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

Rapid HIV Screening at the Point of Care:

Legal and Ethical Questions

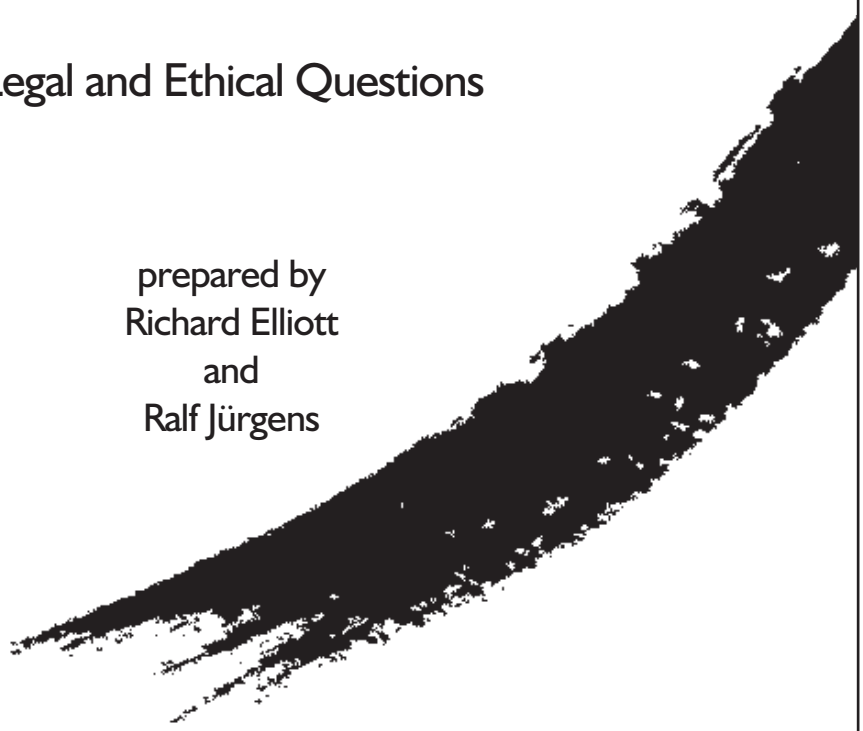
Canadian Strategy on HIV/AIDS

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

Rapid HIV Screening at the Point of Care:

Legal and Ethical Questions

prepared by
Richard Elliott
and
Ralf Jürgens



Rapid HIV Screening at the Point of Care: Legal and Ethical Questions

Prepared by
Richard Elliott
and
Ralf Jürgens
for the Canadian HIV/AIDS Legal Network

For further information about this publication, please contact:

Canadian HIV/AIDS Legal Network
484 McGill Street, Suite 400
Montréal, QC H2Y 2H2
Tel: 514 397-6828
Fax: 514 397-8570
Email: info@aidslaw.ca
Website: www.aidslaw.ca

Further copies can be retrieved at www.aidslaw.ca
or ordered through the
Canadian HIV/AIDS Clearinghouse
Tel: (613) 725-3434
Fax: (613) 725-9826
Email: aids/sida@cpha.ca

ISBN 1-896735-40-1

Canadian Cataloguing in Publication Data

Elliott, Richard

Rapid HIV screening at the point-of-care: legal and ethical questions

Includes bibliogaphical references.
Text in English and French, on inverted pages.

ISBN 1-896735-40-1

1. AIDS (Disease) – Diagnosis. 2. HIV infections – Diagnosis. 3. AIDS (Disease) – Diagnosis – Law and legislation. 4. AIDS (Disease) – Diagnosis – Moral and ethical aspects. I. Jürgens, Ralf, 1961 - . II. Canadian HIV-AIDS Legal Network. III. Title. IV. Title: Dépistage rapide du VIH aux points de services.

RC607.A26E44 2000 616.97'92075 C00-940511-9E

To Tasha Yovetich
for her support, comments, and commitment

Acknowledgments
The authors wish to thank Éric Nolet and Anne Renaud of the Canadian HIV/AIDS Legal Network for handling the demanding logistics of this project, the organization of the workshop, and the distribution of materials; Barry Hoffmaster for his preparation of the accompanying ethical commentary; the participants at the national workshop and others who provided comments on an earlier draft of this paper for their input and assistance in locating information and documents; Maria Carballo and Debbie Lepine of Health Canada's Medical Devices Bureau, Janis Tripp of the AIDS Bureau (Ontario Ministry of Health & Long-Term Care) and Dr Susan King, Sick Kids Hospital, Toronto, for responding to many questions; David Garmaise and Ross Hammond for facilitating the workshop and providing comments; Garry Bowers for copyediting the English text; Jean Dussault for translating the original English text into French; Communication Works, Ottawa, for layout; and Rob Champagne for his encouragement and patience. Any errors or omissions are those of the authors alone.

Funding
Funding for this project was provided by the HIV/AIDS Policy, Coordination and Programs Division, Health Canada, under the Canadian Strategy on HIV/AIDS. The opinions expressed in this document are those of its authors and do not necessarily reflect the views or policies or Health Canada or the Canadian HIV/AIDS Legal Network. The affiliations of the individuals who participated in the workshop or otherwise provided comments are included for information only.

Ce document est également disponible en français.

Table of Contents

Executive Summary

Background

Early in the HIV/AIDS epidemic, a concerted effort was made to address the issues surrounding HIV-antibody testing and confidentiality in a way that would respect the human rights of individuals, yet at the same time promote the goals of protecting public health. In particular, in Canada a broad consensus emerged that, except in a few well-defined circumstances, people should be tested only with their informed, voluntary and specific consent; when counseling and education before and following testing are available and offered; and when confidentiality of results or anonymity of testing can be guaranteed. This consensus was expressed in recommendations such as those prepared by the National Advisory Committee on AIDS, which provided an ethical framework for evaluating testing policy based on a careful consideration of the inherent costs and benefits of testing to the individual and to society.

In the past years, new testing technologies, advances in HIV/AIDS treatments, and changing patterns of HIV infection have forced us to reconsider approaches to HIV testing. A comprehensive analysis of the new issues and challenges can be found in *HIV Testing and Confidentiality: Final Report*, released in the fall of 1998 by the Canadian HIV/AIDS Legal Network and the Canadian AIDS Society (and available at www.aidslaw.ca).

Now, in the spring of 2000, another new development forces us to again reexamine approaches to HIV testing in Canada: rapid HIV screening tests will be licensed for sale in Canada in 2000, for use by health professionals at the "point of care."

In order to minimize the reporting of false-positive results, until now, under the standard procedure for HIV testing, no positive result was given to the person being tested until confirmatory testing was undertaken. Because rapid test

New testing technologies, advances in HIV/AIDS treatments, and changing patterns of HIV infection have forced us to reconsider approaches to HIV testing.

All decisions about the use and regulation of rapid HIV tests should be informed not only (and not even primarily) by what is technologically feasible.

kits can provide results within 30 minutes, without being sent to a laboratory, this generally accepted practice is being questioned, although positive results will still need to be confirmed. This, and some of the proposed uses of rapid test kits, raise a number of legal and ethical questions that cannot and should not be ignored. Indeed, all decisions about the use and regulation of rapid HIV tests should be informed not only (and not even primarily) by what is technologically feasible, but by an appreciation of the real-life implications of testing technologies, by ethical considerations, and by an understanding of how Canadian law and policy may or may not adequately address these implications and reflect these ethical considerations.

Therefore, the Canadian HIV/AIDS Legal Network, after extensive consultations, including a two-day national workshop held in January 2000, has prepared a detailed analysis of the key legal and ethical questions raised by the use of rapid HIV test kits for point-of-care testing, in order to provide critical thinking and recommendations regarding their introduction in Canada.

Standard HIV Testing versus Rapid Testing

False-positive results will occur, particularly among patients from populations with a low rate of HIV infection.

Currently in Canada, the *standard procedure* for HIV testing involves a trained health-care worker drawing a blood sample from the person getting tested in a clinical setting (usually a physician's office or a testing clinic), with the blood subsequently being tested in a clinical laboratory to detect the presence of HIV-specific antibodies using an enzyme immunoassay (EIA, or "ELISA" test) as a screening test. A negative result is reported if the EIA screening test is nonreactive. Any blood sample that tests positive, however, undergoes a second, confirmatory test (generally the "Western blot"). Only *confirmed* test results are given to the health-care provider who ordered the test. Although the actual testing does not require much time, typically one to two weeks elapse before results are available. This is because blood samples are generally "batched" (ie, tested in groups) to decrease testing costs, and because time is needed to complete confirmatory testing. Every person getting tested, whether the test is positive or negative, must return to the testing site for a second visit to learn their results from the provider.

In contrast, *rapid tests* can be done on-site. A sample is collected and a result is available within 30 minutes after the sample is taken. When HIV antibodies are present in sufficient concentration in the blood of the person being tested, a colour reaction occurs along a test strip. Licensed rapid HIV test kits will have the same sensitivity, specificity, and performance characteristics as *screening* methods currently used in approved laboratories, ensuring a reliable negative test. This permits the health-care professional to complete the HIV testing and counseling at a single visit *for those testing negative*. However, false-positive results will occur, particularly among patients from populations with a low rate of HIV infection. This means that all positive results and all results that are equivocal must be confirmed, requiring that a blood sample be sent to an approved HIV testing laboratory, where it will undergo confirmatory testing.

At least for now, in Canada rapid HIV screening tests will only be licensed for use by health-care professionals at the "point of care." This distinguishes them from home test kits, which require a person to collect the sample themselves and either mail it to a laboratory and receive the test results by telephone (home sample collection or home-access testing), or obtain the results within a

few minutes (true home tests, also called home self-tests or home validated tests).

Under the Medical Devices Regulations, "health-care professional" is defined as "a person who is entitled under the laws of a province to provide health services in the province." In Health Canada's view, it lacks the jurisdiction to draw any further distinctions within the category of "health-care professional." The result is that provincial/territorial legislation defining "health services" and those who are entitled to provide them may end up defining the parameters of who is legally permitted to administer rapid HIV screening tests. These provisions vary from jurisdiction to jurisdiction, giving rise to concerns about different standards of care.

The Scope of the Paper

The paper prepared by the Legal Network:

- explains rapid HIV testing technologies;
- describes the status of rapid HIV test kits in Canada;
- presents an overview of the Canadian regulatory framework applicable to the approval and use of rapid test kits;
- provides a comprehensive evaluation of the potential benefits of making rapid HIV testing at the point of care available in Canada;
- discusses some of the concerns raised by point-of-care use of rapid HIV screening tests, including potential misuses;
- considers how, in light of the potential benefits and the concerns raised, rapid HIV screening tests should be regulated; and
- presents conclusions and recommendations regarding the use of rapid tests in Canada, directed to federal and provincial/territorial policymakers, health-care professionals, professional associations and regulatory bodies of health-care professionals, and those providing HIV testing and counseling and working in the field of public health.

What Are the Potential Benefits of Using Rapid HIV Screening at the Point of Care?

The following potential advantages of using rapid HIV screening at the point of care have been put forward:

- clients' satisfaction can be improved because they can receive their results sooner;
- rapid screening kits are easier and safer to administer;
- people would be able to chose between conventional testing and rapid testing, enhancing their autonomy;
- more people would receive their test results, since most would not have to return for their results and post-test counseling;
- access to HIV screening could be improved; and
- acceptance of HIV testing could be increased.

In addition, it has been argued that rapid screening

- could make it possible, for women whose HIV status is unknown at the time of labour, to undergo screening during labour and, for those screening

The argument that rapid point-of-care screening will significantly increase the number of people who receive their test results cannot be generalized.

positive, to initiate preventive measures to reduce the risk of mother-to-child transmission; and
- could provide more information for decisions about post-exposure prophylaxis (PEP).

However, closer scrutiny reveals that little is known about how significant some of these benefits would be in the Canadian context. In addition, some potential benefits would be realized only in certain, limited circumstances:

- Whether there would be a benefit to faster delivery of results depends upon the outcome of the test. For those who tested negative, as most people would, their anxieties, worries, and fears could be relieved sooner; for them, there would be a definite benefit. But those who tested positive on the screening test would have to await the result of a confirmatory test, enduring psychological and emotional distress that could be greater than what they would have experienced with the mere uncertainty that accompanies standard testing.
- The argument that rapid point-of-care screening will significantly increase the number of people who receive their test results cannot be generalized. Rates of return will vary across the country, between regions, and/or between testing sites. United States data are not particularly relevant or easily applicable when the available Canadian data indicate a very different context. Without solid Canadian data about many aspects of HIV testing, the size – and thus the importance – of this potential advantage of rapid HIV screening at the point of care is hard to gauge.
- While increasing access to quality HIV testing is important, the potential benefits of providing rapid HIV screening in remote settings should not be overestimated. Rapid HIV screening, on its own, falls below the generally accepted standard of care, and must be accompanied by timely access to confirmatory testing. In remote areas, there is a worry that it could take a long time to get a confirmed result for a positive screening test and that the community might not have the resources to support a person with a preliminary positive result during that difficult period. Therefore, if rapid screening kits are to be used in rural or more remote areas, steps would have to be taken to ensure that those who test positive on rapid screening tests would have improved and quicker access to confirmed test results. Consultation with communities who currently have limited access to testing services, and those who provide HIV testing, counseling and support, or other health-care services to these communities, would also be required.
- Being able to rapidly obtain results of an HIV test could assist a woman in labour and her physician(s) make decisions regarding possible interventions during labour and following the birth of her infant to reduce the chance of transmission. However, whether a woman in labour is capable of making a morally autonomous choice about, or giving voluntary, specific and informed consent to, any form of HIV testing is contentious. In addition, the possibility of implementing preventive measures without making these conditional upon a woman consenting to rapid HIV screening requires further careful consideration and discussion.
- Finally, rapid HIV screening offers some potential benefit with respect to making decisions about *starting* post-exposure prophylaxis, but very

limited benefit with regard to decisions about *continuing* the prophylaxis regime.

What Are the Concerns?

While there are potential (albeit probably limited) advantages in using rapid HIV screening at the point of care, there are also many concerns. These range from concerns about the implications of disclosure of positive screening results when, particularly in low-prevalence settings, a significant number of false-positive results will occur; to concerns that people undergoing rapid HIV screening will not receive adequate counseling (particularly people who receive a positive screening result, for whom provision of best-practice counseling and support is essential); to concerns that some of the health-care professionals who may end up being authorized to administer the test kits would not adequately protect confidentiality; to concerns that women in labour whose HIV status is unknown may be screened without their informed consent; to concerns that in a variety of other situations there will be a push for testing without specific informed consent.

What Must Be Done to Address these Concerns?

The concerns raised are serious, and must be addressed. In particular:

- Wherever rapid HIV screening at the point of care is offered, it must be accompanied by accelerated access to confirmed test results, and support services must be easily accessible to people who receive a positive screening result.
- The availability of rapid HIV screening at the point of care will not remove the legal and ethical imperative that testing only be undertaken with pre-and post-test counseling. Indeed, it highlights the importance of counseling, in addition to posing some challenges that are specific to rapid screening and that will have to be addressed. It highlights the importance of counseling because of the potential harm of disclosing a positive screening result. Today, much testing in Canada, particularly outside of designated HIV testing clinics with trained staff, is done with little or no pre-test counseling. While this is bad enough in the context of the current mechanism of HIV testing, it must not be allowed to happen in the context of rapid screening. Imagine a person receiving a positive screening result without having understood that a screening test is only a screening test, that the result may be a false-positive result, and that it is imperative that the person come back to receive a confirmed result, which could well be negative. Because of the need to ensure that all people who receive a positive screening result have received best-practice counseling, only health-care professionals who have undergone a training program, including on how to provide counseling in the context of rapid HIV screening tests, should be allowed to use such tests.
- Rapid screening should initially only be offered to women in labour whose HIV status is unknown, in those settings where its use can be monitored and its results can be evaluated; in addition, efforts need to be improved to ensure that *all women* have access to HIV testing services and that all women considering pregnancy or already pregnant be routinely offered voluntary HIV testing, with quality pre- and post-test counseling.

Today, much testing in Canada, particularly outside of designated HIV testing clinics with trained staff, is done with little or no pre-test counseling.

- There would be some benefits to be gained from the availability of a rapid screening test with respect to making post-exposure prophylaxis decisions. However, the benefit to the person potentially exposed to HIV of knowing the source person's rapid HIV screening test result does not and should not give rise to an entitlement to compel the source person to be tested without their consent. In particular, the federal government should not support legislation imposing compulsory testing for HIV, and neither should provincial and territorial governments introduce legislation to that effect, such as legislation authorizing compulsory testing in sexual assault cases. Instead, in cases where the source person is known and available, they should be encouraged to undergo voluntary testing. It seems that in cases where the source persons are known and available, the overwhelming majority of them already agree to undergo testing. Nevertheless, a variety of measures could and should be taken to encourage even those few who currently refuse to submit to testing, such as scrupulously protecting confidentiality and preventing test results from being admissible in legal proceedings. In addition, specifically in the area of sexual assault, to deal with the very real concerns of survivors of sexual assault, Health Canada, the Department of Justice, Status of Women, and their provincial counterparts must continue to ensure that best-practice counseling, short- and long-term care, treatment, and other services are made available to sexual assault survivors.
- Rapid HIV screening of patients before medical care is provided to them (or of inmates in correctional institutions) would not be justified.
- Generally, the availability of rapid test kits does not remove the requirement for specific, informed consent to HIV testing. Professional codes of conduct, ethical consciousness, and Canadian law require consent to HIV testing. In order to reinforce that testing can only be undertaken with the specific, informed consent of the person being tested, colleges of health-care professionals, and health-care professionals' associations, should adopt (or update) regulations and/or policies to that effect.
- More research in the area of HIV testing must be funded, so that we acquire solid, systematic, and comprehensive data about testing and counseling, as well as about barriers to testing and counseling. This must include careful investigation, evaluation, and monitoring of the experience with rapid HIV screening at the point of care.

Many, although not all, of the concerns raised are related to *who* could potentially administer rapid HIV screening tests at the point of care. There would be little concern if the test was administered by a test provider in a testing clinic, particularly if that provider had received training in how to administer and apply the tests, and in how to provide counseling using such tests; and if the clinic was able to provide support to a person who screened positive, as well as a confirmed test result within two days.

But there would be concern if the test was administered by a physician who had little experience with HIV testing and counseling, no training specifically about rapid screening kits, and no ability to guarantee the support that a person who screens positive may need. As mentioned above, research has shown that many physicians do not provide adequate counseling, although law and ethics require that testing not be undertaken without it and there are counseling

guidelines that have been widely distributed. There is no reason to believe that a label on the kit requiring counseling and explaining the limitations of the rapid screening tests would be sufficient to prevent testing without adequate counseling. These same concerns (or even greater concerns) would arise if rapid testing was being done by health-care professionals who currently do not administer HIV testing.

Therefore , regulating the use of rapid HIV screening tests will be important. Governments must exercise their regulatory authority to ensure that rapid test kits are only available in those settings and under those conditions in which their benefits will be most likely realized and the potential misuses prevented. In particular:

Governments must exercise their regulatory authority to ensure that rapid test kits are only available in those settings and under those conditions in which their benefits will be most likely realized and the potential misuses prevented.

- In every jurisdiction where these devices are introduced, their use should be phased in by providing rapid testing as an option in specific sites only, followed by evaluation of the experience, before proceeding further with their use.
- Governments should establish, by way of regulation and in consultation with community-based organizations, health-care professionals, and current HIV counseling and testing providers, which "health-care professionals" entitled to provide health services in their province or territory shall be permitted to administer a rapid HIV test.
- Governments should use their regulatory powers, and health-care professionals' regulatory bodies should similarly use their powers, to issue regulations, guidelines, or policies to restrict the use of rapid HIV screening tests to point-of-care settings that ensure that a person receiving a positive screening test will have accelerated access to a confirmed result, and to support while waiting for the confirmed result; and that those providing testing have received training in how to provide quality pre- and post-test counseling, including how to do counseling accompanying the use of rapid screening tests.
- Federal and provincial authorities must ensure that the restrictions placed on the use of rapid test kits to ensure maximum benefit and minimum harm are actually enforced, by responding decisively and swiftly to breaches of these conditions.

Conclusions

We need to be open to the challenges posed by the availability of rapid HIV screening and test our deeply held beliefs. However, we must do so without forgetting the lessons learned over the last 20 years and without forgetting that, because HIV/AIDS continues to disproportionately impact on marginalized populations, leading to discrimination against those infected and affected, it remains different from other diseases. In particular, the new treatments constitute a huge step forward, but do not represent a solution to all problems faced by people with HIV or AIDS – problems that stem from the underlying problems of poverty and discrimination that are both a result and a cause of HIV infection. Therefore, while encouraging people to voluntarily test for HIV must indeed be a priority, we must not forget that the testing at issue here is testing for HIV, a disease that continues to have a social and cultural impact far beyond the numbers of people affected.

Canada must re-commit to *quality* testing and counseling.

Overall, the advent of rapid HIV screening tests offers some benefits. However, the concerns and uncertainties about their use must be addressed. Otherwise, there is a real threat that technology will drive what type of testing will be available in Canada and how testing will be done, rather than a careful consideration of risks and benefits, informed by solid scientific research, that balances an individual's human rights and society's need to maintain public health.

Testing, and increasing access to testing, is not good per se. Although the potential benefits of testing have significantly increased over the last decade, many of them will only be realized if *quality* testing and counseling that maximize the benefits of testing while minimizing the potential harms are undertaken. Rather than lead to an abandonment of the requirement that HIV testing should only be undertaken with the informed consent of the person being tested, with pre-and post-test counseling and when confidentiality of test results can be guaranteed, the introduction of rapid testing must become an opportunity to reaffirm those principles, so that the benefits of HIV testing are maximized while the potential harms are minimized. Canada must re-commit to *quality* testing and counseling.

Introduction

Why a Paper on Rapid HIV Screening Tests?

The technology for conducting rapid HIV screening tests is expected to soon be licensed for sale in Canada, for use by health professionals at the "point of care" (POC). Such "rapid tests" have been in use for some time in other jurisdictions, particularly developing countries (including tests developed with Canadian research),[1] and the US Centers for Disease Control and Prevention (CDC) have recommended their use in some settings.[2] The potential use of rapid HIV tests raises a number of questions, several of which have legal and ethical dimensions.

In the mid-1990s, a short Canadian paper canvassed a number of questions related to the impact of rapid HIV testing in the clinical setting, many of which are discussed in more detail in this paper. A number of the conclusions reached in the earlier paper are consistent with the conclusions and recommendations presented here.[3]

In October 1998, the Canadian HIV/AIDS Legal Network (Legal Network) and the Canadian AIDS Society (CAS) published *HIV Testing and Confidentiality: Final Report* as part of their Joint Project on Legal and Ethical Issues Raised by HIV/AIDS funded by Health Canada. That report provided a brief overview of some of the questions raised by the use of rapid testing, and recommended that a national workshop be held to further discuss the issues raised by new testing technologies.[4]

In March 1999, Health Canada hosted a workshop on HIV Point-of-Care Testing to: provide information regarding the rapid test kits currently undergoing field trial; identify the issues raised by the availability of HIV point-of-care testing; and "understand stakeholders' perception with respect to the conditions necessary to successfully deploy HIV point-of-care testing."[5] Legal and

[1] For example, see: International Development Research Centre. Inexpensive blood screening for HIV. Ottawa: IDRC, 1998, available at <www.idrc.ca/Nayudamma/HIV_60e.html>; PATH Canada. Development of a Rapid Assay for the Detection of Antibodies to HIV-1 and HIV-2: Final Report and Request for Bridging Funds. Ottawa: PATH Canada, January 1991, available at <www.idrc.ca/library>; Eberlee J. An AIDS test that travels well. *IDRC Reports* 1993; 21(2), available at <www.idrc.ca/books/reports>.

[2] CDC. Update: HIV counseling and testing using rapid tests – United States, 1995. *Morbidity and Mortality Weekly Report* 1998; 47(11): 211-215.

[3] Peterkin A. The Impact of Rapid HIV Testing in the Clinical Setting. Ottawa: University of Ottawa Health Services, 1995.

[4] Jürgens R. *HIV Testing and Confidentiality: Final Report*. Montréal: Canadian HIV/AIDS Legal Network & Canadian AIDS Society, 1998, at 111-120.

[5] Intersol Consulting Associates Ltd. Workshop Report: HIV Point-of-Care Testing. Ottawa, 1999.

Decisions about the use and regulation of rapid HIV tests should be informed not only (and not even primarily) by what is technologically feasible.

ethical issues were identified as topics needing discussion, and participants identified several such issues. Health Canada's report on the workshop also recognized the need for further, broader consultation on these questions:

> [C]oncerns on the technical issues, although important, were not as great as those surrounding the implementation of rapid HIV test kits for POC testing and the circumstances under which their use would be appropriate.... Technology is approaching or is at a stage where [rapid] POC testing for HIV could be a reality in the very near future. Questions were raised as to the appropriateness of allowing technology alone to be the driving factor.... [I]t is important to be pro-active and attempt to put in place, before the kits become available on the market, provisions capable of satisfactorily addressing all the concerns regarding POC testing.[6]

As identified both in *HIV Testing and Confidentiality: Final Report* and at the March 1999 workshop, decisions about the use and regulation of rapid HIV tests should be informed not only (and not even primarily) by what is technologically feasible, but by an appreciation of the real-life implications of testing technologies, by ethical considerations, and by an understanding of how Canadian law and policy may or may not adequately address these implications and reflect these ethical considerations. As one commentator observes:

> What we cannot afford to do is to avoid the choices that the rapid testing technology poses. Serious debate on these choices is inevitable. This technology, and additional new developments, are upon us and the choices are posed right now.[7]

Activities Undertaken

In November 1999, the Legal Network and CAS jointly released a backgrounder on some of the legal and ethical questions raised by the anticipated licensing in Canada of rapid HIV screening tests.[8] That backgrounder was distributed to members of both organizations and to participants at the Canadian Skills-Building Symposium in Winnipeg in the same month.

In January 2000, a draft of this paper and the accompanying ethical commentary, including draft recommendations, were circulated to selected recipients for comment; and were discussed at a two-day national workshop organized by the Legal Network and held on 21-22 January 2000 in Toronto. Participants at the workshop came from every region of the country, and included people providing HIV testing and counseling services; representatives from community-based organizations; people living with HIV/AIDS; representatives from Aboriginal and women's organizations; physicians; nurses; representatives from Health Canada (Medical Devices Bureau; HIV/AIDS Policy, Coordination & Programs Division; and Laboratory Centre for Disease Control); provincial and territorial government representatives to the Federal/Provincial/Territorial Committee on AIDS; and representatives from manufacturers who have applied for licensing of rapid HIV tests for sale in Canada.

The workshop created a forum for a focused discussion of the legal, ethical, and policy issues raised by rapid HIV screening tests in POC settings. It was

[6] Health Canada (Medical Devices Bureau). Report on the HIV Point of Care Testing Workshop. Ottawa, 29-31 March 1999, at 2, 3.

[7] Leviton LC. For whom do we test? What do we say? Rapid HIV screening. *Public Health Reports* 1996; 111(1): 54.

[8] Canadian HIV/AIDS Legal Network & Canadian AIDS Society. Rapid Testing for HIV: What Are the Issues? Montréal & Ottawa: The Network & the Society, 1999. Available at <www.aidslaw.ca>.

not its objective to reach a consensus among participants on all issues. However, there were a number of points on which there was widespread agreement, and these points are reflected in some of the conclusions and recommendations contained in this paper.

Scope of the Paper

This paper explains rapid HIV testing technology and the status of rapid HIV test kits in Canada as of the time of publication. It provides a brief overview of the Canadian regulatory framework applicable to the approval and use of rapid test kits, and identifies some needed reforms. The paper then evaluates a number of potential benefits of rapid HIV testing at the point of care, as well as some of the concerns raised by the availability of such tests. It specifically discusses some potential (mis)uses of rapid HIV screening tests that have been identified as areas of particular concern. It does not attempt to cover every possible question raised by the introduction of rapid HIV screening tests in POC settings; rather, it provides a detailed analysis of the most serious of those questions with legal and/or ethical dimensions. Finally, it presents some conclusions and recommendations regarding the use of rapid tests in Canada, directed to federal and provincial policymakers, health-care professionals, professional associations and regulatory bodies of health-care professionals, and those providing HIV testing and counseling and working in the field of public health.

What Happens Next?

Some provinces have begun to address the questions raised in this paper and elsewhere by the licensing of rapid HIV screening tests for sale in Canada. Alberta Health prepared a draft document with recommendations regarding the appropriate uses of such tests, and the Alberta Community Council on HIV prepared a response.[9] The Ontario Ministry of Health prepared a memorandum regarding several of the issues raised by rapid HIV screening at the point of care,[10] and the Ontario Advisory Committee on HIV/AIDS expects to be addressing the issue with provincial health officials.[11] The British Columbia Centre for Disease Control has undertaken additional research regarding the on-site use of rapid HIV screening tests and will be drafting revised counseling guidelines to accompany their use,[12] and the provincial ministry of health is examining the regulatory issues raised by rapid test kits.[13] However, at the time of publication, some provinces had not yet begun to examine these questions and will need to do so.

The Network will widely disseminate the contents of this paper to various audiences and, in particular, to all those to whom recommendations in the paper are directed. Dissemination will include preparation of a series of info sheets on HIV testing, and the publishing of articles in 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 paper.

Notes on Terminology

A review of the scientific literature and other commentary indicates some inconsistency and lack of clarity in the terms used to discuss what are most

[9] McKibben S, for the Alberta Community Council on HIV (Advocacy Committee). Implications of Point of Care Rapid HIV Testing. Edmonton: ACCH, 16 February 2000.

[10] [Ontario] Central Public Health Laboratory (HIV Laboratory). Memo: Issues related to HIV Point of Care Testing. Toronto, 1999, on file.

[11] Communication with L Stoltz, Ontario Advisory Committee on HIV/AIDS, 25 January 2000.

[12] Personal communication with D Spencer, BC Centre for Disease Control Society, 8 February 2000; BioChem ImmunoSystems Inc. Clincial Trial Counselling Fast-Check HIV-1/2 (Whole Blood). Protocol dated 1 August 1999, on file.

[13] Personal communication with E Kanigan, BC Ministry of Health, 10 February 2000.

Currently in Canada, the *standard procedure* (or "algorithm") for HIV testing involves sending blood samples to a central laboratory, where they are tested in batches.

commonly referred to as "rapid tests" (or "rapid assays"). Determining the appropriate use of such tests requires an understanding of their accuracy and their limitations. It is therefore important to clarify at the outset what is meant by various terms used in this discussion paper. The explanations below are offered after a review of the literature in this area.

Rapid Testing versus Standard Testing Procedure

Currently in Canada, the *standard procedure* (or "algorithm") for HIV testing involves sending blood samples to a central laboratory, where they are tested in batches ("batch testing"). Any blood sample that tests positive on the screening test (the "ELISA" test, or EIA) undergoes a confirmatory test that is more attuned to detect antibodies specific to HIV (generally, the "Western blot"). Some provincial laboratories perform a second EIA screening test, and only proceed to confirmatory Western blot testing if the sample tests reactive twice using the EIA. Other provinces perform a single EIA before subjecting any reactive samples to confirmatory testing. Only confirmed test results are given to the health-care provider who ordered the test. This means the person getting tested must return to the testing site for a second visit to learn their results from the provider. This whole process can take two to three weeks. In some more remote communities, it may be the schedule of a visiting health-care practitioner that determines the turnaround time between giving a sample and receiving test results and post-test counseling in person (although results can be communicated by telephone to some communities if necessary).

Rapid tests are those that can be done on-site where the fluid sample is collected and yield a result within 30 minutes after the sample is taken.

Rapid tests are those that can be done on-site where the fluid sample is collected and yield a result within 30 minutes after the sample is taken.[14] This means the results can be provided to the person during a single visit to the testing site. Most of the research has focused on the use of these truly rapid tests, many of which generate results in 15 minutes or less.

Some have raised concerns that simply using the term "rapid test" will mislead people into thinking they are able to rapidly get a *confirmed* test result when, in fact, the rapid test kits under discussion yield only a *screening* result equivalent to the EIA that currently forms the first step of the standard testing procedure. This paper therefore uses the terms "rapid screening test" and "rapid confirmatory test" to distinguish between the two. The title of the paper further indicates that what is specifically being discussed is the possible use of rapid screening tests *in point-of-care settings.*

Point-of-Care Testing versus Home Testing

Point-of-care testing ("POC testing") can be defined as testing in the presence of a health professional,[15] as opposed to a testing procedure that is carried out wholly or partially without any involvement of a health professional. Currently in Canada all HIV testing is point-of-care testing at a health facility of some sort, using the standard EIA/Western blot testing procedure described above.

The term *home testing* "often creates confusion, as it is used to refer to two different forms of testing: home sample collection or home-access testing; and true home testing, sometimes referred to as home self-testing or home validated testing."[16]

- "Home sample collection" (or "home access") testing requires a person to purchase an over-the-counter HIV test kit and collect the sample

[14] Eg, see: Constantine N. HIV Antibody Testing: Methodology. In: Feinberg M, Cohen PT (eds). *The AIDS Knowledge Base*. Editors, 1999, at 4. Available at <hinvinsite.ucsf.edu/akb/1997/section2.html>.

[15] Intersol. Workshop Report: HIV Point-of-Care Testing, supra, note 5 at 2 (n5).

[16] Jürgens, supra, note 4 at 89. See this report and sources cited therein for a more detailed discussion of home HIV testing.

themselves. The sample is mailed to a laboratory and several days later the person can receive the test results by telephone. The testing itself – and the interpretation of the test results – is carried out by trained laboratory professionals.

- "True home tests (also called home self-tests or home validated tests) are essentially rapid tests that can be carried out entirely at home without involvement of an outside party. Home pregnancy testing is an example of true home testing. In this situation, a consumer purchases an over-the-counter kit, receives instructions by pamphlet, collects the sample, conducts the test at home, and obtains the result within a few minutes. Interpretation of results and instructions for follow-up are provided by written materials in the kit.... Although the instructions may urge the user to contact health-care facilities in case of a positive result, it is left to his/her initiative to do so."[17]

To date, proposals for introducing rapid HIV testing in Canada have been limited to considering the use of rapid screening tests for point-of-care use. This is, therefore, the focus of this paper. However, rapid HIV testing technology is relatively simple to use, and may be amenable to use other than at the point of care. This would raise additional serious legal and ethical questions not addressed here.[18]

Screening Test versus Confirmatory (or Supplemental) Test

"The diagnosis of HIV infection is usually made on the basis of the detection of antibodies to HIV. Serological tests for detecting antibodies to HIV are generally classified as screening tests (sometimes referred to as initial tests) or confirmatory tests (sometimes referred to as supplemental tests.) Initial tests provide the presumptive identification of antibody-positive specimens, and supplemental tests are used to confirm whether specimens found reactive with a particular screening test contain antibodies specific to HIV."[19]

The most commonly used screening test is commonly referred to as an EIA (enzyme immunoassay) or ELISA (enzyme-linked immunosorbent assay). Confirmatory tests are more specifically tuned to detecting HIV antibodies than screening tests. The most commonly used confirmatory test is the Western blot. Others include: RIPA (radioimmunoprecipitation assay), IFA (immunofluorescent antibody assay), LIA (line immunoassay), and PCR (polymerase chain reaction) tests.

Sensitivity and Specificity

The accuracy of a testing technology in distinguishing between HIV-infected and HIV-uninfected people is a function of both its *sensitivity* and *specificity*:

> Sensitivity is the probability that the test result will be positive if the specimen is truly positive; specificity is the probability that the test result will be negative if the specimen is truly negative. No real test is 100% sensitive and 100% specific. Screening tests are designed to be sensitive to ensure that no positive person is missed. The price for this high sensitivity is a slightly reduced specificity: some persons who are negative will test false-positive. Another, different, test must be done to differentiate true-positive results from false-positive results.[20]

[17] Ibid at 90.

[18] However, see ibid; Canadian AIDS Society. Position statement: HIV Home Testing. Ottawa: The Society, November 1996; Branson BM. Home sample collection tests for HIV infection. *Journal of the American Medical Association* 1998; 280: 1699-1701; Katz M et al. Home collection versus publicly funded HIV testing in San Francisco: who tests where? *Journal of Acquired Immune Deficiency Syndromes* 1999; 21: 417-422; Fabbri WO. Home HIV Tests Will Reduce the Spread of AIDS, and Portelli CJ. Home HIV Tests Are Unethical. Both in: Roleff TL, Cozic CP (eds). *AIDS: Opposing Viewpoints*. Greenhaven Press Inc, 1998.

[19] WHO/UNAIDS. Operational Characteristics of Commercially Available Assays to Determine Antibodies to HIV-1 and/or HIV-2 in Human Sera (Report 11). Geneva, January 1999, at 2.

[20] CDC. Background on Calculating Comparisons for the Use of Rapid HIV Testing. Available at <www.cdc.gov/nchstp/hiv_aids/pubs/rt/background.htm>.

The lower the prevalence of HIV in a given population, the greater is the likelihood that the positive result is, in fact, a *false* positive result.]

Predictive Value

The *predictive value* of a test is the likelihood, expressed as a percentage, that the result from a test (or a whole testing procedure, consisting of a combination of tests) truly reflects whether a given individual is infected.

- The *positive predictive* value of a test is the probability that a person with a positive test result is actually infected.
- The *negative predictive value* is the probability that a person with a negative test result is not infected.

The predictive value depends on the accuracy (ie, the sensitivity and specificity) of the test itself. However, because it is a figure determined by analyzing the accuracy of a test (or testing algorithm) over a larger number of samples, it also depends on the prevalence of HIV infection in the population being tested (ie, the percentage of persons in that population who are infected).[21] The more people in a given population are actually infected with HIV, the greater the predictive value of a positive test result – that is, the more statistically likely it is that the positive test result does in fact represent a *true* positive result. But the lower the prevalence of HIV in a given population, the less reliably predictive a positive test result becomes; there is a greater likelihood that the positive result is, in fact, a *false* positive result, and that the person is not actually infected.

[21] For a simple explanation of this concept, see: CDC. Sensitivity, Specificity, and Predictive Value. Available at <www.cdc.gov/nchstp/hiv_aids/pubs/rt/sensitivity.htm>.

Background

Advances in HIV Screening Test Technology

Currently, standard HIV testing is done using blood serum or plasma, meaning a larger blood sample must be taken from a person's vein. However, test kits rapid enough to provide a result in minutes have been developed that can test whole blood (in addition to blood plasma or serum) and saliva. This means a simple finger prick or an oral fluid swab is sufficient to obtain a specimen for testing. Truly rapid tests using urine remain at the investigational stage.

Blood Testing

A variety of rapid HIV screening tests use blood samples in some way – some test whole blood, others are used to test blood plasma or blood serum. At the time of writing, only one rapid HIV test had been licensed in Canada for any use: MedMira Laboratories Inc's Rapid HIV Screen Test (which tests blood) has been licensed for laboratory use only. In 1998, two research studies reported positive performance of the MedMira test.[22]

In 2000, researchers from a pan-Canadian clinical trial reported that a rapid HIV-1/2 screening test developed by Merlin Biomedical & Pharmaceutical for point-of-care use had a sensitivity of 100 percent and a specificity of 99.9 percent. Researchers concluded the test "performs at least as well as currently licensed laboratory-based EIA tests and allows all tested individuals to learn their test results within 2 minutes.... Positive POC test results require laboratory confirmation."[23]

Also in 2000, Canadian researchers reported favourable accuracy data for BioChem ImmunoSystems Inc's Fast Check HIV-1/2 tests for whole blood and for serum. The serum test was found to have a sensitivity of 100 percent

[22] Galli RA et al. Performance characteristics of the MedMira Rapid HIV Screen Test for the detection of antibodies to HIV-1 and HIV-2 in clinical specimens. Abstracts of the General Meeting of the American Society for Microbiology 1998 (17-21 May); 98: 154 (abstract no. C-140) (ASM98/98296492); Lubega SN et al. Field trial of the MedMira Rapid HIV Screen Test in an HIV high prevalence area in the US. Abstracts of the General Meeting of the American Society for Microbiology 1998 (17-21 May); 98: 154 (abstract no. C-138) (ASM98/98296491); Inexpensive two-minute HIV test passes first field trial. *UniSci Science and Research News*, 19 May 1998, available at <unisci.com>.

[23] Shafran SD et al. Evaluation of the Merlin Immediate HIV-1 and -2 Test for HIV Antibody Performed at Point-of-Care (POC). 7th Conference on Retroviruses and Opportunistic Infections (CROI) 2000: Abstract 766, available at <www.retroconference.org>; Shafran SD et al and the Canadian HIV POC Test Study Group. Evaluation of the Merlin Immediate HIV-1 and 2 Test for HIV Antibodies Performed at Point-of-Care (POC) – Revised Abstract. 7th CROI 2000, on file.

and a specificity of 99.92 percent, while the whole blood test was found to have a sensitivity of 99.9 percent and a specificity of 99.96 percent.[24]

The United Kingdom has approved at least one rapid screening test using whole blood: Saliva Diagnostic Systems' Hema•Strip HIV™ (with a sensitivity of 99.61 percent and a specificity of 99.96 percent).[25] The company also sells a rapid screening test using blood serum or plasma that is equally sensitive and specific (Sero•Strip HIV™), but is not licensed in the United States or Canada.[26]

In the US, only one rapid HIV test kit has been approved for any use: Abbott Diagnostics' Single Use Diagnostic System (SUDS®) Test Kit for HIV-1 tests blood serum or plasma, which yields results in 10 minutes.[27] The test "has several limitations. In particular, it is classified as a test of moderate complexity (eg, it requires a laboratory with a centrifuge), detects only HIV-1, and several factors – including temperature and centrifuge speed – can affect test results."[28] The test is licensed for sale for use by health professionals to diagnose patients (but note that this is impractical for those without easy on-site access to laboratory facilities, given the requirements of the test).

Recently, researchers reported the results of a study of the accuracy of a rapid test that tests whole blood or blood plasma for HIV-1 RNA. They reported the test could detect HIV-1 RNA of numerous subtypes (including type O strains) approximately 11 days before seroconversion, thus narrowing the window period between infection and detection (good for improving the safety of blood donations). They further reported that the test had no cross-reactivity with other common human viruses, indicating good specificity.[29]

Oral Fluid Testing

HIV tests that use oral fluid samples offer several benefits: ease of collecting the sample, no need for medically trained personnel for sample collection, the elimination of the risk of needle-stick injuries, and greater acceptability to patients than drawing blood. In numerous studies, including some conducted in Canada,[30] several oral fluid tests (both standard screening EIAs and rapid screening tests) have proved to be as accurate or, in some cases, close to as accurate, as a standard EIA blood test.[31]

In 2000, researchers reported that the Saliva•Strip HIV™ rapid test developed by Saliva Diagnostic Systems had a specificity and positive predictive value of 100 percent; however, it was significantly less sensitive (94.6 percent) and therefore had a lower negative predictive value (94.4 percent) than existing blood-based EIAs. This means that while the test did not yield any false *positive* results, it did yield some false *negative* results. Researchers concluded that the sensitivity and negative predictive value were "adequate but not optimal.... For identification of all infected patients, a second assay with increased [sensitivity] is warranted."[32] The manufacturer's earlier claim of a sensitivity of 99.4 percent and specificity of 99.4 percent do not correspond with the results obtained by these researchers.[33] This test, designed "for professional use only," is not approved in the United States or Canada, but was approved for sale in the United Kingdom in 1997.[34]

[24] Communication and data received from Y Côté, BioChem ImmunoSystems Inc, 23 February 2000, on file; Thérien L et al. Multi centers evaluation of FAST CHECK HIV-1/2 SERUM. Abstract submitted to the 2000 Conference of the Canadian Association for HIV Research (CAHR), on file; Côté YP et al. Multi centers evaluation of FAST CHECK HIV-1/2 WHOLE BLOOD. Abstract submitted to CAHR 2000, on file.

[25] Saliva Diagnostic Systems. Hema•Strip HIV™ [promotional materials], available at <www.salv.com/hema.htm>; Saliva Diagnostic Systems. Media release: Saliva Diagnostic Systems to begin aggressive sales campaign for Saliva-Strip™ HIV. 20 August 1997, reproduced at: Rapid Saliva HIV Test to be Marketed in the United Kingdom. *Business Wire*, 20 August 1997, <www.businesswire.com>.

[26] Saliva Diagnostic Systems. Sero•Strip HIV™ [promotional materials], available at <www.salv.com/serostrip.htm>.

[27] Abbott Diagnostics. Human Immunodeficiency Virus Type 1 SUDS® HIV-1 Test [promotional materials], 15 July 1998, Windsor IM et al. An evaluation of the capillus HIV-1/HIV-2 latex agglutination test using serum and whole blood. *International Journal of STD and AIDS* 1997; 8: 192.

[28] Jürgens, supra, note 4 at 114, citing CDC. Rapid HIV tests: issues for laboratories. *CDC Issues*, March 1998, and referencing: Kassler WJ et al. Performance of a rapid, on-site human immunodeficiency virus antibody assay in a public health setting. *Journal of Clinical Microbiology* 1995; 33: 2899-2902.

[29] Kolk D et al. High throughput assay that detects all subtypes of human immunodeficiency virus-1 (HIV-1), including type O strains. HIV Pathogenesis and Treatment Conference 1998: 41 (abstract no. 1009) (AIDS/98930267).

[30] Major CJ et al. Comparison of saliva and blood for human immunodeficiency virus prevalence testing. *Journal of Infectious Diseases* 1991; 163(4): 699-702; Coates R et al. The benefits of HIV antibody testing of saliva in field research. *Canadian Journal of Public Health* 1991; 82(6): 397-398.

[31] Tamashiro H et al. Serologic diagnosis of HIV infection using oral fluids. *Bulletin of the World Health Organization* 1994; 72: 135-143; Saville RD. Evaluation of two novel immunoassays designed to detect HIV antibodies in oral fluids. *Journal of Clinical Laboratory Analysis* 1997; 11: 63-68; Schramm W et al. A simple saliva-based test for detecting antibodies to human immunodeficiency virus. *Clinical and*

Another company, Epitope Inc, has obtained US Food and Drug Administration (FDA) approval for both a screening EIA and a confirmatory Western blot test that use oral fluid (OraSure).[35] These are not rapid tests. To date, no *rapid* HIV test using saliva has been approved for sale in the US.

Urine Testing

As with oral fluid testing, the benefits of urine testing over blood testing include easier use by health-care workers; eliminating accidental needle-sticks or other exposures to blood; being more acceptable to patients because blood need not be drawn;[36] less infrastructure required to collect samples than blood samples; and lower cost.[37] Recently, researchers comparing urine and blood serum test results suggested that evidence of a compartmentalized immune response (urine and serum tests yielding different results) might lead to new information regarding the dynamics of HIV infection.[38]

Currently, no truly "rapid" test using urine samples is available on the market, although technological advances may soon change this. There are two urine HIV tests presently licensed for sale in the US. Both are produced by Calypte Bioemedical Corporation.[39] In 1996, the FDA approved the Calypte HIV-1 Urine EIA, a screening test shown to be as accurate as existing tests using blood serum; and in 1998 it approved Calypte's Cambridge Biotech HIV-1 Urine Western Blot (sold under the trade name Sentinel). This test "is used on samples that are repeatedly reactive in the Calypte HIV-1 urine antibody screening test. The new test completes the only available urine-based HIV test system."[40] This test was found comparable in sensitivity and specificity to existing Western blot tests using blood, meaning it provides confirmed test results. This is an "overnight assay,"[41] not a rapid test.

Accuracy of Rapid Screening Tests

There are over 30 different rapid HIV tests currently marketed worldwide. Many (but not all) have been found to be as accurate as previously accepted EIA screening tests.[42] There is some concern that some of the currently available rapid assays are less accurate when testing blood samples from individuals infected with HIV-1 group O and HIV-2. However, other rapid assays have been found capable of detecting these variants of HIV.[43]

False-Positive Results

As has been noted, a rapid HIV screening test provides a preliminary (ie, unconfirmed) result. This obviously raises questions as to its predictive value – that is, how likely is this preliminary test result to be accurate in diagnosing HIV infection? As noted, screening tests are designed to be highly sensitive, so as not to miss any sample that contains HIV antibodies, yet they are less specific in confirming that the antibodies detected are to HIV and not some other pathogen. The result is a number of false HIV-positive test results. The fewer HIV-infected people in the population being tested, the greater will be the number of people who falsely test positive on a screening test. This is why confirmatory testing is required for those who screen positive.

A number of US studies have demonstrated that, as with other screening tests, rapid HIV screening tests will generate some false positive results (and therefore have a lowered positive predictive value). For example:

Diagnostic Laboratory Immunology 1999; 6(4): 577-80; Gallo D et al. Evaluation of a system using oral mucosal transudate for HIV-1 antibody screening and confirmatory testing. *Journal of the American Medical Association* 1997; 277(3): 254-258; Constantine NT et al. Evaluation of a new generation of rapid/simple assays to detect HIV antibodies in oral fluid. International Conference on AIDS 1996; 11(2): 257 (abstract no. Th.A.4023) (ICA11/96924436); ImmunoScience, Inc. Salivax™-HIV Human Immunodeficiency Virus Types 1 and 2 Quick-Flow Visual Screening Test [package insert], on file and available at <http://immunoscience.com>. For a list of studies of saliva-based HIV tests from 1987 to 1995, see the summary table posted by ImmunoScience, Inc. (Other References on Saliva Based HIV Tests) at <http://immunoscience.com/ref.htm> (accessed 13 February 2000 and on file).

