms*,[1] which grants constitutionally protected rights when dealing with the actions and laws of governments, rights that cannot be interfered with arbitrarily;
- federal statutes (for example, the *Controlled Drugs and Substances Act* (CDSA),[2] the *Food and Drugs Act*,[3] the *Criminal Code*[4]) and provincial statutes (for example, human rights codes, or legislation governing health-care professions and facilities);
- regulations made under federal and provincial statutes;[5]
- the common law that has evolved through successive court decisions (as opposed to being set out in legislation); and
- codes and guidelines of ethical professional conduct for regulated professions (some of which may also be incorporated in legislation).[6]

Not only are there many sources of law, but laws may sometimes overlap or conflict. At the international level, for example, human rights conventions protecting against arbitrary interference with human rights may conflict with international drug conventions that require state action against drug use and sales. For example, obligations to suppress the possession of certain psychoactive substances under international drug-control treaties may result in state action that arguably conflicts with international human rights protections such as the right to be free from arbitrary interference with privacy and the right to life, liberty, and security of the person.

As well, professional codes of ethics might dictate one course of action, but a provincial or federal law might say otherwise. For example, the ethical principle of beneficence ("do good") might mandate the therapeutic prescription of a drug prohibited by the CDSA: medicinal marijuana is perhaps the best example. Similarly, federal and provincial laws may appear to conflict with each other; the courts may be called upon to determine which law will apply. Moreover, laws on subjects within provincial jurisdiction (eg, health professions) differ from province to province. Hospital legislation in one province may

[1] Part I of the *Constitution Act*, 1982, being Schedule B of the Canada Act 1982 (U.K.), 1982, c 11.

[2] SC 1996, c 19.

[3] RSC 1985, c F-27, as amended.

[4] RSC 1985, c C-46, as amended.

[5] Eg, the Narcotic Control Regulations, CRC, c 1041, in force under the CDSA, supra, note 2.

[6] See the discussion of professional codes of conduct in E Oscapella. Privacy and Confidentiality in the Medical Context. In: Royal Commission on New Reproductive Technologies. *Overview of Legal Issues in New Reproductive Technologies*, Volume 3 of the Research Studies. Ottawa: Minister of Supply and Services Canada, 1993, at 192-195.

allow certain activities in hospitals, while the legislation in a neighbouring province may not.

Even federal laws that apply across Canada may be interpreted differently from province to province. An example is the 1997 *Parker*[7] decision in Ontario, in which a judge declared unconstitutional and "read down" the provisions of the federal *Narcotic Control Act*[8] (since repealed) and the CDSA that prevented Mr Parker from cultivating and possessing marijuana to control his epileptic seizures. However, this decision of a provincial trial court does not bind the courts of any other province or even other Ontario courts, which might reach a completely different decision about the same legislation.

Research time for this project was limited; it was therefore not possible to give definitive opinions on the legal questions raised in this paper. This paper should therefore be taken as a preliminary exploration of these issues rather than a comprehensive analysis of each specific issue. The paper sometimes presents the "worst case" scenario that may flow from the current legal state of affairs or from the most zealous opponents of reform. To do otherwise risks misleading those who may seek such reforms. The intent is not to discourage those who wish to move beyond the traditional means of dealing with HIV-positive injection drug users, merely to assist them in considering how to structure their programs in a way that will avoid legal liability for them or for those they are helping. Similarly, the paper identifies some reform possibilities that may be only theoretically possible. As the creation, interpretation, and application of the law is shaped by its social context, some reforms might be legally possible but highly dependent on political or judicial will.

Some reforms might be legally possible but highly dependent on political or judicial will.

[7] *R* v *Parker*, [1997] OJ No 4923 (QL) (Prov Div), Sheppard Prov J.

[8] RSC 1985, c N-1.

Current Legal Status of Drugs and Drug Use

What is the impact of the current legal status of drugs and drug use on HIV/AIDS care, treatment, and support of drug users? What legal issues are raised by possible alternatives to the current legal status? What issues should be considered in moving toward alternatives?

Current Legal Status

Unauthorized drugs: international and domestic law

International law

As noted at the outset, Canada is a signatory to the three major international drug conventions.[9] The *Single Convention on Narcotic Drugs, 1961* (as amended by the *1972 Protocol Amending the Single Convention on Narcotic Drugs, 1961*) and the *Convention on Psychotropic Substances, 1971* are focused primarily on limiting the possession, use, trade in, distribution, import, export, manufacture, and production of drugs exclusively to scientific and medical purposes. The *Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1998* (the "Vienna Convention") is directed more specifically at trafficking, and includes provisions against money laundering and the diversion of precursor chemicals, as well as provisions on international cooperation across jurisdictions (including "controlled delivery" of prohibited substances by law-enforcement officers and extradition of those accused of trafficking).[10] However, provisions in drug-control treaties (or, at least, often their application) may arguably be at odds with both Canada's domestic legislation and obligations under international conventions on human rights, such as the *International Covenant on Civil and Political Rights* and the *International Convention on Economic, Social and Cultural Rights*[11] (which

[9] The text of these conventions may be found at the website of the International Narcotics Control Board at <www.incb.org> or by link from the website of the UN International Drug Control Programme at <www.undcp.org>.

[10] See generally: D Sproule, P St-Denis. The UN Drug Trafficking Convention: An Ambitious Step. *Canadian Yearbook of International Law* 1989: 263 at 264.

[11] (1976), 993 UNTS 3, [1976] CTS 46; acceded to by Canada pursuant to Privy Council decision No 1976-1156, 18 May 1976.

imposes an obligation on signatory States to take steps to protect and promote the right to health).

It should be noted that the international drug conventions contain provisions that permit States to "denounce" a treaty (ie, remove itself as a signatory).[12] Equally important, many of the obligations imposed on signatory States are expressly stated to be "subject to its constitutional principles" and/or "the basic concepts of its legal system." Canada, through interpretation of its own constitutional and other legal norms, thus retains the freedom to develop its own drug laws (with respect to at least some matters, such as possession for personal consumption) in a less punitive fashion than might be called for by a harsher interpretation of the international conventions.[13] Finally, there is strong language in each of the conventions that expressly allows signatory States to adopt "measures of treatment, education, after-care, rehabilitation and social integration" for drug users "either as an *alternative* to conviction or punishment or in additional to conviction or punishment."[14] Again, the punitive approach may be tempered within the existing legal framework.

The punitive approach may be tempered within the existing legal framework.

Canadian law

Domestically, the federal *Controlled Drugs and Substances Act* prohibits several activities relating to specified drugs. In general, the *unauthorized* possession,[15] manufacture,[16] cultivation,[17] trafficking (selling, administering, giving, transfering, transporting, sending, or delivering),[18] export[19] and import[20] of substances listed in several Schedules appended to the statute constitute criminal offences. Currently, those Schedules list cannabis (resin and marijuana), heroin, methadone, cocaine and coca leaf, barbiturates, amphetamines, and a large array of other substances as "controlled." As well, seeking or obtaining a controlled substance is an offence.[21]

Varying criminal penalties apply to violations of the law, depending on the substance in issue (and, in the case of cannabis, the quantity of the substance). For example, unauthorized possession of heroin, methadone, or cocaine is punishable by up to seven years' imprisonment. Unauthorized possession of cannabis is punishable by up to five years' imprisonment, although possession of a small quantity (one gram resin or 30 grams marijuana leaf) carries a maximum penalty of only six months' imprisonment and/or a $1000 fine.[22]

Used drug-injection equipment

As a result of its very broad definition of "controlled substance," the CDSA makes it a criminal offence to possess, import, export, traffic, etc, not only the drugs themselves but also "any thing that contains or has on it a controlled substance and that is used or intended or designed for use (a) in producing the substance, or (b) in introducing the substance into a human body."[23] This means that if a syringe or other equipment (eg, cookers) used for injecting drugs contains residue of a drug, as most used syringes will, that equipment is a "controlled substance" and the person with the syringe could be found guilty of possession under the CDSA. There is no express exemption or protection in the statute (or regulations) for needle/syringe exchange programs or their personnel, who will often knowingly be in possession of used equipment returned by users. Similarly, the operator of an injection room or "shooting gallery" who provided receptacles for the safe return of used syringes would knowingly possess a "controlled substance." (See discussion below regarding Issue 7, Syringe Exchange and Methadone Maintenance Treatment.)

There is no express exemption or protection in the statute (or regulations) for needle/syringe exchange programs or their personnel, who will often knowingly be in possession of used equipment returned by users.

[12] Art 46, 1961 Convention; Art 29, 1971 Convention; Art 30, 1988 Vienna Convention.

[13] Eg, Art 36(1)(a), 1961 Convention; Arts 21, 22(1)(a), 1971 Convention; Arts 3(1)(c), 3(2), 1988 Vienna Convention.

[14] Art 36(1)(b), 1961 Convention; Art 22(1)(b), 1971 Convention; Art 3(4)(d), 1988 Vienna Convention.

[15] Section 4(1).

[16] Section 7(1).

[17] Section 7(1).

[18] Section 5(1).

[19] Section 6(1).

[20] Ibid.

[21] Section 4(2).

[22] Section 4(3)-(5).

[23] Section 2(2).

Syringes (at least unused ones) should arguably not be considered drug paraphernalia.

Drug paraphernalia: instruments and literature

As a result of amendments introduced in 1988, the *Criminal Code* makes it an offence for anyone to "knowingly" import, export, manufacture, promote, or sell "instruments or literature for illicit drug use."[24] Selling includes offering for sale, exposing for sale, possessing for sale, and distributing, whether or not the material is distributed in exchange for money or other valuable consideration.[25] The punishment for a first offence is a maximum fine of $100,000 and imprisonment for six months; for a second or subsequent offence, the maximum penalty is a $300,000 fine and imprisonment for one year.[26] It is important to note that, while mere possession of illicit drugs is an offence (under the CDSA), this is not the case with mere possession of drug paraphernalia. In addition, an Ontario trial court has ruled that the prohibition on "literature" is an unconstitutional infringement of freedom of speech, contrary to the Charter.[27]

Syringes (at least unused ones) should arguably not be considered drug paraphernalia. An "instrument for illicit drug use" is defined as "anything designed primarily or intended under the circumstances for consuming or to facilitate the consumption of an illicit drug, but does not include a 'device' as that term is defined in section 2 of the *Food and Drugs Act*."[28] "Device" is defined in the *Food and Drugs Act* as "any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in ... the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals."[29] Syringes should almost certainly be considered "devices" under the *Food and Drugs Act*, since they are manufactured, sold or represented for medical use. If so, they would be excluded from the definition of "instruments for illicit drug use" in the *Criminal Code*. Some reported case law suggests this interpretation is correct.[30]

However, there is some uncertainty about this conclusion, as the definition in the *Criminal Code* of an "instrument for illicit drug use" includes anything "intended under the circumstances" for consuming an illicit drug. Courts have ruled that this definition is not unconstitutionally overbroad.[31] In many cases, the circumstances will be such that the syringe or other equipment will be intended for this purpose (even if what is intended is that the injection of illicit drugs be "safer," less likely to result in the harm of disease transmission). This leaves open the possibility that, depending on the circumstances, a person who provides a syringe or other injection equipment to another person for the purpose of their consumption of an illicit drug – for instance, an outreach worker in a needle exchange program or the operator of a shooting gallery – could be found guilty of the "sale" of drug paraphernalia. If the syringe in question contained residue of an illicit drug, not only would it be a "controlled substance" itself under the broad CDSA definition, but the residue on the syringe would presumably be strong evidence that, in the circumstances, the syringe was intended for this use. However, it might be possible to argue that what should be required for a conviction is that the person providing the equipment have the "specific intent" that the person receiving the equipment use it to consume an illicit drug.

[24] *Criminal Code*, supra, note 4 at s 462.2.

[25] Ibid at s 462.1.

[26] Ibid.

[27] *Iorfida* v *MacIntyre* (1994), 93 CCC (3d) 395 (Ont Ct Gen Div).

[28] Ibid.

[29] *Food and Drugs Act*, supra, note 3 at s 2.

[30] *R* v *Ramje* (1989), 103 AR 23 (Prov Ct), cited with approval in *R* v *Spindloe*, [1998] SJ No 561 (Prov Ct) (QL).

[31] *Spindloe*, supra, note 30; *R* v *Rizzo*, unreported, 28 February 1993 (Ont Ct Prov Div), Taillon J; *R* v *Temple*, unreported, 12 April 1998, Nfld Prov Ct, Reid PCJ.

Therapeutic access to controlled substances

Canada's criminal laws apply both to drugs used for "recreational" or "self-medication" purposes and to drugs that might be therapeutically indicated for treating symptoms of HIV/AIDS or other conditions. Thus, cannabis (marijuana) is currently prohibited by the CDSA, whether for recreational consumption or as a therapeutic tool. Similarly, the medical prescription of heroin is prohibited. Legal challenges to this prohibition on "medical marijuana" are discussed below. As a result of such challenges, the federal Minister of Health has announced that Canada will introduce clinical trials of cannabis used for medical purposes, and is developing a process whereby those seeking access to marijuana for medical use may apply for a Ministerial exemption from the criminal prohibitions on possession or cultivation.[32]

However, other drugs that are prohibited by the CDSA can nonetheless be made available for therapeutic purposes under Health Canada's Special Access Program (formerly called the Emergency Drug Release Program), which is authorized by the Food and Drug Regulations made under the *Food and Drugs Act*.[33] Under these Regulations, Health Canada may issue a letter of authorization authorizing the sale of a quantity of a new drug for human or veterinary use to a named practitioner for use in the emergency treatment of a patient under the care of that practitioner.[34]

Impact of Current Laws

The most pronounced effect of criminalizing certain drugs is to push drug users to the margins of society. This makes it difficult to reach drug users with educational messages that might improve their health and reduce the risk of further spread of disease. Users may also become distrustful of those associated with authority even if they wish to help users, since it has been the actions of the authorities that criminalized these users in the first place. Marginalizing drug users also reduces public concern about them, since drug users are now "criminals." Marginalizing drug users in the general public in this way increases the dangs to non-users in the general public that flow from increased rates of HIV and other infections among users. The inflated market price of illegal drugs is an incentive to choose the most efficient means of achieving the desired effect of the drug, which often means injecting in ways that put users at increased risk for infection (sharing used syringes, unsterile "works"). As well, the *Criminal Code* provisions prohibiting the selling or manufacture of drug paraphernalia make it difficult for users to obtain some types of sterile equipment other than syringes. The realistic acknowledgment of the harms associated with criminalizing drug use is reflected in *HIV/AIDS and Injection Drug Use: A National Action Plan*:

> The Action Plan ... recognizes that marginalization and stigmatization of drug users in general, and those infected with HIV in particular, are key barriers to progress against the epidemic, and focuses its efforts on reducing these barriers. Placing these individuals at the margins of society reduces access to health-enhancing services, ultimately placing the community-at-large at greater risk from the spread of HIV.[35]

Drug users with HIV/AIDS or other illnesses may also be denied access to a safe and effective supply of some drugs with therapeutic value, since the CDSA prohibits access to these drugs. Cannabis is perhaps the best-known

Marginalizing drug users also reduces public concern about them, since drug users are now "criminals." Marginalizing drug users in the general public in this way increases the dangers to non-users in the general public that flow from increased rates of HIV and other infections among users.

[32] *Wakeford* v *Canada*, [1999] OJ No 1574 (QL) (Gen Div); News Release. Minister Rock tables status report on medicinal marijuana research plan. Ottawa: 9 June 1999, Health Canada; T Harper. Commons a-buzz over grown-in-Canada pot. *Toronto Star*, 28 May 1999, A2; M Kennedy. When it comes to medicinal pot, Rock favours using home-grown. *National Post*, 28 May 1999, A4; A McIlroy. Canadian companies can soon bid to grow pot for medicinal use. *The Globe and Mail*, 9 June 1999, A3.

[33] Supra, note 3.

[34] CRC, c 870, s C.08.010.

[35] *HIV, AIDS and Injection Drug Use: A National Action Plan*. Canadian Centre on Substance Abuse & Canadian Public Health Association, May 1997, at 11.

The illegal status of drugs fosters emotion-laden anti-drug attitudes toward the user, again adding to marginalization of this population, and directs action toward punishment of the "offender," rather than fostering understanding and assistance.
– *HIV, AIDS and Injection Drug Use: A National Action Plan*

example. Those who possess cannabis for therapeutic purposes are declared criminals. Those who cultivate or provide cannabis also face criminal penalties. This constraint on the availability of potentially helpful drugs may hasten illness and death. Accessing substances from illegal suppliers means their safety and efficacy is not assured, again posing a health risk to users.

Laws prohibiting drugs also drive public opinion. If involvement with drugs is a crime, the message sent is that all people who use drugs are "bad." This in turn fosters an unwillingness to help drug users. It may even create hostility toward users, which translates into active opposition to helping them. Thus, while the public may see individuals who acquired HIV/AIDS through (some) other means as worthy of treatment and support, the public may resent or oppose helping those who acquired HIV/AIDS through drug use. Unsurprisingly, this results in barriers to users accessing prevention information and materials, and health and support services. As was recognized by the Task Force that prepared the National Action Plan:

> The illegal status of drugs makes the user afraid to go to health or social services, increasing marginalization.
>
> Service providers themselves may shy away from providing essential education on safer use of drugs for fear of being seen to condone use.
>
> The illegal status of drugs fosters emotion-laden anti-drug attitudes toward the user, again adding to marginalization of this population, and directs action toward punishment of the "offender," rather than fostering understanding and assistance.[36]

Finally, the enormous drug law enforcement bureaucracy – drug police, courts, prosecutors and defence lawyers, the criminal justice infrastructure, and the prison system – drains public resources, to the detriment of the health-care system in general, including that part of the system devoted to dealing with substance use and HIV/AIDS.

Legal and Ethical Issues Raised by Current Laws

The criminalization of certain drugs embodies the legal concept of *mala prohibita* – things that are wrong not because they are inherently evil but because a higher authority has declared them prohibited. For example, if a government were to decree that only royalty could wear the colour purple, it would be "wrong" for ordinary citizens to wear this colour. This would be a *malum prohibitum*.

This may be contrasted with the notion of acts that are *mala in se* – evil in and of themselves. Murder is an example of an act that is most often *malum in se*. In general, society recognizes that the intentional killing of another is wrong, whether or not the law prohibits it. (There may, of course, be exceptions to this general rule. Some would not consider it inherently wrong to assist a terminally ill loved one in dying if the dying person wished to end suffering and made an informed decision.) Because murder is accepted as presumptively wrong in and of itself, the law generally prohibits it. In the case of a *malum prohibitum*, the legal prohibition is what defines the behaviour as wrong; in the case of a *malum in se*, the wrongness of the behaviour may lead to it being prohibited.

Drugs are not inherently evil. Nor is there anything inherently evil about people taking certain substances into their bodies. Indeed, governments have

[36] Ibid at 13.

permitted (and in some cases encouraged) the consumption of some substances (eg, caffeine, tobacco, alcohol, food additives). Nor is there anything inherently evil about consuming substances currently prohibited by Canadian law (eg, cannabis, cocaine, heroin). This, then, is an example of a *malum prohibitum*. In order to be morally legitimate, such prohibitions on "controlled substances" must be justified on some grounds other than the mere whim of authority; some objectively sound and acceptable evidence is required that convincingly demonstrates the validity of criminalizing activities relating to certain drugs but not others.

No conduct should be defined as criminal unless it represents a serious threat to society, and unless the act cannot be dealt with through other social or legal means." – Canadian Committee on Corrections, 1969

To identify an ethical basis for invoking the sanction of the criminal law, reference should be had to the Government of Canada's 1982 report discussing when it is appropriate to use the criminal law rather than other means of social intervention. *The Criminal Law in Canadian Society*[37] concluded that the criminal law should be employed with "restraint." The report referred to previous studies. For example, the Report of the Canadian Committee on Corrections (the "Ouimet Report")[38] concluded that "[n]o conduct should be defined as criminal unless it represents a serious threat to society, and unless the act cannot be dealt with through other social or legal means."[39] In a similar vein, the report of the Law Reform Commission of Canada concluded:

> Criminal law is not the only means of bolstering values. Nor is it necessarily always the best means. The fact is, criminal law is a blunt and costly instrument.... [I]t imposes suffering, loss of liberty, and great expense.... So criminal law must be an instrument of last resort. It must be used as little as possible. The message must not be diluted by overkill – too many laws and offences and charges and trials and prison sentences. Society's ultimate weapon must stay sheathed as long as possible. The watch word is restraint – restraint applying to the scope of criminal law, to the meaning of criminal guilt, to the use of the criminal trial and to the criminal sentence.[40]

The criminal law is to be invoked only where necessary, when the use of other means is clearly inadequate or would depreciate the seriousness of the conduct in question. – Government of Canada, *The Criminal Law in Canadian Society*, 1982

The Government of Canada report accepts these conclusions, reiterating the principle that

> the criminal law should be employed only to deal with that conduct for which other means of social control are inadequate or inappropriate, and in a manner which interferes with individual rights and freedoms only to the extent necessary for the attainment of its purpose.[41]

Further explanatory notes to this principle set out several criteria for determining when it will be justifiable to enact criminal prohibitions:

> As the most serious form of social intervention with individual freedoms, the criminal law is to be invoked only where necessary, when the use of other means is clearly inadequate or would depreciate the seriousness of the conduct in question. As well, the Principle suggests that, even after the initial decision has been made to invoke the criminal law, the nature or extent of the response by the criminal justice system should be governed by considerations of economy, necessity and restraint, consonant of course with the need to maintain social order and protect the public.[42]

This principle and underlying criteria would seem to preclude the use of the criminal law in dealing with at least some activities relating to drugs. Criminalization, the "most serious form of social intervention with individual

[37] Government of Canada. *The Criminal Law in Canadian Society*. August 1982, at 42.

[38] *Toward Unity: Criminal Justice and Corrections. Report of the Canadian Committee on Corrections.* (the Ouimet Report) (Chair: R Ouimet). Ottawa: Queen's Printer, 31 March 1969.

[39] Ouimet Report, cited in *The Criminal Law in Canadian Society*, supra, note 37 at 42.

[40] Law Reform Commission of Canada. *Our Criminal Law*. Ottawa: Minister of Supply and Services Canada, 1976, at 27-28.

[41] *The Criminal Law in Canadian Society*. supra, note 37 at 52-53.

[42] Ibid at 59.

Other, less intrusive and less harmful means are available to respond to the use of drugs in a fashion that still maintains (and in fact may encourage) social order and protection of the public.

There is little to suggest that criminal prohibitions on drugs have yielded any significant benefit for Canadians. But current drugs laws do carry significant human and financial costs, violating the principle of economy in resorting to the criminal law.

freedoms," has not been demonstrated as necessary. But there is much (including experiences of other countries) that suggests other, less intrusive and less harmful means are available to respond to the use of drugs in a fashion that still maintains (and in fact may encourage) social order and protection of the public.

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Finally, criminal prohibitions violate the principle of restraint by unjustifiably infringing the autonomy of individuals and intruding into areas of private human behaviour, subjecting users of drugs declared illegal to extraordinary powers of police and other state intervention. Some of the most intrusive powers of the state – mandatory drug testing, searches and seizures, and widespread surveillance, including attempts to impose state control over the pregnancies of drug-using women – are used to single out private behaviour as a target for punitive laws. This raises the question of whether Canada's drug laws, and their enforcement, violate the letter or spirit of international human rights declarations and conventions,[43] the *Canadian Charter of Rights and Freedoms*,[44] and human rights codes,[45] all of which contain provisions aimed in whole or in part at preventing arbitrary interference with privacy.

Canada's drug laws make criminals of those who use (certain) drugs. Although people who use prohibited drugs are not inherently more evil than their neighbours who consume "legal" drugs, the law places users of illegal drugs at a disadvantage in society. It stigmatizes them and generally fails to treat them as members of society fully entitled to the support of the social welfare infrastructure; the harm caused to users violates the ethical principle of non-malfeasance, and it is questionable whether the harm and its extent are justifiable. In short, the Canadian government has created a *malum prohibitum* in violation of its own principles.

Potential Alternatives to the Legal Status Quo

There are several options available for reducing the harms that derive from present drug laws, ranging from complete decriminalization to the use of various mechanisms for achieving at least partial, de facto decriminalization of some aspects of drug use.

Decriminalization

The most obvious means of reducing harm is to move from criminalizing drugs and paraphernalia to regulating them by non-criminal means, using a harm-reduction philosophy. Doing so would bring multiple benefits. It would

- reduce the marginalization of drug users, likely making it easier to reach them with both educational messages about preventing HIV and other illnesses, and with treatment;
- make currently illegal drugs available for therapeutic purposes;
- remove some of the conditions that lead to high-risk injection behaviour;
- remove legal impediments to manufacturing and selling drug paraphernalia, enabling users to have sufficient "works" for safer drug use;
- help reduce the stigmatization of drug users and make the public less reluctant to help them;

[43] For example, Articles 3 and 12 of the *Universal Declaration of Human Rights, 1948* and Articles 9 and 17 of the *International Covenant on Civil and Political Rights*.

[44] Sections 7 and 8.

[45] Provisions of human rights legislation that seek to prevent discrimination can often have the effect of preventing employers from asking for certain information – for example, race, religion, marital status, and disability.

- reduce the enormous drain on public resources caused by drug-law enforcement, the courts, and the incarceration of users, and free up at least some of those resources for treatment and social welfare programs; and
- result in fewer drug users with HIV/AIDS or other illnesses being imprisoned for drug or acquisitive crimes (property crimes committed in order to obtain the money necessary to pay inflated underground market prices for illegal drugs). Because fewer drug users and fewer *HIV-infected* users would be imprisoned, there would be less drug use in prisons and the drug use that did occur would be somewhat less risky, since the pool of people sharing syringes would be less likely to include users infected with HIV or other bloodborne diseases (such as hepatitis C). This would reduce health risks to other prisoners and, ultimately, to the population outside prisons.

Decriminalizing the possession of small amounts of currently illegal drugs for personal use has already been recommended by the Task Force that prepared the National Action Plan on HIV/AIDS and injection drug use.[46] However, there is currently little political will to decriminalize drugs, as this would involve admitting the failure of current drug policies. It would also require "denouncing" aspects of the three international drug conventions to which Canada is a party. This is feasible under those conventions (see above).

Even if Canada were to remain a party to international drug-control conventions requiring punitive actions against drug users, these should be weighed against Canada's obligations under international human rights law. The *International Covenant on Civil and Political Rights* asserts the right of individuals to protection against excessive state intrusion by guaranteeing the right life, liberty, and security of the person, and protection against arbitrary interference with privacy. Similarly, international conventions guaranteeing the right to health, such as the *International Covenant on Economic, Social and Cultural Rights*, may also be at odds with international or domestic laws based on prohibition and punishment. If the Canadian government truly had the political will to redefine drug use as a health issue rather than a criminal law issue, creative use could be made of provisions in the existing international drug conventions to permit a less punitive approach and to adopt laws and policies based on a harm-reduction model. This is discussed further below in relation to alternative sentencing options.

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Regulatory and exemption powers

An intermediate step, although by no means fully satisfactory, is for the federal government to specify, either by Cabinet regulation or through the use of Ministerial exemption powers, that certain drugs or containers (such as syringes containing drug residue), or certain persons, are exempt from the application of the existing criminal law provisions.

The CDSA gives a broad power to the Governor in Council (ie, the federal Cabinet) to make regulations under the statute, including regulations governing the importation, production, delivery, sale, provision, administration, or possession of a controlled substance. The regulations may also specify the persons or classes of persons to whom the regulation applies and the means by which these persons or classes of persons can be designated.[47] The Cabinet also has the power to order amendments to any of the Schedules to the Act, "by adding to them or deleting from them any item" when Cabinet deems the amendment "to be necessary in the public interest."[48]

[46] *HIV, AIDS and Injection Drug Use: A National Action Plan*, supra, note 35 at 15, 37.

[47] CDSA, supra, note 2 at s 55(1)(a),(b).

[48] Ibid at s 60.

Possession or production of small amounts of some or all controlled substances for personal consumption only could be permitted.

Syringes and other injection equipment containing drug residue could be expressly defined by regulation or by Ministerial exemption as being excluded from the broadly worded definition of "controlled substance."

The Act also empowers the Minister of Health to *exempt* any person (or class of persons) or any controlled substance (ie, illegal drug or item containing residue of an illegal drug) from the application of the Act or regulations made under it. The Minister can do this if s/he is of the opinion that the exemption "is necessary for a medical or scientific purpose or is otherwise in the public interest."[49]

This regulatory power by Cabinet and/or this Ministerial exemption power could be used in a number of ways. Possession or production of small amounts of some or all controlled substances for personal consumption only could be permitted. (The statute itself already specifies a lesser maximum offence for possession of small amounts of cannabis.) Another theoretical, although politically unlikely, possibility would be to permit simple possession or production of any amount, but leave in place prohibitions on trafficking, importing, and exporting.

Syringes and other injection equipment containing drug residue could be expressly defined by regulation or by Ministerial exemption as being excluded from the broadly worded definition of "controlled substance." This would support harm-reduction efforts (safer injection practices and safer disposal of used equipment) by removing the threat of criminal prosecution for being found in possession of used equipment. It would also avoid putting those operating and working in needle-exchange programs in possible technical violation of the law.

Access to certain controlled substances (eg, marijuana, heroin) could be permitted by regulation or Ministerial exemption for therapeutic treatment of those with HIV/AIDS or other illnesses where medically indicated. For example, methadone is currently a controlled substance, but regulations in force under the CDSA already permit physicians, pharmacists, and others to prescribe methadone, and patients to possess it.[50] Access to currently illegal drugs for therapeutic purposes may also be allowed under other legislation. The Food and Drug Regulations[51] allow authorized physicians to prescribe substances that have not yet been formally approved for general therapeutic use. This program first came into existence in response to calls by those with HIV/AIDS for access to experimental drugs. In December 1997, a group of Ottawa doctors and lawyers applied under the program created through these regulations – the Special Access Program (SAP), formerly known as the Emergency Drug Release Program (EDRP) – for access to medicinal marijuana. As of July 1999, Health Canada had not accepted the December 1997 application, citing the need for the applicant to meet procedural requirements. But, as noted above, as a result of litigation, Health Canada has moved to implement a procedure for individuals to access marijuana where medically necessary. Conceivably, this procedure might be used to pursue access to various currently illegal drugs, besides cannabis, for therapeutic purposes.

Reclassifying "criminal offences" as "contraventions"

Yet another partial remedy lies in the use of the federal *Contraventions Act*.[52] Although enacted in 1992, this statute has not yet been proclaimed in force. If and when it does come into force, it may offer reduced penalties for some drug offences, including possession. The Act (s 8) allows the Governor in Council (ie, Cabinet) to make regulations designating as "contraventions" some offences that would otherwise be criminal offences. The power to make regulations is broad enough to include current offences for possession of small

[49] Ibid at s 56.

[50] Narcotic Control Regulations, supra, note 5 at ss 53, 65 & 68.

[51] Supra, note 34 at s C.08.010(1).

[52] SC 1992, c 47.

quantities of illegal drugs or the manufacture and selling of paraphernalia. A person convicted of a contravention would generally have no criminal record and would likely only pay a fine. Thus, the consequences of a *criminal* conviction are avoided.

Prosecutorial and judicial discretion

Another partial solution lies in government *non-prosecution policies*. The Netherlands, for example, has used non-prosecution policies for over 20 years to avoid imposing criminal penalties on drug users. In essence, a non-prosecution policy means that, although certain drugs are technically illegal, the government will not prosecute certain activities relating to those drugs (possession, or possession for treatment, for example).

Police and prosecutors in Canada exercise considerable discretion in deciding whether to prosecute a citizen. Thus, they may tolerate "illegal" activities if, for example, these activities do no great public harm or do not cause concern among politicians. However, relying on police and prosecutorial discretion is not a satisfactory way of resolving legal issues relating to drugs, since political winds and police attitudes can shift quickly and dramatically. Such an environment of uncertainty does not lead to effective, sustainable policies to help HIV-positive injection drug users.

Prosecutorial and judicial discretion also offer partial solutions in cases where persons are charged with drug offences. Amendments to the *Criminal Code* were introduced in 1995 (Bill C-41) that provide a statutory framework for prosecutors to *divert* offenders from the traditional system to "alternative measures programs" rather than proceed with a criminal prosecution. In cases where offenders are prosecuted, the amendments also provide a framework for sentencing courts to impose *alternative measures* (other than incarceration) that are authorized by provincial Attorneys General.[53] In line with the recommendations reiterated in numerous previous reports,[54] these reforms indicate that imprisonment should be a sentence of last resort after consideration of other available sanctions.[55]

Diversion policies have some potential to prevent drug users from acquiring a criminal record. For example, the federal Department of Justice diversion policy (introduced with respect to s 717 of the *Criminal Code*) allows for "minor" drug offences (eg, possession and, in some cases, possession for the purposes of trafficking) to be diverted out of the criminal justice system.[56] Alternative sentencing measures also offer a partial solution in some cases for minimizing the harms associated with criminal prohibitions on drugs. A pilot "drug court" project in Toronto, one component of which is a community advisory committee, is one example that has been generally well received. Accused people who are eligible for this program enter into judicially supervised participation in drug treatment and rehabilitation. Accused people who are assessed as "drug dependent," who meet other eligibility criteria, and who are charged with possession or possession for the purposes of trafficking in small quantities of cocaine or heroin have the option of entering this program before entering a plea on their charge. If they complete the program, the charge is withdrawn or stayed. Offenders charged with actual trafficking have the option of first pleading guilty, then entering the program with their sentencing postponed. If they complete the program, they receive a non-custodial sentence.[57]

Diversion and alternative sentencing measures, where available and appropriate, are clearly preferable to a criminal record or incarceration, but the

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Diversion and alternative sentencing measures, where available and appropriate, are clearly preferable to a criminal record or incarceration, but the question remains whether all drug users who might be diverted under this policy actually *need* treatment, and whether the treatment that is needed will be adequately funded.

[53] *An Act to amend the Criminal Code (Sentencing) and other Acts in consequence hereof*, SC 1995, c 22.

[54] The Ouimet Report, supra, note 38; *Our Criminal Law*, supra, note 40; *The Criminal Law in Canadian Society*, supra, note 37; *Sentencing Reform: A Canadian Approach: Report of the Canadian Sentencing Commission*. Ottawa: Supply and Services Canada, February 1987; *Taking Responsibility: Report of the Standing Committee on Justice and Solicitor General on its Review of Sentencing, Conditional Release and Related Aspects*. Ottawa: Queen's Printer, August 1988, Issue #65.

[55] *Criminal Code*, supra, note 4 at s 718.2.

[56] Referenced in Hon Justice William J Vancise, Court of Appeal for Saskatchewan. Treatment or Incarceration: Smoke Still Gets in Your Eyes: Part XXII and Beyond. Presentation at *Injection Drug Use: Societal Challenges* Conference, University of Montréal, 12-14 March 1999.

[57] Ibid.

question remains whether all drug users who might be diverted under this policy actually *need* treatment, and whether the treatment that is needed will be adequately funded. Furthermore, this diversion policy still leaves largely intact the damaging "war on drugs," with its extensive spending on the criminal justice system.

These reforms encouraging diversion policies and alternative sentencing measures are not in conflict with Canada's obligations under the international drug conventions. Denunciation of these conventions is therefore not necessary in order to pursue these limited reforms to Canada's domestic laws. As noted previously, there is strong language in each of the conventions that expressly allows signatory states to adopt "measures of treatment, education, after-care, rehabilitation and social integration" for drug users "either as an *alternative* to conviction or punishment or in additional to conviction or punishment."[58] It is possible that, were the necessary political will to be mustered, these provisions in the conventions could be interpreted even more broadly, to permit even further de facto decriminalization of drug users than is currently represented by the narrowly defined provisions in the *Criminal Code* dealing with alternative measures.

Litigation as reform strategy

Litigation may at times be useful and necessary in reforming current laws and policies, although some cases are unlikely to succeed. For example, challenges to the general constitutional validity of prohibiting the possession of cannabis have failed.[59] In the *Hamon* case, a Québec appellate court has ruled (with no discussion of the issue) that the prohibition on cultivating and possessing cannabis is not unconstitutional discrimination because "cannabis users are not a class of persons covered by" the equality rights provisions of the Canadian Charter (s 15).[60] The court also found that it did not unacceptably violate the right to liberty protected by the Charter (s 7), on the ground that the prohibition was not irrational or arbitrary because the government had based its decision on scientific evidence (albeit disputed), and that it was necessary to take account of "our cultural traditions."[61] The result in *Hamon* was substantially followed in a subsequent case alleging a breach of s 7 Charter rights.[62] In the *Clay* case, a London hemp-store operator was convicted of trafficking after the court upheld the prohibitions on possessing, trafficking, and cultivating marijuana in the (now repealed) *Narcotics Control Act*, ruling it did not violate principles of fundamental justice.[63] Similar conclusions were reached in several other cases.[64]

Nonetheless, there has been some judicial recognition in recent cases that, at least in the case of marijuana used for therapeutic purposes, the prohibition may be constitutionally problematic.

- In the *Clay* case, the judge noted the medical utility of marijuana and called for Parliament to consider authorizing access to marijuana for medicinal purposes.
- In the *Parker* case, a man with epilepsy who smoked marijuana to control frequent seizures was acquitted of charges of possession and cultivation, and currently has the right to possess and cultivate marijuana, although the Crown has appealed his acquittal.[65]
- In the *Wakeford* case, an HIV-positive man who smokes marijuana to control nausea and loss of appetite caused by anti-HIV medications was

[58] Art 36(1)(b), 1961 Convention; Art 22(1)(b), 1971 Convention; Art 3(4)(d), 1988 Vienna Convention.

[59] *R* v *Lepage* (unreported, 8 May 1989, Que SC), noted in: BA MacFarlane, RJ Frater, C Proulx. *Drug Offences in Canada*, 3rd ed. Aurora: Canada Law Book, 1998, at 4-27; *R* v *Cholette* (1993), 21 WCB (2d) 493 (BCSC).

[60] *Hamon* v *The Queen* (1993), 20 CRR (2d) 181 (Que CA), leave to appeal refused, Doc No 23857, 27 January 1994, (1993), 20 CRR (2d) 181n (SCC).

[61] Ibid at 184-185.

[62] *R* v *St-Maurice* (unreported, 8 Feb 1996, Que Ct), noted in MacFarlane et al, supra, note 59 at 4-28.

[63] *R* v *Clay*, [1997] OJ No 3333 (QL) (Gen Div), McCart J.

[64] *R* v *Malmo-Levine* (1998), 38 WCB (2d) 357 (BCSC); and *R* v *Caine* (unreported, 20 April 1998, BC Prov Ct), and *R* v *Kreiger* (unreported, 16 June 1998, Alta Prov Ct), both noted in MacFarlane et al, supra, note 59 at 4-28.

[65] *R* v *Parker*, supra, note 7.

awarded an "interim constitutional exemption" from the prohibitions on possession and "production and cultivation" of the CDSA until such time as the Minister of Health were to make a decision upon his application for an exemption from these laws (under s 56 of the statute).[66] While the court in *Wakeford* rejected the argument that the prohibition discriminated against the applicant on the basis of disability (his HIV-positive status), it did find a violation of his constitutional right not to be deprived of security of the person except in accordance with "the principles of fundamental justice" (Charter s 7) because there was no system in place by which he could obtain a meaningful Ministerial review of his application for an exemption from the criminal prohibitions. The Minister has subsequently approved the application.[67]

- The *Harichy* case, another constitutional challenge to the marijuana laws brought by an Ontario woman with multiple sclerosis, was expected to be heard in the fall of 1999 (although recent developments as a result of the *Wakeford* case and the Minister's announcement regarding exemptions for medicinal use may make this unnecessary).
- In the US, some appellate courts have recognized a defence of medical necessity to a charge of possession of marijuana, although the authors of the leading Canadian text on drug offences note that in one such case (*Jenks*) the court also indicated the defence would not exist where addiction causes the need to ingest the drug, or where the medical condition could be treated by other, lawful medication.[68]

Litigation could also conceivably be used to secure changes in laws or policies related to drug use and HIV in particular contexts. For example, there could be some strategic political benefit in litigating the denial of clean injection equipment to prisoners as a violation of their constitutional rights to equality (Charter s 15), to liberty and security of the person (Charter s 7), and to be free from "cruel and unusual treatment or punishment" (Charter s 12) because such a denial deprives them of access to the means of preventing HIV infection.[69]

Resort might be had to civil actions to effect change. For example, civil lawsuits for negligence flowing from the HIV risks tolerated by prison authorities have been brought in Australia (inmates seeking access to condoms),[70] and may have been partly responsible for moves by prison authorities to reduce the risks of acquiring or spreading HIV infection in prisons. In Canada, litigation in British Columbia and Québec, and the threat of litigation in Ontario, has been used to challenge prison authorities' refusals to let prisoners who were on methadone maintenance treatment before incarceration continue this therapy once in prison.[71]

Using private criminal prosecutions may also be of some use, although this has not yet been tried in the context of HIV/AIDS. For example, prison authorities who fail to distribute condoms, sterile syringes, or disinfectants might arguably be guilty of *criminal negligence causing death or bodily harm* if HIV infections occur among prisoners who have been refused these means of protecting themselves.[72] However, succeeding with such a private prosecution might be difficult. The provincial Attorney General might exercise their right to assume carriage of the prosecution, then abandon it. Criminally negligent conduct is that which shows a "wanton or reckless disregard" for the lives or safety of others. While denying access to the means of prevention to prisoners might seem at first glance to satisfy this definition, the courts have established

[66] *Wakeford* v *Canada*, supra, note 32.

[67] News Release. Minister Rock tables status report on medicinal marijuana research plan. Ottawa: 9 June 1999, Health Canada; Medical marijuana approved. *The Globe and Mail*, 10 June 1999.

[68] MacFarlane et al, supra, note 59 at 4-30, noting: *State* v *Diana*, 24 Wash App 908 (1979); *State* v *Hastings*, 801 P2d 563 (Idaho 1990); *Jenks* v *State*, 582 So2d 676 (Fla App 1 Dist 1991), review denied 589 So2d 292 (1991).

[69] See the discussion in R Elliott. Prisoners' Constitutional Right to Sterile Needles and Bleach. Appendix 2 in R Jürgens. *HIV/AIDS in Prisons: Final Report*. Montréal: Canadian HIV/AIDS Legal Network & Canadian AIDS Society, September 1996.

[70] I Malkin. Australia – not giving up the fight: prisoners' litigation continues. *Canadian HIV/AIDS Policy & Law Newsletter* 1997; 3(2/3): 32-33; see generally the discussion of possible negligence actions against prison authorities in I Malkin. The Role of the Law of Negligence in Preventing Prisoners' Exposure to HIV While in Custody. Appendix 1 in R Jürgens. *HIV/AIDS in Prisons: Final Report*, supra, note 69.

[71] R Jürgens. Methadone, but no needle exchange pilot in federal prisons. *Canadian HIV/AIDS Policy & Law Newsletter* 1997/98; 3(4)/4(1): 26-27; DA Rothon. Methadone in provincial prisons in British Columbia. *Canadian HIV/AIDS Policy & Law Newsletter* 1997/98; 3(4)/4(1): 27-29; B Turcotte. Judge orders methadone maintenance treatment in prison. *Canadian HIV/AIDS Policy & Law Newsletter* 1996; 3(1): 16-18; C McLeod. Is there a right to methadone maintenance treatment in prison? *Canadian HIV/AIDS Policy & Law Newsletter* 1996; 2(4): 22-23.

[72] *Criminal Code*, supra, note 4 at ss 219-221.

that this requires conduct that shows a "marked departure" from the standard of behaviour expected from a "reasonably prudent person" in the circumstances.[73] As tragic evidence mounts of HIV transmission occurring in prisons, and that interventions such as providing access to clean injection equipment and condoms can help protect the health of prisoners, there may be an increasingly strong factual basis on which to argue that failing to provide such access is indeed a marked departure from the behaviour reasonably expected from prudent correctional services.

However, a stronger prosecution for criminal negligence causing bodily harm might arise out of the refusal by those in authority to allow access to drugs for treatment of HIV disease, thereby contributing to disease progression. This could conceivably include the refusal to permit prisoners to access methadone (to avoid injecting inside, probably using contaminated equipment) or to access marijuana to control side effects such as nausea and appetite loss caused by HIV therapies.

[73] See cases infra at note 120.

Drug Use and Provision of Health and Social Services

What legal issues must be considered in allowing or tolerating drug use in the course of providing health care or social services (primary health care, community clinics, pharmacy services, residential care, palliative care, housing services)?

Introduction

Both civil and criminal law are implicated in this question. Those who could be criminally prosecuted include drug users, health-care providers, and administrators of the health-care or social-services facility. Health-care providers and facilities could also be civilly liable if their conduct were found to cause or contribute to someone's injury. Health-care personnel must also obey professional codes of conduct or legislation governing their particular occupation (physicians, nurses, etc).

The legal issues also depend on the type of facility. A hospital, for example, is required to give patients competent medical care. The health-care workers in the hospital have professional responsibilities and could be found negligent if they fail to do their work competently, whereas a residential facility not staffed by medical personnel and not involved in providing residents with access to medical care might not have a duty to provide such care and so could not be found negligent for failing to provide it.

Criminal Law Issues

In the case of a hospital or treatment centre, several criminal law issues may arise from tolerating or facilitating possession or trafficking of controlled substances on the premises. Criminal liability for the management or employees

The greater the participation of facility personnel in facilitating drug offences, the greater the likelihood that the conduct could be considered to amount to trafficking in drugs.

This broad definition suggests that an employee of a facility who "knowingly has" illegal drugs in the facility for the benefit of a patient is at risk of committing the offence of either constructive or joint possession.

of such a facility might arise in the form of charges for drug offences under the CDSA. Charges might also be possible under the provisions of the *Criminal Code* that impose liability on people who are implicated in offences that are directly committed by someone else, or impose liability for *criminally negligent* behaviour that results in injury to others.

In some cases, there may be one or more legal defences to criminal prosecution. However, since it is not clear which legal defences might be available, this discussion examines the broadest possible range of criminal offences that might be associated with drug use in facilities. The precise legal defences would depend on the specific situation in which the use occurs.

Patients or residents in a hospital, treatment centre, or other facility may violate current drug laws by either possessing or "trafficking" (ie, sharing, administering, or selling) drugs in that setting. What is the liability of the facility and its personnel that might arise in such a situation for tolerating these activities? In this section, the paper considers the possibility that a worker might be open to *possession* charges, or to a prosecution for *criminal negligence causing bodily harm or death* should injury somehow result to someone in connection with tolerating possession or trafficking by a patient/resident. Depending on the degree of facility personnel's involvement in "tolerating" such activities, it might also be the case that *trafficking* or *possession for the purposes of trafficking* charges could also arise. Generally speaking, the greater the participation of facility personnel in facilitating drug offences, the greater the likelihood that the conduct could be considered to amount to trafficking in drugs. However, even if these drug charges were not laid directly against the management or employees, there are possible criminal penalties for those who are implicated in the commission of the offence in some way, such as *counseling* an offence, or *aiding* someone in committing an offence. Finally, even if a facility decided not to tolerate possession or trafficking on its premises, it might still choose not to report known activities to authorities. Does this carry any legal consequences?

Constructive or joint possession charges

Those operating hospitals or other facilities (eg, hospices or shelters) where patients/residents are allowed to possess illegal drugs could themselves be exposed to prosecution charges under the CDSA. The *Criminal Code* encompasses three different forms of possession, referred to by the authors of the leading Canadian text as "personal possession," "constructive possession," and "joint possession."[74] Under the *Criminal Code* definition, the offence of *possession* is made out not only where a person has a drug in their "personal possession" but also where a person "knowingly" has the drug in the actual possession or custody of another person, or has the drug in any place, whether or not that place belongs to or is occupied by him, for the use or benefit of himself or of another person ("constructive possession"); or "where one of two or more persons, with the knowledge and consent of the rest, has anything in his custody or possession, it shall be deemed to be in the custody and possession of each and all of them" ("joint possession").[75]

This broad definition suggests that an employee of a facility who "knowingly has" illegal drugs in the facility for the benefit of a patient is at risk of committing the offence of either constructive or joint possession. In order to be guilty of either constructive or joint possession, the accused must be proved to

[74] MacFarlane et al, supra, note 59 at 4-3.

[75] Section 4(3).

have not only *knowledge* that the drug is present, but also to have some measure of *control* over the drug. Additionally, in the case of a "joint possession" charge, the prosecution must also prove *consent* on the part of the person who does not have the drugs in their actual physical possession.

Knowledge

The case law is clear that there must be some knowledge on the part of the accused that the prohibited drug (as opposed to an innocuous substance such as flour) is present.[76] As is generally the rule, knowledge may be proved (beyond a reasonable doubt) either by direct evidence or as a rational inference from other objective, relevant, and admissible facts in evidence.[77] In the law, actual knowledge is not required if the prosecution can establish that the person was "wilfully blind" or "reckless" as to the presence of the drug.[78] In a leading case, a unanimous Supreme Court of Canada clarified the meaning of these two mental states that will suffice to establish "knowledge," and hence criminal liability, on the part of the accused:

> Wilful blindness is distinct from recklessness because, while recklessness involves knowledge of a danger or risk and persistence in a course of conduct which creates a risk that the prohibited result will occur, wilful blindness arises where a person who has become aware of the need for some inquiry declines to make the inquiry because he does not wish to know the truth. He would prefer to remain ignorant. The culpability in recklessness is justified by consciousness of the risk and by proceeding in the face of it, while in wilful blindness it is justified by the accused's fault in deliberately failing to inquire when he knows there is reason for inquiry.[79]

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Control

In order to make out the offence of possession (whether physical, constructive, or joint), the Crown must also establish that the accused had some "measure of control" over the substance.[80] As noted by MacFarlane et al, this has generally been interpreted as exercising some restraining or directing influence over the drugs.[81] A "casual or hasty manual handling [of the drug] ... under circumstances ... not consistent with one's own purposes or use for a 'fix'"[82] or mere physical contact without any intention to "deal with the object in a deliberate personal manner"[83] has been held not to constitute possession. For example, the person who finds a package of illegal drugs and holds on to it for the purpose of delivering them to authorities is not guilty of "possession" under the law. However, physically handling drugs for the purpose of storing them for another person (eg, a resident of a health-care facility) would likely give rise to a measure of control over the substance that could mean possible criminal liability. As MacFarlane et al note, the courts will look for evidence "that the accused took custody of it willingly and intended to deal with it in some sort of deliberate manner."[84]

Physically handling drugs for the purpose of storing them for another person (eg, a resident of a health-care facility) would likely give rise to a measure of control over the substance that could mean possible criminal liability.

[76] *R* v *Beaver* (1957), 118 CCC 129 (SCC); *R* v *Pierce Fisheries Ltd*, [1970] 5 CCC 193 (SCC).

[77] *R* v *Kelly*, [1967] 1 CCC 215 (BCCA); *R* v *Aiello* (1978), 38 CCC (2d) 485, aff'd 46 CCC (2d) 128n (SCC); *R* v *Vautour*, [1970] 1 CCC 325 (NBCA).

[78] *R* v *Sault Ste Marie (City)* (1978), 40 CCC (2d) 353 (SCC); *R* v *Aiello*, supra, note 77.

[79] *R* v *Sansregret* (1985), 18 CCC (3d) 223 (SCC).

[80] *R* v *Hess (No 1)* (1948), 94 CCC 48 (BCCA); *R* v *Beaver*, supra, note 76; *R* v *Terrence* (1983), 4 CCC (3d) 193 (SCC).

[81] *R* v *Martin* (1948), 92 CCC 257 (Ont CA); *R* v *Lombardo* (1967), 3 CRNS 19 (Ont Co Ct); *R* v *Sparling* (1988), 31 OAC 244 (CA); *R* v *Charlton* (1992), 27 WAC 272 (BCCA).

[82] *R* v *Hall* (1959), 124 CCC 238 (BCCA); *R* v *Vance* (1977), 2 WCB 23 (Ont CA); *R* v *Cantera* (1981), 6 WCB 157 (Alta QB).

[83] *R* v *Spooner* (1954), 109 CCC 57 (BCCA).

[84] See, eg, *R* v *Lee* (1990), 61 CCC (3d) 283 (Ont Ct Gen Div).

A facility employee who stores a patient/resident's illegal drugs and provides them at specific intervals (or perhaps even assists the person to consume them) could likely be convicted of trafficking.

Consent

As already stated, in the case of a joint-possession charge (and only in this case), the prosecution must prove that the person who did not have the drug in their actual physical possession nonetheless consented to another person physically possessing them.[85] While there is no single clear definition of what "consent" means in this context, it has been suggested that it means "active concurrence of the accused in the possession by another..., not merely passive acquiescence unless there should in the circumstances appear to be some obligation to act or speak out."[86] The case law indicates that courts will decide, on the facts of each particular case, whether it can be said that there was "consent" to another person's possession of the drugs; in doing so, they will look at the relationship and activities between the people involved, with a view to determining whether there was some sort of joint venture with respect to the drugs.[87] (Obviously the issues of *control* and *consent* are closely related. Indeed, often the legal analysis overlaps: in two recent cases, appellate courts have said that control is established where there is a right to grant or withhold consent.[88])

In light of the broad definition of possession, prosecutors might argue that a worker or manager in a facility who knows of possession by a patient and who, as the authority exercising control over the premises, tolerates that possession (and thereby arguably "consents" to it), is guilty of constructive or joint possession under the CDSA. The possibility of a charge of either constructive or joint possession might be even greater if the worker actually stores an illegal drug on behalf of a patient or resident. Indeed, depending on the nature of the worker's physical contact with the drug, a charge of physical possession could also be pursued.

The provisions on possession of illegal drugs also apply to anything that contains an illegal drug and that is used to introduce it into the body, including syringes containing drug residue.[89] The foregoing analysis would therefore apply equally to the situation in which the worker in the facility handled or stored used injection equipment for a patient or resident.

Trafficking charges

Those working in a facility providing health-care or other services might also be exposed to trafficking charges in a variety of ways. If they were to go beyond simply ignoring possession of controlled substances by patients or residents, or the trafficking of such substances (eg, one resident providing another with a controlled substance), the possibility of trafficking charges would theoretically be greater. For example, a facility employee who stores a patient/resident's illegal drugs and provides them at specific intervals (or perhaps even assists the person to consume them) could likely be convicted of trafficking. Another scenario might be one in which a patient or resident might, of necessity, ask the employee to physically obtain a controlled substance (eg, marijuana) for them.

The CDSA defines the offence of "trafficking" very broadly, as including "to sell, administer, give, transfer, transport, send, or deliver the substance."[90] Furthermore, the definition includes "offering" to do any of these things, as long as the offer is serious (not in jest), even if no agreement is actually reached and the terms of the offer are never actually carried out.[91] In the leading case on defining these different modes of trafficking, the court ruled that the meaning of each of the words used to define trafficking has to be understood in light of the others similarly used in the definition. The court said these words

[85] *R* v *Colvin* (1942), 78 CCC 282 (BCCA); *R* v *Bunyon* (1954), 110 CCC 119 (BCCA); *R* v *Marshall*, [1969] 3 CCC 149 (Alta CA); *R* v *Miller* (1984), 12 CCC (3d) 54 (BCCA); *R* v *Chambers* (1985), 20 CCC (3d) 440 (Ont CA); *R* v *McRae*, [1967] 3 CCC 122 (Sask CA), leave to appeal to SCC refused [1967] SCR viii; *R* v *Gardiner* (1987), 35 CCC (3d) 461 (Ont CA).

[86] *R* v *Caldwell* (1972), 7 CCC (2d) 285 (Alta CA), leave to appeal to SCC refused [1972] SCR ix.

[87] *R* v *Marshall*, supra, note 85; *R* v *McRae*, supra, note 85; *R* v *Gardiner*, supra, note 85; *R* v *Chambers*, supra, note 85..

[88] *R* v *Savory* (1996), 94 OAC 318 (CA), leave to appeal to SCC refused 104 OAC 320n; *R* v Abdul-Malek (1997), 147 WAC 147 (BCCA). MacFarlane et al (supra, note 59) note that a contrary result was reached in *R* v *Dupont* (1986), 1 YR 234 (Terr Ct); *R* v *Grey* (1996), 47 CR (4th) 40 *sub nom R* v *Escoffery* (Ont CA).

[89] CDSA, supra, note 2 at s 2(2).

[90] Ibid at s 2(1).

[91] *R* v *Pearson* (1994), 89 CCC (3d) 535 (Que CA), leave to appeal to SCC refused 91 CCC (3d) vi; *R* v *Oliver* (1995), 30 WCB (2d) 367 (Que CA); *R* v *Mancuso* (1989), 51 CCC (3d) 380, leave to appeal refused 58 CCC (3d) vi; *R* v *Reid* (1996), 155 NSR (2d) 368 (CA), leave to appeal to SCC refused 160 NSR (2d) 80n.

> imply something more extensive than a use for the actor's own purposes. When one uses the word "sell", "give", "administer", "send", "deliver" or "distribute", he does not contemplate a transaction involving one person alone, but a transaction involving two or more persons.[92]

Given the numerous ways in which drugs can be "trafficked" contrary to law, there are cases that consider how most of these terms may apply to various factual circumstances. The discussion below deals with only a few of the key modes of trafficking, those most likely to arise in the context of providing health or other services.

Selling a controlled substance

The CDSA states that "sell" includes "offer for sale, expose for sale, have in possession for sale, and distribute, whether or not the distribution is made for consideration" (ie, money or other item of value).[93] Although a purely literal reading of this definition would suggest it is broad enough to catch almost any dealing between one person and another with respect to drugs, judicial decisions have narrowed its scope marginally. Because the word "distribute" suggests that something has been apportioned between several or many people, it has been held that merely giving drugs *to the same person* (even if on more than one occasion) does not constitute "distribution."[94] Similarly, the courts have held that a single instance could not amount to "distribution" either.[95] MacFarlane et al conclude that in order to obtain a conviction for selling controlled substances, "the evidence will have to disclose at least two such transactions involving at least two different recipients."[96] Of course, other aspects of the definition of "trafficking" (such as "giving" or "delivering" the substance) would likely still be applicable to a single instance of providing a substance to another person.

Administering a controlled substance

There is contradictory case law as to the exact meaning of "administering" a controlled substance. There is some support for the view that it should be understood in the sense of administering a medicine – that is, "making the drug available by applying or prescribing."[97] However, other decisions have excluded the act of prescribing a drug, saying that a drug is not "administered" until it enters the recipient's system;[98] this seemingly narrows the definition. Yet another view takes a broader interpretation: a court has ruled that two people "administer" the drug to each other when "dirging" hashish (ie, one person heating the substance between two knives and holding it while the other inhales the smoke).[99]

Giving a controlled substance

The broadest aspect of the "trafficking" offence under the CDSA is the inclusion of the term "giving." Existing cases establish that all that is required to make out the offence is the simple act of providing a controlled substance to another person, regardless of the provider's motive or purpose; therefore, the offence is made out even if both people involved are found to jointly own or possess the drug and are merely using it together for their own personal consumption – not the kind of conduct that many would generally understand to be "trafficking" in drugs.[100] MacFarlane et al note, however, two cases in which trial courts have accepted an accused's argument that he was not "giving" the drug when he acted for a drug purchaser throughout a transaction and was

[92] *R* v *Harrington*, [1964] 1 CCC 189 (BCCA), cited in MacFarlane et al, supra, note 59 at 5-5.

