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

Injection Drug Use and HIV/AIDS:

Legal and Ethical Issues

Health Canada Santé Canada

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Caveat
This paper does not constitute legal advice nor should it be relied upon as such. Persons with questions regarding the legality of particular conduct should seek legal advice from a lawyer.

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Executive Summary

The Urgency of the Situation

Canada is in the midst of a public health crisis concerning HIV/AIDS and injection drug use. The spread of HIV (and other infections such as hepatitis C) among injection drug users merits serious and immediate attention. The number of HIV infections and AIDS cases attributable to injection drug use has been climbing steadily. By 1996, half the estimated new HIV infections were among injection drug users.

Drug-injection risk behaviours among injection drug users are prevalent. The sharing of needles is an efficient mode of transmission of HIV (and other infections) and is relatively common among injection drug users. Sharing of other injection drug equipment such as spoons/cookers, filters and water – known as "indirect sharing" – is also associated with HIV transmission. A shift from heroin use to increasing use of cocaine may be a significant factor in the escalation of HIV prevalence and incidence. Cocaine users may inject as often as twenty times a day. Rates of injectable cocaine use are especially high in Vancouver, Toronto, and Montréal, but cocaine use is also an increasing problem in other cities, including Calgary, Winnipeg, and Halifax.

Sexual risk behaviours are also prevalent. Many injection drug users are involved in unprotected commercial sex, and condom use with regular and casual opposite-sex partners is low, as it is among a substantial minority of male injection drug users who have sex with men.

The dual problem of injection drug use and HIV infection is one that ultimately affects all Canadians. However, some populations are particularly affected: women, street youth, prisoners, and Aboriginal people.

The Project

Two major reports released in 1997 concluded that the legal status of drugs in Canada contributes to the difficulty of 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 further examine the legal and ethical issues surrounding HIV/AIDS and injection drug use. In three national workshops held between November 1997 and March 1999, the Network brought together 50 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 identified by workshop participants; and
3. propose recommendations on the priority issues.

Issues Analyzed

Seven priority issues have been analyzed:

1. What is the impact of the current legal status of drugs and drug use on efforts to prevent HIV infection among injection drug users and on the provision of care, treatment, and support to drug users with HIV/AIDS? 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 illegal drug use is permitted 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 illegal drugs on the immune system; (b) the absence of research on the interactions between HIV/AIDS drugs and illegal drugs; and (c) the exclusion of drug users from clinical trials involving HIV/AIDS drugs?
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 illegal drugs and their effects?
7. What legal and ethical considerations should be taken into account when implementing needle exchange and methadone maintenance programs directed at reducing the harms from drug use?

The Current Legal Status of Drugs

The first issue studied is the impact of the current legal status of drugs on injection drug users as well as on efforts to prevent HIV infection, and to provide care, treatment, and support to injection drug users.

The *Controlled Drugs and Substances Act* takes a punitive approach to individuals who consume illegal drugs. Persons who possess drugs listed in the Schedules to the Act can be imprisoned for several years. Injection drug users can also be prosecuted for trafficking, which includes not only selling, but also giving, administering, transporting, or delivering an illegal drug. They may also be incarcerated if they possess needles, syringes, or other drug equipment that contain traces of illegal substances.

The criminal approach to drug use has several effects on drug users, health-care professionals, and society at large, and may increase rather than decrease harms from drug use:

- Because drugs can only be purchased on the underground market, they are of unknown strength and composition, which may result in overdoses or other harm to the drug user.
- Fear of criminal penalties and the high price of drugs cause users to consume drugs in more efficient ways, such as by injection, that contribute to the transmission of HIV and hepatitis.
- Because sterile injection equipment is not always available, drug users may have to share needles and equipment, which further contributes to the spread of infections.
- Significant resources are spent on law enforcement, money that could instead be spent on prevention and the expansion of treatment facilities for drug users.

The most pronounced effect, however, is to push drug users to the margins of society. This makes it difficult to reach them with educational messages that might improve their health and reduce the risk of further spread of disease; makes users afraid to go to health or social services; may make service providers shy away from providing essential education on safer use of drugs, for fear of being seen to condone use; and fosters anti-drug attitudes toward the user, directing action toward punishment of the "offender" rather than fostering understanding and assistance.

Alternatives to the current approach to drug use and drug users in Canada are possible. Alternatives within the current prohibitionist policy that would not require any changes to the current legal framework could include the de facto decriminalization of cannabis possession for personal use, medical prescription of heroin, explicit educational programs, etc. Alternatives to the current prohibitionist approach may require that Canada denounce several international drug-control conventions.

From an ethical perspective, considering alternatives to the current approach is not just possible, but required. Ethical reflection on the current situation involves recognizing those aspects of current drug policy that must be reversed because of their intolerable social consequences. Ethical principles demand a more coherent and integrated drug policy that can withstand rational inquiry and scrutiny, is responsive to the complexity of the current situation,

and allows for public and critical discussion. Ethical reflection should lead to a recognition of what components of current drug policy need to be maintained, what components need to be reversed because of their intolerable social consequences, and what alternatives need to be explored and submitted to controlled experiments.

On the basis of these observations, two overarching directions for future action were identified:

1. Canada must reverse the negative impacts of the current legal status of drugs on drug users and on those who provide services to drug users; and
2. Canada must move to adopt alternatives to the current approach to reducing drug use, and the harms of drug use, among Canadians.

In the long term, the goal must be to institute a more constructive alternative to the current legal status of drugs. In the short term, within the current legal and policy framework, implementing the recommendations in the Report would allow for better provision of care, treatment, and support to drug users, and for more effective efforts to prevent HIV infection and other harms associated with drug use.

Drug Use and Provision of Health and Social Services

The second issue studied is the use of illegal drugs by drug users in health-care and social-service facilities.

Tolerating drug use in the course of providing health care and social services departs from the principle of abstinence as the only acceptable premise, standard, or goal in providing services to drug users. The principle of abstinence is deeply ingrained in drug policies and programs in North America. It has been reconsidered, however, in Europe and other jurisdictions, where there have been a variety of social experiments, including tolerating "injecting rooms" where drug users can come together, obtain sterile injection equipment, condoms, advice, and medical attention. In Canada, the Task Force on HIV, AIDS and Injection Drug Use recommended that the continuum of available services be enhanced by providing treatment options that do not require total abstinence from all drugs.

From a legal perspective, health-care professionals who tolerate or permit illegal drug use on the premises may be prosecuted under the *Controlled Drugs and Substances Act* or subjected to disciplinary action (such as fines or the loss of their professional licence). However, there are a number of ways that criminal prosecution or liability may be avoided. For example, a health-care professional may claim that allowing the use of illegal drugs was a *necessity* for the treatment of the patient; may be able to arrange for access to a specific drug under existing legislation; or might obtain exemptions under section 56 or section 55 of the *Controlled Drugs and Substances Act*.

From an ethical perspective, the *basic issue* is the ethical imperative to mobilize and maintain services necessary to assist people. To adhere to the ethic of humanity, behaviour should not be imposed on drug-dependent individuals that exceeds their current levels of ability. *Derivative ethical issues* include: whether it is ethically justifiable to allow or tolerate illegal drug use in residences and within palliative care services; how a facility can permit illegal drug use without losing its licence or social authorization to operate; staff

concerns about condoning or even collaborating in offences against the law; to what extent staff can allow a resident to continue to deteriorate under drug use; and what rules should be established and enforced regarding tolerable and intolerable behaviour.

Among other things, the Report recommends that, in the short term, guidelines for ethical practice be developed by professional associations that address the situations of service providers who may be caught between legal constraints and ethical imperatives in providing services to HIV-positive drug users. The Report also offers long-term recommendations, including decriminalizing possession of currently illegal drugs for personal use.

Treatment

The third issue studied is poor access to medical treatment by HIV-positive injection drug users. 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?

Antiretroviral therapy (ART) has led to significant improvements in the health and quality of life of many HIV-positive people, and has reduced morbidity and mortality. HIV-positive drug users, however, are not offered ART with the same frequency as other HIV-positive people.

From a legal perspective, withholding medical treatment from HIV-positive drug users or compelling abstinence as a condition of medical treatment may, in some circumstances, violate sections 7 and 15 of the *Canadian Charter of Rights and Freedoms*. Federal and provincial human rights legislation also prohibit discrimination against persons with disabilities, which likely provides some protection for drug-dependent persons.

It is also unethical to insist on cessation of drug use as a condition of medical treatment if this is beyond the capabilities of the drug user. It is also unjust to judge people as likely to be noncompliant with ART simply because they are drug users, and to withhold ART on this basis. Adherence to treatment is profoundly affected by systems of care. When the health-care system is adapted to meet the needs of socially marginalized and indigent persons, there is a vast improvement in adherence to treatment. Ethics therefore requires that we not reduce an assessment of treatment compliance to simply the personal characteristics of people with HIV/AIDS. At the same time, there may be situations where it may be justified to delay or, at the extreme, refuse ART. Such a decision would be ethically unjustifiable if it is reached without honouring the characteristics of an authentic healing relationship: humanity (respect for the full biological and biographical particularity of the person with HIV/AIDS), 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).

The Report therefore recommends that:

- as a matter of principle, treatment should not be refused or withheld simply because someone is a drug user;
- the governing approach in providing care and treatment to HIV-positive drug users should be to adapt the therapeutic regimen to the needs of the

individual, rather than require the individual to adapt to a preconceived clinical ideal;
- a network of physicians with experience in providing care and treatment to drug users be developed;
- simpler HIV drug regimens be developed to make adherence easier; and
- support be provided to drug users who require assistance in adhering to their regimen of HIV therapies, including outreach programs to deliver HIV therapies to drug users.

Prescription of Opiates and Controlled Stimulants

The fourth issue studied is the prescription of opiates and controlled stimulants to drug users. The *Controlled Drugs and Substances Act* and the Narcotic Control Regulations strictly delineate the circumstances in which a physician can prescribe a narcotic. Physicians and other health-care professionals who violate these laws and regulations may be subject to criminal prosecution.

Currently, methadone is the only opioid approved for the long-term treatment of drug-dependent persons in Canada. Although methadone maintenance has many advantages, it is not appropriate treatment for all drug-dependent persons. In contrast to such countries as Switzerland, Britain, Australia, and the Netherlands, Canada has been reluctant to allow medical professionals to prescribe other drugs to treat drug users. Scientists in Canada would like to conduct a study of heroin for the treatment of drug-dependent persons. Health Canada approval is required in order to conduct such a trial. Canada's status as a signatory to international drug-control treaties does not present an insurmountable barrier to the prescription of controlled substances.

From an ethical perspective, those who oppose methodologically sound clinical trials of opiate-assisted treatment programs are promoting the "therapeutic abandonment" of those who cannot benefit from existing treatments.The Report therefore recommends that, in the short term, pilot projects in prescribing heroin, cocaine, and amphetamine be initiated in Canada. In the long term, plans should be developed for the prescription of opiates and controlled stimulants and for the decriminalization of currently illegal drugs.

Drug Users and Studies of HIV/AIDS and Illegal drugs

The fifth issue studied is the lack of adequate clinical information upon which to base treatment of HIV-positive drug users. Drug users are excluded from studies of HIV/AIDS drugs. In addition, there is little research into the effects of currently illegal drugs on the immune system, or the interaction between HIV/AIDS drugs and currently illegal drugs. This hinders the provision of optimal care, treatment, and support to HIV-positive injection drug users. HIV-positive drug users may have a wider range of immunological deficiencies and a different history of the disease; they may respond differently to treatments than other HIV-positive persons.

It is ethically wrong to exclude drug users from the clinical studies that would yield the data necessary to guide both HIV-positive drug users and their health-care professionals in making *informed* treatment decisions. Trials involving illegal drugs are certainly permissible under current Canadian law. However, it may be difficult to argue that the *Canadian Charter of Rights and*

Freedoms or human rights acts require the inclusion of drug users in clinical trials of HIV/AIDS drugs.

The Report therefore recommends that:

- barriers to the participation of drug users in clinical trials be removed;
- community groups and drug users develop recruitment strategies to encourage participation of HIV-positive drug users in clinical trials;
- pharmaceutical companies take a leadership role in promoting studies that test the effect of HIV/AIDS drugs on injection drug users; and
- the Medical Research Council and pharmaceutical companies develop a comprehensive research agenda that identifies priorities in research for injection drug users.

Information about the Use and Effects of Illegal Drugs

The sixth issue studied is the provision of accurate and complete information on illegal drugs to health-care providers, drug users, and the general public. Many professionals in the health fields do not receive adequate education on drug use and the treatment of patients who use drugs. Many existing materials and programs educating youth and the general public are based on abstinence principles. The lack of (accurate) information has a negative impact on the provision of care, treatment, and support of drug users, as well as on efforts to prevent HIV infection and other harms. More programs that provide accurate, non-judgmental information are therefore required.

Legally, the development of educational material about drugs generally falls within the discretion of government health officials. It would be difficult if not impossible to use the law to address the failure to provide accurate information about illegal drugs and their effects.

Ethical principles, however, dictate that individuals in society have accurate and comprehensive information on all matters that require decision, choice, and action. In particular, for health-care professionals to honour the principles of lucidity, fidelity, and humanity, they must obtain accurate information on illegal drugs so they can best care for their patients.

The Report therefore recommends that:

- accurate, unbiased, and non-judgmental information be developed on illegal drugs for health-care providers, drug users, and members of the public;
- ministries of education and health undertake an evaluation of school programs on illegal drugs; and
- universities and colleges ensure that the curricula of health-care professionals include materials, presentations, and discussions of harm-reduction approaches to drug use.

Needle Exchange and Methadone Maintenance Treatment

The seventh, and last, issue studied is the concern that the rules and regulations governing needle exchange programs and methadone maintenance treatment programs may render these programs less effective at reaching their goals.

With regard to needle exchange programs, several barriers have been identified. There is concern that not enough needles are available to injection drug

users at needle exchange sites; sometimes, individual quotas are imposed and used syringes may be required in exchange for sterile syringes. Needle exchange sites are generally located in large cities and may be centralized in these cities. Hours of operation may be restricted. Many pharmacists are reluctant to provide sterile syringes to injection drug users. All of these factors limit access to sterile syringes. Finally, persons involved in needle exchange programs as well as drug users may be criminally liable for traces of illegal drugs found in drug equipment.

With regard to methadone maintenance treatment programs, in comparison with other countries such as Australia, Switzerland, and Belgium, Canada has a low number of heroin-dependent persons who are treated with methadone. Many programs adhere to an abstinence philosophy and some do not offer comprehensive services such as primary health care, counseling, or education. In order for physicians to prescribe methadone, they must obtain federal authorization pursuant to the Narcotic Control Regulations. The provinces have the authority, which is delegated in some jurisdictions to the College of Physicians and Surgeons, to establish the rules under which physicians and patients may participate in methadone programs. Rules in methadone programs that hinder effective treatment of injection drug users include: limits on doses that may be prescribed by physicians; mandatory urine testing while being observed by staff; and restrictions on "carries" or take-home medication.

As a result of such restrictions, drug users often experience their interactions with needle exchange or methadone maintenance programs as disrespectful of their individual dignity, as invading their privacy, or as severely infringing their autonomy. These are not only ethical concerns, but also practical barriers to achieving the objectives of such programs.

The Report therefore recommends that:

- methadone maintenance treatment programs become available to persons in all parts of Canada, including in rural and semi-urban areas, and in prisons;
- review of the methadone regulations and rules be undertaken to ensure that they are in conformity with the care, treatment, and support needs of injection drug users; and
- needle exchange programs become easily accessible to injection drug users in all parts of Canada, including in prisons.

Recommendations

A total of 66 recommendations, some of which have been mentioned above, are made throughout the Report, and are reproduced in Appendix A. Most of these can be implemented in the short term, without making any radical changes to Canada's drug laws. Some are designated as longer-term, requiring changes to these laws. The recommendations are directed to those whose policies and actions (or inactions) affect Canada's ability to prevent the further spread of HIV and other infections among injection drug users, and to provide care, treatment, and support to those already living with HIV or AIDS. This includes: the federal, provincial/territorial, and municipal governments, colleges of physicians and surgeons, professional associations of health-care workers, universities, and community-based agencies. Implementing these recommendations must become an urgent priority.

Background

The Urgency of the Situation

The spread of HIV (and hepatitis C) among injection drug users in Canada merits serious and immediate attention. The number of HIV infections attributable to injection drug use has been climbing steadily since the beginning of the epidemic in the early 1980s. By 1996, half of the estimated new HIV infections were among injection drug users.[1] There have been several studies on prevalence and incidence of HIV among injection drug users in the larger cities of Canada, but a rise in the number of injection drug users with HIV infection has also been observed outside major urban areas.[2] As stated by Health Canada, "given the geographic mobility of injection drug users and their social and sexual interaction with non-users, this dual problem of injection drug use and HIV infection is one that ultimately affects all of Canadian society."[3]

Some of the studies undertaken to date in different parts of Canada illustrate the urgency of the problem.[4]

- HIV prevalence among injection drug users in Montréal increased from approximately five percent prior to 1988 to 19.5 percent in 1997;[5]
- In Vancouver, HIV prevalence among injection drug users increased from about four percent in 1992-93 to 23 percent in 1996-97;[6]
- HIV prevalence among injection drug users in Toronto increased from 4.8 percent in 1992-93 to 8.6 percent in 1997-98;[7]
- In Ottawa, a 1992-93 study[8] of injection drug users found an HIV prevalence of 10.3 percent among persons who attended needle exchange programs; a 1996-97 study showed that prevalence had increased to 20 percent;[9]

[1] Bureau of HIV/AIDS, STD and TB Update Series, Laboratory Centre for Disease Control. *Risk Behaviours Among Injection Drug Users in Canada.* Ottawa: Health Canada HIV/AIDS *Epi Update*, May 1999.

[2] Bureau of HIV/AIDS STD and TB Update Series, Laboratory Centre for Disease Control. *HIV/AIDS Among Injection Drug Users in Canada.* Ottawa: Health Canada HIV/AIDS *Epi Update*, May 1999.

[3] Ibid.

[4] Ibid.

[5] C Hankins, T Tran, D Desmarais et al. Moving from Surveillance to the Measurement of Programme Impact: CACTUS – Montreal Needle Exchange Programs. *Canadian Journal of Infectious Diseases* 1997; 8 (Suppl A): 28A (abstract 223); and Division of Epidemiology, Bureau of HIV/AIDS, STD, and TB, LCDC, Health Canada. *Inventory of HIV Incidence/Prevalence Studies in Canada.* Ottawa: Health Canada, April 1998, cited in *HIV/AIDS Among Injection Drug Users in Canada*, supra, note 2.

[6] RG Mathias, PD Riben, MT Schecter, JE Bardsley. *Evaluation of the Needle Exchange Program in the Cities of Vancouver and Victoria.* Final Report to NHRDP, 1994, cited in *HIV/AIDS Among Injection Drug Users in Canada*, supra, note 2.

[7] P Millson, T Myers, L Calzavara et al. Prevalence of HIV and Other Blood-Borne Viruses and Associated Behaviors in Ontario IDUs. Proceedings of the 7th Annual HIV Epidemiology Meeting organized by the Division of HIV Epidemiology, Bureau of

HIV/AIDS, STD and TB, LCDC, Health Canada, 12-14 November 1998, cited in *HIV/AIDS Among Injection Drug Users in Canada*, supra, note 2.

[8] B Baskerville, L Leonard, S Holtz. *Evaluation of the SITE Project: A Pilot HIV Prevention Program for Injection Drug Users, Ottawa-Carleton Health Department*. Final Report to NHRDP, March 1994, cited in *HIV/AIDS Among Injection Drug Users in Canada*, supra, note 2.

[9] M Alary, C Hankins, R Parent et al. *Updated Results from the SurvIDU Surveillance Network*. Proceedings of the 7th Annual HIV Epidemiology Meeting organized by the Division of HIV Epidemiology, Bureau of HIV/AIDS, STD and TB, LCDC, Health Canada, 12-14 November 1998; and Division of Epidemiology, Bureau of HIV/AIDS, STD and TB, LCDC, Health Canada. *Inventory of HIV Incidence/Prevalence Studies in Canada*. Ottawa: Health Canada, May 1999, cited in *HIV/AIDS Among Injection Drug Users in Canada*, supra, note 2.

[10] Ibid.

[11] See also R Remis, M Millson, C Major. *The HIV Epidemic Among Injection Drug Users in Ontario: The Situation in 1997*. Prepared for the AIDS Bureau, Ontario Ministry of Health, 1997; and C Poulin, P Fralick, E Whynot et al. The epidemiology of cocaine and opiate abuse in urban Canada. *Canadian Journal of Public Health* 1998; 89: 234.

[12] J Blanchard, L Elliott. *Winnipeg Injection Drug Epidemiology Study*. Interim results, April 1999.

[13] Task Force on HIV, AIDS and Injection Drug Use. *HIV, AIDS, and Injection Drug Use: A National Action Plan*. Ottawa: Canadian Public Health Association & Canadian Centre on Substance Abuse, 1997, at 6.

[14] Ibid.

[15] *Risk Behaviours Among Injection Drug Users in Canada*, supra, note 1, with reference to S Strathdee, D Patrick, S Currie et al. Needle exchange is not enough: lessons from the Vancouver injecting drug use study. *AIDS* 1997; 11: 59-65; R Parent, M Alary, C Hankins et al. HIV among IDUs: Second Surveillance Year of the SurvIDU Network. 6th Annual Canadian Conference on HIV/AIDS Research, Ottawa, May 1997. *Canadian Journal of Infectious Diseases* 1997; 8(Suppl A): 27A (abstract 220); and Hankins et al, supra, note 5.

[16] *Risk Behaviours Among Injection Drug Users in Canada*, supra, note 1.

[17] Strathdee et al, supra, note 15.

[18] Poulin et al, supra, note 11.

[19] Ibid.

[20] Ibid.

- Data from needle exchange programs in Québec City and smaller cities in Québec indicate that HIV prevalence among injection drug users is 9 percent in Québec City and as high as 9.6 percent in some semi-urban areas.[10]

Similar findings[11] were documented in the *1999 Winnipeg Injection Drug Epidemiology Study* (WIDE),[12] which showed that in Manitoba injection drug use is an increasingly important risk factor for HIV; and that approximately one in every three new diagnoses is now among injection drug users.

Such findings have led the National Task Force on HIV/AIDS and Injection Drug Use to conclude that "Canada is in the midst of a public health crisis concerning HIV/AIDS and injection drug use."[13] The National Task Force stated that

> despite clear indications of an escalating problem since the mid-1980s and the use of a variety of approaches to address it, the spread of HIV among injection drug users is increasing, as is the incidence of hepatitis and tuberculosis. Epidemics continue to emerge among new populations. Intersecting issues – HIV and AIDS, substance use, mental health – create multiple problems in an individual for which there is no prescribed course of intervention or treatment.[14]

Risk Behaviours

Drug injection and sexual risk behaviours among injection drug users are prevalent. The sharing of needles is a very efficient mode of transmission of HIV (and other infections), and is relatively common among injection drug users. Studies across Canada have shown that about 40 percent of injection drug users report borrowing used needles in the six months prior to the study; a slightly lower percentage report lending their needle in this time frame.[15] Sharing of other injection drug equipment such as spoons/cookers, filters and water – known as "indirect sharing" – is also associated with HIV transmission.[16]

A shift from heroin use to increasing use of cocaine may be a significant factor in the escalation of HIV prevalence and incidence.[17] Cocaine users typically have a high injection rate; they may inject as much as twenty times a day.[18] According to a 1998 study published in the *Canadian Journal of Public Health*, the rates of injectable cocaine are especially high in Vancouver, Toronto, and Montreal.[19] Cocaine use, however, is also an emerging problem in other cities, including Calgary, Winnipeg, and Halifax.[20]

In addition to drug-injection risk behaviours, sexual risk behaviours are prevalent among injection drug users. Many are involved in unprotected commercial sex:

- In a Vancouver study, 23 percent of injection drug users had been paid for sex in the six months prior to being interviewed.[21]
- Among needle exchange program attendees in Ottawa and in Québec, 9.4 percent of men and 47.3 percent of women reported having sex-trade clients. Of these, 63 percent of men and 35 percent of women never or only sometimes used condoms with clients.[22]

Condom use is also low among injection drug users with regular and casual opposite-sex partners.[23] A substantial minority of male injection drug users report unprotected intercourse with same-sex partners.[24]

The Populations Most Affected

As pointed out above, the dual problem of injection drug use and HIV infection is one that ultimately affects all of Canadian society.[25] However, some populations are particularly affected.

Women injection drug users in Canada are at high risk of HIV infection. For women, the proportion of AIDS cases attributed to injection drug use increased from 0.5 percent during the period before 1989 to 16.1 percent during 1989-93 and to 25.8 percent during 1994-98.[26] For men, the increase over this same time period has also been pronounced, but less dramatic: from 0.8 percent to 3.1 percent and finally to 7.6 percent.

Injection drug use is a severe problem among street youth: for example, one-third of a sample of Montreal street youth had injected drugs in the previous six months. Among those who were regular injectors, 47 percent had shared needles in this time frame.[27]

Injection drug use is also a problem among prisoners.[28] Estimates of HIV prevalence among prisoners vary from one to four percent in men and from one to ten percent in women, and in both groups infection is strongly associated with a history of injection drug use.[29] Once in prison, many continue injecting:

- A study on HIV transmission among injection drug users in Toronto found that over 80 percent had been in prison since beginning to inject drugs, with 25 percent sharing injecting equipment while in custody.[30]
- In a study among incarcerated men and women in provincial prisons in Montréal, 73.3 percent of men and 15 percent of women reported drug use while incarcerated; of these, 6.2 percent of men and 1.5 percent of women injected drugs.[31]
- In a study among inmates of a provincial prison in Québec City, 12 of 499 inmates admitted injecting drugs during imprisonment, of whom 11 shared needles and three were HIV-positive.[32]
- In a federal prison in British Columbia, 67 percent of inmates responding to one survey reported injection drug use either in prison or outside, with 17 percent reporting drug use *only in prison*.[33]
- In the 1995 inmate survey conducted by the Correctional Service of Canada, 11 percent of 4285 federal inmates self-reported having injected since arriving in their current institution. Injection drug use was particularly high in the Pacific Region, with 23 percent of inmates reporting injection drug use.[34]

Finally, existing data clearly indicate that Aboriginal people are overrepresented in groups most vulnerable to HIV, such as sex-trade workers and prisoners. In particular, they are overrepresented among inner-city injection drug use communities, including among clientele using needle exchange programs and counseling/referral sites.[35]

[21] *Risk Behaviours Among Injection Drug Users in Canada*, supra, note 1 at 2, with reference to Strathdee et al, supra, note 15.

[22] Ibid, with reference to Parent et al, supra, note 15.

[23] Ibid, with reference to Parent et al, supra, note 15; 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.

[24] Ibid, with reference to Parent et al, supra, note 15; Strathdee et al, supra, note 15.

[25] *HIV/AIDS Among Injection Drug Users in Canada*, supra, note 2.