[32] Calvet G et al. Evaluation of a Rapid Test for Detection of HIV-1/2 Saliva Antibodies in a Cohort of Patients from Brazil, India, and the United States. 7th CROI 2000: Asbtract 764, available at <www.retroconference.org>.

[33] Saliva Diagnostic Systems. Saliva•Strip HIV™ [promotional materials], available at <www.salv.com/salivaStripHIV.htm>.

[34] Saliva Diagnostic Systems. Media release, supra, note 25; New HIV saliva test kit to hit UK markets. *NurseWeek/HealthWeek*, 1 September 1997, available at <www.nurseweek.com/news/salivahiv.html>.

[35] Centers for Disease Control and Prevention, National AIDS Clearinghouse. HIV Oral Fluid Tests. In: *Guide to Information and Resources on HIV Testing*, 1997; Epitope Inc. OraSure HIV-1 Antibody Testing System [promotional materials], undated; Gallo et al, supra, note 31.

[36] Meehan MP et al. Sensitivity and specificity of HIV-1 testing of urine compared with serum specimens. *Sexually Transmitted Diseases* 1999; 26: 590-592.

[37] Calypte Biomedical Corporation. Media release: FDA licences first urine HIV-1 supplemental test, making available first urine-only HIV test system, at <www.calypte.com>.

[38] Urnowitz HB et al. Urine antibody tests: new insights into the dynamics of HIV-1 infection. *Clinical Chemistry* 1999; 45(9): 1602; Published study provides new understanding about HIV infection and significance of urine HIV-1 testing. *Business Wire*, 2 September 1999.

[39] Calypte Biomedical Corporation. Promotional materials: "Urine-based HIV-1 Testing System" and "FAQ Sheet: Urine Testing for HIV-1 Antibody." Calypte, 1998.

[40] Calypte media release, supra, note 37.

- A 1995 US study of samples taken at an STD clinic and an HIV counseling/testing site using Abbott's SUDS® test as a rapid screen showed a positive predictive value of 88 percent for the samples from the STD clinic and 81 percent for the samples from the HIV counseling/testing site.[44]
- A US study presented in 1999 compared the performance in 277 patients of a fingerstick-based rapid HIV screening test and the standard serum-based EIA screening test in a public health outreach setting (a substance use treatment and prevention centre). Investigators found that the sensitivity of the rapid test was 100 percent; however, its specificity was only 98.9 percent. This meant that while the negative predictive value of the rapid test was 100 percent, its positive predictive value was only 87 percent, in a population with a high seroprevalence of 7.2 percent.[45] The investigators concluded that "the specificity of the rapid test is less than traditional laboratory based testing. This increased false positivity will require more supplemental testing to reach a true serostatus. In a less seroprevalent population, the lower specificity may create a testing burden."[46] (Even in this population of high HIV prevalence, the low 87 percent figure for the test's value in correctly predicting those who are actually HIV-positive is of concern.)

False-Negative Results

What about false-negative results? For both rapid HIV screening tests and for the standard testing algorithm of a screening EIA and a confirmatory Western blot, a number of those tested will test negative for HIV antibodies despite actually being infected with HIV. This occurs principally because such persons will be in the "window period" between the point at which they were infected and the point at which the test will detect antibodies in the bodily fluid sample being tested. With current technology, this period is generally estimated to be around 25 days.[47]

In 1999, a US CDC study reported an analysis of data regarding the performance evaluations of rapid HIV-antibody tests submitted by laboratories in 12 surveys from August 1992 through January 1998. The study found that: "The average RT [rapid test] false negative rate for all surveys was 8% ... while the average false positive rate was 2.7%.... The highest percentage of error was associated with false-negative test results being reported for weak positive HIV-[antibody] panel samples obtained from seroconverting donors. The aggregate false-negative error rate for weak positive HIV-[antibody] samples was more than 3 times greater than the aggregate enzyme immunoassay (EIA) error rate for the same samples."[48] In other words, the rapid screening assays had a significantly higher rate of inaccurately yielding HIV-negative results than the standard, laboratory-based screening tests, particularly when it came to detecting individuals in the process of seroconverting.

Rapid Confirmatory HIV Testing

One of the most significant questions in debates over rapid testing is the question of providing people with positive HIV test results that are preliminary, unconfirmed results only. This concern would be significantly reduced if it were to become feasible to provide rapid, same-day *confirmed* test results.

[41] FDA approves supplement to Calypte's HIV-1 serum Western blot assay. *Reuters Health*, 19 November 1999. Available from JAMA HIV/AIDS Information Center at <www.ama-assn.org/special/hiv/newsline/reuters/11197179.htm>.

[42] Giles RE et al. Simple/rapid test devices for anti-HIV screening: do they come up to the mark? *Journal of Medical Virology* 1999; 59(1): 104-109; New rapid HIV tests as accurate as standard immunoassays. *Reuters Health*, 1 September 1999; Ng KP et al. Evaluation of a rapid test for the detection of antibodies to human immunodeficiency virus type 1 and 2. *International Journal of STD and AIDS* 1999; 10(6): 401-404; Weber B et al. Multicenter evaluation of a new rapid automated human immunodeficiency virus antigen detection assay. *Journal of Virological Methods* 1999; 78: 61-70; Pace launches easy to use and rapid diagnostic HIV test. *Doctor's Guide to the Internet*; 15 July 1996, at <www.pslgroup.com/dg/9D12.htm>; Vercauteren G. Evaluation of 7 simple/rapid HIV antibody assays using seroconversion panels. International Conference on AIDS 1994; 10(1): 246 (abstract no. PB0415). AIDSLINE ICA10/94369883; Fernandez Giuliano S et al. Rapid assay evaluation for the detection of antibodies anti-HIV-1/2: Capillus HIV-1/HIV-2. International Conference on AIDS 1998; 12: 795 (abstract no. 42113), AIDSLINE ICA12/98402880; Frerichs RR et al. Local research for local approval – a case study of a rapid HIV serostrip assay for use in developing countries. International Conference on AIDS 1996; 11(1): 33 (abstract no. Mo.C.213). AIDSLINE MED/96920968; Zaw M et al. Local evaluation of a rapid HIV assay for use in developing countries. *Tropical Medicine and International Health* 1999; 4(2): 216-221, MED/99237729; Babu UM et al. A self-contained one-step test for infectious diseases using unprocessed whole blood. Abstracts of the General Meeting of the American Society for Microbiology 1998; 98: 520 (abstract no. V-46) (ASM98/98296626); International Development Research Centre. Inexpensive blood screening for HIV. Ottawa: IDRC, 1998, available at <www.idrc.ca/Nayudamma/HIV_60e.html>; See DM et al. First Check HIV1-2, a two-step, five minute, whole blood immunochromatographic assay to detect HIV 1/2 antibodies. International Conference on AIDS 1996; 11(1): 294 (abstract no. Tu.B.2174) (ICA11/96922379); Hiller G et al. A one-step solid phase immunoassay for rapid detection of antibodies to HIV-1 and HIV-2. International Conference on AIDS 1996; 11(1): 293 (abstract no. Tu.B.2166) (ICA11/96922371); Kassler et al, supra, note 28.

Development of Rapid Confirmatory Tests

In November 1999, Calypte Biomedical Corporation announced FDA approval of its "Day Assay," an HIV-1 Western blot assay that will confirm the presence of HIV-1 antibodies in blood serum samples within five hours.[49] Given the expense of conducting Western blot tests and the technology and expertise required to administer and interpret them, this does not currently represent an economical and feasible means of providing same-day confirmed results. Calypte Biomedical indicates that it hopes to have a similar "day assay" (ie, yielding results in a few hours) Western blot test for use on urine samples developed in 2000.[50] Again, as with other Western blot tests, this would not necessarily make the technology available for rapid use outside a laboratory setting, given the technical requirements.

However, in 1998, researchers from another US company, Universal HealthWatch Inc, reported the results of a trial of a rapid *confirmatory* test equal in accuracy to currently approved Western blot assays. The QUIX Rapid Confirmatory HIV-1 Test uses one drop of blood (whole blood, serum, or plasma), meaning it can be conducted on either a finger-stick specimen (or the standard venipuncture specimen). Results are achieved within five minutes, and reveal the antibody response to major HIV antigens that are considered in traditional Western blot to confirm HIV infection. Researchers reported the test had 100 percent sensitivity and specificity in a study of 190 samples.[51] Subsequent research has yielded similarly encouraging results.[52] According to researchers, this test is suitable for point-of-care testing, as it is "user-friendly" and no laboratory facilities are required; "the availability of this rapid confirmatory assay for HIV makes it possible to provide final results during an initial visit by patients, to eliminate the requirement for instrumentation, and can be performed by individuals with limited instruction."[53] Researchers with Universal HealthWatch Inc state they expect it could be marketed at a per-test price marginally lower than standard Western blot tests.[54] No application for FDA approval has yet been submitted; additional research is underway.[55]

Alternative Combinations of Rapid Screening Tests

The distinction between a screening test and a confirmatory test is somewhat blurred by technological advances and by how testing algorithms are defined. To date in Canada, a reactive result on the standard EIA screening test (or, in some places, a repeatedly reactive result on two EIA screens) has been subsequently confirmed by the use of a supplemental test (eg, Western blot, immunofluorescence assay, etc).

However, according to recommendations recently published by the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO), "studies have shown that combinations of ELISAs or S/R [simple/rapid] assays can provide results as reliable as the WB [Western blot] at much lower cost. WHO and UNAIDS therefore recommend that countries consider testing strategies which use ELISAs and S/R assays rather than ELISA/WB for HIV antibody detection."[56] A series of rapid tests using different testing principles could provide what might be called a "presumptive diagnosis."

UNAIDS and WHO actually recommend three testing strategies to maximize accuracy while minimizing cost, and indicate that "which strategy is most

[43] Constantine N et al. Diagnostic challenges for rapid human immunodeficiency virus assays. Performance using HIV-1 group O, HIV-1 group M, and HIV-2 samples. *Journal of Human Virology* 1997; 1(1): 45-51; Kolk et al, supra, note 29; Constantine N et al. Detection of antibodies to HIV-1 group O by eight screening and four confirmatory assays. International Conference on AIDS 1998; 12: 632: (abstract no 33200), available via <www.aids98.ch>; Hiroyasu A et al. Detection of HIV-1 subtypes by a new rapid immunochromatographic test. International Conference on AIDS 1998 (Abstract 41107), available via <www.aids98.ch>, and: Evaluation of a rapid immunochromatographic test for detection of antibodies to human immunodeficiency virus. *Journal of Clinical Microbiology* 1999; 37(2): 367-370; MedMira Laboratories Inc. Media Release: Rapid Reader 2000 and HIV type O test are latest technologies unveiled by Medmira Laboratories at press conference today. 10 September 1999.

[44] Kassler et al, supra, note 28.

[45] Bennett SB et al. Rapid HIV Testing vs Traditional Testing in a Public Health Outreach Setting. 1999 [US] National HIV Prevention Conference, Abstract 117.

[46] Ibid.

[47] Bartlett JG. *Medical Management of HIV Infection*. Johns Hopkins University, 1999.

[48] Bluer S et al. Statistical Analysis of the CDC Model Performance Evaluation Program (MPEP) Human Immunodeficiency Virus (HIV) Rapid Test Laboratory Performance Data. 1999 [US] National HIV Prevention Conference, Atlanta GA: Abstract 310, available at <www.cdc.gov/nchstp/hiv_aids/conferences/hiv99/abstracts/310.pdf>.

[49] FDA approves supplement to Calypte's HIV-1 serum Western blot assay. *Reuters Health*, 19 November 1999. Available from JAMA HIV/AIDS Information Center at <www.ama-assn.org/special/hiv/newsline/reuters/11197179.htm>.

[50] Personal communication with D Van Maanen, Calypte BioMedical Corporation, 14 December 1999.

[51] Chowdhury MA et al. Development of a rapid confirmatory immunoassay for diagnosis of HIV infection. Abstracts of the General Meeting of the American Society for Microbiology 1998; 98: 154 (abstract no. C-142) (ASM98/98296494). On a small sample, a rapid screening test developed by Universal Health Watch was found to have a specificity, and hence positive predictive value, less than traditional laboratory-based testing. Researchers concluded that specificity must improve in order for the test to become routine in clinical practice: Bennett et al, supra, note 45.

appropriate will depend on the objective of the test and the prevalence of HIV in the population"[57] and the sensitivity and specificity of the tests being used. WHO/UNAIDS distinguish between three main objectives of HIV-antibody testing: (i) *screening* donated blood (and blood products), tissues, organs, sperm or ova; (ii) *surveillance* to monitor prevalence of, and trends in, HIV infection over time in a given population; and (iii) *diagnosis* of HIV infection.

Recently, researchers have assessed the sensitivity, specificity, and positive and negative predictive value of nine different rapid HIV screening tests, and concluded that "using any two 100% sensitive rapid tests yielded a 100% PPV [positive predictive value] illustrating a promising alternative to the traditional testing algorithm (ELISA followed by a Western blot)."[58] In some developing countries, strategies using multiple rapid HIV screening tests have been evaluated and are in use.[59]

The US CDC has indicated that, once additional rapid tests become available for use in the US, it will "re-evaluate testing algorithms using specific combinations of two or more rapid tests for screening and confirming HIV infection."[60] It should be remembered that only one rapid HIV screening test (Abbott Diagnostics' SUDS® HIV-1 Test) has been approved for diagnostic use in the US. However, other rapid screening tests have been submitted for approval. "Such tests ... raise the possibility of implementing strategies such as the one recommended by the World Health Organization, whereby specific combinations of different rapid tests might be used to confirm reactive HIV test results on the same day a person is tested."[61] In March 1999, the US CDC presented some data on new rapid tests currently under study: "it is expected that these will be office or clinic based tests with results interpreted by providers; positive tests should probably have a repeat assay using an alternative rapid test, but results are sufficiently sensitive and specific to exclude the need for confirmatory tests using routine serology."[62]

Researchers conducting clinical trials have proposed that Canadian MedMira Laboratories' rapid HIV-1/HIV-2 screening test "has the potential to serve as a supplemental test for rapid confirmation of EIA-based HIV positive screen results in routine clinical practice; it could be useful even in large central laboratory settings where Western blot confirmation tends to delay the overall turn around time. Rapid tests of this nature could be highly useful and cost effective in many settings, and could contribute to HIV control and prevention programs."[63]

Revisiting HIV Counseling and Testing Practice[64]

Until recently, testing and counseling guidelines issued by the US CDC recommended that, in order to minimize the reporting of false-positive results,

> no positive test results be given to clients/patients until a screening test has been repeatedly reactive on the same specimen and a supplemental, more specific test such as the Western blot has been used to validate these results.[65]

To date, this has also been standard practice in Canada. However, this approach has recently been revisited in the US as a result of advances in rapid testing technology. In addition, US research data from a Dallas study published in 1997 showed a significant number of people not returning to testing sites to

[52] Constantine N et al. A 5-Minute Confirmatory Assay for HIV. 11th International Conference on AIDS/STDs in Africa. Lusaka, 1999: Abstract Book 157 (abstract no. 15PT512-2); Constantine N et al. A Rapid Confirmatory Assay for HIV. 5th ICAAP, 1999 (abstract no. 46/PMAB001).

[53] Ibid.

[54] Personal communication with A Chowdhury, Universal HealthWatch Inc, 16 December 1999.

[55] Ibid; personal communication with B Childs, Universal HealthWatch Inc, 15 December 1999.

[56] UNAIDS/WHO. Operational Characteristics of Commercially Available Assays to Determine Antibodies to HIV-1 and/or HIV-2 in Human Sera. (Report 11). Geneva, January 1999, at 3; UNAIDS/WHO. Revised recommendations for the selection and use of HIV antibody tests. *Weekly Epidemiological Record* 1997; 72: 81-88.

[57] Ibid.

[58] Zahwa H et al. Evaluation of Rapid HIV Testing Platforms. 7th CROI 2000: Abstract 765, available at <www. retroconference. org>.

[59] Stetler HC et al. Field evaluation of rapid HIV serologic tests for screening and confirming HIV-1 infection in Honduras. *AIDS* 1997; 11(3): 369-375; Wilkinson D et al. On-site HIV testing in resource-poor settings: is one rapid test enough? *AIDS* 1997; 11(3): 377-381; Fridlund C et al. Integration and optimization of HIV rapid testing algorithms in client-centered HIV counseling. 5th CROI 1998: 106 (abstract 143).; Steketee R et al. Utility of single or dual rapid tests in the detection of HIV in pregnant women, Kenya. International Conference on AIDS 1998; 12: 793 (abstract 42104).

[60] CDC. Update; supra note 2; Rapid tests could 'revolutionize' screening. *AIDS Alert* 1998 (July); 13(7): 82-84.

[61] CDC. Clinical Update – The new rapid HIV test: issues for HIV prevention counselors. *Clinician Reviews* 1998; 8(6): 149-153, 157-158.

[62] New rapid HIV tests expected soon. *Hopkins HIV Report*, May 1999, at <www. hopkins-aids.edu/publications/report/may99_6.html#12>.

[63] Ratnam S et al. MedMira Rapid HIV Screen as a supplemental test for rapid confirmation of EIA-based HIV positive screen result. International Conference on AIDS 1998; 12: 797 (abstract no. 42122) (AIDSLINE ICA12/98402889); Lubega et al, supra, note 22; Ratnam S et al. MedMira Rapid HIV Screen test: a multinational field trial. Abstracts of the General Meeting of the American Society for

receive test results, and concluded that "[r]apid, on-site HIV testing was feasible, preferred by clients, and resulted in significant improvement in the number of persons learning their serostatus, without increasing the costs or decreasing the effectiveness of counseling and testing."[66]

As Jürgens has reported, in October 1997 the US Centers for Disease Control (CDC) and the US Association State and Territorial Public Health Laboratory Directors (ASTPHLD) held a workshop

> to discuss rapid HIV testing, the potential health benefits and risks of reporting provisional rapid-test results, and the feasibility of changing the recommendations for reporting HIV test results. The purpose of the meeting was to discuss those recommendations "in light of technological advances in rapid screening tests, data that suggest that prevention efforts could be improved by more rapid turnaround of test results, and increased health benefits that may be afforded by more quickly initiating new, effective therapies for HIV."[67]

While participants at that workshop agreed that the optimal procedure is to conduct confirmatory testing before reporting reactive HIV test results, they also took the view that exceptions to this approach are warranted

> when the health benefit of reporting HIV-rapid-test results offsets the potential risk for reporting false-positive rapid-test results (e.g., patients who fail to learn their HIV status because they do not return to receive their test results). Rapid HIV tests can also assist health-care providers who must make immediate decisions about initiating HIV prophylaxis (e.g., caring for health-care workers after occupational exposures and for pregnant women in labor who have not been tested or whose results are not available.)[68]

As Jürgens notes, participants at the US workshop did agree that high-quality testing and appropriate counseling must accompany rapid HIV testing; that testing laboratories must ensure rigorous quality assurance plans (including ensuring the proficiency of testing staff); and that all those with a reactive HIV test result should have another specimen collected and tested according to the currently recommended algorithm. Furthermore, they agreed that decisions about whether to use rapid tests should be based on a combination of the prevalence of HIV in a community and return rates for test results:

> For example, in settings of high prevalence where a low percentage of persons return for their results (e.g., STD clinics), use of rapid tests will be most beneficial. In comparison, rapid tests may be less beneficial in settings of low prevalence where return can be ensured (e.g., most practitioners' offices). Other settings require individual consideration.[69]

Following these workshop conclusions, the CDC issued a report in March 1998 showing its extrapolations from the 1997 Dallas study and other data reported from publicly funded testing sites in 1995. According to the CDC, using the rapid HIV screening test would have meant that, in 1995:

The optimal procedure is to conduct confirmatory testing before reporting reactive HIV test results.

Decisions about whether to use rapid tests should be based on a combination of the prevalence of HIV in a community and return rates for test results.
– [US] Association of State and Territorial Health Officials, 1997

Microbiology 1998 (17-21 May); 98: 153-154 (abstract no. C-137), available via <hiv.medscape.com>.

[64] The information in this section is derived from Jürgens, supra, note 4 at 111-113.

[65] CDC. Interpretation and use of the Western blot assay for serodiagnosis of human immunodeficiency virus type 1 infections. *Morbidity and Mortality Weekly Report* 1998; 38(Suppl 7): S4-S6.

[66] Kassler WJ et al. On-site, rapid HIV testing with same-day results and counseling. *AIDS* 1997; 11(8): 1045-1051 at 1045.

[67] Jürgens, supra, note 4 at 112, citing: Advances in HIV testing technology. *The Association of State and Territorial Health Officials HIV/AIDS Update 1997*; 1(4): section 2.

[68] Advances in HIV testing technology, supra, note 67.

[69] CDC. Update, supra, note 2.

- almost 700,000 more people would have learned their HIV status;
- approximately two million people whose rapid-test results were negative would have learned their HIV status without a second clinic visit;
- an additional 8170 people (22 percent of all positive tests performed in 1995) would have received confirmed positive test results;
- 8301 HIV-negative people would have received preliminary false-positive results after a reactive rapid test, representing 0.4 percent of the 2.1 million people tested for HIV, but 18 percent of those who would have received an initial reactive result. Most (97 percent) would have returned to learn their confirmatory test result was negative. Because of the differences in HIV prevalence at different types of testing sites, the proportion of persons given a reactive rapid-test result who were truly positive ranged from 46 percent at family planning clinics to 88 percent at drug-treatment programs; and
- an additional 1115 HIV-infected people who did not return for confirmed results would have been given a reactive rapid-test result and received counseling about the likelihood of being infected and the need for behavioural changes.[70]

Health Canada has not received any applications for a licence to sell HIV test kits for "home testing," and has only considered licensing rapid test kits for "point-of-care" testing.

The CDC concluded from these figures that

> the use of a rapid test with same-day results for HIV screening in clinical-care settings can substantially improve the delivery of CT [counseling and testing] services. Because most persons who are tested are not infected, they can receive counseling and learn their HIV status in a single visit. In addition, providing preliminary positive results also increases the number of infected persons who ultimately learn their infection status and can be referred for medical treatment and additional prevention services.[71]

Current Status of Rapid Test Kits in Canada

As of February 2000, there was only one rapid HIV test kit licensed for sale in Canada. Manufactured by MedMira Laboratories Inc, this device is a rapid screening test for both HIV-1 and HIV-2. It was licensed in April 1998 as a screening test of blood plasma or serum for laboratory use only.[72]

Two other manufacturers, Merlin Biomedical & Pharmaceutical and BioChem ImmunoSystems Inc, filed applications for licensing for rapid HIV-1&2 screening test kits for use at the point of care. Clinical trials of these devices have been conducted to evaluate their safety and efficacy. Approval for sale in Canada is expected for at least one of these kits in early 2000.

At the time of writing, Health Canada had not received any applications for a licence to sell HIV test kits for "home testing," and has only considered licensing rapid test kits for "point-of-care" testing.[73] Obviously, making HIV test kits available for personal use outside a proper health-care setting raises many concerns. However, even restricting rapid HIV screening kits to "point-of-care testing" raises complicated legal and ethical questions that should be addressed in shaping Canadian law and policy. These are explored further below.

[70] Ibid.

[71] Ibid.

[72] Health Canada (Therapeutic Products Programme) – Expert Advisory Committee on HIV Therapies. Minutes of teleconference of 9 July 1998, available at <www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/advcomm_eachiv.html>.

[73] Personal communication with D Lepine, Medical Devices Bureau, Health Canada, 14 February 2000.

Regulatory Framework

Approval for Sale of Medical Devices

Licensing of Medical Devices

The federal *Food and Drugs Act*[74] (FDA) and the Medical Devices Regulations[75] (MDR) made under that Act, govern the licensing for sale and the sale of medical devices in Canada. The administration of the Act and the Regulations is the responsibility of the federal Minister of Health.[76] This regulation of medical devices has been upheld as within the constitutional jurisdiction of the federal government.[77]

The definition of "device" in the Act includes any article or instrument that is manufactured, sold or represented for use in the diagnosis of a disease.[78] The Regulations apply to the sale and advertising of medical devices, and the importation of medical devices for sale or for use on individuals (other than personal use).[79] They set out a number of rules for classifying medical devices into one of four classes based on the degree of risk posed by the device. Rapid HIV test kits are "*in vitro* diagnostic devices" as defined in the Regulations.[80] They are classified by Health Canada as Class IV devices, the category of highest risk.[81] It should be noted that never before has a Class IV medical device been licensed in Canada for point-of-care use.[82]

No person is permitted to import, sell, or advertise a Class IV medical device unless the manufacturer holds a licence for that device.[83] A manufacturer must submit an application for a medical device licence to the Minister of Health.[84] The Medical Devices Regulations require that a manufacturer ensure the medical device meets the "safety and effectiveness requirements" set out in the regulations, and keep "objective evidence" to establish this,[85] before a medical device licence may be issued.[86] The safety and effectiveness

Never before has a Class IV medical device been licensed in Canada for point-of-care use.

[74] RSC 1985, c F-27, s 1.

[75] SOR/98-282.

[76] FDA s 2 ("Minister," "Department").

[77] *R* v *Wetmore*, [1983] 2 SCR 284.

[78] FDA s 2 ("device").

[79] MDR s 2.

[80] MDR s 2 ("*in vitro* diagnostic device," "test kit"); Health Canada (Medical Devices Bureau). Guidance for the risk based classification system of *in vitro* diagnostic devices (Draft). April 24, 1998, available at <www.hc-sc.gc.ca/hpb-dpgs/therapeut/htmleng/guidmd.html>.

[81] MDR, Sch 1, Part 2, Rule 2(a).

[82] Carballo M, Medical Devices Bureau (Health Canada), Workshop on Rapid HIV Testing, 21-22 January 2000, Toronto.

[83] MDR ss 26-27.

[84] MDR s 32.

[85] MDR s 9.

[86] MDR s 36(1).

Health Canada's assessment of safety and effectiveness is limited to assessing only the device's technical performance.

requirements include, among others, the following provisions relevant to rapid HIV screening kits:

- The manufacturer must identify the risks inherent in the device, eliminate them if possible, or reduce them to the extent possible and provide appropriate protection and information about the remaining risks.[87]
- "A medical device shall not, when used for the medical conditions, purposes or uses for which it is manufactured, sold or represented, adversely affect the health or safety of a patient, user or other person, except to the extent that a possible adverse effect of the device constitutes an acceptable risk when weighed against the benefits to the patient and the risk is compatible with a high level of protection of health and safety."[88]
- The performance of the device must not deteriorate under normal use over its projected useful life to such a degree that the health or safety of a patient, user or other person is adversely affected. Similarly, the performance of the device must not be adversely affected by transport or conditions of storage (taking into account the instructions regarding these).[89]
- The design, manufacture and packaging of the device must minimize any risk to a patient, user or other person from reasonably foreseeable hazards, including the presence of a contaminant, chemical or microbial residue, and fluid leaking from or entering into the device.[90]
- A medical device that performs a measuring function must perform that function within tolerance limits that are appropriate for the medical conditions, purposes and uses for which it is manufactured, sold or represented.[91]

Health Canada's Medical Devices Bureau is responsible for ensuring that medical devices meet the "safety and effectiveness requirements" before licensing them for sale. Health Canada's assessment of safety and effectiveness is limited to assessing only the device's technical performance, although federal regulators do "require the manufacturers of point-of-care testing [kits] to submit data on consumer field evaluation to determine the device's performance when used by lay users, unassisted, following instructions provided in the labelling. The lay users should be representative of the target users for which the test is intended."[92] However, in Health Canada's view, the Medical Devices Regulations "do not allow for the evaluation of these devices in terms of their impact [on] delivery [of test results] to the clients, their impact on current counselling methods, or psycho-social or other related issues."[93]

The Minister of Health *must* refuse to issue a licence if the device does not meet the safety and effectiveness requirements, or if insufficient information is provided to determine whether the device meets the requirements.[94] The Minister *may* refuse to issue a licence if the manufacturer does not comply with any applicable provision of the *Food and Drugs Act* or with Medical Devices Regulations (including the labeling requirements described below).[95]

In issuing a medical device licence, Health Canada may set out "terms and conditions respecting the tests to be performed on a device to ensure that it continues to meet the safety and effectiveness requirements, and the requirement to submit the results and protocols of any tests performed."[96] These terms and conditions may be amended to take into account any new development with respect to the device.[97] The manufacturer holding the licence must comply with any terms and conditions of the licence.[98]

[87] MDR s 10.

[88] MDR s 11.

[89] MDR s 13, 14.

[90] MDR s 16.

[91] MDR s 19.

[92] Health Canada (Therapeutic Products Programme), supra, note 72.

[93] Health Canada (Medical Devices Bureau), supra, note 6 at 3.

[94] MDR s 38(2).

[95] MDR s 38(1).

[96] MDR s 36(2).

[97] MDR s 36(3).

[98] MDR s 36(4).

If a "significant change" has been made to a medical device, an amended licence for the sale of that device is required and must by sought by application.[99] A "significant change" is one that "could reasonably be expected to affect the safety or effectiveness of a medical device," and includes a change to "the intended use of the device, including any new or extended use."[100] It may also include labeling changes. "Changes to labelling intended to allow a device normally accessed through a health care professional to be purchased by the general public are considered significant, and require a licence amendment application."[101]

A health-care professional is defined in the Regulations as "a person entitled under the laws of a province to provide health services in the province."

Labeling Requirements

The Medical Devices Regulations contain requirements regarding the labeling of medical devices.[102] These regulations are made under the authority of the *Food and Drugs Act*, which gives the federal Cabinet the authority to make regulations respecting:

> the labelling and packaging and the offering, exposing and advertising for sale of ... devices, ... and *the sale or the conditions of sale of any ... device*, to prevent the purchaser or consumer thereof from being deceived or misled in respect of the ... performance, intended use, character, ... merit or safety thereof, or to prevent injury to the health of the purchaser or consumer; and
>
> requiring persons who sell ... devices to maintain such books and records as the Governor in Council [ie, Cabinet] considers necessary for the proper enforcement and administration of this Act and the regulations.[103]

The definition of "label" in the *Food and Drugs Act* is sufficiently flexible to include "package inserts, brochures or leaflets" that accompany the device.[104] Health Canada indicates that "package inserts are essential for most IVDDs [*in vitro* diagnostic devices]."[105]

The Regulations prohibit the import or sale of medical devices without a label setting out information such as the name of the device, the name and address of the manufacturer, the control number, the device's expiry date, and any applicable special storage conditions. The label must also set out the medical conditions, purposes, and uses for which the device is manufactured, sold, or represented, including the performance specifications of the device if those specifications are necessary for proper use (unless these are self-evident to the user).

The label must also set out the "directions for use" if these are required for the device to be used safely and effectively. "Directions for use" of a medical device means "full information as to the procedures recommended for achieving the optimum performance of the device."[106] Health Canada practice in licensing medical devices distinguishes between "laboratory use" and "professional use." Use of a test kit by a health-care professional providing care to a patient is also referred to as "point-of-care" testing. A health-care professional is defined in the Regulations as "a person entitled under the laws of a province to provide health services in the province."[107] Legally speaking, a device used outside a laboratory is defined as a "near patient *in vitro* diagnostic device" –

[99] MDR ss 34, 26-27.

[100] MDR s 1 ("significant change"); Health Canada (Medical Devices Bureau). Guidance for the Interpretation of Significant Change. November 9, 1998. Available at <www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/guidmd.html>.

[101] Guidance document, at 10.

[102] MDR s 21; Health Canada (Medical Devices Bureau). Guidance for the Labelling of Medical Devices, Section 21 to 23 of the *Medical Devices Regulations* (with appendices) (Draft). January 11, 1999, available at <www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/guidmd.html>.

[103] FDA s 30(1)(b), (f) [emphasis added].

[104] FDA s 2 ("label"); Health Canada (Medical Devices Bureau). Guidance for the Labelling of Medical Devices, supra, note 102 at 4.

[105] Health Canada (Medical Devices Bureau). Guidance for the Labelling of *In Vitro* Diagnostic Devices (Draft). 19 June 1998, at 5. Available at <www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/guidmd.html>.

[106] MDR s 1 ("directions for use").

[107] MDR s 2 ("health care professional").

Experience in the US has shown the willingness of some manufacturers and/or vendors to engage in highly unethical (and illegal) marketing of unapproved devices.

this includes home use or point-of-care testing (eg, in a pharmacy, a health-care professional's office, or at the bedside).[108]

With regard to labeling, Health Canada also advises that the package insert should clearly indicate the nature of the intended use, including

> if the device is for use in clinical laboratories, alternative care sites, or home use. Note: The Limitations section of the package insert should include any specific training required for test performance or use.[109]

The package insert should also include any required qualifications for personnel performing the test and/or interpreting test results, as well as factors that should be considered in interpreting the test results.[110] Health Canada also indicates that "test marketing of the device labelling may be required in some cases."[111]

The importance of ensuring compliance with labeling – and, perhaps more important, monitoring marketing materials prepared by manufacturers – must not be overlooked. Experience in the US has shown the willingness of some manufacturers and/or vendors to engage in highly unethical (and illegal) marketing of unapproved devices. On at least four separate occasions, federal regulators have laid charges for falsely representing the accuracy of an HIV test,[112] and the US FDA has stated that more than a dozen HIV home test kits are being advertised over the Internet,[113] while only one such kit being sold in the US has received FDA approval for sale.

However, of equal concern is the imprecise and misleading language regarding the function and performance of rapid test kits, which is not uncommon in the marketing of such devices – particularly language of the sort that promises rapid tests can deliver "reliable results in minutes" or "know your HIV status right away," while making only a passing and generally much less prominent reference to the need for further confirmatory testing. This need for further testing must be prominently explained in all "labeling" materials for rapid screening kits. Similarly, as has already been recommended in Canada, product inserts prepared by manufacturers need to emphasize the need for thorough pre- and post-test counseling.[114] While the existing provisions of the Medical Devices Regulations regarding labeling should be sufficient to address such matters, additional regulatory powers (if needed) may be found under section 30 of the *Food and Drugs Act*.

Compliance and Enforcement

The *Food and Drugs Act* provides that no person shall label, sell, or advertise any device in a manner that is "false, misleading or deceptive or is likely to create an erroneous impression regarding its design, ... performance, [or] intended use."[115] The definition of "sell" includes distributing.[116]Any device that is not labeled or packaged as required by the Regulations, or is labeled or packaged contrary to the Regulations, will be considered in breach of this prohibition on misleading labeling.[117]

The Medical Devices Regulations require a manufacturer, importer, or distributor of a medical device to maintain records of any reported problems relating to the performance characteristics or safety of a device (including any consumer complaints), and the actions taken in response to such problems.[118]

[108] MDR s 2 ("near patient *in vitro* diagnostic device").

[109] Health Canada (Medical Devices Bureau), supra, note 105.

[110] Ibid at 10.

[111] Ibid at 13.

[112] FTC shuts down Internet supplier of inaccurate HIV tests. *Reuters Medical News*, 20 January 2000, available at <www.medscape.com/reuters>; Federal Trade Commission. Media release: FTC charges second Internet marketer with misrepresenting accuracy of HIV tests. 1 December 1999, available at <www.ftc.gov>; Federal Trade Commission & Food and Drug Administration. Media release: FTC and FDA warn consumers about ineffective and unapproved HIV test kits; announce joint law enforcement actions. 17 November 1999, available at <www.ftc.gov>; FDA. Media release: Business sentenced to over five years for selling bogus HIV-testing kits. 17 February 1999, available at <www.fda.gov/oashi/aids/ greene.html>; FDA. Warning letters issued for unapproved HIV test kits. Summary list posted 22 November 1999 at <www.fda.gov/oashi/aids/testwarn.html>.

[113] Richwine L. US warns about HIV tests sold on Internet. *Reuters NewsMedia*, 18 June 1999, available at <www.aegis.com/news/re/1999/RE990609.html>.

[114] Peterkin, supra, note 3.

[115] FDA s 20(1).

[116] FDA s 2 ("sell").

[117] FDA s 20(2).

[118] MDR s 57(1).

This record-keeping requirement does not apply to a retailer of a device (although a retailer would, in common parlance, be thought by most people to engage in "distribution") or to a "health care facility in respect of a medical device that is distributed for use within that facility."[119] A "health care facility" is defined as "a facility that provides diagnostic or therapeutic services to patients."[120]

A manufacturer, importer, or distributor is also required to establish and implement documented procedures for carrying out an effective and timely investigation into any reported problems, or for recalling a device.[121]

A manufacturer or importer of a medical device is required to make a preliminary and a final report to the Minister of Health regarding any incident that comes to its attention (inside or outside Canada) regarding a device sold in Canada that is related to the failure or deterioration of a device, or an inadequacy in its labeling or directions for use, where this has led to the death or serious deterioration in the health of a patient, user, or other person, or could have this result if the incident were to recur.[122]

The Act also sets out the power of the Minister of Health or the Minister's designated inspectors to carry out investigations into possible contraventions of the Act or Regulations.[123] Any one who contravenes the Act or Medical Devices Regulations (including labeling requirements, failing to report problems, etc) is guilty of an offence and is liable:

- on summary conviction for a first offence to a maximum fine of $500, or to imprisonment for up to three months, or both, and for a subsequent offence to a maximum fine of $1000, or to imprisonment for up to six months, or both; or
- on conviction on indictment to a maximum fine of $5000, or to imprisonment for up to three years, or both.[124]

The Minister of Health also has the power to suspend a medical device licence if there are "reasonable grounds" to believe that the manufacturer has contravened the Regulations (including labeling requirements) or any applicable provisions of the *Food and Drugs Act*, or has failed to comply with the terms and conditions of the licence.[125]

Regulating the Point-of-Care Use of Medical Devices

Whether or not rapid test kits will end up being purchased, and how their use is regulated (directly or indirectly), falls within the jurisdiction of the provincial/territorial governments. It is "generally agreed that provinces have exclusive jurisdiction over insurance for and supply of health goods and services pursuant to ... the *Constitution Act, 1867*. It is also well settled that it is beyond the federal government's constitutional powers to directly regulate insurance for and the supply of health goods and services."[126]

Each provincial/territorial government has numerous statutes and regulations applicable to different aspects of HIV testing – which would also affect rapid screening tests. For example, provincial/territorial statutes set out the powers and duties of ministers of health in broad terms to take measures to protect and promote the health of residents. Public health legislation in each province or territory (supplemented by regulations in many cases) sets out duties and powers of public health officials with respect to the control of

[119] MDR 57(2).

[120] MDR s 1 ("health care facility").

[121] MDR s 58.

[122] MDR s 59-62.

[123] FDA ss 22-29.

[124] FDA s 31. Any prosecution must be initiated within 2 years of the offence: s 32.

[125] MDR s 40.

[126] Flood C. The Structure and Dynamics of Canada's Health Care System. In: Downie J, Caulfield T (eds). *Canadian Health Law and Policy*. Butterworths: Toronto, 1999, at 12. For this proposition, see: *Reference Re Employment and Social Insurance Act*, [1936] SCR 427 at 451; *R* v *Schneider*, [1982] 2 SCR 112 at 137; *Eldridge* v *British Columbia (AG)* (1997), 151 DLR (4th) 577 at 595-596 (SCC).

"Provincial governments have largely chosen not to interfere with physician decision-making and have delegated regulatory responsibility to the profession itself."

Professional disciplinary proceedings, a civil suit, or a criminal prosecution might appropriately be initiated to address the misuse of a licensed medical device.

communicable diseases and obligations regarding reporting of AIDS and/or HIV reactive test results.[127] Statutes and regulations governing provincial health insurance plans determine which health services are paid for by the government and are therefore available without fee to all eligible residents of that jurisdiction.

The regulation of occupations and professions (including practice by health-care professionals) is also constitutionally a provincial responsibility.[128] Pursuant to this constitutional division of powers, provincial governments have enacted legislation setting out broad parameters for the governance of various health professionals.[129] However, as one commentator notes, "historically, provincial governments have largely chosen not to interfere with physician decision-making and have delegated regulatory responsibility to the profession itself.... Professional self-regulation is still the primary mechanism in the Canadian system used to ensure the quality of health services supplied."[130]

> Self-regulatory regimes are created by provincial statutes which delegate regulatory functions to a profession. This delegation of authority is generally made to a body created by the statute and charged specifically with the protection of the public interest, which may be called a "college," an "association," a "council," or a "board". The statute delegating regulatory functions and outlining the associated responsibilities can be a stand alone statute (ie, specific to the particular profession), or it can be an umbrella statute which establishes self-regulatory bodies for a number of health disciplines under a common framework.... [S]elf-governing health professions are entrusted with establishing standards of practice and ethical guidelines and codes of conduct for their members, through the enactment of detailed regulations, by-laws or policies.[131]

Professional codes of conduct, and guidelines and policies issued to health-care professionals by either professional associations or regulatory bodies, establish a standard of acceptable medical practice. Professional regulatory bodies generally have the authority to discipline members of that profession who engage in professional misconduct or incompetent practice. Aside from disciplinary proceedings, regulation of the conduct of health-care professionals is achieved principally through the ostensible deterrent effect of possible civil liability for *negligence* (for practice falling below the acceptable standard of care), for *battery* (for conducting medical interventions without a patient's informed consent), or other possible statutory or common law causes of action (depending on the nature of the impugned conduct, such as breaching confidentiality without legal authorization). Criminal liability for *assault* might also arise for performing a medical procedure (eg, HIV testing) without consent. Depending on the circumstances – such as performing an HIV test without a patient's informed consent – professional disciplinary proceedings, a civil suit, or a criminal prosecution might appropriately be initiated to address the misuse of a licensed medical device.

[127] *Communicable Diseases Act*, RSN 1990, c C-26; *Health Act*, RSBC 1996, c 179; *Health Act*, RSNB 1990, c H-2; *Health Act*, RSNS 1989, c 195 as amended; *Health Protection and Promotion Act*, RSO 1990, c H.7 as amended; *Public Health Act*, RSA 1984, c P-27.1 as amended; *Public Health Protection Act*, RSQ, c P-35 as amended; *Public Health Act*, RSNWT 1990, c P.12; *Public Health Act*, RSPEI 1988, c P-30; *Public Health Act*, RSY 1986, c 136; *The Public Health Act*, RSS 1994, c P-37.1; *The Public Health Act*, RSM 1987, c P210 as amended.

[128] *Constitution Act, 1867* (UK), 30 & 31 Vict, c 3, reprinted in RSC 1985, App II, No 5.

[129] For example: *Regulated Health Professionals Act, 1991*, SO 1991, c 18; *Health Professions Act*, RSBC 1990, c 50; *Health Disciplines Act*, RSA 1980, c H-3.4; *Professional and Occupational Associations Registration Act*, SA 1985, c P-18.5; *Nursing Profession Act*, SA 1983, c N-14.5; *Registered Nurses Act*, RSN 1990, c R-9; *The Registered Nurses Act, 1988*, SS 1988-89, c R-12.2; *The Medical Profession Act, 1981*, SS 1980-81, c M-10.1; *Medical Practitioners Act*, RSBC 1996, c 285; *Nurses (Registered) Act*, RSBC 1996, c 335; *Nursing Act*, SO 1991, c 32; *Medical Profession Act*, RSA 1980, c M-12.

[130] Flood, supra, note 126 at 39.

[131] McNamara L, Nelson E. Regulation of Health Care Professionals. In: Downie & Caulfield (eds), supra, note 126 at 69-70.

Potential Advantages of Using Rapid HIV Screening at the Point of Care

The following potential advantages of using rapid HIV screening at the point of care have been put forward:

- clients' satisfaction can be improved because they can receive their results sooner;
- rapid screening kits are easier and safer to administer;
- people would be able to chose between conventional testing and rapid testing, enhancing their autonomy;
- more people would receive their test results, since most would not have to return for their results and post-test counseling;
- access to HIV screening could be improved; and
- acceptance of HIV testing could be increased.

In addition, it has been argued that rapid screening

- could make it possible, for women who have had no prenatal care or whose HIV status is unknown at the time of labour, to undergo screening during labour and, for those screening positive, to initiate preventive measures that can reduce the risk of mother-to-child transmission; and
- could provide more information for decisions about post-exposure prophylaxis (PEP).

This chapter critically explores these potential advantages.

Many clients prefer a rapid testing procedure providing same-day results over the current standard procedure involving a return visit.

Improved Satisfaction with Testing for Patients and Providers

Faster Delivery of Results

There is evidence, predominantly from US research, suggesting that many clients prefer a rapid testing procedure providing same-day results over the current standard procedure involving a return visit.

- In 1996, researchers who evaluated the use of a rapid HIV screening test at a New York City hospital serving a patient population with a high HIV prevalence concluded that "[a]ccurate rapid assays offer advantages to patients and providers that may improve the acceptability of counseling and testing programs."[132]
- A 1997 US study evaluating the use of on-site, rapid HIV screening tests in a public testing site found that 92 percent of clients surveyed liked receiving their test results on the same day, and 89 percent understood the meaning of their test results. Of those who had previously been tested, 88 percent responded that they preferred the rapid test.[133]
- At the 1999 [US] National HIV Prevention Conference, researchers reported the results of a counseling and testing preference survey conducted with 460 participants drawn from a needle exchange, an STD clinic, and sex clubs for men who have sex with men. Participants were asked to indicate their preferences as between various alternatives to current blood tests. Twenty-five percent of participants indicated a preference for rapid testing, which ranked highest among the options offered.[134]

However, there is little Canadian data on this point. In 1997, researchers conducted an informal survey by electronic mail of 159 participants in the Vanguard project, an ongoing study of HIV rates and risk factors among young gay and bisexual men in the Vancouver area. Of the 66 participants who responded, 82 percent supported the idea of rapid testing. Although they expressed other concerns, "most felt that rapid testing would encourage more people to get tested, as it would alleviate the anxiety of the two-week waiting period."[135] Data regarding patient and provider preferences from a recent British Columbia Centre for Disease Control rapid-testing-plus-counseling study were unavailable at the time of writing. However, some of the providers participating in the study reported at the national workshop on rapid HIV screening at the point of care held in January 2000 that many participants preferred rapid HIV screening over the standard test, and that providers were generally comfortable administering the test.[136] However, since only very few of the participants in the study screened HIV-positive, the study did not provide enough information about participants' experience of coping with a positive screening result that needs to be confirmed; and about providers' experience with disclosing such results. In addition, departing from the norm, participants who did screen HIV-positive were provided with a confirmed result within two days from undergoing rapid screening, which very likely had a significant impact on their experience of coping with a positive screening result – the experience of someone who would have to wait two weeks rather than two days for a confirmed result after screening HIV-positive may be very different.

[132] Irwin K et al. Performance characteristics of a rapid HIV antibody assay in a hospital with a high prevalence of HIV infection. *Annals of Internal Medicine* 1996; 125(6): 471-475.

[133] Kassler et al, supra, note 66.

[134] Spielberg F et al. "By All Means Necessary:" HIV Counseling and Testing Preferences Among Individuals at High Risk. 1999 [US] National HIV Prevention Conference, Atlanta GA: Abstract 421.

[135] Martindale S. High Demand for Rapid HIV Testing Among Young Gay and Bisexual Men. In: Final Program & Abstract Book, AIDS Impact International Conference on the Biopsychosocial Aspects of HIV Infection, Ottawa, 15-18 July 1999, at 25-26; S Martindale. What if you could get HIV test results in 20 minutes? *The Vanguardian* [project newsletter], April 1998. NB: This is not a scientific survey, given the method of distribution; it was an informal survey.

[136] Workshop on Rapid HIV Screening at the Point of Care, sponsored by the Canadian HIV/AIDS Legal Network, Toronto, 21-22 January 2000; see supra at 2-3.

Clearly, the two-week waiting period for current testing, whether a person tests negative or positive, can be stressful and traumatic. This was confirmed by a 1998 Ontario study of the experience of getting tested for HIV, which reported that "the predominant feeling among test recipients during the waiting period was fear – fear of testing positive and fear of loss of social support if the test was positive."[137] All test recipients in the study who spoke about going for their test result were able to recall the experience vividly. All "experienced heightened anxiety due to a prolonged waiting period, their experience of the pretest encounter or their experience of previous testing."[138] As Hoffmaster says, being "spared that agonizing, arduous ordeal would be a substantial benefit for many people."[139] For some, though, he points out,

> there could be value in living through such a difficult time. Doing so could prompt them to contemplate their mortality and evaluate their lives, consider ways of changing their behaviour, and conclude that they never want to go through this experience again.[140]

Generally, whether there would be a benefit to faster delivery of results depends upon the outcome of the test:

> For those who tested negative, as most people would, their anxieties, worries, and fears could be relieved sooner. Quick reassurance would be a definite benefit for them. But for those who tested positive on the screening test, there would be no real benefit. They would have to await the result of a confirmatory test, enduring psychological and emotional distress that could be greater than what they would have experienced with the mere uncertainty that accompanies standard testing.[141]

Hoffmaster concludes:

> An assessment of this potential benefit depends upon information about how many of those being tested prefer not having to wait two weeks for results and how strong their preferences are, and upon information about the experience of coping with a positive screening result that needs to be confirmed. The numbers favour rapid screening – more people are likely to want a quick result, and more people will test negative. Nevertheless, the potential impact on those who test false positive cannot be discounted.[142]

The predominant feeling among test recipients during the waiting period was fear – fear of testing positive and fear of loss of social support if the test was positive.
– T Myers et al, 1998

Using rapid screening kits would significantly lower the number of instances in which venipuncture is required, yielding overall benefits in terms of patient comfort and health-care worker safety.