[93] Section 2.

[94] *R* v *Cole* (1981), 64 CCC (2d) 199 (Ont CA) at 132.

[95] *R* v *Marino* (1931), 56 CCC 136 (SCC); *R* v *Labine* (1975), 23 CCC (2d) 567 (Ont CA); *R* v *Christiansen* (1973), 13 CCC (2d) 504 (NBCA).

[96] MacFarlane et al, supra, note 59 at 5-18.

[97] *R* v *Eccleston* (1975), 24 CCC (2d) 564 (BCCA) at 573-574, per Seaton JA dissenting.

[98] *R* v *Tan* (1984), 15 CCC (3d) 303 (Sask CA), foll'd in *R* v *Verma* (1996), 112 CCC (3d) 155 (Ont CA). But see contra: *R* v *Rousseau* (1991), 70 CCC (3d) 445, leave to appeal to SCC refused 70 CCC (3d) vi.

[99] *R* v *Ecclestone*, supra, note 97 at 566, per Maclean JA for the majority (McFarlane JA concurring).

[100] *R* v *Taylor* (1974), 17 CCC (2d) 36 (BCCA); *R* v *Verge* (1971), 3 CCC (2d) 398 (BCCA); *R* v *Nittolo* (1978), 44 CCC (2d) 56 (Que CA); *R* v *Lauze* (1980), 60 CCC (2d) 469 (CA); *R* v *Larson* (1972), 6 CCC (2d) 145 (BCCA).

merely handing it over to the purchaser.[101] However, this conduct might be caught under the statute in any event as constituting "transport" or "delivery" of a controlled substance. It has been ruled that "delivering" is synonymous with "giving," so this mode of committing the offence of trafficking is not discussed separately here, even though it makes its own appearance in the statutory definition.[102] In any event, according to a recent Supreme Court of Canada decision, the employee at a facility who merely acted as purchasing agent for a patient/resident, or assisted in the purchase, could still be found liable on the charge of *aiding* or *abetting* the possession of a controlled substance (see discussion of "secondary liability" below).[103]

Transporting a controlled substance

The leading case, subsequently followed by appellate courts in several provinces, suggests that

> the word "transport" in the definition of "traffic" is not meant in the sense of mere conveying or carrying or moving from one place to another, but in the sense of doing so to promote the distribution of the [substance] to another.... [T]here must be something more extensive than mere conveying, or carrying or moving incidental to one's own use of the drug to warrant a conviction.[104]

The provisions of the statute would likely prohibit a "shooting gallery" set up to reduce the harms associated with injection drug use by providing users with sterile injection equipment.

MacFarlane et al point out that inferences as to the accused's purpose in transporting the drug may be drawn: "Accordingly, where the quantity is so small that the only reasonable inference to be drawn is that the accused carried it for his or her own personal use, the court is entitled to acquit on a charge of trafficking. On the other hand, if the quantity is so great as to compel an inference of an intention to distribute, an accused will likely have to provide some form of explanation or stand convicted."[105]

Forfeiture of offence-related property

The CDSA also contains provisions permitting the forfeiture of "offence-related" property, which can mean both personal effects and "real property" (buildings and land).[106] In the United States, forfeiture laws have permitted entire hotels or apartment buildings to be forfeited because of drug transactions occurring in some hotel rooms or apartments.[107] The provisions in Canadian legislation appear too restrictive to allow the forfeiture of a treatment or residential facility simply because a patient or resident inside the facility possessed or trafficked drugs there. (The position of prosecutors and/or judges might be different if those with authority over the premises actually crossed the line into "trafficking" by facilitating possession or trafficking by residents.) Such forfeiture proceedings also seem politically unlikely.

However, the definition of "offence-related property" in the CDSA specifically contemplates that property that can be forfeited can include (but is probably not limited to) "real property built or significantly modified for the purpose of facilitating the commission of a designated substance offence."[108] The offence of mere *possession* of controlled substances is not a "designated substance offence"; however, all other offences (eg, production, trafficking, possession for the purposes of trafficking) are so designated.[109] The provisions of the statute would likely prohibit a "shooting gallery" set up to reduce the harms associated with injection drug use by providing users with sterile injection equipment (and possibly a regulated supply of substances whose composition could be tested for potentially damaging or fatal impurities).

[101] *R* v *Anderson* (1992), 16 WCB (2d) 30 (Ont Ct Gen Div); *R* v *Smith* (1992), 18 WCB (2d) 243 (BCSC).

[102] *R* v *Taylor*, supra, note 100.

[103] *R* v *Greyeyes* (1997), 116 CCC (3d) 334 (SCC).

[104] *R* v *Harrington*, [1964] 1 CCC 189 (BCCA).

[105] MacFarlane et al, supra, note 59 at 5-29, and see cases cited.

[106] CDSA, supra, note 2 at ss 2, 16\'9623.

[107] SB Duke. *America's Longest War: Rethinking our Tragic Crusade Against Drugs*. New York: Tarcher/Putnam, 1993, at 138.

[108] CDSA, supra, note 2 at s 2(1).

[109] Ibid.

Exempting such a facility from the possibility of forfeiture (as well as charges against the operators for possession and/or trafficking) would require a legislative amendment or, as canvassed above, the use of regulatory or exemption power by the federal Cabinet or Minister of Health.

Criminal negligence charges

Prosecutors could also conceivably bring charges of *criminal negligence causing death*[110] or *bodily harm*[111] against those working in health-care or treatment facilities if prosecutors were of the opinion that, by tolerating or facilitating drug possession on the premises, the facility caused or contributed to someone (eg, resident, staff, volunteers, visitors) being injured. The *Criminal Code* states that a person is criminally negligent who, "in doing anything, or in omitting to do anything that it is his [legal] duty to do, shows wanton or reckless disregard for the lives or safety of others."[112] Prosecutors might argue that those operating a medical or other facility are criminally negligent if, by tolerating the use by patients of illegal drugs, they fail to prevent patients from causing harm to themselves or to others.

For example, prosecutors might argue that allowing a pregnant woman to use drugs is criminal negligence because of the harm it does to the fetus. However, such arguments would likely fail because the fetus is not considered a person in Canadian law.[113] In addition, the Supreme Court of Canada has expressed concern that using the coercive power of the state against pregnant women for the purpose of protecting their fetuses not only raises serious constitutional questions about the infringement of autonomy and privacy interests, but may also be counterproductive to securing the health of children born to mothers who use drugs, by driving them underground and away from access to health services that will be to the benefit of both mother and fetus.[114] (The Court has also expressed doubt as to whether civil actions should be permitted by a fetus against a mother for her conduct during the pregnancy; this issue remains unsettled in the law of Canada and other jurisdictions.[115] It is also worth noting that the Royal Commission on New Reproductive Technologies has recommended against any imposition of criminal or civil liability upon a woman for conduct vis-à-vis her fetus during pregnancy.[116])

A more likely scenario would be one in which a centre tolerated (or facilitated) use of a controlled substance by a resident or patient who subsequently did some physical injury to themselves or another resident or worker in the centre. To prove criminal negligence against the management or worker at the centre, the prosecution would need to prove two things.

First, the accused must have done something or failed to do something they had a legal duty to do. If a facility were to actually store a patient's illegal drugs and provide them when requested or as needed, this could be the act upon which a criminal negligence charge is based. Alternatively, someone may be criminally negligent for failing to discharge a duty to act. This can be a duty either under a statute or a duty imposed by the common law.[117] As discussed below, there is likely no legal duty on a facility to report the possession of or trafficking in illegal drugs by patients. However, many facilities (eg, hospitals, community clinics, residential-care facilities) certainly have a legal duty to safeguard the well-being of the patient and of others using the facility. Courts have confirmed that physicians, hospitals, etc, have a common law duty to protect not only the health of patients but, in some circumstances, third parties.[118] A common law duty to avoid conduct that it was reasonably foreseeable could

[110] *Criminal Code*, supra, note 4 at s 220.

[111] Ibid at s 221.

[112] Ibid at ss 219.

[113] Ibid at s 223(1); *R* v *Morgentaler*, [1988] 1 SCR 30; *Tremblay* v *Daigle*, [1989] 2 SCR 530; *R* v *Sullivan* (1991), 63 DLR (3d) 97 (SCC); *R* v *Manning*, [1994] BCJ No 1732 (Prov Ct); *R* v *Drummond* (1996), 112 CCC (3d) 481 (Ont Ct Prov Div).

[114] *Winnipeg Child and Family Services (Northwest Area)* v *DFG*, [1997] 3 SCR 925.

[115] Ibid.

[116] *Proceed with Care: Final Report of the Royal Commission on New Reproductive Technologies*, vol 2. Canada: Minister of Public Works and Government Services Canada, 1993, at 949.

[117] *R* v *Coyne* (1958), 124 CCC 176 (NBCA); *R* v *Popen* (1981), 60 CCC (2d) 232 (Ont CA).

[118] *Wellesley Hospital* v *Lawson* (1977), [1978] 1 SCR 893, 76 DLR (3d) 688; *Dorset Yacht Co* v *Home Office*, [1970] AC 1004 (HL); *Stewart* v *Extendicare Ltd* (1986), 38 CCLT 67 (Sask QB); *Tanner* v *Norys*, [1980] 4 WWR 33 (Alta CA); *Wenden* v *Trikha* (1991), 8 CCLT (2d) 138 (Alta QB), aff'd without reference to this point (1993), 14 CCLT (2d) 225 (Alta CA).

harm others has been accepted as a sufficient basis for imposing criminal liability.[119] It might well be argued that tolerating the use of controlled substances (or, more likely, facilitating their use) breaches this duty; this could be the basis of a criminal-negligence prosecution.

Second, it must be shown that the accused's act, or failure to act, showed "wanton or reckless disregard" for the lives or safety of others. Although there is conflicting case law as to precisely how the notion of "criminal negligence" is to applied, the weight of judicial authority indicates that the accused's conduct must demonstrate a "marked departure" from the standard of behaviour expected of a "reasonably prudent person in the circumstances."[120]

Criminal negligence would generally arise as an issue only in health-care institutions, since a housing facility very likely has no legal duty to safeguard the health of residents by preventing them from using illegal drugs, just as it has no legal duty to prevent them from using legal drugs. A facility that goes beyond simply providing accommodation by providing some additional home support services (but stopping short of medical care) may be in uncertain legal territory.

Secondary liability under the *Criminal Code*

Under Canadian criminal law (which includes the CDSA), a person is guilty of a crime if they actually commit the offence (drug possession, for example). However, even persons who do not actually commit what is called the "substantive" offence (possession) may still have secondary liability – that is, they can still be found guilty of a crime if they are implicated in the offence in certain ways. A person who *conspires* with another person to possess or traffic in drugs will be guilty of a criminal offence.[121] A person who *counsels* another to commit an offence (the possession of an illegal drug, for example) commits a crime.[122] A person is guilty of a crime who does, or omits to do, anything for the purpose of *aiding* any person to commit a crime.[123] As noted earlier, the Supreme Court has ruled that someone who merely aids another in purchasing controlled substances is not guilty of trafficking, but is guilty of aiding or abetting the possession of a controlled substance (which carries a lower maximum sentence).[124] Similarly, someone is a party to (and therefore guilty of) an offence if they *abet* any person in committing a crime (ie, encourage or intend to encourage the offender with acts or words).[125] It is possible that the facility employee who tolerates possession of illegal drugs by a patient/resident could be considered as abetting that offence and therefore be charged as a party to it.[126] (This would be in addition to the possibility of being charged with "joint possession" as discussed above.) Finally, it is remotely possible that an employee of a facility could commit the offence of "receiving, comforting or assisting" a drug offender, knowing of the offender's participation in an offence, for the purpose of enabling the offender's escape; this amounts to the criminal offence of being an *accessory after the fact*.[127]

Liability for not reporting?

Because citizens generally are not compelled by law to perform police functions, it is not a criminal offence to fail to report illegal activities relating to drugs to the police or other authorities. Someone is not an accessory to an offence after the fact simply because they do not disclose to authorities that an offence was committed in their presence.[128]

[119] *R* v *Thornton*, [1993] 2 SCR 445, 82 CCC (3d) 530, aff'g (1991), 3 CR (4th) 381, 1 OR (3d) 480 (Ont CA).

[120] *R* v *Anderson* (1990), 53 CCC (3d) 481 (SCC); *R* v *Barron* (1985), 23 CCC (3d) 544 (Ont CA); *R* v *Tutton* (1989), 69 CR (3d) 289 (SCC); *R* v *Waite* (1989), 69 CR (3d) 323 (SCC); *R* v *Nelson* (1990), 54 CCC (3d) 285 (Ont CA); *R* v *Gingrich* (1991), 65 CCC (3d) 188 (Ont CA); *R* v *Ubhi* (1994), 27 CR (4th) 332 (BCCA).

[121] *Criminal Code*, supra, note 4 at s 465(1)(c).

[122] Ibid at ss 22, 464.

[123] Ibid at s 21(1)(b).

[124] *R* v *Greyeyes*, supra, note 103.

[125] *Criminal Code*, supra, note 4 at s 21(1)(c).

[126] *R* v *Kulbacki*, [1966] 1 CCC 167 (Man CA).

[127] CDSA, supra, note 2 at s 23.

[128] *R* v *Dumont* (1921), 37 CCC 166 (Ont CA).

Furthermore, in the case of health-care workers, although communications from patients are not fully "privileged" (ie, protected from compelled disclosure through criminal or civil legal proceedings),[129] there is a common law duty[130] and a professional obligation[131] to keep such information confidential, subject to breaches of confidentiality either consented to by the patient or "authorized by law." In some provinces, the duty may also be imposed by provincial legislation.

Sometimes, however, non-criminal legislation or policies may impose certain responsibilities on facilities and employees. Provincial laws governing hospitals (or other facilities providing health or other social services), as well as professional codes of conduct, could affect whether employees of facilities can tolerate or allow drug use, possession, or trafficking. As well, allowing or tolerating drug use may violate current facility policies in many instances. This could result in disciplinary action against those involved. It might also result in a refusal of treatment to a drug user, which possibility raises its own legal questions (discussed in greater detail below in response to Issue 3, Treatment).

Also, some provincial legislation imposes reporting requirements, establishing exceptions to the general premise of confidentiality. As an example, in many provinces physicians have a duty under provincial law to report child abuse to authorities.[132] And most provinces require various people (eg, physicians, person in charge of certain institutions such as hospital, prisons, or schools, etc) to report a person's HIV diagnosis; some provinces also require reporting of AIDS diagnoses. Whether reporting is nominal or non-nominal varies, depending on the applicable provincial legislation.[133] In most cases the information that must be reported includes information (if any is received) about the person's injection of (generally) illegal drugs. A summary review of public health statutes across Canada does not reveal any positive obligation on any person (eg, physician, other health-care worker) to report a drug offence by another person to police authorities. However, in some instances, physicians (and possibly other health-care workers, depending on the wording of the legislation) have an obligation to report to public health authorities a person under their care who has a communicable disease and who refuses or neglects to continue "treatment" to the physician's satisfaction (which could include continuing to share injection equipment despite knowing one's HIV-positive status).[134]

Different reporting obligations exist in numerous statutes (or regulations made under statutes) across Canada's various jurisdictions. An exhaustive review of this legislation has not been conducted for this project. However, in the absence of any specific legislation that requires reporting activities relating to illegal drugs, there would be no legal obligation on a facility or person to report drug use, possession, or trafficking to authorities.

In the absence of any specific legislation that requires reporting activities relating to illegal drugs, there would be no legal obligation on a facility or person to report drug use, possession, or trafficking to authorities.

Civil Liability Issues

A facility or employee might face civil liability for allowing or tolerating the possession of illegal drugs. For example, if a hospital allowed a patient to possess (and subsequently use) illegal drugs in the hospital, and the patient suffered harm (eg, an overdose), the hospital might be found liable for negligent care of the patient. The extent of the duty would vary with the type of institution. A hospital or treatment facility staffed by medical personnel would have a greater responsibility toward patients than would a residential facility that simply houses drug users but otherwise offers no assistance to them.

[129] See eg: *John Smith* v *James Jones*, [1999] SCJ No 15 (QL); *Torok* v *Torok* (1983), 38 CPC 52 (Ont Master); *R* v *RJS* (1985), 45 CR (3d) 161 (Ont CA), leave to appeal to SCC refused 61 NR 266; *Hall* v *Hall* (1990), 25 RFL (3d) 394 (Ont HC); *R* v *St-Jean* (1976), 34 CRNS 378 (Que CA).

[130] *Halls* v *Mitchell*, [1928] SCR 125; *Re Inquiry into the Confidentiality of Health Records in Ontario* (1979), 24 OR (2d) 545 (CA); *R* v *Dersch*, [1993] 3 SCR 768; *McInerney* v *MacDonald* (1992), 93 DLR (4th) 415 (SCC).

[131] *St Louis (Litigation Guardian of)* v *Feleki* (1990), 75 DLR (4th) 758 (Ont Ct Gen Div), aff'd on other grounds (1993), 107 DLR (4th) 767 (Ont Div Ct); *Shulman* v *College of Physicians and Surgeons (Ontario)* (1980), 29 OR (2d) 40 (Div Ct).

[132] See the discussion of these and similar reporting requirements in E Oscapella, supra, note 6 at 216-217.

[133] See R Jürgens. *HIV Testing & Confidentiality: Final Report*. Montreal: Canadian HIV/AIDS Legal Network & Canadian AIDS Society, 1998, at 225-237.

[134] See, eg: *Health Protection and Promotion Act*, RSO 1990, c H.7, s 34(1); *Public Health Act*, RSA 1984, c P-27.1, s 49; *Public Health Protection Act*, RSQ 1977, c P-35, s 6.

If a facility were to permit possession (and subsequent use) of illegal drugs, and a patient/resident using such drugs were to injure another person, it might be that the facility could be held liable for negligence in causing, or at least contributing to, the injury.

Similarly, if a facility were to permit possession (and subsequent use) of illegal drugs, and a patient/resident using such drugs were to injure another person, it might be that the facility could be held liable for negligence in causing, or at least contributing to, the injury. Civil lawsuits could be directed against individuals involved (for example, counselors or physicians) or against the facility, or both.

Avoiding Criminal or Civil Liability

Although those who operate facilities could be subject to criminal charges or civil lawsuits, they may have legal defences available to them. In many cases, whether or not criminal or civil liability should be imposed will first depend on the factual circumstances of the particular case. For example, in defence to a civil lawsuit for negligence, a facility might argue that it owed no "duty of care" to the particular plaintiff who was injured, or that the injury suffered by the plaintiff was not a "reasonably foreseeable" consequence of the facility having tolerated drug possession (and use) by a resident/patient.

Beyond a dispute about the application of these legal principles to the facts of a particular case, a facility or employee facing civil or criminal prosecution might claim that allowing the use of illegal drugs was a *necessity* for the treatment of the patient, and/or that, in the circumstances, it would be *negligent to prohibit* possession of a controlled substance by a patient, as this might interfere with essential medical treatment.

Another possible line of defence might be that requiring the health or services facility to carry out the police function of enforcing prohibitions on controlled substances would have the effect of preventing drug-using patients from accessing appropriate health care, infringing on their Charter rights to life, liberty, and security of the person (s 7). It would further have to be successfully argued that this infringement is "not in accordance with the principles of fundamental justice": could it be consonant with such principles to require health-service providers to impose policies effectively denying access to health care to those in need, even in the absence of any risk to other persons? Another constitutional argument might be that requiring such policies on the part of health-service providers, with the disproportionate effect of preventing drug users from access health care, infringes the equality rights provisions of the Charter (s 15). The legal viability of establishing that drug users (or more particularly, users who are dependent on drugs) constitute a group entitled to protection against discrimination on this ground is discussed further below (in response to Issue 3, Treatment). It should be noted that a facility might face an initial difficulty in raising a defence based on the Charter rights of the another person (ie, the patient/resident).

Furthermore, hospitals or other facilities might be able to arrange access to specific drugs under existing legislation, so that drugs that would otherwise be illegal can be allowed or even administered to patients. Health Canada's Special Access Program (formerly the Emergency Drug Release Program) is an example of a program that could prevent criminal charges being brought against those working in facilities.[135]

Additionally, as discussed above, the Minister of Health has the power under the CDSA (s 56) to exempt any person or class of persons from the law. The Act also allows for regulations by Cabinet that could have the same effect (s 55). Thus, current law anticipates exempting certain individuals and groups

[135] *Food and Drug Regulations*, supra, note 34 at s C.08.010.

from criminal penalties. These provisions could be applied to protect facilities that provide care to drug users, and that tolerate possession of illegal drugs, from criminal charges.

Treatment

Enforcing Abstinence As a Condition of Treatment

Identified above in the discussion of Issue 2 (Drug Use and Provision of Health and Social Services) were a number of possible concerns about liability of treatment/service providers for tolerating or facilitating the possession of illegal drugs. But these are concerns about the possible legal consequences for a facility as a result of conduct by residents/patients for which the facility may possibly be held responsible, given its control over the premises and knowledge of the activities. As has been discussed, such fears about liability might be put forward as having some basis in law for facilities' not tolerating possession of controlled substances on their premises.

Issue 3 (Treatment) presents a distinct but related question. There will be many circumstances where a treatment provider does not exercise the degree of control over premises or persons that could possibly give rise to legal liability for tolerating the possession of illegal drugs. In such circumstances (eg, physician in private practice or in a community clinic), does the health-care professional providing treatment to a drug user have any legal basis for *enforcing* abstinence from the use of controlled substances on a person as a condition of providing treatment or services?

Requiring abstinence as a condition of treatment cannot be justified on the basis that the use of controlled drugs is itself illegal, because it is not (although possession of such drugs is, perhaps rendering this distinction insignificant). In any event, the issue of enforcing abstinence is also relevant for legal drugs; abstinence from alcohol or nicotine could also be imposed as a condition of treatment. It should be noted that there has been little suggestion of taking the necessary monitoring steps such as drug testing to enforce abstinence from legal drugs; this suggests it is the "illegal" nature of some drugs that really lies at the root of enforced-abstinence proposals.

In most circumstances, there is little in the way of actual law for compelling abstinence as a condition of providing treatment of or services to a drug user. Significant exceptions to this would be regulations or policies governing certain institutions where there is a general prohibition on the possession of controlled substances (eg, prisons), or restrictions governing the provision of certain health services (eg, methadone maintenance treatment programs, which often require abstinence from use of any other drugs). However, government or institutional policies may also impose abstinence as a condition of access to treatment, residential facilities, or social services. Such policies will have the same effect on the user as would a law; both deprive the user of a service if the user continues to use drugs while seeking treatment. What is the legality of such enforcement of abstinence, given that, in order to be effective, an abstinence condition would need to be enforced through some form of intrusive monitoring (ie, drug testing) that would detect the use of prohibited substances?

Enforced abstinence raises a number of issues examined here: infringements of legally protected autonomy interests; infringements of privacy rights; and, possibly, infringements of equality rights.

Applicability of the Charter

Enforced abstinence raises a number of issues examined here: infringements of legally protected autonomy interests; infringements of privacy rights; and, possibly, infringements of equality rights. The way in which these interests can be legally protected will depend on whether there is some state action underlying the attempt at enforcing abstinence (in which case constitutional rights may be implicated) or whether it is action by a private entity (in which case resort must be had to the common law and statutes applicable to relations between private parties).

Only governments and government action are subject to scrutiny under the Charter, and such constitutional review is not applicable to private parties not connected with government.[136] However, determining whether law, policy, or conduct in a given circumstance constitutes "government action" may sometimes be difficult. For example, the Supreme Court has ruled in the *Stoffman* case that hospitals, in at least some respects, are not part of "government"; as a general rule, their policies or by-laws are thus not subject to Charter scrutiny.[137] However, *Stoffman* left open the possibility that if a particular policy or by-law were instigated by government, or represented the implementation of government policy, then this would attract Charter scrutiny. Subsequently, the Supreme Court has clarified that if a private entity such as a hospital acts in furtherance of a specific government program or policy (including the provision of medically necessary services paid for by the state) then it will be subject to the Charter.[138] Whether or not a particular health-care provider's conduct in enforcing abstinence as a condition of providing treatment will attract Charter scrutiny will depend on the degree to which government retains ultimate responsibility for such a policy or practice.

Absent concern about a patient's mental capacity and the possibility of a patient harming themselves or another, there is no legal mandate for a physician to infringe a patient's bodily freedom to engage in the possession and consumption of illegal (or legal) drugs. It is the function of police, and not physicians, to enforce the penal law prohibiting possession of controlled substances.

Autonomy interests: the right to bodily integrity

The first question raised by action to enforce abstinence from drug use as a condition of medical treatment is whether the infringement of autonomy interests is justifiable. Absent concern about a patient's mental capacity and the possibility of a patient harming themselves or another, there is no legal mandate for a physician to infringe a patient's bodily freedom to engage in the possession and consumption of illegal (or legal) drugs. It is the function of police, and not physicians, to enforce the penal law prohibiting possession of

[136] Charter s 32; *Retail, Wholesale and Department Store Union, Local 580* v *Dolphin Delivery Ltd*, [1986] 2 SCR 573, 33 DLR (4th) 174.

[137] *Stoffman* v *Vancouver General Hospital*, [1990] 3 SCR 483, 76 DLR (4th) 700.

[138] *Eldridge* v *British Columbia (Attorney General)* (1997), 46 CRR 92d) 189 (SCC).

Enforced abstinence forces individuals to disclose information about drug use, information that is not necessarily relevant in the treatment context. It forces individuals to undergo physically intrusive and degrading testing procedures to prove that they have not used the drugs that have been forbidden to them.

controlled substances. If such power were conferred upon physicians or other health-care providers by legislation, it could be subject to constitutional challenge. (This was discussed briefly above with respect to Issue 2, Drug Use and Provision of Health and Social Services.)

For example, this issue has been the subject of some litigation with respect to drug testing in prisons. There is conflicting case law on whether mandatory urinalysis in prisons (with penalties for testing positive for drug use) violates Charter (s 7) rights to not be deprived of liberty and security of the person except in accordance with principles of fundamental justice, and/or Charter (s 8) rights to be free from unreasonable search and seizure. The weight of authority certainly indicates that some objective criteria must exist to justify testing; it is the arbitrariness and lack of procedural due process that is of concern.[139] However, a more recent, appellate decision has upheld random urinalysis in prisons as constitutionally permissible, as infringing neither s 7 nor s 8 of the Charter.[140] Such enforcement of abstinence from controlled substances would likely receive less judicial approval outside the prison context. (As discussed below, drug-testing programs imposed in the workplace have been found to contravene anti-discrimination statutes.)

One specific question is whether pregnant women should be subject to special restrictions to discourage them from using drugs. As already noted, the Supreme Court of Canada recently held that under current law a pregnant woman who had used solvents could not be restrained for the purpose of protecting her unborn child.[141] This appears to run counter to the trend in the United States, where pregnant women have been prosecuted,[142] sometimes successfully, for their drug use.

Even if such power to enforce abstinence were not exercised by "government" or as a result of power conferred by government action such as legislation, but were merely the action of a private person or entity, it is possible that this might not be permissible at common law either. It has been held that our right at common law to bodily integrity and personal autonomy is co-extensive with the constitutional right to security of the person guaranteed by the Charter (s 7).[143] Furthermore, the Supreme Court has indicated that while Charter-rights claims cannot be made directly applicable to the common law in a dispute between private parties, courts should nonetheless ensure that the principles of the common law evolve in a manner that is consistent with "Charter values."[144]

Privacy rights

In addition to representing an infringement of bodily integrity and personal autonomy, enforcing abstinence represents an infringement of a person's privacy. Enforced abstinence forces individuals to disclose information about drug use, information that is not necessarily relevant in the treatment context. It forces individuals to undergo physically intrusive and degrading testing procedures to prove that they have not used the drugs that have been forbidden to them. These testing procedures are physically intrusive in that they require the surrender of a bodily substance. Testing procedures may also require having someone closely watch the individual urinate, surveillance that many would find intrusive, degrading, and humiliating.

International human rights conventions impose the obligation on states not to interfere arbitrarily with the privacy of citizens.[145] Privacy is viewed as a basic right, a right from which some other rights flow. Therefore, privacy should

[139] *Jackson* v *Joyceville Penitentiary* (1990), 555 CCC (3d) 50 (Fed Ct TD) (regulations authorizing prison officials to require mandatory urine samples without any standards or criteria is not in accordance with principles of fundamental justice); *Cruikshanks* v *Canada (Correctional Service)*, [1992] BCJ No 1680 (CA) (QL); *Dion* v *R* (1986), 30 CCC (3d) 108 (Que SC) (principles of fundamental justice may be satisfied if testing is permitted solely when there are reasonable and probably grounds to believe person is impaired).

[140] *Fieldhouse* v *Kent Institution* (1995), 98 CCC (3d) 207 (BCCA).

[141] *Winnipeg Child and Family Services*, supra, note 114.

[142] R Miller. *Drug Warriors and Their Prey: From Police Power to Police State*. Westport: Praeger, 1996, at 174-177.

[143] *Fleming* v *Reid* (1991), 82 DLR (4th) 298 (Ont CA).

[144] *Hill* v *Church of Scientology*, [1995] 2 SCR 1130, 126 DLR (4th) 129.

[145] *Universal Declaration of Human Rights*, Art 12; *International Covenant on Civil and Political Rights*, Art 17.

not be interfered with lightly. Canadian courts have given some consideration to the privacy rights implicated by imposing drug testing. The Supreme Court has ruled that compelling someone to provide a blood or urine sample constitutes an unreasonable search and seizure in violation of the Charter (s 8) because it infringes a reasonable expectation of privacy vis-à-vis personal information that may be disclosed through testing.[146] While lower courts, in earlier decisions, have upheld the compulsory breathalyzer provisions of the *Criminal Code* as constitutionally permissible,[147] the Supreme Court has very strongly stated that the right to privacy includes privacy related to personal information: the Charter protects "the right of the individual to determine for himself when, how, and to what extent he will release personal information about himself."[148]

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Equality rights

Finally, enforcing abstinence through drug testing as a condition of providing medical treatment to drug users may well constitute illegal discrimination against drug-dependent users. Human rights legislation in every Canadian jurisdiction prohibits discrimination in the provision of services on the basis of "disability" (or "handicap" in some statutes) and on the basis of perceived disability. The *Canadian Human Rights Act* specifically defines "disability" to include "previous or existing dependence on alcohol or a drug."[149] The Federal Court of Appeal has expressly confirmed that it would be contrary to the Supreme Court of Canada's interpretation of human rights legislation to limit the definition of disability only to dependence on a "legal" drug; therefore, dependence on illegal drugs also constitutes a disability under federal human rights legislation.[150] Such express recognition of drug dependence as a disability is not necessarily found in the human rights statutes of all provinces. However, the reported case law from human rights tribunals interpreting provincial definitions of "handicap" or "disability,"[151] as well as academic commentary[152] and policy statements[153] from human rights commissions themselves, all indicate that this proposition is seemingly well established in Canadian law.

However, this state of the law only affords protection against discrimination for those users who are actually "dependent" and therefore disabled. A policy or decision to enforce abstinence from illegal drugs as a condition of providing medical treatment would likely constitute impermissible discrimination against those drug users who are disabled, and might therefore be declared illegal. But human rights legislation would presumably not prohibit a policy or decision to enforce abstinence on casual, non-dependent drug users as a condition of treatment.

In the case of governmental action to enforce abstinence as a condition of medical treatment, resort might be had to the Charter's equality provisions as well, although a similar sort of outcome prohibiting discrimination against drug-dependent users could be anticipated. The jurisprudence interpreting human rights statutes' prohibitions on discrimination naturally informs the development of the jurisprudence interpreting the equality provision of the Charter (s 15) and vice versa. Although the issue has not yet been litigated, it would likely be the case that persons dependent on alcohol or drugs would be considered to be a group of persons with a disability against whom discrimination is prohibited by the Charter. But it is doubtful that courts would be willing

[146] *R* v *Dyment*, [1988] 2 SCR 417; *R* v *Collins*, [1987] 1 SCR 265.

[147] *R* v *Altseimer* (1982), 1 CCC (3d) 7 (Ont CA); *R* v *Gaff* (1984), 15 CCC (3d) 126 (Sask CA); *R* v *Kendall* (1982), 17 MVR 231 (Alta Prov Ct); *Curr* v *The Queen*, [1972] SCR 889; *R* v *Holman* (1982), 28 CR (3d) 278 (BC Prov Ct); *R* v *Loewen* (1982), 17 MVR 279 (BC Prov Ct); *R* v *Brown* (1983), 20 MVR 163 (Sask QB).

[148] *R* v *Duarte*, [1990] 1 SCR 30 at 46; see also *R* v *Pohoretsky*, [1987] 1 SCR 945.

[149] RSC 1985, c H-6, s 25, as amended. See also: *Canadian National Railway* v *Niles* (1992), 142 NR 188 (Fed CA).

[150] *Canada (Human Rights Commission)* v *Toronto-Dominion Bank* , [1998] 4 FC 205 (CA).

[151] See, eg: *Entrop* v *Imperial Oil Ltd*, [1996] OHRBID No 30 (Ont Bd Inq) (QL) (alcoholism and substance abuse constitute handicap under Ontario statute), aff'd [1998] OJ No 422 (Div Ct) (QL), leave to appeal to Ont CA granted [1998] OJ No 1927, no Ont CA decision reported; *Handfield* v *North Thompson School District No 26*, [1995] BCCHRD No 4 (BC Council Hum Rts) (QL) (alcoholism is a disability under BC statute).

[152] See, eg: Ontario Law Reform Commission. *Report on Drug and Alcohol Testing in the Workplace*. Toronto: The Commission, 1992.

[153] See, eg: Ontario Human Rights Commission. *Policy Statement on Drugs and Alcohol Testing*. November 1990; Canadian Human Rights Commission. *Policy 88-1: Drug Testing*. Ottawa, 1988.

There is likely little legal justification for withholding medical treatment (including antiretroviral drugs) from HIV-positive drug users simply on the basis that they are persons who use controlled substances. In fact there might be several legal barriers to withholding treatment, although these would likely have to be raised by a drug user in response to the withholding of treatment.

to recognize persons who use illegal drugs as constituting a group of persons who deserve protection from discrimination on the basis of their drug use.

It is certainly arguable that drug users upon whom abstinence is enforced as a condition of receiving medical treatment (through intrusive and demeaning drug testing) have suffered "discrimination" within the meaning of s 15 of the Charter. In its most recent judgment on the interpretation of s 15, the Supreme Court has defined discrimination as differential treatment that imposes a burden (or withholds a benefit) in a manner that reflects the stereotypical application of presumed group or personal characteristics, or that perpetuates or promotes the view that they are less capable or worthy of recognition or value as human beings or as members of Canadian society equally deserving of concern, respect, and consideration.[154]

However, it appears unlikely that Canadian courts will recognize the status of being a user of illegal drugs as a ground "analogous" to those grounds enumerated in s 15 on which discrimination is already prohibited. There is very little Canadian law on this point. In the *Hamon* case (noted earlier), the Quebec Court of Appeal court ruled (with no discussion of the issue) that the prohibition on cultivating and possessing cannabis is not unconstitutional discrimination because "cannabis users are not a class of persons covered by" the equality rights provisions of the Charter (s 15).[155]

Withholding Medical Treatment from HIV-Positive Drug Users

Enforcing abstinence as a condition of providing treatment may, in its ultimate form, amount to withholding medical treatment from HIV-positive drug users. In other circumstances, it may not even be a question of imposing conditions for providing treatment; in some cases, patients known to use illegal drugs (or certain other, legal drugs) may be denied a certain form of treatment altogether.

There is likely little legal justification for withholding medical treatment (including antiretroviral drugs) from HIV-positive drug users simply on the basis that they are persons who use controlled substances. In fact there might be several legal barriers to withholding treatment, although these would likely have to be raised by a drug user in response to the withholding of treatment. These general observations must be qualified with the recognition that there has been relatively little Canadian litigation on this point. A decision to withhold HIV/AIDS treatment from a patient who uses controlled substances could have several legal dimensions.

International human rights

First, *international human rights conventions* protect the right to life, liberty, and security of the person.[156] Similarly, the right to health (the exact content of which is a matter of some debate among jurists) is protected under international law. For example, the *International Covenant on Civil and Political Rights* (Art 12) provides that signatory States "recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health" and that States shall take the necessary steps to create "conditions which would assure to all medical service and medical attention in the event of sickness." The *Universal Declaration of Human Rights* (Art 25) states that everyone has the right to a standard of living adequate for health and well-being, including medical care and necessary social services. These international conventions can be interpreted as obliging signatories to ensure access to

[154] *M* v *H*, [1999] SCJ No 2.

[155] *Hamon*, supra, note 60.

[156] *Universal Declaration of Human Rights*, Art 3; *International Covenant on Economic, Social, and Cultural Rights*, Art 12.

appropriate medical care unless they can justify otherwise. That would mean prohibiting an arbitrary denial of access to medically useful antiretroviral therapy. It is acknowledged, however, that such propositions may have more symbolic value than legal enforceability in most cases.

Charter rights

Second, *Charter rights to equality and security of the person* might be infringed by withholding treatment to drug users (where this was the result of government legislation or action of some sort). The issues raised by a possible Charter s 15 claim have been discussed above. The Supreme Court has ruled that government action denying equal access to medical treatment to persons with disabilities is unconstitutional.[157] Withholding treatment from a person with the disability of drug dependence would likely violate constitutional equality rights and have to be satisfactorily justified under s 1 of the Charter. However, this protection would likely not extend to non-dependent drug users.

Similarly, withholding treatment might violate the Charter s 7 right to life, liberty, and security of the person and the right not to be deprived of this right "except in accordance with the principles of fundamental justice." In striking down the former *Criminal Code* restrictions on women's access to abortion, the Supreme Court ruled in the leading *Morgentaler*[158] case that state interference with bodily integrity constitutes a breach of security of the person;[159] that the right to security of the person must include a right of access to medical treatment for a condition that represents a danger to life or health without fear of criminal sanction;[160] and that the right to liberty is the right to make fundamental personal decisions without interference from the state.[161] In the more recent *Wakeford* case,[162] an Ontario trial court concluded that denying an HIV-positive man the medicinal benefit of marijuana constituted an infringement of his right to security of the person that did not accord with the principles of fundamental justice, because there was no process by which he could obtain effective Ministerial review of his application to be exempt from the criminal prohibition on marijuana possession. These cases both indicate that governmental action withholding medical treatment (even where that treatment consists of an illegal drug) may constitute a prima facie infringement of Charter s 7 rights.

However, Charter rights are not absolute, and are guaranteed "subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society" (s 1). In assessing whether a government can demonstrably justify denying treatment to HIV-positive drug users, the courts will assess whether (i) the government objective in denying treatment is sufficiently important to warrant infringing constitutional rights; (ii) the government action taken in withholding treatment is rationally connected to its stated objective; (iii) the means chosen to pursue the government objective "minimally impair" the constitutional right(s) being infringed; and (iv) there is a proportionality between the harmful effects of the government action infringing constitutional rights and the importance of the objective.[163] It is suggested that, applying this test,

> it will be difficult for a government to justify any action that withholds medications to HIV-positive people simply on the basis that they consume controlled substances. Rather, a rational medical basis for any particular decision to withhold treatment would have to be shown.

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[157] *Eldridge*, supra, note 138.

[158] *R* v *Morgentaler, Smoling and Scott*, [1988] 1 SCR 30, 37 CCC (3d) 449.

[159] Ibid, per Dickson CJC and Lamer J.

[160] Ibid, per Beetz and Estey JJ.

[161] Ibid, per Wilson J.

[162] *Wakeford*, supra, note 32.

[163] *R* v *Oakes*, [1986] 1 SCR 103.

Human rights codes

Third, *human rights codes* also prohibit discrimination in the provision of services on the basis of mental or physical disability and are applicable to both government and private actors. As has been noted, the existing case law indicates that a person with a drug dependency or even a perceived drug dependency would generally be included as having a "disability" (or "handicap" in some legislation). The refusal to provide HIV/AIDS treatment to a drug-dependent user would certainly constitute prima facie discrimination prohibited by legislation. As with the Charter, the protection against discrimination is not absolute; depending on the circumstances, it may be possible to offer some bona fide justification for discriminating on the basis of disability.

Codes of professional conduct

Fourth, *codes of professional conduct* requiring a health-care provider to act in the best interests of the patient might also prevent them from withholding treatment from HIV-positive drug users. However, it must be acknowledged that determining the best interests of the patient will (or should be) largely a good-faith exercise in medical judgment that takes into account the possible clinical outcomes of prescribing a given medication to a patient in the knowledge that it will or may interact with other drugs (legal or prohibited) being consumed by the patient. However, professional codes of conduct also acknowledge that ultimately it is the patient who must make an informed decision about treatment options.

Criminal liability

Fifth, withholding access to HIV/AIDS medications might also constitute *criminal negligence causing bodily harm or death*. As noted earlier, a person is criminally negligent if, in doing something or in omitting to do something they have a legal duty to do, their conduct shows a "wanton or reckless disregard for the lives or safety of patients." Health authorities and physicians have a duty to safeguard and promote the health of patients. Denying access to therapy could arguably meet the test for "wanton or reckless disregard," which has been defined as a "marked departure" from the standard of behaviour expected of a "reasonably prudent person in the circumstances." Again, depending on the parameters of the policy, regulation, or decision to withhold HIV/AIDS medications from an individual or class of individuals, and the medical evidence offered to justify such withholding, a finding of criminally negligent conduct resulting in injury to patients might be possible. Or the evidence may show that denying a particular treatment to a particular patient was the responsible medical decision, and that providing the medication in the knowledge that the patient would also consume another substance (eg, heroin, cocaine) would itself have been negligent.

In the case of prison authorities or others who have charge over an HIV-positive person who is unable to withdraw themselves from that charge by reason of detention, illness, or mental disorder, withholding medications for treatment of HIV/AIDS "without lawful excuse" likely also constitutes the criminal offence of *failing to provide the necessaries of life*,[164] since medical treatment tending to preserve life has been ruled to be a "necessary of life."[165]

[164] *Criminal Code*, supra, note 4 at s 215.

[165] *R* v *Cyrenne* (1981), 62 CCC (2d) 238 (Ont Dist Ct); *R* v *Tutton* (1985), 14 CRR 314 (Ont CA), aff'd (1989), 48 CCC (3d) 1 (SCC).

Possible justifications for withholding treatment

Finally, two *possible justifications* for withholding HIV/AIDS treatment from drug users need to be considered. First, it might be argued that a course of antiretroviral therapy, if not followed consistently, would allow resistance to the therapy to develop. (There is a precedent for this argument with multiple-drug-resistant tuberculosis.) This in turn would reduce the effectiveness of the therapy for both the patient and others in future. On this ground, authorities or health-care providers might argue that it is permissible to refuse certain therapies to someone if they have reason to believe that the person will not follow the course of therapy and may thereby put themselves or others at risk.

However, to justify denying treatment, it would be necessary to show that a given drug user – or any other potential recipient of the therapy – is likely to cause harm to themselves or others by failing to follow the therapeutic regimen. As an alternative, it might be possible to argue that denial of therapy is not appropriate but that strong action is warranted to ensure that those who consent to receiving the therapy agree to follow its course, possibly through some form of intensive monitoring, as is done with tuberculosis. Thus, this is not an issue relating strictly to drug users; it is an issue for anyone who might fail to follow a physician's orders with any course of therapy that might lead to resistant strains of viruses or bacteria.

Second, those providing treatment may well have concerns about possible civil or criminal liability in negligence if they prescribe medications to a patient whom they know is using certain drugs (legal or illegal) that may adversely react with the prescribed medications, causing injury to the patient. Certainly doing so without taking adequate care to explain possible interactions to the patient would constitute professional negligence. But if all known "material risks," including interaction with controlled substances, were explained to the patient, and that patient has the mental capacity to make their own medical decisions with regard to this treatment, then the patient's "informed consent" to the treatment is obtained and the health-care provider is not civilly liable for the patient's decision to take these risks.[166] Similarly, it would be unlikely that a physician taking such steps could be found criminally negligent, as there would be no wanton or reckless disregard for the patient's life or safety.

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[166] *Reibl* v *Hughes*, [1980] 2 SCR 880; *Hopp* v *Lepp*, [1980] 2 SCR 192; *Malette* v *Shulman* (1990), 37 OAC 281 (CA); *Fleming* v *Reid*, supra, note 143; *Van Mol* v *Ashmore*, [1999] BCJ No 31 (CA) (QL).

Prescription of Opiates and Controlled Stimulants

What legal issues must be considered in prescribing opiates and controlled stimulants to drug users in Canada?

Possible liability of the prescribing physician

Criminal liability

The CDSA and the Narcotic Control Regulations forbid medical practitioners (persons registered and entitled under the laws of a province to practise medicine) from administering, prescribing, giving, selling, or furnishing a narcotic to any person except as allowed by the Regulations (s 53 in particular).[167] The Regulations[168] further provide that:

- Where the Minister of Health "deems it to be in the public interest, or in the interests of science," the Minister may authorize (in writing and subject to conditions) any person to possess a narcotic.
- The Minister may also authorize a practitioner to provide methadone to a person under their treatment, or to provide a narcotic (other than heroin) to any person who is also authorized by the Minister to possess a narcotic.
- A person in charge of a hospital may permit methadone to be supplied or administered to an in-patient or out-patient of the hospital, upon receipt of a prescription or written order signed and dated by a practitioner who is authorized by the Minister to prescribe methadone.
- A practitioner may only provide heroin to a patient of a hospital.
- Apart from these restrictions, a practitioner is permitted to prescribe a narcotic only to a patient under their professional treatment, and only if the

[167] Supra, note 6 at s 53.

[168] Ibid at ss 53, 65 & 68.

> narcotic is required for the condition for which the person is receiving treatment.

Thus, there are some carefully circumscribed situations in which practitioners can prescribe narcotics, including opiates, although the prescription of heroin is severely restricted. In situations where the physician has no right to prescribe, penalties for prescribing may flow under the Regulations. In addition, if the physician actually possesses a drug and gives it to a patient (or offers to give it) when the physician has no legal right to possess the drug, the physician may commit three offences under the CDSA – possession, possession for the purposes of trafficking, and trafficking. A physician also commits the offence of trafficking where the physician "sells an authorization" to obtain a controlled substance, or offers to sell such an authorization.[169] Even if not charged with a substantive drug offence, a physician could still face criminal liability for counseling, abetting (ie, encouraging), or aiding someone to commit an offence under the CDSA.

Civil liability

Physicians can be civilly liable for negligent medical treatment. Prescribing an inappropriate drug could constitute negligence. Theoretically, a physician who prescribed opiates (or any other substance, illegal or legal) could be civilly liable if the drug caused the patient harm. As with almost any prescription medication, there is a risk of harm to the patient if the drug is used improperly – sleeping pill overdoses, for example. However, some negligence on the part of the physician in prescribing would have to be shown,[170] regardless of what drug is being prescribed. In other words, the physician must have failed to have a reasonable degree of skill and knowledge, or have failed to exercise the degree of care that could reasonably be expected of a normal, prudent practitioner. Failing to explain any known "material risks"[171] of the medication to the patient or prescribing medication in a fashion that caused "reasonably foreseeable" injury to the patient would amount to negligent practice. Where dangerous drugs are being used[172] or a patient merits special supervision,[173] a higher standard of care will apply to the physician. However, the care that must be exercised by the physician depends upon the nature of the drug itself and of the patient to whom it is prescribed, not on the fact that a drug is classified as legal or illegal. A physician who prescribed opiates or other controlled substances should not be liable if the patient uses the drug in a manner other than that prescribed, unless the physician has reason to believe that the patient will attempt to use the drug in a way not medically indicated or does not have the mental capacity to use it properly.

Civil liability could arise in another context. Using a drug prescribed by a physician, a patient might become impaired or violent and cause harm to others. A physician might, in extreme situations, face civil liability. However, physicians have long prescribed drugs that could lead to harm to others in certain circumstances – sedatives, for example. A physician would likely not be held liable for the actions of a patient who injured someone while driving under sedation, unless the physician had reason to believe that the patient would act irresponsibly or failed to warn the patient of the possible impairment from using the drug. Again, the same arguments about potential civil liability should apply to all drugs prescribed by a physician, regardless of whether they are legal or illegal.

[169] CDSA, supra, note 2 at s 2(1).

[170] See, eg, *Dube Estate* v *Kozma*, 11 December 1987, Doc 8841/83 (Ont HC), aff'd 11 May 1990, Doc CA 89/88 (CA).

[171] *Reibl*, supra, note 166; *Hopp*, supra, note 166.

[172] *Male* v *Hopmans* (1967), 64 DLR (2d) 105 (Ont CA).

[173] *University Hospital* v *Lepine*, [1966] SCR 561; *Worth* v *Royal Jubilee Hospital* (1980), 4 *Legal Medical Quarterly* 59 (BCCA).

Constraints Imposed by International Law

Canada's status as signatory to the three international drug conventions described above does not present an insurmountable barrier to the prescription of controlled substances to drug users.

Canada's status as signatory to the three international drug conventions described above does not present an insurmountable barrier to the prescription of controlled substances to drug users. As noted in a 1995 presentation to the Australian Standing Senate Committee on Legal and Constitutional Affairs, notwithstanding that Australia is a signatory to both the 1961 Convention and the 1988 Vienna Convention, the [Australian] National Centre for Epidemiology and Population Health, after extensive study, reported that pilot heroin-maintenance projects would not violate Australia's obligations under either convention.[174] Indeed, latitude arguably exists within the terms of those conventions that would similarly permit Canada to authorize practitioners to prescribe controlled substances.

For example, the 1988 Vienna Convention specifies that States' obligations to criminalize possession or trafficking in prohibited drugs are undertaken subject to a State's "constitutional principles" and the "basic concepts of its legal system," and that the description of offences and legal defences is reserved to the domestic law of the State.[175] The 1961 Convention contemplates the possible medical purposes of the distribution, use, and possession of drugs (Art 4). Furthermore, the 1961 Convention and the 1971 Convention both require States to "give special attention to and take all practicable measures" to prevent the abuse of drugs and to provide treatment, education, aftercare, rehabilitation, and social reintegration of drug users.[176] Canada could conclude that the regulated prescription of controlled substances may form one component of a harm-reduction approach to providing treatment, care, rehabilitation, and social reintegration of drug users.

Finally, it remains open to Canada to "denounce" its obligations under these treaties if these obligations are considered to pose a barrier to implementing regulated prescription of controlled substances as a harm-reduction measure. All three drug treaties contain denunciation provisions, and this course of action has been recommended to the federal government as an opportunity to demonstrate leadership in adopting a harm-reduction approach to drug use.[177] As is the case with many of the issues discussed in this paper, what is required is a modicum of legal innovation and, more important, the political will to create a legal and policy environment that is conducive to protecting and promoting the health of all Canadians (including those who use currently illegal drugs) rather than one that continues to pursue failed policies of prohibition and punishment.

[174] G Gilmour. The International Covenants "Prohibiting" Drug Activities. Paper presented to the Standing Senate Committee on Legal and Constitutional Affairs, 14 December 1995, at 7.

[175] Art 3.

[176] 1961 Convention, Art 38; 1971 Convention, Art 20.

[177] Presentation of J Conroy, Chair, Canadian Bar Association – Criminal Law Section (Committee on Imprisonment and Release), before the Standing Senate Committee on Legal and Constitutional Affairs, 28 March 1996.

Drug Users and Studies of HIV/AIDS Drugs and Street Drugs

What legal issues relate to the absence of studies of the impact of street drugs on the immune system; the absence of studies of interactions between HIV/AIDS drugs and street drugs; and the exclusion of drug users from studies of HIV/AIDS drugs?

Introduction

As the discussion below indicates, while there is a legal basis for *authorizing* medical research into the effects of street drugs, there is little legal basis for imposing on anyone a positive *duty* to conduct medical research. At best, it might be possible to legally challenge a refusal to permit or enable research involving illicit drugs. However, once undertaken, medical research is governed or affected by law or other forms of policy; legal and ethical considerations must be taken into account in research design and there may be a basis on which to seek a remedy for the exclusion of drug users from studies of HIV/AIDS drugs.

Legal Authority to Conduct Research

Exemption from criminal liability is warranted

Does the illegal status of street drugs present a barrier to research into their effects on the immune system or their interaction with HIV/AIDS drugs? Conducting such studies will involve obtaining, transferring, delivering, administering, or possessing illegal drugs. Unless there is a specific legislative exception, the CDSA makes it a crime to possess, administer, transfer, sell, or deliver a controlled substance. Some may argue that the illegality associated

The illegality of a drug has not necessarily been a bar to research in the past, nor should it be a bar now.

with using street drugs justifies the absence of studies on the impact of street drugs on the immune system. In fact, many research programs have involved illegal drugs. The illegality of a drug has not necessarily been a bar to research in the past, nor should it be a bar now.

Realistically, the likelihood of professional researchers being prosecuted for dealing with illegal drugs in the course of research may be relatively small. What is warranted, however, is exemption from the application of the criminal law for the purposes of research, in order to avoid technical breaches. Canadian law already provides for the possibility of such exemptions. The CDSA contains provisions that permit both the federal Cabinet and the Minister of Health to ensure that medical researchers investigating the effects of illegal drugs, and the participants in the research, are not exposed to criminal liability.

Activities such as possession, transferring, delivering, administering, or selling controlled substances as part of a research study could and should be exempted from the application of the Act.

Cabinet may make regulations under the Act that govern the importation, production, delivery, sale, provision, administration, or possession of a controlled substance. Regulations may also specify a person or class of persons to whom they apply.[178] The federal Minister of Health has the authority to exempt any person or class of persons, or any controlled substance (ie, illegal drug or item containing residue of an illegal drug) from the application of the Act or regulations made under it. The Minister can do this is s/he is of the opinion that the exemption "is necessary for a medical or scientific purpose or is otherwise in the public interest."[179]

The illegal status of drugs also raises another concern for researchers and study participants: what confidentiality is there in the information made available to researchers?

The power therefore lies within the legislation to make lawful what would otherwise be unlawful. Activities such as possession, transferring, delivering, administering, or selling controlled substances as part of a research study could and should be exempted from the application of the Act. As a result, researchers could, at least in theory, obtain the necessary legal exemptions under the CDSA to conduct research of the types identified above. Similarly, those who participate in the research could be exempted from the provisions of the Act. Indeed, the federal Minister of Health has recently announced that Canada will authorize clinical trials of marijuana, and that exemptions have been granted to two Canadians for the possession and cultivation of marijuana for medical purposes.[180] When research has received the necessary institutional and review board approval, the necessary protection from prosecution could and should be given to researchers and participants through either Cabinet regulation or ministerial exemption.

Confidentiality concerns as a barrier to research

The illegal status of drugs also raises another concern for researchers and study participants: what confidentiality is there in the information made available to researchers? Drug users might fear that a loss of confidentiality could imperil their employment or access to services such as insurance. Drug users, already a group targeted by law enforcement, may also be reluctant to participate in studies for fear of having information about their drug use being accessible to police. For example, in March 1999 questions were raised in the media as to how police officers were aware of the identity of persons registered in methadone maintenance programs.[181]

At present, records must be disclosed to the police if the police have a warrant to obtain them. Even the promise of confidentiality offered by the researchers cannot prevent the police or other state agencies from obtaining such information under a warrant. While the common law and provincial statutes establish a duty of confidentiality on health-care professionals, there is not

[178] CDSA, supra, note 2 at s 55(1)(a), (b).

[179] Ibid at s 56.

[180] News Release, supra, note 32; McIlroy, supra, note 32; Medical marijuana approved. *The Globe and Mail*, 10 June 1999.

[181] See eg: T Appleby. Methadone users say program lists available to police. *The Globe and Mail*, 15 March 1999, A3.

an absolute "privilege" protecting the confidentiality of information received by the professional, and the confidentiality is always subject to disclosure where "required by law" (meaning both legislation and the common law).

The only possible limitation on this power to obtain records would come from sections 7 and 8 of the Charter, which respectively deal with the rights to "life, liberty and security of the person, and the right not to be deprived thereof except in accordance with the principles of fundamental justice" and the "right to be secure against unreasonable search or seizure." These two sections have been interpreted by courts to offer privacy in the context of a criminal prosecution, and might also be extended beyond the criminal sphere over time.[182] While one provincial statute prohibits the disclosure of information provided to a medical "research group" in civil proceedings of various kinds, it offers no statutory protection against compelled disclosure for use in a criminal proceeding.[183] Courts may yet be called upon to fully adjudicate the question of whether participants' reasonable expectations of privacy, and society's interest in effective research that requires protecting the confidentiality of research files, are outweighed by society's interest in enforcing laws criminalizing drug use.

However, given that the law likely does not fully protect this sensitive personal information, researchers might consider using anonymous data to the extent possible, so as to reduce the likelihood of research files constituting evidence in criminal drug prosecutions. Specific regulatory or ministerial exemption from liability under the CDSA could perhaps also offer a mechanism for ensuring that study participants need not be concerned about criminal liability resulting from the creation of research data showing their possession of illegal drugs.

Legal Duties in Conducting Research

The discussion above focuses on whether legal *authority* exists to conduct research involving currently illegal drugs. However, there is no positive legal *duty* to conduct research on the impact of street drugs on the immune system and on interactions between HIV/AIDS drugs and street drugs, which studies could yield information of clinical benefit to drug users. While federal and provincial Ministers of Health are empowered by legislation to conduct research[184] and, as noted above, may grant legal authorization to others to enable research dealing with illicit drugs, it is doubtful whether the broadly worded statutory mandates of health officials to "promote and preserve" the health of Canadians[185] could or would be judicially interpreted as imposing positive obligations on government to conduct specific kinds of research.

However, the law does regulate the manner in which research is conducted. The 1998 *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* offers the following observations:

> The law affects and regulates the standards and conduct of research involving human subjects in a variety of ways, such as privacy, confidentiality, intellectual property, competence, and in many other areas. Human rights legislation prohibits discrimination on a variety of grounds. In addition, most documents on research ethics prohibit discrimination and recognize equal treatment as fundamental.

[182] For example, *R* v *Morgentaler, Smoling and Scott*, supra, note 158; *Hunter* v *Southam*, [1984] 2 SCR 145; *R v Edwards*, [1996] 1 SCR 128; *R* v *Plant*, [1993] 3 SCR 28; *R* v *Pohoretsky*, supra, note 148; *R* v *Dyment*, supra, note 146.

[183] *Evidence Act*, RSBC 1996, c 124, ss 51 & 57.

[184] See, eg, Ontario's *Ministry of Health Act*, RSO 1990, c M.26, s 6(2).

[185] See, eg: *Department of Health Act*, RSC 1985, c H-32, s 4; *Ministry of Health Act*, supra, note 184 at s 6(1).

The mere fact that a person engages in criminal activity does not necessarily bear any rational connection to whether they should be eligible for participation in medical research.

Without a rational medical basis – such as a known or reasonably suspected contraindication for combining the medication under study with an illegal drug – the ethical justification for excluding drug users from research studies is weak and unpersuasive.

