

Prevention and Protection:

Enhancing Both
HIV Testing and
Human Rights
in Canada



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Canadian HIV/AIDS Legal Network
2007



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About the Canadian HIV/AIDS Legal Network

The Canadian HIV/AIDS Legal Network (www.aidslaw.ca) promotes the human rights of people living with and vulnerable to HIV/AIDS, in Canada and internationally, through research, legal and policy analysis, education, and community mobilization. The Legal Network is Canada's leading advocacy organization working on the legal and human rights issues raised by HIV/AIDS.

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Table of Contents

Introduction	1
Methods	4
Human rights basis of the “3 Cs”: counselling, consent and confidentiality	5
1. Routine/“opt-out” HIV testing of pregnant women	6
Background	6
Existing policies, their successes and challenges	7
Level of information required to insure informed consent and counselling	8
Pregnant women’s experiences of HIV testing in Canada	9
Health care providers’ experiences, attitudes and practices	14
Conclusions and recommendations: HIV testing of pregnant women	16
(1) Removing barriers to testing and other services	16
(2) Increasing access to HIV testing services that are ethical and respect human rights	17
(3) Judging impact and success of policies for HIV testing of pregnant women	18
(4) Protecting women at high risk of adverse outcomes	19
2. Rapid HIV tests	20
Quality of rapid tests and the use of rapid testing by populations with special needs	21
Link to prompt confirmatory test and surveillance of results	22
Counselling, consent, confidentiality and anonymity	23
Women in labour	24
Risk of misusing rapid tests as a gateway to testing without informed consent	25
At-home use of rapid HIV tests	25
Conclusions and recommendations: Rapid HIV tests	26
Summary of recommendations	28
Bibliography	32





Introduction

Efforts to prevent HIV infection and to ensure access to HIV/AIDS care and treatment are a critical part of Canada's legal obligation to take steps to realize progressively every person's human right to the highest attainable standard of health.¹ Ensuring widespread access to and utilization of HIV testing is a central element of a successful response to HIV/AIDS. Increasing the number of people who know their HIV status is an essential means of preventing HIV transmission and of improving the reach of treatment and care services. Those who learn that they are HIV-positive can be steered to care, treatment and support and can re-evaluate their behaviours and practices. The counselling process associated with testing can also reinforce prevention education for those who learn they are HIV-negative.

The goal of widely available and utilized HIV testing services can be pursued in many ways. At the federal level and in some provinces, governments in Canada state their commitment to human rights-based responses to HIV/AIDS.² This not only means ensuring access to HIV testing as part of protecting and promoting the right to health, it also means that the embodiment of human rights principles and protections is, or should be, at the heart of all policy decisions related to HIV testing. In particular, three elements of many testing policies and programs have direct foundations in human rights principles:

- HIV testing may only occur with specific **informed consent** voluntarily given. This requirement derives from the human *right to security of the person*³ — that is, to being able to control what happens to one's body — as well as from the *right to information*⁴ that is an integral part of the right to health.
- **Pre- and post-test counselling** of good quality gives effect to the *right to information* and is essential for both promoting the mental health of persons getting tested and protecting public health more broadly by helping to prevent onward transmission of HIV. Good quality counselling is of particular importance for people who may not otherwise be able to get appropriate information on HIV/AIDS.
- **Confidentiality** of the results of medical tests, and of the fact of even seeking or having a test, derives from the *right to privacy*⁵ and is a central element of ethical medical practice.

¹ *International Covenant on Economic, Social and Cultural Rights*, 993 U.N.T.S. 3, (1966), Article 12(1) [ICESCR]. See also the interpretation of this right in UN Committee on Economic, Social and Cultural Rights, General Comment No. 14: The right to the highest attainable standard of health: Art. 12, UN Doc. E/C.12/2000/4, 11 August 2000, online via www.ohchr.org/english/bodies/cescr/comments.htm.

² E.g., *Federal Initiative to Address HIV/AIDS in Canada*. Ottawa: Government of Canada, 2004; *Leading Together: Canada Takes Action on HIV/AIDS (2005-2010)*. Ottawa: Canadian Public Health Association, 2005.

³ *International Covenant on Civil and Political Rights*, 999 U.N.T.S. 171, Article 9 [ICCPR]; *Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982 (U.K.)*, 1982, c. 11, at s. 7.

⁴ ICCPR, Article 19.

⁵ ICCPR, Article 17; *Canadian Charter of Rights and Freedoms*, ss. 7 and 8.

From the early years of HIV/AIDS, it was seen through experience that people, especially those already socially marginalized or stigmatized, would be unlikely to seek HIV tests without the protection of confidentiality and, for some people, the possibility of being tested anonymously. Over the years, the importance of counselling to HIV testing as a prevention tool has been confirmed,⁶ and informed consent has been considered a bedrock element of HIV testing in most jurisdictions. Thus the “three Cs” of HIV testing — counselling, consent and confidentiality — are central to the voluntary counselling and testing (VCT) model of HIV testing that has been shown to be effective⁷ and has been endorsed by the United Nations.⁸

In recent years, public health authorities at both the World Health Organization (WHO) and the *Joint United Nations Programme on HIV/AIDS (UNAIDS)* have stepped up calls for more widespread HIV testing, suggesting that the VCT model is too slow or inefficient to prevent the virus’ intransigent spread — and, worryingly, sometimes even dismissing human rights concerns as barriers to “public health” approaches aimed at increasing HIV testing rates.⁹ In response to concerns raised by human rights advocates,¹⁰ WHO and UNAIDS have continued to state that: “Provider-initiated testing and counselling must be implemented in a manner consistent with human rights principles. These include obtaining informed consent, ensuring confidentiality of the test result, and providing appropriate counselling.”¹¹ But it remains uncertain to what extent this oft-stated commitment to human rights will in fact be reflected in either international or national-level policy, or in on-the-ground practice where disregard for the “three Cs” is already observed far too frequently. For example, in October 2006, UNAIDS reported that:

In many settings, the absence of counselling, informed consent and confidentiality are challenges to expanding testing. During the national consultations towards universal access [to HIV prevention, treatment, care and support] earlier this year, stakeholders from 15 countries said that there was insufficient access to confidential HIV testing. In several countries, people are reported to be routinely tested in health care settings without counselling and informed consent and the confidentiality of results is not assured.”¹²

In November 2006, the WHO and UNAIDS released for comment a draft of operational recommendations for what the agencies call “provider-initiated testing and counselling” (PITC), under which approach health care workers in countries with generalized epidemics would routinely test all patients seeking any service in a health-care setting for HIV unless the patient declines the test.¹³

The push for greater HIV testing is especially pronounced in high-prevalence, developing countries, where it has often been presented as a necessary element of the effort to scale up anti-retroviral treatment. For example, Botswana introduced more routine approaches to HIV testing in January 2004. To add to the confusion surrounding this issue, government policy documents and official statements describe the country’s official approach as both “routine offer” of testing and as “routine testing” (in which a patient may, in principle, opt

⁶UNAIDS, *The Impact of Voluntary Counselling and Testing: A Global Review of the Benefits and Challenges*. Geneva, 2001.

⁷The Voluntary HIV-1 Counseling and Testing Efficacy Study Group, “Efficacy of voluntary HIV-1 counselling and testing in individuals and couples in Kenya, Tanzania and Trinidad: a randomised trial,” *Lancet* 2000; 356: 103-12.

⁸UNAIDS/WHO Policy Statement on HIV Testing (Geneva, June 2004).

⁹E.g., KM De Cock et al., “Shadow on the Continent: Public Health and HIV/AIDS in Africa in the 21st Century,” *Lancet* 2002; 360: 67-72; KM De Cock et al., “A Serostatus-Based Approach to HIV/AIDS Prevention in Africa,” *Lancet* 2003; 362: 1847-1849; World Health Organization, “The Right to Know: New Approaches to HIV Testing and Counselling”, UN Doc. WHO/HIV/2003.08 (Geneva: WHO, 2003), online: www.who.int/hiv/pub/vct/en/Right_know_a4E.pdf; KM De Cock, “HIV Testing in the Era of Treatment Scale-Up,” *Health and Human Rights* 2005; 8(2): 31-35. Similar demands have come from other quarters, such as the Global Business Coalition on HIV/AIDS: e.g., R. Holbrooke, “A Global Battle’s Missing Weapon”, *New York Times*, 10 February 2004.

¹⁰E.g., J. Csete & R. Elliott, “Scaling up HIV testing: human rights and hidden costs,” *HIV/AIDS Policy & Law Review* 2006; 11(1): 1, 5-10.

¹¹WHO/UNAIDS Secretariat, *Statement on HIV testing and counselling*, 14 August 2006.

¹²UNAIDS, *Analysis of the potential impact of and implementation issue related to an International HIV Testing Day* (Geneva: UNAIDS, 2006).

¹³WHO/UNAIDS, “Guidance on Provider-initiated HIV Testing and Counselling in Health Facilities” (Draft for public comment) (Geneva: WHO/UNAIDS, 27 November 2006).

out of a test if she or he takes the initiative to do so), using these terms interchangeably even though they are not the same thing. However, it appears that the latter term, routine testing with the right to decline, is the more accurate characterization of Botswana's approach.¹⁴ Concerns about the impact on human rights of such a policy and programmatic shift have been raised,¹⁵ and some early studies have confirmed persistent confusion about whether HIV testing is voluntary.¹⁶ Some other African countries with generalized epidemics, such as Kenya, Zambia, Lesotho and Malawi, have recently implemented, or are moving toward implementing, this approach as well, either for specific populations (e.g., pregnant women, patients at sexually transmitted infection clinics) or for the populations as a whole.¹⁷

Yet this call has also been heard in low-prevalence, high-income countries. In September 2006, the U.S. Centers for Disease Control released new recommendations calling for routine testing; the right to decline testing is supposed to remain, but CDC now recommends eliminating both written consent to an HIV test and pre-test counselling.¹⁸ These recommendations have been criticized by human rights advocates who have said such approaches could easily lead to people being tested without their knowledge or consent, may undermine prevention efforts, and raise serious privacy concerns.¹⁹ Calls for making HIV testing more routine have also been heard in Canada. In particular, the relative availability of HIV/AIDS treatment and the availability of low-cost tools for prevention of perinatal transmission have led to calls for more aggressive approaches to HIV testing of pregnant women, and have led to the implementation of such approaches in various jurisdictions.

The Canadian Paediatric Society has recommended that "HIV testing should be offered routinely to all women as early as possible during each pregnancy" and that "[a]ll HIV testing of women and children should be voluntary and accompanied by appropriate confidentiality, counselling and informed consent."²⁰ The Canadian Medical Association's widely used guidelines on counselling and HIV testing affirm the importance of ensuring informed consent through the pre-test counselling process. The CMA guidelines stress the ethical and legal requirement for informed consent and that:

[s]erological 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.²¹

¹⁴ D. de Korte et al., "Routine HIV Testing and the Role of Leadership in Botswana", undated; U.S. Centers for Disease Control and Prevention, "Introduction of Routine HIV Testing in Prenatal Care — Botswana, 2004," *Morbidity and Mortality Weekly Report* 2004; 53: 1083-1086; P. Nieburg et al., *Expanded HIV Testing: Critical Gateway to HIV Treatment and Prevention Requires Major Resources, Effective Protections* (Washington, D.C.: Center for Strategic and International Studies, 2005); K. Seipone et al., "Introduction of Routine HIV Testing in Prenatal Care," *Morbidity and Mortality Weekly Report* 2004; 53: 1083-1086. In some cases, the Botswana approach has even been characterized as involving "mandatory testing", a description that is technically inaccurate (since individuals still retain the right to refuse testing in theory), but certainly highlights the concern that, in practice, an approach of "routine testing" may shift toward or be experienced as mandatory, contrary to the ostensibly voluntary nature of testing as ethically and legal required through the principle of (informed) consent: e.g., S. Lafraniere, "Mandatory Tests Bolster Botswana's War on AIDS", *New York Times*, 14 June 2004, p. A8 (note: A correction of this description was subsequently published a week later); T. Carter, Botswana's leader defends AIDS testing, *The Washington Times*, 5 October 2004.