[26] Ibid.

[27] *Risk Behaviours Among Injection Drug Users in Canada*, supra, note 1 at 3, with reference to E Roy, N Haley, J Boivin et al. Injection Drug Use among Street Youth: A Dynamic Process. Paper presented at the 6th Annual Conference on HIV/AIDS Research, Ottawa, May 1997. *Canadian Journal of Infectious Diseases* 1997; 8 (Suppl A): 29A (abstract 225).

[28] See HIV/AIDS in Prisons – Info Sheet 2: High-Risk Behaviours behind Bars. Montréal: Canadian HIV/AIDS Legal Network, 1999.

[29] *HIV/AIDS Among Injection Drug Users in Canada*, supra, note 2 at 2-3, with references. See also: HIV/AIDS in Prisons – Info Sheet 1: HIV/AIDS and Hepatitis C in Prisons: The Facts. Montréal: Canadian HIV/AIDS Legal Network, 1999.

[30] P Millson. Evaluation of a Programme to Prevent HIV Transmission in Injection Drug Users in Toronto. Toronto: Toronto Board of Health, 1991.

[31] C Hankins et al. Prior risk factors for HIV infection and current risk behaviours among incarcerated men and women in medium-security correctional institutions – Montreal. *Canadian Journal of Infectious Diseases* 1995; 6(Suppl B): 31B.

[32] A Dufour et al. HIV prevalence among inmates of a provincial prison in Québec City. *Canadian Journal of Infectious Diseases* 1995; 6(Suppl B): 31B.

[33] T Nichol. Bleach Pilot Project. Second unpublished account of the introduction of bleach at Matsqui Institution, dated 28 March 1996. On file with Legal Network.

[34] Correctional Service Canada. *1995 National Inmate Survey: Final Report*. Ottawa: The Service (Correctional Research and Development), 1996, No SR-02 at 138.

[35] *HIV, AIDS and Injection Drug Use: A National Action Plan*, supra, note 13 at 8, with reference.

The Project

The pharmacological effects of the illegal drugs used by [injection drug users] are not, in themselves, necessarily harmful.
– D McAmmond, 1997

Background

The 1997 Consultation Report

In 1997, the AIDS Care, Treatment and Support Program, Health Canada, released *Care, Treatment and Support for Injection Drug Users Living with HIV/AIDS: A Consultation Report*.[36] The report identifies issues that need to be addressed in order to provide effective HIV/AIDS care, treatment, and support to injection drug users (particularly those who are street-involved or marginalized), and proposes initiatives that might begin to address these issues. The issues were identified by participants involved in a national consultation process.

Legal issues are among the key areas singled out for action by the report. Two sets of issues are highlighted:[37]

- *Legal status of drugs as a direct cause of harm*: The report states that the pharmacological effects of the illegal drugs used by injection drug users are not, in themselves, necessarily harmful. It points out that much of the harm is secondary, caused either by the legal status of the drugs themselves, or by things such as dangerous injecting practices, criminal behaviour, and uncertain drug strength or purity that results directly from the legal status of drugs.
- *Legal status of drugs as a barrier to treatment*. The report further states that the legal status of drugs is a barrier to client utilization of much of the addiction and medical services system. It points out that treatment approaches, admission protocols, and staff and public attitudes are more reflective of the legal status of drugs than the treatment needs of the client population. Finally, it states that approaches to managing substance use that are being tried with considerable success in some other countries (eg, prescribing of

[36] D McAmmond. *Care, Treatment and Support for Injection Drug Users Living with HIV/AIDS: A Consultation Report.* Ottawa: Health Canada, March 1997.

[37] Ibid at 14.

heroin or cocaine) are not available in Canada because of legal restrictions on medical practice.

The report suggests two possible initiatives to address these legal issues:[38]

- Exploration of how Canada's drug laws and regulatory framework could be made more flexible by permitting health-care professionals and others involved in the treatment of HIV-positive injection drug users to offer alternative drug therapies in controlled settings.
- Analysis of experience elsewhere (eg, England, the Netherlands) to determine the possibilities in Canada for medical delivery of heroin and cocaine within controlled treatment settings for injection drug users with HIV/AIDS.

The Task Force on HIV, AIDS and Injection Drug Use

In May 1997 the Task Force on HIV, AIDS and Injection Drug Use, a joint project of the Canadian Public Health Association and the Canadian Centre for Substance Abuse, released its National Action Plan.[39] The Plan sets out specific strategies to address issues related to policy and legislation, prevention and intervention, treatment, Aboriginal populations, and women.

Like the Health Canada consultation report, the Task Force observes that the legal status of drugs in Canada contributes to the difficulties encountered in addressing HIV among injection drug users, affecting not only the behaviour of drug users, but also the attitudes of professionals and the structure of programs.[40] To address these difficulties, the National Action Plan recommends a series of specific actions, including that:

- the *Criminal Code* be changed to provide specific exemptions under the legislation to ensure that physicians may prescribe narcotics (eg, heroin, cocaine) to drug users, and to decriminalize the possession for personal use of small amounts of currently illegal drugs;[41]
- steps be taken to eliminate discriminatory attitudes toward drug users with HIV/AIDS by promoting recognition in the justice system and in law enforcement that addiction is better dealt with as a health and social issue than a criminal one;[42]
- access to methadone treatment be improved by revoking the need for physicians to be authorized by the federal Minister of Health to prescribe methadone, reducing barriers to being on methadone (including current restrictions on carrying privileges), and setting up low-threshold methadone maintenance programs with the explicit goal of reducing injection frequency among heroin users;[43] and
- the continuum of available services and information be enhanced by providing treatment options that do not require total abstinence from all drugs, ensuring that each person seeking treatment is evaluated and offered antiretroviral drug therapies that meet current standards of care, initiating clinical trials of prescription morphine, heroin, and cocaine, and supporting research and providing information on interactions between pharmaceutical/therapeutic and currently illegal drugs.[44]

The legal status of drugs in Canada contributes to the difficulties encountered in addressing HIV among injection drug users.

[38] Ibid at 20.

[39] *HIV, AIDS and Injection Drug Use: A National Action Plan*, supra, note 13.

[40] Ibid at 13.

[41] Ibdi at 15.

[42] Ibid at 18.

[43] Ibid at 20.

[44] Ibid at 23.

The Next Step

As a follow-up to *Care, Treatment and Support for Injection Drug Users Living with HIV/AIDS: A Consultation Report* (and in light of the recommendations of the Task Force), the HIV/AIDS Programs, Policy and Coordination Division, Health Canada, recognized the need to identify possible solutions to some of the legal and ethical dilemmas related to (1) providing care, treatment, and support to injection drug users with HIV/AIDS, and (2) reducing the harms of drug use. To this end, the Canadian HIV/AIDS Legal Network was funded to bring together individuals working in the area of HIV/AIDS and injection drug use to identify, analyze, and make recommendations on priority legal and ethical issues.

This report is one of the outcomes of that consultation. Another is *Injection Drug Use and HIV/AIDS: Legal and Ethical Issues. Background Papers*,[45] a compilation of all papers written as background materials for the consultation.

Overview of the Project

Objectives

The objectives of the Project were to:

- bring together key participants from across Canada with knowledge and experience in issues related to HIV/AIDS and injection drug use;
- identify the legal and ethical issues related to (1) providing care, treatment, and support to drug users with HIV/AIDS, and (2) reducing the harms of drug use;
- identify priority issues that need to be analyzed in more detail;
- analyze these priority issues from the perspective of policy, law, and ethics in three background papers; and
- prepare a report that summarizes the discussion of the participants, the analysis of the papers, and the recommendations of the participants on the priority issues and potential solutions; as well as a volume of background materials, containing the background papers.

Phase I

Phase I of the Project started in November 1997 and ended on 31 March 1998. In this first phase of the Project, two workshops were organized, eight priority legal and ethical issues were identified, background papers on four of these issues were written, and a report on the consultation was prepared.[46] This first phase was funded by the AIDS Care, Treatment and Support Program, Health Canada. Co-funding was provided by the Québec Ministry of Health and Social Services.

The first workshop – discussion

Providers of services to injection drug users, members of non-governmental organizations, federal and provincial government representatives, and drug users, met on 17 November 1997. The purpose of the workshop was to discuss legal and ethical issues related to injection drug use and HIV/AIDS. Twelve issues in particular were discussed. What follows is a record of the discussion. The record aims to present as faithfully as possible the various comments of the participants, organized under common headings.

[45] Canadian HIV/AIDS Legal Network. *Injection Drug Use and HIV/AIDS: Legal and Ethical Issues. Background Papers*. Montréal: The Network, 1999.

[46] T de Bruyn. *HIV, Injection Drug Use, and Care, Treatment and Support: Legal and Ethical Issues. Report on the Consultation*. Prepared for the AIDS Care, Treatment and Support Program, HIV/AIDS Policy, Coordination and Programs Division, Health Canada, by the Canadian HIV/AIDS Legal Network. Montréal, March 1998.

The dehumanization of drug users

Injection drug users are stigmatized and dehumanized as a result of the illegal status of drugs, the treatment of drug users by law enforcers and by society in general, and misinformation about drug use. Drug users are seen by many members of the public (and some health-care professionals) not as persons but as criminals and "vectors" of disease.

Workshop participants stated that programs aimed at preventing harms due to drug use are often themselves dehumanizing in the way they treat users and regulate their conduct. Some of the programs do not meet users' needs. Reference was made to one-for-one needle exchange programs and restrictions imposed in methadone programs, such as limited carries and mandatory urine testing of drug users.

Issues of advocacy for drug users

It is common today to hear calls from within the HIV/AIDS movement for greater advocacy or organizing by drug users. Some drug users would support this and be empowered by greater advocacy, but other drug users would not. Workshop participants emphasized that drug users must be free to choose whether to advocate or organize, and that it must be safe for them. A drug user who goes public will be subjected to scrutiny and risks loss of employment, loss of housing, difficulty in obtaining insurance, or inability to get a mortgage. Support to address these consequences is needed if drug users are to organize. It was suggested that it could be effective if parents of drug users organize and advocate on behalf of users.

Problems confronted by service providers

The stigma associated with drug use often extends to individuals who provide services to drug users, such as physicians, nurses, social workers, counselors, and persons who provide housing. Some of these service providers may be marginalized within their profession, and may not be granted much credence when they provide information that counters prevailing programs and myths about injection drug use and injection drug users. They may be censored in their efforts to educate the public. They may be unable to change the context in which they try to provide services to drug users. These service providers have encountered problems securing the requisite funding for innovative programs both to treat and to prevent harms associated with injection drug use. Organizations that provide housing to injection drug users have been seen as facilitating interaction among users and have been accused of encouraging the spread of HIV and other transmissible diseases. The legal and ethical issues that emerge when health-care providers, drug treatment facilities, or housing administrators permit drug use on the premises of hospitals, drug treatment centres, or hospices, were raised by workshop participants.

Organizations that provide services to drug users

Workshop participants identified various problems with organizations that provide services to injection drug users, including treatment for their addictions, social services, and HIV/AIDS services. It was stated that some organizations that profess to take a harm-reduction approach may, by the restrictions they impose or by the manner in which they interact with their client population, demean drug users and consequently discourage them from seeking assistance. Concerns were raised about funding harm-reduction programs

in organizations that until recently required drug users to abstain from drug use as a precondition for participation in programs. It was said that such organizations must demonstrate that they have accepted what it means to provide services to drug users who continue to use.

Another problem that was identified is that, in order to obtain funding for programs, organizations may resort to "token" representation from drug users. However, once funding is obtained, these organizations may develop programs that fit the needs of the organization or its staff rather than the needs of drug users.

Finally, workshop participants pointed out that HIV/AIDS organizations are at various stages in incorporating drug users and programs for drug users into their work. Some organizations are ready to employ and serve drug users, others are not. Drug users who are employed by HIV/AIDS organizations may find that they are marginalized within the organization.

Mixed messages about harm reduction

There is no consensus on the meaning to be attributed to the concept of harm reduction. Health clinics, syringe-exchange programs, drug treatment programs, and housing facilities often subscribe to different notions of harm reduction. As a result, drug users receive conflicting messages. For example, outreach to street youth may coincide with expulsion of street youth from public spaces. Or provision of sterile syringes in exchange for used syringes may be regulated in a way (eg, one-for-one exchange) that does not match users' needs. Such mixed messages undermine the effectiveness of services in reducing the harms of drug use.

Methadone maintenance programs

Discussion centred on the accessibility of methadone programs to injection drug users and on the deficiencies of current programs. Methadone programs are operated by the provinces. While some have expanded their programs and made them more accessible to drug users, others still have no programs. Colleges of Physicians and Surgeons in some of the provinces are responsible for the regulation of the methadone programs and for the accreditation of physicians in dispensing this treatment. In Alberta, the methadone program is operated by the Alberta Alcohol and Drug Abuse Commission (AADAC), an agency of the government of Alberta. Workshop participants questioned whether the methadone regulations and rules in the provinces serve to obstruct rather than encourage injection drug users to participate in programs.

Individuals who have participated in methadone programs expressed concerns regarding mandatory urine testing, penalties imposed for the use of drugs, and limitations on carries. The manner in which some physicians and other health-care providers have interacted with them have made them feel devalued.

Finally, some question whether methadone maintenance itself entails more harms than illegal drugs, since methadone is so addictive. Some would rather see people using heroin than methadone.

Syringe distribution

Workshop participants emphasized that to exchange sterile syringes for used syringes on a one-for-one basis does not work: it does not meet the needs of drug users for sterile syringes and for non-controlling services. They pointed

out that many programs no longer exchange syringes on a one-for-one basis, but provide as many syringes as the user requires (syringe distribution).

Syringes should be more easily and more cheaply available from pharmacies.

According to workshop participants, syringes should be more easily and more cheaply available from pharmacies. It was reported that in some metropolitan areas only one pharmacy was known to be willing to sell syringes to a drug user.

Inequities for prisoners

HIV/AIDS prevention, treatment, support, and care are not as available to prisoners as to persons outside the penal system.

Workshop participants commented that HIV/AIDS prevention, treatment, support, and care are not as available to prisoners as to persons outside the penal system. Prisoners who inject drugs do not have access to sterile syringes and consequently are at greater risk of HIV infection, hepatitis C, and other transmissible diseases. In addition, in many jurisdictions prisoners who were on methadone prior to incarceration cannot continue treatment in prison, and no jurisdiction currently permits prisoners to begin methadone treatment in prison.

Pregnant women who inject drugs

Concerns were expressed by participants at the workshop regarding the mandatory treatment of pregnant women who inject drugs. Child protection legislation and mental health statutes have been resorted to by provincial authorities to confine women and to compel them to follow prescribed treatment during the course of their pregnancy. There have been suggestions that criminal laws be enacted to punish the behaviour of pregnant women who consume drugs. Such actions by the state were considered by several workshop participants to be a deterrent to the use of prenatal care by women drug users and to constitute a deprivation of the liberty of the individual.

Limited treatment options

Workshop participants pointed out that options for both HIV/AIDS treatment and drug treatment are or may be limited for drug users.

Many HIV/AIDS physicians find themselves in a dilemma in deciding whether to prescribe current antiretroviral therapies for HIV-positive drug users because they perceive a high risk of noncompliance among drug users in taking the therapies and the consequent development and transmission of drug-resistant strains of HIV. Drug users argue that many people have difficulty adhering to complex treatment regimens, and that what is required are simpler regimens that everyone could manage more easily.

Regarding drug treatment, certain options, such as prescribing heroin or cocaine, are not available in Canada. Furthermore, it is difficult for both drug users and physicians to obtain accurate pharmacological information about illegal drugs and about their interactions with prescription drugs, including drugs for HIV/AIDS.

It was said that clinical trials are required to investigate opiates and their alternatives, stimulants and their alternatives, and interactions between illegal drugs and prescription drugs (particularly HIV/AIDS drugs). In addition, drug users should be included in clinical trials of HIV/AIDS drugs.

Lack of housing and social support

The lack of affordable housing for drug users is a problem, particularly in large urban centres such as Vancouver and Toronto. It was observed that the limited

availability of social assistance for drug users increases the number of homeless persons; being homeless makes it more difficult to regularly access other services and to adhere to treatment regimens.

The legal status of drugs

Workshop participants felt that the current legal status of drugs creates almost insurmountable barriers to HIV/AIDS prevention, and the treatment, support, and care of injection drug users. This is consistent with views expressed during the preparation of the Consultation Report on *Care, Treatment, and Support for Injection Drug Users Living with HIV/AIDS*:[47] "we know what to do, but we are not able to do it for a variety of reasons," chief among them the barriers created by the legal status of drugs and drug use. Participants in both consultations felt that, unless this changes, it will be difficult to make progress in drug treatment and HIV prevention.

Workshop participants stated that consideration should be given to an alternative regulatory regime that would be more effective in reducing the harms associated with drug use and that would ensure the quality and safety of currently illegal drugs. Finally, the lack of information about what the public actually thinks about drug use is an impediment to changing the current status. Research and accurate information on illegal drugs and public attitudes is required.

The first workshop – identification of priority issues

Workshop participants identified the following eight priority issues for further analysis:

1. What is the impact of the current legal status of drugs and drug use on efforts to prevent HIV infection among injection drug users and on the provision of care, treatment, and support to drug users with HIV/AIDS? 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 illegal drug use is permitted 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 illegal drugs on the immune system; (b) the absence of research on the interactions between HIV/AIDS drugs and illegal drugs; (c) the exclusion of drug users from clinical trials involving HIV/AIDS drugs?
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 illegal drugs and their effects?
7. What legal and ethical considerations should be taken into account when implementing needle exchange and methadone maintenance programs directed at reducing the harms from drug use?

[47] Supra, note 36.

8. What are the legal and ethical considerations that arise regarding mandatory drug treatment for pregnant women drug users?

The first four of these issues were selected for analysis in Phase I of the Project.

The background papers

After the workshop, three individuals prepared 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.

The second workshop

A second workshop, held in February 1998, reconvened the participants from the first workshop, the authors of the papers, and some additional participants. The papers prepared by David Roy, Diane Riley, and Eugene Oscapella were discussed and reviewed. Workshop participants proposed recommendations on each of the issues. The recommendations were made with a view to: what should be achieved in the short term (short-term goals); what should be achieved in the long term (long-term goals); and what are the means toward achieving these short-term and long-term goals.

After the workshop, the authors revised their papers in light of the discussion and information provided, and a report on Phase I of the Project was prepared.

The report on Phase I

The report, prepared by Theodore de Bruyn, summarized the discussion at the first workshop; listed the legal and ethical issues that were identified at the first workshop, including the four priority issues selected for further analysis; summarized the commentary contained in the three papers on each of the four priority issues; and listed the recommendations of the workshop on further action on the four priority issues.

Phase II

In May 1998, funding was secured to continue work on the Project. The three additional priority issues analyzed in this phase of the Project were:

1. What legal and ethical issues are raised by (a) the absence of clinical trials on the impact of illegal drugs on the immune system; (b) the absence of research on the interactions between HIV/AIDS drugs and illegal drugs; and (c) the exclusion of drug users from clinical trials involving HIV/AIDS drugs?
2. 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 illegal drugs and their effects?
3. What legal and ethical considerations arise in the implementation of needle exchange and methadone maintenance programs directed at reducing the harms from drug use?

As in Phase I of the Project, Riley, Oscapella, and Roy prepared background papers on these issues based on their particular perspective and expertise.

Analysis of the eighth issue identified as a priority – legal and ethical issues associated with HIV-positive pregnant drug users – was postponed, as extensive analysis is underway on legal and ethical issues related to HIV testing of pregnant women.[48] It was felt that that analysis should be completed before a study of the distinct but related legal and ethical issues associated with HIV-positive pregnant drug users is undertaken.

The national workshop

A national workshop, held on 15-16 March 1999, brought together 40 people from across Canada with knowledge and experience in issues relating to HIV/AIDS and injection drug use. This included many of the participants in the first two workshops, as well as other drug users, members of AIDS organizations, staff in needle exchange programs, federal and provincial government health officials, employees of organizations that provide methadone programs and other services to drug users, physicians, ethicists, researchers, policy analysts, and a member of an Aboriginal organization.[49] At the workshop, the background papers prepared by Riley, Oscapella, and Roy were discussed, and participants made recommendations for further action on the three priority issues. After the workshop, the authors of the background papers revised their papers in light of the discussion and information provided at the workshop. Finally, the background 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 report

This report on Phases I and II of the Project contains an analysis of the seven priority issues addressed in both phases, and the recommendations developed by the workshop participants. The report is based on the background papers, the report on the first phase of the consultation, and the comments made by workshop participants at the three workshops held between November 1997 and March 1999. However, further research was undertaken on each of the seven issues. This has entailed an examination of court decisions, legal treatises and articles, scientific and medical publications, as well as public health materials. Additional discussions have taken place with members of HIV/AIDS organizations, physicians engaged in trials of HIV/AIDS drugs, public health officials, staff from provincial Colleges of Physicians and Surgeons, scientists, persons involved in organizations that operate methadone programs, and officials from Health Canada.

The volume of background materials

As a companion to this report, a volume containing all the background papers written during Phases I and II of the Project has been produced.[50]

Next Steps

The Project does not end with the release of this Report and the volume of background materials. The Network will focus on disseminating the contents of the report to various audiences. This will include preparing info sheets summarizing the main results to make the information in the Report and background materials more accessible, and publishing articles on the Project in

[48] See L Stoltz, L Shap. *HIV Testing and Pregnancy: Medical and Legal Parameters of the Policy Debate*. Ottawa: Health Canada, 1999. Reproduced in part in *Canadian HIV/AIDS Policy & Law Newsletter* 1999; 4(2/3): 42-44. See also B Hoffmaster, T Schrecker. An ethical analysis of HIV testing of pregnant women and their newborns. *Canadian HIV/AIDS Policy & Law Newsletter* 1999; 4(4): (forthcoming).

[49] See Appendix B for a list of workshop participants.

[50] Supra, note 45.

the *Canadian HIV/AIDS Policy & Law Newsletter* and other publications. In conjunction with others, as appropriate, the Network will undertake follow-up activities directed to the implementation of the recommendations presented in this Report.

The Current Legal Status of Drugs

What is the impact of the current legal status of drugs and drug use on efforts to prevent HIV infection among injection drug users and on the provision of care, treatment, and support to drug users with HIV/AIDS? What are alternatives to the current legal regime on drugs and drug use? What legal and ethical issues are raised?

This chapter points out that Canadian law takes a punitive approach to individuals who consume illegal drugs, criminalizing not only trafficking of certain drugs, but also their possession. The effects of this approach on drug users, health-care professionals, and society at large suggest that it exacerbates rather than reduces harms from drug use. However, some alternatives are possible without drastic changes to Canada's current prohibitionist legal framework. Other, more far-reaching alternatives to the current approach may require that Canada denounce several international drug-control conventions.

This chapter explains the ethical requirement to consider alternatives to the current approach. Ethical reflection must lead to a recognition of which components of current drug policy need to be maintained, which components need to be reversed, and which alternatives need to be explored and submitted to controlled experiments.

There are two overarching directions for future action: (1) Canada must reverse the negative impacts of the current legal status of drugs on drug users and on those who provide services to drug users; and (2) Canada must move to adopt alternatives to the current approach to reducing drug use and the harms of drug use among Canadians. Implementing the recommendations below would allow for better provision of care, treatment, and support to drug users,

and for more effective efforts to prevent HIV infection and other harms associated with drug use.

Legal and Policy Analysis

The Criminalization of Drugs in Canada

Since the early 1900s, criminal statutes aimed at the control of particular drugs have existed in Canada.[51] The *Opium and Drug Act*[52] promulgated in 1911, and then the *Narcotic Control Act*[53] and the *Food and Drugs Act*[54] governed drug use for about 85 years. Then, in May 1997, the *Controlled Drugs and Substances Act* (CDSA)[55] was proclaimed.[56] The Act repealed the *Narcotic Control Act* and parts III and IV of the *Food and Drugs Act*, and consolidated under one statute the major provisions on illegal drugs.[57] Several of the offences in these predecessor statutes are now contained in the CDSA.

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

Offences relating to controlled substances

In general, the *unauthorized* possession,[58] manufacture,[59] cultivation,[60] trafficking[61] (which includes selling, administering, giving, transferring, transporting, sending, or delivering), export[62] and import[63] 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, amphetamine, and a large array of other substances as "controlled."

As well, it is an offence to seek or obtain a controlled substance from a practitioner, such as a physician, without disclosing particulars relating to the acquisition of the Scheduled substance within the preceding thirty days. This offence is commonly referred to as double-doctoring.[64]

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.[65]

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.[66]

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 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

[51] PJ Giffen, S Endicott, S Lambert. *Panic and Indifference: The Politics of Canada's Drug Laws*. Ottawa: Canadian Centre on Substance Abuse, 1991.

[52] *Opium and Drug Act*, SC 1911, c 17.

[53] *Narcotic Control Act*, SC 1960-61, c 35.

[54] *Food and Drugs Act*, SC 1962-63, c 15, Parts III and IV.

[55] *Controlled Drugs and Substances Act*, SC 1996, c 19.

[56] SI/97-47, Can Gaz Part II, 14 May 1997.

[57] B MacFarlane. *Drug Offences In Canada*. Toronto: Canada Law Book Inc, 3rd edition, 1997, at 2-14 and 2-15.

[58] Section 4(1).

[59] Section 7(1).

[60] Section 7(1).

[61] Section 5(1).

[62] Section 6(1).

[63] Ibid.

[64] Section 4(2).

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

[66] Section 2(2).

possess a "controlled substance." As stated by Bruckner,[67] both needle exchange workers and drug users who are in possession of contaminated equipment are required to rely on police or prosecutorial discretion to avoid criminal convictions.[68]

Drug paraphernalia: instruments and literature

Other than its broad definition of "controlled substance" that extends to injection equipment containing traces of illegal drugs, the CDSA does not address injection equipment. However, 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."[69] 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.[70] 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.[71] While mere possession of illegal drugs is an offence (under the CDSA), this is not the case with mere possession of drug paraphernalia.

Drug literature

In addition, an Ontario court has held that the prohibition in section 462.2 *Criminal Code* in relation to "literature" for illicit drug use violates freedom of expression as guaranteed in section 2(b) of the *Canadian Charter of Rights and Freedoms* and is consequently of no force or effect. In *Iorfida* v *MacIntyre*,[72] it was stated that section 462.2 of the Code is aimed at censorship; it is designed to prohibit the dissemination of a particular perspective on a specific topic. The court observed that advocacy of illegal drug use may be inspired by many different reasons: by humane considerations such as medical uses, for the spiritual purposes of religious movements, or for artistic considerations of novelists and other fiction writers. Macdonald J held that silencing messages, even a "distasteful message aimed at popularizing or glamourizing socially undesirable forms of activity,"[73] is inimical to free expression in a democratic society. The statements of Cory JA (as he then was) in *R* v *Kopyto*[74] was cited by the Ontario court for this proposition:

> The concept of free and uninhibited speech permeates all truly democratic societies. Caustic and biting debate is, for example, often the hallmark of election campaigns, parliamentary debates and campaigns for the establishment of new public institutions or the reform of existing practices and institutions. The exchange of ideas on important issues is often framed in colourful and vitriolic language. So long as comments made on matters of public interest are neither obscene nor contrary to the laws of criminal libel, citizens of a democratic state should not have to worry unduly about the framing of their expression of ideas. The very life-blood of democracy is the free exchange of ideas and opinions. If these exchanges are stifled, democratic government itself is threatened.