> REBs [research ethics boards] should also respect the spirit of the *Canadian Charter of Rights and Freedoms*, particularly the sections dealing with life, liberty and the security of the person as well as those involving equality and discrimination....
>
> However, legal and ethical approaches to issues may lead to different conclusions. The law tends to compel obedience to behavioural norms. Ethics aim to promote high standards of behaviour through an awareness of values, which may develop with practice and which may have to accommodate choice and liability to err.[186]

Given that legal principles are applicable to the manner in which research is conducted, there may be some room for advancing the health interests of drug users in generating scientific data on the effects of illicit drugs and their interaction with other medications. It might be possible to resort to the Charter or human rights statutes to challenge the exclusion of drug users from studies of medications prescribed for people with HIV/AIDS or other illness, and to challenge the refusal of government authorities or private institutions to permit research involving illegal street drugs.

Exclusion of drug users from research studies

Should the fact of drug use, often the use of illegal drugs, preclude individuals from the benefits of a modern health-care system, such as participation in studies and access to medical treatments? The Drug Reform Coordination Network (DRCNet) recently reported the case of a US man with hepatitis who died after being denied a liver transplant because he was using marijuana to combat severe appetite and weight loss.[187] Having first been accepted, he was later dropped by a liver- transplant program that demanded he pass a drug test for marijuana. According to DRCNet: "Even though many patients find medical marijuana is useful – not only for weight gain, but also for helping to avoid drugs that are toxic to the liver – it is banned in most transplant programs."[188]

The same type of reasoning might be applied to participation in various research studies: the person is using illegal drugs and is therefore not worthy of inclusion as a research participant. However, the mere fact that a person engages in criminal activity does not necessarily bear any rational connection to whether they should be eligible for participation in medical research. Persons accused or convicted of criminal offences are subject to penalty in accordance with the criminal law, and there is no ethical basis for further punishment by exclusion from medical research simply on this basis. Such exclusion is an example of one barrier to drug users' treatment that reflects the punitive and marginalizing message of declaring drug use a criminal offence: drug users are "bad" and deserve (further) punishment on this basis. Furthermore, many commentators have argued that some drugs have been arbitrarily prohibited and that the legal regime for regulating some drugs is based not on rational pharmacology but on prejudice, misunderstanding, and self-interest.[189]

Without a rational medical basis – such as a known or reasonably suspected contraindication for combining the medication under study with an illegal drug[190] – the ethical justification for excluding drug users from research studies is weak and unpersuasive. The Tri-Council Policy Statement addresses discrimination in research as primarily an ethical, not a legal, issue.[191] However, the ethical approach is to be informed by the law; adverting to the Charter and human rights legislation (discussed below), the Statement concludes that, with respect to research on living individuals, because of their

[186] Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada. *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. Ottawa: Public Works and Government Services Canada, August 1998, at i.8.

[187] *The Week Online with DRCNet*, Issue #71, 18 December 1998, archived at <www.drcnet.org>.

[188] Ibid.

[189] See, eg: CN Mitchell. *The Drug Solution: Regulation Drugs According to Principles of Efficiency, Justice and Democracy*. Ottawa: Carleton University Press, 1990.

[190] See, eg: L Garrett. A dangerous mix revealed: HIV therapy, drugs a danger. *Newsday*, 4 February 1999; SR Hosein. Methadone dose adjustment needed with nevirapine. CATIE *Treatment Update* May 1999; 11(3); Nevirapine interacts with methadone and may induce opiate withdrawal. Reuters Health Information Services, 3 June 1999.

[191] Tri-Council Statement, supra, note 186 at Section 1, Part F, Ethics and the Law.

involvement in "generic activities," researchers are not to discriminate in their choice of subjects unless a valid reason exists for doing so.[192] The Statement elaborates that the principle reflects the ethical notion of distributive justice.

Charter considerations

One might argue that the exclusion of drug users from various studies is in breach of the Charter guarantees of equal protection and equal benefit of the law (s 15) and of the rights to life and security of the person and the right not to be deprived of these except "in accordance with the principles of fundamental justice" (s 7).

However, the Charter generally applies only to government institutions (s 32); constitutional review is not applicable to a private entity unless, "by its very nature or in virtue of the degree of governmental control exercised over it," it can properly be characterized as "government."[193] The extent of the Charter's reach into the quasi-public sector, such as hospitals and universities that might be conducting research into HIV/AIDS drugs, is the subject of an evolving debate, and the parameters of the jurisprudence in this area do not yet reveal any clear principles. The Supreme Court has stated that, as a general rule, hospital policies and by-laws do not represent government action and therefore are not subject to Charter scrutiny.[194] A policy regarding the conduct of clinical trials of HIV/AIDS drugs might, therefore, not be vulnerable to constitutional challenge. However, the Court has indicated that if a particular policy or by-law were instigated by government or represented the implementation of a government program or policy (such as the publicly funded provision of medically necessary services), this would attract Charter review.[195]

Furthermore, it would likely only be open to *drug-dependent* users to claim a breach of their equality rights because s 15 of the Charter prohibits discrimination on grounds either enumerated in the section or analogous to those enumerated. Drug-dependent users are recognized as having a "disability" and would therefore be entitled to Charter protection against discrimination on this basis.[196] The mere status of being a drug user, however, is likely not included within the ambit of the Charter's equality guarantee.[197]

Finally, even if the Charter were held to apply, the rights guaranteed are not absolute and may be subject to "such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society" (s 1). In many cases it would be difficult for researchers or an institution to establish that the exclusion of drug users is "prescribed by law" (and if they were to establish this, it would be difficult to simultaneously maintain that there is no "government" action to be subject to Charter review).

Given the uncertain scope of the Charter's application and questions about whether infringements of Charter rights might be "justifiable," it cannot be firmly concluded that the Charter prevents researchers from excluding drug users from research studies.

It cannot be firmly concluded that the Charter prevents researchers from excluding drug users from research studies.

Human rights statutes

Compelling researchers to comply with these principles must instead be left to federal and provincial human rights legislation, which applies to both the public and private sectors. It is generally accepted in Canadian law that drug dependence constitutes a "disability" or "handicap" within the meaning of federal and provincial human rights statutes that prohibit discrimination on this basis.[198] Non-dependent drug users would not be included within the scope of

[192] Ibid, Article 5.1 and commentary.

[193] *Eldridge*, supra, note 138.

[194] *Stoffman* v *Vancouver General Hospital*, supra, note 137.

[195] Ibid; *Eldridge*, supra, note 138.

[196] See cases cited in note 151 and accompanying text.

[197] *Hamon*, supra, note 60.

[198] *Entrop* v *Imperial Oil Ltd*, supra, note 151; *Canada (Human Rights Commision)* v *Toronto-Dominion Bank*, supra, note 150; *Handfield* v *North Thompson School District No 26*, supra, note 151; Ontario Human Rights Commission, supra, note 153; Canadian Human Rights Commission, supra, note 153.

the statute. However, these statutes prohibit discrimination on the specified grounds in specific areas such as accommodation, employment, and services. In order to succeed against a research body with a human rights complaint of discrimination based on the disability of drug dependence, the complainant would need first to convince a tribunal or court that the research body was providing a "service" within the meaning of the statute. (See also the related discussion above of the legal consequences of withholding medical treatment from HIV-positive drug users.)

Refusal to permit research into illegal drugs

Such arguments invoking the Charter and human rights statutes might be more plausibly and effectively used to challenge the refusal of government authorities or private research entities to fund certain kinds of studies. For example, once a publicly funded hospital has decided to fund research in a given area, a systematic refusal to fund research into the effects of drugs on people with a certain disability (drug dependence or perceived dependence) could be considered discrimination based on disability. The Supreme Court ruled in the *Eldridge*[199] case that a hospital's failure to provide sign-language interpreters for deaf patients as an insured benefit covered by BC's public health insurance plan amount to unconstitutional discrimination on the basis of disability. The Court made it clear that a distinction need not be intended to disadvantage persons on the basis of a prohibited ground in order to breach the Charter equality guarantee; it is sufficient if the policy or action being challenged has the "adverse effect" of denying someone the equal benefit or protection of the law on a prohibited ground. This approach has also been adopted in the case law interpreting human rights statutes, recognizing that discriminatory intent cannot be the sole consideration, and that the focus must instead be on the discriminatory effect of policies or practices.

Apart from the possibility of relying on this "adverse effect" discrimination argument, it seems unlikely that human rights legislation could be used to compel studies to be undertaken. Typically, whether a particular research study is undertaken depends on the interests of the researchers and the availability of funding, not on any *legal* obligation to conduct the study. The only clear legal obligation to perform research relating to drug users would have to come from specific legislation – for example, legislation requiring a research body to examine the interaction between street drugs and HIV/AIDS medications. In any event, the lack of scientific feasibility of some studies might make the question of legal obligations to perform such studies moot.

[199] *Eldridge*, supra, note 138.

Information about the Use and Effects of Illegal Drugs

What legal mechanisms exist for ensuring that health-care providers, drug users, and the general public have accurate and complete information about the use and effects of street drugs?

Introduction

Given the nature of law, this question is of necessity approached circuitously. The law sets obligations that apply to people or entities, and then imposes liability for failing to meet those obligations. However, the law can only operate if it governs the conduct of specific parties, and it is only by imposing penalties for improper conduct that it can seek to encourage proper conduct.

Therefore, in responding to the question of how to ensure that health-care providers, drug users, and the general public have accurate and complete information about street drugs, the following discussion centres on the possible legal ramifications of either providing inaccurate or incomplete information, or of providing no information when there is or may be a legal duty to do so. This discussion first considers possible criminal and civil liability of information providers generally speaking (with reference to specific examples, such as physicians). This is followed by a brief discussion of specific obligations imposed on government that might provide an additional foundation for imposing criminal or civil liability for misinformation.

In many cases, the issue will not be the deliberate spread of misleading information, but rather the spread of misinformation through ignorance or negligence. Another enduring practical difficulty with trying to find a legal remedy against individuals for misinformation about street drugs and their effects is the contentious nature of scientific information surrounding street

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drugs. Many will argue that the information they communicate about drugs is accurate, according to the scientific information they have at their disposal. Thus, the issue of negligent or deliberate spread of misinformation will revolve around a debate on scientific issues. Because there is such a range of "scientific" views about drugs, it may be difficult to claim successfully that a person has misinformed someone else either deliberately or negligently. Furthermore, prosecutors may be reluctant to pursue cases of alleged "criminal" misinformation, particularly if the cases involve government officials or if the information that is potentially the subject of the prosecution reflects the position of their government on the "facts" surrounding drugs. One must therefore not be too optimistic about using the law to address a failure to provide accurate information about street drugs and their effects.

Criminal Liability

Deliberate or negligent misinformation, when one is dealing with drug users, can lead to harm, including death. For example, telling a drug user that it is safe to share a syringe that has been washed in soap and water would expose the user to the possibility of disease. A person providing incorrect information such as this might violate the *Criminal Code* in a number of ways.

Spreading false news

Prior to 1992, the *Criminal Code* (s 181) made it an offence for a person to wilfully publish a statement, tale, or news that the person knows is false and that causes or is likely to cause injury or mischief to a public interest. However, in a case involving the hate publication of antisemitic materials denying the occurrence of the Holocaust, the Supreme Court of Canada ruled that this provision violated the guarantee of freedom of expression under the Charter (s 2) and was therefore of no force and effect.[200] In addition to striking out this section of the *Criminal Code*, the approach adopted in the *Zundel* case suggests that attempting to legislatively prevent ordinary citizens – that is, citizens who have no professional or statutory duty to communicate accurate information – from spreading misleading information might generally be seen as impermissibly infringing constitutionally protected freedom of expression.

Conveying false messages

Criminal liability for deliberately conveying misinformation might be imposed under the *Criminal Code* provision making it an offence to convey false messages. According to the Code (s 372(1)), everyone who "with intent to injure or alarm any person, conveys or causes or procures to be conveyed by letter, telegram, telephone, cable, radio or otherwise information that he knows is false is guilty of an indictable offence and liable to imprisonment for a term not exceeding two years." This section might also be vulnerable to a Charter challenge as impermissibly infringing freedom of expression. However, the rights and freedoms protected by the Charter are not absolute, and are subject "to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society" (s 1). Thus, the prohibition in section 372 of the *Criminal Code* against deliberately spreading false information with intent to injure or harm might be considered an acceptable limitation on the right to freedom of expression. However, a difficulty would remain in proving that the accused person conveyed (a) information they *knew* to be false, and (b) with the deliberate intent of injuring or alarming someone. As noted, in most

[200] *R* v *Zundel*, [1992] 2 SCR 731.

circumstances this is unlikely to be the case. Rather, misinformation is more likely to have been conveyed in ignorance of its falsity. The question in such cases is whether the ignorance arose out of negligence on the part of the person conveying the inaccurate information, and whether that negligence gives rise to merely civil liability, or if it may amount to criminally negligent conduct as well.

Criminal negligence causing death or bodily harm

Failure to provide accurate information, or the deliberate provision of inaccurate information that causes death or bodily harm, could amount to criminally negligent behaviour. The *Criminal Code* (s 219) states that every one is criminally negligent who, in doing anything or in omitting to do anything that it is his duty to do, "shows wanton or reckless disregard for the lives or safety of other persons." The duty may be a duty imposed by statute law or by common law.[201] In fact, in a (criticized) judgment dealing with case of an HIV-positive man who donated his blood to the Red Cross, the Supreme Court of Canada has gone so far as to say that there is a fundamental duty at common law to refrain from conduct that it is reasonably foreseeable *could* cause serious harm to others, and that breaching this duty attracts criminal liability (under the *common nuisance* offence in that case).[202] (This may, in effect, criminalize mere tortious negligence and undermine the prohibition in the *Criminal Code* (s 9) on anyone being convicted of an offence at common law.[203]) The jurisprudence establishes that "wanton or reckless disregard" is made out where the conduct on the part of the accused shows a "marked departure" from the standard of behaviour of a "reasonably prudent person in the circumstances."[204]

Whether or not the offence of criminal negligence is made out for providing misinformation, or for not providing (accurate) information at all, will depend on the particular facts of the case. However, in most circumstances it may be difficult to prove that the bodily harm or death was caused by the criminally negligent conduct. Furthermore, the Supreme Court's decision in *Thornton* notwithstanding, where the criminal liability allegedly rests upon the failure to act, it may be difficult to establish the legal duty to act. Finally, given the conflicting nature of available "scientific information" about the effects of street drugs, it may be difficult to establish that the conduct of the information provider (eg, physician or public health nurse) represents a "marked departure" from the conduct of a reasonably prudent person.

Common nuisance

The offence of *common nuisance* is similar to that of criminal negligence causing either bodily harm or death. The *Criminal Code* (s 180) states that any person commits a common nuisance "who does an unlawful act or fails to discharge a legal duty and thereby endangers the lives, safety, health, property or comfort of the public." As noted above, the Supreme Court ruled in the *Thornton* case that the legal duty is one imposed by either statute or common law, and this can include a duty to refrain from conduct that it is reasonably foreseeable could cause serious harm to others. Unlike the offence of criminal negligence causing bodily harm or death, the offence of common nuisance would not require that anyone have actually suffered harm as a result of having received misinformation. All that is required is that the lives, safety, health or comfort of "the public" be "endangered." There is conflicting case law as to whether acts vis-à-vis one or a few individuals can be considered to endanger

[201] *R* v *Coyne*, supra, note 117.

[202] *R* v *Thornton*, supra, note 119.

[203] See: R Elliott. *Criminal Law and HIV/AIDS: Final Report*. Montréal: Canadian HIV/AIDS Legal Network & Canadian AIDS Society, 1997, at 88; W Holland. HIV/AIDS and the criminal law. *Criminal Law Quarterly* 1994; 36(3): 279-316.

[204] Supra, note 120.

"the public."[205] Certainly the widespread distribution of misinformation would satisfy this requirement, but whether providing misinformation to a handful of specific persons (eg, a physician to three different patients) would suffice remains uncertain.

Disobeying a federal statute

An intentional failure to satisfy a duty imposed by a federal statute may also be a criminal offence. The *Criminal Code* (s 126(1)) states that "every one who, without lawful excuse, contravenes an Act of Parliament by wilfully doing anything that it forbids or by wilfully omitting to do anything that it requires to be done is, unless a punishment is expressly provided by the law, guilty of an indictable offence." This provision might apply, for example, to government officials who have a duty stated in federal legislation to safeguard the health of Canadians (see discussion below).

Civil Liability

A person who fails to discharge a "duty of care" may be held civilly liable for the tort of negligence if their conduct results in injury to another. The duty may be imposed by legislation. (See below for a discussion of some statutory duties of government actors that might be the basis of civil liability for providing misleading information about the use or effects of street drugs.) Or the duty may arise under the common law because, in the circumstances, it is objectively foreseeable (ie, foreseeable by the ordinary person) that failing to exercise reasonable care could cause the harm. Civil liability in negligence means the liability to pay monetary compensation ("damages") to the person injured. In addition, legislation imposing a duty may itself specify penalties for a failure to fulfil legal duties.

It will be obvious that civil liability in negligence is a flexible, open-ended legal doctrine applicable to a wide variety of circumstances and relationships. The manufacturer of a product may be liable in negligence for injuries to consumers as result of product defects; the negligent operator of machinery may be liable to those injured as a result; a physician may be found negligent in providing poor medical care to a patient, etc. The fundamental issues are whether the risk of harm is foreseeable and whether the negligent conduct is causally connected to the injury that was suffered.

Health-care professionals

It would be difficult to conceive of ordinary individuals having a legal duty to educate themselves about aspects of drug use to prevent them spreading incorrect information. However, health-care professionals have a legal duty of care to patients that requires them to demonstrate a "reasonable degree of skill and knowledge" and to "exercise a reasonable degree of care."[206] In the case of prescribing drugs, particularly those that are inherently dangerous, courts have held that the "standard of care ... must, of necessity, be very high."[207] Similarly, the duty of care owed to patients participating in medical research is "at least as great as, if not greater than" the duty ordinarily owed by the physician to the patient.[208]

A medical practitioner who failed to meet the professional standard of the reasonable, prudent practitioner because of an inadequate degree of knowledge about the use and effects of street drugs, and therefore spread misinformation resulting in harm to a patient, could be held civilly negligent. Failing to meet an

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[205] *R* v *Hollihan*, [1998] NJ No 176 (Nfld Prov Ct) (QL); *R* v *Ssenyonga* (1993), 73 CCC (3d) 216 (Ont Ct Prov Div); *R* v *Schula* (1956), 115 CCC 382 (Alta CA).

[206] See the leading case *Lanphier* v *Philpos* (1838), 8 C & P 475 at 478, cited with approval in *Crits and Crits* v *Sylvester*, [1956] OR 132 (2d) 280, aff'd [1956] SCR 991; *University Hospital Board* v *Lepine*, supra, note 173. For an in-depth discussion of health-care professionals' duty of care to patients, see: EI Picard, GB Robertson. *Legal Liability of Doctors and Hospitals in Canada*, 3d ed. Toronto: Carswell, 1996; AJ Meagher, PJ Marr, RA Meagher. *Doctors and Hospitals: Legal Duties*. Toronto: Butterworths, 1991.

[207] *Crossman* v *Stewart* (1977), 5 CCLT 45 (BCSC). See also: *Bruce* v *Robichaud* (1988), 83 NSR (2d) 280, 20 APR 280 (CA); *Granger* v *Craan* (1985), 7 CPC (2d) 39 (Ont HCJ); *Reibl* v *Hughes*, supra, note 166.

[208] *Halushka* v *University of Saskatchewan* (1965), 53 DLR (2d) 436 (Sask CA); *Cryderman* v *Ringrose* (1977), 89 DLR (3d) 32 (Alta QB), aff'd (1978), 89 DLR (3d) 32 (Alta CA); *Zimmer* v *Ringrose* (1978), 89 DLR (3d) 646 (Alta QB), aff'd 124 DLR (3d) 215 (Alta CA), leave to appeal to SCC refused (1981), 37 NR 289 (SCC).

acceptable standard of medical practice could also constitute a breach of professional codes of ethics or practice. In some cases these codes are incorporated into the laws governing the profession or occupation;[209] that is, the code of ethics or practice would in effect become the legal standard for determining whether the practitioner's conduct amounted to negligence. (The mere fact that a physician may be judged civilly liable for negligence does not automatically mean liability for the offence of criminal negligence causing bodily harm or death:[210] as discussed above, the standard for criminal negligence is higher.) In this fashion, the tort law of negligence might offer one deterrence mechanism encouraging health-care providers to ensure they have (and dispense) accurate and complete information about the use of drugs and the effects of drug use.

Specific Legal Obligations of Government Authorities

In some cases, government officials may have a specific duty of care set out in legislation, which could serve as the basis for imposing civil and/or criminal liability for providing misinformation, or failing to provide (accurate) information, about the effects of street drugs.

Correctional systems

For example, the federal *Corrections and Conditional Release Act* states that the Correctional Service of Canada is responsible for "the care and custody of inmates"[211] and that the Commissioner of Corrections, under the direction of the Minister (the Solicitor General of Canada), "has the control and management of the Service and all matters connected with the Service."[212] The Act imposes several legal obligations on the Service, stating that the Service shall do the following:

- "take all reasonable steps to ensure that penitentiaries, the penitentiary environment, the living and working conditions of inmates and the working conditions of staff members are safe, healthful";[213]
- provide every inmate with "essential health care" and "reasonable access to non-essential mental health care that will contribute to the inmate's rehabilitation and successful reintegration into the community," and which "shall conform to professionally accepted standards";[214] and
- "take into consideration an offender's state of health and health care needs (a) in all decisions affecting the offender, including decisions relating to placement, transfer, administrative segregation and disciplinary matters; and (b) in the preparation of the offender for release and the supervision of the offender."[215]

In light of these legal duties under the statute, it would follow that if health-care professionals outside the prison system have the duty to exercise reasonable care in disseminating professional advice concerning drug use, those in charge of the prison health-care system have a corresponding duty to ensure that the advice disseminated to prisoners reflects an equal degree of reasonable care. (An examination of corresponding obligations under legislation governing provincial correctional systems is not included here, but the legal analysis would be substantively the same.) Furthermore, the duty of prison authorities to provide health-care services to prisoners equivalent to those available on the outside is found in the common law as well. As stated in the leading decision

[209] For a discussion of the Ontario example, see R Steinecke. *A Complete Guide to the Regulated Health Professions Act*. Aurora: Canada Law Book Inc, 1999.

[210] See eg, *R* v *Giardine* (1939), 71 CCC 295 (Ont CA).

[211] SC 1992, c 20, s 5(a).

[212] Ibid at s 6.

[213] Ibid at s 70.

[214] Ibid at s 86.

[215] Ibid at s 87.

by the UK House of Lords: "[a] prisoner retains all civil rights which are not taken away expressly or by necessary implication".[216]

Government health authorities

The wording of the *Department of Health Act*[217] setting out the responsibilities of the federal Minister of Health strongly suggests that the Minister and officials who have been delegated the legal authority to exercise the functions of the Minister have a duty to provide accurate information to Canadians regarding their health in all matters over which the federal government has jurisdiction. In particular,

> 4(2) ... the Minister's powers, duties and functions relating to health include the following matters: ...
>
> (a.1) the promotion and preservation of the physical, mental and social well-being of the people of Canada;
>
> (b) the protection of the people of Canada against risks to health and the spreading of diseases;
>
> (c) investigation and research into public health, including the monitoring of diseases;
>
> (d) the establishment and control of safety standards and safety information requirements for consumer products and of safety information requirements for products intended for use in the workplace; ...
>
> (h) subject to the *Statistics Act*, the collection, analysis, interpretation, publication and distribution of information relating to public health; and
>
> (i) cooperation with provincial authorities with a view to the coordination of efforts made or proposed for preserving and improving public health.

Provincial health legislation imposes similar responsibilities on provincial Ministers of Health, or their delegates, on matters falling within their jurisdiction. As an example of provincial counterpart legislation, the Ontario *Ministry of Health Act*[218] identifies responsibilities that could be interpreted as requiring the provision of accurate information about the use and effects of illegal drugs to health-care providers and the general public, including drug users. These responsibilities include:

- advice to the Government in respect of the health of the people of Ontario;
- oversight and promotion of the health and the physical and mental well-being of the people of Ontario;
- development, co-ordination and maintenance of comprehensive health services and a balanced and integrated system of hospitals, nursing homes, laboratories, ambulances and other health facilities in Ontario;
- establishment and operation, alone or in co-operation with one or more persons or organizations, of institutes and centres for the training of hospital and health service personnel;
- governance of the care, treatment and services and facilities therefor provided by hospitals and health facilities and assess the revenues required to provide such care, treatment and services;

[216] *Raymond* v *Honey*, [1982] 1 All ER 756 at 759 (HL), per Lord Wilberforce.

[217] Supra, note 185.

[218] Supra, note 184.

- convening of conferences and the conducting of seminars and educational programs respecting health matters.[219]

Officials of a government department whose mandate is to protect the health of Canadians could theoretically be held civilly liable if it could be shown that they acted negligently in providing inaccurate or incomplete information or in failing to provide (accurate) information where there was a duty to do so. As discussed above, depending on the egregiousness of the conduct, they might also be subject to criminal prosecution for criminal negligence causing bodily harm or death, or for wilfully contravening an Act of Parliament.

Liability for Charter violations?

One could also argue that government policies and actions that result in the withholding of essential information or in the spread of harmful misleading information violate the Charter rights of drug users (and those Canadians who became infected with hepatitis or HIV through sexual contact or sharing injection equipment with users).

For example, the Charter gives everyone the right to "life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice" (s 7). It might be arguable that government policies that withhold helpful information or that spread harmful and misleading information have the effect of depriving individuals of security of the person and, in some cases, life. (This would be a similar to the claim that prison authorities violate the Charter s 7 rights of prisons by denying access to sterile injection equipment.[220]) The Supreme Court of Canada has ruled that s 7 of the Charter applies "where it can be said that a deprivation of life and security of the person could be proven to result from the impugned government act."[221] Judgments from the Supreme Court also indicate that security of the person is infringed not only by an actual impairment of health, but also by a likelihood that health would be impaired.[222]

Section 24(1) of the Charter authorizes a court to order "such remedy as the court considers appropriate and just in the circumstances" for a violation of Charter rights or freedoms. Canadian courts have gone beyond issuing simple declarations confirming that Charter rights have been breached, and have awarded monetary damages as compensation for what have been referred to as "constitutional torts."[223] However, public officials are unlikely to be liable for breaching Charter rights while acting in the course of their statutory duties unless it can be shown that they acted maliciously or in bad faith; reckless or grossly negligent conduct might also suffice.[224]

[219] Ibid at s 6(1).

[220] See the discussion in: R Elliott, supra, note 69.

[221] *Operation Dismantle Inc* v *The Queen* (1988), 45 CCC (3d) 57 (SCC).

[222] *Singh* v *Minister of Employment and Immigration*, [1985] 1 SCR 177.

[223] For a detailed discussion, see K Cooper-Stephenson. *Charter Damages Claims*. Toronto: Carswell, 1990.

[224] *Stenner* v *British Columbia (Securities Commission)* (1993), 23 Admin LR (2d) 247 (BCSC), aff'd without reference to Charter issue 141 DLR (4th) 122 (BCCA), leave to appeal to SCC refused 143 DLR (4th) vii; *Rollinson* v *Canada* (1994), 73 FTR 16 (TD); *Alford* v *Canada (Attorney General)* (1997), 68 ACWS (3d) 826 (BCSC); *Persaud* v *Ottawa (City) Police* (1997), 143 DLR (4th) 326 *sub nom Persaud* v *Donaldson* (Ont Div Ct); *Crispen* v *Kalinowski* (1997), 148 DLR (4th) 720 (Sask QB); *Jane Doe* v *Metropolitan Toronto (Municipality) Commissioners of Police* (1998), 39 OR (3d) 487 (Gen Div).

Syringe Exchange and Methodone Maintenance Treatment

What are the legal regulations governing syringe exchange programs and methadone maintenance treatment programs?

Syringe Exchange Programs

Syringe-exchange programs currently operate in major cities across Canada. This suggests that the political will to tolerate (even fund) such programs would likely also offer some measure of protection against possible criminal prosecution for accepted activities undertaken in conjunction with them. However, syringe exchange or distribution programs do technically face possible barriers under Canada's criminal legislation regarding drugs.[225] In particular, the following aspects are of concern: the broad definition of "controlled substance" in the CDSA, which includes used injection equipment containing drug residue; and the "drug paraphernalia" provisions of the *Criminal Code*.

These provisions appear to make some aspects of such programs illegal. However, provisions in the *Food and Drugs Act*, the legislative intent behind these provisions, the Charter, and existing criminal law doctrine may offer some protection against criminal liability.

Used injection equipment containing drug residue: a "controlled substance"

Because of its very broad definition of "controlled substance," the CDSA makes it a criminal offence to possess, import, export, traffic, etc not only the drugs themselves but also "any thing that contains or has on it a controlled

[225] For a brief discussion of this issue (under previous, but similar, legislation), see: SJ Usprich, R Solomon. Notes on the potential criminal liability of a needle exchange program. *Health Law in Canada* 1988; 8(3): 42-48.

substance and that is used or intended or designed for use (a) in producing the substance, or (b) in introducing the substance into a human body."[226] This means that if a syringe or other equipment (eg, cookers) used for injecting drugs contains residue of a drug, as most used equipment will, that equipment is a "controlled substance" and the person with the equipment could be found guilty of possession under the CDSA. There is no express exemption or protection in the statute or regulations for needle exchange programs or their employees, who will often knowingly be in possession of used syringes containing drug residue returned by users. Similarly, the operator of an injection room or "shooting gallery" who provided receptacles for the safe return of used syringes would knowingly possess a "controlled substance," an offence under the CDSA. An alternative basis of criminal liability might be abetting (ie, encouraging) possession by users of a controlled substance.

Criminal charges for possession

For a full discussion of the different forms of possession and the issues of *knowledge*, *control*, and *consent*, see the section on "Constructive or joint possession charges" under Issue 2 (Drug Use and Provision of Health and Social Services) above. In addition to the material respecting the notion of *knowledge* canvassed there, it may be added that Usprich and Solomon have addressed the issue of when there might be the requisite knowledge on the part of the syringe exchange program.[227] They take the view that where a syringe exchange program accepts the return of used syringes containing a visible residue, it is likely that the requisite "knowledge" of the presence of the illegal drug on the syringe would be made out. In such a case, it would clearly be the case that the person at the syringe exchange receiving the used equipment would be "reckless" as to their possession of a prohibited drug, or at the very least "wilfully blind" as to the presence of the illegal drug in the syringe.[228]

However, Usprich and Solomon also take the position that no criminal liability would be possible in the case where the exchange program personnel receive apparently empty syringes with no visible quantity of any substance, even if the syringe does in fact contain drug residue. In their view, the personnel "would be unaware that they possess the invisible quantity of the drug. They would neither know, nor reasonably suspect, that the apparently empty syringe contained illegal drugs."[229] This position might not be as clear-cut as these commentators suggest. Given the function and nature of a syringe exchange program providing injection equipment to persons who inject drugs that are generally illegal, why would not personnel receiving returned, used syringes reasonably suspect that they contain residue of illegal drugs? It seems plausible that such conduct could also be characterized as "wilful blindness" or even "recklessness."

With regard to the issue of *control*, it may be added that while physically handling used syringes containing drug residue for the purpose of their safe disposal would likely amount to "control," it would still be open to exchange personnel accused of possession to argue that doing so was not exercising control over the substance for the purpose of facilitating the consumption or trafficking of illegal drugs and that therefore, as a matter of policy, courts should refrain from considering such an action to amount to illegal possession.

The issue of *consent* in this context is, as noted, canvassed above. In any event, a charge of "joint possession" against personnel of a needle exchange program seems unlikely. As a matter of public policy, it would be stretching

[226] Section 2(2).

[227] Usprich & Solomon, supra, note 225.

[228] Ibid at 43.

[229] Ibid.

There appear to have been no prosecutions to date for those who work in syringe exchange programs and who receive syringes containing drug residue.

this offence to say that personnel "consent" to the possession of controlled substances by drug users returning used syringes to the program when there is no commonality of interest or "joint venture" between the users and the program personnel to possess illegal drugs in concert with each other.

"De minimis non curat lex"

Even if the prosecutor technically established possession by syringe exchange program personnel of drug residue on used syringes, the recipient of used works charged with possession may have a defence under the legal doctrine of *de minimis non curat lex* (roughly, "the law does not concern itself with trifles"). The Supreme Court of Canada has approved of this formulation of the doctrine: "If the deviation were a mere trifle, which, if continued in practice, would weigh little or nothing on the public interest, it might properly be overlooked."[230]

MacFarlane et al indicate that, unlike in other jurisdictions, the Canadian decisions are mixed on the availability of this defence to charges of possession of minute quantities of controlled substances: "it is difficult, if not impossible, to perceive any one principle of law arising from the existing jurisprudence."[231] After a lengthy analysis of this doctrine, MacFarlane et al conclude that the weight of the limited Canadian authority on this point indicates that the *de minimis* defence does not apply to drug offences.[232]

To ensure the continuation of syringe exchange programs, provincial Attorneys General should issue directives to the effect that personnel in syringe-exchange programs and the drug users who avail themselves of such programs should not be harassed or charged on the basis of the residue that may be found in syringes.

However, MacFarlane et al suggest that the courts may draw a distinction between situations where minute quantities of a usable substance are found, and situations where traces of a useless residue are found. Thus, even a microscopic quantity of a substance in a usable form might found a possession charge; if it is simply because of the minuteness of the quantity involved that the substance is not usable, this will be irrelevant and the *de minimis* defence would be rejected. But in the case where a minute quantity of the substance is found, but the substance has been changed to an unusable composition (eg, through burning), the defence might still succeed. However, any cases suggesting this possibility pre-date the new, expansive definition of "controlled substance" in the CDSA, introduced in 1996. Under the current statute, if the item containing the unusable residue is "used or intended or designed for use in producing the substance, or in introducing the substance into a human body,"[233] then it falls within the definition of "controlled substance." This suggests a *de minimis* defence is not likely to succeed in the case of possession of useless residue either.

In short, it seems that the law regarding possession of minute traces of drugs is not entirely settled. In some cases the recipient may be able to rely on the *de minimis* doctrine. However, this doctrine offers no reasonable guarantee that the recipient of used works will not be found guilty of possession of a controlled substance. The greatest protection for the recipient may come from a lack of knowledge of the precise substance contained in the works (although this is of dubious comfort, in light of the points made above regarding what constitutes "knowledge"), and from common sense on the part of prosecutors and police.There appear to have been no prosecutions to date for those who work in syringe exchange programs and who receive syringes containing drug residue. However, some participants at a meeting held in Montréal in March 1999 to discuss the issues raised by this paper reported stories of police threats of prosecution against individuals on the basis of the residue contained in syringes. To ensure the continuation of syringe exchange programs, provincial

[230] *The "Reward"* (1818), 2 Dods 265 at 269-70, 165 ER 1482, cited with approval in *R* v *Canadian Pacific Ltd* (1995), 99 CCC (3d) 97 at 134 (SCC).

[231] MacFarlane et al, supra, note 59 at 23-2.

[232] *R* v *Quigley* (1954), 111 CCC 81 (Alta CA); *R* v *McLeod* (1955), 111 CCC 137 (BCCA); *R* v *Li* (1984), 16 CCC (3d) 382; *R* v *Brett* (1985), 41 CCC (3d) 190 (BCCA); *R* v *Keizer* (1990), 59 CCC (3d) 440.

[233] CDSA, supra, note 2 at s 2(2)(b)(ii).

Attorneys General should issue directives to the effect that personnel in syringe-exchange programs and the drug users who avail themselves of such programs should not be harassed or charged on the basis of the residue that may be found in syringes.

Drug paraphernalia: instruments and literature

As a result of amendments introduced in 1988, the *Criminal Code* makes it an offence for anyone to "knowingly" import, export, manufacture, promote, or sell "instruments or literature for illicit drug use."[234] Selling includes offering for sale, exposing for sale, possessing for sale, and distributing, whether or not the material is distributed in exchange for money or other valuable consideration.[235] The punishment for a first offence is a maximum fine of $100,000 and imprisonment for six months; for a second or subsequent offence, the maximum penalty is a $300,000 fine and imprisonment for one year.[236] It is important to note that, while mere possession of illicit drugs is an offence (under the CDSA), mere possession of drug paraphernalia is not.

Syringes (at least unused ones) should arguably not be considered drug paraphernalia.

Food and Drugs Act: syringes should be excluded as "drug instrument"

Syringes (at least unused ones) should arguably not be considered drug paraphernalia. An "instrument for illicit drug use" is defined as "anything designed primarily or intended under the circumstances for consuming or to facilitate the consumption of an illicit drug, but does not include a 'device' as that term is defined in section 2 of the *Food and Drugs Act*."[237] "Device" is defined in the *Food and Drugs Act* as "any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in ... the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals."[238] Syringes should almost certainly be considered "devices" under the *Food and Drugs Act*, since they are manufactured, sold, or represented for medical use. If so, they would be excluded from the definition of "instruments for illicit drug use" in the *Criminal Code*.

However, there is some uncertainty about this conclusion, as the definition in the *Criminal Code* of an "instrument for illicit drug use" includes anything "intended under the circumstances" for consuming an illicit drug. In many cases the circumstances will be such that the syringe or other equipment will be intended for this purpose. This leaves open the possibility that, depending on the circumstances, a person – such as an outreach worker in a needle exchange program or the operator of a shooting gallery – who provides a syringe or other injection equipment to another person for the purpose of facilitating the consumption of an illicit drug could be found guilty of the "sale" of drug paraphernalia. If the syringe in question contained residue of an illicit drug, not only would it be a "controlled substance" itself under the broad CDSA definition (as discussed), but the residue on the syringe would presumably be strong evidence that, in the circumstances, the syringe was intended for this use.

Legislative intent was not to criminalize syringe exchange programs

Due consideration should be given to the argument that syringes and other items intended to facilitate the *safer* use of illicit drugs are "devices" under the *Food and Drugs Act*. However, should it fail, another defence to possible criminal liability remains. MacFarlane et al offer the observation that the legislation on drug paraphernalia and literature stemmed from concern about retail sales

[234] *Criminal Code*, supra, note 4 at s 462.2.

[235] Ibid at s 462.1.

[236] Ibid.

[237] Ibid.

[238] *Food and Drugs Act*, supra, note 3 at s 2.

Looking at the intent of Parliament when it drafted the legislation to attack the activities of "head shops," it seems that manufacturing and distributing equipment, if *not* done for a commercial purpose, should not be considered to violate the legislation. However, the legislation is ambiguous about whether distributing injection equipment for noncommercial purposes is an offence.

of paraphernalia in "head shops," and "is quite clearly aimed at those seeking to profit from the huge illegal drug industry, as mere possession of drug paraphernalia or literature is not proscribed."[239] Support for this conclusion is to be found in the 1987 report of the Standing Committee on National Health and Welfare, which expressed concern about *commercial* enterprises whose principal business was the sale of drug paraphernalia and items and which described their use and advocated the use of illicit drugs.[240] The Committee also expressly noted that

> in most cases, items of drug paraphernalia also have legitimate and non-drug applications. The intent of legislation should be to close "head shops" and not to attack the items themselves. The law must be carefully drafted to address those commercial enterprises which glamorize and facilitate drug use.[241]

Looking at the intent of Parliament when it drafted the legislation to attack the activities of "head shops," it seems that manufacturing and distributing equipment, if *not* done for a commercial purpose, should not be considered to violate the legislation. An Ontario trial court has reiterated that this was the Parliamentary intent by striking down the prohibition on drug "literature" as an unconstitutional violation of free speech.[242] A person or organization distributing syringes free or for a minimal charge that is not intended to generate a profit may not be caught by the legislation. However, this is not certain: simply because the legislators seemed to intend the legislation to apply only to commercial enterprises does not mean that the police and government prosecutors will refrain from prosecuting those who distribute syringes or related "works." Furthermore, the definition of "selling" paraphernalia in the *Criminal Code* (s 462.2) states that it includes distributing, "whether or not the distribution is made for consideration." Thus, the legislation is, at the very least, ambiguous about whether distributing injection equipment for noncommercial purposes is an offence.

Charter defences

There might be a number of constitutional defences to charges under the "drug paraphernalia" provisions against personnel operating a needle-exchange program.

Freedom of speech protects "literature" for illicit drug use

Among other prohibitions, section 462.2 banned the import, export, manufacture, promotion, or sale of literature for illicit drug use. In *Iorfida* v MacIntyre,[243] an Ontario trial court struck out the words "or literature" from the section, as unjustifiably violating the freedom of speech guaranteed by the Charter (s 2(b)). In other words, it is no longer an offence to import, export, manufacture, promote, or sell literature for illicit drug use, at least in Ontario. While such a decision (as a trial-level decision) does not bind other courts in other provinces or even in Ontario, it may have some persuasive effect, and strongly suggests that those working in a syringe exchange program need not be overly concerned about possible liability for the distribution of literature regarding risk reduction and the consumption of illegal drugs. However, the prohibitions on "instruments for illicit drug use" remain intact.

Vagueness and overbreadth

MacFarlane et al also suggest it might be possible to successfully challenge the paraphernalia provisions in the *Criminal Code* by arguing that the provisions

[239] MacFarlane et al, supra, note 59 at 12-2 para. 12.120.

[240] Ibid at paras. 12.40, 12.60, 12.80.

[241] Ibid at para 12.80, citing: Standing Committee on National Health and Welfare. Booze, Pills and Dope: Reducing Substance Abuse in Canada. House of Commons, Minutes of Proceedings, No 28, 17 September 1987, at 35-36.

[242] *Iorfida*, supra, note 27, cited with approval on this point in *R* v *Spindloe*, supra, note 30.

[243] *Iorfida*, supra note 27.

are "void for vagueness."[244] The Supreme Court has repeatedly ruled that a law that does not provide "the basis for legal debate and coherent judicial interpretation" or that "does not give fair notice to a person of the conduct that is contemplated as criminal" breaches the guarantee in the Charter (s 7) because it deprives a person of their liberty and security of the person in a manner that does not accord with "the principles of fundamental justice."[245] In the same cases, the Supreme Court has ruled that legislation may be unconstitutionally overbroad. The courts must assess whether a law "applies in a proportionate manner to a particular fact situation,"[246] balancing the state interest against that of the individual. Legislation may be overbroad if it "goes beyond what is needed to accomplish the governmental objective."[247] However, currently the case law does not bode well for such challenges. Applying the jurisprudence from the Supreme Court, trial courts in three provinces have rejected arguments that the prohibition on "instruments for illicit drug use" is unconstitutionally vague[248] or overbroad.[249]

Right to life and security of person

In another variation of a Charter s 7 argument, it might also be possible to argue that making it a criminal offence to distribute instruments that have been shown to protect life and security of the person would deprive drug users of their right to life and to security of the person, not in accordance with the principles of fundamental justice.[250] The argument could be extended even further, so that any legislative prohibition, criminal or otherwise, against distributing these instruments as a means to prevent the spread of disease would violate s 7. One legal hurdle might be the question of whether a worker in a syringe exchange program could invoke another person's Charter rights in challenging the criminal charges laid against the worker. The Supreme Court has ruled (in a civil case) that in order for the court to grant standing to a party to claim a breach of the Charter rights of others, three conditions must be met: (i) a serious issue must be raised as to the constitutional validity of the relevant act; (ii) the person advancing the Charter argument must be directly affected by the act or have a genuine interest in its validity; and (iii) there exists no other reasonable and effective way to bring the act's validity before the court.[251]

Equality and non-discrimination

The Charter (s 15) also guarantees the right to equality before and under the law, and to equal protection and benefit of the law without discrimination, and in particular without discrimination based on mental or physical disability. It has generally been accepted in the interpretation of human rights statutes prohibiting discrimination based on "disability" or "handicap" that alcoholism and dependence on other drugs (including illegal drugs) constitute "disabilities" under non-discrimination law.[252] There would be a strong argument that drug-dependent users have a "disability" within the meaning of this section of the Charter (although non-dependent drug users would be unlikely to be included).[253] Denying people with the disability of drug use the means to protect their lives with syringes and other works may have the effect of denying them the right to equal benefit of the law. Again, however, an initial difficulty might be faced by personnel in a syringe exchange program raising the Charter rights of service users as a defence to criminal liability.

[244] Supra, note 59 at 12-3, para 12.220.

[245] *R* v *Canadian Pacific Ltd*, supra, note 230; *Reference re ss 193 and 195(1)(c) of the Criminal Code*, [1990] 1 SCR 1123, 56 CCC (3d) 65; *R* v *Heywood* (1994), 94 CCC (3d) 481 (SCC); *R* v *Nova Scotia Pharmaceutical Society*, [1992] 2 SCR 606, 74 CCC (3d) 28.

[246] *Canadian Pacific*, supra, note 230 at 141.

[247] *Heywood*, supra, note 245 at 517.

[248] *Spindloe*, supra, note 30; *Rizzo*, supra, note 31; *Temple*, supra, note 31; *Ramje*, supra, note 30.

[249] *Spindloe*, supra, note 30.

[250] See the extensive discussion of the possible Charter rights, including section 7, of prisoners to sterile needles and bleach in R Elliott, supra, note 69.

[251] *Hy and Zel's Inc* v *Ontario (Attorney General)* sub nom *Paul Magder Furs Ltd* v *Ontario (Attorney General)*, [1993] 3 SCR 675. See also *R* v *Wholesale Travel Group Inc* (1991), 67 CCC (3d) 193 (SCC); *R* v *Collins*, [1987] 1 SCR 265 (question raised but not answered).

[252] *Canadian Human Rights Act*, supra, note 149 at s 25; *Canadian National Railway* v *Niles*, supra, note 149; *Canada (Human Rights Commission)* v *Toronto-Dominion Bank*, supra, note 150; *Entrop* v *Imperial Oil Ltd*, supra, note 151; *Handfield* v *North Thompson School District No 26*, supra, note 151; Ontario Human Rights Commission, supra, note 153; Canadian Human Rights Commission, supra, note 153.

[253] *Hamon*, supra, note 60.

Methadone Maintenance Programs

The CDSA identifies methadone as a controlled substance, meaning it is an offence to possess or traffic in methadone unless this is authorized by the regulations made under the statute.[254] The Narcotic Control Regulations[255] in force under the CDSA provide the authorization for pharmacists, hospital employees, practitioners, and others to deal with narcotics (including methadone), and impose strict record keeping and other administrative requirements regarding such dealing. The Regulations also authorize possession of methadone by those to whom it is being supplied by authorized health-care practitioners as long as it is obtained for their own use and under a prescription that is not issued or obtained in contravention of the Regulations.[256]

Authorizations to deal with controlled substances

The Regulations provide that where the Minister of Health "deems it to be in the public interest, or in the interests of science," the Minister may authorize (in writing and subject to conditions) any person to possess a narcotic. The Minister may also authorize a practitioner to provide methadone to a person under their treatment, or to provide a narcotic (other than heroin) to any person who is also authorized by the Minister to possess a narcotic. (A practitioner may only provide heroin to a patient of a hospital.) Apart from these restrictions, a practitioner is permitted to prescribe a narcotic only to a patient under their professional treatment, and only if the narcotic is required for the condition for which the person is receiving treatment.[257]

Hospitals and pharmacists

The Regulations also set out more specific provisions that govern the distribution of narcotics (including methadone) by hospitals and pharmacists. Hospitals are only permitted to supply or administer narcotics in accordance with the Regulations,[258] which state that a person in charge of a hospital may permit methadone to be supplied or administered to a hospital employee or practitioner in another hospital or to a pharmacist, for emergency purposes; and to an in-patient or out-patient of the hospital, upon receipt of a prescription or written order signed and dated by a practitioner who is authorized by the Minister of Health to prescribe methadone.[259]

Pharmacists are generally authorized to supply methadone to licensed dealers, other pharmacists, hospital employees or hospital practitioners, persons authorized by the Minister, and persons from whom the pharmacist has received a valid written order or prescription not issued or obtained in contravention of the Regulations.[260]

Thus, there are some carefully circumscribed situations in which practitioners can prescribe methadone. In situations where the physician has no right to prescribe, penalties for prescribing may flow under the Regulations. In addition, if the physician actually possesses a drug and gives it to a patient (or offers to give it) when the physician has no legal right to possess the drug, the physician may commit three offences under the CDSA – possession, possession for the purposes of trafficking, and trafficking. A physician also commits the offence of trafficking where the physician "sells an authorization" to obtain a controlled substance or offers to sell such an authorization.[261] Even if a physician were not charged with a substantive drug offence, they could still face

[254] CDSA, supra, note 2 at ss 2(1), 4, 5.

[255] Supra, note 5.

[256] Ibid at s 3(1).

[257] Ibid at ss 53 & 68.

[258] Ibid at s 65(1).

[259] Ibid at ss 65(2)-(5).

[260] Ibid at s 31(3).

[261] CDSA, supra, note 2 at s 2(1).

criminal liability for counseling, abetting (ie, encouraging), or assisting someone to commit an offence under the CDSA.

Delegation to provinces

The Minister of Health retains the sole power to authorize practitioners to prescribe and administer methadone; this power has not been delegated to any provincial agency. However, the governments of Ontario and British Columbia currently administer methadone programs through their respective Colleges of Physicians and Surgeons. The Colleges follow guidelines that determine physician eligibility and "regulate" physicians who have been authorized to prescribe methadone. The Ontario College has developed its own guidelines but the BC College uses guidelines promulgated by Health Canada.[262]

In essence, the Colleges are responsible for evaluating and determining physician eligibility to prescribe methadone and for monitoring those physicians who have been granted the authority to prescribe by the Minister. If a physician meets the necessary criteria (training, etc), the College recommends to the Minister of Health that the physician be granted the authority to prescribe methadone under the Minister's power pursuant to the Regulations. The Minister routinely accepts such recommendations, issuing the requisite letter of authorization. In short, the colleges do not have the authority to authorize practitioners to prescribe methadone. They simply pre-screen and "police" the methadone regulations.

Methadone maintenance treatment in prisons

In September 1996, in part as a result of constitutional litigation commenced against the BC Corrections Branch,[263] the Branch officially adopted a policy of continuing methadone for incarcerated adults who were already on a prescribed methadone maintenance program in the community prior to incarceration.[264] In 1997 the Task Force on HIV/AIDS and Injection Drug Use renewed the call for ensuring that this be the case in all correctional systems. The Task Force also repeated the recommendation made by the Canadian HIV/AIDS Legal Network in September 1996[265] that methadone treatment (and methadone detox programs) be made available to opioid-dependent prisoners who were not receiving it prior to incarceration but who wish to start this treatment in prison (and thereby avoid injection of opiates and the health risks associated with injecting, particularly in settings where access to clean injection equipment is almost impossible).[266]

In December 1997 the Correctional Service of Canada announced that it would introduce methadone maintenance treatment for inmates in federal prisons who were already on such treatment prior to incarceration.[267] Today, in the federal and in many – but not all – provincial systems, inmates who were already receiving methadone maintenance treatment outside can continue such treatment in prison. However, no Canadian system has adopted a general policy of making methadone maintenance treatment available to dependent prisoners who were not receiving it prior to incarceration. A few systems are, however, considering doing this in the near future, and the federal system has already implemented an "Exceptional Circumstance" policy under which some inmates who are "in dire need for immediate intervention" can access methadone maintenance treatment even if they were not on such treatment on the outside.[268]

No Canadian system has adopted a general policy of making methadone maintenance treatment available to dependent prisoners who were not receiving it prior to incarceration.

[262] Health Canada. *The Use of Opioids in the Management of Opioid Dependence*. Ottawa: Health Canada, 1992. There have been changes to the guidelines since the 1992 publication but there has been no published update as of July 1999.

[263] McLeod, supra, note 71.

[264] Rothon, supra, note 71.

[265] Jürgens, supra, note 69.

[266] *HIV, AIDS and Injection Drug Use: A National Action Plan*, supra, note 35.

[267] Correctional Service Canada. News Release. Correctional Service of Canada to Introduce Methadone Maintenance Treatment. Ottawa: CSC, 1 December 1997; Jürgens, supra, note 71.

[268] Communication received from Jeff Potts, Program Officer/Analyst, National HIV/AIDS Program, Correctional Service Canada, 15 June 1999.

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Injection Drug Use and HIV/AIDS:

An Ethics Commentary on Priority Issues

prepared by
David Roy

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Table of Contents

Introduction

Background

This paper integrates the major considerations developed in two earlier background papers written as ethics commentaries on seven priority issues identified in the first workshop on HIV and Injection Drug Use: Legal and Ethical Issues, a workshop organized by the Canadian HIV/AIDS Legal Network and held in Montréal on Monday, 17 November 1997.

Following this workshop, a first draft of an ethics commentary on four priority issues was written and submitted for discussion in a second workshop, held in Montréal on Monday, 2 February 1998. Criticisms and suggestions received at this February 1998 workshop led to the preparation of a semifinal version (dated 6 March 1998) of this first ethics commentary on four priority issues.

About a year later, a second ethics commentary was written on the three remaining issues identified in the November 1997 workshop and was submitted for discussion in a third workshop held in Montréal on 15-16 March 1999. Following this workshop, a semifinal version of the second ethics commentary was prepared and dated 23 April 1999.

Both the first and the second ethics commentaries were then sent to peer reviewers and their comments and criticisms were received by mid May 1999. I am taking account of these peer-review constructive criticisms in the preparation of this final integrated and shortened version of the earlier two ethics commentaries.

The Purpose and Limits of This Ethics Commentary

The time and resources available for the preparation of the two earlier ethics commentaries on which this paper is based were very limited. I would have

greatly wished that it would have been possible to write a detailed ethical analysis of the concrete and pressing issues people confront on a daily basis in their work with injection drug users, be it on the street or elsewhere. That would have required extensive meetings and field work, and the time and resources were simply not available.

Moreover, an extensive ethical analysis of any one of the seven issues that come up for commentary in this paper would have demanded both an extensive literature review complemented by personal inquiry and field work with those who confront these issues on a daily basis.

The most I was able to accomplish in the two earlier ethics commentaries on which this paper is based was to sketch the lines that I believe a more complete ethics analysis should pursue. My original mandate was to prepare two brief ethics commentaries that would serve as background papers for the workshops mentioned above, background papers that would stimulate reflection and provoke discussion. This is what I tried to do and that is the mandate I now try to honour in this final paper that integrates the two earlier commentaries.

There will be no resolution, but rather a perpetuation, of the issues considered in this project so long as persons using drugs are seen as being inferior to other human beings and are treated accordingly.

Then there is the question of this paper's intellectual accessibility. Many of the ideas, concepts, and literature references I have used in the writing of this paper are somewhat out of the ordinary. In this final paper, I largely retain these elements of thought that some people find unusual, and I do so for at least the following reasons. First, I spontaneously turned to the concepts and ideas with which I was most familiar in order to rise to the challenge of writing an ethics commentary on a range of very difficult issues on which I have not had the opportunity to date of spending years of work. Second, I have tried to suggest fresh ways of thinking about the November 1997 workshop's priority issues, particularly because so much of the thought given to these issues in the past has been mired in clichés, biases, and the repetition of unexamined assumptions. Third, my mandate was to stimulate reflection and provoke discussion. A promising way to do this is to invite readers to move along unusual paths of thought into quite common, very pervasive, and still unsolved problems.

A practical, down-to-earth ethical guidebook on the issues raised in this project and on a range of other related and highly specific issues still has to be written. This paper is not that guidebook. The writing of such a guidebook would have required more time and resources than were ever available for the writing of the two ethics commentaries that are integrated in this paper. The writing of an ethics guidebook would also have required a very different approach than the one I adopted to respond to the request for a paper that would stimulate reflection and provoke discussion.

The Guiding Theme: The Logic of Exclusion versus the Logic of Humanity

This ethics commentary is written out of the conviction that there will be no resolution, but rather a perpetuation, of the issues considered in this project so long as persons using drugs are seen as being inferior to other human beings and are treated accordingly. A danger lurks in each of the issues under consideration in this project. It is the possibility and the danger of exclusion, the kinds of exclusion that Ignacio Ramonet, Editor of *Le Monde Diplomatique*, calls "the great social crime of our times."[1]

A certain logic, a pattern of moves and acts governs the process of excluding people from enjoying the rights, liberties, opportunities, and privileges of a civilized society.

[1] I Ramonet. Un crime social. In: I Ramonet, A Gresh, C Julien, C de Brie. Le Temps des exclusions. Manière de voir 20. *Le Monde Diplomatique* November 1993:7.

The logic runs something like this.

1. *Reductionism*: a person is reduced to one or another negative characteristic or behaviour.
2. *Magnification of difference*: a person, reduced to a negative characteristic, becomes even more a stranger as their differences from others are magnified, exaggerated, and absolutized.
3. *Blinding*: reductionism and magnification of difference are reinforced by a process of blinding such that so-called normal people can no longer see and appreciate all the features and realities they have in common with those now gradually being pushed into the penumbra of society and community.
4. *Stigmatization*: following on the three above-mentioned moves, people are often publicly branded in some fashion as being terribly different and inferior to the normal run of humanity.
5. *Discrimination*: the logic of the above events comes closer and closer now to social acts of exclusion. People are falsely and unjustly deprived of rights, liberties, opportunities, and goods to which others have unquestioned access.
6. *Marginalization*: the process of exclusion can reach the point at which people are literally pushed out of the common spaces people share in a community. At an extreme, these persons are no longer part of the community; they are, to use an older term, excommunicated.

The logic of exclusion canonizes sameness. One has to be like others to belong. The logic of humanity welcomes and affirms, not simply tolerates, the faces of otherness.

The logic of exclusion canonizes sameness. One has to be like others to belong. The logic of humanity welcomes and affirms, not simply tolerates, the faces of otherness. To belong, one does not have to submit or conform to patterns of behaviour dictated by those with the greatest power, by those with the power to define who are aliens and who are not.

The logic of humanity argues and acts against the force that propels the logic of exclusion, a force Emmanuel Levinas calls *totality*. Levinas uses this term for modes of relationship that torture otherness into conformity. Individuals are strained through grids of thought and grids of norms until, shorn of their differences, they can be admitted into company, into acceptance, and into affirmation. Self-affirmation is not tolerated by a logic of exclusion serving the ethos of Levinas's totality.[2,3] Totality cannot assimilate, it cannot even accommodate, what is unlike itself; and what and whom totality cannot assimilate, it must reject. Hence the workings of a logic of exclusion.

The logic of humanity is a logic of inclusion and it counters each of the above-mentioned six moves of a logic of exclusion. Within the logic of humanity there are no strangers. Within the logic of humanity we are all irreducibly unique and different. Respect and affirmation of that difference is the basis for humanity's logic of inclusion. Within the logic of humanity all who are different, particularly those who are made to suffer because of their diversity, are very much our own. When they are diminished we are diminished, because the logic of humanity is the logic of unconditional solidarity.

An Ethics for Complexity: The Framework for This Commentary

The issues selected by the November 1997 workshop as meriting priority attention exhibit interaction and tension among the multiple and diverse values,

[2] E Levinas. *Totality and Infinity: An Essay on Exteriority*. Translated by Alphonso Lingis. Pittsburgh: Duquesne University Press, 1969.