¹⁵ Botswana Network on Ethics, Law and HIV/AIDS, *Routine vs. Compulsory Tests* (Gaborone: BONELA, 2003); K. Kenyon, "Routine HIV Testing: A View from Botswana," *Health and Human Rights* 2005; 8(2): 21-23; J. Csete et al., "'Opt-out' testing for HIV in Africa: A Caution", *The Lancet* 2004; 363: 493-494.

¹⁶ S.D. Weiser et al., "Routine HIV Testing in Botswana: A Population-Based Study on Attitudes, Practices, and Human Rights Concerns," *PloS Medicine* 2006; 3: 1013-1021.

¹⁷ National AIDS and STD Control Programme, *Guidelines for HIV Testing in Clinical Settings* (Nairobi: Ministry of Health, Republic of Kenya, 2004); UNAIDS/WHO, *Report: Consultative Meeting on HIV Testing and Counselling in the Africa Region*, Johannesburg, South Africa, 15-17 November 2004 (Geneva: UNAIDS, 2005).

¹⁸ U.S. Centers for Disease Control and Prevention, "Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings," *Morbidity and Mortality Weekly Report* 2006; 55 (RR-14): 1-17.

¹⁹ American Civil Liberties Union, News release: ACLU says new CDC HIV testing recommendations raise health and civil liberties concerns, 21 September 2006, online via www.aclu.org.

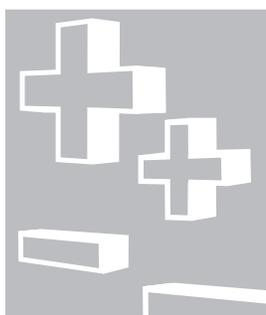
²⁰ Canadian Paediatric Society Statement, "Testing for human immunodeficiency virus type 1 (HIV-1) infection in pregnancy," *Paediatrics and Child Health* 2001; 6: 685-689.

²¹ CMA Expert Working Group on HIV Testing, *Counselling guidelines for HIV testing*, 3rd rev ed. (Ottawa: Canadian Medical Association, 1995).

More recently, however, the CMA has moved beyond the widely supported idea of routinely *offering* HIV testing to all pregnant women and has recommended to governments, health authorities and physicians that all pregnant women in Canada should routinely be *tested* for HIV *unless* they take the initiative to decline testing.²² The Legal Network has criticized this recommendation, noting that routine testing may undermine the seeking of informed consent by health professionals and the giving of it by women.

The use of rapid HIV tests is another measure to which some governments have turned for advancing access to HIV testing, and to support making testing more routine. Rapid tests have been approved in Canada for use at the point of care, partly out of concern for reaching those who may not return for test results in the standard, lab-based testing process. Their use during labour with pregnant women of unknown HIV status is another application. The possible approval of rapid tests for over-the-counter sale and home use is under discussion in the U.S.; this could raise the question of whether Canada will go this route, something that has been opposed by the Canadian HIV/AIDS Legal Network and some other organizations.²³ At this writing, the Public Health Agency of Canada is developing guidelines for use of the newly approved rapid test and any others that may be approved. This is an ideal moment to highlight legal, ethical and human rights issues raised by the use of these tests.

In this paper, we examine briefly these developments in Canada and human rights concerns that are raised by them. In particular, we examine human rights implications of both “opt-out” or “routine” HIV testing of pregnant women, and the use of rapid HIV tests. We present some conclusions and recommendations about ways to increase access to HIV testing that respect, protect and fulfill human rights.



The requirement of informed consent protects the human right to security of the person — that is, to have control over what happens to one’s body — as well as the right to receive information . . .

Methods

The Legal Network conducted a review of existing research on HIV testing experiences in Canada, including both peer-reviewed publications in scientific journals and reports of NGOs and government bodies. To supplement the published research, in March 2006 the Network convened a national consultation of testing and counselling service providers, people living with HIV, people representing communities deemed to be at high risk of HIV, academic experts who have conducted research on HIV testing in Canada, policy-makers, representatives of professional medical associations and others experts. (Participants in the consultation are listed in the annex to this report.) The results of that consultation are referred to throughout this report. Participants in the consultation also heard a presentation by two representatives of bioLytical Laboratories, the British Columbia-based manufacturer of the rapid HIV test approved in 2005 for point-of-care use in Canada. Their presentation stimulated a rich discussion on appropriate uses of rapid tests in Canada and measures needed to prevent abuse of this tool. The Legal Network has published numerous reports, papers and information sheets on human rights issues associated with HIV testing. This paper also relies on that body of work.

²² Canadian Medical Association, Prenatal HIV screening test — Resolution GC02-47 (21 August 2002).

²³ R. Elliott & R. Jürgens, *Rapid HIV Screening at the Point of Care: Legal and Ethical Questions* (Canadian HIV/AIDS Legal Network, 2001); R. Jürgens, *HIV Testing and Confidentiality: Final Report* (Canadian HIV/AIDS Legal Network, 1998), both online via www.aidslaw.ca/testing.

Human rights basis of the “3 Cs”: counselling, consent and confidentiality

Arguments in favour of models of HIV testing that eliminate or minimize informed consent and counselling often do not adequately take into account the link between elements of VCT and human rights. All people have the human right to enjoy the “highest attainable standard” of health, which essentially means the highest attainable standard of health information, goods and services.²⁴ The authoritative comment on this right, from the UN committee that monitors governments’ progress toward its realization, suggests that the right to health includes basic services, including HIV/AIDS-related health services, that are “scientifically and medically appropriate and of good quality,” as well as respectful of culture and medical ethics.²⁵ This includes HIV testing.

The elements of VCT have a clear foundation in human rights law. The requirement of informed consent protects the human right to security of the person — that is, to have control over what happens to one’s body²⁶ — as well as the right to receive information,²⁷ both of which are protected in the *International Covenant on Civil and Political Rights*, to which Canada is a party, as well as in the *Canadian Charter of Rights and Freedoms*. Pre-test counselling contributes to the protection of these same human rights. Post-test counselling also imparts information to which people have a right. Confidentiality of test results and of the fact of seeking an HIV test is part of protecting and respecting the right to privacy.²⁸ Confidentiality of medical records is also a central tenet of medical ethics.

Beyond the components of the testing process itself, governments have a responsibility to ensure that HIV testing, like all other essential health services, is not offered or provided in a way that discriminates against any person or group of people.²⁹ The right to be free of discrimination and the right to security of the person, in our view, also require that in setting HIV testing policy and overseeing its practice, governments take into account the outcomes of HIV testing for people — including stigma, discrimination, violence and other abuse — and do all that they can to prevent human rights violations associated with this health service.

Under international and Canadian law, any public health action by the state that limits human rights must be justified by demonstrating that it is rationally connected to achieving a pressing objective, infringes human rights as little as possible, and finally, the benefit achieved must be proportional to the harm done to individuals’ human rights.³⁰ Canadian courts have affirmed the right to freedom from medical testing or treatment without informed consent. Performing an HIV test in the absence of informed consent could result in legal liability, and provinces should refrain from adopting policies that lead foreseeably to testing without informed consent or foreseeably contribute to a greater risk of HIV testing being done without informed consent.³¹

²⁴ ICESCR, Article 12.

²⁵ General Comment No. 14 at paras. 12(c) and 12(d).

²⁶ ICCPR, Article 9(1).

²⁷ *Ibid.* Article 19(2).

²⁸ *Ibid.* Article 17(1).

²⁹ ICESCR, Article 2(2).

³⁰ *R. v. Oakes*, [1986] 1 SCR 103; UN Economic and Social Council, *Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights*, UN Doc. E/CN.4/1985/4, Annex (1985).

³¹ L. Stoltz & L. Shap, *HIV Testing and Pregnancy: Medical and Legal Parameters of the Policy Debate* (Ottawa: Health Canada, 1999).

1. Routine/“opt-out” HIV testing of pregnant women

Background

Studies have shown that targeting HIV testing only to those pregnant women who report some risk factor associated with HIV would identify only a fraction of women who are HIV-positive and who could benefit from interventions to improve their own health and reduce the likelihood of perinatal HIV transmission.³² It is, therefore, now widely agreed that such an approach is inadequate, and that policies and programmes should aim to ensure all pregnant women have access to HIV testing. Such efforts are particularly important for women from populations that with disproportionately high HIV prevalence and disproportionately low rates of access to health care, including HIV testing. For example, a three-year Health Canada study among First Nations people in British Columbia revealed a rate of HIV infection among pregnant women seven times higher than the average, leading the BC First Nations Chiefs health committee to issue a memo to provincial health professionals recommending that they “ensure all pregnant women in your care, especially First Nations women, are offered voluntary, confidential, prenatal HIV testing, accompanied by pre- and post-test counselling.”³³ The difficult question is how this public health objective is best pursued.

Access to HIV testing and counselling during pregnancy — and ideally before pregnancy — affords women numerous benefits, including:

- referring HIV-positive women for treatment and care for HIV disease, including psychological support;
- providing information to the woman about the full range of measures that can be taken to reduce the risk of perinatal transmission, as well as information that may help her make informed decisions with respect to the current and future pregnancies;
- dramatically lowering the risk of transmission of HIV to the fetus or newborn if the woman is HIV-positive and takes antiretroviral drugs for this purpose;
- allowing the possibility of early diagnosis of HIV in the infant if prevention of perinatal transmission is not successful;
- providing HIV-negative women with information about protecting themselves from HIV transmission.³⁴

It is clear that HIV testing and counselling must be universally available and that pregnant women should be offered counselling and testing. But many questions remain in the Canadian context as to the development and implementation of HIV testing policies that assist the pursuit of public health goals in human rights-based ways. This paper seeks to address the following questions:

- What are existing prenatal HIV testing policies in Canada’s provinces and territories? What is the empirical evidence on the success and failure of traditional VCT and opt-out testing programs under the current provincial and territorial policies? What are barriers to “uptake”

³² L. Samson & S. King, “Evidence-based guidelines for universal counselling and offering of HIV testing in pregnancy in Canada,” *Canadian Medical Association Journal* 1998; 158: 1449 at 151 (and see studies cited therein); Health Canada, *Summary of Research Findings on Women and HIV/AIDS 1995-2000: Final Report* (Ottawa: Health Canada, 2000).

³³ D. Jones, “Pregnant Aboriginals more likely to be HIV positive,” *Canadian Medical Association Journal* 2004; 171: 559; M. Munro, “HIV rate high in pregnant BC natives,” *National Post*, 26 July 2004.

³⁴ S.E. MacDonald et al., “National survey of practices and attitudes of Canadian physicians toward HIV screening of pregnant women,” in: *Perinatal HIV transmission: Study results and implications for policy and program development* (Ottawa: Health Canada, 2001), pp. 3-16 at pp. 3-4.

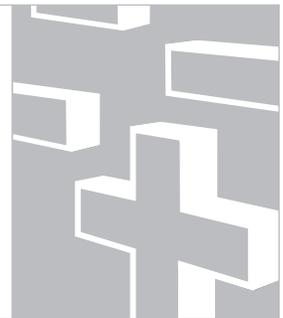
of testing among pregnant women? Is “success” judged only by the numbers of people tested or by evidence of what happens as a result of testing and counselling?

- What level of information or counselling is required for consent to be adequately informed? What is the real experience of provision of information in jurisdictions where opt-out policies are in place versus others?
- What kind of consent should be required to ensure that a test is truly consensual, and what are the characteristics of an offer of testing that is not coercive? How have Canadian women experienced informed consent processes? How do health professionals understand the notion of informed consent?
- Is it possible in practical terms to maintain counselling, consent and confidentiality in an opt-out regime? What have been the best practices in this regard? What lessons have been learned about maintaining the human rights-based aspects of VCT in opt-out systems?
- What are the gaps in knowledge and research needed to inform policy in this area?