The words "or literature" were severed from section 462.2 of the *Criminal Code* by the court in *Iorfida* v *MacIntyre*.

[67] T Bruckner. *The Practical Guide to the Controlled Drugs and Substances Act*. Toronto: Thomson Canada Limited, 1997, at 20.

[68] Ibid.

[69] *Criminal Code*, RSC 1985, c C-46 at s 462.2.

[70] Ibid at s 462.1.

[71] Ibid.

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

[73] Ibid at 408.

[74] *R* v *Kopyto* (1987), 39 CCC (3d) 1 (Ont CA).

Drug instruments

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

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*."[75] "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."[76]

Syringes should 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.[77] 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.[78]

In many cases, 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). Because "selling" is defined to include simply "distributing," even if not done in exchange for money, 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 illegal 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 illegal 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.

International Law

Canada is a signatory to several international drug conventions: the *Single Convention on Narcotic Drugs, 1961*, the *Convention on Psychotropic Substances, 1971*, and the United Nations *Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988*.[79] The 1961 and 1972 conventions focus on limiting the possession of drugs to scientific and medical purposes. The 1988 Convention, containing provisions on money laundering and international cooperation, is primarily directed at trafficking.

The international drug conventions contain provisions that permit States to "denounce" a treaty (ie, remove itself as a signatory).[80] 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 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.[81] Finally, there is strong language in each of the

[75] *Food and Drugs Act*, supra, note 54, at s 2.

[76] Ibid.

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

[78] *Spindloe*, ibid; *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.

[79] Bruckner, supra, note 67 at 7.

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

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

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 addition to conviction or punishment."[82] Again, the punitive approach may be tempered within the existing legal framework.

The Impact of the Current Legal Status

The CDSA, like the predecessor legislation, the *Narcotic Control Act*, takes a punitive approach to individuals who consume illegal drugs. Persons who use such drugs are perceived as criminals deserving of punishment rather than individuals who may need treatment or medical care.[83] As discussed in a 1994 Québec report, *Drug Use and the HIV Epidemic*, this "zero tolerance" approach subscribes to repression and stigmatization of individuals who consume controlled substances.[84]

Drug-control policies in the United States, and to a large extent also in Canada, are founded on the belief that drug use will be curtailed if the supply of drugs (and drug paraphernalia) is aggressively cut off and if drug users, cultivators, sellers, and manufacturers are severely punished. Thus, the essence of drug-control policy is to create a scarcity of drugs and drug injection equipment, and to punish drug users.[85]

The criminal law approach to drugs has several effects on drug users, health-care professionals, and society at large. In situations in which certain drugs are not legally available, these drugs can only be purchased on the black market.[86] Drugs obtained in this manner are of uncertain strength and composition, which may result in overdoses or other adverse effects on the health of the user.[87] In addition, resort is often had to criminal activities, in particular personal and property crimes such as robberies and burglaries, in order to pay the high prices of drugs on the black market. Criminal prosecutions mean that many drug users spend years of their lives in and out of prison. A significant amount of resources are spent on law enforcement at the expense of prevention programs or the expansion of treatment facilities for injection drug users.[88] As some authors have observed, exorbitant sums of money have been spent on an ineffective criminal approach.[89]

This punitive approach also contributes to the transmission of HIV and hepatitis. Fear of being subjected to criminal penalties and the high price of drugs cause users to consume drugs in efficient ways, such as by injection, a very high-risk activity for transmission of HIV and hepatitis.[90]

The most pronounced effect, however, is to push drug users to the margins of society. This makes it difficult to reach them with educational messages that might improve their health and reduce the risk of further spread of disease; makes users afraid to go to health or social services; may make service providers shy away from providing essential education on safer use of drugs, for fear of being seen to condone use; and fosters anti-drug attitudes toward the user, directing action toward punishment of the "offender" rather than fostering understanding and assistance.[91]

Efforts to combat the epidemic of HIV infection associated with drug use have highlighted the polarization in Canada between proponents of two opposing points of view: the zero-tolerance, abstentionist, punitive model, and the harm-reduction or public health model.[92] By contrast to the punitive model,

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

[83] See DC Des Jarlais, D Paone, S Friedman et al. Public health then and now: regulating controversial programs for unpopular people – methadone maintenance and syringe exchange programs. *American Journal of Public Health* 1995; 85: 1577 at 1579.

[84] Gouvernment du Québec, Ministère de la Santé et des Services sociaux, Centre de coordination sur le sida. *Drug Use and the HIV Epidemic: A Frame of Reference for Prevention*. Montréal, June 1994, at 25.

[85] L Goldstein. Law and Policy. In: J Stryker (ed). *Dimensions of HIV Prevention: Needle Exchange*. California: The Kaiser Forums, 1993, at 35.

[86] J Millar. HIV, Hepatitis, and Injection Drug Use in British Columbia – Pay Now or Pay Later? June 1998; P Albrecht. Narcotics Distribution: The Battle Between AIDS and Repression in the Legal Arena. In: D Lewis, C Gear, M Laubi Loud, D Langenick-Cartwright (eds). *The Medical Prescription of Narcotics: Scientific Foundations and Practical Experiences*. Bern: Hogrefe and Huber Publishers, 1997, at 50.

[87] Millar, supra, note 86; and A Goldstein. *Addiction: From Biology to Drug Policy*. New York: WH Freeman and Company, 1994, at 263.

[88] Poulin et al, supra, note 11; Millar, supra, note 86 at 4. See also the discussion of costs in C Hankins. Syringe exchange in Canada: good but not enough to stem the HIV tide. *Substance Use and Misuse* 1998; 33: 1129 at 1131.

[89] B Beyerstein, B Alexander. Why treat doctors like pushers? *Canadian Medical Association Journal* 1985; 132: 337 at 340.

[90] American Bar Association. *AIDS: The Legal Issues*. Discussion Draft of the American Bar Association AIDS Coordinating Committee, Washington, DC, 1988, at 233.

[91] *HIV, AIDS and Injection Drug Use: A National Action Plan*, supra, note 13 at 11, 13.

[92] *Drug Use and the HIV Epidemic*, supra, note 84 at 25.

harm reduction seeks to minimize the harm drug users cause to themselves, their sexual partners, their families, and society at large.[93] Drug dependence is perceived as a public health problem.[94] As Nadelmann states, rather than attempt to wean all illicit drug users off drugs by punitive means, harm reduction attempts to reduce the likelihood that drug users will contact or spread HIV and other infections, overdose on drugs of unknown potency or purity, or otherwise harm themselves or others.[95]

In the context of drug use, is it appropriate to use the criminal law rather than other means of social intervention? In a Government of Canada report entitled *The Criminal Law in Canadian Society*, the following principle was articulated with respect to the use of criminal sanctions:

> The criminal law should be employed only to deal with conduct for which other means of social control are inadequate or inappropriate, and in a manner which interferes with individuals rights and freedoms only to the extent necessary for the attainment of its purpose.[96]

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.

As argued by Oscapella and Elliott,

> 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 freedoms," has not been demonstrated as necessary. But there is much (including experiences of other countries) that suggest 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.
>
> Furthermore, 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.[97]

Options within a Prohibitionist Drug Policy

Options available in Canada

There are several options available for reducing the harms that derive from present drug laws. Some of these are possible without fundamentally changing the current approach to drug use. For example, 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.

[93] Ibid.

[94] Goldstein, supra, note 87 at 235, 268; and R Newcombe. The Reduction of Drug-Related Harm: A Conceptual Framework for Theory, Practice, and Research. In: PA O'Hare, R Newcombe, A Mathews, EC Buning, E Drucker (eds). *The Reduction of Drug-Related Harm*. London: Routledge, 1992, at 1.

[95] E Nadelmann. Progressive Legalizers, Progressive Prohibitionists, and the Reduction of Drug Related Harms. In: N Heather, A Wodak, E Nadelmann, PA O'Hare (eds). *Psychoactive Drugs and Harm Reduction: From Faith to Science*. London: Whurr Publishers, 1993, at 36.

[96] Government of Canada. *The Criminal Law in Canadian Society*. Ottawa: August 1982, at 52-53.

[97] E Oscapella, R Elliott. Injection Drug Use and HIV/AIDS: A Legal Analysis of Priority Issues. In: *Injection Drug Use and HIV/AIDS: Legal and Ethical Issues. Background Papers*, supra, note 45.

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.[98] 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."[99]

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."[100]

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 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 for patients to possess it.[101] Access to currently illegal drugs for therapeutic purposes may also be allowed under other legislation. Pursuant to Health Canada's Special Access Program, formerly known as the Emergency Release Program, physicians can apply to the federal government to be permitted to prescribe illegal drugs for therapeutic purposes.

Furthermore, the government has the discretion to adopt a policy of non-prosecution for particular activities such as, for example, the possession of controlled substances for the purposes of treatment.

Finally, alternatives to full prosecution are available to prosecutors, and alternative sentencing measures are available to judges. These may offer a partial solution in some cases for minimizing the harms associated with criminal prohibitions on drug use. Amendments to the *Criminal Code* were introduced in 1995 (Bill C-41) that provide a statutory framework for prosecutors to *divert* offenders accused of "minor" possession or trafficking offences from the

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

[99] Ibid at s 60.

[100] Ibid at s 56.

[101] Narcotic Control Regulations, CRC, c 1041.

traditional system to "alternative measures programs" rather than proceed with a criminal prosecution resulting in a criminal record for the user.

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.[102] In line with the recommendations reiterated in numerous previous reports,[103] these reforms indicate that imprisonment should be a sentence of last resort after consideration of other available sanctions.[104]

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 persons who are eligible for this program enter into judicially supervised participation in drug treatment and rehabilitation. Accused persons 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.[105]

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. Furthermore, this diversion policy still leaves largely intact the damaging "war on drugs," with its extensive spending on the criminal justice system.

Experiences in other countries

Other countries that have adopted a criminal law approach to drugs have extensive experience with some of the options available for reducing the harms that derive from drug laws.

In the United Kingdom, the medical prescription of drugs with the exception of opium is permitted. The country has extensive harm-reduction programs such as needle exchanges, methadone programs, and explicit educational materials on drugs and drug use.

In some states of Australia, there is de facto decriminalization of possession of cannabis and of cultivation for personal use. There have been proposals for trials of heroin. As in the UK, extensive harm-reduction programs exist in Australia in the form of syringe exchange programs, extensive methadone programs, and explicit educational materials.

There is de facto decriminalization in the Netherlands for the possession of cannabis for personal use. Heroin trials have also been proposed. The harm-reduction programs available to drug users include methadone programs, educational materials on drug and drug use, and syringe exchange programs.

In Switzerland, the prescription of heroin, cocaine, and methadone to drug users is permitted. Harm-reduction programs include syringe exchange programs, methadone programs, and injection rooms.[106]

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

[103] Canadian Committee on Corrections. *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; Law Reform Commission of Canada. *Our Criminal Law*. Ottawa: Minister of Supply and Services Canada, 1976; Government of Canada, *The Criminal Law in Canadian Society*, supra, note 96; *Sentencing Reform: A Canadian Approach: Report of the Canadian Sentencing Commission*. Ottawa: Supply & 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.

[104] *Criminal Code*, supra, note 69 at s 718.2.

[105] Ibid.

[106] See D Riley. Injection Drug Use and HIV/AIDS: Policy Issues. In: *HIV/AIDS and Injection Drug Use: Legal and Ethical Issues. Background Papers*, supra, note 45. See also: E Nadelmann, J McNeely, E Drucker. International Perspectives. In: J Lourinson, P Ruiz, R Millman, J Langrod (eds). *Substance Abuse: A Comprehensive Textbook*. Baltimore: Williams and Wilkins, 1997.

Alternatives to a Prohibitionist Drug Policy

Other options could be implemented only if the current drug laws were changed. The most obvious is to move completely away from criminalizing drugs and paraphernalia to regulating them by non-criminal means, using a harm-reduction philosophy.

Decriminalizing the possession of small amounts of currently illegal drugs for personal use has already been recommended by the Task Force on HIV, AIDS and Injection Drug Use.[107] This would require "denouncing" aspects of the three international drug conventions to which Canada is a party. This is feasible under those conventions (see above).

Ethical Considerations

Ethical Issues Raised

Both "direct and inverse insights" must be examined in order to comprehend the complexity of drug use in contemporary society.[108] Inverse insights focus on those aspects of drug policy that should be reversed because of their adverse social consequences. A criminal approach to drug use:

- has failed to achieve the objectives for which it was designed;
- has the effect of excluding drug users from the community;
- misuses limited resources, contrary to principles of distributive justice;
- stimulates the establishment of socially destructive forces; and
- is responsible for the decline of the humanity that is essential to civilized societies.[109]

Direct insights are a result of a process of inquiry, reflection, discussion, and experimentation that ultimately yields an integrative and constructive response to the complexities of drug use in society. This involves pursuing positions rather than counter-positions.[110] Positions promote development because they are consistent among themselves and, most important, because they are modified in accordance with the demands of inquiring intelligence and reflective reason.[111] Evidence is a prerequisite for decisions and actions. By contrast, counter-positions lack coherence with the demands of inquiring intelligence and reflective reason, and contain irrationalities and errors. Although counter-positions ought to be reversed, a lengthy period of time may elapse before this occurs.[112]

Existing policies, laws, and regulations governing drugs in Canada lack coherence. It is unethical not to consider alternatives to drug laws and policies that harbour counter-positions.[113]

Pursuing Integrative Complexity

Integrative complexity[114] requires that analysis and action be commensurate with the complexity of the particular situation. According to principles of ethics, this involves the capacity for "differentiation" and "constructive" integration.

"Differentiation" means that there are different ways of examining a particular problem, and that a problem will remain unresolved if it is not diagnosed in its complexity. Integration refers to the ability to deal with differentiation in a constructive way – that is, by recognizing which components of the problem,

[107] *HIV, AIDS and Injection Drug Use: A National Action Plan*, supra, note 13, at 15, 37.

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

[109] D Roy. Injection Drug Use and HIV/AIDS: An Ethical Analysis of Priority Issues. In: *Injection Drug Use and HIV/AIDS: Legal and Ethical Issues. Background Papers*, supra, note 45.

[110] Lonergan, supra, note 108 at 387-390, 680-683.

[111] Roy, supra, note 109.

[112] Ibid.

[113] Ibid.

[114] PE Tetlock. Integrative Complexity of Policy Reasoning. In: S Kraus, RM Perloff (eds). *Mass Medical Political Thought*. California: Sage, 1985; PE Tetlock. Monitoring the integrative complexity of American and Soviet policy rhetoric: what can be learned. *Journal of Social Issues* 1988; 44: 101-131; and RJ McCoun, JF Kahan, J Gillespie, J Rhec. A content analysis of the drug legalization debate. *Journal of Drug Issues* 1993; 23: 615-629.

such as Canada's existing drug policies, need to be maintained and which require reversal. It also involves the examination of alternatives to the current system.[115]

Pursuing Public Discussion

Integrative complexity cannot be achieved without public discussion. Two principles are fundamental to public discussion: the freedom and opportunity to speak publicly, and the freedom and opportunity to challenge and respond. Roy states:

> 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.[116]

It is fundamental to the pursuit of public discussion, for the furtherance of positions rather than counter-positions, and for the pursuit of integrative complexity, that matters of fact, meaning, and belief be distinguished. In the context of laws, policies, and regulations that govern psychoactive drugs, the concepts can be applied in the following manner:

> Matters of Fact: The refusal to conduct empirical studies to resolve disputes respecting matters of fact, such as the therapeutic advantages of marijuana or the possible benefits of heroin maintenance, constitutes adherence to counter-positions.
>
> Matters of Meaning: Strategies of silence, selective information, and exaggeration to deter people from using drugs involves the distortion of meaning for manipulative ends.
>
> Matters of Belief: Controversies that involve contradictory fundamental beliefs are difficult to resolve, particularly if resolution means attainment of a compromise or policy with which everyone agrees. The most that can be achieved in such circumstances is political accommodation that maintains the coherence of society, that protects the civil process of public discourse, that fosters respect for personal conscience, and that does not tolerate the subjection of moral minorities to discrimination or harassment.[117]

Overarching Directions for Future Action

Two overarching directions for future action were identified:

- Canada should reverse the negative impact of current drug laws on drug users and on providers of services to drug users.
- Canada should introduce an alternative approach to the reduction of drug use and to the harms associated with the use of drugs.

[115] Roy, supra, note 109.

[116] Ibid.

[117] Ibid.

Recommendations

1. In the long term, federal and provincial governments should establish a more constructive alternative to the current legal framework, and provide the research, educational, and social programming required to reduce the harms of drug use. Governments, and all Canadians, must:
   - acknowledge the extent of drug use and the diversity of drug users in Canada;
   - acknowledge that Canada's current drug laws have a disproportionate impact on the most vulnerable in Canadian society, including Aboriginal people, racial minorities, and women;
   - acknowledge that current laws increase rather than decrease the harms from drug use and, in particular, marginalize drug users;
   - recognize the human rights of drug users, and recognize the ways in which current laws and treaties violate the human rights of drug users in Canada; and
   - if necessary, denounce international drug-control conventions if these present insurmountable barriers to implementing more constructive drug-control policies and laws in Canada that are based on a harm-reduction model.
2. In the short term, under the existing legal framework, the federal and provincial governments should fund research on the differential impact of current drug legislation, policies, and practices according to race, class, gender, and other socioeconomic factors.
3. In consultation with drug users and community-based agencies providing services to drug users, the federal and provincial governments should assess the positive outcomes of initiatives such as diversion policies, alternative measures, and the pilot projects implementing such alternatives. If assessed favourably, such initiatives should be further expanded to temper the punitive approach currently reflected in Canadian drug laws and policies.
4. The federal government should make use of its regulatory and exemption powers under current legislation to expressly exclude injection equipment containing traces of illegal drugs from the definition of "controlled substance" in the *Controlled Drugs and Substances Act*.
5. The federal government should take the necessary steps to clarify that those operating needle exchange or distribution programs are not liable to criminal prosecution under the drug paraphernalia provisions of the *Criminal Code* for the "sale" of "instruments or literature for illicit drug use."
6. The federal government should use its regulatory and exemption power under the *Controlled Drugs and Substances Act* to decriminalize the possession of small amounts of currently illegal drugs for personal use, at least when medically prescribed by a qualified and authorized health-care professional.
7. The federal government should ensure that there is a fair and timely process by which Canadians and their health-care professionals can apply for medical access to currently illegal drugs.

Drug Use and Provision of Health and Social Services

What legal and ethical issues arise in circumstances in which drug use is permitted 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?

Tolerating drug use in the course of providing health care and social services departs from the principle of abstinence as the only acceptable premise, standard, or goal in providing services to drug users. That principle is deeply ingrained in drug policies and programs in North America. It has, however, been questioned by service providers who feel they cannot provide proper care, treatment, and support if they must insist on their clients being and staying abstinent. For example, some hospices for people with HIV/AIDS feel they should not close their doors to a client or potential client who is not (yet) ready to stop using. Some hospitals might prefer to allow their patients to continue using while receiving HIV/AIDS-related medical care, rather than let them suffer withdrawal symptoms that could interfere with their HIV/AIDS treatment.

This chapter shows that, from a purely legal perspective, health-care professionals who tolerate or permit illegal drug use on the premises may be prosecuted under the CDSA, or face professional discipline such as fines or the suspension or revocation of their licences. However, there are a number of ways in which criminal prosecution or liability may be avoided. Health professionals must also confront ethical questions. This chapter makes several detailed recommendations to address situations of service providers who may

be caught between legal constraints and ethical imperatives in providing services to HIV-positive drug users.

Legal Issues

Criminal Liability

In situations in which illegal drug use is permitted or tolerated in health care and social service facilities, both drug users and service providers may be subject to criminal prosecution.[118]

Possession

They may be criminally liable for possession of illegal drugs in contravention of section 4 of the CDSA.[119] 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")[120]

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 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 in order to hold this person criminally responsible.

Note also that health-care providers or other staff who collect used syringes or store drug paraphernalia that contain residue of illegal drugs may be found guilty of possession, given the broad definition of "controlled substance" in the CDSA.

Trafficking

Those working in a facility providing health care or other services might also be exposed to trafficking charges. The CDSA defines the offence of "trafficking" very broadly, as including "to sell, administer, give, transfer, transport, send, or deliver the substance."[121] Furthermore, the definition includes "offering" to do any of these things.

If those working in a facility 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

[118] For a lengthier explanation of how these substantive drug offences have been interpreted in the law, see Oscapella & Elliott, supra, note 97.

[119] Supra, note 55.

[120] Ibid at s 4(3).

[121] Ibid at s 2(1). See Oscapella & Elliott, supra, note 97 for a detailed discussion of how courts have interpreted the different modes of trafficking.

which a patient or resident, of necessity, asks the employee to physically obtain a controlled substance for them.

Aiding and abetting

It is an offence to aid or abet another person to commit a crime. Section 21 of the *Criminal Code* states:

> 21. (1) Every one is a party to an offence who
> (a) actually commits it;
> (b) does or omits to do anything for the purpose of aiding any person to commit it; or
> (c) abets any person in committing it.

A person who aids or abets is a party to the offence committed and is guilty of the same crime as the principal (the person who actually commits the offence). "Aiding" has been defined as providing assistance in the commission of the offence, while "abetting" means being present at the crime and encouraging or procuring the commission of the offence.[122]

The Supreme Court of Canada has ruled that a person is not guilty of aiding or abetting merely because they are present at the scene of the crime.[123] Rather it is necessary to establish that they encouraged the principal, committed an act that facilitates the commission of the offence by the principal, or acted so as to prevent someone else from interfering with the crime being committed.[124]

In order to be liable as aider or abettor, the accused person must intend to assist the principal.[125] It is not necessary for the person to know all the details of the offence; it is sufficient that he be "aware of the type of crime that will be committed"[126] and knows "the circumstances necessary to constitute the offence he is accused of aiding."[127]

Criminal negligence

Prosecutors could also conceivably bring charges of *criminal negligence causing death*[128] or *bodily harm*[129] 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."[130] 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.

In order to establish this offence, it must be proved by the prosecution beyond a reasonable doubt that the accused did something or failed to do something that they had a legal duty to do. The duty may be imposed by statute or the common law.[131] Many facilities have a duty to safeguard the well-being of the patient and others at the institution. It could be argued that facilitating the use of drugs or perhaps tolerating it constitutes a breach of a legal duty.

In addition, 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 be applied, the weight of judicial authority indicates that the accused's

[122] K Roach. *Criminal Law*. Concord, Ontario: Irwin Law, 1996, at 80.

[123] *Dunlop and Sylvester* v *The Queen*, (1979), 47 CCC (2d) 93 at 111.

[124] Ibid.

[125] *R* v *Morgan* (1993), 80 CCC (3d) 16 at 21 (Ont CA).

[126] *R* v *Yanover and Gerol* (1985), 20 CCC (3d) 300 at 329 (Ont CA).

[127] *R* v *FW Woolworth Co Ltd* (1974), 18 CCC (2d) 23 at 32 (Ont CA).

[128] Section 220 *Criminal Code*.

[129] Section 221 *Criminal Code*.

[130] Section 219 *Criminal Code*.

[131] *R* v *Coyne* (1958), 124 CCC 176 (NSSC App Div).

conduct must demonstrate a "marked departure" from the standard of behaviour expected of a "reasonably prudent person in the circumstances."[132]

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.

Civil Actions

Disciplinary action against health-care professionals

Professional codes of conduct may prohibit health-care professionals from allowing patients to ingest or inject illegal drugs. Physicians, nurses, and other health-care providers may be subject to disciplinary measures by the bodies that govern their professions. For example, the College of Physicians and Surgeons in various provinces may fine a physician or suspend or revoke their licence for inappropriate professional conduct.

Civil negligence action

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. 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.

A facility or employee facing civil liability 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.

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.[133]

[132] *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).

[133] Food and Drug Regulations, CRC, c 870 at s C.08.010.

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 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.

However, simple "wilful blindness" to the possession or "trafficking" of illegal drugs on the premises will not exonerate the service provider from liability under the CDSA. The concept of wilful blindness is explained as follows by the author of a leading text:[134]

> if a party has his suspicion aroused but then deliberately omits to make further inquiries because he wishes to remain in ignorance, he is deemed to have knowledge.... He suspected the fact; he realized the probability; but he refrained from obtaining the final confirmation because he wanted in the event to be able to deny knowledge.... It requires in effect that the defendant intended to cheat the administration of justice.

It has been stated by the Supreme Court of Canada that where wilful blindness is established, the law presumes knowledge on the part of the accused:[135]

> 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 wilful blindness is justified by the accused's fault in deliberately failing to inquire when he knows there is reason for inquiry.

Ethical Issues

The Basic Ethical Issue

The basic ethical issue that must be addressed is the ethical imperative to mobilize and maintain services necessary to assist people before they deteriorate irreversibly and perhaps die.[136] Injection drug users are rejected by society because of their illegal drug use, their disturbing behaviour, their disorganized lives, and their afflictions with diseases such as HIV. To adhere to the ethic of humanity, rather than the logic of exclusion, involves the following:[137]

- See and relate to people in terms of their full human particularity. Do not reduce people to any one feature of who they are.
- Distinguish what a person can do now from what surpasses their current levels of ability.
- Respect the ethic of complexity. Like all other persons, drug-dependent persons, including those who are in the process of dying, react to treatment, care, and acts of human kindness.
- Respect the principle of emergence. A long period may elapse and much care may be required for individuals with little self-worth and great instability to make progress.

[134] G Williams. *Criminal Law: The General Part.* 2nd ed. London, England: Stevens and Sons Ltd, 1961, at 157-160.

[135] *Sansregret* v *The Queen*, [1985] 1 SCR 570.

[136] See Roy, supra, note 109.

[137] Ibid.

- Respect the logic of needs. Symbolically, people have first to be brought home before they can build their home. 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 fulfilment of their basic needs will enable them to grow strong and stand tall. One may be ethically required to tolerate many behaviours that offend against dominant social values, sensibilities, and laws while helping people move out of personal and social disruption into living in human dignity.
- 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, dependent on drugs for many years, is in the final stages of a terminal illness such as AIDS. In a palliative care setting, helping the dying to die with dignity is the highest ethical imperative.

Derivative Ethical Issues

The basic ethical issue is the imperative to care adequately for HIV-positive drug users. Given the dominant attitudes, values, laws, and policies of our society on drugs and behavioural minorities, *derivative ethical issues* arise 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. Roy identifies several derivative ethical issues in allowing or tolerating illegal drug use in providing residential or palliative care services.