Easier and Safer to Administer

The rapid HIV screening kits to be licensed in Canada test whole blood, meaning that no venipuncture is required; a single fingerprick with a lancet is sufficient. If and when a rapid screening assay using saliva/oral fluid is licensed, not even this would be required. This means that the process of administering rapid HIV screening is less invasive and painful for the person getting tested. It is also safer and easier for health-care staff to administer, and lowers the chance of occupational exposures through needle-stick injuries.

In most cases, whenever the person getting tested screens HIV-negative, no further specimen is required, assuming only HIV serology is conducted. However, where a person screens positive, blood will still need to be drawn for

[137] Myers T et al. The HIV Test Experience Study: An Analysis of Test Providers' and Test Recipients' Descriptions and Critical Appraisals of the HIV Antibody Test Experience. Toronto: University of Toronto, 1998, at 33, 35.

[138] Ibid.

[139] Hoffmaster B. Rapid HIV Screening at the Point of Care: An Ethical Commentary, infra, Appendix A at A3.

[140] Ibid.

[141] Ibid. at A3-A4.

[142] Ibid. at A4.

laboratory-based confirmatory testing. Nonetheless, using rapid screening kits would significantly lower the number of instances in which venipuncture is required, yielding overall benefits in terms of patient comfort and health-care worker safety.

Choice of Testing Procedure

The debate over the use of rapid tests is being fuelled by US data indicating that follow-up for HIV tests is often poor.

As Hoffmaster points out, having the choice between conventional testing and rapid testing

> would allow people to select the approach that suits them and their current circumstances and thus would enhance their autonomy. It also could produce sounder decisions because the people being tested generally would know their own values and interests better than the people counseling them. Counselors would not be precluded from giving advice and making recommendations, but the decision about what kind of test to have would be left to the person being tested. Were people strongly to prefer one kind of test, allowing them to choose and satisfying their preferences would be benefits in themselves. Respecting autonomy recognizes that giving people choices and accepting their choices are valuable in themselves, regardless of the wisdom of what is chosen. And insofar as the people being tested would be more knowledgeable about their own attitudes and values and more attuned to their own situations, respecting their autonomy also could produce better decisions.[143]

More People Would Receive Test Results

As has been pointed out, "the debate over the use of rapid tests is being fuelled by [US] data indicating that follow-up for HIV tests is often poor.... However, ... follow-up for HIV tests in Canada is better than in the US, making this argument weaker in the Canadian context."[144]

United States Data

Analyzing 1990 US data regarding rates of clients returning for counseling after HIV testing,[145] Valdiserri et al found that:

- On average, 63 percent of clients at publicly funded sites in the US returned for test results and post-test counseling.
- Return rates varied substantially by type of service delivery site. Lower rates were seen at STD clinics (42 percent), family planning clinics (54 percent), and prenatal and obstetric testing sites (58 percent). Higher rates were seen at private physician offices (89 percent), colleges (87 percent), and free-standing HIV counseling and testing centres (85 percent).
- Higher return rates were observed among people who reported that the main reason for their visit was to obtain HIV counseling and testing (74 percent). A much lower return rate (44 percent) was seen among people who reported other principal reasons for their visit.
- The return rate was higher for HIV-positive people (82 percent), compared with people who tested HIV-negative (63 percent).

[143] Ibid.

[144] Jürgens, supra, note 4 at 116.

[145] Valdiserri RO et al. A study of clients returning for counseling after HIV testing: implications for improving rates of return. *Public Health Reports* 1993; 108: 12-18.

Valdiserri et al concluded that their results confirmed previous work indicating that variables of sex, race or ethnicity, age, type of service delivery site, self-reported risk exposure, reason for visit, and HIV serostatus were all associated with return rates. In their research, the variables most strongly associated with returning for post-test counseling and results were being men who self-reported sex with men and being HIV-positive. Other researchers found that clients who were young, non-white, female, HIV-negative, and who reported a history of injecting drug use were significantly less likely to return.[146]

More recent US studies reported a lower rate of failure to return for test results, but still found that a significant number of people do not receive their test results.

1995 data from publicly funded US clinics showed that 26 percent of persons who tested HIV-positive and 33 percent of persons who tested HIV-negative did not return for their test result.[147] As mentioned above,[148] based on this data, CDC researchers projected that using rapid screening tests at all such sites would have resulted in 7874 more HIV-positive and 581,308 more HIV-negative persons learning their test result; and in 10,376 people being given false positive rapid screening results. As a result of these projections, the US Public Health Service changed its long-standing recommendation against giving results from HIV screening tests before confirmation, and started supporting the use of rapid testing in some circumstances.[149] Some researchers have also concluded that the potential to reduce the number of people who do not receive their test result could constitute a benefit of using rapid HIV screening tests.[150] In particular, they have suggested the possibility of "targeted use of rapid HIV tests" for populations with higher rates of failure to return for test results [151] and/or for site-specific counseling strategies to reduce "failure to return" rates.[152]

At the end of 1999, CDC researchers reported that approximately 13 percent of all adults tested in the US in both 1994 and 1995 did not receive their test results, and again concluded that this suggests the need for alternative strategies to increase the rate of returning for test results, including rapid HIV screening assays to provide on-site results.[153]

Canadian Data

However, the Canadian situation may be different, and US data regarding "non-return" rates should not be relied upon in formulating Canadian policy regarding rapid HIV screening. As Hoffmaster points out, Canadian data on non-return rates are sporadic and largely anecdotal.[154] However, one study in Ontario in the early 1990s reported that more than 90 percent of clients of anonymous testing clinics returned to receive their results.[155] More recently, data from Ontario's anonymous testing clinics indicated that fewer than five percent of individuals getting tested for HIV did not return for their test results, and fewer than one percent of those testing HIV-positive failed to return for results.[156] Jürgens explains the difference between US and reported Canadian non-return rates:

> [T]he fact that so many people in the US do not return for their HIV test results is, at least in part, due to the fact that HIV testing is routinely undertaken in many STD clinics. Some of the people tested

[146] Nelson A et al. Failures and delays in returning for HIV test results at publicly-funded clinics, US, 1989-1990. VII International Conference on AIDS 1991: Abstract MC 3342 (poster); Ginsberg MM. Effectiveness of voluntary HIV antibody testing provided at a clinic treating sexually transmitted diseases. V International Conference on AIDS 1989: Abstract MAP 62 (poster); Kappes R et al. Tailoring HIV pre-test counseling in sexually transmitted disease (STD) clinics according to anticipated non-return rates in subcategories of patients. VI International Conference on AIDS 1990: Abstract SC 676 (poster); Rugg D et al. Failure to return for HIV test results: a second look at determinants. V International Conference on AIDS 1989: Abstract E717 (poster).

[147] CDC. Update, supra, note 2; Kassler et al, supra, note 66.

[148] See supra, the section on Revisiting HIV Counseling and Testing Practice, at 12ff.

[149] Branson BM. Rapid test strategies for HIV testing. 5th CROI, 232 (abstract S13).

[150] Golden MR et al. Failure to return for HIV post-test counseling (PTC) among HIV-positive Baltimore STD clinic patients: risk factors and trends. International Conference on AIDS 1996; 11(2): 475 (abstract no. Pub.C.1244). AIDSLINE MED/96925684; Tao G , Kassler WJ, Branson BM, Cohen RA. Rates of receiving the result of an HIV test: data from the US National Health Interview Survey. International Conference on AIDS 1998; 12: 1065 (abstract no. 60354). AIDSLINE ICA 12/98408603; Kelen GD et al. Emergency department-based HIV screening and counseling: experience with rapid and standard serologic testing. *Annals of Emergency Medicine* 1999; 33(2): 147-55 (MED/99122818); Kelen GD et al. Evaluation of two rapid screening assays for the detection of human immunodeficiency virus-1 infection in emergency department patients. *American Journal of Emergency Medicine* 1991; 9(5): 416-420; Molitor F et al. Predictors of failure to return for HIV test result and counseling by test site type. *AIDS Education and Prevention* 1999 (February); 11(1): 1-13; Tao G et al. Rates of receiving HIV test results: data from the US National Health Interview Survey for 1994 and 1995. *Journal of Acquired Immune Deficiency Syndromes* 1999; 22: 395-400.

[151] Golden et al, supra, note 150; Marmor M et al. Rapid versus Standard HIV Testing of Persons at High Risk of HIV Infection. 1999 [US] National HIV Prevention Conference: Abstract 692, available at <www.cdc.gov/nchstp/hiv_aids/conferences/hiv99/abstracts/692.pdf>.

[152] Molitor et al, supra, note 150.

[153] Tao et al, supra, note 150; More than 1 in 8 Americans do not receive HIV test results.

The failure of people who test *negative* to return for their results is not a strong argument for introducing rapid screening.

did not seek out HIV testing in the first place, and it is therefore hardly surprising that a higher number will not return for their test results. In contrast, in Canada HIV testing clinics have achieved higher return rates, at least in part because the primary purpose of people attending these clinics is to be tested for HIV.[157]

Assessing the Benefit

As mentioned above, the potential to reduce the number of people who do not return for their HIV test results is seen as a major potential benefit of introducing rapid HIV screening at the point of care. Apart from the fact that non-return rates seem to be lower in Canada than in the US, how much significance should be attached to the fact that, under the current testing system, some people do not return for their test results? Does this warrant changing the practice of giving out only confirmed test results?

The concern about "failure to return" rates is twofold: concern for the well-being of the person getting tested, and concern for the well-being of others.

Negative test results

In the case of a negative test result, there is no harm to the person who does not receive their result, nor does that person pose a risk of transmission to others. The fact that some people who test *negative* do not return for their results is therefore not a strong argument for introducing rapid screening.

Positive test results

However, in the case of HIV-infected persons who do not return for their positive test results, their failure to return for a test result *may* result in harm to themselves or to others.

Receiving a diagnosis of HIV infection makes it possible to initiate treatment or to take other steps to preserve one's health. The sooner persons receive the diagnosis, the sooner they can seek medical advice and make an informed decision regarding treatments.

As for preventing harm to others, persons who remain unaware of their HIV infection because they do not return for test results may transmit the virus to others. It would be false, however, to assume that every person who fails to return for a positive test result poses a danger to others. Persons may well practise safer sex and avoid other risk behaviours even if they do not return for their results. This may particularly be the case if they suspect they may be positive or have reason for concern given past activities. Information about the need to practise safe behaviours will – or should – have been communicated during pre-test counseling.

Nonetheless, this will not always be the case, and in the end it remains likely that, overall, there is some benefit to be gained, in terms of preventing HIV transmission, from measures that increase the number of people who learn of their HIV-positive status. The question is whether – and in what circumstances – using rapid HIV screening tests would yield a significant enough benefit in this respect to warrant their introduction.

Reuters Health Information, 6 January 1999, available at <www.ama-assn.org/special/hiv/newsline/reuters>.

[154] Hoffmaster, infra, Appendix A at A3.

[155] Ontario Ministry of Health, AIDS Bureau. *Anonymous HIV Testing Evaluation, January 1992 to June 1993*. Toronto: The Ministry, November 1994, at 7.

[156] Personal communications with J Greer, Hassle-Free Clinic (Toronto), 17 February 2000, and C Major, Head, HIV Laboratory, Central Public Health Laboratories (Ontario Ministry of Health), 22 February 2000. Data from New Brunswick indicate a 97 percent return rate among those testing through the province's anonymous testing program (personal communication from I Brophy, New Brunswick Department of Health and Community Services, 3 March 2000). In Québec, the return rate for those tested at anonymous sites ranged from 81.4 to 87.4 percent over 1997-1999 (communication from T Tannenbaum, 9 March 2000). In British Columbia, the percentage of positive test results never given ranged from 9 to 14.6 percent for the province over the years 1995-1999 (communication from L Knowles, 1 March 2000).

[157] Jürgens, supra, note 4 at 115; Wiley DJ et al. Failure to learn human immunodeficiency virus test results in Los Angeles public sexually transmitted disease clinics. *Sexually Transmitted Diseases* 1998; 25(7): 342-345.

Is rapid on-site screening needed to ensure receipt of test results?

Whenever a test provider has identifying information, a person who does not return for a positive test result can be contacted and encouraged to return for the result and for post-test counseling. In fact, there is almost certainly a legal duty on the test provider and/or public health authorities to make all reasonable efforts to ensure that the person learns of their positive test result. Absent unusual circumstances, failure to make such efforts to inform the person of their confirmed HIV infection would amount to negligence giving rise to civil liability.[158]

Whenever a test provider has identifying information, a person who does not return for a positive test result can be contacted and encouraged to return for the result.

In contrast, no follow-up is possible for persons who have been anonymously tested and have not returned to receive their test result. As mentioned above, however, Canadian data from anonymous testing sites in Ontario show that fewer than five percent of individuals getting tested for HIV at those sites do not return for their test results. This suggests that introducing rapid HIV screening would have a relatively small impact in terms of increasing the number of people who receive the results of their HIV tests.

The fact that someone (who will or should have received pre-test counseling) does not return for test results may also, in some cases, be an indication they have decided they are not ready to learn their HIV status. Where this is the reason for not returning, citing a concern for that person's well-being as the justification for introducing rapid HIV screening is a weak and paternalistic argument that ignores that person's autonomy.

While the potential to increase the number of people who learn their test results has been portrayed as a major benefit of rapid screening, upon closer reflection that benefit is more limited than some have suggested.

Another argument for offering the option of providing on-site rapid test results at anonymous testing sites is the concern for the well-being of others. The assumption is that receiving a preliminary result may have some effect in modifying behaviour even if a person does not return for confirmed test results. Whether, and to what extent this is the case, remains a matter of considerable speculation and conflicting data.

In addition, as Hoffmaster points out,

> [d]isclosure of a positive screening result could make it possible to prevent transmission to another person if learning that result meant that the person being tested did not engage in unprotected sex or needle sharing during the two-week waiting period. Again, however, the potential benefit of rapid screening is speculative. A person who is sufficiently concerned to be screened and who receives proper counseling probably would be motivated to avoid risk behaviour and would act on that motivation in the ensuing two weeks anyway. And a person who was not already disposed to avoid risk behaviour probably would not be affected by a preliminary positive result. Either way, disclosing a positive screening result would be unlikely to have a significant impact on preventing transmission to others.[159]

Conclusion

There is no doubt that there will likely be *some* benefit from increasing the number of people who learn their HIV status. However, as Hoffmaster points out, an assessment of this potential benefit requires better, more comprehensive Canadian data.[160] If research confirmed the apparent variability of

[158] *Pittman Estate* v *Bain* (1994), 19 CCLT (2d) 1 (Ont Ct (Gen Div)).

[159] See infra, Appendix A at A9-A10.

[160] Ibid at A5.

non-return rates, the importance of this benefit would be different in the various settings in which rapid testing were to be offered. In particular, the argument that rapid screening should be introduced to reduce the number of people who do not receive their test result because they do not return after the first visit applies only to anonymous testing situations, where follow-up to deliver test results is not possible. In all other situations, follow-up could and should be undertaken whenever a person testing positive does not return to obtain their result. Thus, while the potential to increase the number of people who learn their test results has been portrayed as a major benefit of rapid screening, upon closer reflection that benefit is more limited than some have suggested. And it may be even more limited in the Canadian context than in the United States or other jurisdictions that have high "non-return" rates.

Rapid HIV screening, on its own, falls below the generally accepted standard of care, and must be accompanied by timely access to confirmatory testing.

In addition to knowing little about non-return rates in various testing settings, we do not know enough about *why* people do not return for their test results. How many people who test positive on a rapid screening test would not come back for a confirmed result, and why would they not come back? We do not know. Not returning could indicate that a person is not ready to receive the result, and for such individuals there would be no advantage to rapid screening.

In conclusion, without solid Canadian data about many aspects of HIV testing, the size, and thus the importance, of this potential advantage of rapid HIV screening at the point of care is hard to gauge.

Increased Access

The simpler testing technology of rapid HIV screening tests – no requirement for complicated and expensive laboratory equipment – makes it easier to deliver these tests to "hard to reach," high-risk populations, such as street-involved populations, and in remote settings with little access to testing services and clinical care infrastructure. This may be of benefit particularly for people in the North and in rural areas, and has the potential to improve access to testing for Aboriginal people.

In small communities, there may be heightened concerns about confidentiality. Yet accessing testing outside such communities often requires expensive travel. As Matiation has reported:

> In some parts of the country an Aboriginal person may have to travel long distances at great expense to take advantage of an anonymous testing facility, or even to get tested at a local health centre. The period between taking a test and getting the result is generally much longer in rural and reserve communities than in major cities and may require two expensive trips, one for the test and one for the result. Further, many communities are visited by a health nurse only sporadically. In these circumstances, the chance that a person will get tested or, having been tested, return to the health centre to get the result, is reduced.[161]

However, the potential benefits of providing rapid HIV screening in such settings should not be overestimated. Rapid HIV screening, on its own, falls below the generally accepted standard of care, and must be accompanied by timely access to confirmatory testing. In remote areas, however, there is a worry that it could take a long time to get a confirmed result for a positive

[161] Matiation S. *HIV Testing and Confidentiality: Issues for the Aboriginal Community. A Discussion Paper*. Montréal: Canadian HIV/AIDS Legal Network & Canadian Aboriginal AIDS Network, 2nd edition, 2000. It should be noted that most of those consulted by Matiation did not support "home testing" as an alternative for Aboriginal people, but rather stressed the importance of improving access to testing accompanied by culturally sensitive, quality pre- and post-test counseling.

screening test and that the community might not have the resources to support a person with a preliminary positive result during that difficult period. As participants at one workshop noted, "there is concern about using POC testing in marginalized communities with little or no support systems or networks to assist clients through the waiting period for confirmatory results. As well, marginalized or transient populations may be less likely to return for confirmatory test results."[162]

Improved Prevention

In some circumstances, obtaining preliminary test results from a rapid screening test may assist in making decisions about initiating preventive measures in order to reduce the possibility of transmission.

Preventing Perinatal Transmission

HIV testing of pregnant women makes it possible to initiate, for women who test positive, preventive measures that can substantially reduce the risk of transmitting the infection to their newborns.

The best approach, of course, is to test women early in their pregnancy. But for women who have had no prenatal care, or whose HIV serostatus is unknown at the time of labour, testing during labour could be an option. Even then the risk of transmission from mother to child can be significantly reduced.

Data regarding perinatal transmission

In Canada, the number of infants born to HIV-positive mothers has increased steadily over the last decade. As of the end of 1998, 81 percent of the 181 reported pediatric AIDS cases were attributed to perinatal transmission.[163]

Perinatal (or vertical, or mother-to-child) transmission of HIV can occur during gestation (in utero), during delivery (intrapartum), or after delivery through breastfeeding. Recent research suggests that most perinatal HIV transmission occurs during labour and delivery.[164]

Antiretroviral therapy as pre-exposure prophylaxis

It has been estimated that, without intervention, the rate of transmission in Canada from an HIV-positive mother to her infant is in the range of 15 to 25 percent.[165] Antiretroviral therapy for both mother and infant can significantly reduce the likelihood of transmission,[166] and "for countries that can afford it, the more effective full-course intervention to prevent perinatal HIV transmission is cost-saving compared to the short-course alternative and thus is well worth the additional expense."[167] However, even a short course of AZT monotherapy provided late in the pregnancy and during labour has been shown to have some effect.[168] Preliminary data also suggest that combination therapy may be even more effective than monotherapy in preventing mother-to-child transmission. Although concerns have been raised as to whether protease inhibitors may be associated with premature delivery,[169] subsequent larger, observational studies have not found this to be the case.[170] To date, researchers evaluating over 23,000 infants born to HIV-infected mothers report no significant long-term effects observed in uninfected children exposed to AZT in the womb during pregnancy.[171] However, it should be remembered that such data cover only a few years at most, and it remains to be seen what effects maternal

[162] Tripp J. Memo: HIV Testing Counselling Workshop 1999 – Rapid HIV Testing: Highlights of Discussions. Toronto, 1999, on file.

[163] Laboratory Centre for Disease Control (Health Canada). Perinatal Transmission of HIV. *HIV/AIDS Epi Update*, May 1999. Available at <www.hc-sc.gc.ca/hpb/lcdc/bah/epi>.

[164] Among others, see: Mock PA et al (Bangkok Collaborative Perinatal HIV Transmission Study Group). Maternal viral load and timing of mother-to-child HIV transmission, Bangkok, Thailand. AIDS 1999; 13(3): 407-414; Mofenson L, Wilfert C. Pathogenesis and Interruption of Vertical Transmission. *Paediatric AIDS: The Challenge of HIV Infection in Infants, Children and Adolescents* (in press); see also L Stoltz, L Shap. *HIV Testing and Pregnancy: Medical and Legal Parameters of the Policy Debate*. Health Canada, 1999. Arikan Y, Burdge DR. Human immunodeficiency virus infection in pregnancy. *Canadian Journal of Infectious Diseases* 1998; 9(5): 301-309.

[165] Reduction of HIV transmission from mother to infant. *Canada Communicable Disease Report* 1994; 20(12): 97-101 at 100.

[166] See studies cited in: World Health Organization. Recommendations on the safe and effective use of short-course ZDV for prevention of mother-to-child transmission of HIV. *Weekly Epidemiological Record* 1998; 73: 313-320; and Forbes J et al. Pregnancy outcome in HIV-infected women in British Columbia: the impact of antiretroviral therapy on maternal-infant HIV transmission. *Canadian Journal of Infectious Diseases* 1997; 8(SupplA): 31a; Lapointe N. Antiretroviral Therapy in Pregnant Women (CPARG): Access and Outcome (1995-1997) and the Experience of Transmission of HIV in Treated Pregnant Women at Ste. Justine's Clinic, Québec. In: Proceedings of a Scientific Meeting to Review the Vertical Transmission of HIV in Canada, June 1998.

[167] Pinkerton SD et al. Incremental cost-effectiveness of two zidovudine regimens to prevent perinatal HIV transmission in the United States. *Preventive Medicine* 2000; 30: 64-69.

[168] Shaffer N et al. Short course zidovudine for perinatal HIV-1 transmission in Bangkok, Thailand: a randomised clinical trial. *Lancet*, 1999; 353: 773; Administration of zidovudine during late pregnancy and delivery to prevent perinatal HIV transmission – Thailand, 1996-1998. *Morbidity and Mortality Weekly Report* 1998; 47(8): 151-154; Wiktor SZ et al. Short-course zidovudine for prevention of mother-to-child transmission of HIV-1 in Abidjan, Côte d'Ivoire: a randomised trial. *Lancet* 1999; 353: 781-785; Dabis F et al. 6-month efficacy, tolerance, and acceptability of

use of AZT during pregnancy has on the progression of HIV disease in infants who become infected despite the prophylaxis.[172]

Other findings include:

- A short course of AZT given during the peripartum period has been shown to reduce vertical transmission of HIV-1 infection even in the case of mothers who breastfeed children after birth,[173] although the length of time postnatal AZT prophylaxis must continue to prevent transmission is not clear.[174]
- A two-dose regimen of the drug nevirapine – one dose administered to the mother at the onset of labour, and one dose administered to the newborn within 72 hours following birth – can reduce perinatal transmission by up to 50 percent,[175] but is not as effective as AZT.[176]
- Some new evidence suggests that administering AZT to infants within the first 48 hours after birth may prevent viral transmission, even when their mothers have not received any treatment, although results vary across several different studies, and researchers caution that prenatal treatment is still considered likely to be more effective.[177]
- Vaginal suppositories of benzalkonium chloride have been found to be safe and may now undergo trials to assess their efficacy in reducing perinatal transmission.[178]

Revised US Public Health Service guidelines for the use of prophylactic antiretroviral treatment for pregnant women are expected in 2000.[179]

Elective caesarean delivery to prevent transmission during delivery

The weight of available evidence also strongly suggests that prophylactic caesarian section, both when performed in conjunction with antiretroviral therapy and when performed independently, lowers the risk of transmission from mother to child.[180] There is some evidence to suggest that, even where women receive antiretroviral therapy, cesarean delivery can further lower transmission rates.[181]

However, some concerns have been raised about the possibility of higher and more serious complication rates in HIV-positive women following caesarian section, particularly those who are severely immuno-compromised.[182] A recent study found that HIV-positive women had a "substantially higher risk of post-operative morbidity" than uninfected women.[183] Other investigators have reported similar conclusions.[184] In addition, a European study found that while women who received elective caesarean delivery had a significantly lower mother-to-child transmission rate than women who delivered vaginally, the reduction in transmission risk for women who were also receiving AZT monotherapy prophylaxis was smaller and not statistically significant.[185] The available evidence thus suggests that the possible substantial benefit of a caesarean delivery in reducing the risk of perinatal transmission is most likely for women not taking antiretroviral medications.[186] The American College of Obstetricians and Gynecologists has recommended that all HIV-positive pregnant women be offered scheduled cesarean delivery, and be clearly informed of the risks.[187]

a short regiment of oral zidovudine to reduce vertical transmission of HIV in breastfed children in Côte d'Ivoire and Burkina Faso: a double-blind placebo-controlled multicentre trial. *Lancet* 1999; 353: 786-792.

[169] O'Sullivan MJ et al. Protease inhibitors: is preterm delivery a risk? *American Journal of Obstetrics and Gynecology* 1999; 180:S105 (abstract 353); Stek A et al. The safety and efficacy of protease inhibitor therapy for HIV infection during pregnancy. *American Journal of Obstectrics and Gynecology* 1999; 190: S6 (abstract 14); Morris A et al. A review of protease inhibitor (PI) use in 89 pregnancies. 6th CROI 1999, Abstract 686.

[170] See Frenkel LM. State-of-the-Art Management of the HIV-Infected Pregnant Women. Report from the 7th CROI 2000, at <hiv.medscape.com/Medscape/ CNO/ 2000/retro>.

[171] Culnane M et al. Lack of long-term effects of *in utero* exposure to zidovudine among uninfected children born to HIV-infected women. *Journal of the American Medical Association* 1999; 281: 151-157; Sperling RS et al. Safety of the maternal-infant zidovudine regimen utilized in the Pediatric AIDS Clinical Trial Group 076 Study. AIDS 1998; 12: 1805-1813; Hanson C et al. Lack of tumors in infants with perinatal HIV type 1 exposure and fetal/neonatal exposure to zidovudine. *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology* 1999; 20: 463-467; Blanche S et al. Persistent mitochondrial dysfunction and perinatal exposure to antiretroviral nucleoside analogues. *Lancet* 1999; 354: 1084-1089; and in: Nielsen K. Preventing Perinatal HIV Transmission in the Developing World, One Step at a Time, at <hiv.medscape.com/Medscape/CNO/2000/retro>.

[172] Pitt J et al. Association of Maternal ZDV Use during Pregnancy and Infant ZDV Genotypic Resistance with Rapid Disease Progression among Infants in the WITS. 7th CROI 2000, Abstract 709, at <www.retroconference.org>.

[173] Dabis et al, supra, note 168.

[174] McIntosh K. Short (and shorter) courses of zidovudine. *New England Journal of Medicine* 1998; 339: 1467-1468.

[175] Guay LA et al. Intrapartum and neonatal single-dose of nevirapine compared with zidovudine for prevention of mother-to-child transmission of HIV-1 in Kampala, Uganda: HIVNET 012 randomised trial. *Lancet* 1999; 354: 795-802; Marseille E et al. The cost-effectiveness of a single dose nevirapine regimen to mother and infant to reduce vertical HIV transmission in Uganda. *Lancet* 1999; 354: 803-809.

[176] Guay L et al. A Randomized Trial of Single Dose Nevirapine to Mother and Infant Versus

Increasing uptake of HIV testing among pregnant women

As a result of the above studies showing that the risk of perinatal HIV transmission can be significantly lowered, many jurisdictions have developed guidelines and policies to increase the number of pregnant women who get tested for HIV, so that women testing HIV-positive can be offered antiretroviral therapy or other measures to reduce the risk of transmission to their child.[188] In the United States, the implementation of such guidelines has led to a dramatic decline in the number of pediatric AIDS cases.[189]

In Canada, the Society of Obstetricians and Gynecologists of Canada and numerous other medical associations have recommended that such guidelines be adopted and that all pregnant women be offered HIV testing.[190] Researchers have argued that this would be cost-effective.[191] Some, but not all, provinces and territories have implemented such policies, resulting in an increased number of pregnant women who are tested for HIV.[192] For example, a preliminary analysis of Ontario data in January 2000 indicated that the province's new prenatal HIV testing program has resulted in a significant increase in HIV testing rates among pregnant women. However, it still has only resulted in roughly 50 percent of pregnant women undergoing testing, whereas "British Columbia and Québec have achieved rates close to 80% and Alberta, with its routine approach, even higher screening rates."[193]

It must be stressed that while it is important to ensure that all pregnant women are offered voluntary HIV testing, it is equally important to require that physicians obtain the voluntary, specific, and informed consent of pregnant women before proceeding with HIV testing. In particular, ethical and legal concerns have been raised about policies or programs that require women to "opt out" of HIV testing, rather than securing their specific, informed consent to such a test. Arguably such policies amount to a lower standard for informed consent in the case of pregnant women than for others, which would constitute sex discrimination contrary to human rights statutes and, in the case of government action, the Charter.[194]

Wherever adoption and implementation of policies or guidelines has led to increases in the numbers of pregnant women being offered voluntary HIV testing and counseled about the benefits of knowing their HIV status, this has also resulted in a higher number of women undergoing HIV testing, helping achieve the objective of reducing perinatal transmission. Studies show that pregnant women diagnosed as HIV-positive will, in a majority of cases, choose one or more methods of reducing the risk of transmission to their fetus. For example, a study undertaken in the United Kingdom found that 53 percent of HIV-positive pregnant women had a caesarean section, 68.5 percent took antiretroviral therapy, and 100 percent chose not to breastfeed after birth.[195] A two-year French study found that fewer than one percent of pregnant women enrolled in the study who were diagnosed as HIV-positive refused AZT treatment.[196] In the US, there have also been high "uptake" rates of AZT prophylaxis by pregnant women diagnosed with HIV.[197] (Again, it must be remembered that these studies do not speak to the issue of women's experiences of making these decisions, including the question of their informed consent.)

In contrast, the lack of prenatal care has been shown to increase the risk for perinatal HIV transmission.[198]

Azidothymidine in Kampala, Uganda for Prevention of Mother-to-Infant Transmission of HIV-1 (HIVNET 012). 7th CROI 2000, Abstract S12, at <www.retroconference.org>.

[177] Wade NA et al. Abbreviated regimens of zidovudine prophylaxis and perinatal transmission of the human immunodeficiency virus. *New England Journal of Medicine* 1998; 339: 1409-1414; Fiscus SA, Wilfert C. Short courses of zidovudine and perinatal transmission of HIV [letter]. *New England Journal of Medicine* 1999; 340: 1040-1043; D Burdge et al. The relative importance of antepartum antiretroviral therapy versus intrapartum and neonatal treatment in preventing maternal infant HIV transmission.
12th World AIDS Conference, 1998 (Abstract 23292); and see Luzuriaga K et al (Abstract 211) and Halpern M et al (Abstract 705) from 7th CROI 2000.

[178] Msellati P et al for the DITRAME Study Group. Safety and acceptability of vaginal disinfection with benzalkonium chloride in HIV infected pregnant women in west Africa. *Sexually Transmitted Infections* 1999; 75: 420-425.

[179] Rogers M. Update on Revised USPHS Policy on HIV Screening of Pregnant Women and Treatment of HIV-Infected Pregnant Women, January 2000, via link at <www.cdc./gov/nchstp/hiv_aids/projects/perinatal/ agenda.htm>.

[180] See studies cited by Stoltz & Shap, supra, note 164 at 13 (n37); Read JS, for the International Perinatal HIV Group. Mode of delivery and the risk of vertical transmission of HIV-1 – a meta-analysis of 15 prospective cohort studies. *New England Journal of Medicine* 1999; 341(3): 206; Parazzini F, for the European Mode of Delivery Collaboration. Elective caesarean-section versus vaginal delivery in prevention of vertical HIV-1 transmission: a randomised clinical trial. *Lancet* 1999; 353: 1035-1039; Hudson CN. Elective caesarean section for prevention of vertical transmission of HIV-1 infection [commentary]. *Lancet* 1999; 353: 1030; Ricci E, Parazzini F. Caesarean section and antiretroviral treatment. *Lancet* 2000; 355: 496-502.

[181] Mandelbrot L et al. Perinatal HIV-1 transmission: interaction between zidovudine prophylaxis and mode of delivery in the French Perinatal Cohort. *Journal of the American Medical Association* 1998; 280: 55-60; Halpern et al, supra, note 177.

[182] Samprini AE et al. The incidence of complications after caesarian section in 156 HIV-positive women. *AIDS* 1995; 9: 913-917.

[183] Grubert TA et al. Complications after caesarian section in HIV-1-infected women not taking antiretroviral treatment. *Lancet* 1999; 354: 1612-1613.

[184] See the following in Program and Abstracts of the 6th CROI1999, Chicago IL: Read J et al.

Rapid testing during labour: what is the potential benefit?

What of those women who, by the time of delivery, have not accessed prenatal care, or have accessed such care but not been tested for HIV? As mentioned above, it has been suggested that these women could undergo rapid HIV screening during labour, and offered treatment to prevent perinatal transmission if the screening result is positive.

One study concluded that rapid HIV screening for women in labour who have not had prenatal care or whose serostatus is unknown, combined with a course of intravenous zidovudine during labour, is cost-effective.[199] And a leading researcher on perinatal transmission has argued that "research is needed to explore why women refuse HIV-1 testing and do not return for results, *and to assess the use of rapid HIV-1-testing algorithms*."[200] In her view, "innovative strategies are needed to assess the feasibility of rapid HIV testing during labor or in the immediate postpartum period to identify HIV infection in women who present in labor and have unknown HIV status or have not received prenatal care."[201]

Similarly, the US Institute of Medicine has concluded that "[b]ecause reporting of conventional HIV tests takes about one to two weeks, an accurate rapid test, with results available in hours, might have applications in prenatal, labor, and delivery settings to prevent perinatal transmission in some groups of patients."[202] The Institute continued by saying that

> [w]omen and newborns identified with a rapid test late in pregnancy or intrapartum [ie, during labour] could receive the intrapartum or postpartum component of the ACTG 076 regimen, respectively. In the *prenatal setting*, a rapid test might be especially valuable for women who are unlikely to return for test results.... In the *labor and delivery setting*, a rapid test might be valuable for women who have not been tested previously or have not received prenatal care. The prevalence of HIV infection is elevated in women who have not received prenatal care, and the labor and delivery setting offers the last opportunity to interrupt HIV transmission through administration of intrapartum therapy and advice to avoid breast-feeding. Since this is not an ideal time to obtain consent to testing and to discuss the implications of a positive result, program design and implementation would need to address these issues.

There is no doubt that being able to rapidly obtain results of an HIV test could assist a woman in labour and her physician(s) to make decisions regarding possible interventions during labour and, following the birth of her infant, to reduce the chance of transmission. Whether a woman in labour is capable of making a morally autonomous choice about, or giving voluntary informed consent to, any form of HIV testing is, however, contentious. This concern will be discussed below, in the chapter on "Concerns Raised by the Use of Rapid Tests."

Post-Exposure Prophylaxis

Finally, rapid testing could provide more information for decisions about post-exposure prophylaxis (PEP). When a person has been exposed to the risk of HIV transmission, for example, as a result of an accidental needle-stick in a

Mode of delivery and postpartum morbidity among HIV-infected women: The Women and Infants Transmission Study (WITS) (Abstract 683); Watts H et al. Complications according to mode of delivery among HIV-positive women with CD4 counts < 500 (Abstract 684).

[185] Parazzini, supra, note 180. The study did not address the effect of caesarian delivery in women receiving combination therapy.

[186] Stringer JSA, Rouse DJ, Goldenberg RL. Prophylactic cesarean delivery for the prevention of perinatal human immuno- deficiency virus transmission: the case for restraint. *Journal of the American Medical Association* 1999; 281: 1946-1949. See also: Frenkel, supra, note 170.

[187] American Society of Obstetricians and Gynecologists. ACOG News Release: ACOG Recommends Scheduled C-Sections for HIV+ Women. 31 July 1999, available at <www.acog.org>.

[188] See Appendix: Current Approaches to the HIV Testing of Pregnant Women by Canadian Provinces and Territories. In Stoltz & Shap, supra, note 164 at 93; Samson L, King S. Evidence-based guidelines for universal counselling and offering of HIV testing in pregnancy in Canada. *Canadian Medical Association Journal* 1998; 158: 1449-1457.

[189] Lindegren ML et al. Trends in perinatal transmission of HIV/AIDS in the United States. *Journal of the American Medical Association* 1999; 282: 531; see also: Prenatal discussion of HIV testing and maternal testing – 14 states, 1996-1997. *Morbidity and Mortality Weekly Report* 1999; 48(19): 401-404.

[190] Society of Obstetricians and Gynaecologists of Canada. HIV Testing in Pregnancy. Policy Statement No 62, June 1997. Available at <sogc.medical.org>.

[191] Remis RS, Vandal AC. Cost-effectiveness of universal and selective screening of pregnant women in Québec [abstract]. *Canadian Journal of Infectious Diseases* 1997; 8 (Suppl A): 24A; Government of Alberta. Press release and backgrounder: Routine Prenatal HIV Screening Program Launched. Edmonton, 25 August 1998, available at <www.health.gov.ab.ca.>; Patrick DM et al. Routine prenatal screening for HIV in a low-prevalence setting. *Canadian Medical Association Journal* 1998; 159(8): 942-947.

[192] For a comprehensive review, see Stoltz & Shap, supra, note 164 (Appendix).

[193] Remis RS, Major C & HIV Seroprevalence Research Team. Preliminary Analysis of Prenatal HIV testing in Ontario, 1999, on file. See also: Laboratory Centre for Disease Control (Health Canada). Perinatal Transmission of HIV. *HIV/AIDS Epi Update*, May 1999, available at <www.hc-sc.gc.ca/hpb/lcdc/bah/epi/peri_e.html>.

hospital or of a sexual assault, decisions have to be made about the *initiation* of PEP and about the *continuation* of PEP once it has begun. Initiation decisions have to be made quickly. Rapid testing could offer a potential benefit in these situations, but how big would that benefit be?

Occupational exposure

The US CDC has suggested offering antiretroviral drugs to health-care workers who have had percutaneous occupational exposure to HIV in order to prevent actual infection, but "recommends" such PEP only for exposures that involve large volumes of blood and/or blood containing a high HIV titer.[203] Health Canada has issued a similar recommendation.[204]

It should be remembered that "the estimated rate of seroconversion after a needle-stick injury involving a known HIV-positive patient is only 0.3%."[205] The US CDC has reported 54 documented cases of health-care workers seroconverting following occupational exposure,[206] while in Canada there have been only three cases of HIV infection in a health-care worker resulting from occupational exposure. Significantly, one of these three cases occurred in a laboratory, not a patient-care setting.[207]

The US CDC has "identified five factors associated with a risk of occupational infection: deep injury, visible blood on the device causing injury, injury with a needle that had been placed in the source patient's artery or vein, terminal illness in the source patient, and less likelihood of having taken zidovudine postexposure prophylaxis."[208]

The administration of zidovudine chemoprophlyaxis to health-care workers exposed to HIV has been associated with an 80 percent reduction in the risk for occupational infection.[209] Nevertheless, the evidence regarding the efficacy of PEP following occupational exposure remains suggestive rather than conclusive. There is still a "lack of direct evidence of [post-exposure prophylaxis] efficacy," and researchers therefore urge that all occupational exposures be reported and that "[a]ny possible seroconversions following occupational exposure to HIV in a [health-care worker] who received [PEP] ... be carefully investigated."[210]

Non-occupational exposure

Existing recommendations regarding PEP following occupational exposure do not address instances of non-occupational exposure. In the absence of any direct data regarding its efficacy outside the occupational setting, debate continues as to whether PEP should be made available in the case of non-occupational exposure (eg, sexual exposure or exposure from shared injection equipment), and if so, under what circumstances.[211]

As a Health Canada report notes, non-occupational PEP

> remains controversial for many reasons, including the considerable expenses of the medications and associated treatments. Other concerns include adverse effects on quality of life from medication toxicity, the potential for transmission of antiretroviral-resistant viruses, and potential unintended increases in risky behaviours among PEP users.[212]

[194] See: Stoltz & Shap, supra, note 164; Hoffmaster B, Schrecker T. An ethical analysis of HIV testing of pregnant women and their newborns. *Canadian HIV/AIDS Policy & Law Newsletter* 1999; 4(4): 5-11.

[195] Lyall EG Hermione et al. Review of uptake of interventions to reduce mother to child transmission of HIV by women aware of their HIV status. *British Medical Journal* 1998; 316: 268-270.

[196] Mayaux MJ et al. Acceptability and impact of zidovudine for prevention of mother-to-child human immunodeficiency virus-1 transmission in France. *Journal of Pediatrics* 1997; 131(6): 857-862.

[197] Fiscus et Wilfert, supra, note 177; Lindegren et al, supra, note 189.

[198] A Bardeguez et al. Perinatal HIV Transmission among Women with No Prenatal Care. 7th CROI 2000: Abstract 711, available at <www.retroconference. org>.

[199] Stringer JS, Rouse DJ. Rapid testing and zidovudine treatment to prevent vertical transmission of human immunodeficiency virus in unregistered parturients: a cost-effectiveness analysis. *Obstetrics and Gynecology* 1999; 94(1): 34-40.

[200] Mofenson LM. Short-course zidovudine for prevention of perinatal infection [commentary]. *Lancet* 1999; 353: 766 [emphasis added].

[201] Mofenson LM. Can perinatal HIV infection be eliminated in the United States? [editorial] *Journal of the American Medical Association* 1999; 282(6): 577.

[202] Stoto MA et al (eds). (Institute of Medicine). *Reducing the Odds: Preventing Perinatal Transmission of HIV in the United States*. Washington, DC: National Academy Press, 1998. [emphasis added]

[203] CDC. Public Health Service Guidelines for the Management of Health-Care Worker Exposures to HIV and Recommendations for Postexposure Prophylaxis. *Morbidity and Mortality Weekly Report* 1998; 47(RR-7); CDC. Provisional Public Health Service Recommend- ations for Chemoprophylaxis after Occupational Exposure to HIV. *Morbidity and Mortality Weekly Report* 1996; 45(22): 468-472; Henderson DK. Postexposure chemoprop- hylaxis for occupational exposures to the human immunodeficiency virus. *Journal of the American Medical Association* 1999; 281: 931-936.

[204] Health Canada. An Integrated Protocol to Manage Health Care Workers Exposed to Bloodborne Pathogens. *Canada Communicable Disease Report* 1997; 23(Suppl 23S2).

[205] Bell DM. Occupational risk of human immunodeficiency virus infection in healthcare workers: an overview. *American Journal of Medicine* 1997; 102(Suppl 5B): 9-15.

Some commentators have characterized PEP for non-occupational exposures as a "non-validated practice," and have called for formal research to determine whether it is safe and effective.[213] The US CDC has similarly characterized it as an "unproven clinical intervention" requiring "careful consideration of the potential risks and benefits ... with a full awareness of the gaps in current knowledge," and has concluded that it "cannot definitively recommend for or against antiretroviral agents in these situations because of the lack of efficacy data."[214] In 1999, the CDC announced the opening of a national US registry for monitoring cases of non-occupational exposure to HIV and PEP following such exposures which, in conjunction with data from other countries, should provide a clearer picture of the use and efficacy of PEP for non-occupational exposures.[215]

Three factors determine the likelihood of HIV transmission: the frequency of exposure; the probability the source person is HIV-positive; and the probability of transmission if the source is infected. As Lurie et al point out: "In the occupational setting, the HIV status of the source patient is often known or can be readily determined. In contrast, in sex or drug exposures, the source may not be available or the HIV status may be unclear."[216] And quantifying the risk of transmission from sexual or needle-sharing exposures is less certain than in the case of better documented occupational exposures, although Lurie et al conclude that at least for receptive anal intercourse and sharing drug injection equipment with an HIV-positive partner the risk is "at least as great as the risk that the CDC believes warrants offering PEP in the occupational setting."[217]

In Canada, the Canadian AIDS Society and some other AIDS service organizations have taken the position that access to PEP should not be restricted to those with occupational exposures, but that PEP should also be available to those who have had non-occupational exposures.[218] Some Canadian research has examined the utilization of PEP for both occupational and "community" exposures, and has found that community exposures are being increasingly reported in the population accessing PEP.[219] In the United States, researchers with the San Francisco Postexposure Prevention pilot trial reported in early 2000 that "relatively few individuals appeared to rely on PEP instead of practising safe sex," and that within a six-month period only 12 percent of people returned for treatment following another potential exposure, suggesting the possible educational value of offering PEP for non-occupational exposures.[220]

Rapid testing following exposure: what is the benefit?

As has been said above, rapid testing could provide more information for decisions about PEP. When a person has been exposed to the risk of HIV transmission, decisions about the *initiation* of PEP have to be made quickly, and decisions may also have to be made about the *continuation* of PEP once it has been begun.

Available evidence regarding the efficacy of PEP suggests it is unlikely to be effective if taken more than 72 hours after exposure. Ideally, PEP should be initiated within two to four hours of exposure. Following the standard testing procedure, test results cannot be obtained quickly enough to provide any clinically useful information to a health-care provider and the person exposed within the short time frame for deciding whether to *initiate* PEP. Some have therefore proposed that having a rapid HIV screening assay available would make it possible to test the "source person" and obtain, within a clinically

[206] CDC. Reported Cases of AIDS and HIV Infection in Health Care Workers. Atlanta: CDC, 28 December 1998.

[207] Canadian Medical Association. HIV infection in the workplace. *Canadian Medical Association Journal* 1993; 148(10): 1800A-D; Gimenez-Lambert A et al. *A Comprehensive Guide for the Care of Persons with HIV Disease - Module 3: Nursing Care*. Ottawa: Canadian Association of Nurses in AIDS Care, 1996.

[208] Henderson, supra, note 203, with reference to two leading studies: Cardo DM et al. A case-control study of HIV seroconversion in health care workers after percutaneous exposure. *New England Journal of Medicine* 1997; 337: 1485-1490; Case-control study of HIV seroconversion in health-care workers after percutaneous exposure to HIV-infected blood – France, United Kingdom, and United States, January 1988-August 1994. *Morbidity and Mortality Weekly Report* 1995; 44: 929-933.

[209] Henderson, supra, note 203.

[210] Jochimsen E et al. Investigations of possible failures of postexposure prophylaxis following occupational exposures to human immunodeficiency virus. *Archives of Internal Medicine* 1999; 159: 2361-2363.

[211] Henderson, supra, note 203; Katz MH, Gerberding JL. The care of persons with recent sexual exposure to HIV. *Annals of Internal Medicine*, 1998; 128: 306-312; Katz MH, Gerberding JL. Postexposure treatment of people exposed to the human immunodeficiency virus through sexual contract or injection-drug use. *New England Journal of Medicine* 1997; 336: 1097-1100; Gostin L et al. HIV testing, counseling and prophylaxis after sexual assault. *Journal of the American Medical Association* 1994; 271(18): 1338.

[212] Bayoumi A. Economics of Non-Occupational Post-Exposure Prophylaxis for HIV. Report prepared for the Federal/ Provincial/Territorial Advisory Committee on AIDS. Ottawa: Health Canada, 1998.

[213] Baylis F, Ginn D. Expanding access to PEP: ethical and legal issues. *AIDS and Public Policy Journal* 13; 3: 106-133. For a reprint of the most relevant sections, see the *Canadian HIV/AIDS Policy & Law Newsletter* 1999; 4(4): 29-38. The full text is available at <www.medicine.dal.ca/bioethics, or www.hc-sc.gc./hppb/hiv_aids/>. See also the summary of proceedings of a national conference published by Health Canada on the issue of HIV PEP for non-occupational exposures: Health Canada. *HIV Post-Exposure Prophylaxis in the Non-Occupational Setting: Decision Making in the Face of Uncertainty*. Summary of Proceedings of a National Conference, October 23-24, 1998.

[214] CDC. Management of possible sexual, injecting-drug-use, or other nonoccupational exposure to HIV, including considerations related to antiretroviral therapy. *Morbidity and*

useful period of time, some additional information to inform this decision. Swiss researchers recently concluded, in a study of *occupational* exposures:

> The HIV status of the source patient is often unknown, leading to unnecessary PEP administration until the HIV status of the source-patient is established.... [I]mmediate HIV testing [of a source patient] could be useful in reducing PEP use and thus cost, potential side effects, and anxiety.... Immediate HIV testing of source patients leads to a cost-effective, marked decrease of PEP prescription.[221]

So rapid testing could offer a potential benefit in these situations, but how big would that benefit be? As Hoffmaster points out, "the significance of the benefit depends upon the value of the information that rapid screening would provide."[222] So what is the value of that information?

First, deciding whether to begin PEP depends upon an assessment of the risk to the person who has been exposed, and that risk assessment is a function of several factors, including the type of exposure and the time of exposure. The result of a screening test would be only one factor, albeit an important one, in the overall risk assessment. Moreover, the result of the screening test, whatever it is, would not be able to provide *certainty*. If the result is negative, the person tested could still be infected, but be in the window period between infection and seroconversion. Nevertheless, many may decide not to initiate PEP if the person at the source of the exposure tests negative. If the result is positive, it could be a false positive. Indeed, in most cases of either occupational or non-occupational exposure, those at the source of the exposure are likely to be HIV-negative. This means that even a very specific rapid assay would produce a relatively high proportion of false positive results.[223] In any event, a rapid screening test does not allow one to *know* whether a source person is infected. A decision about whether to initiate PEP still would depend on probabilities, even if the decision may be made easier by information provided by the rapid screening test.