Existing policies, their successes and challenges

While there apparently remains at least a theoretical commitment to informed consent and pre-test counselling in all Canadian jurisdictions, there are clear differences of views among governments about approaches to testing. At this writing, several provinces and territories — Alberta, Manitoba, New Brunswick, Newfoundland and Labrador, the Northwest Territories, and Nunavut — have adopted “opt-out” HIV testing for pregnant women.³⁵ Under this policy, being tested for HIV is the “default” option for all pregnant women who seek services at antenatal care facilities; women must explicitly refuse testing to avoid an HIV test. All other jurisdictions appear at this time to support routinely *offering* HIV testing to pregnant women, retaining the elements of the VCT model, meaning that a woman must indicate her consent for the test to be done.³⁶

[M]any questions remain in the Canadian context as to the development and implementation of HIV testing policies that assist the pursuit of public health goals in human rights-based ways.



Increasing the coverage of HIV testing among pregnant women has been the main motivation for the change to opt-out approaches. It appears that coverage has, in fact, increased as a result of these policies. For example, Alberta adopted an opt-out strategy for prenatal HIV testing in 1998. In the first four months under the new policy, 4.7% of pregnant women eligible for prenatal testing declined; this figure was 3.3% in 1999, and 1.5% in 2000.³⁷ The experience of some provinces, however, shows that high rates of testing can occur without such

³⁵ Public Health Agency of Canada, *HIV/AIDS Epi Updates*, May 2005 (Ottawa: PHAC, 2005), p. 41. Information on New Brunswick’s recent switch to opt-out testing of pregnant women was communicated by Lucie Audet of AIDS Saint John at the national consultation on HIV testing and human rights that informed this paper (March 2006).

³⁶ *HIV/AIDS Epi Updates*, p. 41.

³⁷ F.J. Wang et al., “Potential factors that may accept acceptance of routine prenatal HIV testing,” *Canadian Journal of Public Health* 2005; 96: 60-63; G Jayaraman et al., “Mandatory reporting of HIV infection and opt-out prenatal screening for HIV infection: effect on testing rates,” *Canadian Medical Association Journal* 2003; 168: 679-682.

policies. Ontario adopted a policy of routine offer of HIV testing to pregnant women in 1999 at a time when less than half of pregnant women were being tested.³⁸ Recent results from Ontario, for example, show that up to 90% of women in the province accepted HIV testing under an “opt-in” approach.³⁹ As Frank McGee of the AIDS Bureau of the Ontario Ministry of Health and Long-term Care recounted to the March 2006 meeting that was convened to inform this report, Ontario over time made a concerted effort to increase testing uptake — through repeated mailings to physicians, reminding them that offering HIV tests to pregnant women with informed consent was part of their work, developing written HIV informational materials, and even hiring a public relations firm to work with the media on stories highlighting the importance of HIV testing.⁴⁰ While retaining a commitment to informed consent and pre-test counselling, at least in theory, Ontario’s coverage went from 34% before the first mail-out to between 85 and 90% at this writing. In absolute numbers, in 2000 some 139,711 HIV tests were administered to pregnant women, while the figure in 2004 was 156,567.⁴¹

“Uptake” of HIV testing appears to be the principal measure used by provinces to indicate impact of their prenatal testing policies in their regular reporting. Regular provincial HIV reports reviewed for this paper did not contain any information linking HIV testing data to data about follow-up services or other outcomes for those who tested positive or negative. A number of participants at the March 2006 meeting said they work with populations in which women are at risk of violence and abuse if it is found out that they are HIV-positive. There appear not to be studies of the degree to which such fears have been realized in Canada. A few provinces, notably Alberta and Ontario, conducted special evaluations of their prenatal HIV testing services (discussed below), which included some evaluation of pregnant women’s experiences of the testing process but not of follow-up services or support.

Level of information required to insure informed consent and counselling

Many of the participants in the March 2006 meeting suggested that the “opt-in” vs. “opt-out” policy debate is a false one in the sense that the real issue is the quality of counselling and information about HIV given to pregnant women. To the best of the knowledge of those at the meeting, no jurisdiction in Canada has officially espoused a policy of testing without pre-test counselling or informed consent. Commitment to pre-test counselling and informed consent is in contrast, for example, to the 2006 policy recommendation of the U.S. Centers for Disease Control and Prevention, which include the following recommendations:

- Separate written consent for HIV testing is not required. General consent for medical care is sufficient to encompass consent for HIV testing;
- Prevention counselling need not be conducted in conjunction with HIV testing;
- Prevention counselling is not recommended as part of routine HIV screening programs in health care settings.⁴²

Several participants at the March 2006 meeting were familiar with the CDC recommendations, which were released shortly before the meeting, and they deemed these recommendations to be far from the spirit and letter of policies of Canadian governments and professional associations. The counselling guidelines on

³⁸ R.S. Remis, *Report on HIV/AIDS in Ontario 2004* (Ontario Ministry of Health and Long-Term Care, Public Health Branch, 2006), p. 5.

³⁹ *HIV/AIDS Epi Updates*, p. 36; R.S. Remis et al., “Uptake of HIV Testing among Pregnant Women in Ontario: Results to June 2003,” 2003 OHTN Research Conference; R.S. Remis et al., *Report on HIV/AIDS in Ontario 2004*, at p. 108. In 2005, the reported figure was 85% of pregnant women: R. Remis et al., “Evaluation of HIV screening in pregnancy in Ontario: an update,” *Canadian Journal of Infectious Diseases & Medical Microbiology* 2006; 17 (Suppl. A): 41A.

⁴⁰ For a description of how Ontario’s policy approach has changed over time, up to 2001, see: *Testing Times: Ontario’s Prenatal HIV Testing Programme: Application, Acceptability and Advancement* (Toronto: AIDS Bureau, Ontario Ministry of Health and Long-Term Care, June 2001).

⁴¹ *Report on HIV/AIDS in Ontario 2004* at 30.

⁴² U.S. Centers for Disease Control and Prevention, “Revised recommendations of HIV testing of adults, adolescents and pregnant women in health care settings,” *Morbidity and Mortality Weekly Report* 2006; 55 (RR14): 1-17 (22 September 2006), at p. 1.

HIV testing issued by the Canadian Medical Association in 1995 recommend a routine offer of both HIV testing and HIV counselling to all pregnant women in Canada.⁴³ In 2002, the Federal/Provincial/Territorial Advisory Committee on AIDS issued a “reminder” that the “common principles of voluntarism, confidentiality and informed consent ... should apply to policy development regarding HIV testing of women during pregnancy.”⁴⁴

Although the World Health Organization, for example, has recently suggested that “opt-out” approaches may be acceptable if people to be tested have a clear and informed opportunity to decline the test, it has at the same time reiterated that informed consent, counselling and confidentiality must be ensured.⁴⁵ According to WHO, there are three crucial elements in obtaining truly informed consent: (1) providing pre-test information on the purpose of testing and on treatment and support available following the result; (2) ensuring understanding by the person getting tested; and (3) respecting the individual’s autonomy.⁴⁶ The 2004 policy statement on HIV testing of WHO and UNAIDS, moreover, suggests a minimum content of the information provided to ensure that informed consent is truly informed, which is information on the following points:

- the clinical benefit and the prevention benefits of testing;
- the right to refuse the test;
- the follow-up services that will be offered; and
- in the event of a positive test result, the importance of anticipating the need to inform anyone at ongoing risk who would otherwise not suspect they were being exposed to HIV infection.⁴⁷

At the March 2006 meeting that informed this paper, statements from both service providers and users of services highlighted the importance that they attach to pre-test counselling and informed consent. Numerous participants noted that just identifying HIV infection has no preventive or therapeutic value. The opportunity for counselling and sharing information that surrounds HIV testing is where the value lies for prevention and, in the case of HIV-positive women, for informing them about treatment and care and gaining their confidence in a health system with which they will have frequent contact. “Whenever I am challenged about AIDS exceptionalism and the ‘gold standard’ of pre-test counselling — is pre-test counselling over the top? — I know from experience that the value of the conversation [with the woman] is greater than the test,” noted Daphne Spencer of the BC Centre for Disease Control.

Pregnant women’s experiences of HIV testing in Canada

While consensus apparently remains strong on the value, at least in theory, of informed consent and pre-test counselling, it is another question to know the actual practice across Canada of HIV counselling for pregnant women and the sharing of information associated with informed consent. There is a modest amount of published research to inform an analysis of how provincial policies and guidelines are being experienced in real terms by people. Some studies have focused on barriers to seeking HIV testing or accepting offers of testing among women, while others have focused on barriers at the level of the physician or other care-provider.

⁴³ Expert Working Group on HIV Testing, *Counselling guidelines for HIV testing* (Ottawa: Canadian Medical Association, 1995).

⁴⁴ Federal/Provincial/Territorial Advisory Committee on AIDS, “Guiding Principles for Human Immunodeficiency Virus (HIV) Testing of Women During Pregnancy — 2002,” *Canada Communicable Disease Report* 2002; 28(13): 105-108 at 105.

⁴⁵ WHO and UNAIDS held a policy consultation in July 2006 with the objective, among other things, of exploring guidelines on wider use of “provider-initiated” HIV testing that would still respect the human rights norms of HIV testing that the United Nations agencies still espouse. At this writing, WHO and UNAIDS have requested public comment on draft guidelines in this area. See WHO/UNAIDS, “Guidance on Provider-initiated HIV Testing and Counselling in Health Facilities” (Draft for public comment) (Geneva: WHO/UNAIDS, 27 November 2006).

⁴⁶ WHO, “The Right to Know: New Approaches to HIV Testing and Counselling”, UN Doc. WHO/HIV/2003.08 (2003).

⁴⁷ WHO/UNAIDS, *Policy statement on HIV testing* (Geneva: WHO/UNAIDS, 2004).

An important body of work was overseen by Dr. Lynne Leonard of the University of Ottawa in the late 1990s when she and her colleagues sought to understand the HIV testing experience of pregnant women in Alberta, Ontario and Nova Scotia. Some 105 women, 35 from each province, were interviewed in depth. This study shows that policy and practice may differ greatly with respect to pre-test counselling and informed consent. Summarizing their conclusions, the authors noted:

... there is clear evidence that the established Canadian principles of HIV counselling and testing, which require HIV testing to be carried out only after the person has given [her] voluntary informed consent in the context of pre- and post-test counselling, are not always maintained in ... programmes that offer to test women during pregnancy. While the majority of the women interviewed did accept testing when it was offered, many reported that they did not experience the offer to test as voluntary and did not feel that they had given their specific informed consent to be tested. Many women interviewed also reported not having been given adequate information to assess the risks and benefits of HIV testing for themselves or for their unborn child.⁴⁸

In a pilot phase to this study, detailed interviews with women revealed that at that time, some women thought that HIV testing in pregnancy was mandatory.

I was given a requisition form with all manner of other tests on it. I recognized my test for my thyroid, and I think maybe one or two other tests on it. And I did notice written in “HIV”, which I didn’t question or ask why because I was just assuming it was mandatory at that point.⁴⁹

Some women felt that there were good reasons for not “making a fuss” about the testing offer before them, as in this example;

I sort of felt like, this is a bit obnoxious. But I’m not going to make a fuss because I know it is not an issue for me I mean, it’s a very delicate thing, your relationship with your obstetrician. Because as much as you want to stand up for yourself, the bottom line is you also want to please your obstetrician because you want him to be there for you I really want him to like me and I want him to come to my birth These guys are pressed for time and they don’t make guarantees.⁵⁰

Other women explicitly questioned whether the test was mandatory and, at least in some cases, appeared to receive little explanation of the benefits or costs of testing beyond the fact that testing was not mandatory. For example:

I was asked by my obstetrician whether I wanted to actually have an AIDS test, and I asked whether it was mandatory, and I was told, no it wasn’t. Therefore, my husband and I said no, there’s no need It was very much, would you like to have the AIDS test and, we were sort of looking at each other and saying no. It was more that we didn’t see any necessity for it.⁵¹

Some women did not recall having been offered an HIV test at all, or thought that an HIV test may have been presented as part of a long list of tests, as in the following account:

I mean, I knew that it was a general rundown It was just like I knew it was the battery test. She probably told me what was in the battery of tests, and I immediately forgot it because I write it off

⁴⁸ L. Leonard et al., “HIV counselling and testing among pregnant women in Canada: Best practices,” in: C. Amaratunga and J. Gahagan, eds., *Striking to the Heart of the Matter: Selected Readings on Gender and HIV* (Halifax: Atlantic Centre of Excellence on Women’s Health, 2002), pp. 65-74 at pp. 67-68.