> The central derivative ethical issue is whether it is ethically justifiable to allow or tolerate illicit 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 ... 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 identified by Roy include:

> *First*, how can one arrange to allow illicit drug use without the establishment's losing its licence or social permission and authorization to operate? The ethical dilemma is: does the allowance of illicit drug use imperil the very raison d'être of the establishment, to be a haven for those who, because of their illicit drug use, are abandoned and threatened with evolving physical, psychosocial, and social deterioration? The other horn of the dilemma is: non-allowance of illicit 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 illicit drug use.
>
> *Third*, to what extent can staff, well-intentioned in their toleration of illicit 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 their improvement? In other words, what do staff in a residence do when persons not only fail to stabilize and improve, but actually get worse, under their care and services?
>
> *Fourth*, how does one ethically assure accessibility to illicit drugs when residents are incapacitated to the point where 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.[138]

To these might be added other derivative ethical issues identified by Riley:[139]

- At what age should illicit drug use be tolerated or allowed in institutions that provide health care, residential services, or palliative care?
- Should measures be taken to ensure that the drugs used on the premises of these institutions are pure and of a specified dose?
- Should the rules that exist in institutions regarding intolerable behaviour be applied in the same way to persons who use stimulants as opposed to depressants? Depressants, such as heroin, are used every few hours. Methadone is generally ingested every 24 to 36 hours. By contrast, stimulants such as cocaine may be taken 20 times a day, which can result in chaotic behaviour if used over a period of days.
- What measures should be taken to avert possible conflicts between residents in institutions who do and do not use illicit drugs?
- What issues arise when pregnant women wish to participate in programs that permit drug use?

An Ethics for Complexity

An "ethics for complexity"[140] describes the tensions between the basic ethical and derivative issues, and the practical problems that emerge. Institutions and staff that allow or tolerate drug use in the course of providing residential or palliative care services may experience the following:[141]

[138] Ibid.

[139] See Riley, supra, note 106.

[140] See Roy, supra, note 109.

[141] Ibid.

- conflicts between the "horizon" of a prohibitionist and abstentionist drug policy ("horizon ethics");
- conflicts between the "norms" that have developed within the "horizon" of an abstentionist or prohibitionist drug policy and "norms" that have developed within the horizon of residential and palliative care ("normative ethics"); and
- conflicts between what is "practical" for a particular situation for the drug user, other residents at the institution, the staff, and for other involved individuals ("practical ethics").

An ethics for complexity recognizes the need to maintain a consistent interplay between these three levels of ethics – horizon, normative, and practical ethics. This interplay will inevitably produce tensions. For example, practical ethical judgments regarding the need to adhere to harm-reduction policies will conflict with societal norms and laws that subscribe to radically different philosophies regarding drug use. Practical ethics recognize the diversity of each person, which may be inconsistent with normative ethics.[142]

With specific regard to the issue of tolerating drug use in the course of providing services, resolutions proposed to deal with derivative ethical issues must address the basic 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." If what emerges from inquiry, reflection, and judgment on the ethical issues associated with allowing or tolerating drug use does not address this basic ethical issue, then the tension that is natural or inevitable in an ethics for complexity is lost, indicating that ethical decisions are no longer responding to the whole of the complexity, but only part of the complexity. If that happens, the reflective ethical actor must ask: whose complexity is this response dealing with, and whose complexity is this response ignoring?

Recommendations

8. In the long term, laws should be changed so as to enable provision of currently illegal drugs to drug users while they are in care, so as to remove a barrier to drug users accessing health care and other social services and to remove the threat of criminal liability for service providers who wish to provide care, treatment, and support without insisting on abstinence by patients who use currently illegal drugs.
9. In the short term, within the current legislative/regulatory framework, the federal government should adopt a regulation that authorizes the release of psychoactive drugs in the context of palliative care, respecting the dignity of drug users in the dying process.
10. Health Canada should fund an ethical and legal analysis of four or five situations or scenarios frequently encountered in the provision of HIV-related services to drug users (such as providing an injection room for drug users in a residential or institutional setting). These situations should be selected in collaboration with agencies and organizations that provide these services.
11. Professional associations should develop ethical and practice guidelines for service providers in different areas of care involving HIV/AIDS and injection drug use – primary health care, community clinics, pharmacy services, residential care, palliative care, housing services. These guidelines should address the tensions between the legal constraints and the ethical imperative of providing services to HIV-positive drug users. The guidelines should be

[142] Ibid.

developed in consultation with drug users and community-based organizations providing services to drug users and/or people with HIV/AIDS.

12. Professional associations should organize a comprehensive training program for health-care providers, social service providers, members of the police force, and lawyers, after the legal/ethical analysis has been completed and the guidelines have been developed.
13. Federal and provincial health officials should fund a series of national meetings of front-line workers and drug users to discuss the policies and practices involved in the care of drug users. The purpose of the meetings is to share information and experiences, delineate best practices, and contribute to the development of training programs and the ethical and practice guidelines.

    Federal and provincial health ministries and professional associations should organize regular workshops and seminars for providers of HIV-related services to drug users. This will provide a forum for information sharing, problem solving, and skills building. HIV/AIDS medication, support services, housing, hospices, and palliative care are some topics to be explored.
14. As part of the Canadian Strategy on HIV/AIDS, Health Canada should develop and implement, in close collaboration with relevant stakeholders, a strategy for integrating HIV/AIDS and drug programming in Canada. In developing such integrated programming, due consideration must be given to the implications for drug laws and policies of a public health, harm-reduction model of responding to the use of illegal drugs.

Treatment

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?

Introduction

Antiretroviral therapy (ART) has led to significant improvements in the health and quality of life of many HIV-positive persons, and has reduced morbidity and mortality. HIV-positive drug users, however, are not offered ART with the same frequency as other HIV-positive persons. From a legal perspective, compelling abstinence as a condition of medical treatment, or withholding medical treatment from HIV-positive drug users, may constitute a violation of the *Canadian Charter of Rights and Freedoms*, human rights codes, professional codes of conduct, and international human rights conventions.

Similarly, it is unethical to insist on cessation of drug use as a condition of medical treatment if this is beyond the capabilities of the drug user. It is also unjust to judge people as likely to be noncompliant with ART simply because they are drug users, and to withhold ART on this basis. Ethics requires that we not reduce an assessment of treatment compliance to simply the personal characteristics of people with HIV/AIDS, but also consider how to adapt systems of care to make health care accessible. While there may be situations in which delaying or refusing ART is warranted, such a decision would be ethically unjustifiable if it is reached without honouring the characteristics of an authentic healing relationship.

This chapter makes several detailed recommendations for improving access to treatment for HIV-positive drug users.

Reconciling Drug Use and Health Care: The Harm-Reduction Approach

The principle of abstinence, rooted in a law-enforcement model,[143] has dominated drug policy in North America. Persons who use illicit drugs are viewed as deserving of punishment rather than in need of health care or treatment. As stated in the 1994 Québec government report *Drug Use and the HIV Epidemic,*[144] the "zero tolerance" approach calls for the repression and stigmatization of individuals who consume illicit drugs; "drug users are viewed as criminals whose illegal activities must be punished." Some government officials and members of the public as well as health-care professionals subscribe to this approach despite the fact that punishment, such as incarceration, is likely to be ineffective in modifying the behaviour of the drug user.

Proponents of the abstinence approach prohibit drug users who seek health services from using drugs. They argue that abstinence from non-medicinal drugs is a fundamental component of healthy behaviour. As one author notes, adherents of this philosophy view "total and permanent abstinence from drug use as the only sign of successful treatment, when in fact diminution in drug use may in itself be a valuable outcome."[145] They fail to understand that lack of provision of health services and treatment for drug users endangers not only the health of the drug-dependent individual but also the well-being of the community as a whole.[146]

AIDS and the transmission of HIV, both within the drug-user population and to other members of society, have caused a fundamental re-evaluation of the services and programs provided to drug-dependent persons.[147] It is being slowly recognized that complete withdrawal from drugs is not a goal that is attainable for many drug users.[148] Moreover, it is estimated that only approximately five to 10 per cent of drug users are prepared to contemplate participation in abstinence-based programs.[149] Therefore, addiction treatment and other health-care services that stipulate abstinence as a precondition to participation will deter many drug users from obtaining assistance for illnesses such as HIV/AIDS or other medical conditions.

The concept of harm reduction, based on a public health model,[150] became a focus for academics, scientists, and members of the health-care profession in the late 1980s.[151] The preoccupation with this alternative approach was the result of two factors: the spread of HIV to injection drug users, and the belief that existing strategies to combat drug use exacerbated rather than ameliorated the problem.[152]

Harm-reduction strategies seek to reduce the likelihood that drug users will contract or spread HIV, hepatitis, and other infections, overdose on drugs of unknown potency or purity, or otherwise harm themselves or other members of the public.[153] Such an approach attempts to reduce the specific harms associated with drug use without requiring abstinence from all drug use.[154] Harm-reduction strategies are based upon a hierarchy of goals,[155] and stress short-term, achievable, pragmatic objectives rather than long-term idealistic goals.[156]

There has been growing support for a harm-reduction approach to the dual epidemics of drug dependency and AIDS.[157] As de Burger states in a 1997

There has been growing support for a harm-reduction approach to the dual epidemics of drug dependency and AIDS.

[143] Newcombe, supra, note 94 at 1.

[144] Supra, note 84 at 24.

[145] J Normand, D Vlahov, LE Mose. Preventing HIV Transmission: The Role of Sterile Needles and Bleach. Panel on Needle Exchange and Bleach Distribution Programs, Commission on Behavioral and Social Sciences and Educatioon, National Research Council and Institute of Medicine, Washington, DC, 1995, at 130.

[146] Des Jarlais et al, supra, note 83 at 1579.

[147] S Henderson. HIV and Drugs. In *The Reduction of Drug-Related Harm*, supra, note 94 at 130.

[148] Federal Department of Justice, Bern, Switzerland. The Controlled Dispensation of Hard Drugs: A Legal Notice Issued by Mandate of the Federal Office of Public Health. In *The Medical Prescription of Narcotics: Scientific Foundations and the Practical Experience*s, supra, note 86 at 56.

[149] PA O'Hare. A Note on the Concept of Harm Reduction. In *The Reduction of Drug-Related Harm*, supra, note 94.

[150] Newcombe, supra, note 94 at 1; and Goldstein, supra, note 87 at 269.

[151] O'Hare, supra, note 94.

[152] Ibid.

[153] Nadelmann, supra, note 95 at 36.

[154] Des Jarlais et al, supra, note 83 at 1578.

[155] Canadian Centre on Substance Abuse. Syringe Exchange: One Approach to Preventing Drug-Related HIV Infection. Policy Discussion Paper, December 1994, at 1.

[156] DC Des Jarlais, S Friedman. Aids, Injecting Drug Use and Harm Reduction. In *Psychoactive Drugs and Harm Reduction: From Faith to Science*, supra, note 95 at 297.

[157] O'Hare, supra, note 94.

Drug users are less likely to receive antiretroviral therapy (ART) than other groups.

editorial published in the *Canadian Journal of Public Health*, harm reduction is a public health philosophy that

> recognizes that a pragmatic, non-judgmental approach, especially in dealing with addictions, is a more effective way to minimize the harm done by drug use than a model that insists on abstinence as a prior condition of treatment. While neither condoning or condemning drug use, the harm reduction model accepts the fact that drug use continues to occur and that it is not to preclude undertaking preventive initiatives. Needle exchange programs are a good example of an effective intervention that recognizes the reality of injection drug use but offers at least significant protection against the spread of communicable diseases such as HIV or hepatitis C.[158]

There are several components to a comprehensive harm-reduction approach. They include:[159]

(1) the provision of medical services to drug users;
(2) the availability of different models of treatment programs;
(3) the provision of mental health services;
(4) street outreach strategies;
(5) needle exchanges and the availability of condoms;
(6) the provision of housing and clothing;
(7) peer support groups for drug users;
(8) vocational services; and
(9) the inclusion of drug users in the design and planning of harm-reduction strategies.

Services provided to drug-dependent persons in Canada have often been based upon the abstinence approach.[160] While this is changing, many barriers to effective care of injection drug users continue to exist because of continued adherence to this philosophy.[161] For example, injection drug users who continue to consume drugs may be denied health services, treatment, or housing.[162]

Access to Antiretroviral Drugs

Several arguments have been put forth for denying drug users access to medical treatment. Some simply assert that drug users do not deserve the same access to medical treatment as persons who do not ingest illegal drugs. Others say that people dependent on drugs abuse the health system by demanding a disproportionate share of emergency services. Still others argue that drug users are not capable of adhering to complicated HIV treatment regimens.[163]

Advances in antiretroviral therapy have improved the survival and quality of life of many HIV-positive people[164] and have reduced morbidity and mortality.[165] Despite the benefits of ART, studies have found that drug users are not offered this treatment with the same frequency as other HIV-positive people. In an article published in the *New England Journal of Medicine*,[166] researchers concluded that drug users are less likely to receive ART than other groups. This situation exists, according to the authors, despite studies that document good compliance with therapy when it is delivered in the context of outpatient HIV services in drug treatment programs or hospitals.[167]

[158] R de Burger. Heroin substitution in Canada: a necessary public health intervention. *Canadian Journal of Public Health* 1997; 365.

[159] Millar, supra, note 86 at 15.

[160] Ibid at 16.

[161] Ibid.

[162] Ibid.

[163] R Batey. Denying treatment to drug and alcohol-dependent patients. *Addiction* 1997; 92: 1189 at 1190.

[164] 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.

[165] P Selwyn. The impact of HIV infection on medical services in drug abuse treatment programs. *Journal of Substance Abuse Treatment 1996*; 397 at 402.

[166] P O'Connor, P Selwyn, R Schottenfeld. Medical Progress: medical care for injection drug users with Human Immunodeficiency Virus infection. *New England Journal of Medicine* 1994; 331: 450 at 455.

[167] Ibid.

A study published in 1998 involving HIV-positive injection drug users in Baltimore, Maryland supported these findings.[168] Only 14 percent of participants in the study reported that they had received potent antiretroviral therapy; 63 percent had received no antiretroviral treatment.[169] It was found that the following factors were associated with the failure of drug users to receive such treatment: non-enrollment in a drug treatment program, active injection drug use, lack of primary care, and lack of health insurance.

This phenomenon is not restricted to the United States. In a study conducted in British Columbia by Strathdee and colleagues,[170] it was found that barriers to ART exist in Canada for injection drug users with HIV. This occurs in a universal health-care system in which ART is provided without cost to the recipient of the treatment. 1106 HIV-positive injection drug users participated in the Strathdee study. The researchers found that only half the injection drug users received ART; women, young people, and individuals not enrolled in drug or alcohol programs were less likely to receive antiretroviral drugs. It was also observed that physicians with little experience in ART were less likely to prescribe this treatment for their HIV-positive injection drug user patients.[171]

As mentioned above, there are several reasons for drug users' poor access to ART. Physicians often do not receive adequate training in medical school, residency training, or continuing education programs regarding the care of drug users. Mental illness, psychosocial problems, and chronic liver disease are some of the reasons physicians are reluctant to prescribe ART to drug users.[172] In addition, some physicians subscribe to the view that drug users are incapable of following the prescribed regimen for antiretroviral therapy. They are concerned that if ART is not conscientiously followed, resistance to the therapy will develop.

However, several measures can be taken by physicians to ensure optimal outcomes for drug users who use ART.[173] They include the simplification of regimens by reducing dose frequencies and pill numbers.[174] A particularly important factor is a physician/patient relationship characterized by trust and accessibility. As is stated by Sherer, "armed with strategies and tools to promote adherence, physicians can enable access to treatments" through "rational prescribing practices for patients with complex management problems, including IDUs."[175] This is supported by Selwyn, who argues that drug users should be offered therapies for HIV in an effective manner and context: "when treatments are delivered in the setting of a drug treatment program or a well-functioning referral system, it has been demonstrated repeatedly that drug users engage and adhere to them at high levels, comparing favourably to other populations."[176]

Legal Issues

Compelling abstinence as a condition of medical treatment, or withholding medical treatment such as antiretroviral therapy from drug users, may violate the *Canadian Charter of Rights and Freedoms*, human rights codes, professional codes of conduct, and international human rights conventions.

Enforcing Abstinence as a Condition for Treatment

Government or institutional policies may impose abstinence as a condition of access to treatment, residential facilities, or social services. This deprives the

[168] DD Celantano, D Vlahov, S Cohn et al. Self-reported antiretroviral therapy in injection drug users. *Journal of the American Medical Association* 1998; 280: 547-549. See R Sherer. Adherence and antiretroviral therapy in injection drug users. *Journal of the American Medical Association* 1998: 280: 567.

[169] Note that French researches have also reported that HIV-positive injection drug users are much less likely to be recipients of antiretroviral therapy. January 1999 issue of the *Journal of Epidemiology and Community Health*. Source: Reuters Health Information Services, 19 January 1999 – Injected Drug Use Linked to Restricted Anti-HIV Therapy in France.

[170] Strathdee et al, supra, note 164.

[171] Ibid.

[172] Sherer, supra, note 168.

[173] Ibid.

[174] Ibid.

[175] Ibid.

[176] Supra, note 165.

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: 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). (For a more detailed legal analysis, see the *Background Papers*).[177]

Applicability of the Charter

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.[178] 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.[179] 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.[180] 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.

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 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 such a practice. 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.

First, *international human rights conventions* protect the right to life, liberty, and security of the person.[181] Similarly, the right to health (the exact content of

[177] See Oscapella & Elliott, supra, note 97.

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

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

[180] *Eldridge* v *British Columbia (Attorney General)* (1997), 46 CRR (2d) 189 (SCC).

[181] *Universal Declaration of Human Rights*, Art 3; *International Covenant on Civil and Political Rights*, Art 9.

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 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.

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 Supreme Court has ruled that government action denying equal access to medical treatment to persons with disabilities is unconstitutional discrimination in violation of the equality rights guaranteed by section 15 of the Charter.[182] As discussed below with respect to the interpretation of human rights statutes, the weight of Canadian legal authority indicates that dependence on drugs or alcohol constitutes a disability. Withholding treatment from a person with the disability of drug dependence would likely violate constitutional equality rights and would have to be satisfactorily justified under section 1 of the Charter. However, this protection would likely not extend to users who do not have the disability of drug dependence.

Similarly, withholding treatment might violate section 7 of the Charter, which protects the 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*[183] case that:

- state interference with bodily integrity constitutes a breach of security of the person;[184]
- 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;[185] and
- the right to liberty is the right to make fundamental personal decisions without interference from the state.[186]

In the more recent *Wakeford* case,[187] 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. Both *Morgentaler* and

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.

– *R* v *Morgentaler*, Supreme Court of Canada, 1988

[182] *Eldridge*, supra, note 180.

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

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

[185] Ibid, per Beetz and Estey JJ.

[186] Ibid, per Wilson J.

[187] *Wakeford* v *Canada*, [1999] OJ No 1574 (QL) (Gen Div).

A rational medical basis for any particular decision to withhold treatment would have to be shown.

Wakeford 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 governmental objective.[188]

The weight of authority in Canadian law recognizes dependence on illegal drugs as a disability under human rights legislation.

It is suggested here 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.

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. The *Canadian Human Rights Act* defines "disability" as a "previous or existing dependency on alcohol or a drug."[189] It was stated by the Federal Court of Appeal in *Canada* v *Toronto-Dominion Bank*[190] that it would be contrary to the Supreme Court of Canada's interpretation of human rights legislation to limit the definition of disability to dependence on legal drugs. It follows that dependence on illegal drugs constitutes a disability under human rights legislation.

Some provincial human rights statutes do not contain the same definition of "disability" (or "handicap") as the *Canadian Human Rights Act*. However, case law from human rights tribunals that have interpreted the provincial definitions of "disability," policy statements from human rights commissions, and academic commentary, have considered drug dependence to constitute a disability within the meaning of the respective provincial legislation.[191] The refusal to provide HIV/AIDS treatment to a drug-dependent user would certainly constitute prima facie disability 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.

Fourth, *professional codes of 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

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

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

[190] *Canada* v *Toronto-Dominion Bank*, [1998] 4 FC 205 at 256.

[191] See *Entrop* v *Imperial Oil Ltd*, [1996] OHRBID No 30, aff'd [1998] OJ No 422 (Div Ct), 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); Ontario Human Rights Commission. Policy Statement on Drugs and Alcohol Testing. November 1990; Canadian Human Rights Commission. Policy on Drug Testing. Ottawa: 1988; and Ontario Law Reform Commission. *Report on Drug and Alcohol Testing in the Workplace*. Toronto: 1992.

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.

Fifth, withholding access to HIV/AIDS medications might also constitute *criminal negligence causing bodily harm or death*. As noted above, 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."[192] 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. However, the strength of any such argument will depend largely upon the circumstances of a particular case; particularly because the physician's conduct must be assessed in light of generally accepted, clinically sound practice among reasonably skilled and informed practitioners, it may often be difficult to prove that the decision to withhold treatment rises to the level of *criminal* negligence.

However, 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 receive 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.

[192] *Criminal Code*, ss 219-221.

It is unjust to judge people as likely to be non-compliant with triple antiretroviral therapy simply because they use illegal drugs, and to withhold treatment on this basis.

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 should not be held civilly liable for the patient's decision to take these risks.[193] Similarly, it seems 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.

Ethical Issues

Enforcing Abstinence as a Condition for Treatment

A strong argument can be made that it is ethically unjustifiable "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 abandonment of treatment being a possible or probable consequence."[194]

Withholding Medical Treatment from HIV-Positive Drug Users

Treatment decisions are to be made jointly by the physician and the HIV-positive person, guided to the extent possible by sound clinical data and experience. The decision to begin medically complex ART for HIV-positive persons requires the balancing of the following factors:[195]

- willingness of the person to commence therapy;
- the degree of immune deficiency as measured by CD4 and T cell count;
- the risk of disease progression as gauged by viral load measurements;
- the potential risks and benefits of initiating such treatment for the person; and
- the likelihood, after counseling and education, that the patient will adhere to the triple therapy regimen.

An ethical analysis of situations in which one may withhold antiretroviral drugs from drug users turns on two questions:

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 fulfilment 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?

[193] *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*, (1991), 82 DLR (4th) 298 (Ont CA); *Van Mol* v *Ashmore*, [1999] BCJ No 31 (CA) (QL).

[194] Roy, supra, note 109.

[195] United States Department of Health and Human Services, Panel on Clinical Practices for Treatment of HIV Infection. See Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents, Federal Register Draft Document, at 4.

It is unethical to insist on cessation of drug use as a condition of medical treatment if this is beyond the capabilities of the drug user. It is also unjust to judge people as likely to be noncompliant with ART simply because they are drug users, and to withhold ART on this basis. Adherence to treatment is profoundly affected by systems of care. When the health-care system is adapted to meet the needs of socially marginalized and indigent persons, there is a vast improvement in adherence to treatment. Ethics therefore requires that we not reduce an assessment of treatment compliance to simply the personal characteristics of people with HIV/AIDS. At the same time, there may be situations where it may be justified to delay or, at the extreme, refuse ART. Such a decision would be ethically unjustifiable if it is reached without honouring the characteristics of an authentic healing relationship: humanity (respect for the full biological and biographical particularity of the person with HIV/AIDS), 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).

Recommendations

The following measures would improve access to good care, treatment, and support for drug users with HIV/AIDS:

Basic Principles

15. Health-care professionals should ensure that the provision of services to drug users is not contingent upon drug users' agreement to enter drug treatment programs.
16. Health-care professionals must not withhold or refuse treatment (including appropriate pain medication) simply because a person with HIV/AIDS is a drug user.
17. The governing approach in providing care and treatment to HIV-positive drug users should be to adapt the therapeutic regimen to the needs of drug users, rather than require drug users to adapt to the therapeutic regimen.
18. Physicians and drug users should jointly explore therapeutic options regarding the most appropriate regimen. This process should be governed by principles of humanity, autonomy, lucidity, and fidelity.
19. Provincial human rights commissions that have not done so should adopt policies clearly stating that drug dependency constitutes a prohibited ground of discrimination.

Medical Treatment

20. Health-care professionals and ethicists should collect information for the purpose of developing guidelines on the clinical and ethical issues that arise in practice with respect to the medical treatment of drug users. This should include the assessment of the appropriateness of imposing restrictions on drug users, such as the cessation of drug use, in specific clinical situations.
21. The Canadian Medical Association, provincial medical associations, and provincial Colleges of Physicians and Surgeons should establish a network of physicians who have experience and/or interest in the delivery of health care and treatment to drug users, to discuss pertinent issues and to advocate for change with respect to the medical treatment of HIV-positive drug users.

HIV Antiretroviral Therapy

22. The pharmaceutical industry must develop simpler HIV drug regimens that can be more easily adhered to by HIV-positive drug users (as well as other people with HIV/AIDS).
23. Public health should offer or make available support to drug users who require assistance in adhering to HIV therapies. This should include funding outreach programs designed to deliver HIV therapies to drug users.

Prescription of Opiates and Controlled Stimulants

What legal and ethical issues are raised in the context of prescribing opiates and controlled stimulants to drug users in Canada?

Introduction

The *Controlled Drugs and Substances Act* (CDSA) and the Narcotic Control Regulations (Regulations) strictly delineate the circumstances in which a physician can prescribe a narcotic. Physicians and other health-care professionals who violate these laws and regulations may be subject to criminal prosecution. This chapter presents the history of methadone maintenance treatment in Canada, as well as its advantages and limitations. The experience of other countries, in which prescription of drugs other than methadone is being undertaken, is also presented. Those who oppose the establishment of methodologically sound clinical trials of opiate-assisted treatment programs are promoting therapeutic abandonment of those who cannot benefit from existing treatments. This chapter recommends that, in the short term, pilot projects in prescribing heroin, cocaine, and amphetamine be initiated in Canada; and that, in the long term, plans should be developed for the prescription of opiates and controlled stimulants.

Legal Issues

Criminal Liability

The CDSA prohibits the unauthorized "trafficking" of a narcotic. As noted above, the offence of "trafficking" is defined in the CDSA quite broadly, and

Criminal law to control addiction has had more than a fair trial and has been found wanting.

– Beyerstein & Alexander

includes "administering" a controlled substance. The term "administer" has been subject to varying interpretations.

In *R* v *Tan*,[196] the Saskatchewan Court of Appeal rejected the argument that "administer" could be interpreted as the act of prescribing a drug. The Court held that a drug was not administered until it entered the intended recipient's system. The term "administer" was described by the Court as the application of a medicine or to give remedially rather than to make the narcotic available by prescription. This interpretation was followed by the Ontario Court of Appeal in *R* v *Verma,*[197] where the Court held that the sale of a prescription of a narcotic by a physician did not constitute "trafficking" as the physician had no control over whether the prescription would be exchanged for drugs. By contrast, the Québec Court of Appeal held in *R* v *Rousseau*[198] that a physician who sells a prescription for narcotics can be guilty of trafficking.

However, authorized prescription of a controlled substance is permissible. 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 (ie, trafficking) a narcotic to any person except as allowed by the Regulations.[199] The Regulations[200] 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 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 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.