Second, testing could not legally occur without the informed, voluntary consent of the person being tested. In cases of sexual assault, the source person could be unknown, unavailable, or unwilling. In cases of occupational exposure, the source person is generally known, and the occupational exposure team in a hospital, for example, could ask the source person for a rapid test. But any source person being asked for a voluntary rapid test would have to be informed about what the screening test could and could not do. How and by whom a source person is approached could substantially influence whether that person agrees to be tested. Perhaps the most important objective in this regard is to make it safer for source persons to be tested voluntarily, by, for example, destroying test results, scrupulously protecting confidentiality, and preventing test results from being admissible in legal proceedings. The upshot, in any event, is that whatever benefits rapid screening might offer here would result only if a source person agreed to be tested.

Rapid screening of a source person might provide information relevant to *continuation* decisions.[224] An exposed person (particularly a person who cannot tolerate the side effects of the drugs in the PEP regimen) might be willing to discontinue the drugs if the source person tests negative, and if these results

Mortality Weekly Report 1998; 47(RR-17): 1-14.

[215] Opening of Nonoccupational Postexposure Prophylaxis Registry. *Morbidity and Mortality Weekly Report* 1999; 48(2): 496-497; see also registry homepage at <www.HIVpepregistry.org>.

[216] Lurie P et al. Postexposure prophylaxis after nonoccupational HIV exposure. *Journal of the American Medical Association* 1998; 280: 1769-1773.

[217] Ibid.

[218] Canadian AIDS Society. Advocacy Report: Post-Exposure Prophylaxis (PEP) and HIV/AIDS. Ottawa, 21 December 1998; for other examples, see: AIDS Committee of Toronto. Position Statement on Post-Exposure HIV Prophylaxis (PEP). Toronto, 16 April 1998; AIDS Committee of London. Post-Exposure Prophylaxis Philosophy Statement. London, June 1998; Simcoe County Committee for the Management of Bloodborne Pathogens. Guidelines for the Post Exposure Management of Bloodborne Pathogens. 1999.

[219] Beardsell A et al. Utilization and Adherence of a Population-Based Post-Exposure Prophylaxis Program. Poster presentation at AIDS Impact: International Conference on the Biopsychosocial Aspects of HIV Infection, Ottawa, July 1999, on file.

[220] Mitchell D. Postexposure Prophylaxis Can Change HIV Risk Behaviors. *Reuters Medical News*, 7 February 2000, available at <hiv.medscape.com/reuters>; Martin JN et al. Post-Exposure Prophylaxis after Sexual or Drug Use Exposure to HIV: Final Results from the San Francisco Post-Exposure Prevention (PEP) Project. 7th CROI 2000: Abstract 196, available at <www.retroconference. org>.

[221] Greub G et al. Spare Postexposure Prophylaxis with Immediate HIV Testing of the Source Patient. 7th CROI 2000: Abstract 494, available at <www.retroconference. org>.

[222] Hoffmaster, infra, Appendix A at A6. Parts of the following text are taken from his ethical commentary.

[223] Roland ME et al. HIV-1 RNA Testing by DNA and PCR in Asymptomatic Patients After Sexual Exposure to HIV. 7th CROI 2000: Abstract 776, available at <www.retroconference.org>.

[224] Some of this text is taken from Hoffmaster, infra, Appendix A at A7.

can be received quickly, the exposed person can avoid taking drugs while waiting for a laboratory to do the full testing routine on the source person's sample.

Whether there is a (significant) added benefit of rapid test kits for informing decisions about (dis)continuation of PEP following an exposure will depend on how long the wait would ordinarily be for confirmed test results to be received from the laboratory. The length of this waiting time for lab test results will vary from place to place. In some places it is possible to "jump the queue" for HIV testing to inform decisions regarding PEP. In these cases, instead of doing the slower batch testing, a laboratory will test an individual sample from a source person with a speedy turnaround time. The result will not be available in 15 minutes as it would with a rapid screening kit, and so will not be of use in making decisions about whether to *initiate* PEP. However, in some places it may be available the next working day, or within a few days at most – faster than the usual waiting period for confirmed test results. The exposed person can then make a decision about whether to discontinue PEP based on the source person's test results, potentially avoiding weeks of unnecessary drugs. The potential advantages of rapid screening for PEP decisions are stronger where there is no access to an expedited standard testing procedure. Again, however, given all the uncertainties and probabilities associated with such a decision, the result of a screening test would remain but one factor, albeit a significant one.

In settings where expedited standard testing is feasible,

- the potential advantages of rapid screening for PEP *continuation* decisions are therefore weaker; but
- the potential advantages for *initiation* decisions remain since, as mentioned above, PEP should ideally be initiated within two to four hours after exposure and even accelerated standard testing does not provide a result that quickly – meaning that currently people for whom PEP is indicated are initiated on PEP while waiting for the result of accelerated standard testing.

In conclusion, therefore, there is *some* potential benefit with respect to making PEP *initiation* decisions to be gained from the availability of a rapid screening test, and some limited benefit with regard to PEP *continuation* decisions.

Conclusions

Closer scrutiny reveals that, although quite a few potential benefits of making rapid HIV screening at the point of care available have been raised, little is known about how significant some of these benefits would be in the Canadian context. In addition, some potential benefits would be realized only in certain, limited circumstances. In particular:

- Whether there would be a benefit to faster delivery of results depends upon the outcome of the test. For those who tested negative, as most people would, their anxieties, worries, and fears could be relieved sooner. For them, there would be a definite benefit. But those who tested positive on the screening test would have to await the result of a confirmatory test, enduring psychological and emotional distress that could be greater than what they would have experienced with the mere uncertainty that accompanies standard testing. As Hoffmaster puts it: "The numbers favour rapid screening –

more people are likely to want a quick result, and more people will test negative. Nevertheless, the potential impact on those who test false positive cannot be discounted."[225]

- The argument that rapid point-of-care screening will significantly increase the number of people who receive their test results cannot be generalized. Rates of return will vary across the country, between regions, and/or between testing sites. United States data are not particularly relevant or easily applicable when the available Canadian data indicates a very different context. Without solid Canadian data about many aspects of HIV testing, the size, and thus the importance, of this potential advantage of rapid HIV screening at the point of care is hard to gauge.
- While increasing access to quality HIV testing is important, the potential benefits of providing rapid HIV screening in remote settings should not be overestimated. Rapid HIV screening, on its own, falls below the generally accepted standard of care, and must be accompanied by timely access to confirmatory testing. In remote areas, there is a worry that it could take a long time to get a confirmed result for a positive screening test and that the community might not have the resources to support a person with a preliminary positive result during that difficult period. Therefore, if rapid screening kits are to be used in rural or more remote areas, steps would have to be taken to ensure that those who test positive on rapid screening tests would have improved and quicker access to confirmed test results. Consultation with communities who currently have limited access to testing services, and those who provide HIV testing, counseling and support, or other health-care services to these communities, would also be required.
- Being able to rapidly obtain results of an HIV test could assist a woman in labour and her physician(s) make decisions regarding possible interventions during labour and following the birth of her infant to reduce the chance of transmission. However, whether a woman in labour is capable of making a morally autonomous choice about, or giving voluntary informed consent to, any form of HIV testing is contentious. This will be discussed in the next chapter.
- Finally, there is *some potential* benefit with respect to making PEP *initiation* decisions to be gained from the availability of a rapid screening test, and some limited benefit with regard to PEP *continuation* decisions.

[225] Ibid at A4.

Concerns about Rapid HIV Screening at the Point of Care

Participants in the Vanguard study in Vancouver responding to an informal survey in 1997 regarding rapid HIV testing, while generally supportive, nevertheless raised a number of important questions:

> Many were concerned ... that the introduction of rapid testing could lead to home testing, leading to people testing positive at home without any counselling or support. Some drew attention to the wider societal implications of the introduction of faster test kits. If they are ever available for retail sale, will people start to rely on them to screen their sexual partners? Will rapid HIV test kits someday be used at borders between countries or even in job interviews to screen out people with HIV? How would the introduction of rapid testing alter the role of health care workers? Among other changes, standards for pre- and post-test counselling for rapid testing would have to be developed."[226]

Similarly, at the "HIV Point of Care Testing" workshop held by Health Canada in March 1999,

> the urgent need to define the population(s) where these kits would be most effective was identified. Would it be more effective in ... post exposure prophylaxis (PEP), women in labour, occupational exposure, low prevalence populations, outreach areas, street people? Would the inclusion of this type of test be of added benefit to

[226] Martindale, supra, note 135.

> current test practices? This is an area where it was felt provincial authorities would have to assess the added benefits and risks. By defining the appropriate population(s), the potential for abuse in certain other populations ... could be averted or at least mitigated.... However, trying to define the appropriate population requires a broader consultation which in turn leads to other questions. How and by whom will the use of these tests be controlled? Where, when and who will be performing the tests? Issues such as liability (is it different for performing the test and for interpreting test result?; are counsellors left in a vulnerable position?), proper training and education, confidentiality, potential abuse regarding informed consent situations (eg, women in labour, etc) among others must be addressed. It was suggested that controlling the distribution of the test kits by Provincial authorities could help alleviate some of these concerns."[227]

About two-thirds of the people who tested positive on the screening test are in fact HIV-negative upon confirmatory testing.

The last chapter critically explored the potential benefits of rapid screening tests. This chapter explores the concerns and questions about them, and ways to reduce potential harms. In particular, it addresses the following issues:

- the implications of disclosing positive screening results when, particularly in low-prevalence settings, the positive predictive value of the test is low;
- the implications for pre- and post-test counseling;
- the possibility of breaches of confidentiality if HIV testing becomes available outside the settings in which it is currently available;
- issues of quality control of a technical nature; and
- the potential that, in a variety of situations (women in labour whose HIV status is unknown; after a potential exposure to HIV in occupational and non-occupational settings; and before medical procedures), there will be a push for testing without informed specific consent.

Finally, the chapter discusses implications for the regulation of the use of these tests.

Potential Harms from Communicating Positive Screening Test Results

Against the potential benefit of increasing the number of people who would learn their HIV status, and of fast delivery of *negative* results, must be weighed the harms that may flow from providing the results of rapid screening tests when, in most populations being tested, the highly sensitive but less specific rapid screen will generate a significant number of false-positive results.

Rapid test kits under investigation for possible licensing in Canada have been shown to meet the same sensitivity and specificity standards as the laboratory-based ELISA tests currently in use. But participants at a recent HIV test counseling workshop in Ontario noted that of approximately 300,000 HIV ELISA screens performed each year in the province, approximately 3000 are reactive but only approximately 1000 are true positive results. This means that about two-thirds of the people who tested positive on the screening test are in fact HIV-negative upon confirmatory testing.[228]

[227] Health Canada (Medical Devices Bureau). Report on the HIV Point of Care Testing Workshop, supra, note 6 at 2-3.

[228] Tripp, supra, note 162.

How much harm then would be done to those who receive a positive screening result that turns out to be a false positive?

It is likely that most of those who receive a preliminary positive result on a rapid screen will be willing to undergo confirmatory testing and return for their results. The US CDC has projected that 93 percent of those who would receive a positive screening result would return for a confirmed result.[229] But clearly the waiting period between receiving a preliminary positive screening result and a confirmed positive or negative result "will add additional anxiety to an already stressful situation."[230] Reporting screen results has therefore been considered to be substandard to current practice.[231]

Inadequate counseling is not only unethical and poor practice, it is also arguably contrary to the legal doctrine that medical interventions require a patient's informed consent.

Disclosing preliminary results raises ethical concerns, as Hoffmaster points out:

> How much harm then would be done to those who receive a positive screening result that turns out to be a false positive? They would certainly be worried, anxious, and fearful. Perhaps their distress could be mitigated by how they are told and what they are told.... The moral question that remains, though, is whether it would be justifiable to give potentially inaccurate HIV-positive screening results to some people because there would be benefits to other people who test negative on rapid screens, when everyone could be provided with confirmed results using the standard testing procedure, albeit a bit more slowly.[232]

Hoffmaster continues by saying:

> Without knowing more about the impact of receiving a preliminary positive result from a screening test, it is hard to answer that question. Simply comparing the numbers of people who would test negative and positive is not enough. How those people would be affected also needs to be considered, taking into account the view that the moral duty not to harm people is generally considered more stringent than the moral obligation to help people.[233]

In order to address this concern, wherever rapid HIV screening at the point of care is offered, this should be accompanied by accelerated access to confirmed test results, as was done in the British Columbia Centre for Disease Control rapid testing study mentioned above.[234] In that study, people who screened positive were provided with access to a confirmed test result within two days of the initial screen. While harm could still be done to those who receive a positive screening result that turns out to be a false positive, reducing the time between the receipt of the screening result and the confirmed result would help. In addition, support services would have to be easily accessible for people who receive a positive screening result. Finally, research needs to be funded to investigate patients' experience of coping with a positive screen result that needs to be confirmed, as well as providers' experience with disclosing such results.

Counseling

There is widespread agreement that quality pre- and post-test counseling are essential components of any HIV testing procedure.[235] Indeed, inadequate counseling is not only unethical and poor practice, it is also arguably contrary

[229] Branson, supra, note 149.

[230] Tripp, supra, note 162.

[231] Ibid.

[232] Hoffmaster, infra, Appendix A at A10.

[233] Ibid.

[234] See supra, note 135.

[235] For a review, see Jürgens, supra, note 4 at 73-83.

to the legal doctrine that medical interventions require a patient's informed consent.[236]

As stated in the Canadian Medical Association (CMA) Counselling Guidelines,

> [s]erologic testing for HIV without counselling has a psychological, medical and social impact on patients. Therefore, ... testing must be preceded and followed by appropriate counselling by trained or experienced professionals.[237]

Yet both anecdotal evidence and research studies reveal serious inadequacies in counseling experienced by many of those getting tested for HIV.[238] A recent qualitative study in Ontario reported numerous negative experiences of the testing/counseling process.[239] Research has also specifically identified poor testing/counseling experiences of women[240] (including pregnant women[241]) and for Aboriginal communities.[242] In addition, a qualitative evaluation of the CMA's Counselling Guidelines showed that over one-third of the randomly chosen primary-care physicians participating reported not having a copy of the guidelines.[243] While 80 percent of the physicians who had tested patients for HIV within the previous six months reported that they provided counseling for them, 17 percent indicated that they had provided counseling only for those who tested positive. As Jürgens notes

> few incentives exist for doctors who have relatively little experience with HIV in their medical practice to improve their counselling skills. They are required to deal with a myriad of health problems and often do not have – and are not adequately paid for – the time and attention required for effective counselling.[244]

The availability of rapid HIV screening at the point of care will not remove the legal and ethical imperative that testing only be undertaken with pre-and post-test counseling. Indeed, it highlights the importance of counseling, in addition to posing some challenges that are specific to rapid screening and that will have to be addressed. It highlights the importance of counseling because of the potential harm of disclosing a positive screening result. As mentioned above, today much testing in Canada, particularly outside designated HIV testing clinics with trained staff, is done with little or no pre-test counseling. While this is bad enough in the context of the current mechanism of HIV testing, it must not be allowed to happen in the context of rapid screening. Imagine a person receiving a positive screening result without having understood that a screening test is only a screening test, that it has a lower positive predictive value, and that it is imperative that the person come back to receive a confirmed result, and that that result could well be negative.

One challenge is to ensure that rapid screening does not also mean rapid counseling. In this regard, Hoffmaster writes:

> With rapid screening, in addition to all the other matters that have to be covered in counseling for HIV testing, the lower positive predictive value of a screening test and the implications of this would have to be addressed. That entails an explanation that a single, intentionally over-sensitive test would be done rather than two tests using

[236] Stoltz & Shap, supra, note 164 at 27-30.

[237] Canadian Medical Association. *Counselling Guidelines for HIV Testing*. Ottawa: The Association, 1995, at 4.

[238] See Jürgens, supra, note 4 at 75-77 and sources cited therein.

[239] Myers et al, supra, note 137; Myers T, Haubrich DJ. The HIV Test Experience Study. *Canadian HIV/AIDS Policy & Law Newsletter* 1999; 4(4): 25-28; Myers T et al. Strategies Used to Manage the Impact on HIV Test Providers of Giving a Positive Test Result. In: Final Program & Abstract Book, AIDS Impact International Conference on the Biopsychosocial Aspects of HIV Infection, 15-18 July 1999, Ottawa, at 26-27.

[240] Jackson LA et al. HIV-positive women living in the metropolitan area: their experiences and perceptions related to HIV testing. *Canadian Journal of Public Health* 1997; 88(1): 18-22; Philips KA et al. HIV counseling and testing of pregnant women and women of childbearing age by primary care providers: self-reported beliefs and practices. *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology* 1997; 14(2): 174-178.

[241] Leonard L, Shap L. A Different Kind of Risk? – Pregnant Women's Experience of HIV Testing in Pregnancy. *Canadian HIV/AIDS Policy & Law Newsletter* 1999; 5(1): 18-21; Philips et al, supra, note 240.

[242] See Matiation, supra, note 161.

[243] Rowan MS et al. Qualitative evaluation of the Canadian Medical Association's counselling guidelines for HIV serologic testing. *Canadian Medical Association Journal* 1996; 154: 665-671.

[244] Jürgens, supra, note 4 at 76.

The concern is that compressing the time for counseling, testing, and disclosure of result into such a short period may result in poorer quality counseling precisely where quality counseling is even more important.

> different testing principles, the second of which is designed to be specific to detecting HIV antibodies; and that for any given individual the positive predictive value of a test will depend on how "at risk" the person being tested is, given his or her past activities (thereby requiring an exploration of this matter in the counseling), and on how prevalent risk activities are among the people within the population to which the person being tested belongs. Information that complicated cannot be communicated easily or quickly. Moreover, it must be conveyed in a manner that the person being counseled can understand and appreciate, so that that person is able to make a morally autonomous choice about rapid screening and give informed consent to a test. Yet a harried health-care professional in a busy clinic or private practice might be sorely tempted to present the screening test as "quick and easy," to gloss over necessary details, to avoid explaining points that seem to create difficulty, and to discourage questions.[245]

He continues:

> Proper time and care are also necessary in post-test counseling, regardless of whether the result is negative or positive. If it is negative, the need for vigilant, conscientious preventive measures must be stressed; a negative test result must not be allowed to engender a sense of false security. If the result is positive, ... the caution that the result might be a false positive needs to be reiterated and a confirmatory test must be arranged.[246]

But what exactly should a person who screens positive be told? Generally, as noted in an earlier Canadian paper on rapid HIV screening in clinical settings, which pointed out that abuses and lapses in obtaining informed consent and in performing and scheduling adequate pre- and post-test counseling are already "alarmingly common," the concern is that "a rapid testing technology could further abbreviate a counselling process which is already irregularly or incompletely performed, often with distressing consequences for the patient."[247] In short, the concern is that compressing the time for counseling, testing, and disclosure of result into such a short period may result in poorer quality counseling precisely where quality counseling is even more important.

Changing the Practice of Providing Testing and Counseling

Generally, when following standard testing procedure, the provider knows the confirmed test results before the patient arrives for the return visit, meaning there is time to adequately prepare for the session with this information in mind (eg, setting aside additional time for post-test counseling, arranging for additional supports, being psychologically prepared). With rapid HIV screening, however, this opportunity to prepare to the same extent is lost. As noted by participants in a 1999 Ontario test counseling workshop:

> Facilities should be prepared to offer immediate support to those with a POC reactive result. This will require staff time, space, privacy, and the ability to provide follow up support during the wait[ing] period for confirmatory results. Clinic schedules and

[245] Hoffmaster, infra, Appendix A at A11.

[246] Ibid.

[247] Peterkin, supra, note 3 at 10.

> appointments will need to be very flexible in order to accommodate clients in need of immediate support.[248]

The US CDC has also identified that introducing rapid POC screening carries implications for the practice of HIV testing and counseling, saying that "[r]apid HIV testing will change how and when HIV prevention counseling is delivered."[249]

Ugandan researchers learned this lesson from a study that examined the challenges encountered in counseling clients when giving same-day HIV test results.[250] In 1997, four testing sites began providing HIV counseling and testing using a combination of three rapid tests for confirmed, same-day results. With the new approach to offering testing and counseling, researchers reported a longer waiting period for most clients, especially at times of peak demand for testing. They also reported an increase in the rate of repeat testers and noted:

> Adapting the counseling protocol for repeat testers has required creative approaches. Some clients are inadequately prepared for test results which are different than expected; this problem can occur with both HIV+ and HIV- clients. The intense and compressed encounter with clients can be more stressful for counselors."[251]

The authors identified the following lessons:

> When giving same day test results, it is essential to have an adequate number of staff during high demand days and hours. Repeat testers may need a modified counseling protocol. Clients who disbelieve test results can be offered repeated bleeding and testing on the same day or later as desired.... Training in stress reduction skills can help counselors deal effectively with demands created by same day test results.[252]

Changing the Content of Counseling

The current CMA Guidelines acknowledge that the use of rapid HIV tests "would affect the content of counselling information provided," and state that "their introduction will have to be accompanied by changes to counselling guidelines."[253] They emphasize that it would, however, not "in any way abbreviate counselling protocols," and "not decrease the need for quality assurance in the testing methods and the training of those carrying out counselling and testing."[254]

As one commentator points out, rapid testing means that most people (those who screen HIV-negative) will no longer need to return for a second visit. The resulting compression of pre- and post-test counseling session into a single session, with the absence of a two-week waiting period for HIV-negative results, has raised concern that the counseling associated with rapid testing may not be as effective as the standard procedures in promoting HIV risk reduction.[255] However, in a study undertaken by Kassler et al, using one indirect measure of HIV risk – acquisition of new STD following HIV testing – no difference was found between STD clinic patients counseled using rapid-test procedures and patients receiving standard pre- and post-test counseling. This led Kassler et al to conclude that, although "larger trials may be needed to definitively resolve some of these issues, these data indicate that program managers considering

[248] Personal communication with J Tripp, Ontario AIDS Bureau, Ministry of Health and Long-Term Care, 23 November 1999; [Ontario] Central Public Health Laboratory (HIV Laboratory). Memo: Issues related to HIV Point of Care Testing. Toronto, 1999, on file; Tripp, supra, note 162.

[249] CDC. Rapid HIV Tests: Issues for Counselors Providing HIV Prevention Counseling. *CDC Issues*, March 1998, at <www.cdc.gov>; or see CDC. Clinical Update – The New Rapid HIV Test: Issues for HIV Prevention Counselors. *Clinician Reviews* 1998; 8(6): 149-153.

[250] Katarikawe E. Challenges encountered and solutions adopted in counseling clients while giving same day HIV test results. International Conference on AIDS 1998; 12: 870 (abstract no. 43115). AIDSLINE ICA12/98404467.

[251] Ibid.

[252] Ibid.

[253] CMA Guidelines, supra, note 237 at 4, 19.

[254] Ibid.

[255] Kassler et al, supra, note 66 at 1050.

the use of rapid testing to improve service delivery can be reassured that counseling associated with rapid testing does not appear to be less effective."[256] Although, as Kassler himself acknowledges, more research may be necessary to answer this question, everybody would agree that more important than the question of counseling people who test negative is the question of "what to do about those who screen positive."[257] As Leviton puts it:

> The test information is, after all, preliminary. What should be shared? In what form should it be shared? If rapid testing is implemented, it will not be feasible to selectively withhold the preliminary screening information. The public will be aware that screening results can be made available immediately. If people do not immediately receive information that they are negative, the inference is that they screened positive.[258]

In the United States, Bayer et al have argued not only that "counselors must be alert to these issues [false positives] and to the importance of further testing and clinical evaluation" but also that "[t]he conditions of licensure of the tests should address these issues."[259] The Expert Advisory Committee (EAC) on HIV Therapies of Health Canada's Therapeutic Products Programme has made similar recommendations. In July 1998, the Committee noted that the "high rate of false positives" is one of the concerns regarding rapid HIV test kits, and considered whether a guidance document should be issued for those providing point-of-care testing, and if so, whether it should precede the licensing of the kits intended for point-of-care testing. The Committee

> strongly advised that a guidance document be prepared by the manufacturer and included in each test kit. In addition the EAC strongly advised that the manufacturer be directed to provide a single sheet using grade 8 language that is given to the individual with the results clearly marked upon the sheet at the time of testing. The sheet must clearly describe in simple terms the meaning of negative and positive results; and in particular the possibility of false positive results for low risk groups and direct that the individual see a physician. The EAC also advised that this form of testing should take place in centres that can then draw a blood sample for confirmatory testing and that the individual be directed to a physician.[260]

Subsequently, in March 1999, the Committee "strongly endorsed and recommended that appropriate resources be set in place to educate about the use of these kits."[261]

As for the content of counseling, the US CDC has advised that

> [t]he content of the prevention counseling session before providing a reactive test result will have to be tailored to each person, because it involves both an understanding of the technical aspects of screening tests and an assessment of each client's behavioral risk for HIV infection.... [T]he positive predictive value of a test is low in populations with low prevalence.... However, studies have shown that an assessment of behavioral risk factors can substantially improve the predictive value of an HIV screening test. That is, a reactive test for

[256] Ibid.

[257] Leviton, supra, note 7.

[258] Ibid.

[259] Bayer R, Stryker J, Smith M. Testing for HIV infection at home. *New England Journal of Medicine* 1995; 332: 1296-1299. While these points were made with respect to home collection kits, they are equally valid for counselors giving preliminary results from a rapid screening test.

[260] Health Canada (Therapeutic Products Programme), supra, note 72.

[261] Health Canada (Therapeutic Products Programme) – Expert Advisory Committee on HIV Therapies. Minutes of teleconference of 29 March 1999, available at <www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/advcomm_eachiv.html>.

> an individual with risk behavior(s) is more likely to represent a true positive than is a reactive test for an individual with no identifiable risks for HIV....
>
> Each clinic will need to establish its own policy to guide counselors in the correct interpretation of reactive rapid HIV test results. These policies will need to take into consideration the proportion of reactive rapid-test results that may be false-positive. This proportion will differ, as it depends on the prevalence of HIV infection among the clients tested. Staff of each clinic should develop suggested language for counselors to use when explaining the results of reactive rapid HIV tests.[262]

US researchers have suggested that there are several considerations in deciding how to communicate the meaning of a reactive screening result: the likelihood that a reactive client is truly HIV-positive (ie, positive predictive value of the test), how best to communicate that probability to the client, and what the client should do in response to a reactive result with respect to health seeking and risk behaviours.[263] In evaluations of on-site, rapid testing in public clinics undertaken to date in the US,[264] a series of phrases were recommended to communicate to patients the likelihood of being infected with HIV, given a preliminary positive result. When the positive predictive value (PPV) was 81 percent, the terms "probably infected, likely to be infected, a good chance of being infected" or "usually means you are infected" were used. When the PPV was 88 percent, the terms "very likely" (or "highly likely") infected, or "a very good chance of being infected" were used. When the PPV was 97 percent, the terms "most likely infected" or "probably infected" were used. In practice, based on their individual assessment of the client's risks during counseling, the counselor either strengthened or qualified the phrases used to communicate the probability of infection given a preliminary positive result.

Counselors were initially reluctant, but found these protocols acceptable: "After 1 month's experience with the new counseling and testing procedures, most of these concerns had been resolved. Counselors believed they became more efficient with their time. After adjusting to the new procedures, counselors did not report increased stress in their clients in response to the procedures."[265]

Hoffmaster, however, questions such a practice:

> How much harm then would be done to those who receive a positive screening result that turns out to be a false positive? They would certainly be worried, anxious, and fearful. Perhaps their distress could be mitigated by how they are told and what they are told. It might not be a good idea to tell individuals with a positive screening result that they are *likely* to be infected, that they are *probably* infected, or that they have a *good chance* of being infected. Instead they could be told that they have a preliminary positive result but that no diagnosis is possible until there is a result from a confirmatory test. Given the reasons mentioned above, there would seem to be no point to saying more than that. Moreover, such a cautious statement reiterates and emphasizes that

[262] CDC. Rapid HIV tests: issues for counselors providing HIV prevention counseling. *CDC Issues*, March 1998, at <www.cdc.gov>.

[263] See Jürgens, supra, note 4 at 119, with references.

[264] Ibid, with references.

[265] Ibid.

> rapid screening is *screening* only – that an additional *test* is necessary to obtain a confirmed result.[266]

In Canada, the BC Centre for Disease Control conducted a study in late 1999 evaluating the incorporation of BioChem's rapid HIV screening test into its testing and counseling protocol. At the time of writing, it had not yet released revised counseling guidelines, but was expecting to do so soon.[267] Health Canada also expects to release a short "guidance" document for health-care professionals (accompanied by a reference section) in the spring of 2000, after external review and consultation.[268]

Ensuring Quality Testing and Counseling

As Hoffmaster puts it:

> No HIV testing should occur in the absence of quality counseling; that requirement is even more stringent for rapid screening.[269]

This means that in issuing any licence for any medical device to perform rapid HIV testing, the Medical Devices Bureau of Health Canada should require that the use of the device must be accompanied by pre- and post-test counseling in accordance with accepted professional standards. In addition, as recommended by the Expert Advisory Committee on HIV Therapies of Health Canada's Therapeutic Products Programme,[270] Health Canada should require that the device be distributed with an accurate, accessible, plain-language guidance document for those providing point-of-care testing, explaining in particular the possibility of false-positive results and the need for confirmatory testing for those who screen HIV-positive.

But would this be enough? Providing adequate pre-test and post-test counseling is

> difficult enough with the standard testing procedure. Would health-care professionals who are not experienced with HIV/AIDS but who begin offering rapid screening have the training, the time, and the incentives to provide proper counseling? How would such providers get the education and skills they need? Where would they find the time, amidst their myriad clinical responsibilities, to do diligent, effective counseling? And how much motivation would they have to find that time if the financial incentives for counseling are sparse?[271]

Therefore, other, additional measures are required to ensure quality counseling and to reduce potential harms from inadequate counseling, particularly when persons screen positive, and when counseling is provided outside designated testing clinics in which people have expertise in counseling.

As Hoffmaster has suggested, rapid screening should either "be restricted to venues where appropriate counseling is currently available and can readily be adapted to rapid screening [such as designated testing clinics], or the resources needed to provide appropriate counseling and support services in new venues where rapid screening would be offered must be forthcoming."[272]

[266] Hoffmaster, infra, Appendix A at A10.

[267] Personal communications with: Y Côté, BioChem ImmunoSystems Inc, 13 December 1999; L Knowles, BC Centre for Disease Control, 14 December 1999; D Spencer, BC Centre for Disease Control Society, 8 February 2000. Note that the US CDC has initiated a study to compare the effectiveness of a single counseling sessions with a rapid HIV test in preventing STDs with the effectiveness of two counseling sessions with the standard HIV test in achieving that goal. Study results will not be available until the end of the study, currently projected for June 2001: CDC. Materials on the RESPECT-2 Study, available at <www.cdc.gov/nchstp/hiv_aids/projects/respect-2>.

[268] Communication with G Bally, Health Canada, 14-15 February 2000, on file.

[269] Hoffmaster, infra, Appendix A at A18.

[270] See supra, note 72.

[271] Hoffmaster, infra, Appendix A at A12.

[272] Ibid. at A17.

Hoffmaster continues:

> Rapid screening might be less costly than the standard testing procedure because laboratory costs could be lower and no second visit to receive the test result would be required. But if that were the case, those savings should then be used to fund the counseling and support services that are required to make rapid testing *quality* testing.[273]

The best solution is to allow use of rapid HIV screening tests only by health-care professionals who have undergone a training program.

The best solution is to allow use of rapid HIV screening tests only by health-care professionals who have undergone a training program, including on how to provide counseling using such tests. This would avoid the potential harms from uses of the test by physicians with little HIV testing experience and little time, and even more so by other health-care professionals such as dentists, unless they have received training, in which case any concerns would be significantly reduced. In practice, this would probably lead to making these tests available first in designated testing clinics, where providers already have a lot of experience with HIV testing and counseling. The requirement of a specific training program or even a licence was also suggested by participants at the 1999 HIV test counseling workshop in Ontario, who felt that

> a training program should be available for staff intending to offer POC testing. Some suggested that staff should be required to obtain a licence or certificate through training before being allowed to offer POC testing.[274]

Although not specific to HIV testing, the Canadian Society for Medical Laboratory Science has also adopted a position statement stating that professional expertise of a licenced or accredited clinical laboratory is needed in determining the appropriateness of point-of-care testing, and in:

- evaluating and selecting instruments and test materials;
- training and periodic re-certification of all non-laboratory staff involved in testing;
- regular quality checks on all instruments, reagents and strips; and
- operating quality control and quality management programs.[275]

Finally, in addition to training those who administer rapid HIV screening tests, this should be seen as an opportunity to enhance the quality of all HIV testing in Canada, by reinvesting in counseling, recognizing that counseling maximizes the benefits of all HIV testing while minimizing its harms.[276] At a minimum, colleges and universities providing professional education to health-care professionals should include, as mandatory components of their curricula, training in counseling principles and techniques generally, as well as training on HIV/AIDS, HIV test counseling (including using rapid screening tests), and psychosocial issues related to HIV. In addition, professional associations, regulatory bodies, and/or provincial health ministries need to provide training and education to health-care professionals in HIV counseling and testing, including how to administer and apply rapid HIV screening tests and how to provide counseling using such tests.

[273] Ibid.

[274] Tripp, supra, note 162.

[275] Canadian Society for Medical Laboratory Science. Position Statement: Point-of-Care Testing. Hamilton, Ontario: The Society, 3 March 1995, available at <www.csmls.org/POSITION.HTM>.

[276] For a comprehensive discussion, see Jürgens, supra, note 4 at 73-83.

Confidentiality

Breaches of confidentiality are a concern for all forms of HIV testing. That concern, however, is magnified with respect to rapid screening.

As Hoffmaster points out, breaches of confidentiality are a concern for all forms of HIV testing.[277] That concern, however, is magnified with respect to rapid screening,

> because implementing it would allow HIV testing to be more dispersed and localized. Were rapid screening to proliferate, scrutiny and supervision of it would become more difficult. In addition, the people performing the screening might not be aware of how scrupulously the confidentiality of test results must be maintained, and they might not be familiar with the kinds of procedures that need to be in place.[278]

Hoffmaster continues by saying:

> Confidentiality needs to be protected for both practical and moral reasons. With respect to the former, willingness to be tested can depend on confidence in the measures taken to protect privacy and ensure confidentiality. The prospect that insurance companies or employers, for example, might be able to obtain the results of rapid screening tests could jeopardize the success of the program. With respect to the latter, health-care professionals have an ethical duty to protect people's privacy.[279]

Hoffmaster concludes that safeguards tailored to the diverse and idiosyncratic settings in which rapid screening could become available need to be designed and carefully implemented:

> Perhaps those safeguards would have to take the form of allowing rapid POC screening to be offered only by health-care professionals who are subject to unequivocal ethical and legal duties to maintain confidentiality, and to clearly specified professional and legal sanctions for breach of those duties.[280]

In any case, training programs for those who want to administer rapid HIV screening, as recommended in the previous section, should include a component on confidentiality.

Technical Issues

Questions about quality control of a more technical nature have also been raised. Existing public laboratories that provide HIV testing have quality assurance controls in place, but it would be impossible to ensure proper testing protocols are followed at the point of care by health-care professionals administering and interpreting rapid screening tests. While some rapid test kits include a "control" built in to each individual kit to indicate whether the chemical components are active and have been combined according to the proper procedure, not all do.[281]

Similarly, quality assurance of each lot of test kits could be lost. Laboratories can perform quality assurance testing of each new lot of product against a panel of known positive and negative specimens. If problems are detected, these can be reported to Health Canada for appropriate investigation and, if

[277] Hoffmaster, infra, Appendix A at A12.

[278] Ibid.

[279] Ibid.

[280] Ibid.

[281] [Ontario] Central Public Health Laboratory, supra, note 248.

necessary, recall under the Medical Devices Regulations. However, if rapid test kits can be made available directly to health-care professionals for their POC use, how will quality assurance of each lot be ensured? If problems with the performance of a lot are not detected and reported, this could have serious consequences for those who receive inaccurate results because of a defective kit or lot of kits.[282]

Finally, the availability of rapid, on-site HIV test kits raises the question of possible civil liability of the health-care professional who negligently performs or interprets the test. As with a defective device, giving a patient an inaccurate interpretation of the test results could carry serious consequences.[283] Health-care professionals' colleges and associations need to ensure their members are aware that they face potential civil liability if they are not trained and negligently administer rapid HIV tests.

Testing without Informed Consent

Despite a general consensus that HIV testing should generally be undertaken only with the informed consent of the person being tested, there have been repeated calls for mandatory or compulsory testing of certain groups of the population, or in certain situations. In particular, some have called for mandatory testing of all pregnant women, of people at the source of a potential exposure to HIV, or of patients. In Canada, such calls have been rejected,[284] but nevertheless they are made from time to time, such as most recently by a Reform Party Member of Parliament, who introduced a private member's bill, Bill C-244 (*Blood Samples Act*), that would permit compulsory blood testing of persons for HIV or hepatitis B/C where peace officers, firefighters, or other emergency services or health-care workers may have been occupationally exposed to possible infection.[285]

There have been repeated calls for mandatory or compulsory testing of certain groups of the population, or in certain situations.

Why does the issue of testing without informed consent have to be addressed in the context of rapid HIV screening? The concern is that some of the potential benefits of rapid HIV testing, such as ease of testing and the ability to obtain quick results, may also mean a heightened risk that people will be tested without their voluntary, specific, informed consent. The "compressed" process of counseling and testing that goes with the implementation of rapid HIV screening tests means increased pressure at the point of care to test. The likelihood of this pressure being applied in urgent situations generally makes both the *necessity* and the *difficulty* of obtaining informed consent even more important. The question is whether, as a result of the ability to obtain test results quicker, making them potentially more useful, testing without informed consent may become justified in some circumstances.

This section therefore first reviews the generally accepted Canadian position that specific informed consent to HIV testing is always required. It then reviews existing legal doctrines and developments relevant to the issue of consent to HIV testing. Finally, it examines in detail three specific situations in which there may be a push to conduct HIV testing without informed consent:

- women in labour whose HIV status is unknown;
- post-exposure situations in which decisions about PEP must be made; and
- screening before providing medical attention.

[282] Ibid.

[283] Ibid.

[284] See review in Jürgens, supra, note 4 at 121-207.

[285] Bill C-244, *An Act to provide for the taking of samples of blood for the benefit of persons administering and enforcing the law and good Samaritans and to amend the Criminal Code*, 2nd Sess, 36th Parl, 1999.

The General Consensus

There is widespread agreement in Canada and in most other jurisdictions that HIV testing should generally only be undertaken with the voluntary, informed and specific consent of the person being tested.[286] According to the widely referenced CMA *Counselling Guidelines for HIV Testing*,

- informed consent cannot be implied or presumed;
- obtaining informed consent "involves educating, disclosing advantages and disadvantages of testing for HIV, listening, answering questions and seeking permission to proceed through each step of counselling and testing"; and
- to obtain informed consent for testing to HIV, a patient must be deemed competent, must understand the purposes, risks, harms and benefits of being tested, as well as those of not being tested, and his/her consent must be voluntary.[287]

The Guidelines also identify the need for HIV testing to "be preceded and followed by appropriate counselling by trained or experienced professionals."[288] Professional guidelines for physicians adopted by other regulatory bodies are consistent with the CMA Guidelines:

> HIV testing must be specifically agreed to by the patient.... It is generally understood that testing for HIV seropositivity is a serious matter for patients since the consequences of discovering that one is HIV sero-positive may have a profound effect on the life of the patient. While it is understandable that some physicians might be tempted to ignore consent requirements concerning HIV testing, it is important to remember that conducting procedures which require consent in the absence of such permission is contrary to the Canadian Medical Association Code of Ethics and may constitute professional misconduct.[289]

The American Medical Association also stated that "[p]hysicians should ensure that HIV testing is conducted in a way that respects patient autonomy and assures patient confidentiality as much as possible"; that they "should secure the patient's informed consent specific for HIV testing before testing is performed"; that "[b]ecause of the need for pretest counseling and the potential consequences of an HIV test on an individual's job, housing, insurability, and social relationships, the consent should be specific for HIV testing"; and that consent for HIV testing cannot be inferred from a general consent to treatment.[290]

Informed Consent for Medical Interventions

In insisting on informed consent to HIV testing, the CMA Guidelines parallel general principles enunciated in Canadian law regarding consent to medical interventions.[291] The Supreme Court of Canada and provincial appellate courts have repeatedly affirmed the doctrine of informed consent, ruling that care providers will be liable in tort (for negligence or battery) if they carry out a medical intervention without such consent.[292] Obviously, the law is protective of a person's right to refuse a medical intervention.[293] In some provinces,

[286] See Jürgens, supra, note 4, at 33-52.

[287] CMA Guidlelines, supra, note 237 at 6.

[288] Ibid at 4.

[289] For example: College of Physicians and Surgeons of Ontario. "Patient consent for HIV test" and "Doctor's Notes: Patient Consent for HIV Testing" (1 November 1996), available at <www.cpso.on.ca>. See also: Code of Ethics of the Canadian Medical Association (approved 15 October 1996), available at <www.cma.ca>, and the policies issued by the College of Family Physicians of Canada, the College of Physicians and Surgeons of Manitoba, and the College of Physicians and Surgeons of British Columbia.

[290] American Medical Association. AMA Ethical Opinions on HIV/AIDS Issues – HIV Testing. Available at <www.ama-assn.org/special/hiv/policy/amapol.htm>. Updated June 1996. Note, however, that the AMA has unfortunately abandoned this position in the case of pregnant women and where health-care workers have been occupationally exposed: AMA (House of Delegates). Policy H-20.930: Counseling and Testing of Pregnant Women for HIV. Approved June 1996 (Res 425, A-96); Policy H-20.958: Testing for HIV without Explicit Consent. Approved 1990 (Res 257, A-90); Policy H-20.947: Expansion of Existing AMA Policy on HIV Testing. Approved 1991 (Res 415, I-91).

[291] For a review of Canadian law on consent, see: Nelson E. "The Fundamentals of Consent"; and Dickens B. "Informed Consent", in: Downie & Caulfied (eds), supra, note 126 at 102-116.

[292] *Hopp* v *Lepp*, [1980] 2 SCR 192; *Reibl* v *Hughes*, [1980] 2 SCR 880; *Ciarlello* v *Schachter*, [1993] 2 SCR 119; *Malette* v *Shulman* (1990), 37 OAC 281 (CA); *Fleming* v *Reid* (1991), 82 DLR (4th) 298 (Ont CA); *Canadian AIDS Society* v *Ontario* (1995), 25 OR (3d) 388 (Gen Div); *Videto* v *Kennedy* (1981), 33 OR (2d) 497 (CA).

[293] *Fleming*, supra, note 292; *Malette*, supra, note 292; *Ciarlello*, supra, note 292; *Rodriguez* v *British Columbia (Attorney General)*, [1993] 3 SCR 519; *Nancy B* v *Hôtel Dieu de Québec* (1992), 86 DLR (4th) 385 (Que SC); *Walker (Litigation Guardian of)* v *Region 2 Hospital Corp* (1994), 116 DLR (4th) 476; *Re K(LD)* (1985), 48 RFL (2d) 164 (Ont Prov Ct).

legislation has also codified some of the law regarding consent to medical treatment.[294] As one commentator notes,

> while there are exceptions to the consent requirement [for medical treatment], the exceptions are very limited. Only in the case of (1) an emergency, or (2) a legislative provision mandating treatment regardless of lack of consent, can treatment be provided without the consent of the patient.[295]

For clarity's sake, it should be understood that there must a "true" emergency in which treatment is necessary to preserve the life or health *of the patient* and the patient is unable to provide consent. This "emergency exception" to the requirement of consent "does not extend, however, to situations in which it would simply be convenient for the treatment to be performed and the patient is unable to consent."[296]

Legal Developments Regarding HIV Testing and Consent

While it is clear that medical *treatment* requires informed consent, *testing* is not quite the same as treatment. The law in this area is less clear, although the starting premise remains that testing without consent requires some specific legal authority, either statutory or judicial. And there is strong authority, developed principally in the criminal law, from both the Supreme Court of Canada and provincial appellate courts which suggests forced HIV testing by the state or pursuant to state authority (eg, statute) is prima facie illegal:

> The use of a person's body without his consent to obtain information about him, invades an area of personal privacy essential to the maintenance of his human dignity.... [T]he protection of the *Charter* extends to prevent a police officer, an agent of the state, from taking a substance as intimately personal as a person's blood from a person who holds it subject to a duty to respect the dignity and privacy of that person.[297]

> [The *Charter* protects] "the right of the individual to determine for himself when, how, and to what extent he will release personal information about himself.[298]

> [T]he forcible taking of parts of a person, in the absence of legislation authorizing such acts, is an infringement of the right to security of the person and constitutes an unreasonable seizure [prohibited by the *Charter*].[299]

The constitutional aspects of HIV testing without consent were considered in the civil context in the unusual case of *Canadian AIDS Society* v *Ontario*.[300] The issue in that case was whether the positive results of HIV testing on frozen blood samples, conducted by the Red Cross and the federal Laboratory Centre for Disease Control ten years after collection, could or should be reported to the donors in question and public health authorities as required by the reporting obligations in Ontario law. The donors had never been presented with the question of HIV testing at the time of donation. For obvious reasons, they were not participants in the proceedings. However, the Canadian AIDS Society sought a declaration that applying the statutory reporting requirements in these

[294] For example, see: *Health Care Consent Act, 1996*, SO 1996, c 2; *Health Care (Consent) and Care Facility (Admission) Act*, SBC 1993, c 48 [not yet proclaimed in force]; *Hospitals Act*, RSNS 1989, c 208; *Health Act*, SYT 1989-90, c 36; Art 11 CCQ; *Health Care Directives Act*, SM 1992, c 33; *Dependant Adults Act*, SS 1989-90, c D-25.1.

[295] Nelson, supra, note 291 at 105. See cases cited: *Mulloy* v *Sang*, [1935] 1 WWR 714 (Alta CA); *Parmley* v *Parmley*, [1945] 4 DLR 81 (SCC); *Marshall* v *Curry*, [1933] 3 DLR 260 (NSSC); *Murray* v *McMurchy*, [1949] 2 DLR 442 (BCSC).

[296] Nelson, supra, note 291 at 105.

[297] *R* v *Dyment*, [1988] 2 SCR 417 at 431-432; see also *R* v *Collins*, [1987] 1 SCR 265.

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

[299] *R* v *Legere*, (1988) 43 CCC (3d) 502 at 513 (NBCA).

[300] (1995), 25 OR (3d) 388 (Gen Div); aff'd (1996), 31 OR (3d) 798 (CA); leave to appeal to SCC dismissed 8 May 1997, SCC Bulletin 1997, p 873, noted at 31 OR (3d) 298 (note).

The court expressly found that the donors' consent to testing was required as a matter of law.

circumstances would constitute testing without consent, in violation of the donors' *Charter* rights to liberty and security of the person (section 7) and to be free from unreasonable seizure (section 8).

The court at first instance expressly found that the donors' consent was required as a matter of law, and that their samples had been tested without their consent. Reviewing Supreme Court jurisprudence, Wilson J also found that the *Charter* right to "security of the person" had been interpreted as including "a notion of personal autonomy involving, at the very least, control over one's bodily integrity free from state interference and free from state-imposed psychological stress."[301] The court also concluded that there is a right to privacy in the civil context.

Nonetheless, the court ruled that the provincial reporting statutes in question struck "an appropriate balance between the goal of the state to promote public health, and the privacy rights of the individual."[302] Wilson J therefore concluded that the infringement of the donors' rights to liberty and security of the person was "in accord with the principles of fundamental justice" (meaning no breach of section 7 of the *Charter*) and that the seizure was "reasonable" (meaning no breach of section 8 of the *Charter*). She also concluded, in the alternative, that even if there had been a breach of the donors *Charter* rights, the breach would have been justified under section 1: "The important privacy rights of the 13 men who altruistically donated their blood over ten years ago must yield to the more compelling public objectives of public safety."[303]

Rapid Testing of Women of Unknown HIV Status during Labour

As discussed above,[304] the ability to rapidly obtain results of an HIV screening test could assist pregnant women in labour whose HIV status is unknown make decisions regarding possible interventions during labour and following the birth of the infant in an effort to prevent transmission to their children.[305] What must be kept in mind, of course, is that in a low HIV prevalence setting such as Canada, a rapid test would yield a significant number of false positive results. Decisions by women in labour about interventions to prevent transmission would therefore be based on less than optimal test results.

The concern here is that the temptation of quick results and the opportunity for quick action on the results that rapid screening would provide could bring about testing without the informed consent of the pregnant women. As Jürgens points out: "In the rush to respond to the availability of therapy that can significant reduce the risk of HIV transmission from mother to child, there is a serious risk that the basic rights of the mother will be swept aside."[306]

In addition, it is contentious whether a woman in labour is capable of making a morally autonomous choice about, or giving voluntary informed consent to, any form of HIV testing. Would it be ethically appropriate or legally sound to use rapid HIV screening for women in labour at all?