⁴⁹ L. Leonard et al., “Pregnant women’s experiences of screening for HIV in pregnancy: What they have to say about what constitutes an appropriate policy for HIV testing of pregnant women in Canada (a pilot study),” in: Health Canada, *Perinatal HIV transmission: Study results and implications for policy and program development* (Ottawa: Health Canada, 2001).

⁵⁰ L. Leonard & L. Shap, “A different kind of risk? — Pregnant women’s experience of HIV testing in pregnancy,” *Canadian HIV/AIDS Policy and Law Newsletter* 1999; 5(1): 18-21 at 20.

⁵¹ L. Leonard et al., “Pregnant women’s experiences”, at p. 27.

as, you know, their procedure Since I can't understand I just figure they have their reasons you know, I don't really need to know the whole details.⁵²

Of the women from Alberta in this study, many said they experienced the “opt-out” system without having been given a clear option to “opt out” of being tested.⁵³ The authors note with concern that a number of women in the study, particularly those not living in urban areas, had little information on reduction of the risk of mother-to-child transmission through antiretroviral prophylaxis, leading some to believe that aborting their pregnancies was the only way to avoid HIV transmission. In this study, women in all provinces said they needed access to more information on HIV/AIDS than what was offered to them in contacts with any health officials surrounding HIV testing.⁵⁴

“Many women interviewed also reported not having been given adequate information to assess the risks and benefits of HIV testing for themselves or for their unborn child.”

In 2000, Alberta Health and Wellness, the provincial health ministry, and the Alberta Medical Association commissioned an evaluation of the “routine” prenatal HIV testing program. The evaluators distributed questionnaires to 868 health professionals, of whom about 40% responded, and to about 3000 pregnant women, of whom about 40% also responded, though response rates of women varied greatly — from 0% to 97% — the health regions within the province.⁵⁵ The evaluators noted that the sample of pregnant women was biased in favour of those who sought prenatal care, those living near to health facilities, and HIV-negative women (only two HIV-positive women were in the sample). The Alberta evaluation noted that since the establishment of the “opt-out” policy, very few women had actually opted out of the test. In the evaluation sample survey, only 11 women reported having formally declined an HIV test, most of them either because they had been recently tested or perceived themselves not at risk. One woman said she declined because she “would not want to know the results.”⁵⁶ Some women were missed in testing because of improperly submitted requisition forms. Some 61% of the women surveyed reported having been told that the HIV test was routine. Only about a quarter of the women surveyed said they had seen the materials developed by Alberta Health and Wellness to inform pregnant women about HIV/AIDS.⁵⁷

The Ontario AIDS Bureau oversaw an evaluation of the province’s prenatal HIV testing program in 2000-01 following adoption of the 1999 policy of requiring physicians and midwives to offer HIV testing and counselling to all pregnant women. Some 56 women from across the province were interviewed as part of this evaluation. The authors summarized key results as follows:

Many pregnant women experienced the offer to test as less than voluntary and did not feel that the choice to be tested was theirs to make, perhaps reflected in the fact that nearly a quarter (22%) of

⁵² Ibid. at p. 26.

⁵³ Ibid. at p. 70.

⁵⁴ Ibid. at p. 70, 72.

⁵⁵ Howard Research and Instructional Systems, Inc., *Alberta routine prenatal HIV screening program: Final evaluation report* (Alberta Medical Association and Alberta Health and Wellness, 2001), pp. 15 and 17.

⁵⁶ Ibid. at p. 24.

⁵⁷ Ibid. at p. 3.

all providers surveyed were not adhering to the provincial policy in always explaining to women that the HIV test is optional and that one third (34%) of all providers did not believe that pregnant women in any case should have a choice in whether to be tested for HIV. Many of the pregnant women were very clear that they had not given their *informed* consent to be tested as required in the provincial policy, and 12% of providers surveyed reported that they “did not always obtain verbal consent for HIV testing.”

Most pregnant women went along with prenatal HIV testing in absence of any meaningful pre-test discussion, thus precluding their ability to give *informed* consent, just as over one-third (37%) of all providers did not always counsel their prenatal patients on the reasons, risks and benefits of HIV testing, two-thirds (69%) did not always provide education about HIV transmission, the majority (89%) did not always give pregnant women written information about the HIV test, and 24% did not in any case agree that HIV testing should include special counselling about the test [emphasis in original text].⁵⁸

At the March 2006 consultation, Frank McGee described measures taken to improve provider performance based on this evaluation, including repeated mailings to physicians and the development of written materials for use in HIV counselling. Data from a 2003 Ontario study among 199 women about their HIV testing experiences during pregnancy at two teaching hospitals indicated that, of those reporting having discussed HIV testing with their health care provider during pregnancy, 85% stated they were satisfied with how the HIV test was explained to them, and 89% agreed to have the test. However, only 72% felt that had the option to refuse the HIV test if they had wanted to, and 15% wished they had had more information before making a decision about the test. Among the minority who declined testing, the most common reasons given were that they were not at risk for HIV or had been tested before the pregnancy.⁵⁹

Participants in the March 2006 meeting corroborated the concerns in Leonard’s earlier work that many women in reality either are not offered tests or are not given the counselling and information that are recommended by medical professional associations and assumed to be part of official policy. Le-Ann Dolan of AIDS Calgary noted that it is common for women to call her organization because they know they are being tested for HIV under Alberta’s opt-out system but they have not received basic information about the test or about HIV. “We often give counselling over the phone in these cases, which is not ideal,” she said.

Meeting participants noted that there are several categories of women who may be likely to refuse the test even if it is offered with information and counselling and if risks are explained to them. These include those already tested during an earlier pregnancy and those tested because they donated blood or for occupational reasons. In addition, women may also decline a test on the grounds that they have already been tested in the immigration process. Since 2002, Citizenship and Immigration Canada has mandated HIV testing of all persons requiring a medical examination for an application for permanent residency or long-term visas.⁶⁰

Some women may be unlikely to seek HIV testing or, in some cases, even to seek early prenatal care. Stigma and fear undoubtedly remain important impediments to seeking HIV testing for some women, as they have been from the beginning of the HIV epidemic. Women from countries where HIV is endemic may face numerous barriers to seeking HIV testing, and they constitute an important percentage of women living with HIV in Ontario and Quebec. In Ontario, for example, from 1992 to 2004, an estimated 60–90% of children (the highest percentage in Toronto and in recent years) who became HIV-positive through perinatal transmission were in families from countries where HIV is endemic, largely in Africa or the Caribbean.⁶¹

⁵⁸ L. Leonard, *Testing times: Ontario’s prenatal HIV testing programme: application, acceptability and advancement* (Toronto: Ontario AIDS Bureau, 2001) pp. viii-ix.

⁵⁹ A. Barbara, “Rapid HIV testing in the delivery room: What is it like to be offered an HIV test during pregnancy?” 2003 OHTN Research Conference, online via www.ohtn.on.ca.

⁶⁰ Ibid.

⁶¹ Ibid. at p. 24.

In Quebec, another province with a relatively high percentage of people of African and Caribbean descent, about 60% of women identified as HIV-positive in 2004 were from countries where HIV is endemic.⁶² This percentage is virtually unchanged since 1998, according to the most recent provincial statistics.

Women from these communities may have many reasons to fear HIV testing and its results, including racism, fear or uncertainty about their immigration status, fear of reactions in their households and communities to a positive result or even to the fact of having sought a test, unfamiliarity with the Canadian medical system, and not speaking the language of service-providers. Esther Tharao of Women's Health in Women's Hands in Toronto noted that some African and Caribbean women may be discouraged by their husbands or other family members from seeking testing.

Tharao and colleagues documented concerns about seeking HIV care among women of Caribbean and African origin in Toronto in a 2004 study. These authors report women's experiences of "multiple oppressive systems", including health service systems, in which they have little say and face many social and economic pressures.⁶³ They note further that women from these communities may lack money to travel to a health facility or for childcare while they seek HIV testing or counselling, may be unable to take time off from work or family responsibilities, may lack health coverage if they do not have residency status, or may not know enough about HIV to assess their own risk or to seek testing.

In British Columbia, about 30% of women who were tested for HIV and found to be positive were from First Nations, Inuit or Metis communities, a percentage virtually unchanged since 1998, according to provincial statistics.⁶⁴ At the consultation on HIV testing and human rights, Michelle George, executive director of the Red Road HIV/AIDS Network Society in Vancouver, articulated a number of barriers to seeking testing among some Aboriginal women. In the "moral-based communities" from which many Aboriginal women come, they may fear having others know if they are HIV-positive. They fear lack of confidentiality in health facilities where "the doctor gives the news where the door's not closed and there's a lobby full of people.," George noted. In addition, women fear loss of custody of their children if they are found to be HIV-positive.

Based on her extensive interviews with pregnant women about their experience of HIV testing, Lynne Leonard said that many women react strongly against the presentation of HIV as "just another disease" is a list of tests they are meant to undergo. This angers them, she said, because they see HIV as having enormous consequences compared to other illnesses. The presentation of the HIV test as part of the standard tests performed in pregnancy was a common practice in Alberta, for example, according to the early evaluation of that province's practices: over 60 percent of the women surveyed in this work said that they were told HIV testing was part of the routine care and testing associated with pregnancy.⁶⁵

Several participants noted that pregnant women naturally feel or are easily made to feel that they must do anything for the sake of the health of their babies. "If a professional recommends that they have a test, no 'true mother' would refuse," said Lynne Leonard. "They are a captive audience in that sense, and there is a power dynamic that goes with that." Ann Livingston from the Vancouver Area Network of Drug Users said those pressures are even stronger, for example, for women in methadone programs who fear that if they don't do everything they are told, their children will be taken away from them. Several participants noted that effective counselling must focus on the woman for herself and not just as a "vessel" of a baby.

The 2006 U.S. Centers for Disease Control guidelines for HIV testing of pregnant women propose repeated offers of HIV testing to women before, during and after pregnancy. With reference to these guidelines,

⁶² R. Allard et al., *Portrait des infections transmissibles sexuellement et par le sang (ITSS), de l'hépatite C, de l'infection par le VIH et du sida au Québec, décembre 2004* (Santé et Services sociaux, Gouvernement du Québec, 2005) at p. 34.

⁶³ E. Tharao et al., *Silent voices of the HIV/AIDS epidemic: African and Caribbean women in Toronto – the final report* (Toronto: Women's Health in Women's Hands Community Health Centre, 2006), online via www.whiwh.com.

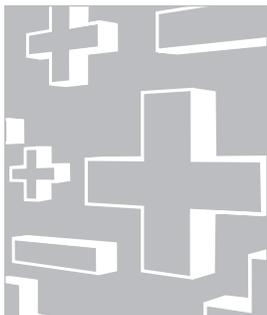
⁶⁴ D. Haag et al., *HIV/AIDS update — year end 2004* (British Columbia Centre for Disease Control, STD/AIDS Control, 2005) at p. 22.

⁶⁵ *Alberta routine prenatal HIV screening program*, *supra* note 55 at p. 28.

Melody Isinger of the Office of Ethics of the Canadian Medical Association, asked whether repeated offers of HIV testing, depending on their frequency, may become coercive. “How many times do women have to say no before the providers quit asking?” she asked. Other participants noted that this proposed policy appears to be based on a lack of confidence that pregnant women can make decisions in the best interest of themselves and their children.

Health care providers’ experiences, attitudes and practices

There are a several published studies of the attitudes and practices of physicians and other health care providers with respect to HIV testing of pregnant women. In a study conducted in 1997–98, MacDonald and colleagues concluded that attitudes of physicians toward HIV and HIV testing constituted a barrier to HIV testing of pregnant women. In particular, their national survey of over 3000 family practice physicians and obstetrics/gynecology specialists in Canada revealed that over 40% of male family practice doctors and of obstetric specialists agreed with the statement “The prevalence of HIV in my patient populations is too low to justify counselling all of my pregnant patients about HIV screening.”⁶⁶ About 30% of the physicians overall also indicated that their training and experience did not prepare them for counselling pregnant women about HIV testing. More than 80% of all physicians said they were not adequately remunerated under provincial health insurance plans for providing HIV counselling for pregnant women.