[3] W Farley. Ethics and reality. Dialogue between Caputo and Levinas. *Philosophy Today* 1992; 36/3: 210-220.

experiences, rights, and responsibilities linked to the need to prevent HIV transmission and to the need to treat, care for, and support persons who use drugs. The social situations giving rise to these issues are complex and they will remain resistant to any form of simplification ethics and policy, such as approaches based upon the metaphors of war or upon unexamined ideas about the unlimited power of the human will ("Just say no!"). Moreover, the lives of those involved in drug use often exhibit a particular kind of biographical complexity marked by the coexistence of multiple personal, emotional, and medical problems, many of which reach deep into the past.

The ethical issues related to the prevention of HIV transmission as well as to the treatment, care, and support of persons using drugs are unlikely to be analyzed adequately or resolved effectively by a deductive method of ethics that simply tries to apply a small core of oft-repeated ethical principles, such as the principles of autonomy, beneficence, non-maleficence, and justice. Complex problems, such as the public health problem of the impact of poverty on health and premature death; the application of new genomic technologies to multifactorial disease; the negative impact of globalization on health-care systems; and the multiple causes and consequences of drug use tend to generate ethical issues that combine multiple and interacting levels of right and wrong as well as ranges of occasions where some evils (physical, social, moral) have to be tolerated for a time to avoid the occurrence of even greater catastrophes. It is for the analysis and management of such issues that there is a need to develop a new way of doing ethics, a way or method called an ethics for complexity.

Although an ethics for complexity is still under development and will take on several diverse forms rather than one single approach, we may characterize ethical issues as being complex when they exhibit one or several of the following *indices of complexity*. A selection of those indices of complexity most relevant to the seven priority issues subject to ethics commentary in this paper will be briefly described and these indices will be referred to in the ethics commentaries on the seven priority issues.

The following indices of ethical complexity are presented here not in any linear, sequential, or hierarchical order, but rather in a phenomenological fashion. We examine the phenomenon of ethical complexity from different perspectives, and these perspectives define the features or indices of complexity.

The tension index

An ethical issue is complex if it inevitably involves the need to maintain a tension between two or more values that may be in conflict. Simplification would favour the sacrifice of one or another of these values. Complexification requires that both or all be maintained, but in tension. A dynamic interaction is set up so that across time one value may be emphasized for a while over others, without the others being abandoned or sacrificed.

This tension is reflected in the statement of Sir Karl Popper: "If we wish to remain human, then there is only one way, the way into the open society. We must go on into the unknown, the uncertain and insecure, using what reason we have to plan as well as we can for *both security and freedom*."[4] (Emphasis added)

[4] KR Popper. *The Open Society and Its Enemies*. Vol. 1. *The Spell of Plato*. 5th ed. London: Routledge and Kegan Paul, 1966, at 200-201.

The unintended-consequence index

An ethical issue is complex if it centres on courses of action that, although initiated with the best of often unenlightened intentions and for high moral and social purposes, can become radically separated both from these initial purposes and their first agents. These courses of action can, indeed, become totally diverted from their opening directions and can come to wreak havoc that the initiators of these actions would now totally abhor. The opposite can also occur. Unforeseen consequences of great good can come to be when actions initiated by some are taken to new heights of achievement by others.

This index of complexity, the likelihood of unintended consequences, is reflected in the statement of Edgar Morin: "l'action se déracine de l'acteur... "[5] (actions become uncoupled from their agents).

The praxis–plurality index

An ethical issue is complex if its resolution cannot be reduced to the application of some one or several fundamental, universal, and invariant principles.

This index is reflected in Ivar Ekeland's statement about how each time we think we have found the ultimate component of reality, the fundamental building block of the universe, the particle breaks *downwards* into smaller pieces, as in the story of King Olaf's dice recounted by Ekeland in his book on chance, *The Broken Dice*.[6] In similar fashion, an ethical issue is complex when the principle (or principles) that supposedly govern the course of action at issue tend(s) to break apart *upwards* into an unfinished and novel plurality and diversity of practical ethical judgments deriving from a related diversity of human beliefs, experiences, and explorations.

The feedback index

An ethical issue is complex when its management requires multiple turns in the cycle of interplay between horizon ethics, normative ethics, and practical ethics.[7]

Normative ethics is the work of formulating principles, norms, procedures, or regulations to reduce the complexity of divergent and conflicting interests, desires, behaviours, and courses of action to some kind of stable order capable of guiding human activity away from chaotic movement.

Horizon ethics focuses on the intellectual, cultural, social, philosophical, and moral context within which normative ethics operates. Horizon ethics deals with the limits and conflicts affecting what people believe, perceive, conceive, and what they seize upon as values to be maintained at all cost versus values that can be abandoned or compromised when circumstances leave no other choice.

The work of *practical ethics* is to produce particular judgments or decisions, and this work requires comprehensive attention to the full particularity of specific cases and situations, whether these involve individuals or populations.

A complex ethical issue will typically foster cycles of feedback and interplay between these three levels or phases of ethics. A practical ethical judgment or decision on a course of action in a particular situation may enter into conflict with, and stimulate a reassessment of, existing social norms, perceptions, and basic assumptions. The converse may also occur. A course of action, initially thought to be ethically acceptable or tolerable, may, upon

[5] E Morin. *La Méthode. 2. La Vie de la vie*. Paris: Éditions du Seuil, 1980, at 82.

[6] I Ekeland. *The Broken Dice*. Chicago, London: The University of Chicago Press, 1993, at 28.

[7] DJ Roy, G Kramar, G Cleret de Langavant. Ethics for Complexity. In: BM Knoppers, CM Laberge, M Hirtle (eds). *Human DNA: Law and Policy*. The Hague, London, Boston: Kluwer Law International, 1997, at 189-209.

reconsideration in the light of governing assumptions and principles, have to be reversed.

The emergence index

The order in normative ethics is *explicate*:[8] the principles, norms, and laws governing behaviour are already worked out in advance of any applications made of them to concrete action. That order is explicate because it can be laid out, made evident as a whole, and appeal is made to that order to ground conclusions about the ethical justifiability, unacceptability, or tolerability of actions and policies.

An *implicate* order cannot be made explicit, cannot be set out in its complete and finished form. That order is manifested or emerges slowly and only partially as it takes shape across sequences of, and interactions between, practical ethical judgments and decisions. Certain ethical issues cannot be resolved once and for all on the basis of existing normative orders. It is an index of complexity that certain issues require an ethical order that emerges across ranges of practical judgments that have to be made on situation after situation reflecting and expressing such issues – in this case, in the domain of HIV prevention and of the treatment, care, and support of those involved in drug use.

The surd index

Complex numbers in mathematics are combinations of rational and so-called irrational numbers. Rational numbers include, for example, the whole numbers and fractions made up of integers as nominator and denominator. The square root of 2, indicated symbolically as $\sqrt{2}$, is called a surd, or irrational number, because it is greater than 1 and less than 2 but is not a rational fraction of two integers.

In an analogous fashion, social situations resulting from the cumulative interaction of individual and group decisions can come to be something like the complex numbers, namely, a compound of the rational and the irrational. The irrational component grows as decisions increasingly depart from the demands of intelligence.

The understanding and resolution of issues that are ethically complex because they combine both rational and irrational components requires the combination of direct and inverse insights.

Direct insights are the components that are absent from our knowledge when we do not understand something, and are added to our knowledge when we do come to understand. Inverse insights bring the realization that inquiry in a given direction is never going to discover anything, that action in a given direction is never going to achieve anything. Inverse insights help people to stop struggling to find answers to false questions, to stop seeking results and success with methods that are doomed to failure.[9]

The resolution of ethical issues that are complex in the sense of being a combination of rational and irrational elements requires direct insights to grasp the components of the situation meriting development; and inverse insights to grasp the components of the situation that need to be reversed if the ethical-social surd is not to grow and approximate a point of absurdity.

The frozen-accident index

The term "frozen accidents"[10] refers to chance events (accidents) of which the outcomes have a multiplicity of long-term consequences, all related by their

[8] D Bohm. *Wholeness and the Implicate Order*. London: Routledge and Kegan Paul, 1980.

[9] BJF Lonergan. *Insight. A Study of Human Understanding*. New York: Longmans, 1957, at 54-57.

[10] M Gell-Mann. *The Quark and the Jaguar. Adventures in the Simple and the Complex*. New York: WH Freeman and Company, 1994, at 133-134, 227-230.

common ancestry. Some of these accidents come to take on the character of regularities, rules, or laws for the future; they become frozen.

A frozen accident can occur in ethics when lower viewpoints favouring cycles of decline take on the character of a regularity or a policy or an entrenched pattern of behaviour that serves as a rule (for now and for the future). They can also occur when social responses – be these principles, regulations, policies, or laws – adopted generations ago to manage a given problem become seriously maladaptive because they are simply maintained, repeated, and enforced years later when social circumstances, attitudes, and understanding have changed.

An ethical issue's complexity may result from an enduring dissonance between entrenched positions and policies versus new perceptions and policies required when circumstances have changed radically.

The irreversibility index

Irreversibility is a central index of complexity in ethics. In the domain of the biomedical sciences and biotechnology, in particular the science–biotechnology process initiated with the Human Genome Project, it is often impossible to specify what is ethically mandatory, tolerable, or to be prohibited as morally reprehensible until the exploration of what is scientifically or technologically possible has begun and has advanced. The chains of consequences–developments–further consequences of a biotechnological undertaking can often be perceived and understood when they can no longer be avoided or reversed. Prior to their emergence, these chains of consequences and their impacts cannot generally be adequately enough specified in thought experiments to allow for their ethical evaluation. When these chains of consequences and their impacts can be ethically evaluated, it may be too late to reverse them and their damage, if damage has been caused.

Ethical issues exhibiting the irreversibility index have already arisen in the areas of the prevention of HIV transmission and injection drug use. The failures to provide syringe/needle programs and to screen blood donations adequately have each had irreversible consequences for those infected.

The complementarity index

Ethical issues may reflect a feature of complexity similar to the complexity Prigogine has recognized in the description of physical systems. His emphasis is on the fact that no single theoretical language can exhaust the physical content of a system. Various possible languages and points of view are needed and are complementary in efforts to comprehend and describe a physical system. All these languages and descriptions focus on the same reality but it is impossible to reduce them to any one single language or description. "The irreducible plurality of perspectives on the same reality expresses the impossibility of a divine point of view from which the whole of reality is visible."[11]

This feature of complexity underscores the occasions when the wealth of reality overflows any single language and any single logical structure. Courses of action that reflect or generate such a wealth of reality may well give rise to ethical issues that cannot be understood or resolved on the basis of any one single ethical language or system of analysis. Issues exhibiting this feature of complexity will require multiple kinds of ethical analysis that are irreducible to any one approach of ethical analysis and evaluation. For any given ethical issue with these features of complexity, it remains an open question whether a higher, more comprehensive ethical viewpoint and a correspondingly more

[11] I Prigogine, I Stengers. *Order Out of Chaos*. London, Toronto: Bantam Books, 1984, at 225.

integrative ethical judgment can emerge from the interplay of the complementary ethical languages and perspectives required to match the ethical reality.

The fractal index

Where some would want to suppress diversity in beliefs, values, and behaviours as being a source of moral error, a fractal ethics respects such diversity as being a potential source of moral wisdom. In analogy with Mandelbrot's fractal geometry,[12] respect for the rich, if not infinite, diversity of beliefs about human life, and for the many diverse ways of living humanity, requires a fractal ethics.

Fractal geometry was developed to explore and capture the form of structures in nature that seemed to be pathological because they failed to conform to classical geometrical patterns. In an analogous way, fractal ethics seeks to explore, understand, respect, and evaluate the very diverse ways of living a human life, a diversity that many people find to be in contradiction with their classical view that there should be one ethic for all people in all places and at all times.[13]

[12] BB Mandelbrot. *The Fractal Geometry of Nature*. San Francisco: WH Freeman and Company, 1983.

[13] DR Roy. Diversity: a matter of ethics. In: SE Nancoo, S Ramcharan (eds). *Canadian Diversity: 2000 and Beyond*. Mississauga, Ontario: Canadian Educators' Press, 1995, at 334-354.

Current Legal Status of Drugs and Drug Use

Priority issue 1 was stated in the form of the following questions:

- What is the impact of the current legal status of drugs and drug use on HIV/AIDS care, treatment, and support of drug users?
- What are possible alternatives to the current legal status?
- What legal and ethical issues are raised?
- Are there ethical reasons for moving to alternatives?

The thrust of these questions is toward the need for a modification of existing law and public policy approaches regarding psychoactive drugs. Because it is utterly impossible in the few pages allotted for this issue to consider comprehensively the ethical aspects of this issue, I will restrict this commentary to a sketch of some of the most important considerations that I think should govern a more developed and extensive ethical analysis.

Inverse Insight

I open this commentary with a reference to the unintended-consequence index and to the surd index of ethical complexity discussed in the preceding section.

It is scientifically crucial to realize when continuing research in a given direction is simply advancing ever more deeply into a cul-de-sac and will lead to no discovery. Likewise, it is ethically crucial to recognize and acknowledge that a given course of action, when such is the case, is no longer advancing the achievement of the ends for which it was initiated, but is now becoming destructive of these ends. Such a realization has been called *inverse insight*.

Direct insights are the components that are absent from our knowledge when we do not understand something, and are added to our knowledge when

The irrational component in current drug policies has reached the point of an imperative for reversal. Continuance of these policies and campaigns for control of all aspects of drugs now declared illicit can no longer be ethically justified.

Social responses – be these laws, policies, or regulations – adopted generations ago and representing a needed and justifiable social adaptation in the circumstances and in the general social context of the time, may become seriously maladaptive when they are simply maintained, repeated, and enforced years later when social circumstances, attitudes, and understanding have changed.

we do come to understand. Inverse insights bring the realization that inquiry in a given direction is never going to discover anything, that action in a given direction is never going to achieve anything. Inverse insights help people to stop struggling to find answers to false questions and to stop seeking results and success with methods that are doomed to failure.

The impacts of the current legal status of drugs and of the campaigns launched by the so-called war on drugs, impacts described with precision and detail in the background papers of Oscapella/Elliott and Riley, indicate that the irrational component in current drug policies has reached the point of an imperative for reversal. Continuance of these policies and campaigns for control of all aspects of drugs now declared illicit can no longer be ethically justified, for the following reasons. The currently reigning criminalizing approaches:

- have failed to achieve the goals for which they were designed and promoted;
- feed the logic of exclusion, described earlier in this paper;
- involve misuses of limited resources that amount to an ethically intolerable social sin against distributive justice;
- stimulate the rise to power of socially destructive and violent empires; and
- fuel a spiral of decline of the humanity that is essential to civilized societies.

These currently observable and socially intolerable consequences were never really intended, but they have occurred and will continue to occur so long as laws and policies fail to recognize and acknowledge and come to terms with the irreducible complexity of psychoactive drug use in contemporary society.

Positions and Counter-Positions

Part of the complexity affecting psychoactive drug use derives from the policies, laws, and regulations a society has adopted and maintained to control or outrightly prohibit the use of such drugs. The term *complexity*, as used here, has at least two components or meanings. First, as in the case of complex numbers mentioned above, social policies and resulting social situations shaped by such policies may comprise both rational and irrational components. Secondly, the complexity of social policies and resulting social situations derives from their history. Existing policies and laws, in this case against psychoactive drugs, may represent what are called "frozen accidents" in complexity theory (see the "frozen-accident index" discussed above). Social responses – be these laws, policies, or regulations – adopted generations ago and representing a needed and justifiable social adaptation in the circumstances and in the general social context of the time, may become seriously maladaptive when they are simply maintained, repeated, and enforced years later when social circumstances, attitudes, and understanding have changed. It is no accident that policies that have become "frozen accidents" can provoke unintended but socially very destructive consequences.

It is at this point that the notions of positions and counter-positions come into play.[14] The key to understanding the difference between the two is the idea of coherence with inquiring intelligence and reflective reasonableness. Positions invite and promote development because they are not only consistent among themselves, but fundamentally because they are coherent with, and modified in accordance with, the demands of inquiring intelligence and reflective reason. These demands include the need for evidence as the basis for decision and action. Counter-positions, while they may be consistent with one another, invite reversal because they lack coherence with the demands of

[14] Lonergan, supra, note 9 at 387-390, 680-683.

inquiring intelligence and reflective reason. Counter-positions harbour irrationalities or deep errors that cannot withstand the onslaught of intelligence and reason. Counter-positions, however, may be difficult to reverse, and their reversal may take a very long time if they are backed and defended vigorously by power that steadfastly refuses to submit to the demands of intelligence and reason.

Existing policies, laws, and regulations governing psychoactive drugs are not totally coherent.

Existing policies, laws, and regulations governing psychoactive drugs are not totally coherent. They harbour at least the following scientific errors:

> such as 1) bad pharmacology – that marijuana is an addictive narcotic and that tobacco does not contain a drug; 2) bad psychology – that repetitive drug use can always be controlled through intentional behaviors; 3) bad sociology – that the drugs used by foreigners and minority groups are the bad drugs, and that criminal laws can effectively reduce psychoactive drug use at a low cost to society; and 4) bad economics – that the increased "cost of business" for selling an illegal product will outweigh the increased profits to be made from selling through illegal markets.[15]

The social surd surrounding psychoactive drug use has also been reinforced by strategies that act directly against the imperatives of inquiring intelligence and reflective reason. Musto has observed how "severe penalties, silence and, if silence was not possible, exaggeration, became the basic strategies against drugs after the decline of their first wave of use."[16] *Severe penalties* reached a high point in the United States in the mid-1950s when the federal government introduced the death penalty as an option for anyone older than 18 who provided heroin to anyone under 18 years of age.[17] A 1936 article in the *American Journal of Nursing* illustrated the heights *exaggeration* can attain when it warned that marijuana users will turn with murderous violence against anyone nearest to them. They will run amuck with knife, axe, gun, or anything else that is close at hand, and they will kill or maim without any reason.[18] *Silence* can encompass not only the refusal to inform students adequately and honestly about drug use, but also the refusal to know as reflected in the NIH's consistent refusal to fund research on marijuana despite rising numbers of claims about marijuana's benefits in alleviating a range of medical conditions.[19]

It is seriously unethical not to consider seriously alternatives to drug laws and policies harbouring counter-positions that invite and require reversal.

Integrative Complexity

The ethical challenge spanning the four parts of Issue 1 is to grasp the components of current drug law and policy that merit development and to identify those components that need to be reversed if the social surd is not to continue its development into intolerable absurdity. This is an ethical challenge to develop the workings of what has been called *integrative complexity*.

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The concept of integrative complexity has been developed and used to analyze political rhetoric[20,21] and it has also been used to analyze modes of argumentation in the ongoing debates over the decriminalization or legalization of psychoactive drugs.[22]

Simplification thinking and simplification ethics employ undifferentiated views. Both tend:

- to focus on the here and now and to avoid attending to history;

[15] DC Des Jarlais. Editorial: Harm reduction – A framework for incorporating science into drug policy. *American Journal of Public Health* 1995; 85(1): 10-12.

[16] DF Musto. Opium, cocaine and marijuana in American history. *Scientific American* July 1991: 46.

[17] Ibid.

[18] Ibid.

[19] GJ Annas. Reefer madness – The federal response to California's Medical-Marijuana Law. *New England Journal of Medicine* 1997; 337(6): 438.

[20] PE Tetlock. Integrative complexity of policy reasoning. In: S Kraus, RM Perloff (eds). *Mass Medical Political Thought*. Beverley Hills, California: Sage, 1985.

[21] PE Tetlock. Monitoring the integrative complexity of American and Soviet policy rhetoric: what can be learned. *Journal of Social Issues* 1988; 44: 101-131.

[22] RJ MacCoun, JP Kahan, J Gillespie, J Rhee. A content analysis of the drug legalization debate. *Journal of Drug Issues* 1993; 23(4): 615-629.

- to focus on means and ignore the relationship of means to the ends they are supposed to serve; and
- to employ black-and-white judgments in situations calling for very diverse and interrelated ethical assessments when multiple values of greater and lesser importance are in conflict.

Differentiation is the first component of integrative complexity as a method both of rhetoric and of ethics. Differentiation means not only that there are many different ways of looking at a problem, but that problems will remain unresolved and become ever more resistant to resolution if they are reduced to one or another of their components and are not diagnosed in their complexity. An undifferentiated view of alternatives to current policy and legislation may tend, for example, to close all discussion by invoking the wrong signals and messages that any change in legislation would send to the general public, and particularly to young people. Other messages that are now being sent, loudly and clearly, by the disastrous consequences of current policy are passed over in silence; they do not enter the process of argumentation or decision.

Decision is the point where integration, the completing component of integrative complexity, comes into play. If real problems are to be resolved, it is not enough simply to set out the various ways of looking at our current drug problem. "Integration refers to the ability to deal with differentiation in a constructive way."[23] Constructiveness involves the ability to recognize which components in drug policy need to be maintained; which components need to be reversed; and which alternatives need to be explored and submitted to controlled experiment if we are ever to free ourselves from whirlpools and navigate into steady and desired currents.

[23] Ibid at 621.

Drug Use and Provision of Health and Social Services

The second priority issue raised in the November 1997 workshop was framed in the following way: "What legal and ethical issues must be considered in allowing or tolerating drug use in the course of providing health care and social services (primary health care, community clinics, pharmacy services, residential care, palliative care, housing services)?"

My commentary on this question will focus on the ethical issues to be considered in allowing or tolerating drug use in the course of providing residential and palliative care services. The commentary has grown out of numerous readings, but particularly out of conversations with staff working at "Chez ma cousine Evelyn" in Montréal and with a key person working at "May's Place" in Vancouver. Reports of the work and experience of "Chez ma cousine Evelyn" have featured prominently among my readings.[24]

For the purposes of this commentary, we may distinguish two kinds of ethical issues: the basic ethical issues and the derivative ethical issues. The *basic ethical issue* is: What is the ethical imperative to mobilize and maintain all services needed to "bring people home" before they deteriorate irreversibly and then die in society's zones of total abandonment? The *derivative ethical issue* arises – given the dominant attitudes, values, laws, and policies of our society on drugs and behavioural minorities – once the commitment is made and actions are undertaken "to bring home" those who are treated as though they are not one of us, who are treated as though they do not belong in our society and community.

Before focusing on the basic ethical issue, I shall comment briefly on some of the recurrent derivative issues people face when they undertake to house and offer palliative care services to persons who, by and large, have no home; often have no family; are HIV-infected; are dependent drug users; may, in addition,

[24] Corporation Chez ma cousine Evelyn. Rapport. Montréal, 12 December 1997; R LeClerc. Hébergement pour sans-abri vivant avec le VIH/sida. Chez ma cousine Evelyn Inc., Montréal, 1992; Corporation Chez ma cousine Evelyn. Rapport annuel d'activités 1996-1997. Montréal; Corporation Chez ma cousine Evelyn. Rapport annuel d'activités 1995-1996. Montréal.

have multiple illnesses; and are often not accustomed to living anything like a stable life.

Derivative Ethical Issues

The central derivative ethical issue is whether it is ethically justifiable to allow or tolerate illegal drug use in residences and within palliative care services for HIV-infected and drug-use dependent persons.

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The central derivative ethical issue is whether it is ethically justifiable to allow or tolerate illegal drug use in residences and within palliative care services for HIV-infected and drug-use dependent persons. This is, I would emphasize, *only* a derivative ethical issue. It is not the basic ethical issue. The basic ethical issue, to be discussed later, deals with the ethical imperative to care adequately for these persons and with the included ethical issue of what is essential for the adequate care of these persons.

Additional derivative ethical issues derive from the central derivative ethical issue of tolerating or allowing illegal drug use. Among a range of such issues, the following seem to recur and pose considerable difficulties.

Non-allowance of illicit drug use may protect an establishment's license or social authority to operate, but at the cost of being able to operate a largely empty haven.

Non-allowance of illicit drug use may protect an establishment's license or social authority to operate, but at the cost of being able to operate a largely empty haven.

First, how can one arrange to allow illegal drug use without the establishment's losing its licence or social permission and authorization to operate? The ethical dilemma is: does the allowance of illegal drug use imperil the very raison d'être of the establishment, to be a haven for those who, because of their illegal drug use, are abandoned and threatened with evolving physical, psychosocial, and social deterioration? The other horn of the dilemma is: non-allowance of illegal drug use may protect an establishment's licence or social authority to operate, but at the cost of being able to operate a largely empty haven.

Second, with very limited resources, how can one arrange adequately to care for staff who may have considerable difficulty living with the realization that they are condoning or even collaborating with offences against the law? Particularly difficult, aggressive, or abusive residents may well awaken the latent vulnerabilities and uncertainties of the staff. This issue also reflects on the related ethical issue of the criteria that have to be established for the selection of persons to work in residences and within palliative care services when these very services require the allowance of illegal drug use.

Third, to what extent can staff, well-intentioned in their toleration of illegal drug use in a residence, allow a resident to continue to deteriorate under the drug use the very allowance of which was meant to be conducive to his or her improvement? In other words, what do staff in a residence do when persons fail to stabilize and improve, but actually get worse, under their care and services?

Fourth, how does one ethically assure accessibility to illegal drugs when residents are incapacitated to the point that they can no longer move about to contact their dealers and obtain their drugs themselves?

Fifth, residences and palliative care services could not survive without clearly defined rules regarding tolerable and intolerable behaviour. When residents are afflicted with multiple psychological and behavioural difficulties, and marked by a history of disorganized living habits, situations will inevitably arise that present ethical conflicts about enforcing house rules versus tolerating violations of these rules to maintain eventually stabilizing relationships with those who break out into disturbing behaviours.

These and a range of other ethical issues centering on the responsibilities of staff as well as on the rights, needs, and often limited behavioural capacities of residents all emerge from the basic ethical imperative to care for those who are without resources and are at or already over the borders of total abandonment.

The Basic Ethical Issue

The basic ethical issue underlying Issue 2 is contained in the question: "Is there nothing between us?"[25] The *us*, here, involves all those who are despised, rejected, and abandoned because of their drug use, their disorganized lives, their disturbing behaviour, their HIV infection, their sexual orientation, or a combination of all of these factors. The *us* involves those who reject and abandon other human beings for all of these and other reasons. The *us* involves those who recognize the ethical imperative contained in the logic of humanity: the responsibility to care is strongest when the need for such care is for those who have become most distanced from their human dignity. The basic ethical issue is whether we endorse or whether we move far beyond the logic of exclusion expressed chillingly in the last line of Sylvia Plath's poem "Medusa," where she declares: "There is nothing between us."[26]

The responsibility to care is strongest when the need for such care is for those who have become most distanced from their human dignity.

The basic ethical issue here is whether we will live the ethic of humanity. To do so we have to enter a space that is not dominated by Levinas's criticized totality, a space not dominated by the despising of diversity and its related logic of exclusion. For humanity is a space. Humanity is the space where those who limp through time, far out in the shadows and beyond the margins of respectability, status, privilege, and power, are brought into the light of honour, rights, peace, and dignity. Humanity is the space where those who are broken by their guilt, their losses, their disease, by their social rejection and abandonment and, eventually, by their impending death, do not have to live and die lonely and alone. Humanity is the place where crushed spirits find persons who have the patience to breathe gently on the flaking gray ash of a human being's dying hopes to awaken a flame, a flickering flame at least, of courage. Humanity is the place where people are accepted as they are, and are not – because of their diversity – denied their basic human and related civil rights, including in particular the right and need to see themselves as genuine and equal members of society and of the community in which they live.

The ethic of living and acting within this space called humanity includes the following positive and negative imperatives.

1. See and relate to people in terms of their full human particularity of body, behaviour, and biography. Do not reduce people to any one feature of who they are.
2. Distinguish what a person can do now from what surpasses their current levels of ability. Do not impose upon people standards of behaviour when such demands will only force them more rapidly down spirals of decline.
3. Respect the principle and the ethic of complexity. Any person's biography, even when we find it at its lowest levels of decline, or even in its final stages, is still emerging as the totally dejected, disheveled, or even dying person confronts and reacts to treatments, to care, and to unexpected experiences of human kindness and concern. The ethics of complexity is expectant of an opening horizon of hope that can happen from the joining of the biographies of those who are abandoned with the biographies of those who can care.
4. Respect the principle of emergence. Moving upward out a long spiral of decline and degradation and loss of sense of self-worth takes time, a lot of time, a lot of care, and a lot of simple acceptance by other human beings. A biography that has now reached chapter 10, with earlier chapters

[25] DJ Roy. Is there nothing between us? *Journal of Palliative Care* 1995; 11(2): 3-4.

[26] Quoted here from George Steiner's essay on Sylvia Plath (Dying Is an Art) in: G Steiner. *Language and Silence. Essays on Language, Literature and the Inhuman*. New York: Atheneum, 1982, at 299.

consisting largely of stories of abuse, rejection, abandonment, and massive instability, cannot suddenly shift in chapter 11 to stories of emancipation, stability, and nearly miraculous social and personal achievement. Such stories will come in later chapters, after intervening chapters of that person's biography can recount the tales of other persons' constant and sensitive support while the broken person slowly comes back together again.

5. Respect the logic of needs. Symbolically, people have first to be brought home before they can build their home. What can this mean? It can and does mean that caring for broken people has its own ethical imperative: feed them, clothe them, treat their illnesses, shelter them, nurture their nearly extinguished sense of personal dignity and worth, and support and tolerate the satisfaction of other needs, such as their need to use drugs, while and until the sustained fulfillment of their basic needs will enable them to grow strong and stand tall. One may ethically have to tolerate many behaviours that offend against dominant social values, sensibilities, and laws while helping people move out of personal and social disruption into a living in human dignity.
6. Recognize what is of highest importance in situations marked by unsurpassable limits. Attempting to free a person from addiction is not the value to be pursued when that person, having been dependent on drugs for years, is now in the final stages of advanced HIV disease or any other disease. In this palliative care context, helping the dying to die with the dignity that comes from sensing that one has arrived, one is at home, one is affirmed and cherished, not just tolerated, is the highest ethical imperative of the moment. If our ethic does not allow us to embrace these people with their drugs, it does not really allow us to embrace them at all.

Attempting to free a person from addiction is not the value to be pursued when that person, having been dependent on drugs for years, is now in the final stages of advanced HIV disease or any other disease.

Living out the imperatives of an ethic of humanity may well permit us to say of one another what Seamus Heaney, in the last two lines of his poem "Seeing Things," said of himself and his father:

> And there was nothing between us there
> that might not still be happily ever after.[27]

[27] S Heaney. *Seeing Things*. London, Boston: Faber and Faber, 1991, at 18.

Treatment

The third priority issue centers on treatment of injection drug users and was framed in terms of the following two questions:

- Is it legal and ethical to make cessation of drug use a condition for treatment for a drug user?
- Is it legal and ethical to withhold antiretroviral drugs (particularly current triple and quadruple combinations of drugs) from HIV-positive drug users?

Cessation of Drug Use As a Condition for Treatment

I cannot, with the time and space available, presume to offer an exhaustive and comprehensive commentary on all the situations in which this question might arise. However, the following brief case study will illustrate how the ethics analysis of this question might be conducted.

He is 27 years old and is hospitalized for a fairly lengthy period to undergo antibiotic treatment for his endocarditis, caused by infections following upon his frequent injection use of drugs. The hospital has a no-smoking policy, so he goes outside periodically to smoke. That is when his friends meet him and furnish him with drugs.

The clinical team is in an uproar. One team member threatens to put this young man before the choice: stop taking drugs while you are in this hospital or we stop treating you.

Two ethically and clinically relevant questions arise at this point. *First*, is the particular drug this young man is taking on the sly interfering with his antibiotic therapy? *Second*, what are the consequences of stopping the antibiotic therapy for the endocarditis?

Stopping the antibiotic therapy will lead to disastrous consequences, deterioration and eventually death. Of course, this will also occur if the young man continues to take the drug and if the particular drug taken is nullifying the

Are the clinical staff ethically justified in controlling access of friends to the young man's hospital room, and thereby blocking this supply of drugs?

antibiotic treatment. Is this drug rendering the antibiotic treatment useless? In this case, the answer was no, it was not.

So it would not be ethically justifiable to insist on cessation of drug use as a condition for treatment of the endocarditis in this case, particularly if this insistence were to provoke the young man to leave hospital and interrupt the course of treatment.

Are the clinical staff ethically justified in controlling access of friends to the young man's hospital room, and thereby blocking this supply of drugs? They might be so justified, particularly if the visits were a disruption of order on the ward; or if the particular drug supplied, even if it did not interact destructively with the antibiotic therapy, destabilized the young man and provoked him to behaviours that interfered seriously with the therapy.

In the particular case under consideration, the visiting friends were not disruptive of hospital order and the young man did not fall into chaotic behaviour.

However, other ethical aspects of this case came to the fore. Some of the staff members had never dealt with injection drug users before. They became aware of their own attitudes of disgust toward this young man. They became aware also of the power game they were beginning to play. "Here, my friend, you follow our rules, no matter what!" They also became aware that this power game was disrupting the therapeutic relationship, a relationship that can rapidly disintegrate if it is not built on respect and on the trust that requires mutual respect.

Once that respect was re-established, the staff came to see this young man in a very different light and to learn things about him that they never knew or suspected: first, that he had been trying for some time to stop his injection drug use; and second, that he had life plans. His deep desire was to get back to university and become the engineer he always wanted to be.

The major barrier to his realizing his life plans was another power game, power game two of this real-life story. This young man's friends exercised a very strong influence over him. They manipulated him and intended to help him within their circle of influence, and his going back to university and abandoning injection drug use would have broken the spell of influence they enjoyed over him.

However, this young man simply had to smoke, and it is when he would go to smoke that his friends would have their prime chance, not under surveillance as they would be in visits to his hospital room, to continue exercising their influence over the young man, an influence mediated by the supply of drugs.

Well, why did the young man have to go outside the hospital to smoke? This is where power game three comes to the fore. The hospital had reasonably established a no-smoking policy and, again reasonably, this policy included "no exceptions." However, were not the circumstances of this case particular enough to justify a reconsideration of the "no exception" part of the no-smoking policy? Staff members were somewhat surprised to realize that they could ethically consider this possibility. A way was found and the young man successfully completed his endocarditis antibiotic therapy. Moreover, the length of the treatment period was also a period of freedom from his friends, a period of freedom sufficient to start him on the road to greater independence.

So, the bottom-line response to the question of whether it is ethically justifiable to make cessation of drug use a condition for treatment is an "It depends" kind of response. The underlying method is the method of conditional ethics: specify the conditions under which it could be justifiable as well as the

conditions under which demanding cessation would be utterly intolerable. The above case history (suitably modified to protect the confidentiality of the young man, the institution, and the clinical staff) illustrates some of these conditions.

This case, for example, illustrates that it would be clinically irresponsible and ethically reprehensible not to insist on cessation of drug use if such use were to nullify the antibiotic therapy for endocarditis, with ensuing death as a likely consequence. On the other hand, if the particular drug used were not to interfere destructively with treatment, it would be ethically unjustified to insist on cessation of drug use as a condition for treatment if such cessation were to be beyond the capacities of the drug user at the moment or if such insistence were to imperil the therapeutic relationships, with the drug user's possible abandonment of treatment being a possible or probable consequence.

Are there conditions under which use of treatments that include a protease inhibitor and two other antiviral medications are likely to cause more harm to the HIV-positive person, and indirectly to society, than would simpler treatments now considered by many to be suboptimal?

Withholding Antiretroviral Drugs: Points for Consideration

The second question of priority issue 3 was worded: "Is it legal and ethical to withhold antiretroviral drugs (particularly current combinations of drugs) from HIV-positive drug users?"

This simply worded question masks great scientific and medical complexity,[28] too great to be discussed in detail in this brief ethics commentary. Under this proviso, I open this commentary with two ethics questions hidden within this second question, and they are:

1. How can one fulfill a professional and ethical obligation – the obligation to treat HIV disease with the best treatments available – in conditions that render that fulfillment extremely difficult, unlikely to succeed, or impossible?
2. Are there conditions under which use of treatments (for HIV disease) that include a protease inhibitor and two other antiviral medications are likely to cause more harm to the HIV-positive person, and indirectly to society, than would simpler treatments now considered by many to be suboptimal?

Among all the scientific and clinical observations and knowledge accumulated to date in the treatment of HIV disease, the following several selected points for consideration are the most immediately relevant for this ethics commentary on this second question and the above-mentioned related questions for ethics.

Point 1: Guides for treatment decisions

Treatment decisions (to be made jointly by physicians and HIV-positive persons) should be clinically guided by the HIV-positive person's virologic and immunologic status. Decisions to initiate or change antiretroviral therapy regimes should be primarily, although not exclusively, guided by the HIV-positive person's viral load (plasma HIV RNA) and $CD4_+$T cell count.

Point 2: Medical complexity of antiretroviral therapy regimens

The immediate medical goals of treatment are to achieve maximal suppression of viral (HIV) replication and preservation cum increase of $CD4_+$T cells. The antiretroviral treatment regimens (triple therapies, including one of the most potent protease inhibitors) currently most effective to achieve these goals are also very complex. These treatment regimens have important specific side

[28] M Feinberg. Commentary. Hidden dangers of incompletely suppressive antiretroviral therapy. *Lancet* 1997; 349: 1408-1409; CCJ Carpenter, MA Fischl, SM Hammer et al. Consensus statement. Antiretroviral therapy for HIV infection in 1997. Updated recommendations of the International AIDS Society – USA Panel. *Journal of the American Medical Association* 1997; 277(24): 1962-1969; British HIV Association (BHIVA) Guidelines Co-Ordinating Committee. Consensus statement. British HIV Association guidelines for antiretroviral treatment of HIV seropositive individuals. *Lancet* 1997; 349: 1086-1092; SG Deeks, M Smith, M Holodniy, JO Kahn. HIV-1 protease inhibitors. A review for clinicians. *Journal of the American Medical Association* 1997; 277(2): 145-153.

Ethically justifiable treatment decisions are all the more likely if they come out of a relationship between HIV-positive persons and physicians that is marked by the four characteristics: autonomy, lucidity, fidelity, and humanity.

effects and interactions among the drugs used and they are far from easy to follow faithfully.

Point 3: Viral resistance

Non-compliance (or non-adherence) with antiretroviral treatment regimens that include a protease inhibitor, as well as uses of suboptimal or subtherapeutic dosages of the protease inhibitors, are two potent contributors to the development of viral resistance. That resistance reduces an HIV-positive person's future treatment options and may lead to the transmission of treatment-resistant strains of HIV.

Point 4: The initiation of triple therapy: factors to be balanced

The decision to start medically complex triple antiretroviral treatments for HIV-positive persons who are asymptomatic involves the need to balance at least the following factors (as identified in the US DHHS Guidelines):[29]

- willingness of the person to begin such therapy;
- degree of existing immunodeficiency as measured by the $CD4_+$T cell count;
- the risk of disease progression as gauged by viral-load measurements;
- the potential risks and benefits of initiating such treatment, as estimated for each individual person;
- the likelihood, after counseling and education, of faithful adherence to the combination therapy regimen.

It is unjust and intellectually false to judge people as likely to be non-compliant with triple therapy simply because they are prisoners, for example, or homeless, or drug users.

It is with this last factor that we return to the second question of this section and to its related questions identified above.

Ethically justifiable treatment decisions are all the more likely if they come out of a relationship between HIV-positive persons and physicians that is marked by the four characteristics: autonomy, lucidity, fidelity, and humanity.[30] I emphasize here the last of these essential characteristics of an authentic healing relationship: humanity.

Humanity in this context means respect for the full (biological and biographical) particularity of the HIV-positive person. Each person is unique and treatment decisions have to be tailored to match that uniqueness. The healing relationship and its humanity and justice break down when the HIV-positive person is not being seen in their full particularity, but is being obscurely and distortedly perceived through a film of bias. It is unjust and intellectually false to judge people as likely to be non-compliant with triple therapy simply because they are prisoners, for example, or homeless, or drug users. Moreover, barriers to adherence to treatment are often very complex and cannot be reduced to the personal characteristics of HIV-positive persons. Such barriers may be profoundly system-of-care related. Improve that system and adherence to treatment increases. This was demonstrated in Harlem, New York, for adherence to multiple-drug treatment for active tuberculosis. When the health-care system was adapted to meet the needs of socially marginalized and indigent persons, the treatment adherence of these persons rose from 11 to 91 percent.[31]

Situations, however, may well arise when HIV-positive persons, now living very unstable lives, have to be stabilized (psychologically, socially) before starting triple therapy. Decisions to delay and, at the extreme, to refuse triple-drug antiretroviral treatments to HIV-positive persons may be justified.[32] That justification, however, will be forthcoming only if the principle of justice

[29] Panel on Clinical Practices for Treatment of HIV Infection (Department of Health and Human Services – DHSS – and the Henry J Kaiser Family Foundation). Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents. Federal Register Draft Document, at 4.

[30] C Fried. *Medical Experimentation. Personal Integrity and Social Policy*. Amsterdam, Oxford: North Holland Publishing Company, 1974.

[31] D Bangsberg, JP Tulsky, FM Hecht, AR Moss. Protease inhibitors in the homeless. *Journal of the American Medical Association* 1997; 278(1): 63-65.

[32] Ibid. See also R Bayer, J Stryker. Ethical challenges posed by clinical progress in AIDS. *American Journal of Public Health* 1997; 87(10): 1599-1602.

(equal access for all to optimal treatments) is qualified by the principle of humanity (theoretically optimal treatment is not optimal for this person now). This latter decision is ethically unjustifiable if it has been reached without honouring the related characteristics of an authentic healing relationship, namely: autonomy (respect of the person's way of life and life plans); lucidity (transparent sharing of all relevant information); and fidelity (understanding and respect for the expectations of the sick).

Prescription of Opiates and Controlled Stimulants

The fourth priority issue was identified with the question: "What legal and ethical issues are raised by prescribing opiates and controlled stimulants to drug users?"

I focus attention in this commentary on the prescription of opiates for the treatment of addiction to heroin. The ethical issues fall into at least three categories: clinical ethics, research ethics, and social ethics. These issues can hardly be defined without reference to the best currently available understanding of addiction. That understanding itself has direct implications for the dubiousness of using the criminal justice system against those whose only crime is that they possess illegal drugs for their personal use. Moreover, an adequate understanding of addiction is essential for an adequate understanding of treatment. The understanding of both is essential for an ethics analysis.

The Current Understanding of Addiction

As recently as 1996, two leaders in the treatment of addiction thought it necessary to ask whether it is not now time to judge the worth of treatments for chronic addiction by the same standards used to assess treatments for other chronic diseases.[33] The understanding underlying this question is that drug addictions, such as heroin addiction, are not, as widely thought during the early part of this century, a manifestation of manipulative, criminal sociopathic behaviour, best managed by imprisonment.[34] Nor is heroin addiction, as many continue to think, merely an acute condition to be treated and even cured by detoxification methods.[35] Addiction is now increasingly understood to comprise more than the phenomena of tolerance and dependence and is rather a syndrome marked by compulsive drug-seeking behaviour resulting in a disruption

[33] CP O'Brien, AT McLellan. Myths about the treatment of addiction. *Lancet* 1996; 347: 240.

[34] A Goldstein. *Addiction. From Biology to Drug Policy*. New York: Will Freeman and Company, 1994, at 143.

[35] O'Brien & McLellan, supra, note 33 at 237.

of the addicted person's social and psychological functioning and in damage to health.[36] Addiction is a chronic relapsing disorder involving drug use–induced changes in brain pathways, changes that persist long after a person stops using drugs. If addiction is a relapsing disease of the brain, with essential behavioural, psychological, social, and even genetic components, treatment must be as multifactorial as is the syndrome.[37] If the syndrome or the disease is chronic, the treatment, depending on an individual's response, may have to last for a long time, even, in certain cases, for a lifetime.[38]

Prescription of Opiates for the Treatment of Addiction

The use of methadone – a synthetic opioid developed in Germany during World War II to replace morphine as a pain medication, opium supplies to Germany having been cut off due to the war[39] – to treat heroin addiction grew out of studies initiated in the early 1960s by Vincent P Dole (biochemist), Marie Nyswander (psychiatrist), and Mary Jeanne Kreek (at that time a resident in internal medicine).

The first clinical trials of methadone treatment showed that heroin addicts, after being stabilized on a daily dose of methadone, stopped their compulsive search for heroin, improved physically and psychologically, and were able to be rehabilitated and undertake regular employment over the ensuing years. A number of clinical studies demonstrated the safety of methadone treatment and that methadone maintenance did not adversely affect cognitive or psychomotor function, performance of skilled tasks, or memory.[40]

A range of other studies have demonstrated that effective methadone treatment programs:

- lead to a highly significant reduction in all types of risk associated with illegal opiate use, including both medical and social risk reductions;
- result in the highly significant reduction or cessation of illegal opiate use;
- have a positive impact on preventing the spread of HIV infection;
- increase the numbers of heroin addicts who become socially rehabilitated (able to run a home, attend school, hold a job); and
- lead to a reduction in arrests and imprisonments for crimes against property or person.[41]

However, *what does an effective methadone treatment program involve*? Reference was made above in the discussion of the concept of addiction to the concept of addiction as being a complex syndrome involving genetic, neurochemical, psychological, and social components. A randomized, controlled study of three levels of medical and psychosocial services, conducted in the early 1990s and involving 92 male intravenous opiate users, seems to support the view that a complex syndrome requires complex treatment if the effectiveness of that treatment is to be maximized.

This randomized, controlled trial studied three treatment groups for a period of six months. The trial participant drug users were randomly assigned to one or another of the three following groups:

1. minimum methadone services (MMS) – a minimum dose of 60 mg/d but no regular counseling and no extra services;
2. standard methadone services (SMS) – a minimum close of 60 mg/d plus regular supervised counseling, but no extra services;

A complex syndrome requires complex treatment if the effectiveness of that treatment is to be maximized.

[36] CP O'Brien. A range of research-based pharmarcotherapies for addiction. *Science* 1997; 278: 66-70.

[37] AI Leshner. Addiction is a brain disease, and it matters. *Science* 1997; 278: 45-47.

[38] O'Brien & McLellan, supra, note 33 at 239.

[39] Goldstein, supra, note 34 at 143.

[40] Ibid.

[41] MJ Kreek. Biological correlates of methadone maintenance pharmacotherapy. *Annals of Internal Medicine* 1994; 145(Suppl M.3): 9-14.

Methadone alone may well be a necessary, but not a sufficient, treatment for heroin addiction.

3. enhanced methadone services (EMS) – a minimum dose of 60 mg/d plus regular counseling, plus on-site medical/psychiatric care, family therapy, and employment counseling.[42]

The results of this study indicate that methadone alone may well be a necessary, but not a sufficient, treatment for heroin addiction. The SMS treatment group in this study demonstrated significantly more and greater improvements than did the MMS group and the EMS group showed greater improvements than did the SMS group.[43]

This study's investigators concluded that their results "are consistent with a growing body of work showing that those substance abuse patients who receive the most services during treatment have the best outcomes ... and that those substance abuse treatment programs that provide the most services to their clients have the best programmatic results."[44]

Prescription of Heroin?

In her background paper,[45] Diane Riley has pointed out that "methadone is not the drug of choice for all drug-dependent users because it does not work well in all cases, and users may end up going back to street heroin or other illegal opiates." She then describes the plans that were made in Australia to conduct a multi-stage trial to assess the impact of a policy shift toward the controlled availability of heroin to people already on the drug. These plans have been underway for some time and a study was published in 1993 to anticipate and analyze the ethical issues that such a trial would raise. This ethics study noted that at the time of its writing,

> political deliberations and further feasibility research are still underway. Thus it is not yet clear whether there will be a trial at all and, if so, what form it will take.[46]

Toward the end of her discussion of this proposed Australian trial of heroin maintenance, Dr Riley informs us that the Australian Federal Cabinet decided in August 1997 not to pass the legislation required for the importation of heroin for the trial and not to allow financial support for the trial.

At about the same time as the Australian decision not to support a heroin maintenance trial, the Swiss published a report of their three-year PROVE Study, PROVE standing for the Medical Prescription of Narcotics Programme.[47] This study involved a comparison of morphine, methadone, and heroin for intravenous and oral use, as well as a cigarette form of heroin. The points of comparison were the effects of these drugs (and modes of administration) on the health, social integration, and dependent behaviour of the research participants. The 1146 participants were persons with chronic heroin dependency, a history of failed attempts with other forms of treatment, and marked deficiencies in health and social integration. Those participants previously on methadone treatment had continued to use illegal heroin to a large extent during their methadone treatment.

Heroin, prescribed in this program's three-year study as part of a comprehensive approach involving psychosocial care, patient education, and therapy, resulted in improvement in the participants' state of health, dependent behaviour, and social integration. The report concludes that heroin-assisted treatment is useful for the target group of the study and that continuance of heroin-assisted treatment can be recommended for persons with the characteristics or indications selected for in this study.

[42] AT McLellan et al. The effects of psychosocial services in substance abuse treatment. *Journal of the American Medical Association* 1993; 269(15): 1954.

[43] Ibid at 1953.

[44] Ibid at 1959.

[45] Published in this volume, see infra, C22-24.

[46] R Ostini, G Bammer, PR Dance, RE Goodin. The ethics of experimental heroin maintenance. *Journal of Medical Ethics* 1993; 19: 175.

[47] A Uchtenhagen. Summary of the synthesis report. In: A Uchtenhagen, F Gutzwiller, A Dobler-Mikola (eds). *Programme for a Medical Prescription of Narcotics: Final Report of the Research Representatives*. Institute for Social and Preventive Medicine at the University of Zurich, Zurich, 1997.

There was also news published in the autumn of 1997 about a randomized controlled study involving the use of heroin as an experimental treatment for heroin addicts who had been declared as untreatable because they had gone through other treatment programs without success.[48]

As of the date of writing (June 1999), a protocol is nearing completion for a controlled North American multi-site trial to compare the use of injectable heroin (in conjunction with oral methadone according to need or desire) with the use of standard oral methadone as treatments for chronic injection drug users. Supportive medical, psychological, and social services will be standardized between the treatment arms. The goal of the study is to determine whether heroin (with or without methadone) is more successful as a substitution therapy than methadone alone in attracting, retaining, and benefiting (clinically and psychosocially) chronic injection drug users. A prime motivation for the organization and mounting of this study is the growing realization that chronic injection drug users are seriously in need of alternative substitution therapies. Conventional methadone treatment programs, even if they were sufficiently available, and they are not, could not meet the needs of many chronic injection drug users.

Chronic injection drug users are seriously in need of alternative substitution therapies. Conventional methadone treatment programs, even if they were sufficiently available, and they are not, could not meet the needs of many chronic injection drug users.

Clinical Ethics

The outcomes of clinical ethics are practical judgments about what should be done now to help persons make those therapeutic choices that will best correspond to their clinical needs and total-life interests. In clinical ethics, *the patient is the norm* governing the decisions and practical judgments to be made. The patient's body and biography – history of health and illness, clinical course, relationships, life plans, and total-life interests – constitute this norm. Clinical ethics works with patients' biographies to interpret the meaning of principles, to determine what principles (and related regulations and even law) command, permit, tolerate, or prohibit *for this particular person*.

In light of the information presented above on addiction as a chronic condition, on the effectiveness of methadone treatment as part of an accompanying program of medical and psychosocial services, and on emerging evidence of the potential effectiveness of heroin-assisted treatment accompanied by a similar comprehensive program of services for addicts who do not respond well to methadone maintenance, it would be *clinically unethical not to use these treatments* for persons who consent to these treatments and who stand to benefit from them.

Some may think that methadone-assisted or, even worse, heroin-assisted treatments are nothing more than the substitution of one addiction for another (in the case of methadone) or the perpetuation of the very addiction one is supposedly trying to treat (in the case of heroin-assisted treatment). However, such a way of thinking ignores the chronic nature of addiction that, like other chronic conditions (such as diabetes, hypertension, asthma), may well require long-term or lifelong treatment.[49] Moreover, the clinical ethics of using methadone-assisted or, where necessary, heroin-assisted treatment cannot, given the chronic nature of the addiction condition, be governed by the goal of achieving total and permanent abstinence. That is unrealistic and in many cases simply impossible. The clinical goal governing the clinical ethics of prescribing methadone or heroin within a treatment plan encompassing comprehensive medical and psychosocial services is to improve the addicted person's physical and

[48] I Hurkmans. Heroin provision makes its debut in the Netherlands. *Jellinek Quarterly* 1997; 4(3): 11-12.

[49] Goldstein, supra, note 34 at 150; O'Brien & McLellan, supra, note 33 at 239.

psychological health and to help these persons to achieve their maximum of social integration and productive satisfying living.

Not to offer these treatments to persons who need them, who want them, and who can benefit from them, is inhumane. It is the refusal to offer these treatments, not the use of these treatments, that needs to be ethically justified. That refusal cannot be justified so long as evidence for the safety and efficacy of methadone-assisted or heroin-assisted treatments is available.

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We have spent long years of debate and have gone through many judicial proceedings in North America to build the ethical and legal justifications for discontinuing or not initiating life-prolonging treatments that are therapeutically useless and not in the sick person's best interests.[50] Now another long process of public discourse, and social conversion, may well be needed before we can achieve ethical consensus on the clinical justification and imperative of using life-enhancing methadone-assisted or heroin-assisted treatments for those who have a chronic addiction condition.

This clinical–ethical imperative for optimum treatment of persons with chronic drug addiction has implications for research ethics and social ethics as well.

Research Ethics

There are many sources of uncertainty in the diagnosis, treatment, and prevention of disease. We are here centering attention on two of these sources: first, the uncertainty due to the sheer complexity of the human body and its diseases; second, the uncertainty resulting from the utter individuality and variability, genetic, physiological, psychological, and biographical, of each body and person regarding susceptibility to disease and response to treatment.

Uncertainty in the diagnosis, explanation, treatment, and prevention of disease involves matters of fact, and such uncertainty cannot be reduced or cleared away by discourse, debate, or argument. Neither can it be cleared away by observation alone. Nature – in medicine, the human body, and the person – is the one and only source of medical knowledge, and experimentation is the mode of questioning that will prod nature to reveal how it works and, when there is breakdown, how these workings can be repaired and restored. It is to reduce uncertainty about the diagnosis, explanation, treatment, and prevention of disease that methodologically sound research, be it fundamental, epidemiological, or clinical research, has expanded over this century.

The *clinical imperative* of initiating opiate-assisted comprehensive treatment programs for drug addiction grows in strength with the solidity of the research-based evidence upon which that imperative rests. The *ethical imperative* is to plan and conduct the studies needed to obtain that evidence. However well-intentioned they may be, those who oppose the mounting of methodologically sound clinical trials of opiate-assisted treatment programs are in fact promoting therapeutic abandonment of those who have not benefited or cannot benefit from existing treatments. That abandonment is just one more expression of the logic of exclusion.

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Social Ethics

Four years ago, Goldstein observed that there has always been, and continues to be, insufficient funding to offer treatment to all addicts who want and need such treatment. He also observed that total funding of heroin addiction

[50] DJ Roy, N MacDonald. Ethical issues in palliative care. In: D Doyle, GWC Hanks, N MacDonald (eds). *Oxford Textbook of Palliative Medicine*. Second edition. Oxford, New York, Tokyo: Oxford University Press, 1998, at 97-138.

treatment in the United States had actually decreased, with no new methadone clinics having opened in New York City since 1981.[51]

There is, indeed, a great gap between theory and practice. Charles P O'Brien has stated that treatment of substance-use disorders should, theoretically, be a high priority for the health-care system because of its cost-effectiveness alone, if for no other reason.[52]

In practice, however, treatment programs are inadequate in number and quality. Clinicians are poorly trained and comprehensive treatment programs are often considered too costly. The complexity of care is not keeping up with the complexity of the disease. "Although the level of complexity of these patients is generally quite high, with multiple drug problems and multiple coexisting psychiatric disorders, the primary therapists have relatively little training to deal with this complexity. Even when physicians are consulted, they often have little training in the psychopharmacology of addiction because this subject is poorly covered in most residency and medical school curricula."[53]

The width of the gap between what should be done and what is in fact being done for addicted persons in need of treatment is a measure of the injustice that reigns in a society. That injustice rests upon a counter-position that harbours both moral and scientific incoherence. That counter-position needs to be reversed because it leads to increasing social chaos and to a perpetuation of the suffering and disintegration of people seriously in need of treatment. But above all, this counter-position needs to be reversed because it betrays the ethic of a civilized society and leads to the kinds of dehumanization provoked by the logic of exclusion.

The width of the gap between what should be done and what is in fact being done for addicted persons in need of treatment is a measure of the injustice that reigns in a society.

[51] Goldstein, supra, note 34 at 149.

[52] O'Brien, supra, note 36 at 69.

[53] Ibid.

Drug Users and Studies of HIV/AIDS Drugs and Illegal Drugs

The fifth priority issue raised at the November 1997 workshop focuses on research and is expressed in the following three questions:

- What ethical issues are raised by the absence of studies of the impact of illegal drugs on the immune system?
- What ethical issues are raised by the absence of studies of interactions between HIV/AIDS drugs and illegal drugs?
- What are the ethical implications of excluding drug users from trials of HIV/AIDS treatments?

Impact of Illegal Drugs on the Immune System

A fully developed ethical commentary on the issues raised by the absence of studies of the impact of illegal drugs on the immune system of drug users would require a prior extensive scientific and methodological analysis of how such studies could be designed and successfully conducted. In the absence of such an analysis, the most I can do here is sketch how an ethics commentary on this first question could begin to take shape. The following four considerations centre on whether such studies are possible and, if so, on whether there are clinical and public health reasons that amount to an ethical imperative to plan and conduct such studies.

First consideration

It would be questionable to assume that studies of the impact of illegal drug use on the immune system cannot be conducted due to scientific or management

reasons. The recent development of quantitative assays of exquisite specificity that permit the determination of how specific subsets of T cells are being stimulated should open one avenue to the initiation of such studies,[54] provided other conditions for the conduct of valid studies could be fulfilled.

It would be very difficult to do prospective studies of the impact of illegal drug use on the immune system by simply starting with a group of study candidates invited from the street to participate. How would you be able to ascertain if any problem with the immune system detected in such a study was due to the use of that particular illegal drug or due rather to a combination of other factors (poor nutrition, poor sleeping patterns, ranges of psychological and social stresses) that can place enormous strains on the immune system?

We should not be basing the clinical care of HIV-infected drug users on the premise that their immune systems are functioning in ways similar to the systems of HIV-infected people who are not drug users.

Second consideration

Mounting evidence that the course of progression of HIV infection and hepatitis C infection is different in drug users than in other subgroups of the population would specify one reason why these immune-system studies should be undertaken.

Third consideration

If it is clinically imperative for doctors to know what they are doing when they therapeutically intervene in the bodies and lives of HIV-infected people, it would seem that it is also a research imperative that studies be conducted to give clinicians the knowledge they need to treat patients with careful attention to their biological particularity. We should not be basing the clinical care of HIV-infected drug users on the premise that their immune systems are functioning in ways similar to the systems of HIV-infected people who are not drug users.

There are scientific, clinical, public health, and humanitarian reasons that militate for the design and conduct of studies of the impact of illegal drug use on the immune system.

Fourth consideration

The following consideration strengthens the argument that it is highly important to obtain knowledge about the impact of illegal drug use on the immune system of drug users, and particularly of HIV-infected drug users. Some HIV-infected drug users may find it very difficult to adhere to what are currently considered to be optimal therapeutic regimens. If, in addition to this, HIV drug users are experiencing a weakening of their immune responses, they may well become incubators of treatment-resistant strains of a number of infectious agents. Prevention of the transmission of such strains should be a prime public health imperative.