Members of the medical profession have argued that governments and licensing bodies should increase physicians' options for the maintenance of patients who are dependent on drugs. At the Parliamentary Committee hearings on the proposed CDSA, there was testimony from the Canadian Medical Association to the effect that doctors require protection from criminal sanctions when they prescribe Scheduled substances in a legitimate fashion but not strictly in accordance with accepted medical procedures. An example provided is the situation in which physicians provide an addicted patient with a narcotic or with the means of obtaining a narcotic in the belief that they are treating the addiction. The Canadian Medical Association argued that physicians who

[196] *R* v *Tan* (1984), 15 CCC (3d) 303 (Sask CA).

[197] *R* v *Verma* (1996), 112 CCC (3d) 155 (Ont CA).

[198] *R* v *Rousseau* (1991), 70 CCC (3d) 445 (Que CA).

[199] Supra, note 101 at s 53.

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

engage in such behaviour should not be liable to criminal prosecution for trafficking.[201]

Beyerstein and Alexander take objection to officials attempting to solve drug-use problems by treating doctors "as if they are pushers."[202] They argue that a physician's prerogative to prescribe controlled substances should be increased, saying that drug-dependent persons "need more, not less, medical involvement."[203] They point out that there is no convincing evidence that prohibition laws have addressed the problems of drug-dependent persons: "criminal law to control addiction has had more than a fair trial and has been found wanting."[204] In their view, legislation should be promulgated to permit physicians to treat drug-dependent persons with "a broader range of options than simply oral maintenance therapy with methadone."[205]

Legislation should be promulgated to permit physicians to treat drug-dependent persons with "a broader range of options than simply oral maintenance therapy with methadone."

Civil Liability

Professional statutes that regulate the conduct of physicians in each province also provide penalties for doctors who deviate from accepted medical practice. For example, the Ontario *Regulated Health Professions Act, 1991*[206] states that a physician's right to practise may be revoked or suspended if he or she commits an act of professional misconduct. Similar statutes exist in other provinces of Canada.

Physicians may also be civilly responsible for negligent medical treatment. Theoretically, a physician who prescribed opiates could be liable if the opiate caused the patient harm. For such an action to be successful, it must be demonstrated that the physician failed to possess a reasonable degree of skill or knowledge, or did not exercise the degree of care that could reasonably be expected of an average prudent practitioner. Failure to explain any known "material risks"[207] of the medication to a patient, or prescribing medication in a manner that caused "reasonably foreseeable" injury to the patient would constitute negligence. In circumstances in which dangerous drugs are used[208] or a patient merits special supervision,[209] a higher standard of care will apply to the physician. The care that must be exercised by a physician is dependent on the nature of the drug itself and on the patient to whom it is prescribed, not on the fact that the drug is legal or illegal.

The government of Canada has the latitude under international law to regulate the prescription of controlled substances as a component of a harm-reduction approach to providing treatment, care, rehabilitation, and social integration of drug users.

International Law

Canada's status as a signatory to the three international drug conventions previously described does not present an insurmountable barrier to the prescription of controlled substances. Article 3 of the 1988 *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances* specifies that a State's obligation to criminalize possession in prohibited drugs is subject to the "constitutional principles" of the State and the "basic concepts of its legal system"; the description of offences and legal defences is reserved to the domestic law of the State. Article 4 of the 1961 Convention contemplates the medical purposes of distribution, use, and possession of such substances. Furthermore, both the 1961[210] and the 1971[211] drugs conventions require States to "give special attention to and take all practicable measures" to prevent the abuse of drugs and to provide "treatment, education, after-care, rehabilitation, and social reintegration to drug users." The government of Canada has the latitude under international law to regulate the

[201] T Bruckner, supra, note 67 at 17.

[202] Beyerstein & Alexander, supra, note 89 at 337.

[203] Ibid at 340.

[204] Ibid.

[205] Ibid.

[206] *Regulated Health Professions Act, 1991*, SO 1991, c 18, section 51.

[207] *Reibl*, supra, note 193.

[208] *Male* v *Hopmans* (1967), 64 DLR (2d) 105 (Ont CA); *Hopp* v *Lepp*, supra, note 193; and *Malette* v *Shulman*, supra, note 193.

[209] *University Hospital* v *Lepine*, [1966] SCR 561; and *Worth* v *Royal Jubilee Hospital* (1980), 4 L Med Q 59 (BCCA).

[210] Article 38.

[211] Article 20.

Methadone "is the cheapest and most effective weapon we have for dealing with large-scale heroin dependence."
– Le Dain Commission, 1973

prescription of controlled substances as a component of a harm-reduction approach to providing treatment, care, rehabilitation, and social integration of drug users.

Canada also has the option of denouncing its obligations under those drug treaties if it considers that they pose barriers to the implementation of the regulated prescription of controlled narcotics. Each of the three treaties contains denunciation provisions.

Prescribing Methadone

Methadone remains the only opioid approved for long-term treatment of opioid dependence.[212] Methadone, the most thoroughly studied of all drug treatment methods,[213] is a synthetic narcotic drug used by persons who are dependent on heroin and morphine.[214] It is a long-acting opioid that can be orally ingested, by contrast to short-acting drugs administered by injection.

A Short History

It was Dr Robert Halliday in Vancouver, British Columbia who established methadone maintenance as a legitimate form of treatment in Canada for opiate-dependent persons.[215] In 1959, Dr Halliday obtained the approval of the federal Department of Health to conduct a small controlled experiment with methadone. The purpose of the study was to examine the value of prescribing methadone for withdrawal management or short-term detoxification in persons who were dependent on opiates. Subsequent to the establishment of the methadone withdrawal management program at the Narcotics Addiction Foundation in British Columbia, Dr Halliday decided to shift the program to "prolonged withdrawal."[216] Halliday took the position that methadone maintenance was analogous to the treatment of diabetes with insulin. Abstinence was no longer the primary purpose of the treatment. By the 1960s, methadone maintenance was widely considered as an effective form of treatment for opiate addiction.

Approximately two dozen methadone treatment programs existed in Canada by 1972.[217] The Commission of Inquiry into the Non-Medical Use of Drugs, commonly known as the Le Dain Commission, concluded that methadone "is the cheapest and most effective weapon we have for dealing with large-scale heroin dependence."[218] The Commission recommended that methadone maintenance be available to opiate addicts throughout the country. It proposed that it be administered solely by physicians affiliated with accredited specialized clinics equipped with the necessary laboratory facilities and other ancillary services.[219]

Possible misuses of methadone became a concern of the federal government in the early 1970s. The Department of National Health and Welfare established a Special Joint Committee on Methadone, which consisted of government health officials and representatives of the Canadian Medical Association.[220] It proposed that guidelines be developed that would delineate appropriate practices to be followed by physicians and that would have effect of restricting availability.[221] The Committee recommended that methadone be administered solely to long-term opiate addicts by physicians in specialized clinics who had authorization from the federal government to dispense this opioid. Methadone

[212] The College of Physicians and Surgeons of Ontario, Addiction Research Foundation; Ontario College of Pharmacists. Methadone Maintenance Guidelines, 1996.

[213] J Zweben, JT Payte. Methadone maintenance in the treatment of opioid dependence: a current perspective. *Western Journal of Medicine* 1990: 588.

[214] Millar, supra, note 86 at 2; and DR Gerstin. The Effectiveness of Drug Treatment. In: C O'Brien, J Jaffe (eds). *Addictive States*. New York: Raven Press Ltd, 1992, at 254-255.

[215] H Kent. Harm-reduction strategies weapon of choice in BC's battle with drug addiction. *Canadian Medical Association Journal* 1996, 155: 572; and 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.* Bern: University of Bern, 10-12 March 1999.

[216] B Fischer. Prescription, power and politics: the turbulent history of methadone maintenance in Canada. *Journal of Public Health Policy* 1999 (forthcoming).

[217] Fischer, supra, note 215.

[218] Commission of Inquiry into the Non-Medical Use of Drugs (Le Dain Commission). Ottawa: Information Canada, 1973. *Treatment Report* at 30.

[219] Supra, note 218, *Final Report* at 152-168.

[220] Ibid at 157.

[221] Ibid.

was to be ingested only in oral form and detailed records of each patient were to be maintained by health-care professionals.[222]

The Committee's recommendations were accepted by the federal government. Regulations under the *Narcotic Control Act* were passed in 1972.[223] Pursuant to these regulations, no practitioner was to administer, prescribe, give, sell, or furnish methadone to any person unless so authorized by the federal government. Pharmacists were prohibited from filling a prescription for methadone unless it had been authorized by the Health Minister. Guidelines were developed by the Department of National Health and Welfare for practitioners who wished to apply for authorization to prescribe methadone to their patients.[224]

The Narcotic Control Regulations had a drastic impact on the methadone programs that existed in the country. From 1972 to 1975 the number of methadone prescribers as well as patients decreased by one-third. By 1982, the numbers further declined to two-thirds.[225] Canada continues to have one of the lowest rates of methadone placements compared with western countries in which methadone is legally available.[226] As one author states:[227]

> when looking at national rates of methadone treatment spots per million capita in Canada, Canada finds itself at the bottom end in comparison with public-health oriented jurisdictions like Australia (1,020), Switzerland (2,000), Belgium (1,000) or countries such as Germany (247) which started to use methadone treatment a few years ago.

In the mid nineties, federal government health authorities decided to transfer licensing and control of methadone prescriptions to the provinces.[228] In July 1995, British Columbia became the first jurisdiction to operate a methadone maintenance program independent of the Federal Bureau of Drug Surveillance. In some provinces, such as Ontario and British Columbia, the College of Physicians and Surgeons has been given responsibility for monitoring the programs.

Advantages and Limitations of Methadone Maintenance Treatment

The safety and effectiveness of methadone maintenance treatment (MMT) has been documented in scientific and medical publications.[229] As previously mentioned, an important advantage of methadone for opiate-dependent persons is its long-lasting effect.[230] A drug user need only receive a single dose of methadone in a 24- to 36-hour period. Methadone does not cause euphoria, sedation, or analgesia.[231] This is to be contrasted with the shorter action and dramatic highs and lows of heroin, morphine, and other opiates.[232] The long-lasting effect of methadone allows a drug user to seek employment and, as well, facilitates reintegration into the community.[233]

Methadone maintenance treatment programs have been credited with decreasing opioid use, reducing criminality, and improving the general health of the drug user.[234] Moreover, MMT reduces individual mortality and morbidity.[235] Another important benefit of MMT is that it helps decrease the spread of HIV, as methadone is typically administered orally rather than by syringe.[236] MMT has thus become a "critical resource in the struggle against injection

Canada continues to have one of the lowest rates of methadone placements.

The safety and effectiveness of methadone maintenance programs has been documented in scientific and medical publications.

[222] See discussion in Fischer, supra, note 215.

[223] Order-in-Council PC 1972-1033, 16 May 1972, SOR 72-155.

[224] Commission of Inquiry, supra, note 215 at 972-973.

[225] Fischer, supra, note 215.

[226] Ibid.

[227] B Fischer. The case for a heroin substitution treatment trial in Canada. *Canadian Journal of Public Health* 1997; 88: 367 at 368.

[228] Hankins, supra, note 88 at 1141.

[229] Gerstin, supra, note 214; Zweben & Payte, supra, note 213 at 597-598.

[230] A Mino. Personal Considerations. In *The Medical Prescription of Narcotics,* supra, note 86 at 42.

[231] Supra, note 212.

[232] Gerstin, supra, note 214 at 255.

[233] Kent, supra, note 215 at 573; Federal Department of Justice, supra, note 148 at 59.

[234] Zweben & Payte, supra, note 213 at 588; MD Anglin, YI Hser. Drug Abuse Treatment. In: R Watson (ed). *Drug Abuse Treatment.* New Jersey: The Humana Press Inc, 1992, at 6; Millar, supra, note 86 at 17; and Methadone Maintenance Guidelines, supra, note 212.

[235] Kent, supra, note 215 at 573.

[236] R Price, T D'Aunno. The Organization and Impact of Outpatient Drug Abuse Treatment Services. In *Drug Abuse Treatment*, supra, note 234 at 46.

Other treatment options need to be expanded, including maintenance on other drugs.

drug use and AIDS."[237] Methadone clinics are also potentially excellent sites for disease prevention and education. Patients can be offered screening and counseling for transmissible diseases; and can be provided information on safe sex, on the dangers of sharing needles, and on methods for cleaning syringes.

Despite the significant advantages of methadone, there are some limitations. Although methadone is effective for heroin addiction, it is not a treatment for dependence on cocaine, amphetamine, and other non-opiate drugs.[238] In some parts of Canada, such as in British Columbia and in Montréal, a greater proportion of drug users are injecting cocaine than heroin. "Because there is clearly no effective pharmacological treatment for cocaine addiction," "other treatment options need to be expanded including maintenance on other drugs."[239] In addition, methadone is not indicated for multiple addictions.[240] Another limitation of methadone is that it is addictive.[241] In fact, the withdrawal symptoms from methadone may be worse and more difficult to manage than the withdrawal symptoms from heroin.[242] Thus, while methadone treatment is effective in achieving harm-reduction objectives, it is not a sufficient solution to many of the problems associated with drug dependency.[243] Therefore, it is necessary to explore other methods of addressing drug addiction.

Canada, with one of the world's most developed public health consciousness and system, has fallen far behind numerous Western countries in Europe and Australia.

Heroin Maintenance Treatment

Given the limitations of MMT, some members of the scientific and medical community in Canada, as well as some drug users, have advocated that drugs other than methadone ought to be provided to drug-dependent individuals. Treatment with heroin, it is argued, may avoid some of the limitations of MMT, while achieving the same objectives: improving the physical and mental health of drug users, preventing the spread of HIV and hepatitis, reducing the level of crime associated with drug use, and facilitating rehabilitation among the drug-using population.[244] As stated by Ostini et al, a prime reason for a "trial of the controlled availability of heroin is to obtain hard data" "about alternative regimes for dealing with heroin dependency."[245]

In contrast to countries such as Switzerland, Britain, Australia, and the Netherlands, Canada has been reluctant to prescribe drugs other than methadone to drug-dependent individuals. A professional at the Centre for Addiction and Mental Health writes:

> Canada, with one of the world's most developed public health consciousness and system, has fallen far behind numerous Western countries in Europe and Australia which have dealt with similarly daring challenges in the area of injection opiate addiction and related social harms and costs in a much more determined, timely, and effective fashion.[246]

The British System

In the United Kingdom, physicians are permitted to prescribe heroin, cocaine, morphine, amphetamine, and other drugs for their drug-dependent patients.[247] In 1926, the Rolleston Report identified addiction as a medical condition. Addiction treatment was placed within the domain of doctors who were given the freedom to prescribe otherwise illegal drugs for medical purposes. Physicians have the discretion to either maintain drug-dependent persons or to gradually

[237] Zweben & Payte, supra, note 213 at 598.

[238] Nadelmann et al, supra, note 95.

[239] Millar, supra, note 86 at 17.

[240] Federal Department of Justice, Bern, Switzerland, supra, note 148 at 59.

[241] Anglin & Hser, supra, note 234 at 6.

[242] Fischer, supra, note 227 at 369.

[243] Ibid.

[244] Millar, supra, note 86 at 18; and F Gutzwiller, A Uchtenhagen. Heroin Substitution: Part of The Fight Against Drug Dependency. In *The Medical Prescription of Narcotics*, supra, note 86 at 299.

[245] R Ostini, G Bammer, P Dance, R Goodin. The ethics of experimental heroin maintenance. *Journal of Medical Ethics* 1993; 19: 175 at 181.

[246] Fischer, supra, note 215 at 8-9.

[247] Mino, supra, note 230 at 42-43.

detoxify them by prescribing drugs of choice. Although the Rolleston Report explicitly referred to heroin and morphine, prescription of other drugs such as cocaine, amphetamine, pethidine, dicanol, cyclimorph, and dipipanone, have also been permitted.[248] As noted by Nadelmann et al, "this flexibility and authority given doctors to treat addictions with pharmacological agents represents the core of what has long been known as the 'British System.'"[249]

Heroin substitution and heroin maintenance are reasonable alternatives that have a place in an overall public health approach to injection drug use in Canada.

Switzerland

The Swiss government has been conducting a multi-city study to assess whether the prescription of heroin, morphine, or injectable methadone reduces disease, crime, and other drug-related problems. Approximately one thousand volunteers have participated in the experiment. Eligibility requirements included the following: the individual is a heroin addict, is at least twenty years of age, and has a minimum of two unsuccessful experiences in treatment programs.[250] Virtually all the participants in the study preferred heroin to the drugs prescribed for them by the physicians. Substantial health and social services were also offered.[251]

The preliminary results from the study are: the commission of criminal offences has decreased, there has been a significant reduction in the illegal use of heroin and cocaine, stable employment has increased, and the physical health of the drug users has improved. There have been no deaths from overdoses, and the prescribed drugs have not been diverted to the black market.[252] Several of the study participants have commenced abstinence therapy.

The experience in other jurisdictions, the lesson learned in addictions treatment and the necessity of dealing with an urgent public health problem now mean that Canadians ought to be prepared to try heroin maintenance and substitution trials.

Proposals for a Heroin Trial in Canada

As mentioned above, scientists, physicians, and public health representatives,[253] as well as drug users and others, have been advocating that a heroin maintenance trial be implemented in Canada. It is noteworthy that over 25 years ago the Le Dain Commission made this same recommendation.[254] In a 1998 report, British Columbia provincial health officer Dr Millar advocated that "the controlled legal availability of heroin in a tightly controlled system of medical prescription be pilot tested as an option, as part of a comprehensive harm reduction program."[255] A similar position is taken by Dr de Burger, who states that "heroin substitution and heroin maintenance are reasonable alternatives that have a place in an overall public health approach to injection drug use in Canada."[256] He further states:[257]

> The experience in other jurisdictions, the lesson learned in addictions treatment and the necessity of dealing with an urgent public health problem now mean that Canadians ought to be prepared to try different approaches.

The Centre for Addiction and Mental Health in Toronto is exploring the possibility of a controlled heroin multi-site treatment trial in North America. The trial would be aimed primarily at opiate-dependent persons who have not benefited from other forms of treatment.[258] It would compare the effectiveness of a heroin maintenance program with that of existing treatments for such persons. The study proposal is expected to be completed in late 1999. Health Canada's approval is required in order to conduct such a trial. Moreover, the

[248] Nadelmann et al, supra, note 95; The Lindesmith Center. *Heroin Maintenance Treatment*. New York, 1998.

[249] Nadelmann et al, supra, note 95.

[250] Ibid; The Lindesmith Center, supra, note 248.

[251] Ibid.

[252] Ibid; and A Uchtenhagen, A Dobler-Mikola, F Gutzwiller. Medically Controlled Prescription of Narcotics: Fundamentals, Research Plan, First Experiences. In *The Medical Prescription of Narcotics*, supra, note 86 at 27.

[253] Fischer, supra, note 227; Centre for Addiction and Mental Health. *Heroin Prescription Trials for Opiate Addicts*, 1998.

[254] Fischer, ibid; de Burger, supra, note 158.

[255] Millar, supra, note 86 at 18.

[256] de Burger, supra, note 158.

[257] Ibid.

[258] Fischer, supra, note 215.

Canadian government would have to obtain permission from international drug-control authorities.[259]

Ethical Issues

Improved health and social integration, not abstinence, should be the prime objective of the treatment.

Ethical consideration of whether to prescribe opiates or controlled stimulants to drug users must be based on an adequate understanding of addiction and of effective treatment for addiction. Research and practice indicates that addiction is a chronic condition, not sociopathic behaviour best managed by imprisonment, and not an acute condition to be treated or cured by detoxification. Furthermore, treatment for addiction requires a comprehensive program of ongoing services, including medical, psychological, and social services. This assessment has implications for clinical, research, and social ethics.

Implications for Clinical, Research, and Social Ethics

Clinical ethics

Understanding drug dependency as a chronic condition and drug treatment as a complex program of ongoing services has implications for clinical ethics. Improved health and social integration, not abstinence, should be the prime objective of the treatment. Roy states that

> 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.
>
> ...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 psychological health and to help these persons to achieve their maximum of social integration and productive satisfying living.[260]

Roy concludes that it would be clinically unethical not to use methadone-assisted and heroin-assisted treatments for persons who consent to them and who stand to benefit from them:

> 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.[261]

Research ethics

As regards research ethics, it is imperative to conduct research that would provide the basis for sound clinical decisions, including research into prescribing opiates or controlled stimulants. "Methodologically sound research and clinical trials are an integral part of the fundamental ethical imperative that doctors and other professionals should *know* what they are doing when they intervene in the bodies, minds, and lives of sick people."[262] Those who oppose the establishment of methodologically sound clinical trials of opiate-assisted treatment

[259] Centre for Addiction and Mental Health, supra, note 253.

[260] Supra, note 109.

[261] Ibid.

[262] Ibid.

programs are promoting therapeutic abandonment of those who cannot benefit from existing treatments.[263]

Social ethics

As will be discussed later in this paper, the number of comprehensive treatment programs in Canada for drug-dependent persons is inadequate and an insufficient number of physicians in Canada are trained in drug addiction. As Roy states, "[t]he complexity of care is not in keeping with the complexity of the disease."[264] Such clinical inadequacies invoke the ethical imperatives of social justice and humanity.

The width of the gap between what should be done and what is in fact being done for drug-dependent persons in need of treatment is a measure of the injustice that is present in society. That injustice is based upon a counter-position that harbours moral and scientific incoherence. This counter-position must be reversed, according to Roy, because "it betrays the ethic of a civilized society and leads to the kind of dehumanization provoked by the logic of exclusion."[265]

The number of comprehensive treatment programs in Canada for drug-dependent persons is inadequate and an insufficient number of physicians in Canada are trained in drug addiction.

Recommendations

The following measures would improve drug users' access to more comprehensive drug treatment options:

24. In the longer term, Health Canada should develop plans to permit physicians to prescribe opiates and controlled stimulants.
25. In the shorter term, pilot projects involving the prescription of heroin, cocaine, and amphetamines should be authorized, funded, and initiated in Canada. The pilot projects should:
    - involve both drug users and general practitioners in the design, implementation, assessment of outcomes, and recommendations for practice;
    - be accompanied by public education at the local, provincial, and national levels that presents the benefits of the project to drug users and to the community at large;
    - contain a multi-phase design that includes plans once the trials are completed for implementing such treatment options more widely if the pilot projects are deemed successful in achieving harm-reduction objectives; and
    - address the problems likely to be encountered by drug users and health-care providers when the transition is made from a controlled clinical trial to general practice.

[263] Ibid.
[264] Ibid.
[265] Ibid.

Drug Users and Studies of HIV/AIDS and Illegal Drugs

What legal and ethical issues are raised by (a) the absence of scientific trials on the impact of illegal drugs on the immune system; (b) the absence of trials on the interactions between HIV/AIDS drugs and illegal drugs, and (c) the exclusion of drug users from scientific trials involving drugs for HIV/AIDS?

Introduction

HIV-positive drug users may have a wider range of immunological deficiencies, a different history of the disease, and may respond differently to treatments than other HIV-positive persons. Yet the lack of clinical data on the effects of illegal drugs on the immune system, and the interactions between HIV/AIDS drugs and currently illegal drugs, hinders the provision of optimal care, treatment, and support to HIV-positive injection drug users.

This chapter explains that, while there is a legal basis for *authorizing* medical research into the effects of illegal 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 illegal 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.

From an ethical perspective, there are scientific, clinical, public health, and humanitarian reasons to conduct studies of the effect of using currently illegal drugs on the immune system, and of the interactions of illegal drugs with HIV/AIDS treatments. It is clinically and ethically wrong to exclude injection

drug users from the clinical studies that are needed to determine whether they need different medical treatment than people with HIV/AIDS who do not use narcotics and psychotropic substances.

The chapter recommends that barriers to the participation of drug users in clinical trials be removed and that the Medical Research Council and pharmaceutical companies, in consultation with community groups and drug users, develop a comprehensive research agenda that identifies priorities in research for injection drug users.

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

Legal Issues

Legal Authority to Conduct Research

Exemption from criminal liability

The first legal question is whether the illegal status of some drugs presents 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 with using such drugs justifies the absence of studies on their effect 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.

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.[266] 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 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."[267]

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

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

[267] Ibid at s 56.

two Canadians for the possession and cultivation of marijuana for medical purposes.[268]

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. They 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 MMT programs.[269]

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 an absolute "privilege" protecting the confidentiality of information received by the professional, and the confidentiality is always subject to disclosure where "required by law."

The only possible limitation on this power to obtain records would come from sections 7 and 8 of the Charter. 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.[270] 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.[271] 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.

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 illegal drugs on the immune system and on interactions between HIV/AIDS drugs and illegal drugs. While federal and provincial Ministers of Health are empowered by legislation to conduct research[272] and, as noted above, may grant legal authorization to others to enable research dealing with illegal drugs, it is doubtful whether the broadly worded statutory mandates of health officials to "promote and preserve" the health of Canadians[273] 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:

[268] Medical marijuana approved. *The Globe and Mail*, 10 June 1999.

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

[270] For example, *R* v *Morgentaler, Smoling and Scott*, supra, note 183; *Hunter* v *Southam*, [1984] 2 SCR 145; *R v Edwards*, [1996] 1 SCR 128; *R* v *Plant*, [1993] 3 SCR 28; *R* v *Pohoretsky*, [1987] 1 SCR 945; *R* v *Dyment*, [1988] 2 SCR 417.

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

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

[273] See, eg: *Department of Health Act*, RSC 1985, c H-32, s 4; *Ministry of Health Act*, supra, note 272 at s 6(1).

> 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.
>
> 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.[274]

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 illegal 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 drugs.

Exclusion of drug users from research studies

The Charter

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."[275] 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.

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. As discussed above, drug-dependent users may be considered to have a "disability" pursuant to s 15, and therefore would be entitled to Charter protection. However, drug users who are not drug-dependent will likely not fall within the ambit of the Charter's equality guarantee.[276]

[274] 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, section i.8.

[275] *Eldridge*, supra, note 180.

[276] *Hamon* v *The Queen* (1993), 20 CRR (2d) 181 (Que CA), leave to appeal refused.

Human rights legislation

Both federal and provincial human rights legislation apply to the public and private sectors. As discussed in the context of previous issues, drug dependence is considered a "disability" or "handicap" within the meaning of federal and provincial and human rights statutes, a prohibited ground of discrimination.[277] However, these statutes prohibit discrimination in specified areas such as accommodation, the purchase or sale of property, employment, and access to services.[278] For a human rights complaint to succeed against a research body on the grounds of discrimination based on drug dependence as a disability, it would be necessary to establish that the research body was providing a service.