Meeting participants who work with women of African and Caribbean origin said that generally these women are assumed to be at risk and are always urged to be tested.

Another analysis of the data collected in this same physician survey indicated that provincial policy was the most important predictor of whether an HIV test would be offered to pregnant women. Whether a province or territory had a policy of routine offer of testing was the overriding factor, even after controlling for factors such as physicians’ perceptions of whether HIV prevalence was too low to justify widespread HIV testing.⁶⁷ This is the only study we could locate on the link between testing policy in Canada and health-care providers’ practices with respect to HIV testing of pregnant women.⁶⁸

Just as health care providers’ attitudes and approach can be a barrier to HIV testing for pregnant women, it can also contribute to higher HIV testing rates but also the denial of women’s rights to autonomy in making testing decisions. In a study of Ontario prenatal care providers (predominantly family physicians, but also including obstetricians and midwives) published in 2003, researchers found that providers who reported higher rates of HIV testing of their pregnant patients also tended to hold the view that HIV testing should be routine; researchers also reported that encouraging women to test and not providing them with written information or choice about testing were independently associated with high testing rates. Researchers concluded that the

⁶⁶ MacDonald et al., at p. 12.

⁶⁷ K.S. O’Connor et al., “The influence of prevalence and policy on the likelihood that a physician will offer HIV screening in pregnancy,” *Canadian Journal of Public Health* 2002; 93(1)31-35.

⁶⁸ A study conducted at a Toronto clinic that adopted an opt-out policy at the clinic level (even though Ontario is an opt-in jurisdiction) reported higher rates of uptake of HIV testing than the provincial average at the time the study was performed in 2004: M. Yudin et al., “HIV screening in pregnancy: testing acceptance rates are influenced by strategy used (opt-in vs. opt-out) and patient race,” *Canadian Journal of Infectious Diseases & Medical Microbiology* 2006; 17 (Suppl. A): 53A-54A.

“strongest predictors of high prenatal HIV testing rates were attitudes and practices that favoured a routine approach to testing and that placed little emphasis on informed consent.”⁶⁹

Physicians, midwives and nurses were surveyed in the evaluation of the Alberta opt-out program. Over 80% of health-care providers reported that in their practices they *always* advised pregnant women that HIV testing was part of routine care, but only 67% said they advised women that they had the option to decline the HIV test.⁷⁰ When questioned as to why they did not inform women of the “opt-out” possibility, the health professionals offered the following explanations; (1) the test is generally well accepted; no opt-out possibility is needed; (2) the option to decline should be explained to only those women who seem concerned about the test; and (3) they would not want to provide prenatal care to a woman who is unwilling to have a test, and therefore they do not offer that option.⁷¹ (Of those who indicated that they did not always explain that women could opt out of the test, only a small number offered explanations of why they did not offer explanations.)

According to a 2002–03 survey of primary care physicians in British Columbia, about 70% of male physicians and about 90% of female physicians offered HIV testing and counselling to pregnant women in their practices.⁷² In addition, in this sample, only 70% of the respondent physicians said they understood informed consent to be a necessary part of HIV testing.⁷³ The offer of HIV testing was not always made to patients presenting with other STDs. Physicians in rural areas were much more likely than their urban counterparts to report that they felt they had inadequate information or not enough knowledgeable colleagues to help them with questions about HIV counselling. Respondents also said they didn’t have enough time to meet patients’ needs for HIV counselling. The authors concluded that many physicians find it harder to speak to their patients about sex or sexual orientation than even, say, drug use or alcohol use.⁷⁴

The observations of participants at the March 2006 consultation that informed this report indicated that problems of the kind suggested by these physician surveys may have influenced the adoption of routine-offer policies in some provinces. Joanne Embree of the University of Manitoba and the Canadian Paediatric Society said that before the opt-out policy was adopted in Manitoba, many physicians in the province did not apparently see the value in HIV counselling and some felt they were inadequately remunerated for it. Other participants suggested that it still happens, even in opt-out jurisdictions, that physicians make a judgment about the HIV risk a woman faces, and they may choose not to offer HIV testing or talk about HIV based on those judgments. Denise Becker of the British Columbia Persons with AIDS Society (BCPWA) noted that many women living with HIV with whom she has worked favoured routine testing and not just routine offer of testing because they are women who would not be seen by doctors as high risk and might not be offered a test as a result. Some doctors may assume that women without obvious risk factors, particularly women they have known for some time in communities where prevalence is low, are not in need of HIV counselling and testing.

Meeting participants who work with women of African and Caribbean origin said that generally these women are assumed to be at risk and are always urged to be tested. Malubungi Mueni of the Réseau des chercheuses africaines in Toronto echoed this observation. “Our women ‘from Africa’ are tested automatically and not given a choice even if they have been here a long time; it’s as though someone thinks they brought AIDS with them in their luggage,” she said. In addition, participants noted that health-care settings not geared to deal with women from these communities, and there may be little capacity to help women think through the complexities of a possible positive diagnosis, including knowing how to disclose their status and working with them to anticipate and prevent the most damaging reactions to a positive test or even to the fact of having been tested.

⁶⁹ D. Guenter et al., “Prenatal HIV tests: routine testing or informed choice?” *Canadian Family Physician* 2003; 49: 1334–40.

⁷⁰ *Alberta routine prenatal HIV screening*, *supra* note 55 at 30.

⁷¹ *Ibid.*

⁷² L. Hansen et al., “STD and HIV counselling practices of British Columbia primary care physicians,” *AIDS Patient Care and STDs* 2005; 19(1):40–48.

⁷³ *Ibid.* at p. 46.

⁷⁴ *Ibid.*

Participants urged more resources for peer counselling and specialized services for women who are new to Canada. Esther Tharao, among others, also said that while routine testing of pregnant women may work in some populations, many women in African and Caribbean communities struggle with being told that they are HIV-positive without having been prepared by counselling or informed consent. She also suggested that counsellors and physicians offering tests should be trained to help women understand testing as part of a whole package of services and a broader prevention strategy. “Without that broader piece happening, it won’t make sense,” she noted.

Conclusions and recommendations: HIV testing of pregnant women

Based on this review of research and the consultation with experts from across Canada, we offer the following conclusions and recommendations regarding HIV testing of pregnant women:

(1) Removing barriers to testing and other services

Every pregnant woman in Canada should have easy access to HIV testing in a supportive environment with an expectation of confidential and well informed pre-test counselling and a chance to decline or accept the test. Yet it appears that many women experience difficult barriers even to seeking a test, including women without health coverage, those who are new to Canada and unfamiliar with health systems, those with language barriers, those in remote or rural communities, those who fear government services because they have been in conflict with the law, those who fear losing custody of their children (for whatever reason), those who have difficulties getting time off from work, women who fear violence or other negative consequences at home if it is known they are seeking an HIV test, women such as those who use drugs or are in the sex trade and are therefore criminalized, and many others. Many of the women who face these barriers to use of testing services also face situations of high HIV risk in their lives. No woman should end up in a situation of reaching the end of her pregnancy without having had the chance to learn her HIV status in a non-coercive way and with access to the services she needs to support her in dealing with a positive test result. Design of more effective programs will require the meaningful involvement of women, including those who regularly live in difficult circumstances or face human rights abuses.

Recommendation 1: Identifying barriers HIV testing and reasons for declining

The Public Health Agency of Canada, and the ministries of health of provinces and territories, should support assessments to identify the barriers impeding some women from HIV testing, as well as the reasons why some women decline HIV testing when offered. Based on these assessments, all provinces and territories should have budgeted plans to reach all women, including marginalized and criminalized women, with HIV/AIDS prevention services, including good quality counselling regarding HIV testing and voluntary testing that proceeds based on informed consent.

Recommendation 2: Linking HIV testing to care, treatment and support

All provinces and territories should also assess the link between testing and other HIV/AIDS services for women, including the content of post-test counselling that will connect women with services that will help with prevention, treatment, care and support. The design and implementation of such plans must include meaningful involvement of women, particularly those who face additional barriers to HIV testing and other health services.

Recommendation 3: Support for peer-based services

Provincial and territorial ministries of health should increase their support for peer-based HIV services for pregnant women, particularly in communities where there is fear or wariness of government health services. The experience of the few services that offer peer counselling and other HIV services to pregnant women in Canada should be assessed and lessons shared.

Recommendation 4: Involving men

Provinces and territories should encourage physicians to offer HIV testing to men who are considering fathering a child and to counsel men with HIV-positive test results to encourage their sexual partners, including women who may be pregnant or considering pregnancy, to be referred for voluntary counselling and testing.

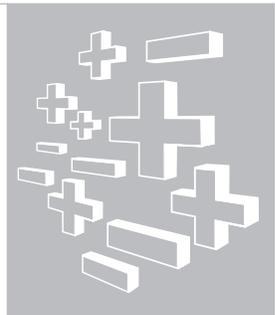
(2) Increasing access to HIV testing services that are ethical and respect human rights

Beyond eliminating barriers that may keep women from seeking or having access to voluntary counselling and testing, provinces and territories should support the effectiveness and coverage of HIV testing in pregnancy with other actions.

Recommendation 5: Encouraging women to test, and to know their rights

Provincial and territorial health authorities should undertake, and support such work by health services providers and community-based service providers, to educate pregnant women and those considering pregnancy about the importance of HIV testing in pregnancy as well as their right to have an HIV test and to pre- and post-test counselling, to give their informed consent to any HIV test, and to the confidentiality of test results.

No woman should end up in a situation of reaching the end of her pregnancy without having had the chance to learn her HIV status in a non-coercive way and with access to the services she needs to support her in dealing with a positive test result.

**Recommendation 6: Working with health care providers**

Provincial and territorial health authorities should undertake systematic outreach to and education of physicians and other health care providers on the importance of recommending HIV testing to all pregnant women or women considering pregnancy, and on the importance of women's right to quality pre- and post-test counselling, informed consent, and confidentiality of test results. They must also ensure appropriate compensation to physicians and other health professionals involved in HIV testing in pregnancy for adherence to good practices.

Recommendation 7: Creating a culture of encouraging HIV testing and respect for women's rights

Provincial and territorial governments should conduct extensive public education campaigns that encourage all persons to seek HIV testing, and this can include particular education efforts to encourage women who are pregnant or considering pregnancy to get tested. However, provincial and territorial health authorities should not designate HIV testing of pregnant women as "routine", which risks encouraging the view that testing for HIV can be done without obtaining specific, informed consent. Rather, there should be clear directives to health care workers that all pregnant women should routinely be *offered* HIV testing, and even that such testing should be recommended to them. There must be equally clear directives that health care providers should explain that women are not obliged to be tested, that test results are kept confidential (except where disclosure may be required by law), and that their testing decision will not affect their care or their legal rights. In jurisdictions that have adopted policies encouraging routine, opt-out testing of pregnant women (notwithstanding the recommendations against such an approach), public education campaigns encouraging HIV testing must ensure that women are aware that HIV testing is a routine part of pre-natal care and that they have a right to refuse the test. Public education campaigns should be re-run periodically to ensure that this information is widely

known (including to those women who are new to the jurisdiction, young women who are becoming sexually active, etc.).

Recommendation 8: Laboratory requisition forms for prenatal HIV testing

Whether requisitioning an HIV test is done on a separate form or on the same form as other tests that form part of optimal pre-natal care, laboratory forms required for physicians to request an HIV test should support informed consent processes by noting that HIV tests require informed consent, following pre-test counselling suitable for the individual woman to make an informed decision. Laboratory requisition forms should not include HIV among “default” tests that may proceed in the absence of informed consent by the patient.