There are, then, scientific, clinical, public health, and humanitarian reasons that militate for the design and conduct of studies of the impact of illegal drug use on the immune system.

Studies of Interactions between HIV/AIDS Drugs and Illegal Drugs

In 1998 the results were published of a study undertaken to determine the effects of methadone treatment in the disposition of zidovudine (ZDV) in HIV-infected drug users.[55]

The *hypothesis* of the study was that pharmacokinetic interactions between these agents may affect drug efficacy, toxicity, and compliance.

[54] AJ McMichael, CA O'Callaghan. A new look at T cells. *Journal of Experimental Medicine* 1998; 187(9): 1367-1371.

[55] EF McCance-Katz, PM Rainey, P Jatlow, G Friedland. Methadone effects on zidovudine disposition (AIDS Clinical Trials Group 262). *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology* 1998; 18: 435-443.

Methadone alone may well be a necessary, but not a sufficient, treatment for heroin addiction.

The following *observations* motivated the strategy of this study:

- Because injection drug users are much underrepresented in clinical studies of HIV therapies, information regarding the benefits and toxicities of HIV treatments for these persons is inadequate.
- When methadone-maintained patients with HIV diseases complain of malaise, insomnia, and dysphoria under ZDV therapy, the clinical response is often to attribute these symptoms to opiate withdrawal and to increase the dose of methadone.
- However, could these symptoms be rather due to increased exposure to ZDV?

This study confirmed that methadone-maintained patients receiving standard ZDV doses experienced greater ZDV exposure (due to inhibition of ZDV glucuronidation and decreased renal clearance of ZDV) and may be at increased risk for ZDV side effects and toxicity.

The investigators concluded that:

- it will be crucial to determine whether illegal drugs (called substances of abuse in the study) have similar important interactions with ZDV; and
- it is necessary to determine whether illegal drugs and treatments for illegal drug use have important interactions with other HIV therapeutic agents.[56]

Clinical, public health, economic considerations, as well as reasons of humanity, would enter into the construction of a reasonable ethical argument that there is a responsibility incumbent both upon the pharmaceutical industry and the medical profession to join efforts in mounting and conducting studies of the interactions of illegal drugs with HIV/AIDS treatment agents.

Equitable Participation in HIV/AIDS Clinical Trials

Historical background: a change of perspectives

The equitable selection of human subjects for participation in clinical trials is one of the criteria for Institutional Review Board (IRB) approval according to the Code of Federal Regulations of the United States.[57] Until recently, the prime ethical concern was to protect vulnerable people against exploitation in research, against being forced to carry a disproportionate share of the burdens of research. The leading contemporary perspective is that women, the economically disadvantaged, the socially marginalized, and people belonging to ethnic and minority groups often suffer discrimination and injustice by their exclusion from, or underrepresentation in, clinical trials of promising new treatments.

The history of clinical research, and of the development of research ethics, leading up to this change of perspective and to the contemporary emphasis on equitable access to the benefits of participation in clinical trials is complex. A series of ethically most dubious, if not tragic, events stretching over nearly a century formed the perception that research was dangerous, of little or no benefit to participants, and that vulnerable people and minority groups were used as guinea pigs for the advancement of scientific knowledge.[58]

Vikenty Veressayev, whose *Memoirs of a Physician* were published in English in 1916, chastised his colleagues as "those zealots of science who have ceased to distinguish between their brothers and guinea pigs."[59] He was

[56] Ibid.

[57] Department of Health and Human Services Rules and Regulations. 45 CFR 46 (Title 45: Code of Federal Regulations; Part 46), 46.111, (a) (3), here cited from Appendix 1, p. 264, in: RJ Levine. *Ethics and Regulation of Clinical Research*. Baltimore, Munich: Urban & Schwarzenberg, 1981.

[58] McCarthy CR. Historical background of clinical trials involving women and minorities. *Academic Medicine* 1994; 69(9): 695-698.

[59] V Veressayev. *The Memoirs of a Physician*. Translated from the Russian by S Linden. New York: Knopf, 1916. Here quoted from J Katz (ed). *Experimentation with Human Beings*. New York: Russell Sage Foundation, 1972, at 291.

writing about the use of vulnerable and helpless people in gonorrhea and syphilis research conducted during the latter half of the 1800s in Germany, France, Russia, Ireland, and the United States. The use, and we would now say the exploitation, of subjugate populations, was the trend in research in the nineteenth, and in the early part of the twentieth, centuries.[60] These subjugate populations included American slave women in nineteenth century surgical research,[61] and prisoners and institutionalized persons in the early part of the twentieth century.[62] Exclusively helpless people were involved in the medical experiments conducted by the Nazi doctors condemned in the Nuremberg trials of 1947. Twenty years later, Dr Harvey K Beecher documented the unethical use of vulnerable people in research conducted in the United States.[63] There were also the reports of the Tuskegee Syphilis Study with black men,[64] and the Willowbrook Studies of Infectious Hepatitis conducted on mentally handicapped children in a New York State institution.[65] After the thalidomide tragedy, women of childbearing age and pregnant women came to be quite generally excluded from clinical trials that could affect the fetus.[66]

The recent emphasis on assuring women, ethnic and minority groups, and economically disadvantaged people fair access to clinical trials stems in part from a recognition that people often receive better treatment within a clinical trial than in ordinary practice. Moreover, the HIV epidemic has also highlighted the awareness that participation in university hospital–based or community-based clinical trials is often the only way to obtain access to promising new treatments. There is also the concern about the generalizability of clinical trial results if the trial participants are not representative of the disease population for which a treatment under study is intended.

These and other considerations have prompted recent changes in the Food and Drug Administration (FDA) and the National Institutes of Health (NIH) policies concerning equitable selection of women and ethnic and minority groups in clinical trials.[67] One should also note that the Canadian *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans* has a chapter on "Inclusion in Research." That chapter is based on the principle of distributive justice: "members of society should neither bear an unfair share of the direct burdens of participating in research, nor should they be unfairly excluded from the potential benefits of research participation."[68] However, this concern for equity, long overdue, has to be balanced against what is scientifically meaningful and feasible,[69] and will be constrained by what is socially difficult.[70]

The controlled clinical trial[71]

Research, in whatever field, is a methodological and systematically planned investigation, undertaken with specific safeguards to reduce bias, so that the results of the research have a high probability of being valid and reliable. Only such results merit to be called new *knowledge*. Research, then, is undertaken to produce new knowledge, to reduce uncertainty, and to resolve controversies over matters of fact by producing accumulations of reliable data that offer decisive evidence. The overall goal of research, to take up a theme reaching back to ancient philosophy, is to distinguish reality from mere appearances.

Clinical research on drug or surgical treatments is undertaken to provide reliable answers to questions such as:

- Will this treatment prevent or remedy a particular disease?

[60] RB Merkatz, S White Junod. Historical background of changes in FDA policy on the study and evaluation of drugs in women. *Academic Medicine* 1994; 69(9): 703-707.

[61] TL Savitt. *Medicine and Slavery: The Diseases and Health Care of Blacks in Antebellum Virginia*. Urbana, Illinois: University of Illinois Press, 1978, at 297-298; MS Pernick. The Calculus of Suffering in 19th Century Surgery. In: JW Leavitt, RL Numbers (eds). *Sickness and Health in America.* Madison, Wisconsin: University of Wisconsin Press, 1985, at 100.

[62] E Ethridge. Pellagra: An Unappreciated Reminder of Southern Distinctiveness. In: TL Savitt, JH Young (eds). *Disease and Distinctiveness in the American South*. Knoxville, Tennessee: University of Tennessee Press, 1988, at 110-119; J Mitford. Cheaper than chimpanzees. In: J Mitford. *Kind and Usual Punishment. The Prison Business*. New York: Vintage Books, 1974, at 151-184.

[63] HK Beecher. Ethics and clinical research. *New England Journal of Medicine* 1966; 274: 1354-1366.

[64] AM Brandt. Racism and research: the case of the Tuskegee Syphilis Study. *Hastings Center Report* 1978; 8(6): 21-29.

[65] R Ward et al. Infectious hepatitis: studies of its natural history and prevention. *New England Journal of Medicine* 1958; 258: 407-416; J Katz, supra, note 59 at 1007-10.

[66] McCarthy, supra, note 58; Merkatz & White Junod, supra, note 60.

[67] RB Merkatz et al. Women in clinical trials of new drugs. A change in Food and Drug Administration policy. *New England Journal of Medicine* 1993; 329: 292-296; US Congress Public Law 103-43. National Institutes of Health Revitalization Amendment. Washington, DC, 10 June 1993.

[68] Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada. Tri-Council Policy Statement. *Ethical Conduct for Research Involving Humans*. Ottawa, 1998, at 5.1

[69] JC Bennett. Inclusion of women in clinical trials – policies for population subgroups. *New England Journal of Medicine* 1993; 329: 288-292; E Marshall. New law brings affirmative action to clinical research. *Science* 1994; 263: 602; S Piantadosi, J Wittes. Letter to the editor. Politically correct clinical trials. *Controlled Clinical Trials* 1993; 14: 562-567.

[70] HP Freeman. The impact of clinical trial protocols on patient care systems in a large city hospital. *Cancer* 1993; Suppl 72: 2834-2838; W El-Sadr, L Capps. The challenge of minority recruitment in clinical trials for AIDS. *Journal of*

- Will this treatment do more good than harm to patients with this particular disease?
- Will this treatment do more good than available alternative treatments?

These questions may seem to be direct and simple, but the research procedures required to obtain reliable evidence and convincing answers to these questions are complex, difficult, time-consuming, expensive, and, for their implementation, depend upon the collaboration of many hospitals, universities, drug companies, scientists, physicians, surgeons, nurses, and patients.

Strategies and tactics to counter bias

The strategy most widely used today to protect clinical research against the potential ravages of bias is the *controlled clinical trial*.

Careful strategies are needed for research, set up to produce the knowledge for reliable recommendations about how best to treat hundreds and thousands of patients afflicted with, perhaps, seriously incapacitating or fatal diseases.

The strategies have been contrived to counter bias. *Bias* is used in a technical sense here, and may be defined as any of the many processes that can inadvertently skew research toward results or conclusions that differ systematically from the truth.[72] Strategies are required because bias is pervasive in research, in the sense that there are many sources of accidental bias and they can distort the scientific process at any stage of clinical research, from design of the research protocol, through selection of patients and conduct of the clinical study, to analysis, interpretation, and reporting of research results. Dr David Sackett and colleagues at McMaster University have identified at least 65 sources of bias that can distort the research process.[73] Bias, if unsuccessfully countered, can vitiate a study of therapies to a point where the research results are worthless, and the whole research exercise ends up offering no reliable guidance at all about how sick people should be treated. At worst, undetected bias can create a false belief that ineffective or harmful treatments are therapeutic.

The strategy most widely used today to protect clinical research against the potential ravages of bias is the *controlled clinical trial*. The world *trial* is used when a comparison is set up between two available treatments for a disease, and the goal of the research is to determine whether one is superior (safer and more effective) to another. When only one treatment is available – for example, for a newly discovered disease – the comparison may be set up between that treatment and no treatment at all, or between that treatment and an inactive substance called a placebo (or in popular terms, a sugar pill). This kind of a trial is called *clinical* (from the Greek word for bed) because it seeks to discover the best way of treating patients, the best way of managing care "at the bedside." The trial is said to be *controlled* when the results of one treatment are being monitored by comparison with the results of another treatment (or of no treatment or of a placebo) on similar groups of patients affected by the same disease or disorder.

The *strategy* of the controlled clinical trial uses certain *tactics* to eliminate, or at least minimize, the distortion of bias on the results of research to evaluate the safety and efficacy, or the relative worth, of treatments.

Randomization is one such tactic, and it is used to block *selection bias*, the bias that can distort a research project on treatment if the patients participating in the project are not similar. Consider, for a moment, a research project in which surgery will be compared to a medication, as treatments for a disease condition; for example, a heart problem linked to blocked arteries. The results

the American Medical Association 1992; 267: 954-957; LS Brown. Enrollment of drug abusers in HIV clinical trials: a public health imperative for communities of color. *Journal of Psychoactive Drugs* 1993; 25(1): 45-52.

71 CL Meinert, S Tonaseia. *Clinical Trials. Design, Conduct, and Analysis*. New York: Oxford University Press, 1986.

72 EA Murphy. *The Logic of Medicine*. Baltimore, London: The Johns Hopkins University Press, 1976, at 239-262.

73 DL Sackett. Bias in analytic research. *Journal of Chronic Diseases* 1979; 32: 51-63.

of such a clinical trial would be highly untrustworthy and invalid if doctors regularly assigned their sickest patients to medication, and their least sick patients to surgery, or vice versa. The results of such a trial would be biased for or against one of the treatments, depending upon how patients were selected for one or another of the treatments by their physicians. To avoid this bias, patients in a controlled trial are randomly assigned by some lottery system to receive one or another of the treatments under study.

Double-blinding is another tactic used whenever possible in controlled clinical trials. This means that the patient and the treating physician participating in such a trial are "blinded," that is, kept in ignorance of which of two treatments (and one "treatment" may be a placebo) the patient is receiving during the course of the trial. The tactic of double-blinding is particularly useful when the treatment outcomes that will be used to judge the efficacy or relative worth of treatments are not of the either–or kind, such as death, or objectively measurable, such as the growth of a tumour or the spread of an infection. Subjective measures are such matters as how patients say they feel, and how well observers find them to be functioning.

Randomization and double-blinding are two of the very important tactics employed in controlled clinical trials to minimize bias and increase the probability of producing reliable results. Because uncertainty is inherent in medical science, and because the reliability of research results is measured in terms of probabilities and rarely in terms of absolute certitude, there are also crucially important statistical conditions that have to be respected if a clinical trial is to produce both valid and credible results. Sample size, or the numbers of patients to be enrolled in the trial, is an example, since a clinical trial conducted on too few patients can prove nothing.[74]

When exclusion is scientifically and ethically justifiable

At least six prerequisites have been identified as necessary conditions for conducting a clinical trial that is likely to be funded and finished and to produce results that are credible, valid, and generalizable to a specific population. The fourth of these six prerequisites is that the inclusion and exclusion criteria strike a balance between efficiency and generalizability.[75]

If a wise use of limited financial resources dictates that a clinical trial include as small a number of subjects as required to achieve a reliable answer to the trial's study question, efficiency indicates a preference for limiting entry into a clinical trial to those persons who are at high risk for the clinical event under study and who are likely also to be highly responsive to the treatment being tested. However, if these persons, the high-risk high responders, are only a minority of the persons afflicted with the disease or condition featured in the clinical trial, the trial results may have very limited generalizability.[76] This very succinct summary of Sackett's discussion of entry criteria as reflecting the tension between efficiency and generalizability of results in a clinical trial serves to introduce a more comprehensive consideration of the reasons that can be the grounds for a scientifically justifiable and ethically fair exclusion of people from participating in a clinical trial.

Some people are excluded from participation in a clinical trial because they are geographically unavailable or because they refuse to participate. However, the focus here is on exclusions that are imposed by clinical investigators. Alvan Feinstein has catalogued the reasons for imposing exclusions from participating in clinical trials under the following headings.[77]

[74] Ibid at 61.

[75] DL Sackett. On some prerequisites for a successful clinical trial. In: S Shapiro, TA Louis (eds). *Clinical Trials and Approaches*. New York, Basel: Marcel Dekker, 1983, at 65-79.

[76] Ibid at 72-74.

[77] AR Feinstein. *Clinical Epidemiology. The Architecture of Clinical Research*. Toronto: WB Saunders Company, 1985, at 277-285.

Therapeutic exigency

People may have to be excluded from participation in a controlled (randomized) clinical trial if one or the other of the interventions under study is either mandatory or contraindicated for a candidate participant.

Prognostic susceptibility

People with a short life expectancy may be reasonably excluded from participation, for example, in a clinical trial designed to measure the long-term results of an intervention. On the other hand, people having only very mild forms of a disease may be reasonably excluded from a clinical trial of a treatment that has to be vigorously challenged by serious forms of the disease if the trial's results are to be clinically meaningful.

Exclusion of people from participation in a clinical trial on the grounds of their potential for non-compliance requires very careful ethical consideration.

Therapeutic vulnerability/invulnerability

Patients may also be reasonably excluded from participation in a clinical trial if they do not have the condition or lesion that is being targeted by the intervention or if they have such an aggravated form of the condition that the intervention is highly unlikely to do any good whatsoever. People may also be reasonably excluded from participation in a controlled clinical trial if they are vulnerable to or threatened by the effects of a study treatment that is presumed to be beneficial for a condition. Pregnant women are often excluded from participation in a clinical trial of treatments for a condition with which they are afflicted because one or the other of these treatments under study could be damaging to her fetus. People with asthma may be excluded from clinical trials of agents that provoke bronchospasms.

Contamination of manoeuvres

People may be reasonably excluded from a clinical trial if they are taking, and must continue to take, a medication that could interfere with or mask the effect of a treatment under study in the trial.

Spectral homogeneity

If a candidate population for a proposed clinical trial includes a mix of very different types of concomitant clinical conditions, clinical investigators may be justified in excluding some people so that a level of subject homogeneity can be obtained to facilitate analysis of the clinical trial results.

Investigative efficiency

To avoid a waste of resources and efforts – clinical trials are both expensive and time-consuming – people may reasonably be excluded from participation in a clinical trial if, for example, they are likely to move away from the site where the clinical trial is being conducted or if they are likely to be non-compliant with the procedures that are necessary for a successful conduct of the trial.

Exclusion of people from participation in a clinical trial on the grounds of their potential for non-compliance requires very careful ethical consideration. Such exclusion, when based on unfounded and arbitrary impressions of those running the clinical trial, is unfair and unjustly discriminating. People can be very harmed by such discrimination, and people can also be deeply wronged without being seriously harmed.[78]

[78] AM Capron. Protection of research subjects: do special rules apply in epidemiology? *Journal of Clinical Epidemiology* 1991; 44(Suppl I): 81S-89S.

When exclusion is ethically questionable or wrong

Those populations cited in the literature as being regularly, even if not systematically, excluded from or underrepresented in clinical trials include: women, pregnant women, poor and socially marginalized people, people of colour, minorities, children and the aged, the homeless, alcoholics, and injection drug users. Gender, socioeconomic status, age, or behaviour may singly or in continuation be grounds for a person's exclusion from participation in clinical trials and from the potential benefits of such participation. When clinical trials are mounted to verify the safety and efficacy of new treatments for HIV/AIDS, those excluded from participation have often been women, the poor, people of colour, the socially marginalized, and injection drug users.

The purpose of this section of the commentary is to discuss when exclusion of persons from participating in clinical trials is ethically questionable or downright wrong and unjustifiable. This discussion begins with a set of observation, moves forward through a series of ethical reflections on the observations, and ends with a number of conclusions.

The participation of injection drug users in HIV-related clinical trials lags unacceptably behind the proportion of HIV infection and AIDS cases associated with injection drug use.

Observations

1. People may end up excluded from participation in clinical trials because the very thought of such participation is excluded from their minds due in great part to the unrelenting social and economic stress under which they have to live. HP Freeman has observed that "the significance of participation in clinical trials may be totally removed from the concerns of people who must concentrate on day-to-day survival, with priorities such as how to obtain food, clothing, and shelter and avoid crime."[79]

2. Participation in clinical trials becomes quite unlikely in proportion both to the mistrust certain populations may have toward the medical establishment and clinical scientists as well as to the indifference physicians and clinical scientists may exhibit toward the poor, the socially marginalized, and those, such as injection drug users, who are perceived to be difficult deviants.[80]

3. LS Brown has observed that the participation of injection drug users in HIV-related clinical trials lags unacceptably behind the proportion of HIV infection and AIDS cases associated with injection drug use. Moreover, in a number of countries this lag occurs in a sociopolitical context that discourages any type of research – basic, clinical, epidemiological, anthropological – on illegal drug use.[81]

4. The participation of injection drug users in clinical trials may never be sought by clinical investigators or, more aggressively, injection drug users may be outrightly rejected from consideration as HIV/AIDS clinical trial participants because they are perceived to be, and often may well be, manipulative, untrustworthy, and non-compliant.[82] This observation in particular will be submitted to critical reflection in the following subsection of this commentary.

5. Participation in clinical trials for HIV/AIDS, as well as for cancer, hypertension, and cardiovascular disease, may be almost utopian for the poor,

[79] Freeman, supra, note 70.

[80] Brown, supra, note 70 at 48.

[81] Ibid.

[82] Ibid.

the marginalized, and those perceived to be socially deviant for the geographical reason – already cited earlier in this commentary as a reason for exclusion – that the trials are simply not conducted where these people receive their primary care. Wafaa El-Sadr and Linnea Capps have made this observation and proceed to emphasize that "physicians who practice in overcrowded and understaffed public clinics and hospitals are often overwhelmed and barely able to provide necessary primary care. They often have inadequate nursing assistance and little clerical help and function in an environment of turmoil and urgency. This is combined with the patients' many social needs, which may seem more urgent than their medical problems. These providers have neither the time nor the resources to seek out appropriate trials for their patients."[83]

6. C Hankins, N Lapointe, S Walmsley and the Canadian Women's HIV Study Group draw attention to the underrepresentation in HIV/AIDS clinical trials of injection drug users, non-white women, women of lower education, and women not receiving antiretroviral therapy. These investigators also emphasize that "extra effort must be made to assist injection drug users in actively participating in clinical trials if studies are to provide results that can be generalizable to the average population of HIV-positive women. An added benefit is the collection of information on the interactions of antiretroviral agents and currently illegal drugs."[84]

Reflections

The exclusion of persons from participation in HIV/AIDS clinical trials becomes ethically questionable or outrightly ethically wrong if and when that exclusion results from a failure to respect a corpus of considerations that circumscribe the ethics of research for and with human beings. The following is a summary of these basic considerations.

1. Research ethics and scientific research pursue a common cognitive or epistemological goal: to distinguish mere appearances from reality.

   Basing actions upon unquestioned and unexamined perceptions is to risk succumbing to appearances that may diverge widely from reality. To perceive someone as likely to be non-compliant with clinical trial procedures because that person is an injection drug user and then to exclude that person from clinical trial participation without carefully criticizing this perception; without taking the time to come to know the person in question; without examining whether potential non-compliance will be due to drug use or to a range of other potentially modifiable circumstances of life and environment – to act without doing these examinations is a failure to respect epistemological ethics.

   Compliance of injection drug users with medical treatment and clinical trial procedures is a complex story that encompasses so much more than simple, unexamined negative perceptions can ever grasp. Indeed, the experience of a number of clinical investigators that injection drug users were able to achieve high compliance or, at least in some cases, levels of compliance that were no worse than that of other populations,[85] is an indication that "access to care and health care delivery system problems may

[83] El-Sadr & Capps, supra, note 70 at 956.

[84] C Hankins, N Lapointe, S Walmsley. Participation in clinical trials among women living with HIV in Canada. *Canadian Medical Association Journal* 1998; 159(1): 1364.

[85] TA Slays et al. Therapy compliance of HIV-infected intravenous drug users (IVDU). Paper presented at the VIII International Conference on AIDS. Amsterdam, 1992. Abstract No PoD 5711; B Broers et al. Compliance of drug users with zidovudine treatment. Paper presented at the VIII International Conference on AIDS. Amsterdam, 1992. Abstract No PoD 5722.

be a more important predictor of compliance than individual behavioral issues."[86]

2. As initial observations in a scientific endeavour may fail to reveal true correlations between phenomena, in a similar fashion, spontaneous desires, compulsions, or revulsions may not correlate with what we really ought to do. True values, like real correlations between phenomena, are not always immediately obvious. Value judgments, like judgments of fact or of truth, are governed in part by assent to sufficient evidence of importance, not by submission to custom, convention, or the rule of "that's the way we have always done it."

   If it is an imperative of clinical ethics that we should not intervene in the bodies and lives of persons without *knowing* what we are doing, it is an imperative of epistemological ethics that we strive systematically to obtain the knowledge needed to fulfill the clinical responsibilities of treatment, care, and support. To systematically exclude women, injection drug users, the poor and undernourished from clinical trials and studies is equivalent to a systematic refusal to seek the knowledge needed to care adequately for those who are often most in need of care.

   To systematically exclude women, injection drug users, the poor and undernourished from clinical trials and studies is equivalent to a systematic refusal to seek the knowledge needed to care adequately for those who are often most in need of care.

   However, this systematic exclusion is also a capitulation to unexamined assumptions. It is uncritical and scientifically unfounded simply to assume that women's bodies respond as do the bodies of men to various treatment drugs; that HIV-seropositive injection drug users have a course of HIV disease similar to HIV-infected people who do not inject drugs; that injected drugs will not interact unfavourably or dangerously with antiretroviral treatments.

   So the value judgment of importance regarding the participation in clinical trials is this: "When a homogeneous response cannot be assumed for specific subgroups of the population, it is essential that enough members of the relevant subgroups be included so that a differential response can be detected and measured. Exclusion of a given subgroup from a study precludes formal inferences about the expected results for that subgroup."[87]

   Because women are exposed to different natural and synthetic hormones than are men;[88] because HIV-seropositive injection drug users may have a wider range of immunological deficits and follow a very different history of HIV disease and response to treatment than other HIV-seropositive persons; because the poor and socially marginalized people have, for example, such significantly lower five-year survival rates for cancer than do people who are affluent – because of these and other differences, it is clinically and ethically wrong to exclude these people from the clinical studies that are needed to demonstrate whether these persons may well need to be treated very differently than is now the case.

   Because HIV-seropositive injection drug users may have a wider range of immunological deficits and follow a very different history of HIV disease and response to treatment than other HIV-seropositive persons, it is clinically and ethically wrong to exclude them from the clinical studies that are needed to demonstrate whether they may well need to be treated very differently than is now the case.

Points of emphasis

To close this ethics commentary, I emphasize the following points from the document *Building a New Consensus: Ethical Principles and Policies for Clinical Research on HIV/AIDS*.

> Exclusion of representatives of groups of prospective subjects who are believed to be non-compliant (e.g. intravenous drug users) may

[86] Brown, supra, note 70 at 49.

[87] Bennett, supra, note 69 at 290.

[88] Marshall, supra, note 69.

arguably enhance validity and efficiency; however, such exclusions are unacceptable on grounds of both generalizability and the requirement for equitable distribution of both burdens and benefits (distributive justice).[89]

Criteria for inclusion in phase II and III clinical trials should be based on a presumption that all groups affected by the research are eligible, regardless of gender, social or economic status, use of illicit drugs, or stage of illness unless the study is specifically designed to look at a particular stage of illness.[90]

No group should be categorically excluded, on the basis of age, gender, mental status, place of residence or incarceration, or other social or economic characteristic from access to clinical trials or other mechanisms of access to experimental therapies. Special efforts should be made to reach out to previously excluded populations. However, people who are vulnerable for any of these reasons require special consideration in the design and implementation of trials.[91]

[89] C Levine, N Neveloff Dubler, R Levine. Building a new consensus: ethical principles and policies for clinical research on HIV/AIDS. IRB 1991; 13(1-2): 7.

[90] Ibid at 8.

[91] Ibid at 14.

Information about the Use and Effects of Illegal Drugs

The sixth priority issue takes the form of the question: "What are the ethical grounds for ensuring that health-care providers, drug users, and the general public have accurate and complete information about street drugs and their effects?"

The ethical grounds for ensuring the acquisition and transmission of accurate and reasonably comprehensive information about street drugs and their effects should emerge from the following *eight lines of thought*.

The Link Between Language, Thought, and Action

I open with the Confucian warning: "If language is not correct, then what is said is not what is meant, and what ought to be done remains undone."

There is a link between word, thought, and deed; between language, meaning, and reality. If the link is confusion, distortion, bias, and manipulation rather than clarity and proportionality – either between language and meaning, or between both and reality – a cycle of decline starts to turn within the real world. What should not be done is advanced as a solution; what should be done remains undone. If the cycle continues unchecked, reality becomes chaotic. Each deed expressing a confused and distorted view of the world further corrupts the words, thoughts, and meanings with which we struggle to find where we are and where we should be going. The cycle of decline becomes an ever faster-turning spiral. We can become utterly dizzy and disoriented. We no longer know what to do because we no longer know what to think, or how to think, about the worlds, big and small, in which we live.

Our existing drug laws and policies motivate us to speak in very different ways about legal and illegal drugs. These ways of speaking condition very

Our existing drug laws and policies motivate us to speak in very different ways about licit and illicit drugs.

different ways of perceiving and acting regarding these legal categorizations of drugs: ways of speaking, thinking, and acting that are often distorting simplifications of a very diverse and complex structure of risks, harms, and benefits linked to the seven-fold family of drugs – 1. nicotine; 2. alcohol and related drugs; 3. the opiates; 4. cocaine and amphetamines; 5. cannabis; 6. caffeine; 7. the hallucinogens.[92]

Moreover, although I would not dispute the possibility, even the necessity, of using the term "addiction" in a scientific, medical, and policy context,[93] the terms "addiction" and "addict" are now thickly encrusted with overlays of distorting bias that provoke incessant waves of discrimination and injustice.

An ethics for complexity cannot bypass the purification and de-biasing of the key words we use in all discussions of HIV and drug use.

Drug Discourse in an Open Society

A wise, now elderly physician taught me one of the most basic principles of practical ethics: "Donner la parole à l'autre," he said: "Give others a chance to talk."

Like most simple principles, the physician's "give others a chance to talk" can be quite exacting, particularly when these others want to say publicly what some other people do not want to hear said at all. When these other people have power and use it to suppress "otherness" in thinking and action, we move away from differentiation and integrative complexity toward the "totality" approach criticized by Levinas as tolerating individuals only when they are shorn of their diversity and reduced to sameness.[94]

Closed societies suppress public discussions of matters considered dangerous by those with the power to refuse an imprimatur. Social, political, and moral stability, it is thought (erroneously), can be thereby secured, at least for a while. Life in an open society can be much more uncertain. In such societies, people are generally free to say and write what they want, and there is power in the spoken and written word. Skillfully expressed ideas about how the world and about how policies and laws should be changed, can and do change the ways people think, act, and live.

Discourse in open societies about matters of high importance can bring us all right up to the edge between complexity and chaos. That is why the old physician's principle, "give others a chance to talk," cannot stand alone. There is also the principle of challenge and response. The freedom and the opportunity (which many do not have even if they in principle have the freedom) to speak publicly on matters of high importance to an entire society requires the availability of others who will rise to challenge and criticize views that may be biased, expressive of too narrow a range of experience, or simply erroneous. Then, in turn, the challengers themselves should be exposed to challenge. That is how the range of differentiation required for integrative complexity can be attained.

Public discourse in an open society about matters that call forth profound and conflicting beliefs – and drugs are such a matter – can be very demanding and perilous. The stakes in this discourse are quite high, and the divisions of belief and perception are quite profound, and who wants to fail in their defence of either health or liberty? What if those advocating what I consider to be disastrously wrong are so much better than I and my co-thinkers in writing, arguing, and persuading? How high the levels of anxiety must be for those who may

[92] Goldstein, supra, note 34 at 3-5.

[93] Ibid; Leshner, supra, note 37.

[94] Levinas, supra, note 2.

find themselves in the predicament of believing they possess the truth and of suspecting they are not intellectually or rhetorically up to its defence!

Those who are almost as preoccupied over public discussion of drug use as they are about drug use itself might consider the link between Karl Popper's reflection on Plato and his advice about the requirements of living in an open society.[95] The funeral oration of Pericles is one of antiquity's clearest and most powerful descriptions of life in an open society. A central idea in that oration is that public discourse is not a stumbling block, but rather an indispensable preliminary to acting wisely.

Plato was deeply impressed by that creed in the oration of Pericles but at the same time saw the *breakdown of a closed society* as the source of the evils of insecurity, uncertainty, and aimless drifting of people away from clear and defined standards of how to live a human life. If Popper's interpretation of Plato is correct, Plato's choice of adherence to the closed society, and to its securities and certainties, led him to adopt the very methods of tyranny he had once hated and denounced. Plato illustrates the lesson that it is impossible to maintain the standards of civilization and the ethics of humanity if we refuse to bear what Popper calls the cross of humanness, the cross of reason and responsibility.

The strategies of silence, selective information, and exaggeration bordering on lies, cited earlier in this paper as strategies to deter people from using drugs, involve the distortion of meaning to achieve the ends of manipulation.

Standards of Public Discourse about Drugs

An open society's freedom to speak publicly on matters of high importance to all citizens is constrained by the balancing responsibility, the responsibility both of reason and humanness, to honour the standards of public discourse: the standards of clarity and precision; of evidence-based statements; of distinguishing personal opinion from knowledge; of honesty; of restraint in generalization; of civility in debate.

The logic of public discourse in an open society ruthlessly requires that we distinguish matters of fact, matters of principle, matters of meaning, and matters of belief. Only sound studies can produce the cumulative data needed to answer questions about matters of fact. Such studies, for example, could conceivably resolve uncertainties about the therapeutic advantages of marijuana; about the possibility and possible benefits of heroin maintenance. The adamant refusal to conduct such studies betrays adherence to a counter-position that, because of its incoherence with the demands of intelligence, is likely to be reversed and overthrown.

Matters of meaning are also matters of ethics, and the link between the two is expressed in the Confucian warning cited earlier in this paper: "If language is not correct, then what is said is not what is meant, and what ought to be done remains undone." The strategies of silence, selective information, and exaggeration bordering on lies, cited earlier in this paper as strategies to deter people from using drugs, involve the distortion of meaning to achieve the ends of manipulation. This is a refusal to bear Popper's cross of reason. This refusal also reflects a profound distrust of the workings of reason and a preference for the workings of power.

Drug discourse inevitably reaches into the domain of *matters of belief*. Fundamental beliefs, usually dormant in the routine of everyday life, are particularly apt to be awakened by words and acts that centre on values of high human importance. The use of drugs, history has shown, is clearly such an act. Diverse and conflicting world-view beliefs cluster, for instance, around the requirements of respect for human dignity and human rights; around the relative importance of health and liberty when these values are brought into conflict by

[95] Popper, supra, note 4 at 185-201.

particular behaviour; around the range of dominion people should be acknowledged to have over their own lives; about the role of law in an open society.

These beliefs cannot easily be changed or shaken by accumulations of data, facts, or information, because they are the field, the lighted space, or the horizon within which data, facts, and information are interpreted and acquire their meaning and value.

Reason's logic would direct us to recognize and respect the difference between matters about which we may productively argue in an open society and matters about which we must make basic and personal choices. Controversies involving contradictory fundamental beliefs can rarely be resolved, particularly if resolution means attainment of a compromise or policy with which everyone can agree. The most that can often be achieved in such profound controversies is a political accommodation, moderately tolerable to most, that maintains the coherence of a society, protects the civil process of public discourse, fosters respect for personal conscience, and refuses to tolerate the subjection of moral minorities on any issue to discrimination, harassment, or ridicule.[96]

Within the context of such an accommodation, if it can be attained, people advocating the most contradictory positions on drugs may come to the point of listening attentively to one another's diverse experiences. When that happens, one may even be graced with the discovery that one can be enriched and enlightened precisely by those with whom one disagrees most profoundly.

The Foundation of Ethics

The root of ethics, Lonergan has argued, lies neither in sentences nor in propositions nor in judgments, but in the dynamic structures of rational self-consciousness. This means that the real principles of ethics, the sources of ethics, are not propositions or statements, but existing persons.[97] Ethics emerges from the interlocking, unfolding, and development of rational self-consciousness of persons in interaction and in communication with each other. Ethics is distorted at its source when individuals or groups of persons are excluded from that communication.

If the foundation of ethics is understood in this way, then that foundation is the primordial ethical ground for ensuring that everyone has accurate and comprehensive information on any and every matter requiring decision, choice, action, and the exercise of responsibility. The refusal to share such existing information, or to distort that information, or to falsify that information is to block one's own way, and the way of others, to responsible decision and action; is tantamount to manipulating and stifling the development of the rational self-consciousness of others. This is so because we are rationally self-conscious when we scrutinize the reasons for our decisions, acts, or behaviours, and those reasons, essentially although not exclusively, include information and reliable knowledge.

The Principle of Consistency

Ethics requires the achievement of consistency between my knowing and my doing, that I respect in my decisions and actions what I have come to know to be a right or wrong or ethically intolerable course of action. Ethics is violated on the level of my own intelligence when I do exactly the opposite, namely, when I tailor my knowledge so that it will fit what I want to do, or what I want others to do, right or wrong.

[96] DJ Roy, JR Williams, BM Dickens. *Bioethics in Canada*. Scarborough, Ontario: Prentice-Hall Canada Inc, 1994, at 32-37.

[97] Lonergan, supra, note 9 at 604.

How can one have a chance of achieving consistency between one's knowing and one's doing in the matter of drug use – whether one be a drug user, a health-care professional, or a citizen contributing to the formulation of public policy on drug use – if one's knowing is vitiated at its very source by being rooted in distorted, biased, incomplete, or falsified information? Well, one can be misinformed and still behave in an ethically correct fashion if one's doing so is consistent with the knowledge one happens to have. However, all this means is that ethically correct behaviour can, indeed, contribute to perpetuating cycles of personal and social decline. That is what happens when vitiated information leads to vitiated knowledge and both end up governing decisions and actions, however unenlightened and well-motivated one may in fact be.

The Principle of Lucidity

Charles Fried, in his 1970s book on medical experimentation, used four terms to characterize an authentic relationship between a doctor and a person seeking medical help and advice. These terms, which, indeed, characterize an authentic relationship between any two human beings, and not only the professional–client relationship, are: autonomy, lucidity, fidelity, and humanity.[98]

These terms name four basic ethical imperatives that are respected when a relationship is authentic and that are violated when one person manipulates, blinds, dominates, or enslaves another. Relationships that are inauthentic almost always express one version or another of people no longer being seen and treated as ends in themselves, but rather of people being reduced to means of a sort to advance the achievement of the ends of others.

These four terms and imperatives are interlinked in a variety of ways, but we will concentrate here on how lucidity is linked to fidelity, humanity, and autonomy. Autonomy implies that a person is in command of their life, that they know their own personal laws, and that they have the knowledge needed to make their own decisions and pursue their own life plans. When they do not have that knowledge, they seek help, counsel, advice, from professionals who claim to have, and who are socially recognized as supposedly having, the knowledge they seek to keep their life on track or to get their life back on track if it has been derailed.

Given the multiplicity and diversity of human needs, and given the ranges of specialized knowledge required to meet those needs, professionals exist in a society to give the specialized information, knowledge, or treatment we need to sustain ourselves to develop, and to achieve ourselves. Professionals exist, in a sense, to serve the autonomy of their clients.

This service of autonomy withers without lucidity. When a person seeks out a professional for advice, knowledge, or treatment, they need lucidity. They need to receive information, advice, knowledge that is precise, validated, and comprehensive. Obscurantism comes to distort the professional–client relationship, and the ethical imperative of lucidity is violated, when the person seeking the professional help they need in order to be themselves receives – if we could summarize the deficit in these terms – less than the truth, the whole truth, and nothing but the truth regarding what is known, as well as what is not known, about their problem or condition. Diminished lucidity means diminished autonomy.

Fidelity as an imperative means that a person seeking professional help has a right to expect that their reasonable expectation will be respected and honoured. A person seeking professional help has a right to expect that they will

[98] Fried, supra, note 30 at 101-104.

not be made subservient to ends and purposes that have nothing to do with, or worse still, that are contradictory to their own life plans. They have a right to expect that they will not be deceived or kept in the dark about matters that they essentially need to steer their own life.

Fidelity and lucidity, concomitant ethical imperatives in the service of autonomy, risk coming to naught if the imperative of humanity is not honoured in the professional–client relationship. Humanity here means, first of all, that each person is unique and utterly particular in body and biography. This is what is intended when we rightly speak of the genetic, biochemical, psychic, and social individuality of human beings. This being said, humanity as the fourth ethical imperative of an authentic relationship means that a professional needs accurate information and knowledge, not only about diseases, conditions, and treatments in general, but accurate and relatively comprehensive (relative to the needs for which the person is seeking professional help) knowledge of the person seeking information, knowledge, advice, or treatment. We seek professional assistance, in part, to honour the Socratic dictum: Know thyself! The correlative imperative for the professional is: Know thy Patient or Client!

The principle of lucidity implies that drug users have the duty to themselves to seek, as well as the right to receive, accurate, reliable, and comprehensive information about illegal drugs, their interactions with other drugs and medications, and the effects of both on their body and psyche and social life. The principle of lucidity as a professional imperative, buttressed by the concomitant imperatives of autonomy, fidelity, and humanity, as described above, sets the basis for the principle of responsibility, another of the interlocking ethical grounds for ensuring that adequate information about drugs and their effects is available and given.

The Principle of Responsibility

Hans Jonas has titled one of his most important works *Das Prinzip Verantwortung*,[99] or the "principle of responsibility." The point here is not to summarize Jonas's lengthy discussion or even to apply that discussion to our issue, but rather more modestly to signal that the principle of responsibility, related as it is to the four marks and imperatives of the professional–client relationship, is an extension of the ethical grounds for ensuring the availability and communication of information about drugs and their effects on persons who use them.

When a person or persons are said to be responsible for something, it means at least that they cannot say the equivalent of: "That's not my problem, that's got nothing to do with me." *Responsibility* means at least being able to give a response; more strongly, being under moral, or professional, or legal obligation to give a response. About what? About what one has done, or should have done, but did not do. At least that.

The principle of responsibility links drug users, health-care professionals, researchers, the general public, and government authorities in quite different ways to the exigency for precise, reliable, and comprehensive information about the use of illegal drugs and the effects of such use on the bodies and lives of drug users as well as on the commonweal of the communities within which they live. That is one direction of the information we all require. Another

[99] H Jonas. *Das Prinzip Verantwortung*. Frankfurt am Main: Insel Verlag, 1979.

direction, no less imperative, is about the causal or aggravating effects of societal inequalities, inequities, and exclusions on drug users and their use of drugs.

Drug users, in the name of personal autonomy, have a responsibility to seek out the most reliable and comprehensive information available to guide them in the choices and decisions that will advance or frustrate their own life plans, and perhaps the life plans of the person with whom they interact or to whom they are bound.

Health-care professionals, if they are to honour the imperatives of lucidity, fidelity, and humanity, imperatives that are intrinsic to their professional relationships to their clients, carry the responsibility to assure that they master the drug-use information and knowledge they need to care for those whose needs fall within their professional mandate. They also have a responsibility to signal to the health-care community, to the research community, and to society where, in their experience, there is a dearth of needed information and knowledge.

Health-care researchers and those who organize and conduct clinical studies and clinical trials bear a rather unique form of responsibility regarding information and knowledge about the effects of various therapeutic drugs on the bodies and health of biochemically diverse sub-populations; about the effects of therapeutic drugs on the bodies and health of illegal drug users. Researchers generate the needed information and knowledge, and their primary scientific–ethical responsibility is to ethically design and conduct studies that will produce reliable and generalizable information and knowledge. Researchers also bear responsibility to avoid the sins of omission that will be committed when representatives of sub-populations that stand to be affected by clinical trials are unreasonably or negligently excluded from participation.

The responsibility of the general public, that is, of citizens and their government representatives, to become adequately informed about drug use and the effects of such use derives from their central role and power in the formulation, passage, and implementation of public policy regarding all aspects of drug use, including: the criminalization of drug use; prevention and education programs; harm-reduction programs; care, treatment, and support of drug users.

Health-care professionals carry the responsibility to assure that they master the drug-use information and knowledge they need to care for those whose needs fall within their professional mandate.

The Principle of Democracy

The unfettered and continuing generation, transmission, and discussion of information and knowledge about all matters affecting the commonweal of peoples is a necessary, if not sufficient, condition for the achievement and sustenance of democracy. The use, more systematic than sporadic, of secrecy, misinformation, disinformation, and lies tends to mark off totalitarian regimes, at whatever level of society, from spaces where the democratic principle of transparency governs.

Limitations successfully imposed upon the generation, communication, and discussion of information and knowledge tend to foster the accumulation of power and authority of some over the many. Sustained ignorance of the many works toward the same effect.

Even societies that can reasonably lay claim to having a government of the people, by the people, and for the people are not by that very fact utterly immune to what John Stuart Mill has called the tyranny of "prevailing opinion and feeling" and the "tyranny of the majority."[100]

[100] JS Mill. *On Liberty*. Vol. 18. Collected Works of John Stuart Mill, JM Robson (ed). Toronto & London, 1981, at 219-220; I Berlin. Two Concepts of Liberty. In: Isaiah Berlin. *The Proper Study of Mankind. An Anthology of Essays*, H Hardy, R Hansheer (eds). London: Chatto & Windus, 1997, at 191-242.

Ignorance, and the fears ignorance often stimulates, can quite well bring about the tyranny of prevailing opinion and feeling, the tyranny of the majority. Emancipation from such tyranny is an imperative of the democratic principle. That principle, in its own way, is an ethical ground for the generation, dissemination, and critical discussion and appropriation of reliable information and knowledge about all aspects of drug use and its effects.

Syringe Exchange and Methadone Maintenance Treatment

The last of the issues to be considered in this ethics commentary comes up in the question: "What ethical considerations need to be taken into account when implementing syringe and methadone maintenance programs directed at reducing the harms from drug use?"

I must restrict this commentary to several general ethical considerations. These would need to be complemented by a more extensive set of detailed ethical considerations regarding specific everyday aspects of syringe exchange and methadone maintenance programs. These detailed ethical considerations, to be realistic and practical, would require field work with at least one of each of the programs under consideration here. However, because these programs tend to differ in their specifics from place to place, detailed ethical considerations worked out for one program and place would not necessarily apply to other programs. The several general ethical considerations to be developed here should have relevance to all syringe exchange and methadone maintenance programs.

The Principle of Dignity

An issue is a question or a problem for which the answers or solutions proposed to date are provoking controversy or are marked by uncertainty as to their real effectiveness. Needle exchange programs (NEPs) and methadone maintenance treatment programs (MMTPs) are issues, are still now, years after their initiation in some places, foci of controversy and uncertainty.

Syringe exchange and methadone maintenance programs do not work as effective means when they are operative in ways that impose restrictions that condemn the programs to fall far short of the needs of the persons for whom they were designed.

The autumn 1997 consultation for this project directed attention to several problematical aspects of NEPs and MMTPs, and in particular emphasized that some of these programs are being implemented in ways that defeat their purpose. The governing purpose or end of these programs is the reduction or elimination of a constellation of harms that accompany addiction to drugs and injection drug use. The NEPs and MMTPs are means to achieve that end.

However, these programs do not work as effective means when they are operative in ways that impose restrictions that condemn the programs to fall far short of the needs of the persons for whom they were designed. These programs also fail if their mode of implementation contradicts one of the essential ends of the program. In the case of MMTPs, one of the goals is to help people stabilize their lives and become socially rehabilitated (able to run a home, attend school, hold a job), in short, to regain increasing levels of human dignity. How can this happen, however, if the MMTPs are run in a fashion that ridicules a person's dignity, invades a person's basic privacy, and denies a person's autonomy?

The Harm-Reduction Ethic within an Ethics for Complexity

I open this consideration with Castoriadis's statement about how crushing a fact of human life it is that the difference between Good and Evil is often very obscure in specific circumstances and the Good, in certain circumstances, can only be achieved by sacrificing other goods.[101] In other circumstances we may have to suffer or tolerate some lesser evils to prevent greater evils that would drag us beyond the boundaries of what human beings should ever tolerate. This Castoriadis-inspired reflection opens into a consideration of the harm-reduction ethic.

The harm-reduction ethic derives from a most basic ethical principle: respect for human life and for the dignity of the person. That basic principle is a foundation for achieving the goal of sustained development, a process marked by the logic that survival is for emancipation and emancipation is for transcendence. Emancipation here means freeing oneself and being freed from all the obstacles that would restrict or frustrate the biological, psychological, intellectual, personal, and societal flowering of a human being. Transcendence here means moving beyond where one is already; means moving upland along the gradient of human values; means actualizing the potentials of humanity during one's life.

For all that to happen, life and survival in health are essential preconditions. The harm-reduction principle dictates working to ensure survival and protection against immediate and serious threats to survival, rather than rushing ahead and trying prematurely to push and pull someone to higher levels of emancipation before they are ready and prepared.

In simple terms, the harm-reduction ethic recognizes that the better can be the enemy of the good, and the good can be the enemy of the essential and the possible. The harm-reduction principle is at home within an ethics for complexity and is alien to a utopian ethics that tends toward an "all-now-or-nothing ethic," a "be-perfect-now-or-else ethic."

A utopian ethics operates, as it were, outside of time. An ethics for complexity – and within it the harm-reduction ethic – works within a notion of time that expresses the principle of emergence. Moving upward out of a long spiral of

[101] C Castoriadis. *La Montée de l'insignifiance. Les Carrefours du Labyrinthe IV*. Paris: Éditions du Seuil, 1966, at 212.

being abused and degraded, out of a long spiral of decline from human dignity and loss of sense of self-worth both takes a lot of time and requires the convergence of one's own time with the time of many other people – if the present and the future are not to be simply a repetition of the past.

An ethics for complexity, and its harm-reduction ethic, function within a complex notion of time that incorporates elements of, but is radically different from, two of the central notions of time in mathematics.[102] There is the notion of deterministic time, in operation when astronomers predict future eclipses of our sun and moon or calculate the exact dates of eclipses in the distant past. They do so on the basis of data about the present state of the planets. The past and future, at least of our solar system, are entirely contained in the present. The present was determined by the past as the future is determined by the present. There is also the randomistic notion of time. Randomness is the independence of the future both from the past and the present. Within this notion of time, the traces of the past disappear very quickly, and each instant of time brings something new.[103]

The harm-reduction ethic is based on the notion that a drug user's present is influenced, perhaps heavily influenced, by the past, but that the past does not determine the drug user's future. That future is open to new achievement and freedoms, but the traces of the past are not fleeting or likely to disappear or lose their influence very quickly.

The harm-reduction ethic holds that any step to reduce the harms accompanying or following from drug use is valuable. "Harm reduction encompasses abstinence as a desirable goal, but recognizes that when abstinence is not possible, it is not ethical to ignore the other available means of reducing human suffering."[104]

The harm-reduction ethic is based on the notion that a drug user's present is influenced, perhaps heavily influenced, by the past, but that the past does not determine the drug user's future.

Ends and Means in Ethics

Confusion about ends will almost inevitably contaminate the choice, and frustrate the implementation, of means to achieve an end. The harm-reduction ethic is not governed by the end of "achieving abstinence now." However, if and when that end continues to lurk in the shadows and to influence harm-reduction methods and means, the end result can easily become a means reduction, a minimalization of the means needed to reduce harms; a parsimonious use of these means, influenced perhaps by a "Don't think we're going to let you get away with everything!" attitude.

When this occurs, the distant end of abstinence – not now, if ever, achievable – distorts the means of the harm-reduction ethic and frustrates the achievement of harm-reduction ends. The harm-reduction ethic, rather than emphasizing the sending of "right and wrong messages," confronts drug use pragmatically, without moralizing.[105] The end governing the use of harm-reduction means is the prevention *now* of death, the transmission of death-dealing infection, the destruction of health, and the continuance of a disruption of a person's family and social life.

It is when people think, erroneously, that the rightness or wrongness of harm-reduction means can be judged in the abstract; indeed, and even more so, it is when these means, such as syringe exchange, are judged in the abstract to be morally wrong, that feelings of guilt and uneasiness set in to reduce these means, as implemented, to powerlessness. The program may be allowed, but

[102] I Ekeland. *Mathematics and the Unexpected*. London: University of Chicago Press, 1988.

[103] Ibid at 111.

[104] N Gunn, C White, R Srinivasan. Primary care as harm reduction for injection drug users. *Journal of the American Medical Association* 1998; 280: 1191-1195.

[105] Ibid.

its workings are paralyzed by moral ambivalence or by sentiments that the program itself is a capitulation to deviance.

The mistake in ethics is at the starting point of the thinking that leads to this ambivalence. The relationship of means to ends cannot be worked out, judged as right or wrong, in abstraction from the total context within which the harm-reduction ends and means are to operate. Here is where the principle of totality comes into play. The principle of totality here means concrete comprehensiveness. It is only within the comprehensive context surrounding drug use and drug users' lives – their risks, their impulsions, their limits, their possibilities, the points where they are in their life trajectories, the specific environments within which they live – that the specific and essential ends of harm reduction, and the means to achieve these ends, can be determined and judged to be right or wrong. When the ends are seen to be essential, and when the means are likely to be effective and not in moral contradiction to these ends, there is little excuse for the ambivalence and restricted implementation behaviours that can doom a harm-reduction program to failure.

The Shadows of Reductionism in the Harm-Reduction Ethic

Reductionism is a term with many meanings,[106] several of which have a direct bearing on the workings of the harm-reduction ethic in its use, for example, of NEPs to reduce the transmission of HIV. To the extent that reductionism truncates or distorts our understanding and knowledge of the smaller or larger worlds in which we have to act, it also diminishes the knowledge with which ethics dictates that our doing should be consistent. Reductionism leads to flaws not only in methodology and epistemology; it also plays havoc with ethics to the extent that it leads us to promote and implement policies that are likely to fail or to produce results that are opposite to those for which a harm-reduction program was initiated.

Glimpses of reductionism in molecular biology and mathematics

We should first distinguish reductionism as a pragmatic method of inquiry from reductionism as an explanatory principle.[107] Reductionism as a pragmatic method of inquiry is, indeed, a very effective way of obtaining limited but very exact knowledge. Reductionism as an explanatory principle seeks to locate the causes of higher, complex phenomena at the lowest level of a phenomenon's structure. Reductionism in molecular biology, for example, assumes that the fundamental understanding of biology comes only from the level of DNA,[108] the so-called blueprint (beware of metaphor even if we need them)[109] for living systems.

The peril of reductionism as a pragmatic method of inquiry – isolate, if possible, and study the smallest parts of a complex system – is that we leave a realm of potential knowledge behind at each step of the reduction and analysis. "Each time we fix our gaze on a particular feature, we lose the context of the whole in which it is embedded."[110] The corrective implication with respect to reductionism as explanatory principle in molecular biology is this: "If we cannot fully understand an organism without its environment, neither can we understand genes without organisms."[111]

[106] SN Auyang. *Foundations of Complex-Systems Theories in Economics, Evolutionary Biology, and Statistical Physics*. Cambridge, New York, Melbourne: Cambridge University Press, 1998, chapter 2; D Charles, K Lennon (eds). *Reduction, Explanation, and Realism*. New York: Oxford University Press, 1992.

[107] C Holdrege. *Genetics and the Manipulation of Life. The Forgotten Factor of Context*. Hudson, NY: Lindisfarm Press, 1996, at 88.

[108] AI Tauber, S Sarkar. The Human Genome Project: has blind reductionism gone too far? *Perspectives in Biology and Medicine* 1992; 35(2): 228.

[109] G Lakoff, M Johnson. *Metaphors We Live By*. Chicago, London: University of Chicago Press, 1980.

[110] Holdrege, supra, note 107 at 88.

[111] Ibid at 15.

This neglecting of the principle of context comes to expression in the statement of a leading molecular biologist, cited by Lewontin, to the effect that if he had a powerful enough computer and the complete DNA sequence of an organism, he could, in principle, *compute* the organism: *compute the organism* meaning that he could totally describe its anatomy, physiology, and behaviour.[112] The *deterministic* component of this view of life is that for every action taken, there are causal mechanisms that preclude any other action. The *reductionistic* component would situate these causal mechanisms in the sequence of DNA. Some believe that mapping and sequencing the genome, *combined* with tracing the pathways linking genes to behaviour, will sketch a deterministic view of human life.[113] The implication of this view, as in the above idea of computing the organism, is that mastery of DNA causal mechanisms and of the contexts in which they operate would be equivalent to a power to predict human development and human behaviour.

This view is quite totally ignorant of the fact that living organisms, preeminently human beings, are complex adaptive systems.[114] The development and behaviour of such systems at any moment is the expression of a unique history resulting from the non-predictable interaction of internal and external forces, of an organism and its environment. Moreover, the world in response to which an individual organism develops – these external forces – is also modified and shaped by the activities of the organism itself.[115] Those who view life in reductionistic, deterministic terms are using *linear models* of thought. Unfortunately for reductionism and determinism, living organisms, and certainly human beings, exemplify the workings of *nonlinear* dynamics. In nonlinear dynamic systems, the whole really can be, and usually is, greater than the sum of its parts.[116]

Reductionism has not tried to feed only on molecular biology. It has a very great appetite, and once, in the work of the great mathematician David Hilbert, tried to swallow the whole of mathematics into a collection of formal statements with a finite alphabet of symbols, a finite set of axioms and rules of inference. To solve mathematical problems, Hilbert sought "a decision process that would operate on symbols in a purely mechanical fashion without requiring any understanding of their meaning."[117] This was a reductionistic project of great ambition and it failed. Kurt Gödel showed, with his famous theorem, that reductionism does not work in pure mathematics. The truth of a statement can be decided "only by studying its meaning and its context in the larger world of mathematical ideas."[118]

The glimpses of reductionism sketched above illustrate the failure to consider, among other essentials:

- a phenomenon in its broad, if not total, context;
- the interaction of single parts of a system with the system as a whole and vice versa;
- the causal effects of feedback on any intervention into a system.

A further illustration of reductionism – and it relates directly to the ethics of ends and means – is the tendency toward the "technological fix," the tendency to imagine that the relationship of means to end takes the form of a simple linear relationship between a singleton means (MS) to the achievement of an end

[112] Lewontin RC. The dream of the human genome. *New York Review of Books* 1992; XXXIX (28 May): 31-40.

[113] US Congress, Office of Technology Assessment. *Mapping our Genes. The Genome Project: How Big, How Fast?* Washington, DC: US Government Printing Office, 1995, at 86.

[114] MM Waldorp. *Complexity. The Emergency Science at the Edge of Order and Chaos*. New York, Toronto: Simon & Schuster, 1992.

[115] Lewontin, supra, note 112 at 34.

[116] Waldorp, supra, note 114 at 64.

[117] F Dyson. The scientist as rebel. *New York Review of Books* 1995; XLII (25 May): 32.

[118] Ibid.

Syringe exchange and needle exchange activities are, based on evidence now available, not only useful, but also necessary elements in a harm-reduction program.

(E): MS → E. This form of practical reductionism – practical because it relates to action to achieve a purpose, the reduction of harms linked to drug use – also tends to confuse necessary with sufficient conditions. Syringe exchange and needle exchange activities are, based on evidence now available, not only useful, but also necessary elements in a harm-reduction program. But these activities are of themselves, so recent evidence seem to indicate, not sufficient to attain the ends of harm reduction, particularly the reduction of the transmission of HIV.

Closing Reflection: When Some Things Are Simply Wrong

It is little more than a cliché, so often repeated, to say that we are living in an age of rapid change. But we are. Related to this characteristic of our period in history is the experience, sometimes called the postmodern experience, of living within ever-expanding zones of uncertainty. It sometimes seems as though our moral North and South poles have exchanged positions and the moral compasses we used in earlier times seem no longer able to give us direction.

Moreover, the social, economic, political, historical, and medical complexity intertwined in all of the major issues raised by drug use may, at first sight, seem to cloud over ever more thickly our view of the directions we should follow to resolve these issues. However, we should recall and dwell for a moment on the thought that complexity is not the same as complication.