Ethical Issues

Studies of the Impact of Illegal Drugs on the Immune System

As Roy points out, 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 and extensive scientific and methodological analysis of how such studies could be designed and successfully conducted.[279] In the absence of such an analysis, Roy sketches how an ethics commentary on this question could begin to take shape. He presents four considerations that 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 them. Roy concludes that 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.[280]

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-positive drug users.[281] The study showed 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 would be crucial to determine whether illegal drugs have similar important interactions with ZDV; and that it is necessary to determine whether illegal drugs and treatments for illegal drug use have important interactions with other HIV therapeutic agents.[282]

Therefore, Roy concludes 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."[283]

Equitable Participation in HIV/AIDS Clinical Trials

Historical background: a change of perspective

Since World War II, concerted efforts have been made to exclude vulnerable people from participating in scientific and medical trials. In the past 40 to 45 years, people belonging to ethnic and minority groups, mentally challenged

[277] *Entrop* v *Imperial Oil*, supra, note 191; *Canada* v *Toronto-Dominion Bank*, supra, note 190; Ontario Human Rights Commission Policy Statement on Drugs and Alcohol Testing (1990) and Canadian Human Rights Commission on Drug Testing, supra, note 191.

[278] See for example *Canadian Human Rights Act* RSC 1985, c H-6; or Nova Scotia *Human Rights Act*, RSNS, c 214.

[279] Roy, supra, note 109.

[280] Ibid.

[281] 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.

[282] Ibid.

[283] Roy, supra, note 109.

individuals, and socially marginalized persons have been precluded from being subjects in medical experimental studies.

The exclusion of these groups from scientific trials has its roots in medical research conducted in the nineteenth and first half of the twentieth century. During this period, ethically questionable medical experiments were performed on vulnerable persons. In Germany, France, Russia, Ireland, and the United States, vulnerable people were recruited as subjects and exploited in gonorrhea and syphilis research.[284] Female slaves in the US were involved in surgical experiments.[285] Prisoners, children, and persons in institutional settings were also recruited for scientific studies in many countries.[286] The experiments performed in Nazi Germany on Jewish people, Gypsies, and mentally challenged persons are well known. The Tuskegee Syphilis Study on black men and the Willowbrook Study of Infectious Hepatitis conducted on mentally challenged children in the United States are further examples of vulnerable person subjected to scientific experimentation.[287]

Since the late 1940s a prime ethical concern has therefore been the protection of vulnerable people against medical exploitation. The *Nuremberg Code*, the *International Code of Medical Ethics*, and the *Helsinki Declaration* were developed after the Second World War to protect individuals from medical and scientific exploitation.

In recent years, however, there has been a change in perspective. Although the protection of research subjects continues to be an important concern, the view now advanced is that there should be equitable access to participation in clinical trials. It is asserted that women, the economically disadvantaged, the socially marginalized, and persons 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 Canadian 1998 *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans* contains a section entitled Inclusion in Research. Based on the principle of distributive justice, the provision in the Statement reads:[288]

> 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.

In the United States, the equitable participation of human subjects in clinical trials is one of the criteria for Institutional Review Board (IRB) approval.[289] There have also been recent changes in the policies of the US Food and Drug Administration (FDA) and the National Institutes of Health (NIH) on the equitable selection of women and of ethnic and minority groups in clinical trials.[290]

There are several reasons for the recent change in perspective. Of prime concern is the generalizability of clinical trial results in circumstances in which participants in a medical study are not representative of the disease population for which a treatment under study is intended. Also, participants in a scientific trial may have access to medication and treatments not available to other members of the population. Involvement in university hospital–based or community-based clinical trials is often the only way to obtain access to promising new treatments.[291]

[284] Ibid. See also CR McCarthy. Historical background of clinical trials involving women and minorities. *Academic Medicine* 1994; 69: 695-698; and V Veressayev. *The Memoirs of a Physician*. New York: Knopf, 1916.

[285] 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; and 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.

[286] See J Mitford. Cheaper than Chimpanzees. In: J Mitford (ed). *Kind and Unusual Punishment: The Prison Business*. New York: Vintage Books, 1974, at 151-184; EE 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; and HK Beecher. Ethics and clinical research. *New England Journal of Medicine* 1966; 274: 1354.

[287] AM Brandt. Racism and Research: The Case of the Tuskegee Syphilis Study. *Hastings Center Report* 1978: 21-29; R Ward et al. Infectious hepatitis: studies of its natural history and prevention. *New England Journal of Medicine* 1958; 258: 407-416; and J Katz. *Experimentation with Human Beings*. New York: Russell Jage Foundation, 1972, at 1007-1010.

[288] Supra, note 274.

[289] United States Department of Human and Health Services Rules and Regulations 45 CFR 46 (Title 45: Code of Federal Regulations, Part 46).

[290] 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; and United States Congress Public Law 103-43, National Institutes of Health Revitalization Amendment, Washington, DC, 10 June 1993.

[291] Roy, supra, note 109.

The controlled clinical trial

Research is conducted to produce new knowledge and to resolve controversies regarding particular medication or treatments by producing reliable data that offer conclusive evidence. Clinical research on drugs or surgical treatments is undertaken to provide answers to some of the following questions:[292]

- Will this treatment prevent or remedy a particular disease?
- Will this treatment do more good than harm to patients with this particular disease?
- Will this treatment be more beneficial than available treatments?

Bias can skew research toward results or conclusions that differ systematically from the truth.[293] There are several sources of bias that can distort the scientific process at different stages of the clinical research – from the design of the research protocol, through selection of patients and the conduct of the clinical study, to the analysis, interpretation, or reporting of the research results. Dr David Sockett and colleagues at McMaster University have identified at least 65 sources of bias that can distort research results.[294]

Several safeguards are employed in research to reduce bias, to ensure that the results of the trials have a high probability of validity. A controlled clinical trial is designed to protect clinical research against bias. The word "trial" is used when a comparison is made between two available treatments for a disease. The purpose of the research is to determine which treatment is safer and more effective. When only one treatment is available, a comparison can be made between that treatment or no treatment, referred to as a placebo. The trial is controlled when the results of one treatment are monitored by comparison with the results of another treatment, or no treatment, on similar groups affected by the same disease.[295]

Randomization is a further method employed to reduce or eliminate bias in research studies. It is used to block selection bias, which can distort a trial if the patients participating in the study are not similar. Double-blinding is a further method. The patient and the treating physician are blinded, or kept in ignorance regarding which of the two treatments (note that one of the "treatments" may be a placebo) the patient is receiving during the course of the trial. Because uncertainty is inherent in medical science, and because the reliability of research is generally measured in terms of probabilities, there are also important statistical conditions that must be respected for a clinical trial to produce credible results. The sample size or number of persons enrolled in a clinical trial is one, as a trial conducted on too few persons will generally yield unreliable results.[296]

Selection and exclusion criteria in a controlled clinical trial

When is it fair and justified, both scientifically and ethically, to exclude people from participating in a clinical trial?

Several prerequisites have been identified as necessary conditions for a clinical trial to produce credible, valid, and generalizable results for a specific population. One of these preconditions is that the inclusion and exclusion criteria strike a balance between efficiency and generalizability.[297] For example, if, due to limited financial resources, a clinical trial includes a small number of subjects, efficiency principles would dictate that participants be limited to

[292] Ibid.

[293] Ibid.

[294] DL Sackett. Bias in analytic research. *Journal of Chronic Diseases* 1979; 32: 51-63.

[295] Roy, supra, note 109.

[296] Ibid.

[297] Ibid.

persons who are at high risk for the clinical event under study and who are likely to be highly responsive to the treatment being studied. However, if these high-risk high responders are only a minority of the persons afflicted with the disease, the trial results may have limited generalizability.[298]

Feinstein has enumerated reasons for excluding individuals from participating in clinical trials. They include the following:[299]

1. Therapeutic Exigency: Participation in a controlled clinical trial may be contraindicated for the candidate.
2. Prognostic Susceptibility: Patients with a short life expectancy may be excluded if the trial is designed to measure the long-term results of an intervention. Also people with mild forms of a disease may be precluded from participating in a study designed to test the treatment against serious forms of the illness.
3. Therapeutic vulnerability/invulnerability: Persons may be excluded from a clinical trial if they do not have the condition 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 produce any benefit. Also, persons who may suffer adverse effects from a treatment presumed to be beneficial for their medical condition may be excluded. For example, pregnant women are often precluded from being a research subject in trials of conditions for which they are afflicted because of the damage that may ensue to the fetus.
4. Persons who take medication that could potentially interfere with, or mask the effect of, the treatment under study in a trial may be excluded from the clinical trial.
5. Because of the expense and time involved in many clinical trials, people may be excluded if they are likely to move a far distance from the trial site or if they are likely to be non-compliant with aspects of the clinical trial.

When exclusion is ethically questionable or wrong

Some of the populations regularly excluded from or underrepresented in clinical trials are women, poor and socially marginalized persons, children, the elderly, people of colour, minorities, alcoholics, and injection drug users.[300] Gender, socioeconomic status, age, or behaviour, singly or in combination, have been responsible for excluding these persons from participating in clinical trials. When clinical trials have been established to test the safety and efficiency of new treatments for HIV/AIDS, injection drug users and persons of low economic status have been precluded from being subjects in the studies.[301]

Persons subject to undue economic or social pressure may not be participants in clinical trials for several reasons. Freeman notes that participating in clinical trials may be far 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...."[302] A further reason that may explain lack of participation is the mistrust that persons may have toward the medical establishment and toward clinical scientists. In addition, physicians and clinical scientists may exhibit indifference toward the poor, the socially marginalized, and those who inject illegal drugs.[303]

[298] 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.

[299] AR Feinstein. *Clinical Epidemiology: The Architecture of Clinical Research*. Toronto: WB Saunders Company, 1985, at 277.

[300] Roy, supra, note 109.

[301] Ibid.

[302] HP Freeman. The impact of clinical trial protocols on patient care systems in a large city hospital. *Cancer Supplement* 1993; 72: 2834-2838.

[303] LS Brown. Enrollment of drug abusers in HIV clinical trials: a public health imperative for communities of color. *Journal of Psychoactive Drugs* 1993; 25: 45-52.

In a number of countries, exclusion of injection drug users from HIV-related clinical trials occurs in a sociopolitical climate that discourages research (basic, clinical, epidemiological, anthropological) on illegal drug use.[304] In a Canadian study, Hankins et al reported that non-white women, women injection drug users, and women of lower education were underrepresented in HIV/AIDS clinical trials.[305] They emphasized the importance of actively recruiting injection drug users to these trials, and stated that information is lacking on the interactions between antiretroviral drugs and illegal drugs such as heroin, cocaine, amphetamines, ecstasy, as well as methadone and potential opiate substitutes such as buprenorphine, naltrexone, and LAAM (L-alpha-acetylmethadol).[306]

Exclusion of individuals from participating in clinical trials on the grounds of non-compliance necessitates careful ethical consideration. In circumstances where the exclusion is based upon unfounded and arbitrary views, the exclusion is unjust, unfounded, and discriminatory. It is contrary to ethical principles to perceive a person as likely to be non-compliant with clinical trial procedures because that person is an injection drug user, without taking the time to obtain information on that person and without examining whether possible non-compliance may be due to modifiable circumstances of life and the environment.[307] It is noteworthy that some clinical investigators have reported that the compliance level of injection drug users has been commensurate with other members of the population.[308]

It is an ethical imperative that health-care professionals strive to obtain the knowledge required to fulfill the clinical responsibilities of treatment, care, and support. To systematically exclude injection drug users, women, and the poor from clinical trials is tantamount to a refusal to obtain the knowledge necessary to adequately treat those who are often most in need of care. It is scientifically unfounded to assume that HIV-positive injection drug users have a course of HIV disease similar to HIV-positive persons who do not inject drugs, or that injected drugs do not interact unfavourably with antiretroviral drugs.[309] As stated by Bennett:[310]

> 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 from that subgroup.

HIV-positive injection drug users may have a wider range of immunological deficiencies, a different history of HIV disease,[311] and may respond differently to treatments than other HIV-positive persons. It is therefore clinically and ethically wrong to exclude these people from studies that may reveal whether HIV-positive injection drug users need to be treated differently from others living with HIV.[312]

In conclusion, the principles articulated in "Building a New Consensus: Ethical Principles and Policies for Clinical Research on HIV/AIDS" must be considered:[313]

[304] Ibid.

[305] C Hankins, N Lapointe, S Walmsley. Participation in clinical trials among women living with HIV in Canada. *Canadian Medical Association Journal* 1998; 159: 1359.

[306] Ibid at 1364.

[307] Roy, supra, note 109.

[308] See TA Slays et al. Therapy Compliance of HIV-Infected Intravenous Drug Users. Paper presented at the VIII International Conference on AIDS, Amsterdam; and B Broers et al. Compliance of Drug Users with Zidovudine Treatment. Paper presented at the VIII International Conference on AIDS, Amsterdam, 1992.

[309] Roy, supra, note 109.

[310] JC Bennett. Inclusion of women in clinical trials – policies for population subgroups. *New England Journal of Medicine* 1993; 329: 288-292.

[311] See P Pehrson, S Lindbäck, C Lidman, H Gaines, J Giesecke. Longer survival after HIV infections for injecting drug users than for homosexual men: implications for immunology. *AIDS* 1997; 11: 1007.

[312] Roy, supra, note 109.

[313] C Levine, N Dubler Neveloff. Institutional Review Board 1991; 13: 7, 8, 14.

Exclusion of representatives of groups of prospective subjects who are believed to be non-compliant (e.g. intravenous drug users) may 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).

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 illegal drugs, or stage of illness unless the study is specifically designed to look at a particular stage of illness.

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.

Recommendations

The following recommendations, if implemented, would go a long way toward ensuring that important information for the treatment of HIV-positive injection drug users becomes available, in particular, information about the impact of illegal drugs on the immune system, and on the interactions between HIV/AIDS drugs and illegal drugs. In addition, they would help ensure that drug users are included in scientific trials involving drugs for HIV/AIDS.

The Research Agenda

26. The Medical Research Council and pharmaceutical companies, in consultation with community groups and drug users, should develop a comprehensive research agenda that identifies priorities in research for injection drug users.
27. Members of the medical and scientific professions should conduct research on issues relevant to HIV/AIDS and drug use, such as the interactions between illegal and prescribed drugs, and the effects of illegal drugs on the progression of HIV disease.
28. Pharmaceutical companies should take a leadership role in promoting studies that test the interaction of HIV/AIDS drugs with illegal drugs.
29. Clinical researchers should recognize the importance of conducting research for and by First Nations groups as well as other communities affected by HIV/AIDS.
30. The National Health Research and Development Program of Health Canada should provide funding to develop capacity building for community-based research.

Research into Illegal Drugs

31. The provincial/territorial ministries of health should take measures to ensure that laboratories are established across Canada to test controlled substances used by drug users.
32. Provincial/territorial ministries of health should provide funding for test kits for drug users that measure the dose and purity of drugs.

Participation in Research

33. As a general principle, clinical researchers and professional associations should take measures to ensure the removal of barriers to the participation of drug users in clinical trials.
34. Those conducting clinical trials, in consultation with community groups and drug users, should develop recruitment strategies to encourage participation of HIV-positive drug users in clinical trials.
35. Medical researchers should establish study sites for clinical trials in geographical areas that are easily accessible to drug users.
36. Those conducting clinical trials should offer child-care and transportation costs to prospective participants, to encourage individuals to take part in trials.
37. Medical researchers should provide information on proposed medical studies (including consent forms) to drug users in language that is accessible.
38. The National Council for Ethics in Human Research should develop guidelines for research involving marginalized persons.
39. The Canadian HIV Trials Network should develop guidelines for researchers on ensuring that research participants who are drug users provide informed consent for their participation. Such material could include a model informed consent form that does not automatically exclude those using illegal drugs, but also specifically addresses questions such as the interactions between the study drug and illegal drugs (when known), as well as outlining the steps taken to protect the confidentiality of data gathered from the participant (including information regarding use of illegal drugs) and the possible limits on that confidentiality.
40. Federal and provincial officials, including law enforcers, should be prohibited from having access to identifying information respecting participants in research files.

Information about the Use and Effects of Illegal Drugs

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 illegal drugs and their effects?

This chapter starts by describing two different types of educational programs on drugs and drug use: one based on abstinence principles, the other based on harm-reduction principles. It points out that, generally, there is a sense that there is not enough provision of accurate and complete information on illegal drugs to health-care providers, drug users, and the general public, and that this lack of (accurate) information has a negative impact on provision of care, treatment, and support, as well as on prevention efforts. The chapter then undertakes a legal analysis, concluding that legally, the development of drug educational material generally falls within the discretion of government health officials. It would be difficult, if not impossible, to use the law to address the failure to provide accurate information about illegal drugs and their effects. The following ethical analysis, however, concludes that ethical principles dictate that individuals in society have accurate and comprehensive information on all matters that require decision, choice, and action. 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.

The chapter concludes by recommending, among other things, that accurate, non-biased, and non-judgmental information on illegal drugs be developed for health-care providers, drug users, and members of the public.

Drug Education

Educational Programs Based on Principles of Abstinence

In many Western countries, including Canada, the main response to illegal drug use has been directed to primary prevention.[314] The essential philosophy underlying many of these programs is abstinence. Those promoting such programs argue that individuals, particularly young persons, should be counseled on the dangers of illegal substances and instructed to refrain from using such drugs.

In the DARE (Drug Abuse Resistance Education) program in the United States, abstinence is the primary objective. Youths are told that any behaviour beyond one-time experimentation with an illegal drug constitutes drug abuse, that alcohol and cigarettes are "stepping stones" to the consumption of illegal drugs, and that taking drugs like marijuana will lead to consumption of other drugs such as heroin and cocaine.[315] Police officers are responsible for conducting the DARE program. According to the US Department of Justice, the purpose of DARE is "to help children say 'no' to drugs by teaching them techniques to avoid peer pressure."[316] Another objective of the program is to promote greater respect for the law.[317] In Canada, the Royal Canadian Mounted Police have trained police officers to teach the DARE program to children. Officers from Alberta, British Columbia, Saskatchewan, and the Northwest Territories have recently undergone such training.

Harm-Reduction Educational Programs

Harm-reduction educational programs take a non-judgmental approach to the consumption of drugs. They seek to provide accurate information on the composition and effects of different substances and recommend sources of assistance to persons who consume drugs. Programs geared to adolescents attempt to provide young persons with skills in assessment, communication, assertiveness, conflict resolution, and decision-making.[318]

Educational programs based on a harm-reduction model strive to:

- reduce the prevalence of unsafe frequencies and methods of ingesting drugs;
- decrease the rate of heavy or dependent consumption;
- reduce experimentation with drugs most likely to cause medical problems; and
- improve the ability of users and others to respond to drug-related problems.

An example of information imparted to heroin injection users that adheres to such an approach is the following:[319]

- because heroin can cause many problems, it is best to avoid this drug as a method of "getting high";
- but if you do use heroin, smoke or sniff it rather than inject it;
- but if you are going to inject it, do not share your needles or other injection equipment with other persons;
- but if you do share your needles, make sure to obtain fresh supplies of needles, syringes, and condoms;

[314] See: E Single. Canadian Centre on Substance Abuse. New Developments in Drug Education in Canada. International Conference on Drug Education in Schools. Hong Kong, 1997.

[315] See Riley, supra, note 106.

[316] United States Department of Justice. An Introduction to the National DARE Program, June 1993.

[317] United States Department of Justice. An Invitation to Project DARE: Drug Abuse Resistance Education, June 1988.

[318] Riley, supra, note 106.

[319] Ibid.

- and if you do share your needles and syringes, ensure that you follow the correct procedures for cleaning the injection equipment.

Some jurisdictions have introduced educational programs on drugs based on a harm-reduction approach. In the United Kingdom, HRDE (Harm-Reduction Drug Education) is premised on the notion that taking risks and experimenting are common adolescent behaviours. It subscribes to the view that all drug use cannot be prevented. HRDE is non-judgmental; it neither condones nor condemns drug use. It seeks to provide accurate information on drugs to young persons and to ensure that measures are taken to minimize health and other risks to the drug user and to society at large.[320]

Some government ministries and agencies in Canada, such as the Addiction Research Foundation and Health Canada,[321] have published information for the public based on harm-reduction principles. However, there is concern that the amount of drug education and publications that are based upon these principles and are distributed to youth, drug users, and members of the public, do not have wide circulation.

It has also been asserted that health-care providers such as physicians, pharmacists, and nurses in North America receive an inadequate education on drug addiction, illegal drugs, and treatments for drug-dependent persons. As stated in "Medical Care for Injection Drug Users with Human Immunodeficiency Virus Infection,"[322] there is a need to improve the education of physicians in the area of substance use: "Comprehensive substance abuse education beginning in first year of medical school and continuing through residency training is necessary if these patients are to receive optimal care." A study conducted in British Columbia came to a similar conclusion. Medical students and residents stated time should be devoted in the curriculum to drugs other than alcohol.[323] The Canadian Psychiatric Association has also discussed the need to improve the "current inadequate level of training in most programs in the field of substance abuse."[324]

Legal Issues

Responsibility to Provide Public Education

Provincial health officials, pursuant to public health statutes, are responsible for providing health education to members of the public. However, officials have the discretion to decide what types of materials and to which sectors of the public the material will be directed. The language of the statutory provisions is permissive. For example, the Nova Scotia *Health Act*[325] states that the "Minister may conduct, direct, and promote programs dealing with or related to drug dependency." Section 133 further states that "Programs conducted, directed or promoted by the Minister dealing with or related to drug dependency *may* include:

> the experimentation in methods of education, prevention, treatment and rehabilitation regarding drug dependency;
> (1) education respecting the causes and effects of drug dependency;
> (2) the dissemination of information respecting the recognition, prevention, and the treatment of drug dependency.

[320] See M Rosenbaum. *Kids, Drugs, and Drug Education: A Harm Reduction Approach*. San Francisco: National Council on Crime and Delinquency, 1996.

[321] See discussion in Riley, supra, note 106.

[322] Supra, note 166 at 457.

[323] A Towle, Faculty of Medicine, University of British Columbia. Addiction Medicine and Intercollegial Responsibility (AMIR): Evaluation Report, 1996.

[324] N el-Guebaly, Y Garneau. Curriculum guidelines for residency training of psychiatrists in substance-related disorders. *Canadian Psychiatric Association Bulletin* 1997; 29.

[325] *Health Act*, RSNS, 1989, s 133.

Therefore, the principles upon which educational material on drugs is based and whether it is directed to youth, drug users, or members of the public generally fall within the discretion of government health officials.

Criminal Liability

It is conceivable that either the failure to provide accurate information or the deliberate provision of erroneous information could constitute criminal negligence if the omission or act results in death or bodily harm. The *Criminal Code*[326] states that everyone is criminally negligent who, in doing anything or in omitting to do anything that is his [legal] duty to do, "shows wanton or reckless disregard for the lives and safety of others." The duty may be imposed by statute or common law.[327] "Wanton or reckless disregard" is established where the conduct of the accused shows a "marked departure" from the standard of behaviour of a "reasonably prudent person in the circumstances."[328]

It may be difficult to prove the constituent elements of the offence of criminal negligence. First, it will likely be difficult to establish that bodily harm or death was caused by the negligent conduct. Second, it may be difficult to prove a legal duty to act. Finally, given the conflicting nature of medical and scientific information on the effects of illegal drugs, it may be difficult to establish that the conduct of the information provider, such as a public health nurse or physician, was a "marked departure" from the conduct of a "reasonably prudent person."

Civil Liability

As far as civil liability is concerned, a person who fails to discharge a "duty of care" may be held liable for the tort of negligence. As is the case with criminal negligence, the duty may be imposed by legislation or the common law. Under the common law, a duty may arise if it was objectively foreseeable by an ordinary person that failing to exercise reasonable care could cause the harm.[329] Civil actions will not be successful if it cannot be established that the negligent conduct was causally connected to the injury that was suffered or if the risk of harm was not foreseeable.[330] It will likely be difficult to establish the constituent elements of the tort in circumstances in which government health officials or health-service providers do not provide accurate and complete information on illegal drugs to drug users or members of the public.

Ethical Issues

Part of the complexity affecting psychoactive drug use derives from the policies, laws, and regulations that a society has adopted and maintained in order to control or to prohibit the use of such substances.[331] Existing policies, laws, and regulations that prohibit psychoactive drugs may represent "frozen accidents." Responses adopted in the past may be maintained despite the fact that knowledge, attitudes, and social circumstances have changed. Policies that have become "frozen accidents" can produce unintended but socially destructive consequences.[332]

The notion of positions and counter-positions as expressed by Lonergan[333] directly relates to the issue of providing accurate and comprehensive information on illegal drugs to members of the public, health-care providers, and drug users.[334] Positions are not only consistent among themselves but are coherent

[326] Section 219.

[327] *Coyne*, supra, note 131.

[328] *R* v *Waite*, [1989] 1 SCR 1436; and *R* v *Tutton*, [1989] 1 SCR 1392.

[329] Ibid.

[330] See: A Linden. *Canadian Tort Law*, 5th ed. Toronto: Butterworths, 1993, at chapter 9.

[331] Roy, supra, note 109.

[332] Ibid.

[333] Lonergan, supra, note 108 at 387-390 and 680-683.

[334] Roy, supra, note 109.

with, and are modified in accordance with, the demands of inquiring intelligence and reflective reason. Evidence is a prerequisite for decisions and actions. By contrast, counter-positions harbour irrationalities and errors. This may include distortion, falsification, or withholding of information.[335] Musto has observed that "silence and exaggeration" were strategies resorted to in the United States to address the problem of illegal drugs.[336]

The standards of public discourse in an open society must be honoured. This entails clarity and precision, evidence-based statements, a distinction between personal opinion and knowledge, honesty, restraint in generalization, and civility in debate.[337]

It is important that individuals in society have accurate and comprehensive information on all matters that require decision, choice, and action. The refusal to share existing information, or measures taken to distort or falsify information, obstruct responsible decision-making and actions. This stifles the development of rational self-consciousness of individuals. Principles of ethics are violated when knowledge is tailored for the purpose of promoting a particular course of behaviour on the part of individuals.[338]

The four ethical principles of autonomy, lucidity, fidelity, and humanity are infringed when a person manipulates, blinds, or dominates others.[339] *Autonomy* implies that a person has the requisite knowledge to make decisions and thus is in command of their life. When such an individual lacks that knowledge, advice and counseling may be sought from members of society considered to possess this information, such as professionals.[340]

Lucidity, fidelity, and humanity are connected to the concept of autonomy. The principle of *lucidity* implies that drug users have the duty 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. *Fidelity* means that a person seeking professional help has a right to expect that their reasonable expectation will be respected and honoured. People seeking professional help have a right to expect that they will not be made subservient to ends and purposes that have nothing to do with or, worse still, 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. According to the ethical principle of *humanity*, it is incumbent on a professional, not only to obtain accurate information regarding diseases, conditions, or treatments of the patient, but also to obtain information on the patient who seeks advice, knowledge, or treatment.[341]

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

It is important that individuals in society have accurate and comprehensive information on all matters that require decision, choice, and action.

[335] Ibid.

[336] DF Musto. Opium, Cocaine and Marijuana in American History. *Scientific American* 1991: 46.

[337] Roy, supra, note 109.

[338] Ibid.

[339] C Fried. *Medical Experimentation, Personal Integrity and Social Policy*. Amsterdam: North Holland Publishing Company, 1974, at 103.