(3) Judging impact and success of policies for HIV testing of pregnant women

It is not surprising that routine, “opt-out” testing programs would result in higher percentages of women tested; under such an approach, the default position is to perform an HIV test unless a woman explicitly refuses. However, as noted above, high rates of testing have also been seen in jurisdictions that maintain opt-in policies and approach the public health challenge of increasing uptake of HIV testing in other ways. In any event, simply monitoring the percentage of pregnant women who are tested for HIV, which has been the primary focus of research to date, is not the only or a sufficient measure for evaluating HIV testing policies or programs. High coverage of HIV testing is not an end in itself, but rather needs to be part of a comprehensive program of HIV/AIDS services for prevention, treatment, care and support, and needs to be done in ways that respect, protect and fulfil women’s rights.

However, there is little research on the key question of how the quality of HIV counselling, and of the process for women to make an informed decision about getting tested, is related to provincial and territorial policy on HIV testing of pregnant women. The one study on this subject that we located focuses simply on whether providers are more likely to offer the test based on varying policy directives. There is also a need for more research on the way in which HIV testing is experienced by pregnant women, under both opt-out or opt-in policies. Although most of the published studies of pregnant women’s experiences of HIV testing are somewhat dated, there is little reason to believe that the present situation is much different from the discouraging picture these studies paint about the quality of pre-test counselling and informed consent processes. The experience of several provinces indicates that policy and practices do not adequately prioritize and protect the right of women to decide, with adequate information, whether or not to be tested. The modest amount of research available on this subject indicates that the opportunity for counselling and information-sharing that HIV testing affords is not being used effectively from the point of view of women who are offered a test.

Recommendation 9: Strengthening counselling guidelines and standards

Provincial and territorial governments, and relevant health care professional regulatory bodies and associations, should urgently review and, if necessary, improve their informed consent policies and guidelines. Best counselling practices, which may come from settings specialized in HIV testing and counselling with a focus broader than pregnant women, should be documented and shared. The federal government should develop best-practice standards and guidelines for training programs as well as guidance on monitoring and evaluation of the quality of counselling and informed consent processes.

Recommendation 10: Research into quality of counselling and women’s experiences

Federal, provincial and territorial governments, and research funding bodies, need to support research to assess the quality of counselling and HIV information given at the time of testing, whether information is sufficient to ensure truly informed consent, and whether information and counselling are accessible, understandable and appropriate to women’s circumstances. Priority should be given to research that allows women to recount their experiences of testing, including whether they were allowed truly to decide voluntarily to be tested, whether they felt pressured, and whether they perceived that they had adequate information to make their decisions.

Recommendation 11: Influence of policy on counselling and consent

Federal, provincial and territorial governments, and research funding bodies, need to support research that examines whether the quality of counselling and informed consent processes differ between opt-out and opt-in policy regimes.

Recommendation 12: Linking testing process with care, treatment and support

Monitoring and evaluation of HIV testing of pregnant women should include, even if only on a small sample of women, some assessment for HIV-positive women of the way and degree to which they continue to be supported with follow-up care. They should also include assessment of the degree to which testing is used as an opportunity for information sharing and counselling for HIV-negative women.

(4) Protecting women at high risk of adverse outcomes

A corollary of overcoming barriers to HIV testing for women in difficult circumstances is to ensure that testing programs for pregnant women pay attention to the rights and safety of women who are or may be at risk of violence or abandonment, or who fear loss of child custody or other repercussions. While recognizing that no system will pick up every such case, it will be of benefit to establish clear protocols for the HIV testing and counselling process that will increase the chance of identifying, and planning for, these concerns that are realities for some women.

Recommendation 13: Protecting women at risk

All provinces and territories should establish protocols for the HIV counselling and testing process that include assessing risks to women's safety in unthreatening, non-invasive and confidential ways. Every test provider should have a clear and well established system of referral to appropriate services in the case of violence and abuse, and clear assurances of confidentiality of HIV test results for women who fear repercussions from law enforcement or child welfare authorities.

2. Rapid HIV tests

Conventional HIV tests used by government laboratories in Canada may require several days to get a result. In 2000, Health Canada approved the first rapid HIV test for “point-of-care” use in Canada. It was subsequently withdrawn from the market following concerns about accuracy; all rapid test kits approved by Health Canada must meet the same performance standards for sensitivity and specificity as those screening tests approved for laboratory use.⁷⁵ A second test, the Insti HIV-1 rapid test, which can give an indication of HIV antibodies within 60 seconds, was licensed for sale in Canada in October 2005, also for point-of-care use. Health Canada has emphasized that rapid tests are not authorized for over-the-counter sale or use at home and that a “presumptive” positive result obtained using a rapid test must be confirmed by the usual laboratory procedures before a firm diagnosis of HIV infection can be made.

Rapid tests have been promoted by health authorities and some consumer groups for a number of reasons. People being tested would not have to return to a health facility a second time for their test results and post-test counselling. Many people might find a test without an extended waiting period to be more acceptable and might be more likely to seek HIV testing services. Rapid tests have been shown to be safe and easy to administer. Some proponents of rapid testing have pointed to the particular situation of women of unknown HIV status who go into labour and could still be reached with measures to reduce the risk of mother-to-child transmission of HIV; standard testing would be too slow to provide an indication of their HIV status. Similarly, because of the importance of rapid initiation of post-exposure prophylaxis (a four-week course of anti-retroviral drugs that reduce the possibility of HIV infection after exposure), rapid tests may be useful in cases of exposure to HIV through sexual assault or by emergency or health workers.

There are, however, numerous legal, ethical and human rights concerns about rapid point-of-care testing for HIV, many of which were summarized in a Legal Network report in 2000.⁷⁶ Most of these concerns are still relevant. At this writing, Health Canada is undertaking a review of its existing guidance for health-care professionals on the use of rapid HIV testing at the point-of-care.⁷⁷ This section summarizes a discussion of some of these issues at the March 2006 consultation, including the following:

- What measures are in place to ensure the accuracy of rapid tests? If rapid tests are less accurate than conventional tests, is their use still appropriate, including for people with poor access to conventional testing services?
- What measures do federal, provincial and territorial governments have in place for the regulation and monitoring of the use of rapid point-of-care tests? Does monitoring include attention to confidentiality, informed consent and pre-and post-test counselling? Have governments taken measures to ensure that the use of rapid tests is linked to prompt confirmatory tests and efficient transmission of confirmatory test results?
- How widespread is the demand for rapid HIV tests in Canada? Are there significant numbers of people who would seek rapid HIV testing more readily than HIV testing using standard methods?
- What legal and ethical questions are raised by the offer of rapid testing to women in labour? What questions are raised by the use of rapid tests in the home?
- What are the gaps in research that would help inform policy on the use of rapid HIV tests?

⁷⁵ D. Kilby et al., “Point-of-Care HIV Testing Using Simple/Rapid HIV Test Kits: Guidance for Health-Care Professionals,” *Canada Communicable Disease Report* 2000; 26-07: 49-59.

⁷⁶ Canadian HIV/AIDS Legal Network, *Rapid HIV Screening at the Point of Care: Legal and Ethical Questions* (Legal Network, 2000), online via www.aidslaw.ca/testing.

⁷⁷ Kilby et al., *supra* note 75.

Quality of rapid tests and the use of rapid testing by populations with special needs

The March 2006 consultation on HIV testing in Canada heard a presentation from Richard Galli, director of research and development for bioLytical Laboratories, the Richmond, BC-based company that produces the Insti HIV-1 rapid test approved in 2005 for point-of-care use in Canada. According to the company, trials conducted at Health Canada's behest showed that the Insti test in both point-of-care and laboratory settings was equivalent in sensitivity, specificity and early antibody detection to the Health Canada-approved laboratory test of record (Abbott Ax Sym GO).⁷⁸

The quality of any rapid test should be continually monitored by government. If rapid tests are more inaccurate to any significant degree than standard tests, they must be used with the greatest of caution and with full information about their accuracy provided to those tested. Hassle Free Clinic in Toronto at this writing is conducting a trial of the Insti test. Hassle Free also piloted and used the earlier rapid test and so is well placed to compare the newer product to the previous one. As several meeting participants noted, after the experience of the earlier rapid test, the government should have a strict protocol for ensuring the sustained accuracy of the test.

The rapid test can in theory open opportunities for more widespread HIV testing, including for communities currently facing barriers to conventional testing. Canada's previous experience with a rapid test that turned out to be of lower quality than claimed by the manufacturer led one participant to wonder whether rapid HIV testing might risk being a suboptimal service, something that people already marginalized from HIV/AIDS services could ill afford. Several of the meeting participants, however, suggested that some people who are underserved or not well served by existing HIV testing sites would benefit greatly from a rapid test, even if its quality was not of the highest calibre.

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Michelle George of Red Road in Vancouver, for example, suggested that with the rapid test, Aboriginal people who are currently very underserved might at least have a greater prospect of being tested and having some awareness of their status. "It's sad to say, but Aboriginal people are already used to suboptimal care," she noted, and who is to say that rapid testing would make them worse off? She added that Aboriginal women are often not tested until later stages of pregnancy, and Aboriginal people living with HIV tend to be tested later in the course of the disease than in other communities in Canada, and the rapid test might help create situations in which testing would be easier. She said any tool that can help empower marginalized communities to take control of their health should be made as accessible as possible. "We shouldn't start imposing the same rules [on the rapid test] that are keeping them from being tested already." She said communities with this tool at their disposal might find occasions such as community testing days or teenager health events where HIV testing could be offered in a way that would not be threatening or stigmatizing for people who would not normally go to an AIDS centre.

⁷⁸ bioLytical Laboratories, "Results from a multi-centre Canadian clinical trial of a rapid HIV antibody test for use in point-of-care, clinical and laboratory settings" (Richmond, BC: bioLytical Laboratories, 2005), online: www.biolytical.com/clinical2.php.

Stacie Migwans of Positive Women's Network in Vancouver said Aboriginal communities rarely get proper counselling or the opportunity to be tested. "I am excited about the rapid test and how it could benefit our communities," she said, noting that anything that might allow the community greater control and autonomy over health services could be beneficial. She suggested that the test would also be useful for people living on the street who are unlikely to return for the result of a slower test. She also said First Nations people on reserves who move around or those off-reserve who may be quite mobile might similarly benefit from this tool.

Dianne Tobin of VANDU added that many people in the Downtown Eastside of Vancouver are not tested because they don't use standard HIV testing centres and might benefit from the offer of rapid tests in non-threatening settings. Ann Livingston agreed, noting that people who are outside the law or who fear contact with official systems should have a way of knowing their HIV status. If rapid tests can be used by doctors they trust, it might open up an important avenue of services for them. Women in methadone programs, for example, might seek a rapid test from someone other than the methadone doctor if it was available from someone they could trust. Esther Tharao suggested that it would be useful to have a pilot demonstration of the use of the rapid test targeting people without health coverage who might not go to a conventional testing site. She added that rapid testing could be of great benefit for women who have difficulties getting time off from work for medical appointments.

Frank McGee of the Ontario AIDS Bureau said it is wrong to regard the rapid test as suboptimal as though there were proof that the current process is necessarily the best one. The rapid test, he said, is just a different technology. He asserted that if there were unlimited resources, the ideal system probably would involve a faster testing procedure than is currently the "gold standard".

Link to prompt confirmatory test and surveillance of results

A positive result from a rapid test requires a confirmatory test, as with conventional methods of testing. In this case, however, the confirmatory test will be awaited by someone who already has a preliminary result. If a person tests positive according to the rapid procedure, awaiting the result of the confirmatory test may cause more psychological and emotional distress than simply waiting in uncertainty for the results of a standard test. This may be a particular concern for remote settings and for communities where support services for someone with a "presumptive" positive result may be limited.

The World Health Organization as early as 1992 issued HIV testing guidelines for use of rapid antibody tests. WHO suggests a rapid HIV antibody test can act as a confirmatory test for a first rapid test.⁷⁹ A participant at the March 2006 raised the possibility of using two rapid tests (if a second one is approved) as a confirmatory process. (WHO guidelines from 2004 suggest that in HIV testing for diagnostic purposes in low-prevalence populations, it may be useful to do a third rapid test for confirmation.⁸⁰ Jane Greer of Hassle Free Clinic said that, based on experience with the earlier rapid test, it is important to establish a clear consent procedure for two (or more) tests. In her view, people should be allowed to consent separately for a second test and should not be assumed to be consenting to two tests at the beginning of the process.