Requirement for women's informed consent widely accepted

Certainly common sense and existing Canadian guidelines and policy statements support routinely offering voluntary HIV testing to all pregnant women, both in their interest and that of their fetus.[307] The Canadian Medical Association, while urging that HIV testing be "strongly recommended to all pregnant women," has also reiterated that a patient's informed consent must be obtained

[301] *CAS* v *Ontario*, supra, note 300 (Gen Div), citing *Rodriguez*, supra, note 293, *R* v *Videoflicks Ltd* (1984), 48 OR (2d) 395 at 433 (CA), and *R* v *Morgentaler* [1988] 1 SCR 30.

[302] *CAS* v *Ontario*, supra, note 300 at 397 (Gen Div).

[303] Ibid at 407 (Gen Div).

[304] Supra, in the section on "Preventing Perinatal Transmission."

[305] Ibid.

[306] Jürgens, supra, note 4 at 149.

[307] CMA Guidelines, supra, note 237 at 17-18; Informed consent needed before HIV testing of mothers: CMA. *Canadian Medical Association Journal* 1997; 156(8): 1108. For a detailed discussion, see Stoltz & Shap, supra, note 164.

prior to testing,[308] as have the Society of Obstetricians and Gynaecologists of Canada,[309] several colleges of physicians and surgeons,[310] and provincial and territorial health ministries.[311] As the United Nations Joint Programme on AIDS has stated:

> Regardless of the presence of risk factors or the potential for effective intervention to prevent transmission, women should not be coerced into testing, or tested without consent. Instead, they should be given all relevant information and allowed to make their own decisions about HIV testing.[312]

Ethical considerations

Testing a woman without her informed consent is unethical.[313] Some have characterized coerced HIV testing as "minimally invasive and virtually free of risk."[314] However, as Bayer points out:

> [T]his statement disregards the extent to which the imposition of knowledge about a woman's HIV status is psychologically burdensome. The results of an HIV test could, after all, tell a woman that she has a lethal condition. More important, I reject the proposition that such coerced screening can be justified because it would set the stage for a freely chosen and fully informed decision about treatment. The freedom to elect or reject therapy includes the right to determine whether to be informed of the condition that would warrant such treatment. This is true not only for ethical reasons, but also because it is a mistake to begin discussing with a woman a potential course of zidovudine treatment on the basis of a test she did not elect. The mere possibility that compulsory testing would enhance the prospect of a choice to act "responsibly" is not sufficient warrant.[315]

According to Hoffmaster, a "morally enlightened approach to testing would not pit vulnerability against vulnerability."[316] Instead,

> [a] morally inspired and sympathetic approach would take the interests of women and the interests of their children to be congruent and would strive to promote all those interests. It would assume that mothers care for their children and want to do what is best for them even if that requires personal sacrifice. It would seek to understand the barriers that deter women from courses of action that seem to be in their own and their children's best interest and require, as a matter of public policy, that those barriers be reduced or removed. Voluntary testing has the potential to do all that. Non-voluntary testing should be a moral last resort.[317]

The danger, according to Hoffmaster, is that non-voluntary rapid screening of women in labour could be viewed as simpler and cheaper as the efforts (and resources) that are necessary to make voluntary testing programs successful. As he says, this could make such a quick fix "practically and politically … irresistible."[318] But it would not make it ethically defensible.

[308] CMA endorses HIV testing during pregnancy. *Canadian Medical Association News* 1997; 7(6): 5; Informed consent needed, supra, note 307.

[309] Society of Obstetricians and Gynaecologists of Canada. Practice Guidelines for Obstetrical and Gynaecological Care of Women Living with HIV. Ottawa: The Society, 1994, at 6; Society of Obstetricians and Gynaecologists of Canada. *HIV Testing in Pregnancy. It's Best to Test!* Ottawa: The Society, 1997.

[310] See, for example: College of Physicians and Surgeons of British Columbia. HIV in Pregnancy. Policy Manual, ss H-3 & H4. June 1995; College of Physicians and Surgeons of Manitoba. Maternal and Neonatal HIV Testing and Management (Guideline 635), 1994; Northwest Territories Health and Social Services. HIV Infection and AIDS Information for Health Professionals. November 1996; Ministère de la Santé et des Services sociaux. HIV infection and pregnancy – Intervention programme. Québec: Government of Québec, 1997.

[311] Eg: Reproductive Care Program of Nova Scotia. Guidelines for Antenatal Laboratory Screening and Testing. May 1994; British Columbia Ministry of Health. HIV Testing in Pregnancy. Health Files #38a, January 1997.

[312] UNAIDS. *UNAIDS Policy on HIV Testing and Counselling*. Geneva, August 1997, at 1.

[313] Hoffmaster B, Schrecker T. An Ethical Analysis of HIV Testing of Pregnant Women and Their Newborns. (unpublished manuscript). August 1999, summarized at: Hoffmaster & Schrecker, supra, note 194.

[314] Hoffman CA, Munson R. Letter to the Editor re: Ethical issues in the use of zidovudine to reduce vertical transmission of HIV. *New England Journal of Medicine* 1995; 332: 891.

[315] R Bayer. Letter to the Editor, re: Ethical issues in the use of zidovudine to reduce vertical transmission of HIV. *New England Journal of Medicine* 1995; 332: 891.

[316] Hoffmaster, infra, Appendix A at A14.

[317] Ibid., at A14-15.

[318] Ibid., at A15.

Legal considerations

In addition to being ethically indefensible, testing a pregnant woman without her consent, in the interests of a subsequent intervention to prevent harm to her fetus, would also be untenable as a matter of Canadian common law, and if done with state authority, would likely attract constitutional scrutiny as possibly in breach of women's equality rights and right to security of the person.[319] Canadian law does not recognize the fetus as a "person" with rights that trump those of its mother to bodily autonomy.[320]

Clearly, pregnant women do not lose their capacity to make medical decisions regarding their care; such paternalism is unacceptable.

Offering rapid testing to women in labour

The more difficult question is whether it is ethically appropriate or legally sound to use rapid HIV testing for women in labour *at all*. Minkoff and O'Sullivan acknowledge that "this is not the ideal circumstance in which to provide counseling, and an argument could be made that merely proffering the offer is a violation of standards of informed consent."[321] However, they argue that women in labour are often asked to consent to surgery (caesarean section), and that

> depriving women of the right to consent to be tested and treated for HIV, if such therapy could potentially spare their children lethal infections, may represent more of an assault on autonomy than a discussion of testing would entail. Women untested and untreated, who deliver children who eventually succumb to HIV may not be grateful that they were not burdened with the difficulties of decision making during labor.[322]

Clearly, pregnant women do not lose their capacity to make medical decisions regarding their care; such paternalism is unacceptable. However, the equation of consenting to HIV testing during labour with consenting to a caesarian section is dubious. The nature and consequences of the decisions are significantly different, and the ability to appreciate these goes directly to the question of "informed" consent. This is not to say that ensuring truly *informed* consent to HIV testing on the part of a woman in labour should be abandoned, only that the added difficulty should be acknowledged.

A 1995 study examined the effect of postnatal HIV antibody testing on infant care and on maternal informed consent. Investigators found that 78 percent of women interviewed *after* consenting to HIV-antibody testing (after birth, not during labour) did not identify any socioeconomic risks associated with testing HIV-positive. This in itself suggests their consent was less than "informed" and/or "voluntary." Furthermore, while 88 percent stated an interest in learning their serostatus, only 22 percent returned for rest results. Again, the question must be asked: is this low return rate indicative of a less than fully informed and voluntary initial decision to agree to testing? The study researchers concluded that "despite the benefits of HIV antibody testing of at-risk infants, current testing and counselling procedures inadequately inform women, limiting the testing benefits to them."[323]

Perhaps such results should not be surprising. Another study published two years later examined San Francisco primary-care providers' self-reported beliefs and practices regarding HIV counseling and testing of pregnant women: 61 percent of the 180 participating physicians supported routine HIV testing of

[319] *Winnipeg Child and Family Services (Northwest Area)* v *DFG*, [1997] 3 SCR 925; see also the cases and discussion in Stoltz & Shap, supra, note 164 at 30-40; and see Rodgers S. "State Intervention in the Lives of Pregnant Women. In: Downie & Caulfield (eds), supra, note 126 at 275-301; American Civil Liberties Union. ACLU Position Statement on Prenatal and Newborn HIV Testing. New York: ACLU, 1996.

[320] *Dobson (Litigation Guardian of)* v *Dobson*, [1999] 2 SCR 753; *Winnipeg Child and Family Services (Northwest Area)*, supra, note 319; *R* v *Morgentaler*, supra, note 301; *Tremblay* v *Daigle*, [1989] 2 SCR 530; *R* v *Sullivan* (1991), 63 DLR (3d) 97 (SCC); *R* v *Manning*, [1994] BCJ No 1732 (Prov Ct); *R* v *Drummond* (1996), 112 CCC (3d) 481 (Ont Ct Prov Div).

[321] Minkoff H, O'Sullivan MJ. The case for rapid HIV testing during labor. *Journal of the American Medical Association*. 1998; 279: at 1744.

[322] Ibid.

[323] Lester P et al. Postnatal human immunodeficiency virus antibody testing – the effects of current policy on infant care and maternal informed consent. *The Western Journal of Medicine* 1992; 156: 371-375.

women without explicit consent, and 55 percent supported mandatory HIV testing of pregnant women.[324] Despite its general pronouncement (noted above) about the importance of specific, informed consent to HIV testing, the American Medical Association has endorsed mandatory HIV testing of pregnant women (and newborns),[325] and has also adopted the position that physicians should be allowed to test, without explicit informed consent, patients suspected of being HIV infected.[326] In Canada, a survey of randomly sampled family physicians and obstetricians in Newfoundland found that 54 percent favoured mandatory testing of pregnant women (this figure rose to 80 percent among physicians who had been practising for over 20 years), and 16 percent said they would test without consent.[327]

Such attitudes may well result in women being coerced or pressured into "consenting" to HIV testing, particularly if in labour. Although not focusing on women in labour, a recent pilot study conducted in Ottawa and Montréal of pregnant women's testing experiences found that a majority of the women with whom HIV testing had been discussed "felt they had no choice but to undergo HIV testing," and that "only one woman's experience could be judged to meet the standard of consent specified in the [CMA] Counselling Guidelines."[328] UK researchers studying HIV test uptake among almost 700 pregnant women also reported that many women were not aware of their right to refuse tests and over a third did not believe their permission would even be sought.[329]

Should alternatives be offered?

Given that truly informed consent to HIV testing may be difficult to achieve in the circumstances of labour, there may be another acceptable, albeit unorthodox, approach. Women in labour whose status is unknown and who do not wish to be tested for HIV could, as an alternative to rapid HIV screening, be offered the same options to reduce the possibility of vertical transmission as are offered to women known to be HIV-positive. In other words, women of unknown serostatus could be offered the preventive measures of antiretroviral therapy and/or cesarean section during labour, followed by the clinically recommended short course of therapy for the newborn.

These preventive measures could be taken without the woman being required to make the decision to undergo HIV testing while in labour, yet still achieve the goal of reducing the chance of transmitting HIV to the child should the mother in fact be HIV-positive. Why should accessing the benefits of antiretroviral therapy or elective cesarean delivery necessarily be contingent upon consenting to HIV testing? Indeed, in order for the woman in question to make an informed decision about HIV testing itself, she needs to be informed about alternative courses of action,[330] and these should arguably include information about possible means of preventing HIV transmission to her infant that do not necessarily require her to agree, while in labour, to being tested for HIV.

The investigators who reported the effectiveness of a single dose of nevirapine for both mother during labour and the newborn after delivery also suggest such a course of action of providing antiretroviral therapy even in the absence of HIV test results. Guay et al propose that:

> A combination of counselling and rapid testing for HIV-1 antibody for pregnant women at or near the time of labour, with immediate provision of nevirapine could increase the number of women

[324] Phillips et al, supra, note 240.

[325] American Medical Association (House of Delegates). Policy H-20.930, supra, note 290.

[326] American Medical Association (House of Delegates). Policy H-20.945: HIV Testing Without Explicit Consent. Approved 1987, re-affirmed 1996 (Rules & Credentials Committee, A-96). Available at <www.ama-assn.org>.

[327] Reddy H. HIV testing in pregnancy: a duty or a choice? *Canadian HIV/AIDS Policy & Law Newsletter* 1997; 3(2/3): 7-8, with reference to B Blackie, H Reddy et al, 1995, unpublished data.

[328] Leonard & Shap, supra, note 241.

[329] Sherr L et al. HIV Test Uptake in London Pregnant Women – Predictors and Comparisons. In: Final Program & Abstract Book, AIDS Impact International Conference on the Biopsychosocial Aspects of HIV Infection, 15-18 July 1999, Ottawa (Poster 94): 206.

[330] For example, see the statutory requirements for informed consent in Ontario's *Health Care Consent Act, 1996*, SO 1996, c 2, Schedule A, s 11(2)-(3).

> treated. However, until appropriate counselling and testing infrastructures can be put in place, one option that should be taken into account is to provide *all pregnant women in high HIV-1 seroprevalence areas* with nevirapine before or at onset of labour if the drug proves to be safe in long-term follow-up.... This approach would be cost-effective and would bring the number of women receiving an effective intervention to a maximum, compared with giving the drug only to pregnant women who are identified as HIV-1 infected.[331]

While these investigators are referring specifically to women from areas in resource-poor settings with high HIV prevalence areas, could such an approach equally apply to women of unknown serostatus who do not consent to rapid HIV testing during labour, or at least to some of them?

There are a number of questions about how to implement such an approach in clinical practice with women in labour:

- The timing of initiating anti-retroviral therapy is important for there to be any benefit. Which drug, or combination of drugs, to administer would also need to be considered, as would the method of administering the drug(s). Currently, there is little data available to identify with confidence at which point during labour it may no longer be of benefit to initiate therapy. AZT (or AZT in combination with another drug) may need to be administered intravenously several hours before delivery; a single oral dose of nevirapine may be easier to administer, but there is no clear indication as to when during the process it may still have some effect.
- In the case of cesarean sections, the prophylactic benefit is greatest if performed before the rupture of membranes. Where in the hospital surgical staff's "priority list" for this procedure should women electing a cesarean section be placed if their HIV status is unknown and rapid HIV screening has been refused?
- In a fairly low-prevalence setting such as Canada, most pregnant women are HIV-negative. This means that among those who will test HIV-positive on a rapid screening test, there will be a significant number of false positives. We should avoid, as much as possible, administering anti-retroviral therapy or performing cesarean sections unnecessarily. This raises the question: Among those women who do not wish to undergo rapid HIV screening, should these possible interventions be offered only to women identified as being at "high risk" of being infected? How will that assessment be made? A woman may not disclose past risk activities (eg, sharing injection equipment) for any number of reasons, and health-care professionals may not necessarily always identify a woman as being at risk of infection.

These questions require further discussion in order to develop appropriate policy and practice for such situations. Already, in a very small handful of cases, physicians have prescribed anti-retroviral therapy as a prophylactic measure for newborns in the absence of HIV test results for their mothers, and some guidance in this area would be helpful.[332]

[331] Guay et al, supra, note 175 [emphasis added]. See also: Musoke P et al. A phase I/II study of the safety and pharmacokinetics of nevirapine in HIV-1 infected pregnant Ugandan women and their neonates (HIVNET 006). *AIDS* 1999; 13: 479-486.

[332] The discussion of some of these questions benefited from personal communications with Dr S King, Hospital for Sick Children, on 26 and 28 February 2000. Her help is gratefully acknowledged.

In addition to these practical, clinical questions that need to be addressed, there are also two ethical questions raised by this proposal that require further discussion.

Ensuring informed consent

Decisions about caesarian section and/or antiretroviral therapy would, of course, require informed consent on the woman's part. As the International Perinatal HIV Group argues, "HIV-infected pregnant women deserve the opportunity to make informed decisions about all the potential interventions ... to prevent vertical transmission."[333] But offering the woman in labour the choice between rapid testing or preventive interventions (caesarian section and/or antiretroviral therapy) requires communicating even more information at a difficult time. Does this address the concern about ensuring *informed* consent?

Ethics of administering treatment without diagnosis of HIV infection

Another ethical question is raised with respect to proceeding with interventions in the absence of the results of any HIV testing (rapid or otherwise) indicating either confirmed or possible HIV infection on the part of the woman. Is it ethical to provide antiretroviral therapy or elective caesarian section when these may adversely affect the child? Conversely, given that these interventions may also result in substantial benefit to the child by preventing HIV infection, is it ethical to withhold them from the woman who refuses HIV testing?

In the case of opting for a caesarian section, there is primarily a risk of harm to the woman herself; while there are risks to the baby, these are minor in the vast majority of circumstances. Thus, there is no strong basis on which to deny the mother to choose this intervention to reduce the likelihood of transmission to her child, as it is primarily her interests that are at stake.

However, the use of antiretroviral therapy as a preventive intervention may carry greater implications for the child's interests. As has been noted above, prior to birth, ethically and legally the pregnant woman's decisions regarding medical treatment are to be respected. In the case of the woman who refuses testing and is in fact HIV-positive, there can be no objection if she decides to initiate antiretroviral therapy – she is following the clinically recommended course of action for HIV-positive pregnant women, to the likely (net) benefit of her child (as far as can be predicted based on currently available medical evidence). Had she agreed to HIV testing, initiating antiretroviral therapy would have been recommended to her.

It is only in the case of the woman who refuses rapid testing and who is in fact HIV-negative that initiating antiretroviral therapy raises the issue that the harm of possible toxicity for mother and newborn could have been avoided had she consented to being tested. In such a case, it remains the woman's right to choose for herself whether to undergo antiretroviral therapy. The only question is how to weigh the newborn's interest in avoiding unnecessary therapy against the mother's interest in autonomy by refusing to be tested during labour. How different is this from other post-exposure situations? As Hoffmaster points out, a police officer or a paramedic who has been exposed does not have a legal right to compel the source person to be tested for HIV, even though doing so could mean that the police officer or paramedic would not have to take a month-long course of antiretroviral therapy as post-exposure prophylaxis.[334]

[333] Read, supra, note 180.

[334] Hoffmaster, infra, Appendix A at A15.

Pressuring or coercing women in labour into being tested is ethically and legally unacceptable.

However, that case, although similar, is also different in one respect: the infant, unlike the independently existing exposed person, cannot make a choice about whether to take PEP – the mother makes the decision about testing and about whether or not to expose the infant to PEP before birth. Again, however, at law, this remains her decision to make.

There are no easy answers to these complicated practical and ethical questions. It would be premature at this point to propose complete answers to them. However, if rapid HIV screening is to be offered to women of unknown HIV status while in labour, for the purpose of making decisions about possible interventions to prevent perinatal transmission, then a careful examination of possible courses of action where women do not wish to be tested is also required. There are ethical and legal dimensions to that discussion. Some of these have been raised here in the interests of contributing to the development of sound practices in such situations.

Conclusions

As explained above, being able to rapidly obtain results of an HIV test could assist a woman in labour and her physician(s) make decisions regarding possible interventions during labour and following the birth of her infant to reduce the chance of transmission. However, it would be unethical, certainly professional misconduct, and possibly illegal to deny pregnant women the freedom of choice in making the decision about whether to be tested. Pressuring or coercing women in labour (or any person) into being tested is ethically and legally unacceptable:

> Using information to purposely manipulate a patient's decision ... is both ethically inappropriate and legally risk-laden. The legal role of information is to serve the patient's autonomy, permitting the patient to exercise choices among feasible options that accord with ... her own wishes.[335]

Because obtaining truly informed consent to rapid HIV screening raises so many difficult issues, participants at the national workshop on rapid HIV screening at the point of care suggested that rapid screening of pregnant women in labour should be phased in gradually and carefully, and initially offered only in settings where its use can be monitored and its results can be evaluated:[336]

> One component of the required evaluation concerns the ability of women in labour to give voluntary, informed consent to rapid screening. Another concerns the accuracy of the screening test for pregnant women. An initial test commonly used in the standard testing procedure, the EIA, produces more false-positive results and more indeterminate results with pregnant women because of all the antibodies in their bodies. Confidence in it is the result of accumulated clinical and laboratory experience in administering the test to pregnant women. The same kind of scrutiny and assessment would be required for rapid screening of pregnant women in labour. That research needs to be conducted before rapid screening could be offered to pregnant women generally.

[335] Dickens, supra, note 291.

[336] Workshop on Rapid HIV Screening at the Point of Care, sponsored by the Canadian HIV/AIDS Legal Network, Toronto, 21-22 January 2000; this recommendation is repeated in Hoffmaster, infra, Appendix A at A18.

In those settings where women in labour whose HIV status is unknown would be offered rapid screening, it should be offered to all women for whom there is no evidence of prenatal care, including HIV screening – not just to women perceived to be at high risk. Were rapid screening to be offered selectively to only some pregnant women in labour, the risks of discrimination and subsequent disenfranchisement would simply be too great.

In addition, in those settings in which offering rapid screening of pregnant women in labour would be piloted, women of unknown HIV status who refuse screening following counseling may still wish to opt for possible interventions that could reduce (depending on the clinical circumstances) the chance of transmission to their infants, including the possibility of initiating antiretroviral therapy for her during labour and her infant after delivery, and of electing a cesarean delivery. Information about the risks and benefits of such alternatives would be required for her to make an informed decision as to whether to take such an alternative. Experience with this approach should also be carefully evaluated in order to inform the development of guidelines in this area that represent good clinical practice and ethically sound approaches to informed decision-making by patients.

Finally, in order to reduce the number of pregnant women who are unaware of their HIV status at the time of labour, provincial and territorial governments, in conjunction with health-care professionals' associations and regulatory bodies, should improve efforts to ensure that *all women* have access to HIV testing services, and that all women considering pregnancy or already pregnant be routinely offered voluntary HIV testing, with quality pre- and post-test counseling.

Canadian law currently provides little basis for compulsory testing of a "source person" following an exposure.

Rapid Testing to Inform Decisions Regarding PEP

As discussed above,[337] there are some benefits to be gained from the availability of a rapid screening test with respect to making PEP decisions.

In cases where the source person receives quality pre-test counseling and provides informed consent to (rapid) HIV testing, there is no difficult legal or ethical issue to be resolved. However, what of the circumstance where the source person refuses testing? The question raised by the possible availability of rapid HIV screening tests is whether the benefit to the exposed person of knowing the source person's preliminary test result does or should give rise to an entitlement to compel the source person to be tested without their consent.

Legal considerations

Testing without consent is not legally permissible under Canadian law unless there is a true emergency (the person is not capable of consenting, and testing is required immediately to protect *their* health) or there is legal authorization.[338]

Currently, Canadian law provides little basis for compulsory testing of a "source person" following an exposure – whether as a result of assaultive conduct (sexual or otherwise) or an accidental occupational exposure.

Testing following occupational exposure

Should occupational exposure occur as a result of an alleged criminal offence (eg, an assault), the discussion in the next section with respect to testing following sexual assault would be applicable. But what about other occupational exposures where there is no such conduct (eg, needle-stick injuries)? Under

[337] See supra, the section on "Post-Exposure Prophylaxis."

[338] This is discussed in more detail supra, in the section on "Testing without Informed Consent."

Testing the accused will not be possible for most survivors of sexual assault because of the small percentage of assailants who are arrested and convicted in a timely manner.

provincial occupational health and safety legislation, employers have a legal duty to take reasonable precautions to ensure a safe working environment. It could conceivably be argued that this gives rise to a right to impose HIV testing of a source person when an employee has been exposed in the course of performing their work duties, so as to provide rapid test results to the exposed employee for the purposes of informing decisions regarding post-exposure prophylaxis.[339] It does not appear that such an argument has been advanced in any reported case in Canada.

In March 1999, a Reform Party Member of Parliament introduced a private member's bill, Bill C-483 (*Blood Samples Act*), that would permit compulsory blood testing of persons for HIV or hepatitis B/C where peace officers, firefighters, or other emergency services or health-care workers may have been occupationally exposed to possible infection.[340] The Alberta Federation of Police Associations and the Canadian Police Association supported the bill.[341] However, it was reported in December 1999 that the Liberal government was unlikely to support the legislation because it would violate the Charter guarantee to security of the person.[342] The bill had not passed first reading when Parliament prorogued in September 1999. However, substantially the same bill (with some minor modifications) was reintroduced by another Reform Party Member of Parliament in October 1999 as Bill C-244 (*Blood Samples Act*). At the time of writing, it had not progressed beyond first reading.

The Canadian HIV/AIDS Legal Network has expressed its concerns about the proposed bill, emphasizing that the possible benefits of compulsory HIV testing in these cases are quite limited, while the harms to the rights of those to be forcibly tested are significant. In particular, the Network submitted that the state authorization of forced HIV testing proposed in Bill C-244 breaches the right to security of the person guaranteed by the *Charter* (section 7) and is not in accord with the "principles of fundamental justice"; and that forced HIV testing violates the *Charter* right to be secure against "unreasonable search or seizure" (section 8). The Network concluded by emphasizing that

> more constructive solutions to the risks faced by emergency services personnel would both offer greater protection against possible exposure to communicable diseases and respect the rights of Canadians to privacy and bodily integrity. Pro-active efforts to educate police, firefighters, and health care workers about how HIV and hepatitis are transmitted (and how they are *not* transmitted), as well as encouraging the use of universal precautions to reduce the likelihood of infection, are preferable responses.[343]

Testing following sexual (or other) assault

As commentators have pointed out, "testing the accused will not be possible for most survivors [of sexual assault] because of the small percentage of assailants who are arrested and convicted in a timely manner."[344] Aside from the fact that testing is usually impractical, what does the law say? While many US states have legislation specifically authorizing compulsory testing of offenders (either pre- or post-conviction, or both),[345] there is no such legislation in Canada, and several Canadian organizations and experts have rejected proposals for compulsory testing of persons accused or convicted of sexual assault.[346] A Working Group of the (federal) Interdepartmental Committee on Human

[339] Flanagan notes this possibility with respect to administrators of health-care facilities proposing to test patients, ostensibly in the interest of protecting health-care workers. See Flanagan W. AIDS-related risks in the health care setting: HIV testing of health care workers and patients. *Queen's Law Journal* 1993; 18: 71-128 at 104.

[340] Bill C-483, now replaced by Bill C-244, supra, note 285.

[341] Police want justice minister to push law on deadly viruses. *CP Wire*, 15 August 1999; Nagy S. Bill seeks to protect police. *Calgary Herald*, 17 August 1999: A10; Naumetz T. Liberals 'unlikely' to back mandatory blood samples. *Ottawa Citizen*, 14 December 1999: E2.

[342] Naumetz, ibid.

[343] Letter by Ralf Jürgens, Executive Director of the Canadian HIV/AIDS Legal Network, to the Federal Minister of Justice, Anne McLellan, dated 13 January 2000 (on file).

[344] Silverman DC. HIV testing, counselling and prophylaxis following sexual assault [2 parts]. *Reproductive Health Matters*, 1 May 1995: 104-115, shortened from: L Gostin, DC Silverman et al. HIV testing, counselling and prophylaxis following sexual assault. *Journal of the American Medical Association* 1994; 271(8): 1436-1445.

[345] Ibid.

[346] Eg, Human immunodeficiency virus antibody testing in Canada. Recommendations of the National Advisory Committee on AIDS. *Canada Diseases Weekly Report* 1989; 15(8): 37-43; see also: Jürgens, supra, note 4, at 164-179.

Rights and AIDS also concluded that compulsory testing of persons accused of sexual assault is "misguided."[347]

Existing criminal legislation provides no authority for compulsory HIV testing. The general provisions regarding search warrants in the *Criminal Code* do not authorize the taking of blood without consent in the course of criminal proceedings.[348] The specific provisions regarding warrants for blood samples in the case of impaired driving charges are limited to those investigations and authorize only testing for alcohol or other drugs.[349] The provision regarding the use of investigative devices (generally used for authorizations of video or audio surveillance) expressly indicates that it does not "permit interference with the bodily integrity of any person."[350] While there are specific legislative provisions in the *Criminal Code* for obtaining a warrant in the course of a criminal proceeding to obtain bodily substances for DNA testing, these provisions also expressly prohibit the use of a bodily substance obtained by warrant for any purpose other than forensic DNA analysis.[351]

In addition to the absence of statutory authorization, there is also strong authority from higher courts that HIV testing without consent is not legally permissible.

In the one known case in which the question of testing persons who are simply *accused* of sexual assault has arisen, *R* v *Beaulieu*,[352] a Canadian court has refused to order HIV testing, citing the protection of security of the person and the right to refuse medical interventions in the *Civil Code* of Québec and the Québec and Canadian *Charters*, as well as the Supreme Court of Canada's decision in *Dyment*.[353]

Nonetheless, in two cases Canadian courts have ordered HIV testing of a person *convicted* of sexual assault, with the test results to be communicated to the victim. However, in those cases the proposed testing was not opposed by the offender. Therefore, these cases are not precedents in Canadian law for the proposition that HIV testing can be ordered against a person's wishes. In addition, they are limited to cases of persons *convicted* of sexual assault.[354]

In the first case, *R* v *JPB*,[355] even though the offender was willing to be tested for HIV, the court granted the victim's request for an order for HIV testing. The court distinguished the *Beaulieu* case because the offender had already been convicted. The court recognized that there was no legislative authority in the *Criminal Code* for compulsory blood testing for HIV. Citing the "peace of mind and succour of the victim," and an unreported US decision finding compulsory HIV testing of a sexual assailant constitutionally permissible, the court based its order for HIV testing on the *Young Offenders Act*, which allows the court to impose "reasonable conditions" that it "deems advisable and in the best interests of the young person and the public."[356]

In the *JPB* case, the court also cited the earlier case of *R* v *GDM* as a precedent for the use of the *Young Offenders Act* in this fashion, even though in *GDM* testing was not ordered for the purpose of providing the test result to any person who had been exposed. In *GDM*,[357] a youth court judge had relied on a different provision of the *Young Offenders Act* in imposing a condition of probation that, once a month for six months, a young offender be required to furnish a medical certificate to his youth worker stating that he had been examined "for AIDS and other venereal diseases" within the previous month (although the test result itself was not required to be disclosed). The young

[347] Interdepartmental Committee on Human Rights and AIDS. Report of the Working Group on Sexual Assault and HIV Antibody Testing: Human Rights Issues Relating to HIV Antibody Testing of Persons Accused or Convicted of Sexual Assault. Ottawa: The Committee, 19 April 1994.

[348] *Criminal Code*, RSC 1985, c C-46, s 487; *Laporte* v *Laganière* (1972), 8 CCC (2d) 343 (Que QB); *R* v *Miller* (1987), 62 OR (2d) 97, 38 CCC (3d) 252 (Ont CA); *R* v *Tomaso* (1989), 70 CR 93d) 152 (Ont CA); *R* v *Legere*, supra note 299.

[349] *Criminal Code*, ss 256-258.

[350] *Criminal Code* s 487.01(2).

[351] *Criminal Code*, s 487.04–487.09.

[352] *R* v *Beaulieu*, [1992] AQ No 2046 (Court of Québec) (QL).

[353] Supra, note 297.

[354] *R* v *JPB*, [1992] NWTJ No 207 (Youth Ct) (QL); *DC* v *Paul Bernardo*, infra, note 358.

[355] *JBP*, supra, note 354.

[356] *Young Offenders Act*, RSC 1985, c Y-1, s20(1)(l).

[357] [1988] BCJ No 3056 (Co Ct) (QL).

person was "a 17 year old homosexual prostitute" who had pleaded guilty to a charge of soliciting for the purposes of prostitution. On appeal, the court did not address the argument that such an order was an unreasonable search prohibited by the *Charter*. The appeal court agreed that "the requirement of an AIDS test is a condition which tends to promote the good conduct of the offender in this case and to prevent the commission of further offences," but found the requirement for monthly testing "excessive" and reduced the requirement to but one test.

In the second case dealing with a person convicted of sexual assault, *DC* v *Paul Bernardo*,[358] a woman suing the offender for damages brought a motion pursuant to Ontario's *Rules of Civil Procedure*[359] for an order that he provide blood samples for testing for HIV and other sexually transmitted diseases – although the assault had taken place years before, rendering the test results meaningless for the victim. The offender took no position on the victim's request. The court ordered him to be tested, and the results of his HIV test were provided to the victim. However, a subsequent motion was brought for a further order requiring him to undergo more invasive tests for other sexually transmitted diseases or, in the alternative, ordering corrections officials to proceed with such testing if he would not consent. The offender did not consent to this testing, and Correctional Services Canada took the position that it did not have the authority to forcibly test him for STDs and that, in the absence of express statutory jurisdiction, the court also had no jurisdiction to force testing. Noting the need for judicial caution in the absence of statutory authority, and the lack of any evidentiary basis to suggest that further testing was medically or legally necessary, the court refused to order further testing.

So a person in a situation where a decision about PEP has to be made could not legally be tested without their giving voluntary informed consent. But the law notwithstanding, could a moral argument for testing a source person without consent be made?

The law notwithstanding, could a moral argument for testing a source person without consent be made?

Ethical considerations

As has been noted above, testing a person for HIV without their consent is prima facie unethical, absent some compelling justification for violating autonomy and privacy. That proposition has been reiterated in the context of testing a source person following occupational exposure and making PEP decisions – by, among others, Health Canada's Laboratory Centre for Disease Control and various colleges of physicians and surgeons.[360]

What about the testing of a source person who *intentionally* caused harm to another person? Hoffmaster has analyzed whether in such a case a moral argument could be made for testing a source person without consent. According to him,

> [t]he argument might be that if a source person intentionally and voluntarily caused harm to another person, the source person has a moral duty to mitigate the amount of harm that person suffers. The source person, in other words, owes the person harmed something, and one way of fulfilling that obligation would be to perform a rapid test, even without the consent of the source person.[361]

[358] *DC* v *Paul Bernardo et al* (23 September 1996), Toronto 93-CQ-46124 (Ont Ct Gen Div, MacDonald J), subsequently reproduced in *DC* v *371149 Ont Ltd (cob Forest Manor)*, [1997] OJ No 2367 (Gen Div, MacDonald J) (QL).

[359] RRO 1990, Reg 194, Rules 60.05, 60.06, 60.11.

[360] Laboratory Centre for Disease Control (Health Canada), supra, note 204; College of Physicians and Surgeons of British Columbia. Management of Accidental Exposure to HIV. Policy Manual, s H-7. February 1997; College of Physicians and Surgeons of Manitoba. Guideline: 315: Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV) Post-Exposure Protocol. 1993, revised 1997. See also: Canadian AIDS Society, supra, note 218 at 5.

[361] Hoffmaster, infra, Appendix A at A12.

However, he points out that "the exact nature of this obligation is unclear":

> The obligation might be understood as a matter of retributive justice – the wrongful conduct of the source person has set the moral scales out of balance, and that balance must be restored. Reestablishing the balance could be accomplished by imposing a disadvantage on the source person that would offset whatever advantages the source person gained from the wrongful conduct. It is hard to see, however, how a non-consensual rapid test could morally rectify a sexual assault, say, for the respective harms are not commensurate. Moreover, moral retribution might degenerate into revenge or vindictiveness – the view that one assault deserves another. Alternatively, the obligation might be understood as a matter of corrective justice, that is, providing compensation for harms suffered. But the goal of rapid screening would be forward-looking not backward-looking – to reduce future harm, not to try to make up for harm already suffered.[362]

Therefore, he concludes that "neither type of justice would morally justify testing a source person without consent."[363]

Conclusions

There would be some benefits to be gained from the availability of a rapid screening test with respect to making PEP decisions. However, as legal and ethical analysis reveals, the benefit to the person potentially exposed to HIV of knowing the source person's rapid HIV screening test result does not and should not give rise to an entitlement to compel the source person to be tested without their consent. In particular, the federal government should not support Bill C-244 or similar legislation imposing compulsory testing for HIV, and provincial and territorial governments should also not introduce legislation to that effect, such as legislation authorizing compulsory testing in sexual assault cases.

Instead, in cases where the source person is known and available, they should be encouraged to undergo voluntary testing. Indeed, as Hoffmaster has pointed out, "perhaps the most important objective in this regard is to make it safer for source persons to be tested voluntarily."[364] It seems that in cases where the source persons are known and available, the overwhelming majority of them already agree to undergo testing. At the workshop on rapid HIV screening at the point of care held in January 2000, it was said that nearly all of them do. Nevertheless, a variety of measures could and should be taken to encourage even those few who currently refuse to submit to testing, such as scrupulously protecting confidentiality and preventing test results from being admissible in legal proceedings. In addition, specifically in the area of sexual assault, to deal with the very real concerns of survivors of sexual assault, Health Canada, the Department of Justice, Status of Women, and their provincial counterparts must continue to ensure that best-practice counseling, short- and long-term care, treatment and other services are made available to sexual assault survivors.[365]

[362] Ibid., at A12-13.

[363] Ibid., at A13.

[364] Ibid., at A7.

[365] For more details, see Jürgens, supra, note 4 at 177-179.

There are many reasons why rapid HIV screening of patients without their consent is not justified.

The Health-Care Setting: Rapid Screening before Providing Medical Attention

Another concern is that availability of rapid HIV screening could lead to (increased instances of) involuntary rapid screening of patients (or at least those assessed or perceived as being at "high risk" for HIV infection) prior to medical procedures. The argument would be that this is justified by the interests of health-care workers in avoiding risk of infection. The attraction, of course, is that rapid HIV screening would make it possible to obtain a screening result within 15 minutes, which would allow for testing and obtaining results in situations where this is currently not possible, such as before emergency procedures, by dentists, etc. Similarly, the availability of rapid screening could lead to proposals that health-care workers be subject to such screening, in the interests of avoiding the risk of infection to patients.

Yet such proposals are largely impractical, and rest on weak legal and ethical ground. The issue of compulsory testing of *health-care workers* has been discussed at length elsewhere, and compulsory testing has been rejected.[366] The discussion here focuses on the proposed use of rapid HIV screening tests on *patients* without their consent. To a large extent, however, it applies also in the context of other situations in which people have claimed that they "need to know" the HIV status of people with whom they are in contact, in order to take some "extra precautions." Such claims have been made, for example, by some prison staff.

Would screening be justified?

There are many reasons why rapid HIV screening of patients (or of inmates in a correctional institution) without their consent is not justified:

- It violates the autonomy and privacy of the patient.
- It is unnecessary because universal precautions can be taken (which protect patient health as well), and knowledge of a patient's (preliminary) HIV test result will make little, if any, difference. "[I]t has never been demonstrated that knowledge of a patient's HIV status will make it possible for HCWs [health-care workers] to reduce the risk of transmission. In fact, in most of the cases of reported hospital transmission, the patient's HIV status was already known to the HCW in question. Studies also indicate that the rate of percutaneous exposure to patients' blood is not significantly reduced when surgeons believe that patients are at a high risk for HIV infection. Provided that universal precautions are already in effect, it is not clear what additional precautions could be taken to reduce the risk of transmission once an HIV-infected patient has been identified."[367] Some might argue that additional precautions would or could be taken if a patient is known to be HIV-positive; for example, use of double layer of latex gloves for procedures involving exposure of health professionals' hands to a significant volume of blood.[368] However, the obvious answer is that, if such a concern exists, erring on the side of additional precautions achieves the goal of protecting both the health-care worker and the patient's autonomy and privacy.
- It is ineffective and possibly counter-productive. A negative HIV test result for a patient in the "window period" between infection and seroconversion may lull the provider into a false sense of security. It also ignores the possible presence of other, more communicable bloodborne pathogens. Less

[366] See the discussion on HIV testing of health-care workers in Jürgens, ibid at 186-196, and the references cited therein; Flanagan, supra, note 339.

[367] Flanagan, supra, note 339 at 101, citing: Brandt A. Routine Hospital Testing for HIV. In: Gostin L (ed). *AIDS and the Health Care System*. New Haven: Yale University Press, 1990, at 115; Gerberding J et al. Risk of exposure of surgical personnel to patients' blood during surgery at San Francisco General Hospital. *New England Journal of Medicine* 1990; 322: 1788.

[368] Korniewicz DM et al. Barrier protection with examination gloves: double vs. single. *American Journal of Infection Control* 1994; 22(1): 12-15.

careful adherence to universal precautions could end up putting the health professional at higher risk of infection, as well as putting the patient at risk of infection from the health-care worker.

- It can result in poor medical practice: discrimination encourages patients to conceal their HIV-positive status (if testing is not routinely done on all patients) and/or their risk activities (if testing is done only on those deemed to be at risk of infection). This undermines full disclosure of information to health-care professionals that is potentially relevant to decisions about optimal treatment for that patient.
- Finally, HIV testing of patients will often be a prelude to illegal discrimination in the provision of medical services, by health-care professionals who refuse to treat patients who test positive. Unfortunately, discriminatory refusal of treatment by health-care professionals persists in Canada,[369] although refusing to treat a patient in need of medical attention – certainly when there is no significant risk to the provider – breaches the professional obligation of health-care workers. The Canadian Medical Association and the Canadian Dental Association have both adopted policy statements regarding their members' obligations to treat patients with HIV/AIDS.[370] In addition, there is Canadian judicial authority that the refusal to provide medical treatment to a person living with HIV or AIDS amounts to prohibited discrimination on the basis of disability.[371] Similarly, several human rights commissions have adopted policy statements indicating that refusing medical treatment to people with HIV/AIDS is prohibited discrimination.[372] The US Supreme Court has also ruled that a dentist who refused to treat an HIV-positive woman violated the federal *Americans with Disabilities Act*, which prohibits discrimination based on disability.[373]

Conclusion

Rapid HIV screening of patients before medical care is provided to them (or of inmates in correctional institutions) would not be justified. In order to reinforce that testing can only be undertaken with the informed, specific consent of the person being tested, colleges of health-care professionals, and health-care professionals' associations, should adopt (or update, as the case may be) regulations and/or policies governing their members and their members' practice that: (1) unequivocally state that performing HIV testing without informed consent, or pressuring or coercing patients into testing, is unethical, could give rise to civil or criminal liability, and amounts to professional misconduct that may carry disciplinary sanctions; (2) specifically state that rapid HIV testing technology does not remove the requirement for informed consent to testing; and (3) require a patient's informed consent to HIV testing to be recorded in writing. These regulations and/or policies should be communicated to their members.

A Slippery Slope?

Another concern that has been voiced is that the introduction of rapid HIV screening could lead to home testing, which raises additional serious legal and ethical questions.[374] Hoffmaster writes:

> Would the introduction of rapid POC screening lead to home testing? Would it start an irreversible slide down a slippery slope?

[369] For example, see: McCarthy GM et al. Factors associated with refusal to treat HIV-infected patients: the results of a national survey of dentists in Canada. *American Journal of Public Health* 1999; 89(4): 541, reporting that 16 percent of Canadian dentists surveyed would refuse to treat HIV-positive patients. See also de Bruyn T. *HIV/AIDS and Discrimination: A Discussion Paper*. Montréal: Canadian HIV/AIDS Legal Network & Canadian AIDS Society, 1998.

[370] Canadian Medical Association. CMA Position: Acquired immunodeficiency syndrome. *Canadian Medical Association Journal* 1989; 140: 64a; Canadian Medical Association. HIV infection in the workplace. *Canadian Medical Association Journal* 1993; 148(10): 1800A; Canadian Dental Association. Statement on the Ethical and Legal Considerations of Treating Patients with Infectious Diseases. Ottawa: The Association, 3 April 1988.

[371] *Hamel* v *Malaxos* (25 November 1993), Joliette 730-32-000370 929 (Quebec Small Claims Court), unreported.

[372] Eg, see: Carpentier D. *Refus de soins dentaires à une personne porteuse du VIH*. Commission des droits de la personne du Québec, 1992 (Cat 120-12); Canadian Human Rights Policy on HIV/IDS, June 1996 (available at <www.chrc-ccdp.ca>); Ontario Human Rights Commission. Policy on HIV/AIDS-Related Discrimination (available at <www.ohrc.on.ca>).

[373] *Bragdon* v *Abbott*, 118 S Ct 2196 (1998). See also discussion thereof in: Annas GJ. Protecting patients from discrimination – the Americans with Disabilities Act and HIV infection. *New England Journal of Medicine* 1998; 339: 1255-1259; Gostin L, Feldblum C, Webber D. Disability discrimination in America: HIV/AIDS and other health conditions. *Journal of the American Medical Association* 1999; 281: 745-752.

[374] For an analysis and recommendations, see Jürgens, supra, note 4 at 91-111.

> There are two variants of slippery-slope arguments, one conceptual and one causal [reference omitted]. According to the conceptual version, home testing is not, in principle, distinguishable from rapid POC screening. There are not, in other words, any morally relevant differences between the two kinds of testing; thus, if rapid POC screening is morally permissible, so is home testing. That argument is easy to rebut because there is a glaring, morally relevant difference between rapid POC screening and home testing – home testing could occur without either the pre-test counseling or the post-test counseling that is essential to a responsible testing program, and in the absence of trained professionals who can interpret test results and explain what they mean. Whatever benefits home testing seems to offer might well be offset by the harms that would result from allowing testing to occur in the absence of counseling. So logically or conceptually, rapid POC screening *does not* entail home testing. But reason does not always, or perhaps even frequently, prevail in the world. Regardless of whether rapid POC screening and home testing are morally distinguishable, licensing rapid POC screening might, in practice, lead to the introduction of home testing. That is what a causal version of the slippery-slope argument contends.
>
> Causal slippery-slope arguments are, however, notoriously difficult to assess because the empirical claims on which they rest are often speculative. What would the causal links between the acceptance of rapid POC screening and the consequent introduction of home testing be, and how likely is it that these connections would actually occur? Would the practice of rapid testing, and the expedited, cursory counseling that could accompany it, soften our attitudes about the necessity of counseling for all HIV testing? Would the economic or political interests marshaled behind rapid POC testing subsequently coalesce behind home testing, despite previous dismissals of the concern that approving rapid POC screening could lead down a slippery slope to home testing? It is hard to envisage precisely what the causal mechanisms might be. But uncertainty about *how* rapid POC screening might pave the way to home testing then breeds uncertainty *that* rapid POC screening would in fact pave the way to home testing. That is the weakness of a causal slippery-slope argument.
>
> In theory, that weakness must be acknowledged. Yet the practical worry this argument encapsulates is hard to shake. If testing is good, and if rapid POC screening makes testing easier and more accessible, then why not home testing, which would make testing easier still and even more accessible? That reasoning could be practically and politically persuasive, the ethically qualitative differences between rapid POC screening and home testing notwithstanding.[375]

There is a real threat that technology will drive what type of testing will be available in Canada, and how testing will be done, rather than a careful consideration of risks and benefits, informed by solid scientific research, that

[375] Hoffmaster, infra, Appendix A at A15-16.

balances an individual's human rights and society's need to maintain public health. Broad discussion and consultation about the legal and ethical issues raised by home testing need to start immediately. In addition, however, more research in the area of HIV testing must be funded, so that we acquire solid, systematic, and comprehensive data about testing and counseling, as well as about barriers to testing and counseling. As Hoffmaster has pointed out, unless we do so, "the same difficulty [as with rapid screening] will plague all future developments in HIV testing technology."[376] This must include careful investigation, evaluation, and monitoring of the experience with rapid HIV screening at the point of care. Finally, as has been recommended by the Expert Advisory Committee on HIV Therapies, greater transparency by industry and regulators in the process of submissions, review, and approval of products (which would include medical devices) is required, including opportunities for industry "to share and discuss with the regulator the information presented to [it], in the presence of consumer and health care representatives."[377]

Conclusions

While there are potential advantages of using rapid HIV screening at the point of care, there are also many concerns. These range from concerns about the implications of disclosing positive screening results when, particularly in low-prevalence settings, the positive predictive value of the test is low; to concerns that people undergoing rapid HIV screening will not receive adequate counseling (particularly people who receive a positive screening result, for whom provision of best-practice counseling and support is essential); to concerns that some of the health-care professionals that may end up being authorized to administer the test kits would not adequately protect confidentiality; to concerns that women in labour whose HIV status is unknown may be screened without providing informed consent; to concerns that in a variety of other situations there will be a push for testing without informed specific consent. These concerns are serious. They must be addressed. In particular:

- wherever rapid HIV screening at the point of care is offered, this must be accompanied by accelerated access to confirmed test results, and support services must be easily accessible for people who receive a positive screening result;
- quality pre- and post-test counseling must be ensured for all HIV testing; in particular, because of the need to ensure that all people who receive a positive screening result have received best-practice counseling, only health-care professionals who have undergone a training program, including on how to provide counseling using rapid HIV screening tests, should be allowed to use such tests;
- the availability of rapid test kits does not remove the requirement for specific informed consent to HIV testing. Professional codes of conduct, ethical consciousness, and Canadian law require consent to HIV testing. In order to reinforce that testing can only be undertaken with the specific informed consent of the person being tested, colleges of health-care professionals, and health-care professionals' associations, should adopt (or update) regulations and/or policies to that effect;

[376] Ibid at A17.

[377] Expert Advisory Committee on HIV Therapies. Minutes of Meeting of May 8, 1998. Available at <www.hc-sc.gc.ca/ hpb-dgps/ therapeut/htmleng/advcomm_eachiv.html>.

- rapid screening should initially only be offered to women in labour whose HIV status is unknown, in those settings where its use can be monitored and its results can be evaluated; in addition, efforts need to be improved to ensure that *all women* have access to HIV testing services, and that all women considering pregnancy or already pregnant be routinely offered voluntary HIV testing, with quality pre- and post-test counseling; and
- more research in the area of HIV testing must be funded, so that we acquire solid, systematic, and comprehensive data about testing and counseling, as well as about barriers to testing and counseling. This must include careful investigation, evaluation, and monitoring of the experience with rapid HIV screening at the point of care.