[340] Roy, supra, note 109.

[341] Ibid.

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 unique form of responsibility regarding information and knowledge about the effects of various therapeutic drugs on the bodies and health of biochemically diverse subgroups; 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 for avoiding the sins of omission that will be committed when representatives of subgroups 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; and care, treatment, and support of drug users.[342]

Recommendations

The following recommendations, if implemented, would go a long way toward ensuring the provision of accurate and complete information on illegal drugs to health-care providers, drug users, and the general public. This, in turn, would have a beneficial impact on provision of care, treatment, and support of HIV-positive injection drug users, as well as on prevention efforts.

41. Federal, provincial, and territorial health officials should provide the funding for the development and wide distribution of accurate, non-biased, and non-judgmental information on illegal drugs for health-care providers, drug users, and members of the public.
42. Hospitals should be required to forward information on drug overdoses to provincial public health departments, which in turn should create a database on drug overdoses. This information should be disseminated to organizations that deal with drug use and should also be available to members of the public.
43. Federal, provincial, and territorial health officials as well as community organizations should provide information on currently illegal drugs and community organizations in a format and in language that is accessible to different cultural groups in various geographical locations in Canada (eg, Aboriginal communities).
44. Provincial and territorial governments, government agencies, and community-based organizations should develop education programs based on a harm-reduction philosophy.
45. Hospitals and professional associations should organize educational sessions on drug use for health-care professionals (eg, grand rounds, continuing education programs).
46. Provincial and territorial ministries of education and health should undertake an evaluation of school programs on illegal drugs.
47. Universities and colleges should ensure that the curricula of health-care professionals include accurate, unbiased, and non-judgmental materials,

[342] Ibid.

presentations, and discussions about drugs, drug use, and harm-reduction approaches to drug use.

48. Provincial and territorial governments should create a body to oversee the adherence of best-practice guidelines by health-care workers and other persons who administer care and treatment to drug users.
49. Federal, provincial, and territorial officials should convene a forum for the discussion of educational material that should be disseminated. It should include federal, provincial, and territorial health officials, the police, drug users, and organizations such as the Centre for Addiction and Mental Health.

Needle Exchange and Methadone Maintenance Treatment

What legal and ethical considerations should be taken into account when implementing needle exchange and methadone maintenance treatment (MMT) directed at reducing the harms from drug use?

Introduction

This chapter first provides a short history of needle exchange programs in Canada. It explains why needle exchange programs are important, and shows that many studies have revealed that they are effective harm-reduction measures. However, it then points out that several barriers exist that limit access to needles. Among these are the criminal laws that subject persons involved in needle exchange programs as well as drug users to liability for traces of illegal drugs found in drug equipment.

The chapter then examines methadone maintenance treatment programs, and points out the numerous barriers that exist in Canada to effective methadone treatment of injection drug users.

The chapter then undertakes an ethical analysis of the issues raised. It concludes by making several recommendations that, if implemented, would increase access to needle exchange programs and to methadone maintenance treatment.

Needle Exchange Programs

The Establishment of Needle Exchange Programs in Canada

Needle exchange programs (NEPs) are an important strategy in a harm-reduction approach to injection drug use.[343] A fundamental rationale for their establishment is that injection drug users typically share needles and syringes, a frequent mode of transmission of HIV. The philosophy underlying NEPs is that if injection drug users are provided with sterile syringes and needles, this will reduce the sharing of drug equipment and thus decrease the transmission of bloodborne diseases such as HIV and hepatitis C.[344] Many drug users report that an important reason for the sharing of needles and syringes is the scarcity of injection equipment.[345]

NEPs have been controversial, particularly in the United States. As observed by some writers, they contradict the "anti-drug" symbolism in public discourse.[346] It is argued by their opponents that if psychoactive drugs are bad for one's health, illegal, and an activity that should be discouraged, why should governments fund programs that provide people with the equipment to inject drugs?[347] Gostin writes:[348]

> Few issues at the intersection of law, policy, and public health are as fraught with conflict as the distribution of sterile injection equipment to impede the spread of infection with human immunodeficiency virus (HIV) among injection drug users. At the heart of the controversy is a fundamental conflict between deeply entrenched drug control policies and newly emerging public health policies.

The first NEP in Canada was established in 1989 in Vancouver.[349] The program was financed by the municipal government and was located in the eastside section of the city. Within six months of its creation, NEPs were established in Montréal and Toronto. This was soon followed in other major Canadian cities.[350]

By the end of 1990, eight publicly funded NEPs existed in Canada. The models for the programs differed among the cities. In some, one central site was established; other programs offered syringes and needles in mobile vans or on foot; and some NEPs were a combination of mobile and fixed sites.[351] It is estimated that there are currently over a hundred needle exchange sites in Canada.[352] Vancouver's NEP is reported to be the largest in North America.[353]

The Importance of NEPs

NEPs can be more than simply a place at which sterile syringes are provided to injection drug users.[354] They are important sites for conveying educational messages about AIDS, for raising consciousness about health risks, and for offering counseling, support groups, and other services.[355] As stated in a Health Canada publication, in addition to providing clean syringes, NEPs are an important mode of "getting in touch with an otherwise hard to reach population in order to educate, counsel, and provide referral services to health care and drug treatment."[356]

[343] Goldstein, supra, note 87 at 234; S Loue, P Lurie, S Lloyd. Ethical issues raised by needle exchange programs. *Journal of Law, Medicine and Ethics* 1995: 382.

[344] Goldstein, supra, note 87 at 231.

[345] L Gostin. Law and Policy. In: J Stryker (ed). *Dimensions of HIV Prevention: Needle Exchange*. USA: The Kaiser Forums, 1993.

[346] Des Jarlais et al, supra, note 83 at 1578.

[347] Ibid.

[348] Gostin, supra, note 345.

[349] Hankins, supra, note 88 at 1133.

[350] Ibid. See also J Bruneau, F Lamothe, E Franco 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: 994 at 995.

[351] Hankins, supra, note 88.

[352] Ibid at 1134 and 1142.

[353] Strathdee et al, supra, note 15 at F60.

[354] DC Des Jarlais, S Friedman, N Peyser. Regulating Syringe Exchange Programs: A Cautionary Note. Letter to the editor. *Journal of the American Medical Association* 1994: 272: 431.

[355] Goldstein, supra, note 87 at 234.

[356] *Risk Behaviours Among Injection Drug Users in Canada*, supra, note 1.

NEPs can provide access to health services to persons who are stigmatized in society;[357] offer HIV and tuberculosis screening; provide access to condoms and bleach; and offer the opportunity to participate in drug treatment programs.

Studies conducted over the past several years have concluded that NEPs are effective in reducing the spread of HIV. Research in Europe in cities such as London and Glasgow, as well as in North America in Hartford, Connecticut and New York City, have demonstrated that there is decreased equipment sharing among injection drug users who attend NEPs.[358] A 1997 study published in *Lancet* found that in cities with NEPs, HIV incidence among injection drug users decreased, while in cities without NEPs, HIV incidence increased among the drug-user population.[359] Similar findings are cited by Loue, Lurie, and Lloyd, who reported that NEPs were responsible for a 40-percent reduction in HIV incidence and a seven- to eightfold decrease in the incidence of hepatitis B and C.[360] Kilwein has also concluded that NEPs prevent the spread of HIV and hepatitis, and bring drug-dependent persons in contact with drug rehabilitation services.[361] As Hankins states, NEPs have proven their capacity to attract injection drug users and to facilitate behavioural change.[362] Finally, based on the results of various studies, Health Canada has concluded that NEPs prevent HIV infection among injection drug users, are not responsible for an increase in the number of drug users, and are not responsible for lowering the age at which persons inject drugs for the first time.[363]

NEPs are well-established in the United Kingdom, the Netherlands, Australia, and Switzerland.[364] The results of such programs have been positive. In an increasing number of prisons in Switzerland, Germany, and Spain, sterile syringes are also provided to prisoners.[365]

Concerns about NEPs

The findings of a study conducted in Montréal by Bruneau and colleagues[366] initially raised concerns regarding needle exchange programs. It was found that NEP users in Montréal have higher seroconversion rates and participate in more risk behaviours than drug users who do not attend NEPs. There was also concern that NEPs were a gathering place for isolated injection drug users and would thus facilitate the formation of new sharing networks.

Members of the scientific and medical community who have carefully analyzed the Bruneau study have concluded that the Montréal results do not cause them to question the effectiveness of NEPs. As one commentator states:

> Do these results demonstrate that NEPs, far from preventing HIV transmission, actually cause an increase in transmission as some NEP opponents have claimed? And do the results mandate the abandonment of HIV prevention policies for IDUs based on the provision of sterile syringes? The simple answer to both of these questions is "no."[367]

As Lurie states, the Bruneau study confirms that more at-risk injection drug users in Montréal attend NEPs.[368] Those who frequent NEPs are less likely to be involved in drug treatment programs and more likely to be frequent injection users. They are more apt to share drug equipment with an HIV-positive person and are more likely to attend shooting galleries. As Lurie asserts, if NEPs are attracting the highest-risk injection drug users, they are ideal sites to provide

[357] Des Jarlais et al, supra, note 83 at 1579.

[358] See discussion in Bruneau et al, supra, note 350 at 995.

[359] S Hurley, D Jolley, J Kaldor. Effectiveness of needle-exchange programmes. *Lancet* 1997; 349: 1797 at 1800.

[360] Supra, note 343.

[361] JH Kilwein. On needles, breasts and bullets: health and the conflict of values. *Journal of Clinical Pharmacy and Therapeutics* 1996; 21: 363.

[362] Hankins, supra, note 88 at 1142.

[363] *Risk Behaviours Among Injection Drug Users in Canada,* supra, note 1. See also *Preventing HIV Transmission: The Role of Sterile Needles and Bleach*. Panel on Needle Exchange and Bleach Distribution Programs, Commission on Behavioral and Social Sciences and Education, National Research Council and Institute of Medicine, edited by J Normand, D Vlahov, L Moses. Washington, DC: National Academy Press, 1995, at 132 and 725; and Goldstein, supra, note 87.

[364] Hurley et al, supra, note 359 at 1797.

[365] See HIV/AIDS in Prisons (Info Sheet 6). Prevention: Sterile Needles. Canadian HIV/AIDS Legal Network, 1999.

[366] Bruneau et al, supra, note 350.

[367] P Lurie. Invited Commentary: Le Mystère de Montréal. *American Journal of Epidemiology* 1997; 146: 1003.

[368] Ibid. This is consistent with the results of a 1998 Vancouver study that found that females who habitually use NEPs inject more frequently, are more likely to have a non-legal source of income, and are more likely to inject at shooting galleries. In the study, males who attended NEPs reported high levels of cocaine use. See CP Archibald, M Ofner, S Strathdee et al. Factors associated with frequent needle exchange program attendance among injection drug users in Vancouver, Canada. *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology* 1998: 160.

more intensive risk-reduction intervention.[369] In his view, "what is needed to reduce the terrible toll of HIV among Montreal IDUs is not less needle exchange but more."[370] Similarly, Canadian scientists have stated:[371]

> If NEP attract higher risk IDUs, then an appropriate public health response should be to capitalize on this window of opportunity by using NEP as a vehicle to change social norms surrounding needle sharing. From this perspective, it is crucial that NEP be maintained as a cornerstone in HIV prevention.

Need for Improvement in NEPs in Canada

Although NEPs have existed in major Canadian cities since the late 1980s, restrictions imposed on NEPs have often limited their effectiveness.

In many NEPs there is a limit on the number of syringes distributed to injection drug users at each visit. Individual quotas are imposed. As Bruneau and colleagues explain, such limitations have been well-intentioned but have had unintended negative consequences. For example, some NEPs have limited the number of needles to encourage multiple visits by the injection drug users,[372] to enable NEP staff to offer health care, support, and counseling on a more frequent basis. Or, as Hankins states, NEPs have established a quota system to avoid diversion of syringes to dealers, and to bring drug users into regular contact with an access point to the health and social service system.[373]

Another restriction imposed by some NEPs is that used syringes must be exchanged for new syringes. This is to ensure the safe disposal of used syringes, which may contain bloodborne pathogens. For example, the policy of CACTUS, the largest NEP in Montréal, was based on a ratio of 1:1 with a maximum of 15 syringes per person per day.[374]

Generally, there is concern among health-care professionals that the number of needles distributed in Canada is significantly less than the actual numbers required by injection drug users. A 1998 Québec report states that there are an insufficient number of syringes to meet the estimated need.[375] The quota system has a significant impact on cocaine users, who may inject as much as 20 times per day.[376] It has therefore been argued that there should be unrestricted access to clean syringes.[377] Health-care professionals have also emphasized that secondary distribution of sterile injection equipment from persons who attend NEPs should be encouraged.[378]

Other limitations are the insufficient number of NEPs in Canada and the fact that they are generally located in large cities. Persons who live in rural areas or in small towns generally have little access to such programs. Moreover, NEPs have been centralized within cities; this has occurred partly for reasons of political expediency, that is, to avoid the approval process that is often necessary in neighbourhoods in which a proposed NEP will be situated.[379] Also, persons incarcerated in federal and provincial prisons in Canada are not provided with sterile syringes.[380] As stated in a provincial government report, only a small proportion of injection drug users have access to NEPs.[381]

The hours of operation of NEPs constitute a further restriction on their effectiveness. For example, CACTUS in Montréal was open only from 9:00 am to 4:00 pm. In rural areas, clean needles provided in community clinics or hospital emergency departments may be available only for two hours each week.[382]

[369] Lurie, supra, note 367 at 1003-1004.

[370] Ibid at 1005. See also J Bruneau, N Lachance, J Soto et al. Changes in HIV seroprevalence rates of IDUs attending needle exchange programs (NEP) in Montreal: the Saint-Luc cohort. *Canadian Journal of Infectious Diseases* 1999 (Suppl B); 10. Abstracts of Eighth Annual Canadian Conference on HIV/AIDS Research, May 1999.

[371] Strathdee et al, supra, note 15.

[372] Bruneau et al, supra, note 350 at 1001.

[373] Hankins, supra, note 88 at 1141.

[374] Bruneau et al, supra, note 350 at 1001.

[375] *Les Programmes de Prévention du VIH chez les utilisateurs de drogues par injection du Québec: Une démarche collective d'évaluation*. Centre de Santé publique du Québec, Ministère de la Santé et des Services Sociaux, 1998.

[376] Ibid; and Hankins, supra, note 88 at 1141.

[377] American Bar Association, supra, note 90 at 233; H Stover, K Schaller. AIDS Prevention with Injecting Drug Users in the Former West Germany: A User-Friendly Approach on a Municipal "Level." In *The Reduction of Drug-Related Harm*, supra, note 94 at 192.

[378] Des Jarlais et al, supra, note 83 at 1582.

[379] Hankins, supra, note 88 at 1141.

[380] R Jürgens. *HIV/AIDS in Prisons: Final Report*. Montréal: Canadian HIV/AIDS Legal Network & Canadian AIDS Society, 1996; and Hankins, supra, note 88 at 1138.

[381] Gouvernement du Québec, supra, note 84 at 35.

[382] Hankins, supra, note 88.

The reluctance of pharmacists in most parts of Canada to provide syringes to injection drug users is another concern. In the 1980s, several provincial Colleges of Pharmacy advised their members not to sell injection equipment to persons likely to be illegal drug users. This was based on the erroneous belief that pharmacists would be subject to criminal prosecution for aiding and abetting a criminal act. As one observer notes: "There is no doubt that restricted sales contributed in subsequent years to the heightened vulnerability of drug users to HIV, Hepatitis B and C, and other blood-borne infections."[383] The Canadian Pharmaceutical Association subsequently recommended to pharmacists that needles and syringes be available for sale to drug users. Despite this shift in orientation, a national study published in 1995 stated that more effort was required from these professionals "if pharmacists were to become optimally effective prevention partners."[384]

The critical role of pharmacists in facilitating needle availability has been emphasized.[385] Some pharmacists continue to be reluctant to make needles available to drug users. They may be concerned about the potential negative effects on their business revenues and on the quality of services provided to other customers; or worry about increases in theft, or the return to pharmacies of used needles contaminated with HIV-infected blood.[386]

It has been argued that measures must be taken in Canada to encourage more pharmacists to make available sterile syringes to injection drug users. Particularly in rural and semi-urban areas, pharmacies may be one of the few ways in which injection drug users can access such equipment. It has been suggested that pharmacists who have participated in such harm-reduction activities offer peer education to colleagues to encourage them to partake in such health-prevention measures.[387] It has also been recommended that pharmacists contemplate reducing the price of syringes for persons who return their used syringes,[388] as is the case in New Zealand.[389]

In order for NEPs to be optimally effective in minimizing the transmission of HIV, it is fundamental that they not merely provide clean syringes to drug users. Health care, counseling, education, and support should also be offered. A 1997 British Columbia study found that in cities in which comprehensive programs are *offered* at NEPs that include HIV testing, counseling, education, and drug treatment options, HIV incidence and associated risk behaviours declined significantly.[390] However, NEPs should not *require* drug users to participate in other services provided by the NEP as a condition for the provision of clean syringes.[391] Another important component, instrumental to the success of NEPs, is that staff treat injection drug users as individuals and with respect.[392]

Legal Issues

As previously discussed, it is legal in Canada to give or sell sterile syringes to injection drug users. However, NEP staff and drug users may be criminally charged under the CDSA for possessing traces of illegal drugs contained in used syringes. It is also worth noting that while there is no legal obligation to volunteer information on illegal drug use or to answer police questions, NEP personnel can be compelled by subpoena to give evidence and to produce the facility's records at trial.[393] It has been suggested that needle exchange program staff collect minimal information on the individuals who participate in

[383] Ibid at 1136.

[384] Discussed in Hankins, ibid.

[385] *Preventing HIV Transmission*, supra, note 363 at 123; Des Jarlais et al, supra, note 83 at 1582.

[386] *Preventing HIV Transmission*, supra, note 363 at 124.

[387] Hankins, supra, note 88 at 1136.

[388] Ibid.

[389] Loue et al, supra, note 343 at 386.

[390] Strathdee et al, supra, note 15 at 63.

[391] Des Jarlais et al, supra, note 83.

[392] Ibid.

[393] S Uspich, R Solomon. Notes on the Potential Criminal Liability of a Needle Exchange Program. *Health Law in Canada* 1988; 42.

the program; in particular, the client's name and other identifying information should not be amassed by counselors and other persons who work at needle exchange programs.

Methadone Maintenance Treatment Programs

MMT has been endorsed internationally as a means of addressing opiate dependence.[394] As stated by Des Jarlais and Friedman, MMT is an important example of harm reduction that emphasizes short-term pragmatic goals in place of long-term idealistic objectives.[395]

As discussed above, in the chapter on Prescription of Opiates and Controlled Stimulants, MMT has many advantages, and strong evidence has accumulated over the years respecting the safety and effectiveness of methadone.[396] In particular,

> [m]ethadone maintenance has been demonstrated to result in substantial and sustained reductions in the use of illicit drugs, behavior that places patients at risk for HIV, medical complications of injection-drug use, and criminal activity, and with a subsequent improvement in overall medical, social and vocational functioning.[397]

Current policies place "too much emphasis on protecting society from methadone and not enough on protecting society from the epidemics of addiction, violence, and infectious diseases that methadone can help reduce."

Barriers to Effective Methadone Programs

Restrictions imposed in methadone treatment programs have occurred for several reasons. They include philosophical opposition to methadone treatment, and reliance on such treatment to achieve abstinence from psychoactive drugs.[398] As one observer writes, "methadone maintenance treatment provides a clear example of how regulations can reduce the public health effectiveness of a controversial program for unpopular people."[399] The US Institute of Medicine concluded that current policies place "too much emphasis on protecting society from methadone and not enough on protecting society from the epidemics of addiction, violence, and infectious diseases that methadone can help reduce."[400] The same observation has been made in Canada, where it has been stated that the rules and regulations of methadone programs are often barriers to effective care of injection drug users.[401]

Low numbers, little funding, and other issues

The number of heroin-dependent persons in Canada who have been treated with methadone is low. According to a Québec report, Switzerland, Australia, and even the United States have a higher proportion of heroin-dependent persons in methadone maintenance programs.[402] A similar conclusion was reached by a professional at the Centre for Addiction and Mental Health in Ontario, who states that an examination of methadone-treatment spots per million capita reveals that Canada is at "the bottom end" in comparison with public health jurisdictions such as Australia, Switzerland, and Belgium."[403]

In addition, the funding of methadone programs in Canada is inadequate, and too few physicians and pharmacists participate in providing MMT.[404] As will be discussed, the programs in Canada have also been criticized for the array of rules and regulations to which patients are subjected. They include rigorous assessment procedures, mandatory daily visits, abstinence as a

[394] Nadelmann, supra, note 95 at 52.

[395] Des Jarlais & Friedman, supra, note 156.

[396] Gerstin, supra, note 214 at 254.

[397] 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 at 454.

[398] Des Jarlais et al, supra, note 83 at 1581.

[399] Ibid at 1583.

[400] *Federal Regulation of Methadone Treatment*. Washington DC: National Academy Press, 1995. Cited in Des Jarlais, ibid at 1581.

[401] Millar, supra, note 86 at 17.

[402] R Cloutier. Rapport du Comité sur les traitments et les services cliniques associés à la méthadone, présenté au sous-ministre adjoint à la Santé publique, 9 April 1999.

[403] Fischer, supra, note 227 at 368.

[404] Millar, supra, note 86 at 17.

condition of treatment, and random urine sampling.[405] Other barriers are user fees imposed on participants in methadone programs, and pharmacy fees.[406]

Methadone programs have been criticized for their abstinence orientation. Patients in many of these programs are expected to refrain from non-prescription drug use. Urine testing is used as the primary means of determining compliance. Such regulations are considered a deterrent to the treatment of drug-dependent persons. It has been stated that:[407]

> Drug services are to prioritize the need to make and maintain contact with injecting drug users in order that they might work upon changing behavior. In order to maximize contact, services can no longer afford to work with those who seek to stop using drugs. It has been estimated that only between 5 to 10% of the drug-using population are prepared to consider entering an abstinence-oriented program at any time.

Rules and regulations

Pursuant to section 68(1)(d) of the Narcotic Control Regulations, the Minister of Health may in writing authorize any practitioner to sell, prescribe, give, or administer methadone. Requests for authorization to prescribe methadone are reviewed by the Bureau of Drug Surveillance. Authorization is provided by the Therapeutic Products Program on behalf of the Minister of Health.[408]

In 1972 it became mandatory for physicians to obtain authorization from the federal government to prescribe methadone. As previously discussed, this new process resulted in a reduced number of health-care providers who were prepared to treat opioid-dependent persons with methadone. In 1992 the federal Health Protection Branch produced guidelines on methadone maintenance entitled The Use of Opioids in the Management of Opioid Dependence.[409] Requirements to be met for physicians to prescribe methadone, criteria for admission of patients to methadone programs, urine drug testing, dosage, and carry privileges were contained in the federal guidelines. There were complaints by physicians and patients that the guidelines were overly restrictive and that they impeded access to treatment.[410] In 1996, the federal government transferred authority to the provinces to delineate the conditions under which physicians are permitted to prescribe methadone.[411] It is still necessary for physicians to obtain federal authorization pursuant to the Narcotic Control Regulations to prescribe and administer methadone to their patients.

Physicians, other health-care professionals, and patients continue to view the current process in Canada as a disincentive for drug-dependent persons to seek treatment for their drug dependence. In January 1999, an Ontario physician wrote:[412]

> Tremendous controversy exists about the severe restrictions applied to patients taking methadone – restrictions which do not apply in any fashion to the prescribing of other equally or more dangerous narcotics. It would take a treatise to explain the political and philosophic history underlying the severity of standards which must be met by Ontario methadone patients... [who] generally view the Guidelines as oppressive and in contradiction to patient autonomy.

[405] Ibid.

[406] Ibid.

[407] PA O'Hare. A Note on the Concept of Harm Reduction. In *The Reduction of Drug-Related Harm*, supra, note 94.

[408] National Consultation Meeting on Methadone Maintenance Treatment, 19-20 February 1998.

[409] Ottawa: Minister of Supply and Services, 1992.

[410] National Consultation Meeting, supra, note 408, presentation by JM Ruel on a historical perspective of methadone treatment in Canada.

[411] Hankins, supra, note 88 at 1141.

[412] Letter dated 7 January 1999 from P Berger.

Another health-care professional in British Columbia has stated that the rules and regulations that currently exist – rigorous assessment procedures, daily visits, and random urine sampling – deter many drug-dependent persons from seeking treatment.[413]

Inadequate dosages of methadone for patients, for example, have been a subject of controversy. As one observer notes, the goal of physicians is to achieve a therapeutically effective dose. It is asserted that relatively high-dosage treatment that includes the participation of patients in discussions results in higher retention rates.[414] In North America, most methadone programs lose an average of one-third of their clients in the first 12 months and another third in the following 12 to 24 months.[415] It is stated that considerable variation exists in the rate at which patients metabolize methadone due to differences in metabolism and absorption from the gastrointestinal tract.[416] The complexity and rigidity of regulations imposed on physicians, it is argued, is contrary to the notion that treatment is individualized in accordance with the needs of the patient.[417] As some health professionals state, maximum doses may be dictated by politics or policy rather than by medical criteria.[418]

A brief review will be undertaken of the methadone guidelines or regulations that exist in some of the provinces – Alberta, Ontario, and British Columbia. This summary will reveal some of the conditions imposed on physicians and patients who participate in programs that treat opioid dependence.

Ontario

In 1996 the Ontario College of Physician and Surgeons, the Addiction Research Foundation, and the Ontario College of Pharmacists developed Methadone Maintenance Guidelines[419] for the province. To be eligible to participate in an Ontario methadone program:

- the candidate must be at least eighteen years old;
- he or she must meet the criteria set out in Diagnostic and Statistical Manual for Mental Disorders (DSM-IV) for opioid dependence;
- the candidate must have or had extensive past opioid use and/or failed treatment; and
- the results from a urine test for opioids must be positive.

Both medical and psychological assessments are conducted on the prospective patient. A treatment agreement that delineates the responsibilities and obligations of the patient must be signed. The patient must be informed if the addiction treatment centre at which they are seeking treatment does not provide comprehensive medical care.

Urine toxicology screening is conducted to ensure that the patient is ingesting the methadone that is prescribed, as well as to detect whether the patient is using any other non-prescribed drugs. It is stated in the Guidelines that "as a general rule, the validity of urine screen results increases if the collection is done under supervision." A urine sample is taken from the patient twice a week during the period of methadone stabilization, after which it is conducted randomly. A suggested protocol is provided in the Ontario guidelines for doses of methadone.

Carry or take-home medication is not recommended during the first three months of stabilization. After that period, patients considered to be

[413] Millar, supra, note 86 at 17.

[414] Zweben & Payte, supra, note 213 at 591.

[415] Price & D'Aunno, supra, note 236 at 46.

[416] Fischer, supra, note 215.

[417] Zweben & Payte, supra., note 213 at 591.