Several participants in the March 2006 meeting noted that there will need to be some attention to the role of laboratories, which are not currently prepared to monitor point-of-care testing. Several people raised the question of how the government would monitor the number of negative results detected by the rapid test, given that these would not have to be sent to a lab or any central place for confirmation. In this case, the full "denominator" of the number of people tested, as well as the negative results themselves, may be lost to surveillance unless there are procedures in place. As Micheline Fauvel of Quebec's provincial public health laboratory said, the collection of negative data and the correct denominator are crucial for the continued quality

⁷⁹ WHO Global Programme on AIDS, "Recommendations for the selection and use of HIV antibody tests," *Weekly Epidemiological Record* 1992; 67:145-152.

⁸⁰ WHO & UNAIDS, *HIV assays: operational characteristics – Report 14, Simple/rapid tests* (Geneva: WHO/UNAIDS, 2004).

control of the reagents of the new rapid test. Joanne Ember speculated that health-care settings where HIV testing is done regularly would be able to modify their reporting systems easily, but the rapid test may be used in doctor's offices and more remote areas where HIV testing is not routine. It might, she suggested, be necessary to require that doctors not be reimbursed for the cost of the test kits until they make full reports of results.

Counselling, consent, confidentiality and anonymity

Pre- and post-test counselling are essential elements of HIV testing, regardless of the rapidity of the testing procedure. Indeed, counselling may take on greater importance for a person who has to live with a preliminary positive result before receiving a confirmed test result (whether positive or negative). Informed consent is also a central element of good HIV testing practices and of protection of human rights of those tested. The ease and rapidity of administering these new tests could lead to taking short-cuts in pre-test counselling, but counselling and informed consent remain essential to ensure that the test is well understood and that the person being tested is prepared for the procedure.

Jane Greer said at the March 2006 meeting that Health Canada's plan for evaluation of the rapid test approved in 2000 was focused on accuracy but not on the broader impact of the test on those taking it and those administering it. Hassle Free Clinic with the Community-Linked Evaluation AIDS Resource (CLEAR) Unit at McMaster University in Toronto undertook to document how rapid testing procedures were experienced by those tested and counsellors alike.⁸¹ In this case, 91% of people to whom the rapid test was offered chose to take it, and all of them, including those who were found to be HIV-positive, reported that they were satisfied with the experience. Jane Greer noted that this result occurred "in the context of a lot of support from the counselor". She said: "People offering this test have to be sophisticated in their understanding of how HIV testing works and what each part of the test tells, and how to communicate that to patients. They have to understand clearly what the test does and doesn't say."

Because rapid tests are simple to use, there may be the temptation in health facilities with limited resources to allow these tests to be administered by persons who are not trained in HIV counselling or who do not have an appreciation of the central importance of informed consent and confidentiality. As noted above, health facilities must not decide that rapid tests are an open door to curtailing counselling and consent practices. According to Jane Greer, any training associated with the new test should not just be about the device itself but on how counselling and support processes should accommodate a rapid testing without the quality of counselling being compromised.

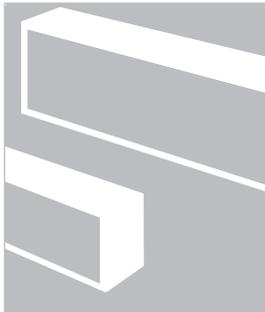
Greer also raised the concern that anonymity would be compromised with use of the rapid test outside anonymous testing sites. If the designated anonymous HIV testing sites choose not to use the rapid test and people want a rapid result, they may have to choose between anonymity and rapidity in HIV testing. Denise Becker noted that people would have to realize that rapid tests at the doctor's office would become part of a person's permanent medical record, not like a test at an anonymous testing centre.

Daphne Spencer of the BC Centre for Disease Control said she thought that rapid testing might make some health-care providers more conscientious about the quality of pre-test counselling. Faced with the prospect of having to give a quicker test result, some test providers would realize that pre-test counselling is crucial to set the right tone for a result to follow soon after. She also stressed the benefit of post-test counselling opportunities with people who will not be lost because of not coming back for their results. Indeed, justifying the higher cost of rapid tests may depend on the degree to which people do not return for the results of slower assays.

⁸¹ D. Guenter et al., *The effects of a rapid point-of-care HIV testing program – Hassle Free Clinic, Toronto*, CLEAR Working Paper Series C03-3 (Hamilton, ON: McMaster University, 2003), online: <http://www.fhs.mcmaster.ca/slru/clear/paper/PaperC03-3.pdf>.

Women in labour

Offering a rapid HIV test to women already in labour whose HIV status is unknown is a practice that was recommended by some provinces after the first government approval of a rapid HIV test in 2000.⁸² This practice raises numerous legal and ethical questions, including whether a woman in labour can be counselled and give informed consent without feeling coerced and whether this use of rapid tests can be monitored and evaluated. While studies have demonstrated that rapid testing during labour is feasible and delivers accurate and timely test results, there has been little in the way of evaluation of women's experiences of testing in such circumstances.⁸³ One small study (of 16 women) in Ontario asked women who had previously given birth to review consent forms, one for use with women in labour seeking their participation in a rapid testing study, and the other for intrapartum treatment for those women who were to test HIV-positive during labour. Recurring themes in the respondents' assessment of the consent forms included the following: women felt strongly this test should be available during labour; women in labour could understand what a rapid HIV test is and appreciate the implications of having it done; and information read and discussed during the consent process was generally recalled well.⁸⁴ Participants at the March 2006 meeting felt generally that rapid HIV testing was an important tool for this situation. Participants highlighted the clinical benefits of rapid testing in this case, including not only prevention of perinatal HIV transmission, but also ruling out HIV for interventions such as BCG vaccination, which would be counter-indicated if HIV is present.⁸⁵



[B]ringing the real experience and voices of women in difficult circumstances into the policy process is the only way to understand the complexity of these situations and to be sure that broad human rights protections can be put in place for both women and children.

Lori Stoltz, a Toronto lawyer who has representing women in HIV testing cases, noted that women are asked for consent for procedures such as caesarean sections and epidurals during labour. Legally, asking for consent for a rapid HIV test would have many precedents. Lynne Leonard of the University of Ottawa observed that a rapid test offered to a woman in the throes of labour is, unlike a test offered early in pregnancy, not an opportunity for a women to take control of her own health but must rather be understood as a test that is motivated by a concern for the baby more than the mother. Esther Tharao noted that though the test would have a different intent, it is nonetheless an important intent. “Many women would be sorry not to have been asked about the test if they weren’t [asked] — they would want to do anything for their children,” she said. Malubungi Mueni of the Réseau des chercheuses africaines in Toronto said that many hospitals need interpreters so that women in this situation can be spoken to in a language they understand. In addition, she noted, many women would want to make a decision like this in consultation with family and community members, which would generally not be possible in a delivery room.

Other participants suggested that offering rapid testing in the labour room would inevitably be construed as a “guilting out” a woman by holding up to her the health of her baby. Ann Livingston of VANDU said this

⁸² See, e.g., A.E. Singh, “New resources on screening for HIV in Pregnancy,” *Alberta RN* 2005; 61(8):11. See also *Alberta routine prenatal HIV*, *supra* note 55 at p. 25.

⁸³ M. Butlerys et al., “Rapid HIV-1 testing during labor: A multicenter study,” *Journal of the American Medical Association* 2004; 292: 219-223.

⁸⁴ R. Zlotnik-Shaul et al., “Rapid HIV testing in the delivery room: is a valid informed consent possible?” 2003 OHTN Research Conference, online via www.ohtn.on.ca.

⁸⁵ *Alberta routine prenatal HIV*, *supra* note 55 at pp. 26-27.

is a particularly hypocritical when the health of the baby is pulled out as a justification for testing the mother, but then other policies will ignore babies in marginalized families with respect to housing, welfare and social services. She suggested that there should be mechanisms to understand how a woman could get to the position of being at risk of HIV, not knowing their status and being about to deliver a baby. She said that bringing the real experience and voices of women in difficult circumstances into the policy process is the only way to understand the complexity of these situations and to be sure that broad human rights protections can be put in place for both women and children.

Risk of misusing rapid tests as a gateway to testing without informed consent

The availability of a new technology can unfortunately sometimes drive policy and practice in ways that may not be foreseen when the technology is introduced. There is a concern that the availability of a rapid test, plus the push to “routinize” or “normalize” HIV testing, will contribute to situations where counselling is short-circuited further and patients feel pressured to accept HIV testing rather than giving truly voluntary, informed consent. As noted above, rapid tests may be useful, for example, as one factor to consider in judging the need for post-exposure prophylaxis in the case of sexual assault or exposure to HIV by emergency workers. But the availability of a rapid test should not give rise to an entitlement to compel the source person to be tested without his or her consent.

Jane Greer noted that inappropriate uses of rapid tests are often championed, including use with incarcerated people, mobile populations and others for whom there might be little control over the quality of counselling, the issue of consent and anonymity. Le-Ann Dolan of AIDS Calgary raised the concern of widespread availability of rapid tests at a time when several provinces are passing laws allowing for mandatory HIV testing in certain situations — that is, laws that give the state the power to compel a person to undergo an HIV test without consent where another person is exposed to his or her blood or body fluids.⁸⁶

Frank McGee emphasized that the rapid test by law would have to be administered by a health professional — a doctor, nurse or midwife. He suggested that the tests should not be used by health professionals without experience in HIV testing using non-rapid tests, but it is not clear how such use would be controlled or monitored.

At-home use of rapid HIV tests

There is one HIV test for use at home that is authorized by the U.S. Food and Drug Administration (FDA). This test, which may be purchased on the internet, allows people to take their own blood samples at home and send them to a laboratory for testing.⁸⁷ At this writing, the U.S. FDA is considering whether to licence rapid HIV tests for over-the-counter sale so that an individual may perform the test at home, with no link to any health care provider or counselling.

To date, Canada has not authorized over-the-counter sale of rapid HIV tests for home use; rapid tests are approved only for use in a laboratory or by a health care provider at the point of care. But, as with prescription-only medications, it is not impossible that rapid test kits will make their way into the hands of people outside health facilities. Richard Galli of bioLytical Laboratories, the manufacturer of the Insti test, told the March 2006 gathering that bioLytical understood from Health Canada that it was not obliged to report to the government where and to whom the test is sold. However, the federal *Medical Devices Regulations* do require that a manufacturer maintain distribution records sufficient enough to permit a complete and rapid

⁸⁶ See, e.g., Canadian HIV/AIDS Legal Network, *Occupational exposure to HIV and forced HIV testing: Questions and answers* (Legal Network, 2002).

⁸⁷ U.S. Food and Drug Administration, “Testing yourself for HIV-1, the virus that causes AIDS” (2006), online at www.fda.gov/cber/infosheets/hiv-home2.htm.

withdrawal of a device from the market should this prove necessary, and Health Canada could request this information.⁸⁸

Participants at the March 2006 meeting generally noted concern about home-use HIV tests, particularly because of the importance of pre- and post-test counselling, which is presumably absent from at-home testing. But several participants said that any measures that increase access to tests for Aboriginal communities and others that are chronically underserved by health facilities could be worth considering.

Conclusions and recommendations

Recommendation 14: Need for comprehensive guidelines

In consultation with provincial and territorial health officials, AIDS service organizations, people living with and affected by HIV, and other representatives of civil society, the Public Health Agency of Canada should develop guidelines for the use of rapid HIV tests that include the following elements:

- Guidance on best practices in pre- and post-test counselling and informed consent linked to general use of rapid tests.
- Guidance on the offer and use of rapid testing with *women in labour*, including best practices of informed consent, how to present key clinical information at this sensitive moment, and how to deal with women's refusal of the test. This element should be developed in consultation with women's groups, women living with HIV, and others who can share first-hand experience in the matter.
- Guidance on *appropriate settings* for use of rapid tests, including on the HIV testing experience and capacity needed on the part of providers of rapid test services.
- Regulations for the development and maintenance of sustainable systems for *quality control* of rapid HIV tests in the provinces and territories.
- Suggestions for appropriate and creative uses of rapid tests to increase access to HIV testing for *marginalized or remote communities*.