The real world, whether it be of a science, an economy, a society, or an individual, is always complex, but complexity is not the same as complication.

We speak of medical complications when the normal and expected course of healing is slowed down or blocked, for example by an intervening infection. More generally, complication, whether it be of complicated phenomena, constructions, processes, or effects, needs unraveling. The movement of intelligence seeking simplification for the sake of understanding and explanation is backward and downward. The strategy is typically analytical, reductive, and abstractive. Intricate operations or processes, such as a chemical reaction, are factored into a sequence of linked steps, each step being both the resultant of a prior triggering move and, in turn, a trigger for the next move. Baffling constructions of multiple elements are decomposed into their basic and main structural elements. Tangled phenomena are subjected to modeling, and the

models are designed to reveal everything essential and to reflect nothing extraneous.

There is a view that ethical problems and conflicts can be resolved by using the strategies that work for unraveling complicated phenomena. This approach seeks to reduce ethical problems, conflicts, and issues to one principle or at least to a set of ordered principles that determine the choices and decisions people should make if they want to be ethically rational, consistent, and coherent. This approach would seek to reduce complex and messy human situations of value conflict to a model of the basic ethical principles involved. The ethical solution would derive from the order inherent in these principles, modeled to reveal rationality and to reflect nothing of the irrationality, uncertainty, ambiguity, and ambivalence that characterize human beings when they face their own disturbing behaviour, or the disturbing behaviour of others who are trapped far out on the margins of society.

It is *ethically* wrong to continue to tolerate complacently the tragic gap that exists between what can and should be done in terms of comprehensive care for drug users and what is actually being done to meet these persons' basic needs.

This reductive and obstructive approach will not work as the method required to resolve the ethical issues of drug use. That method will not work because it is designed for unraveling complications and abstracts from the very realities that make these issues complex and not only complicated, although these issues may be complicated as well. The movement of intelligence seeking to understand complexity is forward and upward and takes the recursive relationship of drug user–society as its starting point.

An ethics for complexity directs attention methodically to the full particularity of drug users and of the communities and society with which they interact. An ethics for complexity assumes that a society cannot solve the drug problem without profoundly reforming itself, without undergoing a profound intellectual and moral conversion. One of these conversions has to be a turning away from an ethic of exclusion and a turning toward an ethic of humanity.

At the end of this ethics commentary, I bring forward certain implications of this intellectual and moral conversion. I present these implications as positions, and not as conclusions, because this commentary had neither the time nor the resources for the kind of full-scale ethical analysis required for thoroughly justified conclusions.

A turning away from an ethic of exclusion to an ethic of humanity implies that some things are ethically simply wrong.

- It is *ethically* wrong to continue criminalizing approaches to the control of drug use when these strategies: fail to achieve the goals for which they were designed; create evils equal to or greater than those they purport to prevent; intensify the marginalization of vulnerable people; and stimulate the rise to power of socially destructive and violent empires.
- It is *ethically* wrong to continue to tolerate complacently the tragic gap that exists between what can and should be done in terms of comprehensive care for drug users and what is actually being done to meet these persons' basic needs.
- It is *ethically* wrong to continue policies and programs that so unilaterally and utopically insist on abstinence from drug use that they ignore the more immediately commanding urgency of reducing the suffering of drug users and assuring their survival, their health, and their growth into liberty and dignity.

- It is *ethically* wrong utterly to neglect to organize the studies needed to deliver the knowledge required to care more adequately for persons who use drugs and are HIV-infected.
- It is *ethically* wrong to exclude HIV-infected drug users from participation in clinical trials when that exclusion is based not on scientific reasons but rather on prejudice, discrimination, or simply on considerations of clinical trial convenience for the investigators.
- It is *ethically* wrong to tailor or suppress the information about illegal drugs that individual users, professionals, and citizens generally need to know to act responsibly.
- It is *ethically* wrong to set up treatment or prevention programs in such a way that what the program gives with one hand it takes away with the other.

Finally, it is *imperative* that persons who use drugs be recognized as possessing the same dignity, with all the ethical consequences of this ethical fact, as of all other human beings.

It is *imperative* that persons who use drugs be recognized as possessing the same dignity, with all the ethical consequences of this ethical fact, as all other human beings.

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Injection Drug Use and HIV/AIDS:

Policy Issues

prepared by
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ABOUT THE AUTHOR
Diane Riley has studied the socio- and bio-behavioural effects of drug use for more than twenty years, working in Australia, Canada, England, Papua–New Guinea, and Sweden. After carrying out treatment research at the Addiction Research Foundation in Toronto, she worked with community groups to set up the first bleach-kit programs and syringe exchanges in Toronto. From 1990 to 1996 she was Senior Policy Analyst with the Canadian Centre on Substance Abuse. She is currently a Policy Analyst with the Canadian Foundation for Drug Policy and an Adjunct Professor in the Faculty of Medicine, University of Toronto.

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CAVEAT
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Table of Contents

Introduction

This paper considers some policy aspects of seven priority issues related to HIV prevention for injection drug users, and to the access of HIV-positive injection drug users to care, treatment, and support. The companion papers in this volume provide a similar exploration of the same issues from a legal and an ethical perspective respectively. In this paper, the issues addressed from each of these perspectives are as follows.

Issue 1: Current Legal Status of Drugs and Drug Use
What is the impact of the current legal status of drugs and drug use on HIV/AIDS care, treatment, and support of drug users? What are possible alternatives to the current legal status?

Issue 2: Drug Use and Provision of Health and Social Services
What issues must be considered in allowing or tolerating drug use in the course of providing health care or social services (primary health care, community clinics, pharmacy services, residential care, palliative care, housing services)?

Issue 3: Treatment
What issues are raised by making cessation of drug use a condition for treatment for a drug user? What issues are raised by withholding antiretroviral drugs (particularly current triple or quadruple combinations of drugs) from HIV-positive drug users?

Issue 4: Prescription of Opiates and Controlled Stimulants
What issues must be considered in prescribing opiates and controlled stimulants to drug users in Canada?

Issue 5: Drug Users and Studies of HIV/AIDS Drugs and Illegal Drugs
What do we know about the impact of illegal drugs on the immune system? Have any trials been undertaken? What do we know about the interactions

between HIV/AIDS drugs and illegal drugs? Have any trials been undertaken? What do we know about the practice regarding the inclusion or exclusion of drug users from trials of HIV/AIDS drugs, in Canada and internationally?

Issue 6: Information about the Use and Effects of Illegal Drugs
What can be done to ensure that health-care providers, drug users, and the general public have accurate and complete information about the use and effects of street drugs?

Issue 7: Syringe Exchange and Methadone Maintenance Treatment
What are the regulations governing syringe exchange programs and methadone maintenance treatment programs?

Current Legal Status of Drugs and Drug Use

First, do no harm.
– Hippocrates

Canada can best be described as a country with a prohibitionist drug policy, with little by way of harm-reduction programs.

What is the impact of the current legal status of drugs and drug use on HIV/AIDS care, treatment, and support of drug users? What are possible alternatives to the current legal status?

The Current System in Canada

At present, Canada can best be described as a country with a prohibitionist drug policy, with little by way of harm-reduction programs. The *Controlled Drugs and Substances Act*,[1] the drug law that came into force in 1997, is prohibitionist in form and intent.[2] There are needle exchanges throughout the country, but many of them are inadequate in their policies and practices, as will be described in detail in the chapter on Syringe Exchange and Methadone Maintenance Treatment; and some methadone programs, all of which are run along fairly rigid lines, despite the fact that they may call themselves harm-reduction programs. There is little national coordination of efforts with respect to reducing the harms of drug use, and little funding for treatment programs with a non-abstinence orientation.

The Effects of Prohibitionist Drug Laws

Drug laws in Canada, as in other countries where there is drug prohibition, have had many negative consequences. Among other things, they have:[3]

- encouraged users to ingest illegal drugs in more efficient ways (where there is less drug to carry and maximum effect is desired), often by injecting. Injecting with contaminated equipment greatly increases the risk of contracting HIV and other bloodborne infections;

[1] SC 1996, c 19.

[2] For further details on the *Controlled Drugs and Substances Act* and Canada's drug laws, see Canadian HIV/AIDS Legal Network. *Injection Drug Use and HIV/AIDS: Legal and Ethical Issues*. Montréal: The Network, 1999; and E Oscapella, R Elliott. Injection Drug Use and HIV/AIDS: A Legal Analysis of Priority Issues, in this volume.

[3] For a review of these issues, see, eg, R Jürgens. Drug laws and HIV/AIDS. *Canadian HIV/AIDS Policy & Law Newsletter* 1996; 2(3): 26-28; D Riley, E Oscapella. Bill C-7: Implications for HIV/AIDS prevention. *Canadian HIV/AIDS Policy & Law Newsletter* 1995; 1(2): 1, 11-13; D Riley, E Oscapella. Canada's new drug law: implications for HIV/AIDS. *The International Journal of Drug Policy* 1996; 7(3): 180-182.

Drug laws have created a culture of marginalized and stigmatized people, driving them from traditional social support networks – non-using family members, friends, and co-workers.

- created a culture of marginalized and stigmatized people, driving them from traditional social support networks – non-using family members, friends, and co-workers. It is difficult to reach marginalized communities with educational messages about safe drug-use practices or drug treatment;
- created a climate in which service providers and services for drug users are undervalued and stigmatized;
- created a punitive attitude toward users, making it difficult for them to access non-punitive treatment, particularly for pain relief;
- fostered a reluctance to educate both users and non-users about safe drug-use practices, for fear that this will be perceived as condoning or encouraging the use of illegal drugs. This has created a climate where accurate, explicit information on drugs and harm reduction is seen as "encouraging drug use";
- generated opposition to life-saving needle exchange programs and other harm-reduction measures; while needle exchange programs exist in several cities across Canada, many cities have not endorsed these programs – when there is limited access to sterile syringes, injection drug users borrow and lend needles, or they may purchase syringes off the street that may or may not be sterile;
- highly inflated the price of illegal drugs, so that some drug users are forced into high-risk forms of sex to pay for their habit. This increases the risk of HIV infection for drug users, their clients, and unsuspecting contacts of both;
- led to the creation of a very profitable illegal drug trade, with a great deal of corruption and violence among the various parties involved. Innocent bystanders are caught in this violence, and society as a whole is adversely affected by the ongoing violence and corruption;
- caused some drug users to fear being arrested for possession of illegal drugs (and also to fear having their syringes used as evidence against them), and so forego using their own drugs and syringes. Some go to "shooting galleries," where they may be given syringes contaminated with HIV, hepatitis viruses, and other pathogens;
- fostered public attitudes that are vehemently anti-drug, and the view that drug users do not care about their own lives. In such a climate it is difficult to persuade Canadians to care about what happens to their fellow citizens who use illegal drugs;
- focused too much attention on punishing people who use drugs, downplaying critically important issues such as why people use drugs and what can be done to help them stop unsafe drug-use practices;
- created a poor funding climate for care, treatment, and support;
- made it unattractive for universities and colleges to provide training on these issues for service providers working in these areas;
- made it next to impossible to raise funds or obtain funding for research on interactions between illegal drugs and HIV medications;
- resulted in policies that make it more likely that drug-dependent women who are pregnant or who have children will not seek help for fear of having their children taken from them. When women with children do seek help, few services provide child care or other means of allowing them to obtain treatment and still fulfil their role as caregivers. Female drug users who are HIV-positive, and their unborn children, are especially at risk if these women feel that they cannot seek appropriate services; and

- exposed drug users to adulterated drugs of unknown levels of purity, leading to many deaths from overdoses of illegal drugs.[4]

In addition to the above effects, current drugs laws greatly increase the risk that drug users will be sent to prison, that HIV will be spread in prisons, and that harms to HIV-positive users in prison will be exacerbated.[5] Current drug laws have:

- resulted in users being placed in high-risk prison environments where many continue to use drugs, but have no access to sterile injection equipment;
- increased the likelihood that dependent users desperate enough to pay the exorbitant market price of illegal drugs – a price that is the product of prohibition – will commit crimes, including burglaries and robberies, to procure the necessary means to maintain their habit. Thus, drug laws are an indirect cause of crimes other than illegal drug use that result in dependent users being placed in high-risk prison environments;
- contributed to a reluctance to provide condoms in prisons, which stems in part from the fear that they will be used to hide illegal drugs;[6]
- led to a reluctance to provide bleach to clean the syringes in circulation in prisons, as its availability might be seen as condoning illegal activity;[7]
- resulted in prohibition of access to clean syringes in prisons, in part because this might be seen as condoning illegal activity. As a result, the considerable amount of injection drug use that occurs in prisons involves the sharing of syringes that may be contaminated with HIV, hepatitis viruses, or other pathogens;[8]
- restricted attempts to educate prisoners about safe injection practices, for fear of being seen as condoning an illegal activity;
- encouraged the establishment of drug-testing programs within prisons. These programs can lead to the increased use of heroin and cocaine instead of marijuana,[9] since heroin and cocaine cannot be detected for more than a few days after use. In prison environments, these drugs are often injected using unsterile equipment, thereby greatly increasing the risk of infection and harm;
- led to an overrepresentation in prisons of people charged with drug offences, making it more likely that infections will spread there. In addition, a number of prisoners report using drugs and injecting for the first time in their lives when they are in prison;
- diverted moneys from more important concerns: resources that could – and should – be devoted to reducing the harms associated with drug use are being devoted to incarcerating drug users. Within prisons, a considerable amount is spent on drug testing, while not enough is spent on AIDS prevention and on care and support of HIV-positive prisoners.

Current drugs laws greatly increase the risk that drug users will be sent to prison, that HIV will be spread in prisons, and that harms to HIV-positive users in prison will be exacerbated.

Care and Support Needs of HIV-Positive Drug Users

The following issues have been raised by HIV-positive drug users. They are not necessarily the products of current drug policy only, but they do arise from the nature of current legal and social systems:[10]

- lack of information on the interactions between illegal drugs and drugs used to treat HIV and opportunistic infections;
- need for research into the effects of HIV treatments on the livers of individuals with both HIV and hepatitis C;

[4] See, eg, the Report of the Task Force into Illicit Narcotic Overdose Deaths in British Columbia, Office of the Chief Coroner, 1994, for an overview of the situation in BC in 1993, when more than 300 people died in BC alone from overdoses, and for recommendations.

[5] For a more detailed review, see R Jürgens. *HIV/AIDS in Prisons: Final Report*. Montréal: Canadian HIV/AIDS Legal Network, 1996; D Riley. Drug Use in Prisons. In: *HIV/AIDS in Prisons: Final Report of The Expert Committee on AIDS and Prisons. Background Materials*. Ottawa: Minister of Supply and Services Canada, 1994, at 152-161; and Canadian HIV/AIDS Legal Network. *HIV/AIDS in Prisons: Info Sheets 1-13*. Montréal: The Network, 1999.

[6] While most Canadian prison systems now provide access to condoms, some still don't. See Canadian HIV/AIDS Legal Network. *HIV/AIDS in Prisons – Prevention: Condoms* (info sheet

[7] For more information, see Canadian HIV/AIDS Legal Network. *HIV/AIDS in Prisons – Prevention: Bleach* (info sheet 5). Montréal: The Network, 1999.

[8] For more information, see Canadian HIV/AIDS Legal Network. *HIV/AIDS in Prisons – Prevention: Needles* (info sheet 6). Montréal: The Network, 1999.

[9] See Jürgens, supra, note 5, at 21-25.

[10] For reviews of these issues, see D Burrows. Care and support needs of HIV positive injecting drug users in Australia. 3rd International Conference on HIV/AIDS in Asia & the Pacific, Chiang Mai, 1995; Riley & Oscapella, supra, note 3.

- systematic discrimination against and stigmatization of HIV-positive users ("userphobia");
- need for coordination between services;
- inadequate pain management: drug users are often offered ineffective pain relievers such as aspirin when in fact they need more potent analgesics. Users may then have other drugs smuggled to them or may discharge themselves prematurely;
- unsuitable support groups: some have been established for specific groups such as HIV-positive gay men or HIV-positive women and are not acceptIng of drug users' lifestyles;
- need for harm-reduction, rather than abstinence-based, services;
- need for information and training on HIV-positive drug users for researchers, clinicians, physicians, and all service workers.

Potential Alternatives to the Status Quo

There are various alternatives to the present approach to drugs and drug use in Canada:[11]

1. *A harm-reduction approach within a prohibitionist framework*
   Such an approach has been adopted in (parts of) the Netherlands, the United Kingdom, and Australia. While existing laws and policies may pose barriers to comprehensive harm-reduction approaches, many initiatives can nevertheless be put into place that allow (some of) these barriers to be effectively overcome.

2. *Decriminalization*
   This is a system in which the possession and/or cultivation and/or distribution of drugs do not result in criminal charges.

3. *Legalization*
   This is a system in which the possession and/or cultivation and/or distribution of drugs do not result in any legal penalty, criminal or otherwise. All legalization models proposed to date involve some degree of government control over drugs, including controls on advertising, distribution outlets, and health warnings. In no countries do working models of such an approach exist at the national level.

4. *Free-market drug economy*
   In such a system, drugs are treated like any other commodity. There has been little examination of the short- or long-term implications of such a system, and in no countries do working models exist at the national level.

5. *Approaches that combine elements of the above*
   One could imagine, for example, a harm-reduction approach within a decriminalization framework. Such an approach would:

   - allow for possession of substances for personal use; allow for cultivation of plants (eg, marijuana, coca) for personal use; allow for the selling of substances in specified dosages (priced so that the least harmful forms of the drug are much less costly than more harmful forms) and of known purity, clearly labeled, through licensed and controlled outlets to adults;

[11] For a review, see D Riley, P O'Hare. Harm Reduction: History, Definition and Practice. In: J Inciardi, L Harrison (eds). *Harm Reduction and Drug Control*. Berkeley: Sage, 1999.

- ensure easy access to sterile needles and syringes, clean forms of drugs of known potency, explicit materials on drug effects and safer methods of use, and medical and other services (including injecting rooms) for drug users, thereby minimizing the number of users experiencing harms;
- provide appropriate, research-based education to health professionals, drug sellers, and users;
- provide easily accessible, noncoercive treatment and services, with harm-reduction as well as abstinence options; and
- allow for the prescription of psychoactive drugs (oral, smokeable, injectable, or patch) to certain individuals in certain conditions.

Examples of Existing Approaches outside Canada

United Kingdom[12]

In the UK, there is prohibition with medical prescribing of all illegal drugs except opium. There is extensive harm-reduction programming in the form of syringe exchanges, flexible methadone programs, the prescribing of other drugs, and provision of support services and explicit educational materials. At present there is a move toward tougher enforcement of prohibition for dealers, traffickers, and multiple-offence users. Drug testing was introduced into prisons in 1997. Police have played a vital role in sustaining harm-reduction approaches by taking part in educating the community and practising a policy of cautioning, in which first-time drug offenders are referred to drug services. The result is that there are very low levels of HIV seropositivity in drug users.

Australia[13]

Although Australia functions under a prohibitionist model, there is de facto decriminalization of cannabis possession and cultivation for personal use in some states. There have been moves toward a heroin-prescribing trial.[14] Extensive harm-reduction programs in the form of methadone treatment, syringe exchange, and explicit educational materials are in place. There is methadone maintenance in some prisons. Police in some states follow very progressive harm-reduction approaches. The response to the AIDS threat was rapid and pragmatic. National and state advisory committees on AIDS and drug use were set up early and were, for the most part, able to achieve a great deal. As a result, Australia has a low level of HIV infection among drug users, and there is very little spread of infection in this group. Measures introduced to combat the spread of AIDS in Australia included syringe exchange schemes and the marked expansion of methadone maintenance programs. The criteria for admission to these programs were also made less stringent, and many more spaces were allowed for maintenance of clients who have little motivation to change their drug-using behaviour. These changes to drug programs have been supported by a change in national and state policy toward drug use – the highest priority has been given to the containment of HIV and other drug-related harms. At present there is a move back toward tougher enforcement of prohibition (see the chapter on Prescription of Opiates and Controlled Substances under "Australia" for further details).

In Australia, the response to the AIDS threat was rapid and pragmatic.

Germany[15]

There is prohibition, with decriminalization of possession of marijuana for personal consumption, but the amount permitted varies greatly from state to state.

[12] Detailed overviews can be found in Riley & O'Hare, ibid.

[13] A Wodak. AIDS and injecting drug use in Australia. In: J Strang, G Stimson (eds). *AIDS and Drug Misuse*. London: Routledge, 1990, at 132-141; A Symonds. Australian drug law reform. Drug Policy Foundation Conference, New Orleans, 1997.

[14] See infra, the chapter on Prescription of Opiates and Controlled Substances, for details.

[15] W Schneider. How my city chartered a new drug policy course. *The Drug Policy Letter* 1993; 21: 7-9.

In the Netherlands, the extensive and comprehensive social services network available to all citizens takes the edge off many of the problems faced by drug users in other countries.

The city of Frankfurt has adopted a harm-reduction approach to drug users: it has established three crisis centres close to the drug scenes, provided a mobile ambulance to provide needle exchange services and medical help, and offers first-aid courses to users. The police have maintained their policy of apprehending dealers, but have initiated a policy of tolerating an open scene within a clearly defined area of one of the parks. The policy has led to a significant reduction in the number of homeless drug users, drug-related crimes, and drug-related deaths in the city. A heroin-prescribing trial is planned as soon as approval is received from the federal government.

The Netherlands[16]

There is prohibition, but with de facto separation of soft (cannabis) and hard drugs for enforcement purposes and de facto decriminalization of the possession of marijuana for personal use and for purchase and use in "coffee shops." A first heroin trial began in 1998.[17] Extensive harm-reduction services are available – flexible methadone programs, syringe exchanges, and social service support**.** Rotterdam has informally adopted a policy known as the "apartment dealer" arrangement, in which police and prosecutors refrain from arresting and prosecuting dealers living in apartments provided they do not cause problems for their neighbours. The extensive and comprehensive social services network available to all citizens takes the edge off many of the problems faced by drug users in other countries. This is thus not simply a matter of changing drug laws, but of a comprehensive overhaul of social policies.

Switzerland[18]

Switzerland has a longstanding history and high per capita prevalence of broad-based methadone treatment, and has conducted a multi-city study to assess whether the prescription of heroin, morphine, or injectable methadone reduces disease, crime, and other drug-related problems. As part of the study, cocaine was prescribed to a few subjects. Switzerland still features very heavy (and recently increasing) enforcement against drug users not in treatment. There is harm-reduction programming in prisons, including syringe exchanges and the prescription of methadone and heroin.

United States[19]

The model is prohibitionist, with some de facto decriminalization of marijuana possession in some states. Most methadone clinics have harsh regulations. There are few needle exchanges, and Gostin et al have reported that in 47 US states laws exist that prohibit the sale or possession of syringes without a prescription.[20] In addition, there is a congressional ban on the use of federal funds to support needle exchange programs in the US. As a result, many existing needle exchange programs are illegal and are less likely to provide valuable ancillary services such as HIV testing or referral to drug treatment.[21] There is widespread drug testing, including in the workplace, and there are very harsh penalties for all drug offences, with sentencing according to strict mandatory minimum guidelines. Many politicians in the US view harm reduction as being equivalent to a movement to legalize drugs, and the US is putting increasing pressure on other countries to adopt their war on drugs (and drug users) approach.

[16] Riley & O'Hare, supra, note 11. The Editor. *Jellinek Quarterly* 1998; 1: 1-2.

[17] Central Committee on the Treatment of Heroin Addicts, Utrecht, Netherlands. Investigating the medical prescription of heroin: A summary of the Dutch planned randomized trial to evaluate the effectiveness of medically co-prescribed heroin and oral methadone, compared to oral methadone alone in chronic, treatment-refractory heroin addicts (May 1998). In: *Heroin Maintenance Treatment Research Summary*. New York, NY: The Lindesmith Center, 1998, 19-21.

[18] A Uchtenhagen et al. *The Swiss Heroin Trials: Final Report*. Swiss Federal Office of Public Health, 1997; A Uchtenhagen. Programme for a medical prescription of narcotics: summary of the synthesis report (July 1997). In *Heroin Maintenance Treatment Research Summary*. New York, NY: The Lindesmith Center, 1998, 7-14.

[19] E Drucker. US drug policy. In: P O'Hare et al. *The Reduction of Drug Related Harm*. London: Routledge, 1992; E Drucker. Drug Prohibition and Public Health: 25 Years of Evidence. *Public Health Reports* 1999; 114(1): 14-29 (reprinted in *The Drug Policy Letter* 1999; 40: 4-18. See *The Drug Policy Letter*, the newsletter of The Drug Policy Foundation, Washington, DC; it contains some analysis of US drug policy in every issue.

[20] LO Gostin et al. Prevention of HIV/AIDS and other blood-borne diseases among injection drug users – a national survey on the regulation of syringes and needles. *Journal of the American Medical Association* 1997; 277(1): 53-62.

[21] D Paone et al. Syringe exchange in the United States, 1996: A national profile. *American Journal of Public Health* 1999; 89(1): 43-46.

Drug Use and Provision of Health and Social Services

Society's failure to accept drug use as a legitimate form of risk-taking poses a significant barrier to tolerance of drug use.

What issues must be considered in allowing or tolerating drug use in the course of providing health care or social services (primary health care, community clinics, pharmacy services, residential care, palliative care, housing services)?

Harm Reduction[22]

Harm reduction is a relatively new approach that offers an alternative to abstinence-based approaches to drugs and drug use. Its aim is to reduce the negative consequences of drug use to the individual, the community, and society as a whole. It is an approach that tolerates and even allows drug use, accepting that abstinence is not a realistic goal for some users either in the short or long term. Indeed, the goal of the harm-reduction approach is to attract drug users who will not consider abstinence-based programs or services.

Barriers to Harm Reduction

There are numerous barriers to both the policy and practice of harm reduction in many countries. One of the main barriers to the adoption of non-prohibitionist policies is idealism. Adopting harm reduction means accepting that some harm is inevitable. The zero-tolerance approach of the United States is an example of a policy that by definition excludes all compromise. Canada, like the US, has inherited an abstinence-based morality wherein total abstinence is seen as the only acceptable goal of treatment for the "abuse" of legal drugs and the only acceptable "normal" state with respect to illegal drugs. In North America, the "drug war" mentality has built additional serious barriers, since any seeming support for drug users has been construed by some as support for drug use.

[22] For an overview of harm reduction in theory and practice, see Riley & O'Hare, supra, note 11; D Riley et al. Harm reduction: Concepts and practice. *Substance Use and Misuse* 1999; 34(1): 9-24.

Another impediment to harm reduction is lack of public education regarding the nature and effects of drug policy.

Society's failure to accept drug use as a legitimate form of risk-taking poses a significant barrier to tolerance of drug use. While societies tolerate and even encourage some forms of risk that are associated with a much greater likelihood of harm than drug use (such as car-racing, mountain-climbing, and jet-skiing), harm reduction is viewed as promoting something that is necessarily bad, something evil. Religious and other beliefs that hold that people should be punished for committing sins against morality also stand in the way of harm reduction. AIDS and other drug-related harms are sometimes viewed as just deserts.

Legal barriers, such as paraphernalia and other drug laws, can stand in the way of harm reduction. Another impediment is lack of public education regarding the nature and effects of drug policy. The lack of adequate treatment and other services for drug users in many countries also stands in the way of significant progress. This criticism is particularly true of our correctional systems.

The most obvious question raised by the harm-reduction approach is the meaning of the term "harm" itself. In deciding what constitutes harm, which harms are to be reduced, and in what order, scientific, political, moral, and other factors are clearly brought to bear. There are as many applications of harm reduction as there are harms to be reduced, but one person's harm may be another's benefit – and there's the rub. It would be all too easy for the harms selected for reduction to become only society's harms, not those of the individual and the community as well. Indeed, there are many who believe that imprisoning drug users is a form of harm reduction. We need to clarify the nature of the harm-reduction approach sufficiently in order to prevent such arbitrary designations.

Abstinence

The abstinence-based model, together with drug prohibition policies in most countries, has made it very difficult to allow drug use – including alcohol use – in facilities where health care or social services are provided. The justification for this, which has seldom needed stating because it is so ingrained in the culture, has been, either implicitly or explicitly, that:

- abstinence is the goal of all treatment: these people need treatment, therefore they should be dealt with as they would be in an abstinence-based treatment program;
- abstinence is the only way of "curing" legal drug misuse and the only way of approaching illegal drug use;
- all drug misuse is bad and cannot be condoned;
- allowing drug use would send the wrong message to users and to the public;
- the public would not approve of their moneys being spent in this way; and
- drug users should be punished.

This difficulty with respect to tolerating drug use is particularly extreme in North America, where both abstinence and prohibition have deep roots. This situation is exacerbated by an underlying puritanism. Given the resistance to a change in approach in North America, it is necessary to look elsewhere for innovation with respect to harm-reduction programs for users. Even in Europe, however, there has been resistance to allowing drug (including alcohol) use in programs because of the "message" that would be sent to users and the public. The exception to this has been the allowance of methadone use in clinics,

One innovative harm-reduction approach involves toleration by authorities of facilities known as "injection rooms."

hospitals, shelters, and so on. Methadone use by those registered in a program has been looked on much more favourably than has the use of other drugs because it is legal (as opposed to heroin) and stabilizing (unlike alcohol).

Over the last two decades, some European countries have been forced to reexamine their policies with respect to tolerance of drug use because of the increasing number of visible users, the civic unrest triggered by their activities, and the spread of HIV and other infections among and from users. This has given rise to a number of planned and unplanned pilot projects in the form of parks, stations, shelters, and injection rooms.

New Solutions Adopted outside Canada

Needle Park[23]

In 1987 the Platzspitz, a park situated right beside the train station in the centre of Zurich, was allowed to operate as an open drug scene. This was not so much the product of liberal thinking as the result of the users being chased from one location to another by the police. The authorities decided for pragmatic reasons to leave the users in the park alone. At first there was little negative impact on the neighbourhood, but the place became very popular and attracted users from elsewhere – more than 80 percent of the users were from outside Zurich or Switzerland. The park – which came to be known as Needle Park – was closed down when the unsanitary conditions, overdoses, and complaints became too great a problem for the city to deal with. In order to avoid the mistakes of Needle Park, the Swiss government agreed in 1992 to take over some responsibility from the cities and so began the three-year drug treatment trial involving prescribing of heroin and other drugs (see the chapter on Prescription of Opiates and Controlled Stimulants).

Injection Rooms

One innovative harm-reduction approach being practised in Switzerland (and in the Netherlands and Germany) involves toleration by authorities of facilities known as "injection rooms," "health rooms," "contact centres," or similar terms. These are facilities where drug users can get together and obtain clean injection equipment, condoms, advice, medical attention, and so on. Most allow users to remain anonymous. Some include space where drug users, including injectors, can take drugs in a comparatively safe environment. This is regarded as better than the open injection of illegal drugs in public places or in "shooting galleries" that are usually unhygienic and controlled by drug dealers.

In Switzerland, the first drug rooms were established by private organizations in Bern and Basel in the late 1980s. By the end of 1993 there were eight such facilities, most operated by city officials. Several other cities in the German-speaking parts of Switzerland opened drug rooms in 1994. An evaluation of three of these facilities after their first year of operation showed that they had been effective in reducing the transmission of HIV and the risk of drug overdose.[24]

Apartment Dealers

In addition to drug rooms and "coffee shops," Rotterdam has also informally adopted a policy known as the "apartment dealer" arrangement, which is part of a "safe neighbourhood" plan in which residents and police work together to keep areas clean, safe, and free of "nuisance."[25]

[23] European cities: laboratories of reform. *The Drug Policy Letter* 1993; 21 *passim*; E Nadelmann. Beyond Needle Park. *The Drug Policy Letter* 1995; 27: 12-14.

[24] Ibid.

[25] European cities: laboratories of reform, supra, note 23; E Leuw, I Marshall. *Between Prohibition and Legalization: The Dutch Experiment in Drug Policy Reform*. Amsterdam: Kugler, 1994; L Zaal. Police Policy in Amsterdam. In: O'Hare et al, supra, note 19.

The Frankfurt Model

In Frankfurt, as in many other European cities, users and dealers live in the centre of the city, making drug use and dealing a very public event. Because the drug scene was located around the railway station, the 80,000 daily commuters were exposed to the scene on a regular basis. Each day, several thousand people would meet to buy and sell drugs within a small area close to the banks and city hall. In 1980 it was decided that the police should clear out the drug scene. Dependent users were forced to choose between abstinence, or treatment with that goal, and imprisonment. As a result, there was a great deal of migration of both dealers and users from place to place in the city centre. By the end of the 1980s, the scene was five times larger than it had been, and many people realized that the enforcement approach had failed. Residents filed numerous complaints about the situation, and businesses – especially the large banks – also complained. The situation had become intolerable for both the community and the users.

AIDS is a greater threat to public health than drug misuse.
– UK Advisory Council on the Misuse of Drugs

In 1991, new methods were introduced. Mobile ambulances were stationed near a park at the centre of the drug scene to provide syringes and emergency assistance. A portion of the park was covered to provide shelter from cold and snow. First-aid courses were provided to users in the area. Police were present, but only to define the limits of the drug scene and to prevent violence. The police worked with a group that met weekly (the Monday Group) and was made up of city officials and administrators, doctors, and police officials. Each week the group would review the state of the park and the drug-using community and decide what should be done next.

The Frankfurt situation was similar to that in Zurich's Needle Park, in that it allowed the drug scene to function without much pressure. But the weekly working group could do a great deal to adapt the approach to the users and the park. For example, the size of the area could be regulated. One way in which overcrowding was prevented was to drive ambulances to other parts of the city, offering clean needles and medical services. The police presence was also crucial, in that if any of the dealers caused problems they could be arrested. What mainly prevented the Frankfurt situation becoming like that in Needle Park was the fact that other cities in Germany and the region, some with similar parks, were also providing services for drug users. The park was always considered a temporary measure – it was used until November 1992, when a network of crisis and helping centres was ready to take in users.

The new harm-reduction policy was actually called for by the community, following a process of education and discussion. Meetings were held and the banks made donations for a new foundation to provide services for users. The support of the banks attracted other donations, and the money was used to build a network of crisis centres and services, including injection rooms, throughout the city. While not all the problems have been solved, there has been a decrease in crime and violence, and fewer overdose deaths have occurred. Public health and social service workers find it easier to provide services when drug scenes are readily accessible and relatively stable.[26]

Adoption of a Hierarchy of Objectives for Behaviour Change[27]

In the UK, the government's statutory Advisory Council on the Misuse of Drugs (ACMD) has stated that AIDS is a greater threat to public health than drug misuse, and has recommended that drug services modify their policies to

[26] Schneider, supra, note 15.

[27] Riley & O'Hare, supra, note 11.

make contact with and change the behaviour of the maximum number of drug users even when they are still actively using drugs. The ACMD advised that drug services should now proceed according to a hierarchy of objectives for behaviour change, starting with the cessation of sharing of injection equipment, followed by a switch to non-injecting drug use, a reduction in drug use and, ultimately, cessation of drug use.

At present, the UK is the only country that "officially" allows the use of psychoactive drugs in clinics, hospitals, and palliative care centres. Most appear to do so by "turning a blind eye," but the UK prescribing programs do allow for much more flexibility than is found in any other country. Anecdotally, users and workers report tolerance of use in health centres as long as behaviour remains "orderly." In many counties users on methadone maintenance are allowed to stay on the drug while in state-run centres, with the exception of most prisons.

The Situation in Prisons

Methadone is available in some prisons in an increasing number of countries, including Australia, Switzerland, the United States, the United Kingdom, Spain, Denmark, and Germany.[28] In Canada, in September 1996 the British Columbia Corrections Branch adopted a policy of continuing methadone for incarcerated adults who were already on a prescribed methadone maintenance program in the community prior to incarceration.[29] Other Canadian prison systems, including the federal prison system, have also started allowing prisoners who were on methadone maintenance treatment outside prison to continue the treatment in prison, and in a few systems prisoners may be allowed to start such treatment in prison.[30] In one prison in Switzerland, a small number of inmates are being maintained on heroin, so far with good results.[31]

The Situation in Canada

Most facilities in which care is provided do not allow alcohol or other drug use, though some will "unofficially" tolerate it if it is not too disruptive to other clients or patients. Possession of drugs on the premises is less tolerated because of the legal ramifications (use of illegal drugs is not in itself illegal, while possession is). There are some shelters, known as "wet shelters," that do allow alcohol use and a few hospices that have tolerated drug use.

Facilities that consider allowing or tolerating drug use must consider many issues. Among them are:

- facilities are likely to be more tolerant of drug use when users are terminally ill, but what of possession and the purchasing of drugs on the premises?
- facilities need to be able to provide using and non-using areas so that users who are trying to abstain don't feel pressured: this increases costs;
- if drug use is tolerated, there need to be guidelines with respect to the kinds of behaviours that will be tolerated by the facility, so that it is clear that it is the behaviour rather than the drug use per se that is of chief concern;
- training of staff with respect to drug effects, especially in HIV-positive users, must be greatly improved if drug use is to be successfully tolerated in a facility.

[28] For an overview, see Canadian HIV/AIDS Legal Network. *HIV/AIDS in Prisons – Methadone (Info sheet 7)*. Montréal: The Network, 1999. See also Jürgens, supra, note 5 at 68-70.

[29] C McLeod. Is there a right to methadone maintenance treatment in prison? *Canadian HIV/AIDS Policy & Law Newsletter* 1996; 2(4): 22-23. See also D Rothon. Methadone in provincial prisons in British Columbia. *Canadian HIV/AIDS Policy & Law Newsletter* 1998; 3(4)/4(1): 27-29.

[30] See *HIV/AIDS in Prisons – Methadone (Info sheet 7)*, supra, note 28.

[31] B Kaufmann, R Drelfuss, A Dobler-Mikola. Prescribing narcotics to drug-dependent people in prison: some preliminary results. *Canadian HIV/AIDS Policy & Law Newsletter* 1998; 3(4)/4(1): 38-40.

The primary obstacles to allowing drug use during treatment would appear to be related to policy rather than to ethical or legal concerns.

Treatment

What issues are raised by making cessation of drug use a condition for treatment for a drug user? What issues are raised by withholding antiretroviral drugs (particularly current triple or quadruple combinations of drugs) from HIV-positive drug users?

Cessation of Drug Use As a Condition for Treatment

Background

Treatment of drug users in North America is more akin to religion than it is to science.

The primary obstacles to allowing drug use during treatment would appear to be related to policy rather than to ethical or legal concerns. Throughout the 20th century, abstinence has been viewed as the only "cure" for drug dependence and the only normal condition with respect to illegal drugs. The strict abstinence philosophy underlying the approach taken by social services is even more pronounced in a treatment context because abstinence is always the goal of treatment, at least in North America, where the disease concept of drug use is firmly embedded. This situation is exacerbated by the profound influence of the Alcoholics Anonymous model of drug use, which views the drug as both a stimulus for disease and an evil power. Treatment of drug users in North America is more akin to religion than it is to science.

Health-care workers' job is to ensure health, and – according to the models predominant in this century – abstinence from non-medical drugs is a fundamental part of healthy behaviour. To the extent that a drug produces serious health and social consequences for an individual or the community, this is no doubt true. But what of the needs of users who are better off on drug maintenance than they would be having to live with the problems associated with failed abstinence? These users may refuse to enter treatment or may, having done so, simply leave the program early, often returning to the street and its attendant harms. Many users avoid treatment and services because they are not

willing or able to contemplate a goal of abstinence either in the short or long term. It is important to ensure that drug users feel that they are welcome at services that can meet their needs. Furthermore, it has been demonstrated that users do better in treatment if they are given a *choice* of treatment goals, abstinent and non-abstinent.[32] Indeed, even users who enter an abstinence-oriented treatment regime do significantly better if they are allowed to choose this goal for themselves rather than have it determined for them. Providing non-abstinent treatment goals is thus an important way of reducing drug-related harm, and is in no way contrary to the most fundamental medical principle: First, do no harm.

Another barrier to permitting drug use during treatment is the view that drug users have inflicted their problems upon themselves. This barrier is more pronounced in the case of HIV-positive users, who are sometimes seen as having made a lifestyle choice to inject drugs and are therefore not deserving of treatment. Implicit in this approach is the view that drug users deserve punishment, not help. This gives rise to one of the central contradictions of our approach to drugs and drug users in the latter part of the 20th century: drug use is said to be a disease, yet users of illegal drugs are regarded as criminals.

Drug use is said to be a disease, yet users of illegal drugs are regarded as criminals.

In some cases there are obviously legitimate grounds for wanting to prevent the continuation of drug use. These include physical "justifications" such as the following:

- liver problems or failure: the user should abstain from drugs such as alcohol, which are difficult on the liver; this is especially so for HIV-positive users (in particular those with hepatitis), since combination therapy can result in liver failure;
- adverse interactions between HIV drugs and illegal drugs (see below, the chapter on Drug Users and Studies of HIV/AIDS Drugs and Illegal Drugs);
- the claim that illegal drugs compromise the immune system and therefore accelerate the course of AIDS (see below). Even if drugs do "impair" the immune system, is this grounds for withholding treatment that can help repair it?

They also include psychological "justifications": for example, drugs may exacerbate mental problems such as AIDS dementia (however, this is not true of all drugs or of all people); and drugs may cause the patient to be so disruptive that the care and well-being of other patients is threatened (this is clearly a real concern in residential treatment centres, but cannot be extended to patients who live off-site).

Even though there may be clearly valid justifications for recommending abstinence from certain drugs, it is by no means clear that forbidding drug use rather than simply helping the user to stop or to reduce harms will result in a better treatment outcome. In fact, the reverse seems to be the case: harsh treatment and inflexible demands tend to drive users from treatment and the help they need.

Methadone: The Exception to the Rule

An increasing number of countries are going beyond the abstinence model and allowing the prescription of methadone for both detoxification and maintenance programs. Such a move has opened the door to other kinds of prescribing, such as is available in the UK and as is most strikingly seen in the Swiss heroin-prescribing trial. The fact that in many countries HIV-positive

[32] Institute of Medicine. Broadening the Base of Alcohol Treatment. National Academy Press: Washington, 1990.

Drug users involved in the Project have been given HIV combination therapies, and have been able to meet the requirements of the strict schedule.

users have priority when applying for entry into methadone programs itself raises serious ethical concerns: users may become infected deliberately in order to become eligible for a space in limited methadone programs.

As described in more detail in the chapters on Prescription of Opiates and Controlled Stimulants and on Syringe Exchange and Methadone Maintenance Treatment, below, the acceptance of methadone programs as a treatment has more to do with the reduction of crime and disruption for the community than it does with reducing harms to the user. In the current political climate, any other non-abstinence approach will also have to prove itself to be a means of reducing economic, social, and health problems for the community rather than for the user. While this may be unethical, it is nonetheless politically correct.

Cessation of Drug Use as a Condition for Receipt of Antiretroviral Therapy

One cannot assume non-compliance.

The claim is often made that drug users are "non-compliant" in following a medical regime, and cannot be trusted to take medication as instructed. There is no evidence to support this claim with respect to the majority of users most of the time; some stimulant users do have periods during which their behaviour can become chaotic for a few days at a time. If the claim were true, then failure to provide drugs could be partly justified on the grounds of money or, in the case of antibacterials, on the grounds that incomplete courses of medication can give rise to drug-resistant strains of pathogens such as TB that pose a serious threat to the general population.

There are international examples of good policy and practice. For example, in the UK, attempts are being made to coordinate the work of drug-dependency services and HIV physicians with respect to psychoactive drug use and AIDS treatment.[33] In the Netherlands, the Amsterdam Health Authority Hospital Project coordinates services to HIV-positive drug users. In addition to methadone distribution, this can involve housing, monthly benefits, or buddies. The Project helps to minimize problems in communication between drug users and medical staff, counsels health workers on how to deal with drug users, and makes sure that users keep their appointments. Drug users involved in the Project have been given HIV combination therapies, and have been able to meet the requirements of the strict schedule. The Project also ensures that there is monitoring of any drug interactions and that users and health-care workers are informed of these.[34]

Some General Issues

While it may be justifiable to require users not to use while in residential treatment (disruptive behaviour, legal liability), how can this be justified when the user is not an in-patient?

If there are problematic drug interactions, users and health-care workers should be advised of them.

One cannot assume non-compliance. What may be more difficult to ensure is that users are able to meet with the strictures around drug–drug and drug–food interactions: users of illegal drugs can seldom guarantee the kind of regularity of meals and acid/fat balance needed for proper absorption of HIV drugs, but setting examples of foods and drinks and timing in easily understandable form may help, as would drop-in centres where users could get regular advice and even store their HIV medication.

[33] R Elion. Primary care. In: Strang & Stimson, supra, note 13.

[34] R Kerssemakers. Combination HIV therapy for drug users. *Jellinek Quarterly* 4 December 1997, at 1-2.

There is a need for research on HIV drug/psychoactive (legal and illegal) drug interactions.

We need to focus on the fact that it is the illegal drug users' lifestyle that leads to problems, including inability to ensure safety of medication and appropriate use of it. Medication will be much more effective if the problems associated with illegal drug use are addressed at the same time.

What of HIV-positive pregnant users? There are special needs and concerns regarding the fetus as well as the woman.

The failure of the present system is a judgment on that system and points to the need to create a system that can work with drug users, not push them away: if this need is not met, the situation poses serious problems for users and for the community in general.

Prescription of Opiates and Controlled Stimulants

What issues must be considered in prescribing opiates and controlled stimulants to drug users in Canada?

Origins of and Rationale for the Prescribing of Drugs

The practice of prescribing drugs to drug-dependent users for the purposes of reducing harm was first formalized in the UK in the 1920s. Until that time, drug prescribing and replacement were practised in a number of countries on an ad hoc basis and were as much a product of fashion as of medical knowledge. The British system emerged as a response to the recommendations of the Rolleston Committee, a group of leading physicians experienced in the treatment of dependent drug users. The purpose of the Committee was "to consider and advise as to the circumstances, if any, in which the supply of morphine and heroin ... to persons suffering from addiction to those drugs may be regarded as medically advisable, and as to the precautions which it is desirable that medical practitioners should adopt for the avoidance of abuse, and to suggest any administrative measures that seem expedient for securing observance of such precautions."[35] One of the most significant conclusions of the Committee was the following:

> When ... every effort possible in the circumstances has been made, and made unsuccessfully, to bring the patient to a condition in which he is independent of the drug, it may ... become justifiable in certain cases to order regularly the minimum dose which has been found necessary, either in order to avoid serious withdrawal symptoms, or to keep the patient in a condition in which he can lead a useful life.

[35] Rolleston Report. Report of the Departmental Committee on Morphine and Heroin Addiction. London: HMSO, 1926, at 18.

This approach formed the basis of the policy of prescribing drugs to dependent users that has come to be known as the "British system," an approach that has begun to draw the attention of other countries because of its success in helping to reduce drug-related harm. Prescribing of drugs to users is a key part of a harm-reduction model, with emphasis on minimizing exposure to infections, involvement in crime, and other consequences of drug use, rather than on abstinence.[36]

Staff in prescribing programs are able to reach a significant number of other people to provide information about AIDS and other health problems, to make referrals, and to do counseling. Many clients who have HIV disease may be unemployed and others may be homeless, so they can be helped significantly by having access to prescribing programs. In all countries, one of the key factors underlying the success of drug prescribing as a harm-reduction measure is that it brings users back into the community rather than treating them like outsiders or criminals. This not only allows for rehabilitation of the user; it also means that the drugs-and-crime cycle can be broken.

Prescribing Methadone

Methadone is a synthetic alkaloid chemically similar to morphine. Its effects are similar to those of the opiates, the main difference being that some last longer than those of morphine or heroin and that the duration of withdrawal symptoms following chronic use is also longer. When taken intravenously, methadone is not distinguishable from heroin by the majority of users. The opiates themselves appear to be relatively free from having significant long-term physiological side effects. Since most users are unable to obtain drugs that are pure, however, they can be harmed by impurities in the drugs. Where users inject the opiate, they can be harmed by the infection transmitted through contamination of needles and other parts of their drug paraphernalia.[37]

Background

In 1939, researchers in Germany discovered an effective opioid analgesic drug, which they called Dolantin.[38] As with diamorphine (heroin) and buprenorphine, the hope that this would be a non-addictive analgesic were not fulfilled. Pethidine was being produced commercially by 1939. In 1941, application was made for a patent for a related drug, polamidon (methadone). After the war, the allies requisitioned all German patents and trade names. The factory that manufactured methadone was taken over by the Americans. The formula was distributed around the world and used by many pharmaceutical companies (hence the many trade names). The Eli-Lilly pharmaceutical company gave it the trade name Dolophine in North America.

In Canada, the use of methadone in the treatment of opiate dependency began in 1959 when Dr Robert Halliday of the Narcotic Addiction Foundation of British Columbia began using it to help users in withdrawal. In 1963 Halliday began to use methadone on a prolonged basis and so established one of the first, if not the first, methadone maintenance programs. The programs of Dole and Nyswander in New York were started the following year. Much of the research on methadone treatment has been undertaken in the US. Methadone has been delivered in many different ways in the US, demonstrating that these may be as important as the drug per se in determining outcome.

US drug policy began to take a very different direction from that of the United Kingdom as early as 1922, when a legal case determined that it was a

[36] Riley & O'Hare, supra, note 11; J Strang. The roles of prescribing. In: Strang & Stimson, supra, note 13.

[37] For a more detailed and referenced version of these sections, see D Riley. The Role of Methadone in the Treatment of Opiate Dependence. Ottawa: Canadian Centre for Substance Abuse, 1991; for a summary, see D Riley. Methadone and HIV/AIDS. *Canadian HIV/AIDS Policy & Law Newsletter* 1995; 2(1): 1, 13-15.

[38] A Preston. *The Methadone Briefing*. London: ISDD, 1996.

crime for a physician to prescribe a narcotic to an addict.[39] This was clearly quite different from the course determined by the Rolleston Committee in the UK.[40] By 1938, about 25,000 physicians had been prosecuted on narcotics charges and 3000 had served prison sentences. Federal agents relied to a great extent on drug users to get these convictions, supplying small amount of drugs to get the evidence. After World War II there were only two treatment centres giving in-patient treatment to users. Marie Nyswander and Vincent Dole began to investigate the stabilization of opiate users with methadone.[41] They discovered that once an adequate dose had been reached they could maintain users at the same levels for long periods. The US Bureau of Narcotics attempted to stop the work, but Dole stood his ground and "Methadone Maintenance Treatment" was developed. Dole and Nyswander based their approach on the assumption that opiate addicts suffer from a metabolic disorder much like diabetes. Methadone was said to be the insulin of opiate addiction. Nyswander and Dole argued for high doses of methadone (80-150 mg) to ensure a "pharmacological blockade" of the effects of heroin, to prevent euphoria. The methadone was combined with intensive psychosocial counseling. Success levels with this approach were high.[42]

The use of methadone maintenance treatment spread rapidly in the US, but it was often carried out in such a rigid manner that it lost some of the original features of the method. As a result, few programs have produced such good results as the early work of Dole and Nyswander.[43] By the 1970s, political and other factors had given rise to heavy government regulation. The medical treatment was – and is – encased in a rigid delivery system. In most programs, patients attend daily to drink methadone and are regularly monitored through testing of urine samples (supervised collection) and counseling. Some programs offer a range of psychosocial treatments. Once stabilized, patients can earn take-home doses of methadone for one or more days. There is great variation in the rehabilitation and psychosocial services offered and in the dosages employed. Over half the patients receive under 60 mg daily (the therapeutic minimum in the US), which is well below the level recommended by Nyswander and Dole's research.

Outside the US, the rising pressures of drug-related crime, hepatitis, and HIV gave an impetus to the expansion and liberalization of methadone programs. In the UK in the early 1980s, a second period of dramatic increase in heroin use (the first had been in the 1960s) occurred. This meant that services had to expand and become more widely available. The emergence of HIV and its rapid spread in cities such as Edinburgh prompted a review of drug policy, resulting in the 1988 report of the Advisory Council on the Misuse of Drugs, which advocated a comprehensive harm-reduction approach to the prevention of the spread of HIV. "This reversed the abstinence-oriented prescribing policy of the preceding years as it legitimized longer-term prescribing to enable users to stop injecting.... The services that were set up ... have almost certainly been instrumental in maintaining relatively low rates of HIV seroprevalence among injecting drug users."[44] The shift toward more maintenance prescribing was not universal, with some cities closing services. At the same time, in Merseyside some doctors revived the prescribing of heroin in injectable and smokable forms.[45]

[39] Ibid.

[41] See supra.

[41] Preston, supra, note 38.

[42] Ibid.

[43] Ibid; VP Dole, M Nyswander, A Warner. Successful treatment of 750 criminal addicts. *Journal of the American Medical Association* 1968; 206: 2708-2311.

[44] Preston, supra, note 38 at 16.

[45] Ibid.

Advantages and Limitations of Methadone

Advantages

Both pharmacological and non-pharmacological approaches have been used in an attempt to treat people dependent on opiates. Psychological, social, and physical health issues are seen to be of central concern in the treatment of the drug user, with drugs being a complement to non-drug interventions and not a substitute for them. An evaluation of the efficacy of non-pharmacological treatments for opiate dependence indicates a very low level of efficacy of psychotherapeutic techniques. As a consequence, problematic though it is, methadone in conjunction with other interventions is at present the most effective legal means of treatment for people with opiate-related dependence.

The benefits of methadone maintenance treatment (MMT) have been established by hundreds of scientific studies, and there are almost no negative health consequences of long-term methadone treatment, even when it continues for 20 or 30 years. The success of MMT in reducing crime, disease, death, and drug use is well-documented.[46] In particular, it has been shown that methadone treatment

- is the most effective treatment for heroin addiction;[47]
- reduces and often eliminates heroin use among addicts;[48]
- helps to prevent the spread of HIV/AIDS by reducing needle sharing;[49]
- reduces criminal behaviour;[50]
- is cost-effective;[51] and
- is effective outside traditional clinic settings.[52]

In summary, methadone maintenance is one of the few proven cost-effective interventions for opiate dependence. Involvement in methadone programs is associated with decreased morbidity and mortality, especially with respect to HIV, decreased involvement in crime, and increased mental and physical well-being. The prescribing of drugs to users is a key part of a harm-reduction model, with an emphasis on minimizing exposure to infections, involvement in crime, and other consequences of drug use, rather than on abstinence. Staff in prescribing programs are able to reach a significant number of other people to give information about AIDS and other health problems, to make referrals, and to do counseling. Many clients who have HIV disease may be unemployed and/or homeless, so they can be helped significantly by having access to prescribing programs and the services they can provide. In all countries, one of the key factors underlying the success of drug prescribing as a harm-reduction measure is that it brings users back into the community rather than treating them like outsiders or criminals. This not only allows for rehabilitation of the user but also means that the drugs-and-crime cycle can be broken.

Limitations

Despite the significant advantages of methadone, there are some limitations. It is well-documented that methadone is very addictive, and there may well be a physiological basis to the complaint often heard from clients that withdrawal from methadone is in fact more difficult than from heroin. This points to the need for careful monitoring of methadone detoxification, and sensitivity on the part of staff to the possibility of relapse. It also highlights the need for alternative forms of drug maintenance in the reduction of drug-related harm.

[46] See, eg, JC Ball, A Ross. *The Effectiveness of Methadone Maintenance Treatment*. New York: Springer Verlag, 1991; MD Anglin, WH McGlothlin. Outcome of narcotic addict treatment in California. In: FM Tims, JP Ludford (eds). *Drug Abuse Treatment Evaluation: Strategies, Progress and Prospects*. NIDA Research Monograph 51. Rockville, MD: US Department of Health and Human Services, 1984, at 106-128; RL Hubbard, JV Rachal, SG Craddock, ER Cavanagh. Treatment outcome prospective study. In: Tims & Ludford, supra, this note; VP Dole, JW Robinson, J Orraca et al. Methadone treatment of randomly selected criminal addicts. *New England Journal of Medicine* 1969; 280: 1372-1375; RG Newman, WB Whitehill. Double-blind comparison of methadone and placebo maintenance treatments of narcotic addicts in Hong Kong. *Lancet* 1979; 8141: 485-488; JB Murray. Effectiveness of heroin maintenance for heroin addicts. *Psychological Reports* 1998; 83(1): 295-302.

[47] See, for example, Hubbard et al, supra, note 46; RL Hubbard et al. *Drug Abuse Treatment: A National Study of Effectiveness*. Chapel Hill: University of North Carolina Press, 1989; J Ward, R Mattick, W Hall. *Key Issues in Methadone Maintenance Treatment*. New South Wales, Australia: NSW University Press, 1992.

[48] RG Newman. *Methadone Treatment in Narcotic Addiction*. New York: Academic Press, 1977; Hubbard et al 1984, supra, note 47; S Magura, Q Siddiqi, RC Freeman, DS Lipton. Changes to cocaine use after entry to methadone treatment. In: *Cocaine, AIDS and Intravenous Drug Use*. New York: Haworth Press, 1990; Ball & Ross, supra, note 46; A Fairbank, GH Dunterman, WS Condelli. Do methadone patients substitute other drugs for heroin? *American Journal of Drug and Alcohol Abuse* 1993; 19: 465-474.

[49] DM Novick, H Joseph, TS Croxson et al. Absence of antibody to human immunodeficiency virus in long-term, socially rehabilitated methadone maintenance patients. *Archives of Internal Medicine* 1990; 150: 97-99; S Abdul-Quadar, SR Friedman, DC des Jarlais et al. Methadone maintenance and behaviour by intravenous drug users that can transmit HIV. *Contemporary Drug Problems* 1987; 14: 425-434; A Chu, LS Brown, S Banks et al. Intravenous heroin use: its association with HIV infection in patients in methadone treatment. In: LS Harris (ed). *Problems of Drug Dependence*. NIDA Research Monograph 95. Rockville, MD: US Department of Health and Human Services, 1989; RE Chaisson, P Bachetti, D Ormond et al. Cocaine use and HIV infection in intravenous drug users in San Francisco. *Journal of the American Medical*

There has long been concern about the ethical issue of "social control" that is implied by methadone maintenance.

There are also problems specific to the use of methadone syrup in the treatment of opiate dependence. Many users complain of nausea, vomiting, tooth decay, and weight gain after prolonged use. Since methadone syrup does not provide a "buzz," some clients report that their need for the experience they crave is not dealt with, and so they look for a comparable experience elsewhere, using the syrup to keep them stable. This observation has been put forward as a partial explanation of the increase in the use of other drugs such as cocaine and crack by users on low levels of methadone.

While oral methadone seems useful as a stabilizer, it does not seem to be sufficient for the maintenance of some users, especially in the early stages of intervention. The most serious drawback of maintenance with methadone syrup is that users may return to injection drug use, either with prescribed or black-market drugs, and this is still one of the most hazardous routes of drug administration. One approach to this problem is to supply higher levels of methadone syrup to determine if a level that will prevent relapse to injection can be reached. For those who relapse, providing a supply of injectable methadone ampoules, with clean injection equipment, may be a solution. Such an approach is working very successfully in the Merseyside program.

There has long been concern about the ethical issue of "social control" that is implied by methadone maintenance. Treatment agencies may require proof of employment, a stable accommodation, provision of urine specimens, and cessation of illegal drug use as eligibility criteria, but it is not clear how these are relevant to the needs of the user. This raises questions about whose ends are being served by such programs.