[418] Des Jarlais et al, supra., note 83 at 1581.

[419] Methadone Maintenance Guidelines, supra, note 212.

"functionally stable" are eligible for carry privileges. A list of criteria is provided for this assessment, which includes abstinence, active participation in the methadone program, and social integration such as securing employment. Patients involved in the methadone program for a three-month period are permitted three take-home doses, five doses are given to those who have participated in the program for six months, and patients who have completed twelve months are eligible for six take-home doses.

The Ontario Ministry of Health, which funds the College of Physicians and Surgeons of Ontario to administer the methadone program, has asked the College to provide quality assurance. In 1998 the College audited physicians who prescribe methadone. Some physicians were instructed by the College to refrain from prescribing methadone, as they failed to strictly adhere to the guidelines. Legal counsel was retained by the physicians and a settlement was reached with the Ontario College.

British Columbia

The College of Physicians and Surgeons of British Columbia, like their Ontario counterparts, also have methadone maintenance guidelines.[420] Eligibility to participate in a methadone program is similar to the Ontario guidelines. In terms of urine drug testing, samples are taken from patients two times a week during the first three months of treatment. Some patients are supervised while they urinate. After this period, random urine testing occurs at least twice a month. Patients are instructed not to use illegal drugs. Positive urine test results may result in withdrawal from the methadone program.

Carry privileges are limited, according to the BC guidelines, because of the possibility of methadone diversion. In all circumstances, carry privileges are limited to a maximum of four days. Daily doses of methadone that exceed 100 mg must be justified and the reasons clearly documented on the file of the patient; consultation must have taken place with the medical licensing authority, and Health Canada must be informed in writing. With the exception of carrying privileges, daily methadone doses must be ingested under the direct supervision of a health professional. The number of patients a private practitioner may treat is dependent on the professional and therapeutic involvement required for each patient. The maximum case load is to be determined by Health Canada and the medical licensing authority.

Alberta

In Alberta, an agency of the provincial government, the Alberta Alcohol and Drug Abuse Commission (AADAC), has published guidelines on methadone.[421] Only those persons who have long-term opiate addictions and who have unsuccessfully tried other forms of treatment may enter a methadone program. Patients are expected to abstain from the consumption of all other drugs. This includes marijuana/hashish, alcohol, and other mind-altering and narcotic analgesic drugs. Urine testing is routinely conducted to ensure that patients are compliant with this rule. A heat-sensitive strip is placed in the urine. Patients who continue to use unauthorized drugs are placed on mandatory withdrawal.

After four to six weeks in the program, clients who are stabilized on a specific dose of methadone are permitted to obtain their methadone from a community pharmacy. Clients are required to pay for their methadone and

[420] College of Physicians and Surgeons of British Columbia, *Methadone Maintenance*; and College of Physicians and Surgeons of British Columbia, *Golden Rules Methadone Treatment Guidelines*.

[421] See references in: AADAC Adult Services. Opiate Dependency Program – Client's Manual. West End Treatment Centre. Edmonton, September 1998; AADAC Adult Services. A brief description of West End Treatment Centre Opiate Dependency Program, undated; AADAC Adult Services. Opiate Dependency Program – Pharmacist's Manual. West End Treatment Centre. Edmonton, 1997.

must consume their dosage at the pharmacy. This is designed to prevent diversion. Carry-out privileges are permitted for a maximum of four days.

Prison Policies

Concern also exists about limited access to MMT in prisons. In September 1996 the British Columbia Corrections Branch adopted a policy of continuing methadone for incarcerated adults who were already on MMT in the community, becoming the first correctional system in Canada to make MMT available 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, 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 MMT even if they were not on such treatment on the outside.[422]

Ethical Considerations

Roy writes:

> 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?[423]

According to the harm-reduction ethic, any step to reduce the harms associated with drug use is valuable.[424] Drug addiction is confronted pragmatically without moralizing. The harm-reduction ethic does not seek to achieve abstinence now:

> 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.[425]

The ethics of harm reduction is founded on the notion that a drug user's present is influenced by the past, but that the past does not determine the drug user's future. New achievements can be accomplished in the future but the past will not quickly dissipate. If needle exchange and methadone programs are judged

[422] See *HIV/AIDS in Prisons - Info Sheet 7. Prevention and Treatment: Methadone*. Montréal: Canadian HIV/AIDS Legal Network, 1999.

[423] Roy, supra, note 109.

[424] Ibid.

[425] N Gunn, C White, R Srinivasan. Primary care as harm reduction for injection drug users. *Journal of the American Medical Association* 1998; 280: 1191 at 1195.

to be morally wrong, or are considered a capitulation to deviance, the means required to reduce harms to drug users will be obstructed.

In Loue et al,[426] the four principles of (1) beneficence and non-maleficence; (2) respect for persons (autonomy and dignity); (3) justice and fairness; and (4) utilitarianism are applied to NEPs. These principles can be equally applied to methadone programs.

Beneficence and non-maleficence reflect the principle of maximization of good to the patient and the minimization of harm. Needle exchange programs benefit participants by reducing the risk of fatal diseases such as HIV or hepatitis C in injection drug users. Respect for persons entails the right of an individual to self-determination, or the ability to make informed decisions regarding the course of action to be taken.[427] NEPs seek to help drug users make healthy decisions such as the use of sterile syringes in the injection of drugs. NEPs can also promote respect for persons by increasing access to drug treatment services and by making counseling available. Respect for persons also requires that confidentiality of clients be rigorously maintained, particularly when the failure to do may result in social stigmatization and criminal prosecution.[428] The ethical principle of justice and fairness mandates an equitable distribution of burdens and benefits among individuals in a community. Insufficient resources have been allocated in our society to address the problems of injection drug users. The principle of utilitarianism dictates the maximization of good to society. When injection drug users enter treatment programs on the recommendation of NEP staff, the number of individuals in a community who require medical care is reduced; this has an impact on drug-related morbidity.[429]

Recommendations

The following recommendations, if implemented, would go a long way toward ensuring that needle exchange and methadone maintenance treatment programs in Canada better fulfill their goals.

Methadone

50. Federal, provincial, and territorial governments should take measures to ensure that methadone maintenance programs are available to persons in all provinces and territories, including in rural and semi-urban areas.
51. Government health officials and Colleges of Physicians and Surgeons should ensure that comprehensive services are available to persons who participate in methadone programs. This includes primary health care, counseling, education, and support services.
52. Correctional systems should ensure that prisoners who were in a methadone maintenance program prior to incarceration are able to continue methadone maintenance treatment while incarcerated, and that prisoners are able to start such treatment in prison whenever they would have been eligible for it outside.
53. To dispel the existing myths about methadone maintenance treatment, provincial and territorial health departments should take measures to ensure that public education programs and materials on methadone programs are disseminated in all areas of the country.
54. Health Canada, provincial and territorial health ministries, and Colleges of Physicians and Surgeons, in consultation with drug users and community-based agencies, should undertake a review of the methadone regulations

[426] Loue et al, supra. note 343.

[427] Ibid.

[428] Ibid.

[429] Ibid.

and rules to ensure that they are in conformity with the care, treatment, and support needs of injection drug users.

55. The Association of Canadian Medical Colleges, health science facilities at universities, and the Canadian Association of Teaching Hospitals should ensure that courses on drug use, methadone maintenance programs, and pain management are introduced into the curricula of schools of medicine, pharmacy, and nursing.
56. Health Canada and provincial and territorial health officials, in consultation with drug users and community-based agencies, should develop quality-control measures for methadone programs in Canada.
57. Federal, provincial and territorial health officials should ensure that methadone programs are responsive to the needs of different populations (eg, Aboriginal persons).
58. Provincial and territorial health officials and Colleges of Physicians and Surgeons should take measures to ensure that methadone programs are based on principles of harm reduction. Respect for persons, flexibility of treatment, and consistency in treatment should be integral components of every program.
59. Colleges of Physicians and Surgeons should consider whether a speciality in addiction medicine should exist.

Needle Exchange Programs

60. The federal, provincial, territorial, and municipal governments should ensure that needle exchange programs are easily accessible to injection drug users in all parts of Canada.
61. The federal government should repeal criminal laws that subject drug users and needle exchange staff to criminal liability for having in their possession drug paraphernalia containing residue of illegal substances.
62. A meeting should be funded by the federal, provincial, territorial, and municipal governments for people working in needle exchange programs across the country in order to develop best-practices documents.
63. Health officials should ensure that a quota system on needles exchanged at needle exchange programs is abandoned; injection drug users should have access to as many needles as they require, at no cost.
64. Health Canada should fund a study of the legal and ethical issues surrounding the provision of sterile needles to minors.
65. Correctional systems should make sterile injection equipment available in prisons.
66. Pharmaceutical associations as well as licensing bodies should encourage pharmacists to distribute sterile syringes.

Conclusion

Canada is in the midst of a public health crisis concerning HIV/AIDS and injection drug use. The number of HIV infections and AIDS cases attributable to injection drug use has been climbing steadily. By 1996, half of the estimated new HIV infections were among injection drug users.

Canada's response to this crisis is far from being concerted and effective. Indeed, the lack of appropriate action has led some to conclude that another public health tragedy, comparable to the blood tragedy in the 1980s, is underway, illustrating that little if anything has been learned from the lessons taught by that tragedy. As Skirrow says:

> A marginalized community (in this case injection drug users) is experiencing an epidemic of death and disease resulting not from anything inherent in the drugs that they use, but more from the ineffective and dysfunctional methods that characterize our attempts to control illegal drugs and drug users. There is the same unwillingness to carefully analyze the problem or to depart from traditional methods and conventional thought that was integral to the blood tragedy. There is a struggle for power and control over the issue between law enforcement and public health. There is a profound lack of understanding among decision-makers and many health professionals regarding the nature of the community and individuals at risk.[430]

This report and the extensive consultations leading to it have shown, once again, that the legal status of drugs in Canada contributes to the difficulties encountered in addressing HIV among injection drug users. However, it also shows that much can be done now, without waiting for the much-needed legal

[430] J Skirrow. Lessons from Krever – A Personal Perspective. *Canadian HIV/AIDS Policy & Law Newsletter* 1999; 4(2/3): 35-41 at 40-41.

changes, within the current legal framework; indeed, much *must* be done, as ethical analysis reveals, because current approaches do not withstand ethical scrutiny:

> 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 in order 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.
>
> 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.[431]

Implementing the recommendations in this report will have an immediate impact on Canada's ability to prevent the further spread of HIV and other infections among injection drug users, and to provide care, treatment, and support to those already living with HIV or AIDS. Implementing these recommendations must therefore become an urgent priority.

[431] Roy, supra, note 109.

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Appendix A: List of Recommendations

The Current Legal Status of Drugs

1. In the long term, federal and provincial governments should establish a more constructive alternative to the current legal framework, and provide the research, educational, and social programming required to reduce the harms of drug use. Governments, and all Canadians, must:
   - acknowledge the extent of drug use and the diversity of drug users in Canada;
   - acknowledge that Canada's current drug laws have a disproportionate impact on the most vulnerable in Canadian society, including Aboriginal people, racial minorities, and women;
   - acknowledge that current laws increase rather than decrease the harms from drug use and, in particular, marginalize drug users;
   - recognize the human rights of drug users, and recognize the ways in which current laws and treaties violate the human rights of drug users in Canada; and
   - if necessary, denounce international drug-control conventions if these present insurmountable barriers to implementing more constructive drug-control policies and laws in Canada that are based on a harm-reduction model.
2. In the short term, under the existing legal framework, the federal and provincial governments should fund research on the differential impact of current drug legislation, policies, and practices according to race, class, gender, and other socioeconomic factors.

3. In consultation with drug users and community-based agencies providing services to drug users, the federal and provincial governments should assess the positive outcomes of initiatives such as diversion policies, alternative measures, and the pilot projects implementing such alternatives. If assessed favourably, such initiatives should be further expanded to temper the punitive approach currently reflected in Canadian drug laws and policies.
4. The federal government should make use of its regulatory and exemption powers under current legislation to expressly exclude injection equipment containing traces of illegal drugs from the definition of "controlled substance" in the *Controlled Drugs and Substances Act*.
5. The federal government should take the necessary steps to clarify that those operating needle exchange or distribution programs are not liable to criminal prosecution under the drug paraphernalia provisions of the *Criminal Code* for the "sale" of "instruments or literature for illicit drug use."
6. The federal government should use its regulatory and exemption power under the *Controlled Drugs and Substances Act* to decriminalize the possession of small amounts of currently illegal drugs for personal use, at least when medically prescribed by a qualified and authorized health-care professional.
7. The federal government should ensure that there is a fair and timely process by which Canadians and their health-care professionals can apply for medical access to currently illegal drugs.

Drug Use and Provision of Health and Social Services

8. In the long term, laws should be changed so as to enable provision of currently illegal drugs to drug users while they are in care, so as to remove a barrier to drug users accessing health care and other social services and to remove the threat of criminal liability for service providers who wish to provide care, treatment, and support without insisting on abstinence by patients who use currently illegal drugs.
9. In the short term, within the current legislative/regulatory framework, the federal government should adopt a regulation that authorizes the release of psychoactive drugs in the context of palliative care, respecting the dignity of drug users in the dying process.
10. Health Canada should fund an ethical and legal analysis of four or five situations or scenarios frequently encountered in the provision of HIV-related services to drug users (such as providing an injection room for drug users in a residential or institutional setting). These situations should be selected in collaboration with agencies and organizations that provide these services.
11. Professional associations should develop ethical and practice guidelines for service providers in different areas of care involving HIV/AIDS and injection drug use – primary health care, community clinics, pharmacy services, residential care, palliative care, housing services. These guidelines should address the tensions between the legal constraints and the ethical imperative of providing services to HIV-positive drug users. The guidelines should be developed in consultation with drug users and community-based organizations providing services to drug users and/or people with HIV/AIDS.

12. Professional associations should organize a comprehensive training program for health-care providers, social service providers, members of the police force, and lawyers, after the legal/ethical analysis has been completed and the guidelines have been developed.
13. Federal and provincial health officials should fund a series of national meetings of front-line workers and drug users to discuss the policies and practices involved in the care of drug users. The purpose of the meetings is to share information and experiences, delineate best practices, and contribute to the development of training programs and the ethical and practice guidelines.

    Federal and provincial health ministries and professional associations should organize regular workshops and seminars for providers of HIV-related services to drug users. This will provide a forum for information sharing, problem solving, and skills building. HIV/AIDS medication, support services, housing, hospices, and palliative care are some topics to be explored.
14. As part of the Canadian Strategy on HIV/AIDS, Health Canada should develop and implement, in close collaboration with relevant stakeholders, a strategy for integrating HIV/AIDS and drug programming in Canada. In developing such integrated programming, due consideration must be given to the implications for drug laws and policies of a public health, harm-reduction model of responding to the use of illegal drugs.

Treatment

Basic Principles

15. Health-care professionals should ensure that the provision of services to drug users is not contingent upon drug users' agreement to enter drug treatment programs.
16. Health-care professionals must not withhold or refuse treatment (including appropriate pain medication) simply because a person with HIV/AIDS is a drug user.
17. The governing approach in providing care and treatment to HIV-positive drug users should be to adapt the therapeutic regimen to the needs of drug users, rather than require drug users to adapt to the therapeutic regimen.
18. Physicians and drug users should jointly explore therapeutic options regarding the most appropriate regimen. This process should be governed by principles of humanity, autonomy, lucidity, and fidelity.
19. Provincial human rights commissions that have not done so should adopt policies clearly stating that drug dependency constitutes a prohibited ground of discrimination.

Medical Treatment

20. Health-care professionals and ethicists should collect information for the purpose of developing guidelines on the clinical and ethical issues that arise in practice with respect to the medical treatment of drug users. This should include the assessment of the appropriateness of imposing restrictions on drug users, such as the cessation of drug use, in specific clinical situations.

21. The Canadian Medical Association, provincial medical associations, and provincial Colleges of Physicians and Surgeons should establish a network of physicians who have experience and/or interest in the delivery of health care and treatment to drug users, to discuss pertinent issues and to advocate for change with respect to the medical treatment of HIV-positive drug users.

HIV Antiretroviral Therapy

22. The pharmaceutical industry must develop simpler HIV drug regimens that can be more easily adhered to by HIV-positive drug users (as well as other people with HIV/AIDS).
23. Public health should offer or make available support to drug users who require assistance in adhering to HIV therapies. This should include funding outreach programs designed to deliver HIV therapies to drug users.

Prescription of Opiates and Controlled Substances

24. In the longer term, Health Canada should develop plans to permit physicians to prescribe opiates and controlled stimulants.
25. In the shorter term, pilot projects involving the prescription of heroin, cocaine, and amphetamines should be authorized, funded, and initiated in Canada. The pilot projects should:
    - involve both drug users and general practitioners in the design, implementation, assessment of outcomes, and recommendations for practice;
    - be accompanied by public education at the local, provincial, and national levels that presents the benefits of the project to drug users and to the community at large;
    - contain a multi-phase design that includes plans once the trials are completed for implementing such treatment options more widely if the pilot projects are deemed successful in achieving harm-reduction objectives; and
    - address the problems likely to be encountered by drug users and health-care providers when the transition is made from a controlled clinical trial to general practice.

Drug Users and Studies of HIV/AIDS and Illegal Drugs

The Research Agenda

26. The Medical Research Council and pharmaceutical companies, in consultation with community groups and drug users, should develop a comprehensive research agenda that identifies priorities in research for injection drug users.
27. Members of the medical and scientific professions should conduct research on issues relevant to HIV/AIDS and drug use, such as the interactions between illegal and prescribed drugs, and the effects of illegal drugs on the progression of HIV disease.
28. Pharmaceutical companies should take a leadership role in promoting studies that test the interaction of HIV/AIDS drugs with illegal drugs.

29. Clinical researchers should recognize the importance of conducting research for and by First Nations groups as well as other communities affected by HIV/AIDS.
30. The National Health Research and Development Program of Health Canada should provide funding to develop capacity building for community-based research.

Research into Illegal Drugs

31. The provincial/territorial ministries of health should take measures to ensure that laboratories are established across Canada to test controlled substances used by drug users.
32. Provincial/territorial ministries of health should provide funding for test kits for drug users that measure the dose and purity of drugs.

Participation in Research

33. As a general principle, clinical researchers and professional associations should take measures to ensure the removal of barriers to the participation of drug users in clinical trials.
34. Those conducting clinical trials, in consultation with community groups and drug users, should develop recruitment strategies to encourage participation of HIV-positive drug users in clinical trials.
35. Medical researchers should establish study sites for clinical trials in geographical areas that are easily accessible to drug users.
36. Those conducting clinical trials should offer child-care and transportation costs to prospective participants, to encourage individuals to take part in trials.
37. Medical researchers should provide information on proposed medical studies (including consent forms) to drug users in language that is accessible.
38. The National Council for Ethics in Human Research should develop guidelines for research involving marginalized persons.
39. The Canadian HIV Trials Network should develop guidelines for researchers on ensuring that research participants who are drug users provide informed consent for their participation. Such material could include a model informed consent form that does not automatically exclude those using illegal drugs, but also specifically addresses questions such as the interactions between the study drug and illegal drugs (when known), as well as outlining the steps taken to protect the confidentiality of data gathered from the participant (including information regarding use of illegal drugs) and the possible limits on that confidentiality.
40. Federal and provincial officials, including law enforcers, should be prohibited from having access to identifying information respecting participants in research files.

Information about the Use and Effects of Illegal Drugs

41. Federal, provincial, and territorial health officials should provide the funding for the development and wide distribution of accurate, non-biased, and non-judgmental information on illegal drugs for health-care providers, drug users, and members of the public.
42. Hospitals should be required to forward information on drug overdoses to provincial public health departments, which in turn should create a database on drug overdoses. This information should be disseminated to organizations that deal with drug use and should also be available to members of the public.
43. Federal, provincial, and territorial health officials as well as community organizations should provide information on currently illegal drugs and community organizations in a format and in language that is accessible to different cultural groups in various geographical locations in Canada (eg, Aboriginal communities).
44. Provincial and territorial governments, government agencies, and community-based organizations should develop education programs based on a harm-reduction philosophy.
45. Hospitals and professional associations should organize educational sessions on drug use for health-care professionals (eg, grand rounds, continuing education programs).
46. Provincial and territorial ministries of education and health should undertake an evaluation of school programs on illegal drugs.
47. Universities and colleges should ensure that the curricula of health-care professionals include accurate, unbiased, and non-judgmental materials, presentations, and discussions about drugs, drug use, and harm-reduction approaches to drug use.
48. Provincial and territorial governments should create a body to oversee the adherence of best-practice guidelines by health-care workers and other persons who administer care and treatment to drug users.
49. Federal, provincial, and territorial officials should convene a forum for the discussion of educational material that should be disseminated. It should include federal, provincial, and territorial health officials, the police, drug users, and organizations such as the Centre for Addiction and Mental Health.

Needle Exchange and Methadone Maintenance Treatment

Methadone

50. Federal, provincial, and territorial governments should take measures to ensure that methadone maintenance programs are available to persons in all provinces and territories, including in rural and semi-urban areas.
51. Government health officials and Colleges of Physicians and Surgeons should ensure that comprehensive services are available to persons who participate in methadone programs. This includes primary health care, counseling, education, and support services.
52. Correctional systems should ensure that prisoners who were in a methadone maintenance program prior to incarceration are able to continue methadone

maintenance treatment while incarcerated, and that prisoners are able to start such treatment in prison whenever they would have been eligible for it outside.

53. To dispel the existing myths about methadone maintenance treatment, provincial and territorial health departments should take measures to ensure that public education programs and materials on methadone programs are disseminated in all areas of the country.
54. Health Canada, provincial and territorial health ministries, and Colleges of Physicians and Surgeons, in consultation with drug users and community-based agencies, should undertake a review of the methadone regulations and rules to ensure that they are in conformity with the care, treatment, and support needs of injection drug users.
55. The Association of Canadian Medical Colleges, health science facilities at universities, and the Canadian Association of Teaching Hospitals should ensure that courses on drug use, methadone maintenance programs, and pain management are introduced into the curricula of schools of medicine, pharmacy, and nursing.
56. Health Canada and provincial and territorial health officials, in consultation with drug users and community-based agencies, should develop quality-control measures for methadone programs in Canada.
57. Federal, provincial and territorial health officials should ensure that methadone programs are responsive to the needs of different populations (eg, Aboriginal persons).
58. Provincial and territorial health officials and Colleges of Physicians and Surgeons should take measures to ensure that methadone programs are based on principles of harm reduction. Respect for persons, flexibility of treatment, and consistency in treatment should be integral components of every program.
59. Colleges of Physicians and Surgeons should consider whether a speciality in addiction medicine should exist.

Needle Exchange Programs

60. The federal, provincial, territorial, and municipal governments should ensure that needle exchange programs are easily accessible to injection drug users in all parts of Canada.
61. The federal government should repeal criminal laws that subject drug users and needle exchange staff to criminal liability for having in their possession drug paraphernalia containing residue of illegal substances.
62. A meeting should be funded by the federal, provincial, territorial, and municipal governments for people working in needle exchange programs across the country in order to develop best-practices documents.
63. Health officials should ensure that a quota system on needles exchanged at needle exchange programs is abandoned; injection drug users should have access to as many needles as they require, at no cost.
64. Health Canada should fund a study of the legal and ethical issues surrounding the provision of sterile needles to minors.

65. Correctional systems should make sterile injection equipment available in prisons.
66. Pharmaceutical associations as well as licensing bodies should encourage pharmacists to distribute sterile syringes.

Appendix B: List of Workshop Participants

This is a list of the participants in the three workshops organized in both phases of the Project. Some people participated in all three workshops; others only in one or two. Organizational affiliations indicated are those at the time of the workshop, and may since have changed.

Russell Armstrong	Canadian AIDS Society, Ottawa
Rafi Ballion	Queen Street Community Health Centre, Toronto
Sharon Baxter	Canadian AIDS Society, Ottawa
Ronda Bessner	Legal and Policy Consultant, Toronto
Reeta Bhatia	AIDS Care, Treatment and Support Program, Health Canada, Ottawa
Suzanne Brissette	Hôpital St-Luc, Montréal
Paula Braitstein	BC Persons with AIDS Society, Vancouver
Erica Burnham	Canadian HIV/AIDS Legal Network, Montréal
Walter Cavalieri	Toronto
Carmen Charest	Centre québécois de coordination sur le sida, Montréal
Richard Cloutier	Centre québécois de coordination sur le sida, Montréal
Pierre Côté	Clinique Quartier Latin, Montréal
Theodore de Bruyn	Research Consultant, Ottawa
Suzanne Deschênes	Chez ma cousine Evelyn, Montréal
Anne Marie Dicenso	Prisoners with HIV/AIDS Support Action Network, Toronto
Arlo Yuzicapi Fayant	All Nations Hope AIDS Network, Regina
Richard Elliott	Canadian HIV/AIDS Legal Network, Toronto
Melissa Eror	Vancouver Area Network of Drug Users, Vancouver
Elizabeth Evans	Portland Hotel, Vancouver

Benedikt Fischer	Centre for Addiction and Mental Health, Toronto
Catherine Hankins	Direction de la santé publique de Montréal-Centre, Montréal
Alain Houde	Canadian AIDS Society, Ottawa
Theresa Jasperson	Boyle McCauley Co-op Streetworks, Edmonton
Ralf Jürgens	Canadian HIV/AIDS Legal Network, Montréal
Tyleen Katz	May's Place, Vancouver
Paul Kenney	AIDS Care, Treatment and Support Program, Health Canada, Ottawa
Nancy Kotani	Vancouver/Richmond Health Board, Vancouver
Lise Ladouceur	Chez ma cousine Evelyne, Montréal
Claire Lahaie	CACTUS, Montréal
Rosanne LeBlanc	Nova Scotia Advisory Commission on AIDS, Halifax
Trudo Lemmens	University of Toronto Joint Centre for Bioethics, Toronto
Brian MacKenzie	Vancouver
Diane McAmmond	Consultant, Duncan, BC
Tom McAulay	Canadian Treatment Advocates Council, Vancouver
Carole Morissette	Direction de la santé publique de Montréal centre, Montréal
Joanne Mussell-Oppenheim	Vancouver Native Health, Vancouver
Eugene Oscapella	Canadian Foundation for Drug Policy, Ottawa
Brent Patterson	Community AIDS Treatment Information Exchange, Toronto
David Patterson	Consultant, Geneva, Switzerland
Cindy Reardon	Street Health AIDS Project, Toronto
Anne Renaud	Canadian HIV/AIDS Legal Network, Montréal
David Roy	Centre for Bioethics/IRCM, Montréal
Diane Riley	International Harm Reduction Association, Toronto
Jan Skirrow	Consultant, Duncan, BC
Marianne Tonnelier	CACTUS, Montréal
Mark Townsend	Portland Hotel, Vancouver
Richard Walsh	Chez ma cousine Evelyn, Montréal
Cheryl White	Queen Street Community Health Centre, Toronto
Beth Wolgemuth	Street Health AIDS Project, Toronto