Recommendation 15: Training on use of rapid tests

Colleges and universities providing professional education to health professionals should include as a mandatory component training on best practices in the use of rapid point-of-care HIV tests. Colleges of physicians should offer refresher training on this subject as part of their other HIV training.

Recommendation 16: Support for best practices

Provincial and territorial governments and health professionals' regulatory bodies should issue regulations and guidelines that ensure that:

- a person receiving a positive result from a rapid test will have accelerated access to a confirmed result and to support while waiting for the confirmatory test;
- that those providing testing with the use of rapid tests have received training on appropriate counselling practices to accompany rapid HIV tests.

Recommendation 17: Monitoring sale of rapid tests

The Public Health Agency of Canada should establish a sustainable system to monitor the sale of rapid HIV tests so as to ensure that sale is restricted to health professionals certified and trained to administer

⁸⁸ Medical Devices Regulations, SOR/98-292, ss. 52-56.

HIV tests. The role of provinces and territories in this monitoring should be clarified and communicated clearly to all governments concerned.

Recommendation 18: Labelling of rapid HIV tests

Health Canada should maintain the requirement that any licensed rapid HIV test be labelled clearly so as to indicate that:

- the device may legally be sold to or used only at a laboratory of by a health-care professional as permitted by law;
- the use of the device should be accompanied by pre- and post-test counselling in accordance with accepted professional standards; and
- the device may not be sold or represented as being for any other use than that intended by law.

Health Canada should also require that rapid tests be distributed with accurate and accessible explanations of the possibility of false-negative and false-positive results, the need for repeat testing for those who test negative but may be in the process of sero-converting, and the need for confirmatory testing for those who test positive.

Recommendation 19: Use outside points of care

In consultation with provincial and territorial health officials, the Public Health Agency of Canada should establish a system to monitor the places and ways in which rapid HIV tests are used, with special attention to preventing uses outside points of care or by health service providers without adequate training or experience in HIV testing and counselling.

Recommendation 20: Research on experiences of providers and persons tested

There is a need for more research on the real experience of use of rapid HIV tests, from the perspectives of both the providers of the test and those tested. The trial and research conducted by the Hassle Free Clinic and the CLEAR Unit of McMaster University on the test approved in 2000 is a useful model for this kind of research. Research should include detailed assessment of the knowledge and practices of test providers, their views on the advantages and drawbacks of rapid tests, and the experiences of those tested, including their views on the quality of counselling and informed consent processes.

Summary of recommendations

Recommendation 1: Identifying barriers HIV testing and reasons for declining

The Public Health Agency of Canada, and the ministries of health of provinces and territories, should support assessments to identify the barriers impeding some women from HIV testing, as well as the reasons why some women decline HIV testing when offered. Based on these assessments, all provinces and territories should have budgeted plans to reach all women, including marginalized and criminalized women, with HIV/AIDS prevention services, including good quality counselling regarding HIV testing and voluntary testing that proceeds based on informed consent.

Recommendation 2: Linking HIV testing to care, treatment and support

All provinces and territories should also assess the link between testing and other HIV/AIDS services for women, including the content of post-test counselling that will connect women with services that will help with prevention, treatment, care and support. The design and implementation of such plans must include meaningful involvement of women, particularly those who face additional barriers to HIV testing and other health services.

Recommendation 3: Support for peer-based services

Provincial and territorial ministries of health should increase their support for peer-based HIV services for pregnant women, particularly in communities where there is fear or wariness of government health services. The experience of the few services that offer peer counselling and other HIV services to pregnant women in Canada should be assessed and lessons shared.

Recommendation 4: Involving men

Provinces and territories should encourage physicians to offer HIV testing to men who are considering fathering a child and to counsel men with HIV-positive test results to encourage their sexual partners, including women who may be pregnant or considering pregnancy, to be referred for voluntary counselling and testing.

Recommendation 5: Encouraging women to test, and to know their rights

Provincial and territorial health authorities should undertake, and support such work by health services providers and community-based service providers, to educate pregnant women and those considering pregnancy about the importance of HIV testing in pregnancy as well as their right to have an HIV test and to pre- and post-test counselling, to give their informed consent to any HIV test, and to the confidentiality of test results.

Recommendation 6: Working with health care providers

Provincial and territorial health authorities should undertake systematic outreach to and education of physicians and other health care providers on the importance of recommending HIV testing to all pregnant women or women considering pregnancy, and on the importance of women's right to quality pre- and post-test counselling, informed consent, and confidentiality of test results. They must also ensure appropriate compensation to physicians and other health professionals involved in HIV testing in pregnancy for adherence to good practices.

Recommendation 7: Creating a culture of encouraging HIV testing and respect for women's rights

Provincial and territorial governments should conduct extensive public education campaigns that encourage all persons to seek HIV testing, and this can include particular education efforts to encourage women who are pregnant or considering pregnancy to get tested. However, provincial and territorial health authorities should not designate HIV testing of pregnant women as "routine", which risks encouraging the view that testing for HIV can be done without obtaining specific, informed consent. Rather, there should be clear directives to health care workers that all pregnant women should routinely be *offered* HIV testing, and even that such testing should be recommended to them. There must be equally clear directives that health care providers should explain that women are not obliged to be tested,

that test results are kept confidential (except where disclosure may be required by law), and that their testing decision will not affect their care or their legal rights. In jurisdictions that have adopted policies encouraging routine, opt-out testing of pregnant women (notwithstanding the recommendations against such an approach), public education campaigns encouraging HIV testing must ensure that women are aware that HIV testing is a routine part of pre-natal care and that they have a right to refuse the test. Public education campaigns should be re-run periodically to ensure that this information is widely known (including to those women who are new to the jurisdiction, young women who are becoming sexually active, etc.).

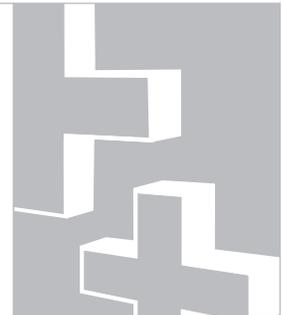
Recommendation 8: Laboratory requisition forms for prenatal HIV testing

Whether requisitioning an HIV test is done on a separate form or on the same form as other tests that form part of optimal pre-natal care, laboratory forms required for physicians to request an HIV test should support informed consent processes by noting that HIV tests require informed consent, following pre-test counselling suitable for the individual woman to make an informed decision. Laboratory requisition forms should not include HIV among “default” tests that may proceed in the absence of informed consent by the patient.

Recommendation 9: Strengthening counselling guidelines and standards

Provincial and territorial governments, and relevant health care professional regulatory bodies and associations, should urgently review and, if necessary, improve their informed consent policies and guidelines. Best counselling practices, which may come from settings specialized in HIV testing and counselling with a focus broader than pregnant women, should be documented and shared. The federal government should develop best-practice standards and guidelines for training programs as well as guidance on monitoring and evaluation of the quality of counselling and informed consent processes.

[P]rovincial and territorial health authorities should not designate HIV testing of pregnant women as “routine”, which risks encouraging the view that testing for HIV can be done without obtaining specific, informed consent. Rather, there should be clear directives to health care workers that all pregnant women should routinely be *offered* HIV testing, and even that such testing should be recommended to them.



Recommendation 10: Research into quality of counselling and women’s experiences

Federal, provincial and territorial governments, and research funding bodies, need to support research to assess the quality of counselling and HIV information given at the time of testing, whether information is sufficient to ensure truly informed consent, and whether information and counselling are accessible, understandable and appropriate to women’s circumstances. Priority should be given to research that allows women to recount their experiences of testing, including whether they were allowed truly to decide voluntarily to be tested, whether they felt pressured, and whether they perceived that they had adequate information to make their decisions.

Recommendation 11: Influence of policy on counselling and consent

Federal, provincial and territorial governments, and research funding bodies, need to support research that examines whether the quality of counselling and informed consent processes differ between opt-out and opt-in policy regimes.

Recommendation 12: Linking testing process with care, treatment and support

Monitoring and evaluation of HIV testing of pregnant women should include, even if only on a small sample of women, some assessment for HIV-positive women of the way and degree to which they

continue to be supported with follow-up care. They should also include assessment of the degree to which testing is used as an opportunity for information sharing and counselling for HIV-negative women.

Recommendation 13: Protecting women at risk

All provinces and territories should establish protocols for the HIV counselling and testing process that include assessing risks to women's safety in unthreatening, non-invasive and confidential ways. Every test provider should have a clear and well established system of referral to appropriate services in the case of violence and abuse, and clear assurances of confidentiality of HIV test results for women who fear repercussions from law enforcement or child welfare authorities.

Recommendation 14: Need for comprehensive guidelines

In consultation with provincial and territorial health officials, AIDS service organizations, people living with and affected by HIV, and other representatives of civil society, the Public Health Agency of Canada should develop guidelines for the use of rapid HIV tests that include the following elements:

- Guidance on best practices in pre- and post-test counselling and informed consent linked to general use of rapid tests.
- Guidance on the offer and use of rapid testing with *women in labour*, including best practices of informed consent, how to present key clinical information at this sensitive moment, and how to deal with women's refusal of the test. This element should be developed in consultation with women's groups, women living with HIV, and others who can share first-hand experience in the matter.
- Guidance on *appropriate settings* for use of rapid tests, including on the HIV testing experience and capacity needed on the part of providers of rapid test services.
- Regulations for the development and maintenance of sustainable systems for *quality control* of rapid HIV tests in the provinces and territories.
- Suggestions for appropriate and creative uses of rapid tests to increase access to HIV testing for *marginalized or remote communities*.

Recommendation 15: Training on use of rapid tests

Colleges and universities providing professional education to health professionals should include as a mandatory component training on best practices in the use of rapid point-of-care HIV tests. Colleges of physicians should offer refresher training on this subject as part of their other HIV training.

Recommendation 16: Support for best practices

Provincial and territorial governments and health professionals' regulatory bodies should issue regulations and guidelines that ensure that:

- a person receiving a positive result from a rapid test will have accelerated access to a confirmed result and to support while waiting for the confirmatory test;
- that those providing testing with the use of rapid tests have received training on appropriate counselling practices to accompany rapid HIV tests.

Recommendation 17: Monitoring sale of rapid tests

The Public Health Agency of Canada should establish a sustainable system to monitor the sale of rapid HIV tests so as to ensure that sale is restricted to health professionals certified and trained to administer HIV tests. The role of provinces and territories in this monitoring should be clarified and communicated clearly to all governments concerned.

Recommendation 18: Labelling of rapid HIV tests

Health Canada should maintain the requirement that any licensed rapid HIV test be labelled clearly so as to indicate that:

- the device may legally be sold to or used only at a laboratory of by a health-care professional as permitted by law;
- the use of the device should be accompanied by pre- and post-test counselling in accordance with accepted professional standards; and
- the device may not be sold or represented as being for any other use than that intended by law.

Health Canada should also require that rapid tests be distributed with accurate and accessible explanations of the possibility of false-negative and false-positive results, the need for repeat testing for those who test negative but may be in the process of sero-converting, and the need for confirmatory testing for those who test positive.

Recommendation 19: Use outside points of care

In consultation with provincial and territorial health officials, the Public Health Agency of Canada should establish a system to monitor the places and ways in which rapid HIV tests are used, with special attention to preventing uses outside points of care or by health service providers without adequate training or experience in HIV testing and counselling.

Recommendation 20: Research on experiences of providers and persons tested

There is a need for more research on the real experience of use of rapid HIV tests, from the perspectives of both the providers of the test and those tested. The trial and research conducted by the Hassle Free Clinic and the CLEAR Unit of McMaster University on the test approved in 2000 is a useful model for this kind of research. Research should include detailed assessment of the knowledge and practices of test providers, their views on the advantages and drawbacks of rapid tests, and the experiences of those tested, including their views on the quality of counselling and informed consent processes.

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