Implications: Regulating the Use of Rapid HIV Screening Kits

The previous sections in this chapter have detailed many of the concerns that have been raised about rapid HIV screening at the point of care. Many, although not all, of these concerns are related to *who* could potentially administer these tests.

There would be little concern if the test was administered by a test provider in a testing clinic, particularly if that provider had received training in how to administer and apply the tests, and in how to provide counseling using such tests; and if the clinic was able to provide support to a person who screened positive, as well as a confirmed test result within two days.

But there would be concern if the test was administered by a physician who had little experience with HIV testing and counseling, no training specifically about the rapid screening kits, and no ability to guarantee the support that a person screening positive may need. Research has shown that many physicians do not provide adequate counseling, although law and ethics require that testing not be undertaken without it and there are counseling guidelines that have been widely distributed. There is no reason to believe that a label on the kit requiring counseling and explaining the limitations of the rapid screening tests would be sufficient to prevent testing without adequate counseling, which, as explained above, is of particular concern in the context of rapid HIV screening because of the low positive predictive value of the test. These same concerns would arise if rapid testing was being done by health-care professionals who currently do not administer HIV testing.

It is for these reasons that regulating the use of rapid HIV screening tests is so important. Testing, and increasing access to testing, is not good per se. Although the potential benefits of testing have significantly increased over the last decade,[378] many of them will only be realized if *quality* testing and counseling that maximize the benefits of testing while minimizing the potential harms are undertaken.

The Current Situation

Health Canada has indicated that the two manufacturers with current applications for licences for rapid HIV screening tests are seeking permission to sell these devices for "point-of-care" use only – that is, use by a "health-care professional." Health Canada has also indicated that, as the regulatory body, this is all that it is currently contemplating.[379] As has been noted above,[380] under the

[378] For a detailed account, see Jürgens, supra, note 4 at 11-17.

[379] Personal communications with M Carballo, 20 October 1999; 13 December 1999; 21 December 1999.

[380] Supra, the section on "Labeling Requirements."

Medical Devices Regulations, "health-care professional" is defined as "a person who is entitled under the laws of a province to provide health services in the province."[381]

In Health Canada's view, it lacks the jurisdiction to draw any further distinctions within the category of "health-care professional."[382] The result is that provincial/territorial legislation defining "health services" and those who are entitled to provide them may end up defining the parameters of who is legally permitted to administer rapid HIV screening tests. These provisions vary from jurisdiction to jurisdiction – giving rise to concerns about different standards of care. Because in most cases health-care professionals are self-regulating, this is reflected in provincial/territorial statutes that delegate (or at least share) with professional regulatory bodies (ie, the College or equivalent body of each profession) the authority to establish legally binding codes of conduct and standards of practice.

Provincial/territorial legislation defining "health services" and those who are entitled to provide them will end up defining the parameters of who is legally permitted to administer rapid HIV screening tests.

Defining "health-care professional"

It is not possible to canvass here each jurisdiction's legislation governing health-care professionals, so a few examples must suffice:

- In British Columbia, "health profession" means a profession "in which a person exercises skill or judgment or provides a service related to the preservation or improvement of the health of individuals, or the treatment or care of individuals who are injured, sick, disabled or infirm."[383] Recognized health professions include practitioners ranging from physicians and surgeons, registered nurses, dental technicians, and psychotherapists, to pharmacists, naturopaths, chiropractors, massage therapists, and optometrists.[384]
- In Alberta, the *Medical Profession Act* applies to "medical practitioners" and "practitioners of osteopathy," governed by the provincial College of Physicians and Surgeons.[385] However, other "designated health disciplines" are governed by the *Health Disciplines Act*, which includes practitioners such as respiratory therapists, acupuncturists, psychiatric nurses, medical laboratory technologists, midwives, emergency medical technicians, mental deficiency nurses, and orthotists and prosthetists.[386]
- Under Ontario's *Regulated Health Professions Act, 1991*, members of 23 self-regulating disciplines are defined as members of a "health profession," ranging from medicine, nursing, midwifery, dentistry, psychology, and medical laboratory technology, to optometry, dietetics, occupational therapy, chiropractic and massage therapy.[387] All these professions are subject to some common governance and discipline laws.[388] However, each profession is also governed by its own statute, which sets out those acts that a registered member of the profession is entitled to perform in providing health-care services.

Regulating practice by health-care professionals

While varying in language and approach, legislation in each province or territory generally contains a prohibition on someone who is not a registered or recognized member of a health profession from providing health-care services. For example, Ontario's *Regulated Health Professions Act, 1991* (RHPA, 1991) prohibits anyone from performing a "controlled act" unless they are

[381] MDR, s 2 ("health care professional").

[382] Personal communication with M Carballo and D Lepine, Medical Devices Bureau (Health Canada), 20 October 1999.

[383] *Health Professions Act*, RSBC 1996, c 183, as amended.

[384] *Health Professions Regulation*, BC Reg 237/92 as amended.

[385] *Medical Profession Act*, RSA 1980, c M-12, s 18(1).

[386] *Health Disciplines Act*, RSA 1980, c H-3.5, s 1 & Schedule.

[387] SO 1991, c 18, s 1 ("health profession") & Schedule 1.

[388] RHPA, 1991, Sch 2 (Health Professions Procedural Code). This Code is incorporated by reference into each statute governing a regulated health profession.

authorized by one of the statutes governing health professionals (or have had the act delegated to them by an authorized health professional.)[389] Breaching this prohibition is an offence carrying a maximum penalty of a $25,000 fine, six months' imprisonment, or both.[390] The definition of "controlled act" includes the following provisions of relevance to HIV testing:

- communicating a diagnosis of disease in circumstances in which it is reasonably foreseeable the person will rely on the diagnosis;
- performing a procedure on tissue below the dermis;
- putting an instrument into "an artificial opening into the body."[391]

However, beyond the broad boundaries set out by this statute, in Ontario as in other jurisdictions, the regulation of health professionals' practice is generally left to the governing body of the profession itself.

For example, under Ontario's statute, each profession's College regulates the members of that profession and establishes and maintains standards of practice.[392] In carrying out these tasks the College has a duty to serve and protect the public interest.[393] The College is empowered to establish ethical codes, and to make regulations prescribing standards of practice of the profession and prohibiting members from acting beyond the scope of practice of the profession.[394] Furthermore, any regulation setting out a standard of practice may adopt by reference any code, standard, or guideline relating to standards of practice and may require compliance with these as part of the standard of practice.[395] The College is also empowered to make regulations requiring members to participate in continuing education programs.[396]

This means that if a College were to issue – as they have – a regulation stating that HIV testing without consent is not permissible, or that testing should be done in accordance with the CMA Guidelines, then this becomes a legally binding standard of practice on physicians. Even without such an explicit statement of practice requirements, such a standard may nonetheless become legally binding as a matter of common law because it is accepted as "the standard" that a reasonably knowledgeable and skilled practitioner must satisfy in order to not be negligent – but this requires a civil action and a court making such a finding to be sure that the practice is a matter of law.

Technical quality control

In Ontario, all private laboratories are required to establish a quality control program,[397] and the provincial Cabinet may make regulations designating an agency or agencies to carry out examinations and evaluations of proficiency in the performance of tests in private laboratories, and establish a committee to obtain advice in setting standards and procedures for such evaluation.[398] (In practice, the province's public health laboratories are subject to the same requirements.[399]) However, any legally qualified medical practitioner who does laboratory tests for the exclusive purpose of diagnosing or treating their own patients in the course of medical practice (and any laboratory operated by a provincial ministry) is exempt from these requirements under the *Laboratory and Specimen Collection Centre Act* (and the regulation on "laboratories" made under it).[400]

As has been noted above, this raises significant concerns about how to ensure quality controls are observed for testing done by a variety of health-care

[389] RHPA, 1991, s 27(1). See also College of Physicians and Surgeons of Ontario. Policy Statement: The Delegation of Controlled Acts. September 1999, available at <www.cpso.on.ca>. For other examples, see: College of Physicians and Surgeons of British Columbia. Delegation of a Medical Act. Policy Manual, Chapter D-1. June 1995, available at <www.cpsbc.ca>; College of Physicians and Surgeons of Manitoba. Delegation of Clinical Function to the Registered Nurse (Guideline 132), available at <www.umanitoba.ca/cgi-bin/colleges/cps/college.cgi/132.html>.

[390] RHPA, 1991, s 40(1).

[391] RHPA, 1991, s 27(2). However, taking a blood sample from a patient's vein or by skin pricking is exempt from the Act's prohibition on "controlled acts" if the person taking the blood sample is employed by a licensed (private) laboratory or specimen collection centre: O. Reg 107/96 ("Controlled Acts"), s 11, with reference to *Laboratory and Specimen Collection Centre Act*, RSO 1990, c L.1 (LSCCA). This means that an authorized health professional, or an employee of a laboratory or specimen collection centre, can administer an HIV test (standard venipuncture or rapid fingerprick). However, communicating the results and diagnosis to the person being tested would still only be legally performed by a member of a "health profession."

[392] RHPA, 1991, Sch 2 (Health Professions Procedural Code), s 3.

[393] Ibid.

[394] Ibid, ss 94(1)(k), 95(1)(n).

[395] Ibid, s 95(1.1).

[396] Ibid, s 95(2.1).

[397] RRO 1990, Reg 682, s 9.9(1)(d).

[398] LSCCA s 18(r), 19-20. The Ontario Medical Association has been so designated: RRO 1990, Reg 682, s 14.

[399] Personal communication with C Major, [Ontario] Central Public Health Laboratory, 1 March 2000; [Ontario] Central Public Health Laboratory, supra, note 248.

[400] RRO 1990, Reg 682, s 11, 13.

professionals at the point of care.[401] In light of these concerns, each province or territory – which has the responsibility for regulating laboratory standards – needs to carefully consider how it will ensure that HIV testing done at the point of care will meet quality control standards regarding:

- the administration and interpretation of the rapid test;
- the release of product lots for use in point-of-care testing that have met performance standards; and
- reporting of any problems with performance of test kits to manufacturers, provincial authorities responsible for laboratory quality assurance, and federal regulators.

Provincial health insurance plans

Could provinces use their jurisdiction over public health insurance plans to regulate the use of medical devices such as rapid HIV screening kits?

Could provinces use their jurisdiction over public health insurance plans to regulate the use of medical devices such as rapid HIV screening kits? While this would be a less direct means of regulating their use, relying as it does on financial disincentives, it would likely have a significant impact on the degree to which rapid screening would be available in a province.

The Canadian public health-care system is not a single, national system; rather it consists of ten provincial and three territorial health insurance plans.[402] These systems are loosely connected by way of the *Canada Health Act*,[403] in which the federal government sets out the "national standards" that each such plan must meet in order to be entitled to funding from the federal government. The CHA sets out five criteria "in respect of insured health services and extended health care services provided under provincial law"[404] that must be satisfied before the federal government must make a full financial contribution to health expenditures in that province. Those criteria are comprehensiveness, accessibility, universality, portability, and public administration.[405]

In order to meet the comprehensiveness criterion, the provincial health insurance plan must "insure all insured health services provided by hospitals, medical practitioners or dentists, and where the law of the province so permits, similar or additional services rendered by other health care practitioners."[406] In order to satisfy the CHA criterion regarding accessibility, the provincial plan must provide for (1) payment for insured health services in accordance with a tariff or system of payment established by provincial law; (2) "reasonable compensation" for all insured health services rendered by medical practitioners or dentists; and payments to hospitals in respect of the cost of insured health services.[407]

The CHA also prohibits the provinces from allowing patients to be personally charged for "insured health services" through "extra billing" or "user charges" – that is, it requires that these services be covered by the province's public health insurance plan.[408] "Insured health services" are defined as "medically necessary" or "medically required" hospital services, physician services, and surgical-dental services that are required to be performed in a hospital.[409]

However, the CHA does not define "medically necessary" and "medically required." What this means in practice is that each province has ended up defining the parameters of what it considers "medically necessary" health services that will be covered by its public health insurance plan. And as Flood points out, this "has historically resulted in leaving physicians to determine what health services to supply to whom."[410] However, it ultimately remains the

[401] See section above on "Concerns about Rapid HIV Screening at the Point of Care."

[402] For an excellent overview of this topic, see Flood, supra, note 126 at 5-50.

[403] RSC 1985, c C-6.

[404] Ibid, s 4.

[405] Ibid, s 7.

[406] Ibid, s 9.

[407] CHA, supra, s 12.

[408] Ibid, ss 2, 12, 18-20.

[409] Ibid, s 2. These prohibitions on extra billing and user charges do not apply to "extended health services," nor do the five criteria apply to these services.

[410] Flood, supra, note 126.

Rather than relying on the indirect incentives achievable through provincial health insurance plans, a better approach would be to directly regulate the conditions of sale and use of rapid HIV test kits.

task of a provincial government to determine which services it deems "medically necessary" services that will be covered by its health insurance plan. (The federal government may also play a role in determining which services are "medically necessary," by withholding federal funding from a province if the province's failure to cover that service means its plan does not meet the comprehensiveness criterion required by the CHA.)

There is no doubt that HIV testing is a "medically necessary" service. The question is: should rapid HIV testing be considered medically necessary? Provincial governments that do not provide for reimbursing the cost of these test kits out of provincial health plans will create a financial disincentive for physicians and hospitals to make them available for widespread use in providing HIV testing to patients. But this will not prevent a physician or hospital from purchasing and using such tests (in accordance with the conditions of licensing and labeling imposed by Health Canada) and providing rapid HIV testing to patients. It also remains open for any "health care professional" to purchase rapid test kits, absent any more specific restrictions by either federal or provincial/territorial governments regarding the conditions of sale.

However, excluding rapid test kits from provincial health plan coverage would mean that either the physician/hospital or the patient would have to bear the cost of the device. And this would probably mean that many physicians and hospitals would be unlikely to purchase these kits for widespread use unless this cost can be passed along to the patient. In the absence of provincial health insurance covering this expense, it would be patient demand, and willingness to pay, for these kits that would determine who can access rapid HIV screening. While this could mean, in practice, that rapid HIV testing would not be widely available, it could also mean different standards of care in HIV testing based on ability to pay.

Rather than relying on the indirect incentives achievable through provincial health insurance plans, a better approach would be to directly regulate the conditions of sale and use of rapid HIV test kits. The regulatory framework of federal and provincial laws applicable to rapid HIV test kits, and the standard-setting functions of health-care professionals' regulatory bodies, have been identified above. The next section considers how these regulatory powers could and should be used to ensure that their potential benefits are maximized and the potential harms from misuse are prevented or minimized.

What Needs to Happen?

Federal regulation of "conditions of sale"

As noted above, Health Canada, as the country's federal regulatory agency, takes the position that, when licensing rapid HIV screening kits for point-of-care use by "health care professionals only," it lacks the jurisdiction to draw any further distinctions within the category of "health-care professional."[411] However, the *Food and Drugs Act* (FDA) also authorizes the federal Cabinet to enact regulations respecting:

> the labelling and packaging and the offering, exposing and advertising for sale of ... devices, ... and *the sale or the conditions of sale of any ... device*, to prevent the purchaser or consumer thereof from being deceived or misled in respect of the ... performance, intended

[411] Supra, note 382.

> use, character, ... merit or safety thereof, or to prevent injury to the health of the purchaser or consumer; and
>
> requiring persons who sell ... devices to maintain such books and records as the Governor in Council [ie, Cabinet] considers necessary for the proper enforcement and administration of this Act and the regulations.[412]

If federal regulators do not wish to interpret the existing provisions regarding "safety and effectiveness requirements" in the Medical Devices Regulations more broadly than assessing only the technical performance of a device, this provision in the FDA is broad enough to permit Cabinet to make regulations restricting the sale of medical devices beyond simply labeling them as being "for professional use only." It permits the federal regulatory authority to impose a variety of conditions – whether this be restricting the sale of rapid test kits to only certain specified "health-care professionals," or limiting their sale to particular sites where training in proper counseling and the use of test kits is demonstrated, etc.

Rapid HIV test kits have illuminated a problem with the current regulatory system and suggest the need for additional attention to this area .

Because of the potential harms to the health of people that could result from administration of rapid HIV screening kits by certain health-care professionals, the federal Cabinet should exercise its regulatory authority under the FDA to restrict the sale of rapid HIV test kits to physicians, nurses and other "health-care professionals" who are certified by either their professional regulatory body or by provincial authorities providing such training as having received adequate training in pre- and post-test counseling and the proper administration of such devices.

In addition, it should be remembered that rapid HIV screening kits are a Class IV medical device under the Medical Devices Regulations. To date, no Class IV medical device has been licensed in Canada for point-of-care use. As such, rapid HIV test kits have illuminated a problem with the current regulatory system and suggest the need for additional attention to this area to keep Canada's legislative regime governing the approval of medical devices up to date and reflective of an approach to HIV testing that is appropriate in the Canadian context.

At a minimum, as has been recommended by the Expert Advisory Committee on HIV Therapies, greater transparency by industry and regulators in the process of submissions, review and approval of medical devices is required, including opportunities for industry "to share and discuss with the regulator the information presented to [it], in the presence of consumer and health care representatives."[413]

Provincial/territorial regulation

Should the federal Cabinet decide not to exercise its regulatory authority under the FDA to restrict the sale of rapid HIV test kits, provinces and territories would have to act swiftly to ensure appropriate regulation. In particular, they should:

- establish, in consultation with community-based organizations, health-care professionals, and current HIV counseling and testing providers, which "health care professionals" entitled to provide health services in their province shall be permitted to administer a rapid HIV test;

[412] FDA, s 30(1)(b), (f) [emphasis added].

[413] Expert Advisory Committee on HIV Therapies. Minutes of Meeting of May 8, 1998. Available at <www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/advcomm_eachiv.html>.

- restrict the use of rapid HIV screening tests to those who have received adequate training in pre-and post-test counseling and the proper administration of such devices; and
- phase in the use of rapid HIV tests by providing them first as an option in specific sites (where quality control, appropriate training, and quality counseling are guaranteed), followed by evaluation of the experience.

Governments must exercise their regulatory authority to ensure that rapid test kits are only available in those settings and under those conditions in which their benefits will be most likely realized and the potential misuses prevented.

Provincial/territorial health-care professionals' regulatory bodies also have a role to play in this regard, given the delegation of regulatory powers to them by provincial governments. Each College of health-care professionals may approach this function somewhat differently in formulating guidelines and policies, but should nonetheless ensure that it is clearly articulated to their members that the standards of professional practice require training in the administration of HIV testing and in the provision of quality pre- and post-test counseling.

Responding to unlicensed use of rapid test kits

The decentralized distribution of rapid HIV test kits raises a concern about the development of possibly illegal distribution (including sale for profit) of rapid HIV test kits for use outside point-of-care settings. Of particular concern would be the increased potential for a kit to be used to test people without their consent, should the kits be available be people other than health professionals who are subject to ethical codes and legal standards of professional conduct. Any such illegal sale (in breach of labeling restrictions specifying for "professional use only") violates section 20 of the FDA, carrying the penalties discussed above.[414] Instances of using rapid test kits to test people for HIV without their consent require prompt responses by regulators to prevent such abuses.

Conclusion

Governments must exercise their regulatory authority to ensure that rapid test kits are only available in those settings and under those conditions in which their benefits will be most likely realized and the potential misuses prevented. This means ensuring quality pre- and post-test counseling, adequate training of test providers, and determining which health-care professionals shall be legally permitted to administer rapid HIV tests. It also means that health-care professionals' regulatory bodies and professional associations must articulate standards of practice for the use of rapid HIV test kits and accompanying counseling, and hold test providers accountable if and when these standards are not met. Finally, federal and provincial authorities must ensure that the restrictions placed on the use of rapid test kits to ensure maximum benefit and minimum harm are actually enforced, by responding decisively and swiftly to breaches of these conditions.

[414] See supra, the section on "Approval of Medical Devices for Sale in Canada."

Summary of Conclusions and Recommendations

> We know that the HIV test is an enormously effective public health tool, but it's only effective when deployed in ways that are socially, politically, and medically appropriate. If it's not, it can actually be a detriment to public health.[415]
>
> Although we know a lot about preventing HIV disease, we tend to focus our hopes on technological fixes. Many of these hopes have been disappointed and have prevented us from taking a look at the kind of social, behavioral, and preventive programs that could have a very positive effect right now.[416]
>
> [A]lthough circumstances of treatment and ongoing assessment may be changing, the circumstances necessary to ensure ethical observance of testing procedures have not. Physicians are ethically required to offer testing as an option for those who are concerned about their lifestyle history or state of health; the patient can and must still choose whether or not to be tested in the light of available information and their own situation.[417]

Early in the HIV/AIDS epidemic, a concerted effort was made to address the issues surrounding HIV-antibody testing and confidentiality in a way that would respect the human rights of individuals, yet at the same time promote the goals of protecting public health. In particular, in Canada a broad consensus emerged that, except in a few well-defined circumstances, people should be tested only with their informed, voluntary and specific consent; when

[415] Brandt A, Professor of the History of Medicine at Harvard Medical School, cited in Abrams S. Mandatory HIV testing: the search for a quick fix. *Harvard AIDS Letter* May/June 1995.

[416] Ibid.

[417] Miller A, Pinching AJ. HIV tests and counseling: current issues. *AIDS* 1989; 3(Suppl 1): S187-S192 at S191.

We need to be open to the challenges posed by the new developments and test our deeply held beliefs.

Canada must re-commit to *quality* testing and counseling.

counseling and education before and following testing are available and offered; and when confidentiality of results or anonymity of testing can be guaranteed. This consensus was expressed in recommendations such as those prepared by the National Advisory Committee on AIDS,[418] which provided an ethical framework for evaluating testing policy based on a careful consideration of the inherent costs and benefits of testing to the individual and to society.

In the past few years, new testing technologies, in particular the availability of home testing kits and rapid testing, new treatments, and changing patterns of HIV infection have forced us to reconsider approaches to HIV testing. In the context of rapid testing, this means questioning whether we should continue to always only give out confirmed test results, or whether there should be situations in which a non-confirmed test result can be given to the person being tested and, if yes, how. We need to be open to the challenges posed by the availability of rapid HIV screening and test our deeply held beliefs. However, we must do so without forgetting the lessons learned over the last 20 years and without forgetting that, because HIV/AIDS continues to disproportionately impact on marginalized populations, leading to discrimination against those infected and affected, it remains different from other diseases. In particular, the new treatments constitute a huge step forward, but do not represent a solution to all problems faced by people with HIV or AIDS – problems that stem from the underlying problems of poverty and discrimination that are both a result and a cause of HIV infection. Therefore, while encouraging people to voluntarily test for HIV must indeed be a priority, we must not forget that

> the testing at issue here is testing for HIV, a disease that, to revert to Levine and Bayer's still timely warning, "continues to have a social and cultural impact far beyond the numbers of people affected" [reference omitted]. Although the notion of "AIDS exceptionalism" is controversial, it remains valuable insofar as it highlights the stigmatization and discrimination that continue to afflict people with HIV/AIDS.[419]

As Hoffmaster puts it, a "worry about rapid screening is that it would promote the "normalization" of HIV testing, that is, treat it the same as testing for any other disease or condition, when the social contexts within which HIV testing takes place and the social realities with which people who test positive live are just not the same."[420] Rather than leading to an abandonment of the requirement that HIV testing should only be undertaken with the informed consent of the person being tested, with pre-and post-test counseling, and when confidentiality of test results can be guaranteed, the introduction of rapid testing must become an opportunity to reaffirm those principles, so that the benefits of HIV testing are maximized, while the potential harms are minimized. Canada must re-commit to *quality* testing and counseling.

Overall, the advent of rapid HIV screening tests offers some benefits. However, a number of concerns and uncertainties about their use must be addressed. Additional research is required in areas such as "non-return rates," the reasons people seek HIV testing, and the experience of HIV counseling and testing for both recipients and providers (and for particular populations, such as pregnant women), both when following the standard testing procedure and

[418] See supra, note 346.

[419] Hoffmaster, infra, Appendix A at A18, with reference to Levine C, Bayer R. The ethics of screening for early intervention in HIV disease. *American Journal of Public Health* 1989; 79: 1661.

[420] Ibid.

when using rapid screening kits. Governments must exercise their regulatory authority to ensure that rapid test kits are only available in those settings and under those conditions in which their benefits will be most likely realized and the potential misuses prevented.

Recommendations

Licensing and Labeling

1. In issuing any licence for any medical device to perform rapid HIV testing, Health Canada (Medical Devices Bureau) should require clear labeling indicating that
   - the device may only legally be sold to or used at a laboratory or by a health-care professional as permitted by applicable federal or provincial/territorial law;
   - its use must be "accompanied by pre- and post-test counseling in accordance with accepted professional standards"; and
   - it may not be sold or represented as being for any other use and, in particular, not for personal or home use.

   In addition, Health Canada should require that the device be distributed with accurate, accessible, plain-language material explaining the possibility of false-negative and false-positive results, the need for repeat testing for those who test HIV-negative but may be in the process of seroconverting, and the need for confirmatory testing for those who test HIV-positive.

2. The federal Cabinet should exercise its regulatory authority under the *Food and Drugs Act* to restrict the sale of rapid HIV test kits to physicians, nurses, and other "health-care professionals" who are certified by either their professional regulatory body or by provincial authorities providing such training as having received adequate training in pre- and post-test counseling and the proper administration of such devices.

3. Health Canada should take steps to ensure that, as has been recommended by the Expert Advisory Committee on HIV Therapies, greater transparency by industry and regulators in the process of submission, review, and approval of products (including medical devices) is achieved, including opportunities for consumer and health-care representatives to participate in discussions of information presented by industry to government regulators.

Post-Approval Monitoring

4. Health Canada should strike a working group to monitor the introduction of rapid HIV tests, to ensure they are properly regulated, and to ensure that proper policies and guidelines for their use are developed, including developing a national standard of care with respect to counseling and rapid HIV screening at the point of care. This working group should, at a minimum, include representation from people with HIV/AIDS, community-based organizations working in HIV/AIDS, primary care physicians and nurses, HIV counseling and testing providers, the Federal/Provincial/ Territorial Committee on AIDS, the Canadian Society for Medical Laboratory Science, the Canadian Medical Association, Health Canada's Medical Devices Bureau, and Health Canada's Laboratory Centre for Disease Control.

5. Federal and provincial authorities should ensure that any person who sells or distributes a rapid HIV test kit contrary to the conditions of its licence, or for use contrary to its labeled or permitted use, is subject to the penalties provided for illegal dealing with a medical device in the *Food and Drugs Act*.

6. Provincial/territorial governments should develop regulations, protocols, or policies to ensure that HIV testing done at the point of care will meet technical quality control standards regarding:
   - the administration and interpretation of the rapid test;
   - the release of product lots for use in point-of-care testing that have met performance standards; and
   - reporting of any problems with performance of test kits to manufacturers, provincial authorities responsible for laboratory quality assurance, and federal regulators.

Research

7. Manufacturers of HIV testing devices, and federal and provincial governments, should fund research
   - to obtain demographic data regarding rates of return to receive test results under the standard testing system, including data differentiating between testing sites/providers, and additional research to determine the reasons for not returning to receive results;
   - to obtain demographic data regarding who accesses rapid HIV screening and why; and
   - to assess the testing and counseling experience using rapid HIV screening, for both counselors and those getting tested, which should inform the development of counseling guidelines constituting a national standard of practice for rapid HIV screening at the point of care.

8. Manufacturers of HIV testing devices, and federal and provincial governments, should fund specific research
   - to determine the reasons why some women (including pregnant women) continue to find it difficult to access HIV testing, are not offered HIV testing, refuse testing, or do not return for test results; and
   - to assess the use of rapid HIV testing for women in labour, establish its accuracy for pregnant women, and assess the process of making decisions regarding interventions to prevent perinatal transmission, which research should include the experiences of women, those providing the testing to them, and their attending health-care professionals.

9. Manufacturers of HIV testing devices, and federal and provincial governments, should fund specific research into the feasibility and accuracy of using combinations of different rapid screening tests in point-of-care settings, so as to assess whether it is possible to deliver a same-day testing procedure as accurate as the current, standard laboratory-based procedure of a screening test followed by confirmatory testing with a more sensitive test. This could reduce the number of false positive and negative results from a testing procedure that involves only one rapid screen.

Education and Training

10. Colleges and universities providing professional education to health-care professionals should include, as mandatory components of their curricula, training in general counseling principles and techniques, and on HIV/AIDS (including psychosocial issues related to HIV/AIDS). The curricula for those health-care professionals likely to encounter patients requesting HIV testing in their practice should also include specific training on HIV test counseling (including using rapid screening tests).

11. Professional associations, regulatory bodies, and/or provincial/territorial health ministries need to provide training and education to health-care professionals in HIV counseling and testing, including how to administer and apply rapid HIV screening tests and how to provide counseling using such tests.

12. Health care professionals' colleges and associations need to ensure their members are aware that they face potential civil liability for the negligent administration and interpretation of rapid HIV tests, and for not following quality control guidelines or standards for point-of-care HIV testing.

Availability of Rapid Screening Tests

13. While not every province/territory may choose to make rapid HIV test kits available (or may differ in how widely they make such kits available), in every jurisdiction where these devices are introduced, their use should be phased in by providing rapid testing as an option in specific sites only (those where quality control, appropriate training, and quality counseling are guaranteed), followed by evaluation of the experience, before proceeding further with their use.

14. The provincial/territorial governments should establish, by way of regulation and in consultation with community-based organizations, health-care professionals, and current HIV counseling and testing providers, which "health-care professionals" entitled to provide health services in their province or territory shall be permitted to administer a rapid HIV test.

15. The provincial/territorial governments should use their regulatory powers, and health-care professionals' regulatory bodies should similarly use their powers, to issue regulations, guidelines, or policies to restrict the use of rapid HIV screening tests to point-of-care settings that ensure:
    - that a person receiving a positive screening test will have accelerated access to a confirmed result, and to support while waiting for the confirmed result; and
    - that those providing testing have received training in how to provide quality pre- and post-test counseling, including how to do counseling accompanying the use of rapid screening tests.

16. Even in the absence of any clear regulations restricting the sale of rapid HIV test kits to certain health-care professionals, manufacturers of such devices should demonstrate responsibility by respecting "guidelines" that may be developed by federal, provincial, or territorial governments or by health-care professionals' associations or regulatory bodies, regarding the appropriate distribution of such devices to qualified health-care professionals.

17. Rapid HIV screening (followed by subsequent confirmatory testing for positive results) should not be the only testing option. Persons getting tested should still be able to get tested following the standard testing algorithm; some may prefer to wait for a confirmed test result, rather than be told a screening result.

Rapid Testing and Preventing Perinatal Transmission

18. Provincial and territorial governments, in conjunction with health-care professionals' associations and regulatory bodies, should improve efforts to ensure that all women have access to HIV testing services, and that all women considering pregnancy or already pregnant be routinely offered voluntary HIV testing, with quality pre- and post-test counseling. Pregnant women should only receive HIV testing with their specific, informed consent.

19. Provinces and territories should phase in the use of rapid HIV screening tests for women in labour whose HIV status is unknown through pilot studies and evaluation, before any decision is made about recommended practice. This process should also be used to develop guidelines on how to counsel women in labour whose HIV status is unknown about HIV testing and possible interventions to reduce the chances of perinatal transmission. In addition, research should include evaluating and developing clinically, legally, and ethically sound practice guidelines for cases where women in labour whose HIV status is unknown do not consent to HIV testing, but consider possible interventions to reduce the chances of transmission.

Preventing Testing without Consent

20. Federal and provincial governments should refrain from enacting any legislation authorizing compulsory HIV testing, including for those accused or convicted of sexual assault or of persons at the source of an occupational exposure. The availability of rapid testing kits does not remove the need for specific, informed consent to testing.

21. Instead of authorizing compulsory HIV testing, and in order to make voluntary disclosure safer for persons who are the source of a potential exposure, federal and provincial governments should ensure that their legislation scrupulously protects the confidentiality of those who disclose their HIV-positive status, and health-care professionals' regulatory bodies should ensure that breaches of patient confidentiality are taken seriously.

22. To deal with the very real concerns of sexual assault survivors regarding possible exposure to HIV, Health Canada, the Department of Justice, Status of Women, and their provincial counterparts, as well as employers, must continue to ensure that best-practice counseling, short- and long-term care, treatment, and other services are made available to sexual assault survivors. Similarly, Health Canada, provincial health authorities, employers, professional associations, and workers' compensation plans should ensure that counseling, testing, treatment, and support services are available to those who may have had occupational exposures to HIV.

23. Colleges of health-care professionals, and health-care professionals' associations, should adopt (or update, as the case may be) regulations and/or policies governing their members and their members' practice that:

- unequivocally state that performing HIV testing without informed consent, or pressuring or coercing patients into testing, is unethical, could give rise to civil or criminal liability, and amounts to professional misconduct that may carry disciplinary sanctions;
- specifically state that rapid HIV testing technology does not remove the requirement for informed consent to testing in every circumstance; and
- require a patient's informed consent to HIV testing to be recorded in writing.

They should communicate these regulations and/or policies to their members.

Bibliography

Statutes, Regulations, & Bills

Bill C-244: *An Act to provide for the taking of samples of blood to detect the presence of certain viruses*, 2nd Sess, 36th Parl, 1999.

Canadian Charter of Rights and Freedoms

Code civil du Québec, Art 11.

Communicable Diseases Act, RSN 1990, c C-26.

Constitution Act, 1867 (UK), 30 & 31 Vict, c 3, reprinted in RSC 1985, App II, No 5.

O. Reg 107/96 ("Controlled Acts")

Criminal Code, RSC 1985, c C-46.

Dependant Adults Act, SS 1989-90, c D-25.1.

Food and Drugs Act, RSC 1985, c F-27.

Health Act, RSBC 1996, c 179.

Health Act, RSNB 1990, c H-2.

Health Act, RSNS 1989, c 195.

Health Act, SYT 1989-90, c 36.

Health Care Consent Act, 1996, SO 1996, c 2.

Health Care (Consent) and Care Facility (Admission) Act, SBC 1993, c 48 [not yet proclaimed in force].

Health Care Directives Act, SM 1992, c 33.

Health Disciplines Act, RSA 1980, c H-3.4.

Health Professions Act, RSBC 1990, c 50.

Health Professions Regulation, BC Reg 237/92

Health Protection and Promotion Act, RSO 1990, c H.7.

Hospitals Act, RSNS 1989, c 208.

Laboratory and Specimen Collection Centre Act, RSO 1990, c L.1

Medical Devices Regulations, SOR/98-282

Medical Practitioners Act, RSBC 1996, c 285.

Medical Profession Act, RSA 1980, c M-12.

The Medical Profession Act, 1981, SS 1980-81, c M-10.1.

Nurses (Registered) Act, RSBC 1996, c 335.

Nursing Act, SO 1991, c 32.

Nursing Profession Act, SA 1983, c N-14.5.

Professional and Occupational Associations Registration Act, SA 1985, c P-18.5.

Public Health Act, RSA 1984, c P-27.1.

Public Health Protection Act, RSQ, c P-35.

Public Health Act, RSNWT 1990, c P.12.

Public Health Act, RSPEI 1988, c P-30.

Public Health Act, RSY 1986, c 136.

The Public Health Act, RSS 1994, c P-37.1.

The Public Health Act, RSM 1987, c P210.

Registered Nurses Act, RSN 1990, c R-9.

The Registered Nurses Act, 1988, SS 1988-89, c R-12.2.

Regulated Health Professionals Act, 1991, SO 1991, c 18.

Rules of Civil Procedure, RRO 1990, Reg 194.

Young Offenders Act, RSC 1985, c Y-1.

Cases

Bragdon v *Abbott*, 118 S Ct 2196 (1998).

Canadian AIDS Society v *Ontario* (1995), 25 OR (3d) 388 (Gen Div); aff'd (1996), 31 OR (3d) 798 (CA); leave to appeal to SCC dismissed 8 May 1997, SCC Bulletin 1997, p 873, noted at 31 OR (3d) 298 (note).

Ciarlello v *Schachter*, [1993] 2 SCR 119.

DC v *Paul Bernardo et al* (23 September 1996), Toronto 93-CQ-46124 (Ont Ct Gen Div, MacDonald J), subsequently reproduced in *DC* v *371149 Ont Ltd (cob Forest Manor)*, [1997] OJ No 2367 (Gen Div, MacDonald J) (QL).

Dobson (Litigation Guardian of) v *Dobson*, [1999] 2 SCR 753.

Eldridge v *British Columbia (AG)* (1997), 151 DLR (4th) 577 (SCC).

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

Hamel v *Malaxos* (25 November 1993), Joliette 730-32-000370 929 (Québec Small Claims Court), unreported.

Hopp v *Lepp*, [1980] 2 SCR 192.

Laporte v *Laganière* (1972), 8 CCC (2d) 343 (Que QB).

Malette v *Shulman* (1990), 37 OAC 281 (CA).

Marshall v *Curry*, [1933] 3 DLR 260 (NSSC).

Mulloy v *Sang*, [1935] 1 WWR 714 (Alta CA).

Murray v *McMurchy*, [1949] 2 DLR 442 (BCSC).

Nancy B v *Hôtel Dieu de Québec* (1992), 86 DLR (4th) 385 (Que SC).

Parmley v *Parmley*, [1945] 4 DLR 81 (SCC).

Pittman Estate v *Bain* (1994), 19 CCLT (2d) 1 (Ont Ct Gen Div).

R v *Beaulieu*, [1992] AQ No 2046 (Court of Québec) (QL).

R v *Collins*, [1987] 1 SCR 265.

R v *Drummond* (1996), 112 CCC (3d) 481 (Ont Ct Prov Div).

R v *Duarte*, [1990] 1 SCR 30 at 46.

R v *Dyment*, [1988] 2 SCR 417 at 431-432.

R v *GDM*, [1988] BCJ No 3056 (Co Ct) (QL).

R v *JPB*, [1992] NWTJ No 207 (Youth Ct) (QL).

R v *Legere* (1988), 43 CCC (3d) 502 (NBCA).

R v *Manning*, [1994] BCJ No 1732 (Prov Ct).

R v *Miller* (1987), 62 OR (2d) 97, 38 CCC (3d) 252 (Ont CA).

R v *Morgentaler*, [1988] 1 SCR 30.

R v *Pohoretsky*, [1987] 1 SCR 945.

R v *Schneider*, [1982] 2 SCR 112.

R v *Sullivan* (1991), 63 DLR (3d) 97 (SCC).

R v *Tomaso* (1989), 70 CR 93d) 152 (Ont CA).

R v *Videoflicks Ltd* (1984), 48 OR (2d) 395.

R v *Wetmore*, [1983] 2 SCR 284.

Re K(LD) (1985), 48 RFL (2d) 164 (Ont Prov Ct).

Reference Re Employment and Social Insurance Act, [1936] SCR 427.

Reibl v *Hughes*, [1980] 2 SCR 880.

Rodriguez v *British Columbia (Attorney General)*, [1993] 3 SCR 519.

Tremblay v *Daigle*, [1989] 2 SCR 530.

Videto v *Kennedy* (1981), 33 OR (2d) 497 (CA).

Walker (Litigation Guardian of) v *Region 2 Hospital Corp* (1994), 116 DLR (4th) 476.

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

Books, Articles, Reports, Abstracts, etc

Abbot Diagnostics. Advertising materials re: Single Use Diagnostics System (SUDS®) Test Kit. Abbott Park, IL: July 1998.

Abbott Diagnostics. Human Immunodeficiency Virus Type 1 SUDS® HIV-1 Test [promotional materials], 15 July 1998.

Abrams S. Mandatory HIV testing: the search for a quick fix. *Harvard AIDS Letter* May/June 1995.

Administration of zidovudine during late pregnancy and delivery to prevent perinatal HIV transmission – Thailand, 1996-1998. *Morbidity and Mortality Weekly Report* 1998; 47(8): 151-154.

AIDS Committee of London. Post-Exposure Prophylaxis Philosophy Statement. London, June 1998.

AIDS Committee of Toronto. Position Statement on Post-Exposure HIV Prophylaxis (PEP). Toronto, 16 April 1998.

American Civil Liberties Union. ACLU Position Statement on Prenatal and Newborn HIV Testing. New York: ACLU, 1996.

American Medical Association. AMA Ethical Opinions on HIV/AIDS Issues – HIV Testing. Available at <www.ama-assn.org/special/hiv/policy/amapol.htm>. Updated June 1996.

American Medical Association. Policy H-20.930: Counseling and Testing of Pregnant Women for HIV. Approved June 1996 (Res 425, A-96).

American Medical Association. Policy H-20.958: Testing for HIV without Explicit Consent. Approved 1990 (Res 257, A-90).

American Medical Association. Policy H-20.947: Expansion of Existing AMA Policy on HIV Testing. Approved 1991 (Res 415, I-91).

American Medical Association (House of Delegates). Policy H-20.945: HIV Testing Without Explicit Consent. Approved 1987, re-affirmed 1996 (Rules & Credentials Committee, A-96).

American Society of Obstetricians and Gynecologists. ACOG News Release: ACOG Recommends Scheduled C-Sections for HIV+ Women. 31 July 1999, available at <www.acog.org>.

American State & Territorial Health Officials. Advances in HIV Testing Technology: Rapid Testing. *ASTHO HIV/AIDS Update* 1997; 1(4). Available at <hivinsite.ucsf.edu/topics/testing/2098.351e.html>.

Ana-Sal HIV Test Approved for Use. *Business Wire,*18 May 1999, <www.aegis.com/news/bw/1999/BW990507.html>.

Annas GJ. Protecting patients from discrimination – the Americans with Disabilities Act and HIV infection. *New England Journal of Medicine* 1998; 339: 1255-1259.

Arikan Y, Burdge DR. Human immunodeficiency virus infection in pregnancy. *Canadian Journal of Infectious Diseases* 1998; 9(5): 301-309.

Babu UM et al. A self-contained one-step test for infectious diseases using unprocessed whole blood. Abstracts of the General Meeting of the American Society for Microbiology 1998; 98: 520 (abstract no. V-46) (ASM98/98296626).

Bardeguez A et al. Perinatal HIV Transmission among Women with No Prenatal Care. 7th Conference on Retroviruses and Opportunistic Infections, 30 January–2 February 2000, San Francisco CA: Abstract 711, available at <www.retroconference.org>.

Bartlett JG. *Medical Management of HIV Infection*. Johns Hopkins University, 1999.

Bayer R. Letter to the Editor, re: Ethical issues in the use of zidovudine to reduce vertical transmission of HIV. *New England Journal of Medicine* 1995; 332: 891.

Bayer R, Stryker J, Smith M. Testing for HIV infection at home. *New England Journal of Medicine* 1995; 332: 1296-1299.

Baylis F, Ginn D. Expanding access to PEP: ethical and legal issues. *AIDS and Public Policy Journal* 13; 3: 106-133 available at <www.medicine.dal. ca/bioethics> or <www.hc-sc.gc./hppb/hiv_aids/>.

Baylis F, Ginn D. Expanding access to PEP: ethical and legal issues. *Canadian HIV/AIDS Policy & Law Newsletter* 1999; 4(4): 29-38.

Bayoumi A. Economics of Non-Occupational Post-Exposure Prophylaxis for HIV. Report prepared for the Federal/Provincial/Territorial Advisory Committee on AIDS. Ottawa: Health Canada, 1998.

Beardsell A et al. Utilization and Adherence of a Population-Based Post-Exposure Prophylaxis Program. Poster presentation at AIDS Impact: International Conference on the Biopsychosocial Aspects of HIV Infection, Ottawa, July 1999.

Bell DM. Occupational risk of human immunodeficiency virus infection in healthcare workers: an overview. *American Journal of Medicine* 1997; 102(Suppl 5B): 9-15.

Bennett SB et al. Rapid HIV Testing vs Traditional Testing in a Public Health Outreach Setting. 1999 [US] National HIV Prevention Conference, Abstract 117.

BioChem ImmunoSystems Inc. Clinical Trial Counseling Fast-Check HIV-1/2 (Whole Blood): Protocol dated August 1, 1999, on file.

Blanche S et al. Persistent mitochondrial dysfunction and perinatal exposure to antiretroviral nucleoside analogues. *Lancet* 1999; 354: 1084-1089.

Bluer S et al. Statistical Analysis of the CDC Model Performance Evaluation Program (MPEP) Human Immunodeficiency Virus (HIV) Rapid Test Laboratory Performance Data. 1999 [US] National HIV Prevention Conference, Atlanta GA: Abstract 310, available at <www.cdc.gov/nchstp/hiv_aids/conferences/hiv99/abstracts/310.pdf>.

Branson BM. Home sample collection tests for HIV infection. *Journal of the American Medical Association* 1998; 280: 1699-1701.

Branson BM. Rapid test strategies for HIV testing. 5th Conference on Retroviruses and Opportunistic Infections, 1-5 February 1998, 232 (abstract S13).

British Columbia Ministry of Health. HIV Testing in Pregnancy. Health Files #38a, January 1997.

Calvet G et al. Evaluation of a Rapid Test for Detection of HIV-1/2 Saliva Antibodies in a Cohort of Patients from Brazil, India, and the United States. 7th Conference on Retroviruses and Opportunistic Infections, 30 January–2 February 2000, San Francisco, CA: Asbtract 764, available at <www.retroconference.org>.

Calypte Biomedical & Cambridge Biotech Corporation. Advertising materials re: Urine Testing for HIV-1 Antibody. Undated.

Calypte Biomedical Corporation. Media release: FDA licences first urine HIV-1 supplemental test, making available first urine-only HIV test system, at <www.calypte.com>.

Calypte Biomedical Corporation. Promotional materials: "Urine-based HIV-1 Testing System" and "FAQ Sheet: Urine Testing for HIV-1 Antibody." Calypte, 1998.

Canadian AIDS Society. Advocacy Report: Post-Exposure Prophylaxis (PEP) and HIV/AIDS. Ottawa, 21 December 1998.

Canadian AIDS Society. Position statement: HIV Home Testing. Ottawa: The Society, November 1996.

Canadian AIDS Society & Canadian HIV/AIDS Legal Network. Rapid Testing for HIV: What Are the Issues? A Backgrounder. November 1999.

Canadian Dental Association. Statement on the Ethical and Legal Considerations of Treating Patients with Infectious Diseases. Ottawa: The Association, 3 April 1988.

Canadian Human Rights Commission Policy on HIV/AIDS, June 1996, available at <www.chrc-ccdp.ca>.

Canadian Medical Association. CMA Position: Acquired immunodeficiency syndrome. *Canadian Medical Association Journal* 1989; 140: 64a.

Canadian Medical Association. Code of Ethics of the Canadian Medical Association (approved 15 October 1996), available at <www.cma.ca>.

Canadian Medical Association. *Counselling Guidelines for HIV Testing.* Ottawa: The Association, 1995.

Canadian Medical Association. HIV infection in the workplace. *Canadian Medical Association Journal* 1993; 148(10): 1800A-D.

Canadian Society for Medical Laboratory Science. Position Statement: Point-of-Care Testing. Hamilton, Ontario: The Society, 3 March 1995, available at <www.csmls.org/POSITION.HTM>.

Cardo DM et al. A case-control study of HIV seroconversion in health care workers after percutaneous exposure. *New England Journal of Medicine* 1997; 337: 1485-1490.

Carpentier D. *Refus de soins dentaires à une personne porteuse du VIH*. Commission des droits de la personne du Québec, 1992 (Cat 120-12).

Case-control study of HIV seroconversion in health-care workers after percutaneous exposure to HIV-infected blood – France, United Kingdom, and United States, January 1988-August 1994. *Morbidity and Mortality Weekly Report* 1995; 44: 929-933.

CMA endorses HIV testing during pregnancy. *Canadian Medical Association News* 1997; 7(6): 5.

Côté YP et al. Multi centers evaluation of FAST CHECK HIV-1/2 WHOLE BLOOD. Abstract submitted to 2000 Conference of the Canadian Association for HIV Research (CAHR).

[US] Centers for Disease Control. Background on Calculating Comparisons for the Use of Rapid HIV Testing. At <www.cdc.gov/nchstp/hiv_aids/pubs/rt/background.htm>.

[US] Centers for Disease Control. Clinical Update – The New Rapid HIV Test: Issues for HIV Prevention Counselors. *Clinician Reviews* 1998; 8(6): 149-153.

[US] Centers for Disease Control and Prevention. HIV Oral Fluid Tests. In: *Guide to Information and Resources on HIV Testing*, 1997.

[US] Centers for Disease Control. Interpretation and use of the Western blot assay for serodiagnosis of human immunodeficiency virus type 1 infections. *Morbidity and Mortality Weekly Report* 1998; 38(Suppl 7): S4-S6.

[US] Centers for Disease Control. Letter from the Directors [National Center for HIV, STD, and TB Prevention], 27 March 1998, re: Rapid HIV Testing. Available at <hivinsite.ucsf.edu/ topics/testing/2098.394e.html>.

[US] Centers for Disease Control. Management of possible sexual, injecting-drug-use, or other nonoccupational exposure to HIV, including considerations related to antiretroviral therapy. *Morbidity and Mortality Weekly Report* 1998; 47(RR-17): 1-14.

[US] Centers for Disease Control. Project RESPECT Documents. Available at <www.cdc.gov/ nchstp/hiv_aids/projects/respect/default.htm>.

[US] Centers for Disease Control. Project RESPECT-2 Documents. Available at <www.cdc.gov/ nchstp/hiv_aids/projects/respect2/default.htm>.

[US] Centers for Disease Control. Provisional Public Health Service Recommendations for Chemoprophylaxis after Occupational Exposure to HIV. *Morbidity and Mortality Weekly Report* 1996; 45(22): 468-472.