Finally, methadone is not the drug of choice for all drug-dependent users because it does not work well in all cases, and users may end by going back to street heroin or other illegal opiates. In addition, not everyone needs or wants it (for example, users who are not heavily dependent on heroin, or users of stimulants and other non-opiate drugs – the latter do not need depressant substitution, but may require controlled availability of stimulants).

Prescribing Other Drugs

Given the limitations of methadone treatment, other methods of addressing drug addiction have been used in some countries.

Canada

Canada has been reluctant to prescibe drugs other than methadone to drug-dependent individuals, but many have called for such trials,[53] and the Centre for Addiction and Mental Health in Toronto is exploring the possibility of a controlled multi-site heroin treatment trial in a number of cities, as part of a multi-city North American study.[54]

United Kingdom

Although there have been some important changes to the British system because of the changing nature of the user population and the tightening of controls over physicians in response to over-prescribing in the 1960s, in many ways the recommendations of the Rolleston Report are still being followed. This is particularly true in the Mersey Region, where services take the approach that even if you can't "cure" dependence you can still care for drug users, providing injectable opiates and other drugs to registered users. The local police play a vital role in ensuring the success of this approach by not

Association 1989; 261: 561-565; Ball & Ross, supra, note 46; JC Ball, WR Lange, CP Myers, SR Friedman. Reducing the risk of AIDS through methadone maintenance treatment. *Journal of Health and Social Behaviour* 1988; 29: 214-226; Ward et al, supra, note 47; Hubbard et al 1984, supra, note 46; RG Newman, N Peser. Methadone treatment: experiment and experience. *Journal of Psychoactive Drugs* 1991; 23: 115-121.; Hubbard et al 1984, supra, note 46.

[50] Hubbard et al 1984, supra, note 46; Ball & Ross, supra, note 46; Newman & Peser, supra, note 49.

[51] H Harwood, RJ Hubbard, JJ Collins, JV Rachal. The costs of crime and the benefits of drug abuse treatment. In: CG Leukefeld, FM Tims (eds). *Compulsory Treatment of Drug Abuse*. NIDA Research Monograph 86. Rockville, MD: US Department of Health and Human Services, 1988, at 209-235; Criminal Justice Institute. *The Corrections Yearbook*. New York: The Institute, 1995.

[52] SR Yancovitz, DC Des Jarlais, NP Peyser et al. A randomized trial of an interim methadone maintenance clinic. *American Journal of Public Health* 1991; 81: 1185-1191;

[53] See, eg, R de Burger. Heroin substitution in Canada: a necessary public health intervention. *Canadian Journal of Public Health* 1997; 365.

[54] B Fischer. Opiate Addiction Treatment, Research, and Policy in Canada – Past, Present and Future Issues. Forthcoming in M Rihs-Middel et al (eds). *Proceedings of Symposium. Heroin-Assisted Treatment for Dependent Drug Users: State of the Art and New Research Perspectives: Scientific Findings and Political Perspectives*. Berne: University of Berne, 10-12 March 1999.

placing drug services under observation and by referring drug users who have been arrested to these services. The majority of clients receive oral methadone, but some receive injectable methadone, others injectable heroin, and a small number receive amphetamines, cocaine, or other drugs. These drugs are dispensed through local pharmacists. Although the Mersey Region has the second highest rate of notified addicts of any Regional Health Authority in the UK, the level of HIV infection among drug injectors in the Mersey Region is very low, at approximately one percent.[55] There have been significant decreases in property-related crime, robbery of pharmacies, and break and enters.[56] However, since no experimental trials or controlled studies have been conducted in this region, the data are considered to be too unrealiable for the purposes of setting policy in other countries.[57]

In some parts of the UK users can also be prescribed smokable drugs. Drug users who are able to give up injecting often find that they are not able to switch immediately to oral prescriptions, which don't provide the "rush" that an injected drug does; smokable drugs provide this rush.[58]

Australia

The Legislative Assembly of the Australian Capital Territory (ACT) appointed a Select Committee on HIV, Illegal Drugs and Prostitution in 1989. In 1991, the Legislative Assembly authorized the Committee to submit an interim report on illegal drugs. The Committee concluded that current policy implementation with regard to controlling and/or reducing the use of illegal drugs (prohibition) might not be effective. The Committee accepted the international evidence that prohibition policies have not reduced the illegal supply of opiates and have not reduced the number of people taking drugs, and it considered alternative policy approaches. It was decided to undertake a feasibility study to examine the many unanswered questions about the outcomes and efficacy of medical prescription of heroin for dependence, and "specifically whether the benefits of exploring such questions through a scientific trial outweighed the risks."[59]

The first stage of the four-year investigation found that a trial of heroin prescription as treatment for heroin dependence was feasible in principle and identified the constraints within which a trial would have to operate.

A detailed study of logistic feasibility followed. It had three components: identifying the risks associated with a trial and analysis of ways of dealing with them; developing a workable clinical service; and defining the critical research questions in the current Australian context and appropriate ways of addressing them.

A number of potential risks were identified. The research recognized that risks cannot be eliminated and developed an overall strategy, which was to acknowledge all the likely risks, to devise ways to minimize them, and to monitor them as part of the trial evaluation. Two risks were identified as being of overriding public concern. The first was that a trial might be linked with more permissive attitudes to illegal drug use and hence encourage illegal drug use, especially among young people. The second was that dependent users from around Australia might move to the trial city. The feasibility investigation, however, showed that a trial and permissiveness were not inextricably linked.

The central research question for the evaluation was identified in 1991 and, although it was carefully scrutinized in the following years, it was not substantially changed. It was: "If maintenance treatment for opioid dependence is

[55] Home Office. Statistics on the Misuse of Drugs. Government Statistical Office, 1996; Drugs in Mersey. Mersey Regional Health Authority, 1996.

[56] For more details see Riley & O'Hare, supra, note 11.

[57] Ibid.

[58] Riley & O'Hare, supra, note 11.

[59] G Bammer. 2nd Interim Report. Feasibility Research into the Controlled Availability of Opioids. National Centre for Epidemiology and Population Health, Canberra, 1991.

expanded so that both injectable diacetylmorphine (heroin) and oral methadone are available, is this more effective than current maintenance treatment which involves the provision of oral methadone only?"[60] At the core of the evaluation would be a randomized controlled trial comparing those who have a choice of treatment options (injectable heroin alone, injectable heroin plus oral methadone, and oral methadone alone) with those who have access to oral methadone only. The measures of effectiveness would be the ability to improve outcomes in health, criminal behaviour, and social functioning. Cost-effectiveness would also be examined. Three groups of dependent users would be eligible – those who have never been in treatment, those currently in methadone treatment who would prefer an expanded range of options, and those who have dropped out of treatment.

The trial itself would only be undertaken if the results of pilot studies were positive. At the end of the trial, it would be possible to assess (a) whether or not expanding maintenance treatment to include heroin is both effective and cost-effective and (b) whether the social benefits outweigh the risks. On the basis of these outcomes it would be possible to decide if further trialing was warranted. This would focus on long-term effects of heroin prescription, particularly on institutionalization, marginalization, and the achievement of abstinence from heroin. Evidence-based decisions could then be made on whether heroin should be a standard treatment option for heroin dependence.

In July 1997, a pilot study with 40 participants was supported by a two-thirds majority of health and police ministers from every Australian jurisdiction, leading to preparations for its commencement. In an unusual move, the Prime Minister and cabinet withdrew "all cooperation" as a federal government less than three weeks later. The primary reason given was that it would send "an adverse signal," particularly to young people, and that this outweighed the potential benefits. The federal government's refusal to assist with funding for the study and to support the study in the necessary international fora, notably the International Narcotics Control Board and the Commission on Narcotic Drugs, meant that the trial could not proceed.[61]

Switzerland

In January 1994, the Swiss government began a multi-year, multi-city scientific trial to provide drugs to long-term dependent users in order to assess the effects on their health, social integration, and behaviour. The program began with 700 dependent users in eight cities. Users had to be at least 20 years old, be residents of the same Swiss canton in which the program city was located, and have at least a two-year history of opiate dependence or have suffered demonstrable health or social problems as a result of opiate dependence. In addition, other forms of treatment must have failed or been deemed unsuitable. The program was later expanded to include 1146 patients in seven cities at 18 treatment centres. There was a small daily fee (US$13). The program:

- provided participants with medical access to injectable, oral, and in some cases smokable heroin, morphine, methadone, and – under some conditions – cocaine. Most users preferred heroin to morphine. Two programs allowed clients to take a few heroin reefers home each night;
- offered lodging, employment assistance, treatment for disease and psychological problems, clean syringes, and counseling;

[60] Ibid at 17.

[61] Ibid at 18.

- allowed health officials in participating cities the option of providing cocaine to dependent users with the aim of determining the extent to which the problem of cocaine psychosis will occur in a population that is otherwise taken care of. Opinion was divided over using a maintenance approach with heavily dependent cocaine users;
- set no strict limits on dosage, but provided guidelines concerning what constitute typical doses; and
- maintained eight inmates in one prison on heroin.

Retention rates were high for both the six- and 18-month research periods. Patients showed improvement in physical health, mental health, and social integration, and there was a reduction in new HIV infections. The final report was released on 10 July 1997 by the Swiss Federal Office of Public Health. The heroin maintenance experiment was declared a success: crime dropped by 60 percent, unemployment by 50 percent, and significant public funds were saved due to a reduction in the costs of criminal procedures, imprisonment, and disease treatment.[62] In a study released in 1999, the World Health Organization was "cautiously optimistic" about the results of the trial. However, WHO warned that, due to the design of the study, it could not be determined whether the results were due to the heroin maintenance per se or to the many other psychosocial interventions employed in the trial. The results may therefore not be generalizable beyond wealthy nations with a complex social safety net such as Switzerland.[63]

The heroin maintenance experiment was declared a success.

The Netherlands

Because of increasing evidence that a proportion of heroin-dependent patients respond insufficiently to treatment with methadone, the former Minister of Welfare, Health and Cultural Affairs asked the Health Council of the Netherlands to give advice about the conditions under which the prescription of heroin can be regarded as good clinical practice. In an advisory report, written in response to this request, it was concluded that the medical prescription of heroin to heroin-dependent patients may have positive effects on the physical and mental condition and on the dependence of the patient, and that medical treatment with heroin of patients with heroin dependence is therefore expedient if medical–scientific research has established a positive balance between the effectiveness and harmful effects of this treatment. The Health Council advised conducting such a study in the Netherlands with severely heroin-dependent patients who have responded insufficiently to the currently available medical interventions.[64]

With the agreement of the Dutch parliament, the government subsequently decided to prepare and conduct the study proposed in the advisory report of the Health Council. The Minister of Health, Welfare and Sport installed the Central Committee on the Treatment of Heroin Addicts, with the task of reporting to the Minister on the intended and adverse effects of treatment with heroin on the basis of the scientific study.

Based on extensive discussions, the Central Committee developed protocols for the study. The Committee considers that these protocols "provide the basis for a scientifically sound and controllable study, which can provide an unequivocal answer to an important medical question."[65] In August 1997, the study proposal was presented to the Minister of Health, Welfare and Sport. The Minister accepted the study, which includes 750 participants in eight units in

[62] Uchtenhagen et al, supra, note 18.

[63] World Health Organization. *The Swiss Heroin Trial*. Geneva: WHO, 1999.

[64] Central Committee on the Treatment of Heroin Addicts, supra, note 17 at 20. The following description is taken from that article.

[65] Ibid at 21.

Who are prescribing programs for, users or the community?

several cities, and in September 1997 the Dutch parliament approved a first phase of the study with approximately 150 participants. At the time of writing (summer 1998), the study had begun in Amsterdam and Rotterdam, and it was expected that, if evaluation shows no unacceptable problems, the study would be continued and extended, with full results expected in 2001.[66]

Prescribing of Stimulants versus Depressants

Depressants such as heroin calm users and are used only every few hours; methadone can last for 24 hours or more. As a result, stabilization of users on depressants is not difficult. By contrast, it is hard to stabilize someone on stimulants, especially short-acting ones like cocaine. Users may develop a pattern of using several times an hour and this can last for days at a time, resulting in chaotic behaviour. One partial solution is to prescribe longer-acting stimulants such as amphetamines, with some cocaine when a "rush" is needed. Another approach is to use a combination of antidepressants and stimulants. Yet another is to shift the user to more natural and less powerful forms of the drugs, such as coca-leaf preparations. The cocaine-prescribing part of the Swiss drug trial was merely a pilot, and although the results were "encouraging" the number of subjects was too small to draw firm conclusions. The prescribing of cocaine and amphetamine to drug users by physicians continues in the UK, with apparently good results, but critics argue that the data are not reliable and that a controlled trial is required.

The dispute over stimulant versus depressant prescribing raises some other considerations about the aims of prescription programs. First, who are prescribing programs for, users or the community? The desire to have "stabilized" and well-behaved patients is usually raised as a requirement. Second, why is there no place for pleasure in prescribing programs? It is always argued that methadone is important because it does not provide – indeed blocks – the euphoria of heroin, and that heroin trials should take place in strictly clinical, on-site settings. The resistance to prescribing stimulants may be related to the reluctance of the state to provide drugs that will result in pleasurable consequences, especially if the pleasure renders the user incapable of working.

[66] Ibid.

Drug Users and Studies of HIV/AIDS Drugs and Illegal Drugs

Policy questions include the following: What do we know about the impact of illegal drugs on the immune system? Have any trials been undertaken? What do we know about the interactions between HIV/AIDS drugs and illegal drugs? Have any trials been undertaken? What do we know about the practice regarding the inclusion or exclusion of drug users from trials of HIV/AIDS drugs, in Canada and internationally?

Impact of Illegal Drugs on the Immune System

The effects of illegal drugs on the human immune system is of concern because any such effects may promote or delay the progression of diseases such as HIV/AIDS. Studies of the natural history of HIV infection among gay men and injection drug users have explored the possibility that use of illegal drugs may be a cofactor in HIV disease progression. A large number of studies have been conducted in this regard, and most show no significant relationship. Among studies of injection drug users, the literature paints a conflicting picture. While laboratory studies investigating the effects of opiates and narcotics on the immune system (and virologic activity), as reviewed below, suggest that some drugs do have an effect, epidemiologic studies tend to find none. Thus, the situation remains somewhat confusing.

Much available information is anecdotal. Predictions are based on modeling and on known pathways of drug action but are not tested in human subjects; data are animal-based and so have the limitations of the animal model; there

are inherent limits to randomization trials with human subjects; and there is a need to consider the feasibility of studies at a time of limited resources.

The problems with anecdotal data are obvious, although – in the absence of other reliable data – anecdotal information can provide some guidance insofar as it is in line with other data, such as known pathways of drug action. The problems with animal studies are less obvious, but nonetheless serious. Most are conducted on rats or mice, which, although they are mammals, are not primates. Many studies deliver levels of drug far in excess of levels used by human users. Many deliver drugs in a manner quite different from that of human users, for example by direct exposure to tissue. Many deliver drugs in an environment quite different from that of human users; animals, for example, are frequently held in a cage with only a lever to press, with no other distractions or reinforcers. Their behaviour is therefore often quite aberrant, and rats may "press to death for drug" simply because there is no other source of reward and they are distressed.

To the extent that there have been studies (the following observations also apply to anecdotal evidence), there are general problems with data on the effects of illegal drugs on any aspect of biology or physiology because: illegal drugs are not uniform in pharmacological makeup, purity, or dose; users often use more than one drug and may not report all the drugs they use; taking drugs "on the street" is quite different from doing so in a laboratory – drug effects are the result of an interaction between drug, set, and setting.

Furthermore, the "immune system" is an extremely complex multiplicity of systems, and thus a "bad" effect on one part of the immune system may have a "good" effect on another. What looks like a benefit in the short term may be neutral or even negative in the longer term, much as with some HIV drugs. The brain and central nervous system (and therefore the mind and emotion, cognition, and motivation) influence and are part of the immune system, increasing the importance of set and setting.

Given these complexities, what would be needed to study the effects of illegal drugs on the immune system?

Controlled trials: Randomized trials with illegal drugs would be unethical. Some other form of trial could be carried out if, after being offered alternatives such as treatment, users agreed to participate in the trial. The number of participants would have to be large enough to ensure generalizability if an effect were found. Large numbers would be needed because there would have to be so many factors to be controlled and balanced for each cell – gender, age, experience with drugs, differing states of immunity, diet, and so forth. These trials raise a number of questions: Who would fund such studies? Would subjects be paid? If so, how much? How long would such a trial have to last to permit valid assessment of effects?

Monitoring of non-controlled behaviour: This is a feasible option, but likely it would be useful in some countries more than others because it requires users being open about their drug use with a physician or some other monitor. The lack of a formal comparison group would limit the validity of these findings. Who would have access to such data, and how would the database be controlled?

Animal studies: Such studies are limited, for the reasons given above, but if some of these concerns were addressed, better animal experiments could be carried out.

Modeling and hypotheticals: A great deal of what is "known" about drug effects and interactions is based on known pathways of action. This will continue to be an important source of information that needs to be constantly updated for illegal drugs and interactions (including with alcohol). Information needs to be made available to treatment workers and to users and be made accurate, balanced, and accessible (see the chapter on Information about the Use and Effects of Illegal Drugs).

Review of Studies

To understand the relationship between injection drug use, malnutrition, and HIV infection, researchers studied 36 women, some of whom were infected with HIV and all of whom injected drugs. All the women were undergoing voluntary detoxification for at least six months. Tests were carried out on blood and skin (a crude measure of cell-mediated immunity). Even the HIV-negative women were found to have seriously impaired T-cell function. In general, it was found that the type of immunity needed to control the infections seen in HIV/AIDS was severely weakened in both HIV-infected and non–HIV-infected women. This weakening was attributed primarily to the malnutrition that occurred during the women's drug-using periods. Despite detoxification, the damage to the immune system was not quickly repaired.[67] Interpretation of the results of this study is rendered difficult by the fact that the sample of women was small and subject to selection bias.

Alcohol

Alcohol causes the thymus to produce fewer activated T cells and lowers the efficacy of macrophages. Acetaldehyde, one of the breakdown products of alcohol, binds to proteins on the surface of liver cells, and the immune system attacks these. There has long been circumstantial evidence that alcohol and certain other drugs harm the immune system. For example, injection drug users are prone to tuberculosis and pneumonia, which are transmitted through the air rather than via infected needles and which usually only affect people with weakened immune systems. Injection drug users are also prone to bacterial infections. Alcoholics are prone to hepatitis, tuberculosis, and other infections.[68] A question repeatedly raised in connection with such findings is the extent to which they are due to direct effects on the immune system rather than to lifestyle or the effects of alcohol on the liver.

Opiates

Theoretically, there is good reason to suspect that opiates are involved in the progression of HIV-1 infections to AIDS. To date, however, epidemiologic approaches have been unable to link decline in CD4 T-cell counts, as a marker of AIDS progression, with opiate use. Other indices of AIDS progression have yet to be evaluated in this regard. In addition, the effect of opiate use on opportunistic infections occurring prior to or concurrent with HIV-1 infection has not been closely studied.[69]

Despite considerable evidence that opiates can exacerbate HIV-1 infections, there is suggestive evidence from clinical and basic studies that homeostatically balancing conditions of chronic, consistent opiate exposure

[67] P Varela, A Marcos, I Santacruz et al. Human immunodeficiency virus infection and nutritional status in female drug addicts undergoing detoxification: anthropometric and immunologic assessments. *American Journal of Nutrition* 1997; 66: 504s-508s.

[68] H Friedman et al (eds). *Drugs of Abuse: Immunity and Infections*. Florida: CRC Press, 1996; Highs and lows. *New Scientist*, 25 October 1997, at 36-39.

[69] R Donahoe, D Vlahov. Opiates as potential cofactors in progression of HIV-1 infections to AIDS. *Journal of Neuroimmunology* 1998; 83: 77-87.

may protect the host from the progression of HIV-1 infections. However, this pattern of use is likely to be different from that of the average user, for whom opiate dependence is not consistently maintained.

Taken together, the information from basic studies – including those with monkeys – and epidemiologic studies indicates that the effects of opiates on progression from HIV infection to AIDS may be conditional upon the variables involved.

Cocaine

Findings are mixed. In human users, it is difficult to disentangle direct effects from those associated with lifestyle. At the meeting of the American Society for Microbiology in May 1997, Lefkowitz and Grattendick of the Texas Technical University reported that adding cocaine, at levels cocaine users would have in their blood, to cultured mouse macrophages (immune cells) boosts their production of interferon by about 30 percent. Interferons carry messages in the immune system and prevent viruses from infecting healthy cells. Cocaine also slows the replication of hepatitis viruses in cultured mouse macrophages. The effect is dose-dependent: viral replication falls as more cocaine is added. These effects last up to a day after the administration of cocaine.

On the negative side, David Ou and colleagues at the University of Illinois at Chicago have shown that, in mice, cocaine kills thymocytes (cells that move to the thymus, where they mature into T cells). Ronald Watson at the University of Arizona found that the numbers of two types of T-cells, CD-4 and CD-8, fall more rapidly in mice infected with a retrovirus similar to HIV if they are given cocaine.

Some researchers contend that there is a wide-ranging capacity for cocaine to suppress the immune system and that cocaine has an effect on the infectivity and replication of HIV. While sometimes contradictory, both human and animal studies document that cocaine alters the function of natural killer cells, T cells, neutrophils, and macrophages, and alters the ability of these cells to secrete immunoregulatory cytokines. Cocaine also enhances the infectivity and/or replication of HIV when tested using human cells in vitro.[70]

Marijuana

T cells have receptors for the cannabinoids. Herman Friedman of the University of South Florida in Tampa reported that mice become more susceptible to bacteria that cause Legionnaire's disease if they are injected with THC (tetrahydrocannabinol, the active principle of cannabis) rather than cannabidiol or cannabinol (nonpsychoactive constituents). Twice as many bacteria were found in their livers and spleens and they produced very high levels of certain cytokines, causing the immune system to attack the animals' own tissue. In the test tube, THC reduces antibody production by B cells from mice and impedes the capacity of T cells to destroy infected or cancerous cells. The ability of immune cells such as macrophages to destroy microorganisms is also reduced.[71]

The fungus histoplasmosis, which causes an opportunistic infection, can be found in marijuana. Marijuana, however, is one of the few illegal drugs not associated with chronic bad health in human users.

Ecstasy

Little is known about the effects of ecstasy (3,4-methylenedioxymethamphetamine). Robert House and colleagues at the IIT Research

[70] Goodkin et al. Cocaine abuse and HIV-1 infection: epidemiology and neuropathogenesis. *Journal of Neuroimmunology* 1998; 83: 88-101. G Baldwin et al. Acute and chronic effects of cocaine on the immune system and the possible link to AIDS. *Journal of Neuroimmunology* 1998; 83: 133-138.

[71] Highs and lows. *New Scientist*, supra, note 68.

Institute in Chicago found that ecstasy levels one-hundredth those in the blood of the typical user boosted production of interleukin-2 by mouse cells in a test tube. Interleukin-2 stimulates production of other T cells. Ecstasy also boosted the activity of mouse natural killer cells in culture. Very high levels of ecstasy (above the levels lethal to humans) suppressed the proliferation of mouse T-cells, which kill infected cells. Ecstasy use by youth in Europe and North America is increasing, so further studies are called for.

Nitrites

Inhalation exposure to the nitrites produced a nonspecific cytotoxicity, depleting many cells of the immune system. Inhalation of nitrites also impairs a variety of immune mechanisms, affecting both humoral and cell-mediated immunity. Inhalant-increased macrophage production of the inflammatory cytokine tumor necrosis factor alpha can directly stimulate HIV replication and can stimulate the growth of Kaposi's sarcoma cells.[72]

Interaction between Illegal Drugs and HIV/AIDS Drugs

Any adequate answer to this question would require a baseline obtained through answers to the previous question. While baseline studies were underway, studies on interactions would have to begin so as to address concerns in a timely fashion. Many of these concerns pertaining to interactions between illegal drugs and HIV/AIDS drugs were raised with regard to the foregoing issues. Various kinds of complexity are even more of an issue here because we are dealing with interactions and thus with a significant increase in possible outcomes.

Trials

Controlled trials: As noted above, because illegal drugs are involved, randomized trials would not be ethical. If other options were offered, users could be asked to participate in an arm of the study but would have to be fully informed of possible side effects. This raises an immediate scientific dilemma: by telling subjects what sorts of effects to expect, placebo and other factors come into play. Since set and setting are so important in assessing drug effects, it is certainly possible that one would simply be getting experimental results. The only way around this would be to not inform subjects of possible effects (as one tries to do now in controlled experiments), but not informing subjects of potentially damaging effects raises enormous legal and ethical issues.

Monitoring: As with the issue of monitoring discussed above in the section on the Impact of Illegal Drugs on the Immune System, this seems to be the most feasible option for the study of interactions, but it faces the same challenges, in this case magnified due to the complexity of the interactions. Monitoring could occur through ongoing observational cohort studies of HIV-infected persons, with comparisons of effects in non-infected persons.

Animal trials: While awaiting a baseline for trials involving human subjects, as discussed above, animal trials on interactions could and should be underway. Primate, especially simian, models would be useful, especially if genetics are analyzed as a factor, as they should be.

[72] L Soderberg. Immunomodulation by nitrite inhalants may predispose abusers to AIDS and Kaposi's sarcoma. *Journal of Neuroimmunology* 1998; 83: 157-161.

Modeling and hypotheticals: Such trials would face the same problems as indicated in the previous section, but the need for such approaches is increased when dealing with these interactions because of the sheer complexity and difficulty of doing anything else.

Some General Concerns

A baseline is needed for human trials before a decision can be made as to how to monitor these interactions, but what standards should be used? There are many factors to take into account: measurement of immune functions; the fact that liver, kidneys, and pancreas may already be compromised in long-term drug users; genetic confounders; and scientific, legal, and ethical complexities. To raise questions about the absence of studies is premature: what are the priorities, especially given economic constraints? Studies may be feasible, but are they practical?

The scientific and ethical complexity of the issue, not to mention the complexity of the immune system itself, would mean that a program of studies would be needed to assess simple effects and interactions. Only if potential subjects are offered all alternatives, such as treatment for drug use, would it be justifiable to invite them to be part of a study of the effects of illegal drugs.

While there is a great deal of information about protease inhibitors and other prescribed drugs, there is little reliable evidence about possible interactions with illegal drugs.

There are at least five points at which drugs may interact in the human body: stomach and intestines; liver; bloodstream; within cells; and kidneys.

If a drug that requires that the stomach be acidic is taken at the same time as an antacid-containing drug, one or both may be inadequately processed. Once a drug has been absorbed in the gut it passes to the liver, where some of the drug may be broken down by enzymes. Only a small number of different enzymes are involved in breaking down most drugs, and some drugs may take up most of an available enzyme for a short period, meaning that other drugs accumulate rather than being broken down. Interactions may also occur because some drugs may stimulate the liver to produce increased amounts of certain enzymes, thereby affecting the levels of drug metabolized by those enzymes. Once they reach the bloodstream, some drugs bind tightly to proteins such as albumin and become inactive, being quickly removed from the body. If a drug is highly protein-bound, the dose is selected so that a sufficient proportion of each dose remains unbound and active. Drugs vary considerably in their tendency to be protein-bound. If two protein-bound drugs are taken together, the result can be the equivalent of taking an overdose of one of the drugs.

Package inserts for drugs such as protease inhibitors contain a great deal of information on possible interactions with other prescription drugs. In some cases this information comes from clinical trials, but for the most part it is based on how the drug is metabolized. Even some prescription drugs used by many people with HIV, such as methadone, have been poorly researched. Most of the guidelines on possible interactions are in fact "informed guesswork" based on the way the drugs in question are metabolized by liver enzymes.[73] There is very little on possible interactions with illegal drugs, and what little there is comes from informed guesswork or anecdotal information, and is complicated by several factors: deaths have been reported from a single dose of some drugs when no other drugs are present; it is not clear how some illegal drugs are processed in the body; available information may relate to the pure

[73] E King. Recreational dangers. *AIDS Treatment Update* March 1997; 51: 1-3.

form of a drug such as MDMA (ecstasy), but illegal drugs are rarely pure; doses of illegal drugs are not controlled; genetic factors play a role; and research is hampered because of the concern of governments and drug companies not to be seen to "condone" illegal drug use.

Of the non-nucleoside reverse transcriptase inhibitor (NNRTI) HIV drugs, delavirdine is likely to substantially increase levels of methadone, while nevirapine is likely to decrease methadone levels. Rifampicin dramatically reduces levels of methadone, so patients need about a threefold increase if they are to avoid withdrawal symptoms. If a patient were to stop taking rifampicin while still taking three times the normal dose of methadone, they could die from a methadone overdose. Some doctors recommend leaving as many hours as possible between a dose of protease inhibitor and a drug such as ecstasy.[74]

HIV Therapy–Opioid Interactions

One recent study shows that all three of the originally released protease inhibitors interact with methadone and buprenorphine. Although there have been previous anecdotal reports that protease inhibitors (particularly ritonavir) decrease the effectiveness of methadone, this is the first published study to date.[75]

The HIV-1 protease inhibitors ritonavir, indinavir, and saquinavir are extensively metabolized by liver cytochrome P450 3A4. This P450 isoform is involved in the metabolism of about 50 percent of drugs, so co-administration of protease inhibitors with other drugs may lead to serious effects due to enzyme inhibition. In these in vitro studies of human liver microsomes, ritonavir was the most potent competitive inhibitor of methadone and buprenorphine. The rank of inhibition potency against metabolism of methadone and buprenorphine was ritonavir>indinavir>saquinavir.

The metabolism of methadone is dramatically increased with rifampin (and related drug rifabutin); within several days classic signs of opioid withdrawal appear. Patients on methadone who start on one of these drugs may need to have their dose progressively changed. Because patients receiving long-term methadone therapy develop tolerance to its analgesic effects, they may require a higher than usual dose when opioid analgesia is needed, as well as more frequent administration.[76]

Ecstasy and HIV Medication

Concerns about possible adverse interactions between HIV medication and ecstasy were heightened in 1996 following an isolated report from Europe of a death purportedly due to the mixing of ritonavir and ecstasy. According to the Internet posting on the death, the dead man's blood showed MDMA levels of 4.6 mg (one tablet produces levels of 0.2 mg in the bloodstream), but according to friends he had consumed no more than two tablets. He had taken some of the same ecstasy three weeks earlier with no ill effects, but had started taking ritanovir in the interim, reaching the full dose of 6 x 100 mg twice a day two days before his death. Abbott Laboratories, the manufacturer of ritonavir, began an investigation. Reviewing the scientific literature on ecstasy and comparing it with their information about the metabolism of ritonavir, the company concluded that "a moderate (2- to 3-fold) increase in 'ecstasy' levels is theoretically predicted when coadmininstered with [Norvir]."[77] Ritonavir is metabolized by the liver through the CYP2D6 pathway. Because the protease inhibitor can partially block this pathway, the drug has major interactions with other substances that are metabolized by the same pathway. The possible

[74] Ibid.

[75] C Iribarne et al. Inhibition of methadone and buprenorphine N-dealkylations by three HIV-1 protease inhibitors. *Drug Metabolism and Disposition* 1998; 26(3): 257-260.

[76] P O'Connor, P Selwyn, R Schottenfeld. Medical care for injection drug users with human immunodeficiency virus infection. *New England Journal of Medicine* 1994; 331: 450-458.

[77] Party at your own risk. *Positively Aware* May/June 1997, at 32-37.

dangerous interactions between ritonavir and common therapeutic drugs are extensive, so many physicians consider interactions with illegal drugs likely. Yet few data are available to predict which specific illegal drugs might be dangerous. Further, the liver takes approximately two weeks to fully process ritonavir and during that time the CYP2D6 pathway is almost completely blocked, dramatically increasing the possibility of drug interactions. Abbott noted that five to nine percent of the Caucasian population have deficiencies in the CYP2D6 pathway and poorly metabolize drugs that use it. They noted that "A person who is a poor metabolizer of CYP2D6 substrates taking ecstasy would be expected to have higher concentrations (possibly as much as 5- to 10-fold) of ecstasy than a person who is an extensive metabolizer of CYP2D6 substrates." According to Dr Howard Grossman, people who mix ketamine (Special K), an animal tranquilizer commonly used in dance clubs, and ritonavir, may also be at risk.[78]

Lack of Data

Some have argued that drug companies should study interactions between their products and common illegal drugs. Company representatives say that such studies would probably be impossible and would almost certainly be unhelpful. Many companies have expressed similar concerns:

- the conduct of clinical trials using illegal drugs would necessarily require permission from the federal government, which has been exceedingly reluctant to allow such studies for fear of being perceived as "soft on drugs";
- finding a supply of pure drug would, in some cases, be difficult. There are no approved versions of drugs such as cocaine. For legal and ethical reasons, drug companies are unwilling to manufacture test versions of such drugs in their own laboratories, even if the government granted permission;
- illegal drugs are seldom pure, are often contaminated by other substances, and may contain very little or none of the advertised ingredient;
- illegal drugs rarely have standardized doses: what could be a relatively minor interaction at one dose could be serious at another;
- there is little financial incentive for pharmaceutical companies to do the work on this;
- some protease inhibitors have been found to have effects in real life opposite to those predicted in the test tube (eg, there have been instances of decreased methadone levels in human users where test tube experiments had predicted such levels would increase);
- manufacturers are concerned about legal liability should they offer advice based on uncertain or potentially incomplete data.

In the absence of interaction studies, drug users with HIV have looked to the Food and Drug Administration (FDA) in the US, but so far without result. The FDA's system for tracking serious risks of marketed drugs (MedWatch) is a voluntary reporting system that allows physicians to inform the agency about potentially serious or life-threatening health risks of approved health technologies. Many physicians simply do not bother to respond because of lack of time. In addition, a physician's ability to report a possible interaction with illegal drugs depends on the patient's reports of drug habits. Understandably, many users are unwilling to inform their doctor about their drug use. This in itself compromises the quality of information collected by MedWatch.

[78] Ibid.

The FDA is also restricted by laws governing drug regulation. Since the FDA rarely conducts clinical trials, it is often unable to meet the standard of proof required for withdrawing a drug from the market. In some cases, the FDA cannot even require manufacturers to post warnings on the labels.

Abbott laboratories has compiled theoretical models of possible interactions between ritonavir and common illegal drugs. These data were provided to European investigators and summarized in the UK newsletter *AIDS Treatment Update* and in the US *AIDS Treatment News*. According to Abbott, ritonavir can cause a moderate decrease (about 50 percent) in blood levels of heroin. Mixing ritonavir and methadone can result in a large (about threefold) decrease in methadone levels, and an increase in methadone dose of about 50 percent may be necessary. Norvir may double or triple levels of amphetamine. No serious interaction with cocaine is predicted.

Other drug companies have not expressed interest in carrying out mathematical modeling of this kind, possibly because of concerns about liability if the models prove incorrect. The [US] National Institute of Drug Abuse (NIDA) has not expressed interest in carrying out these kinds of studies. This kind of mathematical modeling, as noted above, may not be applicable to illegal drugs.

There are several updated P450 pharmacology charts on the Internet to help health providers assess potential drug interactions, but these focus on legal drugs or foodstuffs. The Internet site for the newsletter *HIVPlus* provides a table on "HIV–Recreational Drug Interactions." The table analyzes potential drug interactions based on case reports and pharmacological analyses.[79]

Neither the Medicines Control Agency in the UK nor the Food and Drug Administration in the US has a specific policy on how companies should deal with the problem of reporting interactions. In addition, pharmaceutical companies have argued that to clarify the dangers would be to send out a reckless signal to the public. Ray Brettle, who runs the Infectious Diseases Unit at City Hospital in Edinburgh, claims that the companies are simply trying to protect their corporate image. Brettle asserts that the companies could make the dangers clear without appearing to support illegal activity.[80]

The World Health Organization's guidelines on drug safety information say nothing about adverse interactions involving illegal substances (apparently the pharmaceuticals industry lobbied to exclude any specific recommendations). Where information about the interactions between illegal and prescribed drugs does exist, there is disagreement over what should be done with it. Some individuals and organizations express the view that the state does not have an obligation to protect those who break the law. Others believe this to be a dangerous argument because a large number of people are users of illegal drugs.

Lack of Access to Clinical Trials

Most treatments tested on people with HIV fall into the following categories: drugs that fight the virus, called antiretrovirals or anti-HIVs; drugs that treat cancer; treatments that reinforce the immune system, known as immunostimulators or immunomodulators; vaccines that could prevent or cure HIV infection; and gene therapies.

While in a trial, participants may not be permitted to take certain medications if the trial medication may interfere with other drugs, making one or more less effective, or if the trial medication might cause a reaction that another drug may make worse.

[79] *HIVPlus*. September 1998, Number 1, at 1-2. The Internet site is <http://library.jri.org/news/misc/misc000532.html>.

[80] See King, supra, note 73.

People who are not accepted into a trial or who want to participate may still be able to get experimental treatments through compassionate access or open-label trials, or buyers' clubs.

Certain populations such as women, injection drug users, prisoners, and people of colour have often had trouble being included in clinical trials. Very few trials to date in Canada or internationally have included drug users because of the complexity of the effects of illegal drugs, the supposed (but not demonstrated) failure to "comply" with a given regimen, and the general neglect of drug users as "normal" members of society who have rights.[81] Drug users have been denied access to HIV therapies on the grounds that they will not adhere to the regimen and that this will result in the development and transmission of resistant strains of the virus. Not only is it clear that drug users can adhere to a therapy regimen if it is appropriately designed,[82] but there "is little evidence to suggest that ineffective therapy leads to widespread transmission of resistant strains."[83]

In their review of issues pertaining to HIV therapy for drug users, Freidman et al note that:

> First, no physician should refuse effective therapy to a patient who wants it. This is unethical, and may also promote increased black market activity in medicines.[84]
>
> Second, community groups, such as gay or bisexual men, IDU, and neighbourhood associations, have been key actors in developing behavioural norms for risk reduction. They are also crucial for developing effective norms to minimize therapy misuse.[85]

These two points need to be borne in mind by all involved in providing HIV therapy to drug users.

Access to HIV Treatment

Two studies by researchers at the Johns Hopkins School of Public Health and the University of BC found that about half the infected injection drug users studied who were eligible for lifesaving antiretroviral therapy were not receiving it.[86] One study showed that only half the HIV-positive injection drug users in Baltimore were receiving proven HIV therapies, even though many were no longer using illegal drugs. Researchers in BC found that 60 percent of HIV-positive injection drug users were not receiving any antiretroviral therapy, despite universal health care and the availability of free HIV therapies in Canada. On average, the HIV-positive drug users in Vancouver had been eligible to receive free HIV therapies for over a year. In Vancouver, female drug users were half as likely to receive HIV therapy as males, while drug users not enrolled in drug or alcohol treatment programs were three times less likely to receive HIV treatment. Drug users who had physicians with the least experience treating HIV infection were five times less likely to receive therapy.

In the Baltimore study, active injection drug use, lack of advanced disease, not being in a substance abuse program, and not having a usual source of primary care or health insurance were associated with not receiving therapy. In the Strathdee et al study, only 40 percent were receiving any antiretroviral therapy, most commonly double combination therapy (66 percent), and only 17 percent were reported as receiving potent antiretroviral therapy.

Physicians often lack training in the care of injection drug users and have negative attitudes toward them. Comorbidities among injection drug users,

[81] See S Freidman, M Wainberg, E Drucker. Therapeutic ethics and communities at risk in the presence of potential mutation to resistant strains to HIV antiviral medications. *AIDS* 1998; 12: 2089-2093 for a review.

[82] R Sherer. Adherence and antiretroviral therapy in injection drug users. *Journal of the American Medical Association* 1998; 280: 567-568.

[83] Freidman et al, supra, note 73 at 2091.

[84] Ibid.

[85] Ibid at 2092.

[86] S Strathdee, A Palepu, P Cornelisse et al. Barriers to use of free antiretroviral therapy in injection drug users. *Journal of the American Medical Association* 1998; 280: 547-549; D Celentano, D Vlahov, S Cohn et al. Self-reported antiretroviral therapy in injection drug users. *Journal of the American Medical Association* 1998; 280: 544-546.

chronic liver disease, and a myriad of psychosocial problems "complicate their medical care and frustrate their clinicians."[87] Concerns regarding adherence and fears of transmission of multi-drug-resistant HIV affect responses. In his editorial commentary on adherence and antiretroviral therapy in injection drug users, Sherer notes that the question of how physicians should prescribe potent antiretroviral therapy to ensure optimal outcomes and minimize transmission of multi-drug-resistant strains is increasingly important; chemical dependency complicates each step in the process. Some adherence lessons are simple: for example, adherence in patients with hypertension improves as regimens are simplified, dose frequencies and pill numbers reduced, and adverse effects minimized. Once- or twice-daily regimens yield adherence rates of 80 to 90 percent compared with 60 to 65 percent with three daily doses. A past history of substance use is not a predictor of poor adherence to treatment, but active alcohol use or use of other drugs is.[88]

Critical data on exactly how much adherence to potent antiretroviral therapy is sufficient and how little is too little are lacking. The association between poor adherence and virologic failure with respect to resistance has been clearly established, although incompletely characterized and understood. The best opportunity for maximal viral suppression is with the first regimen, when the patient is drug-naive.[89]

Sherer makes the following comments:

- A history of past drug use or current stable enrollment in a methadone program are not contraindications to the administration of potent antiretroviral therapy. Active use of alcohol or other drugs is a reasonable reason to defer, rather than deny, potent therapy for HIV infection in some patients while attempting to engage them in substance abuse treatment. Other reasons may include temporarily unstable housing, acute mental illness, or major life crisis; adherence requires a modicum of stability as defined by the patient.
- Nationally [in the United States] to date IDUs and women have benefited less than non-IDUs and men from potent antiretroviral therapy in terms of reduced morbidity and mortality. Yet IDUs have been shown to have clinical outcomes equal to those of non-IDUs when engaged in stable primary care with an experienced physician and adequate support services.
- There is evidence of broad access to the benefits of antiretroviral therapy in Chicago, inclusive of IDUs.

Sherer continues: "Improved outcomes are compelling arguments for expanded substance abuse treatment; more training in the care of persons with HIV infection and of IDUs, and ability to enhance patient adherence; and specific care programs with peer support and counseling for chemical dependency. Women with HIV infection and chemical dependency can benefit from and adhere to targeted programs with on-site child-care services, support groups, and chemical dependency counseling."[90] Flexible clinic hours, accessible clinicians, and cash or food-voucher incentives have been able to facilitate adherence to daily treatment in San Francisco; adherence-enhancing interventions for injection drug users can and do work.

Conclusion

As Freidman et al state: "The overall goal must be increased enrollment in effective treatment both to protect individual patients and to reduce viral loads and transmission. Working with communities at risk can increase treatment

[87] Sherer, supra, note 82.

[88] Ibid.

[89] Ibid.

[90] Ibid at 568.

enrollment, increase adherence, and reduce transmission risk behaviours by patients in whom therapy fails to control the disease."[91]

It is imperative that we begin trials that do include drug users. One reason is simply that drug users are human beings and have the right to be included. Another is that they form an increasingly large percentage of those who are infected with HIV, in North America and worldwide. Another is that there are no valid reasons to exclude them as a group: users can and do adhere if an attempt is made to develop a workable plan that fits their lifestyle.

[91] Freidman et al, supra, note 81 at 2092.

Information about the Use and Effects of Illegal Drugs

Policy questions include the following: What information about illegal drugs and their effects is currently available to health-care providers, drug users, and the general public, in Canada and elsewhere? How can we ensure that health-care providers have accurate and complete information about illegal drugs and their effects? How can we ensure that drug users have accurate and complete information about illegal drugs and their effects? How can we ensure that the general public has accurate and complete information about illegal drugs and their effects?

Information Currently Available

Responses to Drug Use: Prevention Strategies

The kinds of available educational materials on illegal drugs fall into two main categories: those for the general public and those for high-risk or special populations. In the first category there is a considerable amount of material for youth that is either school- or community-based. Programs range from those designed and taught by the police to "general health and well-being" education taught by regular school staff. Outside the school setting, materials are provided through a number of main sources: pharmacies, doctors' offices, provincial and federal governments (health and law enforcement divisions), and non-governmental organizations. For high-risk or special populations the main providers are those non-governmental organizations that cater to the groups in question. Federal and provincial governments and organizations funded by them provide some materials to such groups as Aboriginal people and high-risk youth.

Much of the educational material on drugs that is available falls into what has been called the moral/legal model of drug use. This approach relies heavily on punishment and the threat of punishment for the possession and use of drugs; it is assumed that punishment and threats of punishment will deter undesired behaviour, and this leads to the application of punitive laws.[92]

In most Western countries the main response to increasing levels of illegal drug use among young people has been the development of school and mass media programs based on primary prevention (demand reduction). The message has been "say no to drugs" and abstinence has been regarded as the only legitimate goal.[93] There are a number of different approaches to primary prevention:

- the shock/scare approach;
- the information approach, in which young people are given the "facts" about drugs (especially the dangers associated with them) on the assumption that they will decide not to use drugs if they know the "facts";
- the attitudes/values approach, in which the attempt is made to develop "personal responsibility" and "strong moral beliefs" and the attractions of a "drug-free lifestyle" are emphasized;
- teaching refusal skills, since young people are regarded as being open to peer pressure and in need of the ability to "just say no";
- teaching decision-making skills: a more sophisticated version of the "refusal skills" approach, in which it is assumed that young people lack the general skills to make rational decisions and that if they learn these skills they will decide not to use drugs;
- the "alternative highs" approach, in which the attempt is made to replace drug use with other forms of risk taking, on the assumption that drugs will no longer be needed;
- enhancing self-esteem, where the emphasis is on the individual rather than the drugs, the assumption being that it is mainly young people with low self-esteem who use drugs;
- peer education, in which it is assumed that young people will listen to peers giving the anti-drug message.

The above list is roughly chronological, although the older approaches are still used.

A number of evaluation studies have shown that a wide array of primary prevention programs and media campaigns have failed to prevent or reduce illegal drug use among young people.[94] Some critics believe that the approach is inherently flawed: "A critical analysis of primary prevention suggests that it is based on untenable assumptions about young people's drug use and that it will continue to be ineffective in whatever form it takes."[95]

Primary prevention assumes that young people's drug use is abnormal, even pathological, behaviour and that young people who use drugs must be lacking in knowledge, skills, or self-esteem. "The fact that drug use is functional, often has immediate benefits and is mostly experienced as pleasurable, with only a minority experiencing significant problems, is ignored."[96] The widely held assumption that young drug users are somehow "inadequate" is not supported by the evidence. A 1991 UK evaluation of the impact of drug education on young people stressed that positive health practices and high self-esteem do not mean that someone will not use drugs and that peer leaders are often the first to experiment with drugs.[97]

[92] GF van de Wijngaart. *Competing Perspectives on Drug Use*. Amsterdam: Swets and Zeitlinger, 1991, at 83.

[93] J Cohen. Achieving harm reduction through education. N Heather et al (eds). *Psychoactive Drugs and Harm Reduction: From Faith to Science*. London: Whurr, 1993, at 65-76.

[94] Cohen, ibid; N Coggans, N Shewan, M Henderson. The impact of school based drug education. *British Journal of Addiction* 1991; 86(9); 1099-1109; N Tobler. Meta-analysis of 143 adolescent drug prevention programs: quantitative outcome results of program participants compared to a control or comparison group. *Journal of Drug Issues* 1986: 537-567; R Bangert-Drowns. The effects of school-based substance abuse education – a meta-analysis. *Journal of Drug Education* 1988; 18(3): 243-264; J Green, J Kelley. Evaluating the effectiveness of a school drug and alcohol prevention curriculum: a new look at "Here's looking at you, two." *Journal of Drug Education* 1989; 19(2): 117-132; J O'Connor, B Saunders. Drug education: an appraisal of a popular preventative. *International Journal of the Addictions* 1992; 27(2): 165-185; M Rosenbaum. *Kids, Drugs and Drug Education*. San Francisco: The National Council on Crime and Delinquency, 1996.

[95] Cohen, supra, note 93.

[96] Ibid.

[97] Coggans et al, supra, note 94.

Primary prevention has been criticized for individualism and victim blaming; it forces a gap between "users" and "abstainers" and focuses on the need for individuals to resist peer pressure to use drugs.[98] Peer pressure is seen as negative despite the fact that peer groups are so important for young people and are generally experienced positively by them. Traditional primary prevention portrays a very negative view of drug use in that misleading assertions are often made, stereotypes perpetuated, and dangers exaggerated.[99] The reality of drug use often contradicts the information given through school and the media. The result is that many people do not trust such information sources and that dialogue between youth who are using or thinking about using drugs and adults is compromised. One danger of such primary prevention is that it pushes drug use underground and results in "deviancy amplification." Another danger is that in not having anything of relevance to say to those who use drugs, primary prevention itself contributes to drug-related harm.[100]

The reality of drug use often contradicts the information given through school and the media.

School-Based Education

School-based drug education is often portrayed as the solution to problem drug use. There is not, however, a strong empirical relationship between school-based drug education and drug use. Several reviews of the effectiveness of school-based prevention programs (primarily consisting of drug education) present similar findings.[101] The idea of integrating drug-education content with standard subjects is attractive in theory, but in practice there are many barriers. Teachers may find that it takes more time to do this and there will be varying degrees of teacher enthusiasm toward the subject of drugs. Keeping drug education within the physical and health education curriculum may make more sense and prevent the content from becoming even more diluted than it is now.

In their extensive review of school-based drug-education programs, O'Connor and Saunders found that while such education influences knowledge and attitudes, it has little impact on behaviour.[102] They contend that in most programs the value and meaning of being a drug user is misunderstood and the benefits of drug use are underestimated. Existing health-promotion models have in the main failed to adopt a systematic approach to drug use and have focused too much attention on individual change at the expense of a broader social understanding of behaviour. It is proposed that with regard to illegal drugs, further educational programs should take the form of training in lower-risk drug use within a harm-reduction paradigm, and that with regard to alcohol such strategies need to be augmented by social and legislative changes. The authors conclude that if a systemic harm-reduction approach is adopted, preventive education will lose some of its popularity, since such an endeavor will be more challenging, politically difficult, and socially complex.

Drug Abuse Resistance Education (DARE)

DARE is school program that was developed in the US in the 1970s and 1980s, at a time when the emphasis in drug education was on fear, information, and refusal skills, and when abstinence and the "Just Say No" approach were the only approaches considered by schools or communities.[103] The DARE program is taught over several years by police officers who provide information on drugs, their effects, and the law. The DARE program has been taught widely in the US and in some parts of Canada (it forms one part of the RCMP program). DARE has been extensively studied and criticized by researchers,

[98] Cohen, supra, note 93.

[99] Cohen, ibid; RD Newcombe. High time for harm reduction. *Druglink*. January/February 1987, at 10-11.

[100] Ibid.

[101] Coggans et al, supra, note 94; Tobler, supra, note 94; Bangert-Drowns, supra, note 94; Green & Kelley, supra, note 94; O'Connor & Saunders, supra, note 94.

[102] O'Connor & Saunders, supra, note 94.

[103] Rosenbaum, supra, note 94.

DARE's limited influence on adolescent drug use behavior contrasts with the program's popularity and prevalence.

parents, and politicians, yet for a long period the research went unpublished.[104] As the results of the studies spread and as a growing number of parents express concerns about the limitations of the approach, DARE is beginning to lose popularity and alternatives are being sought.[105] Numerous evaluations have shown no long-term effects resulting from the DARE program.[106] A study funded by the National Institute of Justice found the following:

> DARE's limited influence on adolescent drug use behavior contrasts with the program's popularity and prevalence. An important implication is that DARE could be taking the place of other, more beneficial drug use curricula that adolescents could be receiving.[107]

DARE is based on several assumptions:[108] abstinence is the only acceptable goal; anything other than one-time experimentation is abuse; alcohol and cigarettes are stepping stones to illegal drugs, and softer illegal drugs like marijuana are a gateway to "harder" drugs; experimentation with drugs is necessarily risky or hazardous; youth have little to contribute to their own drug education.

From 1991 to 1994, researchers in California conducted one of the largest evaluations of school-based programs in the United States.[109] The study examined programs ranging from DARE to health and science classes to determine whether the programs positively influenced youth's drug decisions. According to the initial report, most students were not positively influenced by their anti-drug programs. When the researchers sent their report to the California Department of Education, it did not publish the study and stopped the researchers' funding.[110] According to Joel Brown, lead author of the reviews of DARE and similar programs, "The no-substance-use message contributes to drug education program failure. Youth believe the information they receive is inaccurate and misleading."[111] Brown and colleagues concluded that the US should "implement and evaluate programs emphasizing the decision-making capabilities of the majority of youth who experiment with substances, provide credible information, serve to reduce the potential harm resulting from substance use, and offer assistance to the majority of youth who need it."

Policy analysts such as Marsha Rosenbaum see the "Just Say No" curriculum as inherently dangerous:

> When kids are told that illegal drugs, including marijuana, are extremely dangerous and addictive, and then learn through experimentation that this is false, the rest of the message is discredited. Honest drug education is one key to ensuring that individuals know how to make informed decisions. But such an approach is inconsistent with the "Just Say No" campaign.[112]

To be effective, argues Rosenbaum, drug education should be based on realistic assumptions about drug use: "Programs must address the needs of individuals within their social context and be as flexible, open, and creative as the young people they must educate."[113]

Other Materials Available in Canada

Pharmacies and doctors' offices: Materials are usually listings of facts about alcohol and other drugs aimed at adults; these are primary-prevention materials and do not include suggestions about safer use.

[104] J Brown, M D'Emidio-Caston, J Horowitz. Listening to the students. *The Drug Policy Letter* 1996; 30: 20-25.

[105] Famwoch Internet information service, at <www.familywatch.org>.

[106] Brown et al, supra, note 104; E Wysong, A Aniskewicz, D Wright. Truth and DARE. *Social Problems* 1994; 41(3); D Rosenbaum, R Flewelling, S Bailey et al. Cops in the classroom: a longitudinal evaluation of Drug Abuse Resistance Education (DARE). *Journal of Research in Crime and Delinquency* 1994; 31: 3-34.

[107] In Rosenbaum, supra, note 94 at 8.

[108] Rosenbaum, supra, note 94; Brown et al, supra, note 104.

[109] Ibid.

[110] *The Drug Policy Letter* 1996; 30: 20 (editorial comments).

[111] News Briefs, March-April 1997.

[112] M Rosenbaum. Just Say What? An Alternative View on Solving America's Drug Problem. San Francisco: National Council on Crime and Delinquency, 1990.

[113] Ibid at 17.

Provincial governments and organizations: Government agencies such as the Addiction Research Foundation in Toronto provide a wealth of information for adults and youth on drugs and their effects. The emphasis in the past has been on primary prevention, with some use of "scare-based" tactics in the materials for youth. The exception to the primary-prevention focus has been with alcohol-related materials; since the 1980s there has been an increasing focus on the reduction of alcohol-related harms rather than on abstinence, with such programs as designated drivers and Drink Wise.[114] There is a slow trend toward the publication of materials that include information on drug-related harms and materials for high-risk groups.

Federal government: Both the RCMP and Health Canada provide materials for adults and youth; the RCMP is also involved in school-based programs, including DARE Canada. The emphasis is on primary prevention and the RCMP programs include extensive coverage of legal and related issues. The RCMP also offers a First Nations drug education program entitled Aboriginal Shield. Health Canada has published excellent booklets containing facts about drugs and their effects; some of these are now out of print. While the federal government has provided some funding for preparation of materials on the reduction of drug-related harms, including booklets for HIV-infected drug users, they do not distribute these themselves.

Non-governmental organizations: An increasing number of community-based organizations are producing materials for drug users and the general public, some of which is targeted to high-risk groups. These materials are focusing more on the reduction of drug-related harms than in the past; some are quite explicit in their description of drug-related harms and ways to avoid them, and are intended for specific, high-risk audiences.

The Internet: The Internet is being used more and more as a vehicle for drug education. The advantage of using the Internet is that it allows more explicit and honest education about illegal drugs and drug interactions. The disadvantages are those of the Internet in general: who checks the material for validity and efficacy?

We need to direct our education efforts toward safer drug use rather than toward the single goal of no drug use.

Other Approaches to Drug Education

As mentioned above, the literature on drug education indicates that material intended to deter youth from using drugs is often ineffective, especially with regard to changing behaviour.[115] This has suggested to a number of educators that we need to direct our education efforts toward safer drug use rather than toward the single goal of no drug use. This applies not only to school programs but also to drug education in general. "Drug education is vital to the prevention of drug abuse. Traditional approaches, however, because they are based on questionable assumptions about drug use in general and adolescent behaviour in particular, have not succeeded in achieving this goal."[116]

In light of the ineffectiveness of primary prevention in dealing with the realities of drug use and concurrent with the emergence of harm-reduction practice in the treatment area, a harm-reduction approach to drug education has developed, especially in the UK.[117] Harm-Reduction Drug Education (HRDE) views drug use as a normal part of adolescent behaviour. Experiencing new sensations and states of consciousness, experimenting and taking risks, and doing things that adults tell you not to do, are all seen as part of the natural process

[114] Drink Wise is an ARF/Homewood manual and course based on the pioneering work of Martha Sanchez-Craig, available through the Addiction Research Foundation, Toronto, Ontario.

[115] Newcombe, supra, note 99; Cohen, supra, note 93.

[116] Rosenbaum 1990, supra, note 112 at 17.

[117] I Clements, J Cohen, J Kay. *Taking Drugs Seriously*. Liverpool: HealthWise, 1991. J Cohen, J Kay. *Don't Panic – Responding to Incidents of Young People's Drug Use*. Liverpool: HealthWise, 1992; Newcombe, supra, note 99; Cohen, supra, note 93; P O'Hare. One hundred and fifty years from Liverpool to Geneva. Paper presented at the 10th International Conference on the Reduction of Drug Related Harm, Geneva, March 1999.

of growing up and becoming independent. Responding in a positive way to adolescent drug use is regarded as a way of reducing the number and severity of casualties.[118] "Studies conducted to discover the reasons why teenagers quit using marijuana found that health reasons, short term problems and negative drug effects, *based on students own experience*, motivated them. Thus, any form of drug education should interact with and respect both their ability to reason and their own experience."[119]

HRDE is secondary prevention based on the belief that "we cannot prevent drug use per se and attempts to do so may be counterproductive."[120] It is education about rather than against drugs.[121] It is non-judgmental and neither condones nor condemns drug use, but accepts the fact that it occurs. A key aim of the approach is to develop an open and honest dialogue with young people. The right of young people to make their own decisions about drug use is respected.

HRDE involves examining the benefits as well as the risks of drug use within the context in which that use takes place. According to this approach, drug, set, and setting have to be manipulated in order to reduce potential harms.[122] These factors are affected by social and economic policy but can also be influenced by drug education. This means giving youth accurate information about drugs, their properties and effects, reducing risks, the law and legal rights, and where to get help if needed. Adolescents also need to develop a wide range of skills in assessment, communication, assertiveness, conflict resolution, decision-making, and safer use. Although information is crucial, it is only useful if people have the skills necessary to act upon it.

Harm-reduction education is a form of secondary rather than primary prevention: it focuses on the reduction of drug-related problems such as AIDS, accidents, and damage to the brain and other organs because of unsafe use of drugs. Harm-reduction education rests on four observations about the nature of drug use:[123]

1. Most people like to alter consciousness by chemical or other means, and this observation is true for all places and all times. Harm reduction does not view drug use as deviant, but recognizes instead that many normal motives underlie drug use. Even so-called "dependent" drug use can be viewed as an example of the basic human need to repeat activities that have been rewarding in the past.

2. Most illegal psychoactive substances are probably less harmful to health than many legal products such as tobacco, alcohol, prescription drugs, polluted air, contaminated water, pesticides, and nuclear waste. "The message that drugs are unhealthy is likely to be regarded by many people in industrialized societies as akin to warning soldiers on the battlefield that chewing gum can cause indigestion."[124]

3. There is an increasing awareness that unless society changes its repressive laws and policies toward drug users, most users will remain underground, out of reach of the services that could help them. Harm-reduction strategies are based on a caring and non-judgmental approach.

4. The context in which a drug is used is crucial to safe use; drug use, and misuse, are the product of an interaction between the drug, the psychological state of the user, and the setting in which the drug is used.[125]

[118] Cohen, supra, note 93.

[119] Rosenbaum 1990, supra, note 112 at 10.

[120] Ibid at 69.

[121] Riley & O'Hare, supra, note 11.

[122] Cohen, supra, note 93.

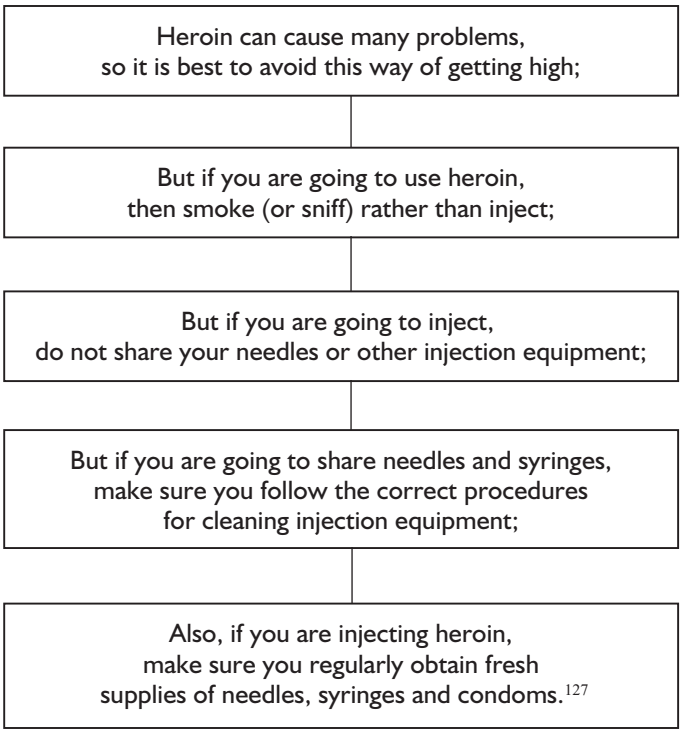
[123] Newcombe, supra, note 99; Rosenbaum, supra, note 94.

[124] Newcombe, supra, note 99 at 10.

[125] N Zinberg. *Drug, Set and Setting*. New Haven: Yale University Press, 1984.

Educational materials based on a harm-reduction approach need to be based on empirical findings, and thus they need to be updated regularly. Materials include facts on the psychological and physiological effects of legal and illegal drugs, safer methods of administration, advised quantities of use, advice on obtaining help for drug-related problems, and alternative means of altering consciousness. The harm-reduction approach to education is centred on the notion of controlled use, which is the result of rational choice and moderation. This is clearly quite different from an abstinence-oriented approach that asks the person to "just say no," without adequately preparing them for what happens if they say "yes."[126]

A harm-reduction approach provides "safety nets" to catch different kinds of drug user, with the aim of keeping harm to the individual, the community, and society to a minimum. For example, advice on preventing AIDS for injecting heroin users follows a "flow chart" structure of messages:



Education programs based on harm-reduction principles have also been targeted at accidental overdosing by drug users.[128]

Examples of Materials Available

United Kingdom

One of the most prominent sources of drug-education materials in the UK is the Institute for the Study of Drug Dependence (ISDD), an independent charity that receives grants from the Department of Health. The ISDD publishes a comprehensive drug-education booklet called *Drug Abuse Briefing*, which provides an honest overview of the effects and harms of drugs. The organization is considered to be a mainstream provider of drug education in the UK, but

[126] Newcombe, supra, note 99.

[127] Ibid.

[128] See, for example, materials by the Harm Reduction Coalition in the United States. Their website is <www.harmreduction.org>.

The "war on drugs" mentality poses a serious barrier to balanced drug education for professionals and public alike.

some of its statements would be considered heretical in North America, especially in the US. For example, in the section entitled "Drugtaking and Risktaking" it states: "The vast majority of people who use drugs come to no harm and may feel that they have benefited (and may well have done so) from the relaxation, diversion or temporarily improved social, intellectual or physical performance that can be afforded by some drugs."[129]

The government-funded organization HealthWise has produced several publications by the team of Julian Cohen, Ian Clements, and James Kay, who have taken a comprehensive approach to what they call HRDE (see above). *Taking Drugs Seriously*[130] is a package designed to be used mainly in schools, colleges, and youth projects with youth 12 years of age and over. It contains guidance for the facilitator and group work exercises in: facts about drugs; personal drug use; attitudes; harm reduction; the law and drugs; giving and receiving help; community action; parents; and community workshops. An accompanying package, *Don't Panic – Responding to Incidents of Young People's Drug Use*,[131] is an information, individual learning, and training package aimed at all professions and establishments that work with young people. It encourages calm and considered responses to the increasing number of incidents of drug use coming to the attention of schools, colleges, clubs, etc. This is important, since caring rather than punitive responses increase the probability that youth will seek help, if needed, at an early stage; trust and open dialogue are unlikely to develop if establishments overreact to actual incidents of use.

The Netherlands

The Jellinek Institute provides treatment services and produces drug-education pamphlets that describe how drugs affect the mind and body, and the risks involved. Like the British materials, they also address ways to minimize the risks of drug use. The pamphlet on ecstasy advises buying from a reliable source, using only when mentally ready and in a proper setting, and drinking lots of non-alcoholic fluids to avoid overheating and dehydration. Dutch health workers test the purity of ecstasy at parties, and the government has established guidelines for party organizers.

Ensuring Accurate and Complete Information

Barriers to Accurate Information

Because of the ways in which illegal drugs are viewed in our society, provision of "accurate and complete information" is not simply a matter of an organization deciding that it is going to make such materials available. For one thing, organizations themselves are immersed in the culture of the "drug war" and may regard all illegal drugs as "bad." Should an organization decide to provide such materials, there remains the question of where accurate and complete information can be drawn from when there are a conflicting accounts of drugs and drug effects. Once an organization does take the step of providing frank materials, it may face criticism to the effect that it is condoning drug use.[132]

The "war on drugs" mentality thus poses a serious barrier to balanced drug education for professionals and public alike. This is hardly surprising since, as Bruce Alexander has noted, war propaganda is designed not only to generate fear of the enemy but also to generate distrust of the truth itself.[133]

Media coverage of illegal drugs poses a barrier to access to accurate information. In their review of crack cocaine in the United States, Craig Reinarman

[129] Institute for the Study of Drug Dependence. *Drug Abuse Briefing*. London, 1994, at 1.

[130] See supra, note 117.

[131] Cohen & Kay, supra, note 117.

[132] See an example of the first publication on safe ecstasy use by the Mersey Drug Training and Information Centre (now HIT) in O'Hare, supra, note 117.

[133] B Alexander. *Peaceful Measures*. Toronto: University of Toronto Press, 1990.

and Harry Levine thoroughly document the role of the media in drug scares and provision of misinformation.[134] Crack never became a popular or widely used drug in the US or anywhere else in the world. This, however, is not the way in which the mass media and politicians talked about crack from 1986 to 1992, when crack was portrayed as the most addictive and destructive substance known.[135] On occasion a given magazine or television program would do a follow-up that contradicted its earlier accounts. For example, in 1990 *Newsweek* ran an article that contained the following: "Don't tell the kids, but there's a dirty little secret about crack; as with most other drugs, a lot of people use it without getting addicted. In their zeal to shield young people from the plague of drugs, the media and many drug educators have hyped instant and total addiction."[136] *Newsweek* did not tell readers that it had been one of the first to have "hyped instant and total addiction" and to have quoted the "drug educators" who did the same. Similarly, in 1989, after being one of the main sources for the news that crack was an epidemic in the suburbs, the *New York Times* noted that just the opposite was true. "By and large, the media and politicians' pronouncements about drugs spread exaggerations, misinformation, and simplistic theories of cause and effect.... This was not the first time the press, politicians, and supposed medical and scientific 'experts' in America have blamed an array of social problems on a drug and linked the drug with a 'threatening' group."[137]

"By and large, the media and politicians' pronouncements about drugs spread exaggerations, misinformation, and simplistic theories of cause and effect."

Reinarman and Levine contend that drug scares do not work very well to reduce drug problems and that they may well promote the behaviour they claim to be preventing:

> The news media and politicians played the most important roles in establishing what we have called "the crack scare." ... We maintain that the media and the politicians misrepresented or ignored the evidence and instead provided propaganda for the drug war.... The drug war was not effective or wise policy, but politicians promoted it nonetheless because, among other reasons, it provided a convenient scapegoat for enduring and ever growing urban poverty.[138]

Reinarman and Levine describe how, prompted by the crack "crisis" and inspired by the success of patriotic propaganda in WWII, the Partnership for a Drug-Free America ran a massive advertising campaign against drugs.[139] From 1987 to 1993, the Partnership placed over $1 billion worth of advertising. The Partnership claims to have made a "measurable impact" by "accelerating intolerance" to drugs and drug users. Yet the association between the advertising and any declines in drug use appear to be spurious. Drug use was declining well before the founding of the Partnership; drug use increased in the mid-1990s in precisely those groups that had been targeted by the advertisements, while drug problems continued throughout the campaign. Partnership ads avoided any mention of the two forms of drug use most prevalent among youth: smoking and drinking. This may be related to the fact that the Partnership is a partnership between the media and advertising industries, which make millions from tobacco and alcohol advertising each year, and with the fact that alcohol and tobacco companies contribute financially to the Partnership's campaign against illegal drugs.[140]

According to Reinarman and Levine, exaggerated anti-drug campaigns may have increased drug-related harm in the US by increasing interest in drug use, just as Brecher showed how exaggerated newspaper reports of dramatic police raids in 1960 functioned as advertising for glue sniffing.[141] "When the media

[134] C Reinarman, H Levine (eds). *Crack in America.* University of California Press, 1997.
[135] Ibid.
[136] Ibid at 5.
[137] Ibid.
[138] Ibid at 19.
[139] Ibid.
[140] Ibid.
[141] Ibid at 45.

and politicians claimed that crack is 'the most addictive substance known to man,' there was some commonsense obligation to explain why. Therefore, alongside all the statements about 'instant addiction,' the media also reported some very intriguing things about crack: 'whole body orgasm,' 'better than sex,' and 'cheaper than cocaine.'"[142]

The spread of misinformation about crack served to enlarge the gap about the real harms attendant upon its use. The abrasions to the lips that occur in many crack smokers are thought to promote HIV transmission among them. Such harms can be reduced or avoided through the use of different pipes and certain salves. This important educational information has been largely neglected by a media and public more interested in the "evils" of the latest "most addictive" drug.

Overcoming Barriers

These barriers to honest education about drugs and drug use are clearly enormous ones to overcome. One solution is to ensure provision of accurate and balanced information about drugs and reduction of risks through whatever means possible. There are, however, problems with harm-reduction education programs both in terms of content and presentation. Clearly, harm-reduction programs need to be put into practice in such a way as to make it likely that they will be successful. Scientific knowledge of increasing program efficacy is needed here, but there are also practical problems that make successful implementation difficult. The majority of young people have neither tried nor plan to try illegal drugs. Some educators think that this makes it risky to stimulate interest by giving information about the effects and methods of drug use.[143] Others argue that, given the right conditions, nearly all youth are likely to experiment with drugs, so education programs should be given to everyone. One possible solution to this dilemma is to give harm-reduction education only to those children already using drugs, or who are most likely to do so in the future. The problem here is to identify those most at risk of using drugs, before they start to use. Research suggests that heavy use of alcohol and tobacco, planning to try drugs or having pro-drug attitudes, and having large numbers of friends who smoke and drink, are strong indicators of later drug use.[144] These indicators could be used as a means of targeting youth for programs, based on their responses to questionnaires. This would require that they respond truthfully to such questionnaires. It would also raise the problem of having different programs within a single school, which would only raise the curiosity and questions of all involved, and which might well lead to a "self-fulfilling prophecy" effect. One possible solution to this would be to target all youth in a school in a "high-risk" area.

Given that harm-reduction programs require scientific knowledge of drug use, it may be best that they be taught by specialists with training in the medical and social sciences. Another possibility would be to train teachers with relevant experience, using courses of six to 12 months' duration. It may also be best if harm-reduction programs are separated from the regular curriculum.[145] Introduction of such programs will likely meet with strong opposition from many parents, teachers, youth workers, and community groups, especially in North America. It would be wise, therefore, to meet with representatives of these groups to ensure their understanding and cooperation. Educators such as Cohen, Kay, and Newcombe suggest that harm-reduction programs for adults

[142] Ibid.

[143] Newcombe, supra, note 99.

[144] DB Kandel. Epidemiological and psychological perspectives on adolescent drug use. *Journal of the American Academy of Child Psychiatry* 1982; 21(4): 328-347; Newcombe, supra, note 99.

[145] Newcombe, supra, note 99.

should be taught at the same time as those for youth, so that parents and teachers can be better informed.[146]

There are a number of concerns to be addressed when attempting to implement HRDE:[147] giving drug education in school, especially HRDE, will make parents think there is a drug problem in the school; many teachers feel that HRDE will be seen as "condoning" drug use; the easy options are for schools to avoid drug education altogether and to revert to punitive measures against students using drugs.

One obvious way of increasing the amount of information about illegal drugs provided to health-care professionals would be to substantially increase the amount of training given in this area. Currently, most programs – including medical school curricula – give little time to issues pertaining to illegal drugs and to dependence.

Evaluation

One of the key issues in ensuring that accurate information is conveyed in such a way as to bring about behaviour change is evaluation of materials and programs. Obviously, education programs are valuable only if they have been properly evaluated in the long as well as the short term. Very few have been carefully assessed. Most prevention programs have never been evaluated or have been evaluated using flawed research methods.[148] People on both sides of the argument agree that drug-education programs are difficult to evaluate because test results are not always an indicator of failure or success. Many programs claiming effectiveness use weak pre-test and post-test evaluation designs. Most use evaluations in which there is no control or comparison group in the drug-prevention program.[149] Differences between pre- and post-test scores may be the result of a number of factors that are unrelated to participation in the program. In addition, the gap between knowledge and behaviour always looms large as a problem for educational efforts and evaluation of their effects: people may report reasons for avoiding drugs yet use them anyway.

In order to evaluate the level of harm to the individual, educators recommend that programs:[150] reduce the prevalence of unsafe frequencies and methods of use; reduce the rate of heavy or "dependent" consumption; reduce experimentation with drugs most likely to cause medical problems (eg, tobacco, solvents) or social problems (eg, crack); and improve the ability to recognize and respond to drug-related problems.

Examination of these factors requires that schools and agencies adopt an atmosphere that enables youth to talk freely and honestly about drug use. This is in itself often difficult to ensure and is yet another barrier to good education about drugs.

Finally, evaluation data must be reported honestly and disseminated widely in order to be effective. "Prevention education research is corrupted when unexpected and unwanted findings are not released by the funding agency. Two recent examples are California DATE [Drug, Alcohol and Tobacco Education] evaluation and the US Justice Department's evaluation of DARE. Both studies found that popular education programs lacked effectiveness. Both studies were not released by the funding agencies until demanded by the public."[151]

[146] Cohen & Kay, supra, note 117; Newcombe, supra, note 99.

[147] Cohen, supra, note 93; Newcombe, supra, note 99.

[148] Rosenbaum, supra, note 112 at 6.

[149] Ibid.

[150] Cohen, supra, note 93; Cohen & Kay, supra, note 117.

[151] Brown et al, supra, note 104 at 25.

Conclusion and Recommendations

Bruce Alexander, in one of his many insightful pieces about drug education, writes that it is notable that people generally assume that other people behave more intelligently when they are well-informed: such an assumption seems natural for hazardous products like cars, power tools, household chemicals, and computers. Yet in the case of drugs, society takes quite another approach, shying away from the truth.[152]

There are many real dangers in the use of psychoactive substances and we should not ignore that fact when designing materials and programs. The most difficult task is to communicate the real harms and ways to reduce them in a manner that is appropriate for the particular audience: all material must be sensitive to the very different needs of individuals with different backgrounds, different cultures, and different drug-use experiences.

The following would help to ensure provision of more accurate information about illegal drugs to professionals, the public, and users themselves:

1. More resources should be devoted to the development of harm-reduction education.
2. In order to reduce drug-related harms, drug education should first include facts about the physiological effects of drugs, as well as their risks and benefits.
3. There should be more examples of good practice within the school system, the media, and more informal means of education.
4. Curricular time for education of professionals regarding illegal drugs, including at medical and pharmacy schools, should be increased.
5. More resources should be devoted to materials that are sensitive to the ethnic and cultural needs of the audience, including Aboriginal peoples.
6. There should be more research on the effects of solvents and improved educational materials on them, including information on ways to reduce harms.
7. There should be more and improved research into the outcomes of education programs, and this should include examining alternatives to the risk-factor model.
8. Programs should be disseminated only after they have been demonstrated to be successful.
9. It is crucial that research findings be reported responsibly.
10. Better incorporation of youth's experience, expertise, and intelligence in drug education is necessary.
11. There should be increased use of peer education and "confluent education" (information coupled with experience).
12. Positive role models should be included in drug education, for example, individuals who have non-problematic experiences with drugs.

[152] Alexander, supra, note 133.

13. Teaching practices based on a holistic model of learning should be improved.
14. Teachers should encourage students to arrive at solutions on their own rather than take a didactic approach.
15. Rather than a risk-factor approach, a resiliency approach based in public health should be used.
16. Youth who have problems should be provided with appropriate support and intervention services; drug-education programs cannot address poverty, joblessness, lack of adequate housing, and poor training.
17. Programs should ensure that what is learned informs behaviour: although information is crucial, it is only useful if people have the skills necessary to act upon it.

Syringe Exchange and Methadone Maintenance Treatment

What are current practices surrounding syringe exchange programs and methadone maintenance programs in Canada? What is their impact? Have other countries adopted different approaches and what do they look like?

Syringe Exchange

Background[153]

Traditionally, heroin has been the primary injection drug in Canada, but cocaine is now being used increasingly by injection drug users, either on its own or in combination with heroin. There is also increasing use of anabolic steroids by athletes, dancers, and males in general throughout Canada.

There are a number of strategies for limiting the spread of HIV and other infections to and among injection drug users. These include bleach kits, provision of smokable drugs, and methadone maintenance and other forms of treatment. One of the approaches that has been adopted because of its ease and cost-effectiveness is syringe or needle exchange. Because bleach does not kill hepatitis and is not always effective in killing HIV, provision of sterile syringes has become the approach of choice to ensure that injection drug users are using clean injection equipment.

Sharing syringes is an effective means of transferring blood from one person to another**.** Injection drug users share syringes because of difficulties in obtaining them. These include legal and distributional barriers, a dislike of carrying syringes (especially where laws prohibit syringe possession or where they may

[153] Background material on syringe exchange is taken from the Canadian Centre on Substance Abuse National Working Group Policy Paper on Syringe Exchange, Ottawa: CCSA, 1994; Riley & O'Hare, supra, note 11. See below, The Impact of Syringe Exchange, for a detailed review of the literature.

be used as evidence of drug possession), and unavailability at the time they are needed (such as late at night, when buying drugs, or when in prison).

Given the high incidence of injection drug use and the low number of drug-treatment facilities, needle exchange programs (NEPs) are a cost-effective means of decreasing the prevalence of needle sharing, and thus of HIV transmission, among injection drug users and in the general population. The exchange of needles within the context of counseling provides an opportunity to educate users about HIV transmission and prevention, the goal being sustained change of risk behaviours. Further, NEPs often carry out HIV-antibody testing, and provide an opportunity to refer interested injection drug users to drug-treatment programs and thus enable health officials to estimate the amount of funding for new treatment programs to meet this demand. One other important consideration is that the costs of needle exchange and drug-treatment programs are minimal compared with the costs of treating injection drug users and their partners who have contracted HIV/AIDS.

The arguments for and against NEPs are based in part on different assumptions about the injection drug–using population. Proponents of NEPs argue that a substantial proportion of injection drug users are willing and able to change their behaviour to minimize the risk of HIV infection and that sustained behaviour change will be more likely if appropriate, culturally relevant educational messages and services are available. They maintain that drug users, even those who are severely drug-dependent, have some control over drug-use behaviour. The high level of participation in NEPs supports this view. Requesting that syringes be exchanged helps to ensure that syringes are kept off the streets. Other public health measures, including disposal units and education programs, can help to ensure that used syringes pose a minimal health risk.

Needle exchange is simply one component of a package of outreach services that should be planned and operated in consultation with all those affected, including drug users.

Current Practices in Canada

Syringe exchanges opened unofficially in Canada in 1987, with the first official exchange opening in Vancouver in March of 1989. Services were initially provided through fixed sites and street outreach, as well as limited representation at other agencies providing services to drug users in downtown areas. Over time, mobile vans have been added to services in several cities. Kits containing needles, bleach, and condoms are distributed through these agencies.

Although the provision of needles to drug users still remains controversial in some jurisdictions, in the past four years there has been a rapid growth in provincially funded outreach programs that include this service. Programs are now operating in Yukon, the Northwest Territories, Calgary, Edmonton, and Halifax, as well as in a number of cities and towns in BC, Ontario, and Québec. There are currently more than two hundred syringe exchanges in Canada, mainly in urban areas, with many more under development. In addition, there are now numerous clinics, pharmacies, and other facilities that provide syringe exchange services.[154]

There is now a strong consensus among all players that prevention efforts must be multidimensional and integrated. Needle exchange is simply one component of a package of outreach services that should be planned and operated in consultation with all those affected, including drug users.[155]

Until a rapid increase in HIV rates occurred in some cities, most exchanges operated on an "official" one-for-one exchange policy with low (eg, three) maximum daily limits on exchanges. Even at that time, however, workers

[154] Health Canada, Laboratory Centre for Disease Control. AIDS Surveillance Reports. Ottawa: Health Canada, 1999.

[155] See Canadian Public Health Association. *The National Task Force Report on AIDS and Injection Drug Use*. CPHA: Ottawa, 1997, for recommendations regarding syringe exchange and drug use treatment in Canada.

report exceeding the limit and not requiring strict one-for-one exchange. This flexibility was highly variable, however, and many users complained of the rigid nature of some exchanges. Once it became clear that HIV rates were still rising and that cocaine users need many more needles per day than do heroin users, some exchanges increased their daily maximums to very high levels or removed caps altogether. Exchanges became much more flexible about strict exchange, operating more as syringe distribution centres. This is not true of all exchanges in Canada: some still report a maximum of five needles at a time, with strict one-for-one exchange and few exceptions made.

Vancouver[156]

Despite the fact that needle exchange was introduced in Vancouver as early as 1988, needle sharing remains common. Strathdee and colleagues found that after controlling for HIV serostatus, factors independently associated with borrowing were: injecting more than four times a day, multiple drug use, and having experienced non-consensual sex. Depression was associated with borrowing, although barriers or lack of access to clean needles were not. Social determinants, particularly a history of sexual abuse, were found to be among the most significant predictors of needle borrowing among Vancouver injection drug users. Strathdee et al found no evidence to suggest that limited availability of sterile needles accounted for needle borrowing. In 1995, the Vancouver needle exchange program exchanged 1.8 million needles in a city with a metropolitan-area population of 1.5 million. Syringes could also be purchased from a number of local pharmacies. Borrowers and non-borrowers reported reusing their own needle three to four times on average. More than two-thirds of all subjects in this study reported having needles confiscated, especially by police. This may be one reason why users did not consistently use sterile needles.

Montréal[157]

A study by Bruneau and colleagues reported that needle exchange participants in Montréal were more than twice as likely to get HIV than those who do not use such programs. Of the 1559 users studied between 1988 and 1995, 5.1 percent became infected with HIV each year. The yearly infection rate was 7.9 percent for those in exchange programs compared with 3.3 percent for those who did not attend needle exchanges. According to the study, Montréal is an exception mainly because of a large increase in cocaine as the drug of choice of injection drug users. The researchers believe that frequent cocaine injectors are more likely to use each other's HIV-infected syringes when their supply of clean ones runs out. In the period studied before 1995, Montréal needle exchange programs supplied only 15 syringes per individual per day. That number was far below demand. Since 1995 there has been no limit. The researchers report that by not expanding the program earlier, they may have created problems for themselves.

In a commentary in the *New York Times*,[158] Julie Bruneau and Martin Schechter discussed the use by needle exchange opponents of their reported findings on HIV incidence among program participants. Bruneau and Schechter stated that McCaffrey (head of US drug policy) and others who have cited their results as evidence of the danger of implementing and encouraging such programs are misinterpreting the findings. The authors note that the injection drug users who are not involved in the exchanges – which are run in inner-city neighbourhoods and serve those at greatest risk of infection – often

[156] S Strathdee, D Patrick, C Archibald et al. Social determinants predict needle-sharing behaviour among injection drug users in Vancouver, Canada. *Addiction* 1997; 92(10): 1229-1347.

[157] J Bruneau et al. High rates of HIV infection among injection drug users participating in needle exchange programs in Montreal: results of a cohort study. *American Journal of Epidemiology* 1997; 146(12): 994-1002.

[158] *New York Times*, 20 December 1996, A20.

did not need them since they could afford to buy syringes in pharmacies themselves. In addition, non-participating injection drug users were less likely to engage in high-risk behaviour. A more recent study by Schechter and colleagues supported this interpretation of the data, finding that attendance at a syringe exchange did not increase the risk of HIV; rather, people at higher risk of HIV were found to be more likely to attend exchanges.[159]

Bruneau and Schechter estimated that Vancouver and Montréal would each require 10 million clean needles annually to prevent the reuse of syringes.

The Aboriginal community

Strategies and programs must be sensitive to the cultures and needs of the Aboriginal community. There is concern about the high rates of HIV among Aboriginal injection drug users.[160] Recent data (1993-98) from British Columbia, Alberta, and Saskatchewan show that Aboriginal people account for 15 percent, 26 percent, and 30 percent respectively of newly diagnosed HIV-positive cases, and that injection drug use and heterosexual behaviours were the most significant risk factors.[161] In some cities, 11 to 75 percent of clientele using inner-city services such as needle exchange and counseling/referral sites are Aboriginal.[162]

The role of pharmacies[163]

Not all drug users take advantage of NEPs. Because such programs are limited mainly to large cities, they are not readily accessible to all users. Other users avoid syringe exchanges because they are afraid of being stigmatized. Although most pharmacies stock needles and syringes, pharmacists have traditionally been reluctant to sell needles to known or suspected drug users or to make disposable syringes available. More recently, however, an increasing number of pharmacists have responded to the AIDS problem by selling needles and syringes on request. This change in approach has been facilitated by the fact that a number of provincial regulatory bodies have liberalized their policies with respect to the sale of needles and syringes.

All pharmacists can play a major role in helping to prevent the spread of HIV through the sale of clean needles and syringes to drug users. Pharmacies are located in almost every neighbourhood and are therefore accessible to everyone. Pharmacists are also in a position to provide counseling to customers who request needles and syringes. As noted above, studies have shown that the distribution of clean needles will not in itself limit the spread of HIV unless it is accompanied by education and support. Such counseling could include advice about sterilizing the injection site to avoid infection, the safe disposal of used needles and syringes, cleaning needles and syringes before re-using, and using other precautionary measures to reduce the risk of spreading HIV.

Pharmacists can also check for apparent problems related to injection and discuss possibilities for addiction treatment and testing for HIV.

There are a number of potential problems involved in serving injection drug users – increased risk of theft, alienation of other customers, and an increase in the number of needles discarded unsafely in the neighbourhood. As a result, individual pharmacists must exercise both professional and managerial judgment. By restricting the inventory of syringes to the dispensing area, being personally involved in each sale, and working in cooperation with other public health programs and treatment services, pharmacists can minimize the risks in order to maximize the health benefits.

[159] MT Schecter, SA Strathdee, PGA Cornelisse et al. Do needle exchange programmes increase the spread of HIV among injection drug users? an investigation of the Vancouver outbreak. *AIDS* 1999; 13: F45-F51.

[160] Health Canada. *HIV/AIDS Epi Update: HIV and AIDS Among Aboriginal People in Canada.* Ottawa, May 1999.

[161] Ibid.

[162] Ibid, with numerous references.

[163] See T Myers, R Cockerill, P Millson et al. *Canadian Community Pharmacies, HIV/AIDS Prevention and Health Promotion: Results of a National Survey*. Ottawa: Canadian Public Health Association, 1995 for more details.

In general, in Canada's provinces and territories, access to needle exchange programs often remains a problem.

Pharmacists can also assist public health programs by joining them in encouraging manufacturers and distributors of needles and syringes to develop packaging that incorporates warnings about the spread of HIV and diagrammatic instructions for safe disposal. Many more sites for safe disposal of used needles and syringes are needed if programs are to be successful at not only distributing clean equipment but also ensuring that it is disposed of appropriately, and pharmacists can play a part in this process.

Summary

Some users of syringe exchanges interviewed by the author in Montréal, Toronto, and Vancouver in early 1999 expressed concerns about: lack of accessibility of programs (limited times and places); restrictions on number of syringes available at any one time, resulting in users having to go to programs several times every day; and lack of anonymity.

In general, in Canada's provinces and territories, access to needle exchange programs often remains a problem: there are too few exchanges too far apart, with often inflexible, limited hours. Where programs exist, there are often other limitations: there are no exchange machines for non-service hours; there is insufficient mobile exchange; some programs may still enforce one-for-one exchange (ie, they will not distribute needles and syringes) or have restrictive daily maximums; there are not always links to other services such as treatment (including methadone), STD testing, or HIV testing; only a few pharmacies act as exchanges and/or sell syringes to drug users; and there is no syringe exchange or availability in Canadian prisons.

The Impact of Syringe Exchange

There are multiple lines of evidence regarding the efficacy of syringe exchange, as reviewed below:

- biologic plausibility: removing potentially infected syringes from circulation and replacing them must decrease new infections;
- behavioural data: the majority of studies show a decrease in HIV risk behaviour and none show an increase;
- significant decrease in new hepatitis B and C infections;
- mathematical models demonstrating a significant decrease in infections.

In particular, there is evidence that:

- access to sterile syringes helps reduce the spread of bloodborne diseases.[164] Most reviews of syringe exchange show that it decreases sharing and HIV, and is cost-effective relative to having no exchange. There is now direct evidence that increasing the availability of clean injection equipment reduces the spread of HIV, and indirect evidence also exists on what occurs when the supply of needles and syringes is very limited. Both forms of evidence demonstrate that access to sterile injecting equipment, as well as outreach and development of trust between health-care officials and injection drug users, are critical in limiting the spread of HIV infection.
- syringe exchanges decrease risky injection behaviour by more than 70 percent.[165] Numerous studies have shown that injectors will change their behaviour to reduce their risk of HIV infection and that they are motivated to seek help in doing so. Behaviour change has been shown to occur more often among attendees of needle exchanges than among non-attendees.
- pharmacy sales reduce risky injection behaviour by 40 percent.[166]

[164] The Lindesmith Center. Facts about Needle Exchange. New York: The Center, 1997; J Normand, D Vlahov, L Moses (eds). *Preventing HIV Transmission: The Role of Sterile Needles and Bleach*. Washington, DC: National Academy Press, 1995. P Lurie, A Reingold. *The Public Health Impact of Needle Exchange Programs in the United States and Abroad*. Berkeley, CA: University of California, 1993. DC Des Jarlais, SR Friedman, JL Soethern et al. Continuity and change within an HIV epidemic. *Journal of the American Medical Association* 1994; 271: 121-127.

[165] DC Des Jarlais, M Marmor, D Paone et al. HIV incidence among drug users in New York City syringe-exchange programs. *Lancet* 1996; 348: 987-991; SF Hurley. Effectiveness of needle-exchange programs for prevention of HIV infection. *Lancet* 1997; 349: 1797; Strathdee et al, supra, note 156; Normand et al, supra, note 164; H Hagan, DC Des Jarlais, SR Friedman et al. Reduced risk of hepatitis B and hepatitis C among injection drug users in the Tacoma syringe exchange program. *American Journal of Public Health* 1995; 85: 1531-1537; EH Kaplan. Probability models of needle exchange. *Operations Research* 1995; 43: 558-569; R Heimer, K Khoshnood, FB Jariwala et al. Hepatitis in used syringes. *Journal of Infectious Diseases* 1996; 173; 997-100; Lurie & Reingold, supra, note 164; P Lurie, E Drucker. An opportunity lost: HIV infections associated with lack of a national needle-exchange program in the USA. *Lancet* 1997; 349, 604-608.

[166] Lurie & Reingold, supra, note 164; A Ganz, C Byrne, P Jackson. Role of community pharmacies in prevention of AIDS among injection drug misusers: findings of a survey in England and Wales. *British Medical Journal* 1989; 299: 2076-2079.

- access to syringe exchange does not increase the number of improperly discarded syringes.[167] Reasonable return rates of used equipment have been recorded even for underground and illegal exchanges, although return rates for fixed sites are better than those for mobile sites.
- access to sterile syringes does not encourage people to increase drug use or to start injecting drugs.[168] There is no evidence of increased drug use in any of the communities where syringe exchanges are now operating.
- access to sterile syringes does not impede other treatment efforts.[169]

In summary, syringe exchanges are successful at reaching large numbers of injection drug users, many of whom are not in touch with other services and have had little former help with drug problems. One major problem for syringe exchanges is the poor retention rate; there tends to be a high turnover of clients at most exchanges. Reasons for turnover include positive outcomes such as referral to treatment and cessation of injecting, and negative outcomes such as imprisonment and death. There is also turnover due to clients moving on to other exchanges. Most attendees live within five kilometres of the exchange they use. Evidence from several countries indicates that syringe exchange is less successful in reaching young injectors, those with a shorter history of injecting, and women. Non-users of services report concerns regarding lack of confidentiality and being identified.

Factors Influencing the Effectiveness of Syringe Exchange

While there are few studies of the components of syringe exchange programs that maximize their effectiveness, reports from syringe exchanges around the world suggest that several factors are important for ensuring their effectiveness. These include: physical accessibility; temporal accessibility; social and cultural acceptability in the community; absence of police surveillance or other perceived harassment; "user friendly" staff; adequate education and counseling concerning drug use, sex, and HIV; and supportive public health programs.

While effective in reducing a number of the negative consequences associated with injection drug use, syringe exchange has several limitations:

- One of the chief obstacles in setting up syringe exchanges is lack of public education on injection drug use and HIV/AIDS.
- Needle exchanges have had less success attracting young or female injection drug users than older males.
- The syringe exchange prevention strategy does not adequately address the problem that many people find it difficult to adopt safer behaviour. Injection drug users who attend NEPs are those who practise the riskiest behaviour, and this raises the need to focus on changing risky behaviours.
- Because of the initial preoccupation with delivering syringes, there has been insufficiently rigorous attention to methods for helping people change their behaviour.
- At the political level, syringe exchange remains a controversial approach in some communities.
- Other barriers to syringe exchange and risk reduction include the fact that users often lack skills for approaching support services or exchanges and many users and non-users alike are unable to negotiate safer use and safer sexual practices.

[167] Normand et al, supra, note 164; KM Oliver, SR Friedman, H Maynard. Impact of needle exchange program on potentially infectious syringes in public places. *Journal of AIDS* 1992; 5: 380; Lurie & Reingold, supra, note 164; MC Doherty, RS Garfein, D Vlahov et al. Discarded needles do not increase soon after the opening of a needle exchange program. *American Journal of Epidemiology* 1997; 145: 730-737.

[168] Normand et al, supra, note 164; D Paone, DC Des Jarlais, R Gangloff. Syringe exchange: HIV prevention, key findings and future directions. *International Journal of the Addictions* 1995; 30: 1647-1683. J Watters, MJ Estilo, GL Clark, J Lorvick. Syringe and needle exchange as HIV/AIDS prevention for injection drug users. *Journal of the American Medical Association* 1994; 271: 115-120. Lurie & Reingold, supra, note 164; Drug Policy Foundation. The Clinton Administration's Internal Reviews of Needle Exchange Programs. Washington, DC: The Foundation, 1993; E Kaplan, K Khosnood, R Heimer. Client shift or needle exchange. *American Journal of Public Health* 1994; 84; 1991-1994; R Heimer, E Kaplan, E O'Keefe et al. Three years of needle exchange in New Haven: what have we learned? *AIDS and Public Policy Journal* 1994; 9: 59-74; EC Buning. Effects of Amsterdam needle and syringe exchange. *International Journal of the Addictions* 1991; 26, 1303-1311.

[169] Heimer et al, supra, note 165; J Wolk, A Wodak, J Guinan et al. The effects of needle and syringe exchange on a methadone maintenance unit. *British Journal of Addictions* 1990; 85: 1445-1450.

There are other issues as well:

- the ease with which hepatitis B and C are spreading, creating an even more pressing need for comprehensive harm reduction, as well as research into less harmful modes of drug ingestion;
- the lack of other programs and services, including safe injection sites;
- the need to emphasize the importance of the cleanliness of all paraphernalia, not just syringes (raises the issue of the need to be able to provide safer crack pipes).

International Approaches

United States

Although almost all scientific associations in the US support needle exchange,[170] nine states and Washington, DC have prescription laws prohibiting the sale, distribution, and possession of syringes without prescription. Pharmacy regulations or practice guidelines exist in 23 states. In total, 47 states and Washington, DC have drug paraphernalia laws prohibiting the sale, distribution, and/or possession of syringes known to be used to introduce illegal drugs into the body.[171]

The Clinton Administration's first internal review, signed 10 December 1993, was never made public. The second review (November 1994), with more positive outcomes reported, was also withheld until the Drug Policy Foundation made it public in March 1995.

On 11 September 1997 the US House of Representatives voted not to allow local communities to use federal funds for needle exchange programs. The American Public Health Association and several other organizations have called repeatedly for the Clinton Administration to lift the ban, but this has been declined. This continued despite an announcement in April 1998 by Donna Shalala, Secretary of Health and Human Services, that such programs effectively reduce HIV transmission and do not encourage drug use.

The human and fiscal costs of AIDS continue to rise.[172] Federal officials estimate that 33 people are infected with HIV each day as a result of dirty needles; 40 percent of new HIV infections in the US are directly or indirectly related to contaminated needles, and among women and children this figure is 75 percent.[173] Peter Lurie, who in 1993 coordinated a federally funded study of the effectiveness of needle exchange programs, estimates that needle exchanges could have saved 17,000 lives since Clinton took office in 1993. According to a study by Peter Lurie and Ernest Drucker, needle exchange programs could have prevented nearly 10,000 HIV infections among injection drug users, their sex partners, and children in the US since 1987. An additional 11,000 infections could be prevented by the year 2000. The estimated cost of treating the preventable HIV infections that occurred between 1987 and 1995 ranges from $244 million to $538 million, enough to have funded between 161 and 354 NEPs.[174]

In 1996 the National Institutes of Health approved a syringe-exchange study in Alaska. The study is to determine the efficacy of counseling and needle exchange versus counseling and buying inexpensive needles through a pharmacy. The study has been criticized as being unethical for not allowing all injection drug users access to syringe exchange, and has been delayed until concerns about informed consent have been adequately addressed.

[170] See Lindesmith Center, supra, note 164 for a review.

[171] See Gostin et al, supra, note 20.

[172] Update: trends in AIDS incidence – United States, 1996. *Morbidity and Mortality Weekly Report* 1997; 46: 861-867; SD Holmberg. The estimated prevalence and incidence of HIV in 96 large US metropolitan areas. *American Journal of Public Health* 1996; 86: 642-654; D Day. *Health Emergency 1997: The Spread of Drug-Related AIDS among African-Americans and Latinos*. Princeton, NJ: Dogwood Center, 1997.

[173] Centers for Disease Control and Prevention. HIV/AIDS Surveillance Reports.

[174] Lurie & Drucker, supra, note 165.

Despite continued lack of federal funding, syringe exchange programs expanded in terms of the number of syringes exchanged, the geographic distribution of programs, and the range of services offered. There are more than a hundred syringe exchange programs in 30 states and the District of Colombia. Using data from 87 of them, researchers estimated that 14 million syringes were exchanged in 1996. Of the 87 programs surveyed, 53 percent were legal, 23 percent were illegal but tolerated, and 34 percent were illegal and underground.[175]

Increasing syringe availability is a simple, inexpensive HIV-prevention measure.

Other countries

In many parts of Western Europe and Australia syringes are widely accessible through needle exchanges and pharmacies. In over a dozen European and Australian cities, syringes are also available from vending machines that provide a clean syringe when a used one is deposited. In Australia there are numerous sites in cities, mobile exchange, and vending machines. There is concern, however, that this will not be adequate for dealing with increased need as cocaine injection becomes more popular. In the UK there are many sites, including pharmacies, and comprehensive programs, including drug prescription. In Switzerland there are many sites, mobile exchange, dispensing machines, distribution in some prisons, and comprehensive programs, including prescription. In Germany there are many sites, mobile exchange, and the country now has some prison programs. In the Netherlands there are also many sites, mobile exchange, and syringes are available in some police stations.

Syringe exchanges are a cost-effective way of providing means, education, counseling, and access to treatment and other services.

While other countries have more extensive and varied means of exchanging and distributing syringes, this in itself is not the main concern for ensuring the reduction of drug-related harm. As the experiences in Vancouver and Montréal illustrate, exchange alone is not enough. What is needed in Canada are truly comprehensive harm-reduction strategies and programs that include education, outreach, support, drug prescription, and treatment.

Conclusions and Recommendations

Provision of sterile needles and syringes is one way to reduce the risk of spreading HIV infection. It is also a way of providing contact with drug users through outreach services. Increasing syringe availability is a simple, inexpensive HIV-prevention measure. The evidence clearly shows that given both the means and education regarding HIV/AIDS and drug use, injection drug users will reduce their risk behaviours; healthier choices are made possible when they are made easier. Syringe exchanges are a cost-effective way of providing means, education, counseling, and access to treatment and other services. There is no evidence of an increase in drug use or of injecting in any of the communities where syringe exchanges are now operating.

Syringe exchanges, however, are not a panacea. In some cities, such as Vancouver and Montréal, the level of HIV infection is high despite the presence of syringes exchanges. Syringe exchanges are also relatively ineffective in changing the sexual behaviours of drug users. Prevention strategies need to address the factors that make it difficult for injectors to adopt and sustain safe behaviour. Other approaches, including outreach, are needed, as are approaches oriented to groups rather than individuals. It is now widely agreed that syringe exchanges should be but one element of larger, comprehensive, and innovative programs for reducing the harms associated with injection drug use. Data from Canada, as elsewhere, suggest that the impact of syringe

[175] Paone et al, supra, note 21.

exchanges is limited if they do not meet the above recommendations and do not have multiple distribution systems and sites. If this is not so, syringe exchange merely gives the appearance that something is being done and gives rise to complacency.

We must be cautious, however, about being too complacent over the apparent "successes" of other countries with respect to syringe exchange. It is only in North America that cocaine injection has as yet become so popular; other countries that to date have been dealing mainly with users of heroin and other depressants are concerned that this will test the limits of syringe exchange.[176]

Based on the foregoing, it is recommended that:

- availability of services for injection drug users, including those with HIV infection, be substantially increased;
- education regarding HIV prevention and relevant services be included in existing drug prevention and treatment programs. Injection drug users should be encouraged to, if possible, stop injecting. If they continue to inject they should be provided with the knowledge and means to inject safely. Provision of sterile injection equipment is the option of first choice to prevent the spread of infection to and among injection drug users;
- HIV prevention programs for injection drug users and their partners be implemented in all regions, and in correctional facilities; existing programs in urban areas should be expanded and coordinated. The programs should include needle exchange and outreach programs that put workers on the street;
- needle and syringe exchange programs be established throughout Canada that are readily accessible to drug users (in terms of location and hours of service), and that these include programs that meet the needs of steroid users and other groups, including diabetics. These services should be accessible to all who need them;
- special attention be paid to the needs of Aboriginal people;
- pharmacists consider the public health benefits of selling needles and syringes to injection drug users, a mode of distribution less stigmatizing than NEPs;
- further education be provided to pharmacists in order to increase their knowledge about addiction assessment/referral services and other addiction treatment services in the community;
- further collaboration take place between public health units, community groups, pharmacies, government officials, regulatory bodies, and law enforcement officials in the provision of services to injection drug users;
- opportunities for safe disposal of used needles and syringes be increased in all communities;
- manufacturers and distributors of needles and syringes be encouraged to develop packaging that incorporates warnings about the spread of HIV, and diagrammatic instructions for safe disposal; and
- more research on and evaluation of harm-reduction programs for injection drug users be carried out, including research on effective methods for destroying HIV and hepatitis in injecting equipment.

[176] Wodak, supra, note 13.

Methadone

Current Practices in Canada

Health Canada guidelines

General guidelines for the use of methadone were last released by Health Canada in 1992; the previous guidelines had been prepared in 1971. In 1998 Health Canada held meetings with physicians and users as part of the process of again revising the methadone guidelines. At the time of writing, the revised guidelines had not yet been released, and in the meantime more responsibility for the guidelines has been handed over to the provinces. In the following discussion, federal and provincial guidelines will be discussed in general terms unless there is a specific reason to differentiate them.

In 1999 there may be more than 12,000 people in methadone treatment programs in Canada.

In 1999 there may be more than 12,000 people in methadone treatment programs in Canada (the federal government no longer keeps national records, so calculation must be done on a province-by-province basis, and not all jurisdictions systematically collect methadone treatment data). While numbers have increased more than fourfold since the early 1990s, there are still far too few places to meet the demand; many more users await places in programs. Even if a much greater proportion of those awaiting treatment were to be placed, these numbers are clearly small enough to allow consideration of treatment approaches along the lines of some UK or other European programs rather than to force the adoption of approaches used in the US. Examples of UK and other interventions that are relevant to Canada are discussed below.

Both pharmacological and non-pharmacological approaches have been used in an attempt to treat people dependent on opiates. Health Canada acknowledges the importance of non-pharmacological interventions, stating that "pharmacotherapy is not effective for all opioid dependent persons, and not effective as a treatment in itself,"[177] a view reflected in the Guidelines, which require that counseling be given to methadone users.

Many users attend methadone programs each day to receive their single dose, which they consume on the premises. Some users earn the privilege of "carries," meaning they can obtain one to several days worth of methadone from their pharmacist. Urine samples are often taken, under staff supervision, from methadone clients. Waiting lists are long in all provinces.

Currently, only methadone syrup is available to those on programs in Canada. There are some serious problems specific to the use of methadone syrup in the treatment of opiate dependence. It is well documented that methadone syrup is very addictive, and many users complain of nausea, vomiting, tooth decay, and weight gain after prolonged use. Since methadone syrup does not provide a "buzz," clients report that their need for the experience they crave is not dealt with, and so they look for a comparable experience elsewhere, using the syrup to keep them stable.

A number of issues are also raised by guidelines dealing specifically with methadone administration.[178] With respect to the criteria for detoxification with drug therapy, the determination of signs of opiate withdrawal is a controversial issue in a number of centres because of failure to adhere to clearly-set-out procedures. This points to a need to better train staff to follow explicit steps using a standardized scale that maximizes the use of measures that cannot be easily faked. It would be helpful if the federal and provincial committees could devise such a scale, along with explicit guidelines for assessing the signs requested. Reliance on verbal reports and somatomotor measures

[177] 1990 Guidelines, at 5.

[178] Health and Welfare Canada. Methadone Guidelines. Ottawa: Health and Welfare Canada, 1992.

such as vomiting and restlessness allows for ready faking of results. The use of more objective measures would ensure a more accurate assessment of level of drug needed, and thereby shorten the withdrawal process. The criteria should include confirmation of withdrawal signs by medical examination, a urine screen, and naloxone assessment where possible. With respect to medical examination, the majority of programs appear to rely on nurses' assessments for determination of dose level. Naloxone challenge is, rightly, seen as too harsh in the majority of cases. Even urine is not always collected. Failure to comply with guidelines is not, of course, a problem that the federal and provincial committees can address, but such failure does point to the need for more explicit, easily followed, and objective criteria that also take into account the realities of how programs actually operate. The nurses who work in such programs are an invaluable source of information in this regard because they can tell us where the discrepancies between the idea and the reality are.

The Health Canada guidelines for methadone maintenance at times appear harsh and unrealistic. Frequent checking of urine, with the recommendation that repeated positive urine tests for unacceptable drugs will require consideration that methadone be withdrawn, seems punitive and humiliating and is likely to drive users from treatment, back to the needle and black-market drugs.

Provincial guidelines

Alberta, British Columbia, Ontario, and Québec have province-wide methadone programs with formal guidelines. These guidelines are based on those of Health Canada (1992), but where the federal guidelines were meant to be just that, the provincial guidelines often interpret the federal document as rigid minimal standards and not as flexible suggestions. Concerns are thus raised about the requirement of frequent urine tests (under supervision), lack of flexibility regarding take-home medication, and inadequate doses. Privacy concerns are also raised by the auditing of patients files.

The College des médecins du Québec (one of the two physicians' associations in Québec) recently endorsed a position in favour of a greater use of methadone treatment to help injection drug users. They stated that the prohibitionist approach has failed and that a harm-reduction approach with methadone treatment would be better for the health of injection drug users.

Concerns

There are a very limited number of places in programs. Too few physicians are prescribing, and they are required to have special training and a licence to dispense. Much paper work and auditing puts doctors off. Many programs gave minimal doses, so users would "top up" from street sources. The treatment is all oral, so there is no transition from needle use. There is strict enforcement of guidelines, even stricter than required by the federal guidelines. Urine testing is required, and is supervised. There are few "carries" or take-outs, and this limits users' ability to go to work and to travel. Some users have been removed from programs for positive urine, even if the positive result was for alcohol. Often programs are inflexible and not user-friendly.

International Approaches

United Kingdom

"Methadone prescribing services in the UK could be described as patchwork, with most areas having a service of some kind but with many variations

between health districts."[179] In addition to GPs, there are three main types of community service:

- street agencies, which are designed to be easily accessible and easily approached, with a wide range of services that includes needle exchange and advice;
- community drug teams that focus on prescribing and counseling services; and
- drug clinics, which are usually based in hospitals and emphasize out-patient medical care.

Clients may have to attend several times a week to obtain their prescriptions. In some cases, such as with "low threshold" programs, they may be required to drink their methadone at the clinic in front of a staff member. Some clinics have been prescribing reefers (cigarettes injected with diamorphine or methadone hydrochloride) to clients who want to stop injecting. The reefers are prescribed alone or in conjunction with methadone syrup, and the injecting behaviour of clients is monitored. One reason for introducing this program was that a number of clients who had been prescribed Tang had returned to the use of injectable drugs, reporting that they were unable to cope on methadone syrup alone. Part of this inability to cope was due to the fact that the methadone syrup was said not to produce a "buzz." To date, the results from the UK programs are encouraging, with very few reefer users returning to injection. The main advantages of this formulation is that it provides an acceptable alternative to injection and associated health risks, it provides the "buzz" that some users crave, and it is less addictive than methadone syrup and therefore easier to withdraw from. Methadone can also be made available in injectable and tablet form.

Australia[180]

Measures introduced to combat the spread of AIDS in Australia included the marked expansion of methadone programs. The criteria for admission to these programs were also made less stringent, and many more spaces were allowed for maintenance of clients with little motivation to change drug-using behaviour.

The Netherlands

The Netherlands, one of the birthplaces of harm reduction, began methadone prescribing programs in the 1970s. They were expanded and liberalized in the 1980s in order to deal with hepatitis, HIV, drug-related crime, and other harms (the rigidity of programs is positively related to rates of crime, other drug use, and exposure to infection). In Amsterdam and other cities, methadone is used in three different ways – to contact heroin users, to stabilize heroin users, and to detoxify and treat users. By providing methadone without too many impediments, contact can be made with large sections of the heroin-using population. The Netherlands has a three-tiered system of methadone services:

- Low-threshold services provide methadone to be taken on the spot and without urine testing; the dose of methadone provided is generally low. The main aim of this program is to contact users and bring them into the network of services. There is a "methadone bus" program in which buses are used to distribute methadone throughout the drug-using community (no take-home dosages are provided). Clients are also assisted if they face problems

[179] Preston, supra, note 38 at 18.

[180] A Wodak. Shall we snatch defeat from the jaws of victory? Paper presented at the 10th International Conference on the Reduction of Drug Related Harm, Geneva, March 1999.

concerning housing and financial and legal matters. Medical help is given in the form of regular medical examination. Methadone is also made available in police stations.
- Intermediate-threshold services are provided to stabilize users and to introduce them to the possibility of longer-term treatment and more rigid requirements, such as urine testing for non-prescribed drugs. Detoxification and maintenance services are available, usually with little delay.
- High-threshold services require users to take urine tests and to abstain from drugs other than methadone and others that are prescribed. Both maintenance and detoxification services are provided; some of these services are residential in nature.

In Canada, methadone was rarely prescribed to anyone in prison until quite recently. However, this is changing.

One of the main reasons that methadone programs have proven effective in getting people into treatment in Amsterdam is that the methadone bus program requires no urine samples and no mandatory contact with counselors. The number of people entering drug-free treatment and resocialization programs in Amsterdam has more than doubled since the introduction of the methadone buses and the needle exchange schemes. The primary disadvantages of the Dutch programs appear to be that they, like the US programs, do not maintain all clients on levels of methadone that are high enough to prevent heroin use, and they do not provide anything other than oral methadone (a heroin prescribing trial has recently begun in several cities).

Other European countries

Several Western European countries greatly expanded their methadone programs in response to concerns about the spread of AIDS. Countries such as Germany and Switzerland, like the Netherlands, have introduced considerably more flexibility into the methadone distribution system. In some cities in Germany, methadone is now available on a same-day basis.

Prisons

Worldwide, an increasing number of prison systems are offering MMT to inmates. For example:

- In a 1997 survey undertaken in Europe, nine of the 22 systems that participated offered MMT to opiate-dependent prisoners.
- In approximately half the prisons in New South Wales in Australia, MMT is provided to prisoners.
- In the United States, Rykers Island, New York City, has an MMT program.

In Canada, methadone was rarely prescribed to anyone in prison until quite recently. However, this is changing, partly because of the many recommendations urging prisons systems to provide MMT, partly because of legal action. One such case was in British Columbia: an HIV-positive woman undertook action against the provincial prison system for failing to provide her with methadone. The woman, who at the time of her sentence was on MMT, had been refused continuation of the treatment in prison. She argued that, under the circumstances she found herself in, her detention was illegal. In response, the prison system arranged for a doctor to examine the woman, and he prescribed methadone for her. After this, she withdrew her petition.

In another case, a man with a longstanding "serious heroin problem" was sentenced to two years less one day in prison – and thus to imprisonment in a provincial prison in Québec – because that prison had agreed to provide him

with methadone treatment. The defence had submitted that it was necessary to deal with the root causes of the man's crimes, namely his heroin addiction, and that treatment with methadone was essential to overcoming that addiction.

In September 1996 the British Columbia Corrections Branch officially adopted a policy of continuing methadone for incarcerated adults who were already on MMT in the community prior to incarceration, thereby becoming the first correctional system in Canada to make MMT available to inmates in a uniform way. On 1 December 1997 the federal prison system followed suit. Today, in the federal and in many – but not all – provincial systems, inmates who were already on MMT outside can continue such treatment in prison. However, no Canadian system has adopted a policy of making MMT available to opiate-dependent prisoners who were not receiving it prior to incarceration. A few systems are, however, considering doing this in the near future.

A Canadian Methadone Users' "Wish List"[181]

- Doctors should be allowed to, and required to, prescribe methadone as a basic part of health-care service;
- standardized prescribing and access across Canada, and an interface with the international system;
- standards of care and dispensing should be uniform and monitored by independent ethics committees that include users;
- alternatives to oral methadone (injectable, pill, and reefer) should be readily available;
- alternatives to methadone maintenance (eg, heroin maintenance) should be easily available;
- pharmaceutical drugs to assist with methadone withdrawal (eg, buprenorphine) should be easily accessible to all methadone clients and chronic opiate users;
- all pharmacies should provide methadone and all pharmacists be trained to deal appropriately with users;
- provide a private place for use (as is the case in Australia);
- methadone to be covered by OHIP or other provincial plans;
- shorter wait for carries; amount of carries determined by needs of client and capacity to store methadone safely;
- remove punitive aspects of urine testing; use urine tests only to check on health of client and for research purposes; ensure that relationship with physician is therapeutic, not punitive;
- no forced counseling component in order to access methadone program; counseling should help, not hinder;
- all shelters, treatment centres, supportive housing programs and so on should allow clients to leave every day to access methadone and bring carries back; a safe, refrigerated space must be provided for clients to store methadone and other medications;
- health-care workers should be trained in pain management for methadone clients;
- easy access to non-opiate pain killers for clients coming off a methadone program should be provided; and
- methadone tapering programs should be accessible.

[181] This is based on a list compiled by Cheryl White of Toronto. Many thanks, Cheryl, for years of support and enlightenment.

Strategies and programs must be sensitive to the cultures and needs of the Aboriginal community.

Recommendations

The foregoing comments are meant to point out the need to establish alternatives to our present methadone programs that would minimize the harms of opiate use. Opiate substitute programs in Canada should be expanded and made more accessible and flexible. Programs modeled after some of those being used in Europe (including the UK) would help drug users deal not only with their drug-use problems but also with HIV/AIDS. Injection drug users are the major risk group for AIDS in North America, and they are also the means by which HIV is most frequently transmitted to the general population. In the context of HIV/AIDS, the notion of a drug-free existence becomes meaningless, since the primary concern is reducing the impact of the syndrome on the lives of users and their families and friends. This harm reduction may need to include heroin or a substitute for the remaining life of the infected user if this reduces the spread of infections, both by and to the user, or otherwise improves quality of life. Methadone programs in Canada need to change to meet changing demands, and they need to change quickly. As the above examples indicate, models from around the world are available from which Canada can learn a great deal.

Strategies and programs must be sensitive to the cultures and needs of the Aboriginal community. Greater collaboration is needed between all national, provincial, and community-based HIV/AIDS service providers serving the Aboriginal population on and off reserve. These comments clearly apply not only to considerations pertaining to methadone maintenance but to syringe exchange, education, and treatment as well.

Common to the more effective programs are flexibility, options, user friendliness, and being part of a truly comprehensive harm-reduction program. This includes working with HIV-positive users who are on HIV therapies. There should be closer links between prescribing physicians and general hospitals and AIDS clinics to ensure a more efficient response to the current and future needs of the HIV-infected population. Staff in prescribing programs and physicians with clients on prescribed drugs can be trained to deal with the special needs of clients with HIV or AIDS.