[US] Centers for Disease Control. Public Health Service Guidelines for the Management of Health-Care Worker Exposures to HIV and Recommendations for Postexposure Prophylaxis. *Morbidity and Mortality Weekly Report* 1998; 47(RR-7).

[US] Centers for Disease Control. Questions and Answers Concerning the Saliva HIV Antibody Test. *CDC National AIDS Hotline Training Bulletin #113*, 1994.

[US] Centers for Disease Control. Rapid HIV tests: issues for counselors providing HIV prevention counseling. *CDC Issues*, March 1998, <hivinsite.ucsf.edu/topics/testing/ 2098.394e.html>.

[US] Centers for Disease Control. Rapid HIV tests: issues for laboratorians. *CDC Issues*, March 1998, <hivinsite.ucsf.edu/topics/testing/ 2098.394e.html>.

[US] Centers for Disease Control. Rapid HIV Tests: Issues for program and clinic managers. *CDC Issues*, March 1998, <hivinsite.ucsf.edu/topics/testing/ 2098.394e.html>.

[US] Centers for Disease Control. Reported Cases of AIDS and HIV Infection in Health Care Workers. Atlanta: CDC, 28 December 1998.

[US] Centers for Disease Control. Sensitivity, Specificity, and Predictive Value. Available at <www.cdc.gov/nchstp/hiv_aids/pubs/rt/sensitivity.htm>.

[US] Centers for Disease Control. Update: HIV Counseling and Testing Using Rapid Tests – United States, 1995. *Morbidity and Mortality Weekly Report*, 1998; 47(11): 211-215.

[Ontario] Central Public Health Laboratory (HIV Laboratory). Memo: Issues Related to HIV Point of Care Testing. Toronto, 1999.

Chowdhury MA et al. Development of a rapid confirmatory immunoassay for diagnosis of HIV infection. Abstracts of the General Meeting of the American Society for Microbiology 1998; 98: 154 (abstract no. C-142) (ASM98/98296494).

Coates R et al. The benefits of HIV antibody testing of saliva in field research. *Canadian Journal of Public Health* 1991; 82(6): 397-398.

College of Physicians and Surgeons of British Columbia. Delegation of a Medical Act. Policy Manual, Chapter D-1. June 1995, available at <www.cpsbc.ca>.

College of Physicians and Surgeons of British Columbia. HIV in Pregnancy. Policy Manual, ss H-3 & H4. June 1995.

College of Physicians and Surgeons of British Columbia. Management of Accidental Exposure to HIV. Policy Manual, s H-7. February 1997.

College of Physicians and Surgeons of Manitoba. Delegation of Clinical Function to the Registered Nurse (Guideline 132), available at <www.umanitoba.ca/cgi-bin/colleges/cps/college.cgi/132.html>.

College of Physicians and Surgeons of Manitoba. Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV) Post-Exposure Protocol. Guideline 315, 1993, revised 1997.

College of Physicians and Surgeons of Manitoba. Maternal and Neonatal HIV Testing and Management. Guideline 635, 1994.

College of Physicians and Surgeons of Ontario. “Patient consent for HIV test” and “Doctor’s notes: patient consent for HIV testing” (1 November 1996), available at <www.cpso.on.ca>.

College of Physicians and Surgeons of Ontario. Policy Statement: The Delegation of Controlled Acts. September 1999, available at <www.cpso.on.ca>.

Connor ME et al (for Pediatric AIDS Clinical Trials Group Protocol 076 Study Group). Reduction of maternal–infant transmission of human immunodeficiency virus type 1 with zidovudine treatment. *New England Journal of Medicine* 1994; 331: 1173-1180.

Constantine N et al. Detection of antibodies to HIV-1 group O by eight screening and four confirmatory assays. International Conference on AIDS 1998; 12: 632: (abstract no 33200), available via <www.aids98.ch>.

Constantine N et al. Diagnostic challenges for rapid human immunodeficiency virus assays. Performance using HIV-1 group O, HIV-1 group M, and HIV-2 samples. *Journal of Human Virology* 1997; 1(1): 45-51.

Constantine NT et al. Evaluation of a new generation of rapid/simple assays to detect HIV antibodies in oral fluid. International Conference on AIDS 1996; 11(2): 257 (abstract no. Th.A.4023) (ICA11/96924436).

Constantine N et al. A 5-Minute Confirmatory Assay for HIV. 11th International Conference on AIDS/STDs in Africa. Lusaka, 1999: Abstract Book 157 (abstract no. 15PT512-2).

Constantine N. HIV Antibody Testing. In: Feinberg M, Cohen PT(eds). *The AIDS Knowledge Base*, 1999.

Constantine N et al. A Rapid Confirmatory Assay for HIV. 5th ICAAP, 1999 (abstract no. 46/PMAB001).

Culnane M et al. Lack of long-term effects of *in utero* exposure to zidovudine among uninfected children born to HIV-infected women. *Journal of the American Medical Association* 1999; 281: 151-157.

Dabis F et al. 6-month efficacy, tolerance, and acceptability of a short regiment of oral zidovudine to reduce vertical transmission of HIV in breastfed children in Côte d'Ivoire and Burkina Faso: a double-blind placebo-controlled multicentre trial. *Lancet* 1999; 353: 786-792.

de Bruyn T. *HIV/AIDS and Discrimination: A Discussion Paper.* Montréal: Canadian HIV/AIDS Legal Network & Canadian AIDS Society, 1998.

Dickens B. Informed Consent. In: Downie J, Caulfield T (eds). *Canadian Health Law and Policy.* Toronto: Butterworths, 1999.

Eberlee J. An AIDS test that travels well. *IDRC Reports* 1993; 21(2), available at <www.idrc.ca/books/reports>.

Epitope Inc. OraSure HIV-1 Antibody Testing System [promotional materials], undated.

Epitope Inc. OraSure Oral HIV-1 Antibody Testing System [advertising materials]. Undated.

Evaluation of a rapid immunochromatographic test for detection of antibodies to human immunodeficiency virus. *Journal of Clinical Microbiology* 1999; 37(2): 367-370.

Fabbri WO. Home HIV Tests Will Reduce the Spread of AIDS, and Portelli CJ. Home HIV Tests Are Unethical. In: Roleff TL, Cozic CP (eds). *AIDS: Opposing Viewpoints*. Greenhaven Press Inc, 1998.

Farnham PG et al. Counseling and Testing for HIV Prevention: Costs, Effects, and Cost-Effectiveness of More Rapid Screening Tests. *Public Health Reports* 111(1): 1996. Available at <hivinsite.ucsf.edu/social/public_health/2098.2662.html>.

FDA approves supplement to Calypte's HIV-1 serum Western blot assay. Reuters Health, 19 November 1999. Available from JAMA HIV/AIDS Information Center at <www.ama-assn.org/special/hiv/newsline/reuters/11197179.htm>.

[US] Federal Trade Commission. Media release: FTC charges second Internet marketer with misrepresenting accuracy of HIV tests. 1 December 1999, available at <www.ftc.gov>.

[US] Federal Trade Commission & Food and Drug Administration. Media release: FTC and FDA warn consumers about ineffective and unapproved HIV test kits; announce joint law enforcement actions. 17 November 1999, available at <www.ftc.gov>.

[US] Food and Drug Administration (Center for Biologics Evaluation and Research). Guidance for Industry in the Manufacture and Clinical Evaluation of *In Vitro* Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Viruses Types 1 and 2. Rockville, MD: Food and Drug Administration, December 1999. Available at <www.fda.gov./cber/ guidelines.htm>.

[US] Food and Drug Administration. Media release: Business sentenced to over five years for selling bogus HIV-testing kits. 17 February 1999, available at <www.fda.gov/oashi/aids/greene.html>.

[US] Food and Drug Administration. Warning letters issued for unapproved HIV test kits. Summary list posted 22 November 1999 at <www.fda.gov/oashi/aids/testwarn.html>.

Fernandez Giuliano S et al. Rapid assay evaluation for the detection of antibodies anti-HIV-1/2: Capillus HIV-1/HIV-2. International Conference on AIDS 1998; 12: 795 (abstract no. 42113), AIDSLINE ICA12/98402880.

Ferri RS. Oral mucosal transudate testing for HIV-1 antibodies: a clinical update. *Journal of the Association of Nurses in AIDS Care* 1998; 9(20): 68-72.

Flanagan W. AIDS-related risks in the health care setting: HIV testing of health care workers and patients. *Queen's Law Journal* 1993; 18: 71-128.

Flood C. The Structure and Dynamics of Canada's Health Care System. In: Downie J, Caulfield T (eds). *Canadian Health Law and Policy.* Butterworths: Toronto, 1999, at 12.

Forbes J et al. Pregnancy outcome in HIV-infected women in British Columbia: the impact of antiretroviral therapy on maternal–infant HIV transmission. *Canadian Journal of Infectious Diseases* 1997; 8(Suppl A): 31a.

Frenkel LM. State-of-the-Art Management of the HIV-Infected Pregnant Woman. Report from the 7th Conference on Retroviruses and Opportunistic Infections, 30 January–2 February 2000, San Francisco CA, available at <hiv.medscape.com/Medscape/CNO/2000/retro>.

Frerichs RR et al. Local research for local approval – a case study of a rapid HIV serostrip assay for use in developing countries. International Conference on AIDS 1996; 11(1): 33 (abstract no. Mo.C.213). AIDSLINE MED/96920968.

Fridlund C et al. Integration and optimization of HIV rapid testing algorithms in client-centered HIV counseling. 5th Conference on Retroviruses and Opportunistic Infections, 1-5 February 1998: 106 (abstract 143).

FTC shuts down Internet supplier of inaccurate HIV tests. *Reuters Medical News*, 20 January 2000, available at <www.medscape.com/reuters>.

Galli RA et al. Performance characteristics of the MedMira Rapid HIV Screen Test for the detection of antibodies to HIV-1 and HIV-2 in clinical specimens. Abstracts of the General Meeting of the American Society for Microbiology 1998 (17-21 May); 98: 154 (abstract no. C-140) (ASM98/98296492).

Gallo D et al. Evaluation of a system using oral mucosal transudate for HIV-1 antibody screening and confirmatory testing. *Journal of the American Medical Association* 1997; 277(3): 254-258.

Gerberding J et al. Risk of exposure of surgical personnel to patients' blood during surgery at San Francisco General Hospital. *New England Journal of Medicine* 1990; 322: 1788.

Giles RE et al. Simple/rapid test devices for anti-HIV screening: do they come up to the mark? *Journal of Medical Virology* 1999; 59(1): 104-109.

Gimenez-Lambert A et al. *A Comprehensive Guide for the Care of Persons with HIV Disease – Module 3: Nursing Care*. Ottawa: Canadian Association of Nurses in AIDS Care, 1996.

Ginsberg MM. Effectiveness of voluntary HIV antibody testing provided at a clinic treating sexually transmitted diseases. V International Conference on AIDS 1989: Abstract MAP 62 (poster).

Greub G et al. Spare Postexposure Prophylaxis with Immediate HIV Testing of the Source Patient. 7th Conference on Retroviruses and Opportunistic Infections, 30 January–2 February 2000, San Francisco CA: Abstract 494, available at <www.retroconference.org>.

Grubert TA et al. Complications after caesarian section in HIV-1-infected women not taking antiretroviral treatment. *Lancet* 1999; 354: 1612-1613.

Golden MR et al. Failure to return for HIV post-test counseling (PTC) among HIV-positive Baltimore STD clinic patients: risk factors and trends. International Conference on AIDS 1996; 11(2): 475 (abstract no. Pub.C.1244). AIDSLINE MED/96925684.

Gostin L et al. HIV testing, counseling and prophylaxis after sexual assault. *Journal of the American Medical Association* 1994; 271(18): 1338

Gostin L, Feldblum C, Webber D. Disability discrimination in America: HIV/AIDS and other health conditions. *Journal of the American Medical Association* 1999; 281: 745-752.

Government of Alberta. Press release and backgrounder: Routine Prenatal HIV Screening Program Launched. Edmonton, 25 August 1998, available at <www.health.gov.ab.ca.>.

Guay LA et al. Intrapartum and neonatal single-dose of nevirapine compared with zidovudine for prevention of mother-to-child transmission of HIV-1 in Kampala, Uganda: HIVNET 012 randomised trial. *Lancet* 1999; 354: 795-802.

Guay L et al. A Randomized Trial of Single Dose Nevirapine to Mother and Infant Versus Azidothymidine in Kampala, Uganda for Prevention of Mother-to-Infant Transmission of HIV-1 (HIVNET 012). 7th Conference on Retroviruses and Opportunistic Infections; 30 January–2 February 2000, San Francisco, CA: Abstract S12, available at <www.retroconference.org>.

Guidelines for the Post Exposure Management of Bloodborne Pathogens. Simcoe County Committee for the Management of Bloodborne Pathogens, 1999.

Halpern M et al. Prevention of Mother-to-Child Transmission of HIV by Elective Cesarean Section: Costs, Outcomes and Cost-Effectiveness. 7th Conference on Retroviruses and Opportunistic Infections; 30 January–2 February 2000, San Francisco(Abstract 705), available at <www.retroconference.org>.

Hanson C et al. Lack of tumors in infants with perinatal HIV type 1 exposure and fetal/neonatal exposure to zidovudine. *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology* 1999; 20: 463-467.

Health Canada. Guidelines for HIV Simple/Rapid Test Kits (excerpts from draft document). BC Centre for Disease Control et al, June 1997.

Health Canada. An Integrated Protocol to Manage Health Care Workers Exposed to Bloodborne Pathogens. *Canada Communicable Disease Report* 1997; 23(Suppl 23S2).

Health Canada (Laboratory Centre for Disease Control). Perinatal Transmission of HIV. *HIV/AIDS Epi Update*, May 1999, available at <www.hc-sc.gc.ca/hpb/lcdc/bah/epi/peri_e.html>.

Health Canada (Laboratory Centre for Disease Control). Perinatal Transmission of HIV. *HIV/AIDS Epi Update*, May 1999. Available at <www.hc-sc.gc.ca/hpb/lcdc/bah/epi>.

Health Canada (Medical Devices Bureau). Guidance for the Labelling of Medical Devices, Section 21 to 23 of the *Medical Devices Regulations* (with appendices) (Draft). January 11, 1999. Available at: <www.hc-sc.gc.ca/hpb-dpgs/therapeut/htmleng/guidmd.html>.

Health Canada (Medical Devices Bureau). Guidance for the Risk Based Classification System of *In Vitro* Diagnostic Devices. (Draft). 24 April 1998. Available at: <www.hc-sc.gc.ca/hpb-dpgs/therapeut/htmleng/guidmd.html>.

Health Canada (Medical Devices Bureau). Guidance for the Interpretation of Significant Change. November 9, 1998. Available at <www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/guidmd.html>.

Health Canada (Medical Devices Bureau). Guidance for the Labelling of *In Vitro* Diagnostic Devices (Draft). 19 June 1998, at 5. Available at <www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/guidmd.html>.

Health Canada. *HIV Post-Exposure Prophylaxis in the Non-Occupational Setting: Decision Making in the Face of Uncertainty.* Summary of Proceedings of a National Conference, October 23-24, 1998.

Health Canada (Medical Devices Bureau). Report on the HIV Point of Care Testing Workshop, March 29-31, 1999.

Health Canada (Therapeutic Products Programme) – Expert Advisory Committee on HIV Therapies. Minutes of meeting of 8 May 1998. Available at <www.hc-sc.gc.ca/hpb-dgps/therapeut/advcomm_eachiv.html>.

Health Canada (Therapeutic Products Programme) – Expert Advisory Committee on HIV Therapies. Minutes of teleconference of 9 July 1998, available at <www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/advcomm_eachiv.html>.

Health Canada (Therapeutic Products Programme) – Expert Advisory Committee on HIV Therapies. Minutes of teleconference of 29 March 1999, available at <www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/advcomm_eachiv.html>.

Henderson DK. Postexposure chemoprophylaxis for occupational exposures to the human immunodeficiency virus. *Journal of the American Medical Association* 1999; 281: 931-936.

Hiller G et al. A one-step solid phase immunoassay for rapid detection of antibodies to HIV-1 and HIV-2. International Conference on AIDS 1996; 11(1): 293 (abstract no. Tu.B.2166) (ICA11/96922371).

Hiroyasu A et al. Detection of HIV-1 subtypes by a new rapid immunochromatographic test. International Conference on AIDS 1998 (Abstract 41107), available via <www.aids98.ch>.

Hoffman CA, Munson R. Letter to the Editor re: Ethical issues in the use of zidovudine to reduce vertical transmission of HIV. *New England Journal of Medicine* 1995; 332: 891.

Hoffmaster B, Schrecker T. An Ethical Analysis of HIV Testing of Pregnant Women and Their Newborns. (unpublished manuscript). August 1999.

Hoffmaster B, Schrecker T. An ethical analysis of HIV testing of pregnant women and their newborns. *Canadian HIV/AIDS Policy & Law Newsletter* 1999; 4(4): 5-11.

Hoffmaster B. Rapid HIV Screening at the Point of Care: An Ethical Commentary, infra, Appendix A.

Howard B et al. Urine antibody tests: new insights into the dynamics of HIV-1 infection. *Clinical Chemistry* 1999; 45(9): 1602.

Hudson CN. Elective caesarean section for prevention of vertical transmission of HIV-1 infection [commentary]. *Lancet* 1999; 353: 1030.

Human Immunodeficiency Virus Antibody Testing in Canada. Recommendations of the National Advisory Committee on AIDS. *Canada Diseases Weekly Report* 1989; 15(8): 37-43.

ImmunoScience, Inc. Other References on Saliva Based HIV Tests [table]. At <http://immunoscience.com/ref.htm>.

ImmunoScience, Inc. Salivax™-HIV Human Immunodeficiency Virus Types 1 and 2 Quick-Flow Visual Screening Test [package insert], on file and available at <http://immunoscience.com>.

Inexpensive two-minute HIV test passes first field trial. *UniSci Science and Research News*, 19 May 1998, available at <unisci.com>.

Informed consent needed before HIV testing of mothers: CMA. *Canadian Medical Association Journal* 1997; 156(8): 1108.

Interdepartmental Committee on Human Rights and AIDS. Report of the Working Group on Sexual Assault and HIV Antibody Testing: Human Rights Issues Relating to HIV Antibody Testing of Persons Accused or Convicted of Sexual Assault. Ottawa: The Committee, 19 April 1994.

International Development Research Centre. Inexpensive blood screening for HIV. Ottawa: IDRC, 1998, available at <www.idrc.ca/Nayudamma/HIV_60e.html>.

Intersol Consulting Associates Ltd. HIV Point-of-Care Testing (report on 29-31 March 1999 workshop). Ottawa: 1999.

Irwin K et al. Performance characteristics of a rapid HIV antibody assay in a hospital with a high prevalence of HIV infection. *Annals of Internal Medicine* 1996; 125(6): 471-475.

Jackson LA et al. HIV-positive women living in the metropolitan area: their experiences and perceptions related to HIV testing. *Canadian Journal of Public Health* 1997; 88(1): 18-22.

Jochimsen E et al. Investigations of possible failures of postexposure prophylaxis following occupational exposures to human immunodeficiency virus. *Archives of Internal Medicine* 1999; 159: 2361-2363.

Jürgens R. *HIV Testing and Confidentiality: Final Report*. Montréal: Canadian AIDS Society & Canadian HIV/AIDS Legal Network, October 1998.

Kamb ML et al. Efficacy of risk-reduction counseling to prevent human immunodeficiency virus and sexually transmitted diseases. *Journal of the American Medical Association* 1998; 280: 1161-1167.

Kane B. Rapid testing for HIV: why so fast? *Annals of Internal Medicine* 21 September 1999. Available at <www.acponline.org/journals/annals/21sep99/bkane.htm>.

Kappes R et al. Tailoring HIV pre-test counseling in sexually transmitted disease (STD) clinics according to anticipated non-return rates in subcategories of patients. VI International Conference on AIDS 1990: Abstract SC 676 (poster).

Kassler WJ et al. HIV prevention counseling using an on-site, rapid HIV assay. International Conference on AIDS 1994; 10(2): 60 (abstract no. 518B/D). AIDSLINE ICA10/94372409.

Kassler WJ et al. On-site, rapid HIV testing with same-day results and counseling. *AIDS* 1997; 11(8): 1045-1051.

Kassler WJ et al. Performance of a rapid, on-site human immunodeficiency virus antibody assay in a public health setting. *Journal of Clinical Microbiology* 1995; 33: 2899-2902.

Katarikawe E. Challenges encountered and solutions adopted in counseling clients while giving same day HIV test results. International Conference on AIDS 1998; 12: 870 (abstract no. 43115). AIDSLINE ICA12/98404467.

Katz MH, Gerberding JL. The care of persons with recent sexual exposure to HIV. *Annals of Internal Medicine* 1998; 128: 306-312.

Katz M et al. Home collection versus publicly funded HIV testing in San Francisco: who tests where? *Journal of Acquired Immune Deficiency Syndromes* 1999; 21: 417-422. In: Roleff TL, Cozic CP (eds). *AIDS: Opposing Viewpoints*. Greenhaven Press Inc, 1998.

Katz MH, Gerberding JL. Postexposure treatment of people exposed to the human immunodeficiency virus through sexual contract or injection-drug use. *New England Journal of Medicine* 1997; 336: 1097-1100.

Kelen GD et al. Emergency department-based HIV screening and counseling: experience with rapid and standard serologic testing. *Annals of Emergency Medicine* 1999; 33(2): 147-55 (MED/99122818).

Kelen GD et al. Evaluation of two rapid screening assays for the detection of human immunodeficiency virus-1 infection in emergency department patients. *American Journal of Emergency Medicine* 1991; 9(5): 416-420.

Kolk D et al. High throughput assay that detects all subtypes of human immunodeficiency virus-1 (HIV-1), including type O strains. HIV Pathogenesis and Treatment Conference 1998: 41 (abstract no. 1009) (AIDS/98930267).

Korniewicz DM et al. Barrier protection with examination gloves: double vs. single. *American Journal of Infection Control* 1994; 22(1): 12-15.

Lapointe N. Antiretroviral Therapy in Pregnant Women (CPARG): Access and Outcome (1995-1997) and the Experience of Transmission of HIV in Treated Pregnant Women at Ste. Justine's Clinic, Québec. In: Proceedings of a Scientific Meeting to Review the Vertical Transmission of HIV in Canada, June 1998.

Leonard L, Shap L. A different kind of risk? – pregnant women's experience of HIV testing in pregnancy. *Canadian HIV/AIDS Policy & Law Newsletter* 1999; 5(1): 18-21.

Lester P et al. Postnatal human immunodeficiency virus antibody testing – the effects of current policy on infant care and maternal informed consent. *The Western Journal of Medicine* 1992; 156: 371-375.

Levine C, Bayer R. The ethics of screening for early intervention in HIV disease. *American Journal of Public Health* 1989; 79: 1661.

Leviton LC. For whom do we test? What do we say? Rapid HIV screening. *Public Health Reports* 1996; 111(1): 54.

Lindegren ML et al. Trends in perinatal transmission of HIV/AIDS in the United States. *Journal of the American Medical Association* 1999; 282: 531.

Lubega SN et al. Field trial of the MedMira Rapid HIV Screen Test in an HIV high prevalence area in the US. Abstracts of the General Meeting of the American Society for Microbiology 1998 (17-21 May); 98: 154 (abstract no. C-138) (ASM98/98296491).

Lurie P et al. Postexposure prophylaxis after nonoccupational HIV exposure. *Journal of the American Medical Association* 1998; 280: 1769-1773.

Lyall EG Hermione et al. Review of uptake of interventions to reduce mother to child transmission of HIV by women aware of their HIV status. *British Medical Journal* 1998; 316: 268-270.

Major CJ et al. Comparison of saliva and blood for human immuno- deficiency virus prevalence testing. *Journal of Infectious Diseases* 1991; 163(4): 699-702.

Mandelbrot L et al. Perinatal HIV-1 transmission: interaction between zidovudine prophylaxis and mode of delivery in the French Perinatal Cohort. *Journal of the American Medical Association* 1998; 280: 55-60.

Marmor M et al. Rapid versus Standard HIV Testing of Persons at High Risk of HIV Infection. 1999 [US] National HIV Prevention Conference: Abstract 692, available at <www.cdc.gov/nchstp/hiv_aids/conferences/hiv99/abstracts/692.pdf>.

Marseille E et al. The cost-effectiveness of a single dose nevirapine regimen to mother and infant to reduce vertical HIV transmission in Uganda. *Lancet* 1999; 354: 803-809.

Martin JN et al. Post-Exposure Prophylaxis after Sexual or Drug Use Exposure to HIV: Final Results from the San Francisco Post-Exposure Prevention (PEP) Project. 7th Conference on Retroviruses and Opportunistic Infections, 30 January–2 February 2000, San Francisco CA: Abstract 196, available at <www.retroconference.org>.

Martindale S. High Demand for Rapid HIV Testing among Young Gay and Bisexual Men. In: Final Program & Abstract Book, AIDS Impact International Conference on the Biopsychosocial Aspects of HIV Infection, Ottawa, 15-18 July 1999, at 25-26.

Martindale S. What if you could get HIV test results in 20 minutes? *The Vanguardian* [project newsletter], April 1998.

Matiation S. *HIV Testing and Confidentiality: Issues for the Aboriginal Community. A Discussion Paper*. Montréal: Canadian HIV/AIDS Legal Network & Canadian Aboriginal AIDS Network, 2nd edition, 2000.

Mayaux MJ et al. Acceptability and impact of zidovudine for prevention of mother-to-child human immunodeficiency virus-1 transmission in France. *Journal of Pediatrics* 1997; 131(6): 857-862.

McCarthy GM et al. Factors associated with refusal to treat HIV-infected patients: the results of a national survey of dentists in Canada. *American Journal of Public Health* 1999; 89(4): 541.

McIntosh K. Short (and shorter) courses of zidovudine. *New England Journal of Medicine* 1998; 339: 1467-1468.

McKibben S, for the Alberta Community Council on HIV (Advocacy Committee). Implications of Point of Care Rapid HIV Testing. Edmonton: ACCH, 16 February 2000.

McKenna SL et al. Rapid HIV testing and counseling for voluntary testing centers in Africa. *AIDS* 1997; 11 (Suppl 1): S103-110.

McNamara L, Nelson E. Regulation of Health Care Professionals. In: Downie J, Caulfield T(eds). *Canadian Health Law and Policy*. Toronto: Butterworths, 1999.

MedMira Laboratories Inc. MedMira Rapid HIV Screen (advertising materials). Undated.

MedMira Laboratories. Media release: Health Canada authorizes MedMira's Rapid HIV-1 & HIV-2 Screen Test for sale in Canada. Halifax: MedMira, 27 May 1998.

MedMira Laboratories Inc. Media release: Rapid Reader 2000 and HIV type O test are latest technologies unveiled by Medmira Laboratories at press conference today. 10 September 1999.

Meehan MP et al. Sensitivity and specificity of HIV-1 testing of urine compared with serum specimens. *Sexually Transmitted Diseases* 1999; 26: 590-592.

Miller A, Pinching AJ. HIV tests and counseling: Current issues. *AIDS* 1989; 3(Suppl 1): S187-S192 at S191.

Ministère de la Santé et des Services sociaux du Québec. HIV infection and pregnancy – Intervention programme. Québec, 1997.

Minkoff H, O'Sullivan MJ. The case for rapid HIV testing during labor. *Journal of the American Medical Association* 1998; 279(21): 1743-1744.

Mitchell D. Postexposure prophylaxis can change HIV risk behaviors. *Reuters Medical News*, 7 February 2000, available at <hiv.medscape.com/ reuters>.

Mock PA et al (Bangkok Collaborative Perinatal HIV Transmission Study Group). Maternal viral load and timing of mother-to-child HIV transmission, Bangkok, Thailand. *AIDS* 1999; 13(3): 407-414.

Mofenson LM. Can perinatal HIV infection be eliminated in the United States? [editorial] *Journal of the American Medical Association* 1999; 282(6): 577.

Mofenson LM. Short-course zidovudine for prevention of perinatal infection [commentary]. *Lancet* 1999; 353: 766

Mofenson L, Wilfert C. Pathogenesis and Interruption of Vertical Transmission. *Paediatric AIDS: The Challenge of HIV Infection in Infants, Children and Adolescents* (in press), cited in: Stolz L, Shap L. *HIV Testing and Pregnancy: Medical and Legal Parameters of the Policy Debate*. Health Canada, 1999.

Molitor F et al. Predictors of failure to return for HIV test result and counseling by test site type. *AIDS Education and Prevention* 1999 (February); 11(1): 1-13.

More than 1 in 8 Americans do not receive HIV test results. *Reuters Health Information*, 6 January 1999, available at <www.ama-assn.org/special/hiv/newsline/reuters>.

Morris A et al. A review of protease inhibitor (PI) use in 89 pregnancies. In: Program and Abstracts of the 6th Conference on Retroviruses and Opportunistic Infections, 31 January–4 February 1999, Chicago IL, Abstract 686.

Msellati P et al for the DITRAME Study Group. Safety and acceptability of vaginal disinfection with benzalkonium chloride in HIV infected pregnant women in west Africa: ANRS 049b phase II randomised, double blinded placebo controlled trial. *Sexually Transmitted Infections* 1999; 75: 420-425.

Musoke P et al. A phase I/II study of the safety and pharmacokinetics of nevirapine in HIV-1 infected pregnant Ugandan women and their neonates (HIVNET 006). *AIDS* 1999; 13: 479-486.

Myers T et al. The HIV Test Experience Study: An Analysis of Test Providers' and Test Recipients' Descriptions and Critical Appraisals of the HIV Antibody Test Experience. Toronto: University of Toronto, 1998.

Myers T, Haubrich DJ. The HIV test experience study. *Canadian HIV/AIDS Policy & Law Newsletter* 1999; 4(4): 25-28.

Myers T et al. Strategies Used to Manage the Impact on HIV Test Providers of Giving a Positive Test Result. In: Final Program & Abstract Book, AIDS Impact International Conference on the Biopsychosocial Aspects of HIV Infection, 15-18 July 1999, Ottawa, at 26-27.

Nagy S. Bill seeks to protect police. *Calgary Herald*, 17 August 1999: A10.

Naumetz T. Liberals 'unlikely' to back mandatory blood samples. *Ottawa Citizen*, 14 December 1999: E2.

Nelson E. The Fundamentals of Consent. In: Downie J, Caulfield T (eds). *Canadian Health Law and Policy*. Toronto: Butterworths, 1999.

Nelson A et al. Failures and delays in returning for HIV test results at publicly-funded clinics, US, 1989-1990. VII International Conference on AIDS 1991: Abstract MC 3342 (poster).

New rapid HIV tests as accurate as standard immunoassays. *Reuters Health*,1 September 1999.

New rapid HIV tests expected soon. *Hopkins HIV Report*, May 1999, at <www.hopkins-aids.edu/publications/report/may99_6.html#12>.

New HIV saliva test kit to hit UK markets. *NurseWeek/HealthWeek*, 1 September 1997, available at <www.nurseweek.com/news/salivahiv.html>.

Nielsen K. Preventing Perinatal HIV Transmission in the Developing World, One Step at a Time. Available at <hiv.medscape.com/Medscape/CNO/2000/retro>.

Ng KP et al. Evaluation of a rapid test for the detection of antibodies to human immunodeficiency virus type 1 and 2. *International Journal of STD and AIDS* 1999; 10(6): 401-404.

Northwest Territories Health and Social Services. HIV Infection and AIDS Information for Health Professionals. November 1996.

Ontario Human Rights Commission. Policy on HIV/AIDS-Related Discrimination. Available at <www.ohrc.on.ca>.

Ontario Ministry of Health, AIDS Bureau. *Anonymous HIV Testing Evaluation, January 1992 to June 1993*. Toronto: The Ministry, November 1994, at 7.

Opening of Nonoccupational Postexposure Prophylaxis Registry. *Morbidity and Mortality Weekly Report* 1999; 48(2): 496-497.

O'Sullivan MJ et al. Protease inhibitors: is preterm delivery a risk? *American Journal of Obstetrics and Gynecology* 1999; 180:S105 (abstract 353).

Pace launches easy to use and rapid diagnostic HIV test. *Doctor's Guide to the Internet*; 15 July 1996, at <www.pslgroup.com/dg/9D12.htm>.

Parazzini F, for the European Mode of Delivery Collaboration. Elective caesarean-section versus vaginal delivery in prevention of vertical HIV-1 transmission: a randomised clinical trial. *Lancet* 1999; 353: 1035-1039.

PATH Canada. Development of a Rapid Assay for the Detection of Antibodies to HIV-1 and HIV-2: Final Report and Request for Bridging Funds. Ottawa: PATH Canada, January 1991, available at <www.idrc.ca/library>

Patrick DM et al. Routine prenatal screening for HIV in a low-prevalence setting. *Canadian Medical Association Journal* 1998; 159(8): 942-947.

Peterkin A. The Impact of Rapid HIV Testing in the Clinical Setting. Ottawa: University of Ottawa Health Services, 1995.

Philips KA et al. HIV counseling and testing of pregnant women and women of childbearing age by primary care providers: self-reported beliefs and practices. *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology* 1997; 14(2) 174-178.

Pinkerton SD et al. Incremental cost-effectiveness of two zidovudine regimens to prevent perinatal HIV transmission in the United States. *Preventive Medicine* 2000; 30: 64-69.

Pitt J et al. Association of Maternal ZDV Use during Pregnancy and Infant ZDV Genotypic Resistance with Rapid Disease Progression among Infants in the WITS. 7th Conference on Retroviruses and Opportunistic Infections; 30 January–2 February 2000, San Francisco CA: Abstract 709, available at <www.retroconference.org>.

Police want justice minister to push law on deadly viruses. *CP Wire*,15 August 1999.

Prenatal discussion of HIV testing and maternal testing – 14 states, 1996-1997. *Morbidity and Mortality Weekly Report* 1999; 48(19): 401-404.

Published study provides new understanding about HIV infection and significance of urine HIV-1 testing. *Business Wire*, 2 September 1999.

Rapid tests could 'revolutionize' screening. *AIDS Alert* 1998 (July); 13(7): 82-84.

Ratnam S et al. MedMira Rapid HIV Screen as a supplemental test for rapid confirmation of EIA-based HIV positive screen result. International Conference on AIDS 1998; 12: 797 (abstract no. 42122) (AIDSLINE ICA12/98402889).

Ratnam S et al. MedMira Rapid HIV Screen test: a multinational field trial. Abstracts of the General Meeting of the American Society for Microbiology 1998 (17-21 May); 98: 153-154 (abstract no. C-137), available via <hiv.medscape.com>.

Read JS, for the International Perinatal HIV Group. Mode of delivery and the risk of vertical transmission of HIV-1 – a meta-analysis of 15 prospective cohort studies. *New England Journal of Medicine* 1999; 341(3): 206.

Read J et al. Mode of delivery and postpartum morbidity among HIV-infected women: The Women and Infants Transmission Study (WITS). Program and Abstracts of the 6th Conference on Retroviruses and Opportunistic Infections, 31 January–4 February 1999, Chicago IL (Abstract 683).

Remis RS, Vandal AC. Cost-effectiveness of universal and selective screening of pregnant women in Québec [abstract]. *Canadian Journal of Infectious Diseases* 1997; 8 (Suppl A): 24A.

Remis RS, Major C, & HIV Seroprevalence Research Team. Preliminary Analysis of Prenatal HIV testing in Ontario, 1999 [umpublished].

Ricci E, Parazzini F. Caesarean section and antiretroviral treatment. *Lancet* 2000; 355: 496-502.

Richwine L. US warns about HIV tests sold on Internet. *Reuters NewsMedia*, 18 June 1999, available at <www.aegis.com/news/re/1999/RE990609.html>.

Reddy H. HIV testing in pregnancy: a duty or a choice? *Canadian HIV/AIDS Policy & Law Newsletter* 1997; 3(2/3): 7-8

Reduction of HIV transmission from mother to infant. *Canada Communicable Disease Report* 1994; 20(12): 97-101 at 100.

Reproductive Care Program of Nova Scotia. Guidelines for Antenatal Laboratory Screening and Testing. May 1994.

Rogers M. Update on Revised United States Public Health Services (USPHS) Policy on HIV Screening of Pregnant Women and Treatment of HIV-Infected Pregnant Women. Presentation at: Perinatal HIV Prevention Grantee Meeting, 11-12 January 2000, Atlanta, Georgia. Available via link at <www.cdc./gov/nchstp/hiv_aids/projects/perinatal/agenda.htm>.

Rodgers S. State Intervention in the Lives of Pregnant Women. In: Downie J, Caulfield T (eds). *Canadian Health Law and Policy.* Toronto: Butterworths, 1999.

Roland ME et al. HIV-1 RNA Testing by DNA and PCR in Asymptomatic Patients after Sexual Exposure to HIV. 7th Conference on Retroviruses and Opportunistic Infections, 30 January–2 February 2000, San Francisco CA: Abstract 776, available at <www.retroconference.org>.

Rowan MS et al. Qualitative evaluation of the Canadian Medical Association's counselling guidelines for HIV serologic testing. *Canadian Medical Association Journal* 1996; 154: 665-671.

Rugg D et al. Failure to return for HIV test results: a second look at determinants. V International Conference on AIDS 1989: Abstract E717 (poster).

Saliva Diagnostic Systems. Hema•Strip HIV™ [promotional materials], available at <www.salv.com/hema.htm>.

Saliva Diagnostic Systems. Media release: Saliva Diagnostic Systems to begin aggressive sales campaign for Saliva-Strip™ HIV. 20 August 1997, reproduced at: Rapid Saliva HIV Test to be Marketed in the United Kingdom. *Business Wire*, 20 August 1997, <www.businesswire.com>.

Saliva Diagnostic Systems. Saliva•Strip HIV™ [promotional materials], available at <www.salv.com/salivaStripHIV.htm>.

Saliva Diagnostic Systems. Sero•Strip HIV™ [promotional materials], available at <www.salv.com/serostrip.htm>.

Samprini AE et al. The incidence of complications after caesarian section in 156 HIV-positive women. *AIDS* 1995; 9: 913-917.

Samson L, King S. Evidence-based guidelines for universal counselling and offering of HIV testing in pregnancy in Canada. *Canadian Medical Association Journal* 1998; 158: 1449-1457

Saville RD. Evaluation of two novel immunoassays designed to detect HIV antibodies in oral fluids. *Journal of Clinical Laboratory Analysis* 1997; 11: 63-68.

Schramm W et al. A simple saliva-based test for detecting antibodies to human immunodeficiency virus. *Clinical and Diagnostic Laboratory Immunology* 1999; 6(4): 577-80.

See DM et al. First Check HIV1-2, a two-step, five minute, whole blood immunochromatographic assay to detect HIV 1/2 antibodies. International Conference on AIDS 1996; 11(1): 294 (abstract no. Tu.B.2174) (ICA11/96922379).

Shaffer N et al. Short course zidovudine for perinatal HIV-1 transmission in Bangkok, Thailand: a randomised clinical trial. *Lancet* 1999; 353: 773.

Shafran SD et al. Evaluation of the Merlin Immediate HIV-1 and -2 Test for HIV Antibody Performed at Point-of-Care (POC). 7th Conference on Retroviruses and Opportunistic Infections, 30 January–2 February 2000, San Francisco CA: Abstract 766, available at <www.retroconference.org>.

Shafran SD et al and the Canadian HIV POC Test Study Group. Evaluation of the Merlin Immediate HIV-1 and 2 Test for HIV Antibodies Performed at Point-of-Care (POC) – Revised Abstract. 7th Conference on Retroviruses and Opportunistic Infections, 30 January–2 February 2000, San Francisco, CA.

Sheon N. New Testing Technologies: Impact on Prevention Strategy. 5 June 1998. Available at <www.managingdesire.org/ntt.html>.

Sherr L et al. HIV Test Uptake in London Pregnant Women – Predictors and Comparisons. In: Final Program & Abstract Book, AIDS Impact International Conference on the Biopsychosocial Aspects of HIV Infection, 15-18 July 1999, Ottawa (Poster 94): 206.

Silverman DC. HIV Testing, Counselling and Prophylaxis Following Sexual Assault [2 parts]. *Reproductive Health Matters*, 1 May 1995: 104-115, adapted from: Gostin L, Silverman DC et al. HIV testing, counseling and prophylaxis following sexual assault. *Journal of the American Medical Association* 1994; 271(8): 1436-1445.

Simonds RJ et al. Impact of zidovudine use on risk and risk factors for perinatal transmission of HIV. Perinatal AIDS Collaborative Transmission Studies. *AIDS* 1998; 12(3): 301-308.

Society of Obstetricians and Gynaecologists of Canada. *HIV Testing in Pregnancy. It's Best to Test!* Ottawa: The Society, 1997.

Society of Obstetricians and Gynaecologists of Canada. HIV Testing in Pregnancy. Policy Statement No 62, June 1997, available at <sogc.medical.org>.

Society of Obstetricians and Gynaecologists of Canada. Practice Guidelines for Obstetrical and Gynaecological Care of Women Living with HIV. Ottawa: The Society, 1994,

Sperling RS et al. Maternal viral load, zidovudine treatment and the risk of transmission of human immunodeficiency virus from mother to infant. *New England Journal of Medicine* 1996; 335: 1621.

Sperling RS et al. Safety of the maternal-infant zidovudine regimen utilized in the Pediatric AIDS Clinical Trial Group 076 Study. *AIDS* 1998; 12: 1805-1813.

Spielberg F et al. "By All Means Necessary:" HIV Counseling and Testing Preferences among Individuals at High Risk. 1999 [US] National HIV Prevention Conference, Atlanta GA: Abstract 421.

Spielberg F, Kassler WJ. Rapid testing for HIV antibody: a technology whose time has come. *Annals of Internal Medicine* 1996; 125(6): 509-511.

Stek A et al. The safety and efficacy of protease inhibitor therapy for HIV infection during pregnancy. *American Journal of Obstectrics and Gynecology* 1999; 190: S6 (abstract 14).

Stetler HC et al. Field evaluation of rapid HIV serologic tests for screening and confirming HIV-1 infection in Honduras. *AIDS* 1997; 11(3): 369-375.

Steketee R et al. Utility of single or dual rapid tests in the detection of HIV in pregnant women, Kenya. International Conference on AIDS 1998; 12: 793 (abstract 42104).

Stetler HC et al. Field evaluation of rapid HIV serologic tests for screening and confirming HIV-1 infection in Honduras. *AIDS* 1997; 11(3): 369-375. Abstract available at <hivinsite.ucsf.edu/topics/testing/ 2098.3884.html>.

Stoltz L, Shap L, *HIV Testing and Pregnancy: Medical and Legal Parameters of the Policy Debate*, Health Canada, 1999. <www.aidslaw.ca>

Stoto MA et al (eds). (Institute of Medicine). *Reducing the Odds: Preventing Perinatal Transmission of HIV in the United States*. Washington, DC: National Academy Press, 1998.

Stringer JS, Rouse DJ. Rapid testing and zidovudine treatment to prevent vertical transmission of human immunodeficiency virus in unregistered parturients: a cost-effectiveness analysis. *Obstetrics and Gynecology* 1999; 94(1): 34-40.

Stringer JS, Rouse DJ, Goldenberg RL. Prophylactic cesarean delivery for the prevention of perinatal human immunodeficiency virus transmission: the case for restraint. *Journal of the American Medical Association* 1999; 281: 1946-1949.

Tao G, WJ Kassler, BM Branson, RA Cohen. Rates of receiving the result of an HIV test: data from the US National Health Interview Survey. International Conference on AIDS 1998; 12: 1065 (abstract no. 60354). AIDSLINE ICA 12/98408603. Available at <www.aegis.com/pubs/aidsline/ 1998/decM98C5999.html>.

Tao G et al. Rates of receiving HIV test results: data from the US National Health Interview Survey for 1994 and 1995. *Journal of Acquired Immune Deficiency Syndromes* 1999; 22: 395-400.

Tamashiro H et al. Serologic diagnosis of HIV infection using oral fluids. *Bulletin of the World Health Organization* 1994; 72: 135-143.

Thérien L et al. Multi centers evaluation of FAST CHECK HIV-1/2 SERUM. Abstract submitted to the 2000 Conference of the Canadian Association for HIV Research (CAHR).

Tripp J. Memo: HIV Testing Counselling Workshop 1999 – Rapid HIV Testing: Highlights of Discussions. Toronto, 1999

Urine HIV screen is accurate and more acceptable to patients, *Reuters Health*, 5 November 1999, at <www.ama-assn.org/special/hiv/newsline/reuters/11057077.htm>.

Urnowitz HB et al. Urine antibody tests: new insights into the dynamics of HIV-1 infection. *Clinical Chemistry* 1999; 45(9): 1602.

UNAIDS/WHO. Operational Characteristics of Commercially Available Assays to Determine HIV-1 and/or HIV-2 in Human Sera (Report 11). Geneva, January 1999.

UNAIDS. Revised recommendations for the selection and use of HIV antibody tests. *Weekly Epidemiological Record* 1997; 72: 81-88.

UNAIDS. *UNAIDS Policy on HIV Testing and Counselling*. Geneva, August 1997.

Universal HealthWatch Diagnostics Inc. Scientific Presentations & Publications on Development and Evaluation of: Quix™ HIV-1 Rapid Antibody Identification Test [promotional materials, research data & abstracts, package insert]. Columbia, MD: Univeral HealthWatch Diagnostics, 1998-1999.

Urine HIV screen is accurate and more acceptable to patients. *Reuters Health*, 5 November 1999, available at <www.ama-assn.org/special/hiv/ newsline/reuters/11057077.htm>.

Valdiserri RO et al. A study of clients returning for counseling after HIV testing: implications for improving rates of return. US Department of Health and Human Services, 1993. Available at <hivinsite.ucsf.edu/prevention/best_of_science/2098.20e4.html>.

Vercauteren G. Evaluation of 7 simple/rapid HIV antibody assays using seroconversion panels. International Conference on AIDS 1994; 10(1): 246 (abstract no. PB0415). AIDSLINE ICA10/94369883.

Watts H et al. Complications according to mode of delivery among HIV-positive women with CD4 counts < 500. Program and Abstracts of the 6th Conference on Retroviruses and Opportunistic Infections, 31 January–4 February 1999, Chicago IL (Abstract 684).

Weber B et al. Multicenter evaluation of a new rapid automated human immunodeficiency virus antigen detection assay. *Journal of Virological Methods* 1999; 78: 61-70.

Wiktor SZ et al. Short-course zidovudine for prevention of mother-to-child transmission of HIV-1 in Abidjan, Côte d'Ivoire: a randomised trial. *Lancet* 1999; 353: 781-785.

Wiley DJ et al. Failure to learn human immunodeficiency virus test results in Los Angeles public sexually transmitted disease clinics. *Sexually Transmitted Diseases* 1998; 25(7): 342-345.

Wilkinson D et al. On-site HIV testing in resource-poor settings: is one rapid test enough? *AIDS* 1997; 11(3): 377-381.

Windsor IM et al. An evaluation of the capillus HIV-1/HIV-2 latex agglutination test using serum and whole blood. *International Journal of STD and AIDS* 1997; 8: 192.

World Health Organization. Recommendations on the safe and effective use of short-course ZDV for prevention of mother-to-child transmission of HIV. *Weekly Epidemiological Record* 1998; 73: 313-320.

Zahwa H et al. Evaluation of Rapid HIV Testing Platforms. 7th Conference on Retroviruses and Opportunistic Infections, 30 January–2 February 2000, San Francisco CA: Abstract 765, available at <www.retroconference.org>.

Zaw M et al. Local evaluation of a rapid HIV assay for use in developing countries. *Tropical Medicine and International Health* 1999; 4(2): 216-221, MED/99237729.

Appendix A: Rapid HIV Screening at the Point of Care: An Ethical Commentary

*This ethical commentary was prepared by Barry Hoffmaster, Professor in the Departments of Philosophy and Family Medicine at the University of Western Ontario. The author would like to thank Richard Elliott and Ralf Jürgens for their careful reading of several drafts of this commentary, for their helpful, incisive criticisms and suggestions, and for their support. Many of the points and ideas in this commentary are taken from the remarks and suggestions of people who participated in the Workshop on Rapid HIV Screening at the Point of Care held in Toronto on 21-22 January 2000 and sponsored by the Canadian HIV/AIDS Legal Network. The author thanks all those who attended this workshop for their candour and their generos*ity.

Introduction

Continual advances in the diagnosis and treatment of HIV/AIDS require unstinting scrutiny of the moral issues inherent in testing and therapeutic decisions. As Carol Levine and Ronald Bayer pointed out a decade ago, moral concerns can easily be subjugated to enthusiasm for the latest scientific or technological development:

> It is precisely when medicine's capacity to enhance patient welfare appears to be increasing that there is a danger that important ethical concerns can be overridden or disregarded. This is especially so in the case of AIDS – a disease that will continue to exact an enormous toll in human suffering for the foreseeable future and that continues

No technology is an unalloyed blessing; there are always risks and dangers.

Testing is not done for the sake of testing, but for the sake of the goals that testing makes it possible to attain.

> to have a social and cultural impact far beyond the numbers of people affected.[1]

The prospect of rapid HIV screening[2] at the point of care (POC) poses the kind of moral danger that worries Levine and Bayer. The benefits seem real and immediate. More people would receive their test results; access to testing for some populations could be improved; HIV prevention efforts could be enhanced; and treatment could be started sooner. In addition, rapid screening may be preferable to those being tested. So what is the problem?

The problem is that no technology is an unalloyed blessing; there are always risks and dangers, even if they are hidden or remote. Because any single screening test has a lower positive predictive value than a testing procedure that provides confirmed results, some people with a positive result would not actually be infected and thus could be harmed by being informed that their screening result is positive. Given its greater ease and simplicity, rapid screening might be offered by health-care professionals who have neither the time nor the training to do adequate pre- and post-test counseling. In "emergency" situations, rapid screening might be performed without the knowledge and consent of the person being tested. And, gazing ahead, licensing rapid screening could pave the way for home testing.

Moral issues are, therefore, unavoidable and central to a decision about whether rapid screening should be permitted, and if it is, to decisions about how it should be offered and to whom it should be offered. The general matters raised by rapid screening are not new – for example, sorting out the prospective benefit/harm ratio, ensuring informed and voluntary consent, providing adequate counseling, and controlling the information obtained from testing. But these issues take on a new cast in this context and therefore must be addressed anew.

Background

The Goals of HIV Testing

Despite the pace and the extent of change with respect to HIV testing, the starting point for any ethical examination of testing must remain the same – the recognition that HIV testing is not an end in itself but a means to an array of different ends, both individual and social. The value of HIV testing is, in other words, merely instrumental. Testing is not done for the sake of testing, but for the sake of the goals that testing makes it possible to attain. So a moral analysis of testing always has to ask: What are the aims, goals, or purposes that HIV testing is supposed to achieve? Those goals need to be identified in order to determine what counts as a good or bad moral argument in favour of doing testing in a particular way or of using a particular kind of test in a given setting.

Moreover, recognizing that HIV testing is only a means has an important moral implication. It entails that questions about access to HIV testing are not questions about access to just any kind of testing but access to *quality* testing. Why? Because whether the benefits that testing makes possible will actually be realized depends upon the quality of the testing that is done, in particular, the quality of the counseling that accompanies testing.

[1] Levine C, Bayer R. The ethics of screening for early intervention in HIV disease. *American Journal of Public Health* 1989; 79: 1661.

[2] The term "screening" might be thought inappropriate here because, for example, it is populations, not individuals, who are screened, or because screening is done in blood banks. Those uses of the term do not fit the diagnostic testing of individuals provided by rapid POC screening tests. But as long as a positive result of a single rapid test is preliminary and needs to be confirmed by a subsequent test, it is appropriate to describe this kind of testing as "screening" in a different sense of the term. "Screening" is used in the latter sense throughout this paper to highlight the provisional nature of a positive result from a rapid test.

Respect for Autonomy: The Requirement of Informed and Voluntary Consent

Another constant in any ethical examination of HIV testing is the moral requirement of respect for autonomy, along with its legal analogue, informed and voluntary consent. The criteria for making a morally autonomous choice about HIV testing and giving legally informed consent to HIV testing coincide because the legal doctrine of informed consent is grounded in the moral principle of respect for autonomy. Two criteria are central: the decision must be based on sufficient information, and it must be voluntary. One of the purposes of pre-test counseling is to provide individuals with adequate information in a form and manner they can understand. How well an individual has understood and appreciated the information presented can be difficult to determine. Yet assessing the voluntariness of a decision is more difficult still. If a man hesitates, vacillates, and seems unsure, but eventually agrees, is his choice voluntary? If a woman agrees because she feels pressured by a partner, is her choice voluntary? Those are hard calls to make and will depend, in large measure, upon contexts and circumstances.

But not all the factors that can make a decision involuntary are even that apparent. The pressures that compel a person to be tested could be more subtle and hidden – inherent in, say, a bleak economic plight. Just as a husband and father whose only alternative to welfare is a dangerous job in a mine really has no choice, so, too, someone who desperately needed a job and was applying to an employer who used rapid screening to test all potential employees really would have no choice. The compulsion that operates in these examples is situational, unlike an individual instance of coercion, such as the robber who sticks a gun in your back and says, "Your money or your life." Moreover, an inducement can work as effectively as a threat of harm to remove voluntariness. If someone were offered a highly desirable reward contingent upon agreeing to rapid screening, the voluntariness of that agreement would be suspect. Submission to screening required by an athletic team would be similarly suspect. Because rapid screening would make these kinds of scenarios more tempting and easier to conceal, greater scrutiny of and more caution about whether decisions to be tested are voluntary, not just informed, would be required.

The two-week waiting period for current testing can be stressful and traumatic. Being spared that agonizing, arduous ordeal would be a substantial benefit for many people.

Potential Benefits

Faster Delivery of Results

With the standard testing procedure, people can wait two to three weeks for the results of their tests. With rapid testing, the result can be available in 15 minutes. The two-week waiting period for current testing can be stressful and traumatic. Being spared that agonizing, arduous ordeal would be a substantial benefit for many people. For some, though, there could be value in living through such a difficult time. Doing so could prompt them to contemplate their mortality and evaluate their lives, consider ways of changing their behaviour, and conclude that they never want to go through this experience again. Reactions to testing, like decisions to be tested, are individual and idiosyncratic.

Whether there would be additional benefits to faster delivery of results depends upon the outcome of the test. For those who tested negative, as most people would, their anxieties, worries, and fears could be relieved sooner.

Were people strongly to prefer one kind of test, allowing them to choose and satisfying their preferences would be benefits in themselves.

Quick reassurance would be a definite benefit for them. But for those who tested positive on the screening test, there would be no real benefit. They would have to await the result of a confirmatory test, enduring psychological and emotional distress that could be greater than what they would have experienced with the mere uncertainty that accompanies standard testing. Moreover, they would not have the option of starting treatment immediately because they would have to have a CD4 test and a viral load test before any treatment could be begun. Even so, whether there would be any therapeutic benefit to beginning treatment sooner is unclear. For those who are actually HIV-infected (not false positive), medical opinion remains divided about whether there is a substantial clinical benefit to instituting antiretroviral therapy two weeks earlier than it could be begun with the standard testing approach.

An assessment of this potential benefit depends upon information about how many of those being tested prefer not having to wait two weeks for results and how strong their preferences are, and upon information about the experience of coping with a positive screening result that needs to be confirmed. The numbers favour rapid screening – more people are likely to want a quick result, and more people will test negative. Nevertheless, the potential impact on those who test false positive cannot be discounted.

Enhanced Autonomy

Because decisions about testing are highly personal and individual, having a choice between conventional testing and rapid testing would allow people to select the approach that suits them and their current circumstances and thus would enhance their autonomy. It could also produce sounder decisions because the people being tested generally would know their own values and interests better than the people counseling them. Counselors would not be precluded from giving advice and making recommendations, but the decision about what kind of test to have would be left to the person being tested. Were people strongly to prefer one kind of test, allowing them to choose and satisfying their preferences would be benefits in themselves. Respecting autonomy recognizes that giving people choices and accepting their choices are valuable in themselves, regardless of the wisdom of what is chosen. And insofar as the people being tested would be more knowledgeable about their own attitudes and values and more attuned to their own situations, respecting their autonomy also could produce better decisions.

More Results Delivered

Introducing rapid screening would increase the number of people who receive their test results. The magnitude of that increase is unclear, however. Recent research from the Centers for Disease Control and Prevention indicates that about 13 percent of adults in the United States who were tested for HIV in 1994 and 1995 never received their test results.[3] Not surprisingly, those whose test was not self-initiated were significantly less likely to obtain their results.

But it could be that Canada has a significantly lower rate of "non-returners," in part because many people in the United States are routinely tested at STD clinics to which they did not go to be tested for HIV. Canadian data on non-return rates are sporadic and largely anecdotal. At a recent workshop on rapid HIV screening at the POC, it was reported that the non-return rate for an STD

[3] Tao G et al. Rates of receiving HIV test results: data from the U.S. National Health Interview Survey for 1994 and 1995. *Journal of Acquired Immune Deficiency Syndromes* 1999; 22: 395-400.

clinic in Edmonton was 24 percent; that in a clinic in British Columbia in 1996, 14 percent of reactive test results were not received; and that the non-return rate for 33 anonymous testing centres in Ontario was 0.7 percent.[4] These numbers suggest that there is substantial variability in return rates across testing settings. That the return rate could depend on factors such as the population to whom testing is offered, the type of testing offered, and the nature and the quality of the counseling provided is not surprising.

An assessment of this potential benefit requires better, more comprehensive Canadian data. If research confirmed the apparent variability of non-return rates, the importance of this benefit would be different in the various settings in which rapid testing were to be offered. At the same time, not enough is known about why people do not return for their test results. How many people who test positive on a rapid screening test would not come back for a confirmed result, and why would they not come back? We do not know. Not returning could indicate that a person is not ready to receive the result, and for such individuals there would be no advantage to rapid screening. Without solid Canadian data about many aspects of HIV testing, the size, and thus the importance, of this benefit is hard to gauge.

How many people who test positive on a rapid screening test would not come back for a confirmed result, and why would they not come back? We do not know.

Increased Access to Testing

Because rapid screening does not require laboratory facilities, it could make it easier to provide HIV testing in remote communities and thus could increase the number of people who have timely access to results in places distant from established testing sites. With standard testing, a health unit in a remote location might, for example, routinely wait until five tubes of blood have been collected before sending them to a laboratory, thereby adding to the time it already takes to send blood to a laboratory and get the results back. In geographically remote locations the simplicity of rapid screening could increase access to and the speed of HIV testing.

In remote areas, though, there is a worry that it could take a long time to get a confirmed result for a positive screening test and the community might not have the resources to support a person with a preliminary positive result during that difficult period. Good counseling would be the way to deal with that potential problem. The alternative testing approaches, and the advantages and disadvantages of both, should be explained, and the person being tested should be allowed to choose.

As with any health-care service, there are additional problems and challenges to providing HIV testing in a remote community. As well, there are fewer people in remote areas who might need and use the service. Consequently, the potential benefit of offering rapid testing in remote communities could seem small. There is, however, an important moral consideration that overrides that conclusion – equity. People who live in remote areas are already disadvantaged with respect to countless benefits and services that society provides. And Aboriginal peoples who live on reserves have had, in addition, to endure a long and painful history of discrimination. With respect to services as important as health care, people in remote areas are entitled to equitable access. Because rapid POC screening could improve their access to HIV testing, there is a compelling moral argument for providing it.

[4]Workshop on Rapid HIV Screening at the Point-of-Care, sponsored by the Canadian HIV/AIDS Legal Network, Toronto, 21-22 January 2000.

Rapid testing would substantially increase the number of people tested only if it were implemented in a way that eliminated the real barriers to testing that currently exist.

Increased Acceptance of Testing

The convenience, speed, and simplicity of "one-stop" testing might induce some people to get tested who otherwise would not be tested, even in areas where conventional HIV testing is readily available. The number of people to whom the technology alone might make a difference is unclear, however. Rapid screening could, for example, make testing acceptable to people who are so averse to venipuncture that they avoid the standard testing procedure. Yet it is probably a small number of people who, despite concern about their serostatus, adamantly refuse to be tested for HIV because of the venipuncture. Less painful and intrusive means of collecting fluid samples, such as a finger-stick, or an oral fluid swab or urine sample, should such tests eventually be approved in Canada, would be preferable to everyone tested. But that is not to say that venipuncture is a deterrent to testing.

There could be an increase in the number of people tested immediately after rapid screening were introduced, but that increase would most likely be temporary. So whether more people would be tested because of the technology itself is speculative, and in any event the magnitude of such an increase would be small.

The information that a rapid screening test could provide would be of limited value to a decision about whether to initiate PEP.

Rapid testing would substantially increase the number of people tested only if it were implemented in a way that eliminated the real barriers to testing that currently exist. People who want to get tested will get tested using the standard procedure *as long as they have access to testing services*. The absence of on-site testing is not a major impediment to testing where testing is now readily available. More formidable barriers to testing include: lack of information; fear of being tested; concerns about privacy and confidentiality; and physicians who dissuade people because they do not regard them as being at risk. If those barriers to testing were systematically eliminated, the number of people being tested could substantially increase regardless of the testing technology.

Improved Prevention

Post-Exposure Situations

Rapid testing could provide more information for decisions about post-exposure prophylaxis (PEP). When a person has been exposed to the risk of HIV transmission, for example, as a result of an accidental needle-stick in a hospital or a sexual assault, decisions have to be made about the *initiation* of PEP and about the *continuation* of PEP once it has begun. Initiation decisions have to be made quickly. It is recommended that someone who has been exposed to the risk of HIV transmission begin PEP within two hours. So rapid testing could offer a potential benefit in these situations, but how big would that benefit be?

The significance of the benefit depends upon the value of the information that rapid screening would provide. A health-care worker who has suffered an accidental needle-stick will want to know the HIV status of the patient from whom the blood came. A victim of sexual assault will want to know the HIV status of the perpetrator. Those demands are understandable. Nevertheless, the information that a rapid screening test could provide would be of limited value to a decision about whether to initiate PEP.

Deciding whether to begin PEP depends upon an assessment of the risk to the person who has been exposed, and that risk assessment is a function of

several factors: the type of exposure, the time of exposure, and the probability that the source person has engaged in risk behaviour. The result of a screening test would be only one additional factor in that overall risk assessment, and it is unlikely that it would be determinative or even strongly influential. Moreover, that result, whatever it is, would not provide the desired certainty. If the result is negative, the person tested could be in the window period, which can last as long as six months. If the result is positive, it could be a false positive. A rapid screening test does not allow one to *know* whether a source person is infected. Consequently, a decision about whether to initiate PEP still would depend on probabilities, and the result of a rapid screening test of the source person would add little to the assessment of those probabilities. All of this assumes, moreover, that PEP is beneficial. But the benefits of PEP have not been clinically established, so the contribution that rapid screening might make to PEP decisions remains hypothetical.

In addition, testing could not legally occur without the informed, voluntary consent of the person being tested. In cases of sexual assault, the source person could be unknown, unavailable, or unwilling. In cases of occupational exposure, the source person is generally known, and the occupational exposure team in a hospital, for example, could ask the source person for a rapid test. But any source person being asked for a voluntary rapid test would have to be informed about what the screening test could and could not do. How and by whom a source person is approached could substantially influence whether that person agrees to be tested. Perhaps the most important objective in this regard is to make it safer for source persons to be tested voluntarily, by, for example, destroying test results, scrupulously protecting confidentiality, and preventing test results from being admissible in legal proceedings. The upshot, in any event, is that whatever benefits rapid screening might offer here would result only if a source person agreed to be tested.

Rapid screening of a source person might also provide information relevant to *continuation* decisions. An exposed person (particularly one who cannot tolerate the side effects of the drugs in the PEP regimen) might be willing to discontinue the drugs if the source person tests negative, and if these results can be received quickly, the exposed person can avoid taking drugs while waiting for a laboratory to do the full testing routine on the source person's sample.

The added benefit of rapid test kits for informing decisions about whether to (dis)continue PEP following an exposure will depend on how long the wait would ordinarily be for confirmed test results to be received from the laboratory. The length of this waiting time for lab test results will vary from place to place. In some places it is possible to "jump the queue" for HIV testing to inform decisions regarding PEP. In these cases, instead of doing the slower batch testing, a laboratory will test an individual sample from a source person with a speedy turnaround time. The result will not be available in 15 minutes as it would with a rapid screening kit, and so will not be of use in making decisions about whether to *initiate* PEP. However, in some places it may be available the next working day, or within a few days at most – faster than the usual waiting period for confirmed test results. The exposed person can then make a decision about whether to discontinue PEP based on the source person's test results, potentially avoiding weeks of unnecessary drugs. The potential advantages of rapid screening for PEP decisions are stronger where there is no access to an

Whether a woman in labour is capable of making a morally autonomous choice about, or giving voluntary informed consent to, any form of HIV testing is contentious.

expedited standard testing procedure. Again, however, given all the uncertainties and probabilities associated with such a decision, the result of a screening test would remain but one factor, albeit a significant one.

Pre-Exposure Situations: The Example of Pregnant Women in Labour

HIV testing of pregnant women makes it possible to initiate, for women who test positive, preventive measures that can substantially reduce the risk of transmitting the infection to their newborns. That, of course, is an enormous benefit. It is a benefit not only to the child but also to the child's mother – a family benefit.

The best approach, of course, is to test women early in their pregnancy. But for women who have had no prenatal care, or whose HIV serostatus is unknown at the time of labour, testing during labour could be an option. Even then the risk of transmission from mother to child can be significantly reduced.

Whether a woman in labour is capable of making a morally autonomous choice about, or giving voluntary informed consent to, any form of HIV testing is, however, contentious. While Minkoff and O'Sullivan recognize that merely proffering the option in such conditions could violate the standards of informed consent, they point out that women in labour are allowed to consent to elective caesarean sections, and they argue that

HIV testing is not just another medical procedure.

> depriving women of the right to consent to be tested and treated for HIV, if such therapy could potentially spare their children lethal infections, may represent more of an assault on autonomy than a discussion of testing would entail. Women untested and untreated, who deliver children who eventually succumb to HIV, may not be grateful that they were not burdened with the difficulties of decision making during labor.[5]

But Jürgens rejects the analogy with caesarean sections: "[T]he issue of whether a woman could indeed provide fully informed consent to testing for HIV during labour is not the same ... as the issue of whether a woman can provide informed consent to a cesarean section during labour."[6] That, of course, is correct, especially when the "fully informed" nature of the consent is emphasized. The risks of a cesarean section are more immediate and more limited. A positive result from an HIV test could have profound, sweeping implications; it could expose a mother and her child to stigmatization and various forms of social and economic discrimination that could be devastating to their lives. A woman in labour might not be able to "appreciate" the potential consequences of HIV testing and thus could not give informed consent to such testing.

This is a matter that needs more research and more debate. Qualitative research on women's experiences with making decisions during labour and their reactions to those decisions would be particularly helpful. As well, more analysis needs to be done with respect to the requirement of informed consent. How high are the standards for "informed" or "fully informed" consent, and might those standards vary depending on the nature of the decision and the circumstances in which the decision must be made? Given that women in labour are allowed to consent to epidurals and cesarean sections, one should be reluctant to disenfranchise them in other respects. Yet HIV testing is not just another medical procedure.

[5] Minkoff H, O'Sulliivan MJ. The case for rapid HIV testing during labor. *Journal of the American Medical Association* 1998; 279: 1743-1744 at 1744.

[6] Jürgens R. *HIV Testing and Confidentiality: Final Report*. Montréal: Canadian HIV/AIDS Legal Network & Canadian AIDS Society, 1998, at 118.

Potential Harms

Disclosure of Preliminary Positive Results

As long as there were a time lag between a positive screening result and confirmation of that result, a decision about whether to disclose an unconfirmed positive screening result to the person being tested would have to be made. Whether to reveal information that is uncertain and perhaps even speculative is a common problem in health care. Consider this vignette. A young woman comes to her family doctor complaining of an episode of temporary blindness in one eye. A careful history and physical examination reveal nothing. The woman is referred to an ophthalmologist, and the ophthalmologist's report comes back negative. The family doctor knows that such an episode can be an early presenting sign of multiple sclerosis. Should the doctor inform the woman of this possibility? On the one hand, it could be argued that the doctor has only a suspicion. Telling the woman could harm her by inducing needless worry and anxiety. On the other hand, this information could be relevant to important decisions that are imminent in the woman's life. Perhaps she is considering getting married or trying to become pregnant. Perhaps she is embarking on a career, and were she to know of the possibility of multiple sclerosis, she would change her plans or defer them so she could travel. Depriving her of this information could compromise her autonomy – her right to make significant decisions about her life in terms of her own beliefs and values.

This vignette is a reminder of the role of respect for autonomy in decisions about what information to divulge. Moral decisions about disclosing information can be framed in consequentialist terms – as predictions and assessments of the potential harms and benefits for the person involved. But there are twin dangers in that restricted perspective. One is that the decision will be paternalistic, that it will rest on the health-care provider's view of what is best for the person rather than the person's own view.[7] The other is that it will be too limited, that it will ignore potential harms to others.

Both dangers exist, in theory, with a policy of non-disclosure of positive screening results. Not disclosing positive results *could* preclude individuals from making important decisions about their lives and *could* increase the risk of transmission to others. Yet a confirmed test result would be available in two weeks, so the moral force of both potential harms is weak. It is hard to imagine a major, irreversible life decision that would be made in that brief interval or that would be drastically affected by having to wait for a confirmed result. Nor, for the reasons given already, would an individual be able to decide to start treatment sooner. So disclosure of a preliminary positive result would do little, if anything, to advance autonomy.

Disclosure of a positive screening result to the person being tested could make it possible to prevent transmission to another person if learning that result meant that the person being tested did not engage in unprotected sex or needle sharing during the two-week waiting period. Again, however, the potential benefit of rapid screening is speculative. A person who is sufficiently concerned to be screened and who receives proper counseling probably would be motivated to avoid risk behaviour and would act on that motivation in the ensuing two weeks anyway. And a person who was not already disposed to

[7] At a workshop on rapid POC screening, this worry was raised more generally: "Are we being too 'paternalistic' about this issue?" See HIV Point-of-Care Testing (Report of a Workshop held at the Lord Elgin Hotel on 29-31 March 1999). Ottawa: Intersol Consulting Associates Limited, 1999, at Appendix B.

How much harm then would be done to those who receive a positive screening result that turns out to be a false positive?

avoid risk behaviour probably would not be affected by a preliminary positive result. Either way, disclosing a positive screening result would be unlikely to have a significant impact on preventing transmission to others. Consequently, neither a moral principle of respecting autonomy nor a moral principle of preventing harm would support the disclosure of a preliminary positive screening result in the way that it might support the disclosure of a possible diagnosis of multiple sclerosis.

But even if a policy of non-disclosure were morally defensible, it would not be practically sustainable. Rapid screening is attractive because it produces rapid results. Negative results will be disclosed forthwith. In that context any result that is not disclosed will, naturally and inevitably, be assumed to be positive:

> If rapid testing is implemented, it will not be feasible to selectively withhold the preliminary screening information. The public will be aware that screening results can be made available immediately. If people do not immediately receive information that they are negative, the inference is that they screened positive.[8]

The moral question is whether it would be justifiable to give potentially inaccurate HIV-positive screening results to some people because there would be benefits to people who test negative on rapid screens, when everyone could be provided with confirmed results using the standard testing procedure, albeit a bit more slowly.

A policy of non-disclosure would, therefore, be a de facto policy of disclosure of positive results. So *if* rapid screening were implemented, it would not be possible to withhold positive results. How much harm then would be done to those who receive a positive screening result that turns out to be a false positive? They would certainly be worried, anxious, and fearful. Perhaps their distress could be mitigated by how they are told and what they are told. It might not be a good idea to tell individuals with a positive screening result that they are *likely* to be infected, that they are *probably* infected, or that they have a *good chance* of being infected. Instead they could be told that they have a preliminary positive result but that no diagnosis is possible until there is a result from a confirmatory test. Given the reasons mentioned above, there would seem to be no point in saying more than that. Moreover, such a cautious statement reiterates and emphasizes that rapid screening is *screening* only – that an additional *test* is necessary to obtain a confirmed result.

The moral question that remains, though, is whether it would be justifiable to give potentially inaccurate HIV-positive screening results to some people because there would be benefits to other people who test negative on rapid screens, when everyone could be provided with confirmed results using the standard testing procedure, albeit a bit more slowly. Without knowing more about the impact of receiving a preliminary positive result from a screening test, it is hard to answer that question. Simply comparing the numbers of people who would test negative and positive is not enough. How those people would be affected also needs to be considered, taking into account the view that the moral duty not to harm people is generally considered more stringent than the moral obligation to help people.

Inadequate Counseling

Rapid screening does not mean rapid counseling. Yet counseling conducted over a shorter time might be rushed and abbreviated and thus not as effective. Whether the counseling that would accompany rapid POC screening would be inferior or inadequate is an open question. On the one hand, a compressed

[8] Leviton LC. For whom do we test? What do we say? Rapid HIV screening. *Public Health Reports* 1996; 111(1): 54.

period of time might mean that the counseling is hasty and that people do not have sufficient opportunity to assimilate what they have been told, reflect, and ask questions. On the other hand, in one visit all the counseling could be done by the same person, with a likely improvement in continuity, consistency, and confidentiality, and a better rapport between the person being tested and the counselor.

Addressing this question requires, first of all, that the purposes of counseling be articulated and distinguished. They include:

- achieving informed consent;
- reinforcing prevention information and messages;
- changing behaviour to avoid future risk activities so as to protect the person against infection or reinfection and/or prevent transmission to others;
- obtaining information for partner notification; and
- helping the person to cope with a diagnosis and make treatment decisions.

Abbreviated counseling *might* be adequate with respect to attaining the goals of reinforcing prevention messages and changing behaviour; however, this point needs to be studied. And helping someone to cope with a diagnosis of infection will, in any event, require ongoing counseling.

But the ease and speed of rapid screening might encourage shortcuts with respect to obtaining informed consent. Proper time and care are necessary in pre-test counseling for individuals to make morally autonomous choices about whether to be tested and to give legally informed consent to testing. With rapid screening, in addition to all the other matters that have to be covered in counseling for HIV testing, the lower positive predictive value of a screening test and the implications of this would have to be addressed. That entails an explanation that a single, intentionally over-sensitive test would be done rather than two tests using different testing principles, the second of which is designed to be specific to detecting HIV-antibodies; and that for any given individual the positive predictive value of a test will depend on how "at risk" the person being tested is, given his or her past activities (thereby requiring an exploration of this matter in the counseling), and on how prevalent risk activities are among the people within the population to which the person being tested belongs. Information that complicated cannot be communicated easily or quickly. Moreover, it must be conveyed in a manner that the person being counseled can understand and appreciate, so that that person is able to make a morally autonomous choice about rapid screening and give informed consent to a test. Yet a harried health-care professional in a busy clinic or private practice might be sorely tempted to present the screening test as "quick and easy," to gloss over necessary details, to avoid explaining points that seem to create difficulty, and to discourage questions.

Proper time and care are also necessary in post-test counseling, regardless of whether the result is negative or positive. If it is negative, the need for vigilant, conscientious preventive measures must be stressed; a negative test result must not be allowed to engender a sense of false security. If the result is positive, therapeutic options have to be discussed, along with matters of prevention and partner notification. At the same time, the caution that the result might be a false positive needs to be reiterated and a confirmatory test must be arranged.

Proper time and care are necessary in pre-test counseling for individuals to make morally autonomous choices about whether to be tested and to give legally informed consent to testing.

Breaches of confidentiality are a concern for all forms of HIV testing. That concern is magnified with respect to rapid screening.

Providing adequate pre-test and post-test counseling is difficult enough with the standard testing procedure. Would health-care professionals who are not experienced with HIV/AIDS but who begin offering rapid screening have the training, the time, and the incentives to provide proper counseling? How would such providers get the education and skills they need? Where would they find the time, amidst their myriad clinical responsibilities, to do diligent, effective counseling? And how much motivation would they have to find that time if the financial incentives for counseling are sparse?

Breaches of Confidentiality

Breaches of confidentiality are a concern for all forms of HIV testing. That concern is magnified with respect to rapid screening, however, because implementing it would allow HIV testing to be more dispersed and localized. Were rapid screening to proliferate, scrutiny and supervision of it would become more difficult. In addition, the people performing the screening might not be aware of how scrupulously the confidentiality of test results must be maintained, and they might not be familiar with the kinds of procedures that need to be in place.

Confidentiality needs to be protected for both practical and moral reasons. With respect to the former, willingness to be tested can depend on confidence in the measures taken to protect privacy and insure confidentiality. The prospect that insurance companies or employers, for example, might be able to obtain the results of rapid screening tests could jeopardize the success of the program. With respect to the latter, health-care professionals have an ethical duty to protect people's privacy. Safeguards tailored to the diverse and idiosyncratic settings in which rapid screening would be available therefore need to be designed and carefully implemented. Perhaps those safeguards would have to take the form of allowing rapid POC screening to be offered only by health-care professionals who are subject to unequivocal ethical and legal duties to maintain confidentiality, and to clearly specified professional and legal sanctions for breach of those duties.

Testing Without Consent

The temptation of quick results and the opportunity for quick action on those results that rapid screening would provide could bring about testing without informed consent, for example, of source persons or pregnant women in labour. As noted earlier, a source person in a situation where a decision about PEP is being made could not legally be tested without their giving voluntary informed consent. But legal and moral issues need to be disentangled here. The current legal requirements notwithstanding, could a moral argument for testing a source person without consent be made? The argument might be that if a source person intentionally and voluntarily caused harm to another person, the source person has a moral duty to mitigate the amount of harm that person suffers. The source person, in other words, owes the person harmed something, and one way of fulfilling that obligation would be to perform a rapid test, even without the consent of the source person.

The exact nature of this obligation is unclear, however. The obligation might be understood as a matter of retributive justice – the wrongful conduct of the source person has set the moral scales out of balance, and that balance must be

restored. Reestablishing the balance could be accomplished by imposing a disadvantage on the source person that would offset whatever advantages the source person gained from the wrongful conduct. It is hard to see, however, how a non-consensual rapid test could morally rectify a sexual assault, say, for the respective harms are not commensurate. Moreover, moral retribution might degenerate into revenge or vindictiveness – the view that one assault deserves another. Alternatively, the obligation might be understood as a matter of corrective justice, that is, providing compensation for harms suffered. But the goal of rapid screening would be forward-looking not backward-looking – to reduce future harm, not to try to make up for harm already suffered. So neither type of justice would morally justify testing a source person without consent.

That does not mean that preventing a harm from continuing or from materializing in the future is not a matter of moral concern. It means only that the concern cannot be supported by an appeal to a principle of justice. But without the moral strength of a principle of justice, and given all the doubt about how useful information from rapid screening of a source person would be anyway, making a compelling moral case for screening a source person without consent would be exceedingly difficult.

Making a compelling moral case for screening a source person without consent would be exceedingly difficult.

Rapid screening could also be used to test pregnant women in labour whose HIV status is unknown, without their knowledge and their consent, and if the result is positive, antiretroviral therapy that can significantly decrease the probability of HIV transmission from mother to child could be administered.[9] For proponents of non-consensual testing of women in labour, the potential therapeutic benefits to the child are so substantial that they outweigh whatever harms might be imposed on the child's mother. And, proponents argue, violating the mother's autonomy would be justified. Even in societies devoted to promoting individual freedom, there are restrictions on the exercise of that freedom. Freedom may be limited when it threatens to harm others, as John Stuart Mill's classic articulation of "the harm principle" makes clear:

> [T]he sole end for which mankind are warranted, individually or collectively, in interfering with the liberty of action of any of their number is self-protection.... [T]he only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others.[10]

Women could, quite rationally and understandably, be averse to taking any drugs during pregnancy or labour.

Thus, when the interests of a child and its mother collide so dramatically, it would be morally permissible, proponents of non-voluntary testing conclude, to test a pregnant woman in labour without her permission and consent.

The allure of this argument depends upon the way in which the interests of a mother and her child are neatly severed and how the conflict between a mother and her infant is carefully and abstractly framed.[11] Women, it is assumed, cannot be relied upon to act in ways that an external observer would define as being in the best interests of their children. And given that assumption, the apparent reluctance of a pregnant woman to be tested voluntarily counts as evidence of indifference to the health and welfare of her child.

That inference is inappropriate for a variety of reasons. The point of screening a woman in labour would be to begin treatment if the preliminary result were positive. But women could, quite rationally and understandably, be averse to taking any drugs during pregnancy or labour, given the extent to

[9] For a more extended discussion of the testing of pregnant women, see the unpublished paper written for Health Canada by Barry Hoffmaster and Ted Schrecker – An Ethical Analysis of HIV Testing of Pregnant Women and Their Newborns (August 1999). A condensed version of this paper has been published: Hoffmaster B, Schrecker T. An ethical analysis of HIV testing of pregnant women and their newborns. *Canadian HIV/AIDS Policy & Law Newsletter* 1999; 4(4): 5-11.

[10] Mill JS. *On Liberty*. Shields CV (ed). Indianapolis, IN: Bobbs-Merrill, 1956 [1859], at 13.

[11] Most of the remainder of this section is taken from Hoffmaster and Schrecker, supra, note 9.

The moral danger here is that concern for women can easily be subordinated to concern for their fetuses or newborns.

which they are bombarded by warnings about alcohol, tobacco, caffeine, street drugs, and even prescription drugs, reminded of events such as the DES tragedy, and importuned not to harm their babies. Moreover, evidence about the long-term effects of antiretroviral drugs on fetuses and children remains unclear, and concerns about the toxicity of AZT and the side effects of other anti-HIV drugs have been raised. Given all that, it is not hard to see why a woman might refuse to take the drugs to which screening could lead, even if there is strong evidence that the drugs can reduce (but not eliminate) the risk of transmission, and that refusal is even more understandable in light of the preliminary positive screening result – which could well be false positive – on which it would be based. And if she is not willing to take the drugs, what is the point of rapid screening?

The inference is also inappropriate because it ignores the realities of life for many HIV-positive women. Because of their social and economic marginalization, these women confront substantial barriers to care. Women who are poor and vulnerable must constantly juggle the exigencies of daily life and may have to balance their own health-care needs against those of existing children as well as a fetus or newborn. Women would also worry about the multiple forms of social and economic discrimination that attend testing positive, and they could fear that they would even lose custody of their child. In such circumstances, a woman's decision to forego testing is not necessarily reprehensible or irrational, given the demands imposed upon her and the options available to her. The moral danger here is that concern for women can easily be subordinated to concern for their fetuses or newborns. Non-voluntary testing could treat women "as mere vessels or vectors of disease"[12] – as no more than means to the attainment of ends that are regarded as self-evidently desirable for their infants.

Non-voluntary testing should be considered only if there is conclusive evidence that voluntary testing programs have irretrievably failed.

That inference is also premature. If a genuine conflict between a mother and her child is accepted at all, that acceptance should come at the end of an analysis, not at the beginning, and it should be a firm signal that morality and public policy have failed. Non-voluntary testing should be considered only if there is conclusive evidence that voluntary testing programs have irretrievably failed.

As of now, that evidence does not exist. Uptake rates for voluntary testing programs vary widely, ranging from roughly 50 percent in Ontario to over 90 percent in Alberta.[13] The reasons for such differences need to be understood and addressed as matters of public policy, before any data about low uptake rates can be used to argue for non-voluntary testing. As well, one factor that seems linked to the acceptance of voluntary testing is the adequacy of the counseling a woman receives. Improved counseling could make very high uptake rates feasible within voluntary testing programs. Before resorting to any non-voluntary testing, conscientious attempts must be made to use the most successful voluntary programs as benchmarks for the design and implementation of voluntary testing efforts across Canada.

When a conflict between a mother and her child is portrayed so starkly and so abstractly, it is a conflict the woman cannot win. A morally enlightened approach to testing would not pit vulnerability against vulnerability. A morally inspired and sympathetic approach would take the interests of women and the interests of their children to be congruent and would strive to promote all those interests. It would assume that mothers care for their children and want to do

[12] Faden RR, Geller G, Powers M et al. HIV Infection, Pregnant Women, and Newborns: A Policy Proposal for Information and Testing. In: Faden, Geller, & Powers (eds). *AIDS, Women, and the Next Generation*. New York: Oxford University Press, 1991, at 335.

[13] See the section on "Increasing Uptake of HIV Testing Among Pregnant Women" in R Elliott. Rapid HIV Screening at the Point of Care: Legal and Ethical Questions (in this volume, with references). For earlier data see also: Silversides A. With HIV prevalence among women increasing, more provinces encourage prenatal testing. *Canadian Medical Association Journal* 1998; 158(11): 1518.

what is best for them even if that requires personal sacrifice. It would seek to understand the barriers that deter women from courses of action that seem to be in their own and their children's best interest and require, as a matter of public policy, that those barriers be reduced or removed. Voluntary testing has the potential to do all that. Non-voluntary testing should be a moral last resort.

Rapid screening threatens that conclusion. What is morally worrisome about all proposals for non-voluntary testing is the hidden assumption that the efforts and resources that might be necessary to make voluntary testing programs successful would not be worth it. Non-voluntary rapid screening of women in labour, for example, could be viewed as simpler and cheaper and as directed at those who are most deserving: completely vulnerable, completely innocent newborns. Practically and politically, such a "quick fix" could be irresistible.

Would the introduction of rapid POC screening lead to home testing?

Perhaps this controversy can be circumvented, though, by offering a woman in labour whose HIV status is unknown, as an alternative to being tested for HIV using a rapid HIV screening kit, the option of taking antiretroviral therapy during labour, and having a short course administered to her newborn as a prophylactic measure. If the woman had had a rapid screening test and had tested positive (either truly or falsely), she would in any event have been required to make a decision about antiretroviral therapy. Of course, it is true that if she had had a rapid screening test and had tested negative, antiretroviral therapy would not have been necessary (unless there was some reason to believe she might be in the window period between being infected and testing positive for HIV antibodies).

This raises the question of whether it would be morally permissible to administer likely unnecessary antiretroviral therapy to her newborn as a preventive measure because she refuses to be tested. But how different is this from any other post-exposure situation? A police officer or a paramedic who has been exposed does not have a legal right to compel the source person to be tested for HIV, even though doing so could mean that the police officer or paramedic would not have to take a month-long course of antiretroviral therapy as post-exposure prophylaxis. However, that case, although similar, is also different in one respect: the infant, unlike the independently existing exposed person, cannot make a choice about whether to take PEP – the mother makes the decision about testing and about whether or not to expose the infant to PEP before birth. Again, however, at law, this remains her decision to make.

A Slippery Slope?

Would the introduction of rapid POC screening lead to home testing? Would it start an irreversible slide down a slippery slope? There are two variants of slippery-slope arguments, one conceptual and one causal.[14] According to the conceptual version, home testing is not, in principle, distinguishable from rapid POC screening. There are not, in other words, any morally relevant differences between the two kinds of testing; thus, if rapid POC screening is morally permissible, so is home testing. That argument is easy to rebut because there is a glaring, morally relevant difference between rapid POC screening and home testing – home testing could occur without either the pre-test counseling or the post-test counseling that is essential to a responsible testing program, and in the absence of trained professionals who can interpret test

[14] For analyses of slippery-slope arguments see: Lamb D. *Down the Slippery Slope*. New York: Croom Helm, 1988; van der Burg W. The slippery slope argument. *Ethics* 1991; 102: 42; and Schauer F. Slippery slopes. *Harvard Law Review* 1985; 99: 361.

results and explain what they mean. Whatever benefits home testing seems to offer might well be offset by the harms that would result from allowing testing to occur in the absence of counseling. So logically or conceptually, rapid POC screening *does not* entail home testing. But reason does not always, or perhaps even frequently, prevail in the world. Regardless of whether rapid POC screening and home testing are morally distinguishable, licensing rapid POC screening might, in practice, lead to the introduction of home testing. That is what a causal version of the slippery-slope argument contends.

Were rapid POC screening to be introduced, a core moral issue would be who should have access to it.

Causal slippery-slope arguments are, however, notoriously difficult to assess because the empirical claims on which they rest are often speculative. What would the causal links between the acceptance of rapid POC screening and the consequent introduction of home testing be, and how likely is it that these connections would actually occur? Would the practice of rapid testing, and the expedited, cursory counseling that could accompany it, soften our attitudes about the necessity of counseling for all HIV testing? Would the economic or political interests marshaled behind rapid POC testing subsequently coalesce behind home testing, despite previous dismissals of the concern that approving rapid POC screening could lead down a slippery slope to home testing? It is hard to envisage precisely what the causal mechanisms might be. But uncertainty about *how* rapid POC screening might pave the way to home testing then breeds uncertainty *that* rapid POC screening would in fact pave the way to home testing. That is the weakness of a causal slippery-slope argument.

In theory, that weakness must be acknowledged. Yet the practical worry this argument encapsulates is hard to shake. If testing is good, and if rapid POC screening makes testing easier and more accessible, then why not home testing, which would make testing easier still and even more accessible? That reasoning could be practically and politically persuasive, the ethically qualitative differences between rapid POC screening and home testing notwithstanding.

Access to Rapid Screening

Were rapid POC screening to be introduced, a core moral issue would be who should have access to it. A group of participants at the Health Canada–organized March 1999 workshop on "HIV Point-of-Care Testing" stated flatly: "The group does not agree that universal access to POC is appropriate."[15] Once that view is accepted, the task is to define for which populations rapid screening would be "most suitable"[16] or "most effective."[17]

But why should access to rapid screening be restricted in the first place? The answer is familiar – a single rapid screening test is not as accurate as the standard testing procedure, which consists of a screening test (the ELISA test, or EIA) and subsequent confirmation of repeated positive tests (usually by the Western blot). A rapid screening test has a lower positive predictive value, which means that it would yield more false-positive results, particularly when used in populations where the prevalence of HIV is lower. In other words, the current testing algorithm is accepted as the gold standard for HIV testing, and any test that does not at least match its accuracy will be restricted to situations where the likely benefits of using the less accurate test are deemed to outweigh the likely harms that would result from more false-positive results. Given this

[15] HIV Point-of-Care Testing, supra, note 7 at 7.

[16] Ibid at 8.

[17] Medical Devices Bureau. Report on the HIV Point-of-Care Testing Workshop. Ottawa: 29-31 March , 1999, at 2.

position, access to rapid screening would depend upon appraisals of its anticipated benefits and harms for specific populations. Thus, it might be acceptable in an anonymous testing site or in an STD clinic, venues where the positive predictive value would be fairly high, but not in a family medicine clinic in a suburban neighborhood, where the positive predictive value would be appreciably lower.

But why should access to rapid screening depend solely upon a favorable benefit/harm ratio for a population? Why could rapid screening not be offered universally, with those being tested allowed to choose between the slower but more accurate standard testing procedure and quicker but less accurate rapid screening? Why should those being tested not be permitted to exercise their autonomy and decide whether speed or accuracy is more important to them?

Moreover, what impressions would be created and what conclusions would be drawn if rapid screening were offered only to populations in which the prevalence of HIV is higher and those populations are marked by poverty or composed largely of members of a particular racial or ethnic group? Would it be recognized that special benefits were being directed to people who are worse off or marginalized? Or would those people suspect that they are, yet again, the recipients of a lower standard of care?

Were rapid screening to be approved, either it should be restricted to venues where appropriate counseling is currently available, or the resources needed to provide appropriate counseling and support services in new venues where rapid screening would be offered must be forthcoming.

Allocation of Resources

No health care issue can be discussed these days without raising matters of resource allocation. Were rapid screening to be offered, and were the number of people to be tested to increase as a result, more resources would be needed to cope with the heightened demand. Where would those resources come from?

The worry about adequate resources is particularly acute with respect to counseling. Were rapid screening to be approved, either it should be restricted to venues where appropriate counseling is currently available and can readily be adapted to rapid screening, or the resources needed to provide appropriate counseling and support services in new venues where rapid screening would be offered must be forthcoming. Rapid screening might be less costly than the standard testing procedure because laboratory costs could be lower and no second visit to receive the test result would be required. But if that were the case, those savings should then be used to fund the counseling and support services that are required to make rapid testing *quality* testing.

If rapid screening were to be introduced, the experience with it would need to be carefully investigated, evaluated, and monitored.

Conclusions

Because the information about Canadian HIV testing and the counseling that accompanies it is so skimpy, impressionistic, anecdotal, and sporadic, an assessment of the potential benefits and harms of rapid screening has to be speculative and uncertain. If research in this area is not done and solid, systematic, comprehensive data are not acquired, the same difficulty will plague all future developments in HIV testing technology. Concerted research therefore needs to be funded, and if rapid screening were to be introduced, the experience with it would need to be carefully investigated, evaluated, and monitored.

Because people who live in geographically remote locations are morally entitled to equitable access to health-care services, rapid screening could be offered to them. At the same time, those people must have access to the

No HIV testing should occur in the absence of quality counseling; that requirement is even more stringent for rapid screening.

counseling and support services needed to ensure that rapid screening would be *quality* testing.

Rapid screening could be offered to other populations where the resources to provide quality counseling about rapid screening to a population are available and it is demonstrable that quality counseling is in fact being delivered to that population. Individuals in such populations then could choose between standard testing and rapid screening. The restrictions with respect to counseling do not violate the moral principle of respect for autonomy. Respect for autonomy does not entitle people to whatever health-care services they desire or feel they need. What respect for autonomy does do is allow people to make their own individualized appraisals of the potential benefits and harms of a health-care service. In order to do that, however, people have to have complete and relevant information about a service. Providing that information about rapid screening and helping people to make autonomous choices about whether to be tested – and, if so, how to be tested – are among the goals of quality counseling. No HIV testing should occur in the absence of quality counseling; that requirement is even more stringent for rapid screening.

Rapid screening of pregnant women in labour could be phased in gradually and carefully, but it should be offered only in settings where its use can be monitored and its results can be evaluated, and only where it is impossible to get quick delivery of reliable test results, ie, only where a laboratory could not do for women in labour the kind of expedited standard testing that is possible in cases of PEP. One component of the required evaluation concerns the ability of women in labour to give voluntary, informed consent to rapid screening. Another concerns the accuracy of the screening test for pregnant women. An initial test commonly used in the standard testing procedure, the EIA, produces more false-positive results and more indeterminate results with pregnant women because of all the antibodies in their bodies. Confidence in it is the result of accumulated clinical and laboratory experience in administering the test to pregnant women. The same kind of scrutiny and assessment would be required for rapid screening of pregnant women in labour. That research needs to be conducted before rapid screening could be offered to pregnant women generally. Moreover, were rapid screening to be offered to pregnant women in labour, it should be offered to all women for whom there is no evidence of prenatal care, including HIV screening – not just to women perceived to be at high risk. Were rapid screening to be offered selectively to pregnant women in labour, the risks of discrimination and subsequent disenfranchisement would simply be too great.

The testing at issue here is testing for HIV, a disease that, to revert to Levine and Bayer's still timely warning, "continues to have a social and cultural impact far beyond the numbers of people affected."[18] Although the notion of "AIDS exceptionalism" is controversial, it remains valuable insofar as it highlights the stigmatization and discrimination that continue to afflict people with HIV/AIDS. A final worry about rapid screening is that it would promote the "normalization" of HIV testing, that is, treat it the same as testing for any other disease or condition, when the social contexts within which HIV testing takes place and the social realities with which people who test positive live are just not the same.

[18] Supra, note 1.

Appendix B: Workshop Participants and Commentators

Jacqueline Barnett	British Columbia Centre for Disease Control Society, Vancouver
Neil Burke	Canadian HIV/AIDS Clearinghouse, Canadian Public Health Association, Ottawa
Reeta Bhatia	Health Canada (Care, Treatment & Support Program), Ottawa
Maria Carballo	Health Canada (Medical Devices Bureau), Ottawa
Hermes Chan	MedMira Laboratories Inc, Halifax
Timothy Christie	New Brunswick Department of Health & Community Services (Public Management Systems), Fredericton
Clarence Crossman	AIDS Committee of London
Yvan Côté	BioChem ImmunoSystèmes, Montréal
Marlene Daly	CLSC Métro – Centre d'intervention, Montréal
Magdi Dawood	Manitoba Health – Provincial HIV Laboratory, Winnipeg
Annette Dimmer	Newfoundland & Labrador AIDS Network, St John's
Éric Doyon	MIELS-Québec, Québec City
Richard Elliott	Canadian HIV/AIDS Legal Network, Montréal
Angela Favretto	Health Canada (Prevention & Community Action Programs), Ottawa
Lesley Fleming	Canadian AIDS Society, Ottawa

Monique Fong	Atlantic First Nations AIDS Task Force, Halifax
David Garmaise	Consultant, Ottawa
Jane Greer	Hassle-Free Clinic, Toronto
Barry Hoffmaster	Department of Philosophy, University of Western Ontario, London
Barbara Jones	Health Canada (Prevention & Community Action Programs), Ottawa
Beverly Jones	Positive Women's Network, Vancouver
Ralf Jürgens	Canadian HIV/AIDS Legal Network, Montréal
Debra Keays	Nova Scotia Department of Health (Public Health/Health Promotion), Halifax
Susan King	Hospital for Sick Children – HIV/AIDS Unit, Toronto
Bryce Larke	Alberta Health, Edmonton Chair, Federal/Provincial/Territorial Committee on AIDS
Lina Leblanc-Roy	Centre québécois de coordination sur le sida, Montréal
Rick Lines	Prisoners with HIV/AIDS Support Action Network, Toronto
Lynne Leonard	University of Ottawa
Debbie Lepine	Health Canada (Medical Devices Bureau), Ottawa
Joanne MacKinnon	Northwest Territories Department of Health & Social Services, Yellowknife
Carol Major	Ontario Central Public Health Laboratory (HIV Laboratory), Toronto
Steve Martindale	British Columbia Centre for Excellence in HIV/AIDS, Vancouver
Sherry McKibben	AIDS Network of Edmonton Society
Mary Lou Miller	BC Centre for Excellence in HIV/AIDS, Vancouver
Ted Myers	University of Toronto, Faculty of Medicine
Lina Racine	Coalition des organismes communautaires du Québec sur le sida (COCQ-sida), Montréal
Stephen Shafran	University Hospital (Division of Infectious Diseases) – University of Alberta / Merlin Biomedical & Pharmaceutical
Daphne Spencer	British Columbia Centre for Disease Control Society, Vancouver
Lori Stoltz	Goodman & Carr, Toronto, & Canadian HIV/AIDS Legal Network, Montréal
Donald Sutherland	Health Canada (Laboratory Centre for Disease Control), Ottawa
Janis Tripp	Ontario Ministry of Health & Long-Term Care (AIDS Bureau), Toronto
Tasha Yovetich	Canadian AIDS Society, Ottawa